

SUGGESTED POLICY FOR THE MONITORING AN ULTRASONIC CLEANER DAILY

SUBJECT: ULTRASONIC CLEANER MONITORING DAILY

DEPARTMENT: CPD, CSSD, SPA, MDRD, SPD, dental offices, medical offices and department using a sonic cleaner

APPROVED BY:

EFFECTIVE:

REVISED: 1/2018

PURPOSE:

To *monitor* the **ULTRASONIC CLEANING** process and to ensure proper cleaning *and reduce risk to personnel or patients.*

POLICY:

This policy is for inspection and testing of any sonic cleaner and its various functions (cavitation, removal of soil from a medical device / instruments, both flat surface and lumen) each day it is used. This is to ensure that the cleaning process is occurring and the ultrasonic cleaner is functioning properly.

RATIONALE:

According to ANSI / AAMI ST 79 every medical facility (as defined in ST 79) that has an medical sonic 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 a sonic clearers cavitation, then how it can remove residual contaminants off a medical devices both flat surface and lumen after applying the established cleaning process. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks, once these benchmarks have been defined.

The standards support mechanical cleaning equipment performance should be tested each day (daily) it 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.

The sonic cleaner is considered a piece of medical equipment. Medical sonic 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, thus it must be verified.

ANSI/ AAMI ST 79 states depending on your sonic cleaner you will need to perform the following types of test each day the sonic 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 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, the procedures are ineffective. Dried blood on instruments is hazardous to the employees of the hospital and to the next surgical patient upon which the instruments are used.

An ultrasonic cleaner enables thorough cleaning of equipment by ultrasonic agitation that dislodges soil from instruments.

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.

Ultrasonic vibration at the frequency used for cleaning and does not kill microorganisms and infective aerosols may be produced. It is for this reason that the lid of the tank must be tightly closed during operation.

Ultrasonic cleaners work by subjecting instruments to high frequency, high-energy sound waves (cavitation). This causes the soil to be dislodged from

instruments and drop to the bottom of the tank, or be sufficiently loosened that it will 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 sonic bath (solution). The cavitation process lifts / removes the soil of the device and as stated is deposited on the bottom of the tank or suspended in solution.

The detergent used in the ultrasonic tank must be carefully selected in accordance with advice from the sonic 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 solutions 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 operated for a specific time according to the OEM of the sonic. The time required for degassing varies considerably, based on tank capacity and solution temperature, and type / model of the sonic cleaner.

Rinsing of an instrument is important after the sonic cleaning process. If the ultrasonic cleaning equipment does not have a rinse cycle, rinse the devices before inspecting them for cleanliness. It should also be noted while some sonic have a rinse cycle it might not perform properly and you need to make sure the spray system jets are not clogged, if clogged you will not get the proper rinse.

Routine cleaning

Cleaning the ultrasonic cleaner and replacement of the cleaning solution is necessary at least daily or more frequently if solution soiled. Follow the OEM manufactures IFU for changing the solution in your tank / bath. Many of the newer models are now automatically changing the bath solution after each cycle. Follow OEM IFU on changing filters, wiping and cleaning the tank and other duties.

Performance testing

The efficacy of the ultrasonic cleaner should be tested each day the sonic cleaner is used. The results of the testing shall be documented as part of the proof of process.

Sonic cleaners fail for many reasons. *Tests* should provide a means of monitoring the 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, and insufficient amount of chemicals and equipment failure and most importantly with a sonic cleaner is cavitation really taking place, this is a separate test as outlined in ANSI /AAMI ST 79. The cavitation is the key reason medical facilities use a sonic cleaner for the deep cleaning, hard to reach areas of medical devices.

Proper cleaning is critical. The SonoCheck test kit and the Lumcheck (if you have pulse / retro flow for lumens devices) provides an independent objective test of clean and allows the Sterile Processing professional to monitor / verify and ensure proper cleaning in the sonic process including cavitation has taken place.

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

- **Verification** of sufficient cavitation energy **with the** SonoCheck™ monitoring vials*. Designed to change color (blue to yellow) when the ultrasonic cleaner is supplying sufficient energy and conditions are correct (degassed water, temperature, etc.) the SonoCheck™ is an easy to use and interpret method for monitoring cavitation energy. Failure to change color indicates that either the sonic bath conditions were not correct, or a failure of one or more of the ultrasonic transducers.
- **Cleaning Efficacy (Indicator) testing**. You must remember that we test the sonic for cavitation and that there is not a one-to-one correlation between cavitation activity and cleaning effectiveness that is why you also run the TOSI® inside a sonic together with a SonoCheck™. You show both cavitation and cleaning ability. You must pass the SonoCheck™ and clean a TOSI® at the same time. Just turning yellow is not enough and just passing the TOSI® by itself is not enough. You need to have enough "sonic power - cavitation" to clean a surgical instrument. Thus, the TOSI® should be used to test the sonic cleaner for cleaning efficacy of medical device.
- **LumCheck** is used to verify the pulse / retro flow of a sonic 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"

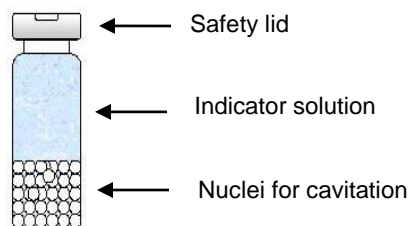
Please note as with any sonic cleaning process rinsing is very important. If the sonic cleaner does not have a rinse cycle the TOSI® must be rinsed off (like you would your instruments). This is important because you want to make sure if any

organic soil was re-deposited back onto the coupon it is washed off (just like an instrument). 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 sonic cleaner to remove any redeposited residual soil for the five seconds before reading the TOSI.

PROCEDURE:

Sonic Cleaners should be tested each day they are used.

Directions for use



Daily Inspection & Testing

- Follow manufacture guidelines concerning the daily inspection of equipment (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 allow a visual inspection if the solution is actual being used
- Log all observations in a report, as daily observations
- Report any concerns to the proper management staff within the department to address

Types of Testing of the Sonic Cleaner

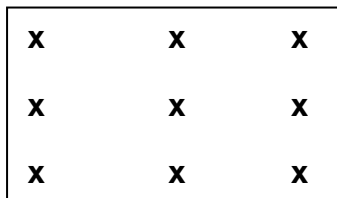
The **functional test** will check the uniform operation of the empty ultrasonic cleaner's tank. This testing should be done on installation of the equipment and or after major repairs. The diagram below gives the suggested placement of SonoChecks™ in relation to the sonic tank size. This helps you confirm that cavitation is taking place in all areas of the tank / bath solution.

Remember that degassing should always be done before any testing cycle begins.

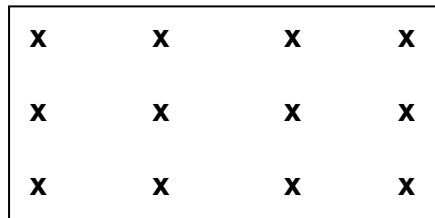
Record all results for trend analysis and for help in any troubleshooting issues.



Small up to 5 ltrs or (1.5 gals)



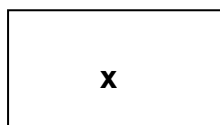
Medium size tank
5 to 20 ltrs or (1.6- 5 gals)



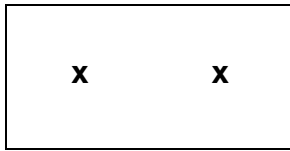
Large above 20 ltrs or greater than 5 gals.

Daily Testing of the Sonic Cleaner

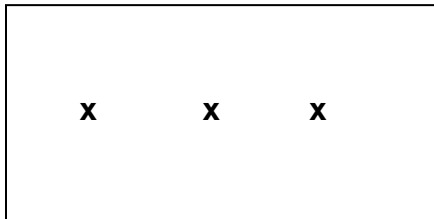
The **daily test** will also monitor the performance of the sonic cleaner. The daily test is performed under normal conditions in an empty tank that has been degassed. Frequency of testing is each day the sonic cleaner is used. The diagram below gives the suggested placement of SonoChecks™ in relation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



Small up to 5 litres or (1.5 gals)



Medium size tank 5 to 20 liters or (1.6- 5 gals)



Large above 20 liters or greater than 5 gals.

Daily Sonic & Blood Soil Test placement - TOSI

- Make sure that the ultrasonic cleaner has been degassed prior to running the test and has the correct amount of cleaning solution in the tank/bath. Note in new models this is part of the cycle.
- The number of Sonochecks™ placed in the tank will be dependent on the volume of the tanks (see daily testing).
- Place the correct amount of SonoChecks™ in the appropriate stray for testing according to tank size
- Secure one (1) TOSI® to the middle of an empty surgical tray
- TOSI® and SonoCheck™ can be placed in the same tray
- Run the Sonic 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
- A 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, please refer to the troubleshooting guide
- Record all information in log book
- Using these test help verifies both cavitation and soil removal independently according to ANSI / AAMI ST 79

****Please note as with any sonic cleaning process rinsing is very important. If the sonic cleaner does not have a rinse cycle the TOSI® must be rinsed off (like you would your instruments). This is important because you want to make sure you if any organic soil was re-deposited back onto the coupon it is washed off (just like an instrument).**

Testing the Sonic Cleaner ability to clean lumens

The LumCheck™ should be used in sonic cleaner that has the capability to clean lumens/cannulated items.

It is recommended when possible to run all three tests at one time in the same cycle. The LumCheck can be run with both the SonoCheck and TOSI

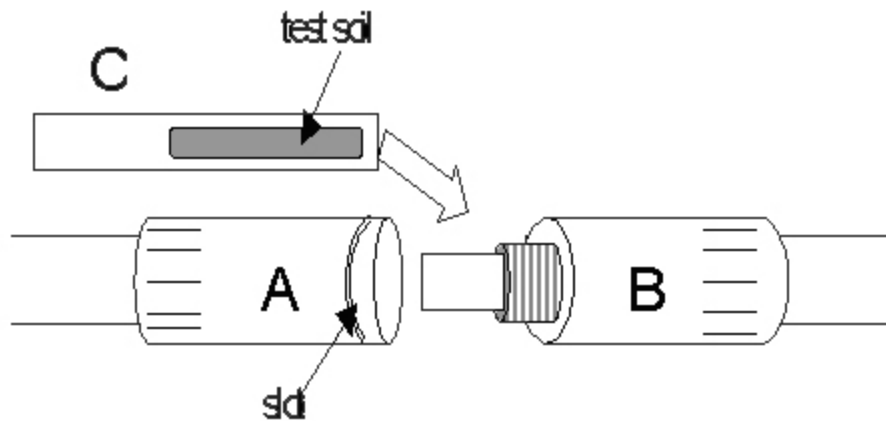
Sonic cleaners use a flow / retro flow system to flush (or pull / suction) lumens/cannulated items (with approved cleaning solution), the LumCheck™ should be used to check the performance of these types of sonic cleaning units.

TOSI®LumCheck™ blood soil test is designed to monitor the cleaning function of an sonic cleaners 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 sonic 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.
 - a. If a sonic cleaner has two pumps for the flow / retro pump system it is suggested to test a port that uses each pump to ensure that both pumps are working.
3. Unscrew LumCheck™ – device; detach part A (marked with slot) from part B (see diagram below).
4. Open protective pouch of TOSI® – LumCheck™ and insert the test object (part C) in part B as shown in diagram. Do not touch the area covered with test soil.
5. Close LumCheck™ – device again.
6. Connect LumCheck™ –
 - a. Sonic Cleaner
 - i. Connect the LumCheck™ device with one of the channel irrigation system of the sonic (for example luer-lock). If equipment has more than one channels (ports) you must check at least one port. If checking more than one port (channel) they must all be checked at the same time.
 - ii. After connection start the cycle according to your manufactures manual instructions (example 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 a test using the SonoCheck Test Kit™ and Lumcheck for lumens to ensure that the equipment is cleaning properly.
- Follow the weekly test process.
- Have the maintenance person wait until the test results are complete

Please note the Sonic test kit contains both the TOSI and the SonoCheck.

RESPONSIBILITY:

Central Service personnel are responsible for the proper use, result interpretation, and documentation of the Sonic Test Kit and LumCheck when used on a sonic cleaner.

In-service and training of the staff should be done at least yearly on the equipment (sonic) and the use of the sonic test kit and LumCheck products.

Various Sample log sheet to record results

Equipment name _____ Equipment Serial # _____

Detergent type _____

Date Test Run	Testers Initials	SonoCheck™ Result	TOSI® Result	Cycle length	LumCheck	Comment
	SMK	Yellow	0	6	0	Pass

1/1/2010				minutes		

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

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

Date: Facility: Sonic: Name:

Aquachek (circle result)

Target Values	Water in Tank before Chemical	Comments
P: <input type="text"/>	pH Level:	<input type="text"/>
A: <input type="text"/>	Alkalinity:	<input type="text"/>
H: <input type="text"/>	Hardness:	<input type="text"/>

TempaChek-LC (reversible thermometer)

Target Temp:
 Range:

www.hmark.com
 °F 50 70 80 90

Comments

TOSI

Record Result (circle result)

0	
1	
2	
3	
4	
5	

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

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

SonoCheck™ trouble-shooting 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
De-gassing	Dissolved gasses will absorb ultrasonic energy	De-gas solution according to equipment manual
Water level	Ultrasonic energy may reflect off of 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 operating 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	Transducer efficiency may	Perform functional test,

failure	decrease with age. Individual transducers may fail while others in the equipment continue to function	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	Varies trays (the material they are made out of) absorb and inhibit the transfer of sonic energy within the sonic tank. They can change the energy distribution.	Test with a different tray (change types of tray). Use a tray that does not absorb or inhibit the transfer of sonic energy.

General References:

2017 Association for the Advancement of Medical Instrumentation; ANSI/AAMI ST79:2017

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.