STERIS STEAM DECON Cycle in AMSCO Medium Steam Sterilizers

INSTRUCTIONS FOR HEALTHCARE FACILITIES: Preparation and Collection of Compatible N95 Respirators for Decontamination using STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers (hereafter referred to as the "STERIS STEAM Decon Cycle) for use in decontaminating **3M N95 respirator models 8210, 1860, 1860S, and 1804** (hereafter referred to as "compatible N95 respirators") for single-user reuse by healthcare personnel (HCP) to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. HCP should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by the STERIS STEAM Decon Cycle.

The STERIS STEAM Decon Cycle is authorized to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, for a maximum of 4 decontamination cycles per respirator, for single-user reuse by healthcare personnel. The STERIS STEAM Decon Cycle has neither been cleared nor approved for this use. The STERIS STEAM Decon Cycle is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Respirators that are NIOSH-approved before decontamination (https://wwwn.cdc.gov/niosh-cel/) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

For each cycle run, the healthcare facility must document exposure conditions, including time, temperature, and pressure, and confirm that the specified conditions were met to achieve decontamination of compatible N95 respirators. The STERIS STEAM Decon Cycle should be operated by central processing division personnel who are familiar with and perform decontamination services; such personnel should wear personal protective equipment (PPE) and follow the method outlined below.

- **The STERIS STEAM Decon Cycle currently limited to the decontamination of 3M 8210, 3M 1860, 3M 1860S, and 3M 1804 NIOSH-approved N95 respirators only.**
- **All compatible N95 respirators used in the STERIS STEAM Decon Cycle must be free of visible damage and soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids).**
- **Discard and do not collect compatible N95 respirators that are visually soiled or damaged.**
- **Discard compatible N95 respirators after exceeding 4 decontamination cycles.**
- **Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.**
- **Decontaminated, compatible N95 respirators are not sterile.**
- **The STERIS STEAM Decon Cycle has neither been cleared or approved by FDA but has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.**
- **The emergency use of the STERIS STEAM Decon Cycle is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.**

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EXAMPLE METHOD

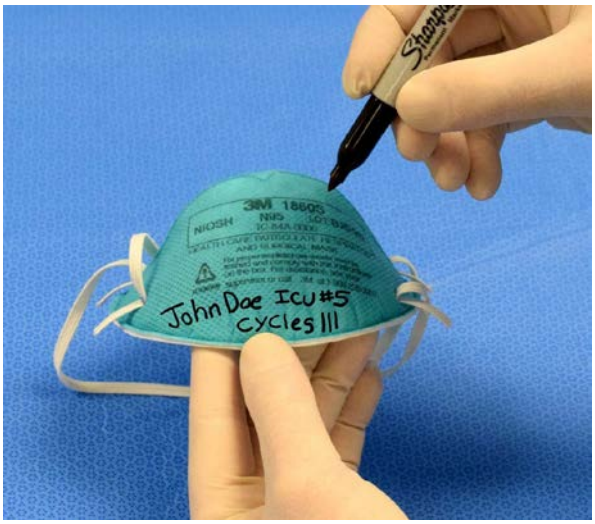
PLEASE FOLLOW THESE INSTRUCTIONS CAREFULLY. COMPATIBLE N95 RESPIRATORS CAN BE DECONTAMINATED UP TO 4 TIMES.

MATERIALS

- AMSCO® 400 Series Medium Steam Sterilizers (36H, 48H, 60H, 36SL, 48SL, 60SL, 36CH, 48CH, 60CH, 36CSL, 48CSL, 60CSL) or Century® Medium Steam Sterilizers 26" x 37.5" (x 36", 48", or 60")
- Updated software for the AMSCO 400 Series or Century Medium Steam Sterilizer.
  NOTE: STERIS service personnel are required to install the new software.
- Pouches: Self-seal pouches designed to permit moist heat transfer into the pouch, for example Vis-U-All® High Temperature Self-Seal Pouches (size 7.5" by 13" or larger).
- Trays (Optional): Compatible N95 respirators may be placed in unwrapped instrument trays.

COLLECTION AND PREPARATION

1. COLLECT MARKED COMPATIBLE N95 RESPIRATORS



1. With a permanent marker, the healthcare personnel labels their own individual compatible N95 respirators with their name and/or other identifier, and number of decontamination cycles (as shown).
2. Create a collection station at the point of generation (e.g., hospital floor/unit) by using a collection container lined with a bag provided by the healthcare facility to collect pouched, compatible N95 respirators with the following note:
   NOTE: Only compatible N95 respirators in sterilization pouches can be placed at this collection station for decontamination. No other items will be decontaminated in the same cycle.
3. Instruct healthcare personnel to place their own pouched, compatible N95 respirator into the bag.
4. Instruct transport personnel to seal the bag, close the collection container, and wipe down the exterior of the container with disinfectant prior to transport to the decontamination location.
5. Instruct transport personnel to place the collection container into the appropriate transportation carrier, such as a closed case cart. The case cart shall have a location identifier that indicates the location in the hospital where the respirators were utilized. Transport the case cart to the healthcare facility's

decontamination location.

2. PREPARE COMPATIBLE N95 RESPIRATORS

- INSPECT pouched, compatible N95 respirators for visible damage and/or excessive soil (e.g., blood, dried sputum, makeup, other soil).
- DISCARD compatible N95 respirators if damaged or contain visible soil. DO NOT decontaminate.
- PREPARE LOAD - OPTIONS:
  PLACE pouched, compatible N95 respirators directly on the loading cart rack or shelves OR PLACE pouched, compatible N95 respirators in instrument trays (as shown).

12 N95 RESPIRATORS IN INSTRUMENT TRAY

N95 RESPIRATOR ON SHELF

CONFIRM STERIS STEAM DECON CYCLE IS AVAILABLE ON EQUIPMENT:

- STERIS service personnel are required to install the special software to decontaminate compatible N95 respirators. Following software install, the sterilizer will have a new cycle available to decontaminate compatible N95 respirators. The cycle name is “DECON.”

Cycle Parameters

Parameter	Value	Description
Exposure Temperature	149° F (65° C)	Chamber temperature setpoint
Pressure	21 inHg	Chamber pressure setpoint (sea level)
Exposure Time	30 min	Amount of time the cycle is held at the decontamination parameters
Dry Time	1 min	Amount of time for the Dry phase

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3. STERILIZER OPERATIONAL RECOMMENDATIONS:

NOTE: The sterilizer has a low temperature steam DECON cycle that has a temperature parameter well below the normal operating temperature of your steam sterilizer. In order to run a DECON cycle, the sterilizer will first prompt you to run a WARM/COOL cycle in all of the following scenarios:

- To condition the chamber when the sterilizer is powered up or turned on from Standby;
- After completion of a standard High Temperature cycle, to prevent the sterilizer from heating up too much; and
- If a warning screen appears when a DECON cycle is selected but cannot be run.

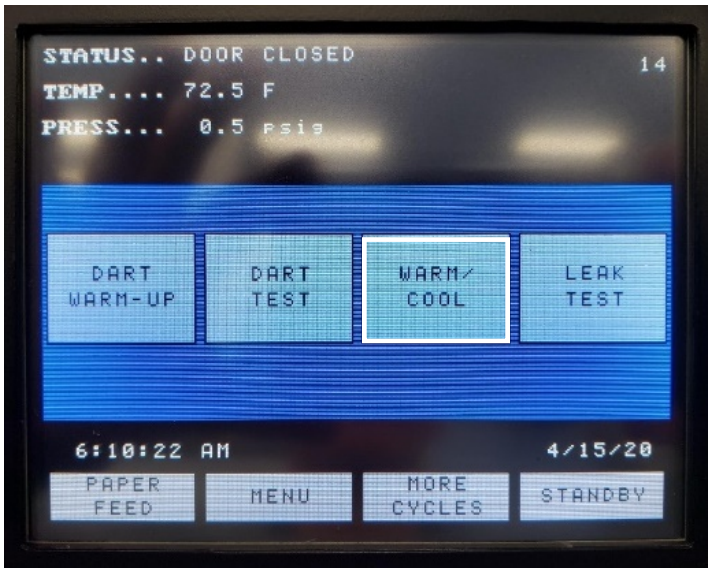
The WARM/COOL cycle can be selected from the warning screen that appears if a DECON cycle is selected that cannot be run, or from the test cycles screen. (Press 'More Cycles' to reach the test cycles screen.)

THE FOLLOWING ORDER OF OPERATIONS IS RECOMMENDED FOR THE STERILIZER AT START OF DAY:

1. As the first cycle of the day from standby mode, run the WARM/COOL cycle. The chamber will warm and will control at 149°F (65°C).
2. Upon completion of WARM/COOL cycle, decontaminate compatible N95 RESPIRATORS using the DECON cycle. Process as many loads as needed.

THE FOLLOWING ORDER OF OPERATIONS IS REQUIRED TO RUN THE DECON CYCLE FOLLOWING HIGH TEMPERATURE CYCLES:

1. Following a High Temperature cycle, run the WARM/COOL cycle.
2. At the end of the cycle, open the sterilizer door wide when instructed to do so on the screen.
3. Wait about 1 ½ hours for the sterilizer to cool to the appropriate temperature to allow a DECON cycle to be operated.
4. Confirm that the sterilizer is ready to run the DECON cycle.
5. When initiating a STERIS STEAM Decon Cycle, if the sterilizer temperature is either too hot or too cool, you will be prompted to run a WARM/COOL cycle.



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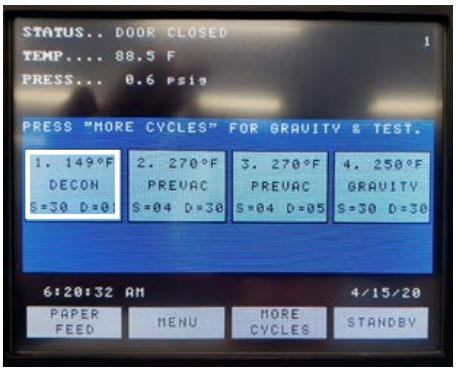
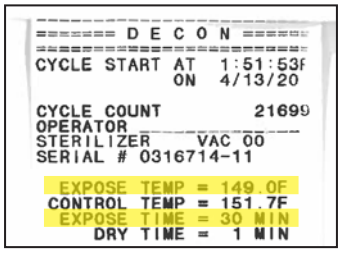
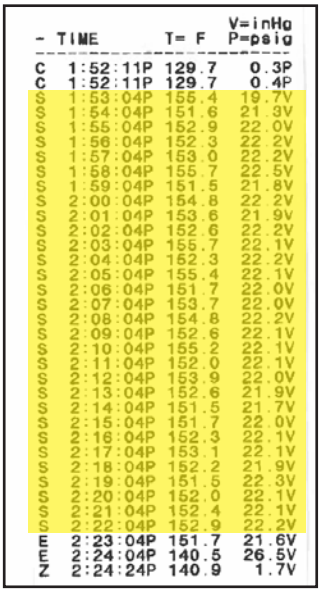
PROCESS

4. LOAD AND DECONTAMINATE COMPATIBLE N95 RESPIRATORS



- Don the appropriate PPE prior to operating the sterilizer.
- PLACE load in chamber using loading cart or rack and shelves.
- CLOSE and LOCK door.
- SELECT DECON cycle on display.
- After cycle is complete, the display will read STATUS…COMPLETE".
- OPEN door.
- REMOVE compatible N95 respirators from sterilizer.
- VERIFY that processing parameters were achieved by examining the cycle printout for temperature, pressure, and time.
- **During the exposure phase (S prints), if result of temperature (EXPOSE TEMP) is between 145.4 – 163.4° F, pressure is between 10 - 24 inHg, and time (EXPOSE TIME) is 30 min, <u>all compatible N95 respirators processed within that load may be considered successfully decontaminated</u> and the cycle will complete normally.**
- **If these temperature, pressure, and time parameters were not achieved, an alarm will sound, and the load must be held for failure of the cycle. Remove the load from the sterilizer while the reason for the failure is determined and transport the load back to the decontamination area and prepare for decontamination as described in Section 1. Identify and correct the reason for failure; a <u>passing result is required prior to providing the compatible N95 respirators to healthcare personnel</u>. Add a tick mark to the compatible N95 respirator to account for the failed cycle using a permanent marker. Discard any compatible N95 respirators that already have 4 tick marks. Once the reason for failure has been corrected, the compatible N95 respirators must be prepared per the instructions in Section 1 of this protocol.**





- **Keep the cycle tape as a record of successful decontamination. Documentation for use of the STERIS STEAM Decon Cycle must be maintained consistent with current healthcare facility protocols.**

RETURN

5. RETURN DECONTAMINATED COMPATIBLE N95 RESPIRATORS TO HEALTHCARE PERSONNEL

Upon completion of the STERIS STEAM Decon Cycle required to decontaminate the compatible N95 respirators, load the compatible N95 respirators back in disinfected trays or containers and place the container in a closed case cart or trolley following department policy for identifying/labeling processed loads. The documentation must include a clean copy of the location identifier to ensure return of the compatible N95 respirators to the original location in the facility for distribution to the original healthcare personnel.

Upon return of the compatible N95 respirators to the appropriate individuals (i.e., the same user), check the compatible N95 respirator for strap fit and breathability, and ensure that the identifier is still legible. If not legible, or the respirator is damaged, wet, or has improper fit, discard the respirator.

NOTES:

- Prior to use, inspect compatible N95 respirators for visible damage and/or excessive soil (e.g., blood, dried sputum, makeup, other soil). Discard any compatible N95 respirators that are damaged or contain visible soil.
- Upon completion of the STERIS STEAM Decon Cycle, decontaminated N95 respirators may be stored in the pouch until ready to use.
- Discard compatible N95 respirators after exceeding 4 decontamination cycles.
- Maintain chain of custody on each respirator to minimize the risk of cross-contamination.

REUSE INFORMATION:

See Instructions for Healthcare Personnel and Fact Sheet for Healthcare Personnel for more information.

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