

**SUGGESTED POLICY FOR
THE MONITORING OF THE CLEANING EFFICIENCY OF
ULTRASONIC CLEANERS (SONOCHECK™ ONLY)**

SUBJECT: ULTRASONIC CLEANER MONITORING

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: 12/09

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. (1,6,7,8,9,10,13,14)

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.***

The Joint Commission states in standard E.C.6.20 that medical equipment is maintained tested and inspected. (17)

"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.

Performance testing

The efficacy of the ultrasonic cleaner should be tested at least weekly. 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, initial heat, drying, obstructions, and insufficient amount of chemicals and equipment failure. (7)

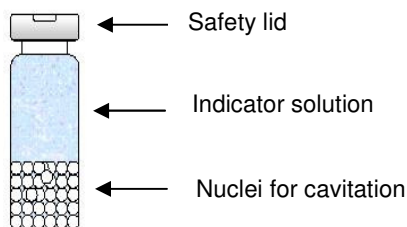
Proper cleaning is critical. The SonoCheck test kit provides an independent objective test of clean and allows the Sterile Processing professional to monitor and ensure proper cleaning in the sonic process.(1)

JCAHO and AAMI both recommend that Sterile Processing department have process performance in place (1,5). Using the sonic check according to the manufacture's guidelines helps ensure adherence to both JCAHO 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"(21)

Directions for use



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

SonoCheck™ Test

- Make sure that the ultrasonic cleaner has been degassed prior to running the test
- Place one (1) TI-108 in the center of an empty tray (see Fig. 1). Please note that you can place three Sonocheck in a tank; it depends on the size of the sonic equipment and the tank (figure 2). You must test with at least one SonoCheck.
- Run Ultrasonic through normal cycle and record re-sults. The recommended time found in the operator's manual.
- Record the time the SonoCheck changes color (it can turn as quickly as 10 seconds). Color change should be from green to yellow.
- If a color change did not occur by the end of the cycle report results.
- The time in ultrasonic processing that is needed to generate the color change will provide additional information regarding the ultrasonic energy and cavitation generation.
- Figure 1 – Test location of TI1-108 are placed in the center of an empty tray along the bottom

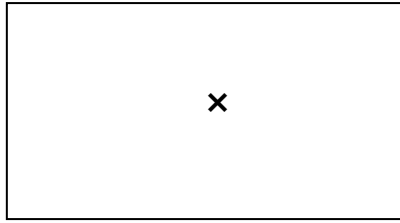


Figure 1

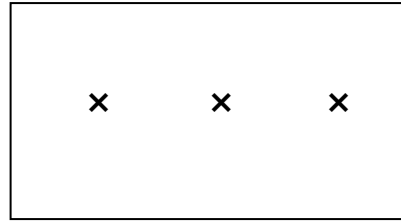


Figure 2

x= Sonic Check Location

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

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 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.

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 of 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
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