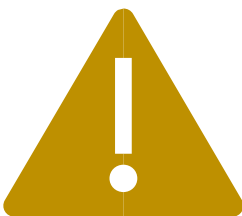


Instructions for Healthcare Personnel, Healthcare Facilities, and Community Partners: Emergency Decontamination of Compatible N95 Respirators Using the Yale New Haven Health FFR Decontamination System

*These respirators have been decontaminated to deactivate the SARS-CoV-2 virus, but they are not sterile.

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the Yale New Haven Health FFR Decontamination System (hereafter referred to as the “Yale Decontamination System”) operated by Yale New Haven Health for use in decontaminating 3M N95 respirator models 1860 and 1870 (“compatible N95 respirators”) that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of three (3) decontamination cycles per respirator, for multiple-user reuse (i.e., healthcare personnel may receive a different respirator following decontamination than the one they had previously used) by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. Healthcare personnel must follow these instructions, as well as procedures at their facility (either a healthcare facility or community partner, referred to as “facility” in these instructions), to prepare compatible N95 respirators for decontamination by Yale New Haven Health using the Yale Decontamination System.

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 Yale Decontamination System is only authorized for use with 3M N95 respirator models 1860 and 1870.**
- **Healthcare personnel 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.**
- **Healthcare personnel must either receive the same model of decontaminated, compatible N95 respirator for which they were fit tested or healthcare facilities and community partners must provide healthcare personnel with fit testing if the healthcare personnel receives an alternative model of decontaminated, compatible N95 respirator.**
- **All compatible N95 respirators that will be decontaminated with the Yale Decontamination System must be free of visible damage and visible soil or contamination (e.g., blood, dried sputum, bodily fluids, makeup).**
- **Discard and do not collect compatible N95 respirators that are visibly soiled or damaged.**

- Discard compatible N95 respirators after 3 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.
- Do not use decontaminated, compatible N95 respirators during surgical procedures.
- The Yale Decontamination System 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 multiple-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.
- The emergency use of the Yale Decontamination 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.

Compatible N95 Respirator Collection

1. Your facility must create a collection station at the point of generation (i.e., hospital floor/unit). Each station must have a bag provided by the facility to collect compatible N95 respirators. **NOTE: Bags are for compatible N95 respirators only. Do not throw other personal protective equipment (PPE), paper towels, or waste in the collection bag.**
2. Bags containing the contaminated, compatible N95 respirators to be decontaminated by Yale New Haven Health (“primary collection bag”) must be closed.
3. Place the contaminated bags into a rigid, closed box (supplied by the facility) clearly labeled with a biohazard symbol, and ensure that the box is securely shut.
4. Label the outside of the box with the Organization Name, Contact Name, Contact Number, and Address.
5. Coordinate with your organization’s courier service to arrange transfer to the Yale New Haven Health Regional Operations Center at 600 Derby Ave., West Haven, CT between Monday – Friday, 7am – 3pm.
6. The courier service must call 475-248-3187 when arriving at the loading dock of the Yale New Haven Health Regional Operations Center and a staff member will receive your shipment.
7. The box will be safely transported in a case cart to the decontamination area.

Reuse Information:

Following decontamination, your facility will request decontaminated, compatible N95 respirators (including the appropriate respirator model number(s) needed) from Yale New Haven Health when your facility needs respirators. Facilities internal to the Yale New Haven Health System should request respirators by following standard processes for acquiring PPE through Yale’s internal computer system and external facilities should call the Yale New Haven Health Regional Operations Center at 475-248-3187. Then, you will be provided



decontaminated, compatible N95 respirators that have been processed through a decontamination system for reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

The facility must inspect each returned, decontaminated, compatible N95 respirator for numeric indication of the decontamination cycle number (maximum of 3).

Any problems should be immediately reported to Yale New Haven Hospital: reprocessFFR@ynhh.org.