



Building Quality in Endoscope Reprocessing

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- I am an employee of Healthmark Industries Fraser, Michigan - USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation or for travel to and from the seminar
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Objectives

- Discuss the key quality assurance parameters that should be build into endoscope reprocessing
- Identify best practices in reprocessing of flexible endoscopes
- Discuss how various methods of cleaning verification and surveillance testing can reduce Hospital Acquired Infections (HAI) and Surgical Site Infections (SSI) and help to determine if an endoscope is patient ready

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The ECRI 2019 List

The List for 2019

1. Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations
2. "Clean" Mattresses Can Ooze Body Fluids onto Patients
3. Retained Sponges Persist as a Surgical Complication Despite Manual Counts
4. Improperly Set Ventilator Alarms Put Patients at Risk for Hypoxic Brain Injury or Death
5. Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections
6. Confusing Dose Rate with Flow Rate Can Lead to Infusion Pump Medication Errors
7. Improper Customization of Physiologic Monitor Alarm Settings May Result in Missed Alarms
8. Injury Risk from Overhead Patient Lift Systems
9. Cleaning Fluid Seeping into Electrical Components Can Lead to Equipment Damage and Fires
10. Flawed Battery Charging Systems and Practices Can Affect Device Operation

- Cleaning and disinfecting flexible endoscopes between uses is known to be a challenging process.
- Failure to precisely follow a robust reprocessing protocol can lead to debilitating or even fatal infections.

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ECRI Endoscope Recommendations 2019

- Improper handling and storage can recontaminate disinfected scopes.
 - Improper drying after HLD remaining bacteria can multiply.
 - To promote drying ECRI recommends purging endoscopes with clean air after reprocessing.
 - Handle reprocessed scopes with clean gloves.
 - Transport disinfected and dried scopes in a clean, enclosed, dedicated container and prevent from contacting potentially unclean surfaces.

Reference ECRI 2019: https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_19.pdf

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The FDA is Recommending Transition to Duodenoscopes with Innovative Designs to Enhance Safety: FDA Safety Communication

- 8/29/19 – Recommending transition to newer designs of that aid in or eliminate reprocessing (e.g. disposable scopes, disposable tips)
- **Ensure staff are meticulously following reprocessing instructions.**
- Postmarket safety surveillance programs are finding a ~ 5% culture positive with high concern organisms after proper reprocessing
- Human factors study showing that user materials for Olympus duodenoscopes are not sufficient to consistently ensure user adherence in these core reprocessing area and therefore users are not following the IFU properly.
 - i.e. Steps are not being complete as written.

<https://www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication>

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Other important FDA recommendations

- Institute a quality control program that includes sampling and microbiological culturing, and other monitoring methods.
- Consider reprocessing with supplemental measures such as sterilization or use of a liquid chemical sterilant processing system consistent with the device's labeling.
- Monitor your reprocessing procedures. Examples of monitoring are sampling and culturing using the [Duodenoscope Surveillance Sampling & Culturing](#)
- Develop schedules for routine inspection and periodic maintenance in accordance with the duodenoscope manufacturer's instructions.

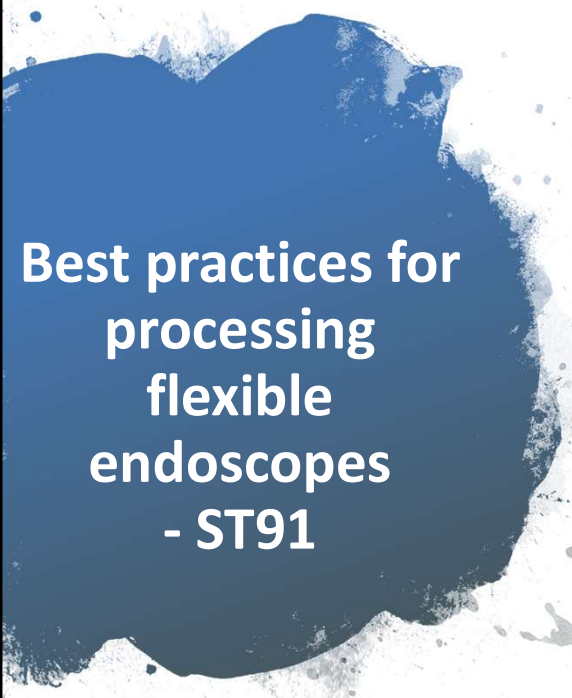
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ATP Confusion: from FDA

- **Potential for Monitoring Reprocessing Effectiveness**

“One potential method to monitor the effectiveness of duodenoscope reprocessing is the use of test strips that detect adenosine triphosphate (ATP), an indicator of the presence of live microbes. While some manufacturers of ATP test strips are promoting ATP test strips for assessing duodenoscope cleaning, as of August 29, 2019, we are not aware of any ATP test strips legally marketed for this use. The FDA premarket review is necessary to assess whether ATP test strips for this use are adequately validated and properly labeled. We have contacted manufacturers of ATP test strips advising them of our requirements for manufacturing, testing and labeling for medical devices promoted for assessing duodenoscope cleaning.”

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Best practices for processing flexible endoscopes - ST91

- Meticulous attention to all steps in processing endoscopes, their components and accessories is critical making them safe for subsequent patient use
- Steps are outlined in the document in detail and include the following categories
 - Precleaning, transportation, leak testing, manual cleaning, rinsing, inspection or testing for cleanliness, high-level disinfection & sterilization and monitoring of the process, rinsing, drying, alcohol flush, & storage

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Best practices in Precleaning

- Prevents buildup of bioburden, development of biofilms, drying of patient secretions
- Occurs at point of use immediately after the procedure
- Don fresh PPE
- Prepare a cleaning solution (or water if validated) according to the solution manufacturer's written IFU.
- Wipe insertion tube with a low or non-linting cloth/sponge soaked in the freshly prepared cleaning solution.

— Note: cloth/sponge is single-use only

Remember to follow the IFU for the endoscope and detergent!



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Best practices in precleaning

- Ensure that controls are in the free/unlocked position.
- Suction solution through the suction channel as per manufacturer's written IFU.
- Flush the air/water channels with solution using the cleaning adapter per manufacturer's IFU.
- Flush all other channels (e.g., auxiliary water or elevator channels) with solution, if present.
- Suction the solution through the endoscope until clear.
- Detach the endoscope from the light source and suction pump.
- If applicable, attach the fluid-resistant cap.
- Visually inspect the endoscope for damage.

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Contaminated Transport

- From procedure room to reprocessing area
- Closed, labeled transport containers
- Place a single endoscope in a container by naturally coiling it in large loops.
- Separate endoscopy accessories.
- Governed by OSHA regulation!
 - Leak proof sides and bottom
 - Puncture resistant
 - Labelled appropriately as biohazard



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Keep Items Moist for Transport

- AORN:
 - V.b.2. Semicritical items should be kept wet or damp, but not submerged in liquid during transport.
 - Keeping the items wet helps dilute, soften, and ease removal of organic soils.
 - Dried organic materials and debris can make the item more difficult to clean and potentially lead to the formation of biofilm.
 - Submerging the device in liquid during transport may increase the risk of spillage and could lead to fluid invasion if the device has an unknown leak.



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Best practices for Leak Testing

- Ensure fluid-resistant cap is on prior to submersion
- Use a basin of **water** large enough that the endoscope is not coiled too tightly to mask holes
- Allow for sufficient time to observe the endoscope for leaks, manipulate knobs and buttons, flex the scope
- Flush with syringe full of water to remove trapped air



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Common Leakage Testing Errors

- Not performed every cycle
- Moisture in connector or water tight cap
- Soapy or reused water
- Too small sink (< minimum 16x16)
- Entire scope not immersed
- Not flushing with syringe of water
- Scope not pressurized before immersion
- Angulation controls and switches not manipulated
- Performed too quickly (30 seconds at least)
- Scope not properly depressurized
- Leaking scopes not properly HLD or ETO

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Check your leak testers!

- Faulty leak tester are an Infection Control risk
- Incorrect pressure output is a common repair issue
- Push the button on the connector to hear hiss each time its used
- Check pressure on these
 - Pressure gauge or repair company
- Send for repair if not functioning properly



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Delayed Reprocessing

- General Rule: Anything beyond 60 minutes for Olympus scopes
 - Pentax and Fuji = NO TIME DELAY
- Perform before patient material dries and hardens
- Potential for biofilm formation when delays following manual cleaning
- Problematic for channels that don't get brushed
- Common for emergency procedures at night and on weekends
- Extended soak in detergent required.



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Delayed Reprocessing

- 1 hour hold time between precleaning & manual cleaning, and between manual cleaning & high-level disinfection
- IFU: Soak for up to 1 hour surgical scopes & up to 10 hours for GI scopes
 - Olympus customer statement 2018:
 - <http://medical.olympusamerica.com/sites/default/files/pdf/delayedreprodiffficultoclean.pdf>
 - Reprocessing Manuals: Presoak for Excessive Bleeding and/or Delayed Reprocessing”

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You have 1 hour to Manually Clean!

- Note procedure end time/precleaning start time
- Convey that time to reprocessing staff
- AORN: IV.d.3. A procedure should be developed and implemented for recording the times that the procedure is completed and cleaning is initiated.
 - A process for recording the times that the procedure ended and cleaning was initiated enables processing personnel to ascertain how long the endoscope has been awaiting processing, to establish priority order, and to determine whether routine processing within the manufacturer’s recommended time to cleaning is achievable, and if not, to implement the manufacturer’s procedures for delayed processing.

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Best practices for manual cleaning

- Soil remaining on the endoscope may interfere with the ability of the disinfection or sterilization process to effectively kill or inactivate microorganisms
- If process is not initiated immediately, follow written IFU for delayed reprocessing from manufacturer
- General process is outlined including
 - Don fresh PPE, use fresh detergent solution, monitor the temperature of the cleaning solution

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Best practices for manual cleaning

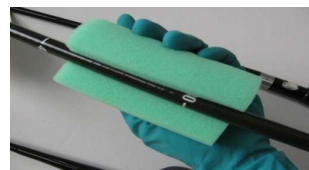
- Cleaning steps:
 - Clean with a single-use lint-free cloth/sponge
 - Submerge scope to prevent splashing contaminated fluids
 - Use a cleaning brush with specifications per manufacturer's IFU
 - Brush all channels, cylinders, openings and forceps elevators per IFU
 - Suction???



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Best practices for manual cleaning

- Cleaning steps (continued):
 - Use recommended cleaning adapters
 - Flush all channels, rinse all channels, air purge all channels
 - Repeat until there is no visible debris
 - Soak, scrub, brush & rinse all reusable/removable parts
 - Automated flushing pumps may be used during manual cleaning



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Brushes – What to use?

- SGNA:
 - Have available appropriate size channel cleaning brushes
 - Use a brush size compatible with each channel
 - Endoscope cleaning brushes should be the appropriate size that assures contact with the surface
- AORN (and ST91):
 - VI.g. All accessible channels and the distal end of the endoscope should be cleaned with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer.

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Automated flushing systems

- If a flushing pump is used, follow manufacturer's written IFU
- Ensure compatibility of endoscope with model of flushing system
- Use fresh solution with each endoscope
- Clean and disinfect tubing and equipment according to manufacturer's IFU
- Perform any other QA testing as recommended (e.g. daily volume verification)



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Rinsing after cleaning

- Thoroughly rinse with copious volumes of potable water
 - AAMI TIR34 – Utility water
- Use recommended cleaning adapters
- Rinse all external and internal surfaces
- Perform an air purge of all channels
- Dry exterior with a lint-free cloth/sponge



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Single-use vs Reusable Valves

- ST91, SGNA, AORN all recommend keeping reusable valves together with the scope through reprocessing
 - Unique identifiable set
 - Tracking difficult
- Consequences: facilities moving to single-use valves
 - Concerns: sticking, set makeup, silicone based, lubricants, etc.

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SGNA Reprocessing Steps

1. Precleaning
2. Leak testing
3. Manual cleaning
4. Rinse after cleaning
- 5. Inspection (includes cleaning verification and visual inspection)**
6. High-level disinfection (manual or automated)
7. Rinse after high level disinfection
8. Drying (alcohol and forced air)
9. Storage

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Best Practices for Endoscope Inspection and Cleaning Verification

- Inspection of endoscopes should include:
 - Both a visual inspection, enhanced inspection
 - Cleaning verification processes
- Cleaning verification is performed following cleaning to verify the effectiveness of a cleaning process **PRIOR TO DISINFECTION**
- Use of methods to detect organic residue should be considered

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Verifying Clean through Inspection



Minimum visual inspection with unaided eye



Perform cleaning verification



Add in enhanced visual inspection with lighted magnification



Consider adding borescope



Common methods for cleaning verification of scopes

Protein
Hemoglobin
Carbohydrates
ATP

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SGNA Cleaning Verification

- **Rapid cleaning verification tests are available. These monitors can provide documentation on cleaning efficacy but do not reflect microbial activity.**
- Real-time testing of endoscope should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD.
- Facilities should consider the use of monitors to verify ongoing cleaning adequacy.

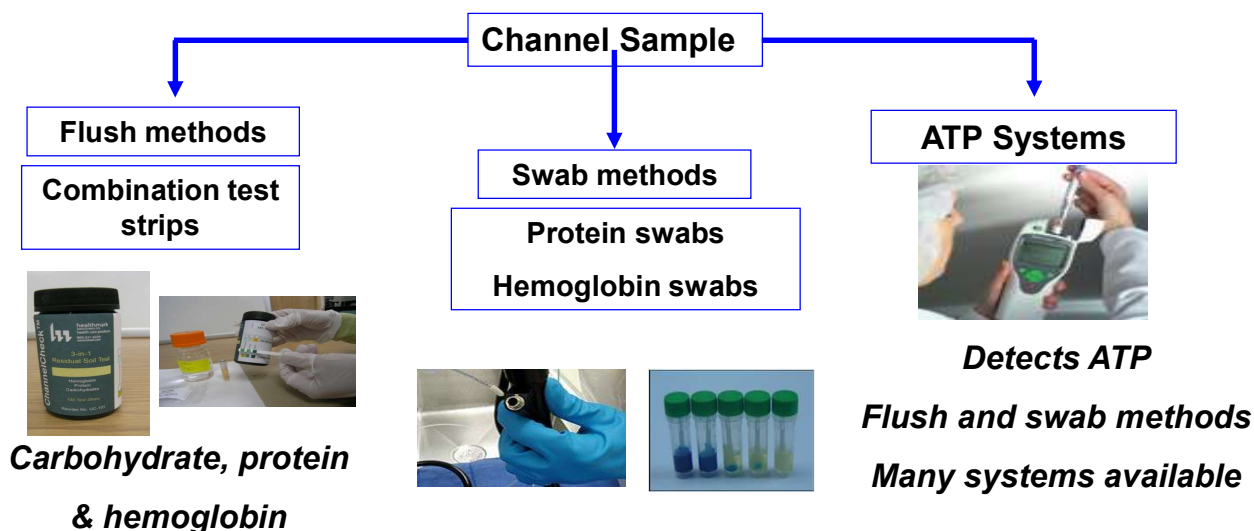
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Cleaning verification recommendations

- Current recommendations support testing of the manual cleaning process at pre-established regular intervals:
 - AAMI ST91: Regular intervals, i.e. **Weekly or preferably daily**
 - AORN: Regular intervals such as with **EACH reprocessing cycle** or daily
 - SGNA: Confirm the adequacy of manual cleaning by using a rapid cleaning monitor. If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. **Frequency determined by facility.**

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Manual Cleaning Verification Monitors



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SGNA – Visual inspection

- Endoscopes and reusable accessories should be visually inspected during all stages of handling, including before, during, and after use, as well as after cleaning and before HLD.
- Damaged endoscopes and accessories should be removed from use for repair or disposal, as this may affect their function and interfere with adequate reprocessing.

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SGNA – Endoscope Inspection

- **Treat as a safety stop or “time out” to ensure 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).
- Use magnification and adequate lighting to help assist in visual inspection.
- **Repeat manual cleaning step(s) if not clean.**



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Optical & Enhanced Inspection

AORN Recommendations:

- 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.
- 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.
- Internal channels of endoscopes may be inspected using a borescope. Borescopes penetrate the lumen and allow for improved visual inspection.



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APIC Duodenoscope 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.”

http://www.apic.org/Resource/_TinyMceFileManager/medialImages/ERCP_Press_Release_APIC_SHEA_02242015.pdf

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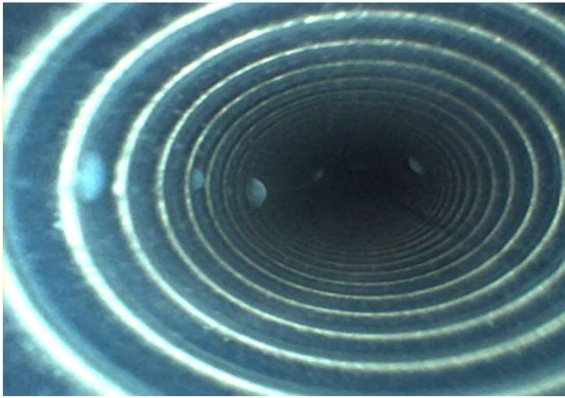
Borescope Usage

- AORN and ST91 recommend, not require
- Internal channels of endoscopes may be inspected using a borescope.
 - Borescopes penetrate the lumen and allow for improved visual inspection.
- When to use it?
 - After manual cleaning (must dry scope prior to inspecting)
 - Or scopes in storage (must reprocess scope)
- Reprocess borescope according to IFU

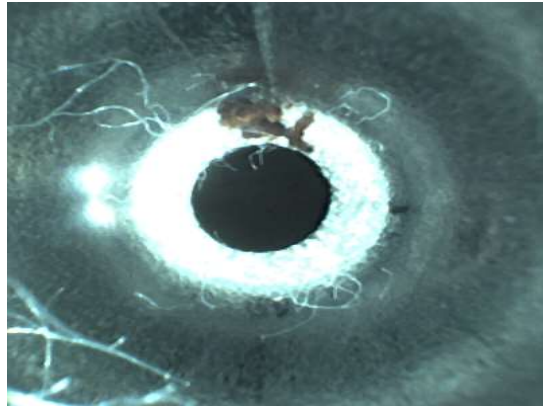


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Borescope Examination Photos



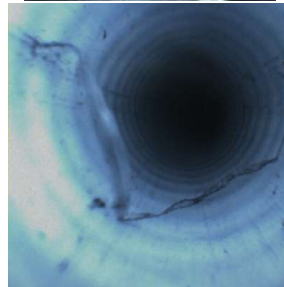
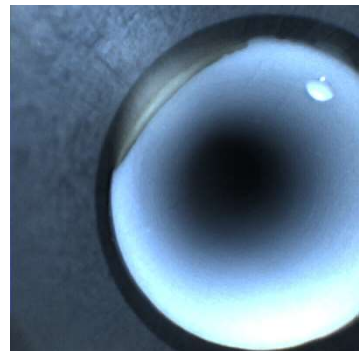
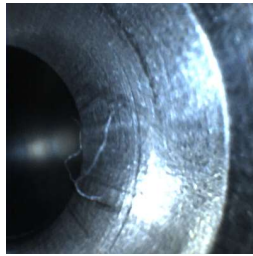
Fluid in Channel of "DRY" scope



Debris inside a channel

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Examples of Debris and Damage Found in Endoscopes.



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Best practices for High-Level Disinfection

- Remains the standard of care for reprocessing semi-critical instruments
 - Those devices which contact mucous membranes
- Sterilization is the preferred processing method!
 - Semi-critical devices should be sterilized.
 - If that is not possible, then HLD. We have defaulted to HLD over the years.
 - It has always been this way!

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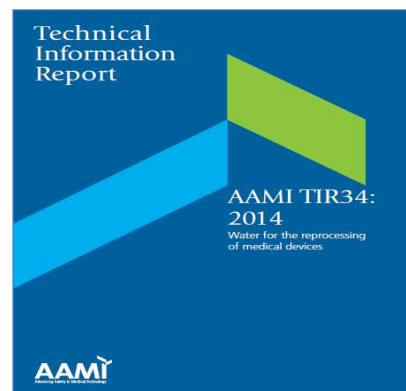
Should you still be performing Manual Disinfection?

- Scope manufacturer must validate manual process
- ST91 and SGNA do not make a preference of manual versus AER
- AORN: Automated process preferred
 - VIII.b. After manual cleaning and when compatible with the endoscope manufacturer's IFU, flexible endoscopes and accessories should be either mechanically cleaned and mechanically processed by exposure to a high-level disinfectant or a liquid chemical sterilant or should be mechanically cleaned and sterilized. *[1: Strong Evidence]*

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Remember to Rinse!

- Rinsing is often overlooked and underestimated
 - Removal of chemicals and residual soil such as protein
 - Devices should not present a toxic risk to patients
- Disconnect between type of water recommended by scope manufacturer and standards/guidelines
 - Tap vs. Critical
 - Number of rinses and rinsing method using fresh water with each rinse
 - Critical water = extensively treated
 - ex. RO, DI, distilled, sterile



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What About Automated Cleaning in an AER?

- Some AERs have FDA cleared cleaning claims.
- SGNA
 - **Risk mitigation strategy** to perform full manual cleaning then follow with machine automated cleaning
 - “Manual cleaning and brushing are still necessary when a washer-disinfector is used in order to assure the overall efficacy of HLD. The **redundancy** achieved by adding an automated washing step following manual cleaning can undoubtedly provide an extra level of safety. Users are cautioned about dispensing with manual cleaning endoscope reprocessing and brushing steps before the capabilities of the new machines are confirmed in independent studies and in clinical practice.”



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Proper maintenance of AERs

- Testing the function of mechanical processors confirms the equipment is operating correctly. Effective processing is dependent on correctly functioning equipment.
- Preventive maintenance should be performed by qualified individuals.
 - Filter changes and water line disinfection cycles
- Remember biofilms can develop in AERs and contaminate scopes.
- Test final rinse water quality in AER.
- What about wiping down the outside?

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Drying and Alcohol Flush

- Alcohol flush recommended by scope manufacturer, AAMI, SGNA
 - AORN = risk assessment
- **Follow manual and AER cycle with a flush of instrument quality forced air to ensure residual alcohol is removed**
- Refer to endoscope IFU for psi recommendations
 - Found in instruction manual, not reprocessing manual
- Dry all removable parts (valves) and do not reattach
- Keep valves with the endoscope to ensure traceability



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Drying Best Practices

- Latest research shows it takes **10 minutes** of drying
- Exterior surfaces should be dried with a soft, lint-free cloth & channels purged with instrument air.
 - Non-linting
 - Sterile wipes?
- **Instrument air:** A medical gas that falls under the general requirements for medical gases as defined by the *NFPA 99: Health Care Facilities Code*, is not respired, is compliant with the *ANSI/ISA S-7.0.01: Quality Standard for Instrument Air*, and is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40° F (-40° C).



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More info on Drying

- Scopes must be completely dry before going into storage.
- Follow manual or AER cycle with instrument quality air drying.
 - AER cycles are an air purge
- AORN: The endoscope channels should be dried by purging with instrument air or mechanically dried with a mechanical processor drying system.
- **SGNA: An endoscope that is not dry must be reprocessed before use.**
- How do you know its dry?
 - Inspect with borescope
 - Use a drying test



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Proper Storage of Reprocessed Endoscopes

- Endoscope should be hung vertically with the distal tip hanging freely in a well-ventilated, clean area following endoscope manufacturer's IFU for storage
- Angulation locks in the free position
- Sufficient space between endoscopes
- All removable parts should be detached, but kept together with the endoscope (small bag or other device)
- **AORN: Wear clean gloves** when handling processed scopes and when transporting to and from the storage cabinet.
 - Certain IFUs say sterile gloves



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Drying in Cabinets

- AORN: Drying cabinet preferred
 - If not, then cabinet with HEPA filtered air
- SGNA: Since drying does not rely on gravity, the endoscopes can be stored horizontally or vertically depending on the design of the cabinet.
 - Can not rely on hanging to dry!
- Cabinet maintenance
 - Check with manufacturer
 - Have it proceduralized



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Length of storage aka “hang time”

- **AAMI ST91:** Due to lack of consensus it is recommended to perform a **risk assessment** to establish maximum length of storage.
- **AORN:** Perform a **risk assessment** with a multi-disciplinary team to establish a policy for maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing.
- **SGNA: 7 days** based on a systematic review, if scopes are effectively reprocessed and stored in a way that keeps them completely dry and free from environmental and human contamination.

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Hang time labelling options



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Labelling for identification

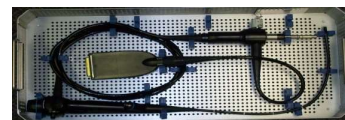
- AORN: Scopes should be clearly identified with a distinct visual cue as processed and ready for use.
- ST91: Develop protocols to ensure that users can readily identify an endoscope that has been processed and is ready for patient use.
- SGNA: Have a system in place to for identify scopes that are clean and ready to use



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Best practices for Sterilization

- Required for devices entering sterile body cavities
 - New IFU from Olympus URF-P6 ureteroscope
 - Requires sterilization and single use brushes
- More modalities compatible with surgical flexible endoscopes, less for GI
- Sterilization is still dependent on adequate **cleaning and drying!**



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New labelling for URF-P6 and P6R

- Ureteroscope recall
- Olympus letter dated 1/17/18
 - Scope tips can break off in patient
 - Also changed reprocessing instructions
 - Requires sterilization
 - Removed HLD info



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Develop an action plan for sterilization



Inventory scopes – what models do you have



Look at compatibility with sterilization methods



Move all scopes that can be easily sterilized to sterilization!

Surgical flexible scopes, ie Bronchoscopes, ureteroscopes, cysto, hystero, ENT, etc.



Look at remaining scope inventory (GI scopes)

Prioritize by risk (eg duodenoscopes)

Based on FDA recommendations, do something

•Sterilize, culture, liquid chemical sterilization, double HLD



May need to adjust inventory levels of scopes

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FDA Duodenoscope Recommendations

Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication - August 4, 2015

- Provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current IFUs for additional risk mitigation.
- Microbiological Culturing
- Ethylene Oxide Sterilization
- Use of a Liquid Chemical Sterilant Processing System
- ~~Repeat High-Level Disinfection~~ This option is no longer mentioned in the new FDA safety alert



<https://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm457132.htm>

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Microbial Surveillance

- Options include:
 - Traditional culturing
 - Gram negative test kits
- **Not ATP or cleaning verification tests**
- AAMI - No recommendation is made in the current version because of the timing of release.
 - Studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing
- AORN: Base decision on a risk assessment
- SGNA: Surveillance cultures can be used as a method for assessing reprocessing quality and aid in identifying particular endoscope defects that hamper effective reprocessing

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FDA Duodenoscope Culture Method

- Released 2-26-18
- Validated method

Duodenoscope Surveillance Sampling & Culturing

Reducing the Risks of Infection

- Supersedes the CDC Interim Method
- Flush – brush – flush method (sterile water)
- Recommends a neutralizer broth and longer incubation time
- <https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ProcessingofReusableMedicalDevices/UCM597949.pdf>

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Monitoring for Gram-negative organisms

- Rapid (12 hour) surveillance test
- Detects enzymes specific to Gram-negative bacteria generating fluorescence
- ST91: Types of verification testing may include enzyme-based tests
- Recent peer-reviewed study
 - Washburn and Pietsch, “Assessment of test methods for evaluating effectiveness of cleaning flexible endoscopes” AJIC 2017. Article in Press
 - Alfa, M. et al., [Endosc Int Open](#). 2019 Feb; 7(2): E268–E273. Published online 2019 Jan 30. Evaluation of an overnight non-culture test for detection of viable Gram-negative bacteria in endoscope channels



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Summary

- With heightened public concern and documented cases of improper reprocessing endoscopes, it is imperative that we must reduce the risk of exposure to improperly reprocessed medical devices.
- This is a shared responsibility among the healthcare facilities responsible for cleaning, disinfecting or sterilizing the devices.
- By engineering in simple quality control steps you can have a high-quality process, every time!

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References

- SGNA Standards of Infection Prevention in Endoscopy, 2015. Accessed 2-22-18: http://www.sgna.org/Portals/0/Standard%20of%20Infection%20Prevention_FINAL.pdf
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- ANSI/AAMI ST91:2015. Flexible and semi-rigid endoscope processing in health care facilities. www.aami.org
- AORN. GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES 2016, Guidelines for Perioperative Practice. February 2016.
- And as noted on slides...

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Thank you
so much!

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