

**Competency for Weekly Testing of the Automatic Washer Process with
TOSI only.**

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 T.O.S.I.(**T**est **O**bject **S**urgical **I**nstrument) 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: Most 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 T.O.S.I. is such a test.

The T.O.S.I. 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 110F, 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 need 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 or 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 - 125F. Alkaline detergents work best at temperatures 150F 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 which allows your department to improve their automatic cleaning 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 D277 guidelines (the only cleaning verification test on the market) and is outlined in the new AAMI ST 79 annex D.

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)..."

AAMI and AORN are now recommending WEEKLY testing of instrument reprocessing equipment, including the washer-disinfector. These recommendations can be found in **AAMI ST 79 Section 7.5 and AORN Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment 2008.**

One very important thing to keep in mind is that 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 uses. Further, the surrogate device should be made of the same type of material as the instrument it represents. This is the T.O.S.I.: dried blood soil on a stainless coupon is directly analogous to dried blood on a stainless steel instrument.

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

JCAHO in standard E.C.6.20- **Medical equipment is maintained, tested and inspected.**

Using the T.O.S.I. blood soil test according to the manufacturer's guidelines helps ensure adherence to both JCAHO, AORN, and AAMI 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.

–**Water**- 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.

–**Agitation** - helps to suspend soils so detergents can remove them, friction

–**Temperature** - increasing or decreasing the temperature changes the rate of chemical reaction

–**Equipment & Employee** - always follow manufactures instruction, understand how your equipment and supplies work and **train your staff in understanding why they are doing each task**

–**Regulations** - guidelines by AAMI, AORN, and JCAHO both support the monitoring of the cleaning process.