SUGGESTED POLICY FOR
THE MONITORING OF THE CLEANING EFFICIENCY OF
AN ULTRASONIC CLEANERS (SONIC & TOSI) WEEKLY

SUBJECT: ULTRASONIC CLEANER MONITORING WEEKLY

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: 10/2016

PURPOSE:

To monitor the ULTRASONIC CLEANING process and to ensure proper cleaning and reduce risk to personnel or patients. (1,10,13,14)

POLICY:

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. (1,6,7,8,9,1013,14)

RATIONALE:

ST 79; 2009A section 7.5.3.3 states this on weekly testing “...Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. 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 replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software...”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.

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 your manufacturer's IFU for changing the solution in your tank/bath. Many of the newer models are now automatically changing the bath solution after each cycle.

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 7.5.3.3; there are other references that support the minimum of weekly testing of all type of sonic equipment with or without "retro flow pulse adapter".

Section 10.2 and ANNEX D states…Health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices…"

Section 7.5.3.3 states…Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs. 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 replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, or computer control or an upgrade to software..

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.

Joint Commission (JC) in standard E.C.6.20 it states that medical equipment is maintained, tested and inspected
So in accordance with ANSI/AAMI ST79-2009; ANSI/AAMI TIR12-2005; JC EC6.20-2005, and AORN, Healthmark recommends at least weekly monitoring of the sonic cleaners ability to provide cavitation within the unit and the cleaning efficacy(indicator) 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 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 caviation 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 - caviation" to clean a surgical instrument. Thus the TOSI should be used to test the sonic cleaner for cleaning efficacy.

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 you if any organic soil was re-deposited back onto the coupon it is washed off (just like an instrument).

JC and AAMI both recommend that Sterile Processing department have process performance in place (1,5). Using the SonoCheck and TOSI according to the manufacture's guidelines helps ensure adherence to both JC and AAMI standards and having a properly functioning cleaning process.
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"(1)

**Directions for use**

- Safety lid
- Indicator solution
- Nuclei for cavitation

**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.

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.

```
 x   x   
 x      
 x    x
```

Small up to 5 ltrs or (1.5 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 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.
**Sonic & Blood Soil Test**

- 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.
- The number of Sonochecks placed in the tank will be dependent on the volume of the tanks (see routine 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 the tray.
- TOSI and SonoCheck can be placed in the same tray.
- Run the Sonic through its normal cycle (record the cycle).
- 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.

**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).**

**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 cleaning 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 an 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.
Equipment name _______________ Equipment Serial # _______________

Detergent type ____________________________

<table>
<thead>
<tr>
<th>Date Test Run</th>
<th>Testers Initials</th>
<th>Sonocheck Result</th>
<th>TOSI Result</th>
<th>Cycle length</th>
<th>Comment Action if needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/2010</td>
<td>SMK</td>
<td>Yellow</td>
<td>0</td>
<td>6 minutes</td>
<td>none</td>
</tr>
</tbody>
</table>

TOSI results are from 0 to 5
SonoCheck record the color change from a blue/green to a yellow
**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:

<table>
<thead>
<tr>
<th>Problem</th>
<th>Reason</th>
<th>Corrective action</th>
</tr>
</thead>
<tbody>
<tr>
<td>De-gassing</td>
<td>Dissolved gasses will absorb ultrasonic energy</td>
<td>De-gas solution according to equipment manual</td>
</tr>
<tr>
<td>Water level</td>
<td>Ultrasonic energy may reflect off of the surface of the solution and change energy distribution</td>
<td>Check equipment manual for correct water level</td>
</tr>
<tr>
<td>Operating cycle time</td>
<td>Time varies with the amount of ultrasonic energy available</td>
<td>Longer operating cycles generally provide better results</td>
</tr>
<tr>
<td>Instrument load</td>
<td>Heavy instrument loading and certain materials can absorb ultrasonic energy</td>
<td>Look for weak points using the functional test and check for ultrasonic absorbent material like silicone or plastics</td>
</tr>
<tr>
<td>Transducer failure</td>
<td>Transducer efficiency may decrease with age. Individual transducers may fail while others in the equipment continue to function</td>
<td>Perform functional test, placing Sonocheck monitors in each transducer location (see equipment manual)</td>
</tr>
<tr>
<td>Low energy</td>
<td>Transducer inefficiency or the ultrasonic basket may absorb too much energy</td>
<td>Check performance without basket in place. Compare performance against another ultrasonic cleaner if available. Call for service</td>
</tr>
<tr>
<td>Tray selection</td>
<td>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.</td>
<td>Test with a different tray (change types of tray). Use a tray that does not absorb or inhibit the transfer of sonic energy.</td>
</tr>
</tbody>
</table>
**General References:**

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


Blood as a soil on surgical Instruments; Chemical profile and cleaning detection (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

**End Note REFERENCES:**

1. ANSI/AAMI-ST 79:2006
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
11. www.aorn.org
15. www.aorn.org