Example Policy of an Ultrasonic Cleaner (SonoCheck™, TOSI® and LumCheck) for Daily Cleaning and Monitoring

NOTE: This document is an example of a policy that may be instituted in a healthcare facility for daily monitoring of an ultrasonic cleaner. The actual policy in a facility must be based on variables, logistics, and risk-assessments specific to your facility.

Subject: Ultrasonic Cleaner Monitoring Daily (SonoCheck™ & TOSI® only)

Department: CPD, CSSD, SPA, MDRD, SPD, dental offices, medical offices, and department using an ultrasonic cleaner

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter the date when this will take effect]

Revised: August 2021

Purpose: The purpose of this example policy is to provide a means of monitoring the ultrasonic cleaning process and ensure proper cleaning/reducing the risk to personnel or patients.

Policy: To inspect and test any ultrasonic cleaner and its various functions (e.g, cavitation, removal of soil from a medical device/instruments), both on flat surface and lumen, each day it is used. This is to ensure the cleaning process is occurring and the ultrasonic cleaner is functioning properly.

Rationale: To test for the presence of cavitation energy in an ultrasonic bath, under normal conditions, in an empty tank that has been degassed. This is performed daily prior to the first use of the day.

Standards and Professional Society Recommendations:

According to ANS/AAMI ST79 every medical facility (as defined in ST79) that has a medical ultrasonic cleaner must put in place a cleaning verification process that consists of defining a cleaning process and its critical aspects so that each step is fully verifiable through personnel training and observation to ensure that it can be followed completely, accurately, and without variation by all individuals who perform it; and providing process controls along with verification methodologies that ensure adequate, consistent cleaning levels. Two principles are involved in verifying a cleaning process. The first consists of establishing, clarifying, and documenting a standard cleaning process that is based on device manufacturers' written IFU and published recommended practices or guidelines and articles. The second concerns measuring and evaluating the ability of an ultrasonic

cleaner's cavitation. Finally, how it can remove residual contaminants off of a medical device (both flat surface and lumen) after applying the established cleaning process. These verification tests are part of continuous quality improvement to show continued compliance with cleaning benchmarks once these benchmarks have been defined.

The standards support mechanical cleaning equipment performance should be tested each day an ultrasonic cleaning unit is used, and all results should be recorded.

The Joint Commission Standard E.C.6.20 states that all medical equipment is maintained, tested, and inspected.

Medical ultrasonic cleaners need to be properly functioning to provide the best patient care possible and to help reduce the incidence of hospital-acquired infections.

"Cleaning, not sterilization (or disinfection), is the first and most important step in any instrument processing protocol. Without first subjecting the instrument to a thorough, validated, and standardized (and ideally automated) cleaning process, the likelihood that any disinfection or sterilization process will be effective is significantly reduced," (11). Thus, the cleaning process must be verified.

ANSI/AAMI ST79 states (depending on your ultrasonic cleaner) you will need to perform the following types of test(s) each day the ultrasonic cleaner is used:

- Test for cavitation in ultrasonic bath
- Test for soil removal (external) in ultrasonic bath
- Test for soil removal (internal within lumens) in ultrasonic bath.

The ultrasonic cleaning process cleans dirty surgical instruments so that they can be handled safely, repackaged, and sterilized for a future surgery. The danger of handling instruments contaminated with blood is obvious in this age of Hepatitis, CJD and HIV. The procedures for sterilizing instruments are based on years of scientific testing of cleaning instruments. If surgical instruments are not clean, then the procedures are ineffective. Dried blood on instruments is hazardous to the employees of the hospital and to the next surgical patient on which the instruments are used. (1,2,3,4,8,).

An ultrasonic cleaner enables thorough cleaning of equipment by producing cavitation in combination with the other factors (e.g., cleaning solution, water quality, and time and temperature) to produce a clean medical device. Ensuring cavitation is taking place is vital for any ultrasonic cleaner. Cavitation is why you purchase an ultrasonic cleaner; thus, you want to make sure cavitation is being produced.

Ultrasonic cleaners do not disinfect instruments. They are used to assist with the cleaning of instruments that cannot be adequately cleaned manually, such as spiral wound instruments, like biopsy forceps.

The wave frequency used for the ultrasonic vibration does not kill microorganisms, and

infective aerosols may be produced. For this reason, the lid of the tank must be tightly closed during operation.

Ultrasonic cleaners work by subjecting instruments to high-frequency, high-energy sound waves. This is called cavitation. Cavitation causes soil to be dislodged from instruments and drop to the bottom of the tank or be sufficiently loosened enough to be removed during the rinsing process.

Agitation of the cleaning solution is also important for removing the soil that is deposited on medical devices and having it suspended in ultrasonic bath (solution). The cavitation process lifts/removes the soil of the device and is deposited on the bottom of the tank (or suspended in solution).

The detergent used in the ultrasonic tank must be carefully selected as per advice from the tank's manufacturer. Optimally, it will be a neutral, low-foaming product; and enzymatic cleaners will have enhanced benefits in this process.

Degassing (freeing of trapped gases in the solution) of cleaning solution is extremely important in achieving satisfactory cleaning results. Fresh solutions (or solutions which have cooled) must be degassed before proceeding with cleaning. Degassing is done after the cleaning chemistry is added and run for a specific time, according to the OEM of the ultrasonic. The time required for degassing varies considerably based on tank capacity, solution temperature, and type/model of the ultrasonic cleaner.

Rinsing of an instrument is important after the ultrasonic cleaning process if the cleaning unit does not have a rinse cycle. Rinse the instruments before inspecting them for cleanliness. Note: While some ultrasonic units have a rinse cycle it might not perform properly. Make sure the spray system jets are not clogged, or you will not get the proper rinse.

Routine Cleaning:

Cleaning ultrasonic cleaner units and replacing their cleaning solution is necessary at least daily or more often if the solution is soiled. Consult the original equipment manufacture's (OEM's) IFU how to change the solution in your tank/bath. Many of the newer unit models can now auto-change the bath solution after each cycle. Follow the OEM IFU on changing filters, wiping, and cleaning the tank as well as other duties.

Performance Testing:

The efficacy of the ultrasonic cleaner should be tested each day it is used. Testing results shall be documented as part of the proof of process (or the PQ).

Ultrasonic cleaners may fail for many reasons. Tests (e.g.: SonoCheck™, LumCheck™,

TOSI™) provide a means of monitoring variables that influence the effectiveness of the ultrasonic cleaning process. Some of these variables are:

Water	Time	Detergent
Enzyme	Temperature	High pH
Agitation	Speed	Tray Selection
Initial Heat	Drying	Obstructions
Chemicals (not enough?)	Equipment failure	Cavitation (happening?)

The test for cavitation is a separate test as outlined in ANSI/AAMI ST79. It is the key reason medical facilities use an ultrasonic cleaner for the deep cleaning, hard to reach areas of medical devices.

It is critical that independent objective testing is performed to check for proper cleaning. The SonoCheck™ test kit and the LumCheck™ (if you have pulse/retro flow for lumens devices) allow the Sterile Processing professional to monitor, verify, and ensure the ultrasonic cleaning process (including cavitation) is taking place.

Healthmark, in accordance with all the various standards and guidelines, recommends verifying every ultrasonic cleaner in the facility (each day it is used) with the following verification test(s) based on each ultrasonic cleaner's ability:

- SonoCheck™—monitoring vials*designed to change color (blue to yellow) when the ultrasonic cleaner is supplying enough energy and conditions are correct (e.g.: degassed water, temperature, etc.) indicating cavitation is present. SonoCheck™ is an easy to use and interpret Failure to change color means either the ultrasonic bath conditions were not correct or a failure of one or more of the ultrasonic transducers
- TOSI®—Indicator used to test the ultrasonic cleaner unit for cleaning efficacy of medical devices. Remember, we test the ultrasonic units for cavitation and to make sure there is not a one-to-one correlation between cavitation activity and cleaning effectiveness. Thus, the TOSI® should be run inside an ultrasonic together with a SonoCheck™ and must pass the SonoCheck™ and clean a TOSI® at the same time. Passing one test or the other is not enough. You need to have enough "ultrasonic power - cavitation" to clean a surgical instrument
- LumCheck™—Verifies the pulse/retro flow of an ultrasonic cleaner's ability to clean lumens

As stated in the STERIS University - Ultrasonic Cleaning - Study Guide 24; (Page 6), a department should test for both:

- Cavitation using some type of indicator specifically for cavitation
- Cleaning indicators— "These test soils should mimic the type of soils that may be found on reusable devices and instrumentation." \

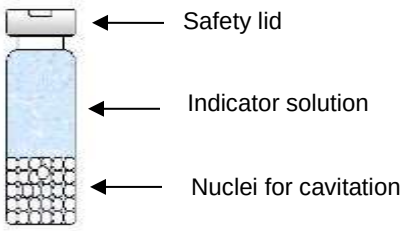
(*Note: As with any ultrasonic cleaning process, rinsing is very important. If the ultrasonic cleaner does not have a rinse cycle, the TOSI® must be rinsed off (like you would your instruments). If any organic soil was redeposited back onto the coupon, make*

sure it is washed off. This is done by placing the TOSI® under running water for at least 5-seconds and exposing the gap to the rinse, or to swish or rinse off the TOSI® when removing it from the ultrasonic cleaner to remove any redeposited residual soil for the 5-seconds before reading the TOSI®.)

Procedure:

Ultrasonic Cleaners should be tested each day they are used.

Directions for use

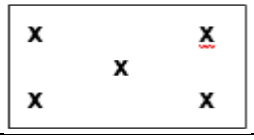


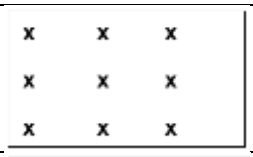
Daily Inspection & Testing:

- Follow manufacture's guidelines concerning the daily inspection of equipment (i.e.: screens…)
- Inspect the level of the detergent daily. Mark the container of the solution daily with the date at the level of the solution in the container. This will give a visual if the solution is being used
- Log all observations in a report as "Daily observations"
- Report any concerns needing addressment to the proper management staff within the department

Types of Testing of the Ultrasonic Cleaner:

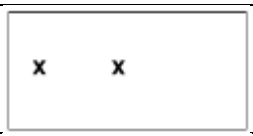
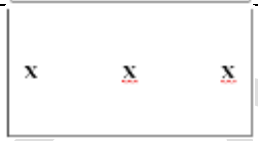
- The functional test will check the uniform operation of the empty ultrasonic cleaner's tank. This testing should be done on installation of the equipment and/or after major repairs. The diagram below gives the suggested placement of the SonoCheck™ in relation to the ultrasonic tank size. This helps confirm cavitation is taking place in all areas of the tank/bath solution
- Remember, degassing should always be done before any testing cycle begins
- Record all results for trend analysis and for help in any troubleshooting issues

SonoCheck™ Placement	Size of Tank	Volume of Solution
	Small	≤ 5 l or (1.3 gal)

	Medium	5 to 20 l (or 1.3 - 5.3 gal)
	Large	> 20 l (or greater than 5.3 gal)

Daily Testing of the Ultrasonic Cleaner:

Frequency of testing is each day the ultrasonic cleaner is used to monitor the performance. Testing is performed under normal conditions in an empty tank that has been degassed.
The diagram shows suggested placement of SonoChecks™ in relation to the ultrasonic tank size for routine testing. This type of placement helps ensure you are testing all areas of the ultrasonic cleaner tank/bath for cavitation. All testing results should be logged and saved for trend analysis and troubleshooting concerns.

SonoCheck™ Placement	Size of Tank	Volume of Solution
	Small	≤ 5 l (or 1.3 gal)
	Medium	5 to 20 l (or 1.3 – 5.3 gal)
	Large	> 20 l (or 5.3 gal)

Daily Ultrasonic & Blood Soil Test Placement - TOSI®:

- Make sure the ultrasonic cleaner has been degassed prior to running the test and the correct amount of cleaning solution is in the tank/bath. Note: This is part of the cycle in new models
- The number of SonoChecks™ placed in the tank will be dependent on the volume of the tanks (see Daily Testing)
- Secure one (1) TOSI® to the middle of an empty surgical tray
- TOSI® and SonoCheck™ can be placed in the same tray
- Run the ultrasonic through its normal cycle (record the cycle). Again, on newer models the degasses with be part of the total cycle time
- Record both the SonoCheck™ and TOSI® results at the end of the cycle

- Color change from blue/green to yellow is a pass for the SonoCheck™
- A passing for a TOSI® is a 0.
- In case of unsatisfactory results, refer to the troubleshooting guide
- Record all information in logbook

Using these tests help verify both cavitation and soil removal independently, according to ANSI/AAMI ST79.

***Note: As with any ultrasonic cleaning process rinsing is very important. If the ultrasonic cleaner does not have a rinse cycle, the TOSI® must be rinsed off (like you would your instruments). This is important to ensure no organic soil was redeposited back onto the coupon.*

Testing the Ultrasonic Cleaner Ability to Clean Lumens:

- The LumCheck™ should be used in ultrasonic cleaners with lumen/cannulated item cleaning capability
- When possible, it is recommended to run all three tests at one time in the same cycle. The LumCheck™ can be run with both the SonoCheck™ and TOSI®
- Ultrasonic cleaners use a flow/retro flow system to flush (or pull/suction) lumens/cannulated items with approved cleaning solution. The LumCheck™ should be used to check the performance of these types of ultrasonic cleaning units
- TOSI® and LumCheck™ blood soil test is designed to monitor the cleaning function of an ultrasonic cleaner's ability to clean cannulated or lumen instruments

LumCheck™ Blood Soil Test

The LumCheck™ is a Daily Test:

1. Testing is done in an empty load (no instruments)
2. Depending on your ultrasonic cleaner, you will at least need to test one-port to ensure it is working properly. Facilities can do as many as they want to challenge their equipment

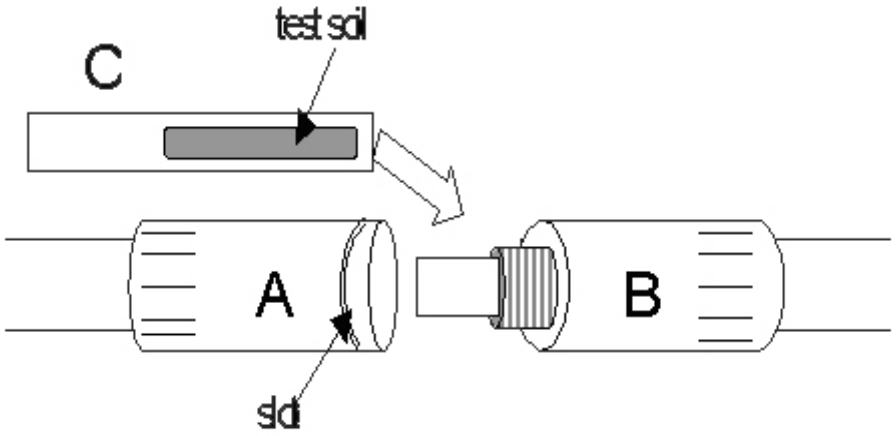
(Note: If an ultrasonic cleaner has two pumps for the flow/retro pump system, it is suggested to test a port that uses each pump to ensure both pumps are working.)

3. Unscrew LumCheck™ device, and detach A (marked with slot) from B (see diagram below)
4. Open protective pouch of TOSI® – LumCheck™ and insert the test object C into B, as shown in diagram.

(Note: Do not touch the area covered with test soil.)

5. Close LumCheck™ device, again
6. Connect LumCheck™ to ultrasonic cleaner

   a. Connect the LumCheck™ device with one of the channel irrigation system ports of the ultrasonic (i.e., luer-lock)
      i. If equipment has more than one channel (ports), you must check at least one-port
      ii. If checking more than one-port (channel), they must all be checked at the same time
   b. After connection start the cycle according to your manufacturer's manual instructions (i.e., MIS cycle)
7. Open the device after the reprocessing cycle: disconnect part A from part B to remove the TOSI® – LumCheck™ without touching the test soil area
8. For visual evaluation of the result, use the TOSI® evaluation table.



Maintenance on Equipment:

- After any maintenance on the equipment, perform an *Ultrasonic Test Kit™ and LumCheck™ ensuring proper functionality
- Follow the weekly test process
- Have the maintenance person wait until the test results are complete

**(Note: The Ultrasonic Test Kit™ contains both the TOSI® and SonoCheck™.)*

Responsibility:

Central Service personnel are responsible for the proper use, result interpretation, and documentation of the Ultrasonic Test Kit™ and LumCheck™ when used on an ultrasonic cleaner.

Inservice and training of the staff should be done at annually on the equipment (ultrasonic) and the use of the Ultrasonic Test Kit™ and LumCheck™ products.

Various Sample log sheet to record results:

Equipment name _____ Model # _____

healthmark

ULTRASONIC CLEANER TEST LOG SHEET

EQUIPMENT NAME:
MODEL:

DATE	TESTER INITIALS	SONOCHECK RESULT LEFT SIDE	SONOCHECK RESULT CENTER	SONOCHECK RESULT RIGHT SIDE	TOSI RESULT	LUMCHECK RESULT	TANK DEGASSED	BATH TEMP.	PROGRAM CYCLE TESTED	ACTION COMMENTS

Testing of the sonic is done daily or each day the sonic is used

SonoCheck Pass = P
(Vial turns from blue/green to yellow)

SonoCheck Fail = F
(Vial stays blue/green in color)

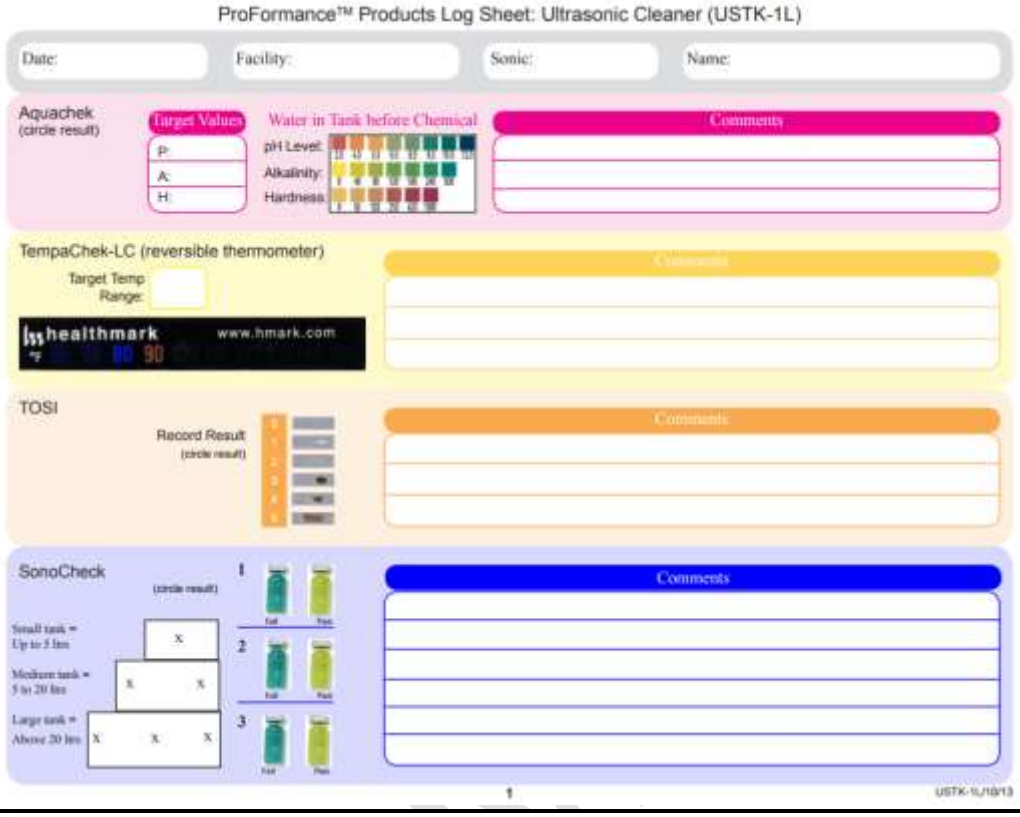
Size of tank determines number of SonoChecks used for testing

SMALL: UP TO 5 LITERS MEDIUM: 5-20 LITERS LARGE: ABOVE 20 LITERS

SMALL TANK MEDIUM TANK LARGE TANK

HMARK.COM | 800.521.6224 | HEALTHMARK@HMARK.COM

**TOSI®/LumCheck™ results are from 0 to 5.*
SonoCheck™ record the color change from blue/green to yellow.


ProFormance™ Products Log Sheet: Ultrasonic Cleaner (USTK-1L)

Date: Facility: Sonic: Name:

Aquachek (circle result)

Target Values: P: A: H:

Water in Tank before Chemical: pH Level: Alkalinity: Hardness

Comments

TempaChek-LC (reversible thermometer)

Target Temp Range:

healthmark www.hmark.com

Comments

TOSI

Record Result (circle result)

Comments

SonoCheck (circle result)

Small tank = Up to 5 ltrs

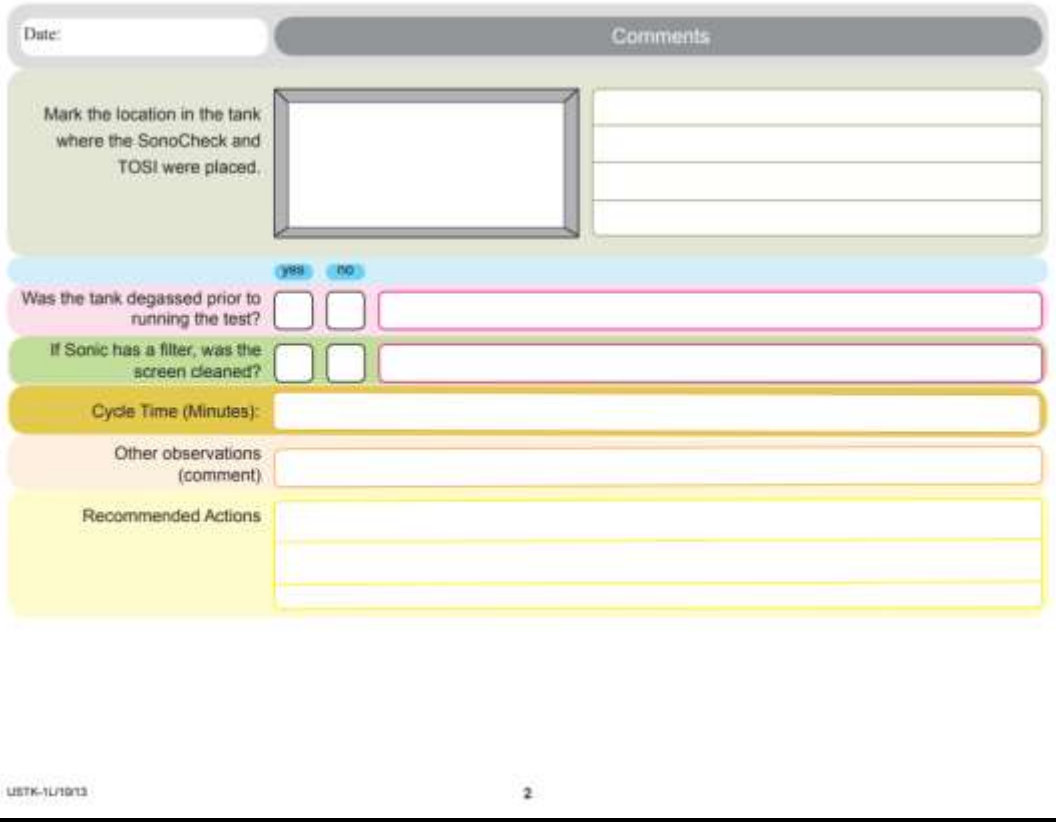
Medium tank = 5 to 20 ltrs

Large tank = Above 20 ltrs

1 2 3

Comments

1 USTK-1L/10/13


Date:

Comments

Mark the location in the tank where the SonoCheck and TOSI were placed.

yes no

Was the tank degassed prior to running the test?

If Sonic has a filter, was the screen cleaned?

Cycle Time (Minutes):

Other observations (comment)

Recommended Actions

USTK-1L/10/13 2

SonoCheck™ Troubleshooting Guide:

If the SonoCheck™ ultrasonic cavitation monitor does not change color or if the time required generating the color-change takes longer than normal, please check the following guide:

Problem		Reason		Corrective action
Degassing		Dissolved gasses will absorb ultrasonic energy		Degas solution according to equipment manual
Water level		Ultrasonic energy may reflect off the surface of the solution and change energy distribution		Check equipment manual for correct water level
Operating cycle time		Time varies with the amount of ultrasonic energy available		Longer running cycles generally provide better results
Instrument load		Heavy instrument loading and certain materials can absorb ultrasonic energy		Look for weak points using the functional test and check for ultrasonic absorbent material like silicone or plastics
Transducer failure		• Transducer efficiency may decrease with age • Individual transducers may fail while others in the equipment continue to function		Perform functional test, placing SonoCheck™ monitors in each transducer location (see *equipment manual*)
Low energy		Transducer inefficiency or the ultrasonic basket may absorb too much energy		• Check performance without basket in place • Compare performance against another ultrasonic cleaner if available • Call for service
Tray selection		Various trays (the material they are made from) absorb and inhibit the transfer of ultrasonic energy within the ultrasonic unit's tank (they can change the energy distribution)		• Test with a different tray (change types of trays) • Use a tray that does not absorb or inhibit transfer of ultrasonic energy

References:

2017 Association for the Advancement of Medical Instrumentation; ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Glennie Report – NHS-Scotland - 2001
Found that 96% of centers using ultrasonic devices failed to check the efficiency of the ultrasonic baths or monitor the cleaning efficacy

Alfa - "Manual versus automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures" - 2004
Established the importance of pulse flow in sonic cleaning

Alfa MJ et al., Cleaning efficacy of medical device washers in North American healthcare facilities, J Hosp Infect (2009), doi:10.1016/j.jhin.2009.06.030

Blood as a soil on surgical Instruments; Chemical profile and cleaning detection (M.Pfeifer, Zentr Steril 1998)

Literature supports using organic contaminants that are representative of the soils likely to be found on the device after clinical use (i.e., protein, hemoglobin, and carbohydrates) as markers.*
*The source for all of this information is taken from: A White Paper; The New Scope of Reusable Device Cleaning Validations-By: Patrick Kenny; Microtest-2011

Coatsworth; Kovach – "Importance of tray selection in sonic cleaning" – 2005 – ICT - The type of tray selected does impact cavitation

Kovach – "Improving the cleaning of your sonic process" – 2010 - MIC
Understand the 9 factors that impact sonic cleaning

STERIS University - Ultrasonic Cleaning - Study Guide 24
Comprehensive study guide on sonic cleaning

The Cleaning Process – Authors Ralph Basile / Steve Kovach – Managing Infection Control/July 2003, pages 66-68.

Validation of SonoCheck for the Monitoring of Ultrasonic Energy of Ultrasonic Cleaners – ZentrSteril – Volume 10 – 2002- Martin Pfeifer

Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385

Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310

OSAKA REPORT; Importance of the cleaning test; University of Osaka, Department of Medicine, Ryo Fushimi, 2000

510(k) Summary and Overview; Safety, Efficacy and Microbiological Considerations. The System 83 plus Washer -Disinfector; Custom Ultrasonics, Inc,1998, page 7.