



**Instructions for Healthcare Facilities: Preparation and Collection 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

- **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.**
- **Decontaminated, compatible N95 respirators are not sterile.**



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.

#### On-Site Collection/Marking:

1. Every patient care location will have a designated collection station bin for contaminated compatible N95 respirators with the following note:  
**NOTE: Collection containers are for compatible N95 respirators only. Do not throw other personal protective equipment (such as gloves), paper towels, or waste in the collection bag.**
2. Healthcare personnel will follow the instructions provided by their facility in *Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by Duke Health using the Duke Health Decontamination System with Hydrogen Peroxide Vapor*.

#### Preparation for Transport:

1. The collection containers with the contaminated, compatible N95 respirators will be closed securely with the provided lid.
2. Decontaminate the outside of the container with alcohol or other suitable decontaminant wipes.
3. The collection container is now ready for transport to Duke's decontamination facility.

#### Transport to Duke's Decontamination Facility:

1. Dedicated personnel will gather the collection containers on carts and transport them directly to a temporary holding area or decontamination facility.

#### Reuse Information:

Following decontamination, the facility will be provided with **decontaminated, compatible N95 respirators** that have been decontaminated using the Duke Decontamination System for reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic. Duke must ensure that HCP 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.

The decontaminated, compatible N95 respirators will be redistributed to the patient care location in clear, clam-shell boxes that are labeled "Clean."



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Before reuse, the healthcare facility will inspect each returned, decontaminated, compatible N95 respirator for:

1. Numeric indication that the decontamination cycle number is **4 or less**. **NOTE: Compatible N95 respirators may be decontaminated a maximum of 4 times. Compatible N95 respirators must be discarded after exceeding 4 decontamination cycles.**



2. Visible damage or soiling. **NOTE: Compatible N95 Respirators must be discarded and not reused if visually damaged or soiled.**

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

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