As an infection-control scientist for Olympus, one of the most common customer questions I receive from healthcare facilities is how they can effectively monitor their scope-cleaning process to ensure they are achieving the best results. They are taking a first step in the right direction. Monitoring is both effective and crucial in your quality-control efforts, and with the new testing technologies on the market, it can be performed with ease.

Cleaning Efficacy

The purpose of manual cleaning is to brush and flush the channels and surfaces of an endoscope after a procedure to remove bioburden and organic matter prior to high-level disinfection (HLD) or sterilization. Unless an item is properly cleaned, residual debris, including microorganisms, can interfere with HLD or the sterilization process. In fact, studies have indicated that the viable bioburden on flexible endoscopes after patient use ranges from 100 to 109 colony-forming units (CFU). Proper reprocessing requires removal or inactivation of these microorganisms to ensure patient safety and minimize the risk of nosocomial infection.1

According to the SGNA, “endoscopes reprocessed appropriately in accordance with reprocessing and infection control guidelines pose virtually no risk of transmission of patient-borne or environmental microorganisms. In the absence of defective equipment, every reported case of hospital-acquired infection associated with a contaminated GI endoscope has been linked to a breach or violation of at least one of several requisite reprocessing steps (ASGE, 2001; Nelson & Muscarella, 2006).”2

But despite publication of consensus reprocessing guidelines, breaches in these standard practices continue to be reported. These incidents emphasize the need for methods to assure compliance with existing guidelines and to identify reprocessing failures quickly.3

Visual Inspection

Although visual inspection after manual cleaning is a common form of monitoring at healthcare facilities, it is woefully ineffective. Visual inspection cannot detect microorganisms or bioburden left behind in an instrument’s channels. This demonstrates why instituting some form of monitoring of scope cleaning efficacy at your facility is absolutely essential as part of your infection control efforts.

Microbial Surveillance

Microbiological surveillance cultures are not practical as a real-time verification of reprocessing efficacy. Because cultures take a minimum of 24 hours to 48 hours to incubate, and there is a clinical demand for reuse of these medical devices in the meantime, surveillance culture results will likely not be obtained until after the endoscope is used on the next patient.

Routine environmental monitoring of endoscopes is not a recommended practice according to “The Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes.” There currently are no standard protocols for performing microbiological surveillance of endoscopes, and the value of such an approach has not been widely accepted; the high rate of false positives and the resources consumed in investigating and following them up have dissuaded most infection-control experts and professional societies from recommending routine surveillance culturing.4

While not appropriate for routine monitoring, microbiological monitoring of endoscopes should be performed as part of an infection control outbreak investigation.

Monitoring Options

The AMMI TIR 12 recommendation is for users to test and validate their cleaning process. There are now a variety of products on the market that provide nearly instantaneous results for residual bioburden and organic matter. These products either test for protein/hemoglobin/carbohydrate residues (ChannelCheck) or for residual adenosine triphosphate (ATP). Some of the products currently on the market include Healthmark Industries Channel Check”, 3M™ Clean-Trace™ System, Charm Sciences’ novaLUM and PocketSwab Plus, Neogen’s AccuPoint™ HC, and Ruhof ATP Complete®, to name a few.

It is important to note here that this article is not meant as an endorsement by Olympus for any particular testing product or a validation of their stated efficacy claims. That aside, individually as an infection-control scientist, and collectively as a company, we advocate some form of monitoring of your cleaning process.

In general, these new testing products are fast, easy to use and suitable for routine monitoring. These products should be used to monitor the process, not necessarily as release criteria to continue onto HLD. These products can play additional roles in infection control by using them as a tool for auditing the process, validating staff competencies and training new employees.

For illustrative purposes only, let’s take a look at two products available for testing scope cleaning efficacy:

Channel Check™

ChannelCheck 3-in-1 test strips can detect the presence of very low levels of protein, carbohydrate and hemoglobin residues. These are the common residues left in or on a scope or other lumened device if it has not been cleaned properly. Essentially, this product is a test strip that is dipped into sterile water that has been flushed through the
endoscope channel after manual cleaning but before HLD. After 90 seconds, the user compares the 3-in-1 test strip to a color guide located on the bottle to determine the presence of protein, hemoglobin or carbohydrates. The ChannelCheck specifically reveals the presence of residues found within patient-used endoscopes, with low detection levels. Thus, the test can be used in-house for cleaning procedure verification.6

**Ruhof ATP Complete®**

The Ruhof ATP Complete is a contamination monitoring system that allows the user to verify the effectiveness of both the cleaning and decontamination process for all scopes and cannulated instruments by detecting the presence of ATP. The ATP enzyme is present in living cells, so an ATP monitoring system works by detecting the amount of organic matter remaining after cleaning. This type of system may also test a variety of environmental surfaces and medical devices.

For scopes, it works by using a special sponge which is passed down the instrument’s channels. The swab is then immersed into a luciferase/luciferin reagent. Within 15 seconds, light is emitted in direct proportion to the amount of ATP present. The test swab device uses a bioluminescent chemistry technology to convert the invisible concentration of ATP present in the sample into a visible light output. The quantitative result is displayed on-screen in terms of relative light units (RLUs), with 1 RLU roughly equivalent to 1 fmol of ATP.7

**Monitoring Limitations**

While monitoring is extremely effective and useful, it is important to understand its limitations.

First, hygiene monitoring systems and test strips are meant to be used as a product residue test, not a bacteria test; they are not intended to replace cultural microbiological testing when it is warranted.

Second, some of the products are specifically designed to quickly test scope channels (ChannelCheck), while others are more comprehensive (most of the ATP systems), and can test environmental surfaces as well.

Third, some products test both cleaning and disinfection steps, while others, like ChannelCheck, only test for cleaning efficacy. It is important to note, however, that proper manual cleaning of a device before HLD or sterilization helps ensure the efficacy of terminal disinfection/sterilization processes.

And fourth, relative to the ATP test systems, there are several things to note:

a. ATP is not produced in certain microbes, most notably viruses, so ATP-based systems cannot detect the presence of these organisms on a surface.8 They are also unable to detect gram-negative bacteria as efficiently because of incomplete cell lysis.9

b. ATP tests cannot differentiate ATP from different sources; since ATP is produced by all living (or recently living) cells, sample contamination with ATP from other sources may contribute to false positive results.8 In addition, residual disinfectants can interfere with the efficacy of the detection system and lead to false readings.9

Furthermore, contamination is not evenly distributed on product contact surface, so ATP cannot be considered a precise indication of the degree of surface contamination. It is appropriate, however, as a sensitive indicator of hygienic status and potential risk.8

c. Although ATP is released by living cells, some residual ATP may still be detected shortly after cell death. Several studies have found that total levels of ATP were unchanged during early stages of apoptosis.10 Therefore, the detection of ATP does not always translate into the detection of viable microorganisms.9

d. As of this writing, a universal ATP RLU standard has not been set to define clean versus contaminated surfaces in the healthcare setting. The RLU value is dependent on the instrument construction and reagent/swab formulations. Since RLU scales will differ between suppliers, it is better to evaluate systems based on their numbers of pass/failure rates at equivalent settings. Another consideration is the comparative background between systems; a larger measurement of background noise and variation based on blank samples reflects poorer system sensitivity. Additionally, claims for ATP tests based solely on the detection of numbers of microorganism are irrelevant since ATP can only detect bacteria when present in large enough numbers and when there is not ATP from any other sources.9

**Monitoring Options**

In spite of the limitations stated above, ATP and test-strip monitoring provide rapid results so that corrective action (e.g., re-cleaning) can be taken immediately. With a number of easy-to-use options now available, every facility should find it possible to implement some form of consistent monitoring. In terms of what to look for in a monitoring tool, it depends on your budget and your needs. If you’re just looking for an easy way to monitor your scope cleaning protocols, ChannelCheck may be the appropriate tool for you. If your lab requires something more comprehensive, then you may want to consider a monitoring system. When evaluating an ATP system, look at its stated reliability, sensitivity and accuracy. And choose a manufacturer that can help your facility establish a monitoring program that you can actually adhere to.

**Conclusion**

Healthcare-associated infections are understandably a major concern for all medical facilities. Implementing a tool to effectively monitor your scope cleaning efficacy is one means for reducing the potential for infection. Because visual inspection cannot detect microorganisms or biofilm in endoscope channels, there is an increasing emphasis on objectively measuring cleaning processes. The testing tools now available provide facilities of any size with simple-to-use tools to test cleaning efficacy, validate staff competency and train new personnel.

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**Reference**


