





Cleaning Monitoring for Flexible Endoscopes

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LEARNING OBJECTIVES

1. Understand why cleaning monitoring is a critical quality control tool for flexible endoscope reprocessing
2. Review the fundamentals of cleaning verification, how adenosine triphosphate monitoring works, and why it is effective for monitoring cleanliness
3. Describe the necessary steps to implement a successful monitoring program

Flexible endoscopes are complex medical devices used in a variety of medical procedures for both diagnosis and treatment. As endoscope design and technology have advanced, flexible endoscopes have grown in complexity and in their use in surgical procedures, advancing the field of minimally-invasive surgeries (MIS). Flexible endoscopes allow access to internal organs and structures through an existing opening or orifice, eliminating the need for a large surgical incision, and thereby, greatly minimizing patient recovery time.

Objective 1: Understand why cleaning monitoring is a critical quality control tool for flexible endoscope reprocessing

While the benefits of such procedures are well understood, the risk of endoscope-associated patient infection has only been widely recognized in the past few years, based on evidence of multiple outbreaks and persistent contamination on fully reprocessed endoscopes.¹⁻⁵ Initially, it was assumed that the main culprit for endoscope-associated infections was one particularly complex type of

endoscope, called a duodenoscope, that has an elevator mechanism at its distal end; however, evidence of outbreaks and persistent contamination for other types of flexible endoscopes continue to be reported.⁶⁻⁸ A colonoscope manufacturer recently reported to the US Food and Drug Administration (FDA) that two US patients developed an infection of carbapenem-resistant *Enterobacteriaceae* (CRE), an antibiotic-resistant superbug, after undergoing procedures involving the same colonoscope in 2018.⁹ Another interesting finding that more and more clinical evidence supports is that upper gastrointestinal (GI) flexible endoscopes are notably dirtier than lower GI endoscopes.^{4,5}

Endoscope processing is a lengthy and complex multi-step process that involves manual cleaning that is most commonly followed by high-level disinfection (HLD) but may, alternatively, be followed by terminal sterilization. Over the past few years, US professional organizations and governmental agencies have issued updated guidelines related to reprocessing flexible endoscopes.¹⁰⁻¹³ While the guidelines vary on some



of the specific recommendations, all include a focus on implementing quality control practices and more thorough manual cleaning procedures. With the renewed focus on manual cleaning, some guidelines specifically recommend the use of rapid cleanliness indicators to be used after the manual cleaning step and before HLD or sterilization.¹¹⁻¹³

Objective 2: Review the fundamentals of cleaning verification, how adenosine triphosphate monitoring works, and why it is effective for monitoring cleanliness

With the recommendation to focus on manual cleaning and to implement a comprehensive quality control program, it is important for reprocessing professionals to understand how they can monitor the cleaning process and recognize what is needed to implement a cleaning monitoring program at their facility.

In order for a surface, device or instrument to be effectively disinfected or sterilized, it must first be effectively cleaned.¹⁴ This means that the cleaning step needs to reduce the amount of soil on the endoscope to a level that is low enough for the following HLD or sterilization steps to be effective. Cleaning is the process of removing clinical soil.

How does one know whether the endoscope is clean? It is nearly impossible to visualize with the naked human eye the bioburden that may remain on an endoscope after the complex cleaning procedure. So what can be done? Reprocessing professionals can check for the presence of soil after cleaning by looking for a component of the soil that will be present if the endoscope is still dirty. There are a variety of organic compounds that can be used as a marker of organic soil. Adenosine triphosphate (ATP) is one example of these organic compounds.

ATP is present in all living cells and what is left behind by living cells. ATP testing does not distinguish between living or dead matter and, therefore, can function well as a universal marker of organic clinical soil.

External surfaces and internal channels can be sampled for ATP using a commercially-available ATP monitoring test. ATP bioluminescence technology uses an enzymatic reaction to convert ATP from the sample collected to light. A luminometer can then detect how much light is produced and report this amount as an objective, numerical result, in Relative Light Units (RLUs). That numerical result, in RLUs, is directly related to how much ATP was present in the sample; therefore, it indicates how clean or dirty the endoscope is. The dirtier the endoscope, the more ATP will be present, and the more light will be produced, resulting in a higher RLU value.

Objective 3: Describe the necessary steps to implement a successful quality monitoring program

The first step in establishing a cleaning monitoring program is to decide which marker and cleaning verification system to use. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*, Annex D, lists the currently available cleanliness markers.¹⁵ Once it has been established which system to employ, the next step is to determine the facility's policies and procedures for the cleaning monitoring program. A useful reference in drafting the facility's policies and procedures is ANSI/AAMI ST91:2015, *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities*, Section 12.4.11 Specifically, AAMI ST91 recommends that facilities:

1. Develop a defined program of cleaning verification that includes frequency of testing; number, and types of endoscopes to be tested;
2. Document cleaning verification results;
3. Establish, clarify and document a process to address cleaning verification failures; and
4. Establish an education, training and competency assessment program.

Regarding the #3 recommendation, some facilities have implemented a policy that if an endoscope fails the cleaning verification test two (or sometimes three) times in a row, that endoscope should be pulled from inventory and sent out for inspection and/or repair (specifying which test point failed the cleaning verification test).

The key components of a successful cleaning monitoring program are shown in Figure 1 and detailed in the following paragraphs.

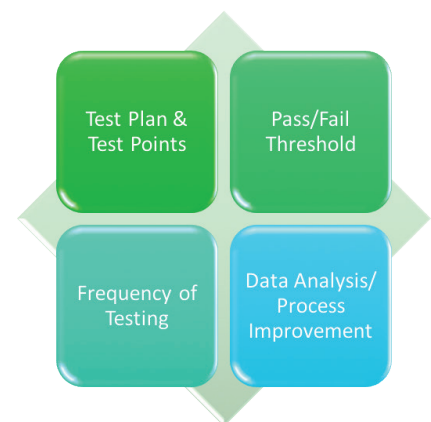


Figure 1: Key components of a successful cleaning monitoring program

First, it must be determined which endoscopes will be tested and which test points on each endoscope type will be tested. One option would be to apply the same standard of care to all endoscopes and monitor every endoscope in inventory. Another option would be to



categorize the endoscopes into high-risk [e.g., duodenoscopes, bronchoscopes, ultrasound endoscopes (EUS, EBUS), and ureteroscopes] and less-risk endoscopes (e.g., colonoscopes) and monitor only the high-risk endoscopes.

Next, it must be decided which test points for each endoscope type will be tested. The facility may choose, for example, to test the instrument/suction channel and the outer distal end for every endoscope type, as well as the elevator mechanism for applicable endoscopes. Additionally, the facility may also consider testing the control handle, the instrument port, the elevator guidewire channel (if present) or any other test point deemed necessary.

Next, it must be decided how often endoscopes will be monitored for cleanliness. Again, one option would be to apply the same standard of care to all endoscopes and monitor every endoscope, every time. Another option would be to monitor depending upon endoscope type or risk level (e.g., Endoscopes could be categorized into high risk and less risk, with every high-risk endoscope monitored every time and lower-risk endoscopes monitored at established intervals, such as when purchased, weekly or daily, or by random sampling).

It will also be necessary to define what “clean” means before testing begins; this includes establishing a pass/fail threshold or condition. For at least a starting point, it will be beneficial to refer to the monitoring system manufacturer’s recommend pass/fail threshold.

Finally, it should be established how the data received from the cleaning monitoring program will be used. Rapid indicator results can be used for immediate feedback and allow for immediate action or correction. If an endoscope fails the cleaning test, the endoscope should be re-cleaned and re-

tested. Only when an endoscope obtains a passing cleaning test result should the endoscope be allowed to proceed to HLD or sterilization. If an endoscope is re-cleaned and re-tested and is unable to achieve a passing cleaning result, the facility will need a policy on how to handle this event and when to send the endoscope out for inspection or repair.


In addition to using the rapid indicator tool for immediate feedback and action, the data collected should also be reviewed on a regular basis to identify trends and actionable items in order to improve the cleaning process overall.

Ongoing review and trend analysis of the collected cleaning monitoring data is an important part of improving the overall endoscope cleaning process. Some ATP monitoring systems collect and trend the data in a way that allows the data to be reviewed in a variety of ways, including:

- Looking at the overall pass/fail rate at a higher level;
- Evaluating staff competencies, education and training;
- Determining whether systematic issues exist for specific test points or endoscope types; and
- Identifying the endoscopes that are hardest to clean and that exhibit repeated cleaning test failures.

While the initial stage of implementing an endoscope cleaning monitoring program can be daunting or even disruptive if endoscope repairs are being deemed necessary more often than in the past, a cleaning monitoring program will allow the manual cleaning process and the condition of the endoscopes to be improved and maintained. As a result, the “fleet” of endoscopes can be improved by identifying damaged or aging endoscopes that may be in need of repair or replacement.

Conclusion

Some patient-ready endoscopes are contaminated and, despite increasing awareness, some problems remain. Cleaning monitoring is an important part of a comprehensive quality control program for endoscope processing. ATP monitoring can provide immediate feedback and allow for corrective action before proceeding to HLD or sterilization, while also providing numerical, objective results that can be tracked and trended over time. This data can be analyzed and reviewed for actionable items that can be addressed to improve the overall process. A successful cleaning monitoring program includes pre-established policies and procedures; a detailed test plan with specific test points for each endoscope to be tested; a predetermined frequency of testing; a predetermined pass/fail threshold; and regular, ongoing data analysis. 

REFERENCES

1. Murray P. Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients. US Senate. Health, Education, Labor and Pensions Committee. Minority Staff Report. Jan.13, 2016.
2. Epstein L, Hunter J, et. al. New Delhi Metallo β -Lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes. *JAMA* 2014(312):1447-55.
3. Oftsead CL, Wetzler HP, Doyle EM, Rocco CK, Visrodia KH, Baron TH, Tosh PK. Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines. *Am J Infect Control*. 2015(43): 794-801.
4. Ofstead CL, Wetzler HP, Eiland JE, Heymann OL, Held SB, Shaw MJ. Assessing residual contamination and damage inside flexible endoscopes over time. *Am J Infect Control*.



- 2016(44): 1675-7.
5. Ofstead CL, Wetzler HP, Heymann OL, Johnson EA, Eiland JE, Shaw MJ. Longitudinal assessment of reprocessing effectiveness for colonoscope and gastroscopes: Results of visual inspections, biochemical markers, and microbial cultures. *Am J Infect Control*. 2017(45):e26-e33.
 6. Wendelboe A, Baumbach J., et.al. Outbreak of cystoscopy related infections with *Pseudomonas aeruginosa*: New Mexico. 2007. *J Urol* 2008;(N180):588-92.
 7. Ofstead CL, Quick MR, Wetzler HP, Eiland JE, Heymann OL, Sonetti DA, Ferguson JS., Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *CHEST* 2018. Nov; 154(4):1024-1034.
 8. Dickson A, et. Al. Possible pseudotransmission of *Enterobacter cloacae* associated with an endobronchial ultrasound scope. *Am Journal Infect Control*. 2018(46):1296-1298.
 9. Muscarella LF. A colonoscope is linked to two infections of the nightmarish 'CRE' superbug. *Discussions in Infection Control*. 2019. <https://www.lfm-hcs.com/2019/01/a-colonoscope-is-linked-to-two-infections-of-the-nightmarish-cre-superbug/> Accessed May 1, 2019.
 10. US Dept of Health and Human Services. Food and Drug Administration. Supplemental measures to enhance duodenoscopy reprocessing. FDA Safety Communications. August 2015.
 11. Association for the Advancement of Medical Instrumentation. *Flexible and semi-rigid endoscope processing in health care facilities*. ANSI/AAMI ST91:2015. Arlington (VA): AAMI, 2015.
 12. Association of periOperative Registered Nurses. Guidelines for Processing Flexible Endoscopes. AORN 2016.
 13. SGNA (Society for Gastroenterology Nurses and Associates): Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes 2018. Standards in Infection Prevention in Gastroenterology Settings 2015. Guideline for Use of High-Level Disinfectants & Sterilants in Gastroenterology Setting 2017.
 14. Rutala W, Weber D. and the Healthcare Infection Control Advisory Committee (HICPAC) Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008.
 15. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. ANSI/AAMI ST79:2017. Arlington (VA): AAMI, 2017.
 16. Alfa MJ, Fatima I, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. *Am J Infect Control*. 2013(41):249-53.



CRCST Self-Study Lesson Plan Quiz - Cleaning Monitoring for Flexible Endoscopes

Lesson No. CRCST 167 (Technical Continuing Education - TCE) • Lesson expires July 2022

1. Infectious outbreaks have been linked to which type of flexible endoscope:
 - a. Duodenoscope
 - b. Gastrointestinal endoscope
 - c. Colonoscope
 - d. All the above
2. Adenosine triphosphate can be used as a marker for:
 - a. Living cells only
 - b. Dead cells only
 - c. Both living and dead cells
 - d. None of the above
3. Adenosine triphosphate monitoring systems employ an enzyme that converts adenosine triphosphate to light, and luminometers that detect the amount of light and report it in Relative Light Units to achieve a numerical result.
 - a. True
 - b. False
4. Cleaning monitoring should be performed after:
 - a. Removing the endoscope from the automated endoscope reprocessor
 - b. High-level disinfection
 - c. Manual cleaning and before high-level disinfection or sterilization
 - d. Leak testing
5. Too much residual soil left on the surface of an endoscope can inhibit:
 - a. The sterilization or disinfection process
 - b. The packaging and sterilization process
 - c. Competency testing
 - d. None of the above
6. It is important to establish policies and procedures specific to:
 - a. The cleaning monitoring program
 - b. Verification practices
 - c. Competency testing
 - d. All the above
7. One of the key components of a successful cleaning monitoring program is:
 - a. Data analysis
 - b. A test plan
 - c. Defined frequency of testing
 - d. All the above
8. Professional and governmental guidelines for endoscope reprocessing all include a focus on:
 - a. Instructions on how to manually clean each type of endoscope
 - b. Quality practices and through manual cleaning
 - c. Manual cleaning and automated endoscope reprocessor operation
 - d. Point-of-use treatment and specific hang times for each type of endoscope
9. Key test parts of the endoscope to consider include:
 - a. Elevator and eye piece
 - b. Instrument channel and distal tip
 - c. Control handle and umbilical cord
 - d. All the above
10. Rapid indicator results allow for:
 - a. Immediate feedback
 - b. Guarantee of a successful high-level disinfection process
 - c. Verification of leak test results
 - d. All the above
11. Components of a cleaning monitoring program include:
 - a. Process improvement
 - b. Pass-fail thresholds
 - c. Test points
 - d. All the above
12. An effective cleaning monitoring program will allow the endoscope manual cleaning process and endoscope condition to improve.
 - a. True
 - b. False
13. Cleaning steps need to reduce the amount of soil on the endoscope to a level that is low enough for:
 - a. High-level disinfection or sterilization steps to be effective
 - b. Proper aseptic presentation
 - c. Use in unsterile procedures
 - d. All the above
14. Some facilities have a policy that if an endoscope fails a cleaning verification test several times:
 - a. The endoscope should be cleaned following manufacturers' instructions for delayed processing
 - b. The endoscope should be sterilized before use
 - c. The endoscope should be sent out for inspection and/or repair
 - d. Staff competencies should be reviewed and revised
15. Trend analysis of cleaning data can help improve the cleaning process by:
 - a. Evaluating staff competencies and training
 - b. Identifying the endoscopes that are most difficult to clean
 - c. Determining if there are cleaning issues with specific test points
 - d. All the above

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