Battelle CCDS Critical Care Decontamination System™

Battelle's Critical Care Decontamination System™ has been tested and proven effective for decontaminating thousands of N95 FFRs during a single process cycle. The benefits of Battelle's CCDS™ include proven 6-log reduction of G. stearothermophilus (G. stearo), FDA Emergency Use Authorization for decontamination of compatible FFRs, and the ability to scale this solution through deployment of multiple decontamination chambers operated with one VPHP generator. The industry standard for medical device sterilization, as well as, removal of items from high containment laboratories (BSL-3) requires a 6-log reduction of biological indicators. This high threshold of inactivation means that the system is proven to not only inactivate SARS-CoV-2 virus, but has also been shown to be effective at that 6-log level against other nosocomial pathogens, and threat agents such as anthrax spores. To date Battelle has partnered with hospital systems across the country and has demonstrated the effectiveness of this process at scale.

Technical Summary of Battelle's Decontamination Research for N95 Respirators

Filtering facemask respirators (FFR) are a common form of personal protective equipment (PPE) used by medical professionals. The SARS-CoV-2 pandemic has resulted in a shortage of FFR due to the surge in demand for protective measures for healthcare workers. In recognition of this risk, in 2009 an interagency government working group published study recommendations (Project BREATHE) that included considerations for the decontamination and repeated use of N95 FFR.

In 2016, Battelle performed a study on the use of VPHP Decontamination for Reuse of N95 Respirators. This work was performed for the Food and Drug Administration (FDA) Office of Counterterrorism and Emerging Threats under Contract No. HHSF223201400098C, Study Number 3245. The project investigated the use of vapor phase hydrogen peroxide (VPHP) to decontaminate N95 respirators, permitting reuse of these respirators in an emergency scenario. VPHP is an industry standard decontaminant used in research, pharmaceutical, and medical facilities. The benefits of VPHP include efficacy of decontamination, low toxicity, and catalytic reduction to oxygen and water. Battelle utilized a condensing VPHP generator, resulting in micro- condensation (i.e. thin film of hydrogen peroxide) on exposed surfaces of N95 FFR, achieving a target plateau of hydrogen peroxide concentration. The micro-condensation phase is followed by an aeration phase where the hydrogen peroxide vapor is catalytically converted into oxygen and water.

Battelle's study for the FDA was divided into three phases. Phase I established the parameters of the VPHP decontamination cycle to ensure a 6-log reduction in organism viability. The decontamination parameters determined by cycle fractionation testing is shown in Table 1. These cycle parameters were sufficient to provide a 6-log reduction of *G. stearothermophilus* inoculated onto N95 FFR swatches. The cycle parameters also allowed sufficient time for FFR to off-gas hydrogen peroxide below the Permissible Exposure Limit (PEL) of 1 ppm, as verified by a hydrogen peroxide monitor.

Table 1. Decontamination Parameters from Phase I of FDA study

Phase	Duration (min)	DRate of VPHP Injection (g/min)
Conditioning	10	N/A
Gassing	20	2.0
Dwell	150	0.5
Aeration	300	N/A

Phase II of this study focused on quantifying the impact of repeated decontamination cycles on the functional performance of the FFR, with N95 FFR subjected to up to 50 VPHP decontamination cycles. FFR performance was quantified by measuring inert and biological aerosol collection efficiency, inhalation resistance, and facial fit on a manikin head form. Test conditions for the inert aerosol tests are shown in Table 2. Collection efficiencies for all of the N95 FFR exposed to VPHP cycles were greater than 99%, exceeding the requirement of 95% for N95 FFRs, even after 50 cycles. The average collection efficiencies for N95 FFR exposed to VPHP was similar (within 0.2%) to the control samples, indicating that the VPHP cycles do not degrade the performance of the aerosol filtration media. Bioaerosol collection efficiency utilized spores of *Bacillus atrophaeus* and had similar results to the inert aerosol tests. Exposure to 50 VPHP cycles did not degrade the performance of the aerosol filtration media under the conditions tested.

Table 2. Test Conditions for Inert Aerosol Collection Efficiency of N95 FFR

Parameter	Target	Tolerance Range
Temperature	25°C	±5°C
Relative Humidity	30% RH	±10%
Flow Rate	85 L/min	±1 L/min
Aerosol Size	0.075 µm	±0.02 µm
Aerosol Challenge Conc	10 mg/m^3	±5 mg/m^3

A preliminary assessment was completed to determine whether VPHP exposure degraded respirator fit. Exposed N95 FFR were donned on a manikin head form and the amount of leakage was measured into the mask with a simulated breathing flow of 20 L/min (representative of a light workload) through the N95 FFR. Testing was performed on N95 FFR subjected for up to 20 VPHP cycles. Form fit testing was also performed on N95 FFR control samples, with As Received results shown in Table 3 along with results after temperature/humidity cycling. The high SWPF results after multiple cycles with VPHP decontamination are encouraging that the fit would not be deteriorated after multiple cycles.

Table 3. Summary of simulated workplace protection factor (SWPF) (target > 100) for N95 FFR

Cycles	Fit Factor					
	#1	#2	#3	#4	#5	Mean
10 VPHP	112	128	100	92	110	108
20 VPHP	185	114	99	95	100	115
As received	97	130	220	85	139	127
10 T/RH	115	70	98	159	119	109
20 T/RH	134	68	84	83	64	84

Phase III of this study subjected N95 FFR for up to 50 decontamination cycles and assessed the mechanical integrity and performance of the FFR after repeated decontamination cycles. Decontamination efficacy was evaluated by loading respirator filters with an aerosol of *G. stearothermophilus*. A 6-log reduction was used as a benchmark value for this project based on a validated method for products with sporicidal claims. After fifty (50) decontamination cycles, all samples exposed to VPHP were negative, while all control samples were positive. This confirms that the VPHP treatment is effective, even for repeated cycles.

Battelle successfully established a VPHP decontamination process, applied to N95 FFRs, and implemented test methods to demonstrate the feasibility of using VPHP. This project offered a comprehensive pilot-scale study which evaluated the efficacy of VPHP for decontamination of N95 respirators for reuse. Complete inactivation (a 6-log reduction) was demonstrated on whole, intact FFRs of a biological indicator, *G. stearothermophilus* spores, when contaminated using either liquid droplets or aerosol exposure. The ability to decontaminate the respirators was demonstrated even after multiple cycles (up to 50) of biological exposure/decontamination. More recent results have demonstrated similar efficacy with SARS-CoV-2.

Battelle's CCDS Critical Care Decontamination System™ Process Verification

The cycle parameters developed for FDA testing further developed to meet the critical parameters in Battelle's scaled up decontamination system. Once this cycle was shown to successfully generate micro-condensation, maintain this condition through dwell phase, and provide > 6-log reduction as indicated by chemical indicator (CI), the cycle was put through a verification process where CI's and biological indicators (BI) were placed throughout the chamber (N=5) to confirm cycle performance. The BI/CI's were placed at each of the 4 corners of the chamber in alternating high/low positions as well as one centrally located. Results for this test are shown in Table 4.

Table 4. Verification Test Results

Chamber Location (N)	BI Result	CI Result
1 Left Front High	negative	Pass (>6-log)
2 Right Front Low	negative	Pass (>6-log)
3 Left Back Low	negative	Pass (>6-log)
4 Right Back High	negative	Pass (>6-log)
5 Center	negative	Pass (>6-log)
Positive Control	positive	NA
Negative Control	negative	NA

CI's are a chemical reaction dye printed onto a card that provides immediate indication that decontamination critical parameters providing 6-log reduction were met. BI's were transferred to a Battelle laboratory after exposure, where they were aseptically transferred from their Tyvek pouch into a prefilled tube containing tryptic soy broth (TSB) containing phenol for culture. A positive control BI sample was also included that was not exposed to the decontamination cycle. A negative control was included that consisted of the growth media with no BI added. Once processed the tubes were placed into an incubator set at 60C and incubated for seven days. After the seven days had elapsed the tubes were inspected for color change and or turbidity and recorded.

The Battelle CCDS Critical Care Decontamination System™ has successfully performed decontamination cycles with thousands of N95 FFRs. All cycles met the critical parameters of micro-condensation and passing chemical indicators ensuring exposure time and concentration equal to a >6-log reduction.

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