A Story about An Expensive Soaking Tub

During a demo I used the SonoChek™ on the large 2 tank floor model Ultrasonic that was in everyday use. From all appearances and sounds it looked and buzzed like a normal unit. After a failed first test and a confirming second test, the unit was declared an expensive soaking tub. A follow up independent service confirmed the transducers were not working. Just because it is making noise does not mean it is working.

The Sonic Cleaning Process

- Many variables
- Many types of equipment
- Dynamic environment

Who is telling SPA to use a sonic cleaner and why?

- “The best method for thoroughly cleaning delicate micro-instruments is to use an ultrasonic cleaner”
- “Most instrument manufacturers recommend ultrasonic cleaning as the most effective way to clean surgical instruments, particularly those with hinges, locks, and other moving parts”

Objectives

- To increase attendee knowledge of medical sonic cleaners used in the Sterile Processing Area (SPA)
- Understand the 9 factors that impact how a medical sonic cleaner performs
- Review the appropriate standards and guidelines that pertain to medical automatic sonic cleaners
- Share a simple Quality Improvement Process to help ensure your medical sonic cleaner is performing correctly

Understanding your Sonic Cleaning Process

Upon completion of this program, the participant will be able to:

- Understand how a medical sonic cleaner works
- Identify the 9 key factors that impact the medical sonic cleaning process
- Discuss the regulations, standards and evidence based articles related to sonic cleaning
- Differentiate the types of tests used to verify sonication
What is the definition & classification of a Sonic Cleaner?

- Ultrasonic Sonic Cleaners are a Class 1 medical device by the FDA
- Ultrasonic cleaners are designed for fine cleaning of medical devices, not for disinfection or sterilization.
- They are used to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods.
- An ultrasonic cleaner is considered a piece of medical equipment (mechanical cleaning)

The Joint Commission

- Joint Commission EC 02.04.01 – requires accredited hospitals to maintain medical equipment inventory
- EC 02.04.04, EP 3 “The hospital identifies the activities, in writing, for maintaining, inspecting, and testing for all medical equipment on the inventory”
  - Mechanical cleaning equipment and sterilizers

AAMI

- 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…”

Basic Sonic facts

- Review: How does it work?
- What is degassing?
- Basic principles
- How do the 9 factors of cleaning apply to a medical sonic cleaner?
- Look at verification of the process
- Many makes and models
  - Medical sonic cleaners

How does a sonic cleaner work?

- Ultrasound is energy in the form of a wave motion which is above the maximum level of audible sound.
- The high-frequency sound is above 20kHz to produce an effect called cavitation (implode, collapse inwardly).
- The high frequency sound is created by an ultrasonic transducer, piezoelectric crystal which converts high frequency electrical power to mechanical energy (vibration).
- Remember, just because it makes a “humming noise” doesn’t mean it is cleaning.
Step 1
- As the sound waves from the transducers radiate through the solution in the bath/tank, they begin to cause alternating high and low pressures in the solution.

Step 2
- During the low pressure stage, microscopic bubbles are made. This is the start of the cavitation process.

Step 3
- During this step, the high pressure stage the bubbles start to collapse or implode. This action gets into all the surfaces of the medical device.
- The next slide breaks down this process.

Cavitation at work
- The photograph shows ultrasonic cleaning in action on a pair of surgical forceps. The formation of bubbles can be clearly seen forming around the item.
- As the bubbles implode and cavitation occurs, the cleaning solution rushes into the gap left by the bubble. The fluid makes contact with the forceps, any bioburden that is present is removed.

Degassing is Key
- Degassing is a process which eliminates air that is trapped in solution when fresh solution is added to the bath.
- Degassing conditions your bath for maximum efficiency in a minimum period of time.
- Degassing of cleaning solutions is extremely important in achieving satisfactory cleaning results.
- The time required for degassing varies considerably, based on tank capacity and solution temperature.
- Air impleads or reduces sonic activity.

http://www.ultrawave.co.uk/pages/Ultrasonic-Technology-54.php
Picture from web address
Basics of Sonic Cleaning

• The ultrasonic process provides additional deep cleaning action.
• Medical devices have specific exposure time to be cleaned properly. Follow the medical device manufacturers IFU for the correct exposure time.
• Following ultrasonic cleaning, instruments must be thoroughly rinsed.
• If a medical sonic cleaner is being used on eye instruments follow the recommendations found in ST 79 Annex.

Basics of Sonic Cleaning

• Use only detergent formulations specifically designed for medical ultrasonic cleaners.
• Cleaning solutions in an ultrasonic unit are changed whenever the detergent is visibly soiled or at least once or twice a shift (very subjective)
  — Newer models of medical sonic cleaners are changing after each use
• Medical ultrasonic cleaners clean by a process called cavitation - implode (collapse inwardly)

Basics of Sonic Cleaning

• Use the correct type of tray to place your medical device in to ensure maximum cavitation
  — Do not use plastic trays
• Load your instruments properly to ensure maximum exposure to cavitation
  — Box locks in open position
  — Take apart
  — Lumens
• Sort and segregate different metal types
  — Example: plated instruments may be damaged by mechanical vibrations, which cause flaking.

Basics of Sonic Cleaning

• The ultrasonic equipment should have a cover or lid to prevent the aerosolization.
• To ensure your medical sonic cleaner is working properly:
  — Follow the original manufacturers PMA
  — Verify your process
  — Document/record your results

Sonic Cleaning Time

• Generally, it is difficult to establish guidelines due to the several factors need to be considered as follows:
  • Wide variety of sizes, weights etc.
  • Using appropriate cleaning solution.
  • Overload the machine with unnecessary mass.
    • Soil, solution, temperature
  • It is therefore wiser to start with a few parts so that they can be cleaned quickly and thoroughly. You can add additional parts and check to ensure the same cleaning results.
• IFU of the instrument manufacture will set the time
What type of tray do I use.

Open wire mesh is the best type

- Items being cleaned should never be placed directly on the tank bottom. Transducers (which produce the ultrasound) are bonded to the bottom of the tank. Items resting directly on the tank bottom can damage the transducers and/or reduce cavitation.
- Additionally, a tray will position the item within the optimal cleaning zone of the tank.
- The tray will also hold the load together and allow for easy, no-touch removal, draining and transport of the items to the next step in the cleaning process.
- Instruments with hinges or box locks should be in the open position during clean

Sonic Cleaning Factors

- Standards & Guidelines – which ones apply? – ST79/IC;ADRN
- Instrument Type & Design – what am I trying to clean? - simple, complex, lumen...understand how it is used
- Water Quality – Monitor for at least hardness, ph
- Temperature – You need to know, is it hot or cold?
- Chemical Activity – Type and amount, how much do I use?
- Mechanical Action – Degassing, time/energy, how much time, pre-cleaning, exposure
- Human Factor – Loading, training, do it right all the time
- Soil – What type of soil am I trying to clean? Mostly blood
- Verification – What do I verify and with what test?

The various combinations of these factors determine how clean your instrument will be.

Clinically Relevant & Evidence-Based Products

Applying the Principles to Product

Literature Review

  - 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.*
- Coatworth; 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
Verification Process

- Always visual
- Sonic cleaning has many processes that need verification
- Depends on model type - Equipment
  - Cavitation indicators
  - Cleaning indicators - “These test soils should mimic the type of soils that may be found on reusable devices and instrumentation” - STERIS University - Ultrasonic Cleaning - Study Guide 24, page 6
  - Lumen indicator – pulse flow/retro flow
- Other factors
  - Water quality
  - Temperature
  - Cleaning solution dilution
- Document/record your results in some manner
- PMA must be followed and documented

Verification of Ultrasonic Cavitation

- Like any mechanical device, from time to time, transducers fail.
- Man and equipment is a mixture that breeds failure.
- Given the nature of ultrasonic cleaning, observation of failure is not easy.
- Also, in a series of transducers, one may be failing, while the remaining units are functioning, creating dead spots within the ultrasonic.
- Verification of the sonic cleaner is supported by:
  - Standards like ST 79
  - JC guidelines
  - Quality improvement process
  - Articles on the topic
- Monitoring devices for detecting cavitation are commercially available.

Test to Verify the process

- Size of the tank/bath of the sonic is important for testing
- Cavitation indicators
  - Ceramic disc method
  - Probe
  - Foil test
  - More than one way
  - Subjective
- SonicCheck
- Cleaning Indicators
  - Surrogate device
  - Appropriate test soil
- Water quality
- Temperature
- Cleaning solution monitoring

Foil Test

- Correct method for size of sonic tank.
- NO: Incorrect way to test a sonic tank this size.
- Correct way to test this size tank with various products

Foil Test

The cleaning effectiveness of an ultrasonic cleaner can be monitored with a piece of aluminum foil. It must be suspended in the cleaning solution extending the full width and depth of the solution. The unit is activated, and after a specific amount of time, the foil can be removed and examined. The presence of significant pitting and a uniform pattern of dents and holes indicates the cleaning unit is performing properly.

This is a very subjective test and you must empty tank after testing because of possible foil pieces left behind.
Aluminum foil test – one example*

- Vertically suspend pieces of aluminum foil in the ultrasonic tank, so that they are evenly spaced between the ends of the cleaning tank.
- Each piece of foil should be approximately 0.025mm thick and extend to approximately 6mm clear from the sides and bottom of the tank.
- Operate the ultrasonic cleaner for 10 seconds. Remove the sheets of foil and observe the number and distribution of perforations and wrinkles.
- Ideally, all sheets of foil should be similarly perforated and wrinkled. That is, if the holes are primarily in the middle sheet of foil, or if the pieces of foil are only wrinkled but without holes, the equipment is considered to have failed the test.
- It may be necessary to provide a simple wire frame to support each sheet of foil during the test.
- On completion of the test, ensure that the tank is drained and thoroughly cleaned, to remove the foil residue.


Foil Test

- Using strips of adhesive tape across the top of the bath, suspend nine strips of the prepared foil in the bath in a 3x3 grid.
- Ensure that the rolled bottom end of each foil strip is no more than 10 mm above, but not touching, the bottom of the bath.

Foil Testing

- When the foil strips are inspected, the areas that show maximum erosion should be at similar positions on all nine foils and each should be eroded to a similar extent.
- On re-testing the extent of erosion, the erosion pattern should remain consistent. If the zones of erosion are markedly different on the nine foils, it indicates poor uniformity of cleaning. Poor uniformity of cleaning might be due to failure of one or more of the transducers that produce the ultrasonic vibration in the base of the bath.

Sonocheck™

The Sonocheck is put in an empty tank. The number of SonoChecks placed in a tank are based on the size of the tank. This allows you to test each zone in the tank. Color change should be from blue/green to yellow. No color change you need to service the equipment. Sonocheck is easy and quick to use.

How do I check lumen instruments?

- Pulse flow / retro flow units
- Surrogate device
- Test soil that represents what you are cleaning
- Must check to make sure it is working

The LumCheck helping you see what is inside?

Did I get it clean?
Pulse Flow Type - Lumen

Lumens items must be hooked up to a pulse flow of some type

What is wrong with this picture?

Correct

Pulse flow testing

Quality Improvement Program

- Almost every group from TJC, FDA, AORN, IAHCSMM, ASTM, CDC, to AAMI, along with medical device manufacturers recommend and support that medical facilities have a Quality Improvement Program in place for monitoring the cleaning process
- Trust But Verify
- Best way to verify & improve the process is a Quality Improvement Program.
  — (Focus PDCA; Lean; Six Sigma...)

© 2014 Association for the Advancement of Medical Instrumentation
Sonic Parameters that should be monitored

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily – Each Load – Cleaning efficacy</td>
<td>Visual inspection all items cleaned</td>
</tr>
</tbody>
</table>
| Daily – Cleaning | Remove all contaminated water from tank. Wash with mild disinfectant and cloth, rinse and dry thoroughly. DO NOT use corrosive chemicals.
| Daily – Equipment Inspection | Seal filters, solutions levels, etc. |
| Minimum Weekly – Cleaning ability | Confirms that the ultrasonic cleaner is capable of removing soil |
| Minimum Weekly – Cavitation | Confirms cavitation is taking place |
| Minimum Weekly – Protein testing instruments | Confirms that the cleaning process retains the capability of removing proteins from loads (sample instruments). |
| Minimum Weekly – Water quality | Confirms that the quality of water is not changing in your process |
| Minimum – Each load – Bath (tank) Temperature | Confirms that the sonic bath (tank) temperature is correct for this process |
| Minimum Weekly – Lumen | Confirms that the ultrasonic cleaner can clean a lumen device |

A FEW PICTURES TO CLOSE THIS PRESENTATION

Watch this Video part 1
Leaking connector and top concerns

Video Part 2
The leak is causing poor flow into the lumens

The Cavitation Zone

- All sonic cleaners have a zone
- Protects the base or bottom of the tank from damage
  - An area that promotes optimal sonic cleaning
    - Base plates
    - Automatic lifters
    - Baskets
    - Others
- This provides the best outcome
The Caviation Zone

Base Plate

- Items being cleaned should never be placed directly on the tank bottom.
- Transducers (which produce the ultrasound) are bonded to the bottom of the tank.
- Items resting directly on the tank bottom can damage the transducers and/or reduce cavitation.

Additionally, a tray will position the item within the optimal cleaning zone of the tank.

- The tray will also hold the load together and allow for easy, no-touch removal, draining and transport of the items to the next step in the cleaning process.

Automatic position of the tray in the sonic cleaner

Bad

Sonic Cleaning - instruments need to be in the open position
Failed SonoCheck but was making a noise

Notice Power switch is off on generator #2 & #3. That is why they are not working.

Communication is key

What do these pictures have in common? Too much cleaning solution. Foam.

Questions to ask when buying a sonic cleaner

- Just a few questions to ask?
  - What frequency is the sonic set at (KHz)?
  - Can I adjust the...?
    - Cycle time
    - Temperature
  - What is the warranty time frame?
  - What type of cleaning solutions can I use in this same?
  - What is your service contract?
  - What type of training do you provide for my staff?
  - Do you any independent studies on this sonic?
    - Cleaning validation
    - Material compatibility
    - Product specific
    - Can I do lumens and medical devices at the same time
    - Robotic arms
  - Not all sonic are created equal

Verification of your process

- Equipment verification
  - Clinically relevant & evidence based products
  - Applying the Principles to Product
    - To help ensure that equipment is performing properly
      - Some tests are designed to challenge the operational level of cleaning equipment
      - Other tests either measure a specific parameter or challenge the cleaning efficiency of the entire system
    - You must understand what a test tells you both when it passes and when it fails
  - Daily inspection check list
  - Think of your sterilizer
  - Document your results
Healthmark offer a paperless program for your records called ProFormance QA

### Highlights of Sonic Cleaning
- Sort and segregate different metal types. Example: plated instruments may be damaged by mechanical vibrations, which cause flaking.
- The ultrasonic process provides additional deep cleaning action.
- Following ultrasonic cleaning, instruments must be thoroughly rinsed.

### Highlights of Sonic Cleaning
- Only detergent formulations specifically designed for ultrasound equipment are used in these units.
- Cleaning solutions in an ultrasonic unit are changed whenever the detergent is visibly soiled or at least once or twice a shift.
- Ultra-sound cleans by a process called cavitation - implode (collapse inwardly).

### Highlights of Sonic Cleaning
- The ultrasonic equipment should have a cover or lid to prevent the aerosalization of bacteria or chemicals.
- Put is a Quality Process to monitor the Sonic Cleaning Process.
- You want to make sure your equipment is working properly.

### Conclusion
- Understand your process.
- Work with your staff & customers.
- Work with your vendors.
- If you do not know, ask & network.
- Properly utilized, sonic energy can contribute significantly to the speed and effectiveness of achieving the desired level of cleanliness needed. Sonic cleaning is not a technology of the future -- it is very much a technology of today.
SONIC means

Sonic cleaners are designed for fine cleaning of medical devices
Only use cleaning solutions designed for the sonic cleaning process
Not degassing a sonic cleaner appropriately can cause poor outcomes in the process
In-services and training of staff is key to successful sonic cleaning of medical devices
Check sonic activity with evidence based products like the SonoCheck, TOSI, and LumCheck