

Understanding the Sonic Cleaning Process

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Objectives

After completion of this self-study activity, the learner will be able to:

1. Explain the factors that influence the sonic cleaning process.
2. Describe the role de-gassing plays in sonic cleaning.
3. Identify test to use to determine if a sonic cleaner is functioning properly.
4. Develop a quality improvement program for sonic cleaning.

Test Questions

True or False

1. Presently the Association for the Advancement of Medical Administration (AAMI) and the Association of periOperative Registered Nurses (AORN) recommend that automatic cleaning equipment like a sonic cleaner be tested during routine use at least weekly.
A. True B. False



Photo is courtesy of Ultra Clean Systems, Inc

Figure 1. Ultrasonic Cleaners by Ultra Clean Systems: 1150V Floor Model is an example of one of the many sonic cleaners available to CSSD.

2. A surgical instrument that is not properly cleaned could fail to be effectively sterilized.
A. True B. False
3. De-gassing conditions the bath/solution for maximum efficiency and should be done for each new fresh bath/solution.
A. True B. False
4. Decontamination Holding Time (DHT) is the amount of time that elapses between an instrument's last use and the start of the cleaning process.
A. True B. False
5. The sonic cleaners used in hospitals work via high-frequency sound waves (usually above 20kHz) to produce an effect called cavitation—tiny bubbles of vaporized liquid that implode (rapidly collapse) and create high pressure shock waves.
A. True B. False
6. The SonoCheck™ is a device that tests for cavitation in a sonic cleaner.
A. True B. False
7. No sonic cleaner has 100% distribution of sonic energy throughout its tank and testing in many areas of a tank is important.
A. True B. False
8. Monitoring the key factors of the sonic cleaning process helps ensure that surgical instruments are getting clean.
A. True B. False
9. Both Joint Commission and AAMI encourage the use of quality improvement programs within Central Service Sterilization Departments (CSSD).
A. True B. False
10. CSSD staff should understand how the sonic equipment works; such knowledge is key to ensuring that instruments are safe to proceed to the next step in their reprocessing cycle.
A. True B. False

Introduction

“Cleaning is critical because residual organic material (e.g., blood, bone, proteinaceous material) can inactivate disinfectants; moreover, if a device is not cleaned thoroughly, sterility may not be achieved.”¹

Surface cleaning is a crucial aspect of any Central Service Sterilization Department’s (CSSD) cleaning process. Effective cleaning of any surgical instrument is important regardless of the complexity of the instrument. There is no such thing as “sterile dirt”.

Almost all surgical instrument manufacturers recommend sonic cleaning in their guidelines for care and cleaning of surgical instruments:

“Ultrasonic cleaners are used to remove soil from joints, crevices, lumens, and other difficult to access locations. The use of enzymatic detergent in the ultrasonic cleaner is recommended. Ultrasonic Cleaners should be monitored routinely to ensure that they are working properly.”²

Instruments have become more advanced and complex, so has the sonic cleaning equipment that can be purchased by hospital CSSDs. These advancements have taken a simple tank with transducers to a level where sonic equipment now can combine the power of irrigation (pulse/retro flow technology) with sonic energy to clean lumen instruments better than ever before. Add the advancements that have been made with cleaning solutions, and today many sonic equipment manufacturers (such as Geddis and UltraClean) claim they can:^{3,4}

- ▶ Improve consistency of cleaning in internal areas of surgical instruments;

- ▶ Reduce risk to staff from airborne and blood-borne pathogens created by manual brushing;
- ▶ Improve patient care by reducing risk of exposure to cross-contaminants;
- ▶ Reduce time spent trying to manually clean places that cannot be seen or reached;
- ▶ Reduce internal and external instrument damage caused by manually brushing, tapping, or bending; and
- ▶ Reduce instrument-repair budgets.

From an instrument manufacturer’s point of view, ultrasonic cleaning is an essential part of the cleaning process and should be used as frequently as possible. Today’s CSSD professionals must understand how sonic cleaning works and are responsible for ensuring that their department’s ultrasonic equipment is working properly. (See Figure 1 on page 70.)

What is sonic cleaning?

Sonic 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.” (ANSI/AAMI ST79 Section 7.5.3.3)⁵

A sonic cleaner can have a single tank or as many as three tanks in a hospital setting. In a multi-tank system, the first tank is usually for cleaning, the second is for rinsing and the third is for drying. In a two-tank system, one tank cleans and the other rinses and dries. When a single tank system is used rinsing and drying after the sonic process is important and done separately from the sonic tank.

The sonic cleaners used in hospitals work via high-frequency sound waves (usually above 20kHz) to produce an effect called cavitation—tiny bubbles of vaporized liquid that implode (rapidly collapse) and create high pressure shock waves. Ultrasonic transducers create this high-frequency sound by converting high-frequency electrical power to mechanical energy (vibrations). This energy is transmitted to the cleaning solution via a bank of transducers attached to the underside of the cleaning tank.

Cleaning takes place as the cavitation dislodges soil from the surface, tiny crevices, and other areas that are difficult to clean on contaminated instruments, which are placed in the tank with a cleaning solution. Cavitation literally sucks soil off the instrument like a vacuum.

Most sonic cleaners have multiple transducers producing the cavitation energy. If one or more of these transducers is not functioning, the sonic cleaner tank can have what are known as “cold spots”—areas within the tank where there is no cavitation. Obviously it is important

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to know the location of any cold spots. In a machine with several cold spots cleaning time will be extended and sonic activity might not even take place in those areas of the tank.

Outside factors that affect the sonic cleaning process

Like any cleaning process, sonic cleaning is affected by outside factors. Factors that influence the effectiveness of sonic cleaning are:

1. *Energy*—created by the mechanical action of the generators and transducers to produce the cleaner's cavitation;
2. *Target Soil*—the type of soil being cleaned (mostly blood);
3. *De-gassing*—freeing trapped air;
4. *Chemical activity*—the type and amount of the cleaning solution chosen;
5. *Type of instrument to be sonic cleaned* (simple or complex)
6. *Water quality*—hardness and pH;
7. *Water Temperature*—hot or cold cleaning solution;
8. *Time*—length of exposure to cavitation;
9. *Human factor*—training, loading procedures, proper use of equipment;
10. *Other issues*—such as pre-cleaning and safety; and
11. *Verification of the process.*

The various combinations of these factors determine how clean an instrument can or will be when placed inside the bath/solution of a sonic cleaner. The first factor, Energy, has been explained above in the section on cavitation. Now let us look at the other factors.

Target soil

Sonic cleaning is used primarily on surgical instruments, so the target soil is usually blood. Many other soils can be present, but blood is a primary concern for the CSSD when cleaning surgical instruments.

“Many types of soil could be present on reusable medical devices, but dried blood is especially difficult to remove. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning. It must be rehydrated and then washed away. Blood adheres to surfaces through mechanical and chemical means. Fibrin filaments in coagulated blood pack themselves into microscopic irregularities in the surface of instruments and have to be mechanically scrubbed away or chemically treated.” (ANSI/AAMI ST79 Section 7.5.2)⁵

Several characteristics of blood are important to know for cleaning. The first is that hemoglobin becomes highly insolvent when it dries out. Secondly fibrin, the coagulating agent in blood, is inherently water insoluble. Third, blood denatures at

temperatures above 110°F (45°C). When blood denatures, it becomes highly insolvent. It bonds strongly to the substrate (i.e., the surface of the instrument) and dries out, becoming very resistant to any cleaning action. Thus it is very important to keep Decontamination Holding Time (the time between when the instruments were last used and the cleaning process starts) to a minimum. The sooner the cleaning process begins the better.

De-gassing

De-gassing is the process of releasing dissolved air bubbles within the cleaning solution. In order for the degassing process to work, it must be done with the detergent/enzyme mixed in the bath solution. It is important to expel these air bubbles because they have a direct effect on the ability of the equipment to clean. The presence of dissolved air weakens the cavitation force of the sonic cleaner.

Degassing is done after the cleaning solution has been added and in an empty tank. The amount of time will vary depending on the type of chemical used (e.g., aqueous or solvent), temperature, size of the tank, and water quality. Generally the process takes as long as one cycle without any instruments in the filled tank. Consult the ultrasonic cleaner's written Instructions for Use (IFU) on the length of time required to de-gas a tank full of solution.

Remember that degassing conditions the bath/solution for maximum efficiency and should be done for each new fresh bath/solution (change bath as per the manufacturer's directions). If the sonic cleaner has not been used for some time, the solution should be de-gassed because dissolved air can re-enter the cleaner.

Chemical activity

There are many types of cleaning solutions on the market today; each has its plusses and minuses. When choosing a solution, always consider the following:

- ▶ The type of instrument to be cleaned (simple or complex);
- ▶ The instrument manufacturer's recommendation;
- ▶ The type of soil to be cleaned;
- ▶ Compatibility of the solution with your sonic equipment;
- ▶ Use of a low foaming solution to minimize foam settling on instruments; and
- ▶ Technical data (such as white papers) supporting the claims of the solution manufacturer. [A material safety data sheet (MSDS) should be provided with any solution. These can be used to evaluate the key ingredients and their possible impact on items being cleaned.]

For proper use of the cleaning solution:

- ▶ Be aware that excess amounts of certain chemical additives will not support sonic cleaning. More is not

always better; if solution must be added manually, use the correct amount.

- ▶ Many solutions are concentrated and must be diluted with water. In some cases, distilled water may be required. The best solution concentration is indicated on the solution container.

Remember not all solutions are created equal. Some solutions need a higher temperature to work at their optimum efficiency. A solution with many features may not be necessary in a particular CSSD. It's more important to know which solution will work best in your department on your instruments.

Although blood is the usual target soil on surgical instruments, a different, somewhat slimy soil is commonly found on orthopedic instruments and is hard to clean. It could be synovial fluid; if so, a product that can remove it must be chosen. I can't stress enough the importance of knowing what type of soil is being removed and choosing the appropriate product or products in each case. In some situations two solutions may be required.

Water quality

Water quality is a broad concept covering several key characteristics of water. For the CSSD professional the relevant measurable characteristics are pH level and hardness.

A pH is the measurement of the acidity or alkalinity of a liquid. The scale goes from 1, which is acidic to 14, which is alkaline. The mid-point, 7, is neutral. The pH scale is logarithmic; meaning each number in the scale represents a 10-fold increase over the previous number. For example, water with a pH level of 4 is ten times more acidic than water at pH 5. The pH level can affect detergent/enzyme performance; thus it is important to know the optimum pH value for the cleaner being used.

Water hardness is defined as the concentration of calcium and magnesium ions expressed in terms of calcium carbonate. These and other minerals bind with the cleaning agents in detergents/enzyme solutions and prevent them from reacting with the soil on instruments. Water that is too hard (containing too many minerals) can cause spotting and filming on instruments, and cause unsatisfactory cleaning outcomes. The pH and hardness values of water can fluctuate over time. These fluctuations will affect the performance of the solution in a sonic cleaner. Therefore it is important to test and monitor water quality to ensure that optimum values are present. A general rule is having water hardness under 200 ppm on a consistent basis.

Water temperature

Equally important to knowing water quality is to understand and know the temperature of the bath/solution in

the ultrasonic cleaner. Each solution has a temperature at which it functions best. The solution must be kept at this optimum temperature in order to clean most effectively. The sonic process itself creates heat, and over time this heat can raise the temperature of the bath/solution to a point where it reduces the cleaning efficacy of a particular solution. Remember, "Hotter is not always better." Achieving the proper temperature and maintaining it throughout the cleaning cycle is key to effective cleaning; thus CSSD professionals would be wise to monitor temperature during the cycle.

Time

Cleaning times can vary depending on the type of soil, the solution used, water temperature, and the degree of cleanliness desired. Instruments should be visibly cleaner almost immediately after they are placed in a sonic cleaner.

The tray/basket used in the machine can affect the cavitation energy the instruments receive.⁶ The type of tray and the density of the load (number of instruments placed in the tray) is directly proportional to length of cleaning time. With certain trays and loads a standard cycle time might not do the job.

Many sonic cleaners have a variable time setting. This is important, because it allows a CSSD to adjust for the many variables associated with sonic cleaning.

Cleaning time is the easiest (and often the wrong) factor to adjust to compensate for process variables. An experienced operator can approximate cycle duration for a certain instrument load, but should verify by actual use with the chosen solution and the actual soiled instruments. An easy way to do this is to test a few instruments at a time.

CSSD staff should ask for the instrument and sonic cleaner manufacturers' recommendations regarding cleaning time for their products. This information provides a starting point from which timing adjustments for particular instruments or soils can be made.

An example would be the cleaning of daVinci™ robotic arms where cycle times vary.

Proper loading of instruments

Loading instruments into a sonic cleaner is very important, so one must:

- ▶ Separate instruments to avoid electrolytic action between different metals (stainless steel instruments should not be mixed with their aluminum, brass or copper counterparts).
- ▶ Remove gross soil from instruments by pre-rinsing prior to sonic cleaning.
- ▶ Not place chrome-plated and ebonized instruments or items made of cork, wood, or glass in the sonic cleaner.
- ▶ Rinse any pre-foam or spray off the instruments; such materials may not be compatible with the cleaning agent used in the tank's bath/solution.

- ▶ Place all box locks in the open position.
- ▶ Fill lumen items with fluid so the cavitation power can work inside the lumen.
- ▶ Spread instruments out over the tray to allow maximum exposure to the cavitation power.
- ▶ If using an irrigation/sonic cleaner, use the correct ports and close off any unused ports. This will allow for maximum flow into the lumen items.
- ▶ Completely submerge instruments in the bath/solution.
- ▶ Make sure the tray/basket is properly located inside the tank. This allows for maximum exposure to the cavitation power.
- ▶ Rinse all instruments after cleaning them in a sonic unit that has only one tank. This is important because residual detergent/enzymes on an instrument are undesirable.
- ▶ Follow manufacturer's directions for the proper rinsing of the instrument. Consult the manufacturer of the instruments to be cleaned and the sonic cleaner manufacturer for any special instructions.

Human factors

CSSD staff should understand how the sonic equipment works; such knowledge is key to ensuring that instruments are safe to assemble and then sterilize. Staff training should involve the following:

- ▶ Demonstration of proper use of sonic equipment by a manufacturer's representative. All shifts must attend a demonstration.
- ▶ Documentation of the in-service/training.
- ▶ Minimum yearly review of the sonic cleaning process for all staff.

Proper in-serving of the staff will help ensure that instruments are properly exposed to the cavitation power of the sonic cleaning process.

Other issues—safety, bath changes, solution levels

Safety is always important when dealing with any powered equipment, including sonic cleaners. All staff should be aware of safety procedures and should be properly attired in the appropriate personal protective equipment (PPE), and be aware of these safety procedures:

- ▶ When the equipment is being used for cleaning (not testing) the lid must always be closed to prevent excess emission of noise and aerosols.
- ▶ No part of the operator's body should be submerged into the bath/solution during operation.
- ▶ The sonic cleaner should be off when inserting or removing trays/baskets from the tank.
- ▶ Carefully lower trays (do not drop quickly) into the bath/solution. This will minimize or reduce the amount of air introduced into the bath/solution.

Professional opinions vary regarding the need to change the bath/solution in the sonic cleaner. The majority of manufacturers recommend immediate replacement of water once it is heavily contaminated. Contaminated solution can result in a loss of cavitation power. My recommendation is to change the solution as often as needed, preferably after each use. After each change of bath/solution, check the screen or trap and clean off any debris, such as bone chips or paper. Many automatic machines will refresh the bath after each use (some also degas before each use, it is a programmed cycle). Again, the key to effective sonic cleaning is cavitation power. Frequent bath changes help maximize this power, ensuring a better cleaning process.

Maintaining the proper level of solution in the tank is also important; sonic cleaning is a "fine tuned system." Improper solution levels can negatively affect the sonic cleaning process and can damage the cleaner. Sonic cleaning systems were tested with specific volumes of solution. Insufficient solution volume can reduce the cavitation effect power.

Another issue is small parts cleaning and keeping them together and making sure they are exposed to the sonic cleaning activity. One way of keeping products together is using the "Ultrasonic Cleaning Pouch" that was developed by the GEDDIS Company. This pouch has been proven helpful in keeping smaller size items together during the sonic cleaning process.

Verification of the sonic cleaning process

Verification of the sonic cleaning process is supported in the present guidelines and standards found in AAMI, AORN, and Joint Commission, as well as all of the professional groups that support quality improvement programs.

AAMI does list a sonic cleaner as a piece of medical equipment in ANSI/AAMI ST79 Section 7.5.3.3; there are other references that support the minimum of weekly testing of all types of sonic equipment with or without "retro flow pulse adapter".

ANSI/AAMI ST79 - 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..."⁵

ANSI/AAMI ST79 - 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, computer control or an upgrade to software...”⁵

The 2011 AORN recommended practice for Cleaning and Care of Surgical Instruments and Powered Equipment Recommendation XXII –Quality section is supporting the testing of mechanical instrument washers before initial use, weekly during service, and after major maintenance.⁷

The Joint Commission in standard EC.02.04.03 states “The hospital inspects, tests, and maintains medical equipment.”⁸

So in accordance with ANSI/AAMI ST79-2010, the Joint Commission standard EC.02.04.03 and AORN, part of a quality improvement program includes monitoring the cleaning efficacy of any sonic cleaner at least weekly, preferably daily during routine use

The following statements support the need for a quality improvement program for the sonic cleaning process.

“A problem analysis should be completed for 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.”⁵

“Ultrasonic Cleaners should be monitored routinely to ensure that they are working properly. Recommended monitoring methods are:

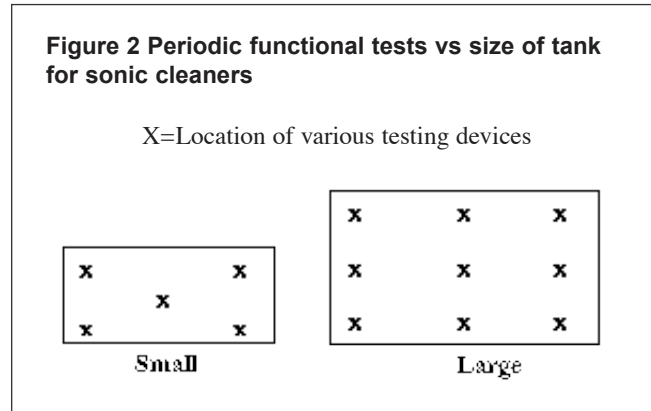
- 1) Sonocheck monitoring vials (from Healthmark Industries Co., 33670 Doreka, Fraser, MI 48026 USA) which change color when the ultrasonic cleaner is supplying sufficient energy and conditions are correct...”²

The Organization for Safety and Asepsis Procedures (OSAP) is a global dental safety organization and this organization recommends routine testing of sonic cleaners within the dental practice.

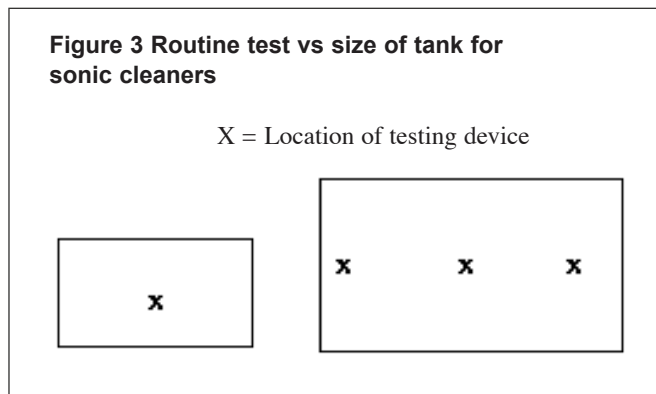
The FDA considers the sonic cleaner a Class 1 medical device. The cleaner must be maintained in proper working order, and CSSD staff must know whether or not it is working properly. One of the best ways to ensure that the machine is functioning properly is to establish a quality improvement program for the sonic cleaning process. A quality improvement program helps ensure adherence to Joint Commission, AORN and AAMI standards and recommended practices.

Testing is a key component of a quality improvement program. Tests provide a means of monitoring the variables that affect the effectiveness of sonic cleaning (i.e., water quality, time, detergent/enzymes, temperature, agitation, speed, initial temperature, chemical concentration, equipment failure). Ultrasonic cleaners should be tested at least weekly, and the results of the test should be documented. Tests fall under two categories: periodic functional tests and routine tests.

A periodic functional test is performed for initial set-up and then quarterly or after repairs. Its purpose is to verify uniform distribution of cavitation in the sonic cleaner. Uniform distribution of sonic cavitation within the bath ensures satisfactory performance by the cleaner and allows performance of routine testing. A periodic functional test can be used to fine-tune the ultrasonic cleaning process if results are found to be unsatisfactory. It also helps identify “cold spots” in the tank. See Figure 2 for placement of testing devices for the periodic functional test.



A routine test is performed weekly to verify that proper cavitation is taking place. Such parameters as water level, de-gassing, instrument load, and energy supplied by the transducers can cause variations in the process that affect performance. Only routine testing will detect ultrasonic performance deterioration and prevent ineffective ultrasonic cleaning. The routine test is performed under normal conditions in an empty tank. See Figure 3 for placement locations for individual test devices. You need to place at least one test in the middle of the tank (depending on the size of the tank you can place more; sometimes 3 tests are placed in a larger tank). See Figure 4 for examples.



A complete test of all inputs of the ultrasonic process should be run each week. Observations and test results should be entered in a log/report.

The following is a simple program for monitoring the sonic cleaning process. CSSD should include it as part of their Joint Commission process improvement program.

Inspection and testing

Daily:

- ▶ Follow manufacturer’s guidelines for daily inspection of equipment (wipe down tank at end of day, check gaskets, clean screens, etc....).
- ▶ Inspect the level of detergent (cleaning solution). Each day, mark the date on the solution container at the level of solution remaining. This will allow staff to see how much solution is being used.
- ▶ Log all observations in a report.
- ▶ Report any concerns to the proper management staff.

Weekly:

A complete test of all inputs of the ultrasonic process should be run each week. Observations and test results should be entered in a log/report.

- ▶ **Step 1—Equipment Inspection:**
Inspect equipment (screens, gaskets, etc.) according manufacturer instructions. Record the results.
- ▶ **Step 2—Water Quality Inspection:**
Measure hardness and pH of the tank bath/solution before adding cleaning solution (A simple dip stick method can be used. Record results, and report any concerns to the proper management staff).
- ▶ **Step 3—Water Temperature Inspection:**
Measure the tank bath/solution temperature with a liquid reversal thermometer. The thermometer should be applied to the inside of the tank wall just below the water line. Record results on a log sheet, and report any concerns to the proper management staff.
- ▶ **Step 4—Test sonic cleaner performance:**
CSSD staffs have traditionally chosen one of four methods—a pencil load test, an aluminum foil test, an ultrasonic activity detector, or a SonoCheck™ to test sonic activity in the cleaning tank.⁶

Procedures for testing sonic activity

Each test will be described in this section. In each case, test results should be recorded and then compared with results of the same test conducted when the cleaner was originally installed. In case of unsatisfactory test results, refer to the troubleshooting guide supplied by the manufacturer of the particular test being used. Any concerns should be reported to the proper management staff to address.

Pencil load test

In a pencil load test (also known as the ceramic disc test), the surface of an unglazed ceramic disc or plate having a matte finish and a diameter of approximately 50 mm (thickness is not critical) is rubbed with a standard HB lead pencil and then immersed in the cleaning tank. Consistent, equal application of the lead onto the disc every time is very important. The Steris® Company has recommended this method in the past, but the disks are no longer available.⁹

A ground glass stopper, a sheet of ground glass, or an aluminum sheet with a thickness of 2-3mm may be substituted for the ceramic disc. The ultrasonic cleaner should completely remove the pencil lead within three minutes. If this type of test is being recommended by a sonic manufacturer, they should provide you with a trouble shooting guide for easy interruption so the proper trouble shooting can be done in case of a failure or decrease in removing the lead.

Strip of aluminum foil

A strip of aluminum foil can also be used to test a sonic cleaner. Several tests using aluminum foil have been described in the literature.¹⁰ Recommendations vary regarding the thickness of the foil strip, but it should be at least 0.025mm. One test recommends suspending nine strips of aluminum foil, 15mm to 20mm wide, within 10mm of but not touching-the bottom of the tank. Another method is to take three pieces of foil, each measuring 10-20cm, and fold them over rods suspended in various areas of the tank. The presence of significant pitting and a uniform pattern of dents and holes in the foil strips after cleaning indicate the unit is working. If a manufacturer of a sonic cleaner is suggesting using the aluminum foil test, make sure they provide you with a chart for easy interruption of the results so proper trouble shooting and result interruption can be done by the user of the test.

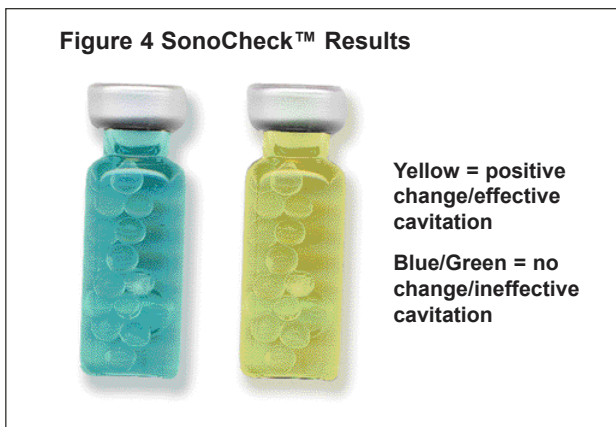
Ultrasonic activity detector

Testing can also be done with an ultrasonic activity detector, a device developed to determine ultrasonic activity levels.¹¹ The device consists of a stainless steel

probe with a plastic handle and connecting cable. The cable plugs into a hand-held instrument that indicates and monitors ultrasonic activity. The probe is placed into various sections of the tank and measurements are taken for each spot tested.

SonoCheck™

The fourth testing method is the SonoCheck™ (see Figure 4), a chemical indicator vial that verifies the cavitation capability of the ultrasonic bath. The test device is a closed vial containing fluid and glass beads.¹² The vial is placed in the sonic bath, which then is switched on. When effective cavitation is achieved, the color of the fluid in the vial changes from blue/green to yellow. The length of time it takes to change color is proportional to the cavitation power of the sonic cleaner. The person conducting the test records the amount of time that elapses prior to the color change. If using this type of test, make sure a trouble shooting guide is provided for ease of interpretation.



Each of these test methods has its pluses and minuses. A CSSD must determine which test is best suited for its particular needs, and then use the chosen test as part of a quality improvement program. Criteria for selecting a test include:

- ▶ Ease of use and interpretation of results—results should be objective. Subjective results can lead to misinformation about the equipment.
- ▶ Availability and cost.
- ▶ Correlation to cavitation.
- ▶ Reliability and reproducibility of the test results.

Information gleaned from running the sonic performance test should help resolve concerns about whether the sonic process is working. It should be noted that no sonic cleaner has 100% distribution of sonic energy throughout its tank and testing in many areas of a tank is important.¹⁹

Procedures for testing sonic cleaning effectiveness (soil test)

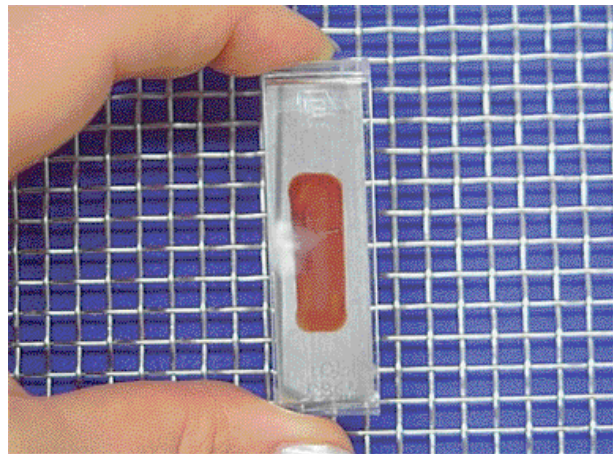
A soil test contains a soil sample that must be completely removed by the sonic cleaning process.

As stated previously in this article, blood is a primary target soil for the sonic cleaner. Logically therefore a soil test should contain a sample of this target soil. Two types of test kits containing blood or a blood substitute are available today—a paint-on type such as an Edinburgh soil, and the TOSI™, a prepared test object.

The paint-on soil is spread over the instruments being tested. The soil must be applied consistently each time the test is performed. The soil is allowed to dry (follow the manufacturer’s instructions regarding length of drying time), and the instruments are loaded into the sonic cleaner using a normal loading pattern. A visual inspection of the instruments is required after the sonic cleaning process. Results are recorded and interpreted according to the soil manufacturer’s guide.¹³

The TOSI (Test Object Surgical Instruments, see Figure 5) has three components: blood soil, a stainless steel plate, and a clear plastic holder. The soil is composed of blood components mixed and applied in a precise manufacturing process, which provides a consistent challenge to the effectiveness of the sonic cleaner. The stainless steel plate is “scratched” or grooved, replicating the uneven surface of surgical instruments. The plate is mounted in the plastic holder at an angle, providing a gradually more difficult cleaning test from one end to the other.¹²

Figure 5 TOSI™ (Test Object Surgical Instrument)



During the test one TOSI is placed inside an empty approved tray/basket for one cycle length. Users should follow the manufacturer’s instructions and refer to the troubleshooting guide in case of unsatisfactory results. Results of the test are recorded, and concerns reported to the appropriate staff for follow-up.

Just as with the sonic energy tests described above, CSSD staff must determine the best test method for their particular

facility, and then use the chosen test in their quality improvement program. Criteria for selection include:

- ▶ Ease of use and interpretation of results;
- ▶ Consistency of application of the test;
- ▶ Availability and cost;
- ▶ Correlation of test soil with human blood;
- ▶ Reliability and reproducibility of the test results; and
- ▶ Ability of the test to identify and resolve concerns regarding cleaning effectiveness.

Procedures for testing sonic cleaning effectiveness for hollow/lumen instruments (soil test)

Many of today’s advanced sonic cleaners have the ability to irrigate (with a pulse flow/ retro-flow technology) lumen/hollow instruments (like suction), allowing the CSSD to better clean lumen/hollow items.

CSSD must remember that lumen/cannulated items like suction can be difficult to process because air can be trapped inside the lumen/cannulated item, thus preventing cleaning from taking place, simply immersing the lumen/cannulated item in a tank of cleaning solution is not enough. To overcome the air entrapment problem sonic manufacturers created the pulse flow/retro flow process. This process is used in other industries like the automatic and aerospace.

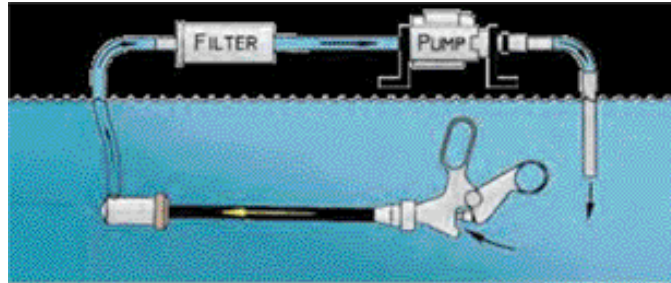
Alfa and Nemes wrote an excellent article entitled Manual versus automated methods for cleaning reusable accessory devices used for minimally invasive surgical procedures.^{14,16} This article goes into great detail on why you should be using a sonic cleaner with this type of irrigation (pulse/retro-flow technology) for cleaning any lumen/hollow instrument such as suction, minimally invasive surgery instruments, robotic arms....

It is because of the trap air issue that a product like the LumCheck™ was developed so sonic cleaners that have this technology can be tested to ensure they are properly functioning. See Figure 6 and 7 for examples.

Figure 6 SurgiSonic® Ultrasonic Cleaner for Tubular Surgical Instruments is an example of a sonic cleaner that cleans lumens (this is only one of the many types available to CSSD)



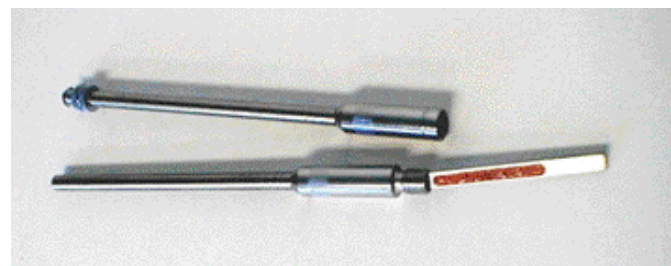
Figure 7 One example of the retro flow/pulse technology courtesy of Geddis Inc.



In the article entitled Cleaning efficacy of medical device washers in North American healthcare facilities, Alfa pointed out the importance of testing with the proper type of soil, “...the TOSI was reflective of the protein and/or hemoglobin levels found on surgical instruments pre and post cleaning in an automated instrument washer and whether reduced fluid flow conditions in a narrow lumen washer could be detected by the TOSI- Lum-Chek... the TOSI Lum-Chek and regular TOSI devices do provide a readily available method for monitoring washers that facilitates ongoing cleaning assessment in the healthcare setting...”¹⁸ The article also stated the reason the TOSI™ was used in this peer reviewed study is it best represented the contamination found on surgical instruments and others tests that just had dye as the indicator and did not represent what was being found on surgical instruments.¹⁸

Having a standardized challenge for the cleaning efficacy of a sonic cleaner with an irrigation system is important because you want to make sure the cannulated/lumen items are getting clean. The LumCheck™ test kit (see Figure 8) allows you to do this, it includes a reusable stainless steel holder (analogous to a lumened instrument) which opens to allow easy insertion of a blood soil test (TOSI™) which correlates to dried blood on a stainless steel instrument.¹⁵ Complete removal of the blood soil (with visual inspection) indicates that the irrigation system is working properly. Users should read the manufacturer’s instruc-

Figure 8 LumCheck™



After any maintenance is done on the sonic equipment, all tests should be conducted to ensure that the equipment is functioning properly.

tions for connecting lumen/hollow instruments to the equipment, and use the same procedure to connect the test device. Run a complete, empty cycle and record the results. If soil remains, the inputs for cleaning need to be checked, including water quality, water temperature, detergent concentration and the pump system. Report any concerns to the appropriate management staff for follow-up.

As of this publishing, the author was not aware of methods other than the LumCheck™ available to medical facilities for testing lumens that use blood soil as the test soil. There are some other tests, but they are not blood soil based tests and thus do not represent what is actually being cleaned in a CSSD. Authors note: “Our data demonstrates that the lumen TOSI is a relatively easy challenge and if residual material remains, it indicates that the lumen cleaning ability of the washer has been severely impaired (less than ½ usual conditions).¹⁷

Equipment maintenance

After any maintenance is done on the sonic equipment, all tests should be conducted to ensure that the equipment is functioning properly. The type of maintenance done and the results of all tests should be documented and recorded. The person who performs the maintenance should not leave until the tests have been completed, so that necessary adjustments can be made immediately. It is also very important that the person repairing and doing the maintenance is qualified and has experience with that particular equipment.

Documentation

As mentioned many times in the article logging or documentation your results are very important. Having a check list of tasks that need to be done daily, weekly, monthly, and according to the PMA of the equipment is vital for “optimum” sonic cleaning.

Healthmark offers a check list (see Figure 9) and offers a web based application for their customers called ProFormance QA that allows CSSD to keep all of their data secure on the web with easy access (http://www.blacktiemedical.com/central_sterile.html). See Check List on page 90.

Summary

A quality improvement program for the sonic cleaning process should include:¹⁷

- ▶ Measuring pH and water hardness;
- ▶ Monitoring the bath/solution temperature;
- ▶ Performing a cavitation test on the equipment;
- ▶ Performing a target soil cleaning test;
- ▶ Performing an appropriate lumen test on cannulated/lumen type cleaning equipment;
- ▶ Daily/Weekly visual inspection of equipment (observations of machine operation/conditions);
- ▶ Constant daily visual inspection of all instruments;
- ▶ Training of staff on a continuous basis
 - De-gassing procedure
 - Loading of instruments
 - Selection of trays
 - Other key factors/inputs relevant to each hospital’s process;
- ▶ Record all results of tests and observations in a log/book;
- ▶ In case of unsatisfactory results refer to the troubleshooting guide for the tests and equipment used;
- ▶ Report any concern to the proper management staff within the department to follow up; and
- ▶ Understanding that when a test fails how that test can help you understand the reason why there was a failure. Just having a test that passes easily is not helpful in a quality improvement program.

Today’s Central Service Sterilization Departments are very active and dynamic. Surgical instrumentation and processes change constantly, and the cleaning equipment needed to process these instruments safely is evolving as well. It only makes sense to have a well-qualified, trained, and competent staff to process these surgical instruments.

A sonic cleaner, like any piece of equipment, can malfunction at any time. Knowledge of when and why the cleaner is malfunctioning is key to ensuring properly cleaned surgical instruments. A quality improvement program helps ensure that staff are protected and patients are receiving the best possible care. It enables CSSD staff to know that their equipment (in particular, the sonic cleaner) is working properly. Then staff can be sure that the instruments are clean and ready for the next stage of the reprocessing cycle.

SonoCheck™, TOSI™, and LumCheck™ are trademarks of Healthmark Industries Fraser, MI

Ultrasonic Cleaners by Ultra Clean Systems: 1150V Floor Model is a trademark of Ultra Clean Systems, Inc

SurgiSonic® Ultrasonic Cleaner for Tubular Surgical Instruments and the SurgiClean® Ultrasonic Cleaning Pouch are trademarks of GEDDIS Inc.

Figure 9. Check list example

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


Date: Facility: Washer: Name:

Aquachek (circle result)

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

TempaChek-LC (reversible thermometer)

Target Temp:
Range:



Comments:

TOSI

Record Result (circle result)

0	
1	
2	
3	
4	
5	
6	

Comments:

SonoCheck (circle result)

1		Comments: <input type="text"/>
2		<input type="text"/>
3		<input type="text"/>

Authors Note: When this article was published all links listed in the References were active. Companies have the right to deactivate links at any time without notice.

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Stephen M. Kovach is the Director of Education at Healthmark Industries located in Fraser, Michigan. He has been in the Hospital field for over 36 years. Stephen has a BS from Central Michigan University, with a Major in Biology and History. He is active both on the state and national levels of various organizations having held many positions. Stephen was the Educational chair for AORN Specialty Assembly for SP/MM (2006-2010). He is a voting member on various AAMI committees. He also has been an instructor at the Community College level and published many articles varying in subject matter from perfusion to the importance of cleaning surgical instruments and chapters in both the IAHCSSM 7th Technical and the Management Manual.

Stephen has received recognition in both his personal and business profession.

He recently received the IAHCSSM Award of Honor for his dedication to improving the role Central Service plays in the hospital. He also was named by Hospital Purchasing News in 2007 as one of the 30 most influential people within the field of Central Service.

Stephen is very proud to say he has "WORKED IN CENTRAL SERVICE".

ANSWERS

- 1. A 6. A
- 2. A 7. A
- 3. A 8. A
- 4. A 9. A
- 5. A 10. A

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Address _____

City _____ State _____ Zip Code _____

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until recertification is required. **DO NOT SEND LESSON OR TEST TO CBSPD.**

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4. Date the application and sign.
5. Answer the true/false CE questions. **KEEP A COPY FOR YOUR RECORDS.**
6. Submit this form and the answer sheet to:
healthVIE.com
PO Box 25310, Scottsdale, AZ 85255-9998
7. For questions, contact craig@firstaccessmedia.com.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of healthVIE.com's receipt of the application.

Application

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City, State, Country, Zip _____

Daytime phone () _____

Position/Title _____

Social Security or Nursing License Number _____

Date application submitted _____

Signature _____

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- 3) Usability of content _____