10th Annual Northeast Regional Meeting
Long Island Association for Central Service
Mid Atlantic Central Service Association
Atlantic City November 18 -19 2018

Keeping Your Patients Safe And Your Hospital Out of The Headlines

Presented by:
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OBJECTIVES

- Identify the challenges affecting the quality of the cleaning process and consequences of failed outcomes
- Identify & discuss the difference between medical device and processing equipment testing
- Discuss validated and standardized soil testing protocols and technology
- Discuss tools and methods needed to develop and implement an effective Quality Assurance program to reduce the incidence and Risks associated with the use of inadequately cleaned instruments

ECRI Institute

Thorough Assessment Conducted
Risk factors are weighed

- Profile. Is the hazard likely to receive significant publicity?
- Preventability. Can actions be taken now to prevent the problem or at least minimize the risks?
- Severity. What is the likelihood that the hazard could cause serious injury or death?
- Frequency. How likely is the hazard? Does it occur often?
- Breadth. are the consequences likely to spread to affect a great number of people?
- Insiiousness. Is the problem difficult to recognize?

2018
Top Ten Health Technology Hazards

1. 1. Ransomware and Other Cybersecurity Threats
2. 2. Endoscope Reprocessing Failures
3. 3. Contaminated Mattresses and Covers
4. 4. Alarm Notification Failures
5. 5. Equipment Failures from Improper Cleaning
6. 6. Patient Burns from Unholstered ESU Pencils
7. 7. Radiation Exposure from Inadequate Use of Digital Imaging Tools
8. 8. Bar-Coded Medication Administration System Workarounds
9. 9. Care Delays from Flaws in Device Networking
10. 10. Slow Adoption of Safer Enteral Feeding Connectors

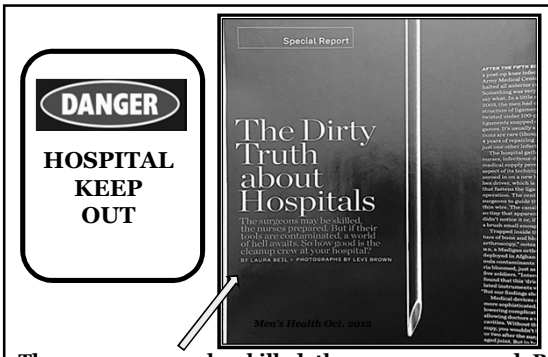
Most Relative to SPD

#2. Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk

#5. Improper Cleaning May Cause Device Malfunctions, Equipment Failures, and Potential for Patient Injury

increased media attention

Uncovers Dirty Surgical Instruments at Houston Hospital - hospital wants 1,000 patients to come in for HIV, hepatitis tests *Hospital re-trains staff after contaminated instruments were used* Couple Gets $1.25 Mill… in Post-Colonoscop… Judgement A grandmother died of hepa… being poisoned by dirty… ment at an NHS hospital. ASHEVILL… *encouraged 1… potentially… following the revel…* Vegas Review… hospital may have… …to a n… an wh… …hents… …ee yest… …The issue stems fro… …properly. the hospital told C… …SDK. CDC … …vestigation Uncovers Dirty Surgical … …s at Houst… …al Human tissue and bone found … …vers and ca… …4, 2012 Out Patient … Surgical to… …d of bit… …ght have expo… …infe… …ril, May and … …Hyd… about 3,30… …shed in… two month… …31/03 Fri… cleaning… …ations are… due to t… …een found o… hospital… …forceps f… …N.B. continues to investigate why st… …properly cle… …sterilize a piece of ultrasound equipment, potentially compromising the health of 27 patients.



The surgeons may be skilled, the nurses prepared. But if their tools are contaminated, a world of hell awaits. So how good is the clean up crew at your hospital?

increased media attention

Uncovers Dirty Surgical Instruments at Houston Hospital - hospital wants 1,000 patients to come in for HIV, hepatitis tests *Hospital re-trains staff after contaminated instruments were used* **Couple Gets $1.25 Million in Post-Colonoscopy Infection Judgement** A grandmother **died of hepatitis B after being poisoned by dirty surgical equipment at an NHS hospital. ASHEVILLE — *Mission Hospital encouraged 10 patients to undergo testing for potentially serious viral infections following the revelation a scope was not properly sterilized in the endoscopy unit*** **Las Vegas Review 3/1/08: Hepatitis C Investigation** At least five VA hospital may have infected people say they contracted … during visits to a medical clinic. **Daily Record Legal Af… woman who was told after a routi… uments used were not ste…** …ows infected 1,800 veterans with hi… …d CNN affiliate … …gical Instru… …ound stuck… …eces of Surg… …the huma… …ncident month… …ry 2003 instead… …The instru… …the last minute due t… …N.B. hospital use… …Medical Center continues to investi… …piece of ultrasound equipment… …of 27 patients. Organic matter found in sterile instrument… …more than 1000 patients- dirty endoscope tested positive for CRE" UMC of El Paso cancels elective and non-emergency surgeries after it was issued a notice of a preliminary denial of accreditation Suit charges negligence at aChicago-area hospital led to patient contracting fatal superbug infection from contaminated scope Dirty instruments found at DMC; probe may reopen investigation - **after a filthy surgical tool interrupted an operation** - ***The News*** **investigation focused on a sterilization department….** MASS DPH reported that sevral may have been exposed to a fatal brain disease from the same specialized surgical instrument used on a patient in New Hampshire.

"Hospital acquired infections are killing about 300 people a day in the U.S. That's like crashing a passenger jet every single day."
Edmond Hooker MD

"An unsterile item used in surgery is as dangerous as a loaded gun."
Bertha Litsky, PhD

Focus on Sterile Processing

The Joint Commission
CMS
CENTERS for MEDICARE & MEDICAID SERVICES
ACHC
ACCREDITED Hospital
ISQua Accreditation STANDARDS
OSHA
CDC
accredited by AAAHC
Accreditation Association for Ambulatory Health Care
FDA
ASF

Healthcare-Associated Infections Cost Nearly $10B Annually

Surgical site infections account for slightly more than one-third (33.7%) of that total

SSIs ($20,785) per case basis

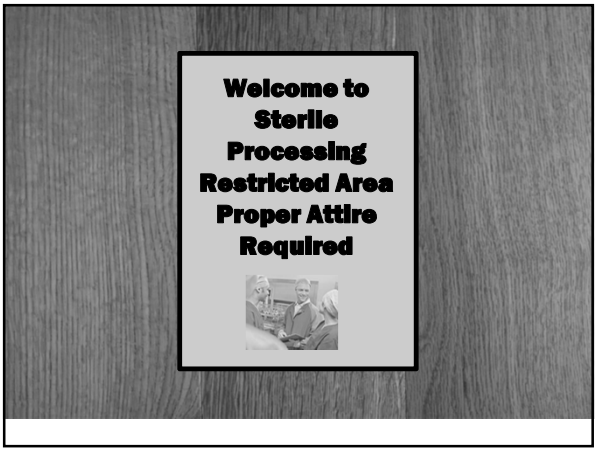
Outpatient Surgery
E-Weekly September 10th, 2013

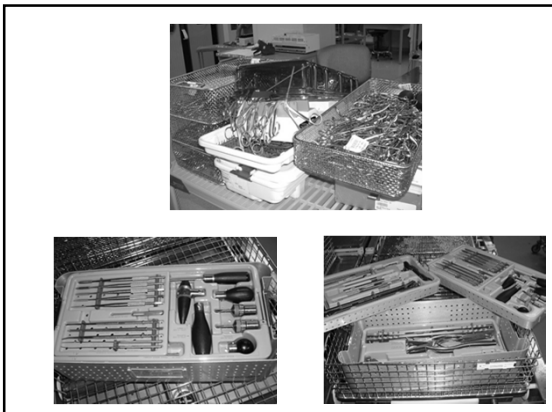
challenges

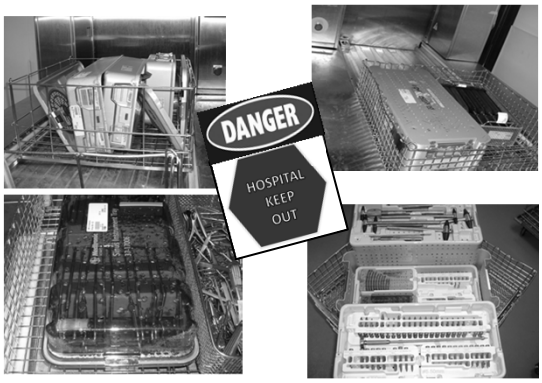
- instrument complexities
- demand for fast turn around
- inadequate human and material resources
- inadequate facilities
- economics
- loaners
- scheduling coordination
- staff competency
- manufacturers IFUs

LET'S TAKE A VIRTUAL TOUR OF WHAT SOME HOSPITALS ARE DOING

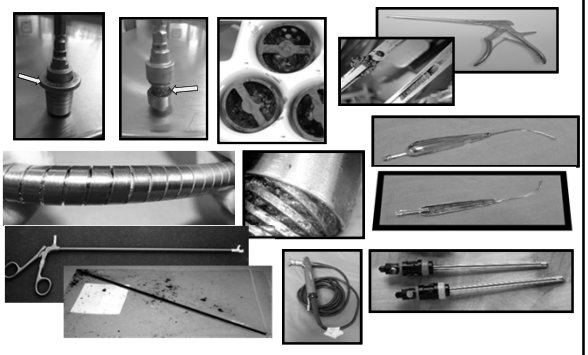
Note: the names and faces have been changed to protect the guilty

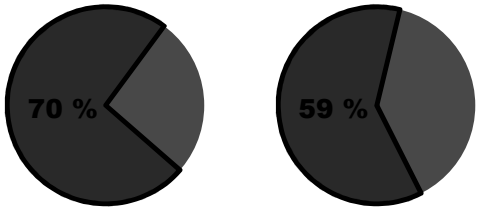






Instrument complexities





National Survey of Healthcare Facilities found that 70% 0f channeled medical devices and 59% of Endoscopes were still dirty following decontamination.

Communique May/June 2015 Stephenson

360 participants in SPD Survey

- 21% state they don't have adequate proper tools to clean devices
- 26% indicate they did not have adequate brushes required to clean medical devices
- 57% do not use visual enhancement device to inspect orthopedic shavers as IFU requires
- 14% do not have ultra sonic cleaner
- 24% not following AAMI standards re: testing automated washers at least weekly (preferably daily)

Kovach survey 2016

Cleaning is ***always*** the first step in the reprocessing cycle !

- **All medical devices must be clean before they can be sterilized.**
- **Cleaning is the removal of visible and ***invisible*** soil.**
- **Cleaning is accomplished either by manual or mechanical means utilizing detergent and water at proper concentrations.**

Seven factors affect the cleaning process: which must be assessed & monitored

1. **Water quality**
2. **Temperature**
3. **Chemical activity**
4. **Mechanical action**
5. **Human factor**
6. **Item to be cleaned**
7. **Type of Soil**

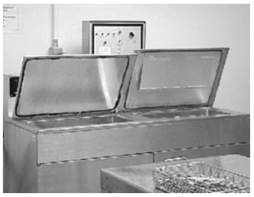
The various combinations determine how clean your instrument will be.



Automated and mechanical processors
So many options, so many choices, so many challenges

Choose wisely ?





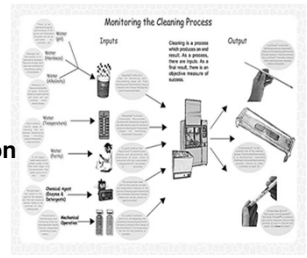

Assessing the Cleaning Process Steps to Take for a Quality Approach

Cleaning is a process…

- **Which produces an end result.**
- **As a process, there are inputs.**
- **As a final result, there is an**
- **objective measure of success.**

The inputs for cleaning are

- **Water quality.**
- **Proper temperature at various stages.**
- **Chemical agent(s)**
- **Mechanical operation**
- **Human operation.**

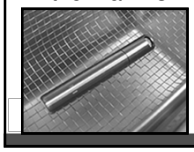


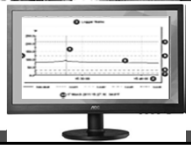
Water Quality

is a broad concept covering several key characteristics of the water used.
The relevant measurable characteristics are pH level, Hardness, and Alkalinity.

Applying Temperature Principles to Automated Instrument Washers

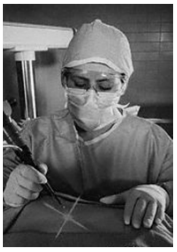
- test and document the cold water rinse stage of the Washer.
- Optionally use to test enzyme rinse stage.
- Test and document thermal Disinfection





Assessing the Cleaning Process

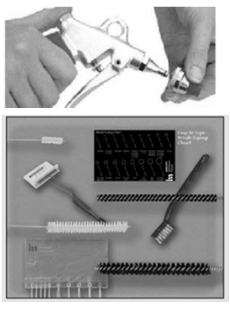
	Manual	Ultrasonic	Auto Washer
Assess work area, environment, facilities	X	X	X
Assess water quality	X	X	X
Assess use of proper chemicals	X	X	X
Monitor temperature for chemical use	X	X	X
Monitor chemical dilutions	X	X	X
Assess proper functioning of equipment		X	X
Check and clean filters & screens		X	X
Observe machine operations		X	X
Monitor staff performance and competency	X	X	X
Visually inspect instruments	X	X	X
Test efficacy with a validated test soil device (soil swab device for manual)	X	X	X
Document and record results of all measurements and observations	X	X	X



The great scientific advances in medical device technology has brought forth monumental challenges for OR & CS in the reprocessing, cleaning and sterilization of this complex and expensive instrumentation.

You need the right tools to "get it clean."

- **spray guns**
- **vertical soakers**
- **proper brushes**
- **verified equipment**
- **magnifying glass**
- **quality improvement program**



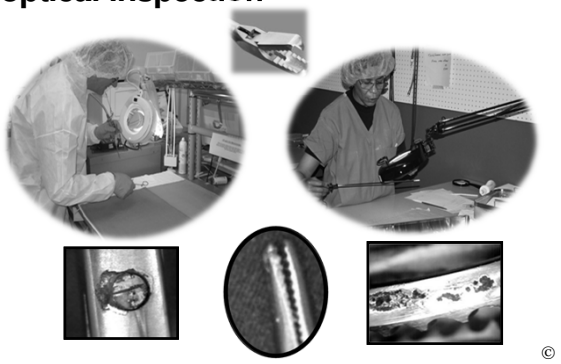
visual inspection

The visual inspection of medical devices is an essential step in verifying the efficacy of the cleaning process and the overall condition of the device.

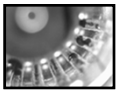
visual inspection

- ✓free of blood, organic matter and other soils
- ✓free of any foreign matter
- ✓damage e.g. cracks, chips, scratches, broken parts
- ✓free of corrosion, staining
- ✓attention to movable parts, hinges, joints, box locks, pivots
- ✓attention to fine points, crevices, serrations, channels
- ✓may require the use of special optical inspection devices, magnifiers, light sources

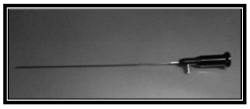
optical inspection

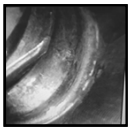


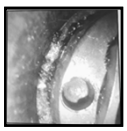
visual inspection is required must Follow Manufacturer's IFUs

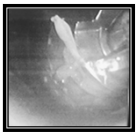


Many require use of a borescope



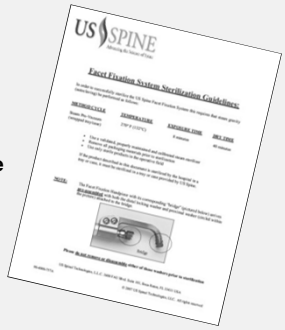






IFUs

It is critical that health care facilities receive and follow the mfgs IFU for all reusable medical devices. Devices that do not have a validated IFU should not be processed. To do so, puts both patients and health care facility at risk.



manufacturer's cleaning IFU orthopedic instruments

1. Submerge in enzymatic detergent.
2. Flush port with 50 ml enzymatic detergent.
3. Soak for 10 min in protein soluble detergent.
4. Scrub with soft bristled brush (agitate instrument while scrubbing).
5. Rinse with warm tap water (38-49℃)
6. Flush port with 50 ml warm tap water.
7. Place in bath of warm water (agitate by hand for at least 1 min). Repeat this process 2 additional times.

manufacturer's cleaning IFU orthopedic instruments cont.

8. Ultrasonic for 10 min with neutral pH detergent (flush port with 50 ml prepared detergent before sonication).
9. Flush port with clean tap water (3 times).
10. Rinse for at least 1 min with tap water.
11. Dry with clean, lint free cloth.
12. Inspect.
13. Lubricate tip mechanism and finger slot (do not lubricate flush port).

(more than 40 minutes)

Technology has evolved over the years reprocessing techniques must keep pace

Quality Assurance of the entire Cleaning process is essential

Verification of cleaning efficacy

Devices
vs.
Processing Equipment

devices

- surgical instruments
- endoscopes
- robotics
- suction apparatus
- complex devices
- medical equipment

processing equipment

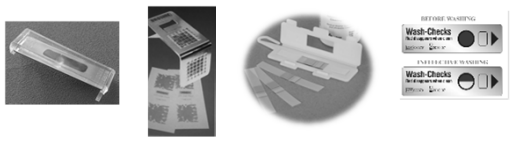
- ✓ all automated mechanical equipment
- ✓ washer decontaminators & accessories
- ✓ ultrasonics & accessories
- ✓ cart washers
- ✓ AERs (automated endoscope reprocessor)

FDA, AAMI & other standards state that:

✓Simulated testing be done with a surrogate device that closely approximates the actual types of soil the instrument is exposed to in clinical use. Further the surrogate device should be made of the same type of material as the medical device.

AAMI TIR30

tools for assessing efficacy of automated washers



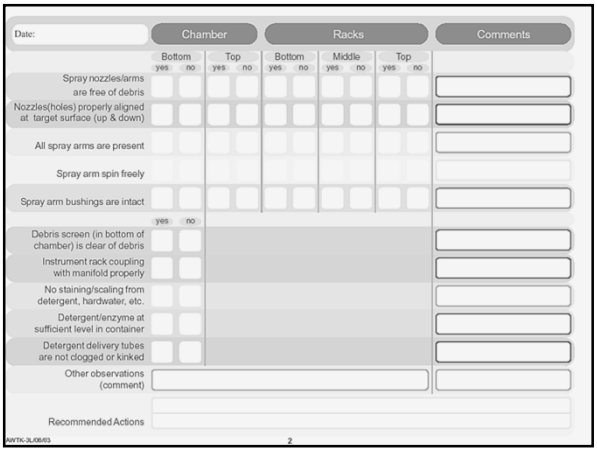
Choose wisely as they do not all assess the key factors nor meet the criteria for a surrogate testing device
1.Water quality 2. Temperature
3. Chemical activity 4. Mechanical action
5. Human factor 6. Item to be cleaned 7. Type of Soil

washer test

Where used?

- **washer decontaminators (all levels)**
  Why?

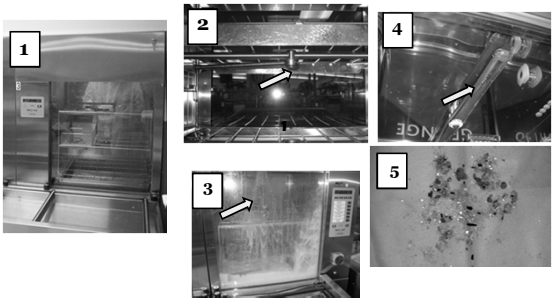
- **ultrasonics**
  Why?



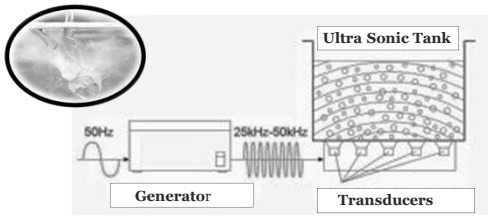
Date:	Chamber				Racks						Comments
	Bottom		Top		Bottom		Middle		Top		
	yes	no	yes	no	yes	no	yes	no	yes	no	
Spray nozzles/arms are free of debris											
Nozzles(holes) properly aligned at target surface (up & down)											
All spray arms are present											
Spray arm spin freely											
Spray arm bushings are intact											
	yes	no									
Debris screen (in bottom of chamber) is clear of debris											
Instrument rack coupling with manifold properly											
No staining/scaling from detergent, hardwater, etc.											
Detergent/enzyme at sufficient level in container											
Detergent delivery tubes are not dogged or kinked											
Other observations (comment)											
Recommended Actions											

AWTK-3L/06/03 2

Test each level for performance



ultrasonic cavitation



sonic cleaning takes place as shock waves dislodge soil from the surface of the instruments in the water bath. This is called cavitation

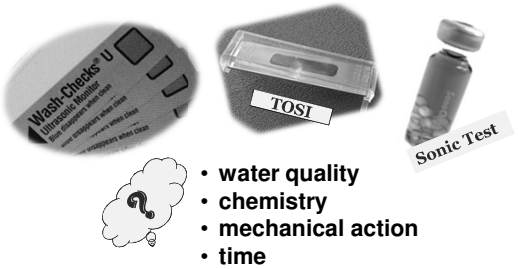
Verification tests for ultrasonic cleaners
AAMI ST79 2017

- Test for cavitation in ultrasonic bath
- Test for soil removal (external) in ultrasonic bath:
- Indication is visual assessment or absence of marker on a coupon placed in the ultrasonic bath.
- Test for soil removal (internal within lumens) in ultrasonic bath

you can test for the presence of cavitation / sonic energy

Perform cavitation testing daily when in use
AAMI ST79 7.6.4.4.1 (2017) ©

tools for assessing efficacy of ultra sonic washer



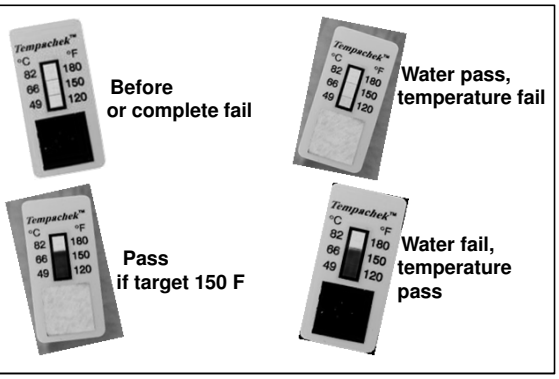
- water quality
- chemistry
- mechanical action
- time
- temperature

cart washers

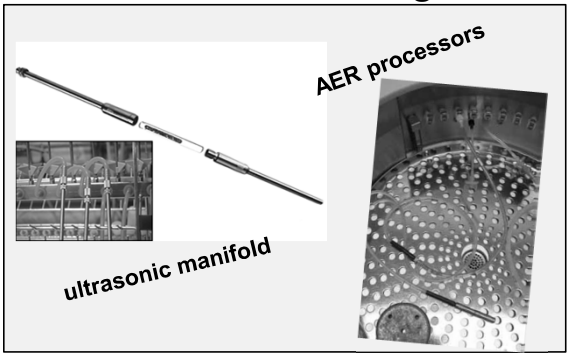
Cart washers are important tools in the overall effort to reduce cross contamination. Often they are used to clean not just surgical case carts, but also basins, instrument trays, wheel chairs and other supply and patient transport equipment.

©

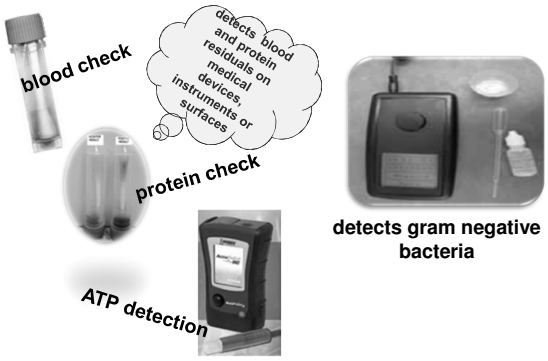
cart washer test



the lumen challenge



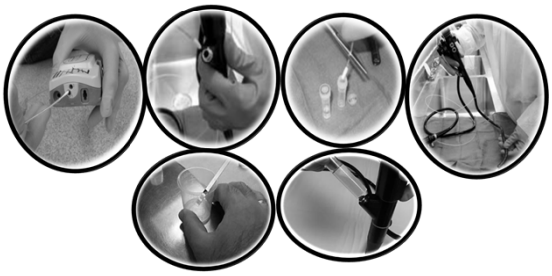
device cleaning verification tools



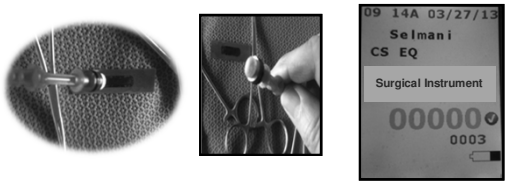
detects gram negative bacteria

scopes, lumen & cannulated devices

Swab & flush tests methods are available to test for residual soils such as blood, Protein and carbohydrates



ATP Degrades and once it does it is not detectable - therefore it would be possible to have visible organic soil on a medical device and still get a Pass number on the ATP testing device



- **It should be noted that ATP is not present in viruses nor is it present in components such as protein, carbohydrate, hemoglobin, lipids, etc.**
- **RLU values vary from system-to-system and are not a standard unit of measurement across systems.**

Recommended Practices

- **Cleaning Verification**
- **Care and handling of instrumentation**

Summary of Standards and Recommendations

- Daily monitoring of all mechanical cleaning equipment and accessories
- Testing for Cavitation in ultrasonic washers
- Verification of cleanliness of specific devices after manual or mechanical cleaning
- Verification testing part of CQI and compliance with defined benchmarks
- Test methods that detect residual specific organic soils
- Emphasis on channels, lumens and adaptors
- Use of enhanced visualization tools-e.g. lighted magnifiers, video borescopes
- Specific markers for blood, protein, carbohydrates, lipids, endotoxins , bioburdens, ATP
- Cleaning begins at point of use , safe transport of soiled goods (OSHA Regulations)
- Need for proper tools and equipment in SPD

AAMI

AAMI ST79 2017 7.6.4.5

Mechanical cleaning equipment performance should be tested each day it is used and all results should be recorded

- **Washer disinfector**
- **Ultrasonic**
- ***Cart Wash***
- ***AER***
- ***Attachments / manifolds***

AAMI

✓ **ANNEX P**

P.2.1 General considerations

Each type or model of mechanical cleaning equipment is designed to significantly reduce the viable number of microorganisms on medical devices through the detergent washing, rinsing, flushing, and draining action of the equipment. Some types of mechanical cleaning equipment are also designed to destroy vegetative or pathogenic microorganisms by means of moist-heat thermal disinfection or chemical disinfection. Such equipment can be labeled as providing low-, intermediate-, or high-level disinfection.

✓ AAMI

Annex D ST79 2017

- **For verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the mechanical cleaning equipment (if used) and the <u>cleanliness of specific devices after manual or mechanical cleaning is completed.</u> These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks, once these benchmarks have been defined.**

Health care personnel may perform verification tests as part of the overall quality assurance program. Methods of verification include the use of devices that directly test individual instruments for residual soils, challenge cleaning effectiveness with standardized test methods, or measure specific key parameters to evaluate the functionality of the cleaning equipment. Key performance outcomes include clean surfaces and adequate fluid flow in equipment that has adaptors for lumened devices….

Verification of the cleaning process

- **Inspection using enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye.**
- **Visual inspection alone might not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure or detect organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (see Annex D for available methods). Appropriate testing is based on the type of equipment.**

AAMI ST79 7.6.4.5

Verification of the cleaning process

……the specific markers that can be used to determine cleaning efficacy have indicated that the following soil markers are useful for benchmarking purposes:

a) protein
b) carbohydrate
c) hemoglobin (blood)
d) endotoxin
e) lipid
f) sodium ion, and
g) Bioburden
h) ATP

AAMI ST79 Annex D.2

AORN **Recommendations 2016**

Recommended Practices for Cleaning and Care of Surgical Instruments III.a.

Preparation for decontamination of instruments should begin at the point of use.

Moistening and removing gross soil at the point of use can help prevent organic material and debris from drying on instruments. Organic material and debris are more difficult to remove from surgical instruments when they are allowed to dry. Removal of organic material and debris at the point of use can improve the efficacy and effectiveness of cleaning and decontamination.

AORN Recommendations 2016

Recommended Practices for Cleaning and Care of Surgical Instruments

III.d. In preparation for transport to a decontamination area, sharp instruments must be segregated from other instruments and confined in a puncture-resistant container …….

The Occupational Safety and Health Administration (OSHA) prohibits processes that require employees to place their hands into basins of sharp instruments because of the risk for percutaneous exposure to bloodborne pathogens……..

AORN Recommendations 2016

Recommended Practices for Cleaning and Care of Surgical Instruments IV

Contaminated instruments must be contained during transport to a decontamination area

Containment of contaminated instruments decreases the potential for injury to personnel or their exposure to blood, body fluids, or other potentially infectious materials and helps prevent damage to the instruments during transport.

AORN Recommendations 2016

Recommended Practices for Cleaning and Care of Surgical Instruments V.d.

The decontamination area should contain automated equipment consistent with the types of instruments to be cleaned and decontaminated, adaptors and accessories to connect instruments with cleaning equipment and utilities, a filtered medical-grade compressed air supply, and access to water of appropriate quality for rinsing instruments (eg, deionized or reverse-osmosis water).

AORN Recommendations 2016

GUIDELINE FOR CLEANING AND CARE OF SURGICAL INSTRUMENTS XVII.a.1

Mechanical cleaners (eg, washer disinfectors/decontaminators) should be tested for correct function on installation, at least weekly (preferably daily) during routine use, after major repairs, and after significant changes in cleaning parameters (eg, changing cleaning solutions).

AORN Recommendations

- **XXII.a Manual cleaning should be evaluated when new types of instruments are reprocessed and at periodic intervals determined by the health care organization.**
- **(XXII.a.1.)Testing washer decontaminators on a regular basis verifies that the equipment is functioning properly or identifies an opportunity for corrective action.**
- **Washer testing products are commercially available.**

WHAT CAN WE DO ?

WHERE DO WE GO FROM HERE?

Top Three Challenges

1. Inadequate facilities and equipment
2. Human Resource Issues
3. Lack of administrative support

We Must Be

- DEDICATE
- PREPARED
- CONNECTED
- INFORMED
- CONFIDENT
- HEARD

When it comes to reprocessing medical devices patients' lives are in our hands. Every HCW plays a major role in infection control- we need to support one another and work collaboratively

HAI → 109,500 Deaths Annually
Men's Health Oct. 2012

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