In response to the increased risk of cross-contamination of flexible endoscopes during reprocessing, several professional organizations have issued revised or new guidelines and recommended practices, including the Association for the Advancement of Medical Instrumentation (AAMI), the Association for periOperative Registered Nurses (AORN) and the Society of Gastroenterology Nurses and Associates (SGNA). Given the criticality of the manual cleaning step to effectively disinfect or sterilize medical devices, the guidelines have added **recommendations for implementing a quality program that includes cleaning verification testing as part of comprehensive, routine quality control** for reprocessing flexible endoscopes.[1,2,3]

How to go from standards and guidelines to implementation of a routine quality control program?

There are five key components that go into the successful design and implementation of a routine cleaning monitoring program for flexible endoscopes using the Clean-Trace ATP Monitoring System:

1. Design a test plan and determine test points.

2. Identify validated Pass/Fail thresholds.

3. Determine frequency of testing.

4. Establish meaningful metrics.

5. Track, trend and regularly review test result data.

1. Design a Test Plan

Clean-Trace ATP testing of the flexible endoscope occurs after manual cleaning and before high-level disinfection. The Clean-Trace ATP Monitoring System is NOT intended to be used for testing after high-level disinfection or automated cleaning/high level disinfection cycles in an automated reprocessing system.

H20: Neogen® Clean-Trace® ATP Water Test H2O
UXC: Neogen® Clean-Trace® ATP Surface Test UXC

Test Point Recommendation

	Elevator Guide Wire Channel Present		No Elevator Guide Wire Channel
	Open channel	Sealed channel	
Suction Biopsy Channel (H2O)	X	X	X
Outer Distal End Surface (UXC)	X	X	X
Elevator Mechanism (UXC)	X	X	
Elevator Guidewire Channel (H2O)	X		

2. Validated Pass/Fail Threshold

Neogen recommends the following validated Pass/Fail thresholds for all test points. These threshold levels were validated in simulated-use studies and then verified in a clinical setting, where it was demonstrated that these Pass/Fall thresholds are effective in the detection of dirty endoscopes.[4,5]

Pass ≤ 200 RLU
Fail ≥ 201 RLU

3. Frequency of Testing

Because flexible endoscope reprocessing has a small margin of safety and given that the risk of pathogen transmission is much higher than previously thought, Neogen recommends healthcare facilities strive to **monitor every endoscope after each use.**[6]

Continued on next page.

Flexible Endoscope Implementation Guide for Routine Cleaning Monitoring

Neogen® Clean-Trace® ATP Monitoring System

Minimum recommended testing frequency:

- Every flexible endoscope in inventory should be monitored a minimum of once per week.[1]
- Endoscope types with high risk of pathogen transmission (e.g. duodenoscopes, EUS scopes, bronchoscopes) should be monitored after each manual cleaning cycle/ each use.[7,8]

Refer to guidelines for additional guidance and rationale to determine the frequency of testing.[1,2,3]

4. Establishing Metrics

The target metrics for the facility should reflect the cleaning monitoring program objectives and may evolve and change over time.

- % Pass/Fail of combined endoscope data for an overall view of cleaning effectiveness.
- % Pass/Fail by endoscope type or serial number provides a means to target problem endoscope or processes.
- % Pass/Fail by staff highlights training successes as well as identifies those needing to increase competency levels.

5. Track and Trend Test Result Data

In order to obtain actionable feedback, sufficient data sets must be collected if a true understanding of cleaning efficacy is to be achieved. The Neogen® Quality Control Data Manager provides an intuitive dashboard for quick, visual snapshots of manual cleaning performance and powerful reporting options to manage and communicate results.

Flexible endoscopes should be monitored at the recommended frequency of testing so that any adverse trends can be detected in a timely manner. It is highly recommended that data be reviewed, at a minimum, once per week and preferably each day the system is used.

Using Monitoring Data to Improve Flexible Endoscope Reprocessing

Monitoring data is typically used in two ways:

1. **Quality Control:** Monitoring results provide real-time feedback on cleaning efficacy. If a flexible endoscope receives a failing result, the endoscope should be immediately re-cleaned and re-tested until a passing result is achieved. If after three attempts an endoscope still shows failing results, this is an indication that the endoscope may have problems and should be sent to the manufacturer for assessment and possible repair.[9]
2. **Process Improvement:** The collection of monitoring results over time offers the opportunity to gather statistically-valid data sets that can be used to improve flexible endoscope cleaning efficacy.

- Identify aging, damaged endoscopes that are difficult to clean.
- Identify when the manual cleaning process is not being performed according to established procedures.
- Understand how soiling levels affect the manual cleaning process, e.g. therapeutic and emergency procedures result in dirtier endoscopes than routine screening procedures.
- Assess effectiveness of training and competency protocols by highlighting both successes and improvement opportunities.

References

1. AAMI (Association for the Advancement of Medical Instrumentation) ANSI/AAMI ST91:2021. Flexible and semi-rigid endoscope processing in health-care facilities. Available for purchase: https://www.aami.org
2. AORN (Association of periOperative Registered Nurses) Guidelines for Processing Flexible Endoscopes. 2016.
3. SGNA (Society for Gastroenterology Nurses and Associates) Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes. 2016.
4. Alfa MJ, Fatima I, Olson N. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. 2013. Am J Infect Control. 41: 245-8.
5. 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. 41:249-53.
6. Rutala WA, Weber DJ. ERCP Scopes: What Can We Do to Prevent Infections? Infect Control Hosp Epidemiol 2015. 36(6):644-648.
7. U.S. Food and Drug Administration. Reprocessed Flexible Bronchoscopes: FDA Safety Communication - Risk of Infection. https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm462949.htm. Updated September 17, 2015.
8. U.S. Food and Drug Administration. Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication. http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm. Updated March 4, 2014.
9. Ofstead CL, et al. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: Results of visual inspections, biochemical markers and microbial culture. 2017. Am Infect Control. 45(2):e26-e33.

NEOGEN®

Neogen Corporation, 620 Lesher Place, Lansing, MI 48912 USA.