

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

NOTE: This document is an example of a policy that may be instituted in a health-care facility for Daily Monitoring of an Ultrasonic Cleaner. The actual policy in a facility must be based on variables, logistics and risk-assessments that are specific to your facility.

SUBJECT: ULTRASONIC CLEANER MONITORING DAILY
(SonoCheck™ only)

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

APPROVED BY:

EFFECTIVE:

REVISED: Jan. 2019

PURPOSE: The purpose of this example policy is to monitor the ultrasonic cleaning process at least weekly (preferably daily) to ensure proper cleaning and reduce risk of infection to personnel or patients. (1,10,13,14)

POLICY: To inspect and test the SonoCheck™ kit is designed to monitor the cleaning function of an ultrasonic cleaner. To ensure that the ultrasonic process is cleaning properly, a sonic check test kit should be used to monitor the occurrence of cleaning instruments. The sonic test kit is to be used according to the manufacture's guidelines to ensure that the cleaning process is occurring, and the ultrasonic cleaner is functioning properly.
(1,6,7,8,9,10,13,14)

RATIONALE: The SonoCheck™ it to test for the presence of cavitation energy in a sonic bath under normal conditions in an empty tank than has been degassed.

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

Standards and Professional Society Recommendations:

ST 79; 2009A section states “... Mechanical cleaning methods minimize person 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, 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. (1,2,3,4,8,)

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 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. 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.

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

The detergent used in the ultrasonic tank must be carefully selected in accordance with 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. Fresh solutions or solutions which have cooled must be degassed before proceeding with cleaning. Degassing is done after the chemical is added and is accomplished by operating the ultrasonic energy and raising the solution temperature. The time required for degassing varies considerably, based on tank capacity and solution temperature, and may range from several minutes for a small tank to an hour or more for a large tank. An unheated tank may require several hours to degas. 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.

Routine cleaning:

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

Performance testing:

The efficacy of the ultrasonic cleaner should be tested at a minimum weekly and daily if possible. 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. (7)

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

AAMI does list a sonic cleaner as a piece of medical equipment in section 13.2

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

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”.

The 2011 AORN RP for Cleaning and Care of Surgical Instruments and Powered Equipment Recommendation XXII –Quality section is now supporting the testing of mechanical instrument washers before initial use, weekly during service, and after major maintenance.

JCAHO in standard E.C.6.20 it states that medical equipment is maintained, tested and inspected

In accordance with ANSI/AAMI ST79-2009; ANSI/AAMI TIR12-2005; JCAHO EC6.20-2005, and AORN, Healthmark recommends at least weekly monitoring of the cleaning efficacy of any sonic cleaning unit with the following verification tests:

- Verification of sufficient cavitation energy with the SonoCheck™ monitoring vials*. Designed to change color (blue/green 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

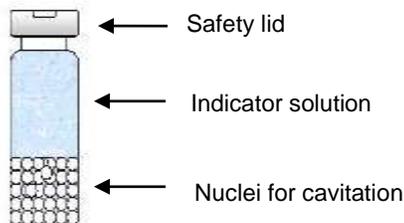
Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

sonic bath conditions were not correct, or a failure of one or more of the ultrasonic transducers.

PROCEDURE:

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

Directions for use:



Daily Inspection & Testing:

- Follow manufacture guidelines concerning the daily inspection of equipment (screens, tank condition, filters...).
- Remember each Sonic unit is different, and staff should be trained on operation and 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 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

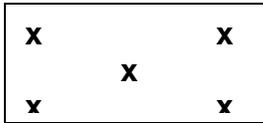
Types of Testing of the Sonic Cleaner with the SonoCheck™

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.

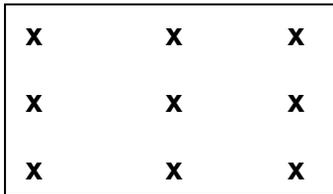
Remember that degassing should always be done before any testing cycle begins.

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

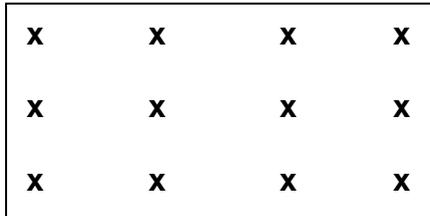
Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring



Small up to 5ltrs or (1.5 gals)



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



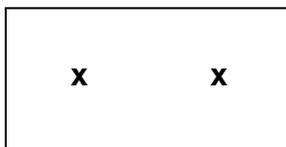
Large above 20ltrs or greater than 5 gals.

Routine Testing of the Sonic Cleaner

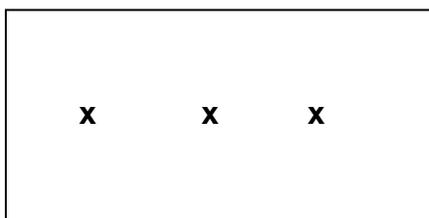
The routine test will also monitor the performance of the sonic cleaner. The routine test is performed under normal conditions in an empty tank that has been degassed. Frequency of testing should be at least weekly but preferably daily. The diagram below gives the suggested placement of SonoCheck™ in relation to the sonic tank size for routine testing. All testing results should be logged and saved for trend analysis and troubleshooting concerns.



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.

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

- In case of unsatisfactory results of the SONOCHECK™, please refer to the troubleshooting guide
- A more detailed testing may be required based on the results (a more routine testing and/or a functional testing, may be required)
- Record all information in log book

Weekly Inspection and Testing of other factors tht can impact the Sonic cleaning process

These tests are done weekly.

- Is a complete testing of all of the inputs of the ultrasonic process (temperature, pH, hardness).

Equipment Inspection:

- Inspect equipment (screens...) according to the manufacture instructions. Clean as needed.

Water Quality:

Follow these directions first for cold water, then hot water

- Use an AquaTest™ (wts-101) test strip.
- Dip entire strip into water for 5 seconds, then remove.
- Shake once briskly to remove excess water from the test strip
- Wait 20 seconds.
- Compare color within 10 seconds to pH, Total Alkalinity, Total hardness on the interpretation chart.
- Report any deviations from expected values.
- Note that water conditions do change seasonal. It is important to have a base line established (target values) for your water and compare your results to the base line (target values).

Water Temperature:

- Use a TempaChek™ -90 for this test.
- Peel thermometer from release paper.
- Apply to any clean dry surface ensuring that the indicator has adhered to the surface that will be submerged under the water level.

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

- Tempachek-90 should be removed and read immediately after the **COLDWATER RINSE** stage.
- Record results on log sheet.
- Temperature should not exceed 100 degrees F. Immediately report any result that exceeds this temperature.
- Record results on log sheet.
- Report any deviation from targeted temperature.

Maintenance on Equipment (6,10):

- After any maintenance on the equipment, perform a test using the SonoCheck™ Test Kit to ensure that the equipment is functioning properly.
- Follow the weekly 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 yearly on the equipment (sonic) and the use of the sonic test kit.

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

SonoCheck™ trouble-shooting guide

If the SonoCheck ultrasonic cavitation monitor does not change color or if the time required to generate 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 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 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

Example of an Ultrasonic Cleaner (SonoCheck™ only) Policy for Daily Cleaning and Monitoring

REFERENCES:

1. ANSI/AAMI ST79; 2017
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