Suggested daily policy for monitoring the performance of sonic cleaners and/or automatic washers cleaning ability for lumens/cannulated items with the LumCheck™ Cleaning verification test.

SUBJECT: Monitoring the performance of a sonic cleaners and/or automatic washers cleaning ability for lumens/cannulated items daily.

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: 08/2017

PURPOSE:

To monitor the automatic cleaning process of lumen/cannulated instruments to ensure proper cleaning and reduce risk to personnel or patients. (1,9,10,11,12)

POLICY:

TOSI® LumCheck™ blood soil test is designed to monitor the cleaning function of an automated instrument washer ability to clean cannulated or lumen instruments. To ensure that the automated instrument washer process is cleaning properly lumen/cannulated instruments, a TOSI® LumCheck™ blood soil test should be used to monitor the occurrence of cleaning lumen / cannulated instruments. The TOSI® LumCheck™ 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. (1,6,7,8,9,10,11,12,13)

RATIONALE:

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...”Sonic cleaners are considered mechanical cleaning equipment by AAMI.
“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)

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)

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. (7)

Proper cleaning is critical. The TOSI® LumCheck™ 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. (1)

JCAHO and AAMI both recommend that Sterile Processing departments have process performance in place (1,5,8,12). Using the TOSI® LumCheck™ 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.”(1)

The LumCheck™ can be used in either an automatic washer that has the capability to do lumens/cannulated items or a sonic cleaner that also has that capability.

Automatic washers have special racks for cleaning lumens/cannulated items. It is these types of racks that should be used. Many sonic cleaners use a flow system to flush (or pull / suction) lumens/cannulated items (with approved cleaning solution), the LumCheck™ should be used to check the performance of these types of sonic cleaning units.

TOSI® LumCheck™ blood soil test is designed to monitor the cleaning function of an automated instrument washer (or sonic cleaner) ability to clean cannulated or lumen instruments.

**LumCheck™ Blood Soil Test**

*The LumCheck™ is a daily test.*

1. Testing is done in an empty load (no instruments).
2. Unscrew LumCheck™ – device; detach part A (marked with slot) from part B (see diagram below).
3. Open protective pouch of TOSI® – LumCheck™ and insert the test object (part C) in part B as shown in diagram. Do not touch the area covered with test soil.
4. Close LumCheck™ – device again.
5. Connect LumCheck™ –
   a. Sonic Cleaner
      i. Connect the LumCheck™ device with one of the channel irrigation system of the sonic (for example luer-lock). If equipment has more than one channels (ports) you must check at least one port. If checking more than one port (channel) they must all be checked at the same time.
      ii. After connection start the cycle according to your manufactures manual instructions (example MIS cycle).
   b. Automatic washer
      i. Connect the LumCheck™ device with one of the channel irrigation system found on the special rack for lumen / cannulated items (a MIS type rack) (for example luer-lock). If equipment has more than one channels (ports) you must check at
least one port. If checking more than one port (channel) they must all be checked at the same time.

ii. After connection start the cycle according to your manufactures manual instructions (example MIS cycle).

6. Open the device after the reprocessing cycle: disconnect part A from part B to remove the TOSI® – LumCheck™ without touching the test soil area.

7. For visual evaluation of the result, use the TOSI® evaluation table.

Blood Soil Test - Continued
- Immediately report any test failure to department management.
  - A failure may suggest testing of other parameters of the cleaning process like temperature, dilution of cleaning solutions and water quality.
  - Use the results found when comparing the test object and to the TOSI chart to determine what, if any, adjustments need to be made. Make necessary adjustments.
  - This test is done at least weekly preferably daily on the equipment.
  - Record all results in a log book (sheet).

Maintenance on Equipment (6,9):
- After any maintenance on the equipment, perform a test using the TOSI® LumCheck™ 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 TOSI® indicator when used on an automated instrument washer. (1,5)

Staff in-service and training on the equipment and proper TOSI® use should be done at least once each year.

REFERENCES:

1. ANSI/AAMI-ST 79;2009 A
2. Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385
3. Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310
4. OSAKA REPORT; Importance of the cleaning test; University of Osaka, Department of Medicine, Ryo Fushimi, 2000
5. www.jcaho.org
11. 510(k) Summary and Overview; Safety, Efficacy and Microbiological Considerations,. The System 83 plus Washer -Disinfector; Custom Ultrasonics, Inc,1998, page 7.
12. www.aorn.org
Competency Record for Using the LumCheck™

Name: __________________________________________

Competency Statement: Complies with policy and procedure for …..

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)

Equipment/Model Number: __________________________________

Evaluator: __________________________________

Learner: _______________________________________________________

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<tr>
<th>Critical Behaviors</th>
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<tr>
<td>Review the specific information(instructions) from the manufacture on the sonic that is being tested (Model/Type/specific)</td>
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<td>Review Hospital Policy on cleaning of instruments with this specific sonic and the Lumcheck™ policy</td>
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<td>Describes the purpose of cleaning and decontamination of surgical instruments especially those with lumens</td>
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<td>Selects and wears the appropriate personal</td>
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protective equipment

Gather appropriate supplies to perform test (LumCheck™…)

Ensure that no instruments are attached to equipment during the testing process (test empty). Must test at least one channel.

Unscrew LumCheck™ – device; detach part A (marked with slot) from part B (see diagram below).

Open protective pouch of LumCheck™ and insert the test object (part C) in part B as shown in diagram. Do not touch the area covered with test soil.

Close Lumcheck™ – device again

Connect LumCheck™ device with one of the channel irrigation system of the equipment to be tested (luer-lock) and start the cycle according to your manufacture instructions.

Open the device after the reprocessing cycle: disconnect part A from part B to remove the LumCheck™ without touching the test soil area.

For visual evaluation of the result, use the TOSI® / LumCheck™ evaluation table

Record Results

A negative result is no test soil is left on the test coupon. If a positive result (test soil left behind) is obtained. Notify the proper person in the department.