Competency Record for the Daily ProFormance™ Automated Washer Test Kit

Name: _____

Competency Statement: Complies with policy and procedure for testing the automatic washer.

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

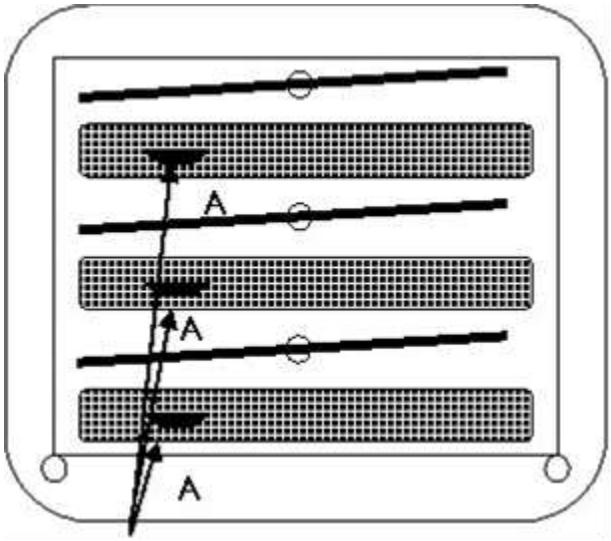
Competency Achieved: _____(Date)

Evaluator: _____

Learner: _____

Critical Behaviors	**1**	**2**	**3**
Completed / Attended the Self Study program supplied by the Vendor			
Describes the purpose of instrument cleaning and decontamination			
Selects and wears the appropriate personal protective equipment			
Gather appropriate supplies to perform test on the automatic washer (AWTK3L Test Kit)			
Inspect automatic washer according to manufacture recommendations & hospital policy (document results)			
Look at the level of detergent and document			

Water Quality • Follow these directions first for cold water, then hot water • Use an AquaTest™ (wts-101) test strip • Dip entire strip into water for 5 seconds, then remove. • Shake once briskly to remove excess water from the test strip • Wait 20 seconds • Compare color within 10 seconds to pH, Total Alkalinity, Total hardness on the interpretation chart. • Report any deviations from expected values. • Note that water conditions do change seasonal. It is important to have a base line established (target values) for your water and compare your results to the base line (target values).			
Pre-Rinse – Water Temperature • Use a TempaChek™–90 for this test • Use one (1) TempaChek™-90 per washer • Peel thermometer from release paper • Apply to any clean dry surface ensuring that the indicator has adhered to the surface (i.e., place / apply to the smooth surface on the TOSI® rack) • Tempachek™-90 should be read immediately after the ***COLD-WATER RINSE*** stage. (On some equipment you have to stop the cycle to read results) if your equipment has a window you can visually see the result and not have to stop the cycle. (With the Belimed you cannot stop the cycle you must read result through the window. If no window a separate cycle testing only the cold water must be run and aborted after pre-wash. Not highly recommended) • Record results on log sheet			

Critical Behavior	1	2	3
<u>Blood Soil Test</u> • A batch type washer (Belimed / Steris 444 / Getinge 8666) uses one rack with multiple levels. Each level should be tested at the same time. If the rack has two levels, then two tests are used if the rack has three levels then three tests are used. One test per level on each rack is the standard.  TOSI® Placement on rack • At the beginning of the week (designate the same day each week that this test should be done) in each washer/disinfector, secure one TOSI®, in the center of an empty tray. Do this as many times as you have shelves. • Test should be done in and empty load (no instruments, etc.) • Place each tray with its TOSI® on each of the shelves if multiple shelves are present. • Load the washer/disinfector with the rack with TOSI® in each machine to be tested. • Process using your normal procedure / cycle. • It is suggested that you test each cycle you process surgical instruments in to make sure that they are working properly. I.e. 3 cycles you should test all cycles each week. • Examine the TOSI® for visual			

cleanliness. Compare the test to the 0-5 TOSI® chart scale. • Record results. • Immediately report any test failure to department management (1-5) • Make any adjustments to the washer/disinfector as needed according to the results found from the test object and comparing them to the TOSI® chart. • The next week, repeat the process. • Record all results. • A tunnel type washer uses only one rack. Use one TOSI® and place in center of rack.			
Critical Behavior **<u>Thermal Disinfection stage</u>** • Use one TempaChek™-170 on each level of the instrument rack • Peel thermometer from release paper • Apply to any clean, dry surface ensuring that the indicator has adhered to the surface (place / apply to the smooth surface on the TOSI® rack) • TempaChek™-170 should be removed and read after the ***<u>THERMAL DISINFECTION STAGE</u>*** and before the drying stage. • Record results on log sheet **Report any deviation from targeted temperature**	**1**	**2**	**3**
Documents all results of the washer test results on the appropriate form			
Communicate results to the proper staff			
Has read the Hospital policy on monitoring the Cleaning process			

Competency for Weekly Testing of the Automatic Washer Process
Keep all information in employee educational file.

Understanding the cleaning process.

"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."

Washers fail to clean for many reasons. *Tests* should provide a means of monitoring the variables that influence the effectiveness of a washer. Some of these variables are water quality, time, detergent, enzyme, temperature, pH level, agitation, speed, initial temperature, drying time, obstructions, and insufficient amount of chemicals.

Proper cleaning is critical. The TOSI® blood soil along with the test kit (temperature and water quality monitoring) provides an independent objective test of clean and allows the Sterile Processing professional to monitor and ensure proper cleaning in the automated instrument washer/disinfector *process*.

What is a washer/disinfector and what does it do?

Cleaning is the removal of all visible dust, soil, any other foreign material and some microorganisms. A washer/disinfector cleans and decontaminates 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 clean 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.

The cleaning of dried blood is much more difficult than cleaning dirt. Blood coagulates, which means it goes from a free-flowing liquid to a solid that contains tough, microscopic fibers called fibrin. These fibers are formed as the blood coagulates and jam themselves into microscopic irregularities in the surface of the stainless-steel instrument. This is a physical attachment to the surface through mechanical means, not just chemical means as with traditional adhesives. The action is similar to the roots of plants growing into cracks in rocks, anchoring themselves to the surface.

The blood cells colored with hemoglobin are fairly easy to wash off instruments, but the clear fibrin material is much more difficult. Thick droplets of dried blood

have so much fibrin; even the colored hemoglobin can be trapped and held in place.

Having the correct temperature is very important in the automatic washer. If the temperature is set to high during the Pre-wash stage blood will denature at 45°C (113°F) the temperature. When blood denatures, it become highly insolvent. It bonds strongly to the substrate (e.g., the surface of instruments) and it dries out – becoming very resistant to the action of solvents.

Another thing that makes blood difficult to clean is its ability to become insoluble when heated. Heating causes blood to "denature." Denaturing is similar to eggs cooking in a frying pan. Transparent uncooked egg whites are fairly easy to wash away, but opaque, cooked egg whites are much more difficult. Dried, uncooked egg is even more difficult to wash away, just like blood. The proteins in blood are similar to albumin proteins in eggs.

What helps the cleaning of blood from instruments?

Water: Water will moisten dried blood and make it possible to wash away. Avoid dried blood by cleaning as soon as possible or keep instruments moist while waiting. The relevant measurable characteristics are temperature, ph level, hardness, alkalinity, and purity (microbial contamination). Water hardness plays an important role in how much detergent / enzyme

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 and prevent them from reacting with the soil on instruments. The amount of hardness minerals and other dissolved solids in water present obstacles to good cleaning. Hardness minerals can cause spotting and filming on instruments. They must be effectively tied up or sequestered if the cleaning results are to be satisfactory. The harder the water the more concentrated the solution will be.

Time: With enough time, simple water will remove all types of blood.

Detergent: The wetting ability of detergent will help water flow to all places in and around the blood, even if water-repellent fats and oils are used.

Enzyme: Enzyme cleaners break down long fibrin fibers, allowing water to wash away the pieces…but time is needed for this action to take place. The time needed to act depends on many factors from concentration, hardness, pH, along with the type an amount of soil to be removed.

Temperature: Low temperature to start (to prevent denaturizing) and higher temperature later to maximize detergent cleaning efficiency. Make sure you have chosen the correct temperature for the correct cycle setting.

pH: The pH scale goes from 0 to 14. The halfway point is 7(neutral); there is a balance between acidity and alkalinity. Such a solution is neutral (7). 0 to 6 on the scale is called an acid. 8 to 14 on the scale is called alkaline or a base

High pH: Moist alkaline conditions dissolve dry proteins and cause fibrin to break, similar to enzyme action.

Agitation: Physical agitation from water spray brings fresh cleaning solution to the soiled area and washes away used-up detergent. Spray impulses loosen blood through physical impact. Spray from different angles helps prevent blocking from instruments piled atop one another. Remember do not stack or over load instruments in any tray. Evenly spread instruments within the tray to provided optimum exposure to the cleaning solution and spray arm action.

Total alkalinity: Is the total concentration of bases in water expressed as parts per million (ppm) of calcium carbonate (CaCO3). Total Alkalinity is a measure of the buffering capability of water to resist changes in the pH level. It is desirable at every given level of pH, to have a high level of Alkalinity. Alkalinity then is the ability to neutralize acids.

What hinders the cleaning of blood from instruments?

Speed: Hospitals that must turn instruments around quickly cannot rely on simple water to do the job. Water must be made more powerful through chemical assistance, enzyme, detergent, high pH, temperature and physical assistance through spray agitation. Each of these elements need time to work.

Initial Heat: The denaturing action of heat on blood makes it insoluble enough to interfere with rapid cleaning. Start with a cool rinse.

Drying: Dried blood and proteins are much more difficult to clean than moist blood. Clean instruments as soon as possible after surgery or keep moist, if possible, while waiting.

Glutaraldehyde: Glutaraldehyde denatures proteins, making them more insoluble.

Obstructions: Closed hinges on instruments are much more difficult to clean. Overloading causes blockage of spray agitation. High mineral content of water causes spray arms to become blocked. Tall items can prevent rotation of spray arms.

Insufficient Amount of Chemicals: Detergents may be weak, or enzymes may be ineffective. Blocked or kinked dispenser tubing may be limiting the amount of chemicals being pumped into the washer/disinfector. Broken pumps, incorrect

temperature, coupling systems and spinner arm concerns all play a role in providing properly chemical activity. Also know how your chemicals are stored because temperature can inactivate them if stored improperly.

Why Monitor the process?

Washers fail to clean for many reasons. Testing provide a means of monitoring the variables that influence the effectiveness of a washer. As stated earlier some of these variables are water quality, time, detergent, enzyme, temperature, pH level, agitation, speed, initial temperature, drying time, obstructions, and insufficient amount of chemicals. Monitoring of the cleaning process should be done with an independent test; the TOSI® is such a test.

The TOSI® is used for cleaning verification. The TOSI® is comprised of components of blood. There is no secret ingredient that biases the TOSI® toward one cleaning method or another.

The TOSI® is comprised of hemoglobin, fibrin and albumin. Hemoglobin is the "red" cells in blood. It is completely water soluble. Thus, no chemistry is needed to wash away this component of the test. Water alone will do it. If hemoglobin remains on the test after a wash cycle, then it means one of two things occurred:

1) Poor mechanical action. In other words, water in sufficient volume did not reach the test. This could happen because of blocked spray arms, twisted spray arms, a bad coupling (so water does not get out to the arms) or a pump failure.

2) Hot water is used during the cold-water pre-rinse. If this occurs, the heat water fixes or denatures the protein. At 110˚F, protein, including blood, is rapidly denatured and becomes highly water insoluble thus water alone will not wash it away.

Albumin is also water soluble and the same rules apply to albumin as the hemoglobin.

Fibrin is the coagulating agent in blood. When we get cut, it is the fibrin cells that bind together to clot and block bleeding. Fibrin is highly water insoluble. On the TOSI® test, it is the translucent layer. It is below the hemoglobin/albumin layer. Being water insoluble, chemical agents, enzymes or high alkaline detergents, are needed to break it down and render it water soluble. This occurs in a process called hydrolysis. Literally, this means the chemical agent alters the fibrin cell, rendering it water soluble. If the fibrin layer remains on the TOSI® test it is indicative of any one of the following errors:

1) Proteolytic detergent (enzymatic of alkaline) did not reach the wash chamber or did not reach the chamber in sufficient concentration to be effective.

2) Exposure time was insufficient. Detergents need time to interact with the insoluble cells and break them down (hydrolyze) to be washed away. By observation, this time period should be for at least 5 minutes.

3) Incorrect temperature. Both enzymatic and alkaline detergents are sensitive to temperature. Enzymatic detergents work best in the range of 100˚ - 125˚F. Alkaline detergents work best at temperatures 150˚F and up. If the temperature is outside of the optimal range, it will reduce the effectiveness and could even render the detergent completely ineffective.

4) Poor water quality. Detergents of any kind are sensitive to water quality - in particular to the water hardness and pH-level. If the water is exceptionally hard, or if the pH level is above or below the optimal range for the detergent, it will render it ineffective.

The TOSI® is part of our Quality Improvement Program (sometimes called Quality Management System) which allows your department to improve their automatic cleaning process. This would be the PQ (Performance Qualification), part of this improvement process.

By implementing a QIP, you will be able to detect concerns before they become a larger problem.

The TOSI® is the standard for cleaning verification for automatic washers. It follows the ASTM D7225 guidelines (the only cleaning verification test on the market, that meets this standard.

Monitoring the cleaning process with **independent verification products** is now becoming the standard. Nancy Chobin has pointed this out in her article “The Value of Monitoring the Cleaning Process “…the processing area needs a reliable methodology that will monitor the effectiveness of the cleaning process similar to the products in use to monitor the effectiveness of various sterilization process…the TOSI® tools clearly identified sub-optimal cleaning processes/practices. The results correlated well to the artificial controls used and identified the lack of parts of the process (e.g., enzymatic pre-soak, ultrasonic cleaning)…”

In 2017 in ST 79 AAMI is recommending at least daily testing of instrument reprocessing equipment, including the washer-disinfector.

One very important thing to keep in mind is that the FDA, suggests that any simulated-use testing be done with a surrogate device that closely approximates the actual types of soils the instrument is to be exposed to in clinical uses. Further, the surrogate device should be made of the same type of material as the instrument it represents. This is the TOSI®: dried blood soil on a stainless coupon is directly analogous to dried blood on a stainless-steel instrument.

Remember that JC, AORN, and AAMI all recommend that medical facilities have Quality Improvement Process in place.

JC in standard E.C.6.20***- Medical equipment is maintained, tested and inspected***. Using the TOSI ® helps you meet this requirement.

Using the TOSI® blood soil test according to the manufacturer's guidelines helps ensure adherence to the various standards and thus a properly functioning cleaning process.

Because cleaning deals with water, remember the word "W.A.T.E.R." when it comes to cleaning and cleaning verification.

–**W**ater- quality of the water being used has a direct effect on the outcome; pH, hardness, taps, distilled or de-ionized. Thus, the reaction of the cleaning agent depends on good water quality and directly impacts the concentration and the time (exposure time) the cleaner has to work, more is better but not always.
–**A**gitation - helps to suspend soils so detergents can remove them, friction
–**T**emperature - increasing or decreasing the temperature changes the rate of chemical reaction
–**E**quipment & Employee - always follow manufactures instruction, understand how your equipment and supplies work and **train your staff in understanding why they are doing each task**
–**R**egulations - guidelines by AAMI, AORN, and JCAHO both support the monitoring of the cleaning process.

Questions

True or False: Circle the best answer

1. The blood cells colored with hemoglobin are fairly easy to wash off instruments, but the clear fibrin material is much more difficult? True or False
2. Moist alkaline detergents dissolve dry proteins and cause fibrin to break, similar to enzyme action? True or False
3. In general, the harder the water the more detergent/ enzyme solution will be used in the cleaning process? True or False
4. The TOSI® is an independent verification product that represents blood on surgical stainless steel? True or False
5. A Quality Improvement Process is supported by AORN, AAMI, and JC for monitoring the cleaning process? True or False
6. Cleaning is the removal of all visible dust, soil, any other foreign material and some microorganisms? True or False
7. AORN and AAMI are stating that medical washers should now be tested at least daily? True or False
8. Following the manufactures instructions is not important in the cleaning process? True or False
9. In the Pre-wash cycle the temperature should be colder (under 113ºC) rather than hotter (greater than 113ºC)? True or False
10. Staff should have at least yearly training on the operation of the automatic washing equipment this is important in making sure instruments are getting clean? True or False

Answers

1. True
2. True
3. True
4. True
5. True
6. True
7. True
8. False
9. True
10. True

Updates SMK 2/2019