



BATTELLE N95 CRITICAL CARE DECONTAMINATION SYSTEM

INFORMATIONAL PACKET

This packet is provided by the State of California as a reference tool for Hospital Administrators, Hospital Infectious Disease Specialists, Hospital Logisticians and Medical Providers.

The State of California, in cooperation with the Federal Emergency Management Agency and the Department of Defense, have worked to provide an additional solution to the N95 shortages that our medical facilities are enduring. Our State Government, the aforementioned Federal Agencies, and the not-for-profit organization Battelle, have established N95 decontamination sites strategically located throughout California. Your facility is receiving this packet because you are located in close geographic proximity to one of these decontamination sites.

Healthcare facilities are encouraged to participate in the N95 decontamination service. This packet aims to explain how facilities can enroll in the program and to simplify the process as much as possible.

The medical authorities of the State of California have reviewed the N95 decontamination process as well as the FDA authorization for the emergency use of this service. We feel confident that the science behind this system is sound and is a science we can leverage to protect our medical providers and patients as we navigate the COVID-19 crisis.

We are proud of the incredible service that our state medical providers are performing on behalf of California and hope that this tool will support your continued efforts.

SIG BLOCK

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Executive Summary – TAB A

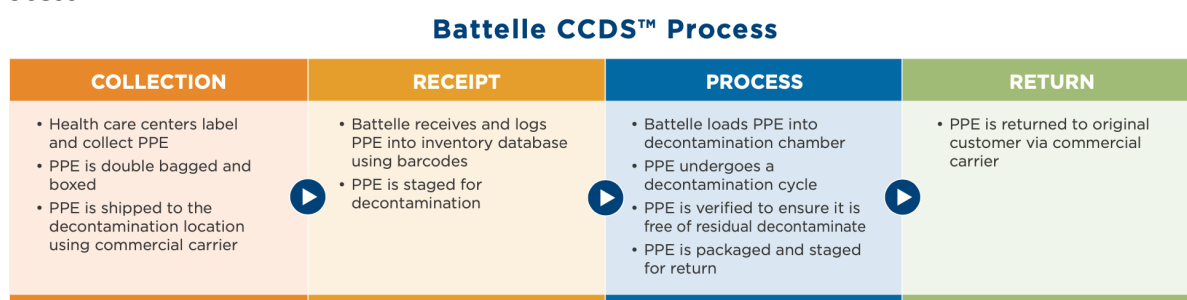
FDA Emergency Use Authorization (EUA)

On March 29, 2020, the FDA authorized an EUA for the emergency use of the Battelle CCDS Critical Care Decontamination System (Battelle CCDS) of the for use in decontaminating compatible N95 or N95-equivalent respirators for reuse by healthcare personnel.

Technology

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.

Process



Decontamination Requirements

All compatible N95 respirators provided to Battelle must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup)

Providers should ensure that their faces are clean and dry when using N95 respirators that are intended to undergo decontamination processing.

Cost

There will be no cost to hospitals to utilize this service.

System Locations

Los Angeles

California Department of Public Health Guidance – TAB B



State of California—Health and Human Services Agency **California Department of Public Health**



GAVIN NEWSOM
Governor

April 7, 2020

AFL 20-36

TO: General Acute Care Hospitals

SUBJECT: Guidance for Decontamination and Reuse of N95 Filtering Facepiece Respirators

All Facilities Letter (AFL) Summary

This AFL provides guidance for the handling of used N95 filtering facepiece respirators so they can be decontaminated and reused as respirator supplies are depleted during the Coronavirus Disease 2019 (COVID-19) pandemic.

Background

The federal Centers for Disease Control and Prevention (CDC) released guidance on the decontamination and reuse of N95 filtering facepiece respirators as a crisis capacity strategy on March 31, 2020. Although there are currently no manufacturer authorized methods for filtering facepiece respirators decontamination prior to reuse, Battelle Decontamination System, a vaporous hydrogen peroxide (H₂O₂) (VHP) system, received emergency use authorization (EUA) from the federal Food and Drug Administration (FDA) on March 29, 2020 for decontamination of N95 respirators. Facilities should continue to monitor the FDA website to determine if other EUAs have been issued.

The National Institute of Occupational Safety and Health (NIOSH) and other researchers have investigated the impact of various decontamination methods on filtration efficiency, facepiece fit, and the ability to reduce viable virus or bacteria on the respirator surface. VHP, in addition to ultraviolet germicidal irradiation (UVGI), and moist heat, showed the most promise as potential methods to decontaminate filtering facepiece respirators.

The State of California is working with Battelle Memorial Institute to deploy their FDA emergency use authorized decontamination systems in California. Hospitals regularly use VHP for decontamination to inactivate highly resistant pathogens, including bacterial spores and viruses for terminal decontamination of hospital rooms, biosafety cabinets, and medical equipment and materials that are intolerant to heat or have diffusion-restricted space. A number of studies (Battelle 2016, 2020; Bergman 2010, Viscusi 2009) have demonstrated that certain N95 respirators can be safely decontaminated with proper use of VHP.

The California Department of Public Health (CDPH) will provide additional guidance on the specifics of how the State plans to transport, decontaminate, and reissue used N95 respirators. Below is guidance for how to preserve used N95 respirators now in order for them to be decontaminated in the very near future.

On-Site Collection

1. Your hospital should create a N95 respirator collection station at the point of generation (i.e. hospital floor/unit).
 - Any N95 or N95-equivalent respirator that does not contain cellulose-based materials is compatible with the Battelle Decontamination System.
 - All compatible N95 respirators must be free of any visual soiling or contamination (e.g. blood, bodily fluids, makeup).
 - Compatible N95 respirators that are visually soiled or damaged should not be collected for decontamination and will be disposed of and not returned after decontamination.
2. Each station should have a bag provided by the healthcare facility to collect compatible N95 respirators.
 - Bags are for compatible N95 respirators only. Do not put other personal protective equipment (such as gloves), paper towels, or waste in the collection bag.
3. With a permanent marker, each compatible N95 respirator should be labeled with a three-digit site code and a 2-digit location identifier (as shown below). The unique site code corresponds to the hospital's last three digits of their CDPH license number. Your organization may designate the location identifier to correspond to a specific location/floor/unit within your site.

_____ -- _____

Site Code ID Site Location ID

Preparation for Shipment or Pick-up:

1. Bags containing the contaminated compatible N95 respirators to be decontaminated ("primary collection bag") should be closed.
2. Place the primary collection bag into another bag ("secondary collection bag") (provided by the hospital), which is then closed.
3. Decontaminate the secondary collection bag with alcohol or other suitable decontaminant.
4. Place the decontaminated bags into a rigid, closed box (supplied by the hospital) clearly labeled with a biohazard symbol, and tape the box securely shut.
5. Label the outside of the box with the 3-digit site code and 2-digit location identifier.

Reuse Information

Following decontamination, each hospital will be provided the decontaminated N95 respirators they submitted. Each hospital should inspect each returned decontaminated N95 respirator for visible damage or soiling. If visually damaged or soiled, decontaminated N95 respirators should be discarded and not reused.

Additionally, staff should be reminded of the following:

- Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the N95 respirator.
- Avoid touching the inside of the N95 respirator.
- Use a pair of clean (non-sterile) gloves when donning and performing a user seal check.
- Visually inspect the N95 respirator to determine if its integrity has been compromised.
- Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit, and seal.
- If the integrity of any part of the N95 respirator is compromised, or if a successful user seal check cannot be performed, discard the N95 respirator.

Battelle Memorial Institute has developed a fact sheet for health care providers who use the decontaminated N95 respirators.

The State will track, through the manufacture number on the mask, for the number of decontamination cycles. N95 respirators will be disposed after 20 decontamination cycles.

If you have any questions about infection prevention and control of COVID-19, please contact the CDPH Healthcare-Associated Infections Program via email at HAIPProgram@cdph.ca.gov or novelvirus@cdph.ca.gov.

Sincerely,

Original signed by Heidi W. Steinecker

Heidi W. Steinecker
Deputy Director

Resources

- CDC Decontamination and Reuse of Filtering Facepiece Respirators
- FDA Emergency Authorization of Battelle Decontamination System (PDF)
- FDA Emergency Use Authorization website
- How to Perform a User Seal Check with an N95 Respirator video
- Battelle Decontamination System Fact Sheet for Healthcare Personnel (PDF)

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA
95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)



FDA Guidance Summary and Emergency Use Authorization – TAB C

FDA Guidance Summary

The U.S. Food and Drug Administration has authorized 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 or N95-equivalent respirators (“compatible N95 respirators”), for reuse by healthcare personnel. Healthcare personnel should follow the instructions provided by Battelle, as well as the procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination by Battelle using the Battelle Decontamination System.

- **Due to incompatibility, the Battelle Decontamination System is not authorized for use with respirators containing cellulose-based materials**
- **All compatible N95 respirators provided to Battelle must be free of any visual soiling or contamination (e.g., blood, bodily fluids, makeup)**
- **If N95 respirators are soiled or damaged, they will be disposed of and not returned after decontamination**

FDA EMERGENCY USE AUTHORIZATION



March 29, 2020

Mr. Jeff Rose
 Battelle Memorial Institute
 505 King Ave.
 Columbus, OH 43201

Dear Mr. Rose:

On March 28, 2020, based on your request, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ (hereafter “the Battelle Decontamination System”) at the Battelle Memorial Institute, for use in decontaminating compatible N95 or N95-equivalent¹ respirators (“compatible N95 respirators”)² for reuse by healthcare personnel (HCP)³ to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic resulting from the Coronavirus Disease 2019 (COVID-19)⁴ pandemic.

On March 29, 2020, in response to your request to operate the Battelle Decontamination System at multiple locations and additional information you provided, and having concluded that revising the March 28, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the March 29, 2020, letter in its entirety with the amendments⁵ incorporated.

¹ For purposes of this EUA, “N95-equivalent respirators” refers to respirators identified in Exhibit 1 of the EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators, available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

² For purposes of this EUA, “compatible N95 respirators” means any N95 or N95-equivalent respirator that does not contain cellulose-based materials. Respirators containing cellulose-based materials are incompatible with the Battelle Decontamination System.

³ HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

⁴ On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). The new names are used throughout this document.

⁵ The amendments to the March 29, 2020 letter revise: (1) the scope of the EUA, authorizing use of the Battelle Decontamination System operated by the Battelle Memorial Institute; and (2) the conditions of authorization for use of the Battelle Decontamination System operated by the Battelle Memorial Institute.

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On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.⁶ Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.⁷

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the Battelle Decontamination System, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Battelle Decontamination System for decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Battelle Decontamination System may be effective at preventing exposure to pathogenic airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic by decontaminating, for a maximum of 20 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, and that the known and potential benefits of the Battelle Decontamination System, when used to decontaminate compatible N95 respirators for reuse by HCP to prevent exposure to pathogenic airborne particulates during FFR shortages during the COVID-19 pandemic, outweigh the known and potential risks; and

⁶ U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 4, 2020) (accessible at <https://www.fda.gov/media/135010/download>).

⁷ U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, March 24, 2020.

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3. There is no adequate, approved, and available alternative to the emergency use of the Battelle Decontamination System for decontaminating compatible N95 respirators for reuse by HCP during FFR shortages during the COVID-19 pandemic.^{8,9}

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the Battelle Decontamination System operated by the Battelle Memorial Institute, for use in decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of 20 decontamination cycles per respirator, for reuse by HCP to prevent exposure to pathogenic airborne particulates during the COVID-19 pandemic.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Battelle Decontamination System, when used and labeled consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the Battelle Decontamination System may be effective at preventing HCP exposure to pathogenic airborne particulates during FFR shortages during the COVID-19 pandemic by decontaminating compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the Battelle Decontamination System, when used to decontaminate compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The Battelle Memorial Institute must provide the following information pertaining to the emergency use of the authorized product before the decontamination process begins (i.e., before a healthcare facility begins preparing and collecting compatible N95s for decontamination), which are authorized to be made available to HCP and healthcare facilities:

⁸ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

⁹ There are not sufficient quantities of FFRs to meet the needs of the U.S. healthcare system. These disposable N95 respirators are an integral part of routine patient care. Due to shortages of N95 respirators, HCP may need to treat patients without personal protective equipment (PPE) or use a bandana or other less effective masks unless single-use N95 respirators can be decontaminated for reuse. Providing a method for decontaminating compatible N95 respirators reduces stress on the supply chain and helps meet the needs of the healthcare system. Providing HCP who are on the forefront of the COVID-19 response with FFRs is necessary in order to reduce the risk of illness in HCP and increase their availability to provide care to affected patients or those suspected of having COVID-19.

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- Instructions for Healthcare Personnel: Preparation of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System (“Instructions for Healthcare Personnel”);
- Instructions for Healthcare Facilities: Preparation and Collection of Compatible N95 Respirators for Decontamination by the Battelle Memorial Institute Using the Battelle Decontamination System (“Instructions for Healthcare Facilities”); and
- Labeling and instructions for use developed by Battelle Memorial Institute (“Battelle”) that include the Fact Sheet, Instructions for Healthcare Personnel, and Instructions for Healthcare Facilities set forth in this section (Section II).

In addition, compatible N95 respirators decontaminated by the authorized product must be accompanied by the following labeling, developed by the Battelle Memorial Institute, upon return to the healthcare facility:

- Fact Sheet for Healthcare Personnel: Battelle Decontamination System for Compatible N95 Respirators (“Fact Sheet”).

The Fact Sheet, Instructions for Healthcare Personnel, Instructions for Healthcare Facilities, and Instructions for Use are referred to as “authorized labeling.”

The Battelle authorized labeling must be provided to HCP and healthcare facilities as directed in Section II, and shall include the specified information as follows:

The Battelle Decontamination System is a self-contained decontamination device that uses vapor phase hydrogen peroxide (VPHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2. N95 respirators containing cellulose-based materials are **not** compatible with decontamination by the Battelle Decontamination System.

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 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.

Instructions for Healthcare Personnel are sent to all healthcare facilities requesting decontamination of compatible N95 respirators and the facility should make these instructions available to HCP to prepare their own individual, compatible N95 respirator for decontamination. Using a permanent marker, the compatible N95 respirator is labeled by the HCP (following the procedure established by the healthcare facility) with a unique three-digit site code and a two-digit location identifier. The unique three-digit site code corresponds to the return delivery address for each respirator following decontamination.

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Instructions for Healthcare Facilities are sent to all healthcare facilities requesting decontamination of compatible N95 respirators. The facility should create a collection station for compatible N95 respirators to be sent to Battelle for decontamination. Collection stations should contain bags (“primary collection bag”) to collect compatible N95 respirators prepared according to the Instructions for Healthcare Personnel. The healthcare facility shall close the primary collection bag. The primary collection bag is then placed into a secondary collection bag, and the facility will appropriately close and decontaminate (using alcohol or other suitable decontaminant) the secondary collection bag. The bags are then placed into rigid, closed boxes clearly labeled with biohazard symbols, taped securely shut, and labeled outside with the three-digit site code and two-digit location identifier. According to the healthcare facility’s agreement with Battelle, the facility should complete the chain of custody form provided by Battelle for each shipment, and send to the designated Battelle location. Upon return of the decontaminated compatible N95 respirators from Battelle to the healthcare facility, the healthcare facility should review the provided chain of custody form indicating successful decontamination, and inspect each compatible N95 respirator for visible damage or soiling, as well as confirm the N95 respirator contains a numerical indicator of the decontamination cycle. Any problems should be immediately reported to Battelle.

Battelle agrees to the following procedures pertaining to the authorized product:

Battelle shall enter into agreements with healthcare facilities requesting decontamination of compatible N95 respirators, and provide such healthcare facilities with the authorized labeling and chain of custody documentation for completion by the healthcare facility to send to Battelle. Upon receipt of the compatible N95 respirators and chain of custody documentation by Battelle, the box of compatible N95 respirators is barcoded and logged into the Battelle Decontamination System tracking database and chain of custody. The used compatible N95 respirator is loaded into the Battelle Decontamination System and undergoes a decontamination cycle. Upon completion of each decontamination cycle, each compatible N95 respirator is removed from the decontamination system. Each compatible N95 respirator is labeled numerically (1, 2, 3, etc.) with a permanent marker to indicate the number of decontamination cycles completed, up to a maximum of 20 cycles. After all decontaminated compatible N95 respirators are labeled, they are boxed and returned to provider with a chain of custody form, which indicates successful decontamination, and the Fact Sheet.

The emergency use of the Battelle Decontamination System must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS’s determination under Section 564(b)(1)(C) described above and the Secretary of HHS’s corresponding declaration under Section 564(b)(1), the authorized Battelle Decontamination System is authorized to be operated by Battelle Memorial Institute for decontaminating compatible N95 respirators that are authorized to be used by HCP in healthcare settings under the terms and conditions of this EUA. Changes to the process, procedures, or labeling for the authorized product may require an EUA amendment

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subject to review and concurrence of the Division of Infection Control and Plastic and Reconstructive Surgery Devices/OPEQ/CDRH and OCET/OCS/OC.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain FDA Requirements

I am waiving the following requirements for the Battelle Decontamination System during the duration of this EUA:

- applicable current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the authorized Battelle Contamination System used in accordance with this EUA; and
- labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements (see Subpart B of 21 CFR Part 801), except that the Battelle Decontamination System must comply with the authorized labeling requirements specified in this EUA (Section II).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Battelle Memorial Institute

- A) The Battelle Decontamination System shall only be operated by the Battelle Memorial Institute (“Battelle”) and shall not be distributed to third parties.
- B) Use of the Battelle Decontamination System on other types of personal protective equipment is not authorized and would require a request for a separate EUA or marketing authorization and data supporting such other use.
- C) Battelle will make available to customers the authorized labeling for the Battelle Decontamination System through posting on the Battelle website and will send the appropriate authorized labeling to each healthcare facility when it returns each shipment of the decontaminated respirators, consistent with Section II of this letter.
- D) Battelle is authorized to decontaminate up to 10,000 compatible N95 respirators per chamber load, consistent with the data provided to FDA. Battelle shall provide FDA weekly reports, including data according to a testing plan (including data from chemical indicators and biological indicators) for scale-up reviewed by FDA, regarding the decontamination of compatible N95 respirators, including any reductions in decontamination ability. Battelle shall provide FDA, in advance of establishing satellite facilities where Battelle will perform decontamination using the Battelle Decontamination System, confirmation that all chambers, critical parameters, logistics, processes, containment systems, and labeling are identical and in place at all satellite facilities. After implementation, at the current and all satellite facilities, if Battelle demonstrates any reduction in decontamination ability for a given site, Battelle shall immediately notify FDA.

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- E) All descriptive printed matter relating to the use of the Battelle Decontamination System shall be consistent with the authorized labeling. No descriptive printed matter relating to the use of the Battelle Decontamination System may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.
- F) Battelle will have a process in place for reporting adverse events about the authorized product and the decontaminated respirators of which they become aware and send such reports to FDA, and will establish a process to collect information from healthcare facility customers regarding degradation of decontaminated N95 respirators and reports of infection or potential infection of users of the decontaminated N95 respirators and send such reports weekly to FDA.
- G) Battelle will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- H) Battelle will maintain records of the chain of custody of the N95 respirators sent to Battelle for decontamination through use of a barcode system and tracking database.
- I) Battelle will track the number of times a N95 respirator is decontaminated up to a maximum of 20 decontamination cycles per N95 respirator. Battelle will maintain records of all decontamination cycles.
- J) Battelle is authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.
- K) Battelle will maintain records and provide reports to FDA of the routine monitoring and testing of its personnel consistent with the monitoring and schedule set forth below:
 - Battelle personnel are to be enrolled in the Battelle SARS-CoV-2 Fever Monitoring Program.
 - Battelle personnel will undergo routine testing for SARS-CoV-2 (subject to availability of diagnostic tests).
 - Battelle will keep records and provide weekly reports to FDA during the decontamination system scale-up process (i.e., data on chemical indicators and biological indicators), and weekly reports to FDA for a minimum of two weeks post-implementation of the full scale-up of the decontamination process to monitor the safe use of the Battelle Decontamination System by Battelle personnel.
 - After the decontamination scale-up process is established and operational, Battelle will provide bi-weekly reports and promptly notify FDA of adverse events relating to infections and exposures of Battelle personnel to SARS-CoV-2.

Healthcare Facilities

- L) Healthcare facilities using respirators that have undergone decontamination using the Battelle Decontamination System (“the decontaminated respirators”) should make available to HCP who are or may be using the decontaminated respirators the authorized Fact Sheet for Healthcare Personnel that is required to be provided by Battelle.
- M) Healthcare facilities using the decontaminated respirators should monitor HCP who use such respirators for the signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to Battelle, so that Battelle can provide a weekly report to FDA consistent with Section IV.F of this EUA. Reports of adverse

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health indications should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus.

- N) Healthcare Facilities using the decontaminated respirators must inspect the decontaminated respirators upon receipt from Battelle. Any discoloration or other signs of degradation with a decontaminated respirator should promptly be reported to Battelle, and the healthcare facility should dispose of such respirator.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of the Battelle Decontamination System during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

Battelle Decontamination Process Overview – TAB D

The Battelle CCDS Critical Care Decontamination System (Battelle CCDS) addresses the current shortage of critical Personal Protective Equipment (PPE) across the United States. Battelle CCDS is designed to decontaminate N95 respirators for the novel coronavirus (SARS-CoV-2).

THE PROCESS

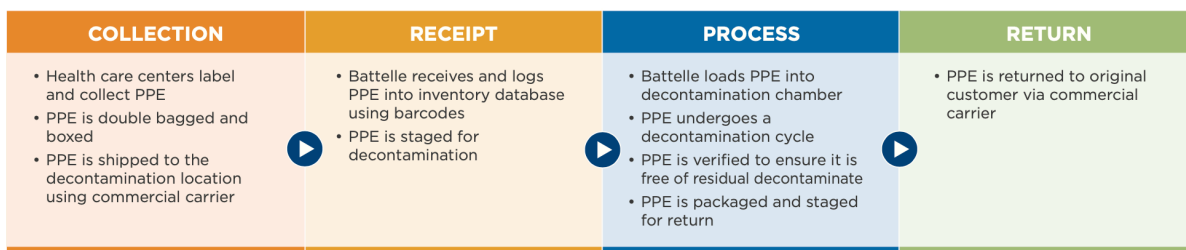
Battelle CCDS can decontaminate thousands of N95 respirators using high concentration, vapor phase hydrogen peroxide (VPHP). The respirators are exposed for hours at the validated concentration level to decontaminate biological contaminants, including the SARS-CoV-2. CCDS can decontaminate the same respirator up to 20 times without degrading N95 filter mask performance. A minimum of five calibrated chemical indicators are dispersed throughout the system to indicate a successful decontamination cycle.

Healthcare systems will collect worn respirators each day in accordance with an approved procedure, and the PPE will be labeled with a barcoded serial number that will be used for tracking the PPE chain-of-custody throughout the decontamination process. This procedure ensures that the hospital system receives its own respirators back.

REGULATORY, SAFETY AND EFFICACY

Battelle CCDS draws on decades of research and is grounded on an FDA study Battelle completed in 2016 to investigate decontamination and durability of N95 respirators in the event of a pandemic. Battelle is currently conducting research to validate that other materials, such as surgical masks and ventilator components, will continue to function as designed following multiple decontamination cycles.

Battelle CCDS™ Process



Compatible N95 Respirators – TAB E

THIS LIST IS SUBJECT TO CHANGE

**ALWAYS CONSULT THE MANUFACTURER FOR THE MOST UP TO DATE INFORMATION IN REGARD TO
N95 COMPOSITION AND COMPATIBILITY WITH VPH DECONTAMINATION**

Cellulose Free N95s

- Gerson: 1730, 2130
- Kimberly Clark: 46867, 46727, 46827
- Moldex: 2200, 2201, 2360
- Honeywell North: 8150-P100
- 3M Health Care Particulate Respirator and Surgical Mask 1860, N95
- 3M Health Care Particulate Respirator and Surgical Mask 1860S, N95
- 3M Aura Health Care Particulate Respirator and Surgical Mask 1870+, N95
- 3M Particulate Respirator 8110S, N95
- 3M Particulate Respirator 8210, N95
- 3M Particulate Respirator 8210 Plus, N95
- 3M Particulate Respirator 8210V, N95
- 3M Particulate Respirator 8211, N95
- 3M Particulate Respirator 8240, R95
- 3M Particulate Respirator 8246, R95, with Nuisance Level Acid Gas Relief
- 3M Particulate Respirator 8247, R95, with Nuisance Level Organic Vapor Relief
- 3M Particulate Respirator 8271, P95
- 3M Particulate Respirator 8511, N95
- 3M Particulate Welding Respirator 8515/07189(AAD), N95
- 3M Particulate Respirator 8516, N95, with Nuisance Level Acid Gas Relief
- 3M Particulate Respirator 8576, P95, with Nuisance Level Acid Gas Relief
- 3M Particulate Respirator 8577, P95, with Nuisance Level Organic Vapor Relief
- 3M Aura Particulate Respirator 9210+/37192, N95
- 3M Aura Particulate Respirator 9211+/37193(AAD), N95

Cellulose Containing N95s

- 3M VFlex Healthcare Particulate Respirator and Surgical Mask 1804, N95
- 3M VFlex Healthcare Particulate Respirator and Surgical Mask 1804S, N95, Small
- 3M VFlex Health Care Particulate Respirator and Surgical Mask 1805, N95
- 3M VFlex Health Care Particulate Respirator and Surgical Mask 1805S, N95, Small
- 3M Particulate Respirator 8200/07023(AAD), N95
- 3M Particulate Welding Respirator 8212, N95 with Faceseal
- 3M Particulate Respirator 8214, N95, with Faceseal and Nuisance Level Organic Vapor Relief
- 3M Particulate Respirator 8233, N100
- 3M Particulate Respirator 8293, P100
- 3M Particulate Welding Respirator 8512, N95
- 3M Particulate Respirator 8514, N95, with Nuisance Level Organic Vapor Relief
- 3M Particulate Respirator 9010, N95
- 3M VFlex Particulate Respirator 9105, N95
- 3M VFlex Particulate Respirator 9105S, N95

Hospital Collection Process – TAB F

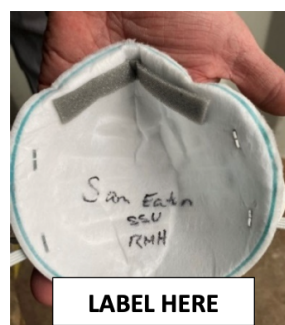
On-Site Collection/Marking

1. Your organization should create a collection station at the point of generation (i.e. hospital floor/unit)
2. Each station should have a bag provided by the healthcare facility to collect compatible N95 respirators.

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

3. With a permanent marker, the healthcare personnel should label their own individual compatible N95 respirators with a three-digit site code and a 2-digit location identifier (as shown below). The unique site code corresponds to the healthcare facility delivery address and will be assigned by Battelle. Your organization may designate the location identifier to correspond to a specific location/floor/unit within your site.

— — — — —
Site Code **Site Location ID**
(Assigned by Battelle Point Of Contact) (Assigned by Healthcare Facility)



Shipping Process – TAB G

Preparation for Shipment:

1. Bags containing the contaminated compatible N95 respirators to be decontaminated by Battelle (“primary collection bag”) should be closed.
2. Place the primary collection bag into another bag (“secondary collection bag”) (provided by the healthcare facility), which is then closed.
3. Decontaminate the secondary collection bag with alcohol or another suitable decontaminant.
4. Place the decontaminated bags into a rigid, closed box (supplied by the healthcare facility) clearly labeled with a biohazard symbol, and tape the box securely shut.
5. Label the outside of the box with the 3-digit site code and 2-digit location identifier.

Shipment under the healthcare facility’s agreement with Battelle:

1. Gather all boxes; complete one chain of custody form (provided by Battelle) per shipment, noting the number of boxes.
2. Coordinate with your organization’s courier service to arrange transfer to designated Battelle location.

Hospital Specific Shipping Information – TAB H

UPS will provide regularly scheduled pick-up and drop off services.

Battelle Shipments should be sent to your local Battelle site:



Shipping Address:

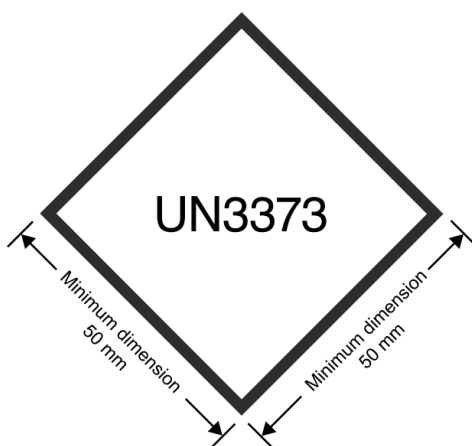
**2910 Clybourn Avenue
Burbank, CA 91505**

UPS Account Code:

5193R8

***THE ACCOUNT CODE SHOULD ONLY BE
USED FOR THE SHIPMENT OF N95 MASKS
TO THE BATTELLE DECONTAMINATION SITE**

Outgoing shipments should have the following label affixed to the outside of the shipping container:



Fact Sheet for Health Care Personnel – TAB I

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 sporidical 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**

FACT SHEET FOR HEALTHCARE PERSONNEL

Battelle Decontamination System for Decontaminating Compatible N95 Respirators

March 29, 2020

**Coronavirus
Disease 2019
(COVID-19)**

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

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

FACT SHEET FOR HEALTHCARE PERSONNEL

Battelle Decontamination System for Decontaminating Compatible N95 Respirators

March 29, 2020

Coronavirus
Disease 2019
(COVID-19)

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>

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**

Environmental Impact – TAB J

Battelle has provided the following report in regard to the environmental impact and considerations as it relates to the decontamination process.

During the decontamination process, VPHP breaks down into water vapor and oxygen; however, at the end of decontamination, the Decontamination Chamber is purged through a stack to the environment, and residual hydrogen peroxide remaining in the Chamber is emitted. OSHA has established a limit of 1 part per million (ppm) in air over 8 hours as a safe exposure limit for hydrogen peroxide. Real time monitoring conducted by Battelle during the purge cycle has indicated 1.2 ppm hydrogen peroxide at 5 meters (15 feet) downstream of the emission stack, slightly above the permissible value of 1 ppm. However, the 1 ppm exposure limit is based on an 8-hour time frame, and no individuals (Battelle or the public) would be in this area for this duration of time. Operators will use a weathervane to indicate downwind plume direction and monitor the area with a hand-held meter.

Contact Information – TAB K

Email: battellesupport@soc.caloes.ca.gov

Phone: 833-998-2381