

Using the Battelle Critical Care Decontamination System™

The shortage of personal protective equipment (PPE) due to the coronavirus (COVID-19) pandemic is posing a tremendous challenge to the U.S. healthcare system and first responder communities. The U.S. Food and Drug Administration (FDA) has authorized use of the [Battelle Critical Care Decontamination System™ \(CCDS\)](#) for the decontamination and reuse of N95 respirators as needed during times of critical shortage.

Why the Battelle CCDS™ is Needed

[The COVID-19 National Preservation Strategy for Addressing Personal Protective Equipment \(PPE\) Shortages](#) seeks to improve PPE availability to protect healthcare workers, first responders, and patients from COVID-19, by implementing three pillars of practice: reduce – reuse – repurpose.

In line with the preservation effort included in the strategy, a single Battelle CCDS™ can decontaminate up to 80,000 N95 respirators a day, making them available for reuse by healthcare workers and first responders. By using the Battelle System, an N95 respirator can be decontaminated up to 20 times and still maintain sufficient filtration performance.

A vaporous hydrogen peroxide method is the authorized decontamination method. According to an FDA [Emergency Use Authorization \(EUA\)](#), the agency reasonably believes the Battelle CCDS™ may be effective at preventing exposures to pathogenic airborne particulates by decontaminating N95 respirators contaminated or potentially contaminated with SARS-CoV-2.

Which Organizations Can Use the CCDS™

N95 respirator decontamination and reuse may be needed during times of critical shortage to ensure continued availability.

In accordance with the FDA EUA, the Battelle CCDS can provide N95 respirator decontamination services for healthcare personnel, including all 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. Such personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, and students and trainees. The FDA EUA defines healthcare personnel to also include contractual staff not employed by the healthcare facility, and persons not directly involved in patient care 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).



FEMA



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FEMA and the U.S. Department of Health and Human Services (HHS) deem the following organizations eligible to use the Battelle CCDS™: hospitals, urgent care centers, nursing homes, rehabilitation facilities, cancer centers, pharmacies, dialysis centers, assisted living facilities, clinical laboratories, emergency medical services (EMS), and private practice/outpatient facilities. Use is not necessarily limited to these organizations. Some situations exist where the following organizations may require use of the Battelle CCDS if experiencing critical shortages of N95 respirators: law enforcement agencies, security firms, fire departments, hazardous materials units, public health departments, public works or utility companies, and emergency management agencies.

How it Works

- State and territorial emergency management agencies interested in obtaining this system must submit a Resource Request to FEMA under the existing Stafford Act Emergency Declaration for COVID-19;
- Once a state, local, tribal or territorial agency is notified by FEMA that a Battelle CCDS™ will be deployed to their area, they are then responsible for fulfilling all Battelle site requirements to accommodate the systems, and to notify healthcare facilities, first responder agencies and other appropriate organizations within reasonable driving distance of their location of this additional capability.
- These entities, once notified of the Battelle CCDS™ in their location, can then register with Battelle on www.battelle.org/decon to initiate service arrangements in decontaminating used N95 respirators.
- Battelle will then inform these registered and participating entities of the specific location to send their used N95 respirators.
- Participating facilities must [follow Battelle's instructions](#) to label, collect, package and deliver used N95 respirators, to ensure the maximum number of respirators are returned decontaminated and safe for reuse.
 - The arrangement between facilities and the Battelle team on-site is similar to those with vendors offering off-site laundry or dry-cleaning services for reusable hospital linens or garments.
 - Since HHS fully funds the production, deployment and operation of these systems, no operating or service fee is required to use the Battelle CCDS™.
 - However, agencies will incur costs for the required site availability, set-up and site maintenance while the systems operate, in accordance with the site requirements described by Battelle.
- After decontamination, these communities can then pick-up their decontaminated N95 respirators for distribution and reuse in accordance with organizational procedures;

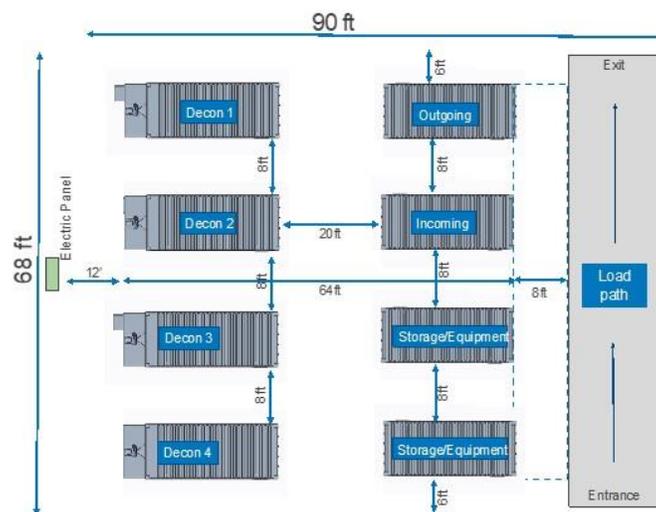
Site Requirements

Requesting state, local, tribal or territorial agencies are responsible for site selection (in coordination with the owner/operator of the selected properties) as well as ensuring that the sites meet the following requirements described to include the site layout:

- Relatively flat, paved area 80- x 120- with semi-truck access
- Forklift rated for 10,000 lbs. to unload 20' Conex (Empty container ~5000 lbs., payload <4000 lbs)
- Lumber upon which to place containers (28 each, 6"x 6"x12' or 4"x 4"x12'; Shim Stock (1"x 6", 1"x 4") to level containers)
- Spirit level

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- 10,000 lb hydraulic jack [NOTE: Not required if containers have leveling feet]
- Power (60 Hz AC; weatherproof connections) with preference for 480V/3-Phase/30A for 4 containers
- Alternate: 208V/3-Phase/40 A for 4 containers and a certified electrician to connect power
- Wireless/wired 1 GB/second network connection for the Conex assigned inbound and outbound N-95 respirator shipments
- Access to biohazard waste streams disposal for both (1) Battelle PPE; and (2) Contaminated HCF or FR agencies' N-95 respirators
- Restroom with toilet, wash basin, shower facilities to include daily servicing
- Lighting and onsite security
- "Keep Out" Zone (i.e. fencing for outdoor locations)



Questions or Concerns

Agencies with questions or concerns about using the Battelle CCDS may contact the company directly at solutions@battelle.org or call (800)201-2011.