Instructions for Healthcare Facilities: Decontamination of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators 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.

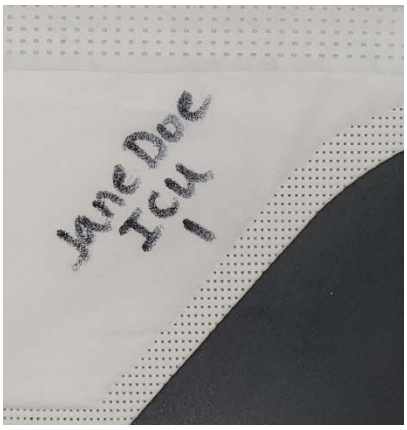
Respirators that are NIOSH-approved before decontamination (https://wwwn.cdc.gov/niosh-cel/) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer.

- 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:

The healthcare facility must ensure that the chain of custody is maintained to minimize the risk of cross-contamination. Prior to collection by the healthcare facility personnel, the HCP must label their own individual respirator with their name and/or other identifier, as well as a location identifier, and a single tick mark to denote the decontamination cycle (as shown **below**) with a permanent marker.

The HCP places their 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator directly into the tote or container provided by the healthcare facility located at the healthcare facility's designated collection station (see below for additional information on collection station). The tote or container will be labeled with the location identifier. 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators will be packed into NovaPouches™ by the healthcare facility's decontamination area staff.



3M Model 1860 or Halyard FLUIDSHIELD N95 Respirators Collection and Transportation:

The healthcare facility will create a collection station at the point of generation (i.e., hospital floor/unit). Each station will have sealable collection container (for example, sealable plastic bag or plastic container) clearly labeled as "SOILED RESPIRATORS; KEEP SEPARATED FROM CLEAN."

NOTE: Only 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators will be placed at the collection station for decontamination. No other items or respirator models will be decontaminated in the same decontamination cycle.

The HCP who are assigned to decontamination (i.e., those with training for collection/transport of such materials) collect the totes or containers of 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators at the collection stations, and place them into the appropriate container for transportation, such as a closed case cart, to minimize risk of environmental contamination. While placing the totes or containers on or into the cart, appropriate personal protective equipment (PPE)

(e.g., gloves) will be worn. The case cart will have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized. The case cart must be transported to healthcare facility's decontamination area.

After decontamination, each respirator will be received from decontamination facility, individually sealed in a transparent plastic bag, with name and/or identifying number visible on the respirator.

Reporting to NovaSterilis:

Healthcare facilities must report any discoloration or other signs of degradation with a decontaminated 3M Model 1860 or Halyard FLUIDSHIELD N95 respirator to NovaSterilis. After contacting NovaSterilis and providing the requested information, the healthcare facility must quarantine the N95 respirator until instructed by NovaSterilis to dispose of it. During the monthly maintenance visits, NovaSterilis staff may collect quarantined N95 respirators for further investigation.

Healthcare facilities will report any adverse events of which they become aware related to the Nova2200 and the decontaminated, 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators. This includes monitoring personnel using the Nova2200 and HCP using the decontaminated, 3M Model 1860 or Halyard FLUIDSHIELD N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. 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 must be immediately reported to NovaSterilis

NovaSterilis Contact: 1-607-330-2772 or Team@NovaSterilis.com