HEALTHCARE PURCHASING NEWS

SELF-STUDY SERIES Sponsored by 3M Health Care

Washer disinfector release for use after maintenance

by Paulo R. Laranjeira, PhD

Surgical instruments and other reusable devices can be washed and disinfected prior to sterilization in an automated washer disinfector. The use of automated equipment helps standardize the cleaning process, providing optimal cleaning and improving patient safety. These types of equipment are subject to maintenance and repairs, and this article aims to present critical operational assessments to be performed by the end-user after maintenance, before release for use.

February 2023

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LEARNING OBJECTIVES

1. *Review the importance of cleaning a reusable medical device before sterilization*
2. *Identify critical mechanical components in an automated washing phase*
3. *Discuss automated washer performance verification*

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Reusable medical devices that are processed in a hospital sterile processing department (SPD) are cleaned, inspected, packaged, and sterilized according to manufacturer's instructions for use (IFU). A medical device is considered sterilized only if the sterility assurance level (SAL) of 10^{-6} was obtained at the end of the sterilization cycle[1].

The SAL requirement is normally seen as a goal of the sterilization process, but in fact it depends on the correct execution of the cleaning and packaging steps that precede the sterilization step. In this article, it will be discussed the cleaning step of sterile processing.

Sterilizer manufacturers validate their sterilization cycle based on a bioburden load (viable spores present on the medical device) of one million spores, 1 x 10^6, and configure the sterilization cycle with process parameters to deliver a medical device with a SAL of at least 10^{-6} at the end of the cycle. The inactivation of viable spores follows a logarithmic expression and the SAL of 10^{-6} is achieved after a 12-log reduction (). Medical device manufacturers validate their IFU using the same criteria of a 12-log reduction[2].

Since sterilizers can't measure the bioburden load on each medical device before the sterilization cycle begins, they will always deliver a sterilization cycle that achieves a 12-log reduction. Therefore, if the bioburden load on a medical device is higher than predicated, the sterilization cycle will not achieve the SAL of 10^{-6} and the medical device cannot be considered sterilized and safe to use on a medical procedure.

Therefore, cleaning before sterilization is extremely important to reduce the bioburden load to the level that the medical device can effectively be sterilized. A dirty instrument will have a higher bioburden load, and the SAL on that device will never achieve 10^{-6}.

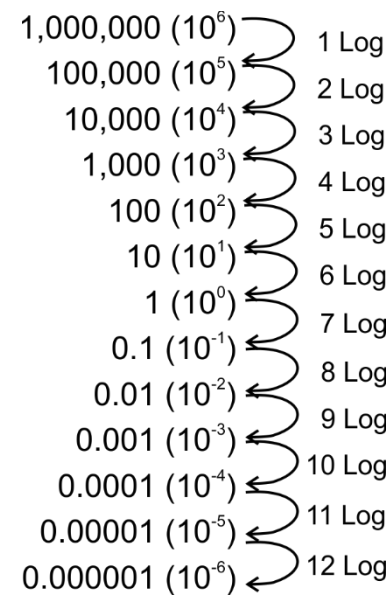

Figure 1: Graphical representation of a logarithmical spore reduction

Automated washers today are an essential tool for an SPD to standardize their cleaning process of reusable medical devices and are expected to deliver the same clean result every time. These washers today aren't considered an expensive replacement for manual cleaning, and they are a mandatory tool for the cleaning of new medical devices that have physical conformities that prevent effective manual cleaning.

Automated washers are complex equipment that require preventive maintenance and have the possibility to break, undergoing corrective maintenance. To illustrate the criticalness of releasing equipment used in an SPD, a steam sterilizer release after maintenance relies on engineering testing performed by the maintenance technician. This will be confirmed afterwards by an SPD professional that will run a Bowie & Dick cycle, an empty chamber cycle with a process challenge device that contains a biological indicator, and an assessment of the printouts from both cycles. If the physical, chemical, and biological indicators show satisfactory results, the steam sterilizer is cleared for use. Unfortunately, automated washers only have cleaning monitoring indicators that are applied on a medical device or are placed in a process challenge artefact, requiring more attention from the SPD professional when assessing the performance of the equipment[3].

As shown above, if a reusable medical device is loaded into a sterilizer with a bioburden above standard, the 12-log reduction that will be obtained at the end of the cycle will not reach SAL of 10^{-6}. Therefore, cleaning plays a critical role in the sterility assurance of reusable medical devices and requires monitoring practices as rigorous as, or more than, of what is used for the steam sterilizer.

Automated washers use pressurized water and detergent that are sprayed on reusable medical devices, at a high temperature, continuously for a period of time, to mechanically remove all residues and dirtiness. A thermal disinfection phase is normally present in a cleaning cycle program, where hot water with temperatures ranging from 140ºF (60ºC) to 203ºF (95ºC) is sprayed for a period of time, reducing the bioburden load. The last phase is the drying phase, where hot air is blown on the instruments (Figure 2). The cycle configuration must follow automated washer and reusable medical device manufacturer's IFU.

The main component used in an automated washer is water. It is essential for the water quality to meet all equipment manufacturer specifications and be evaluated frequently to assure cleaning effectiveness. If the water quality is not specified, a good reference to follow is the Association for the Advancement of Medical Instrumentation (AAMI) Technical Information Report (TIR) 34 – Water for the reprocessing of medical devices[4]. This TIR also suggests the water quality analysis frequency. It is important to know that AAMI is currently working on a new water quality guideline, ST108, that is on the final stages of development.

To improve water cleaning, detergents are added during the cleaning process. There are many different detergents available in the market, and automated washer's and detergent manufacturer's IFUs must be followed, and the correct dosing programmed into the equipment. The correct dose is required on every cycle to assure the desired performance, and a dosing verification device should be used to verify if the dosing system is working correctly. Also, it is important to verify if empty switches are working properly.

In the cleaning phase, water is admitted into the washer chamber at the same time as detergent is dosed. During the washing process, water is continuously circulated and sprayed on medical devices through rotatory arms with holes or injected into lumen devices using specific connectors, linking the washer cart rack to the medical device.

These rotatory arm holes and lumen connectors have very small diameters, and any debris can cause clogs (Figure 3), preventing water to pass through, reducing the cleaning efficiency of the equipment.

Figure 3: Example of debris found inside washer's rotatory arm. Tape, plastic markers, human hair, and other.

Washers are fitted with debris screens to retain all debris, preventing clogging during water recirculation. These screens must be cleaned frequently and correctly installed. If a small space is left, debris will go through and clog the rotatory arms and lumen connectors (Figure 4, next page).

Rotatory sprayers have O-rings on their fixation to the washer cart that allow the rotatory arm to move freely. The rotational movement must be verified on each arm, and if the arm shows any resistance to movement or excessive wobbling, these O-rings have to be replaced.

The procedure and frequency to perform these mechanical verifications should be part of the automated washer manufacturer IFU. Monitoring the clean-

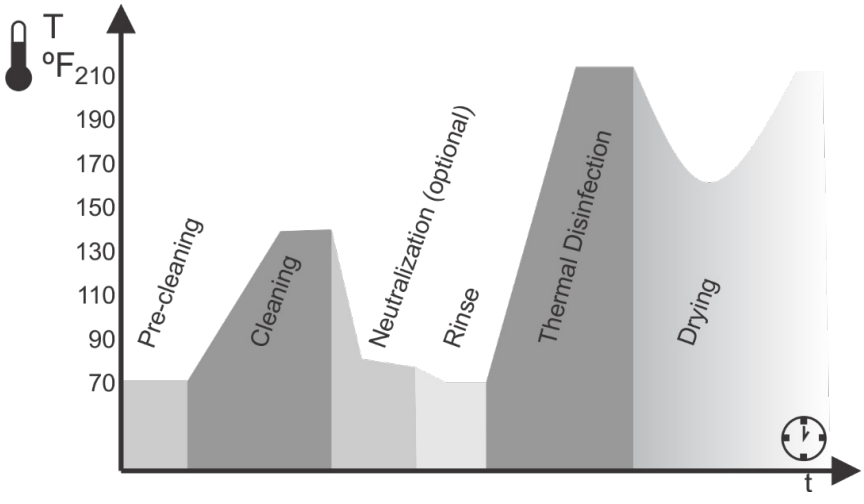

Figure 2: Example of an automated washer cycle phases

Self-Study Test Answers: 1.C, 2.B, 3.C, 4.D, 5.C, 6.D, 7.D, 8.D, 9.C, 10.A

ing efficiency using chemical indicators and residual soil tests is a routine requirement and must follow manufacturer's IFU and guidelines.

After preventive or corrective maintenance of an automated washer, a comprehensive testing and analysis should be performed, including everything that was covered in this article, manufacturer's IFU and guidelines, before the equipment is cleared for use. HPN

References:

1. Perkins J. Principles and Methods of Sterilization in Heath Science. Charles C. Thomas; 1983.

2. Srun SW, Nissen BJ, Bryans TD, Bonjean M. Medical Device SALs and Surgical Site Infections: A Mathematical Model. Biomed Instrum Technol. 2012; May/June:230-237.

3. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. American National Standard; 2017.

4. Association for the Advancement of Medical Instrumentation. ANSI/AAMI TIR34, Water for the Reprocessing of Medical Devices. American National Standard; 2014.

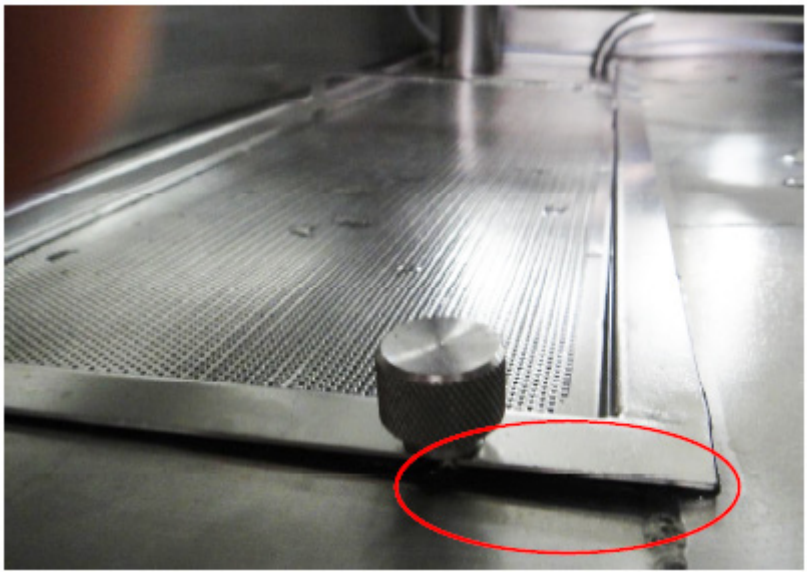

Figure 4: Washer debris screen installed incorrectly.

Dr. Paulo Laranjeira is a process development and qualification professional for sterilization, using steam, hydrogen peroxide, and ethylene oxide, in the pharmaceutical, biomedical, and healthcare areas. He has conducted many investigations with biological and chemical indicators, with different sterile barrier systems, leading to several publications in peer reviewed journals. He is also the author of book chapters, technical documents, and standards in the sterilization of healthcare products area. He is an active participant of AAMI working group 1, 2, 3, 4 and 6; and ISO TC198, Sterilization of Healthcare Products. He is a professor at post graduate schools on equipment qualification and monitoring for the pharmaceutical and healthcare market. Dr. Laranjeira has extensive experience managing multiple professionals in companies in Brazil for over 25 years, has worked as a consultant for multinational medical products companies; and been a globally sought-after speaker at Conferences, Congresses and Symposia.

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Circle the one correct answer:

1. **Medical devices are considered to be sterile only when:**
   A. the device appears clean
   B. the device has been put through a sterilizer
   C. the sterility assurance level of 10-6 was obtained
   D. the device has been washed

2. **Which of the below statements are true about sterilizers?**
   A. Sterilizers can measure the bioburden load on each medical device before the sterilization cycle begins.
   B. At the end of a sterilization cycle, a 12-log reduction of bioburden has been achieved.
   C. Cleaning before sterilization is unimportant.
   D. All of the above

3. **Which of the below statements are true about steam sterilizer maintenance?**
   A. Preventative maintenance is unimportant for everyday sterilization assurance.
   B. Corrective maintenance when a sterilizer breaks is the only type of maintenance that is required.
   C. Regular maintenance provides an opportunity to verify that all parts of the sterilizer are in working order.
   D. None of the above

4. **After maintenance, steam sterilizer release requires:**
   A. engineering testing by the maintenance technician
   B. assessment of a Bowie & Dick cycle and an empty chamber cycle by an SPD professional
   C. inspection of screens and moving parts
   D. All of the above

5. **Which of the below statements of water quality are true?**
   A. Water used for automated washers has the same quality requirement as for drinking water.
   B. Debris contained in water is not a cause for concern with steam sterilization.
   C. The AAMI Technical Information Report 34 suggests the appropriate frequency for water quality analysis.
   D. All of the above

6. **The correct detergent dosing volume to be used with washers is determined by:**
   A. following the detergent manufacturer IFU
   B. following the washer manufacturer IFU
   C. using a dosing verification device
   D. All of the above

7. **Automated washers increase cleaning efficiency by:**
   A. washing at higher temperatures than manual cleaning
   B. reducing the bioburden load on the medical device being sterilized
   C. standardizing the cleaning process
   D. All of the above

8. **When should the rotation of washer cart rotatory arms be verified?**
   A. Never
   B. Only the first time the washer is used
   C. Once a year
   D. Frequently, according to manufacturer IFU

9. **If the automated washer manufacturer does not inform the water quality for its equipment:**
   A. use tap water
   B. assume the same water quality that was used on a different washer is fine
   C. follow the AAMI Technical Information Report 34
   D. assume the water quality doesn't matter

10. **After maintenance of an automated washer, mechanical verification should be performed:**
    A. according to manufacturer IFU
    B. by visual inspection only
    C. only if there are noticeable leaks
    D. as quickly as possible