

Instructions for Healthcare Personnel (HCP): Preparation of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for Decontamination Using the Nova2200 with NovaClean decontamination process

The U.S. Food and Drug Administration (FDA) has authorized an Emergency Use Authorization (EUA) for the emergency use of the Nova2200 with NovaClean decontamination process (“Nova2200”) for use in decontaminating 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for single-user reuse by healthcare personnel (HCP). HCP must follow these instructions, as well as procedures at their healthcare facility, to prepare 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for decontamination using the Nova2200.

The Nova2200 has been authorized by FDA under an EUA for decontamination of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The Nova2200 has not been FDA cleared or approved for this use. The Nova2200 is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, unless the authorization is terminated or 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.

- Nova2200 is authorized for use with 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators; the Nova2200 is not authorized for use with any other N95 respirators.
- 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators that are to be decontaminated using the Nova2200 must be free of any visible damage, soiling, or contamination (e.g., blood, dried sputum, makeup, bodily fluids).
- Do not collect and discard 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators that are visually soiled or damaged.
- 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators must be discarded after 1 decontamination cycle.
- Any 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator whose traceability was lost after the 1 decontamination cycle must be discarded.
- Decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators are not sterile.

3M Model 1860 or Halyard FLUIDSHIELD N95 Respirator Marking and Collection:

1. The chain of custody on the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators must be maintained to minimize the risk of cross-contamination.
2. Inspect the 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator for any visible damage, soil, or contamination. If there is any visible damage, soil, or contamination the N95 respirator must be discarded.
3. Label your own individual 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator with your name and/or other identifier, as well as a location identifier, using a permanent marker. Labeling must be legibly written on the outside OR inside of each respirator, as shown to the right.
4. Place a single tick mark on your respirator to denote the 1 decontamination cycle. **NOTE: your N95 respirator may be decontaminated 1 time.**
5. Confirm that the labeling is legible, and that there is no visible damage, soil, or contamination prior to submitting your respirator for decontamination.
6. Place your 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator directly into the tote or container provided by your healthcare facility located at the healthcare facility's designated collection station. **NOTE: Only 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators are placed at the collection tote or container for decontamination. No other items or respirator models will be decontaminated in the same decontamination cycle.**
7. You will receive your decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator in a sealed, transparent plastic bag. After receiving your decontaminated respirator, check your respirator for the following:
 - Check your respirator to ensure that the respirator is marked with your name and/or identifying information; if at any time the labeling is not legible the respirator must be returned to the healthcare facility for quarantine.
 - If at any time there is visible soil or contamination, discard the respirator.
 - Discard the N95 respirator after one (1) decontamination cycle.
 - Perform a user seal check of the decontaminated respirator prior to use – If a successful user seal check cannot be performed, the respirator must be returned to the healthcare



facility for quarantine.

Reporting

Report any problems with the decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators to your healthcare facility.

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