

QUALITY ASSURANCE MEASURES FOR REPROCESSING ENDOSCOPES



ANGELA LEWELLYN SME, LPN, CHL, CRCST - DIRECTOR OF DEVELOPMENT AND RESEARCH
JHMEID BILLINGSLEA CST, CHL, CIS, CRCST – MANAGING DIRECTOR OF SURGICAL SERVICES

ADVANTAGE SUPPORT SERVICES, INC.

OBJECTIVES

Define and demonstrate **each step** of the processes for HLD/Sterilization

To demonstrate how **compliance** will create uniform patient care Standard Process

To demonstrate the **exception processes** for each step of the HLD/Sterilization process

To define **staff Ownership** to each step of process

To demonstrate **quality controls** to reduce the number of errors

To **present tools** for supervisors and first line technicians to evaluate workflow and outcomes

A magnifying glass is positioned over the word 'Quality', which is written in a large, bold, black font. The magnifying glass's lens is centered on the word, making it appear larger and more prominent. The background is a dark gray with several translucent, realistic-looking bubbles of various sizes scattered throughout. The magnifying glass's handle is visible in the bottom right corner, pointing towards the bottom right of the frame.

GETTING STARTED:

**ESTABLISHING
QUALITY**

Quality

QUALITY CONTROL PROCESS PERFORMANCE (WHY WE FOLLOW THESE PROCEDURES)



Quality assurance is **important in**

Minimizing risk to patients, the environment and health care personnel.



Lessening this risk can be achieved only if reusable medical devices are

Handled At POU
Transported
Cleaned
Decontaminated /
Disinfected



Under the best possible conditions in a well – designed work area.

KEYS ESTABLISHING ASSURANCE PROGRAM



Create

Create Standard HLD/Sterilization processes ensure uniform patient care



Create

Create an exception process

- what to do if things don't go as planned)



Create

Create tools to monitor the process is being followed (Implement assurances)



Train

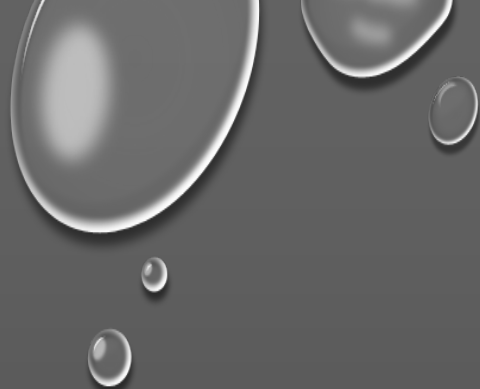
Cross train staff in all steps of the process

LOCATION AND ACCESSIBILITY (BY END USERS)

OF

CURRENT EVIDENCE-BASED GUIDELINES

- **AAMI: – ANSI/AAMI ST58, CHEMICAL STERILIZATION AND HIGH-LEVEL DISINFECTION IN HEALTH CARE FACILITIES**
- **ANSI/AAMI ST90:2017 QUALITY MANAGEMENT SYSTEMS FOR PROCESSING**
- **ANSI/AAMI ST91, FLEXIBLE AND SEMI-RIGID ENDOSCOPE PROCESSING IN HEALTH CARE FACILITIES**
- **TJC BOOSTER HIGH-LEVEL DISINFECTION (HLD) AND STERILIZATION BOOSTERPAK**
- **SGNA POSITION STATEMENTS**
- **AORN GUIDELINES**



**INCLUDE KEY
STAKEHOLDERS
INVOLVED IN
HLD AND
STERILIZATION
PROCESSES IN
YOUR RISK
ASSESSMENT**

- **INFECTION PREVENTIONISTS**
- **ENVIRONMENTAL SERVICES**
- **FACILITIES ENGINEERS (PLANT OPS)**
- **DEPARTMENT LEADERS**
- **DEPARTMENT MANAGERS**
- **FRONT-LINE REPROCESSING STAFF**
- **FLEXIBLE SCOPE END USERS**
- **DIRECTORS**

STAFF COSTS EDUCATION

QUALITY CONTROL ST 91 12.1

GENERAL CONSIDERATION

During implementation, **experienced staff will be needed to conduct cross-training**, which may slow production initially (a preceptor program).

Compare the delay from training to the current delays in production resulting from poor quality outcomes and returned instruments.

The program will allow staff to **troubleshoot and developing quality checks** will **prolong the life of flexible endoscopes**

Consider the **long-term benefit of fully cross-trained staff**

Staff ownership in the entire process will result in personal accountability and commitment to quality.

12.1 **establish and document education, training, and competency verification programs** for all personnel responsible for processing endoscopy equipment and outline schedules for periodic education and training updates and competency verification.

AUDITS: ARE WE DOING WHAT WE TRAINED?

ARE WE FOLLOWING OUR OWN POLICIES & PROCEDURES?

ARE WE CHECKING FOR COMMON ERRORS?

Evaluating and monitoring the effectiveness of the process should be an ongoing effort and is critical to maintaining control over and determining methods for improvement of the product and process.

The review of records and of documented quality control procedures that have been implemented should serve as the basis for monitoring and evaluating the process.

Written procedures should be reviewed, and **current practices audited for compliance** in the areas included in the CQI program.

Are we reviewing the areas that retain bioburden? Do we have objective tests that **take away the "Human Factor"**?

FLEXIBLE ENDOSCOPE RISK ASSESSMENT



Gap Analysis of current practices vs. best practices



Which things are we doing that could get us in trouble from a patient safety, staff safety or accreditation perspective?

**RISK
ASSESSMENT
SHOULD
INCLUDE THE
FOLLOWING:**

**INFECTION
PREVENTION PLAN
AUTHORED BY THE
MULTIDISCIPLINARY
TEAM**

What are **your organization's vulnerabilities** with HLD and/or sterilization?

What is your **volume of reprocessing** for HLD and/or sterilization? Daily? Weekly?

How many of each **endoscope type do you have?**

Are you **turning over one scope more than the others?**

How far is reprocessing from your procedure rooms?

- Distance from one area to another – Creates Problems

Do you have all of the equipment and supplies needed?

What is your **staff turnover rate?**

**RISK
ASSESSMENT
SHOULD
INCLUDE THE
FOLLOWING:

INFECTION
PREVENTION PLAN
AUTHORED BY THE
MULTIDISCIPLINARY
TEAM**

Do you have adequate documented **training and competency**?

Are you performing **concentration tests** of HLD solution between each use?

Are you **testing the temperature** of high-level disinfectant?

Are test strips **control tested** and not expired?

Is **preventative maintenance** of equipment and devices being performed as scheduled?

Are any **scopes being quality monitored**? Cleaning verification tested and/or sent out to an environmental lab?

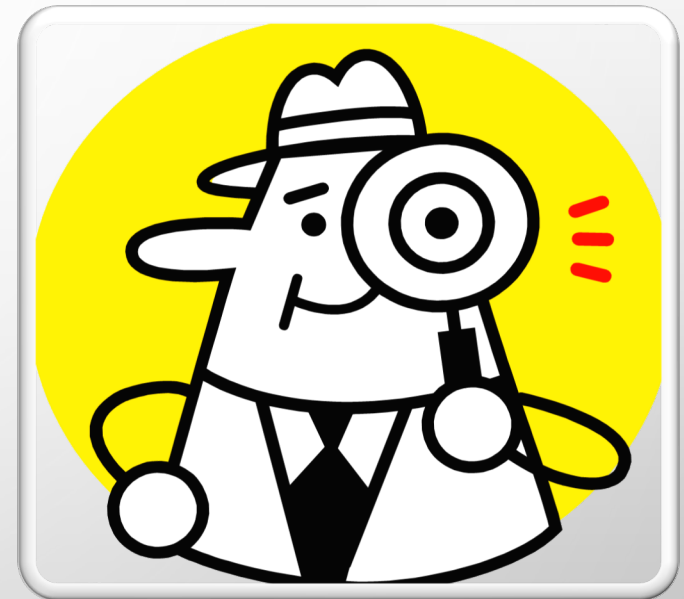
Are flexible endoscopes being sent out to be sterilized on basis determined by the multidisciplinary team? **Consideration Tool**

RISK ASSESSMENT CHART

Components Probability Risk/ Impact	Risk/ Impact	Current Systems	Score
POINT OF USE CLEANING			
SCOPE TRANSPORTATION AFTER PROCEDURE			
SCOPE CLEANING			
AER USE			
SCOPE STORAGE			
QUALITY AUDITS			
SCOPE TRANSPORT TO ROOM			

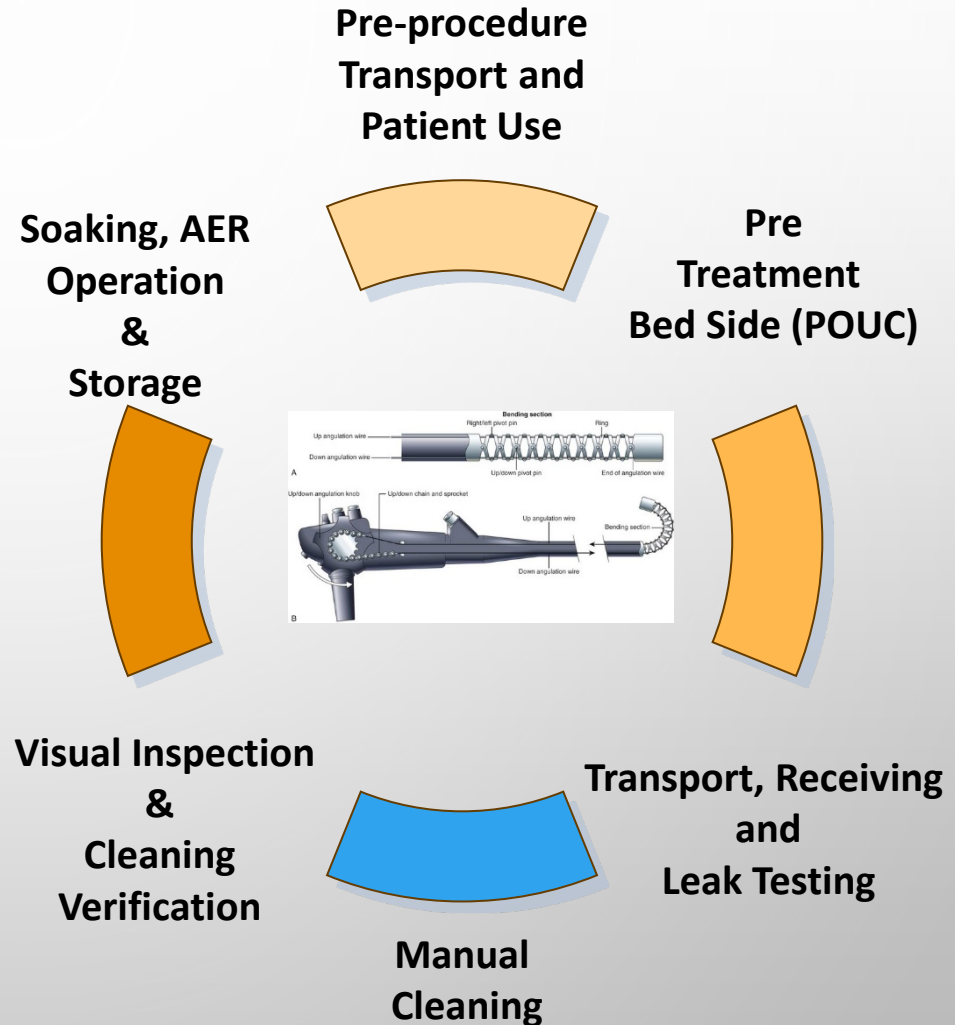
QUALITY ASSURANCE CHECKS FOR THE ENTIRE FLEXIBLE SCOPE PROGRAM

1. Do all personnel performing Scope cleaning have a detailed competency for the process?
2. Do all personnel performing scope cleaning have a Vendor led or Vendor directed initial orientation to all Equipment and supplies in the department?
3. Are brushes that match Manufacturer's IFU's located and clearly labeled in the scope processing area?
4. Are policies and procedures up to date with proper references and clear statements on: Hang times? Authorized Disinfectants? Button storage? PPE? Documentation storage? Quality Audit targets? After hours processing and call ins?

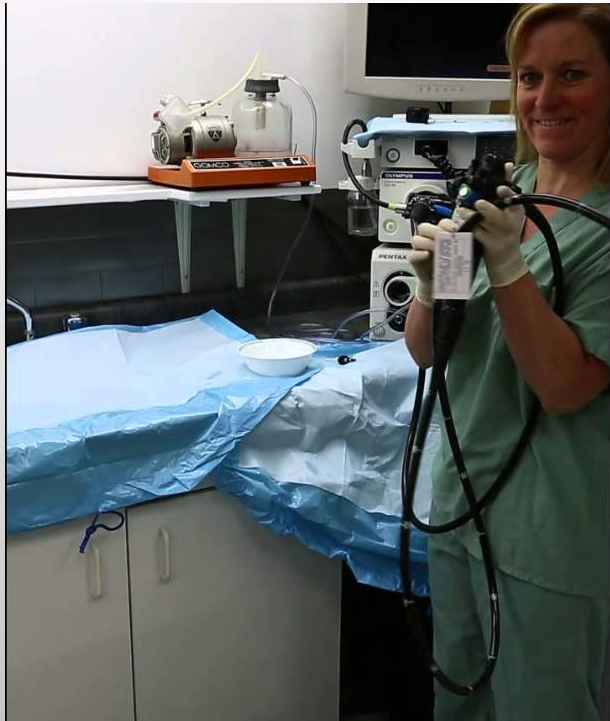


THE FLEXIBLE ENDOSCOPE PROCESS

1. **PRECLEANING –BED SIDE**
2. **TRANSPORT**
3. **LEAK TESTING**
4. **MANUAL CLEANING**
5. **CLEANING VERIFICATION**
6. **AER**
7. **HANDLING TRANSPORT**
8. **HANG PROCESS AND TIME**
9. **QUALITY AUDIT OF CLEANED AND DISINFECTED FLEXIBLE SCOPES**



STEP 1: PRE-CLEANING/BEDSIDE HINTS FOR ASSESSING



- Utilization of PPE
- Cleaning solutions, IFU & potable water
- Disposable cloths at POU
- Position of locks on scope
- Suction per IFU
- Cleaning adaptors
- Channel flushing
- Distal end in solution
- Detaching – caps
- Visual inspection

**Training/ Evaluation / Annual
Competency**

ANSI/AAMI ST 91:
5.2
CLEANING AND
HIGH-LEVEL
DISINFECTION

VISUAL INSPECTION

POINT OF USE

CLEANING AT
BEDSIDE

**PRECLEANING AT THE POINT OF USE
PREVENTS BUILDUP OF BIOBURDEN,
DEVELOPMENT OF BIOFILMS, AND DRYING
OF SECRETIONS.**

**PRECLEANING SHOULD TAKE PLACE AT THE
POINT OF USE (POU) IMMEDIATELY
FOLLOWING THE PROCEDURE**

**IT IS IMPERATIVE THAT THE WRITTEN IFU
FROM THE ENDOSCOPE, AER, AND
CLEANING SOLUTION MANUFACTURERS
ARE AVAILABLE TO END USERS AND
FOLLOWED PRECISELY!!!**

ANSI/AAMI ST 91 5 CLEANING AND HLD VISUAL INSPECTION / POINT OF USE

BEFORE THE ENDOSCOPE IS DETACHED FROM THE LIGHT SOURCE AND/OR VIDEO

A) don fresh PPE, including gloves and skin and eye protection.

B) prepare a cleaning solution according to the solution manufacturer's written ifu. Some endoscope manufacturers prescribe the use of potable water as the sole precleaning agent.

C) wipe the insertion tube with a wet, low-linting or non-linting cloth or sponge soaked in the freshly the cloth or sponge should be single use and disposed of after use.

D) suction the solution through the suction/biopsy channel as indicated in the endoscope manufacturer's written ifu.

E) flush the air/water channels with solution using the endoscope's cleaning adapter or by ifu-instructed air/water flow.

G) flush with the minimally prescribed volume of solution and ensure that the channels are not blocked.

H) place the distal end of the endoscope in the cleaning solution and suction the solution through the endoscope until clear.

I) detach the endoscope from the light source and suction pump.

J) attach a fluid-resistant cap over any electrical components, if applicable.

K) visually inspect the endoscope for damage.

TRANSPORTATION AT END OF CASE HINTS FOR ASSESSING



- **Isolating scopes in a single container – coiling loops**
- **SEPARATING ACCESSORIES / PREVENTING DAMAGE (consider packs and disposable buttons)**
- **Leakproof container w biohazard signage**
- **Sharps separate**
- **Transport clean from contaminated to decon area**



Each endoscope should be isolated and transported with its components in its own closed system to the next stage of processing, as it is considered contaminated.

To avoid puncture and penetration damage to the endoscope, devices such as forceps and wires used in the procedure should be transported in their own containers.

The system should be marked with a biohazard label and must meet osha (29 cfr 1910.1030) requirements for transporting hazardous items. The system should be large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.

Transporting steps:

A) isolate and immobilize a single endoscope in a container by naturally coiling it in large loops.

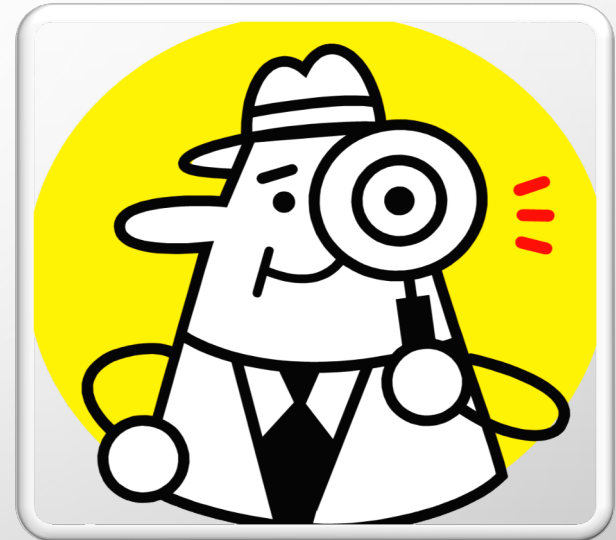
B) separate endoscopy accessories from the contaminated endoscope to prevent puncture and penetration damage.....

ANSI/AAMI ST91:2015

TRANSPORTING USED ENDOSCOPES

QUALITY ASSURANCE CHECKS FOR BED SIDE CLEANING

1. Is all gross debris removed from the outside of the scope?
2. Was suction used to “clear” debris from the scope channel?
3. Was the scope flushed with Enzymatic Solution at POU?
4. Were buttons removed and wiped down?
5. Was Patient Sticker placed on transport implement?
6. Was a bedside cleaning time written on sticker or transport implement?



RECEIVING SCOPES



Are transport containers disinfectable with facility approved chemicals?

How do we clean transport containers?

How do we know the scope does not need extended reprocessing? Golden Hour?

How do we monitor time frame from POUC to reprocessing?

Is the patient sticker attached?

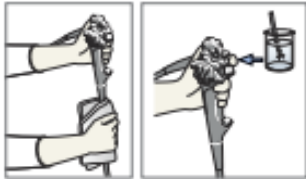
Is there a way to notify reprocessing staff when scopes arrive?

Is there a logbook or instrument tracking scan for scope drop off?

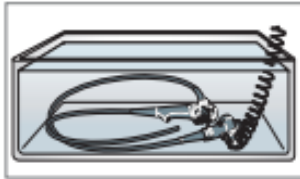
RECEIVING SCOPES

Longer than 60 minutes- ADD PROLONGED SOAKING

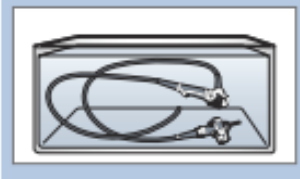
PRECLEANING - Immediately after use



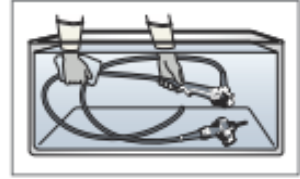
LEAK TESTING



PROLONGED SOAKING

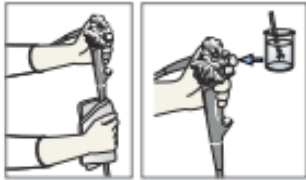


MANUAL CLEANING

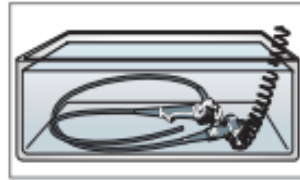


Under 60 minutes- BEGIN LEAK TESTING AND MANUAL CLEANING

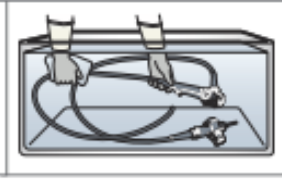
PRECLEANING - Immediately after use



LEAK TESTING



MANUAL CLEANING



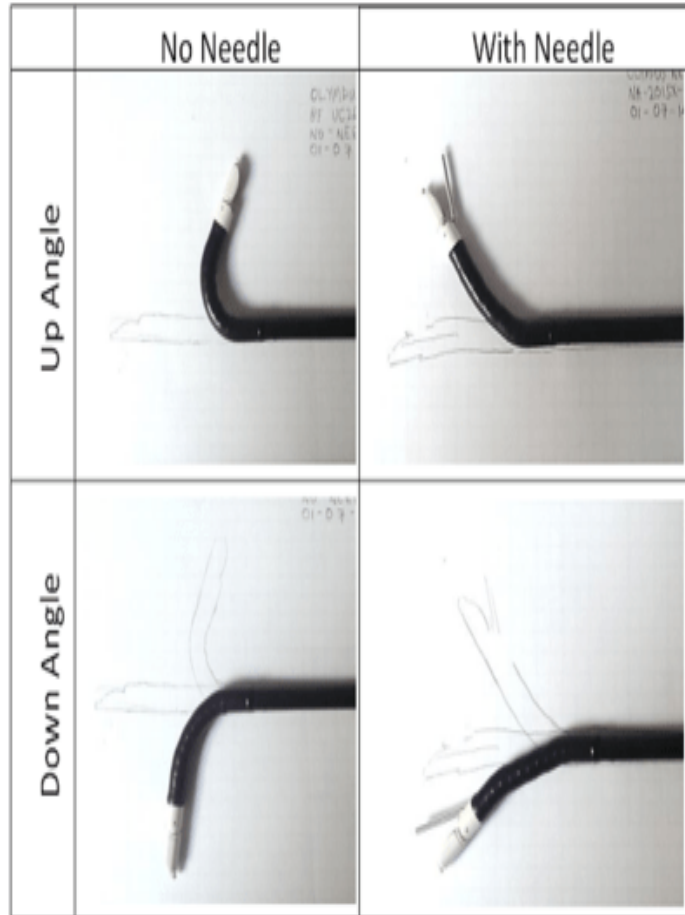
QUALITY ASSURANCE STEPS FOR FLEXIBLE SCOPE RECEIVING

- 1. Did transporter have on proper PPE?**
- 2. Does the Scope Reprocessor don full PPE?**
- 3. Do Patient Stickers remain on dirty side?**
- 4. Is POU time marked?**
- 5. Are IFU's and/or Visual processing guides available?**
- 6. If transport bins are used; Are they properly disinfected?**



LEAK TESTING

HINTS FOR ASSESSING



- **Deflect distal end in several positions for 15 secs**
- **Rotating focus ring**
- **Observe reduce pressure**
- **Distal end to neutral – release pressure**
- **TAKE alternative ACTION IF LEAK DETECTED**

ANSI/AAMI ST 91 5.4

LEAK TESTING

Leak testing should be performed as soon as possible after the endoscope arrives in the processing area and before immersion of the endoscope into processing solutions.

Leak testing can detect damage to the endoscope that may, if undetected, allow for fluid invasion into the areas not designed for fluids. These fluids can be a combination of accumulated water, chemicals, and/or biological matter that have collected from the time the endoscope's integrity was breached until the time the hole is identified.

Follow the endoscope MIFU

Wear proper PPE.

Prior to leak testing, the fluid-resistant cap should be applied, if indicated in the MIFU.

A well-lighted work surface should also be provided. Sufficient time should be allowed to permit a thorough water-tight exam. Environments, distractions, and or time limits can jeopardize a successful process.

DRY AND WET LEAK TESTING

ANSI/AAMI ST 91 5.4.2 &3

MANUAL (DRY) LEAK TESTING

FOLLOW THE WRITTEN IFU

Don fresh PPE

Remove all valves and biopsy port covers....

Attach the leak tester. Pressurize the endoscope - **loose configuration**

Gently rotate each directional knob and elevator control ... watching for changes in the established pressure.

Massage video or remote switches in a circular manner to more readily detect holes in these components.

Maintain pressure and **inspection for a minimum of 30 seconds.**

Release air pressure..... If the endoscope is water-tight, proceed with cleaning and disinfection processes.

Document outcome of leak test.

MECHANICAL (WET) LEAK TESTING

FOLLOW THE WRITTEN IFU

Don fresh PPE, - remove all valves and biopsy port covers, ... Attach the leak tester. ... Turn the air compressor on and pressurize the endoscope. Establish pressurization by confirming that the bending rubber has expanded.

Place the endoscope in a **loose configuration** in a large sink ... **clean water** to completely immerse it.

Completely flush Gently rotate each directional knob and elevator control, looking for bubbles at the bending rubber as well as at the knobs. Massage video or remote switches in a circular manner ... manipulate the insertion tube and light guide tube...

Perform a **complete visual inspection** if static bubbles are attached to the endoscope, brush them away and inspect to ensure that bubbles do not return.

Maintain pressure and inspection for a minimum of 30 seconds. - According to the mifu, remove the leak ...listen for the sound of evacuated air.

If the endoscope is watertight, proceed with cleaning and disinfection - **document outcome** of leak test.

QUALITY ASSURANCE STEPS FOR LEAK TESTING

1. When was Leak Tester last verified for function?
2. Is there enough light to process the scope and to see the bubbles for wet leak test?

Work area/function	Least illuminance	Average illuminance	Highest illuminance
General inspection	500 lux	750 lux	1,000 lux
Detailed inspection	1,000 lux	1,500 lux	2,000 lux
Sink areas	500 lux	750 lux	1,000 lux
General work areas	200 lux	300 lux	500 lux
Processed storage	200 lux	300 lux	500 lux



3. Consider the purchase of inexpensive mechanical tester over manual.
4. Can staff verbalize reprocessing steps if a scope fails Leak Test before sending it out?

MANUAL CLEANING KEY STEPS: HINTS FOR ASSESSING



- **Submerge the endoscope in the enzymatic solution**
- **REMOVE GROSS BIOBURDEN with sponge or low lint cloth**
- **Attach cleaning adapters and flush each channel with a solution separate from soak solution**
- **Use small brushes for channel openings, removable and moving parts such as elevators**
- **SOAK for IFU required TIME**
- **Rinse channels with separate water of the highest available quality (see AAMI TIR34 for critical water information)**
- **Rinse external surfaces with treated water**
- **Purge channels with air of a lower PSI than MIFU'S allow**

USING SCOPE FLUSHING MACHINES



- **Ensure tubing is disinfected or changed according to MIFU'S**
- **Hook the endoscope up using proper tubing**
- **Never use the soak water as the flushing water**
- **Never use the flushing or soak water as the rinse water**
- **This can be accomplished using labeled disinfectable buckets (which saves time throughout the day)**
- **Ensure scope flushing is programmed to match the endoscope ifu's**
- **Repeat process until flush water is free of debris**
- **Switch feeder suction to rinse water and flush until water runs clear**

ANSI/AAMI ST: 91 5.5 MANUAL CLEANING & 9. PROCESSING OF ENDOSCOPE ACCESSORIES

BRUSHES

Clean all valve cylinders, openings, and forceps elevator housings with a cleaning **brush** of the length, width, and material designated in the endoscope MIFU Note 1—endoscope valves need to be manually actuated to ensure coverage of all internal parts.

Brush all channels according to the endoscope MIFU until there is no visual debris. Note 2—cleaning **brushes** should either be single use and disposed of or reusable and receive high-level disinfection or sterilization after each use, according to their written ifu.

Repeat cleaning, **brushing**, and rinsing steps until there is no visible debris or solution residual.

Soak, scrub, **brush**, and rinse all reusable and removable parts (valves, buttons, port covers, tubing).

9 processing of endoscope accessories

Reusable endoscope components such as air/water and suction valves, biopsy port covers, water bottles, and tubing require the same level of inspection, cleaning, and high-level disinfection or sterilization as the endoscopes themselves.

Actuate the valves during cleaning to facilitate access to all surfaces. Continue to **brush and flush** the valves until no visible soils remain. Alternately, consider the use of single-use, disposable valves.

ANSI/AAMI ST 91: 5.6 MANUAL RINSING TIR 34

Using the cleaning adaptors provided by the manufacturer, **ensure copious amounts of potable water** through each lumen.

Rinse all exterior endoscope surfaces with freely flowing potable water.

Purge channels with air using a syringe to evacuate residual rinse water. **If compressed air is used**, it should be oil-free and used at a pressure not to exceed

Rinse all valves and other removable components .

Dry the exterior of the endoscope with **a lint-free** cloth or sponge..

After cleaning, all detachable **valves should be kept together** with the same endoscope as a unique set.

QUALITY ASSURANCE STEPS FOR MANUAL CLEANING

1. Is there a **lighted magnifying** glass available at the sink for enhanced visual inspection?
2. Are sinks marked to determine **proper dosing** for enzymatic solutions?
3. Is there **scheduled documented testing for automatic dosing implements** and clearly marked signs with pumps for manual dosing and backup?
4. How is **temperature** of enzymatic solution **monitored**?
5. Are all **three “waters” separate** for the entire process?
6. Is **automated flushing machine disinfected** and serviced as required in IFU'S?
7. Is the disinfection and **change of tubing** documented?
8. Is the **final rinse performed according** to IFU'S?
Example: three rinses



CLEANING VERIFICATION METHODS



- **Cleaning verification tests - level the playing field** and ensure that the scopes achieve the same level of cleanliness regardless of which team member cleans an endoscope
- **The multidisciplinary team** should choose between ATP based tests and strip based tests
- The test should be accompanied by **documented training** to perform
- A protocol should be established for documentation and repeat cleaning based on failed cleaning verification tests
- **Supervisors should be notified of repeat failed tests** to monitor and assist with the next repeat of the test

ANSI/AAMI ST 91 12: QUALITY CONTROL

CLEANING VERIFICATION

Cleaning verification tests are performed following cleaning and are used to verify the effectiveness of a cleaning process to remove or reduce to an acceptable level the organic soil and microbial contamination that occurs during the use of an endoscope.

When developing a user verification procedure for the cleaning process, reprocessing personnel should ensure that:

The facility has established, clarified, and documented a standard cleaning process for the device

Facilities should develop a defined program of cleaning verification that includes frequency of testing, number, and types of endoscopes to be tested.

Cleaning verification results are documented. The facility has established, clarified and documented a process to address cleaning verification failures.

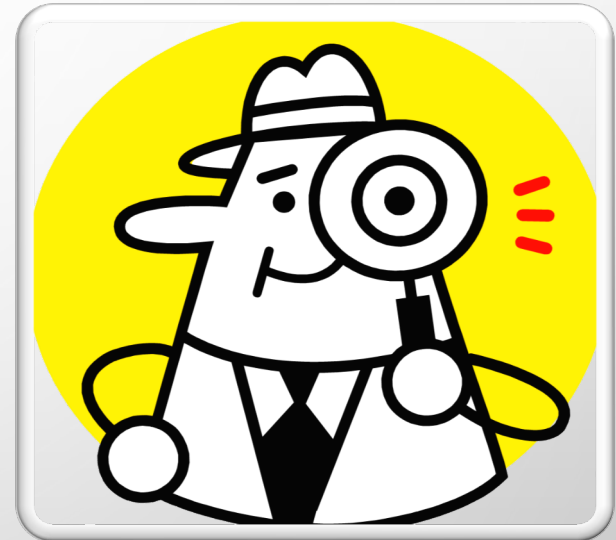
The facility has established an education, training, and competency assessment program that verifies personnel are consistently achieving the expected level of cleaning.

Cleaning verification of flexible and semi-rigid endoscopes by users should include:

Visual inspection combined with other verification methods (see section 12.4.3) that allow the assessment of both external surfaces and internal housing and channels.

QUALITY ASSURANCE STEPS FOR CLEANING VERIFICATION

1. Does Cleaning Verification **start with Visual inspection** of the Endoscope, Accessories and movable parts?
2. Were proper cleaning **brushes used** according to endoscope IFU's?
3. Are all **staff trained** on Cleaning Verification and **can demonstrate**?
4. Is there a protocol that **EVERY endoscope is tested**?
5. Are all test results **documented with the Scope SN#**?
6. Are all testing **supplies unexpired**?



MANUAL HIGH-LEVEL DISINFECTION OF ENDOSCOPES: HINTS FOR ASSESSING



- **Post instructions** per manufacturer
- **Don PPE** and use only containers validated FOR HLD for this purpose
- **Prepare solution** according to MIFU, then test the solution for minimum effective concentration (**MEC**)
- Fully **immerse** the endoscope and flush solution into channels of endoscope
- Cover the basin and **soak the endoscope** for the time and at the temperature required by the **MIFU'S**
- **Document the process** (MEC, time and temp) at the conclusion of the timed cycle
- Document **the patient** the endoscope was last used on
- **Rinse** the endoscope with water and purge channels with air
- **Flush with alcohol** to aid with drying **if allowed** by MIFU'S

AUTOMATED HIGH LEVEL DISINFECTION OF ENDOSCOPES: HINTS FOR ASSESSING



- **Post instructions** per manufacturer
- Ensure staff has **documented training** on operation of AER
- Ensure the proper **patient information** from the last use is documented
- Ensure the AER has **enough solution and alcohol** to function properly
- Ensure proper **connections**
- Check the processing receipt for the **following parameters**: HLD CONTACT TIME, basin temperature, leak testing results, dry time and alcohol and air flush

PROCESSING OF ENDOSCOPE ACCESSORIES: HINTS FOR ASSESSING

- **All accessories should be manually cleaned and placed in a containment implement that carries them to the proper endoscope**
- **Check the IFU'S to see if the item can be run in the aer or requires manual soaking**
- **If items can be sterilized, partner with your sterile processing department to achieve this state**
- **Consider single use accessories to prevent an outbreak of multi drug resistant organism because disinfection is not as lethal as sterilization**



DOCUMENTATION 12.3.1

- **Assigned lot number**, including chemical sterilizer, AER, or soaking container identification and cycle number;
- **Specific contents** including quantity, processing area, and a description of the items;
- **Patient's name** and unique patient identifier;
- **Procedure, physician**, and, if applicable, serial number or other identification of the item;
- **Shelf-life date**, if applicable, **the lot number**, and **the date that the original container of LCS/HLD was opened**; **the use-life of the open container**; **the date that the product was activated** or diluted; the date that the activated, diluted, or ready-to-use solution **was poured into a secondary container**; and **the reuse-life of the solution**;
- **Exposure time and temperature**, if not provided on the physical monitors;... **date and time of cycle**;
- **LCS/HLD type and concentration**; **ph test results** if required by facility policy or manufacturer's written IFU.
- **Name or initials of the operator**;
- **Results of MRC or MEC solution monitoring strip**, if applicable;
- **Results of the quality control of test strips**, if applicable;
- **Testing results** (as indicated by **solution test strips** or chemical monitoring devices); and any reports of positive microbial contamination testing

QUALITY ASSURANCE STEPS FOR HIGH LEVEL DISINFECTION STEPS

- 1. Is the AER physically separated or at least 36" from Cleaning Area?**
- 2. Are Timers and validated Thermometers available when manual soaking is used?**
- 3. Is there documented cleaning of AER's and/or soak basins?**
- 4. Are connectors color coded or labeled for easy matching with endoscopes?**
- 5. If Instrument Air is used – Is It Low enough PSI for endoscopes?**
- 6. Is proper PPE used during Disinfection (hair covers)?**
- 7. How and where are disinfection records kept and are they reviewed?**
- 8. Is there clear documentation of AER filter changes?**



STORAGE AND TRANSPORT OF DISINFECTED ENDOSCOPES

HINTS FOR ASSESSING

- **Hangtime follows facility policy (based on AORN or SGNÄ recommendations)**
- **Storage in cabinet validated for endoscopes**
- **Inspect facility temp and humidity**
- **HEPA FILTER/ VENTILATION for continuous drying**
- **“clean” tags with date of disinfection on every endoscope**



STORAGE AND TRANSPORT HINTS FOR ASSESSING

- **Clear trackability of endoscopes to and from patients for recall purposes**
- **Backup protocol, supplies and equipment for manual process when using aer**
- **Attachments dried and separate storage**
- **HANDLING SUPPORTED SCOPE loosely COILED with proper ppe**



ANSI/AAMI ST 91 STORAGE QUALITY ASSURANCE

The CDC recommends that **a policy and procedure** be developed develop protocols

Attach a tag or label (or other method)
For quality assurance, the tag should be labeled with the following information:

- A) **date of processing**
- B) **name(s)** of person(s) who performed the processing
- C) **date of high-level disinfection**

...

Cabinets feature hepa-filtered air that is used to provide positive pressure in the cabinet

... **understand the role** moisture plays in contributing to **microbial growth**

To help ensure that no moisture is left on or in any part of the endoscope all channels **should be flushed with 70–80% alcohol** to facilitate drying ...

All **channels should be purged with filtered medical grade air at the correct PSI ...** special storage cupboards or cabinets designed for endoscopes

The **temperature and humidity** in the area where the scopes are stored should be monitored.

Do not use the carrying case designed to transport clean and processed endoscopes outside of the health care environment

Used to store an endoscope or to transport the instrument within the health care environment.

TABLE 2—ENDOSCOPE STORAGE RISK ASSESSMENT CHECKLIST

Storage of sterilized endoscopes	YES	NO	ACTION
Endoscopes are rotated according to policy			
Storage conditions are monitored according to ANSI/AAMI ST79			
Endoscopes are stored in a vertical non-coil position			
Endoscopes are identified and labeled			

TABLE 2—ENDOSCOPE STORAGE RISK ASSESSMENT CHECKLIST

Storage of high-level disinfected endoscopes	YES	NO	ACTION
Endoscopes are stored so that residual fluid does not remain in the channels			
Endoscopes are stored, with their detachable parts dismantled, in a manner that keeps them secure and together with the endoscope as a unique set			
Endoscopes are stored in a vertical non-coil position			
Tracking is available for each endoscope, including last episode of HLD			
If a storage cabinet is used, all manufacturer's written IFU should be followed and documented			

QUALITY ASSURANCE STEPS FOR STORAGE

1. **Does hangtime match policy? Can the staff verbalize policy? How are expiring endoscopes identified daily?**
2. **Is a documented cleaning schedule present on the storage cabinet?**
3. **Are endoscopes stored in a manner that prevents touching other scopes or the bottom?**
4. **Storage in a clean area only (no outside boxes) marked as a restricted area.**
5. **Is there a clearly documented schedule and plan to change HEPA filter in cabinet?**





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QUESTIONS / DISCUSSION TIME

REFERENCES:

- ALL PICTURES USED IN THIS PRESENTATION: LICENSED UNDER CC BY-NC-ND
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ADVANTAGE SUPPORT SERVICES

Please contact either Angela or Jhmeid to answer any questions / provide solutions

ANGELA LEWELLYN

AMLEWELLYN@ADVANTAGESUPPORTSERVICES.COM

JHMEID BILLINGSLEA

JBILLINGSLEA@ADVANTAGESUPPORTSERVICES.COM