Competency Record for Ultrasonic Cleaning

Name: _____

Competency Achieved: _____ **(Date)**_____

Evaluator: _____

Learner: _____

Comments:_____
_____
_____
_____

Background information on ultrasonic testing

ST79; 2017 section 13.2 states:

> "Mechanical cleaning equipment should be tested upon installation, each day that it is used, and after major repairs. When evaluating or changing to a new type of cleaning solution and after all major repairs, all cycles used should be tested to ensure that the cleaning solution and cleaning action are effective. A major repair is a repair that is outside the scope of routine preventive maintenance and that significantly affects the performance of the equipment. Examples include a software upgrade or the replacement of the water pump(s), detergent delivery system, heating system, water delivery system, water treatment system, ultrasonic generators, or computer controls." AAMI considers ultrasonic cleaners as mechanical cleaning equipment.
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> "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."

Ultrasonic Cleaning Process

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. Dried blood on instruments is hazardous to the employees of the hospital and to the next surgical patient upon which the instruments are used. The procedures for sterilizing

instruments are based on years of scientific testing of cleaning instruments, and if surgical instruments are not clean, then the procedures are ineffective.

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 (i.e., spiral wound instruments—biopsy forceps).

The ultrasonic vibration at the frequency used for cleaning does not kill microorganisms, and infective aerosols may be produced. Therefore, 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 (Mfr.). Optimally, it will be a neutral, low-foaming product. 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. It is performed after the chemical is added and accomplished by operating the ultrasonic energy and raising the solution temperature. The time required for degassing varies considerably based on tank capacity, 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.

Cleaning the ultrasonic cleaner and replacement of the cleaning solution is necessary at least daily or more often if the solution soiled.

Performance testing

Proper cleaning is critical, and the efficacy of ultrasonic cleaners should be tested daily for any failures. Results of the testing shall be documented as part of the proof of process.

Testing 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.

The SonoCheck ™ Test Kit gives Sterile Processing professionals an objective test to monitor and ensure proper cleaning in the ultrasonic process.

AAMI lists ultrasonic cleaners as mechanical equipment in section 7.6.4.3.3. There are other references supporting daily testing of all types of ultrasonic equipment with or without “retro flow pulse adapter”.

ANNEX D.3 states “. . . For verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the mechanical cleaning equipment (if used) and the cleanliness of specific devices after manual or mechanical cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks once these benchmarks have been defined.”

Section 13.2 states, “To ensure that mechanical cleaning equipment is working properly and according to the manufacturer’s specifications, routine monitoring is required. Testing the equipment upon installation, during routine use, and after repairs allows the user to verify its continued effectiveness” (AORN, 2017a).

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

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

Therefore, in accordance with ANSI/AAMI ST79-2017; ANSI/AAMI TIR12-2005; JCAHO EC6.20-2005, and AORN, Healthmark recommends daily monitoring of the cleaning efficacy of any ultrasonic cleaning unit. The Sonocheck™ is an easy-to-use interpretation method for monitoring that verifies:

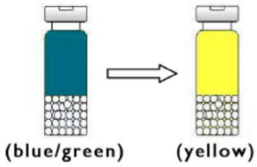
- Sufficient cavitation energy with monitoring vials* designed to change color (blue to yellow) when:
    1. The ultrasonic cleaner is supplying sufficient energy
    2. Conditions are correct (degassed water, temperature, etc.)
- Failure to change color indicates either the:
    1. Ultrasonic bath conditions were not correct
    2. Failure of one or more of the ultrasonic transducers.

JCAHO and AAMI both recommend that Sterile Processing departments have process performance in place. Using the ultrasonic check according to the Mfr.'s guidelines helps ensure adherence to both JCAHO and AAMI standards and having a properly functioning cleaning process.

Competency Statement: Complies with policy and procedure for testing the

Key
1 = Performs independently and consistently. Requests assistance in new situations.
2 = Performs with minimal guidance and direction. Requests assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Critical Behaviors	**1**	**2**	**3**
Reads manufacture's manual for your specific ultrasonic cleaner			
Completes the self-study program supplied by the vendor			
Describes the purpose of ultrasonic cleaning at your facility			
Selects and wears the proper personal protective equipment			
Gathers appropriate supplies to perform test on ultrasonic cleaner			
Inspects the ultrasonic cleaner according to manufacturer's recommendations & hospital policy (*document results*)			
Prepares a bath of cleaning solution (water and detergent) in compliance with instructions for use by the ultrasonic manufacturer and the detergent manufacturer			
Degasses the bath in accordance with ultrasonic manufacturer's instructions			
Ensures the bath is within the proper temperature range as provided by the detergent's manufacturer.			
Selects the appropriate number of SonoCheck™ vials (as shown in the diagram below) based on tank volume and choose the layout that matches the size of the equipment to be tested			
Places the SonoCheck™ (s) in an empty ultrasonic basket and place the basket in the ultrasonic cleaner that has been de-gassed			
Understands the size of the tank equates to the number of SonoCheck™ vials used: • Small tank = Up to 5 liters • Medium tank = 5 to 20 liters • Large = Above 20 liters			
Understands the layout of how to place SonoCheck™ vials:			

<table><tr><th>Small Tank</th><th>Medium Tank</th><th>Large Tank</th></tr><tr><td>x</td><td>x x</td><td>x x x</td></tr></table>  			
Runs the equipment as directed by the ultrasonic manufacturer and record the test results on the "Log Sheet" located on www.hmark.com			
Understands all SonoCheck™ should change from blue/green to yellow within specified time • The time needed for the color change will indicate the level of energy and degree of cavitation provided by the ultrasonic cleaner • A negative result will indicate a blind spot of ultrasonic energy.			
Understands that a color change from blue/green to yellow indicates presence of cavitation energy • Note: Failure for color change to yellow indicates a failure to achieve sufficient cavitation energy to clean. This could mean one or more ultrasonic transducers are failing			
Records all results in a log			
Understands that in the case of an unsatisfactory result, refer to the SonoCheck™ troubleshooting guide.			
Reports any unsatisfactory results to the proper management for corrective action according to the policy of your facility.			