

FACT SHEET FOR HEALTHCARE PERSONNEL

Battelle Decontamination System for Decontaminating Compatible N95 Respirators

March 29, 2020

Coronavirus
Disease 2019
(COVID-19)

You have been given a **decontaminated N95 or N95-equivalent respirator** that has been decontaminated using a decontamination system **for reuse by healthcare personnel in a healthcare setting** to help prevent healthcare personnel 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 N95 or N95-equivalent respirators. These compatible N95 or N95-equivalent respirators have been decontaminated using the Battelle CCDS Critical Care Decontamination System™ (hereafter referred to as “decontaminated N95 respirators” and “Battelle Decontamination System” throughout this Fact Sheet).

Decontaminated N95 respirators that have been decontaminated using the Battelle Decontamination System are authorized for use by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

Whether or not you use a respirator, 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. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

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 decontaminated N95 respirators?

- The Battelle Decontamination System has been authorized for emergency use to decontaminate compatible N95 or N95-equivalent respirators for reuse by healthcare personnel during the COVID-19 pandemic to prevent wearer exposure to pathogenic airborne particulates.
 - Compatible N95 or N95-equivalent respirators under the Battelle Emergency Use Authorization are those that do not contain cellulose-based materials.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through 20 decontamination cycles for sporicidal activity, viricidal activity, filtration efficiency, breathability, form fit testing, and strap integrity testing, per authorized respirator.
- **Use of decontaminated N95 respirators:**
 - ✓ 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
 - ✓ Cellulose-based materials are incompatible with the Battelle decontamination process
 - ✓ The number of times a respirator has been decontaminated is written on the respirator (maximum 20 times)
 - ✓ Report problems with decontaminated N95 respirators to your healthcare facility
- **Monitor healthcare personnel 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 Battelle.
- **Report damage or discoloration** observed upon receipt of the decontaminated N95 respirators, and

Report Adverse events, including problems with test performance or results, 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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potential exposure of healthcare personnel from breaks in or other damage to or degradation of the decontaminated N95 respirators.

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 Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings, Infection Control, and FAQ about 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?

Potential benefits include:

- May help prevent exposure to airborne pathogens, and therefore risk of infection or illness
- Extends the usability of compatible N95 or N95-equivalent 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 Battelle Decontamination System

The Battelle Decontamination System is a self-contained decontamination device that uses vapor phase hydrogen peroxide (VPHP) for decontamination of compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2. N95 or N95-equivalent respirators containing cellulose-based materials are incompatible with the Battelle decontamination process.

Each decontamination cycle in the Battelle Decontamination System consists of injecting VPHP into the decontamination chamber until achieving a saturated atmosphere indicated by micro condensation; maintaining the VPHP exposure for a 150-minute dwell time; and allowing the VPHP to off gas to a level of 1 ppm prior to post decontamination processing. A minimum of five calibrated chemical indicators are dispersed throughout the system to indicate a successful decontamination cycle. This decontamination system enables the reuse of compatible N95 or N95-equivalent respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or decontaminated.

What is an EUA?

The United States FDA has made the emergency use of the Battelle Decontamination System to decontaminate compatible N95 or N95-equivalent 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, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The Battelle Decontamination 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 Battelle Decontamination System may be effective at preventing healthcare personnel exposure to pathogenic airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 20 decontamination cycles per respirator, compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the Battelle Decontamination System is in effect for the duration of the COVID-19 declaration

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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 Personal Protective Equipment:

<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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