Making sense of the standards, guidelines and improvement process for cleaning

What are these based on

- Clinically relevant & evidence based practices
- Peer reviewed literature
- Other articles
- Manufactures research and guidance
- Research and science
- Unfortunately some practices do not have the evidence to support the practice
- Dynamic process

- All the major groups support in principal
  - Quality improvement
  - Quality assurance
  - Monitoring of your process

The Joint Commission National Patient Safety Goals

- NPSG.07.05.01
  - “Implement evidence-based practices for preventing surgical site infections”
- Element of performance #3
  - “…implement policies and practices aimed at reducing the risk of surgical site infections. These policies and practices meet regulatory requirements and are aligned with evidence-based guidelines…”

The Joint Commission: 2012 Hospital Accreditation Standards (HAS)

AORN – 2013- RP Care of Instruments

- RP 4 – page 431 - “…instruments should be wiped as needed …during the procedure to remove gross soil…”
- RP 5 – page 432 - “…instrument’s box locks should be fully open and the instrument secured to prevent closing by using stringers…”
- RP 8 – page 434 - “…water quality assessment should be performed periodically…”
- RP 10 – page 437 - “…operator should ensure that the proper cycle is being used…”

AAMI News: August 2010 Vol 45,NO8 and AAMI News: January 2011,Vol 46,NO 1
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The Joint Commission - 2012 Hospital Accreditation Standards (HAS)

AORN – 2013- RP Care of Instruments

- RP 19 – page 447 - "...competency, education, training..."
- RP 22.a – page 449 - "...mechanical instrument washers should be tested for proper functioning before initial use, weekly during service, and after major maintenance..."
- RP 22.a – page 449 - "...testing washer decontaminators on a regular basis verifies that the equipment is functioning properly..."
- RP 22.a – page 449 - "...mechanical instrument washers should be tested for proper functioning before initial use, weekly during service, and after major maintenance..."

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ASTM Standard

D7225-06 Standard Guide for Blood Cleaning Efficiency of Detergents and Washer-Disinfectors

This guide is based on a standardized test soil correlating to coagulated blood suitable for screening tests and the evaluation of the cleaning efficiency of washer-disinfectors used for reprocessing of surgical instruments. This guide strictly deals with cleaning and does not describe any methods that are related to disinfection.

Articles

- Investigations into reproducible cleaning of instruments based on a worst-case model
  - Critical box loads - various gap (0.03-0.42 mm) (Central Sterile 1/2011; G. Kirmse)
- Literature supports using organic contaminants that are representative of the soils likely to be found on the device after clinical use (i.e., protein, hemoglobin, and carbohydrates) as markers.
  - **A White Paper: The New Scope of Reusable Device Cleaning Validations By: Patrick Kenny, Microtext 2011
- Blood as a soil on surgical instruments; Chemical profile and cleaning detection (Pflueger, Zentori Steril 1998)
Verification of the Cleaning Process
Section 7.5.5
“…Sterile processing personnel are increasingly aware of the need to control and standardize the steps taken to ensure the sterility of devices for patient use. Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function. A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically…."

Why test your washer with a Blood based test?

“It is imperative that all traces of blood, bodily fluids and debris be removed during the wash phase of a mechanical cleaning of a mechanical cleaning equipment cycle. Failure to do so could result in undetected bioburden that could pose a risk to employee or result in patient infection”.

*Mechanical cleaning ANSI/AAMI ST79:2010/A3:2012-7.5.3.3; page 58

Blood as a test soil

- "...the load check washer monitor uses a colored dye imprinted on a plastic sheet and positioned within a grid like metal holder; whereas the TOU device uses organic materials reflective of blood components that are dried on the surface of a metal coupon...the load check indicator was not included in this evaluation as it does not contain an organic soil, so it is not relevant to the cleaning of reusable medical equipment. The TOU device can be used as an indicator to the levels of organic material from patients used items..." *
- Evaluation of washer-disinfector efficacy; new method to apply artificial blood test soil on standard test pieces**
- ISA authored article
- Supporting the use of the Pfeifer blood soil

*Pfeifer, Brian; Holtry, Richard; Cleaning staff of medical device manager in Device Operation or Maintenance facilities, issued report titled: "Blood etc.
**Clinical Environ. May 2015; pages 104-105

Correlation with Blood with the Pfeifer test soil

AAMI

- "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."
- "It is imperative that all traces of blood, bodily fluids and debris be removed during the wash phase of a mechanical cleaning of a mechanical cleaning equipment cycle. Failure to do so could result in undetected bioburden that could pose a risk to employee or result in patient infection"*
- *Mechanical cleaning ANSI/AAMI ST79:2010/A3:2012-7.5.3.3; page 58
- ANNEX D – list various methods to use for verification of your process

# 9 Verification of the process

- Quality improvement program
- Medical device verification
  - Equipment
  - Surfaces
  - Surgical instruments
    - Visual inspection
    - Site/surface testing
    - Stain identification
- Best way to verify & improve the process is a Quality Improvement Program.
  - Focus PDCA;
  - Lean; Six Sigma
  - others
- Trust but Verify
Think Crime Scene

- Think of the “medical device” as part of a crime scene
- You need various tools to find out what is on that “dirty medical device”
  - visual inspection
  - various test methods for the surface of the medical device
- You need to put on your detective hat and find out what is on that dirty medical device
- Equipment is not cleaning properly
  - Verify it is working properly
- You want to be a C.S.S.I.
- Central Sterile Supply Investigator

Let us look at Verification

- Understand your process first
- First, flow-chart your cleaning / decontamination process
- This way you will be sure to capture all the critical stages in the cleaning process
- Second, break down each step and identify how you can monitor each of the cleaning process steps
- Medical Device verification
- Equipment Verification

Medical Device & Equipment Verification to make sure clean Instruments are Produced

- Man & Machine are combined to achieve these results
- Both are not perfect
- Thus regular inspection/testing at each critical juncture helps ensure the highest levels of assurance
- Until recently cleaning equipment wasn’t being challenged – Automated Washers, Sonic Cleaners, Cart Washers,...and instruments were not being tested
- Surrogate devices and test soil that represent “real life” conditions as best as possible should be used for equipment
- Surface testing of medical devices is now possible with many different methods

Clinically relevant & evidence based products Applying the Principles to Product

What markers should be used for user verification for cleaning

- Literature supports using the three most predominant contaminants that are the main components of bodily fluids are protein, hemoglobin, and carbohydrates as markers.
- Regulatory authorities (like the FDA) will be looking for results from device manufactures for two markers of the test soil chosen (for example, protein, hemoglobin, mucus). *
- Alfa has shown that for flexible scope that: Protein; < 6.4 µg/cm2, Carbohydrate; < 1.8 µg/cm2, Hemoglobin; < 2.2 µg/cm2, are excellent markers for cleaning validation and verification. **
- At this time ATP is not a marker accept by the FDA for cleaning validation
- Users should look at testing for the same markers to verify there process as the manufacture of the device

Visual Inspection

- The Standard is first “is it visual clean”
- Thus first and foremost if it is visual dirty re-clean it
- Visual inspection takes place every time you touch an medical device
- Many methods to inspect and enhance the visual inspection process within the S.P.A.
  - Your natural eye sight
  - Lamp magnifier
  - Hand held magnifier
  - Flexible inspection scope
  - USB computer based microscope

Stain identification
- You want to know what is that stain composed of
  - Organic soil
  - Blood
  - Protein
  - Other
- That knowledge helps you correct the concern of a dirty medical device

User Surface and Site Testing
- Type of medical device
  - Equipment
  - Surfaces
  - Instruments
    - Done mostly by flushing or swabbing
    - Color change over time
      - Clean / Dirty
      - Pass / Fail
    - Commercially available products
      - Hemoglobin specific
      - Protein specific
      - ATP
      - Other organic or inorganic
- Different test tell you different things
  - Know what your tests tell you

Equipment Verification
- To help ensure that equipment is performing properly
- These tests are designed to challenge the operational level of cleaning equipment
- These tests either measure a specific parameter or challenge the cleaning efficiency of the entire system
- You must understand what a test tells you both when it passes and when it fails
- Think of your sterilizer

Manual Cleaning
- Measure hardness level for both hot and cold water sources
- Monitor temperature for the cleaning solution
- Monitor the dilution of the cleaning solution
- Log / Record results of all measurements and Visual Inspections

Sonic Cleaner
- Measure hardness level for both hot and cold water sources
- Measure & Monitor temperature of cleaning solutions in the tank / bath
- Do testing for cavitation on a regular time frame
- Test cleaning ability with appropriate type of test
- Clean screens and wipe down equipment
- Results of Visual Inspection of Instruments
  - Use site/surface verification tests
- Observations of Machine Operation / Condition
- Record all results / measurements in a log book

Automatic Washer Measurements
- Hardness level for both hot and cold water sources
- Measure Temperature for the Cold Water rinse stage
- Measure Temperature for the Enzyme Rinse stage (if appropriate)
- Measure Temperature for Wash Stage
- Measure Temperature for Thermal Rinse Stage
- Test with a Standardized Soil Test that reflect your process
- Monitor / record the results of Visual Inspection of Instruments
**Automatic Cleaning**

- Observations of Machine Operations / Condition:
  - Occlusion of Spray Arms
  - Nozzle Directions
  - Freedom of Movement of Spinner Arms
  - Instrument rack Coupler alignment
  - Staining, scaling of inside of chamber
  - Clean screens, wipe down equipment
  - Make sure the light in the washer is working
  - Is the cleaning solution being delivered properly
- Daily, weekly, monthly, quarterly, monitoring needs to be done
- Keep a Record of all results / record in a log book
- Document the Best cycle settings / Keep a copy if they change

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**Some examples of Standardize Test for Efficiency of Equipment**

- **Sonic Cleaning**
  - Foil test
  - Ceramic disc method
  - Probe
  - Sonocheck™

- **Temperature Testing**
  - Irreversible
  - Reversible
  - Thermologgers

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**More examples of Standardize Test for Efficiency of Equipment**

- **Water Quality**
  - Simple dip stick method
  - Comprehensive water study

- **Test Soil**
  - It is important to remember that as stated in AAMI ST 79 clinical soil is a substance consisting of the inorganic, organic and biological matter typically found on medical instruments after clinical use
  - AAMI Annex D

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**More examples of Standardize Test for Efficiency of Equipment**

- **Cart Washer**
  - Functionality of equipment
  - Key parameters

- **Medical Automatic Washer**
  - Functionality of equipment
  - Key parameters

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**Assessing the Cleaning Process**

<table>
<thead>
<tr>
<th>Task</th>
<th>Manual</th>
<th>Ultrasonic</th>
<th>Auto Washer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess work area, environment, facilities</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Assess water quality</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Assess use of proper chemicals</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Monitor temperature for chemical use</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Monitor chemical dilutions</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Assess proper functioning of equipment</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Check and clean filters &amp; screens</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Observe machine operations</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Monitor staff performance and competency</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Visually inspect instruments</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Test efficacy with a validated test soil device (soil swab device for manual)</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Document and record results of all measurements and observations</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
The value of prevention for your cleaning process

- Understanding the 9 factors of cleaning and how they interact will help in preventing dirty medical devices
- An ounce of prevention can yield enormous return for your patient
- It must also be understood that implementation of any quality improvement or risk based program does not always prevent incidences from happening but they will help reduce and understand those incidences better if they do occur

History of Cleaning Verification in North America

- **Timeline**
  - Pre-1999 - visually clean (sterile dirt)
  - The Joint Commission has always supported the testing and monitoring of medical equipment
  - 1999 - cleaning verification arrives - TOSI
  - 2001 - Healthmark introduces TOSI to North American market
  - 2002 - present: additional products are introduced to address cleaning challenges (Sonochek, Endocheck, CartWashCheck...)
  - 2006 - ASTM sets standard for medical automatic washers
  - 2008 - AORN Recommended practices of at least weekly testing
  - 2009 - AAMI ST79 Recommends practices of at least weekly testing
  - 2009 - present: other companies offer cleaning verification products in N.A., not all of them are clinically relevant, evidenced-based products

- **Healthmark’s philosophy**
  - More than just running a test, it is a quality improvement process
  - Clinically relevant, evidence-based, products
  - Support of products both clinically and educationally