

**Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for
Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System for
Return to the Same Healthcare Facility**

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ (hereafter referred to as the “Battelle Decontamination System”) operated by the Battelle Memorial Institute (“Battelle”), 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 Battelle using the Battelle Decontamination System.

The Battelle 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 pandemic. The Battelle Decontamination System has neither been cleared nor approved for this use. The Battelle 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.

Respirators that are NIOSH-approved before decontamination (<https://www.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.

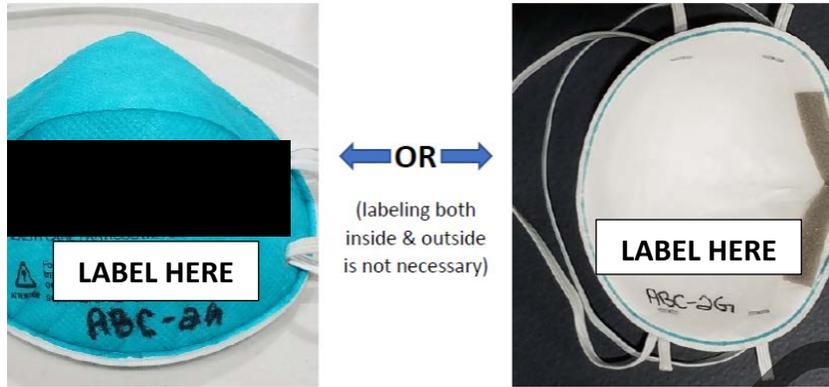


- The Battelle Decontamination System is not authorized for use with the following:
 - Respirators containing cellulose-based materials or antimicrobial agents;
 - Respirators with an exhalation valve or a duck-billed design; and
 - Respirators that are authorized by the Non-NIOSH Approved Disposable 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.
- All compatible respirators provided to Battelle must be free of any visible damage and soiling/contamination (e.g., blood, bodily fluids, makeup).
- Discard and do not collect compatible respirators that are visually soiled or damaged.
- Compatible N95 respirators may be decontaminated a maximum of 4 times.
- Discard any compatible N95 respirator with illegible markings to indicate the number of decontamination cycles.
- The Battelle 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 HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.
- The emergency use of the Battelle 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

Compatible N95 Respirator Marking and Collection:

1. Label your compatible N95 respirator using a permanent marker with the appropriate 3-digit site code and 2-digit site location ID; do not label others' or ask others to label for you.
2. Labeling should be legibly written on the outside OR inside of each compatible N95 respirator (see below).
3. Place your compatible N95 respirator in the collection bag provided by your healthcare facility at a designated collection station at your facility.

NOTE: Collection bags are for compatible N95 respirators only; do not throw other personal protective equipment (such as gloves), paper towels, or waste in the collection bags.



Following decontamination:

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 healthcare facilities must provide HCP with fit testing prior to using an alternative model of decontaminated compatible N95 respirator.

REMOVED