

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

**SUBJECT:** Automated Instrument Washer/Disinfector Cleaning Monitoring

**DEPARTMENT:** Central Service

**APPROVED BY:**

**EFFECTIVE:**

**REVISED:** 06/15/05

**PURPOSE:**

To *monitor* the automated instrument washer/disinfector *process* to ensure proper cleaning *and reduce risk to personnel or patients.* (1,2,19,21,22)

**POLICY:**

T.O.S.I. blood soil test is designed to monitor the cleaning function of an automated instrument washer. To ensure that the automated instrument washer *process* is cleaning properly, a T.O.S.I. blood soil test should be used to monitor the occurrence of cleaning instruments. 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. (1,2,3,4,15,16,17,18,19, 21,22)

**RATIONALE:**

"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." (20)

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. (5,6,7,17,21,22)

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. (5,6)

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. (16)

Proper cleaning is critical. The T.O.S.I. blood soil 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*. (21,22)

JCAHO and AAMI both recommend that Sterile Processing departments have process performance in place (1,2,3,8,9,10,11,21,22). Using the T.O.S.I. blood soil test according to the manufacturer's guidelines helps ensure adherence to both JCAHO and AAMI 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 manufacture guidelines concerning the daily inspection of equipment (spray arms, 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

Bring to the attention any concerns on the equipment that the inspection revealed to the proper person in the department to address.

### **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 and 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 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 (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 8666A) 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.
- Secure one T.O.S.I. to a rack and place it in an empty instrument tray.
- Run in an empty machine.
- Process using the normal procedure/cycle.
- It is suggested that each cycle be tested to ensure that it is working properly. If a machine uses three cycles, all three should be tested each week.
- Examine the T.O.S.I. for visual cleanliness. Compare the test to the 0-5 T.O.S.I. chart scale.
- Record results.

### **Blood Soil Test - Continued**

- 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.

### **Maintenance on Equipment(15,19):**

- 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.

### **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. (1,2,3,4,21,22,12)

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

### **REFERENCES:**

1. ANSI/AAMIST35 - 2003 - 9.2e- Documentation of decontamination processing parameters
2. ANSI/AAMIST35 - 2003 - 9.1 - General Rationale
3. ANSI/AAMIST35- 2003 - 9.2 - Quality process
4. ANSI/AAMIST35 - 2003 - 7.4.3.3
5. Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385
6. Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310
7. OSAKA REPORT; Importance of the cleaning test; University of Osaka, Department of Medicine, Ryo Fushimi, 2000
8. JCAHO - 2000 Hospital Standards -IC.1- The organization uses a coordinated process to reduce the risks of endemic and epidemic nosocomial infections in patients and health care workers.
9. JCAHO - 2000 Hospital Standards - IC.6.2 - The infection control process includes at least one activity aimed at preventing the transmission of epidemiologically significant infections between patients and staff

**REFERENCES continued:**

10. JCAHO - 2000 Hospital Standards- PE.1.15 - Quality control checks, as defined by the hospitals, are conducted on each procedure.
11. JCAHO - 2000 Hospital Standards - Pl.5-Improved performance is achieved and sustained
12. JCAHO - 2000 Hospital Standards - EC.2.1- Staff members have been oriented to and educated about the environment of care, and process the knowledge and skills to perform their responsibilities under the environment of care management plans
13. JCAHO - 2000 Hospital Standards
14. ANSI/AAMI
15. <http://www.proformance-test.com/WallChart/WallChart.html>
16. <http://www.proformance-test.com/SupportMaterial/TechnicalBulletin1.html>
17. <http://www.proformance-test.com/SupportMaterial/BloodAsASoilonSurgicalInstruments.htm>
18. <http://www.proformance-test.com/SupportMaterial/StandardisedTestSoilBlood1.htm>
19. <http://www.proformance-test.com/index.html>
20. 510(k) Summary and Overview; Safety, Efficacy and Microbiological Considerations,. The System 83 plus Washer -Disinfector; Custom Ultrasonics, Inc,1998, page 7.
21. *page 23, Section 9.2 ANSI/AAMIST35 - 2003*
22. *page 19,Section 7.4.4 ANSI/AAMIST35 - 2003*