

Instructions for Healthcare Facilities: Decontamination of Compatible 3M[®] N95 Respirators using the BELIMED MASK 250 cycle in Belimed Steam Sterilizers

3M has confirmed the material compatibility of specific N95 respirators to be reprocessed one time using a special cycle in Belimed Steam Sterilizers. The BELIMED MASK 250 cycle can be used to decontaminate compatible 3M[®] N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, for a maximum of one (1) decontamination cycle per respirator, for single-user reuse by healthcare personnel. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible 3M[®] N95 respirators for decontamination using BELIMED MASK 250 cycle; please refer to the **BELIMED Steam Sterilizer** User's Guide for complete instructions for use.

For each cycle run, the healthcare facility must verify exposure conditions, including time, temperature, and confirm that the specified conditions were met to achieve decontamination of compatible 3M[®] N95 respirators. The BELIMED MASK 250 cycle should be operated by sterile processing personnel who are familiar with and perform decontamination services; such personnel should wear personal protective equipment (PPE) and follow the method outlined below.

- The BELIMED MASK 250 cycle currently limited to the decontamination of **3M[®] 1804, 1804S, 1805, 1805S, 1862+, 1863+, 1870+, 9205+, 9210+, 9320+, and 9330+ NIOSH-approved N95 respirators**. These N95 respirators are labeled with their model numbers. Compatibility of other N95 or N95-equivalent respirators with the BELIMED Mask 250 cycle has not yet been demonstrated.
- All compatible 3M[®] N95 respirators used in the BELIMED Mask 250 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 3M[®] N95 respirators that are visually soiled or damaged.
- Discard compatible 3M[®] N95 respirators after exceeding one (1) decontamination cycle.
- Discard any compatible 3M[®] N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.

MASK 250 cycle in Belimed Steam Sterilizers

Please follow these instructions carefully. Compatible 3M® N95 respirators can be decontaminated up to one (1) time.

Materials needed

- BELIMED Steam Sterilizers, (MST-V 606,609,6012; MST-H 9612,9615,9618)



MST-V



MST-H

- Pouches: Self-seal pouches designed to permit moist heat transfer (size 7.5" by 13" or larger).
- Trays (Optional): Pouched compatible 3M® N95 respirators may be placed in unwrapped instrument trays.

Compatible 3M® N95 respirator marking, collection, and instructions for institutional use

Collect marked compatible 3M® N95 respirators

1. With a permanent marker, the healthcare personnel label their own individual compatible 3M® 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 3M® N95 respirators with the following note:

NOTE: Only compatible 3M® N95 respirators in sterilization pouches can be placed at this collect-ion station for decontamination. No other items will be decontaminated in the same cycle.

3. Instruct healthcare personnel to place their own pouched, compatible 3M® 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.

Prepare compatible 3M® N95 respirators

1. INSPECT pouched, compatible 3M® N95 respirators for observable damage and/or visible soil (e.g., blood, dried sputum, makeup, other soil).
2. DISCARD compatible 3M® N95 respirators if damaged or contain visible soil. DO NOT decontaminate.
3. PREPARE LOAD - OPTIONS:
4. PLACE pouched, compatible 3M® N95 respirators directly on the loading cart rack or shelves OR PLACE pouched, compatible 3M® N95 respirators in instrument trays (as shown).



Confirm BELIMED MASK 250 Cycle is available on equipment

- Belimed service personnel are required to set up the new cycle to decontaminate compatible 3M® N95 respirators. The cycle name is "MASK 250"

Cycle parameters

Parameter	Value	Description
Sterilize Temperature	250° F (121° C)	Chamber temperature set point
Sterilize Time	20 min	Amount of time the cycle is held at the decontamination parameters
Dry Time	6 min	Amount of time for the Dry phase

Sterilizer operational recommendations

NOTE: The sterilizer needs to be equipped with a special cycle called “Mask 250” the parameters of which were chosen to be gentler with the compatible 3M® N95 respirators while still guaranteeing efficacy. Therefore, the plateau temperature is at 250 F/121 C, slightly lower than the standard sterilization temperature (270 F/132 C) but the plateau time is longer with 20 min exposure.

Process

Load and decontaminate compatible 3M® N95 respirators

5. Don the appropriate PPE prior to operating the sterilizer.
 6. PLACE load in chamber using loading cart or rack and shelves.
 7. CLOSE door.
 8. SELECT MASK 250 cycle on display.
 9. After cycle is complete, the display will read STATUS...COMPLETE”.
 10. OPEN door.
 11. REMOVE compatible 3M® N95 respirators from sterilizer.
 12. VERIFY that processing parameters were achieved by examining the cycle printout for temperature and time.
- **During the sterilize phase, if result of temperature (Sterilizing Temp) is between 121.0 – 122.6° C, and time (Sterilizing Time) is 20 min, all compatible 3M® N95 respirators processed within that load may be considered successfully decontaminated and the cycle will complete normally.**
 - If the temperature, 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 passing result is required prior to providing the compatible 3M® N95 respirators to healthcare personnel. Add a tick mark to the compatible 3M® N95 respirator to account for the failed cycle using a permanent marker. Discard any compatible 3M® N95 respirators that already have 1 tick mark. Once the reason for failure has been corrected, the compatible 3M® 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 BELIMED MASK 250 Cycle must be maintained consistent with current healthcare facility protocols.

Return

Return decontaminated compatible 3M® N95 respirators to healthcare personnel

Upon completion of the BELIMED MASK 250 cycle personnel are required to load the compatible 3M® 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 3M® N95 respirators to the original location in the facility for distribution to the original healthcare personnel.

Upon return of the compatible 3M® N95 respirators to the appropriate individuals (i.e., the same user), check the compatible 3M® 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 3M® N95 respirators for visible damage and/or excessive soil (e.g., blood, dried sputum, makeup, other soil). Discard any compatible 3M® N95 respirators that are damaged or contain visible soil.
- Upon completion of the BELIMED MASK 250 Cycle, decontaminated N95 respirators may be stored in the pouch until ready to use.
- Discard compatible 3M® N95 respirators after 1 decontamination cycle and total of two (2) uses.
- Maintain chain of custody on each respirator to minimize the risk of cross-contamination.

Reuse information

See Instructions for Healthcare Personnel for more information.