

Comprehensive guide to steam sterilization and sterility assurance in health care facilities

Suzanne Latta, CSPDT

Education Materials Coordinator

This is an update of the ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities that use steam sterilizers and a go to guide in healthcare facilities. Sterilization and cleaning in the sterile and decontamination rooms comes with training and education for the staff to properly utilize the equipment to prevent potential health hazards to the employees and patients. There are several areas to be conscious of when cleaning the instruments and assembling them on the clean side: the shoes you wear, proper PPE, knowing what to wear underneath your PPE to keep cool, humidity and temperature. This also includes implements that are used to effectively clean the instruments and the proper way to unload sterile packages and rigid containers from the loading cart. Other areas to consider are how sterile packages are stored after sterilization and transporting sterile items and containers to the sterile storage area without damaging or contaminating them. These are standard practices that should be adhered to, to omit potential hazards.

Decontamination

While working in the decontamination room, stay cool and dry as much as possible. Temperature and humidity rises as you are working with no air circulation throughout the decontamination room with a heavy workload, so there should be short periods of work with rest periods in between. Healthmark has designed cool aids to provide more comfortability while working in the decontamination room. Some examples include wearing cooling devices such as a bandana to keep the forehead cool or skull cap or towel around the neck to stay dry and not overheated. When donning PPE, gloves are just as important, so your hands do not encounter contaminated water and instruments. Section 4.5.2 Decontamination area/room states, "Utility gloves that are fitted at the wrist, prevent contact of the wearer's skin with contaminated water, and have cuffs that extend beyond the cuff of the gown." This will prevent contaminated water from reaching underneath the gloves and encountering the skin.

Healthmark offers several different types of decontamination gloves to help protect against contaminating the skin:

- **The Sleeve Glove** that reaches 12 inches in length and overall 28 inches reaching to the upper arm.



- **The Chemotherapy Rated Glove** is thick and tough enough to use in decontamination room.



A face shield is another important factor in PPE. It blocks splash up from the water in the sink and protects the entire face and neck from encountering contaminated water and reduces the “risk of eye injury from hazardous chemicals agents.” (Section 4.5.2)

Healthmark offer:

- **A Face Shield (18000-100)** - with a neck guard attached to protect face and neck from bloodborne pathogens.



- **Decontamination Gown (MN110 SMMD, MN110 LGXL, MN110 2X3X, MN100 4X)**- To help protect the wearer from contamination when working in a decontamination area.



Shoes worn in the decontamination room should be clean with a closed toe and closed heel to protect the feet from contaminated water and prevent injury to the feet if items are dropped. Also, it is important to keep your legs from muscle fatigue, wear compression socks to help wick moisture and increase circulation in the lower legs and feet while standing for long periods of time in decontam.

Healthmark offers different types of compression socks to help with muscle fatigue in the lower legs and feet in four styles: Below Ankle, Ankle, Mid-Calf and Knee High.

- **Swanky Athletic Socks (94737-M, 94699-M)**



- **Compression Socks**



Presoaking instruments prior to being cleaned should have a moist towel covering the instruments or place objects or instrument sets in a moist pack to avoid drying of tissue and gross soil from drying on the object until it reaches the decontamination room for reprocessing.

Section 6.3.5 Prevention of instrument damage talks about keeping instruments moist such as placing items inside a package designed to maintain humid conditions.

Healthmark offers:

- **Humipak (HPSS2035, HPSS4243, HPSS4267, HPSS6577)** - has a highly absorbent material placed in between two layers of waterproof film that keeps the items moist until they are ready to be reprocessed.



Handling and Collection of Contaminated Items

Single-use items are separated from reusable items prior to being delivered to the decontam room.

Reusable items that are contaminated are placed in a bin with a lid and a red biohazard sticker to identify that it is dirty.

Section 6.2 Separation of waste and reusable items at point of use states,

“Contaminated reusable items should be contained: in such a way that the contents of the container are readily identifiable as contaminated by everyone who subsequently handles the items.”

Healthmark offer:

- **SST- 2315** - contains a base tray and is large enough to hold a complete set of instruments. It has a snap down lid and mold -in gasket to provide a near watertight seal.



- **SST-2136 GSK** - is a full-size system which is ideal retrieval for O.R., O.B. instruments and high volume E.R.'s



- **SST-283** - is a midsize system for minor procedures including retrieval for O.R. and O.B. sets. Steristrainer is autoclavable as well and latches are optional.



Brushes

The implements used in the decontamination room are just as important when cleaning instruments. Using the correct size brushes on medical devices will ensure adequate cleaning the first time; this will eliminate re-cleaning if found to be dirty on the clean side and will also eliminate possible contamination of other instruments. It is important to read the manufacturer's IFU to determine which size brush(s) is used for that device. In section 7.6.4.2 Manual Cleaning it states, "Clean lumened devices with a brush of the recommended type, size (diameter and length), and bristle type." Also, "If the device manufacturer specifies a specific brush or cleaning implement, the brush or an equivalent should be used." In addition, some devices can use reusable brushes and others require single-use brushes. A reusable brush should be checked and cleaned every time it is put through a lumened device or other devices before it is pulled back out of the device. Throw the brush away if it is damaged, bristles are bent or will not come clean. Using the flush brush technique, flush the device with water and brush to push gross soil through and continue to do so until instrument is clean. Healthmark offers reusable brushes such as:

- **Toothbrush Style Brushes**



- **LTA Brushes**



- **Tube Brushes - for Cleaning Lumens**



- **Brush Storage Rack (BR001) - to hold the reusable brushes for future use**



- **Brush Soaking Tray (BRS03) - to immerse brushes in cleaning solution for in between uses**
- **Flexistem Brushes**



Single-use brushes are meant for one time use only for certain medical devices such as endoscopes; they are inserted into the channels one time and discarded after use. Whereas, in section 7.4.1 Decontamination, General consideration for all devices and utensils states, “Reusable brushes should be cleaned after each use, disinfected or sterilized at least once a day.” Brushes should not be used on the clean side to clean instruments. If a medical device is found dirty during inspection on the assembly side, it must be send back to the dirty side to be re-cleaned.

Cleaning Agents

Not only are brushes one of the integral factors to cleaning, but cleaning agents are also an important factor in cleaning instruments and medical devices in the decontamination room. Dependent upon how much water is filled in the sink, it is necessary to have the correct dosage of detergent. Reading the detergent manufacturer’s IFU will give you the proper dosage amount to how much water is recommended for effective cleaning of instruments. Knowing the correct level of water to fill the sink is key for effective manual cleaning. It is also important that the water temperature is in the range recommended by the detergent manufacturer for the most effective cleaning. In section 7.6.4.2 Manual Cleaning item i and j states, “Monitor the water temperature as required in the manufacturer’s written IFU; and change the solution after every use (a “use” should be defined in the health care facility’s policies and procedures).” The range of temperature is 80°F to 110°F in order to prevent coagulation.

- Healthmark has **The Healthmark Watermark™ (TEMP-WMK)** - which is bumper sticker size that adheres to the sink below the water line or in the ultrasonic bath. This product indicates a “water fill line” that is a liquid crystal thermometer displaying the temperature of the water.



- Healthmark also offers the **TEMPACHEK-LC (TEMPACHEK-LC)** - which adheres to the side of the sink below the water line that is a crystal liquid thermometer with real time temperature displaying the current temperature of the water providing feedback when compared to the temperature recommended by the detergent manufacturer.



Facilities that have an automatic doser or automatic chemical delivery system should refer to section 7.6.3 Cleaning agents where it states, “the automated doser should be routinely verified or calibrated.” It is recommended to read the medical device manufacturer’s IFU and the instrument manufacturer’s IFU to identify which detergent is correct for cleaning that device, so it is not damaged in the cleaning process.

Cleaning and Mechanical Washing

It is necessary to use non-linting cloths and cellulose sponges when cleaning and drying medical devices that require drying without lint left on the device and will not scratch before sending back to the clean side. Change out the wipes frequently to avoid any potential contamination from previous devices.

- **Healthmark’s Non Linting Wipes (NLW001, NLW002, NLW003)** - Are for immediate use after surgical equipment has been used, and prior to automated or manual disinfection to ensure items or dry.



When loading, heavy instruments should be placed in the tray in a way so that they do not damage delicate instruments during the cleaning process. After manual cleaning is completed, the ultrasonic may be used (check the manufacturer's IFU) as the step prior to loading onto the washer rack for mechanical washing. Before using the ultrasonic, the ultrasonic should be ran on a degassing cycle before first use to ensure proper cavitation and use clean water throughout employee's shift. Section 7.6.4.5 and 13.2 Cleaning verification of Mechanical processes is now **daily** and should be documented. Section 7.6.4.4.1 Ultrasonic cleaning equipment states, "Ultrasonic cleaning equipment designed for cleaning medical devices is used for fine cleaning to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods". Item d also states, "performed with fresh cleaning solution; solution should be changed after each use (a "use" should be defined in the health care facility's policies and procedures)." This allows cavitation to remove the blood from instruments box locks and other hard to reach crevices, and flush lumens when connected to the flush ports on the ultrasonic. To maintain proper use of the ultrasonic, daily testing should be done and after major repairs to "Test for the presence of cavitation energy - the cleaning power - of your ultrasonic cleaner."¹¹ Healthmark offer:

- **SonoCheck™ (TI108)** - which tests the presence of cavitation with a simple to interpret color change to indicate the ultrasonic unit is running correctly. If there is insufficient energy, overloading, or incorrect water level the SonoCheck™ will not achieve the proper color change.



- **SonoCheck™ Hook- (TI108-HK)**- The hook securely holds down the SonoCheck™ vial to the basket during the ultrasonic cycle.



A record log should be kept after every test is completed for future reference. In section 7.6.4.4.2 Loading, “When loading an ultrasonic cleaning equipment, place devices in perforated baskets; place devices in an open position; place heavy items on the bottom; remove rubber or silicone mats in the sonic.” Lumens should be connected to flush ports to allow the water to be pushed through the lumens. Once the sonic is complete, disconnect lumens and rinse items if the sonic does not have a rinse cycle.

- Testing the mechanical washer on a daily basis before the first load of the day will ensure spray arms are functioning properly. **The LumCheck™ Test by Healthmark (WLC-101, WLC-102)**- This is designed as an independent check on the cleaning performance of pulse-flow lumen washers. The stainless-steel plate has blood soil on the test coupon and after washing if the coupon is visually clean, the test indicates the ultrasonic is working properly.



- Mechanical washers can be tested with the **TOSI™ Instrument Washer Test by Healthmark (WT101, WT-111)** - This test will show if there is any blood soil left behind on the test coupon after washing cycle is complete, with the stainless-steel test coupon simulating a soiled instrument.



Routine testing of the washer enhances the ability of visually inspecting instruments. Results should be recorded for reference after the test is completed. When placing instrument sets onto the washer racks prior to putting into the mechanical washer, it is necessary to have all the presoak chemicals washed and rinsed off. Place hinged instruments on a stringer to allow full capability of cleaning in crevices. Load heavy instrument sets on the bottom of the washer rack and more delicate on the top racks. Loose and delicate instruments should be held down with hold down screens, so they do not fly around and become damaged during the wash cycle and also so that the water can drain out. Loaned sets and instrument sets with multi levels should be separated on the washer rack to ensure that all sections have contact with the washer detergent and then reassembled after cycle is finished. As the sets are loaded onto the washer rack, avoid obstructing the spray arms by spinning the arms to check for full range of motion. Also check the spray arm holes for debris; if there is, remove debris to allow full water penetration through the holes. Before sending the cart through the washer, check for debris in the drain filter in the washer (this should be done daily and before every shift starts). Remove the filter and discard contents to allow proper drainage during the wash and rinse cycle. Any debris left in the filter can cause it fly up during the cycle and can potentially end up on the instruments during the wash, also causing the water to not drain out properly.

Medical Cart Washer

The medical cart washer is referenced in ANSI/AAMI ST79 as a piece of cleaning equipment. Cart washers are designed to clean and provide low- to intermediate-level thermal disinfection of such items as stainless steel case carts, wire supply carts, tote bins, basins, and rigid sterilization containers. Some cart washers are validated to wash and disinfect surgical instruments. If the cart washer has an instrument cycle, the washer should be tested at least weekly, preferably daily, on the instrument cycle program. The manufacturer's IFU should be followed for processing the medical devices that can be cleaned with that specific model/type of cart washer. In section 7.6.4.3.3 on Mechanical cleaning and

disinfection equipment the cart washer is included thus, in section 13.2 Monitoring of mechanical cleaning equipment, a cart washer is included and thus as a mechanical cleaning equipment should be tested upon installation, each day that it is used, and after major repairs. The Cart Wash Check™ (CW-101) is a product that can be used to verify that the cart washer is performing properly for the non-instrument cycles. For instrument cycles, the T.O.S.I.™ would be used to meet the requirements found in ST79.

Cart Wash Check™ (CW-101)

- Challenge the mechanical efficiency of the cart washer.
- Easily adhered to any metal surface.
- Place test furthest from the washer jets or in areas where you suspect coverage is most difficult.
- Will change color only if moistened by water.
- The test also reports a minimum temperature level reached, 120°F.



Stringers

The use of stringers to keep instruments open during the cleaning and sterilization process is supported in ANSI/AAMI ST79. Support can be found in sections 6.3.4, 7.4.1, 7.6.4.3.4, informing staff to open all hinged surgical instruments with handles, such as scissors, hemostats, and forceps, to full extension unless contraindicated by the manufacturers' written IFU for the decontamination process whether being cleaned in a medical automatic washer or sonic cleaner. Instruments that are to be sterilized should be in the open position; ratcheted instruments should be unlatched using devices such as racks,

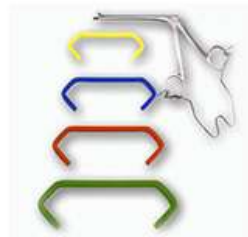
pins, stringers, or other specifically designed devices to keep instruments open in the unlatched position during the sterilization process to allow effective contact of the sterilant on the medical device.

Healthmark has many different stringers for both the cleaning and sterilization of medical devices that have to be kept open. Some of them are:

Clamps & Spreaders (20411, 20408, 20406, 20412, and 20407) - are used to keep surgical instruments in an open position while being cleaned.

Clamps ensure that joints of jaws of the bone forceps remain open.

- Spreaders are for instruments with ring handles that cannot be dismantled.
- They can be cleaned more efficiently in the washer-disinfector or sonic cleaner.
- The jaws remain open during the cleaning process, thus assuring thorough cleaning.¹⁵



Adjustable Stringers (AJS 8, AJS 13, AJS 17) – “Stringers used in the preparation of instruments for sterilization are usually are 2” - 3” in width. Stringers for use in decontam are typically 5” - 6” in width to maximize the openness of the instruments to the spray action of the washer. This has created the need for double inventory of stringers - until now. The adjustable Stringers (AJS 8, AJS 13, AJS 17) adjusts to all sizes of instruments for more effective cleaning of hard to reach areas containing bioburden, and can also be adjusted to the optimal width for placement of instruments inside a tray.”¹⁶ Available in 3 lengths: 8", 13" and 17".

Assembly

When unloading the washer after sets have cooled down and are ready for reassembly, visually check for debris in the baskets and on the instruments. Using lighted magnification to visually enhance the unaided eye will help detect residue on instruments. Section 7.6.4.5 Verification of the cleaning process states, “Inspection using enhanced visualization tools such as light magnification and video borescopes might identify residues not observable by the unaided eye”; “the use of methods that are able to measure or detect organic residues that are not detectable using visual inspection should be considered

in facility cleaning policy and procedures (see Annex D for available methods).” With different devices for lighted magnification, Healthmark has several optical inspection devices to choose from including:

- **Table top lighted magnifiers (26501-DSG, 26505-SIV, 82400-4 BL, 42400-4 RD)**



- **Led 4x Magnifier (MAG-002)**



- **Loupe Set with Smartphone Adapter (LUP-004)-** Rest comfortably in the eye socket, the eye loupes can be used manually by hand or with a phone by connecting the eye loupes to the smartphone and attaching to the phone.



- **USB Microscope (MICR007)-**



- **2.4mm Video Borescope (FIS-004)**- Used to directly visually inspect internal channels of devices. This was designed for instruments with a 2.5mm in diameter or larger, with a 4.5 inch LCD monitor and equipped with an SD card slot and USB port, enabling use without the need for a computer and allows for capturing and saving images and video for later recall and documentation.



Packaging low-profile items in paper-plastic pouches are for small individual items that are separate from sets and are considered extras. The pouches should be a size that accommodates the size of the item and the strength to hold it. When sealing the pouches, it is imperative that the seal is smooth without any creases or gaps in the seal so that item(s) to be sterilized is not compromised. Section 9.5.4 Paper-plastic pouches states, “Double packaging in paper-plastic should only be performed if the pouch manufacturer has validated the product for the use.” The pouch with item inside is inserted into another pouch that is bigger in size without having to fold the inner pouch; both pouches are faced plastic to plastic and paper to paper for proper sterilization.

- Healthmark has a variety of pouches and packaging rolls to fit various size items that are heat seal and self-seal, including gusseted pouches and rolls for oversized contents.



- Packaging for EtO and other low-temperature sterilization methods are available in heat seal, self-seal and roll packaging.



Assembling instrument trays should be lined with tray liners. Section 8.2 Instruments letter states, “Tray liners designed and intended for sterilization may be used to protect instruments from damage and/or absorb moisture.”

- **UnderGuard™ Tray Liners** by Healthmark help fight wet packs. The tray liners absorb the moisture, so condensation does not accumulate during sterilization which can cause the load to have wet packs. This causes the entire load to have new tray liners placed in the sets, rewrapped and sterilized again. It also provides protection from the bottom of the tray, so the instruments do not become damaged during the handling process from sterilization to sterile storage. It is best to place a protective barrier underneath the tray that is tough in construction and absorbent at the same time to give added protection for heavier sets.



- **The Dual UnderGuard™** from Healthmark is tough, tear resistant and designed for heavier sets for better protection.



After sterilization, cooled items may have dust covers placed over them for sterility assurance. Section 9.7 Sterility maintenance covers states, “protective packaging for sterilized items that could be subjected to environmental challenges or multiple handling before use.” The dust cover is not meant to be used as a sterile barrier, but used to keep dust off and moisture out and keep the integrity of the package intact. This is done after sterilization is complete and after the load has cooled down.

- **The Sterility Assurance Dust Covers** by Healthmark do just that by keeping the integrity of the package while the dust cover is sealed with no perforations.



- Healthmark also offers the **Gorilla Bags™ (GB-001 PP, GB-002 PP, GB-003 PP)** - as another way of providing a protective layer to a wrapped tray. This is not intended to be used as a sterile barrier, but another of layer of added protective from environmental conditions.



Each set and pouch are required to have an integrator with it for indication that the sterilization process was completed. Place the integrator in the set that will be the most challenging for steam penetration,

but is easily viewed by the scrub technician opening the container. Trays should be large enough to fit all instruments into it with adequate space between. This will ensure proper sterilization and prevent damage to the instruments.

Verification Tests

Cleaning verification tests help verify if there is any detection of organic residues left behind and Section 7.6.4.5 states, the use of methods that are able to measure or detect organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (See Annex D for available methods). Appropriate testing is based on the type of equipment.” Annex D.3 Cleaning verification tests for user’s states, “verify the functionality of the mechanical equipment (if used) and the cleanliness of specific devices after manual or mechanical cleaning is completed.” After visual inspection of more difficult to clean instruments or medical devices, a rapid test should be performed to verify if any bioburden or organic residue is still present. The test is easily performed and provides quick and accurate results without the need to re-clean after test is complete and will not cause damage to the device or lumened items being tested. There are several tests by Healthmark that allow for fast and easy detection of residue.

- **HemoCheck™ (HC-101)** - checking for blood (hemoglobin)



- **ProChek-II™ (PT-202)** - for detecting protein on instruments or medical devices



- **EndoCheck™** checking for blood or protein residue in endoscopes

EndoCheck™ for blood (EDH-110, EDH-200, EDH-270, EDH-350, EDH-420, EDH-470)

EndoCheck™ for protein (EDP-110, EDP-200, EDP-270, EDP-350, EDP-420, EDP-470)

- **ChannelCheck™(UCC-101)** - for testing of blood, protein and carbohydrates



When tests come back positive they should be sent back to be re-cleaned and retested for negative or positive results.

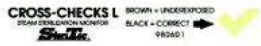
Sterilization

Before the first sterilization load of the day takes place, a Bowie Dick cycle should be performed in an empty chamber as a routine test for dynamic air removal and test for air leaks in the sterilizer. Section 13.4 Sterilization process monitoring Table 3 Types and applications for use of sterilization monitoring devices, box no. 3; Application (release of sterilizer, package, load box) states, “This will test for efficacy of air removal and steam penetration.” This is also done after a repair to the sterilizer with three consecutive Biological Indicators and three consecutive Bowie Dick test cycles one after the other with the test sheets reviewed after with negative results all three times. Healthmark offers:

- **STERI-PAK disposable Bowie-Dick Test Pack (BD 111)**



- Several types of chemical integrators for steam sterilization and EtO sterilization integrators



When loading items onto the sterilization cart to be sterilized, items should be placed on the shelf in a manner that fits onto the cart. Place instrument sets flat on loading cart and pouches in a pouch sterilization rack on the edges to eliminate over stacking and provide adequate drying time. Do not overload cart - this can cause wet packs and condensation to the set during sterilization without an appropriate amount of breathable space between sets. All items on the loading cart require a sticker with the date, lot number, load number and sterilizer number to identify what items were in sterilizer and when. There should be a label stating what the set or item is with the processor name on it to track in inventory. Annex H.7 Loading the sterilizer letter f questions, “Does the manufacturer recommend the use of absorbent sterilizer shelf covers to facilitate drying? Are there shelf liner materials that are contraindicated?”, when placing trays and containers onto the load cart. Place a biological indicator pack on the bottom rack of the load cart prior to putting the sterilizer. This is used to ensure the lethality of the sterilization process (whether the spores were killed or not). Set the proper sterilization type and time on the sterilizer according to the items on the load cart.

- **UnderGuard™ for Autoclave Shelves (SOK008SS, SOK009S, SOK010SS)** - by Healthmark, “absorb and rapidly disperse condensate during sterilization”. These also help eliminate dripping between shelves.



When removing load cart from the sterilizer after sterilization is complete, allow the load to cool to room temperature before touching or removing any pouches or rigid containers from the loading cart. Make sure all parameters have been met and record results. Using heat protecting gloves, move the

loading cart to a low traffic area and keep there until cooled. Healthmark offers heat mitts or gloves to protect hands from extreme heat from the loading carts:

- **Insulated gauntlet (75574, 75524, 73224)**



- **Seamless autoclave gloves (JB-2636)**



- **Shark tooth mitt and heat gloves (SLG-002, SLG-001, 09368)**



- **Terry cloth autoclave gloves (JB-422-5, JB-422-11)**



To check for readiness, locate the temperature indicator device on the cart (if available) to be sure it is safe to touch. Begin unloading the items to be moved to sterile storage for future use.

- **The Safe-to-Touch Indicator: Hot Spot sticker by Healthmark (HS-101)** - that is placed on the loading cart indicates when the cart is hot to touch and when it is cooled to touch.



After the load has cooled, inspect the items for damage before removing from the loading cart. Section 10.4 Handling and inspection after unloading the sterilizer letter A states, “they should be inspected for the following: damage (e.g., holes, staining, tears, non-intact seals, missing security locks), package identification; external indicator visual change; and moisture.”

Sterilized items should be stored in the required storage area, according to Annex H.11 Sterile storage letter c, “Will existing storage shelving and space in all areas of use or handling accommodate the container systems?”. The First-In First Out (FIFO) method of practice is done in a left to right fashion when retrieving inventory from the storage area shelves. Wrapped instruments should be placed side by side unless stated in the wrap manufacturer’s IFU for indications about stacking trays. Personnel should be able to use correct body mechanics when placing and removing the container systems from the storage area and still be able to maintain sterility of the container. Transporting containers within the facility requires carts specifically designed to keep the containers or items from becoming contaminated and prevents damage to the package occurring during transportation.

Aseptic presentation should allow personnel to handle items needed for procedures. This includes locating the label on the rigid container to identify what it is. The locks on the lid are broken when the lid of the container is removed without contaminating the contents inside. Removing the instrument basket from the container should be easy so not to contaminate the items. The container filters should be inspected for proper placement on the inside of the lid and wrapped items should be aseptically opened with ease of keeping the sterility of the items in the basket.

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