

3M™ Clean-Trace™
Hygiene Management System



Hygiene Management Guide for Flexible Endoscopes

3M Infection Prevention Solutions

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Aim

The Hygiene Management Guide is a document outlining the steps necessary to set up and implement an effective adenosine triphosphate (ATP) hygiene monitoring system within a healthcare environment. This document details the application of ATP hygiene monitoring for flexible endoscope reprocessing after manual cleaning and prior to high-level disinfection or sterilization.

Introduction

In the US alone, over 11 million gastrointestinal endoscopy procedures are performed on an annual basis highlighting the beneficial role these procedures play in the prevention, diagnosis and treatment of disease.^{1,2} Endoscopy procedures are performed using complex, reusable, flexible instruments that, when inserted into the body, may become heavily contaminated with patient biomaterial and microorganisms, including potential pathogens. Careful reprocessing of flexible endoscopes between patients is critical to reducing the risk of cross-contamination and the possible transmission of pathogens.

Flexible endoscopes are rated as semi-critical according to the Spaulding classification for medical devices and therefore it is required that these devices be decontaminated by high-level disinfection.⁸ Meticulous cleaning of the endoscope must precede any high-level disinfection of these instruments. "Cleaning is the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products."⁹ Failure to perform proper cleaning leaves behind organic and inorganic residues that may interfere with the disinfection process increasing the risk for reprocessing failures and patient infection.^{5,9,10}

In the case of gastrointestinal (GI) endoscopy, "...all published occurrences of pathogen transmission related to GI endoscopy have been associated with failure to follow established cleaning and disinfection/sterilization guidelines or use of defective equipment."² Because there continues to be recurrent, widespread incidences of lapses in adherence to established reprocessing guidelines patients are routinely put at risk for infection.^{1,4} Although current guideline documents make strong statements about the rarity of pathogen transmission from improperly reprocessed flexible endoscopes, there is now compelling evidence that the risks are much higher than originally thought.^{1,18}

Contaminated endoscopes have been linked to more outbreaks of health-care associated infections (HAIs) than any other medical device.⁹ "Flexible endoscope reprocessing has been shown to have a narrow margin of safety. Any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection."⁶ Current understanding suggests that if the recommendations for reprocessing endoscopes are followed the risk of transmission of pathogens is rare. There is now compelling evidence that these assumptions may be



“ATP hygiene monitoring provides an objective and quantifiable “real-time” approach to assess and measure cleaning efficacy.”

incorrect and that the risks are much higher than presently thought.^{1,17-20}

The current risk estimates for pathogen transmission have been shown to be “inaccurate, outdated and based on flawed methodology.”¹ Documented, prolonged lapses in endoscope reprocessing are common occurrences putting patients at risk of infection.^{1,17-20} Recent studies have shown that multi-drug resistant organisms (MDRO) are being transmitted to patients with infection rates ranging from 6-42% representing a much higher incidence of pathogen transmission than is predicted by the current risk estimates.^{1,20} There is also evidence that current methods for cleaning and reprocessing endoscopes may not be adequate. The result is the use of patient-ready endoscopes that still harbor residual contamination (bioburden/microbes).^{16,19}

The American Society for Gastrointestinal Endoscopy (ASGE) states, “The first and most important step in the prevention of transmission of infection by an endoscope is manual cleaning of the endoscope with detergent solution and brushes.”⁵ Studies have shown that the manual cleaning step is prone to error.^{6,7} Direct observation has revealed that adherence to established protocols for manual cleaning occurs only 43% of the time.^{7,17}

The need to evaluate the efficacy of the cleaning process has been recognized as an important part of flexible endoscope reprocessing.^{5,9,10} It is recommended that both endoscopes and reusable accessories be frequently visually inspected “in the course of their use and reprocessing, including before, during, and after use, as well as after cleaning and before high-level disinfection.”² This method of cleaning verification has severe limitations when applied to flexible endoscopes because the complex, narrow lumens in these devices cannot be directly visually inspected.

Currently, there is no standard to define when a device is “clean,” but it is generally accepted that a cleaning process should include the reduction of the microbial bioburden and the removal of any organic and inorganic matter resulting in an instrument that is visibly clean and can be effectively disinfected or sterilized. The Centers for Disease Control and Prevention (CDC) Guideline on Disinfection and Sterilization in Healthcare Facilities states, “Although the effectiveness of high-level disinfection and sterilization mandates effective cleaning, no “real-time” tests exist that can be employed in a clinical setting to verify cleaning. If such tests were commercially available, they could be used to ensure an adequate level of cleaning.”⁹

ATP hygiene monitoring provides an objective and quantifiable “real-time” approach to assess and measure cleaning efficacy. The test can be performed in less than 30 seconds providing a real-time result that indicates the cleanliness of the instrument tested. This provides an opportunity to take any corrective action required such as re-cleaning and re-processing.

Considering the new information on the increased risk for endoscopy-associated infection it is important to implement a routine monitoring program that detects reprocessing errors and monitors levels of endoscope contamination. A robust monitoring program supports and promotes proper endoscope reprocessing while verifying effectiveness thus supporting increased patient safety.

ATP bioluminescence monitoring technology

What is Adenosine Triphosphate (ATP)?

ATP is the molecule that provides energy for cellular metabolism and is present in all living cells. Consequently it is present in any organic residue (e.g. body fluids, skin cells and microorganisms) making ATP an excellent marker for organic contamination or contamination from a biological source.

The principle of bioluminescence reaction

The 3M™ Clean-Trace™ Hygiene Management System is based on the measurement of levels of ATP present on a surface or the interior of a lumen of a flexible endoscope. 3M™ Clean-Trace™ ATP Surface and Water Test are used to sample defined test points. The test is then activated and is brought into contact with the test enzyme solution (luciferin-luciferase). The enzyme reacts with any ATP residue present on the swab. A product of this reaction is the generation of light by the enzyme solution. The Clean-Trace ATP Surface or Water Test is then placed in the 3M™ Clean-Trace™ Luminometer. This measures the light generated by the enzyme solution and generates a result expressed in Relative Light Units (RLUs). The greater the level of ATP present on the swab, the greater the amount of light generated by the test and consequently, the higher the RLU level produced.

Data analysis and reporting

Rapid results allow for corrective action to be taken at the time of testing. Review and trend analysis of collected data is an important part of maintaining and improving reprocessing standards on an ongoing basis. To provide a mechanism for reviewing ATP results the Clean-Trace Hygiene Management System includes the 3M™ Clean-Trace™ Online Software, a tool for the capture, auto-analysis of results and auto-generation and delivery of reports. Tracking results over time helps to indicate the effectiveness of manual cleaning procedures as well as detect any developing adverse trends. The Clean-Trace Online Software provides a range of reports that allow easy interpretation and review of results that can be shared with key stakeholders at all levels.



3M Recommended Monitoring Plan for Flexible Endoscopes

Although current guidelines do not have clear recommendations for monitoring flexible endoscope reprocessing the Multi-Society Guideline does make the following statement, “Future efforts should be aimed at improving compliance with accepted guidelines in all centers where endoscopy is performed.”² It is well known that one of the best ways to ensure compliance to a process is to monitor the process. What follows in the remainder of this document is the description of a comprehensive monitoring plan that provides a clear path for establishing and growing a complete monitoring program. This plan is composed of two sections that include Education, Training and Competency, Process Assessment and Routine Monitoring.

Section 1 – Education, Training and Competency

It has been shown that positive, supportive educational interventions, training and regular competency evaluations can result in improved performance.¹¹ Such interventions should include efforts to monitor the cleaning process and provide feedback to the reprocessing staff. The more positive training experiences provided for reprocessing staff, the more likely they will exhibit the discipline to do the job right and achieve the consistent results needed to keep your reprocessing procedures under control.

Section 1 Plan focuses on education, training and competency. There are a number of variables that can affect how well a flexible endoscope is cleaned. These may include the complexity of the instrument, the cleaning chemicals that are used, the cleaning protocol followed, as well as the performance of reprocessing staff. Based on continuing research at 3M, the factors showing the largest variability impacting cleaning protocols are the individual staff members (i.e. worker-to-worker variability). Ensuring proper education and training can lead to competency and is the first step in any quality control program.

The following steps provide an example on how to structure an evaluation of Education, Training and Competency.

Education and Training

1. Identify reprocessing staff members (and other staff responsible for cleaning equipment) for whom training is required.
2. Identify the types of endoscopes that will be used during training. It is recommended that one scope of each type be used during training.
3. Conduct training, on each endoscope type, according to your facility's policies and procedures.
4. Measure ATP levels after the bedside flush and prior to manual cleaning. To measure ATP levels in the endoscope prior to manual cleaning, sample the endoscope using the protocol outlined in Appendix 1.
5. Have the reprocessing staff member manually clean the endoscope following your facility's policies and procedures.
6. Using a fresh 3M™ Clean-Trace™ ATP Surface and Water Tests, sample the endoscope again following the protocol outlined in Appendix 1.
7. To complete the initial testing, sample an additional 2 endoscopes following the procedure outlined above.

8. Monitor the effectiveness of training over time. 3M recommends that monitoring occur during initial training with follow up at 1 week, 1 month and 3 months for a total of 4 training intervals. Monitor 3 flexible endoscopes at each interval for a total of 12 endoscopes.
9. Staff should be able to achieve a pass (≤ 200 RLUs) after manual cleaning on 11 out of the 12 endoscopes. If necessary, conduct additional training to improve performance levels.

Evaluating Competency

The competency of reprocessing staff should be monitored at regularly scheduled intervals. 3M recommends that competency evaluations be performed, at a minimum, every 3 months increasing to every month as your quality program develops over time.


Steps 1-9 described under Education and Training can also be used to perform competency evaluations. Competency evaluations should be performed using those endoscopes that demonstrate the highest level of bioburden, typically the upper GI flexible endoscopes (gastrosopes, duodenoscopes).^{15,16}

The 3M™ Clean-Trace™ Online Software enables documentation and trending of both individual and combined staff competency and training results. Several report types are available that can be customized to fit a variety of training record requirements.


Section 1 Plan – Education, Training and Competency – Summary

Education and Training + Competency Audit = Total Tests/Year


E D U C A T I O N A N D T R A I N I N G


#
staff


X


3
endoscopes

X


4
ATP tests **


X


4
quarterly audit


=

**Total #
of Tests**


C O M P E T E N C Y A U D I T


#
staff


X


3
endoscopes

X


4
ATP tests **

X


4
quarterly audit

=

**Total #
of Tests**

E X A M P L E :

Education & Training: 5 staff x 3 endoscopes x 4 tests x 4 intervals = 240 tests

Competency Audit: 5 staff x 3 endoscopes x 4 tests x 4 intervals = 240 tests

480 Tests /Yr TOTAL

* 2 water tests, 2 surface tests

** before and after manual cleaning with surface and water tests

| = surface test

| = water test

Section 2A – Assessment of the Manual Cleaning Process

When beginning any process improvement initiative it is important to first understand the current state of your program. In this section you will be assessing the efficacy of the manual cleaning process for flexible endoscopes in your facility. Because the risk of pathogen transmission is currently unknown it is important to know if your process is under control when measured against the most current cleanliness benchmarks.^{12,13}

What follows is a description of a thorough and robust assessment procedure. Using the 3M™ Clean-Trace™ System to develop your monitoring program provides quantitative and objective data to monitor cleaning performance and supports creating a comprehensive quality improvement program.

Please note that sampling the flexible endoscope after high-level disinfection or sterilization is NOT recommended.

3M recommends that every flexible endoscope be monitored until the requirements of Section 2A have been met.

Initial Assessment

The goal of the initial assessment process is to identify those areas where the process is working well and identify those areas where improvement may be needed. This process involves sampling the scopes and then analyzing the results.

Sample flexible endoscopes

- The sampling protocol can be found in Appendix 1 and 2.
- Sample 20-30 flexible endoscopes. The sample set should include results from all the different types of endoscopes used in your facility. It should also include results that are representative of all reprocessing staff.
- It is recommended that sampling occur after manual cleaning and prior to high-level disinfection or sterilization.
- Recommended test points
 - Outside surface of the distal bending section
 - Suction/biopsy channel
 - *Control head, air/water, biopsy and suction valves, elevator guide wire (EGW) if present on scope
- Pass \leq 200 RLU Fail \geq 201 RLU
- Record results using the 3M™ Clean-Trace™ Online Software

* These test points are not included in the standard sampling protocol but it is recommended that they be sampled during the assessment step to confirm that they are being adequately cleaned.

Analyze results

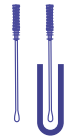
- The 3M™ Clean-Trace™ Online Software will automatically analyze your results and then generate reports.
- Is your program under control? Your endoscopes should show ≤ 200 RLU for all test points.
- Sort your data by test point, endoscope type or reprocessing personnel in order to assess where you are doing well and where improvements should be made.
- Based on your results you can begin to implement targeted process improvements to bring your process up to current standards for manual cleaning. Suggestions on corrective actions and process improvement are included later in this document.

Section 2A – Assessment of Manual Cleaning – Summary



of endoscopes

X



2
ATP tests *

=



tests per week

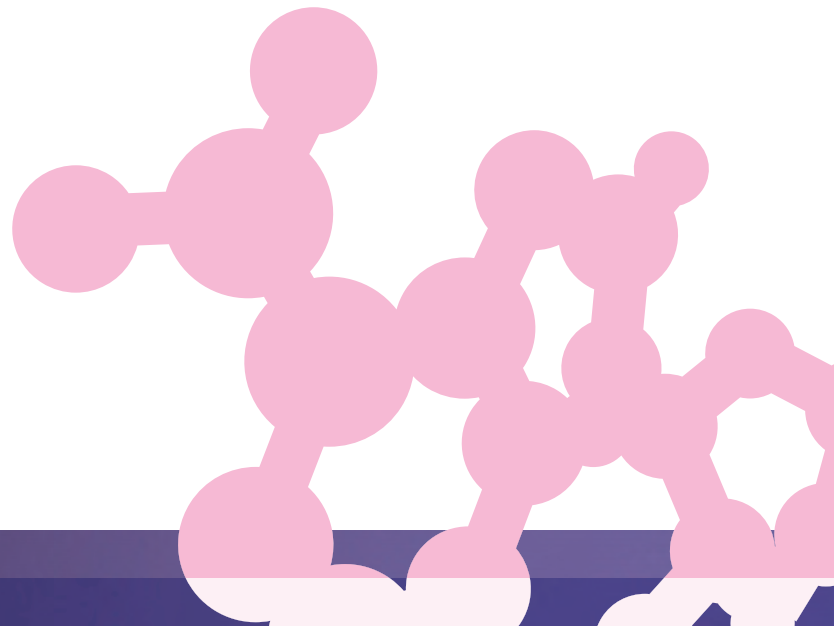
EXAMPLE :

15 Endoscopes x 2 Test Points = 30 Tests per week

* 1 ATP water test, 1 surface test

| = surface test | = water test

Implement Section 2B, Routine Monitoring of the Effectiveness of Manual Cleaning, only when your results consistently demonstrate that your endoscopes have ≤ 200 RLU for all test points as defined in Appendix 1.



Section 2B – Routine Monitoring of the Effectiveness of Manual Cleaning

This section focuses on scheduled and objective monitoring of the effectiveness of the manual cleaning step in flexible endoscope reprocessing. The sampling protocol can be found in Appendix 1 and 2 of this document.

Pass/Fail Recommendation

Pass	≤ 200 RLU
Fail	≥ 201 RLU

Monitoring Frequency

At a minimum, every endoscope in use should be monitored at least once per week. Continue to monitor every endoscope until all show ≤ 200 RLU for all test points.

Section 2B – Routine Monitoring of the Effectiveness of Manual Cleaning – Summary

The diagram illustrates the calculation of total tests per week. It shows an endoscope icon with a '#' symbol and the text 'of endoscopes'. This is followed by a red 'X' symbol, then two U-shaped test icons with the number '2' and the text 'ATP tests *'. This is followed by an equals sign, then a paperclip icon and a calendar icon with the word 'Week' and a '#' symbol, and the text 'tests per week'.

EXAMPLE :
15 Endoscopes x 2 Test Points = 30 Tests per week

* 1 ATP water test, 1 surface test

| = surface test | = water test

Implementation of an ATP hygiene monitoring system

There are a number of steps involved in the successful implementation of an ATP hygiene monitoring program:

1. Identification of test points and sample plans
2. Pass/Fail threshold recommendation
3. Determination of testing frequency
4. Collection of data
5. Establishment of metrics for each section implemented
6. Establishment of corrective action procedures
7. Continuous improvement steps

These steps are detailed below.

1. Identification of test points and sample plans

A flexible endoscope has a very complex design presenting a challenge in choosing test points that accurately reflect the efficacy of the manual cleaning process. Current clinical data suggests that monitoring the suction/biopsy (S/B) channel and outer surface of the distal end of the bending section of the insertion tube provide the best indication that the overall manual cleaning process was properly performed.^{12,13} A 3M™ Clean-Trace ATP Surface test is used to test the outer surface of the endoscope while the 3M™ Clean-Trace™ ATP Water Test is used to sample the S/B channel. The sampling procedures are detailed in Appendix 1 and 2 of this document. Note that some flexible endoscopes have an elevator guide wire (EGW) channel. If this is present on your scopes it is recommended that this channel also be monitored.^{12,13}

A sampling plan consisting of defined test points should be created. The test points should be selected on the basis of a set of criteria such as:

- Provides representative feedback and data of the current cleaning procedure.
- Represents a location on the endoscope where there is a high risk of cross-contamination.
- Represents a location on the endoscope where there is likely to be a high level of organic build-up of contamination as a consequence of a high level of contact or because the area is difficult to clean properly.

Current experience in clinical environments suggests that monitoring the S/B, the EGW channel and outer surface of the distal end of the bending section of the insertion tube are the test points that best meet the criteria outlined above.^{12,13,14} Note that the EGW channel may not be present on all flexible endoscopes.

Sampling of the flexible endoscope occurs after manual cleaning and prior to high-level disinfection.

2. Pass/Fail Threshold Recommendation

3M recommends the following Pass/Fail thresholds for the S/B channel, the EGW channel and the outside distal end of flexible endoscopes. These threshold levels were determined in simulated-use studies and then verified that they were achievable in a clinical setting following the manufacturer's manual cleaning instructions.^{12,13}

Pass	≤ 200 RLU
Fail	≥ 201 RLU

3. Determination of Testing Frequency

In order to obtain valid feedback sufficient data sets must be collected. This is especially important in the early implementation stages if a true understanding of current cleaning efficacy is to be achieved. Moreover, sufficient data is required to allow accurate trending of data on an ongoing basis and to provide key stakeholders with enough result based evidence to make any changes or decisions regarding existing cleaning practices.

It is also important that the frequency of testing address the level of risk associated with the process being monitored. Given that flexible endoscope reprocessing has a very small margin of error¹ and given that the risk of pathogen transmission is much higher than previously thought⁶ 3M recommends that health-care facilities strive to achieve a monitoring program where every endoscope is monitored after each use.

As described previously in this guide, a minimal frequency for monitoring the manual washing step was recommended. The monitoring frequency should be set so that every endoscope is monitored once per week in order to verify that adequate endoscope cleaning is being performed.

4. Collection of Data

When collecting monitoring data it is suggested that results be carefully recorded as evidence of the process of implementation. It is recommended that the 3M™ Clean-Trace™ Online Software be used for this purpose. The Clean-Trace Online Software provides a range of reports that allow easy interpretation and review of results that can be shared with key stakeholders at all levels.

Data should be collected over a sufficient time period to take into account any variation in the reprocessing environment as a consequence of worker-to-worker variability. Because flexible endoscopes are considered “high-risk” they should be routinely monitored so that adverse trends can be detected in a timely manner. It is highly recommended that monitoring data be reviewed, at a minimum, on a weekly basis.

Analysis of RLU results can help identify those endoscopes that are prone to contamination and present a greater risk for reprocessing failure. In addition, these results may help in identifying cleaning issues.

It should be noted that individual flexible endoscopes may exhibit different levels of contamination. This may be due to:

- Flexible Endoscope Type – Different endoscope types (e.g. gastroscope, bronchoscope, etc) routinely show different levels of contamination.¹⁵
- Procedure used – Flexible endoscopes used in therapeutic or emergency procedures tend to be more contaminated than those used for diagnostic purposes.
- The age of the flexible endoscope – Older surfaces may be more damaged or scratched presenting a greater surface area and opportunity for the deposition of organic contamination and biofilm formation. This can make the cleaning process more difficult.

5. Establish metrics for each section implemented

Metrics are standards of measurements by which the efficiency of your cleaning process, efficacy of training programs as well as progress on a quality improvement plan can be quantitatively assessed. Metrics should reflect the objectives of your monitoring program and will evolve and change as, over time, you implement the various sections of the 3M Recommended Monitoring Plan. Careful consideration should be given to your choice of metrics as they form the basis for continual improvement processes.

Metrics should be established for each section of the program implemented. The 3M™ Clean-Trace™ Online Software can be used to automatically record, track and trend the metrics established for each section of the program implemented at your facility. See below for suggestions for appropriate metrics.

Section 1 – Education, Training and Competency

Staff training /Competency

- % of staff that has passed or failed training allows assessment of training efficacy
- Trending of RLU values for each test point allows pinpointing of trouble spots
- % Pass/Fail for each training protocol allows documentation of staff performance
- % Pass/Fail for each test point allows pinpointing of trouble spots

Section 2A - Assessment of the Manual Cleaning Process

Cleaning effectiveness

- % Pass/Fail for all flexible endoscopes allows tracking and trending of cleaning effectiveness
- % Pass/Fail by endoscope type provides feedback on meeting critical benchmarks allowing you to assess if your program is under control
- % Pass/Fail for each flexible endoscope type will help focus process improvement efforts
- % Pass/Fail for every flexible endoscope (by serial number) provides information that each endoscope has met Pass/Fail benchmarks during the assessment period.

Section 2B – Routine Monitoring of the Effectiveness of Manual Cleaning

Cleaning effectiveness

- % Pass/Fail for all flexible endoscopes allows tracking and trending of cleaning effectiveness
- % Pass/Fail by endoscope type provides feedback on meeting critical benchmarks allowing you to assess if your program is under control
- % Pass/Fail for each flexible endoscope type will help focus process improvement efforts

6. Establish Corrective Action Procedures

A corrective action procedure is the process of intervention designed to deal with any identified non-conformance. In the case of ATP testing, this essentially is related to those actions taken in response to Pass/Fail results. The course of action will need to be determined on a case-by-case basis and will be related to the level of risk. Failure in the execution of recommended cleaning procedures is one of the major causes of cross-contamination and possible transmission of pathogens.^{6,7} This can also result in failure RLU levels in the S/B channels, EGW channel and outer surface of the distal end of the scope and should result in immediate corrective action. Trending of RLU values across cycles and time will allow one to determine if the cleaning process is improving over time.

Corrective action interventions could encompass several different options:

- Immediate reprocessing of flexible endoscopes for those showing failing RLU values.
- Ensure brushes used for manual cleaning are of the right size and in good condition; replace those that are old and worn.
- Audit your procedures – extra brushing and/or flushing steps may have to be added to address hard to clean flexible endoscope types.
- Check activity of chemicals and replenish or replace.
- Assess adequacy of training program, review training records, retrain staff
- Institute an environmental surfaces monitoring program for the reprocessing area to ensure the environment remains clean. See the Hygiene Management Guide for Environmental Surfaces for further information.
- Ensure water source is not source of contamination.
- Ensure manufacturer's instructions for reprocessing are being followed.

7. Continuous Improvement Steps

Ongoing review of data should take place to identify opportunities and steps towards continuous improvement. This involves evaluating the data to understand whether the process of routine monitoring and corrective action has led to reduced organic contamination. Successful implementation of improvement initiatives should result in an increase in the percent of flexible endoscopes with passing RLU values. The 3M™ Clean-Trace™ Online Software has seven different report formats to choose from so that continuous improvement results can be tracked and trended.

Appendix 1 – Recommended Procedure for Collection of Samples from Flexible Endoscopes

Although this guide applies to all flexible endoscopes an Olympus® flexible GI endoscope is highlighted for purposes of illustration. Photos for sampling Pentax® and Fujinon® flexible endoscopes are located in Appendix 3.

Materials

- ▶ Flexible Endoscope that has been manually cleaned
- ▶ Clean, lint free towel
- ▶ 3M™ Clean-Trace™ ATP Surface Test
- ▶ 3M™ Clean-Trace™ ATP Water Test
- ▶ 3M™ Clean-Trace™ Water Test Accessory Kit
- ▶ 3M™ Clean-Trace™ NGi Luminometer
- ▶ Sterile 50 mL conical tubes for collection of samples (other sterile containers may be used)
- ▶ Rack to hold the collection tubes
- ▶ 60 cc syringe: sterile, disposable
- ▶ Sterile water, at least 80 mL in a container large enough to accommodate a 60 cc syringe
- ▶ Personal Protective Equipment (PPE): clean gloves, gown and goggles or face shield



Figure 1

Sample Exterior Surface

Using one Clean-Trace ATP Surface Test swab and starting at the distal end of the bending section of insertion tube, swab all sides for a length of 10 cm. (Figure 1) Measure ATP levels using the 3M Clean-Trace Luminometer. Follow the instructions for use for proper operation of the Clean-Trace ATP Surface Test and Luminometer.



Figure 2

Preparation of Flexible Endoscope for Sampling of Suction/Biopsy Channel

Preparation for sampling of the flexible endoscope interior channels requires the installation of a connector. (Figure 2) A connector is required so that a syringe may be used to sample the interior channels of the flexible endoscope. Connectors can be obtained from 3M as part of the 3M Clean-Trace ATP Water Test Accessory Kit. The connectors are for single use only. Appropriate PPE should be worn while preparing and sampling the flexible endoscope.



Figure 3

Placement of Connector

The connector fits on the suction/biopsy channel located on the light guide end of the universal cord of the flexible endoscope. (Figure 3)

The scope is now ready for sample collection.

Appendix 1 – Continued

Sample Suction-Biopsy Channel

Treat all liquid samples as biohazardous. Use sterile technique so that sample integrity is maintained.



Figure 4



Figure 5



Figure 6



Figure 7

1. Fill a 60 cc syringe with air and attach the syringe to the connector. (Figure 4)
2. Depress the Suction Valve located on the Control Head (valve with red dot). Slowly push the air through the lumen. This process removes any cleaning agent in the lumen. (Figure 5)
3. Secure the distal end of the flexible endoscope into the 50 mL conical sample collection tube. To avoid contamination of the sample, make sure that the distal end of the flexible endoscope does not go below the 40 mL mark. (Figure 6)
4. Remove the 60 cc syringe from the connector and draw up 40 cc of sterile water from the water container. Pull up an additional 20 cc of air.
5. Attach the syringe to the S/B connector on the light guide end on the universal cord. Make sure the instrument port is capped to avoid sample leakage. (Figure 5)
6. Depress the Suction Valve located on the Control Head (valve with red dot). (Figure 5)
7. Keeping the suction valve depressed, push the water through the scope by depressing the syringe plunger. The rinsate should flow into the collection tube. (Figure 6)
8. Release the suction valve and detach the syringe from the S/B connector.
9. Draw air into the syringe up to the 60 cc mark.
10. Re-attach the 60 cc syringe to the S/B connector.
11. Depress the Suction valve.
12. Keeping the Suction Valve depressed, use the syringe plunger to push all the air into the scope. This process will displace the 40 mL rinsate into the 50 mL conical collection tube. (Figure 7)
13. Securely cap the sample collection tube to maintain sample integrity.
14. Following the Instructions for Use, measure the ATP level of the 40 mL water rinsate sample using the 3M™ Clean-Trace™ ATP Water Test and the 3M™ Clean-Trace™ Luminometer.

Protocols for sampling the EGW channel and the Air/Water channels are available on request; contact your 3M representative for more information.

Appendix 2 – Alternate Procedure for Collection of Samples from Flexible Endoscopes

The flexible endoscope can be sampled in an alternative manner that involves plugging the suction port on the Control Head.

NOTE: The Alternate Procedure for Collection of Samples from Flexible Endoscopes should ONLY be used on Olympus® brand flexible endoscopes. The silicone plugs in the 3M™ Clean-Trace™ ATP Water Test Accessory Kit do not fit all flexible endoscope models and may cause damage if used.

Materials

- ▶ Flexible Endoscope that has been manually cleaned
- ▶ Clean, lint free towel
- ▶ 3M™ Clean-Trace™ ATP Surface Test
- ▶ 3M™ Clean-Trace™ ATP Water Test
- ▶ 3M™ Clean-Trace™ Water Test Accessory Kit
- ▶ 3M™ Clean-Trace™ NGi Luminometer
- ▶ Sterile 50 mL conical collection tubes (other sterile containers may be used)
- ▶ Rack to hold the conical collection tubes
- ▶ 60 mL syringe: sterile, disposable
- ▶ Sterile water, at least 80 mL in a container large enough to accommodate a 60 cc syringe
- ▶ Personal Protective Equipment (PPE): clean gloves, gown and goggles or face shield

Sample Flexible Endoscope Exterior Surface

Using one 3M™ Clean-Trace™ ATP Surface Test swab and starting at the distal end of the bending section of insertion tube, swab all sides for a length of 10 cm. (Figure 1) Measure ATP levels using the Clean-Trace Luminometer. Follow the instructions for use for use of the Clean-Trace ATP Surface Test and Luminometer.



Figure 1

Appendix 2 – continued

Preparation of Flexible Endoscope for Sampling of Suction/Biopsy Channel



Figure 2



Figure 3



Figure 4



Figure 5

Preparation for sampling of the flexible endoscope interior channels requires the installation of a connector and a small plug. Appropriate PPE should be worn while preparing and sampling the flexible endoscope.

A connector is required so that a syringe may be used to sample the interior channels of the flexible endoscope. (Figure 2) Connectors can be obtained from 3M as part of the 3M™ Clean-Trace™ ATP Water Test Accessory Kit. The connectors are for **single-use only**.

Placement of Connector

The connector fits on the suction/biopsy channel located on the light guide end of the universal cord of the flexible endoscope. (Figure 3)

Plug

This plug fits into the Suction port at the control head of the endoscope and prevents leakage of rinsate during sampling. The plug should be clean and is **for single-use only**. (Figure 4)

Placement of Plug on the Control Head

The plug fits into the suction port located on the control head. This placement prevents leakage of the rinsate during sampling. (Figure 5) A green plug was used for Figure 5 so that placement of the plug could be seen more clearly. The plug is not green, but clear in the accessory kit.

The scope is now ready for sample collection.

Appendix 2 – continued

Sample Suction/Biopsy Channel

Treat all liquid samples as biohazardous. Use sterile technique so that sample integrity is maintained.

1. Fill a 60 cc syringe with air.
2. Attach the syringe to the connector and slowly push the air through the lumen. This process removes any cleaning agent remaining in the lumen. (Figure 6)
3. Remove the 60 cc syringe from the connector and draw up 40 cc of sterile water from the water container.
4. Attach the syringe to the S/B connector on the light guide end on the universal cord. Make sure the instrument port is capped to avoid sample leakage. (Figure 6)
5. Use a 60 cc syringe to draw up 40 cc of sterile water from the water container.
6. Attach the syringe to the S/B connector on the light guide end on the universal cord.
7. With the distal end of the scope inside the 50 mL conical collection tube, depress the syringe plunger to push the water thru the scope and into the collection tube. To avoid contamination of the sample, make sure that the distal end of the flexible endoscope does not go below the 40 mL mark. (Figure 7)
8. Detach the syringe from the S/B connector and draw air into the syringe up to the 60 cc mark.
9. Re-attach the 60 cc syringe to the S/B connector and push all the air into the scope. This process will displace the 40 mL of rinsate into the 50 mL conical collection tube. (Figure 6)
10. Securely cap the 50 mL conical tube to preserve sample integrity.
11. Following the instructions for use, measure the ATP level of the 40 mL water rinsate sample using the 3M™ Clean-Trace™ ATP Water Test and the 3M™ Clean-Trace™ NGi Luminometer.

Protocols for sampling the EGW channel and the Air/Water channels are available on request; contact your 3M representative for more information.



Figure 6



Figure 7

Appendix 3 – Example of Sampling Set up for Pentax® and Fujinon® Flexible Endoscopes

Collecting samples from flexible endoscopes manufactured by Pentax® or Fujinon® are carried out in the exact same manner as described in Appendix 1. The photos below show the correct placement of connectors and syringes.

NOTE: The Alternate Procedure for Collection of Samples from Flexible Endoscopes, found in Appendix 2, should **ONLY** be used on Olympus brand flexible endoscopes. The silicone plugs in the 3M™ Clean-Trace™ ATP Water Test Accessory Kit do not fit all flexible endoscope models and may cause damage if used.

Pentax®

Placement of connector and syringe on Pentax® flexible endoscope



Sampling a Pentax® flexible endoscope



Appendix 3 – continued

Fujinon®

Placement of connector and syringe on Fujinon® flexible endoscope



Sampling a Fujinon® flexible endoscope



Appendix 4 – Example of Procedure for Sampling Olympus® Model Flexible Bronchoscopes

Materials

- ▶ Bronchoscope that has been manually cleaned
- ▶ Olympus® Single Use Suction Valve MAJ-209
- ▶ Olympus® Single Use Biopsy Valve MAJ-210
- ▶ Clean, lint free towel
- ▶ 3M™ Clean-Trace™ ATP Surface Test
- ▶ 3M™ Clean-Trace™ ATP Water Test
- ▶ 3M™ Clean-Trace™ ATP Water Test Accessory Kit
- ▶ 3M™ Clean-Trace™ NGi Luminometer
- ▶ Sterile 50 mL conical tubes for collection of samples
- ▶ Rack to hold the collection tubes
- ▶ 60 cc syringe: sterile, disposable
- ▶ Sterile water, at least 80 mL in a container large enough to accommodate a 60 cc syringe
- ▶ Personal Protective Equipment (PPE): clean gloves, gown and goggles or face shield

Sample Exterior Surface

Using one Clean-Trace ATP Surface Test swab and starting at the distal end of the bending section of the insertion tube, swab all sides for a length of 10 cm. Measure ATP levels using the Clean-Trace NGi Luminometer. Follow the instructions for use for proper operation of the Clean-Trace ATP Surface Test and Luminometer.

Preparation of Bronchoscope for Sampling of Suction/Biopsy Channel

Preparation for sampling of the bronchoscope interior channels requires the installation of the Olympus® single use suction valve. Install the valve according to Figure 1. The biopsy port should also be capped with either a single use biopsy valve or an appropriate cover. Appropriate PPE should be worn while preparing and sampling the bronchoscope.



Figure 1

Appendix 4 – continued

Suction/Biopsy Connector

A connector is required so that a syringe may be used to sample the interior channels of the bronchoscope. Connectors can be obtained from 3M as part of the 3M™ Clean-Trace™ ATP Water Test Accessory Kit. The connectors are for **single-use only**.



Figure 2

1. Attach the suction/biopsy connector to the end of the barb hose located on the single use suction valve. (Figure 2)
2. Fill a 60 cc syringe with air.
3. Attach the syringe to the connector and slowly push the air through the lumen. This process removes any cleaning agent remaining in the lumen.
4. Remove the 60 cc syringe from the connector and draw up 40 cc of sterile water from the water container.
5. Attach the syringe to the connector. Make sure the instrument port is capped to avoid sample leakage.
6. Depress and hold the suction biopsy valve. (Figure 3)
7. With the distal end of the scope inside the 50 mL conical collection tube, depress the syringe plunger to push the water through the scope and into the collection tube. To avoid contamination of the sample, make sure that the distal end of the flexible bronchoscope does not go below the 40 mL mark. (Figure 3)



Figure 3

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3M™ CLEAN-TRACE™ HYGIENE MANAGEMENT SYSTEM PRODUCT LIST

Item No.	SKU	Description	Unit	Division	
	UXC	GH-6205-2095-3	3M™ Clean-Trace™ ATP Surface Test	100/case	IPD
	H2O	GH-6205-3858-3	3M™ Clean-Trace™ ATP Water Test	100/case	IPD
	NGi	DH-8888-0539-6	3M™ Clean-Trace™ NGi Luminometer	Each	IPD
	OLS	70-9999-6082-9	3M™ Clean-Trace™ Online Software	Each	IPD
	ATP10	GH-6205-2249-6	3M™ Clean-Trace™ Surface Positive Control	10/case	FS
	LWATP10	GH-6205-2251-2	3M™ Clean-Trace™ Water Positive Control	10/case	FS
	NSTATION	DH-9999-0489-8	3M™ Clean-Trace™ NGi Luminometer Docking Station	Each	FS
	NGSB1	DH-9999-9607-6	3M™ Clean-Trace™ NGi Luminometer Soft Carry Case	Each	FS
	NGLBP1	GH-6205-1651-4	3M™ Clean-Trace™ NGi Luminometer Battery	Each	FS
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	CDTS	70-2007-7068-6	3M™ Clean-Trace™ Conversion to Data Trending Software	Each	IPD
	WTK	70-2007-7217-9	3M™ Clean-Trace™ WTK Water Test Accessory Kit	Each	IPD
		70-9999-6147-0	3M™ 2-year Extended NGi Luminometer Warranty	Each	IPD

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