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Learning Objectives

1. Explain how a validated washing process improves productivity.
2. Define validation as it pertains to automated washer/disinfectors.
3. Discuss the impact that a cleaning process can have on the sterilization process.

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A validated approach to cleaning

by Myrka Maheux, Daniel Rochette and Nancy Kaiser

As we all know, there are more and more demands being placed on sterile processing departments (SPDs) today. The pressure for greater productivity, the need for repeatable processes and the mandate for protection of staff and patients are three of the most universal demands. It is no surprise that with the growing number of surgical cases, and the increase in number of instruments required per case, hospitals need to find solutions that make their instrument flow and reprocessing cycle as efficient as possible.

There is also a hidden cost associated with instrumentation problems that relates to loss of productivity (and therefore revenue) in operating rooms (ORs). There are more than 10,000 different hand-held surgical instruments in use today, and instrument issues are among the most frequent causes of OR delays. These delays, due to incorrectly assembled or contaminated instrument sets, can cost an average of \$1,000 per hour.¹ To avoid this significant financial loss, a SPD's ultimate service goal for their customer, the OR, should be to deliver 100% clean and sterile instruments, in 100% complete instrument sets, to the OR 100% on time.²

The reprocessing cycle is made up of many varying steps, and every step in that process affects the productivity of the overall process. The cleaning of an instrument in a washer/disinfector is only a small part of the entire process flow that an instrument follows from the time it is used in an OR until it is ready to be used again. However, *cleaning is the single most important step in instrument processing.* Without the complete removal of debris and bioburden, it is impossible to guarantee the sterilization or disinfection processes. Debris that adheres to an instrument can prevent contact with the sterilant, so even if the sterilizer is working perfectly, the sterility of a device that is not clean cannot be ensured.³

The use of automatic washer/disinfectors provides great advantages for today's SPDs. Advances in medical washer technology have resulted in significant improvements to the cleaning process. All of these improvements have an impact on the efficacy of cleaning, but to achieve a controlled and repeatable process, a cleaning cycle should also be tested and validated to ensure consistent results and to meet professional and governing body standards and requirements.

Validation for medical washing systems

As a general definition, "validation" can be described as the proof that a certain process is capable of fulfilling the requirements for its intended use. Validation is performed by the equipment manufacturers, using cycles they have developed to meet cleaning performance standards, against various soils and with different instrument/utensil load configurations. These validations are meant to stress the cleaning system and provide a worst-case soil removal challenge for a washer/disinfector. Typically, validations use large numbers of instruments, load the washer/disinfector racks to capacity, and apply large amounts of organic and inorganic soils. These validations assure that when the equipment is used under the prescribed parameters and is operating correctly, adequate cleaning takes place, even when trays and racks are fully loaded. Conversely, any change from the manufacturer's recommended and validated parameters may result in poorer cleaning outcomes.

Cleaning efficacy is maximized when all of the specific critical performance parameters are met in combination during every cycle. Any change in these critical parameters may impact this sensitive interplay and result in poor cleaning. For example, changes to parameters such as the specific cleaning chemistry or its dosage, or modification in the



wash temperature or wash time, can alter cleaning efficacy.

Cleaning performance must be tested and validated for effectiveness by the manufacturer, but the washer/disinfector must also be capable of monitoring the cycle parameters essential to cleaning on an ongoing basis, to verify compliance and to detect any change in parameters that could lead to failure. The ability to monitor and detect variations is an integral part of any quality control system established for an automated cleaning process.

Factors that influence cleaning efficacy

Mechanical

Washing performance is greatly impacted by spraying technologies and their resultant impingement (force against surfaces), so it is important that the hydraulic (water-driven) circulating system of an automated washer optimizes the use of all hydraulic energy. At a given temperature, chemical concentration and flow rate, a spray arm that directs all water towards the washer load contents and eliminates all possible leakage will not waste water or energy on non-targeted surfaces and will significantly increase cleaning performance.

In order to ensure maximized and accelerated cleaning efficacy, a washing system should be designed to minimize leaks at the rack connections, use watertight spray arm rotating joints, and to have well-designed spray nozzles. A spray nozzle with smaller openings that are positioned for maximized coverage, and with smaller circulating piping for optimal water usage, also will provide improved cleaning efficiency.

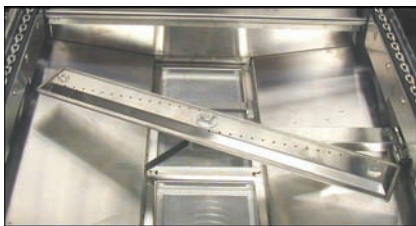


Figure 1

Figure 1 shows a spray arm in a typical low-impingement washing system where there are several loose side connection points and the spray arms use

loose rotating hubs. This type of mechanism can cause significant waste of chemistries and can result in water not being directed efficiently onto the load contents. In addition, low-impingement washing systems cannot sustain higher water pressure and generally require more aggressive chemistries to perform adequately.



Figure 2

Figure 2 shows a spray arm in a high-impingement washer/disinfector where there is an optimized, single bottom connection that is virtually leak-free. This type of single connection also reduces the risks for water loss that can be induced when two or three water connections are required. This type of spray arm technology allows for maximum water energy to be distributed on the load contents while requiring less water overall per cycle.

Monitoring and Verification

Typically, an equipment manufacturer completes validation to establish the reproducibility of a washer's process with a specific set of cycle parameters. Once this is done, it is important that the washer/disinfector has monitoring capability to verify that the specific validated cycle parameters are met each time a cycle is run.

The critical parameters for soil removal during cleaning in a washer/disinfector are mechanical parameters such as water pressure, spray arm rotation and injection of chemicals. Any mechanical disturbances/variances should be detected by the washer/disinfector to prevent negative impact to the cleaning process.

In order to detect changes in washing parameters, a washer/disinfector can be equipped with different types of control systems capable of monitoring vital pa-

rameters. Control systems can verify and confirm that the correct time has elapsed at the target temperature, the accurate dosage of chemistries has been delivered, and that hydraulic pressure is within specifications.

Spray arm rotation also has a direct impact on cleaning efficacy. More advanced washer/disinfectors can be equipped with spray arm rotation detection features. This type of control system would detect the blocking of spray arms, which would be critical since such spray arm failures greatly impede coverage and directly impact cleaning performance.

In addition to monitoring specific pressures, temperatures, injection rates and exposure times, users of healthcare washer/disinfectors can also verify the washing process with the assistance of a cleaning indicator. These indicators are used by the SPD to set a verified process or cycle as a benchmark. A specific time, temperature, chemistries and optimal washer/disinfector performance level are set. Next, a representative soil is either coated on a stainless steel surface or embedded in a plastic matrix to create the cleaning indicators. These "coupons" are used within the washer racks in an empty washer/disinfector cycle to serve as a "standard" soil. Once run through a cycle and evaluated, the coupons can verify that all parameters established during the benchmarking are working together to give a desired cleaning outcome. If the indicator is not completely cleaned, it can be an indication of a problem with washer cleaning parameters that were in balance during the initial verification set-up. "Failed" cleaning indicators also may be caused by such issues as clogged spray arms, improper chemistry dosing, etc. Although an indicator will not tell you whether instruments running through a given cycle are coming out the other side clean, it will indicate that the washer is operating within the same tolerances that were used to establish the verified benchmark cycle.

Drying Performance

As part of the evaluation of a washing system, the effectiveness of its drying phase should also be considered. After the pre-wash, washing, rinsing and thermal disin-

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SELF-STUDY from page 43

fection phases are completed, drying the goods is an equally important phase. Surgical instruments that are not completely dry may impact the next step of the instrument flow process, the pack and prep for sterilization. Packing wet instruments is not a good practice because moisture can compromise some sterilization processes.

In many hospitals, manual drying of instruments is still common because of inadequate drying systems in the washer/disinfectors. Fortunately, significant improvements have been made on washer/disinfectors in recent years to provide better drying capability.

For example, sterile processing managers should ask about the following features if they are selecting a new washer/disinfector:

- Is there a HEPA filter at the air intake? This is critical to ensure that air is filtered before being forced into the chamber onto the items (when the items are wet during the first minutes of the drying phase, air contaminants are easily captured into the residual water left on the loads and will remain on the instruments, since drying is the last stage of the process).
- Is the chamber airtight? If it is not, then the air will enter through door crevices or any other available crack in the system. This air will not be filtered by the HEPA filter and may contaminate the load.
- Is the drying efficient? A good system will be able to dry the load entirely in a short period of time. (Today, there are washer/disinfectors with drying systems that can achieve a complete dry within 5-6 minutes.) There are several air flow designs available on the market, but an optimal system will use a balance of fresh air and heated circulating air within the chamber.
- Is the system forcing air through cannulated instruments to ensure that water is purged from them after all the wet phases are completed?

Chemistries

The mechanical cleaning action of a washer/disinfector works hand-in-hand with chemical cleaning action. The detergents used in a washer/disinfector should be capable of maximizing the efficiency of the system. Any products used in high-impingement systems should be low-foaming, because high-foaming products may reduce spray pressure and lead to poor cleaning outcomes. Figure 3 shows the impact of various enzymatic cleaners on pump pressure in a washer/disinfector.

cation and solubilisation of soils (the dissolving of soils off surfaces and into a solution), all of which improves cleaning performance.

- Optimally formulated cleaning chemistries will not negatively impact pump pressure, and therefore will not reduce spray arm movement.

Validated cleaning technology with optimal mechanics, monitoring, drying and chemistries will really deliver for the SPD
The importance of efficient instrument

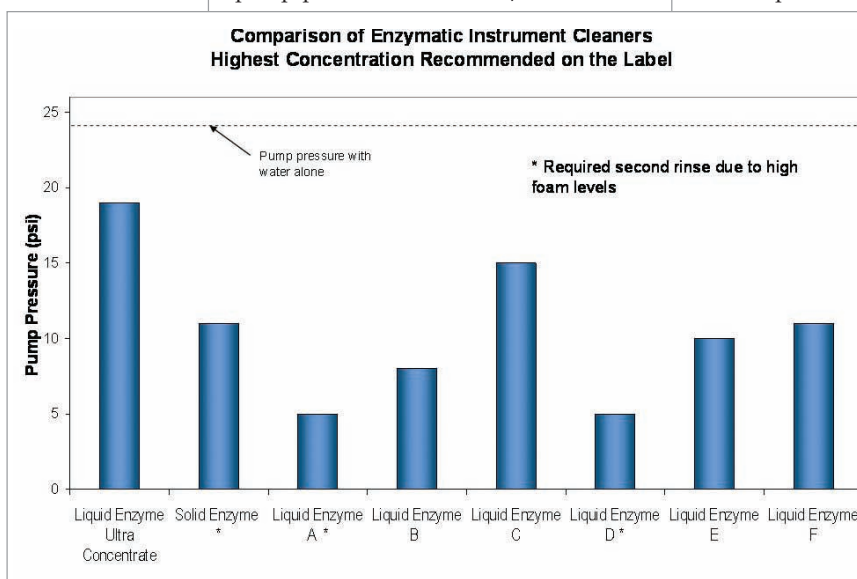


Figure 3

Detergents used for cleaning medical devices are formulated to attack and dislodge both organic and inorganic soils. A system of detergents can provide a broad spectrum of effectiveness for a wide variety of soil types and soil levels. An optimal chemistry system typically includes enzymatic, neutral and alkaline detergents. In addition, the use of an enzymatic prewash can enhance the effectiveness of subsequent detergent washes, and can facilitate the efficiency and reproducibility of the washing process.

The use of the right detergents can also protect surgical instruments from the damaging effects of water and control water hardness and metal ions in solution. Detergents can also help to make water a more efficient cleaning force in several ways:

- The surfactants found in precisely formulated cleaning chemistries can actually improve the use of water's hydraulic energy for more effective impingement.
- Surfactants reduce the surface tension of water, which enhances wetting, emulsifi-

flow from the SPD to the OR and back cannot be understated. Highly effective processes in central services departments are critical to patient safety and surgical productivity in health-care facilities. If the SPD can verify and validate cleaning processes and equipment, then they are assured of the outcome at every step and know that they are producing the best "product" for the next important step - the sterilization

process. Choosing the right washer/disinfector with the right control and monitoring systems, mechanics and chemistries to meet your hospital's specific validation needs will assure an automated cleaning process that is highly effective, efficient and repeatable. This will, in turn, help to assure an overall instrument reprocessing cycle that will enhance the SPD's productivity and turnaround time. **HPN**

References:

1. Source: <http://qualitysurgicalinstruments.com/surgical-instruments-before-and-after>.
2. Johnson, Dan. "A roadmap to optimizing sterile processing workflow" Healthcare Purchasing News, November 2005.
3. Favero, M., and Bond W. Chemical disinfection of medical and surgical materials. In S. S. Block (5th ed). *Disinfection, sterilization, and preservation* (pp. 881-915). Philadelphia, PA: Lippincott Williams & Wilkins, 2001.

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A validated approach to cleaning

Circle the one correct answer:

1. **What is washer validation?**
 - A. Multiple verifications conducted by QA team
 - B. A periodic testing conducted by a third party
 - C. Evidence that the product, as provided, will fulfill its intended use when placed in its intended environment.
 - D. Desirable but not required for manufacturers of washer-disinfectors
2. **What can impede spray arm rotation?**
 - A. Inappropriate loading such as instruments sticking out
 - B. Debris trapped in spray nozzles
 - C. The use of very foaming cleaning chemistry
 - D. All of the above
3. **What are the impacts of slow spray arm rotation or immobilized spray arms?**
 - A. Improper spray coverage
 - B. Reduce cleaning performance
 - C. Very little impact since other parameters come into play
 - D. Only A and B
4. **What can a cleaning indicator be used for?**
 - A. Monitor the cleaning functionality
 - B. Spot problems with washer cleaning parameters in a validated cycle
 - C. Tell whether a specific instrument is clean
 - D. A and B
5. **What are some characteristics detergents used in a washer/disinfectors should possess?**
 - A. Clean both organic and inorganic soils.
 - B. Protect instruments from the damaging effects of water
 - C. Be low foaming to maximize washer efficiency
 - D. All of the above
6. **A "dirty" instrument can affect what?**
 - A. Steam sterilization
 - B. Water quality
 - C. Temperature in a washer
 - D. Washer arm coverage
7. **What is the most important step in instrument processing?**
 - A. Cleaning
 - B. Sterilization
 - C. Prep and packaging
 - D. Transportation to the Operating Room
8. **What feature below is not considered when evaluating washer/disinfectors drying systems?**
 - A. HEPA filter
 - B. Rapid, total drying of the load
 - C. Disinfection level
 - D. Airtight chamber
9. **Which of the following is a critical parameter for soil removal during cleaning in a washer/disinfectors?**
 - A. Water pressure
 - B. Spray arm rotation
 - C. Injection of chemicals
 - D. All of the above
10. **Packing wet instruments is acceptable because they will dry during the sterilization process.**
 - A. True
 - B. False

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