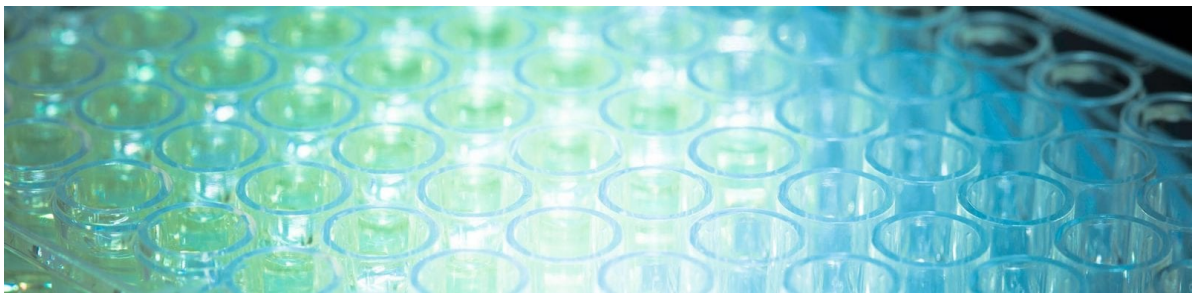
The Ultimate Guide to Cleaning Verification

Historically, the importance of cleaning instruments effectively has been misunderstood. Cleaning was believed to be a simple process that could be evaluated by visual inspection. Recent studies have shown visual inspection to be an insufficient means to determining the cleanliness of instruments and that sterilization processes are not effective if soil remains on the instrument. These findings led the Association for the Advancement of Medical Instrumentation (AAMI) to create recommendations for cleaning monitoring, known as cleaning assurance. AAMI is a non-profit organization that serves as the primary source for standards in the medical device industry, most notably, standards which guide cleaning and sterilization in a hospital setting. AAMI/ISO standards ST-79 and ST-91 provide guidelines for cleaning processes and endoscope reprocessing in the clinical setting. The Association of periOperative Registered Nurses (AORN) also provides guidelines for cleaning and sterilization in hospital settings.

This guide will review acceptable cleaning processes, recommended protocols for cleaning assurance, and the products available for use in the clinical setting as part of any cleaning assurance and infection control protocol.



What is cleaning and cleaning assurance?

Cleaning is the first step in reprocessing reusable medical devices. Cleaning is defined as the physical and chemical removal of organic, and inorganic material; however, it does not kill microorganisms, which is why disinfection and/or sterilization is necessary to complete the process. Cleaning is not only the first step but the most important part of reprocessing, because studies have shown that microbiocidal processes may not be effective if soil is not effectively been removed.

Cleaning should always be performed in accordance with the items instructions for use (IFU). Cleaning begins at instrument's point of use and may include mechanical and manual methods of soil removal. Manual cleaning typically starts with a pre-soak, intended to loosen the soil followed by the physical removal of soil by scrubbing instruments.

Mechanical cleaning includes processing of instruments in an ultrasonic bath, automated endoscope reprocessors (AERs), and washer-disinfectors. Each organization should have written policies and procedures for cleaning reusable medical devices.

Simply put, cleaning assurance is the next logical step in infection control. Assurance of cleaning and sterility for reusable instruments requires monitoring of all equipment and processes performed. A test for Cleaning Assurance should be documented, including digital readouts and cycle printouts.

Cleaning Assurance can be broken down into three phases: Validation Testing, Routine Testing and Verification Testing.

Validation Testing

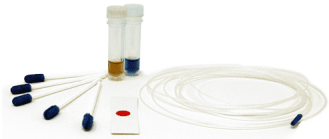
Validation Testing is that which is performed at installation, after major repairs and after routine maintenance. In addition, validation testing should have been performed when changing to a new type of cleaning solution or using a new cycle. Validation testing confirms the functionality of the machinery. These tests are like Bowie-Dick testing for sterilization.

Routine Monitoring

Routine Testing is performed with each cycle to ensure that mechanical cleaning equipment is working properly. Routine testing allows the user to verify its continued effectiveness. Routine tests are similar to chemical indicator monitoring of packages being sterilized.

Verification Testing

Verification Testing is the final stage of cleaning assurance. It is performed after routine testing to confirm and verify that the most-difficult-to-clean instruments were effectively cleaned through the previously performed cleaning processes. It provides the final check before moving on to sterilization. Verification testing is similar to utilizing a test pack containing a biological indicator and an integrator or emulating indicator to challenge the cycle during sterilization for load release.



PRODUCTS FOR CLEANING ASSURANCE

Validation Testing

Propper Washer Disinfector Test Soil

Test Soil is used to confirm the efficacy of a washer-disinfector at installation, after repair, or after routine maintenance. Test soil is designed to mimic the difficult-to-clean residue that may be left on reusable devices as described in ISO 15883-5.

PRODUCTS FOR CLEANING ASSURANCE

Routine Monitoring

OK-Sonic™ Ultrasonic Bath Monitor

OK-Sonic™ is an indicator of efficacy of your ultrasonic bath cycle. It can assist in diagnosis of common ultrasonic bath malfunctions including ineffective cavitation, temperature, and the presence or concentration of detergent.

PRODUCTS FOR CLEANING ASSURANCE

Verification Testing

Pro-Expose™ Protein Test

Pro-Expose™ quickly verifies that there is no residual protein on reusable devices after cleaning processes have occurred prior to sterilization or high-level disinfection. ProExpose™ detects protein to a sensitivity of 1.0ug of protein providing confidence that you are safe to

Propper Test soil is simple to use. Just prior to use, add water and the provided ink to the test soil powder to create a paste. Spread the paste throughout the chamber and allow it to dry for 30 minutes. After the soil has dried, run a typical cycle in your washer-disinfector and visually inspect for any remaining residue in the chamber.

OK-Sonic™ features dual soil markers. The holder allows for direct exposure to one soil mark and indirect exposure to the other representing easy and difficult-to-clean instruments.

WD-Chex™ Washer-Disinfector Monitor

WD-Chex™ is a reliable, repeatable, and consistent method for the routine monitoring of washer-disinfectors. WD-Chex can help to determine whether your automated washer is working effectively or diagnose issues such as clogged spray arms, overloaded instrument trays and the presence and concentration of detergent.

WD-Chex™ features dual soil spots. The holder allows for direct exposure to one soil mark and indirect exposure to the other representing easy and hard to clean instruments.

move forward with sterilization.

To use Pro-Expose™ , swab the surface of a difficult-to-clean instrument using the short swab or the canula of a cannulated instrument using a long swab while they are wet or utilizing sterile water. Place the swab into the vial containing the Coomassie blue solution. If protein is present, the solution will turn blue. The deepness of the blue will vary depending on the amount of protein present on the swab.

Conclusions

It is essential for hospitals to minimize the risk of hospital acquired infections. Utilizing new technologies in cleaning assurance is a necessary part of this process. Sterilization can only be achieved when instruments have been properly cleaned, which requires verification. As with all new products and tests, it is essential for hospitals to consider the increased cost, in dollars and in time, when a new process is implemented. Identifying those products and tests with the easiest transition plan, will enable users and purchasers to identify the best product for their institution.

Want to learn more about Propper Manufacturing Co. Cleaning and Sterility Assurance Products?