

Battelle CCDS Critical Care Decontamination System™

The Battelle Critical Care Decontamination System™ is a self-contained, deployable decontamination system that uses vapor phase hydrogen peroxide (VPHP) to decontaminate N95 filtering facepiece respirators (FFRs). The system is based on [published research](#) that Battelle performed for the FDA in 2015 and is authorized by the FDA for Emergency Use decontamination of compatible FFRs. The CCDS™ method renders SARS-CoV-2 non-infectious on FFRs and enables up to 20 reuses without degrading filter performance to help address the current U.S. FFR shortage.

Battelle is aware of the of the opinions you referenced, and we offer the following for consideration by thoughtful minds on this important topic:

About Battelle CCDS™:

- In 2015, Battelle performed a study for the FDA (Richter et al., 2016) to assess the feasibility of decontaminating N95 FFRs for reuse in the event of a PPE shortage resulting from a pandemic. The results of this study showed that FFRs maintained > 99% filtration efficiency with no degradation to head strap elasticity for more than 20 decontamination cycles using high concentration VPHP. Battelle CCDS™ uses the same decontamination process that was proven effective in the FDA study.
- In the FDA Study, two inoculation methods were used to ensure decontamination of the full thickness of the N95, 1) large droplet inoculation to simulate a splash by a large liquid droplet and 2) aerosol inoculation, to ensure spores drawn into and captured by the FFR were fully decontaminated. The results of this study showed that VPHP decontamination resulted in 6-log inactivation of *Geobacillus stearothermophilus* (*G.stearo*), the industry standard biological indicator organism for hydrogen peroxide-based decontamination. This 6-log spore inactivation threshold is required by FDA to prove sterilization of medical devices and ensures decontamination of both viruses and other nosocomial pathogens.
- More recently Battelle tested VPHP decontamination efficacy against SARS-CoV-2 in our Bio Safety Level 3 (BSL 3) laboratories. Battelle spiked select personal protective equipment (PPE), including N95 respirator masks worn by health care workers, with SARS-CoV-2 followed by exposure to VPHP. The results showed that VPHP renders SARS-CoV-2 non-infectious for FFRs and other healthcare related PPE. In fact, zero viable SARS-CoV-2 was recovered in our test samples post VPHP decontamination.
- In addition to the decontamination efficacy, Battelle evaluated N95 performance after multiple decontamination cycles in our 2016 study for the FDA. Battelle evaluated N95 aerosol collection efficiency, airflow (breathing) resistance, strap properties, and fit to head form.

- Tests on several N95 FFR models showed no measurable adverse effects on aerosol collection efficiency after more than 20 decontamination cycles. The measured aerosol collection efficiency of N95 FFRs that were tested after using the CCDS™ VPHP method was > 99% through 50 decontamination cycles and is comparable to the aerosol collection efficiency of new, as-received N95 FFRs.
 - Battelle evaluated breathing resistance of N95 FFR, using standard test methods, and determined that the breathing resistance of N95 FFR was not affected over the course of 50 decontamination cycles using the CCDS™ method.
 - The fit factor of N95 FFR, as measured on an anthropometrically sized headform provided by NIOSH, donned following 10 and 20 VPHP decontamination cycles were comparable, to headform fit factors of as-received N95 FFRs not exposed to VPHP.
 - Decontaminated N95 FFR straps retained strap elasticity equivalent to as-received N95 FFRs not exposed to VPHP through 20 decontamination cycles indicating the potential to maintain fit when worn.
- Battelle has developed the CCDS™ process to ensure that residual hydrogen peroxide is below the OSHA permissible exposure limit (PEL) after decontamination. Battelle's study for FDA (Battelle, 2016) established an aeration cycle such that no measurable off-gassing of H₂O₂ could be detected. Battelle has performed additional H₂O₂ off-gassing tests to ensure that H₂O₂ off-gassing does not present a hazard to the wearer. After decontamination, N95 FFRs have air at 22 ± 3°C and 50 ± 5% RH passed through them at a continuous flow rate of 32 L/min. The air that has passed through the N95 is monitored for H₂O₂ using an electrochemical cell method to ensure that the [H₂O₂] is less than the OSHA permissible exposure limit (PEL) of 1 ppm. The PEL represents the 8-hr time-weighted average concentration that a worker can be safely exposed to for a 40-hr week. Ongoing testing of N95 models indicates that with proper aeration, an H₂O₂ concentration well below the OSHA PEL is achieved.
 - The Battelle CCDS™ is a custom designed decontamination chamber. The decontamination process uses a commercially available vapor generator with an Environmental Protection Agency (EPA) registered sterilant. This technology has been used for approximately 20 years in life sciences, pharmaceutical, biodefense and healthcare applications. The VPHP process that Battelle has selected for the CCDS system should not be confused with hydrogen peroxide gas plasma which is common in most large hospital systems. Hydrogen peroxide gas plasma has been shown to reduce filter efficiency in as little as 2-3 decontamination cycles. By contrast our VPHP method has shown no reduced filter efficiency or respirator damage through over 20 repeat decontamination cycles. Research conducted by external organizations indicates that alternative decontamination approaches, including moist heat, microwave generated steam, and UVGI, resulted in substandard pathogen inactivation and can damage FFRs making them unsuitable for reuse.

- The Battelle CCDS™ uses calibrated chemical Indicators (CI) to verify effective decontamination for every decontamination cycle. CIs are placed throughout the decontamination chamber to confirm homogeneous distribution of VPHP at concentrations required to achieve 6-log reduction. The CCDS process achieves high-level exposure that is an order of magnitude higher than previous research has shown to be effective against other similar viruses.
- The Battelle CCDS™ is technically validated and immediately available to process FFRs for reuse.

Key Conclusions Relevant to the NNU Position:

- Battelle agrees that the first preference for health professionals is to use a new N95 FFR.
- In the current state of emergency due to the pandemic, there is a strong likelihood of a shortage of new, unused N95 FFR.
- If new N95 FFR are not available, CCDS™ mask decontamination is a viable option to provide health professionals protection that is equivalent to new masks, as proved through laboratory testing.
- Decontaminating of N95 FFR does not relax protective standards. All evidence shows N95 FFR decontaminated with Battelle's CCDS™ method renders SARS-CoV-2 non-infectious on FFRs and enables up to 20 reuses without degrading filter performance or structural integrity.
- There are FDA-approved instructions for use to inform and provide healthcare providers and healthcare institutions about the N95 decontamination process and the masks that are processed.