



The Principles, The Process, and The Results: **Cleaning Verification**

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Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation or for travel to and from the seminar
- All opinions are those of the presenter

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EXTRA! EXTRA!

Making Headlines



New York: Lawrence Hospital – 2011

Possible Hepatitis, HIV Exposure

- Ten surgery patients of Lawrence Hospital Center (LHC) in Bronxville are being notified of the need to get tested for HIV, hepatitis B and hepatitis C due to improperly cleaned equipment.
- The state Department of Health said the hospital reported that nine surgical trays were found to have been improperly sterilized after they had been used during procedures. They had, however, been cleaned and disinfected.
- The notice marks the second time in less than one month that an area health care facility has warned of possible exposure to blood-borne diseases. In February, more than 200 patients of the state-run Rockland Psychiatric Center were told they needed to get tested following a case of hepatitis B transmitted through a lancing device to collect blood samples

<http://www.thebody.com/content/art61004.html?wn>

From [U.S. Centers for Disease Control and Prevention](#)

March 14, 2011

Philadelphia Hospital - 2014

- A Philadelphia hospital was struck last year by an outbreak of drug-resistant bacteria associated with the use of a special kind of hard-to-clean endoscope, according to city data.
- Just reported on 2/6/2015 – one year later
- Eight people examined with the scopes became infected with bacteria resistant to a class of last-resort antibiotics called carbapenems, and two patients died.
- The city Department of Public Health said. These "superbug" bacteria have an estimated mortality rate ranging from 25 percent to 50 percent in those infected.
- But both of the Philadelphia patients who died had serious underlying conditions, so their deaths were deemed "not clearly related" to the infection, department spokesman Jeff Moran said.

Read more at

http://www.philly.com/philly/health/20150206_Superbug_infects_eight_patients_at_Philly_hospital.html#vhjoc74mOVgGIMTF.99

“Any organic matter that remains after manual cleaning lowers the effectiveness of the disinfectant, but the complex nature of endoscopes makes them very difficult to thoroughly decontaminate. With imperfect cleaning, bacteria could survive the disinfection process and infect the next patient.”

Spach D., Silverstein F. & Stamm W.
Annals of Internal Medicine 118, 117-128 (1993).

Nine Factors That Affect the Cleaning Process

- Water quality
- Temperature
- Chemical activity
- Dilution/Concentration
- Mechanical action
- Human factor
- Time
- Item to be cleaned
- Type of soil





The various combinations determine how clean your instrument will be.

Water Quality

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



What is pH ?

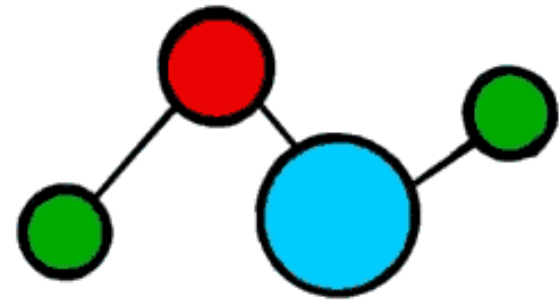
	 Acids							 Bases							
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14
$[H^+]$	10^0	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}	10^{-8}	10^{-9}	10^{-10}	10^{-11}	10^{-12}	10^{-13}	10^{-14}
$[OH^-]$	10^{-14}	10^{-13}	10^{-12}	10^{-11}	10^{-10}	10^{-9}	10^{-8}	10^{-7}	10^{-6}	10^{-5}	10^{-4}	10^{-3}	10^{-2}	10^{-1}	10^0
	Hydrochloric Acid (HCL)	Stomach juice	Lemon juice	vinegar (Acetic Acid)	orange juice	Rainwater	Milk	Pure water	Egg whites	Soap, Baking soda	Potash	Ammonia (NH ₃)	Mineral Lime Ca(OH) ₂		Potassium Hydroxide (KOH)

The pH scale measures the acidity or alkalinity of a liquid.

The diagram shows that the scale ranges from 1 which is acid to 14 which is alkaline, the mid-point between the two being 7 which is neutral. As a guide, water would fall around 7.

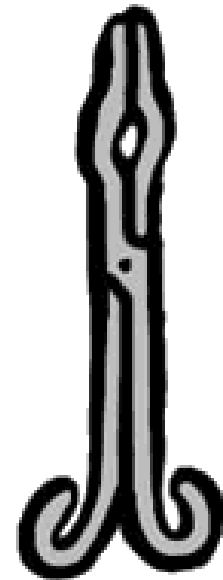
Water Quality: Hardness

- Water hardness is defined as the concentration of calcium and magnesium ions expressed in terms of calcium carbonate.
- These and other minerals bind with the cleaning agents in detergents and prevent them from reacting with the soil on instruments.



Water Quality: Hardness

- The amount of hardness minerals and other dissolved solids in water present obstacles to good cleaning.
- Hardness minerals can cause spotting and filming on instruments. They must be effectively tied up or sequestered if the cleaning results are to be satisfactory.
- You want a low ppm reading number for hardness (less than 200ppm is good).



Water Quality: Alkalinity

- Total Alkalinity is a measure of the buffering capability of water to resist changes in the pH level.
- It is desirable at every given level of pH, to have a high level of Alkalinity (a high number is good).

Water Temperature

- Dependent upon the cycle & machine design
- Pre-wash cold water (target 60-90F)
- Chemistry cycles targeted range
 - Enzyme: 110 - 140 F – See IFU's
 - Detergent: 140-160 F - See IFU's
- Thermal disinfection 180-205 F
 - Time depends on washer manufacturer: 1 – 2 min



Cleaning Activity: Enzymes

- Enzymes speed up cleaning action.
- Enzymes are like living cells which attack and breakdown organic soils
- *Each* enzyme acts on a particular kind of substance, which is called substrate.
- In short, an enzyme is thought to fit its substrate much as a key fits a particular lock.

Chemical Activity: Detergents

- A detergent for medical use must be able to remove all organic and inorganic materials without damaging the device.
- Temperature of water and the storage environment can affect detergent efficacy

Dilution & Concentration

- Precise concentration and dilution is dependent on water quality, soil load and temperature
- Needs to fall into a range based on expectation of cleaning
- More is not better – residuals

Means of Cleaning Mechanics

MANUAL PROCESS



Sink manifold,
lumen flush,
and spray gun



AUTOMATED PROCESSORS



Automated
washers, cart
washers, and
sonic cleaners



Basic Requirements for Cleaning

- An effective management control system which includes all aspects of the cleaning cycle
- Appropriate facilities are provided
- Appropriate equipment is available, and utilized appropriately
- Processing equipment is calibrated, validated and monitored
- Properly trained and supervised staff
- Single use items are not reprocessed
- Records of the decontamination process are maintained

Manual Cleaning

- 3 Sink Process
 - Rinse - Enzyme - Rinse
- Brush & Flush
- Use Cleaning Chemistry
- Water Temp is Important



Automated Processors

- Automated Washer / Decontaminators
- Instrument Washers
- Ultrasonic Washer
- Washer Sterilizer
- Cart Washers





Automated Washers



Let's take a closer look at...

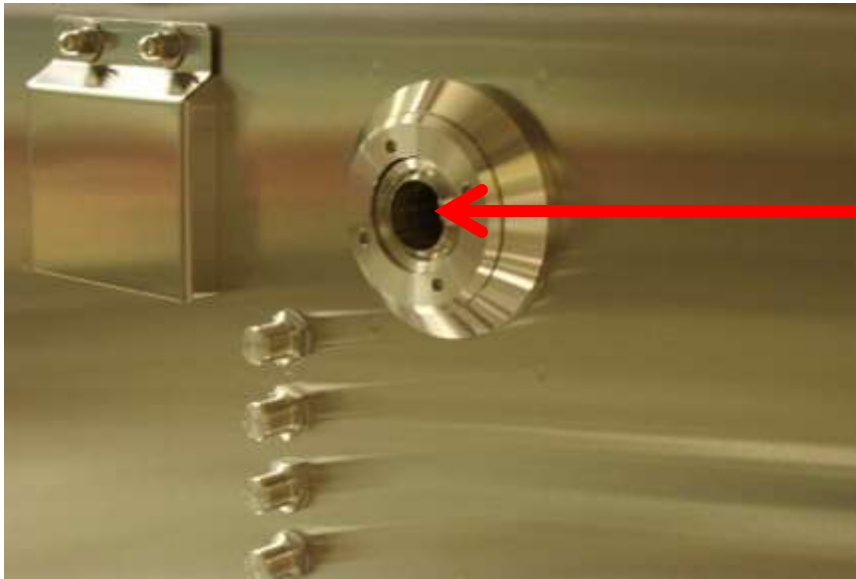
Automated Washers

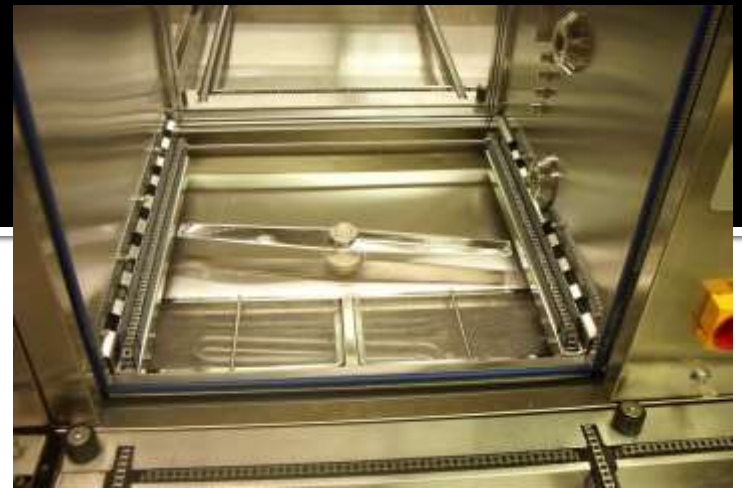


Automatic Cleaning

- 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?
 - Routine monitoring
 - Keep a record of all results (log book)
 - Document the optimal cycle settings (master copy retained)

Racks are Functional Equipment





WHAT'S WRONG

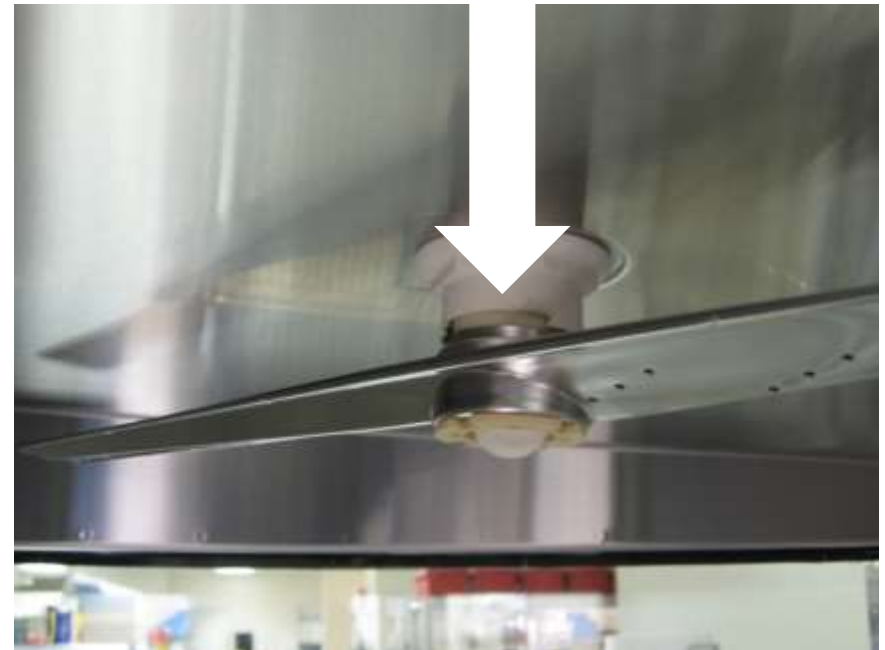


What's wrong?

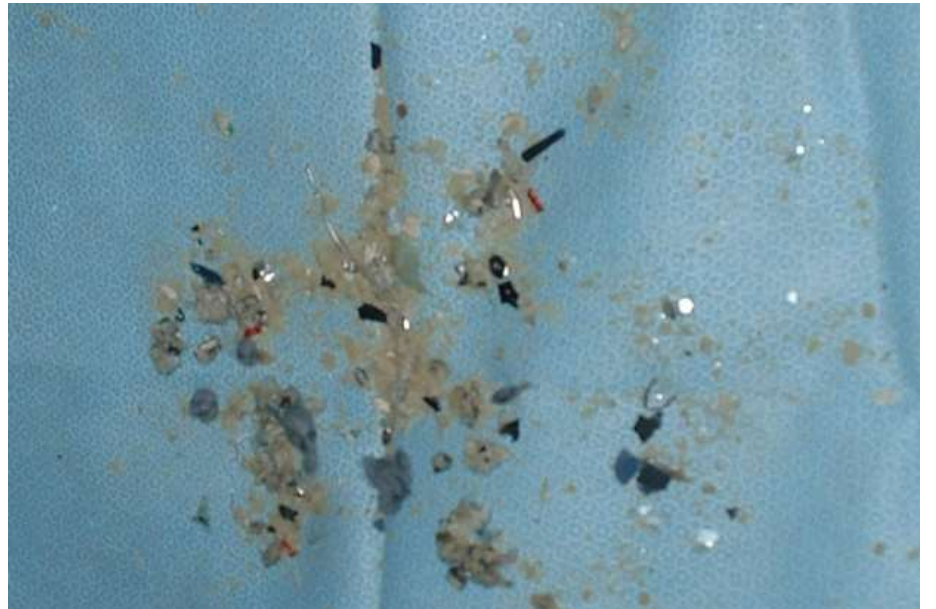
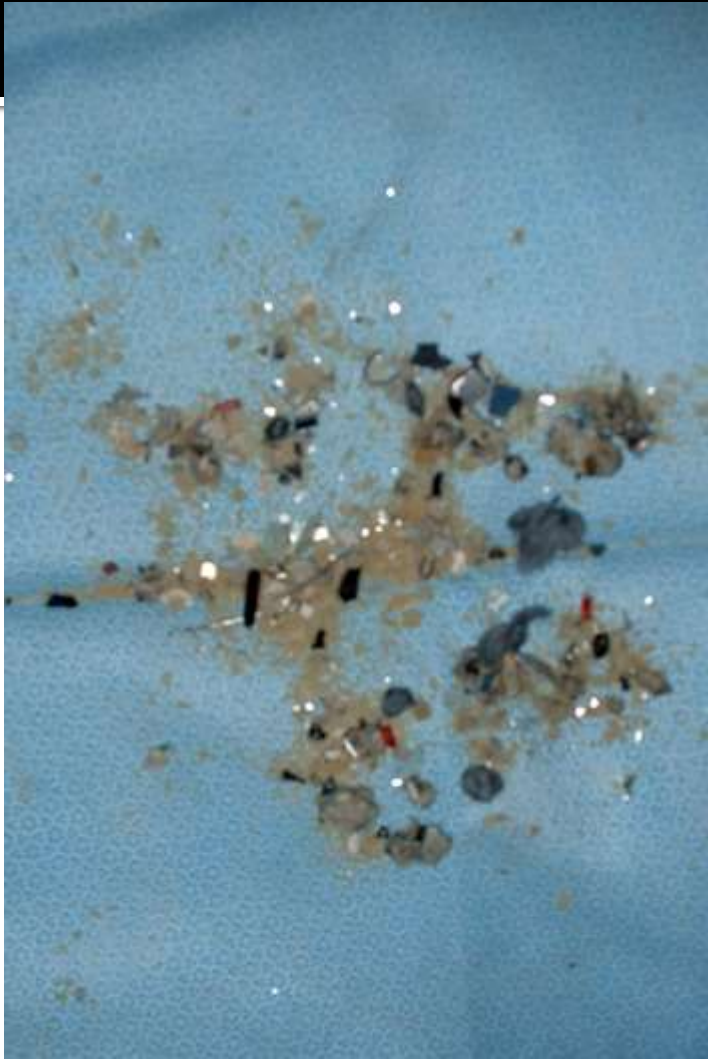


Missing Spray Arm

Broken









The Human Factor: Loading





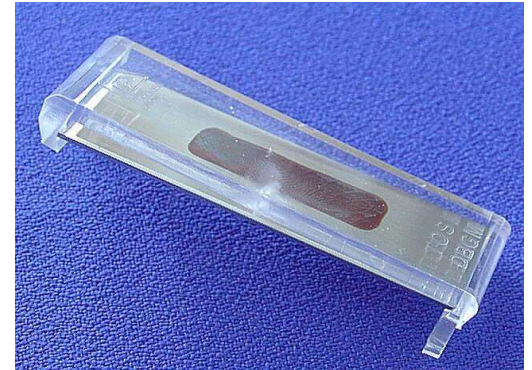


Does this look better?



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



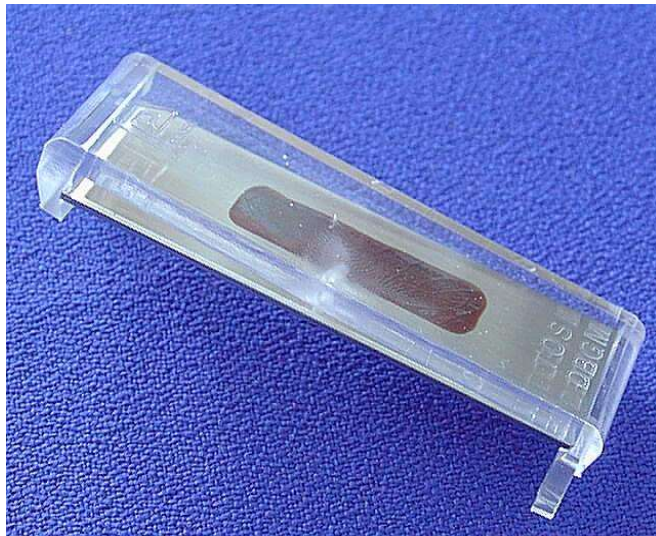
Understand the 9 Factors



TOSI

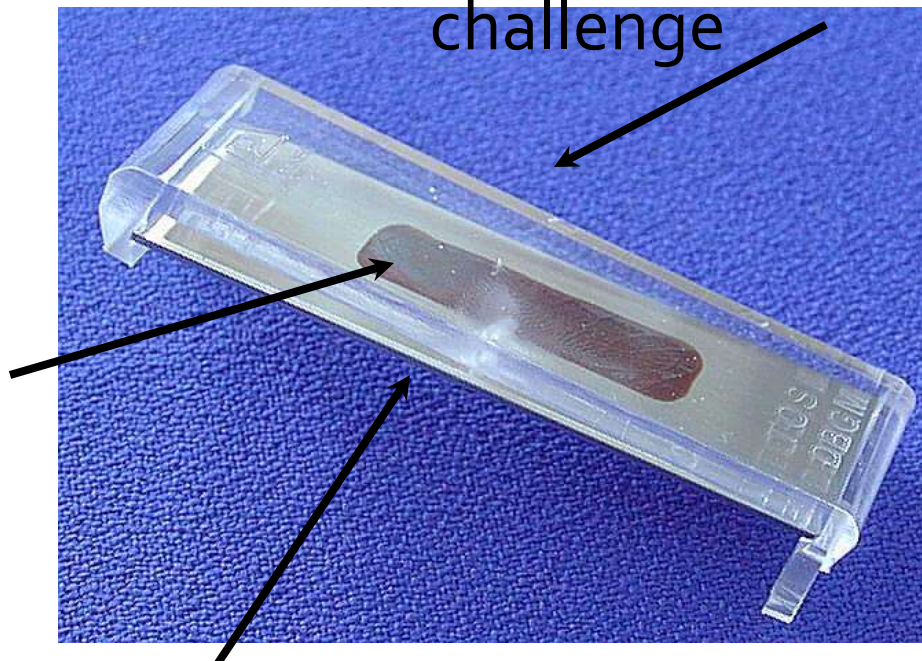
Equals a dirty instrument

- Test Object Surgical Instrument (TOSI)
- Nooks and crannies (e.g box lock)



How does the TOSI work ?

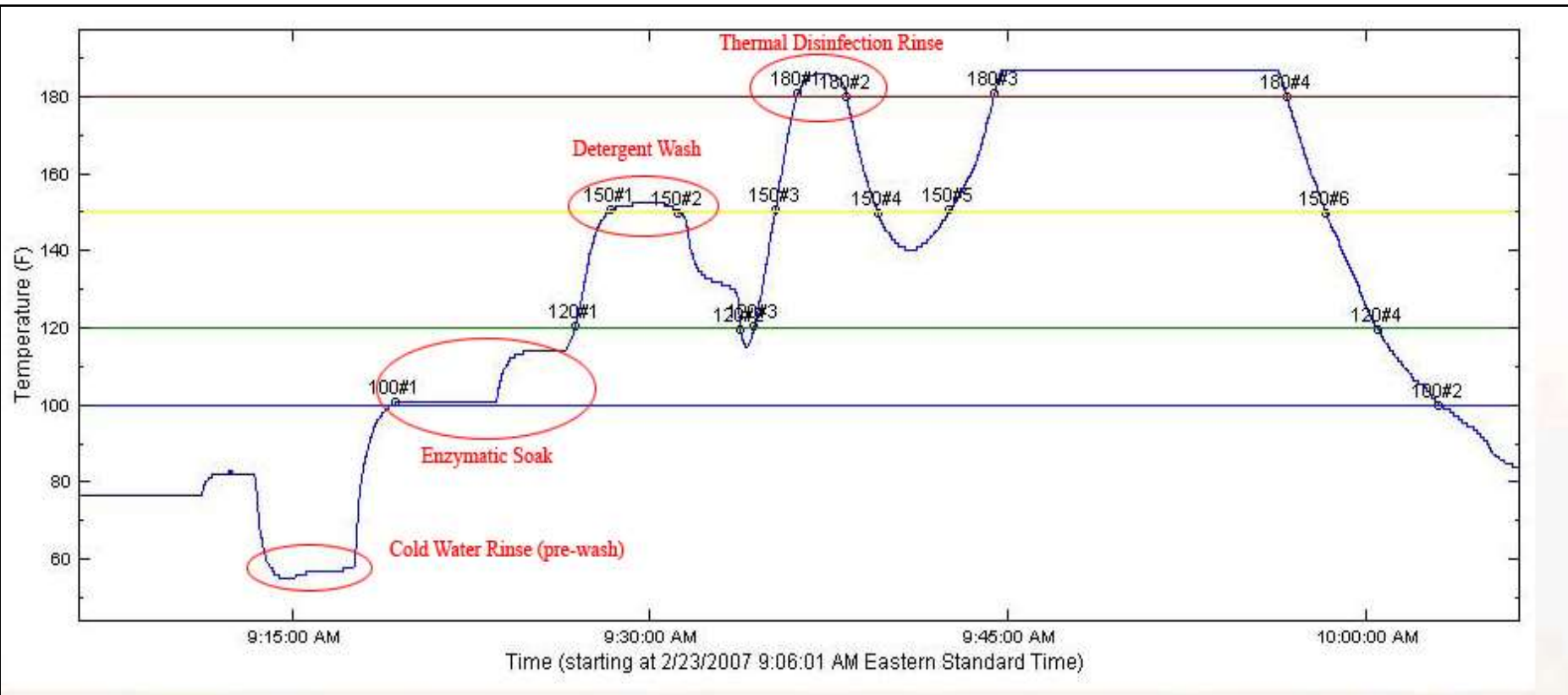
Test Soil -
Mimics dried
blood; same
components
of blood



Transparent Holder –
Angled, provides increasing
challenge

Stainless Steel Plate – Scratched, just like a
surgical instrument may be

Graph the complete temperature profile of the automated washer with the TEMPACHEK-DL 2™



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.

Ultrasonic Cavitation

Ultrasonic cleaners work by producing ultra high frequency sound waves that cause micro explosions.

- These explosions generate very high pressure of water and also create ultra high temperatures.
- This combination helps to blast contaminants off of instruments.

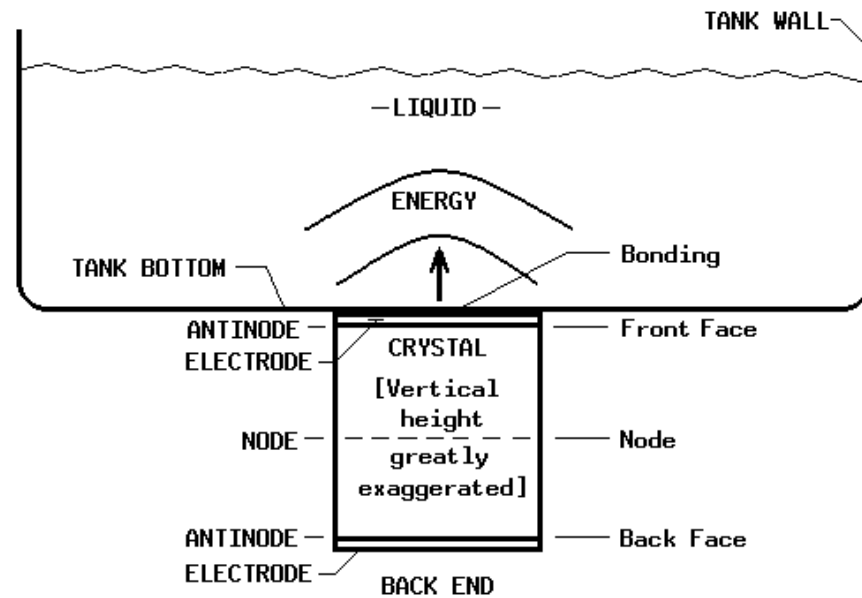


Ultrasonic Cavitation



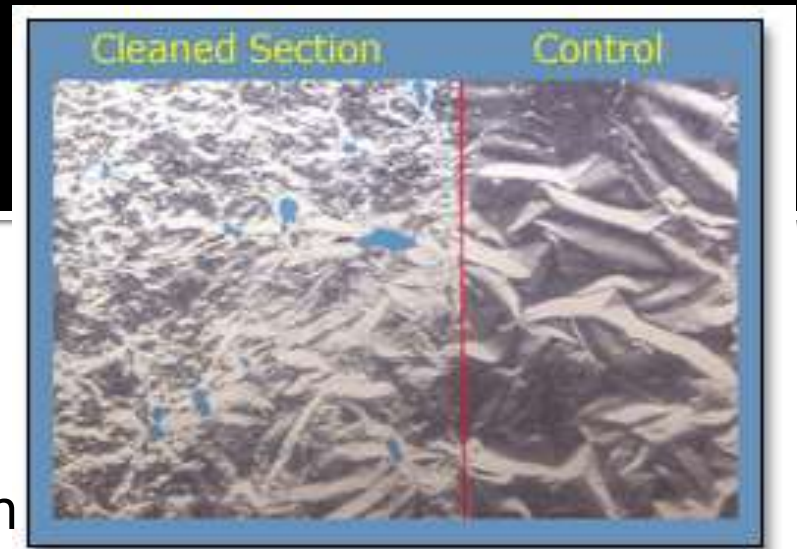
- Like any mechanical device, from time to time, transducers fail.
- Given the nature of ultrasonic cleaning, observation of failure is not easy.
- Also, in a series of transducers, one may be failing, while the remaining units are functioning, creating dead spots within the ultrasonic.
- Monitoring devices for detecting cavitation are now commercially available.

Ultrasonic Cavitation



Foil Test

The cleaning effectiveness of an ultrasonic cleaner can be monitored with a piece of aluminum foil it must be suspended into the cleaning solution extending the full width and depth of the solution. The unit is activated, and after 20-30 seconds, the foil can be removed and examined. The presence of significant pitting and a uniform pattern of dents and holes indicate the cleaning unit is performing properly. This is a very subjective test.



SonoCheck

You Can Test For The Presence Of Cavitation Energy



The Sonocheck is put in an empty tank. Record the time the SonoCheck changes color (it can turn as quickly as 10 seconds). Color change should be from green to yellow. No color change you need to service the equipment. Sonocheck is easy and quick to use.



Tools For Assessing Efficacy Of Ultra Sonic Washer



- 9 Factors
- Water Quality
- Chemistry
- Mechanical Action
- Time
- Temperature



LumCheck™



- Test object simulating cannulated instruments
- Use for monitoring the cleaning efficiency for reprocessing cannulated instruments in washer-disinfectors or ultrasonic cleaners
- Test soil correlating to human blood
- [Video](#)

Assessing the Cleaning Process

(Based on AAMI ST79)

	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

Recommendations and Guidelines

- Customer Reference
 - Decontamination Standards, Guidelines & Articles in support of using the TOSI 2014
- AAMI – New Standard ST-79
 - Weekly, Preferably Daily
 - After all repairs
 - Must be surrogate device
- JCAHO:
 - E.C.6.20 – All medical equipment must be maintained, tested and inspected.
- ASTM Standard D7225-06 for Blood Cleaning Efficiency Of Detergents And Washer-disinfectors
 - 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.

AORN Recommendations

Recommended Practices for Cleaning and Care of Surgical Instruments and Powered

- A quality management program should be in place to test mechanical cleaning equipment.
- Mechanical instrument washers should be tested for proper functioning before initial use, weekly during service, and after major maintenance.
- Manual cleaning should be evaluated when new types of instruments are reprocessed and periodically, at intervals determined by the health care organization.
- Testing washer decontaminators on a regular basis verifies that the equipment is functioning properly or identifies an opportunity for corrective action.

AORN Recommendations, cont.

- Washer testing products are commercially available.
- XXII.a.2. Periodic testing provides an opportunity to evaluate the performance of personnel. Manual cleaning is a learned skill and subject to human error. New instruments can pose unique challenges when cleaning. Protein indicators are commercially available to assist with this evaluation.
- XXII.a.4. Adverse events should be reported in the adverse event reporting system and reviewed for potential opportunities for improvement. When investigating surgical infections, documentation of the cleaning process of instruments should be reviewed. Near misses should be investigated and corrective action taken to prevent serious adverse events.

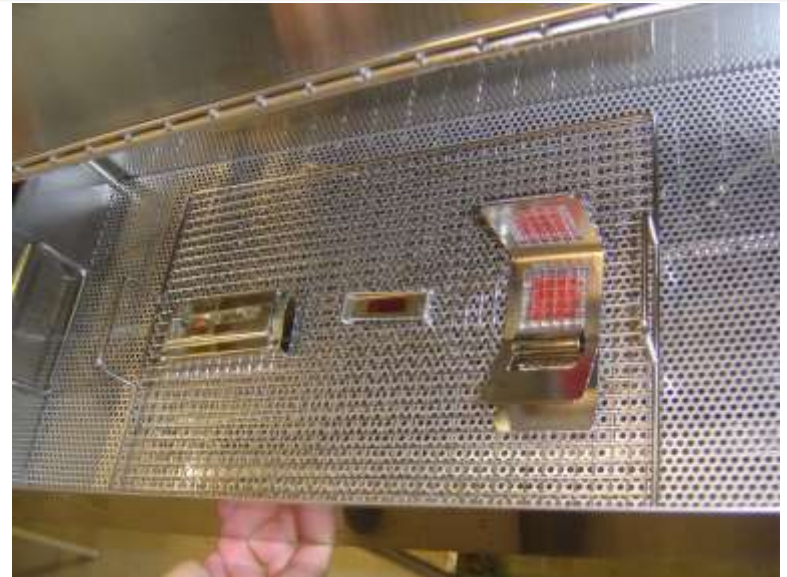
FDA, AAMI & Other Standards State...

- Simulated testing should 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.

Cleaning Verification Success

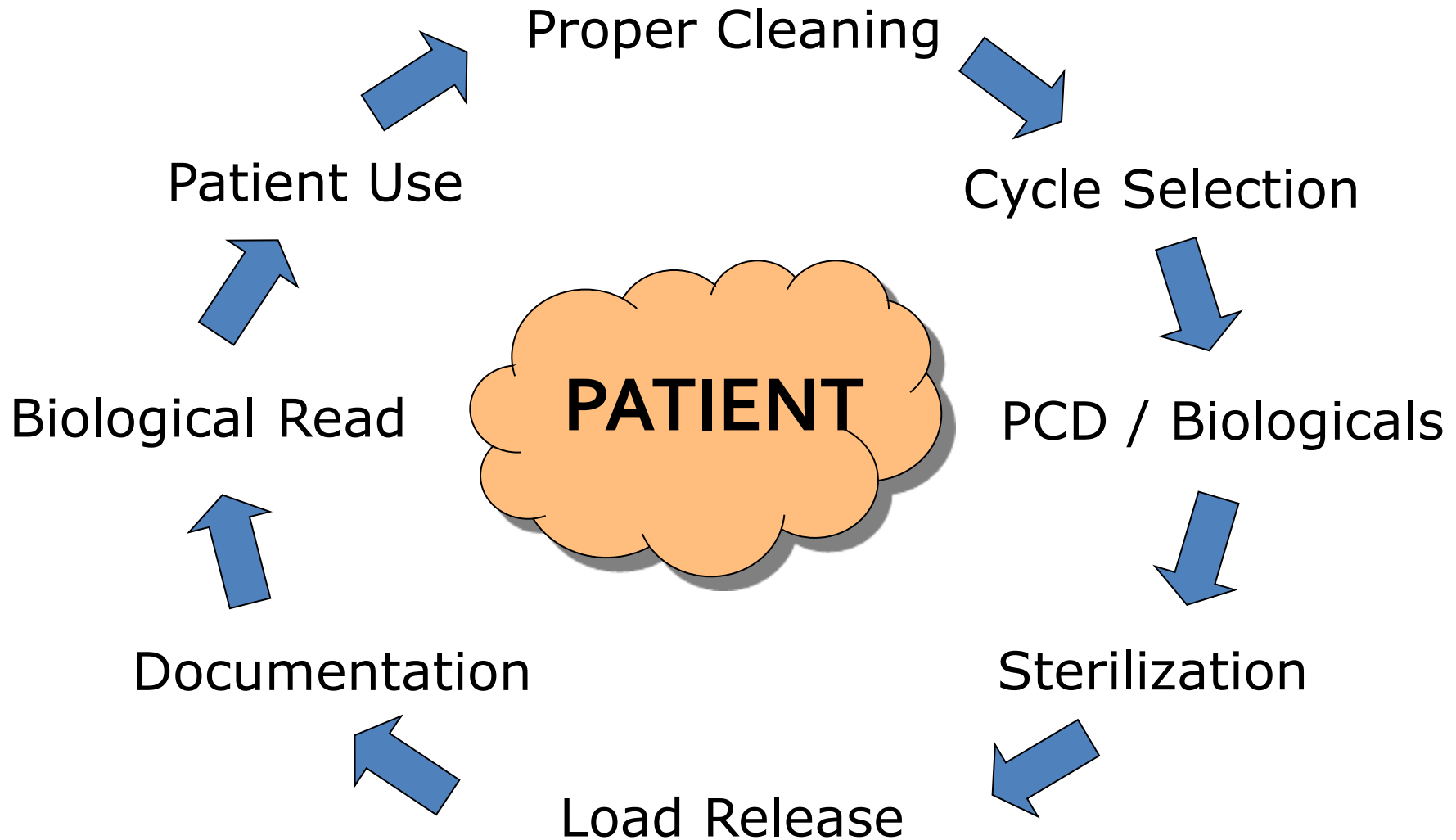
Implement Washer Verification Program

- Test washer performance
 - Load into empty chamber on each level
- Test loading configuration
 - Load into full washer in location of concern



“...Mechanical cleaning equipment should be tested upon installation, weekly (preferable daily) during routine use, and after major repairs” AAMI ST79 2010 7.5.3.3

The Circle of Life



Thank You!

Questions?

On behalf of Healthmark, I would like to thank you all for the opportunity to be here today.

THANK YOU!