Hydrogen Peroxide Methods for Decontaminating N95 Filtering Facepiece Respirators

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Abstract

Introduction: During a pandemic, when the supply of N95 filtering facepiece respirators (FFRs) is limited, FFRs may be decontaminated by methods that inactivate pathogens as long as they do not damage FFR function. Hydrogen peroxide (H2O2) is widely used for decontamination in medical settings.

Objective: To review the literature on the use of H2O2 to decontaminate N95 FFRs and identify methods that inactivate virus and preserve FFR filtration efficiency and fit.

Methods: The literature was searched for studies evaluating H2O2 decontamination methods on inactivating SARS-CoV-2 and other viruses and microorganisms inoculated on N95 FFRs and the effects on respirator filtration efficiency and fit. Current U.S. federal guidelines are also presented.

Results: Findings from relevant laboratory studies (N = 24) are summarized in tables. Commercially available H2O2 decontamination systems differ on how H2O2 is delivered, the temperature, the duration of treatment, and other factors that can impact N95 FFR filtration efficiency and fit. Some methods inactivate SARS-CoV-2 virus-contaminated N95 FFRs with >3 log attenuation, whereas other methods are yet to be evaluated.

Discussion and Conclusion: Most of the H2O2 methods reviewed effectively decontaminate N95 FFRs without damaging FFR function. However, some methods adversely impact N95 fit or filtration efficiency, which could go undetected by the end user and compromise their protection from pathogen inhalation. When making decisions about H2O2 decontamination of respirators, it is important to understand differences in methods, effects on different FFR models, and potential hazards to workers who manage the decontamination process.

Keywords: decontamination, N95, FFR, personal protective equipment

Background

The novel SARS-CoV-2 virus that causes coronavirus disease 2019 (COVID-19) has led to a global shortage of N95 filtering facepiece respirators (FFRs). Whereas a new N95 FFR should be used with every new patient procedure, in this emergency, it may be necessary to reuse FFRs when severe supply shortages exist. In this document, we review the use of vapor generated from aqueous solutions of hydrogen peroxide (H2O2) to decontaminate N95 FFRs with the goal of increasing the useful lifetime of N95 FFRs worn by health care providers during the COVID-19 pandemic. Effective decontamination requires inactivation of the SARS-CoV-2 virus and other microorganisms and maintenance of both the fit and filtration efficiency of the N95 FFR.

H2O2 decontamination methods (Table 1) are established industrial methods used for decontamination of medical instruments, biosafety cabinets, and whole rooms in hospitals, research settings, research animal facilities, pharmaceutical, and medical industries, and by police and fire departments.1 Methods used to generate H2O2 for decontamination vary, as indicated in Table 1,

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but if appropriate concentrations are achieved, they are highly effective for inactivating pathogens including multiple types of viruses and microorganisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) and *Serratia marcescens*, and impervious bacterial spores such as those from *Clostridium botulinum* and *Clostridium difficile*.2

It should be noted that H2O2 decontamination is incompatible with cellulose, which is a component in some N95 FFRs.3

**Mode of action of H2O2**

H2O2-mediated inactivation of microorganisms and viruses is achieved primarily by the oxidation of proteins with H2O2 and the breakage of nucleic acids by hydroxyl and hydroperoxy-free radicals that are produced from the initial reaction of H2O2 with proteins.4 H2O2 is used for decontamination of hospital rooms, laboratories, biosafety cabinets, and medical equipment and materials that are intolerant to heat or have diffusion-restricted space. Individual unwrapped contaminated objects are placed in a sealed room or biosafety cabinet and liquid hydrogen peroxide (LHP) is vaporized or aerosolized and released into the space. H2O2 treatment involves several phases. The process may involve an initial conditioning phase to alter the room humidity (dry or wet treatment) and temperature. All treatments include an injection phase to saturate the room with H2O2 gas or vapor, a dwell phase to maintain a constant concentration, and an aeration or clearance phase during which residual hydrogen peroxide vapor (HPV) is removed by evaporation and fresh air replacement. The target concentration is closely tied to the volume of the room/chamber and internal surface area (load density). The duration of a full decontamination cycle including aeration varies depending on the system used, dosing, load size, and volume of the chamber or room.

Some technologies heat the LHP solution (e.g., Steris and Bioquell) to produce a vapor, and others use a nebulizer to convert the liquid into microdroplets (e.g., SteraMist and Halosil). Microdroplets are distributed into the space in an aerosolized liquid that may form a visible wet fog. Some percentage of the microdroplets evaporate and achieve equilibrium with the environment, forming a combination of liquid aerosol and gas phase H2O2. Viral inactivation is achieved through deposition of the liquid microdroplets or contact of the HPV with the virus on surfaces.

Hydrogen peroxide gas plasma (HPGP) systems (e.g., STERRAD) and ionized hydrogen peroxide (iHP; e.g., SteraMist) use ionization to accelerate the generation of the highly reactive hydroxyl radicals and later eliminate the residual H2O2. These methods are used in hospitals for rapid sterilization of biosafety cabinets and surgical tools. The gas plasma penetrates the material and also rapidly destroys any condensed H2O2.

**Liquid hydrogen peroxide submersion**

Liquid hydrogen peroxide (LHP) solutions have been used as a sterilant for medical and dental tools for many years, and LHP has been approved as a high-level disinfectant by the Food and Drug Administration (FDA-Cleared Sterilants and High-Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices, FDA, April 28, 2020). It is used in clinical settings for disinfection of semicritical devices (e.g., endoscopes) where devices are submerged for 8 to 30 min at 20°C. A detailed summary of the literature on the effectiveness of LHP for inactivating viruses and other microorganisms and methods of action has been compiled by the U.S. Centers for Disease Control and Prevention (CDC).2

**Commercial H2O2 delivery systems**

Commercial systems are currently available from companies such as Bioquell, Battelle, Steris, ASP, Curis, TOMI, and Halosil, most of which differ in the method of delivering and sustaining H2O2 in vapor, gas plasma, or aerosolized liquid phases by concentration, temperature, humidity, and the materials and machinery used. Bioquell uses the term HPV and Battelle uses the term vapor phase hydrogen peroxide (VPHP) for the same method. Steris uses the term vaporized hydrogen peroxide (VHP™) for an only slightly different method. ASP (STERRAD)
DECONTAMINATING N95 FFRS WITH H₂O₂

and TOMI™ (SteraMist®) both use iHP termed, respectively, HPGP and iHP, using different H₂O₂ concentrations, means for external energy addition, and H₂O₂ delivery methods. Curis and Halosil both generate aerosolized hydrogen peroxide (AHP) but achieve biocidal activity by different methods related to air concentration and additives.

The Bioquell wet-HPV systems use 35% H₂O₂ that is vaporized and delivered into a treatment room or chamber. The systems do not control the H₂O₂ air concentration. HPV is delivered until the air in the enclosure becomes saturated and H₂O₂ begins to condense on surfaces. Multiple Bioquell systems can be combined to treat larger rooms or enclosures. The H₂O₂ delivery machines (Clarus C, Z-2, and ProteQ) differ on room conditioning, volume, and dose.

The Steris dry-VHP systems (Steris, Mentor, OH) use 35% H₂O₂ that is vaporized into a dehumidified chamber or room. The system delivers “noncondensing” VHP by drying the vapor stream as it recirculates through the generator. The H₂O₂ delivery machines (V-PRO 1 Plus, maX, and maX2) differ on delivered volume and dose.

The STERRAD system (ASP, Irvine, CA) generates an HPGP from a 58% H₂O₂ liquid solution by applying low frequency power. In this process, a vacuum is first drawn within the chamber containing the items to be decontaminated. Then HPV is delivered to the chamber and a low frequency power is applied to convert HPV to plasma. The system has machines that differ in dose and timing (100S, NX Standard, 100NX Standard, and 100NX Express).

The Curis® system (Oviedo, FL) uses a solution of 7% H₂O₂ with a proprietary blend to create a fog of aerosolized LHP and vapor with concentration between 80 and 150 ppm. The aerosolized droplets form a microcondensation that contributes to the efficacy of the process.

The Halo system (Halosil, New Castle, DE) aerosolizes 5% H₂O₂ (AHP) with a 0.01% biocidal silver nitrate additive. Halo foggers generate a 100–120 ppm HPV and through water evaporation form microdroplets that increase peroxide concentration in the vapor phase above the initial 5%.

The SteraMist system (TOMI, Frederick, MD) uses iHP that is generated as aerosolized LHP (7.8%) and is passed through electrodes and produces a cold plasma field.

Safety considerations for H₂O₂ decontamination systems

It is important that high concentrations of peroxide be handled safely. H₂O₂ gas is a corrosive irritant that can cause skin, eye, and lung damage. The Occupational Safety and Health Administration (OSHA) permissible exposure limit is 1 ppm over an 8-h time weighted average. During the decontamination process, concentrations can exceed 1000 ppm. Furthermore, H₂O₂ does not have a reliable odor, so smell does not provide adequate warning of hazardous concentrations. Therefore, only trained personnel should operate equipment that generates vapor from H₂O₂. Only rooms and chambers that are fully sealed and airtight should be used for decontamination and the surrounding rooms or areas should be checked for leaks during treatment. Room concentrations should be monitored to ensure that off-gassing is complete before entry.

H₂O₂ is an oxidizer that can be an explosion hazard at high concentrations (>60%) in the presence of combustible materials or in a sealed vessel. None of the H₂O₂ technologies reviewed generate concentrations in the treatment rooms near this level. However, the decontamination setup should be evaluated by safety personnel.

Literature Review Process

The purpose of this review is to summarize the literature on the efficacy of different H₂O₂ decontamination methods to inactivate viral contaminated N95 FFRs and their effects on FFR functional integrity. This review addressed two questions: (1) to what extent do H₂O₂ decontamination methods inactivate microorganisms and specifically SARS-CoV-2 that are inoculated on N95 FFRs and (2) what is the effect of H₂O₂ decontamination methods on N95 FFR filtration efficiency and fit. Pubmed and the gray literature were searched for the keywords: “hydrogen peroxide,” “SARS-CoV-2,” “N95,” “respirators,” “filtering facepiece respirators,” “mask,” and “decontamination.” Titles and abstracts of articles were reviewed to identify articles relevant to the questions. Review articles were excluded. Twenty-four articles meeting the search criteria were identified. Some of the articles were not peer reviewed so their findings should be interpreted with caution. These articles are identified as prepublications in the text and also identified in the reference section. The methods and finding of each article are summarized in tables and the findings and implications are discussed. In addition, guidance from U.S. federal agencies relevant to the application of H₂O₂ methods for decontaminating N95 FFRs is summarized.

Summary of Literature Review

H₂O₂ methods and inactivation of SARS-CoV-2

Three recent prepublications demonstrated that VHP (Steris) inactivates SARS-CoV-2 (Table 2). Kumar et al. in occluded N95 FFRs (3M 1860, 3M 1870, 3M 1804, and AO 1054) with SARS-CoV-2 and vesicular stomatitis virus (VSV) Indiana serotype. VHP (ARD system, Steris, peak H₂O₂ concentration >750 ppm) inactivated both SARS-CoV-2 and VSV on all inoculated cutouts (e.g., inoculated area on FFR that is excised). Oral et al. inoculated cutouts of N95 FFRs (3M 1860S, N=3) with SARS-CoV-2 and treated them with VHP (Steris LTS-V ARD1000) at 410 ppm for 3 h (room volume: 20 m³). The treatment inactivated SARS-CoV-2. Fischer et al. inoculated
cutouts from N95 FFRs (AO N9504C) with SARS-CoV-2 and treated the cutouts with VHP (process not identified) for 10 min, which successfully inactivated SARS-CoV-2.

**H₂O₂ methods and inactivation of other organisms**

Considering that FFRs used in the hospital might be exposed to MRSA, TB, or spore-forming pathogens, for example, *C. difficile*, that are more resistant to decontamination methods than are lipid-enveloped viruses such as SARS-CoV-2,⁹–¹¹ it may be useful to employ methods that can inactivate model biological indicators.

Five studies have evaluated the Bioquell, STERRAD, and Curis systems on the inactivation of N95 FFRs inoculated with spore-forming microorganisms other than SARS-CoV-2. In addition, three studies evaluated inactivation of biological indicators placed in a chamber treated with the Bioquell, SteraMist, and Steris systems.

A 2016 report,¹² prepared for the FDA, summarized studies that evaluated effects of HPV (Clarus Cᵀᴹ, Bioquell) on N95 FFR (3M 1860) filter function and *Geobacillus stearothermophilus* spore inactivation. FFRs were inoculated by droplet or aerosol (size: 1 μm mean mass aerodynamic diameter). A 20 min gassing phase (2 g/min) followed by a 150 min dwell phase (0.5 g/min) (chamber volume: 0.3 m³) completely inactivated the spores. There was no detectable H₂O₂ adjacent to the treated FFRs after 5 h of aeration (limit of detection 0.2 ppm; Drager portable gas detector, Lubeck, Germany). Although the N95 FFRs were shown stacked up against each other in the exposure chamber (figure 11), this resulted in variable sensor readings and is not recommended (B. Heimbuch, pers. comm.). A Bioquell system (BQ-50) was also used by Kenny et al.¹³ to decontaminate inoculated N95 FFRs (3M 1870) with three different types of aerosolized bacteriophages. The N95 FFRs were suspended by their elastic strap on racks for a 30–40 min gas phase at 16 g/min, a 25 min dwell phase, and a 150 min aeration phase (room volume 33 m³). The treatment completely inactivated the phages on the N95 FFRs. A different Bioquell system (Q10) was used by Wigginton et al.¹⁴ to treat 3M 1860 FFR cutouts inoculated with phage (MS2, Phi6), influenza, mouse hepatitis virus, *Escherichia coli*, *S. aureus*, *G. stearothermophilus*, and *Aspergillus niger*. Two treatment conditions were tested (1) gassing 446 or 495 ppm, dwell 490 ppm for 20 min, and aeration 68 min and (2) gassing

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**Table 2. Effect of H₂O₂ decontamination methods on viruses and microorganisms**

<table>
<thead>
<tr>
<th>References</th>
<th>Media</th>
<th>Method and dose</th>
<th>Phase times (min)</th>
<th>Organism</th>
<th>Effectiveness (log reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>3M 1860, 1870, 1804 and AO 1054 FFRs (N=1)</td>
<td>VHPᵀᴹ (Steris ARD) 5 g/min then 2.2 g/min</td>
<td>Gas 3; Dwell 30 &gt;750 ppm</td>
<td>VSV</td>
<td>SARS-CoV-2 ≥6</td>
</tr>
<tr>
<td>7</td>
<td>3M 1860S FFR pieces inoculated</td>
<td>VHP (Steris ARD) 410 ppm</td>
<td>180</td>
<td>SARS-CoV-2 ≥5</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>AO N9504C FFR pieces inoculated</td>
<td>VHP 1000 ppm</td>
<td>10</td>
<td>SARS-CoV-2 ≥6</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>3M 1860, 1870, 1804, and AO 1054 FFRs</td>
<td>HPGP (STERRAD 100NX) 1000 ppm</td>
<td>47</td>
<td>VSV</td>
<td>≥6</td>
</tr>
<tr>
<td>12</td>
<td>3M 1860 N95 FFR inoculated with droplets or aerosol</td>
<td>HPV (Bioquell) 2 g/min then 0.5 g/min</td>
<td>Inject 20; Dwell 150</td>
<td><em>Geobacillus stearothermophilus</em> spores</td>
<td>≥6</td>
</tr>
<tr>
<td>13</td>
<td>3M 1870 inoculated (N=3 for each phage)</td>
<td>HPV (Bioquell) 16 g/min</td>
<td>Inject 30–40; Dwell 25</td>
<td>Phage phi-6</td>
<td>≥6</td>
</tr>
<tr>
<td>14</td>
<td>3M 1860 pieces inoculated</td>
<td>HPV (Bioquell) 16 g/min 446–495 ppm</td>
<td>Dwell 20</td>
<td>Phage (MS2, Phi6)</td>
<td>≥2–5</td>
</tr>
<tr>
<td>15</td>
<td>3M 1860, 1870+, 8511, 9211, HW N11125 FFRs inoculated</td>
<td>Curis</td>
<td>Inject 12; Dwell 50</td>
<td>Herpes Simplex Virus 1 Coxackievirus B3</td>
<td>≥6</td>
</tr>
</tbody>
</table>

FFR, filtering facepiece respirator; HPGP, hydrogen peroxide gas plasma; MHV, mouse hepatitis virus; VSV, vesicular stomatitis virus.
659 ppm, dwell 647 ppm for 150 min, and aeration 80 min (room volume 106 m³). Microorganisms were inactivated to between 2 and 5 log depending on the organism and media used.

The only study of HPGP (STERRAD 100NX applied for a standard 47-min cycle) on FFRs (3M 1860S) inactivated with virus found that it inactivated VSV on all cutouts.²

Derr et al.¹⁵ evaluated viral decontamination using the Curis AHP system (room volume 48 m³) on five models of N95 FFRs (3M 1860, 1870+, 8511, 9211+, and Honeywell Sperian N11125) inoculated with herpes simplex virus 1, Coxsackie virus B3, and phage phi6. By the time the treatment had inactivated the biological index (G. stearothermophilus), all viruses were similarly inactivated to >6 log.

Several studies evaluated the effects H₂O₂ processes on N95 FFR filtration but also included biological indicators in the chambers to test for spore inactivation. Bergman et al.¹⁶ studied six different N95 FFRs (industrial N95: 3M 8210, 3M 8000, and Moldex 2200; surgical N95 FFRs: KC PFR95-270, 3M 1870, and 3M 1860; N₉₅ = 6 for each of the FFR models; FFR models are listed in Bergman et al.¹⁷) and applied three cycles of decontamination using HPV (Clarus R⁷; Bioquell). The process involved a room concentration of 8 g/m³ with a 15-min dwell time and 125-min total cycle time (it is possible that this was an error and the gas injection time was 15 min and the dwell time was 110 min) (room volume: 64 m³). Biological indicators containing G. stearothermophilus spores were inactivated (6 log reduction) after the third treatment.

Similarly, but using iHP (Steramist), Cramer et al.¹⁸ reported that G. stearothermophilus spore biological indicators placed under or near N95 FFRs were inactivated to >6 log. The treatment was 90 mL/min for 15 min to achieve a concentration of 17.7 mL/m³ (room volume: 79 m³).

### Standards for evaluating filtration efficiency and fit of N95 respirators

In the United States, the standards for measuring and certifying N95 FFR filtration efficiency and fit are established by NIOSH and OSHA, respectively. Filtration efficiency is a measure of the ability of the respirator to protect the user from small particles. Fit is a measure of how well the respirator seals to the face and prevents leakage between the respirator and the face. For the protection of users, it is important to know whether and after how many cycles a decontamination process degrades these N95 FFR performance measures below established thresholds.

Under the established NIOSH criteria, filtration efficiency is evaluated by measuring the concentration of sodium chloride particles that penetrate through the FFR using a machine dedicated for this purpose (TSI 8130).¹⁹ For an N95 FFR, at least 95% of particles at 0.3 μm in size should be filtered by the FFR.

The OSHA quantitative fit test measures particle count outside the FFR compared with that inside the FFR (TSI PortaCount) while the FFR is being worn by a human test subject.²⁰ A fit factor of 100 (ratio of count outside to inside) or better is required. Levels <100 indicate that either the seal of the FFR against the face is compromised or the filter is compromised. This indicates either an FFR structural problem with loss of edge seal or degradation of the FFR filtration. The NIOSH method is preferred for assessing filtration efficiency over the fit test.

### Table 3. Studies that evaluated the effects of H₂O₂ decontamination on N95 FFR filtration efficiency with the NIOSH method

<table>
<thead>
<tr>
<th>References</th>
<th>N95 FFRs</th>
<th>Dose</th>
<th>Time (min)</th>
<th>No. of cycles</th>
<th>Filtration efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>⁷</td>
<td>3M 1860S (N = 5)</td>
<td>VHP&lt;sup&gt;PM&lt;/sup&gt; (Steris)</td>
<td>180</td>
<td>1</td>
<td>&gt;98.8%</td>
</tr>
<tr>
<td>¹²</td>
<td>3M 1860 (N = 85 total)</td>
<td>HPV (Bioquell)</td>
<td>Inject 20; dwell 150</td>
<td>10, 20, 30, 40, 50</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>¹⁴</td>
<td>3M 8210, Moldex 1511</td>
<td>VHP (Bioquell)</td>
<td>2 g/min then 0.5 g/min</td>
<td>10</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>¹⁴</td>
<td>3M 8210</td>
<td>HPGP (STERRAD)</td>
<td>Inject 3</td>
<td>5</td>
<td>&gt;58%</td>
</tr>
<tr>
<td>¹⁶</td>
<td>Six different models (N = 6 for each model)</td>
<td>HPV (Bioquell)</td>
<td>Inject 15; dwell 120</td>
<td>5</td>
<td>&gt;79%</td>
</tr>
<tr>
<td>¹⁶</td>
<td>Six different models (N = 6 for each model)</td>
<td>HPGP (STERRAD 100S)</td>
<td>55</td>
<td>3</td>
<td>&lt;95% for 4 of 6 models of N95 tested</td>
</tr>
<tr>
<td>¹⁸</td>
<td>3M 1860, Halyard 46767, Gerson 2130, 3M 8210 (N = 2 or 3)</td>
<td>iHP&lt;sup&gt;PM&lt;/sup&gt; (Steramist)</td>
<td>Inject 15; dwell 20</td>
<td>2 to 5</td>
<td>&gt;97.4%</td>
</tr>
<tr>
<td>²²</td>
<td>Six different models (N = 6 for each model)</td>
<td>HPGP (STERRAD 100S)</td>
<td>55</td>
<td>1</td>
<td>&gt;99.2%</td>
</tr>
</tbody>
</table>

| UCSF (pers. comm.) | 3M 1860, Halyard Fluidshield Halosil | Inject 15; dwell 120 | 0, 1, 2, 5 | >99.3 (3M) | >95.5 (HF) |

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[¹⁷] Bergman et al. (2017) evaluated the effects of H₂O₂ processes on N95 FFR filtration but also included biological indicators in the chambers to test for spore inactivation. Bergman et al. (2017) studied six different N95 FFRs (industrial N95: 3M 8210, 3M 8000, and Moldex 2200; surgical N95 FFRs: KC PFR95-270, 3M 1870, and 3M 1860; N₉₅ = 6 for each of the FFR models; FFR models are listed in Bergman et al. (2017) and applied three cycles of decontamination using HPV (Clarus R⁷; Bioquell). The process involved a room concentration of 8 g/m³ with a 15-min dwell time and 125-min total cycle time (it is possible that this was an error and the gas injection time was 15 min and the dwell time was 110 min) (room volume: 64 m³). Biological indicators containing G. stearothermophilus spores were inactivated (6 log reduction) after the third treatment.

[¹⁹] Under the established NIOSH criteria, filtration efficiency is evaluated by measuring the concentration of sodium chloride particles that penetrate through the FFR using a machine dedicated for this purpose (TSI 8130). For an N95 FFR, at least 95% of particles at 0.3 μm in size should be filtered by the FFR.

[²⁰] The OSHA quantitative fit test measures particle count outside the FFR compared with that inside the FFR (TSI PortaCount) while the FFR is being worn by a human test subject. A fit factor of 100 (ratio of count outside to inside) or better is required. Levels <100 indicate that either the seal of the FFR against the face is compromised or the filter is compromised. This indicates either an FFR structural problem with loss of edge seal or degradation of the FFR filtration. The NIOSH method is preferred for assessing filtration efficiency over the fit test.
The effects of H₂O₂ decontamination on filtration efficiency and fit of N95 FFRs

A variety of vapor-generating H₂O₂ processes have been evaluated for their effects on N95 FFR filtration efficiency, fit factor, and structural integrity. Seven studies have assessed the effects of the Bioquell, Steris, STERRAD, and Halo H₂O₂ decontamination processes on filtration efficiency using the NIOSH method (Table 3). Six studies assessed the effects using the OSHA quantitative fit test (data not presented in a table). Some decontamination methods preserve filtration efficiency after many cycles of treatment, whereas other methods damage filtration efficiency after just a few cycles. The effects of decontamination may differ by N95 FFR model.

The HPV/VHP Bioquell system was evaluated in three studies. The 2016 FDA-funded study, referenced previously, evaluated 85 N95 FFRs (3M 1860) treated with the Clarus C process with a 20 min gassing phase (2 g/min) followed by a 150 min dwell phase (0.5 g/min) and 300 min of aeration for 10, 20, 30, 40, and 50 cycles of decontamination (15 FFRs per cycle set). After decontamination, both inert and bioaerosol filtration efficiencies remained >99% for all of the FFRs (NIOSH method). The fit factor using a mannequin did not degrade when tested for up to 20 cycles of decontamination (no fit testing was done beyond 20 cycles). After 30 cycles, strap degradation occurred with strap length elongation and loss of elasticity, which could negatively impact FFR fit. The Bergman et al. study, also referenced previously, found that three cycles of HPV decontamination (Clarus R) did not compromise filter efficiency (>98%) in the six different N95 models tested nor were there observable physical changes to the N95 FFRs. Finally, a large hospital treated 100 N95 FFRs (3M 1860) with one cycle of Clarus C and reported no degradation of the quantitative fit test on three human subjects. The subjects detected no noticeable residual odors on the FFRs. The treatment room (volume 50 m³) attained a 480+ ppm concentration of HPV with an injection time of 25 min and dwell time of 20 min. This study also measured HPV level next to the decontaminated FFRs during the aeration period. After 4 h of aeration, the concentration was below the limit of detection (0.2 ppm) of the monitoring device (TSI PortaSens II sensor).

The VHP (Steris) process was evaluated in four studies. Oral et al. treated N95 FFRs (3M 1860S) with a single cycle of VHP and found no reduction in filter efficiency (NIOSH method). Wigginton et al. treated N95 FFRs (3M 8210, Moldex 1511) with VHP for 10 cycles and filter efficiency remained >99% (NIOSH method). In addition, the fit tests were not degraded. Kumar et al. treated N95 FFRs (3M 1860, 3M 1870, 3M 1804, and AO 1054) with 10 cycles of VHP (ARD Steris) and reported no degradation of the quantitative fit test. Fischer et al. also referenced previously, conducted fit tests after six subjects each completed three rounds of wearing an N95 FFR (3M 9211) for 2 h followed by VHP decontamination (1000 ppm). After the three cycles of decontamination, there was no decline of the quantitative fit factor.

The STERRAD method was evaluated in five studies but the processes differed between studies. Viscusi et al. evaluated six different N95 FFRs (same FFRs as Bergman et al.) and applied one cycle of treatment of HPGP (STERRAD 100S 55-min short cycle, with FFRs in Tyvek pouches) and found no reduction of filtration efficiency (NIOSH method). However, in a follow-up study by the same group, three cycles of HPGP decontamination reduced filtering efficiency by >5% for four of six different FFRs tested. Wigginton et al. treated FFR model 3M 8210 with five cycles of HPGP (STERRAD 100NX express cycle). Filtration efficiency (NIOSH method) was reduced to 58% so the HPGP process was not studied further. Kumar et al. also treated N95 FFRs (3M 1860, 3M 1870, 3M 1804, and AO 1054) with HPGP (STERRAD 100NX 47 min). One cycle of treatment did not affect the quantitative fit factor. However, after five cycles of treatment, all four different FFRs failed quantitative fit testing. A Dutch National Institute for Public Health report summarized similar findings. 3M 8822 FFRs were treated with HPGP (STERRAD NX100, Express cycle with AllClear™). One or two cycles of decontamination did not compromise quantitative fit factor, but three cycles compromised fit and four cycles deformed the FFRs. It is not known why several cycles of the HPGP process degrades N95 filter efficiency compared with other vapor-generating H₂O₂ processes. One possible explanation is that the low frequency power impacts the electrostatic properties of the middle layer polypropylene electret filter of the N95 FFRs.

The SteraMist iHP system was evaluated in one study. Five cycles were applied to two N95 FFR models (3M 1860 and Halyard 46767) and two cycles were applied to two other models (Gerson 2130 and 3M 8210). Filtration efficiency remained >97% in all cases. In addition, there was no degradation of the fit factor for the 3M 1860 or the Halyard 46767 after five cycles of decontamination.

The Halosil fogger was used to treat N95 FFRs (3M 1860 and Halyard Fluidshield) with 0, 1, 2, and 5 cycles of decontamination (The University of California San Francisco Medical Center, pers. comm.). Filter efficiency remained >95% after all treatments (NIOSH method).

Although the manufacturer of the Curis system has internal studies showing a 6 log reduction of G. stearothermophilus spores on N95 FFRs with no failures in fit tests, its impact on filtration efficiency is unknown.

Liquid hydrogen peroxide submersion

Filtration performance of N95 FFRs has been shown to be preserved after immersion in 3% and 6% LHP. Viscusi

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Each subject completed three rounds of wearing an N95 FFR (3M 9211) for 2 h followed by VHP decontamination (1000 ppm). After the three cycles of decontamination, there was no decline of the quantitative fit factor.
et al.\textsuperscript{25} submerged N95 FFRs (3M 1860 and 3M 8000) for 30 min in 3\% or 6\% LHP. After treatment, the FFRs were hung on a peg board and air dried for 72 h before measuring filter efficiency (NIOSH method). The filter efficiency was >99.2\% after both treatments.

Bergman et al.,\textsuperscript{16} also referenced previously, submerged six different N95 FFR models (industrial N95 FFRs: 3M 8210, 3M 8000, and Moldex 2200; surgical N95 FFRs: KC PFR95-270, 3M 1870, and 3M 1860 [FFR models listed in Bergman et al.\textsuperscript{17}]) for 30 min in 6\% LHP. The FFRs were hung on a peg board and dried for 16 h with the aid of a fan, then the treatment was repeated for a total of three cycles of decontamination. The filter efficiency after the third treatment was >95\% for all models (NIOSH method). Submersion of N95 FFRs for 30 min in tap water\textsuperscript{4} did not impact filtration efficiency.

There have been no studies on whether submersion in LHP will decontaminate N95 FFRs that have been inoculated with microorganisms. Also, it has not been determined whether a liquid will penetrate through the outer hydrophobic layers of the N95 and reach the middle electrostatic layers. Food-grade LHP is typically delivered as a 35\% concentration without additives, whereas pharmacy LHP is typically a 3\% concentration with stabilizers, surfactants, or metals added to increase shelf life. Surfactants can degrade N95 filter efficiency\textsuperscript{25}; therefore, if LHP is used for decontamination, a solution without additives should be used.

**Status of federal guidance**

In this unprecedented COVID-19 pandemic, due to a limited supply of N95 FFRs, the CDC have provided guidance that health care workers can practice extended use or limited reuse of N95 FFRs.\textsuperscript{26} In addition, on March 31, 2020, the CDC provided guidance to hospitals on methods for decontaminating N95 FFRs that included H\textsubscript{2}O\textsubscript{2} processes.\textsuperscript{27}

Per FDA guidelines on N95 FFR decontamination, a process is considered to be sufficiently “decontaminating” or “inactivating” when it leads to a ≥3 log reduction (99.9\% reduction) in viral activity.\textsuperscript{28} This definition of decontamination only considers virucidal activity and does not consider mycobactericidal or sporicidal activity. To achieve “sterilization” a ≥6 log reduction is required.

Since March 28, 2020, the FDA has published Emergency Use Authorizations (EUAs) for six H\textsubscript{2}O\textsubscript{2} methods for decontaminating N95 FFRs (Table 4). The EUAs differ on permitted number of decontamination cycles and whether the decontaminated N95 FFRs are single-user or pooled reuse. In a single-user reuse process, the decontaminated FFR is returned to the original user, whereas in a pooled reuse process, the decontaminated FFR goes into a large pool and can be reused by someone other than the original user.

OSHA states that cosmetics or other barriers should not be present during respirator use.\textsuperscript{29} In addition, the FDA stipulates that cosmetics not be present on respirators sent for decontamination.\textsuperscript{28}

Every time that an N95 FFR is donned, whether new or decontaminated, the CDC recommend that a “user seal check” be performed to ensure adequate seal.\textsuperscript{27} A user seal check is important because repeated donning of an N95 FFR will gradually reduce the fit. For some N95 models, the fit factor falls to below acceptable levels after 5 donnings, and for other models this does not occur until 15 donnings.\textsuperscript{30}

**Implementation strategies for decontaminating N95 FFRs**

N95 FFR decontamination processes have been developed on a large scale, with centers that serve hospitals throughout a region. Processes have also been developed for use at the hospital and hospital subunit level. Hospitals must decide whether the decontaminated FFRs are returned to the original user or are returned to a pool to be used by any health care provider. The FDA EUA letters provide guidance on this issue.

A large scale process\textsuperscript{31} has been established at six sites around the United States and each site can decontaminate up to 80,000 FFRs per day. Participating hospitals collect used FFRs, label each with hospital number, unit number (and user name), and ship them to one of the centers. The

<table>
<thead>
<tr>
<th>Process</th>
<th>Date</th>
<th>Permitted no. of decontamination cycles</th>
<th>Reuse type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Battelle CCDS</td>
<td>March 28, 2020</td>
<td>20</td>
<td>Pooled</td>
</tr>
<tr>
<td>STERRAD VHP\textsuperscript{TM} system (V-PRO, maX, and maX2)</td>
<td>April 9, 2020</td>
<td>10</td>
<td>Single user</td>
</tr>
<tr>
<td>STERRAD, ASP (100S, NX Standard, 100NX Express Cycles)\textsuperscript{a}</td>
<td>April 11, 2020</td>
<td>2</td>
<td>Single user</td>
</tr>
<tr>
<td>Sterizone VP4, Stryker</td>
<td>April 14, 2020</td>
<td>2</td>
<td>Single user</td>
</tr>
<tr>
<td>Steriluent HC 80TT</td>
<td>April 20, 2020</td>
<td>10</td>
<td>Single user</td>
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<tr>
<td>Duke Health (Bioquell)</td>
<td>May 7, 2020</td>
<td>10</td>
<td>Pooled</td>
</tr>
</tbody>
</table>

\textsuperscript{a}The STERRAD 100NX Standard process has not received FDA EUA.

COVID-19, coronavirus disease 2019; EUAs, Emergency Use Authorizations; FDA, Food and Drug Administration.
decontaminated FFRs are returned in ~10 days. Some hospitals are using this process and storing the decontaminated N95 FFRs for future needs. Storage in high humidity can damage the FFR.32

A single-hospital process has been established and tested at a large medical center.21 The center has shared a standard operating procedure that involves first visibly screening used N95 FFRs and discarding those with visible blood, hair, or damage. FFRs are hung on racks that are wheeled into decontamination rooms. The concentration of HPV is measured during the process to confirm adequate treatment level and also at the end of aeration to protect the workers who enter the room. After decontamination, the straps are evaluated for elongation and the nose bridge and nose foam are checked for integrity. The protocol does not return the FFRs back to the original user. During the early evaluation of this process, N95 FFRs did not show degradation in fit after multiple cycles of decontamination.

Many hospitals already have systems in house that use vapor-generating H2O2 systems for full room decontamination. Bulk decontamination of N95 FFRs can be achieved with a whole-room decontamination system with a sealed room, controlled air flow, and carts filled with N95 FFRs that can be wheeled in and out. This provides for a decontamination capacity of up to 2000 N95 FFRs per day using a 12 × 12 ft (3.7 × 3.7 m) room. Alternatively, a hermetically sealed air flow-controlled chamber or biosafety cabinet could be temporarily outfitted with a decontamination system7 and would have capacity for decontaminating up to 100 N95 FFRs per cycle, depending on the biosafety cabinet size. Several hospital-based standard operating procedures for decontaminating N95 FFRs that use H2O2 processes are available on the N95DECON.org website.

An important safety point for the protection of the end user is that different methods will require different time durations for residual H2O2 to be eliminated from the FFRs. For example, HPV/VPHP requires lengthy aeration with fresh air to eliminate residual H2O2, whereas methods that ionize the H2O2 lead to more rapid conversion of H2O2 into water and oxygen. Before returning decontaminated FFRs to users, sentinel FFRs should be monitored to confirm that there is no residual H2O2. Measurements of H2O2 in air blown through sentinel N95s can confirm adequate aeration.

Conclusions

Multiple studies7,8,12,13,15,18 have demonstrated that N95 FFRs inoculated with SARS-CoV-2 or other organisms can be effectively inactivated with proper use of decontamination systems that generate vapor from H2O2. However, dosing protocols are complex and could result in incomplete decontamination. To achieve an appropriate concentration of H2O2 during the injection and dwell phase, the specification of the HPV system should be matched to the treated volume. The concentration of HPV can be measured at the end of aeration to protect the workers who enter the room. Another method to confirm adequate dosing is to incorporate standard spore attenuation tests during decontamination.

None of the decontamination methods studied cause damage to N95 FFR filtration efficiency, fit, or FFR integrity after just a single cycle of treatment. However, some methods (e.g., STERRAD) can damage FFR filtration efficiency after a few cycles of decontamination, whereas other methods (e.g., Bioquell) have no effect on filtration efficiency or FFR integrity for up to 20 cycles.12 For the STERRAD system, the proper machine and protocol must be applied to prevent disruption of N95 FFR integrity. It would be useful to understand why some processes damage N95 filtration efficiency after a few cycles of treatment while others do not. Since FFR fit degrades with just repeated donning and doffing, most hospitals are limiting decontamination of an FFR to just two to five cycles.

LHP (3–6%) submersion does not damage N95 FFR filters. However, there are important unknowns that need to be addressed before this process can be endorsed. For example, will LHP penetrate the outer hydrophobic layers of the N95 FFRs and reach the middle layer? There have been no studies to determine whether LHP inactivates virus or other organisms on the electrostatic layer of the FFRs. In addition, there are no studies that measure the effect of LHP immersion on N95 FFR fit. Nor have there been studies to determine required drying time to eliminate residual H2O2.

Some hospitals are decontaminating N95 FFRs and storing them for future needs. Other hospitals are decontaminating N95 FFRs and returning them to health care workers. This provides an opportunity to determine whether workers are experiencing skin, respiratory, or neurologic symptoms related to using decontaminated FFRs. It would also be useful to know the number of treatment cycles that can be applied to used N95 FFRs before the filtration or fit is degraded, since previous decontamination studies were performed in laboratories and not on FFRs that were used during normal hospital activities.

The widespread availability in hospitals of decontamination systems that generate vapor from H2O2 provides substantial capacity for decontamination of N95 FFRs. H2O2’s demonstrated efficacy against SARS-CoV-2 and resistant bacterial spores as well as numerous other viral strains supports its use for N95 FFR decontamination. With proper aeration to eliminate residuals, and attention to FFR integrity, it is an effective means for N95 FFR decontamination during this pandemic.

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DECONTAMINATING N95 FFRS WITH H₂O₂


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