



**Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by Duke Health Using the Duke Decontamination System with Hydrogen Peroxide Vapor**

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Duke Decontamination System with Hydrogen Peroxide Vapor (“Duke Decontamination System”), operated by Duke University Health System (“Duke Health”), for use in decontaminating compatible N95 respirators for multiple-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by Duke Health using the Duke Decontamination System.

The Duke Decontamination System has been authorized by FDA under an EUA for use in decontaminating compatible N95 respirators for multiple-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 outbreak. The Duke Decontamination System has neither been cleared nor approved for this use. The Duke 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 the 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

- **The Duke Decontamination System is not authorized for use with the following:**
  - **Respirators containing cellulose-based materials;**
  - **Respirators containing exhalation valves;**
  - **Respirators containing antimicrobial agents;**
  - **Respirators containing duck-billed design; and**
  - **Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.**
- **All compatible N95 respirators must be free of visible damage and soil/contamination (e.g., blood, dried sputum, bodily fluids, makeup).**
- **Compatible N95 respirators that are visually soiled or damaged will not be collected for decontamination and will be discarded.**
- **Compatible N95 respirators may be decontaminated up to 4 times.**
- **Any compatible N95 respirator with illegible markings to indicate the number of decontamination cycles completed must be discarded.**

breathability) might not consistently meet NIOSH-approved N95 standards.

**Compatible N95 Respirator Collection:**

1. Remove the compatible N95 respirator using the appropriate procedure in [N95 Respirators and Face Shields: Instructions for Extended Use and Reuse](#).
2. **Discard the mask if it has been decontaminated and used 4 times.**
3. Place your compatible N95 respirator into the collection bin (pictured below) located in your patient care location.



If the bin is full or overflowing, please dial 1-919-384-1600, Option #4.

**Receiving Decontaminated, Compatible N95 Respirators:**

The decontaminated compatible N95 respirators will be redistributed to the patient care units in clear, clam-shell boxes that are labeled “Clean.” HCP must receive the same model of decontaminated compatible N95 respirator for which they have been fit tested. If such model of respirator is unavailable, then Duke must provide HCP with fit testing prior to using an alternative model of decontaminated compatible N95 respirator.



After receiving your decontaminated, compatible N95 respirator, please check the following:

1. Ensure there is no visible soil or damage.



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2. Ensure that the number of tick marks on any decontaminated, compatible N95 respirator (shown below) indicating number of decontamination cycles performed is **4 or less**.
3. Perform a user seal check according to OSHA standards prior to beginning a shift. If the user seal check does not pass, discard the respirator.



If at any time there is visible soil or damage or the elastic strap marks are not legible, discard the respirator. **Discard the respirator after 4 decontamination cycles.**

Don the decontaminated, compatible N95 respirator using the appropriate procedure as stated in [N95 Respirators and Face Shields: Instructions for Extended Use and Reuse](#).

**Any problems should be immediately reported to Duke Health.**

**Contact the Occupational and Environmental Safety Office: 919-684-2794**