

Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination Using the 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 1860, 3M 1860S, and 3M 1804 NIOSH-approved N95 respirators only** (hereafter referred to as “compatible N95 respirators”) for single-user reuse by healthcare personnel. Healthcare personnel 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.

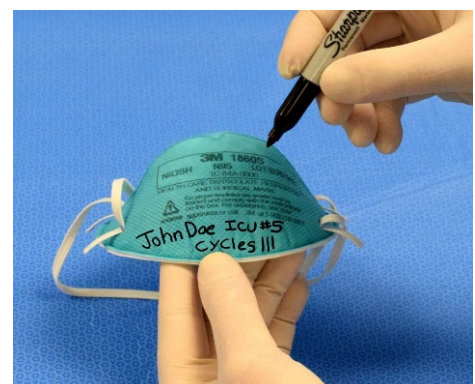
The STERIS STEAM Decon Cycle is authorized to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, for a maximum of 10 decontamination cycles per respirator, for single-user reuse by healthcare personnel. The STERIS STEAM Decon Cycle has not been FDA-approved or -cleared for this use. FDA authorized the STERIS STEAM Decon Cycle for emergency use for the duration of the COVID-19 public health emergency (unless it is otherwise terminated or revoked sooner).



- **The STERIS STEAM Decon Cycle is currently limited to the decontamination of 3M 1860, 3M 1860S, and 3M 1804 N95 NIOSH-approved respirators only. These N95 respirators are labeled with their model numbers. Compatibility of other N95 or N95-equivalent respirators with the STERIS STEAM Decon Cycle has not yet been demonstrated.**
- **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 10 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.**

Compatible N95 Respirator Marking, Collection, and Return:

1. Maintain chain of custody on your compatible N95 respirator to minimize the risk of cross-contamination. Label with your name and/or other identifier using a permanent marker. Labeling should be legibly written on the outside OR inside of each N95 respirator, as shown below.
2. Place a tick mark on your compatible N95 respirator each time to maintain the decontamination cycle count. **NOTE: Your respirator may be decontaminated up to a maximum of 10 times. If your respirator already contains 10 tick marks, discard the respirator.**
3. Confirm that the labeling is legible, and that there is no visible damage or soil/contamination prior to pouching the compatible N95 respirator.
4. Place your respirator in the sterilization pouch provided by your healthcare facility and seal it. Place the pouched respirator at the healthcare facility’s designated collection station.



5. After receiving your decontaminated, compatible N95 respirator, please check to ensure that the respirator returned to you has your name and/or appropriate identifier on it. Check for fit and breathability, and look for any signs of degradation.
6. If at any time the labeling is not legible or there is visible soil or damage, discard the respirator. Discard the respirator after exceeding 10 decontamination cycles.

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.