We are focusing on Medical Automatic Washers (M.A.W.)

Historically, instruments washers were developed from commercial dishwasher technology and adapted to today’s science based requirement

Automated washer
- Designed to increase through-put and consistency
- Use pressure and detergents through delivery systems
- Manage the other inputs

Some have ultrasonic
- Cavitation, detergents and time

Medical Automatic Washer

• The FDA regulates the introduction of medical devices in interstate commerce
  - A medical washer-disinfector intended to clean and provide high level disinfection of medical devices must have a FDA cleared pre-market notification (510(k)) submission before it can be sold. A medical washer intended to clean medical devices or a medical washer-disinfector intended to clean and provide either low or intermediate level disinfection of medical devices is exempt from 510(k) requirements
  - The majority of M.A.W. found in the hospitals within the United States provide low to intermediate level disinfection and are exempt from the 510(k) requirements.

Medical Automatic Washer Fall Into Two Very Distinctive Categories on Theory of Operation Which Are:

• North American
  - Relies on “high impingement”, softer chemistry
• European
  - Relies on “low impingement”, high volume, stronger chemistry

Medical Automatic Washers Also Have Two Basic Model Types, Which Are:

• Batch-type medical automatic washers
• Rack conveyor type medical automatic washers (tunnel washers)

Batch-type

• Batch-type medical automatic washers have a closed cabinet which is linked to the water supply and drainage system. The machines are loaded with the soiled instruments / utensils and the doors locked before the cycle commences and all cycle are done in the one chamber.
A Closer Look at The Mechanics

Tunnel type

- Rack conveyor type medical automatic washers (tunnel washers) operate on a continuous process in which the machines are loaded with the soiled instruments / utensils and the doors locked before the cycle commences and are transported from stage to stage at a fixed speed by means of a conveyor.

Regardless of the Model or the Theory Behind a Medical Automatic Washer If They Are Maintained (Preventative Maintenance by a Qualified Person) and Properly Calibrated and Used Accordingly They All Work.

An Effective Medical Automatic Washer Depends on Many Critical Factors, Which Are Equally Important in Achieving a Successful Result – Clean Instruments That Are Safe to Handle, and Then Sterilized.

Identify the critical factors in the automatic medical washer cleaning process.
The 9 Critical Factors

- Type of soil to be cleaned (blood, synovial fluid...)
- Medical device to be cleaned
- Water quality (pH, hardness...)
- Temperature (cycle, cleaning solution...)
- Chemical activity (cleaning solution)
- Mechanical action (spray arm, sonic,...)
- Human factor
- Standards and guidelines (AAMI, FDA, AORN...)
- Verification of the process (what do I use)

Mechanical and Human

- You can pick the right cleaning solution but if the medical automatic washer is not performing correctly and your staff is not trained, instruments will still come out not clean.
- You can use the wrong cycle setting
- Let us examine how the mechanical and human factors play a role in getting your instruments clean

Cycle Setting: The Various Combinations Determine How Clean Your Instrument Will Be.

Cycle Time – How you Divide it Up?

- Pre-wash
- Wash (enzymes / detergent)
- Disinfection
- Lube
- Final rinse
- Drying

Water quality – hardness, pH
Temperature – cold or hot
Chemical activity – type and amount
Mechanical action – time it is working
Human factor – loading
- Items to be cleaned
- Target Soil

Disinfection and temperature

- Thermal disinfection – Hot Water 180F - Time at least 1 minute
- New washers don’t claim high level disinfection. Some make claims low or mid level disinfection.
- Washer Sterilizer – High Level

Drying and temperature

- Temperatures
  - 210°F – 240°F
- Not Source Disinfection
- Find the right time setting
- Overload will impact
- Trays come out Wet or Dry?
Mechanical Parameters
- Water quality
- Pump pressure
- Spray system
- Instrument load in machine
- Type of chemical cleaner
- You have look for the problems

Observation and Inspection is the Key

Ever Picture tells a story....or a picture is worth a thousand words ...no matter what saying you use ,you will see a lot of pictures today, to help understand better your medical automatic washer

Mechanical Functions

Spray Arms
- Spray arms play a vital role in washing.
- It is these arms, with their spinning action and multiple, widely dispersed nozzles which spread the rinsing and cleaning solutions throughout the chamber of the washer – and all over the instruments.

Spray Arms cont.
- Nozzles should be checked daily
  – Really each time you put trays onto the rack
- Corrosion of parts can lead to spinning arms that are no longer spinning.
- If you are fortunate to have a washer with a window, you may be able to see arms not spinning.
Spray Arms cont.

**Spinner Arms out of Alignment**

- In many washers the spray arms are connected to the spinning axle with a threaded end (e.g., they are screwed in).
- Though this connection allows for easy removal of the arms for cleaning and replacement, the arms can be reinstalled in the wrong direction.

Alignment

**Spinner Arms out of**

- The fluid flow then comes out to the sides, instead of up and down, dramatically reducing the cleaning efficiency of the washer.
- One can easily check this visually and correct the problem fairly easily by simply turning the arms so nozzles are in the correct direction.
Impingement Washing

- The relative efficiency of a washer/disinfector is approximately 60% as a result of the mechanical impingement action of forced water delivered by the spray arms.
- A failure in any one spray arm will effect the washers overall ability to clean the instruments.
- Tim Brooks / Yuma Regional/ Thank you for these slides and information

Automated Instrument Washing is Dependent On

- 60% - Mechanical Water Impingement from Spray Arm Technology
- 40% from: Chemical / Thermal
  - Cold and hot water hardness / temperature
  - RO water purity
  - Enzyme dilution
  - Detergent dilution
  - Lubrication dilution
  - Rinse cycle
  - Load size and configuration affect total

Most Common Used Racks

- 3-Level
- 2-Level
- General Purpose
Spray Arm Impingement Pattern

Spray Arm Pattern

2 – Level Rack

Spray Arm – Machine Mounted

Highest Impingement

Instrument Tray

Spray Arm – Rack Mounted

Reduced Impingement due to distance from spray arm resulting in splashing rather the force of impingement

Instrument Tray

Shelf

Spray Arm – Machine Mounted

20%

10%

20%

15%

Shelf

3 – Level Rack

Spray Arm – Machine Mounted

Highest Impingement

Instrument Tray

Spray Arm – Rack Mounted

Highest Impingement

Instrument Tray

Spray Arm – Rack Mounted

Highest Impingement

Instrument Tray

10%

20%

20%

10%

10%

Shelf

Shelf

Shelf

20%

10%

20%

10%

Shelf

Shelf

Shelf

Spray Arm – Machine Mounted

20%

10%

10%

10%

Spray Arm – Machine Mounted

General Purpose Basket

Spray Arm – Machine Mounted

Least ability to Complete High impingement Due to Splash Effect

Hold Down Screen

Wire mesh basket with perforated instrument tray

Shelf

Spray Arm – Machine Mounted

40%

20%

Shelf

20%

20%

Rack Specifications

- Two-level manifold rack is designed to hold trays of surgical instruments and hard goods individually on each level
- Three-level manifold rack is designed to hold a general purpose rack, or one or two instrument trays on the bottom level, a general purpose rack, or one or two instrument trays on the middle level, and one or two instrument trays on the upper level
- Four-level manifold rack is designed to hold one or two instrument trays on each level
- Five-level manifold rack is designed to hold two mesh instrument trays on each level
Couplers

• Alignment - many washers the rack that holds the baskets of instruments must connect to the washer through a coupler.
• This coupler is a key connection that allows water to reach the spinner arms and insure proper cleaning efficiency.
• Be sure to check to see if the couplers are connected and secure when the rack is in place.

WHAT'S WRONG

Delivery of Cleaning Agents

• Automatically meter the cleaning agents (e.g., enzyme and detergent) into the chamber.
• Volume of agent inferred based upon operation time.
• Often users are not entirely aware of this. The source of confusion is understandable.
Metering of Chemistry

- Error only when Empty
  - Uses a separate float
    - Get’s Stuck or tricked as long as soap
- Clogged nature of detergents
- Kinks
- Melted
- Should be periodically changed - PM

Metering of Chemistry

- A method should be found to track the amount of cleaning agent consumed.
- If each individual Washer draws cleaning agents from a separate jug, a simple method would be to use a graduated container.
- Simply record the amount of soap at the beginning of the cycle and again at the end.
BioFilms

• Develop in hours→days
  – Water pipes
  – Medical devices; wet storage
• Protective effect of biofilms:
  – Difficult to remove
  – Interferes with disinfections and sterilization
• Poor water quality
  – Too much detergent
Human

- How the OR and SPD interact with the instruments after a procedure has a dramatic impact on the net result
  - Pre-clean
  - Pre-soaking or enzymatic spray
  - Overload the basket and racks
  - Disassembling instruments
- Management decision
  - Understand the consequences of your choices
- You can never over train
  - Certification
  - Yearly testing on process

D.H.T

- This stands for Decontamination Holding Time.
- This is the time from when the instrument is last used to when it is received in decontamination and the cleaning process begins. This can vary in length of time from just a few minutes to hours or even days.
Some times you have to manually clean and prepare an item...then get it ready for the next step in cleaning process.
Open Position for Cleaning

- All hinge surgical instruments with handles, such as scissors, hemostats, and forceps must be stringed before being placed in a rack, to optimize cleaning hinges. A maximum of 50 items, open at a 90° angle, must be placed in each Instrument tray.*

*Operator Manual Reliance Synergy (06/01-01) PS0003-015
How clean will these be?

“Gaps”

- Investigations into reproducible cleaning of instruments based on a worst-case model
  - Critical box locks – various gaps (0.03-0.42 mm)

Central Sterile 1/2011; G.Kirmse
Poor Mechanical Cleaning Results in

- Higher instrument costs
- Damaged instruments
- Poor outcomes
- How can I reduce this
  - Training of staff
    - Certification
    - In-service on going
  - Testing verifying the process
    - Standards support at least weekly testing of all equipment
      - Evidence based products
      - Surrogate products that reflect what you are cleaning

Clinically relevant & evidence based products
Applying the Principles to Product

Target Soil

- “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.”
  Page 44 ; ANSI/AAMI 79:2006
- Removing blood from a surgical instrument can be difficult and making sure no residual is left behind is critical to the sterilization process. Using blood as a target soil to monitor the medical automatic washing process would make sense since it is the soil most often encountered

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
“Gaps”

- Investigations into reproducible cleaning of instruments based on a worst-case model
  - Critical box locks — various gaps (0.03-0.42 mm)

You now have many choices
Not all verification tests are created equal
Choose wisely

And Don’t You Think Even a Simple Quality Process Could Have Reduced the Number of Patients That Were Exposed....

Lawyers: Tests Show Hydraulic Fluid Contaminated Instruments

Instruments used in about 3,800 surgeries were accidentally washed in hydraulic fluid instead of soap for two months at the end of 2004

The Sun has Set on this Program……much more to come