Yale NewHaven Health

Instructions for Decontamination Personnel at Yale New Haven Health System: Emergency Decontamination of Compatible N95 Respirators Using the Yale New Haven Health FFR Decontamination System

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.

All personnel involved in the collection and distribution of decontaminated, compatible N95 respirators and those using the decontaminated, compatible N95 respirators will be regularly screened for COVID-19 in accordance with the facility's procedures.

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.**
- **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.**
- **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**

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Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Compatible N95 Respirator Collection

Yale New Haven Health System personnel and community partners will follow instructions outlined in "Instructions for Healthcare Personnel, Healthcare Facilities, and Community Partners: Emergency Decontamination of Compatible N95 Respirators Using the Yale New Haven Health FFR Decontamination System" to collect compatible N95 respirators and send to the Yale New Haven Health Regional Operations Center. Staff at the Yale New Haven Health Regional Operations Center will receive the shipment and safely transport the compatible N95 respirators in a case cart to the decontamination area.

Staging Process

1. Prior to entering the decontamination room, staff will don the appropriate PPE including a respirator, gown, face shield, and gloves.
2. The case carts will be transported into the negative airflow room for sorting and staging of compatible N95 respirators.
3. Each compatible N95 respirator will be examined for stains, damage, and intact elastic bands. If found, the compatible N95 respirator will not be decontaminated and will be discarded.
4. Compatible N95 respirators will be hung on metal racks by hanging the respirator by the elastic band using paper clips and ensuring that the respirators do not touch each other. Up to 270 compatible N95 respirators can be hung on each rack.
5. Once loaded, the rack can be moved into the decontamination room. Up to 10 racks can fit in each of the decontamination rooms, with racks measuring 13' 2" by 16' 0".

Decontamination Process

1. Place the Bioquell vapor generator in the center of the decontamination room and evenly distribute the available aeration units around the enclosure.

2. Place one Bioquell Chemical Indicator (CI) within the enclosure at a point furthest from the generator.

3. Place one Bioquell Biological Indicator (BI) in each the four corners of the room, for a total of four BIs.

4. Program the Bioquell vapor generator to deliver a 6-log sporicidal level of kill and to aerate the decontamination room for 300 minutes. 6-log sporicidal level of kill is verified or determined using four BIs and one calibrated CI.
   a. Refer to the Bioquell vapor generator user manual or contact your Bioquell representative should you require guidance on how to program the system in accordance with the above parameters.

5. Insert the Bioquell hydrogen peroxide sterilant into the vapor generator.
   a. Wear eye goggles and gloves when handling Bioquell hydrogen peroxide.

6. If the room has multiple entry points (i.e., doors) ensure that all but the primary entrance and exit are sealed using Bioquell tape or equivalent and locked (where appropriate).

7. Confirm all vents are sealed with Bioquell or equivalent vent sealers.

8. Confirm aeration units are powered up.

9. Perform a final check on the positions and orientations of the compatible N95 respirators on the racks.

10. Exit the room and seal the door using Bioquell or equivalent tape.

11. Place "No Entry" notices on entry points to the room advising that a decontamination cycle is in progress.
    a. Include a named contact and telephone number to call in case of emergency.

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12. Turn on the low-level hydrogen peroxide monitor.

13. Initiate the decontamination cycle.

14. Use the low-level hydrogen peroxide monitor to check the enclosure for any possible leaks.
    a. Should a leak be detected, seal the source with Bioquell or equivalent tape.

15. At the end of the aeration period, unseal and open the door wide enough to allow the environmental concentration of hydrogen peroxide to be measured using the low-level monitor.
    a. If the monitor reads > 1.0 ppm, close the door and allow the room to continue aerating.
    b. Once the monitor reads $\leq$ 1.0 ppm, turn off the Bioquell vapor generator and aeration units.

16. Access the room, following proper PPE protocols and confirm that the CI shows at least a 6-$\log_{10}$ reduction. Record the results of the BIs and CI in accordance with Yale New Haven Health protocols on the "Central Sterile Supply Bioquell Form."

17. Remove the BIs and aseptically transfer to nutrient broth tubes and place in 57^{o} C water bath for incubation.

18. Record all Bioquell vapor generator parameters in accordance with Yale New Haven Health protocols on the "Room Information Form," including Date, Ward/Unit, Room number, Reason, Exposure Conditions (Time, Temperature, and Pressure), Starting humidity, Gas start, and Critical Process Parameters (Room volume, Injection rate, Dwell time, and Aeration), and Concentration of H_2O_2.

19. Collect the decontaminated, compatible N95 respirators and mark each respirator with a hash mark to indicate the respirator has gone through a decontamination cycle. The number of hash marks on the respirator will indicate the total number of times the respirator has undergone the decontamination process (maximum of 3).

20. Repackage 5 decontaminated, compatible N95 respirators per bag, sorted by type and size. Care shall be taken to prevent possible recontamination of the respirators during the recording and redistribution process.

21. Place a "Load Label" on each bag to indicate the room number, load, and lot number. Write the type, size, and quantity of decontaminated, compatible N95 respirators on the bag and staple the bag closed.

22. The decontaminated respirator area is being continuously monitored for hydrogen peroxide by the portable ChemDaq's SafeSide Hydrogen Peroxide monitor. The monitor is set per regulatory limits for PEL and STEL with visual and audible alarms. All data is recorded and archived by SafeSide program and can be exported if needed.

23. The decontaminated respirators are repackaged into paper bags with labeling describing the compatible N95 respirator model. Multiple bags of the same compatible N95 respirator models are placed in a box with a top and stored in the Yale New Haven Health Regional Operations Center until respirators are requested by a facility. Yale New Haven Health Material Services will send them by courier to be delivered to the requesting facility.

Note: In the event of an emergency, stop the decontamination cycle and activate the aeration units. When a decontamination cycle cannot be completed or if there are protocol deviations, discard the compatible N95 respirators from the decontamination cycle.

Report Adverse events to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.

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

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