

**SUGGESTED POLICY FOR MONITORING THE CLEANING
EFFICIENCY OF AN AUTOMATED INSTRUMENT
WASHER/DISINFECTOR PROCESS USING THE
T.O.S.I. Blood Soil Test(Daily & weekly Testing)**

SUBJECT: Medical Automated Instrument Washer/Disinfector Cleaning Monitoring

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: 11/2010

PURPOSE:

To *monitor* the automated instrument washer/disinfector *process* to ensure proper cleaning *and reduce risk to personnel or patients.* (1, 10, 12, 13)

POLICY:

This policy is for inspection and testing on a daily basis of the medical automatic washer with the T.O.S.I. blood soil test. The T.O.S.I. blood soil test is to be used according to the manufacturer's guidelines to ensure that the cleaning process is occurring and the automated instrument washer is functioning properly. (1, 6, 7, 8, 9, 10, 12, 13)

RATIONALE:

"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"(1).

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..."***

The 2006 JCAHO standard E.C.6.20 states that all medical equipment is maintained, tested and inspected.

The 2008 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. (1, 12)

The medical automatic washer is considered a piece of medical equipment. Medical washers need to be properly functioning to provide the best patient care possible and to help reduce the incidence of hospital-acquired infections

"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." (11,13)

An automated 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 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, 13)

Cleaning 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 form 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 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 to remove. Thick droplets of dried blood have so much fibrin; even the colored hemoglobin can be trapped and held in place. (3, 4, 13)

Another factor that makes blood difficult to clean is its ability to become insoluble when heated. Heating causes blood to "denature.". Denaturing is similar to what happens to eggs cooked 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, as is dried blood. The proteins in blood are similar to albumin proteins in eggs.

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. (7, 13)

Proper cleaning is critical. The T.O.S.I. blood soil provides an independent objective test of clean and allows the Healthcare professional to monitor and ensure proper cleaning in the automated instrument washer/disinfector *process*. (1)

JCAHO, AAMI, AORN, IAHCSSM recommend that Sterile Processing departments have process performance in place (1, 5, 12, 13).

The FDA, AAMI and other regulatory bodies recommend 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 use. Further, the surrogate device should be made of the same type of material as the instrument it represents

Using the T.O.S.I. blood soil test according to the manufacturer's guidelines helps ensure adherence to all guidelines and standards and thus 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)

Begin with performing an equipment inspection as specified on the log sheet. Start with the spray nozzles/arms and proceed with all items listed on the work sheet. After observations and equipment check are completed, proceed with the first test and record all results.

Daily Inspection & Testing

- Follow manufacturer guidelines concerning the daily inspection of equipment (spray arms, screens, etc.)
- 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 visual verification that the solution is actually being used.

- At the beginning of each day pick a washer to test. Test a different washer each day if there is more than one.
- Secure one T.O.S.I. to a rack and place it in an empty instrument tray (in bottom of the tray).
- Select the middle shelf of the rack.
- Run in an empty machine.
- Record all results.
- Examine the T.O.S.I. for visual cleanliness. Compare the test to the 0-5 T.O.S.I. Test chart.
- Make any necessary adjustments to the washer as indicated by comparing the results found on the test object and the T.O.S.I. chart.
- The next day, test another machine. If there is only one machine, rotate the test to a different shelf.
- Over time, continue to vary the shelf and position the tray to test all possible configurations.

A daily test of at least one machine in a multi-machine department will help identify any general issues that may arise with the equipment.

Weekly Inspection and Testing

Do a complete test of all of the inputs of the automatic washer (temperature, pH, hardness, etc.)

Equipment Inspection

- Inspect all washer equipment (spray arms, screens, etc.) according to the log sheet.

Water Quality

Follow these steps first for cold water, then hot water:

- Use an Aqua Test (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 seasonally. It is important to establish a base line (target values) for your water and to compare your results to that base line/value.

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., apply to the smooth surface on the T.O.S.I. rack)
- Tempachek-90 should be removed and read immediately after the **COLD WATER RINSE** stage. If the machine has a window, the result can be read through the window; if not, the cycle must be stopped. Belimed, Getinge, & Hamo machines cannot be stopped; results must be read through the window.
- Record results on log sheet.
- Temperature should not exceed 110 degrees F. Immediately report any result that exceeds this temperature.

Thermal Disinfection stage

- Use one Tempachk-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 (i.e., apply to the smooth surface on the T.O.S.I. rack).
- Tempachek-170 should be removed and read after the **THERMAL DISINFECTION STAGE** and before the drying stage.
- Record results on log sheet.
- Report any deviation from targeted temperature.
- TESTING IS COMPLETED AFTER THIS CYCLE COMPLETES
- Abort cycle if possible

Blood Soil Test

- 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, three tests are used. One test per level on each rack is the standard.
- Once a week on a designated day, secure one T.O.S.I. in the center of an empty tray in each washer/disinfector. Do this as many times as you have shelves.
- If multiple shelves are present, place a tray with a T.O.S.I. on each shelf.
- Load a rack with its T.O.S.I in each washer/disinfector to be tested. The T.O.S.I. should be placed in an empty tray in an empty chamber (bottom of the tray).
- Process using the normal procedure/cycle (usually the instrument cycle).
- Examine the T.O.S.I. for visual cleanliness. Compare the test to the 0-5 T.O.S.I. chart scale.

- Record results.
- Immediately report any test failure to department management.
- Use the results found when comparing the test object and to the T.O.S.I. chart to determine what, if any, adjustments need to be made. Make necessary adjustments.
- The next week, repeat the process.
- Record all results.

Testing to Challenge Staff Practice(15,19):

- Follow this protocol to challenge the loading practices of Sterile Processing Personnel.
 - The frequency of testing is set by the department (daily, weekly...) in each washer/disinfector, secure one ProFormance™ Washer Test, in the center of a tray of dirty instruments.
 - The larger the set, the greater the cleaning challenge for the Washer (use a non-mesh style mini basket).
 - Place the tray on only one of the shelves if multiple shelves are present.
 - Load the washer/disinfector with a normal load of dirty instruments.
 - Process using your normal procedure.
 - Examine the ProFormance™ Washer Test for visual cleanliness.
- Compare the test to the 0-5 ProFormance™ Washer Test chart scale.
- Record results.
 - Make any adjustments to the washer/disinfector, loading practices, etc., as needed according to the results found from the test object and comparing them to the ProFormance™ Washer Test chart.
 - The next testing day, place the tray on a different shelf.
 - Over time, continue to vary the shelf and position the tray to test all possible configurations.
 - Record all results.
 - Make any adjustments to the washer/disinfector as needed according to the results found from the test object and comparing them to the ProFormance™ Washer Test chart.

Maintenance on Equipment (1,5,12,13):

- After any maintenance on the equipment, perform a test using the T.O.S.I. Washer Test to ensure that the equipment is cleaning properly.
- Follow the weekly test process.
- Have the maintenance person wait until the test results are complete before leaving.

Possible False Positive Results with the TOSI

- ***Tiny Red Spot on TOSI Plate:*** Very rarely, but nonetheless possible, is a slight imperfection in the stainless steel plate which leads to oxidation of the metal. The result is a little red spec which could be confused with the hemoglobin soil on the TOSI. The easiest way to double check for such a thing is to directly employ mechanical action (with a gloved hand, preferably with the aid of an instrument cleaning brush) under water. If the spec remains, then it is definitely not the TOSI blood soil that remains.
- ***Ghosting on the TOSI Plate:*** A whitish staining is observed on the TOSI plate, which can be confused with fibrin protein remaining on the TOSI. This usually happens at a facility that has hard water. If allowed to dry and the TOSI is read at that point, hard water staining may be observed on the TOSI plate. The simplest method is to submerge gently the TOSI plate in a bath of water. If the “disappears” when wetted, this indicates a non-test soil residue (likely hard water minerals or detergent) and not the blood test soil.

RESPONSIBILITY:

Central Service personnel are responsible for the proper use, result interpretation, and documentation of the T.O.S.I. indicator when used on an automated instrument washer (1,5,12,13)

Staff in-service and training on the equipment and proper T.O.S.I use should be done at least once each year.

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