***Example* Policy of an Ultrasonic Cleaner (SonoCheck™-only) Checking Cavitation**

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

Subject: Ultrasonic Cleaner for checking cavitation activity (SonoCheck™-only).

Department: CPD, CSSD, SPA, MDRD, dental offices, medical offices and departments using a sonic cleaner.

Approved By: [Name of Dept Supervisor/Manager]

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

Revised: June 2021

Purpose: The purpose of this example policy is to monitor the ultrasonic cavitation process daily to ensure proper cavitation is taking place and reduce risk of infection to personnel or patients. (1,10,13).

Policy: To inspect/test any ultrasonic cleaner with the SonoCheck™ (for cavitation only). The SonoCheck™ is to be used according to the manufacture's guidelines to ensure cavitation is occurring. (1,6,7,8,9,10,13).

Rationale: The SonoCheck™ tests for the presence of cavitation energy in a sonic bath, under normal conditions, with a degassed empty tank.

Standards and Professional Society Recommendations:

ANSI/AAMI ST79:2017 7.6.4.3.1 section states “Mechanical cleaning methods minimize personnel risk of cross-contamination, improve cleaning effectiveness, increase productivity, and are more easily monitored for quality performance.” Sonic cleaners are considered mechanical cleaning equipment by AAMI.

“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).

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, then 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. (1,2,3,4,8).

An ultrasonic cleaner enables thorough cleaning of equipment by producing cavitation in combination with the other factors, such as 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.

The 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.

The detergent used in the ultrasonic tank must be carefully selected 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 of cleaning solutions is extremely important in achieving satisfactory cleaning results. Since air impedes the cavitation process free as much trapped air in the solution to maximize its effects. Degassing is one of the best methods for releasing trapped air in cleaning solutions. Fresh solutions, or solutions which have cooled, must be degassed before proceeding with cleaning. After the chemical is added, degassing is done by using the ultrasonic energy and raising the solution temperature. The time required for degassing varies considerably based on tank capacity and solution temperature It may range from several minutes for a small tank to more than an hour for a large tank. Degassing is complete when small bubbles of gas cannot be seen rising to the surface of the liquid and a pattern of ripples can be seen.

A Quality Management System (QMS) per ANSI/AAMI ST 90 should be developed for the ultrasonic cleaner. The QMS should include the IQ, OQ, and PQ of the ultrasonic cleaner.

Installation Qualification (IQ) = process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification.

Operational Qualification (OQ) = process of obtaining and documenting *evidence that installed equipment operates within predetermined limits* when used in accordance with its operational procedures.

Performance Qualification (PQ) = Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently meets predetermined criteria and product specifications.

Routine cleaning:

Cleaning the ultrasonic cleaner and replacement of the cleaning solution is necessary at least once daily or more frequently if solution soiled. Follow manufacture's guidelines on changing solution.

Performance testing:

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

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. (7).

Proper cleaning is critical. The SonoCheck™ gives an independent objective test of cavitation and allows the Sterile Processing professional to monitor and ensure proper cavitation in the sonic process. (*1*).

AAMI lists sonic cleaners as medical equipment.

- Section 13.2 ANNEX D states, "…users should incorporate test methods that verify the functionality of the mechanical cleaning equipment (if used) and the cleanliness of specific devices after manual or mechanical cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks once these benchmarks have been defined."
- Section 13.2 states "…Mechanical cleaning equipment should be tested upon installation, each day that it is use, and after major repairs. When evaluating or changing to a new cleaning solution and after all major repairs, all cycles used should be tested to ensure that the cleaning solution and cleaning action are effective. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include software upgrade or the replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, ultrasonic generators, or computer controls".

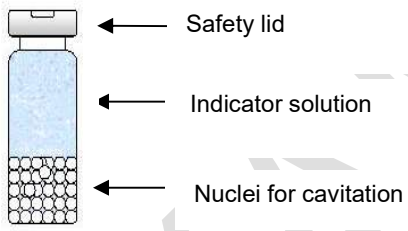
Healthmark recommends daily testing when the unit is used to monitor for cavitation and cleaning efficacy. The SonoCheck™ is an easy to use and interpret method for monitoring cavitation energy. Testing any sonic cleaning unit with the SonoCheck™ monitoring vials* does the following verification tests:

- Sufficient cavitation energy
- Change's color (blue/green to yellow)
    1. When the ultrasonic cleaner is supplying sufficient energy
    2. Conditions are correct (degassed water, temperature, etc.)
    3. Failure to change color indicates either the sonic bath conditions were not correct, or a failure of one or more of the ultrasonic transducers.

Procedure:

"A risk assessment should be completed for any issue with any aspect of decontamination that can pose a risk to personnel or patients. The risk assessment should define and resolve the issue, and the system should be monitored to ensure that the issue has been corrected"(21).

Directions for use:



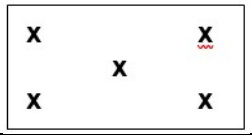
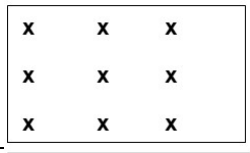
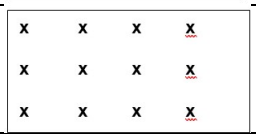
Daily Inspection & Testing:

- Follow manufacturer's guidelines concerning the daily inspection of equipment (i.e.: screens, tank condition, filters…)
- Remember, each Sonic unit is different. Staff should be trained on operation, inspection, and cleaning of the equipment at least yearly
- 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 Sonic Cleaner with the ***SonoCheck™:***

The functional test (OQ) will check the uniform operation of the empty ultrasonic cleaner's tank. This testing should be done at the time of installation of the equipment and/or after major repairs. This would be considered the OQ in a QMS.

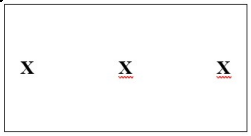
The diagram below gives the suggested placement of SonoChecks™ in relation to the sonic tank size.

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)

- 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

Routine Testing of the Sonic Cleaner:

The routine test (PQ) will also monitor performance of the sonic cleaner. This routine test is performed under normal conditions in an empty tank that has been degassed. Frequency of testing should be each day it is used. The diagram below gives the suggested placement of SonoCheck™ in relation to the sonic tank size for routine testing. 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)

- If results of the SonoCheck™ are unsatisfactory, please refer to the troubleshooting guide
- More detailed testing (routine testing and/or a functional testing) may be necessary based on the results
- Record all information in logbook

Because there are many different ultrasonic cleaners on the market for medical facilities to purchase, checking for cavitation only, according to the standards, might not be enough to ensure an ultrasonic cleaner is working properly as described in ANSI/AAMI ST79. Some other test might need to be performed daily or when the unit is used, such as:

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

Equipment Daily Inspection:

- Inspect equipment (screens…) according to the manufacturer's instructions
- Clean as needed

Weekly Inspection/Testing Other Factors Impacting Ultrasonic Cleaning Process:

We recommend that these tests are done at least weekly or after any major repair because they are important factors that help in ensuring that the sonic cleaner is working properly. These are helpful tests of the various inputs of the ultrasonic process (temperature, pH, hardness).

Maintenance on Equipment (6,10):

- After any equipment maintenance, perform a test using the SonoCheck™ to ensure it is functioning properly
- Follow the OQ test process
- Have the maintenance person wait until the test results are complete

Responsibility:

Central Service personnel are responsible for the proper use, result interpretation, and documentation of the Sonic Test Kit when used on a sonic cleaner. (*1,5,16*).

In-service and training of the staff should be done at least annually on the equipment (ultrasonic) and how to use the SonoCheck™.

SonoCheck™ Trouble-shooting Guide

If the SonoCheck™ ultrasonic cavitation monitor does not change color or takes longer than normal to change color, 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 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 periodic functional test and check for ultrasonic absorbent material(s) 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 periodic 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

References:

1. ANSI/AAMI ST79; 2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
2. Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385
3. Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310
4. OSAKA REPORT; Importance of the cleaning test; University of Osaka, Department of Medicine, Ryo Fushimi, 2000
5. www.jcaho.org
6. http://www.proformance-test.com/WallChart/WallChart.html
7. http://www.proformance-test.com/SupportMaterial/TechnicalBulletin1.html
8. http://www.proformance-test.com/SupportMaterial/BloodAsASoilonSurgicalInstruments.htm
9. http://www.proformance-test.com/SupportMaterial/StandardisedTestSoilBlood1.htm
10. http://www.proformance-test.com/index.html
11. 510(k) Summary and Overview; Safety, Efficacy and Microbiological Considerations, The System 83 plus Washer -Disinfector; Custom Ultrasonics, Inc,1998, page 7.
12. www.aorn.org
13. http://www.healthmark.info/MktingPieces/ProductBrochures/2006/ProformanceJournal.pdf
14. *The Cleaning Process – Authors Ralph Basile / Steve Kovach – Managing Infection Control/July 2003, pages 66-68.*
15. *Validation of SonoCheck™ for the Monitoring of Ultrasonic Energy of Ultrasonic Cleaners – ZentrSteril – Volume 10 – 2002- Martin Pfeifer*
16. *www.aorn.org*