

Instructions for Healthcare Facilities: Emergency Use of Sterilucent Sterilization System to Decontaminate Compatible N95 Respirators

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Sterilucent HC 80TT Vaporized Hydrogen Peroxide Sterilizer (hereafter referred to as the “Sterilucent Sterilization System”) to be used on the Sterilucent N95 Respirator Decontamination Cycle (“Flexible” Pre-Programmed Sterilization Cycle) for use in decontaminating compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. Compatible N95 respirators are any non-cellulose containing respirators that do not have an exhalation valve, antimicrobial agents, or a duck-billed design, and that are either: (1) authorized in the NIOSH-Approved Air Purifying Respirators EUA; or (2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, which are available at <https://www.fda.gov/emergency-preparedness-and-response/mcmlegal-regulatory-and-policy-framework/emergency-use-authorization>. Please see FDA’s website for further information on N95 respirators, available at <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>.

Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the Sterilucent Sterilization System.

The Sterilucent Sterilization System has neither been cleared or approved by FDA, but has been authorized by FDA under an EUA for use in decontaminating compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 outbreak. The emergency use of the Sterilucent Sterilization System 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.

- **The Sterilucent Sterilization System is not authorized for use with the following:**
 - **Respirators containing cellulose-based materials;**
 - **Respirators containing antimicrobial agents;**
 - **Respirators with duck-billed designs;**
 - **Respirators containing exhalation valves; and**
 - **Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.**
- **HCP must perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standards prior to beginning a shift. If the user seal check does not pass,**

discard the respirator.

- Use proper hand hygiene and gloves when removing or handling potentially contaminated N95 respirators.
- All compatible N95 respirators used in the Sterilucent Sterilization System must be free of visible damage, visual soil/contamination (e.g., blood, dried sputum, makeup, soil, bodily fluids), and excessive odor.
- Discard and do not collect compatible N95 respirators that are visually soiled or damaged.
- Each compatible N95 respirator will be individually packaged in a Tyvek® Self-seal pouch, or equivalent pouch.
- Discard the compatible N95 respirators after exceeding 4 decontamination cycles.
- Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles was not able to be identified.
- Decontaminated, compatible N95 respirators are not sterile.

Materials Needed:

- Tyvek pouch identified for use in vaporized hydrogen peroxide, for example, a Tyvek Self-seal pouch, or equivalent pouch
- Sterilucent VH₂O₂ Chemical Indicator (Class 1/Type 1 process indicator)
- Sterilucent “Flexible Cycle” Process Challenge Device (PCD-F) Test Pack (containing a Self-contained Biological Indicator)

Compatible N95 Respirator Marking:

The healthcare facility must ensure that the chain of custody is maintained to minimize risk of cross-contamination. Prior to collection by the healthcare facility personnel, the healthcare personnel will label their own individual compatible N95 respirator with their name and/or identifier, and number of decontamination cycles (as shown below) with a permanent marker. The healthcare personnel will pouch the compatible N95 respirator in a Tyvek pouch, label the pouch with the decontamination cycle count, and seal it. The compatible N95 respirator in the Tyvek pouch will be placed at a designated collection station. See the “*Instructions for Healthcare Personnel*” for details.



Figure 1: Chain of custody identification of N95 compatible respirators

Compatible N95 Respirator Collection and Transportation:

1. The healthcare facility will create a collection station at the point of generation (i.e., hospital floor/unit). Each station will have a basket or container provided by the healthcare facility to collect the pouches containing the compatible N95 respirators for decontamination with the following note:
NOTE: Only compatible N95 respirators in Tyvek, or equivalent, pouches may be placed at this collection station for decontamination. No other items will be decontaminated in the same decontamination cycle.
2. The healthcare personnel who are assigned to decontamination (i.e., those with training for collection/transport of such materials) will collect the Tyvek pouches containing the compatible N95 respirators at the collection stations, and place them into the appropriate container for transportation, such as a closed case cart, to minimize risk of environmental contamination. The case cart will have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized.
3. The case cart will be transported to healthcare facility's decontamination area.

Use of the Flexible Cycle in the Sterilucient Sterilization System:

1. Prior to sterilization, compatible N95 respirators will be individually packaged in a Tyvek Self-Seal pouch or equivalent pouch (Figure 2). A Sterilucient VH₂O₂ Chemical Indicator (Class 1/Type 1 process indicator) must be used in or on every pouch.

2. A maximum of 12 pouched, compatible N95 respirators may be loaded on edge, side-by-side, in a sterilization basket (Figure 3). Tyvek pouches must never be stacked on top of one another. Ensure that respirators are not crushed or damaged when packaged and placed in the sterilization basket. (Caution: Do not combine any other load with the 12-pouch compatible N95 respirator load).



Figure 2: Single compatible N95 respirator packaged in a Tyvek pouch



Figure 3: Up to twelve (12) individually packaged respirators placed side-by-side in a sterilization basket

3. A Sterilucient “Flexible Cycle” Process Challenge Device (PCD-F) Test Pack (containing a Self-contained Biological Indicator) should be used at least daily, but preferably in every sterilization

cycle, to provide assurance that adequate sterilant has been delivered. The Test Pack shall be placed in the rear corner of the sterilization basket.

4. A single basket may be placed inside on the lower shelf of the sterilizer chamber (Figure 4).



Figure 4: Sterilization basket with up to 12 individually packaged respirators, placed inside of the Sterilucient sterilizer

5. After closing the sterilizer door, select the “Flexible Cycle” using the Instructions for Use for the Sterilucient HC 80TT Hydrogen Peroxide Sterilizer, which will run for approximately 35 minutes.

After the Flexible Cycle in the Sterilucient Sterilization System is complete:

1. Upon completion of the cycle, the sterilization basket must be removed from the chamber and allowed to aerate for a minimum of 6 hours before use.
2. Following completion of the Flexible Cycle in the Sterilizer, compare the chemical indicator’s color to the “PASS” reference color (Figure 5). If the indicator color matches the reference color or is lighter, the respirators have been exposed to the vaporized hydrogen peroxide. If the indicator does not match the “PASS” criteria, the compatible N95 respirator must not be considered decontaminated and either repackaged and decontaminated through another Flexible Cycle in the Sterilucient Sterilization System or discarded. Please note that successful completion of the cycle and passing chemical indicator signifies appropriately decontaminated, compatible N95 respirators. These results do not indicate sterility of the decontaminated, compatible N95 respirators. Any respirators with visible damage must be discarded.

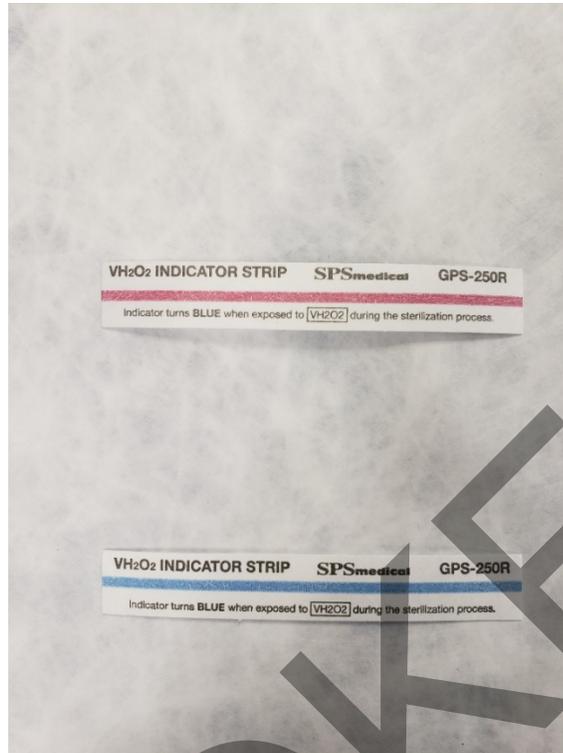


Figure 5: Chemical indicator control color (pink) and processed “PASS” color (blue).

3. Process the Sterilucent Test Pack in accordance with the PCD-F Instructions for Use.
4. Healthcare facilities shall utilize existing processes to decontaminate the case carts and sterilize the transport basket or container for reuse and delivery of decontaminated, compatible N95 respirators back to patient areas.
5. Decontaminated, compatible N95 respirators that match the “PASS” criteria may be loaded back into the sterilized basket or containers and placed in a closed case cart following the healthcare facility’s policy for identifying/labeling processed loads. The healthcare facility will follow similar protocol for identifying processed loads to transport to the operating room for surgical cases. The documentation needs to include a clean copy of the location identifier to ensure return of the decontaminated, compatible N95 respirators to the original location in the facility for distribution to healthcare personnel.
6. The healthcare facility must ensure that the chain of custody is maintained to minimize risk of cross-contamination. Upon return of the decontaminated, compatible N95 respirators to the appropriate individuals, the respirator must be checked for the following:
 - a. Ensure that the name or other identifier and number of decontamination cycles is still legible. Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified must be discarded.
 - b. Any compatible N95 respirator that is visually damaged or soiled must be discarded.
 - c. Any compatible N95 respirator that has exceeded 4 decontamination cycles must be discarded.
 - d. Ensure that the compatible N95 respirator is returned to its previous user.
7. The healthcare facility shall make available the “Fact Sheet for Healthcare Personnel: Sterilucent Sterilization System for Decontaminating Compatible N95 Respirators” upon return

of the decontaminated, compatible N95 respirators.

Additional Information:

1. Prior to use, healthcare personnel shall inspect decontaminated, compatible N95 respirators for visible damage and soil/contamination (i.e., blood, dried sputum, makeup, soil, bodily fluids, excessive odor). Respirators that are damaged or contain visible soil must be discarded.
2. N95 respirators may be safely stored in pouches.
3. It is strongly recommended to maintain chain of custody on the compatible N95 respirator to minimize the risk of cross-contamination between individuals.

Reporting:

Healthcare facilities must report any damage, discoloration, excessive odor, or other signs of degradation with a decontaminated, compatible N95 respirator to healthcare facility management and Steriluent, Inc., and the healthcare facility must discard the respirator.

Healthcare facilities will report adverse events of which they become aware related to the Steriluent Sterilization System and the decontaminated, compatible N95 respirators, including monitoring personnel using the Steriluent Sterilization System and healthcare personnel using the decontaminated, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection.

Contact Steriluent, Inc. as follows:

Phone: 877-721-8405
Email: customer.care@steriluent.com