

Using the Critical Care Decontamination System (TM)

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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 issued several [Emergency Use Authorizations](#) for vaporized hydrogen peroxide sterilizer systems to be used to decontaminate N95 respirators.

[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. Decontamination of N95 respirators is in line with the reuse pillar and can help communities meet critical PPE needs.

The Critical Care Decontamination System (CCDS)™ is one solution for the decontamination and reuse of N95 respirators as needed during times of critical shortage. Other systems currently authorized by the FDA to decontaminate N95 respirators include (1) STERIS V-PRO 1 Plus, V-Pro maX, and V-Pro maX2; (2) Sterizone VP4 Sterilizer; (3) STERRAD 100S, NX, and 100NX Sterilization Systems; and (4) Steriluent HC 80TT Hydrogen Peroxide Sterilizer. The other authorized sterilizer systems exist already in many healthcare facilities providing opportunities to also decontaminate N95 respirators in accordance with the FDA [Emergency Use Authorization \(EUA\)](#).

This fact sheet details the CCDS™ due to the availability of the federal funds to produce, deploy and operate these systems for healthcare personnel to use these systems, at no cost for the duration of the contract period to states, tribes, territories, and localities, as a result of the nationwide emergency declaration pursuant to section 501(b) of the Stafford Act (42 U.S.C. § 5191) for COVID-19 and to mitigate the N95 respirator demands.

What the CCDS™ can do



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A single 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 CCDS™ System, an N95 respirator can be decontaminated up to 20 times and still maintain sufficient filtration performance.

According to an [FDA EUA](#), the agency reasonably believes the 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, or to prepare stockpiles in advance of potential future waves of COVID-19 cases.

In accordance with the FDA EUA, the 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 and the U.S. Department of Health and Human Services (HHS) deem the following organizations eligible to use the federally provided 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.



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Use is not necessarily limited to these organizations. Some situations exist where the following organizations may require use of the CCDSTM 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

- Once a state, local, tribal, or territorial agency is notified by FEMA that a CCDS™ will be deployed to their area, they are then responsible for fulfilling all the company's 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 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 the instructions](#) to label, collect, package and deliver used N95 respirators, to ensure the maximum number of respirators are returned decontaminated and safe for reuse.
- This arrangement 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 for the duration of the contract period to use the CCDS™.
- 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;
- For operational security purposes, participating entities should restrict sharing information on the CCDS™ street address locations.

Site Requirements



The 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 manufacturer 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
- 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 N95 respirator shipments
- Access to biohazard waste streams disposal for both (1) Battelle PPE; and (2) Contaminated HCF or FR agencies' N95 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)

Site Requirements layout

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