The Battelle Critical Care Decontamination System™ is a self-contained, mobile decontamination system that uses vapor phase hydrogen peroxide (VPHP) to decontaminate N95 filtering facepiece respirators (FFRs). Our system is based on published research that Battelle performed for the FDA in 2015, and we are working closely with the FDA in anticipation of receiving Emergency Authorization Use for decontamination of compatible FFRs. Battelle CCDS™ 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.

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 this FDA study.

- The Battelle CCDS™ includes custom designed decontamination chambers, each with a capacity to hold up to 5000 FFRs per decontamination cycle. 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.

- Battelle CCDS™ achieves high concentration VPHP within each decontamination chamber up to the point of “micro-condensation” and maintains high concentration VPHP exposure for a specified dwell time. When the decontamination process is complete, the chamber is aerated and monitored to verify removal of residual decontaminant.

- 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 process achieves high-level exposure that is an order of magnitude higher than previous research has shown to be effective against other similar viruses.

- Battelle CCDS™ is effective against both viral and bacterial agents. 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) 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.

- Research conducted by external organizations indicates that alternative decontamination approaches, including moist heat, microwave generated steam, and UVGI, can damage FFRs making them unsuitable for reuse.

- The Battelle CCDS™ is technically validated and immediately available to process FFRs for reuse.

For more information, contact us at: solutions@battelle.org  |  1-800-201-2011