

Suggested Procedure for Monitoring the Cleaning Function of Washer Disinfectors and Ultrasonic Cleaners Using the PINNACLE™ Monitor for Automated Enzymatic Cleaning Process

PURPOSE:

The PINNACLE™ Monitor for Automated Enzymatic Cleaning Process (AEC) can be used as part of the hospital's program to aid in monitoring the efficacy of automated medical instrument washer disinfectors and ultrasonic cleaners using enzymatic detergents.

POLICY:

Washer disinfectors and ultrasonic cleaners should operate in accordance with the manufacturer's and detergent supplier's guidelines and hospital policies. An appropriate indicator, such as the PINNACLE Monitor for AEC, should be used routinely to facilitate monitoring the cleaning function of automated instrument cleaners. The monitor is designed for use with enzymatic pre-soaks and detergents and should be used in accordance with AAMI ST79:2010/A3:2012ⁱ guidelines to assess that the cleaning process is appropriate and washer disinfectors and ultrasonic cleaners are functioning properly.

RATIONALE:

Automated instrument cleaners, such as washer disinfectors and ultrasonic cleaners, decontaminate and clean soiled surgical instruments to allow safe handling prior to sterilization. After being properly decontaminated, the instruments can be repackaged and sterilized for use in future surgeries.

The PINNACLE Monitor for AEC monitors the washer disinfectant or ultrasonic cleaner cycle conditions that influence the effectiveness of the cleaning process. The device is sensitive to important variables such as enzymatic detergent concentration, enzyme activity and contact time, wash cycle temperature, and mechanical action (impingement, sonics, and spray arm function) collectively. Using the PINNACLE Monitor for AEC according to the manufacturer's guidelines supports Central Processing in conforming to AAMI ST79:2010/A3:2012 guidelines.

RESPONSIBILITY:

Central Service personnel are responsible for following all washer disinfectant/ultrasonic cleaner and enzymatic detergent manufacturers' instructions, all hospital policies and for the proper use, result interpretation, and documentation of the PINNACLE Monitor for AEC when used in automated instrument cleaners.

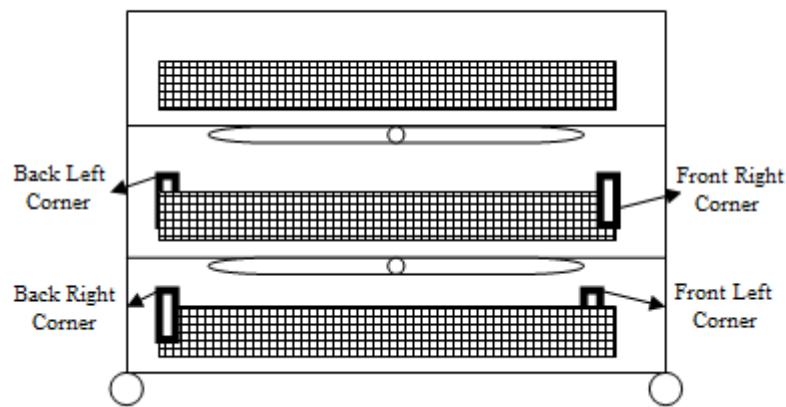
¹ ANSI/AAMI ST79:2010/A3:2012, Annex D. 'Comprehensive guide to Steam Sterilization and Sterility Assurance in Health Care'. www.aami.org

I. PROCEDURE FOR INITIAL EVALUATION OF AUTOMATED INSTRUMENT CLEANERS

Follow all equipment manufacturer guidelines concerning daily physical inspection of the medical washer disinfector or ultrasonic cleaner. Adhere to all enzymatic detergent manufacturers' guidelines and hospital policies concerning automated instrument cleaning equipment.

1. Remove four PINNACLE AEC strips from the bottle. Using a permanent marker, write the equipment identification, date, time and location, if applicable, on the strip handle.
2. Insert a strip into the channel of the holder and, while keeping the holder level, snap it closed. Repeat for the other three strips. Ensure the indicator and internal color standard pads are centered within the window of the holders. (Refer to the wall chart for full instructions).
3. Secure the monitoring devices either inside an empty instrument basket or around the perimeter of the instrument rack.
 - a) To secure the monitoring devices *inside an instrument basket* use the hook on the end of the holder.
 - i) For washer disinfectors, attach two monitoring devices on opposite ends inside a basket located on one of the shelves and attach the remaining two devices on opposite ends inside a basket located on another shelf (Figure 1A).

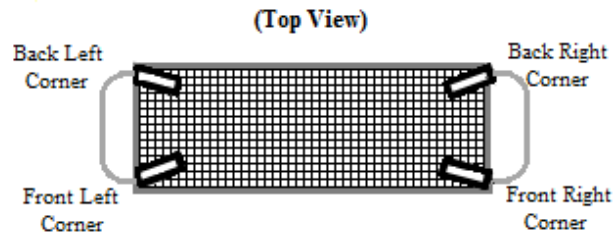
Figure 1A: PINNACLE Monitoring Devices Attached Inside Washer Disinfector Baskets



Note: The middle and lower shelves of the washer disinfector rack represent potential problem areas for decontamination and are recommended for use in evaluating the efficacy of the wash cycle. In rare occurrences, high impingement from the upper spray arm may damage one or both of the indicator pads on the PINNACLE AEC strip.

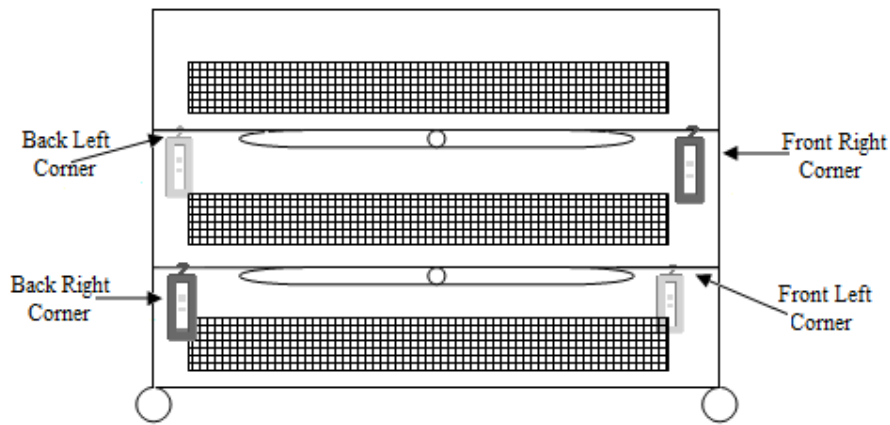
- ii) For ultrasonic cleaners, place a monitoring device in each corner of the instrument basket (Figure 1B).

Figure 1B: PINNACLE Monitoring Devices Inside Ultrasonic Cleaner Basket



- a) To secure the monitoring devices around the perimeter of the washer disinfectant rack use the hook on the end of the holder. Attach two monitoring devices on opposite ends of one shelf and attach the remaining two devices on opposite ends of another shelf (Figure 2). Always attach the devices in the corners farthest away from the spray arms.

Figure 2: PINNACLE Monitoring Devices Attached to Perimeter of Rack



2. Run the instrument wash cycle empty (without any instruments) to determine results under “best case” performance conditions.
3. After the wash cycle is complete, unhook the holders from the baskets or racks and remove the strips. Retain holders for future use.
4. Ensure the pads of the strip are facing up and interpret the results by comparing the color of the larger indicator pad to the smaller internal color standard.

PASS - the indicator pad is **lighter in color** than the internal color standard

FAIL - the indicator pad is **similar to or darker** in color than the internal color standard

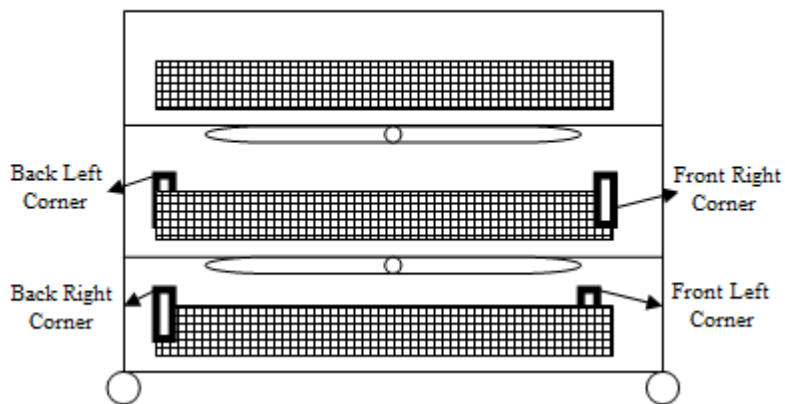
5. Record results. Since the monitor is being run under “best case” performance conditions, the expected result of the PINNACLE Monitor for AEC should be a PASS. If a FAIL result is obtained refer to the PINNACLE AEC Reference Guide and adjust the cleaning conditions to obtain desirable results.
6. Repeat this procedure for each washer disinfectant and ultrasonic cleaner in the facility.
7. Record all changes and adjustments made to the washer disinfectors or ultrasonic cleaners.

II. PROCEDURE FOR ROUTINE MONITORING OF AUTOMATED INSTRUMENT CLEANERS

Follow all manufacturer guidelines concerning daily physical inspection of the medical washer disinfector or ultrasonic cleaner. Adhere to all enzymatic detergent manufacturers' guidelines and hospital policies, concerning medical washer disinfectors and ultrasonic cleaners.

1. Testing the efficacy of washer disinfectors and ultrasonic cleaners should be performed on a routine basis.
2. Remove a strip from the bottle and write the equipment identification, date, time and location, if applicable, on the strip handle.
3. Insert the strip into the channel of the holder and, while keeping the holder level, snap it closed. Make sure the indicator and internal color standard pads are centered within the window of the holder.
4. Secure the monitoring device in one location *inside a washer disinfector or ultrasonic instrument basket* (see Figures 3A & B) or *around the perimeter of the washer disinfector rack* (see Figure 4) using the hook on the end of the holder. Ensure the indicator and internal color standard pads are unobstructed. Run wash cycle.

Figure 3A: Attach a Monitoring Device in One of the Suggested Locations Inside the Washer Disinfector Baskets



Note: The middle and lower shelves of the washer disinfector rack represent potential problem areas for decontamination and are recommended for use in evaluating the efficacy of the wash cycle. In rare occurrences, high impingement from the upper spray arm may damage one or both of the indicator pads on the PINNACLE AEC strip.

Figure 3B: Attach a Monitoring Device in One of the Suggested Locations Inside an Ultrasonic Cleaner Basket

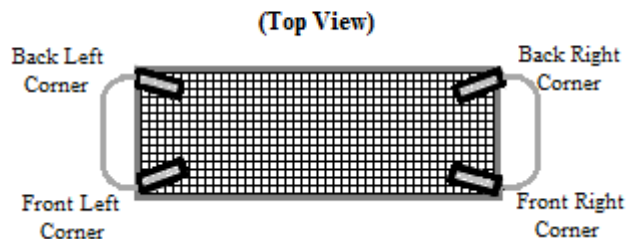
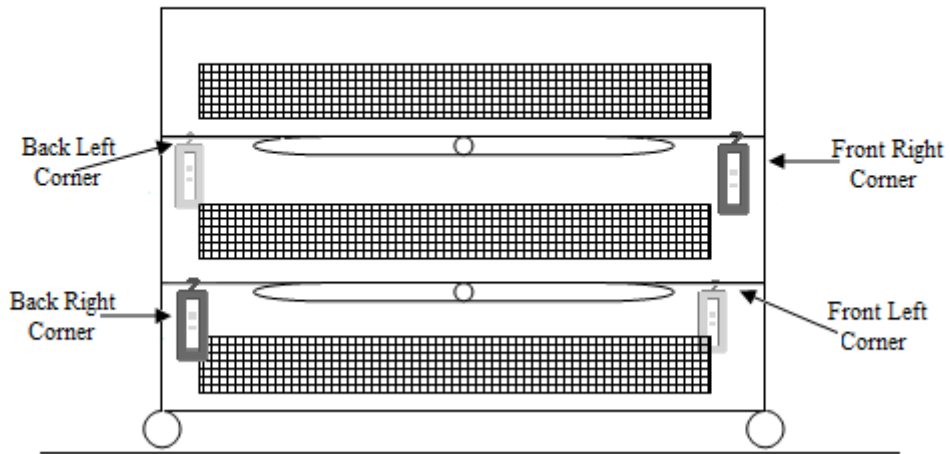


Figure 4: Attach a Monitoring Device in One of the Suggested Locations on the Perimeter of the Rack



5. After the wash cycle is complete, unhook the holder from the basket or rack and remove the strip. Retain the holder for future use.

6. Ensure the pads of the strip are facing up and interpret the results by comparing the color of the larger indicator pad to the smaller internal color standard.

*PASS - the indicator pad is **lighter in color** than the internal color standard*

*FAIL - the indicator pad is **similar to or darker in color** than the internal color standard*

7. Attach strip to log sheet and record results.

8. For unacceptable results, refer to the Reference Guide at www.serim.com.

III. MAINTENANCE ON AUTOMATED INSTRUMENT CLEANERS:

1. After any maintenance or repair on a washer disinfector or ultrasonic cleaner, run a PINNACLE Monitor for AEC (following the “Routine Monitoring of Automated Instrument Cleaners” procedure on page 4) to aid in determining that the equipment is working properly.
2. The service technician should wait until testing is complete and satisfactory results are obtained.