

FACT SHEET FOR HEALTHCARE PERSONNEL

Zoe-Ann Decontamination System for Decontaminating Compatible N95 Respirators

October 20, 2020

Coronavirus
Disease 2019
(COVID-19)

You have been given a **decontaminated N95 respirator** that has been decontaminated using a decontamination system that is authorized to decontaminate compatible N95 respirators **for single-user reuse by healthcare personnel (HCP) in a healthcare setting** (i.e., the same respirator is returned for reuse to the same HCP following its decontamination) to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of decontaminated, compatible N95 respirators. These compatible N95 respirators have been decontaminated using the Zoe-Ann Decontamination System (hereafter referred to as "**decontaminated N95 respirators**" and "Z-A Decon System" throughout this Fact Sheet).

Whether or not you use a surgical mask, respirator, or face shield, always follow infection control measures: wash hands, cover coughs and sneezes, stay home if you may be sick.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of the Z-A Decon System and decontaminated N95 respirators?

- The Z-A Decon System has been authorized for emergency use to decontaminate compatible N95 respirators for single-user reuse by HCP during the COVID-19 pandemic to prevent wearer exposure to pathogenic biological airborne particulates, including SARS-CoV-2.
 - Compatible N95 respirators are either authorized NIOSH-approved respirators or respirators that are authorized and listed in Exhibit 1 to FDA's emergency use authorization (EUA) for non-NIOSH-approved imported filtering facepiece respirators (FFRs) that are not manufactured in China, and that do not have exhalation valves, antimicrobial agents, or duck-billed designs, nor contain cellulose-based materials.
 - The Z-A Decon System is **not authorized** for use with the following:
 - Respirators containing cellulose-based materials;
 - Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - Respirators with duck-billed designs; and
 - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators Manufactured in China EUA.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through four (4) decontamination cycles for sporidical activity, viricidal activity, filtration efficiency, breathability, form fit testing, and strap integrity testing, per compatible N95 respirator. This testing has proven a 6-log reduction in biological contaminant with biological and chemical indicators placed throughout the chamber focusing on areas of the chamber that would be most difficult for hydrogen peroxide vapor to reach.

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

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- **Use of decontaminated N95 respirators:**
 - ✓ Decontaminated N95 respirators are not sterile
 - ✓ HCP must perform a user seal check of the decontaminated N95 respirator according to OSHA standard prior to beginning a shift. If the user seal check does not pass, the respirator must be discarded
 - ✓ Inspect respirators after each use prior to submission for decontamination
 - ✓ Discard respirators with visible soiling (e.g., blood) or damage – do not use and do not send for decontamination
 - ✓ The number of times a respirator has been decontaminated is written on the respirator (maximum 4 times)
 - ✓ Report problems with decontaminated N95 respirators to your healthcare facility
- **Monitor yourself for signs and symptoms** of potential infection with SARS-CoV-2 or other respiratory infection for up to and including 14 days after last contact with the SARS-CoV-2 virus and related material, and promptly report such information to your healthcare facility.
- **Report damage or discoloration** observed upon receipt of the decontaminated N95 respirators, and potential exposure of HCP from breaks in or other damage to or degradation of the decontaminated N95 respirators to your healthcare facility.
- 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.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19 as outlined in the CDC webpages, including *Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus*

Disease 2019 (COVID-19) in Healthcare Settings, Infection Control, and FAQ on PPE.

Current information on COVID-19 for healthcare personnel is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of using decontaminated N95 respirators that were decontaminated using the Z-A Decon System?

Potential benefits include:

- May help prevent exposure to airborne pathogens, and therefore reduce the risk of infection or illness
- Extends the usability of compatible N95 respirators by allowing for decontamination and reuse

Potential risks include:

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens

Overview of the Z-A Decon System

The Zoe-Ann Decontamination System is a fixed and controlled decontamination process that uses vaporized hydrogen peroxide (VHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2.

Each decontamination cycle in the Z-A Decon System consists of injecting VHP into the decontamination chamber until achieving a saturated atmosphere indicated by micro condensation; maintaining the VHP exposure for a 150-minute dwell time; and allowing the VHP to off gas to a level of 1 ppm prior to post decontamination processing. A minimum of ten (10) calibrated chemical indicators are dispersed throughout the chamber to indicate a successful decontamination cycle. This decontamination system enables single-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However,

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respirators that are visibly soiled must be discarded and not reused or decontaminated.

What is an EUA?

The United States Food and Drug Administration (FDA) has made the emergency use of the Z-A Decon System to decontaminate compatible N95 respirators available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices due to insufficient supply during the COVID-19 pandemic.

The Z-A Decon System has been made available under an EUA and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the Z-A Decon System may be effective at preventing HCP exposure to pathogenic biological airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 4 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the Z-A Decon System is in effect for the duration of the COVID-19 declaration justifying emergency use of medical devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/COVID19>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Infection Prevention and Control Recommendations in Healthcare Settings:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FAQ on PPE:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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