

Evaluation of PINNACLE Monitor for Automated Enzymatic Cleaning (AEC) for use in Cart washers

Serim Research Corporation | November 2023

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PURPOSE:

A study was undertaken to evaluate the potential for using Serim's® PINNACLE™ Monitor for **Automated Enzymatic Cleaning (AEC)** to test the **cleaning process in cart washers**. Cart washers are commonly used in Sterile Processing/Central Sterile Departments to clean a variety of items (bed pans, trays, carts etc.), cart washers may have an "instrument cycle" similar to standard cycles in washer-disinfectors. Serim developed our PINNACLE product line over 10 years ago, we did not investigate the potential use in cart washers at that time because an "instrument cycle" was not common in cart washers. Currently, instrument cycles are available on many cart washers. In addition, a number of hospitals have determined that PINNACLE AEC can be used to test their cart washers when using an instrument cycle and an enzymatic detergent.

BACKGROUND INFORMATION

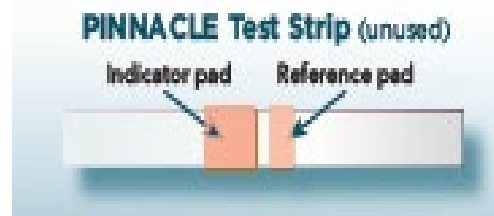
The current **AAMI ST79** guidelines recommend daily verification testing of all automated cleaning units used for medical device reprocessing (sections 7.6.4.5 and 13.2). These guidelines state that effective cleaning is a result of multiple interdependent factors (Annex P) such as time, temperature, detergent concentration, and mechanical action (or cavitation). The guidelines recommend monitoring all of these critical parameters to evaluate performance of mechanical cleaning equipment (section 13.2.c and Annex D). Section 7.6.4.3.3 list cart washers as a type of mechanical washer and Annex P lists cart washer-disinfectors (also validated for instruments) as a type of washer disinfectant. Section P.2.4.4 states "**If a cart wash washer has an instrument cycle, the washer should be tested at least weekly, preferably daily, on the instrument cycle program**". Currently, few cleaning verification tests indicate they can be used to test cart washers in their literature or IFU'S.

PINNACLE AEC GENERAL INFORMATION

The PINNACLE AEC test was designed to test the overall enzymatic cleaning in all mechanical equipment used for reprocessing medical instruments. Enzyme concentration and activity are critical for cleaning medical instruments. Other aspects of the cleaning process, including cycle time, temperature and mechanical action of the equipment affect overall enzymatic activity, especially when there is a deficiency in one of these areas. Currently, enzyme quantities and activity vary by detergent brand and there are not any standards for enzyme type, concentration, and overall activity levels. Therefore, it is imperative to use a cleaning verification test that responds to all of these major factors affecting the cleaning process as **recommended in the AAMI ST79 guidelines**. The current PINNACLE AEC IFU provides instructions for use in automated washers (washer-disinfectors and cart washers) and ultrasonic cleaners.

PINNACLE AEC Tests have two pads as shown in diagram 1. The Indicator pad contains a protein that is broken down by active enzymes in the detergents during a cleaning cycle. The pad becomes lighter in color during a cleaning cycle due to enzyme activity. The Indicator pad color is compared to the Reference pad after completion of the cleaning cycle (the reference pad does not change colors). PASS results are determined when the Indicator Pad is lighter than the Reference pad.

Diagram #1 – PINNACLE AEC test strip



Serim staff have tested multiple detergent brands using the manufacturers recommendations for detergent concentration, cycle times and temperatures. Our testing consistently shows that **PINNACLE AEC responds to all critical factors of cleaning** and that an adequate amount of enzymatic activity is required for PASS results. When testing detergents that recommend a broad range of cycle times and temperature, FAIL results are common with shorter cycle times and lower temperatures. These FAIL results are due to reduced enzymatic activity with these specific conditions.

Enzymatic detergents are designed for specific use(s) and the manufacturer provides the recommended detergent concentration and temperature range for each use on the product label. Some manufacturers include recommendations for both automated equipment and manual cleaning while other detergents indicate use only in automated equipment. Washer-disinfectors and ultrasonic units may have a different recommended detergent concentration and some detergents do not include a recommended dilution for both washers and sonics. Few, if any, enzymatic detergents provide a recommended detergent concentration for cart washers on the label.

STUDY DESIGN

This study looked at two cycles commonly used in cart washers; testing included an instrument cycle and a shorter cycle used for cleaning other items (carts, plastic tray and bins, instrument trays etc.). Instrument cycles in cart washers are similar to standard cycles in washer-disinfecter units, and an enzymatic detergent is normally used with instrument cycles. The standard, non-instrument cycles usually have shorter cycle times, lower temperatures and may not use an enzymatic detergent depending upon the hospital's choice of detergents and the type of equipment being cleaned in the non-instrument cycle.

Both cycles tested included a pre-rinse cycle (water only), two wash and rinse cycles and a heated drying cycle. The cycle times and temperatures for both cycles were pre-set by the manufacturer, no adjustments were made during this testing. The total cycle time was 50 minutes for the instrument cycle and 29 minutes for the non-instrument cycle. For both cycles, the detergent is added before the first wash cycle and heated to the specified temperature prior to starting the timed wash cycle. The detergent solution circulates through the cart washer during heating which increases the total time for enzymatic cleaning.

Multiple PINNACLE AEC tests were randomly attached to the cart wash rack prior to placing the rack into the cart washer (See picture #1). The rack used in this trial had two shelves, one near the top and one in the middle of the shelf, both racks have spray arms that rotate due to water pressure and spray the detergent solution throughout the chamber. The chamber also has a large number of spray nozzles on the walls. Tests were attached to the outside of both shelves in locations where the spray arms would not hit the tests during the wash cycles. (See picture #1). At the completion of the cleaning cycle, the tests were removed from the holder, and results determined. The tests were allowed to completely dry before final determination of PASS/FAIL results if they were damp (See product IFU). The enzymatic detergent used for this cart washer lists a specific concentration for washer-disinfectors and ultrasonic cleaners on the bottle label (See Picture #2). A specific concentration for cart washers is not provided by the detergent manufacturer. The equipment manufacturer's rep was at this hospital during the testing and calculated the detergent amount programmed for the instrument cycle matched the lowest concentration recommended by the detergent manufacturer for automated washers.

Both wash cycles of the non-instrument cycle use an aluminum safe alkaline detergent which does not contain any enzymes. The second wash cycle of the instrument cycle for this cart washer also uses the aluminum safe alkaline detergent. The enzymatic detergent is only used in the first wash cycle of the instrument cycle.

RESULTS

All PINNACLE AEC tests -placed in the cart washer for the non-instrument cycle showed FAIL results (see picture #3). This was the **expected result** since a non-enzymatic detergent was used for this cycle.

The first run with the instrument cycle was aborted due to an issue with the detergent pump/sensor. The specific cause for this failed run could not be determined by the equipment rep. All the tests placed in the cart washer for this aborted run showed FAIL results. This was the **expected result** due to an issue with detergent delivery system and minimal enzyme activity (See Picture #4).

A new set of tests were placed into the washer and a second instrument cycle was run. The second run completed successfully and all of these tests showed PASS results regardless of their placement. These **results indicate that the equipment functioned properly** and provided an appropriate level of enzymatic cleaning (See picture #5).

CONCLUSION

The results of this study show that the PINNACLE AEC test can be used to test instrument cycles of cart washers when using an enzymatic detergent. PINNACLE AEC will produce PASS results when using an appropriate dilution of an enzymatic detergent with mechanical aspects of the equipment (time, temperature, and mechanical action) that provide optimal conditions. FAIL results are expected with a non-enzymatic detergent and cycles with reduced enzyme activity due to a deficiency in one or more

factors of the cleaning process. The results of this study also indicate **the importance of using a verification test that responds to all factors of the cleaning process**. Some verification tests provide PASS results with minimal enzyme activity. Other studies (See recommended references below) have shown that some verification tests are likely to show PASS results with reduced/limited enzyme activity when subjected to sub-optimal conditions as long as some mechanical action is present.

Since enzyme concentration and activity vary by detergent, and detergent manufacturers may not provide a specific dilution for cart washers, each hospital should conduct similar testing with their cart washer(s) to determine the detergent concentration and cycle settings that provide optimal cleaning. Adjustments in detergent concentration and wash cycle settings may be required to determine optimal cleaning conditions. Using PINNACLE AEC as your cart washer test will help determine both the appropriate detergent concentration and cycle settings and ensure your cart washer maintains the required cleaning efficacy.

Recommended References

ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Alfa, MJ, Olson N. Comparison of Washer-Disinfector Cleaning Indicators: Impact of Temperature and Cleaning Cycle Parameters. AM J Infect Control 2014;42 e23 – e26

Serim Research, Evaluation of PINNACLE Monitor for Automated Cleaning (AEC) in Ultrasonic Cleaners. Serim website.

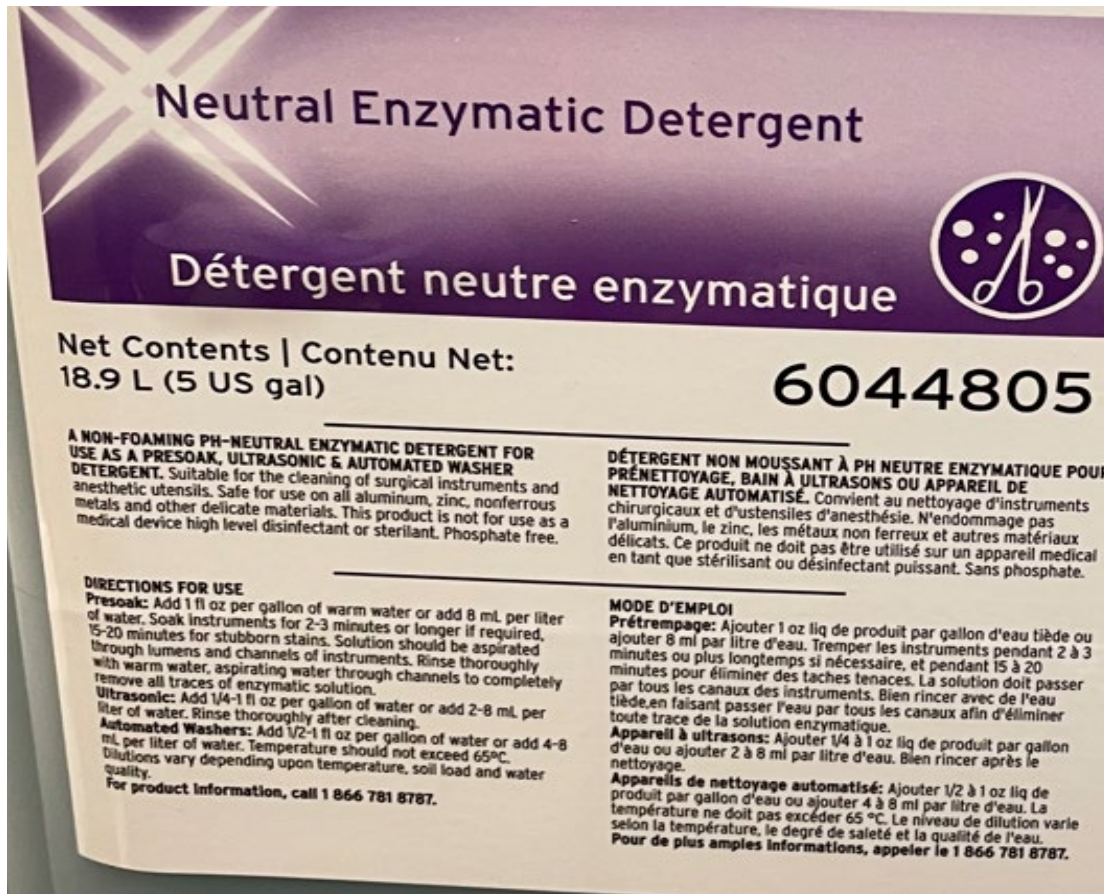
Pictures

Picture #1 Cart in washer before start cycle. PINNACLE tests in white holders are visible on the outside of top and middle rack.



Pinnacle AEC tests in holders

Picture #2 – label of enzymatic detergent showing recommend detergent concentrations



Neutral Enzymatic Detergent

Détergent neutre enzymatique

Net Contents | Contenu Net:
18.9 L (5 US gal)

6044805

A NON-FOAMING PH-NEUTRAL ENZYMATIC DETERGENT FOR USE AS A PRESOAK, ULTRASONIC & AUTOMATED WASHER DETERGENT. Suitable for the cleaning of surgical instruments and anesthetic utensils. Safe for use on all aluminum, zinc, nonferrous metals and other delicate materials. This product is not for use as a medical device high level disinfectant or sterilant. Phosphate free.

DÉTERGENT NON MOUSSANT À PH NEUTRE ENZYMATIQUE POUR PRÉNETTOYAGE, BAIN À ULTRASONS OU APPAREIL DE NETTOYAGE AUTOMATISÉ. Convient au nettoyage d'instruments chirurgicaux et d'ustensiles d'anesthésie. N'endommage pas l'aluminium, le zinc, les métaux non ferreux et autres matériaux délicats. Ce produit ne doit pas être utilisé sur un appareil médical en tant que stérilisant ou désinfectant puissant. Sans phosphate.

DIRECTIONS FOR USE

Presoak: Add 1 fl oz per gallon of warm water or add 8 ml per liter of water. Soak instruments for 2-3 minutes or longer if required, 15-20 minutes for stubborn stains. Solution should be aspirated through lumens and channels of instruments. Rinse thoroughly with warm water, aspirating water through channels to completely remove all traces of enzymatic solution.

Ultrasonic: Add 1/4-1 fl oz per gallon of water or add 2-8 ml per liter of water. Rinse thoroughly after cleaning.

Automated Washers: Add 1/2-1 fl oz per gallon of water or add 4-8 ml per liter of water. Temperature should not exceed 65°C. Dilutions vary depending upon temperature, soil load and water quality.

For product information, call 1 866 781 8787.

MODE D'EMPLOI

Prétrempage: Ajouter 1 oz liq de produit par gallon d'eau tiède ou ajouter 8 ml par litre d'eau. Tremper les instruments pendant 2 à 3 minutes ou plus longtemps si nécessaire, et pendant 15 à 20 minutes pour éliminer des taches tenaces. La solution doit passer par tous les canaux des instruments. Bien rincer avec de l'eau tiède, en faisant passer l'eau par tous les canaux afin d'éliminer toute trace de la solution enzymatique.

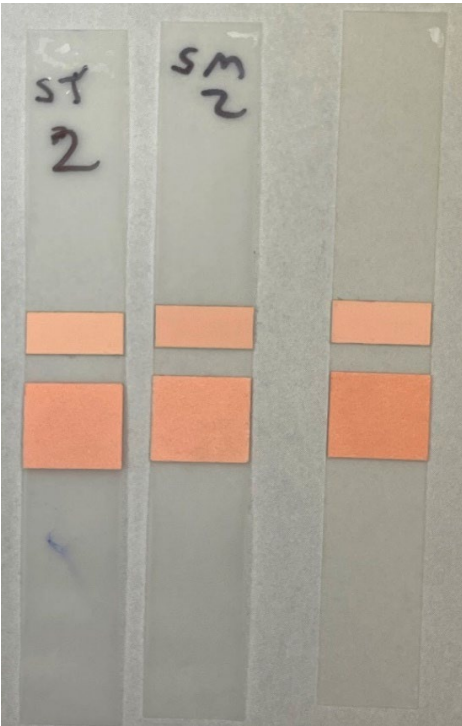
Appareil à ultrasons: Ajouter 1/4 à 1 oz liq de produit par gallon d'eau ou ajouter 2 à 8 ml par litre d'eau. Bien rincer après le nettoyage.

Appareils de nettoyage automatisé: Ajouter 1/2 à 1 oz liq de produit par gallon d'eau ou ajouter 4 à 8 ml par litre d'eau. La température ne doit pas excéder 65 °C. Le niveau de dilution varie selon la température, le degré de saleté et la qualité de l'eau.

Pour de plus amples informations, appeler le 1 866 781 8787.

Picture # 3 – Results for non-instrument cycle, shown with unused strip on the right

FAIL result



Test strip codes
S= short cycle
I= Instrument cycle
T= Top Rack
M= Middle Rack
Numbers = test strip number
X = aborted cycle

Picture #4 Results for Aborted Instrument cycle shown with unused strip on the right



Reference Pad

Indicator pad

Picture #5 – Instrument cycle – complete cycle shown with unused strip on the right
PASS results shown, Indicator pad is lighter in color than reference pad.



Test strip codes
I =Instrument cycle
T=Top Rack
M= Middle Rack
Numbers = test strip number