Evaluation of PINNACLE Monitor for Automated Enzymatic Cleaning (AEC) in Ultrasonic Cleaners

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Purpose:

This study was designed to evaluate the response of PINNACLE™ Monitor for Automated Enzymatic Cleaning (AEC) to a variety of conditions in ultrasonic cleaners. Multiple factors influencing the cleaning process (cavitation, cycle time, and temperature) were assessed in this study under both optimal and sub-optimal conditions.

Background Information:

The current AAMI ST79[1] 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) and recommend monitoring those critical parameters to evaluate performance of mechanical cleaning equipment (section 13.2.c and Annex D). Ultrasonic cleaners should be tested daily when in use (section 7.6.4.4.1); including both removal of soil or marker (Annex D) and cavitation.

Study design:

This study included nine protease enzymatic detergents manufactured for medical instrument cleaning in ultrasonic cleaning units (Appendix A). Six different readers were used, each reader evaluated five tests strips per detergent using a blinded sample study design. Multiple temperature and cycle times were tested and Reverse Osmosis/Distilled (RO/DI) water was used as a control (did not contain any enzymes). For comparison, Wash Checks U test was also evaluated using the manufacturer's instructions for use. Ultrasonic units from three different manufacturers were used in this evaluation, a majority of the testing was conducted using an Amsco Reliance Tabletop Sonic Cleaner.

Enzyme concentration and activity also influences the cleaning process and has been evaluated in many other studies. Detergents used in this study were tested using the manufacturers' recommended concentration.

Conclusions:

This evaluation determined that PINNACLE AEC is a valid verification test for ultrasonic cleaning units and responds to multiple critical factors affecting the cleaning process including cavitation. PINNACLE AEC can be used with multiple detergent brands, PASS results were observed when testing optimal cycle times and temperatures (Tables 1 and 5). When testing

suboptimal conditions, FAIL test results were common (Table 4) due to a deficiency in one or more factors.

FAIL results were observed when soaking PINNACLE AEC in an enzymatic detergent without cavitation (Table 2), this indicates that cavitation is required to achieve PASS results. When tested without enzymatic detergent (15-minute cycle in RO/DI water) FAIL results were observed for all PINNACLE AEC tests (Table 1 and 3) and PASS results were observed for all Wash Checks U tests (Table 1). This indicates that a detergent containing active enzymes is required to achieve PASS results with PINNACLE AEC. Additional testing of PINNACLE AEC with Steris Caviwave, Model CAVI-20-W-E and Medisafe PCF, Model MED11121 ultrasonic units also showed PASS results when testing optimal conditions as determined for those Ultrasonic cleaning units.

The results of this study indicate that there is not a "one size fits all" approach or universal set of conditions for instrument cleaning using ultrasonic cleaners. Each detergent required a different combination of conditions (detergent concentration, cycle time and temperature) to consistently produce acceptable cleaning results (PASS). Changing one or more of these interdependent factors may alter PASS/FAIL results. Therefore, the end user will need to test their detergent concentration and equipment settings (time and temperature) to determine optimal cleaning conditions. Using a cleaning verification test that responds to all factors of the cleaning process like the PINNACLE AEC, is a critical part of determining optimal conditions. Pinnacle AEC's ease of use and economical price support daily testing requirements as stated by AAMI.

Results:

Table 1 - Results for Testing multiple detergents at 45°C for 15 minutes (optimal conditions for detergents and ultrasonic unit)

Detergent	Pinnacle Results (average of 30 readings)	Wash-Check U Results (average of 30 readings)
ProEZ AW Quad	100% Pass	100% Pass
EmPower	100% Pass	100% Pass
MediZym	100% Pass	100% Pass
RO/DI water (no detergent)	100% Fail	***100% Pass***

Table 2 - Soaking PINNACLE AEC in detergent without cavitation

Detergent	**Time**	**PINNACLE** (average of 4 tests)	**Wash-Check U** **(**one test)	**Temperature**
ProEZ AW Quad (½ oz/gal)	15 minutes	100% FAIL	FAIL	45°C

Table 3: Testing PINNACLE AEC in RO/DI water using optimal time and temperature (no detergent present)

Temperature (°C)	Time (minutes)	Results
55	10	100% Fail
45	15	100% Fail
30	30	100% Fail

Table 4: Testing PINNACLE AEC with multiple temperature and cycle time conditions. All conditions were tested using ProEZ AW Quad by Certol at 1/2 oz/gal.

Temperature (°C)	Time (minutes)	Average for 4 tests
Optimal conditions		
27* 27* 27*	20 30 45	100% Pass 100% Pass 100% Pass
45	10	100% Pass
50 50	7 10	100% Pass 100% Pass
55	10	100% Pass
Suboptimal Condition: cycle time shorter than recommended		
45 45	5 7	75% Pass‡ 75% Pass‡
50	5	100% Fail
Suboptimal Condition: temperature above active range for enzymes		
60 60	5 7	100% Fail 100% Fail

*the temperature increased to 34°C in the small bench top unit during the evaluation

‡ - pass/fail determination was difficult with some tests indicating conditions approach failure point

Table 5: Summary of Enzymatic Detergents used in this study producing acceptable (PASS) results when tested with PINNACLE AEC using optimal time and temperature conditions.

Detergent Name	Manufacturer	Concentration
ProEZ AW Quad	Certol	½ oz/gal
EmPower	Metrex	1 oz/gal
Terg-A-Zyme	Alconox	½ oz/1.5L
Endozime Xtreme Power	Ruhof	¼ oz/gal
Endozime AW Triple Plus	Ruhof	½ oz/gal
ProEZ 1	Certol	1 oz/gal
ProEZ 2	Certol	½ oz/gal
Metrizyme	Metrex	1 oz/gal
MediZym	Neodisher	1 oz/gal

[1] American National Standards Institute, Inc, Association for the Advancement of Medical Instrumentation, AAMI ST79. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Arlington (VA) ANSI/AAMI; 2017

Appendix A:

Detergents used during study

- ProEZ AW Quad, ProEZ 1, and ProEZ 2 by Certol
- EmPower by Metrex
- Terg-A-Zyme by Alconox
- Endozime Xtreme Power and AW Triple Plus by Ruhof
- MediZym by Neodisher
- 3E-Zyme by Medisafe

Ultrasonic units used during this study:

- Amsco Reliance Tabletop Sonic Cleaner, Model 150
- Steris Caviwave, Model CAVI-20-W-E
- Medisafe SI PCF System, Model MED11121

Serim does not endorse any detergent or equipment manufacturers and is not affiliated with any companies included in this study.