SUBJECT: Robotic Arm Testing for residue blood

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: 08/2017

PURPOSE: To test for detection of blood residue inside and outside of a robotic arm and to help ensure proper cleaning *and reduce risk to personnel and patients*.(*1,5,9*)

POLICY: The Robotic ARM Check™ (R.A.C.) test detects blood residues inside and outside of the robotic arm. The random testing of various robotic arms is to be used according to the manufacturer's guidelines to ensure that the cleaning process is being done properly. (*1,5,9*)

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*).

One such problem is blood residual inside the channels of a robotic arm.

Detection of blood residues inside the channel of a robotic arm is very important and distinguishing between blood and other types of residues can be very confusing. Finding any blood residue left inside a channel that has been cleaned is never good and the implications are even more serious.

There has been a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies, which under normal conditions; achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt (7). Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate (8).

It is important to test any surface that is suspect of blood residue. The danger of unclean surfaces in a hospital or 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.

"Many types of soil could be present on reusable medical devices, but dried blood is especially difficult to clean. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning."[i]

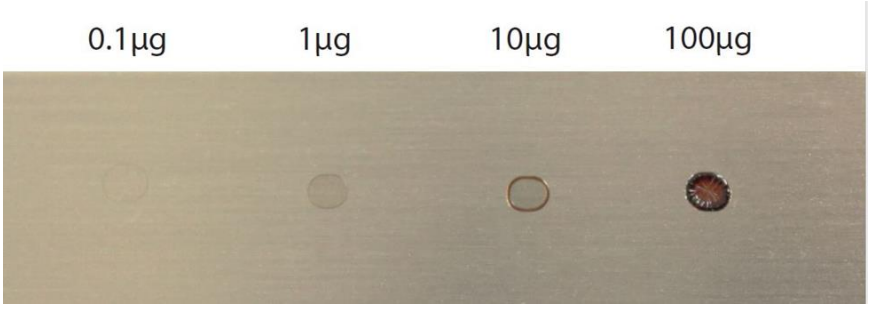
"Blood is composed primarily of water-soluble proteins. If blood remains on an instrument after the wash phase of a mechanical cleaning equipment cycle, the water-soluble proteins will be denatured in any subsequent heated process, such as the hot disinfection phase of a washer-disinfector or washer-sterilizer cycle or a steam sterilization process. Denaturing proteins creates a soil that is much harder to clean the next time through the washing process. It is imperative that all traces of blood, body fluids, and debris be removed during the wash phase of a mechanical cleaning equipment cycle. Failure to do so could result in undetected bioburden that could pose a risk to employee health or result in a patient infection.".[ii]

"…Visual detection alone does not allow one to detect residual bioburden that may remain on cleaned devices…"[iii]

"…16% of the loaner instruments tested positive for blood…."[iv]

Areas such as lumens / channels or devices that are cannulated or have dead ends are by nature difficult to clean let alone check "verify" if they are clean. Medical devices like robotic arms have these types of design features and thus are difficult to verify that they are clean in these areas.

Since the current standard is visually clean, it is assumed that you can see dirt or the stain (bioburden) on a medical device and then re-clean it. The real goal is to detect a level low enough so one can be certain that the item tested is clean in case nothing is visually detected. A stain the size of only 1µg is visible to the naked eye on an instrument and no one would even consider using an instrument on the next patient with a stain that size. As a result, the detection limit to be achieved needs to be at least around this visibility limit of 1µg. [v]



If robotic arms are not clean, the procedures can be ineffective because of the residual bioburden like dried blood left inside a channel or on the outside of the robotic arm distal tip will be an issue. Dried blood is hazardous to the employees and to the next surgical patient upon which the instruments are to be used. Robotic arms especially the channel that comes in contact with patients need to be free from blood residuals. Looking inside a robotic arm channel is nearly impossible without damaging it. The Robotic ARM Check™ does allow you to test specifically for blood residue inside the biopsy channel by swabbing this specific channel surface.

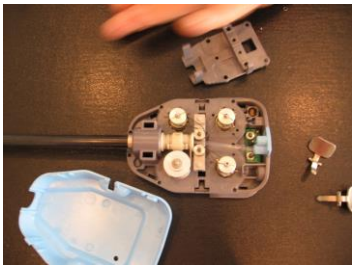
The use of a surface detection tests like Robotic Arm Check based on the HemoCheck™ technology is supported in the AORN Recommended Practices and Guidelines as well as AAMI ST 79. The HemoCheck™ is described in Annex D of ST 79 as one such test. The Robotic Arm Check is a product that helps you verify that your process for cleaning robotic arms is working properly.

Having a quality system to help monitor robotic arm channels that you might suspect have not been cleaned properly and have blood residue is an important function of any Infection Control program. Testing these channels with the R.A.C. and recording results in a log is one such program.

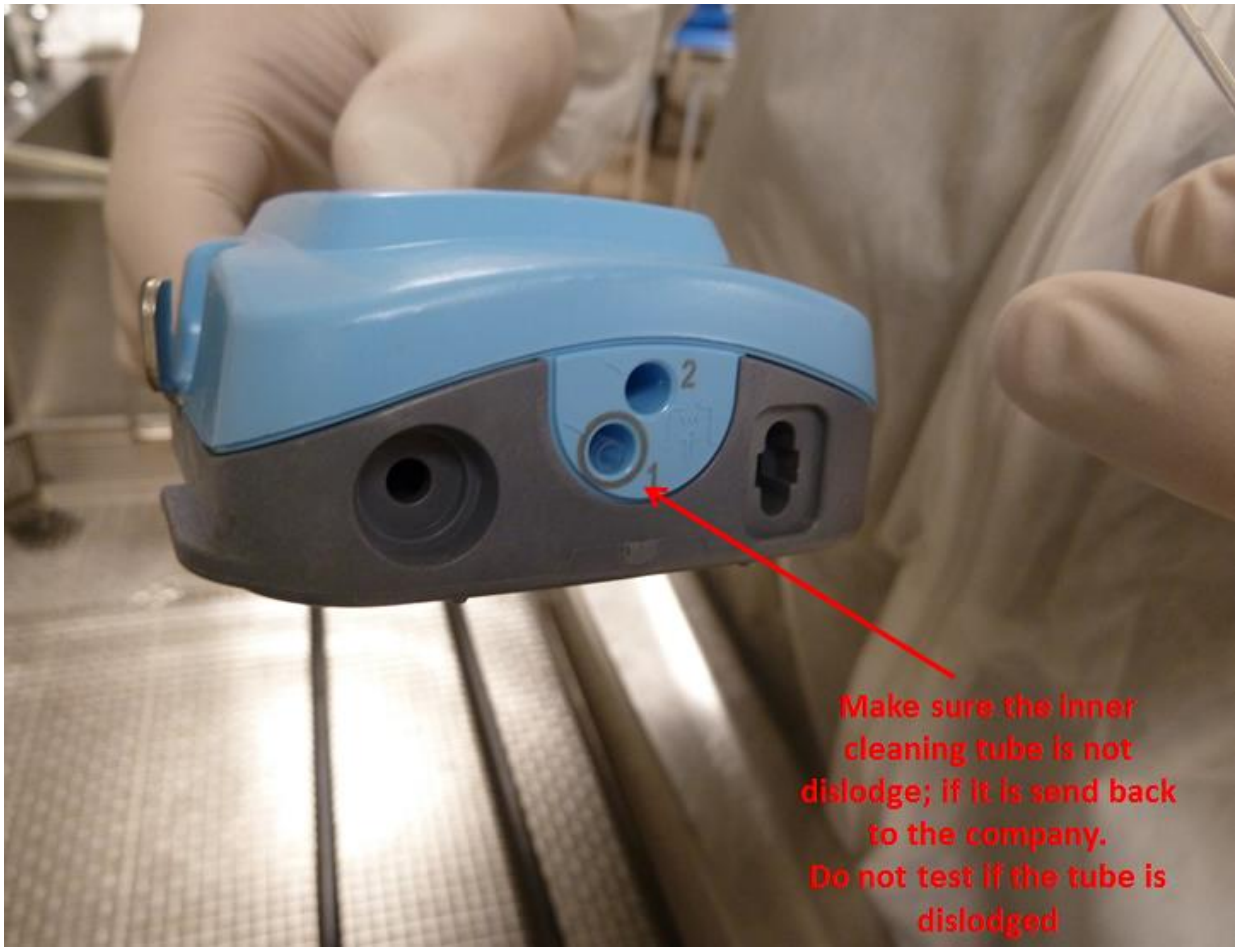
The use of the Robotic ARM Check™ is an excellent tool to use for training of new employees as well as establishing a Quality Improvement Program for checking whether manual or automatic cleaning is done. The frequency of testing (i.e. after each cleaning, daily, weekly, etc.) of Robotic arms needs to be determined by each department.

Models that can be tested with the Robotic Arm Check™

Inside a robotic arm



<u>Do not test if the inner tube is dislodged</u>



PROCEDURE:

RAC™: The test kit for detection of residual blood and or other oxidizing agents inside the channel of a robotic arm. *Read instructions once before testing. Also gather all the appropriate supplies before testing.*

Note: A positive result is proof of remaining residual blood and or other oxidizing agents in the tested area only.

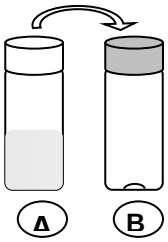


Figure 1

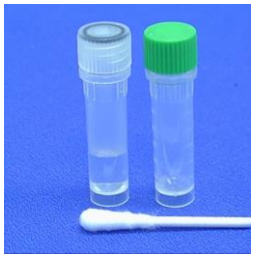


Figure 1

A: Indicator-vial (transparent cap), B: activator-vial (green cap)

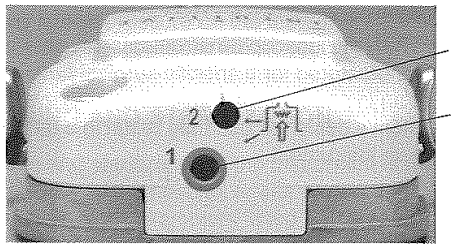


Figure 2

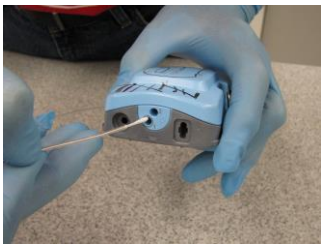


Figure 3

Figure 4

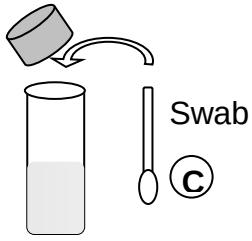


Figure 4

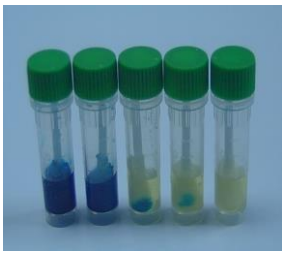


Figure 5

If the test has been refrigerated allow it to come to room temperature before using. Also use the correct PPE when testing (gloves…)

1. **Open the test kit. Included are: holder, sterile water, indicator vial (transparent cap), activator vial (green cap), and special swab.**
2. Testing of a robotic arm channel is done after cleaning and before the sterilization/disinfection process.
3. **Open the indicator vial (transparent cap) and transfer the liquid into the activator vial (green cap) – Figure 1. Place vial in holder.**
4. **Moisten the cotton swab with a drop of clean water. Do not use chlorinated water.**

5. **Before testing look to ensure that the tube/ channel is not dislodged and sticking out. If it is do not test. Return the robotic arm to the manufacture, you should not try and push the tube back into the housing.**

6. **Slowly insert the swab end into the channel you want to test** do not force. (there may be a little resistance to the swab) **If testing a DaVinci® robotic arm channel push the swab into main flush port marked 1 all the way in until it stops at the tip of the channel. Do this one (1) time and pull out slowly making sure the swab does not touch any surface before it is place in the correct vial for testing. – Figure 2 and 3.**

7. **Once you have pulled the swab out of the channel cut the swab end off with scissors into the green capped (activator vial). (Note: you can place the swab tip into green vial before cutting off). Do not touch the swab. Recap the vial with the green cap. – Figure 4.**

8. **Shake the activator (green top) vial at least five times.**

9. **Check the swab over a period of 30 seconds for a color change to any blue-green, which can indicate** residual blood and or other oxidizing agents in the tested area only.

10. **In the presence of large amounts of** residual blood and or other oxidizing agents **the entire indicator solution will become dark blue - Figure 5.**

11. **Record the result immediately—late color changes are not valid. The yellow color change after activation is a normal reaction and does not indicate residue. Any blue or green is a positive result – Figure 5.**

12. **If you obtain a positive result (blue-green) report that result immediately and clean the robotic arm again according to policy. After cleaning retest the robotic arm until you get a negative result. Sterilizing a robotic arm that is dirty can compromise the sterilization process.**

Please Note the following

PRINCIPLE

Due to the high content of Peroxidases in blood an enzymatic reaction is used for detection of blood residues.

MEASURING RANGE

The test kit can detect 0,1 µg of blood by showing a slight blue-green spot. 1 µg of blood in the test will already give a dark blue colour.

INTERFERENCES

Oxidising agent like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a colour change too. In this case the test cannot be used to detect blood residues

STORAGE

Store Robotic ARM Check™ in closed pouches in a cool place (2°C- 25°C). Keep away from light and heat

RESPONSIBILITY:

The Central Service manager is responsible for training, assuring initiation, completion and analysis of the monitoring assessment activity for testing of blood residuals on various surfaces.

Sample Competency for Cleaning of Robotic Arms

Name: _____

Competency Statement: Complies with policy and procedure for cleaning and testing robotic arms with the Robotic Arm Check™ (R.A.C.).

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 Behavior	1	2	3
Review Hospital Policy on cleaning Robotic Arms			
Review and follow manufacture guidelines on cleaning robotic arms			
Describes the purpose of cleaning and decontamination of Robotic Arms			
Selects and wears the appropriate personal protective equipment needed to test robotic arms			
Gather appropriate supplies to perform test on robotic arms			
Once cleaning is done and before sterilization/ disinfection the robotic arm channel / shaft should be tested			
If the R.A.C. test kit has been refrigerated, allow it to come to room temperature before using.			
Open the R.A.C. test kit. Included are: holder, sterile water, indicator vial (transparent cap), activator vial (green cap), and special swab. Make sure you keep swab in package until needed.			
Testing of a robotic arm channel is done after cleaning and before the sterilization/disinfection process. Testing can be done on the clean side during inspection and assembly.			
Open the indicator vial (transparent cap) and transfer the liquid into the activator vial (green cap) – Figure 1. Place vial in holder.			
1. **Moisten the cotton swab with a drop of clean water. Do not use chlorinated water. NOTE: Before testing look to ensure that the tube/ channel is not dislodged and sticking out. If it is do not test. Return the robotic arm to the manufacture, you should not try and push the tube back into the housing.**			

Slowly insert the swab end into the channel you want to test do not force. (there may be a little resistance to the swab) **If testing a DaVinci® robotic arm channel push the swab into main flush port marked 1 all the way in until it stops at the tip of the channel. Do this one (1) time and pull out slowly making sure the swab does not touch any surface before it is place in the correct vial for testing. – Figure 2 and 3.**			
Once you have pulled the swab out of the channel cut the swab end off with scissors into the green capped (activator vial). (Note: you can place the swab tip into green vial before cutting off). Do not touch the swab. Recap the vial with the green cap. – Figure 4			
Shake the activator (green top) vial at least five times.			
Check the swab over a period of 30 seconds for a color change to any blue-green, which can indicate residual blood and or other oxidizing agents in the tested area only.			
In the presence of large amounts of residual blood and or other oxidizing agents **the entire indicator solution will become dark blue - Figure 5.**			
Record the result immediately—late color changes are not valid. The yellow color change after activation is a normal reaction and does not indicate residue. Any blue or green is a positive result – Figure 5.			
If you obtain a positive result (blue-green) report that result immediately and clean the robotic arm again according to policy. After cleaning retest the robotic arms until you get a negative result. Sterilizing a robotic arm that is dirty can compromise the sterilization process.			

Follow Hospital Policy on the Sterilization / disinfection of the robotic arm.

Remember to all ways follow manufactures guidelines on cleaning and sterilization of all robotic arms.

Robotic Arm Test Log

Test Date	**Tester Initials**	**Item Tested Model #**	**Serial or Lot # of item tested**	Robotic ARM Check™ **Result**	**Action Taken**

Record the Color Change for Robotic ARM Check™

Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested scope. In the presence of large amount of blood residue the entire indicator solution will become dark blue.

REFERENCES:

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9. AORN Guidelines 2010 - www.aorn.org

[i] Page 55 ; ANSI/AAMI ST79:2010 & A1 & A2 & A3 & A4
[ii] Mechanical cleaning ANSI/AAMI ST79:2010/A3:2012-7.5.3.3;page 58
[iii] http://www.accessdata.fda.gov/ScienceForums/forum06/B-48.htm
[iv] AORN Journal; March 2007,Volume 85,#3;page 566
[v] TOSI®man's Best, No. 9, Vol. 1/February 2007(www.pereg.de)