Meeting the Challenges of Endoscope Reprocessing and Documentation

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Scope processing professionals are under constant pressure to produce endoscopes processed according to each device's instructions for use and conforming to all industry standards and hospital guidelines requiring documentation on conforming outcomes, quality standards, and performance measurement.

Contending with these factors while meeting the demands of a fast-paced endoscopy case schedule brings challenges to staff and facility processes. Medical device asset management software can help manage workflow documentation and safeguard quality outcomes.

Learning Objectives

1. **List processing challenges and considerations for the seven essential steps of flexible endoscope processing**
2. **Identify how medical device asset management software can lead staff through complex tasks**
3. **Explain how data captured and documentation in software can improve quality, performance, and patient outcomes**

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Challenges of Endoscope Reprocessing

Properly processing an endoscope is extremely complex. Some endoscope manufacturers' Instructions for Use (IFU) contain over 100 steps to leak test, manually clean, and render the endoscope ready to use on the next patient.

Processing endoscopes and capturing all necessary documentation is extremely complex and can be aided by medical device asset management software. Referencing manufacturer instructions for use and guidance documents is critical to a quality process and positive patient outcomes but creates difficulty in the decontamination environment. The wet environment ruins paper while laminated cards can be difficult to handle with bulky gloves. Electronic IFU and on-screen guidance protect instructions during use, allowing access while performing tasks.

A second challenge during endoscope processing is documentation. According to the Healthcare Infection Control Practices Advisory Committee (HICPAC), a federal advisory committee to the Center for Disease Control and Prevention (CDC), there are seven essential steps for flexible endoscope reprocessing: pre-cleaning, leak testing, manual cleaning, visual inspection, disinfection or sterilization, storage, and documentation. Endoscopy processing should "maintain documentation of adherence to these essential steps each time an endoscope is reprocessed. Documentation is essential for quality assurance purposes and for patient tracing in the event a look back is necessary." (HICPAC, 2016, p. 3). Medical device asset management software can help with documentation and quality processes.

Considerations for Each Essential Step

Considerations for Point-of-Use Treatment

Each step of reprocessing presents its own challenges. First, consider point-of-use treatment or pre-cleaning. According to the Society of Gastroenterology Nurses and Associates (SGNA, 2018) guidelines, "Pre-cleaning occurs in the procedure room immediately after removal of the insertion tube from the patient and prior to disconnecting the endoscope from the power source. Pre-cleaning should be performed at point of use, before bioburden has an opportunity to dry and before complete decontamination." (p. 16).

The Association for the Advancement of Medical Instrumentation (AAMI, 2021) concurs within the standard ANSI/AAMI ST91, which states, "To prevent buildup of bioburden, development of biofilms, and drying of secretions, point-of-use treatment is performed immediately after completion of use of the device. It is imperative that the manufacturers' IFU for the endoscope, cleaning equipment, and cleaning solution are followed." (Section 7.2.1).

Point-of-use treatment is the first line of defense in preventing the formation of biofilms. Biofilm is a diverse community of bacteria and fungi that can congregate, attach to surfaces, and create their own extracellular matrix for protection, making them difficult to remove during cleaning. Point-of-use treatment is critical in reducing bioburden and biofilm buildup.

Though point-of-use treatment reduces bioburden, it does not eliminate it. Endoscopes must promptly begin the cleaning process so residual soils do not dry and remaining microorganisms do not have time to create biofilm. Many endoscope IFU give a 60-minute window from the time of point-of-use treatment and the start of manual cleaning. If this time threshold is exceeded, the IFU may require extra processing steps such as extended soak times. Added processing steps and soak times extend the wait time for a patient-ready endoscope.

Manual documentation relies on staff to identify the endoscope's remaining time and prioritize it upon receipt. This dependence can lead to delayed processing or the potential to use normal processing instructions for an endoscope requiring additional processing.

Electronic medical device asset management software can allow for documenting the time of point-of-use treatment completion and prioritization of endoscopes to prevent the need for delayed reprocessing. Some software systems identify the need for delayed reprocessing at the time of manual cleaning, providing guides and steps for processing time delayed endoscopes.

Some software allows procedure room staff to document the room they are serving and the procedure ID. They can scan the endoscope's barcode to associate it with the procedure and document point-of-use treatment in the procedure room.

Considerations for Leak Test and Manual Cleaning

Following IFU, with some endoscopes having over 100 steps, is not simple. It is easy to see why steps might be missed. The complexity continues as cleaning instructions vary between models of the same type of endoscope. An Olympus bronchoscope may have different cleaning instructions from a Pentax bronchoscope. Even different models of bronchoscopes from the same manufacturer may have different cleaning instructions. As stated by SGNA (2018), "Any deviation from the reprocessing protocol can lead to the survival of microorganisms and increased risk of infection." (p. 4) Documentation of each essential step is essential.

Manual checklists can help make sure each step is completed, but this is challenging in practice. Each endoscope make and model may need a different checklist. General checklists with branching instructions can lead to confusion and mistakes.

Some facilities may choose to complete manual documentation after cleaning. However, documenting after the fact can lead to errors. Staff must remember what they did and rework is necessary when missed steps are identified.

Capturing documentation requires a clear process and procedure. All endoscope processing staff must have sufficient training on the process for capturing documentation. They need to know what to document and how to document it.

Medical device asset management software can help staff follow the correct IFU for the endoscope being cleaned and document the manual cleaning process. Some software allows creation of standard work for each endoscope's processing procedures. Processing guides provide step-by-step on-screen instructions during endoscope processing.

Some software systems have guided workflows to help lead staff through each step. This step-by-step guidance

Lesson:

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Quiz Answers:
1. D, 2. B, 3. D, 4. A, 5. B, 6. C, 7. A, 8. D, 9. C, 10. E

can help technicians know what to do in what order, and include required interactions like checkboxes or confirming test results, such as leak test results.

Additional instructions can appear based on the result of a leak test or other interactions. With conditional documentation, instructions can appear on screen based on the test result. For example, if a technician documents that the leak test failed, instruction is provided indicating what to do next per facility policy.

Interactions built into a workflow confirm that critical steps, such as passing visual inspection, were completed. Each checkbox selected, comment made, test result recorded, and date entered is captured in the documentation.

Considerations for automated endoscope reprocessors (AER)

Automated processing of endoscopes can aid documentation of the essential steps. Automated endoscope processors can clean, high level disinfect, liquid chemically sterilize, or perform a combination of these activities. Many AERs have connectors specific to the make and model of the endoscope. As with any medical device, following the IFU is essential.

Cycle printouts and electronic files provided by AERs record and document start times, cycle lengths, cycle parameters, chemistry lot numbers, and other critical factors. Equipment can alert staff to equipment or utility failures through cycle printouts.

Medical device asset management software can guide staff through the process of endoscope placement in the processor. Diagrams for hooking up the endoscope can be attached to the workflow for easy access.

Some AERs can electronically transfer cycle printouts and critical information such as cycle start and end times to medical device asset management software, linking cycle information to the reprocessing record of the endoscope.

Considerations for Visual Inspection

Visual inspection occurs throughout the process. Staff may inspect external surfaces using lighted magnification and internal channels using a borescope.

Staff should document any damage discovered and subsequent repairs. Facilities must have policies and procedures describing actions required when damage is found. Considerations may include additional communications with the patient or the need to look back on previous cases.

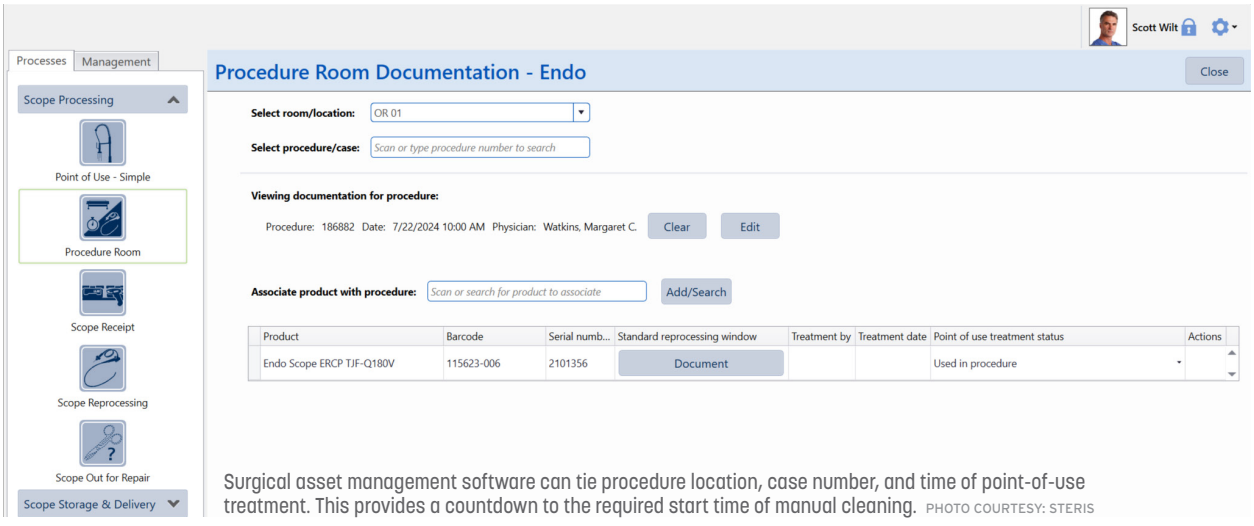
Medical device asset management software allows staff to document inspection results including attaching borescope images. Software can provide guidance and examples during inspection and assist in “look backs” when necessary.

Considerations for drying and storage

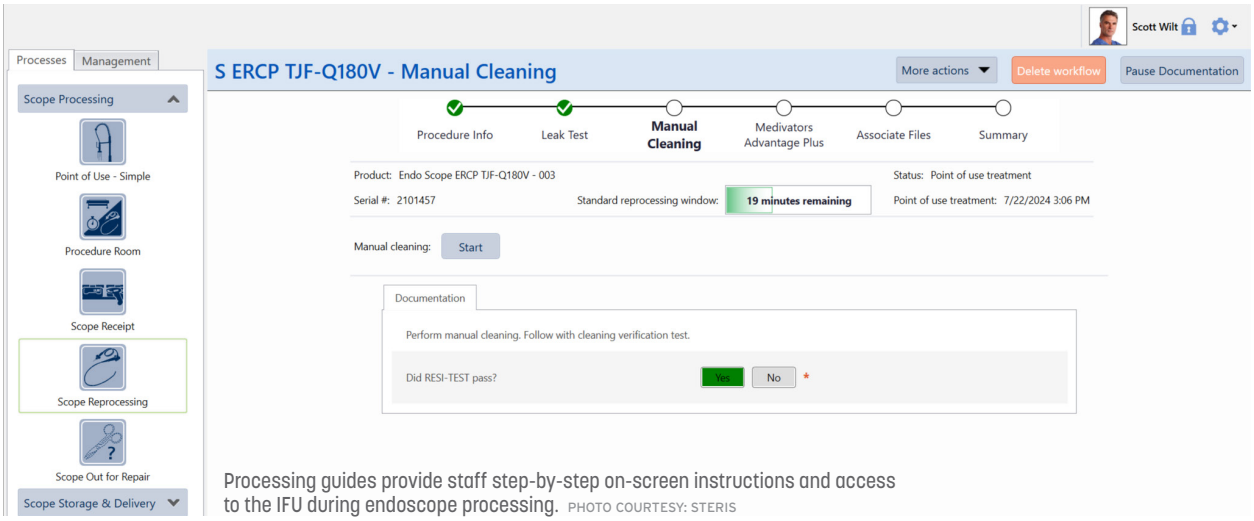
Endoscopes must be dry prior to storage. Residual moisture left in lumens can provide an environment for microorganisms to grow and potentially create biofilms. Facilities should develop procedures to dry endoscopes prior to storage. Facilities may use borescopes or other moisture tests to confirm dryness. All such test results should be documented either manually or in medical device asset management software.

Special storage cabinets can filter air entering the cabinet. Filtration helps reduce the exposure of the endoscope to environmental contamination. However, it is not sterile storage. Each facility should determine how long an endoscope can be stored before it is reprocessed again. The storage time should be documented prior to use of the endoscope. Endoscopes can be manually labeled with the storage time.

Some cabinets track storage time providing alerts when the end of the storage time is approaching or has ended. Medical device asset management software can track storage time,



Surgical asset management software can tie procedure location, case number, and time of point-of-use treatment. This provides a countdown to the required start time of manual cleaning. PHOTO COURTESY: STERIS



Processing guides provide staff step-by-step on-screen instructions and access to the IFU during endoscope processing. PHOTO COURTESY: STERIS

provide warnings when a scope is nearing its expiration, and receive information from storage cabinets to allow efficient scheduling of endoscope usage.

When the endoscope is processed and ready to store, a readily available electronic record of the essential processing steps is stored within the medical device asset management software, fulfilling the seventh essential step detailed by HICPAC (HICPAC, 2016). The record includes all process steps and outcomes, workflow test results, endoscope processor cycle documentation, and users associated with the process.

Ensuring Staff Competency

Staff competency is critical in cleaning and processing flexible endoscopes. Some medical device asset management software includes staff competency features. These features allow staff to demonstrate competency in endoscope cleaning and processing and limit endoscope processing work to qualified users.

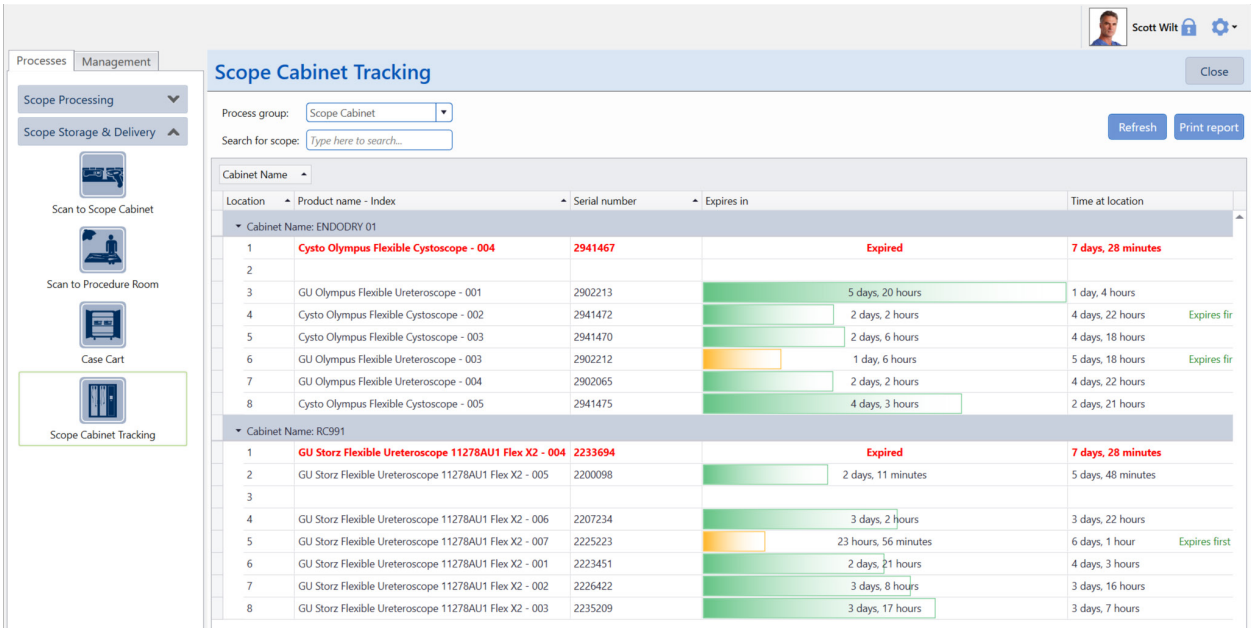
Quality Assurance and Process Improvement

SGNA (2018) states that facilities should have "Consistent oversight, compliance, documentation, and process improvements in place to support a quality program." (p.5)

A quality program helps the department consistently provide endoscopes ready for patient use. Facilities should ensure:

- Policies and procedures are followed
- Staff are competent
- Nonconformities, such as residual soils found after cleaning, are resolved
- Data is evaluated for negative trends

With electronic data capture, quality reporting becomes easier and often more accurate than manual processes. These reporting tools allow review of



Medical device asset management software can help facilitate a first-in, first-out rotation. PHOTO COURTESY: STERIS

processing steps, tests, and repair history down to an individual staff member or endoscope.

Some software includes quality features and the ability to document nonconformities. Quality management features may allow trending reports to identify areas for improvement, document corrective actions taken, and review quality events to drive continuous quality improvement.

Conclusion

Scope processing is a vital and complex process. Medical device asset management software helps ensure all required endoscope processing tasks are completed in a structured, disciplined manner while capturing essential data for a quality program. Software can drive quality and ideal outcomes from point-of-use treatment through every reprocessing step to tracing the endoscope to a patient. Having all the information and tools in one place allows for efficiency in documentation, data retrieval, and process improvement, preparing facilities for the next credentialing audit while providing the best patient outcomes. HPN

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Meeting the Challenges of Endoscope Reprocessing and Documentation - Practice Quiz

1. **Which of these is true of some asset management software?**
   - A. May give staff a guided, disciplined process to follow
   - B. Give technicians access to on-screen resources
   - C. Documentation on conforming outcomes can be easily captured as staff complete work
   - D. All of the above
2. **What is the first line of defense in preventing the formation of biofilms?**
   - A. Decontamination
   - B. Point-of-use treatment
   - C. Manual cleaning
   - D. Visual inspection
3. **What is biofilm?**
   - A. Procedural soils including blood and bacteria
   - B. The pre-sterilization population of viable microorganisms
   - C. Bacteria living on a surface captured in visual inspection
   - D. A diverse community of bacteria and fungi that can congregate, attach to surfaces, and create their own extracellular matrix
4. **Which of these is NOT one of the essential steps in endoscope processing identified by HICPAC?**
   - A. Transport
   - B. Visual inspection
   - C. Documentation
   - D. Storage
5. **What step must happen within 60 minutes after an endoscopy procedure according to many IFUs?**
   - A. Completing point-of-use treatment
   - B. Beginning manual cleaning
   - C. Placing the endoscope in the endoscope processor
   - D. Thoroughly drying the endoscope
6. **What feature in some asset management software can help ensure only qualified users do the work of endoscope processing?**
   - A. Quality events
   - B. Associate files such as IFUs
   - C. Staff competencies
   - D. Conditional workflows
7. **Which of these can occur using conditional documentation in some asset management software?**
   - A. Instructions can appear on screen based on a test result
   - B. The result of a machine run leak test can be captured
   - C. A color-coded timer bar may appear
   - D. Resources such as IFU can be accessed in the workflow
8. **Which of these is NOT something procedure room users document?**
   - A. The room they are serving and procedure ID
   - B. The endoscope used in the procedure
   - C. Performing point-of-use treatment
   - D. Performing manual cleaning
9. **Which of these does SGNA state need to be in place to support a quality program?**
   - A. 30 days of training prior to new staff reprocessing flexible endoscopes independently
   - B. Manual documentation of each essential step in the process
   - C. Consistent oversight, compliance, documentation, and process improvements
   - D. On-screen access to resources such as IFUs, images, or instructional videos
10. **Which of these can be documented in asset management software?**
    - A. All process steps and outcomes
    - B. Workflow test results
    - C. Scope processor cycle documentation
    - D. All associated users
    - E. All of the above

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