The Battelle CCDS
Critical Care
Decontamination System™
Safety & Efficacy FAQs
Technical Summary

July 1, 2020
www.battelle.org/decon
Battelle CCDS™ Safety and Efficacy FAQs

The Battelle CCDS 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 to help address the current U.S. supply shortage.

The CCDS™ process renders SARS-CoV-2 non-infectious on N95s and enables up to 20 reuses without degrading filter performance or fit. This has been independently validated by research teams at NIOSH, 3M, NIH, Massachusetts General Hospital and Duke University.

More information about CCDS™ can be found at www.ccdsfacts.org.

Battelle is aware of the opinions of some union organizations and we offer the following for consideration by thoughtful minds on this important topic:

1. **Does the decontamination method effectively inactivate the SARS-CoV-2 virus and other pathogens?**
   
   **A:** Yes. We have verified our process using the SARS-CoV-2 virus on over 25 makes and models of N95s. We were able to achieve complete inactivation of the SARS-CoV-2 viral load on the FFR materials. Research data related to inactivation of other pathogens using VPHP for bio-decontamination is attached to this document.

2. **Was testing done on the full N95 respirators, including curves, seams, straps, etc.?**

   **A:** Research was conducted on entire N95 masks using both a liquid inoculation as well as an aerosol inoculation where the spores were drawn into the FFR to develop the cycle. Results showed that VPHP renders SARS-CoV-2 non-infectious on all areas of the masks. In fact, zero viable SARS-CoV-2 was recovered in test samples post VPHP decontamination.

3. **Does the decontamination method impact fit, filtration, structural integrity, or performance of N95s?**

   **A:** The CCDS™ process has been independently validated to show no filtration or fit impact through 20 decontamination cycles by research teams at NIOSH, 3M, NIH, Massachusetts General Hospital and Duke University.

   **Battelle 2020 test results** has shown:
   - No reduced filter efficiency or respirator damage through over 20 repeat decontamination cycles. Filtration efficiency has been retained for FFRs and is comparable to as-received FFR efficiencies. Filtration efficiency is well above the 95% limit and has not been deteriorated.
   - No pressure drop through the FFRs was shown, relative to the as-received FFRs, indicating that there is no change in breathability.
   - FFR fit and elastic properties of the straps for various types of FFR were unaffected. FFRs are inspected before and after the decontamination process, and FFR with elastic failures are discarded.
4. **Did Battelle test the impact of their decontamination method on N95s that have been used by nurses for a full shift or even multiple shifts?**
   A: Yes. Battelle is currently working with Massachusetts General Hospital and OhioHealth to test the impact of the CCDS™ process on N95s that had been used by nurses for a full shift and multiple shifts. Nurses use the N95s and send them to a CCDS location for decontamination. Those masks are then sent to our CCDS research team to evaluate. To date (through 10-12 cycles), there is no reduction in filter efficiency or head strap performance for high-wear masks.

5. **Other studies have examined decontamination methods (such as the ASP method that uses vaporized hydrogen peroxide) and found that N95 performance is impacted after just a few cycles.**
   A: The CCDS™ process (VPHP) is very different from ASP type process (hydrogen peroxide gas plasma) which is known to impact N95s in a negative way. That is why they can only use it for 2-3 cycles.

   The VPHP process that Battelle 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.

   Research conducted by external organizations indicate that alternative decontamination approaches, including moist heat, microwave generated steam and UVGI resulted in substandard pathogen inactivation and damage to FFRs, making them unsuitable for reuse.

6. **Are results generalizable to all N95 models?**
   A: Filtration media in N95s are similar and results are expected to be comparable across different makes and models. To date, Battelle has tested over 25 different FFR, with samples from 10 different vendors. In all cases, properties of the N95 have been retained.

   We do not process N95s that contain cellulose or exhalation valves. To help assist you in determining if your N95 respirator contains cellulose, we have created an N95 Guidance document for your reference.

7. **Is there sufficient off-gas time to remove residue which may pose respiratory, skin hazard or odor sensitivity?**
   A: The process uses strict monitoring guidelines to ensure FFR’s have been allowed sufficient time to off-gas post decontamination.

   - We measure and ensure the levels present post decontamination are below the OSHA permissible exposure limit (PEL) of 1 ppm. The PEL is the level at which a staff member may be expose for up to 8 hours per day and over the course of a 40-hour work week.

   - 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 H$_2$O$_2$ using an electrochemical cell method to ensure that the [H$_2$O$_2$] is less than the OSHA permissible exposure limit (PEL) of 1 ppm.

8. **What about reports of headaches and odor sensitivity from health care workers?**  
   **A:** Hydrogen peroxide vapor has no smell and is imperceptible at concentrations below a few hundred PPM. We are well below this limit on our FFR at less than 1 ppm. The level of hydrogen peroxide remaining in the FFRs after aeration is well below the odor detection limit and is also well below the levels where health effects are noted (per the agency for toxic substances and disease registry (ATSDR, [https://www.atsdr.cdc.gov/MMG/MMG.asp?id=304&tid=55](https://www.atsdr.cdc.gov/MMG/MMG.asp?id=304&tid=55))

In a 1986 paper on odor thresholds, the author noted that a slightly sharp odor was present at a concentration of 108 ppm.

From the reference, “*In some applications such as when using sterilizers there is an odor that people sometimes associate with hydrogen peroxide. As far as I know no studies have been performed to identify the origin of this odor, and it is probably the result of partially oxidized volatile organic compounds, perhaps derived from the oxidation of minor components of sterile wraps or other polymeric materials. Similarly, odors can persist after ozone treatment of rooms for much longer than ozone will be present,[6] probably also due to the formation of partially oxidized VOCs. Whatever the source of the smell, people who work near hydrogen peroxide sterilizers who have a hydrogen peroxide monitor present can be glad that it is not hydrogen peroxide vapor.*”


9. **Are levels of hydrogen peroxide even throughout the chamber?**  
   **A:** CCDS chambers use a flow path that forces the flow of H2O2 to traverse the entire length of the decontamination chamber. In addition to this feature, the chamber uses two high flow mixing fans and 5 CI cards to ensure proper mixing within the chamber.

10. **Does inconsistent placement of N95s impact effectiveness?**  
    **A:** Placement in the chamber is not a factor on efficacy.

11. **Does humidity and CO2 from breathing reduce filtration of decontaminated masks?**  
    **A:** No. Humidity and CO2 do not adversely impact the filtration media.

12. **Has Battelle conducted additional studies that included humans wearing the masks between decontamination in order to better simulate real world conditions?**  
    **A:** Yes. Battelle has performed testing on high-wear samples worn by nurses that have gone through 10-12 decontamination cycles. These tests are ongoing and performed per OSHA standards.

    Additionally, Battelle obtained Institutional Review Board (IRB) approval, following the 2016 FDA study, to perform Fit Factor testing with human subjects. Tests were performed over a span of approximately one week. Samples of six (6) different FFR were tested as part of this study, with samples having gone through three (3) decon cycles. The overall conclusion from this study was that decontamination did not adversely impact the fit performance of FFR.
13. Why did Battelle not test real-world conditions in the 2015-2016 FDA study?
   A: The 2015-2016 FDA study did not include human subject testing because that was not part of the scope of the study.

14. At any time between the publishing of your 2016 study and April 2020 did Battelle conduct additional studies that assessed the continued ability of an N95 to maintain filtration of at least 95% of particles 0.3 microns and larger following multiple cycles of decontamination? The 2016 study reports visual inspections of masks.
   A: Filtration studies began in early March 2020 and continue to be performed using a TSI 8130A, the industry standard for aerosol performance evaluation. To date, Battelle has obtained data for over 25 different makes and models of N95 respirators using this instrument. Testing continues to build a data bank on different makes and models of respirators.

15. Are KN95 respirators able to be decontaminated using the CCDS process?
   A: No. Battelle’s Emergency Use Authorization (EUA) is specific for N95 FFRs.

16. Is there oversight by FDA over how the Battelle process is used?
   A: Yes. Oversight from the FDA is an integral part of retaining the emergency use authorization. There are also contractual requirements governing how the Battelle process is used, with a large oversight aspect.

17. Is there transparency over what information FDA received and reviewed in issuing the EUA?
   A: The background documentation supporting the EUA is available through FDA.

18. Is data used to approve the EUA confidential and proprietary?
   A: Data that was used for EUA consideration is largely available in our report that is published on the FDA website.

19. One of the conditions of approval is to collect data from facilities; are there real-world data exits?
   A: To date, Battelle has decontaminated over one million N95 respirators, with many N95s being decontaminated over multiple uses. Some health care providers have asked Battelle to test samples after repeated usage, with results shared with the providers.

**Key Conclusions:**

- Battelle agrees that the first preference for health professionals is to use a new N95 respirator mask.
- 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™ is an effective and viable option to provide health professionals the essential protection equivalent to new masks. This has been validated through multiple independent 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.
- To date, more than one million critical N95 masks have been returned to healthcare workers and first responders to keep them safe.

For more information about the Battelle CCDS™, please visit: www.ccdsfacts.org
Research Reports: Bio-decontamination using VPHP

Vapor phase hydrogen peroxide (VPHP) has been shown to kill a wide range of bacteria and viruses.

1. **Ebola Virus Surrogates MS2 and Phi6 Bacteriophages**

2. **Avian Influenza (H5N1)**

3. **Brucella Suis, Burkholderia pseudomallei, Francisella tularensis, and Yersinia pestis**

4. **MRSA**

4. **Virulent Bacillus anthracis spores**
5. **Large-scale inactivation of Bacillus anthracis**

6. **Yersinia pestis**

6. **Francisella tularensis**

7. **Mycobacterium tuberculosis**

8. **Clostridium botulinum spores**
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 1 of FDA study

<table>
<thead>
<tr>
<th>Phase</th>
<th>Duration (min)</th>
<th>DRate of VPHP Injection (g/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conditioning</td>
<td>10</td>
<td>N/A</td>
</tr>
<tr>
<td>Gassing</td>
<td>20</td>
<td>2.0</td>
</tr>
<tr>
<td>Dwell</td>
<td>150</td>
<td>0.5</td>
</tr>
<tr>
<td>Conditioning</td>
<td>300</td>
<td>N/A</td>
</tr>
</tbody>
</table>
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>
<thead>
<tr>
<th>Parameter</th>
<th>Target</th>
<th>Tolerance Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>25°C ±5°C</td>
<td></td>
</tr>
<tr>
<td>Relative Humidity</td>
<td>30% RH ±10%</td>
<td></td>
</tr>
<tr>
<td>Flow Rate</td>
<td>85 L/min ±1 L/min</td>
<td></td>
</tr>
<tr>
<td>Aerosol Size</td>
<td>0.075 µm ±0.02 µm</td>
<td></td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Cycles</th>
<th>Fit Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>#1</td>
</tr>
<tr>
<td>10 VPHP</td>
<td>112</td>
</tr>
<tr>
<td>20 VPHP</td>
<td>185</td>
</tr>
<tr>
<td>As received</td>
<td>97</td>
</tr>
<tr>
<td>10 T/RH</td>
<td>115</td>
</tr>
<tr>
<td>20 T/RH</td>
<td>134</td>
</tr>
<tr>
<td>10 VPHP</td>
<td>112</td>
</tr>
<tr>
<td>20 VPHP</td>
<td>185</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Chamber Location (N)</th>
<th>BI Result</th>
<th>CI Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Left Front High</td>
<td>negative</td>
<td>Pass (&gt;6-log)</td>
</tr>
<tr>
<td>2 Right Front Low</td>
<td>negative</td>
<td>Pass (&gt;6-log)</td>
</tr>
<tr>
<td>3 Left Back Low</td>
<td>negative</td>
<td>Pass (&gt;6-log)</td>
</tr>
<tr>
<td>4 Right Back High</td>
<td>negative</td>
<td>Pass (&gt;6-log)</td>
</tr>
<tr>
<td>5 Center</td>
<td>negative</td>
<td>Pass (&gt;6-log)</td>
</tr>
<tr>
<td>Positive Control</td>
<td>positive</td>
<td>NA</td>
</tr>
<tr>
<td>Negative Control</td>
<td>negative</td>
<td>NA</td>
</tr>
</tbody>
</table>

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.
Battelle's CCDS Critical Care Decontamination System™ SARS-CoV-2 Verification

In addition to validating with BI’s and CI’s the Battelle CCDS™ VPHP process was further characterized to show efficacy against the SARS-CoV-2 virus, the causative agent of the current COVID-19 pandemic on both N95 and KN95 FFR’s. Two sets of materials were excised from each of the PPE in 2 cm × 2 cm-sized coupons. Stock SARS-CoV-2 was applied as 25 µL droplets (Qty. 4) on each coupon and allowed to dry at ambient laboratory conditions. Once dried, one set of spiked coupons (DECON samples) was moved to the lab scale VPHP exposure chamber. The other set sat at ambient laboratory conditions untreated (CTRL samples) until the Battelle VPHP process had completed its decontamination cycle. As shown in Tables 5, the Battelle VPHP exposure process resulted in zero recoverable SARS-CoV-2 virus as measured by a TCID<sub>50</sub> assay.

Table 5. CCDS efficacy against SARS-CoV-2 virus on N95 and KN95 materials

<table>
<thead>
<tr>
<th>PPE Material</th>
<th>Control Log Recovery</th>
<th>Decon Log Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M 1860 N95</td>
<td>4.10</td>
<td>0.00</td>
</tr>
<tr>
<td>3M 8210 N95</td>
<td>3.76</td>
<td>0.00</td>
</tr>
<tr>
<td>Moldex 2200 N95</td>
<td>3.86</td>
<td>0.00</td>
</tr>
<tr>
<td>BYDP KN95</td>
<td>3.17</td>
<td>0.00</td>
</tr>
<tr>
<td>Dolphin KN95</td>
<td>2.87</td>
<td>0.00</td>
</tr>
<tr>
<td>Powecom KN95</td>
<td>3.03</td>
<td>0.00</td>
</tr>
</tbody>
</table>

The Battelle CCDS Critical Care Decontamination System™ has successfully performed decontamination cycles with hundreds of 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.

More information about Battelle CCDS™ can be found at [www.ccdsfacts.org](http://www.ccdsfacts.org)

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries.

For more information about Battelle, visit [www.battelle.org](http://www.battelle.org)