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 health care environment. This document details the application of ATP hygiene monitoring for surgical instrument reprocessing, prior to sterilization or high-level disinfection.

Introduction

“Every patient undergoing a medical procedure has a basic expectation that the environment and instruments of care will be clean and safe. In recent years, that expectation has been shaken by reports of patients put at risk of serious infection from reusable medical devices that were inadequately cleaned, sterilized, or disinfected — the domain known as reprocessing.”

Cleaning is the first step performed during reprocessing of reusable surgical instruments and medical devices. Yet, the fact that proper cleaning is vital to the effectiveness of the downstream reprocessing steps of sterilization and disinfection has been underappreciated. Cleaning is defined as the removal of adherent foreign material (i.e. blood, tissue, organic contaminants) from the surfaces, crevices, serrations, jaws and lumens of instruments, devices and equipment by a manual or mechanical process. This is normally accomplished using water with detergents or enzymatic products. Thorough cleaning is required before high-level disinfection or sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes running the risk of process failures.1,2

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.2 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.”2 The 3M™ Clean-Trace™ Hygiene Management System provides an objective and quantifiable “real-time” approach to assess and measure cleaning efficacy. The 3M ATP 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 reprocessing. It should be noted that ATP hygiene monitoring will not detect the etiologic agents of Transmissible Spongiform Encephalopathies (TSEs) and Toxic Anterior Segment Syndrome (TASS).
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, surgical instrument or the interior of a lumen. A 3M™ Clean-Trace™ ATP Surface or Water Test is used to sample a selected test point. The test is then activated and the swab 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™ NGi 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. The ATP 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-processing the instruments of concern.

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 Software provides a range of reports that allow easy interpretation and review of results that can be shared with key stakeholders at all levels.
Recommended Monitoring Plan for Surgical Instruments

In the fall of 2011 AAMI and the FDA held a joint summit to address topics of concern in the area of medical device reprocessing. With the goal of preventing reprocessing failures, top priority actions were defined and a path forward proposed. Included in the list of top priorities was the clear need for ongoing education and training, regular testing for competency as well as routine auditing for compliance to established reprocessing procedures.

The 3M recommended monitoring plan focuses on monitoring the efficacy of the cleaning steps that are part of routine surgical instrument reprocessing procedures. These steps include the manual washing process, sonication and the washer-disinfection step. Approaches for optimizing and analyzing these cleaning steps include training and competency evaluation programs, tracking and trending of objective, routine monitoring results as well as risk-based approaches for targeting the most critical elements of surgical instrument reprocessing. 3M does not recommend ATP monitoring after sterilization or high-level disinfection.

What follows in the remainder of this document is the description of a comprehensive monitoring plan consisting of a tiered format allowing for the choice of an approach that best fits the immediate needs of your institution while providing a clear path for growing a monitoring program.

Tier 1 – Education, Training and Competency

It has been shown that positive, supportive educational interventions and regular competency evaluations can result in improved performance. 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.

The 3M Tier 1 monitoring plan focuses on education, training and competency for the manual cleaning process. There are a number of variables that can affect how well an instrument is cleaned. The complexity of the instrument itself, the cleaning chemicals that are used, the cleaning protocol followed, as well as the reprocessing staff, are all known variables in the process. Based on continuing research, the factor showing the largest variability impacting cleaning protocols are the individual staff members (i.e. worker-to-worker variability). Therefore, ensuring proper training and on-going competency is the first step in any quality control program.

The following steps provide an example on how to structure a program to evaluate education, training and competency.
Education and Training Evaluation

Following the example outlined below measure the ATP levels present on the instruments both before and after manual cleaning.

1. Identify all staff members responsible for cleaning and reprocessing equipment.
2. Identify the types of instruments that will be used during training. It is recommended that at least three (3) difficult to clean instrument types be used during training.
3. Conduct training, on each instrument type, according to your facility’s policies and procedures.
4. Before performing the manual cleaning step, use one 3M™ Clean-Trace™ ATP Surface Test to swab the entire surface of the instrument. To measure ATP levels, follow the procedure outlined in the Instructions for Use provided with the 3M™ Clean-Trace™ ATP Surface Test and the 3M™ Clean-Trace™ NGi Luminometer.
5. Have the reprocessing staff member manually clean the surgical instrument following your facility’s policies and procedures.
6. Using a fresh 3M Clean-Trace ATP Surface Test, repeat step 4 to measure ATP levels after performing manual cleaning.
7. Repeat steps 4-6 on an additional two (2) instruments to complete the initial education and training evaluation.
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 surgical instruments at each interval for a total of 12 instruments.
9. Staff should be able to achieve passing RLU levels on 11 out of the 12 surgical instruments. If necessary, conduct additional training to improve performance levels. To set Pass/Fail threshold, see p.11.

To evaluate training and competency for manual cleaning of lumened instruments, a 3M™ Clean-Trace™ ATP Surface Test and a 3M™ Clean-Trace™ Water Test should be used. The procedure for sampling a lumened instrument is located in Appendix 1 of this document.

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 three (3) months. Steps 1-9 described under “Education and Training Evaluation” can also be used to perform the competency evaluations. Competency evaluations should be performed using those instruments that are most difficult to clean.

The 3M™ Clean-Trace™ Online Software enables documentation and trending of both individual and combined staff competency and training results. Several report types can be customized to fit a variety of training record requirements.
**Tier 2A – Routine Audit of the Effectiveness of the Cleaning Process**

The 3M Tier 2A plan focuses on scheduled and objective assessments of the effectiveness of the cleaning steps in surgical instrument reprocessing. 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. The following describes an example of how to structure a program to routinely audit the effectiveness of the cleaning process.

Choosing from different instrument sets, select 3 instruments that represent those categories of instruments that are, in your facility, the most difficult to clean. Routine monitoring would then consist of testing these instruments at the suggested frequency of once per shift. For routine testing it is recommended that the three instruments be monitored after each of the following cleaning steps: manual wash, sonication (if appropriate) and the washer-disinfector. Monitoring surgical instruments after high-level disinfection or sterilization is not recommended.

When performing the routine audits it is important that the sampling approach encompass the cleaning efforts of all reprocessing staff members. This ensures adequate representation of the worker-to-worker variability within your institution.

The Clean-Trace Online Software provides reports that should be reviewed on a weekly basis. This ensures appropriate tracking of your progress allowing you to implement corrective actions or make process improvements in a timely manner.
Tier 2B – Monitoring High-Risk Instruments and Equipment

All surgical instruments are not created equal as some are more difficult to clean than others and therefore, pose a higher risk for reprocessing failure. In 2009, the FDA issued a Medication and Devices Alert and Notice titled “Ongoing safety review of arthroscopic shavers.” This document, along with a televised expose, highlighted the risk of reprocessing failure posed by improper cleaning. In a paper published by Azizi et al, ATP levels, as well as other markers, were used to demonstrate that lumened instruments were especially at risk for reprocessing failure. This is because the channels were so difficult to clean that tissue and debris were routinely present after performing recommended cleaning procedures. High risk instruments and equipment should be monitored, the results recorded and the data used to drive process improvements thus ensuring high standards of reprocessing and infection prevention practice.

The 3M Tier 2B plan has all the same elements as the 3M Tier 2A plan and includes additional high risk surgical instruments and equipment. Examples of high risk instrument categories and equipment include but are not limited to:

- Instruments and equipment that can be only hand-cleaned (e.g. batteries, IV monitors, drills, delicate instruments)
- Robotic instruments and equipment
- Lumened instruments
- Rigid endoscopes

An example procedure for sampling lumened instruments is located in Appendix 1 of this document and requires the use of both a 3M™ Clean-Trace™ ATP Surface and a 3M™ Clean-Trace™ ATP Water Test.
Putting it all together

An ideal monitoring plan includes the implementation of all three tiers. The 3M Recommended Monitoring Plan provides flexibility so that all or part of the different tiers can be customized to create a monitoring program that meets the needs of different facilities.
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 instruments and sample plans
2. Pass/Fail threshold recommendation
3. Determination of testing frequency
4. Collection of data
5. Establish metrics for each tier implemented
6. Establishment of corrective action procedures
7. Continuous improvement steps

These steps are detailed in the remaining pages of this document.

1. Identification of instruments and sample plans

A sampling plan consisting of a list of specific surgical instruments to be tested should be devised. The test instruments should be selected based on the level of risk as well as provide representative feedback and data on the current cleaning procedure. The following should be considered when choosing instruments to be included in your monitoring program:

- The instruments provide representative feedback and data for current cleaning procedures.
- The instruments should represent a class of “hard to clean” instruments and usually have a complex design (e.g. rongeurs, mosquito clamps, lumened instruments).
- The instruments should come from a variety of instrument sets.
- The instruments should be used on a routine basis.
2. Pass/Fail threshold recommendation

Pass/Fail thresholds should be determined for each step of the cleaning process: manual clean, sonication (if appropriate) and washer-disinfector. **It is not recommended that testing be performed after sterilization or high-level disinfection.**

Because of the large degree of variability in the types of instruments, each health care facility must determine its own Pass/Fail benchmarks for the manual cleaning and sonication reprocessing steps. The process for the calculation of Pass/Fail thresholds is described below.

**Manual Cleaning Step: Calculation of Pass/Fail Threshold**

1. Obtain the threshold calculator spreadsheet from your 3M representative.
2. Select your best, most experienced staff member to generate the data.
3. Based on the criteria described in the section titled “Identification of Instruments for Testing” choose three (3) hard to clean instruments.
4. After the manual cleaning process has been performed, use a fresh 3M™ Clean-Trace™ ATP Surface Test to sample the entire surface of the instrument. If sampling lumened instruments follow the example procedure outlined in Appendix 1 which requires the use of both a 3M™ Clean-Trace™ ATP Surface Test and 3M™ Clean-Trace™ ATP Water Test.
5. To measure ATP levels, follow the procedure outlined in the Instructions for Use provided with the Clean-Trace ATP Surface Test and the 3M™ Clean-Trace™ NGi Luminometer. Record the results on the “threshold calculator” spread sheet provided by your 3M representative.
6. Steps 4 and 5 will be repeated over 20–30 decontamination cycles. The same instrument types and the same person should be used to generate the entire data set.
7. Once the data from 20–30 decontamination cycles is collected and entered into the threshold calculator spreadsheet, threshold levels will be automatically calculated.

The threshold calculator uses the average and standard deviation (σ) to calculate the Pass/Fail threshold values. This is a common statistical approach used to make calculations of these types.
**Sonication Cleaning Step: Calculation of Pass/Fail Threshold**

The same steps used to calculate the Pass/Fail Threshold for manual cleaning are used to make the calculation for the sonication cleaning step. Perform the manual cleaning step then measure ATP levels as described above. Clean the same instrument using the sonicator and then measure ATP levels again. A separate Pass/Fail threshold will be calculated for the sonication cleaning step.

This initial period of data collection will provide feedback on the current level of cleaning efficacy. Once the initial period of data collection is complete, regular review of data should be undertaken to determine the threshold levels that best fit the current status of cleaning protocols.

3M recommends the following for Pass/Fail thresholds for the washer-disinfector step:

- **Pass**: \( \leq 150 \text{ RLU} \)
- **Fail**: \( \geq 151 \text{ RLU} \)

### 3. Determination of testing frequency

It is recommended that testing of the manual clean, sonication and washer-disinfector steps be monitored once per shift. This recommendation is based on the AAMI ST79 recommendation for monitoring of cleaning equipment. In section 10.2 describing Monitoring of mechanical cleaning equipment, it is recommended that the frequency for monitoring mechanical cleaning equipment be “weekly (preferably daily) during routine use.” It should also be mentioned that Table D1 in Annex D of ST79 lists ATP as a valid marker for assessing the efficacy of cleaning medical devices.
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.

Data is collected from the identified instruments, for each step of the cleaning process, as listed in a sample plan. In order to accurately determine the level of cleaning efficacy achieved, sufficient quantities of results need to be collected.

Results 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. High-risk instruments and equipment should be routinely monitored so that adverse trends can be detected in a timely manner. It is recommended that monitoring data be reviewed on a weekly basis.

It should be noted that individual surgical instruments may exhibit different levels of cleanliness. This may be as a consequence of:

- The nature of the surface being tested. For example, stainless steel surfaces are easier to clean than other surfaces and may routinely achieve lower RLU results than other surface types.
- The age of the instrument. Older surfaces may be more damaged, scratched or marked, presenting a greater surface area and opportunity for the deposition of organic contamination. This can make the cleaning process more difficult.
- The complexity of instrument design. Complexity will impact ease of access to the surface for cleaning.
- The cleaning method employed. Manual cleaning often is recommended for delicate or complex medical devices, such as microsurgical instruments, lensed instruments, and air-powered drills.
Analysis of RLU results can help identify those areas that are prone to contamination and present a greater risk for reprocessing failure. In addition, these initial results may help in identifying cleaning issues.

5. Establish metrics for each tier 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 tiers 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 tier of the program implemented. The 3M™ Clean-Trace™ Online software can be used to automatically record, track and trend the metrics established for each tier of the program implemented at your facility. See below for suggestions for appropriate metrics.

**Tier 1 – Education, Training and Competency**

**Staff training /Competency**

- % of staff that has passed or failed training allows assessment of training efficacy
- % Pass/Fail for each instrument allows pinpointing of areas for improvement

**Individual Staff training record**

- % Pass/Fail for training protocol allows documentation of staff performance
- % Pass/Fail for each instrument allows pinpointing of areas for improvement

**Tier 2A – Routine Audit of the Effectiveness of the Cleaning Process**

**Cleaning effectiveness**

- % Pass/Fail for CSSD department as a whole allows tracking and trending of cleaning effectiveness
- % Pass/Fail for each instrument allows identification of highest failing test points so you can focus your process improvement efforts

**Tier 2B – Monitoring High Risk Instruments and Equipment**

**Cleaning Effectiveness – High Risk Instruments and Equipment**

- % Pass/Fail for each instrument allows for tracking and trending of cleaning effectiveness
6. Establishment of 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. Typical corrective action would be as follows:

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<th>No action required</th>
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<tr>
<td>Fail</td>
<td>Re-clean and re-test</td>
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</table>

Specific interventions will need to be determined on a case-by-case basis and will be related to the level of risk. One can rely on trending Pass/Fail numbers across cycles and time to determine if the process is getting better or worse before deciding on an intervention. If failures occur after testing high-risk instruments then corrective action procedures should begin immediately. Intervention could encompass several different actions, for example:

- Stop and “quarantine” the instrument tray or load
- Immediate reprocessing of instrument tray or entire load
- Verify washer-disinfector is operating correctly
- Check water quality
- Audit and adjust process parameters
- Check activity of chemicals and replenish or replace
- Ensure that the reprocessing staff has been properly trained and are following established protocols

7. Continuous improvement steps

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

This process underpins the ATP hygiene monitoring system and allows the user to continually review and maintain improved standards of cleanliness in the clinical environment.
Appendix 1 – Example Procedure for Sampling Lumened Instruments with Flush Ports

An arthroscopic inflow/outflow cannula is highlighted for purposes of illustration. This procedure can be adapted to any lumened instrument that has a flush port.

Testing Supplies:
- Surgical Instrument that has been manually cleaned
- 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 or sterile urine sample cup 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

Procedure

Sample Instrument Exterior Surface

1. Using one 3M™ Clean-Trace™ ATP Surface Test swab the entire surface of the manually cleaned surgical instrument. (Figure 1)

2. To measure ATP levels, follow the procedure outlined in the Instructions for Use provided with the Clean-Trace ATP Surface Test and the Clean-Trace NGi Luminometer. Do NOT activate the Clean-Trace ATP Surface Test until ready to read the test.
Sample instrument lumen

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

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

**NOTE: The silicone plugs in the 3M Clean-Trace ATP Water Test Accessory Kit do not fit all instruments and may cause damage if used.**

Prepare instrument for sampling

Preparation of lumened instruments for sampling requires that a connector be attached to the flush port so that the syringe can be used to sample the lumen. Any ports or valves need to be plugged or closed to prevent leakage of the sample. (Figure 3) A green plug was used in Figure 3 so the placement of the plug could be seen more clearly. The plug is not green, but clear in the accessory kit.

Sampling the lumen

1. Fill a sterile 60 cc syringe with air.

2. Attach the syringe to the flush port on the instrument and push the air through the lumen. This process removes any cleaning agent remaining in the lumen. (Figure 4)
3. Remove the syringe from the instrument and fill with 10 cc sterile water. Pull up an additional 30-40 cc of air into the syringe.

4. Attach the syringe to the flush port located on the instrument. (Figure 4)

5. With the other end of the instrument lumen held inside a 50 mL conical tube, push the water and air through the lumen, collecting the water sample in the conical tube. The volume of air ensures that the entire water sample is collected. (Figure 5)

6. Use the 3M™ Clean-Trace™ ATP Water Test to measure the ATP levels present in the water sample by carefully following the Instructions for Use. Note: Clean-Trace ATP Water Tests must be read in the luminometer immediately after collection.
References

# 3M™ Clean-Trace™ Hygiene Management System

## Complete Product List

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To learn more about the 3M Clean-Trace Hygiene Management System, call the 3M Health Care Helpline at 1-800-228-3957 or visit www.3m.com/cleantrace.