Evaluation of Decontamination Techniques for the Reuse of N95 Respirators


FDA Approval of Battelle VHP Decontamination Protocol

“On March 28, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of the Battelle CCDS Critical Care Decontamination System™ at the Battelle Memorial Institute, for use in decontaminating compatible N95 or N95-equivalent respirators (“compatible N95 respirators”) for reuse by healthcare personnel (HCP) to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic resulting from the Coronavirus Disease 2019 (COVID-19) pandemic.”

Summary

A review of the best scientific results published to date points to selecting one of the following N95 respirator decontamination methods (see Table 1):

- Vaporized Hydrogen Peroxide (VHP)
- UVGI (or UV-C)
- Moist Heating (≥ 80% RH)
- Heat Inactivation (low RH)

The COVID-19 Healthcare Coalition (C19HCC) (https://c19hcc.org) has diligently researched and collated the current best methods for decontamination and reuse (i.e., recharging, recycling) of N95 respirators. We acknowledge that knowledge of COVID-19 and the implications of recharging N95 respirators is evolving. This paper represents the best knowledge available in the scientific community at this time. Our goal is to make this information easily accessible to those who are on the front lines of this pandemic.

When investigating available methods, we considered three primary factors:

1) Evidence that the treatment denatured or destroyed similar enveloped ss-RNA viruses to SARS-CoV-2 (COVID-19)
2) Research demonstrating that the filter component maintains the gold standard: blocking >95% of 300nm particles and flow, as measured by pressure drop, post-treatment
3) Practicality of establishing methods, acknowledging that supplies (e.g., UV lights, hydrogen peroxide units, laboratory ovens, etc.) may be limited and set-up could be resource-intensive (if not already available)
Each decontamination method carries caveats, and users should consider these caveats before and during implementation of recharging treatments. We do not have data on the number of treatment iterations N95 respirators can undergo before impact on performance.

It is important to note that effectiveness of the listed decontamination techniques assumes proper fitting of the N95 filtering facepiece respirators (FFRs). A poorly fitted N95 FFR permits leakage of contaminants into the breathing zone by introducing gaps in the interface region between the face and the respirator seal. Therefore, it is imperative that users take into consideration proper fitting of the FFR prior to reuse, regardless of decontamination treatment.\textsuperscript{14}

For healthcare providers and institutions that seek to recycle their N95 resources, Table 1 provides insight the top 4 decontamination techniques for N95 respirators.

If you have additional questions or concerns, please do not hesitate to write the COVID-19 Healthcare Coalition at c19hcc@mitre.org with “Attn: PPE/N95 working group” in the subject line.

We encourage feedback on experience with these or other methods. We will update this guidance as more data becomes available.

\begin{table}[h]
\centering
\caption{Best Guidance in Current Literature on Top 4 N95 Respirator Decontamination Treatments}
\begin{tabular}{|l|p{4in}|p{5in}|}
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\textbf{Method of Decontamination} & \textbf{Overview} & \textbf{Considerations} \\
\hline
\textbf{Vaporized Hydrogen Peroxide (VHP)}\textsuperscript{1,4,7,16, 18} & Respirators are strung across a sealed room and exposed to VHP for duration of decontamination cycle (15 min dwell and 125 min clearance time). VHP has been shown to be sporicidal at temperatures ranging from 4 – 80°C, with sterilant concentrations ranging from 0.5 to <10 mg/L. FFR fit was shown to be unaffected for up to 20 VHP treatments cycles using a head form (straps began to degrade after 30 treatments)\textsuperscript{16} & \begin{itemize}
\item VHP decontamination for a single warm cycle did not significantly affect FFR filter aerosol penetration or filter airflow resistance in study.
\item The only visible physical effect on the FFRs was a slight tarnishing of the metallic nosebands.
\item Respirators may absorb VHP (dependent on respirator type and material).
\item VHP processing is limited by the fact that cellulose-based products (e.g., cotton, which may be present in some head straps or some FFR layers) absorb hydrogen peroxide and can cause the VHP cycle to abort due to low hydrogen peroxide vapor concentration (successful with types N95-A, N95-B N95-C, SN95-D, SN95-E and SN95-F respirators).
\end{itemize} \\
\textbf{Source: Duke Health System, Battelle, and Johns Hopkins Applied Physics Lab, CDC Decontamination Recommendations} & & \\
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<th>Method</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Notes</th>
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<td>Ultraviolet Germicidal Irradiation (UVGI)</td>
<td><strong>Respirators are illuminated with 254 nm UV light for a minimum required dosage of 60 mJ/cm².</strong>&lt;br&gt;The UVGI technique is implemented as ss-RNA viruses, such as SARS-CoV-2, are typically inactivated by UVGI exposure of 2-5 mJ/cm².</td>
<td><strong>10 cycles of UV treatment (254 nm, 30 minutes, 8W bulb) also showed no change in filter properties.</strong>&lt;br&gt;90–100% passing rate after 3 cycles depending on model per CDC guidance.</td>
<td>• Personnel should ensure the respirators are not shadowed during light exposure.&lt;br&gt;• UV-C is highly carcinogenic. Personnel should not come into direct contact with UVC (200 – 280 nm) light, as it may damage the eyes and skin.&lt;br&gt;• Even illumination of the respirators on all sides should be considered.&lt;br&gt;• Components within the respirators can absorb UV and reduce possible effectiveness.&lt;br&gt;• UV treatments will primarily target the surface of the respirators, not necessarily deeper layers.&lt;br&gt;• Healthcare professionals should not wear facial products containing sunblock as it may hamper UV decontamination if these materials are on the respirator.</td>
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<td>Moist Heat (~80% RH)</td>
<td><strong>Respirators are placed in a laboratory incubator at 60°C and 80% relative humidity (RH) for 30 minutes and air-dried for 30 minutes.</strong></td>
<td></td>
<td>• Some respirators experienced partial separation of inner foam nose cushion, compromising seal required for proper protection of respirator.</td>
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<td>Heat (60-75 ºC) Inactivation (~30% RH)</td>
<td><strong>Respirators are placed in a laboratory oven at 60-75 ºC for 30 minutes; this heating time will depend on the respirator materials and manufacturer processes. Measure respirator temperature with an infrared (IR) thermometer to confirm respirator is sufficiently heated.</strong>&lt;br&gt;<strong>Option 2:</strong> Heat in a convection oven for 30 minutes at 75°C showed no change in pressure drop or 0.3 µm particle filtration efficiency after 15 cycles. After 20 cycles, the elasticity of the ear/face straps were not degraded and were still suitable for use.&lt;br&gt;Incubation at 60°C for 30 min resulted in no infectious virus.</td>
<td></td>
<td>• Dry heating temperature refers to the respirator temperature rather than the oven air temperature.&lt;br&gt;• Heat must be kept within the approved usage range of the N95 respirators (please refer to the N95 Material Safety Data Sheet (MSDS)).&lt;br&gt;• Slight filtration efficiency decreases were observed in the respirators in study after dry heating.</td>
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remaining, regardless of the presence of the protein additive.  

References


# Appendix

## Table 1: Decontamination Treatments Under Coalition Investigation and Review, Pending Additional Guidance from Literature

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<tr>
<th>Method of Decontamination</th>
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<td>Steam Heating(^{17})</td>
<td>Six FFR models were placed in microwave steam bags in a microwave oven for 90 seconds. Three FFRs were further evaluated for three cycles of steam exposure and demonstrated no change in filtration performance. Microwave steam bag treatment achieved 99.9% inactivation of MS2 bacteriophage.(^{17})</td>
<td>• It is unclear what effect on more than three treatment cycles has on filter efficiency and water absorption properties of the FFRs.(^{17})</td>
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<td>Liquid Hydrogen Peroxide(^1)</td>
<td>Respirators are submerged in 6% solution of hydrogen peroxide for 30 minutes and dried for a minimum of 16 hours.</td>
<td>• Submersion in liquid reduces the electrostatic characteristics of the filter. • Respirators in the study were required to dry and outgas for 16 hours. • Respirator models containing metal staples were observed to oxidize to varying degrees.</td>
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<td>Ethylene Oxide (EtO)(^{1,4,5})</td>
<td>Respirators are packed in sterilization pouches and placed in a sterilizer/aerator unit. The respirators are exposed to 100% EtO for 1 hour followed by a 4-12-hour aeration cycle. EtO decontamination did not affect the filter aerosol penetration, filter airflow resistance, or physical appearance of the FFRs used in the study.</td>
<td>• Length of time required for sufficient off-gassing of EtO is 5 hours, which may be a limiting factor in the timely processing of large numbers of filtering facepiece respirators (FFRs). • EtO is classified as a carcinogen by the EPA.(^6) • There are upfront costs in acquiring EtO sterilizer/aerator units and necessary auxiliary equipment and consumables.</td>
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Table 2: Non-Recommended Decontamination Treatments

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| **Bleach**\(^{3,4}\)    | Respirators are submerged in 0.6% solution of sodium hypochlorite for 30 minutes, rinsed with deionized water, and dried for a minimum of 16 hours. | • Chlorine gas residue persists even after rinsing with deionized water.  
• Hypochlorite powder, solutions, and vapor can be irritating and corrosive to the eyes, skin, and respiratory tract.  
• Submersion in liquid reduces the electrostatic characteristics of the filter.  
• Respirator models containing metal staples were observed to oxidize to varying degrees. |
| **Isopropanol (IPA)**\(^{9,10}\) | Respirators are dipped into liquid isopropanol for 1 minute and dried by evaporation for at least 24 hours in a hood at room temperature before use. Dipping the filter material in IPA removes the electrostatic charges, resulting in significant increase in penetration to a MPPS range of 200 – 400 nm, which is comparable to filters relying solely on mechanical collection mechanisms.\(^{10}\) | • Submersion in liquid reduces the electrostatic characteristics of the filter.  
• Respirators in the study were required to dry and outgas for at least 24 hours. |
| **Microwave Generated Steam (MGS) Heating**\(^{1}\) | Two pipette tip boxes were filled with ~50mL tap water and placed on the revolving glass carousel of a microwave oven (1100 W manufacturer rated). Respirators were placed outer side down on top of the boxes and irradiated at 750 W/ft\(^3\) for 1 minute on each side. The respirators were dried for 1 hour between exposure.\(^{1}\) | • This process melts the rubber components of the respirator.  
• Some respirators in the study experienced slight melting of head straps during heating cycle.  
• Respirators experienced partial separation of inner foam nose cushion (eliminating necessarily seal components). |
| **Hydrogen Peroxide Gas Plasma (HPGP)**\(^{1}\) | Respirators are packaged in specialized sterilization pouches and placed in hydrogen peroxide gas plasma sterilizer units. The respirators are sterilized for approximately 55 minutes at 45-50°C. | • Decreases structural integrity of respirator.  
• There are upfront costs in acquiring HPGP sterilizer units and necessary auxiliary equipment and consumables. |
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| **Ozone Inactivation**<sup>13</sup> | Airborne viruses required ozone doses of 0.34 to 1.98 and 0.80 to 4.19 min-mg/m³ for 90% and 99% inactivation, respectively. | • While inactivation of bacteriophages (unenveloped) using ozone has been investigated, there are no existing studies on the effect of ozone technique on the SARS-CoV-1 or 2 viruses, or the effects of ozone on N95 respirators and other personal protective equipment (PPE).  
• Ozone at concentrations <10 ppm showed a significant inactivation in 15 seconds. In general, higher inactivation levels were obtained for bacteriophages at 85% relative humidity (RH) compared with the levels at 50% RH. The effect of ozone was attributed to its interaction with capsid protein of the virus.<sup>13</sup>  
• There are upfront costs in acquiring ozone generator and necessary auxiliary equipment and consumables.  
• There are personnel safety concerns with ozone use. |
| **Traditional Dry Cleaning**<sup>11,12</sup> | Respirators are loaded into a large drum machine and cleaned with a perchloroethylene (PCE). The respirators are gently agitated in the solution after which the solvent is drained, filtered, and recycled. Lastly, the respirators would be "rinsed" in a fresh PCE solution. | • Chemical incompatibility with traditional dry cleaning, PCE is incompatible with the polypropylene within the respirators.  
• Carbon dioxide (CO₂) cleaning has potential, but approach not currently used for textiles. |