IX Congreso Panamericano de Esterilización

WFHSS

1er Congreso internacional de Control de Infecciones Hospitalarias
1er Congreso internacional de Pacientes y Salas Quirúrgicas
22 al 24 de Junio del 2016, LATU. Montevideo-URUGUAY

Cleaning Verification

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One of youz Guyz

Objectives

- Review why cleaning is important and AAMI Standards.
- Case study of the types of test devices used in Middlesex Hospitals program
- Detail test devices considered and hands on.
- Discuss how they were put together as a Monitoring Program

Today's Focus

Mechanical aspects of cleaning process

With a specific focus on automated washers, sonic units and cart washer

This is part of a larger system covering training to test devices to post wash tests

Keep in mind:

Hand cleaning processes also require a monitoring / QI program

Why is cleaning important ?

“If it aint clean it’s aint sterile”

The CSSD Mantra

CSSD 101

Regulatory Issues

AAMI-JCAHO-FDA-CDC
AORN

All recommend that Central service departments have a Quality Improvement Program in place to reduce concern over unclean instruments. Specifically when it arises from a poor functioning Medical Automated Washer.

Did I forget the State D.P.H??

Association for the Advancement of Medical Instrumentation

ANSI/AAMI ST79:2010/A4:2013

Published in 2006
Updated using a continuous maintenance process

ANSI/AAMI ST79:2010/A4:2013
Sections 7.5 and 10.2

Section 10 **Quality Control**

Cleaning Verification

10.2 **Monitoring of mechanical cleaning equipment**

Frequency of testing

Upon installation

Weekly (preferably daily) during routine use

After major repairs

Review and initial mechanical washer cycle printouts

Document results

ANSI/AAMI ST79:2010/A4:2013
Annex D User-verification of cleaning processes

Table D.1 Tests to assess efficacy of cleaning medical devices

Expose cleaned device to 2% hydrogen peroxide solution, observe whether solution bubbles. Important to wash or remove after process.

Table D.2 Tests to assess efficacy of washer disinfectors

Metal coupon with pre-applied blood test soil

AORN Perioperative Standards and Recommended Practices (2015)

Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment, Recommendation XXII.a

Cleaning Verification

<u>Test mechanical instrument washers:</u>

Before initial use

Weekly during service

After major maintenance

<u>Evaluate manual cleaning</u>

When new instruments are reprocessed

and periodically

Categories of testing

The products that test for residuals are a little more complex and sophisticated in their use.

If we recall the AAMI standard:

Table D.1 Tests to assess efficacy of cleaning medical devices

Table D.2 Tests to assess efficacy of washer disinfectors

For any start up program I would recommend starting with the Table D2 devices.

If that's not reason enough… you could get fired!!

Medical Automatic Washer

- **Developed from commercial dishwashers & adapted to medical field**
- **Utilize pressure and detergents through delivery systems**
- **FDA Regulated. Manufacturers are required to obtain 510(K) requirement for high level disinfection washers**

Medical Automatic Washer

Three types of units available

- **High impingement or water pressure.**
  Use enzymes and neutral detergents.

- **Low impingement or water pressure.**
  Use stronger chemicals such as Alkaline detergents

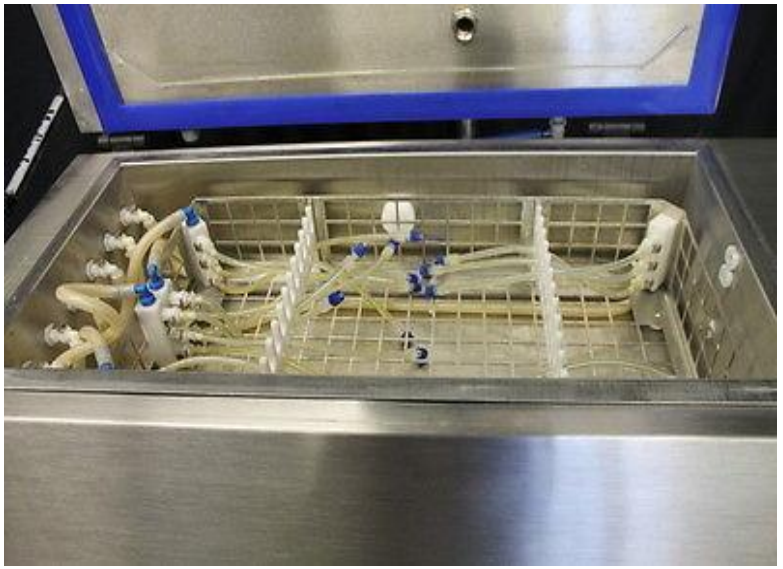
- **Variable impingement (Steris)**

Washer batch type.
Low or high impingement or Variable

Tunnel washer. Indexing. Usually high impingement.

Reg. Sonic

Irrigating Sonic



Test Devices to *Challenge Your Cleaning Equipment*

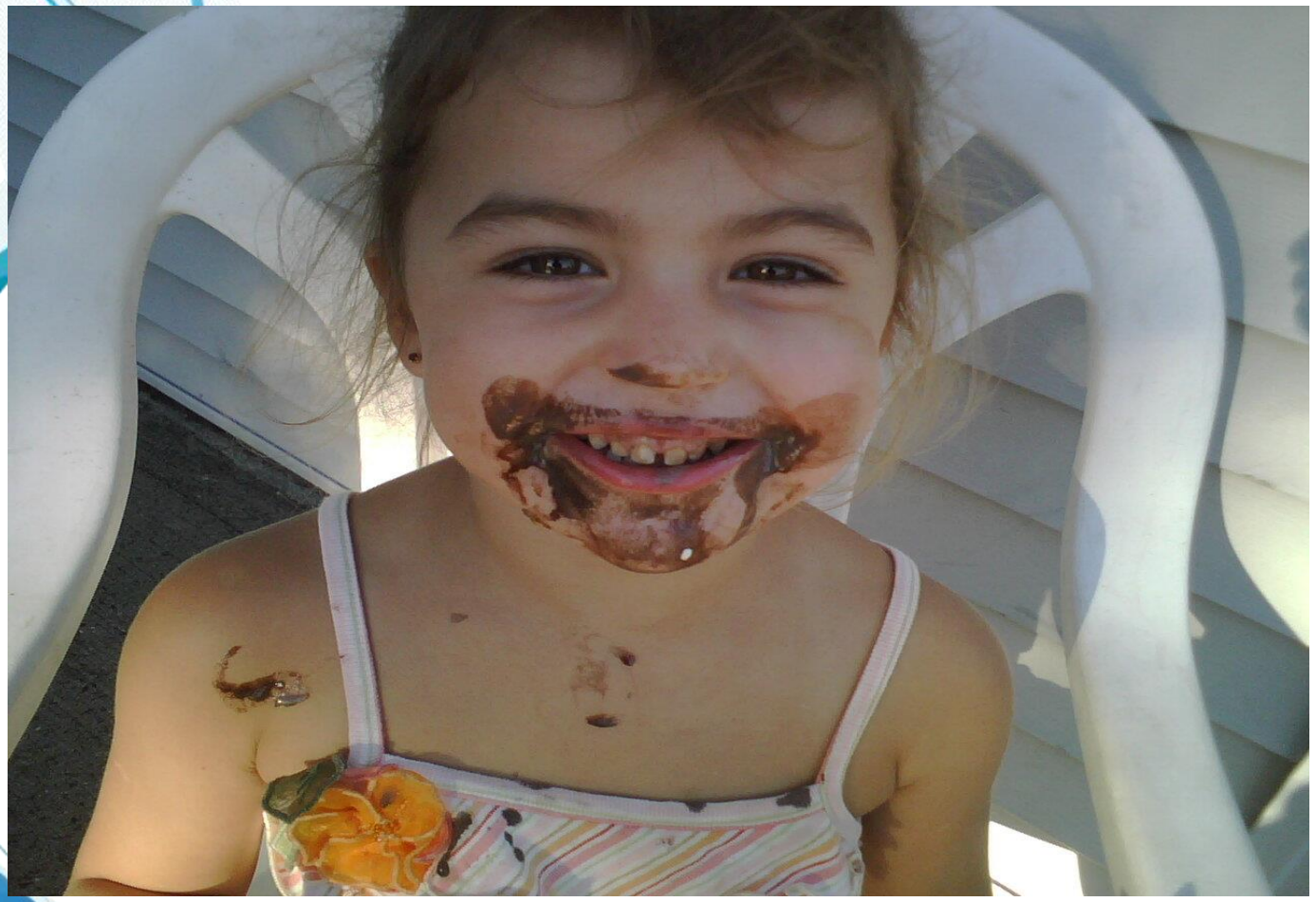
- **Washcheck & Washcheck H**
- **The TOSI**
- **STERIS Verify All clean**
- **The SonoCheck to test your ultrasonic.**
- **Temperature Monitoring Products**

Products to T*est <u>the Residual Soils</u>* found on Instruments and Surfaces

- **ATP test devices**
- **HemoCheck test for residual blood on**
- **ProChek-II test for residual protein on instruments and surfaces**
- **Hydrogen Peroxide!**

So lets just KISS..

Keep It Simple South America



Middlesex Hospital

- Number of Beds:300
- Number of ORs serviced:10 + 3 offsite
- Number of Shifts in Central Services:3 with 18 FTE's
- Number of complaints 0*

*3RD shift when no one is there!

Steps employed for Cleaning verification

1. Check List for visual inspection (per shift)
2. Water Quality
3. Processing Temperatures
4. Automated Cleaning Performance Verification incl. washer print outs
5. Post cycle tests (AAMI Table D1)

   ATP/Swabs/Hydrogen Peroxide

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

AAMI TIR34 :2007 Water Quality

1.1 General

This TIR addresses how to determine the water quality needs for reprocessing various categories of medical devices at various stages of reprocessing and how to assess, generate, monitor, and maintain water meeting those requirements.

AAMI TIR34 :2007 Water Quality

1.2 Inclusions

This TIR covers the quality of the water used to clean, rinse, disinfect, and sterilize medical devices. It defines water types on the basis of hardness, pH, bacterial levels, endotoxin levels, and other characteristics. The following specific topics are covered:

a) importance of water quality and effective water treatment;
b) categories of water quality for medical device reprocessing;
c) selection of water quality;
d) water treatment systems;
e) monitoring of water quality;
f) strategies for bacterial control;
g) personnel considerations; and
h) continuous quality improvement

***Does not cover water used in Hemodialysis**

More on Water Quality

Detergent / Washer Vendors will perform water quality lab tests upon request. Usually at no charge. Test Hot and cold!

Your Hospital Engineering department is required to test water regularly but it may not be specific to your area.

Quality changes throughout year.

Water test strips
3-in-1 Water Quality Test

Strips Measure

PH
Total Alkalinity
Hardness

Why Worry about Hardness?

Middlesex has city water with acceptable ranges of PH Alkalinity and hardness. The main purpose of this testing was to determine (with detergent Rep) the necessary baseline dosing requirements. Our final rinse of instruments is achieved using R.O. water

What were the objectives?

- Confirm washer temps on all cycles we run and at the various stages of each program.
- Sonic temps. We didn't want them too hot as we use enzyme in ours
- Cart washer temps
- Sink temps-Enzymes again. We wanted staff to use and maintain warm water.
- Temps can affect Alkalinity PH up or down.

Experiences on water temp

- **Work with Washer manufacturer and detergent service reps.**
- **When measuring initial wash cycle (enzyme cycle) unit must be stopped when that cycle is over.**
- **Test each SEASON. Different water sources**
- **Develop a frequency of testing based on your individual process.**

Alternatives to thermometers

To make it “easier” we are experimenting with some thermocouples that are available on the market.

These devices are placed into the washer then download to a PC to provide a time temperature profile of the entire cycle.

We are still working on the software!

Testing Devices: Temperature

Stick on single use thermometer

With modern washers, water temperature is typically the key source of thermal disinfection. The level of disinfection, time & temperature to achieve that level differs between brands of Washers.

Middlesex Hospitals Findings

- On one of the units the initial wash cycle on the “ortho” cycle was hot water. This should have been cold as to not coagulate the bioburden is present on the instruments. This was changed by a simple cycle setting change on the program.

Findings continued.

- Sink temps were low.
- Sonics were a bit on the high side (150F-160F)
- Cart washer main wash cycle of program was blazing hot (180F)
- Decontam was hot!! Surprise Surprise ☺

Testing Devices: Sonics

<u>Tests Cavitation</u>

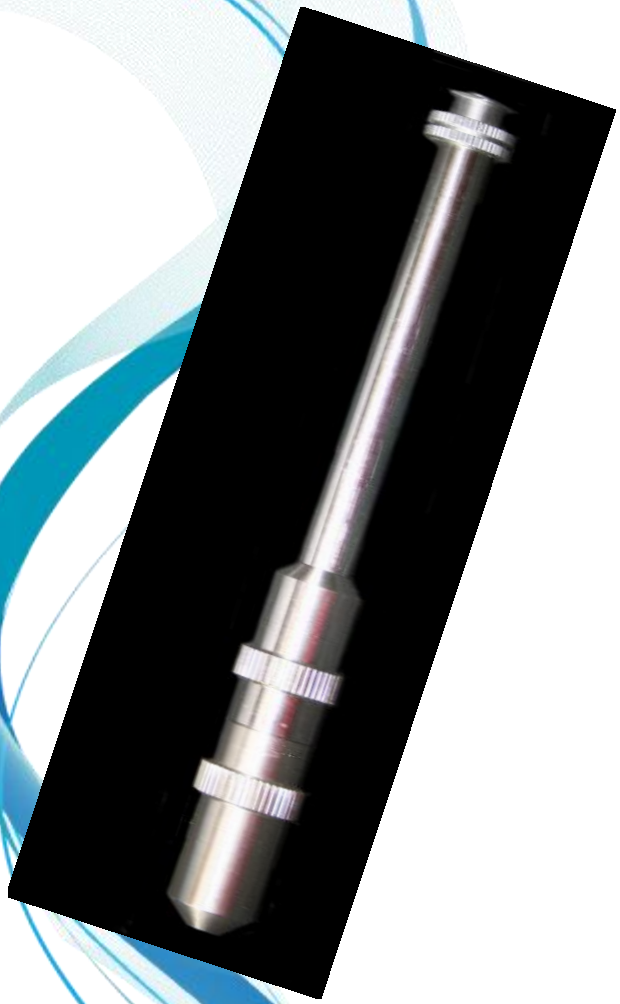
When the ultrasonic cleaner is working correctly SonoCheck will change color.

Varying color indicates a possible bad generator.

We use daily at Middlesex.

You can go also use a piece of aluminum foil

Testing Devices:
Irrigating Sonics



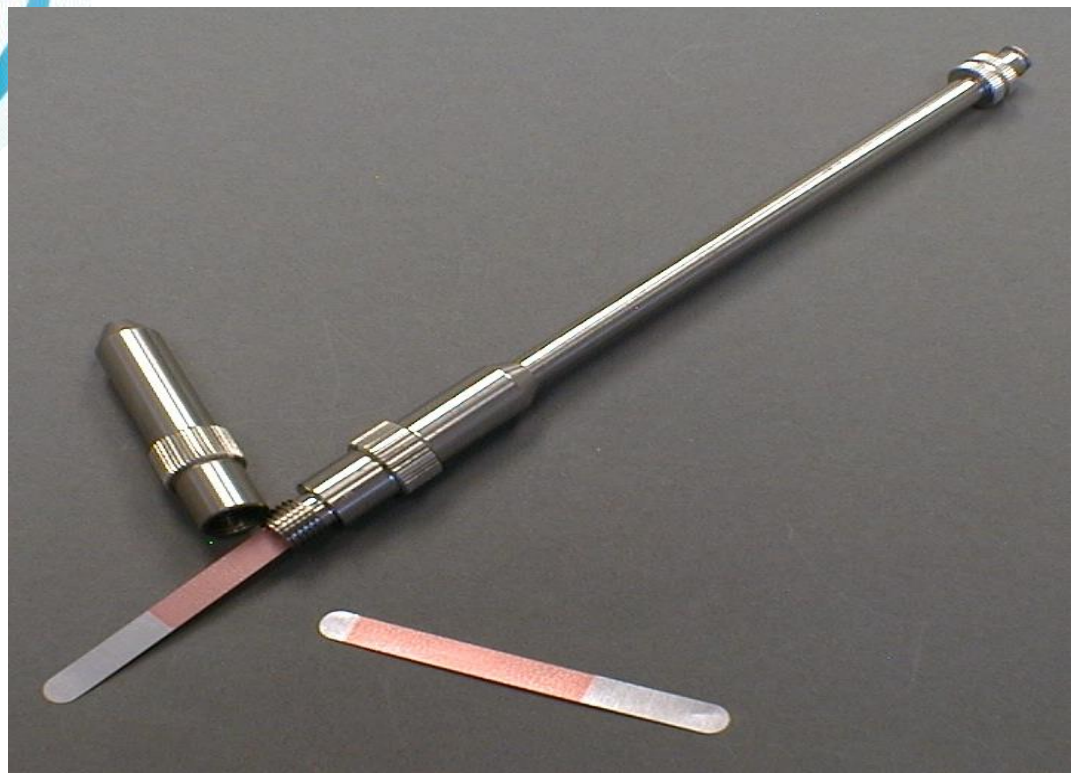
Metal strip with test soil is placed into Lumen holder.

Hook up to sonics irrigation channel.

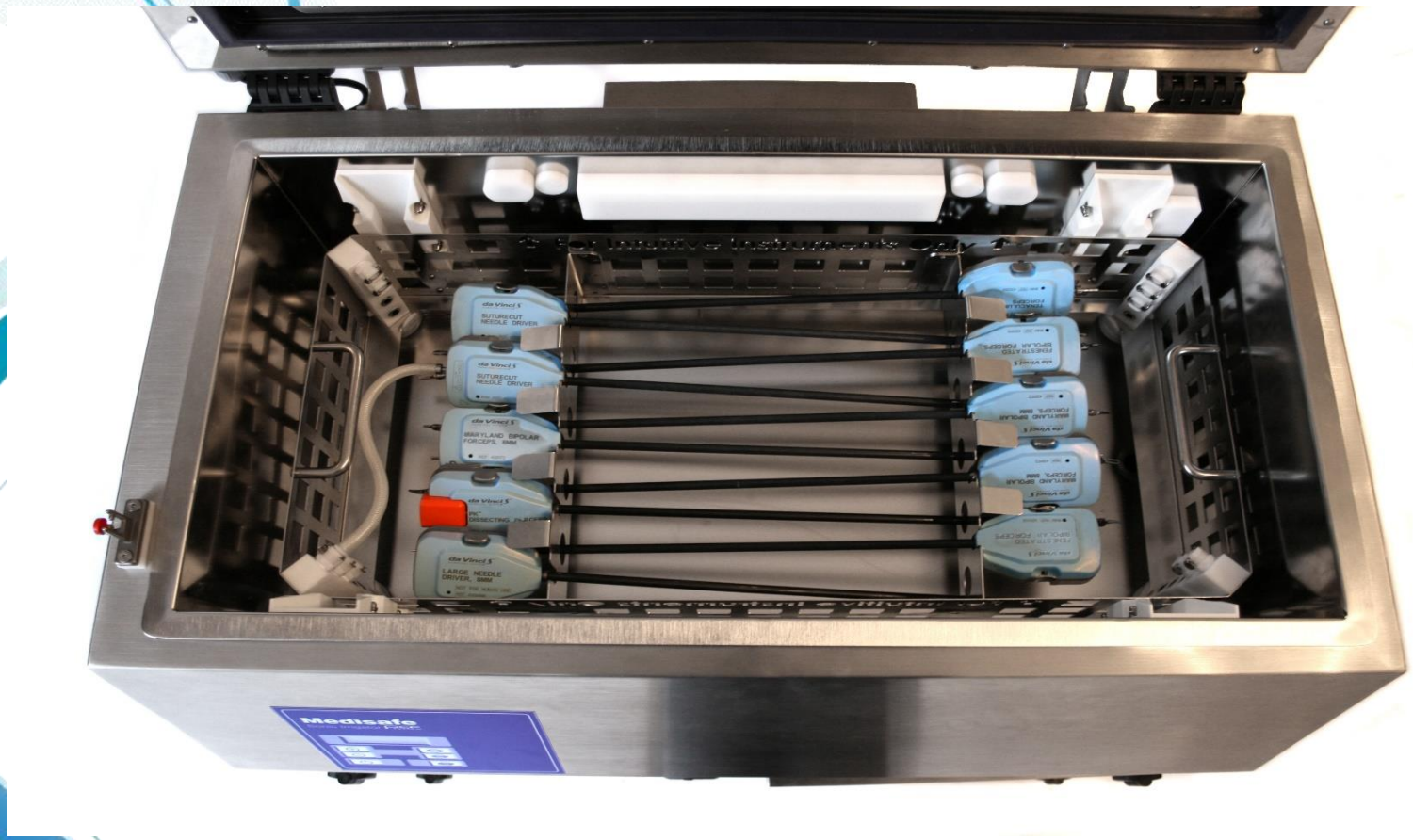
Perfect for justifying capital purchase of Sonic Irrigator.

Run them in regular washer cycle and show Administration the results

WashCheck H



Testing and JUSTIFICATION



Testing Devices: Washers

TOSI

- **Directly correlates to the cleaning challenge of surgical instruments.**

- **Complies with AORN Recommended Practices for Sterilization as well as ASTM Guide D7225.**

What is Fibrin?

A white natural body protein that is deposited on injured tissues, contributes to the stoppage of bleeding, aids tissue repair.

Creates a water insoluble covering

and mixes with Albumin and Hemoglobin to create challenges to cleaning.

Fibrin levels vary in people between 2-4%

That’s why cleaning blood varies in difficulty.

Tosi Minor Fibrin Failure

Minor Fibrin Residue

Mechanical spray activity is good,
try improving chemical activity by increasing enzyme hold time, raising temp. or raising pH.

Tosi Failure : Fibrin Remains

Fibrin Layer Remains

Chemical activity is poor, check for lack of enzyme cleaner and/or lack of high pH detergent.

Tosi Failure Hemoglobin

Minor Hemoglobin Residue

Chemical activity is good but some
obstruction to spray action. Check for
overloading or blocked spray arms

Tosi Failure : Combo

Most of Fibrin Layer and Some Hemoglobin

Poor chemical activity and some Spray obstruction

Tosi Major Failure

Major Lack of Cleaning

Very little activity from both chemical
and spray action. Major blockage or
cold rinse may be too hot

WASHCHECK

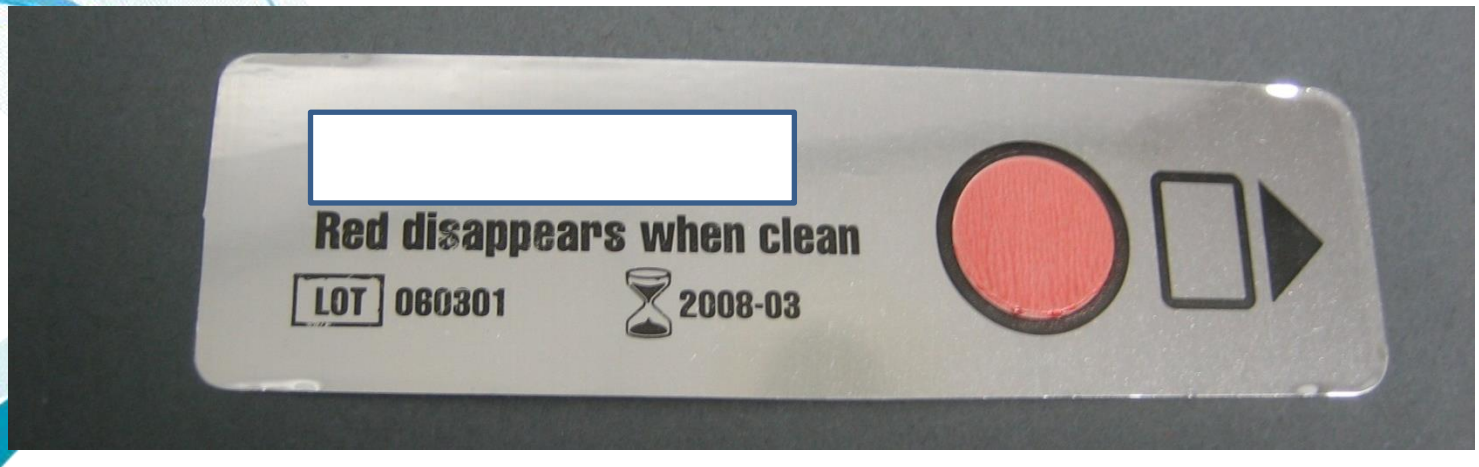
More economical than TOSI

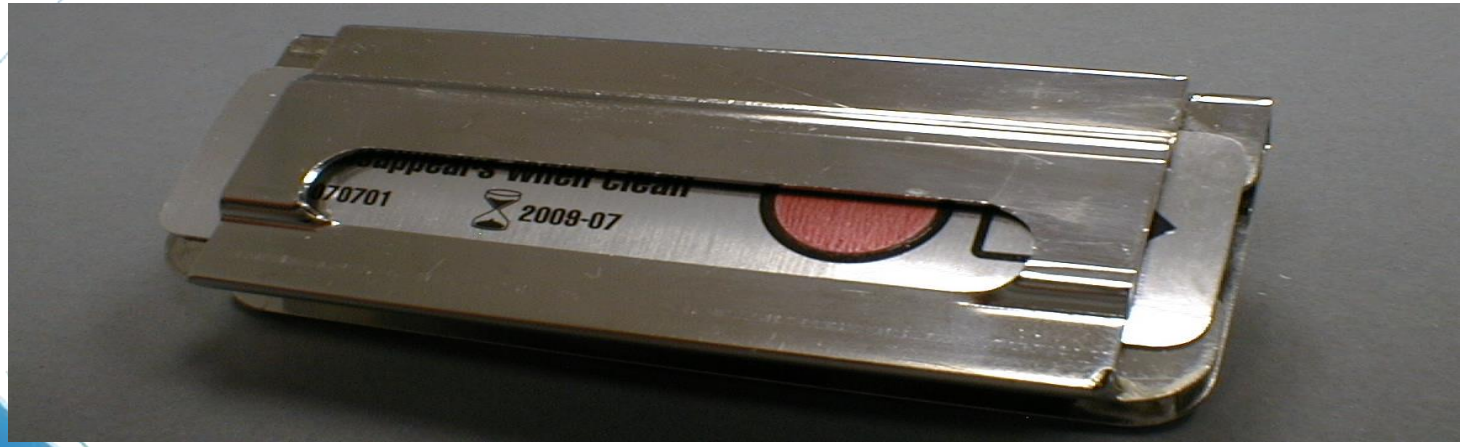
Can be used in conjunction with or as standalone to other devices

Can be run with instrument cycles

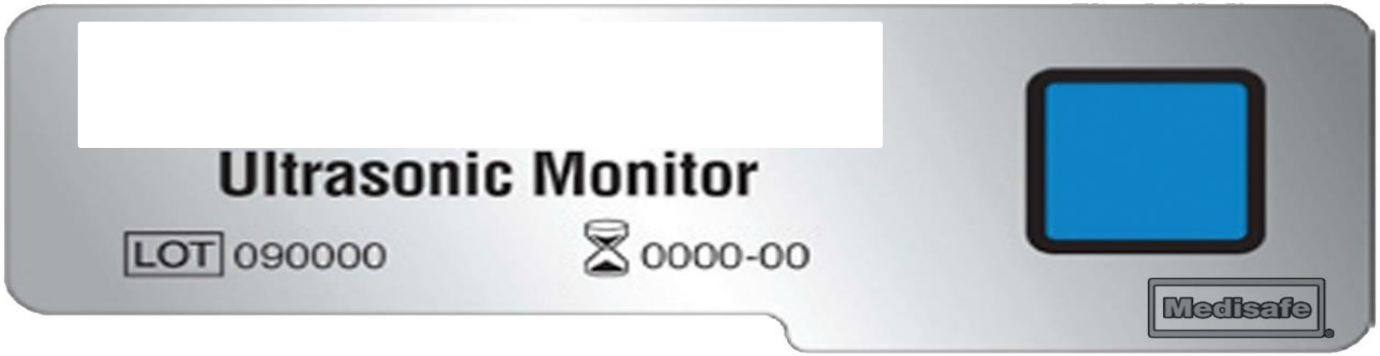
One test shows results of direct and indirect contact with wash spray.

Testing Devices: Wash-Checks





For washers and sonics



Washcheck Log

Wash-Checks Cleaning Record

Machine No.

Date/ Initials	Time or Cycle No.	Result	Staple WASH-CHECKS Monitor Below
		☐ Pass ☐ Fail ☐ Marginal	
		☐ Pass ☐ Fail ☐ Marginal	
		☐ Pass ☐ Fail ☐ Marginal	
		☐ Pass ☐ Fail ☐ Marginal	
		☐ Pass ☐ Fail ☐ Marginal	
		☐ Pass ☐ Fail ☐ Marginal	

Reorder No.: WC 103 A

Testing Devices:
STERIS Verify All-Clean

Directly correlates to the cleaning challenge of surgical instruments.

Steris Verify All-Clean

- Most economical of three devices
- Interpretative instead of Pass/fail*
- 360dg challenge
- Single device center of rack
- Run with instruments. Great challenge and good if you have limited cycle capacity

- Impingement Related Failure
  - Clogged Spray Arm
  - Loss of Pump Pressure
  - Overloading of Rack/Basket
- If processed with instruments
  - Incorrect Positioning of Indicator

- Chemistry Related Failure
  - Enzyme Cycle is too Short
    - Minimum of 2 min
  - Temperature Parameters are not accurate
    - Enzyme Cycle
    - Thermal Cycle
  - Under delivery of chemistry injection

Recap of what we are "challenging" or testing

1. Temperature on..
2. Washers. Cart wash. Sonic
3. Irrigating Sonics. Lumen test
4. Cavitation in Sonic
5. Water Quality: PH-Alkalinity-Hardness
6. Cycle parameters for each program
7. Blood residue/organic soil test.
8. Post wash cycle (As add on later)

Middlesex Hospitals current Verification Program

- **Full program daily tests**
- **Post wash tests. ATP**
- **We run Tosi daily.**
- **We test temp Daily**
- **Water quality monthly**

Middlesex Continued..

Middlesex tests the “hand cleaning" process

with swabs and ATP device

We also run TOSI and Verify through the whole cleaning process.

Normal cleaning practices that occur before the item is placed into the washer.

This may include enzyme pre-spray, hand washing, soaking in sink and sonic etc.

We benchmark the entire cleaning process.

What is ATP??

ATP (adenosine triphosphate) is present in all organic material, and is the universal unit of energy used in all living cells.

ATP is produced and/or broken down in metabolic processes in all living things.

The luminometer uses bioluminescence to detect residual ATP as an indicator of surface cleanliness.

The presence of ATP on a surface indicates improper cleaning and the presence of contamination.

This implies a potential for the surface to harbor and support bacterial growth.

ATP

Middlesex is using ATP device regularly to monitor hand cleaning processes and for lumens in our flexible scopes. We also spot check instrument categories to look for consistency in cleaning from tech to tech and shift to shift

Other systems available, these devices originated in the food industry

ATP Device

Setting up your program.

Who does it?

Designee allows for consistency.

Rotated overtime.

All techs play role in program.

Allows for specialized training and resume building

Document in Policy and Procedure manual.

QA or follow up to problems is important and should be documented

Important steps

- Program is part of Policy and Procedure manual in dept.
- Consult with Infection control dept. when complete.
- Document step by step for next “designee”
- Follow MFGR instructions for use of products

- Make general CSS/SPD staff aware of program and their role in program.
- Present costs/savings to your internal Value analysis if necessary
- Put your logs and records in a dedicated binder for one stop viewing.

Daily “Floor Tech” responsibility

This is where “all” techs play a role. This is not the “designee”. This is a role and function of all Decontam personnel upon start of their shift.

Refer to “Checklist”

Cleaning Screens

Removing debris in chambers
and check for debris in spray arms

Checking cleaners. Full ? Empty ?

Reporting any malfunctioning equipment to supervisor/charge person.

Include in Weekly

Mark line & date on level of soap w. sharpie marker.

Prime lines if department does not remain open 24 hrs. Consult MFGR

Verify Cycle settings/program

Review “Daily” tests and/or checklists and completeness/accuracy of logbooks

QI tech Monthly/Quarterly checks

Run Descaler per Mfgr Instructions.

Number the racks and machines.

Consult service rep on Following:

Hoses Pumps Descaler Valves

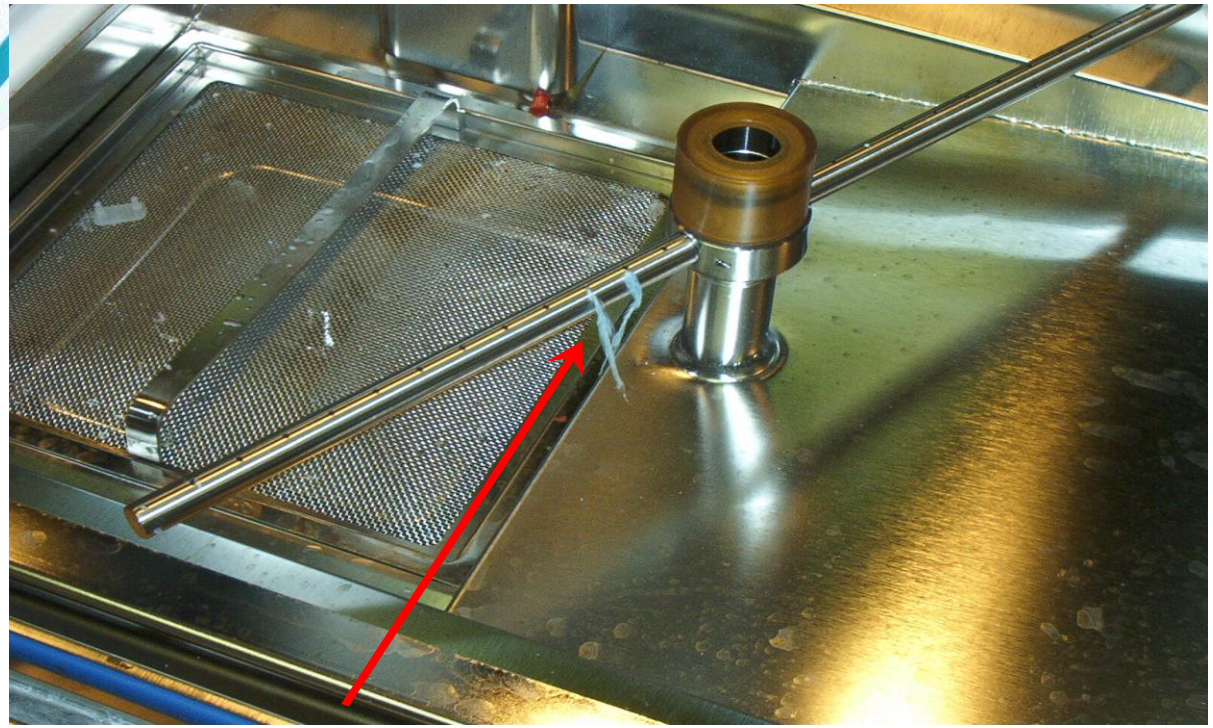
Any related service required

Annual

- Annual review
- QI what common failures occur and is there a common time frame (pump motor failures etc)
- Share your results with infection control committee or other depts. Bring to Value analysis and show them why we are spending all the hospitals money!

Visual check of washers-Detergent lines. Internal and external.
Example of leaks in hoses

Washer check.
Clogged spray arms



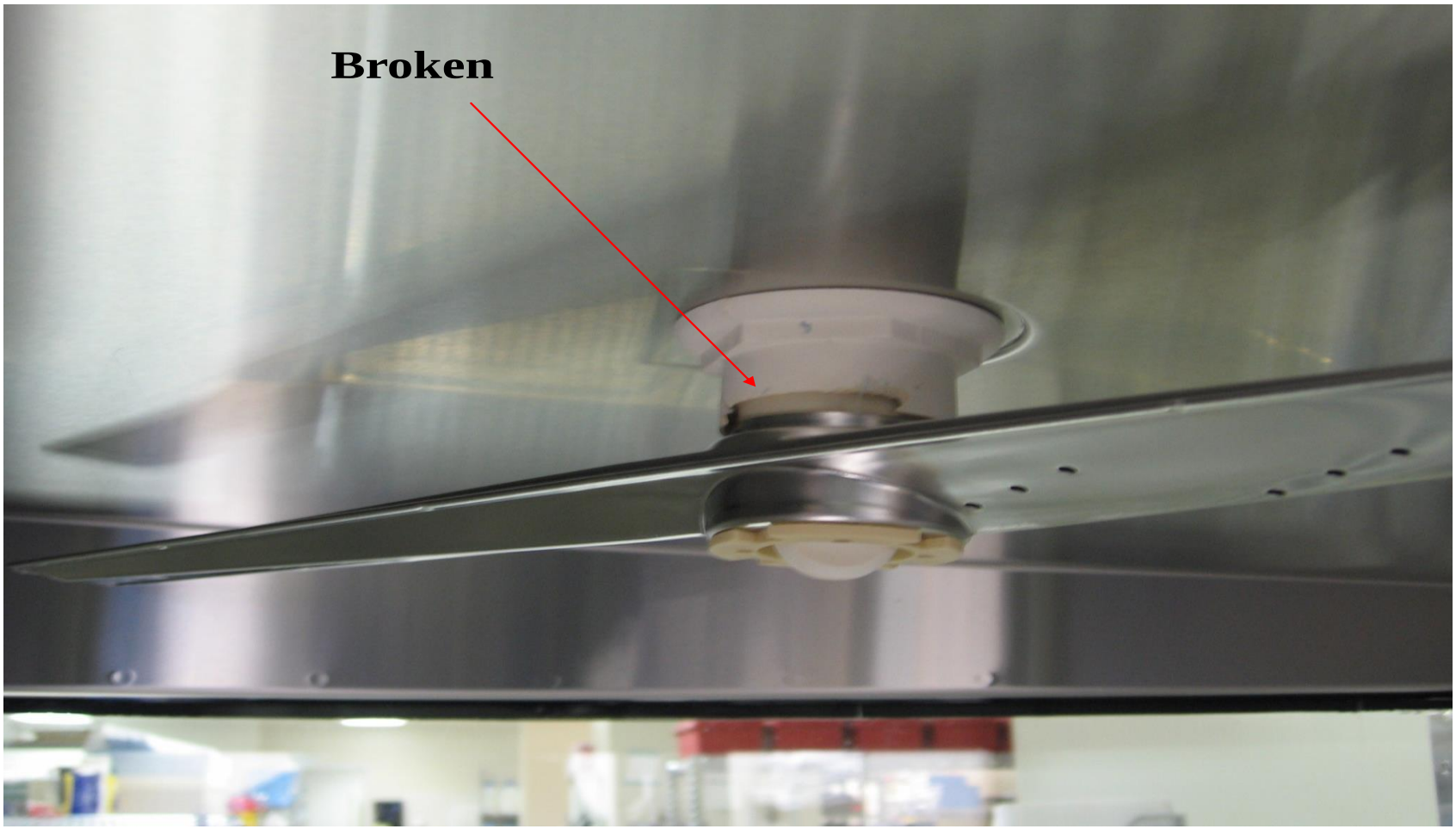
YUCK !!!!

Washer check: No Spray arm!

Washer check:
Blocked spray arm

Washer check: Who needs milk when we have all this Calcium??

Washer check: Broken Spray arm



Support your society!

Join the struggle!!!

“We are They” DJ

- **"Those who expect to reap the blessings of freedom must, like men, undergo the fatigue of supporting it."**

Thomas Paine

Change will not come about through expectation

Dave Jagrosse

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Gracias