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# Filtering Facepiece Respirator (N95 Respirator) Reprocessing
## A Systematic Review

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**IMPORTANCE** The COVID-19 pandemic has resulted in a persistent shortage of personal protective equipment; therefore, a need exists for hospitals to reprocess filtering facepiece respirators (FFRs), such as N95 respirators.

**OBJECTIVE** To perform a systematic review to evaluate the evidence on effectiveness and feasibility of different processes used for decontaminating N95 respirators.

**EVIDENCE REVIEW** A search of PubMed and EMBASE (through January 31, 2021) was completed for 5 types of respirator-decontaminating processes including UV irradiation, vaporized hydrogen peroxide, moist-heat incubation, microwave-generated steam, and ethylene oxide. Data were abstracted on process method, pathogen removal, mask filtration efficiency, facial fit, user safety, and processing capability.

**FINDINGS** Forty-two studies were included that examined 65 total types of masks. All were laboratory studies (no clinical trials), and 2 evaluated respirator performance and fit with actual clinical use of N95 respirators. Twenty-seven evaluated UV germicidal irradiation, 19 vaporized hydrogen peroxide, 9 moist-heat incubation, 10 microwave-generated steam, and 7 ethylene oxide. Forty-three types of N95 respirators were treated with UV irradiation. Doses of 1 to 2 J/cm$^2$ effectively sterilized most pathogens on N95 respirators (>10$^3$ reduction in influenza virus [4 studies], MS2 bacteriophage [3 studies], *Bacillus* spores [2 studies], Escherichia virus MS2 [1 study], vesicular stomatitis virus [1 study], and Middle East respiratory syndrome virus/SARS-CoV-1 [1 study]) without degrading respirator components. Doses higher than 1.5 to 2 J/cm$^2$ may be needed based on 2 studies demonstrating greater than 10$^3$ reduction in SARS-CoV-2. Vaporized hydrogen peroxide eradicated the pathogen in all 7 efficacy studies (>10$^4$ reduction in SARS-CoV-2 [3 studies] and >10$^6$ reduction of *Bacillus* and *Geobacillus stearothermophilus* spores [4 studies]). Pressurized chamber systems with higher concentrations of hydrogen peroxide caused FFR damage (6 studies), while open-room systems did not degrade respirator components. Moist heat effectively reduced SARS-CoV-2 (2 studies), influenza virus by greater than 10$^4$ (2 studies), vesicular stomatitis virus (1 study), and *Escherichia coli* (1 study) and preserved filtration efficiency and facial fit for 11 N95 respirators using preheated containers/chambers at 60 °C to 85 °C (5 studies); however, diminished filtration performance was seen for the Caron incubator. Microwave-generated steam (1100-W to 1800-W devices; 40 seconds to 3 minutes) effectively reduced pathogens by greater than 10$^3$ (influenza virus [2 studies], MS2 bacteriophage [3 studies], and *Staphylococcus aureus* [1 study]) and maintained filtration performance in 10 N95 respirators; however, damage was noted in least 1 respirator type in 4 studies. In 6 studies, ethylene oxide preserved respirator components in 16 N95 respirator types but left residual carcinogenic by-product (1 study).

**CONCLUSIONS AND RELEVANCE** Ultraviolet germicidal irradiation, vaporized hydrogen peroxide, moist heat, and microwave-generated steam processing effectively sterilized N95 respirators and retained filtration performance. Ultraviolet irradiation and vaporized hydrogen peroxide damaged respirators the least. More research is needed on decontamination effectiveness for SARS-CoV-2 because few studies specifically examined this pathogen.

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Multimedia

Supplemental content

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SARS-CoV-2 is an RNA virus that has a diameter of approximately 0.1 µm. It is transmitted by respiratory droplets and aerosols such that one of the most effective ways to prevent infection is to wear filtering facepiece respirators (FFRs). The commonly used FFRs are N95 respirators, devices that by design filter 95% or more of particles larger than 0.3 µm in diameter. In practice, these devices prevent the passage of 99.8% of particles larger than 0.1 µm.[1] RNA viruses are inherently unstable, and transmission of viable SARS-CoV-2 can occur only if the virus is protected from the atmosphere by being contained within moist respiratory droplets or aerosols. The droplets are of various sizes, with large droplets being on the order of 5 µm or larger.[2] Respiratory aerosols can transmit the virus great distances and have particle sizes of about 1 µm. All of these particle sizes are effectively filtered by N95 respirators, as long as they closely fit the contours of the wearer's face, avoiding leaks around the filter material.

The COVID-19 pandemic initially resulted in a critical shortage of all forms of personal protective equipment, especially N95 respirators.[3,4] Because of limitations of the FFR supply chain, N95 respirators remain scarce, with little hope of having an adequate supply while the pandemic lasts. Consequently, most health care institutions have resorted to reprocessing these devices that were intended to be used one time only. Centers for Disease Control and Prevention (CDC) guidance exists for FFR reprocessing in emergency conditions.[5] However, that guidance is associated with few recommendations for how to reprocess these devices. Filtering facepiece respirators can fail if the reprocessing system cannot kill all the pathogens that accumulate within the mask material itself, if the filters are compromised and lose filtering efficiency, or if the mask elasticity is altered such that it no longer provides a tight fit and leaks air around the mask.

To date, several approaches have been tested for the reprocessing of N95 respirators and how they affect filtration efficiency and facial fit characteristics.[6-8] They include UV germicidal irradiation (UVGI), vaporized hydrogen peroxide (VHP), moist-heat incubation (MHI), microwave-generated steam (MGS), and ethylene oxide. How to select the optimal method is uncertain. To determine which method is most clinically useful, we performed a systematic review to assess efficacy and feasibility of each reprocessing strategy.

### Key Points

**Question** What methods of filtering facepiece respirator decontamination are effective and feasible?

**Findings** Five decontamination processes and 42 studies were reviewed. Ultraviolet germicidal irradiation, moist heat, and microwave-generated steam processing were effective for pathogen removal, preserved respirator filtration, and had short treatment times and readily available equipment. Vaporized hydrogen peroxide is a suitable alternative with longer decontamination durations and is more expensive. Ethylene oxide may leave toxic residues and is less easily implemented.

**Meaning** Ultraviolet germicidal irradiation, moist heat, and microwave-generated steam processing of filtering facepiece respirators are effective means for decontamination and are simple to implement.

## Literature Search Methods

### Data Sources and Searches

This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[9] Two librarians developed a search strategy for FFRs (including N95s and respirators), sterilization, UVGI, VHP, MHI, MGS, and ethylene oxide to identify PubMed and EMBASE articles. Research reports were assessed between database inception and January 31, 2021.

### Study Inclusion

Titles were reviewed independently by 2 individuals to determine if the study assessed FFR decontamination results using UVGI, VHP, MHI, MGS, or ethylene oxide. Studies evaluating decontamination of impregnated pathogens (including bacteria, virus, fungus, and spores) from FFRs and/or how this affects the mask's filtration efficiency and facial fit were included. Efficacy of pathogen decontamination was determined by the reduction in pathogen load, with greater than $10^3$ reduction after reprocessing considered efficacious, corresponding to greater than 99.9% inactivation of pathogens per US Food and Drug Administration guidelines.[10] Respirator filtration performance was assessed by filtration efficiency (particle penetration filtered by the material and airflow resistance across the filter material). Facial fit was assessed with quantitative and/or qualitative fit test methods. (The fit factor obtained with a quantitative fit test calculates a ratio of the test agent concentration outside the respirator to the test agent concentration inside the respirator, with a range of 1-200 for N95 respirators, and >100 needed to pass). A comparator group was not required for inclusion.

Studies evaluating decontamination of pathogens on non-FFR surfaces, review articles, and editorials were excluded. Reference mining was performed. The gray literature and manufacturer websites were reviewed for cost data of equipment required for each decontamination method. Direct communication was made with manufacturers when data were not available online. The CDC website was assessed, which identified additional non–peer-reviewed (ie, gray) literature. The full search strategy is provided in eAppendix 1 in the Supplement.

### Terminology

The N95 respirator is one of the most common types of respirators used by health care practitioners. It is 1 of 9 types of disposable particulate FFRs and protects by filtering particles out of the air that is breathed.[11] N95 respirators filter out at least 95% of airborne particles, such as bacteria or virus particles, while those filtering out at least 99% receive a 99 rating and those that filter at least 99.97% receive a 100 rating.[12] Respirators are rated N (not resistant to oil), R (somewhat resistant to oil), and P (strongly resistant [oil proof]). When approved by the National Institute for Occupational Safety and Health (NIOSH), respirators are marked with the manufacturer's name, part number, protection provided by the filter, and the acronym "NIOSH."

### Data Abstraction and Synthesis of Results

Because of heterogeneity in study designs and within-study variations of the processes tested and outcomes measures, data pooling was not possible; hence, the synthesis is narrative. Data were dual

abstracted for decontamination process, treatment system, and 3 indicators of quality of processing, including effectiveness of removal of pathogen, physical integrity/performance of the mask (filtration efficiency and/or facial fit), and safety for users. Throughput (number of FFRs processed per cycle) and processing capability were reported. If only UV intensity and time of exposure were specified, UV dose was calculated using the equation UV dose ($J/cm^2$) = intensity ($W/cm^2$) × time (s).

## Results

The literature search identified 238 articles, with an additional 8 identified through reference mining. After screening, 42 studies were included (eFigure in the Supplement); all were laboratory studies (no clinical trials), and 2 evaluated respirator performance and fit with actual clinical use of FFRs. Of the 42 studies, 26 included evaluations of the following pathogens/organisms: SARS-CoV-2 (5 studies), influenza virus (4 studies), MS2 bacteriophage (8 studies), *Escherichia coli* (2 studies), *Staphylococcus aureus* (1 study), *Mycobacterium smegmatis* (1 study), Escherichia virus MS2 (1 study), vesicular stomatitis virus (1 study), and *Bacillus* and *Geobacillus stearothermophilus* spores (6 studies). Overall, 27 studies evaluated UVGI decontamination, 19 evaluated VHP, 9 evaluated MHI, 10 evaluated MGS, and 7 evaluated ethylene oxide.

### UV Germicidal Irradiation

Sterilization using UVGI depends on total power of UV energy delivered from specialized bulbs or lamps that illuminate a confined space such a box, biosafety cabinet, or entire room. N95 respirators have several layers of material that the UV energy must penetrate. Ultraviolet germicidal irradiation causes radiolytic stress that disrupts a microorganism's DNA but may degrade polymers commonly used in disposable N95 respirators.

#### Effectiveness of Decontamination and Sterilization Processes

The effectiveness of UVGI to sterilize FFRs impregnated with infectious pathogens was examined in 17 of the 27 studies evaluating 31 different commercially available models of N95 respirators. Substantial heterogeneity existed among studies in systems used to deliver UVGI, dose of UV light applied, and FFR models and pathogens studied. Ultraviolet germicidal irradiation energy of 0.03 to 7.2 $J/cm^2$ was applied with exposure times ranging from 1 to 300 minutes. Overall, doses exceeding 1 $J/cm^2$ effectively decontaminated FFRs as measured by reduction in influenza virus (4 studies), MS2 bacteriophage (3 studies), *Bacillus* spores (2 studies), Escherichia virus MS2 (1 study), vesicular stomatitis virus (1 study), and Middle East respiratory syndrome virus and SARS-CoV-1 (1 study) (**Table 1**).

Higher doses of UVGI energy were needed to decontaminate FFRs for SARS-CoV-2 compared with other viruses such as influenza virus and MS2 bacteriophage. Two studies showed that 1.50 to 1.98 $J/cm^2$ were required for SARS-CoV-2 decontamination of FFRs,[13,14] whereas 3 other studies did not find that UVGI effectively decontaminated FFRs.[15-17] In a study requiring 1.98 $J/cm^2$, the power of the UV lamp was lower than in most other studies assessing pathogen decontamination (median, 2.1 [interquartile range, 0.66-13.8] $mW/cm^2$) and may have led to decreased penetration of the UV rays through the N95 respirator's material.[13] No other studies evaluated the specific FFR model that was examined in that study (the AOSafety N9504C). In another study, UV box and whole-room decontamination treatment with an unspecified level of UV power or dose did not effectively decontaminate 3 different N95 respirators types when *Pseudomonas phage φ6* and MS2 bacteriophage were suspended on the outer top, outer edge, and inner surface of the respirator facepiece.[15] Although UV dose was not specified, UV-C colorimetric indicators demonstrated delivery of a dose sufficient to reduce *Clostridioides difficile* spores. Virus was suspended in liquid and spread over a small surface area, which may have led to differences in efficacy compared with droplet and aerosol deposition. The efficacy of UV light increases when an inoculum is spread over a larger surface area.[18] In another study assessing SARS-CoV-2 decontamination of 3 N95 respirator models,[16] 0.63 $J/cm^2$ led to effective virus reduction in only 1 of the models (the 3M 1870+). However, high titers of SARS-CoV-2 were directly infiltrated into the N95 respirators in this study beyond what may occur in a more realistic exposure scenario, such as from a single cough,[19] and only a single decontamination experiment was performed. Certain models of N95 respirators in which UVGI was found to be less effective include the Gerson 1730, the Sperian HC-NB095 (now manufactured by Honeywell), and the Dentec Safety AD2N95A[20,21]; the 3M VFlex 1805 and the Precept 65-3395[21]; and 3M 1860S, the Moldex-Metric 1517, and the Kimberly-Clark 46727.[15]

#### FFR Damage, Process Time, Scalability, and Cost

The potential for UVGI to damage FFRs and diminish their filter performance and facial fit was examined in 23 studies and 30 different commercially available models of N95 respirators. Of these, 1 study demonstrated diminished strength of the respirator materials from UVGI (Table 1). However, this was after very high doses (>120 $J/cm^2$) beyond what is used in clinical practice.[22] Overall, N95 respirator fit characteristics and filtration performance were not affected in up to 20 decontamination cycles with high cumulative doses,[6,16,17,21-27] with the exception of 3 recent studies in which filter efficiency decayed to less than 95% after 1 cycle and 20 cycles with an unmeasured UV dose,[28,29] and the 3M 1860 and 3M 1860S filter performance degraded to 70% to 80% after 9 repeated cycles using whole-room decontamination.[30] In the study applying 20 cycles of UV light,[28] UVGI was applied to melt-blown fabric samples (the most critical filtering layer within the N95 respirator that allows air to pass through while filtering 95% of microbes) and was thus unprotected by other respirator layers.

Commercially available UVGI lamps or bulbs can be placed in chambers or cabinets to construct decontamination devices used to reprocess 4 to 40 masks per 5- to 10-minute cycle, corresponding to 1500 to 5000 masks per day, at a cost of $750 to $1500.[31,32] Because UVGI devices and laboratory hoods are ubiquitous in many hospitals, this approach is feasible and potentially inexpensive.[32,33] While commercial UV-C bulbs are relatively inexpensive ($40-$285),[34] laboratory hoods and commercial UVGI whole-room decontamination systems are more costly ($7000-$21 000[35,36] and $25 000-$40 000,[37] respectively). Recommendations for how to select N95 respirators amenable to UV treatment, the UV sterilization device, and toxicity information are available in eAppendix 2 in the Supplement.

Table 1. Ultraviolet Germicidal Irradiation (UVGI): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators

| Source | Mask (make and model/type) | UV device, power, distance | UV irradiance, time, dose, form, surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Vo et al,[71] 2009 | Willson Saf-T-Fit 1105 | Philips TUV 36 T5 low-pressure mercury lamp in biological safety cabinet<br>Power: 40 W<br>Distance: 42 cm | Irradiance: 0.4 mW/cm$^2$<br>Time: 1-5 h<br>Dose: 1.13-7.20 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: N95 exterior; 1 mask tested at 5 time points, 5 total masks | $10^3$ reduction in level of MS2 bacteriophage with 4.32 J/cm$^2$<br>Undetectable MS2 virus with >7.2 J/cm$^2$ | No filtration efficacy studies | No facial fit studies |
| Viscusi et al,[55] 2009 | 3M 1820, 3M 1860, 3M 1870, 3M 8000, 3M P100-8293, Moldex-Metric 2200, Moldex-Metric P100-2360, Kimberly-Clark C PFR95-270, North P100-8150 | Lamp (make/model not specified)<br>Power: 40 W | Irradiance: 0.18-0.20 mW/cm$^2$<br>Time: 15 min<br>Dose: 0.176-0.181 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: each N95 side; 3 masks from each make/model tested, 27 total masks | Not assessed | No significant changes to filter performance | No facial fit studies, no observable physical changes with UVGI |
| Bergman et al,[8] 2010 | 3M 1860s, 3M 1870<br>3M 8000, 3M 8210, Moldex-Metric 2201, Kimberly-Clark PFR95-174 | UVP XX-40S lamp in laminar flow cabinet<br>Power: 40 W<br>Distance: 25 cm | Irradiance: 1.8 mW/cm$^2$<br>Time: 45 min<br>Dose: 4.86 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: N95 exterior; 3 masks from each make/model tested, 18 total masks | Not assessed | Three-cycle processing caused no change in filter performance | No facial fit studies<br>Three-cycle (15 min each) processing caused no change in physical appearance |
| Salter et al,[47] 2010 | NIOSH- and FDA-approved N95s (S1-S3, P1-P3) | UVP lamp<br>Power: 8 W<br>Distance: 2.54 cm | Irradiance: 3.4 mW/cm$^2$ (UV-C) or 4.0 mW/cm$^2$ (UV-B)<br>Time: 1 h<br>Dose: 27 J/cm$^2$<br>Form: UV-C, 254 nm, UV-B, 302 nm<br>Surface tested: 3 mask coupons (38 mm) from each make/model tested, 18 total coupons | Not assessed | No filtration efficacy studies, no toxic by-products from UV-initiated radical reactions | No facial fit studies |
| Fisher and Shaffer,[72] 2011 | 3M 1860, 3M 1870, 3M 8210, Cardinal N95-ML, Willson Saf-T-Fit 1150, Kimberly-Clark PFR95-174 | Philips TUV 36 T5 low-pressure mercury tube lamp in biological safety cabinet<br>Power: 40 W | Irradiance: 2.5 mW/cm$^2$<br>Time: 2-266 min<br>Dose: 0.03-0.3 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: each side of N95 layer; 1 mask coupon from each make/model tested, 6 total coupons | Internal filter dose >0.1 J/cm$^2$ demonstrated >$10^3$ reduction in MS2 bacteriophage<br>3M 1870 was the least shielded: 2 min to achieve dose<br>Cardinal N95-M was the most shielded: 266 min to achieve dose | UV-C transmits through gaps/pores between the N95 material to reach internal filter<br>Models that allow more transmittance of UVGI through layers require less exposure time to reach desired dose | No facial fit studies |
| Heimbuch et al,[7] 2011 | 3 particulate (P1-P3), 3 surgical (S1-S3) | UVP lamp | Irradiance: 1.6-2.2 mW/cm$^2$<br>Time: 15 min<br>Dose: 1.8 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: N95 exterior; 1 mask tested from each make/model tested; experiments run in 6 replicates (36 total masks) | >$10^4$ reduction in viable H1N1 influenza | No filtration efficacy studies | No facial fit studies, no gross physical signs of deterioration/deformation[a] |

(continued)

Table 1. Ultraviolet Germicidal Irradiation (UVGI): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | UV device, power, distance | UV irradiance, time, dose, form, surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Bergman et al,[51] 2011 | 3M 1860, 3M 1870, Kimberly-Clark PFR95-270 | Bulb in laminar flow cabinet (make/model not specified)<br>Power: 40 W | Irradiance: 1.8 mW/cm$^2$<br>Time: 15 min<br>Dose: 1.62 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: N95 exterior; 10 masks tested from each make/model tested for 4 donning trials; experiments run in duplicate (60 total masks) | Not assessed | No filtration efficacy studies | Fit test passing rate (fit factor >100) ranged from 90% to 100% and varied by N95 model<br>No physical degradation observed in any models after 3 cycles |
| Viscusi et al,[23] 2011 | 3M 1860, 3M 1870, 3M 8000, 3M 8210, Moldex-Metric 2200, Kimberly-Clark PFR95-270 | Bulb in laminar flow cabinet (make/model not specified)<br>Power: 40 W | Irradiance: 1.8 mW/cm$^2$<br>Time: 15 min<br>Dose: 1.62 J/ cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: each N95 side; 10 masks from each make/model tested; experiments run in duplicate (120 total masks) | Not assessed | No filtration efficacy studies | No clinically meaningful reduction in fit, increase in odor, increase in discomfort, or increased difficulty in donning |
| Lore et al,[6] 2012 | 3M 1860S, 3M 1870 | UVP bulb in laminar flow cabinet<br>Power: 15 W<br>Distance: 25 cm | Irradiance: 1.6-2.2 mW/cm$^2$<br>Time: 15 min<br>Dose: 1.8 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: N95 exterior; 9 masks from each make/model tested, 18 total masks | >10$^4$ reduction of influenza A(H5N1) virus<br>Lower levels of detectable viral RNA by polymerase chain reaction than microwave-generated steam and moist heat | No significant changes to filter performance | No facial fit studies |
| Woo et al,[73] 2012 | 3M 1870 | UVP UVG-11 lamp<br>Power: 4 W<br>Distance: 10 cm | Irradiance: 1 mW/cm$^2$<br>Time: 30 min, 60 min<br>Dose: 1.8 and 3.6 J/cm$^2$<br>Form: UV-C, 254 nm<br>Number of masks/coupons tested not specified | Relative humidity does not affect effect the inactivation efficiency of aerosol and droplet containing MS2 bacteriophage<br>Solids present in saliva may protect virus from UV penetration | No filtration efficacy studies | No facial fit studies |
| Lindsley et al,[22] 2015 | 3M 1860, 3M 9210, Gerson 1730, Kimberly-Clark 46727 | T-150 (make not specified); 2 lamps in reflective housing<br>Power: 15 W<br>Distance: 6.2 cm | Irradiance: 1.6-2.2 mW/cm$^2$<br>Dose: 0, 120, 240, 470, or 950 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: each FFR side; 24 mask coupons (37 mm) from each make/model tested, 96 total coupons | Not assessed | No significant changes to filter performance | Higher UVGI doses (>120 J/cm$^2$) led to strength substantially reduced with obvious breaks or tears; mask came apart easily |
| Mills et al,[20] 2018 | 3M 1860, 3M 1870, 3M VFlex 1805, Alpha Protech 695, Gerson 1730, Kimberly-Clark PFR, Moldex-Metric 1512, Moldex-Metric 1712, Moldex-Metric EZ-22, Precept 65-3395, Prestige Ameritech RP88020, Sperian HC-NB095, Sperian HC-NB295F, Dentec Safety AD2N95A, Dentec Safety AD4N95 | OnlineMetals.com Alloys 6061-T6 and 2024-T3 custom model; 8 bulbs<br>Power: 0.39 W/cm$^2$ | Irradiance: 17 mW/cm$^2$<br>Time: approximately 1 min<br>Dose: 1.0 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: N95 exterior; 12 masks tested from each make/model tested, 180 total masks tested | >10$^3$ reduction in influenza A(H1N1) influenza viability with soiling conditions (saliva modeled using mucin buffer and skin modeled using artificial skin oil) in 12 of 15 facepieces and 7 of 15 straps | Hydrophilic N95s cause absorption of virus away from the surface, and presence of ridges causing shadowing may limit UVGI efficiency<br>Greater concern for straps that twist<br>Increased likelihood of infection transmission from handling of straps during doffing | No facial fit studies |

(continued)

Table 1. Ultraviolet Germicidal Irradiation (UVGI): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | UV device, power, distance | UV irradiance, time, dose, form, surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Lin et al,[74] 2018 | 3M 8210 | UVP UVGL-58 handheld lamp<br>Power: 6 W<br>Distance: 10 cm | Irradiance: 18.9 mW/cm$^2$<br>Time: 1, 2, 5, 10, and 20 min<br>Dose: 1.13-22.6 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: each FFR side; 1 mask tested, cut into 6 pieces; experiments run in triplicate | 1.13 J/cm$^2$ (1 min, dose used to treat for virus) effective in reducing survival of *Bacillus* spores to <1%<br>5.67 J/cm$^2$ (5 min) resulted in undetectable colony recovery | No filtration efficacy studies | No facial fit studies |
| Heimbuch and Harnish,[21] 2019 | 3M 1860, 3M 1870, 3M VFlex 1805, Alpha Protech 695, Gerson 1730, Kimberly-Clark PFR, Moldex-Metric 1512, Moldex-Metric 1712, Moldex-Metric EZ-22, Precept 65-3395, Prestige Ameritech RP88020, Sperian HC-NB095, Sperian HC-NB295F, Dentec Safety AD2N95A, Dentec Safety AD4N9 | OnlineMetals.com Alloys 6061-T6 and 2024-T3; 8 bulbs arranged in chamber constructed of aluminum sheet metal measuring 16 × 12 × 40 in<br>Distance: 1 m | Irradiance: 4.2 mW/cm$^2$<br>Time: 7 min 15 s<br>Dose: 0.001, 0.5, 1, and 2 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: 3 masks tested from each make/model, 45 total masks tested | No viable influenza (multiple strains), MERS or SARS-CoV-1 virus found with >1 J/cm$^2$ in the presence of artificial skin oil and saliva (3M 1870)<br>N95s with hydrophilic surfaces and straps showed mean reductions <$10^3$ | No reduction in airflow resistance or particle penetration for up to 20 cycles of UVGI treatment (1 J/cm$^2$ per cycle) on a static head form connected to a breathing machine | No reduction in fit |
| Fischer et al,[13] 2020 | AOSafety N9504C (UVGI decontamination), 3M Aura Particulate Respirator 9211+/37193 (mask integrity) | LEDi2 LED high-power UV germicidal lamp<br>Distance: 50 cm | Irradiance: 0.55 mW/cm$^2$<br>Time: 10, 30, and 60 min<br>Dose: 0.33, 0.99, and 1.98 J/cm$^2$<br>Form: UV-C, 260-285 nm<br>Surface tested: 1 mask coupon from each make/model; experiments run in triplicate (6 total coupons) | SARS-CoV-2 inactivated rapidly from steel (10 min, 0.33 J/cm$^2$) but more slowly on N95 fabric (approximately 60 min, 1.98 J/cm$^2$ for a $10^3$ reduction), attributed to N95 porous nature | No significant effects on filtration efficiency after 2 cycles and 2 hours of wear | No reduction in fit<br>Maintained acceptable performance after 3 rounds (fit factor >100) |
| Jung et al,[17] 2020 | Not specified | KARIS KRS-A1 bulb in UV sterilizer, 42 × 32 × 32 cm<br>Distance: 16.5 cm | Irradiance: 10 W<br>Time: 1 h each side<br>Form: UV-C, 254 nm<br>Surface tested: each side of FFR; number of masks tested not specified | Reduction of *Escherichia coli* up to 82%, indicating incomplete sterilization | No significant effects on filtration efficiency<br>Negligible impact on structural integrity | No facial fit studies |
| Kumar et al,[27] 2020 | 3M VFlex 1804, 3M 1860, 3M Aura 1870, 3M 8210, 3M 9210, AOSafety 1054S | Sanuvox Asept.2X UV-C disinfection unit<br>Distance: 218 cm | Dose: 0.56-1.12 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: 1 mask coupon from each make/model; experiments run in triplicate (18 total coupons) | $10^4$ to $10^5$ reduction of vesicular stomatitis virus with persistent viable virus isolated<br>SARS-CoV-2 decontamination not evaluated | No significant effects on filtration efficiency through 5 cycles | Fit factor >100 for at least 5 cycles<br>No qualitative damage observed on FFRs |
| Purschke et al,[31] 2020 | 3M 1860 | Low-pressure mercury lamps<br>Horizontal, vertical and cylindrical cabinet | Time: 5 min<br>Dose: ≥1 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: 2 masks; experiments run in triplicate (6 total masks) | $10^6$ *Bacillus* spore inactivation from 0.2 to 1 J/cm$^2$ | No significant effects on filtration efficiency through 5 cycles<br>No ozone detected within cabinets | No significant change in fit or strap elasticity through 5 cycles |

(continued)

Table 1. Ultraviolet Germicidal Irradiation (UVGI): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | UV device, power, distance | UV irradiance, time, dose, form, surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Smith et al,[16] 2020 | 3M 1860, 3M 1870+, 3M 8511 | General Electric Germicidal T8 UV-C bulb in biosafety cabinet<br>Power: 30 W | Time: virucidal efficacy experiment, 33 min; mask integrity experiment, 16 h to exterior surface, 4 h to interior surface<br>Dose: virucidal efficacy, 0.63 J/cm$^2$; mask integrity, 18.4 J/cm$^2$ to exterior surface, 4.6 J/cm$^2$ to interior surface<br>Form: UV-C, 254 nm<br>Surface tested: each side of N95 and straps; 1 mask tested from each make/model, 3 masks total | SARS-CoV-2 RNA was detected on all masks exposed to virus<br>Only UV treatment to the 3M 1870+ N95 appeared virucidal (>10$^3$ reduction) | No filtration efficacy studies | Across all N95s, 18-J/cm$^2$ UV exposure significantly impaired mask integrity vs control; however, average fit score remained >100 |
| Cadnum et al,[15] 2020 | 3M 1860S, Moldex-Metric 1517, Kimberly-Clark 46727 | Advanced UV Systems UV-C box with 1 lamp below and 1 above | Time: 1 min<br>Form: UV-C, 254 nm<br>Surface tested: 1 mask from each make/model (virus inoculated on 3 separate areas), 3 masks total | Reductions in MS2 bacteriophage and *Pseudomonas phage φ6* consistently less than methicillin-resistant *Staphylococcus aureus* for most test sites and rarely >10$^3$<br>Reductions were consistently lower for interior surfaces vs exterior surfaces<br>Reductions lower on the 3M 1860S | No filtration efficacy studies | No facial fit studies<br>No visible changes after 3 or more cycles for all N95s tested |
| | | Clorox Optimum UV Low-pressure mercury UV room decontamination device<br>Distance: 3 ft | Time: 15 min to each side of N95 (Moldex-Metric 1517 only)<br>Form: UV-C, 254 nm<br>Surface tested: each side; 1 mask tested (virus inoculated on 3 separate areas) | No viral surrogate reduction >10$^3$<br>Greater reductions were achieved with the longer UV-C cycles vs the short cycles in the UV-C box<br>Reductions on the interior vs exterior surface were comparable | No filtration efficacy studies | No facial fit studies<br>No visible changes after 3 or more cycles for all N95s tested |
| Kayani et al,[33] 2020 | Moldex-Metric (model not specified), 3M 1860 | Synchronous UV decontamination system (SUDS; custom designed by study investigators) with 8 bulbs | Time: 1 min<br>Dose: >2 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: all surfaces of 1 N95; 2 masks from each make/model tested, 4 masks total | Complete reduction in Escherichia virus MS2 when FFR exposed to relatively low viral dose<br>Incomplete sterilization for FFRs soiled or exposed to high dose of inoculum<br>Incomplete decontamination of straps | No filtration efficacy studies | No facial fit studies |
| Ozog et al,[14] 2020 | 3M 1860, 3M 8210, 3M 8511, 3M9211, Moldex-Metric 1511 | Daavlin low-pressure mercury lamp device in biosafety hood<br>Distance: 11.5 cm | Irradiance: 16.5 mW/cm$^2$<br>Time: 60-70 s to each side<br>Dose: 1.5 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: each side of N95; 1 mask from each make/model (virus inoculated on 4 separate areas), 5 masks total | 1.5 J/cm$^2$ effective for SARS-CoV-2 reduction from 3M 1860 and Moldex-Metric 1511 facepieces and for 3M 8210 and Moldex-Metric 1511 straps | No filtration efficacy studies | No facial fit studies |
| Liao et al,[28] 2020 | Melt-blown fabric: Guangdong Meltblown Technology[b]; N95-grade FFRs: 3M 8210 | Lamp in UV sterilizer cabinet (CHS-208A; make not specified), 475-cm$^2$ internal area<br>Power: 8 W | Time: 30 min, and left to stand under ambient conditions for 10 min per cycle<br>Form: UV-C, 254 nm<br>Surface tested: 30 melt-blown fabric samples tested | Not assessed | No reduction in filtration performance after 10 cycles<br>Small degradation in filter efficiency by 20 cycles (approximately 93%) | No facial fit studies<br>No qualitative damage observed on UV-treated FFRs |

(continued)

Table 1. Ultraviolet Germicidal Irradiation (UVGI): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | UV device, power, distance | UV irradiance, time, dose, form, surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Ou et al,[24] 2020 | 3M 1820, 3M 8210 | Xenex LightStrike Germ-Zapping Robots<br>Distance: <1 m | Time: 5 min<br>Dose: approximately 1 J/cm$^2$<br>Form: UV-C, 254 nm<br>Surface tested: N95 respirators hung between light source and UV reflective wall; number of masks tested not specified | Not assessed | No reduction in filtration performance after 10 cycles | No facial fit studies |
| Peltier et al,[30] 2020 | 3M 1860, 3M 1860S | Whole-room decontamination (Surfacide) | Time: 10 min per N95 side<br>Surface tested: 10 masks | Not assessed | Reduction in filtration performance after 9 cycles | No facial fit studies |
| Rohit et al,[29] 2020 | Not specified | UV chamber, 500 × 500 × 300 mm<br>8 lights covering all sides | Irradiance: 18 W<br>Time: 10 min<br>Surface tested: mask suspended in UV chamber; 6 masks from each make/model tested; experiments run in triplicate, 54 masks total | Not assessed | Reduction in filtration performance in 2 of 3 FFRs | No facial fit studies |

Abbreviations: FDA, US Food and Drug Administration; FFR, filtering facepiece respirator; MERS, Middle East respiratory syndrome virus; NIOSH, National Institute for Occupational Safety and Health; UVP, UV Products LLC (now Analytik Jena US LLC).

[a] Visible damage on an FFR may not mean a change in facial fit.

[b] Melt-blown fabric represents the most critical filtering layer of the N95 with initial efficiency ≥95%, representative of how the filtration efficiency in an N95 FFR may change given exposure to these treatments in the worst-case scenario (no protective layer of the FFR). Used because of the shortage of FFRs during the study period.

## Vaporized Hydrogen Peroxide

Vaporized hydrogen peroxide is a sterilant for heat-sensitive medical devices and equipment.[38] Its use as a gaseous disinfectant circulated in an enclosed space or open room is safe given its low toxicity and residual gas vapor decomposition into water vapor and oxygen.

### Effectiveness of Decontamination and Sterilization Processes

Nineteen studies assessed outcomes on 30 N95 respirators using VHP (**Table 2**). There was heterogeneity among studies in the reprocessing systems used (open-room vs closed chambers), in VHP concentration, in FFR models, and in pathogens analyzed. These studies examined commercial VHP generators that converted liquid hydrogen peroxide into vapor and, following hydrogen peroxide vapor treatment, required an aeration phase to safely eliminate toxic residual chemicals. STERRAD $H_2O_2$ gas plasma sterilizer systems (Advanced Sterilization Products) were used in 6 studies, while 10 studies used open-room decontamination systems (Bioquell Room Bio-Decontamination Service Clarus R hydrogen peroxide vapor generator, Bioquell Z system, Steris Life Sciences VHP Victory system, or Radiant Innovations Satej Plus VHP generator). The STERRAD system uses a 100-L (0.1-m$^3$) chamber for decontamination, while the open-room generators that are designed for large-scale decontaminations were placed in 33-m$^3$ to 111-m$^3$ rooms with N95 respirators either hung across on a string or suspended on racks. Cycle time varied from 28 minutes to 300 minutes, with variable aeration times up to 18 hours. Total treatment times ranged from 1 hour to 19 hours. The STERRAD systems were run at 45 °C to 55 °C for 55 minutes. In 3 recent studies, VHP chamber decontamination was evaluated using the Steris V-PRO maX sterilization system[39,40] and a Panasonic incubator with VHP generation capabilities.[13] Cycle times for these 2 systems varied from 28 minutes to 290 minutes, respectively. The concentration of VHP ranged from 7% to 59% based on the device (7%-8% for the Radiant Satej Plus; 30%-35% for the Bioquell Clarus R and Clarus C VHP generator and Z vaporizer chamber and the Steris ARD and VHP Victory; and 58%-59% for the STERRAD NX and 100S and the Steris V-PRO maX).

Overall, VHP effectively decontaminated FFRs as measured by greater than $10^6$ reduction of *Bacillus* and *G stearothermophilus* spores (indicating complete inactivation) (4 studies), inactivation of vesicular stomatitis virus (1 study), and inactivation of SARS-CoV-2 (3 studies) (Table 2). In a 2016 report of the 3M 1860 with a Bioquell Clarus C VHP chamber generator, an optimal 480-minute VHP decontamination process was developed.[41] Total exposure time was 8 hours, and the system could treat more than 50 N95 respirators per cycle. Fifty cycles of VHP treatment demonstrated complete inactivation of *G stearothermophilus* spores after each cycle while preserving filter performance. Additionally, fit was unaffected for up to 20 VHP cycles when tested on manikins. However, more than 30 cycles resulted in elastic strap degradation when stretched. This finding contrasted with a recent study using the Battelle Critical Care Decontamination System in which there was no effect on strap integrity after 20 cycles.[42] The viricidal efficiency of VHP using a 130-minute decontamination process was confirmed by demonstrating complete eradication of *E coli*, *M smegmatis*, and *G stearothermophilus* spores without signs of physical degradation after 15 cycles.[43] Three recent studies assessed SARS-CoV-2 decontamination of N95 respirators. In 2 studies,

Table 2. Vaporized Hydrogen Peroxide (VHP): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators

| Source | Mask (make and model/type) | VHP device, volume, concentration, time | Surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Viscusi et al,[54] 2007 | N95 class, P100 class | Advanced Sterilization Products STERRAD NX standard cycle and STERRAD 100S Standard cycle<br>Concentration: 58% $H_2O_2$ | N95 placed in an individual Tyvek/Mylar self-seal pouch; 1 mask tested from each make/model; experiments run in quadruplicate (8 total masks) | Not assessed | Filter penetration not significantly increased<br>No cycle abortion | Facial fit not assessed<br>Aluminum nosebands were slightly tarnished and visibly not as shiny |
| Viscusi et al,[55] 2009 | 3M 1860, 3M 1870, 3M 8000, 3M 8210, 3M 8293, Moldex-Metric 2200, Moldex-Metric 2360, Kimberly-Clark PFR95-270, North 8150 | Advanced Sterilization Products STERRAD 100S $H_2O_2$ gas plasma sterilizer<br>Standard cycle<br>Volume: 3.5 $ft^3$ (0.1 $m^3$)<br>Concentration: 58% $H_2O_2$<br>Temperature: 45 °C to 55 °C<br>Total time: 55 min | Individual N95 and chemical indicator placed in an individual Tyvek/Mylar self-seal pouch; 3 masks from each make/model tested, 27 total masks | Not assessed | No significant changes to performance (filter aerosol penetration and filter airflow resistance)<br>No cycle abortion | Facial fit not assessed<br>Metallic nosebands were slightly tarnished and visibly not as shiny compared with controls |
| Bergman et al,[8] 2010 | 3M 1860S, 3M 1870, 3M 8000, 3M 8210, Moldex-Metric 2201, Kimberly-Clark PFR95-174 | Bioquell Room Bio-Decontamination Service Clarus R VHP generator<br>Volume: 64-$m^3$ room<br>Concentration: 30% $H_2O_2$, 8 g/$m^3$<br>Time: 15-min dwell, 125-min total cycle time, aeration run overnight | 6 N95 respirators hung on a string stretching across a room; 6 masks from each make/model tested, 36 total masks | *Geobacillus stearothermophilus* spores reduced $10^6$ following treatment | Three-cycle processing caused no change in filter performance<br>No cycle abortion | Facial fit not assessed<br>Three-cycle processing caused no change in physical appearance |
| | | Advanced Sterilization Products STERRAD 100S $H_2O_2$ gas plasma sterilizer<br>Short cycle<br>Concentration: 59% $H_2O_2$<br>Temperature: 45 °C to 50 °C<br>Total time: approximately 55 min | 6 N95s packaged in Steris Vis-U-All Low Temperature Tyvek pouches with chemical indicator strip; 6 masks from each make/model tested, 36 total masks | Not assessed | X HPGP<br>Treatments resulted in mean penetration levels >5% for 4 of 6 N95 models; associated with the stacking order of the N95s in the sample pouch<br>No cycle abortion | Facial fit not assessed<br>No gross physical damage |
| | | Advanced Sterilization Products STERRAD 100S $H_2O_2$ gas plasma sterilizer<br>Short cycle<br>Concentration: 59% $H_2O_2$<br>Temperature: 45 °C to 50 °C<br>Total time: approximately 55 min | 6 N95s packaged in Steris Vis-U-All Low Temperature Tyvek pouches with chemical indicator strip; 6 masks from each make/model tested, 36 total masks | Not assessed | 3X HPGP<br>Treatments resulted in mean penetration levels >5% for 4 of 6 N95 models; associated with the stacking order of the N95s in the sample pouch<br>No cycle abortion | Facial fit not assessed<br>No gross physical damage |
| Salter et al,[47] 2010 | NIOSH- and FDA-approved N95 respirators (surgical [S1-S3]; particulate [P1-P3]) | Advanced Sterilization Products STERRAD 100S system<br>Temperature: 45 °C to 55 °C<br>Time: 55 min, 18-h aeration, total time: 19 h | Triplicate N95s packaged individually in sterilization pouches with sterilization indicator; 3 masks from each make/model tested, 18 total masks | Not assessed | VHP left approximately 1 mg of oxidant on the respirators, mostly on the filtration medium of P1, P2, and P3; unlikely to be a health hazard<br>Cycle aborted whenever >6 N95s were loaded in the chamber | Facial fit not assessed |
| FDA/Batelle,[41] 2016 | 3M 1860 | Bioquell Clarus C VHP Generator<br>Volume: 310-L (0.31-$m^3$) exposure chamber<br>Concentration: 30%-35% $H_2O_2$<br>Time: 10-min conditioning phase, 20-min gassing phase at 2 g/min; 150-min dwell phase at 0.5 g/min and 300-min aeration phase; total time: 8 h | N95s suspended in chamber by elastic straps; 5 masks tested | VHP cycle established for complete inactivation of $10^6$ *G stearothermophilus* spores following 50 repeat cycles | Filter penetration and airflow resistance unchanged after 50 cycles<br>>3 h of aeration needed for residual $H_2O_2$ to be below permissible exposure limit<br>No cycle abortion | Fit unaffected for up to 20 VHP cycles (tested on manikins)<br>No visible degradation after 10-20 VHP cycles<br>More than 30 cycles caused the elastic straps to degrade when stretched |

*(continued)*

Table 2. Vaporized Hydrogen Peroxide (VHP): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | VHP device, volume, concentration, time | Surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Fischer et al,[13] 2020 | VHP decontamination: AOSafety N9504C; mask integrity: 3M Aura Particulate Respirator 9211+/37193 | Panasonic MCO-19AIC-PT incubator with VHP generation capabilities<br>Exposed to VHP (approximately 1000 ppm) for 10 min after inactivation of $H_2O_2$ | One mask coupon from each make/model tested; experiments run in triplicate (6 total coupons) | SARS-CoV-2 inactivated rapidly (>$10^4$ reduction) on both N95 fabric and stainless steel (in 10 min) | Filtration performance not reduced after 2 rounds of decontamination and 2 h of wear | Maintained acceptable performance after 3 rounds (fit factor >100) |
| Kumar et al,[27] 2020 | 3M VFlex 1804, 3M 1860, 3M Aura 1870, 3M 8210, 3M 9210, AOSafety 1054S | VHP: Steris ARD System<br>Concentration: 35% $H_2O_2$<br>Cycle time: 1-h cycle (including 20-min aeration) and 5-h cycle (including 45-min aeration) | One mask coupon from each make/model tested; experiments run in triplicate (18 total coupons) | Complete inactivation (>$10^6$) of vesicular stomatitis virus<br>Complete inactivation of SARS-CoV-2 with 5-h cycle | No significant effects on filtration efficiency through 10 cycles | Fit factor >100 for 10 cycles<br>No qualitative damage observed |
| | | Gas plasma: Advanced Sterilization Products STERRAD 100NX sterilizer<br>Concentration: 59% $H_2O_2$<br>Cycle time: 47 min (no aeration required) | One mask coupon from each make/model tested; experiments run in triplicate (18 total coupons) | Complete inactivation (>$10^6$) of vesicular stomatitis virus | Significant effects on filtration efficiency at 1-10 cycles | Fit factor >100 for 1 cycle<br>No qualitative damage observed |
| Saini et al,[43] 2020 | N95 class | Radiant Innovations SATEJ Plus machine VHP generator<br>Volume: 111-$m^3$ room<br>Concentration: 7%-8% $H_2O_2$<br>Time: 10-min cycle, 2-h aeration; total time, 130 min | Number of masks tested not specified | Complete sterilization of *Escherichia coli* and >$10^7$ reduction in *Mycobacterium smegmatis*<br>Successful disinfection of *G stearothermophilus* spores | Scanning electron microscope demonstrated no change in fiber thickness or damage to outer and melt-blown layers essential for filtration after 15 cycles | Facial fit not assessed<br>No physical tear or deformity noted<br>No change in comfort |
| Smith et al,[16] 2020 | 3M 1860, 3M 1870+, 3M 8511 | Bioquell Z vaporizer chamber<br>Concentration: 30% $H_2O_2$<br>Volume: 30% whole-room VHP<br>Time: 20 min at 10 g/min reaching approximately 500 ppm; dwell at 4 g/min for 60 min at approximately 420 ppm and aeration for 210 min until reaching safe entrance levels <1 ppm; total time, 290 min<br>Relative humidity: 38%-99.5% | N95s placed on a metal rack, exterior surface facing upward; 1 mask tested from each make/model, 3 total masks | SARS-CoV-2 RNA was detected on all masks exposed to virus<br>VHP treatment of the 3M 1860 and 3M 1870+ N95s appeared virucidal ($10^5$ reduction of SARS-CoV-2), while treatment of the 3M 8511 was not | Filtration efficacy not assessed | Across all N95s, 2 cycles of VHP maintained an average fit score of ≥100 with minimal, non-statistically significant degradation of mask components |
| Russo et al,[46] 2020 | 3M 1860, 3M 1860S, 3M 1870, 3M 1870+, 3M 9210, Cardinal Health, Gerson 2130, Gerson 1730, Halyard Fluidshield 46727, Halyard Fluidshield 46827 | Steris VHP Victory system<br>Concentration: 35% $H_2O_2$<br>Time: 4.5-h/cycle conditioning, sterilizing and dwelling; overnight aeration (15-18 h) | N95s hung on racks, stacked, placed in paper bags, or covered with makeup or moisturizer in 2400-$ft^3$ facility; 1250 masks tested of different models (5 validation runs) | Successful decontamination using biological and chemical indicators<br>Stacking in piles of up to 6 reduced time needed to arrange FFRs by two-thirds while tripling facility capacity<br>Makeup and moisturizers did not interfere with decontamination | Filtration efficacy not assessed | Facial fit not assessed |
| Grillet et al,[26] 2020 | 3M 1860, 3M1870+ Aura | Bioquell Clarus C system<br>Concentration: 30% $H_2O_2$<br>Time: 129 min/cycle and aeration | N95s suspended on racks in room; 25 masks tested | Not assessed | No reduction in filtration performance | Manikin fit factor testing >100 (3M 1870+) |
| Jatta et al,[39] 2020 | 3M 8211, 3M 9210 | Steris V-PRO maX low-temperature sterilization system<br>Concentration: 59% $H_2O_2$<br>Time: 28 min/cycle (sterilizing, conditioning, and aeration); total time, 28 min | Masks placed on 2 shelves in sterilizer with sterilization indicator; 2 masks from each make/model, 4 total masks | Not assessed | No significant effects on filtration efficiency for up to 10 cycles | No significant effects on quantitative fit<br>No odor or facial irritation |

(continued)

Table 2. Vaporized Hydrogen Peroxide (VHP): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | VHP device, volume, concentration, time | Surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Levine et al,[44] 2021 | Halyard Fluidshield 46727, 3M 1860, 3M 1860S, 3M 1870, 3M 9210 | Steris VHP Victory system<br>Concentration: 35% $H_2O_2$<br>Time: 3 h/cycle, overnight aeration | N95s hung in room; number of masks tested not specified | Not assessed | Filtration efficacy not assessed | Average fit score of ≥100 maintained up to 8 cycles with 3M 1860 and 3M 1860S<br>Fit factor <100 for 3M 9210 and Halyard Fluidshield 46727<br>4 of 5 FFRs maintained fit when lightly worn and decontaminated for 6 cycles and fit tested by a second user<br>No physical tear, elastic defects, or deformity noted |
| Lieu et al,[40] 2020 | 3M 1860, 3M 1860s, 3M 1870+, Moldex-Metric 1510, Moldex-Metric 1511, Moldex-Metric 1517, Moldex-Metric 1512, ProGear 88020 | Steris V-PRO maX low-temperature sterilization System<br>Concentration: 59% $H_2O_2$<br>Time: 28 min/cycle (sterilizing, conditioning, and aeration); total time, 28 min | Each N95 separately placed in a Tyvek 8 × 14-in pouch; 1 mask each tested on 36 individuals, 36 total masks | Not assessed | Filtration efficacy not assessed | Median number of cycles of respirator fit test or mechanical failure was 2<br>Prolonged use and VHP decontamination associated with early failure<br>User seal check failed to predict test failure in 14 of 18 cases (78%) |
| Peltier et al,[30] 2020 | 3M 1860, 3M 1860S | VHP: Battelle Critical Care Decontamination System, Bioquell, Steris V-PRO maX II<br>Cycle times: 28-150 min | 13 masks tested | Not assessed | VHP systems retained filter performance | Facial fit not assessed |
| | | Gas plasma: hydrogen peroxide (Advanced Sterilization Products STERRAD 100S, STERRAD 100NX Express/Standard)<br>Concentration: 90% $H_2O_2$ (STERRAD 100NX)<br>Cycle times: 28-55 min | 7 masks tested | Not assessed | Sterrad 100NX Express treatment retained filter performance<br>Sterrad 100S and 100NX Standard degraded filter performance | Facial fit not assessed |
| Richardson et al,[42] 2020 | 10 NIOSH-approved N95s | Batelle Critical Care Decontamination System<br>5, 10, and 20 cycles (donned/doffed after each VHP cycle) | 12 masks from each make/model, 120 total masks | Not assessed | Filtration efficacy not assessed | Facial fit not assessed<br>Strap integrity: measured strap loads at 50% and 100% strains after 20 cycles were similar to controls<br>At 200% strains, greater changes were observed, but this strain is likely higher than that experienced during wear |
| Rohit et al,[29] 2020 | Not specified | Advanced Sterilization Products STERRAD 100NX<br>Total time: 72 min; aerated in an opened pouch for 1 h | 6 masks from each make/model; experiments run in triplicate, 54 masks total | Not assessed | No significant effects on fitted filtration efficiency for 1 cycle | Facial fit not assessed |
| Sickbert-Bennett et al,[63] 2020 | 3M 1860 | Device not specified<br>Time: 8 g/min, 260 ppm; 100-min cycle | 1 mask tested | Not assessed | No significant effects on fitted filtration efficiency for 1 cycle | Poor facial fit led to reduced fitted filtration efficiency (90%-95%) |

Abbreviations: FDA, US Food and Drug Administration; FFR, filtering facepiece respirator; HPGP, Hydrogen peroxide gas plasma; NIOSH, National Institute for Occupational Safety and Health.

rapid virucidal reduction in virus was demonstrated while preserving filtration performance and fit after 2 cycles of treatment.[13,16] In the other study, VHP led to complete inactivation of SARS-CoV-2, although an extended 5-hour cycle time was required, compared with 1 hour for vesicular stomatitis virus.[27] Results regarding toxicity are available in eAppendix 3 in the Supplement.

#### FFR Damage, Process Time, Scalability, and Cost

Open-room systems, the Panasonic incubator, and the Steris V-PRO maX system resulted in better FFR filter efficiency and facial fit than did the STERRAD chamber system. In the 6 studies investigating physical appearance and filter performance after STERRAD system treatments, changes to the nosebands or significant reduction in filtration performance were observed (Table 2). When this system was examined with a 3-cycle treatment of 6 N95 respirator models, mean penetration levels increased above the NIOSH certification limit of 5% in 4 of 6 mask models. High exposure from the $H_2O_2$ gas plasma processing conditions may have resulted in reduced filter performance.[8,27,30] There were no physical changes or reduction in filtration ability when open-room VHP systems were used[8,26,27,43] or when FFRs were suspended or placed in exposure chambers.[16,29,30,41] Filtration performance and fit was not reduced after 2 rounds of decontamination and 2 hours of wear using the Panasonic incubator[13] or after 10 cycles with the Steris V-PRO maX sterilization system.[30,39] However, one recent study demonstrated the combination of prolonged clinical FFR use and chamber VHP decontamination to be associated with early mechanical and fit test failure,[40] while another study demonstrated fit test failure with several FFR models after repeated decontamination cycles (Halyard FLUIDSHIELD 46727) and when the mask was worn prior to decontamination (3M 1870).[44]

High-capacity throughput is currently performed using dedicated VHP systems for whole-room decontamination (>1000 N95 respirators per cycle[43,45,46]), although prolonged treatment and aeration times are required. The processing capability of VHP chamber systems may be limited by the volume of the chamber and the specific types of materials that FFRs are made of. Cellulose materials, such as cotton, absorb hydrogen peroxide and can cause the STERRAD device to stop because of low VHP concentrations within the chamber. This was observed in one study in which the sterilization cycle aborted when more than 6 N95 respirators were loaded into the device.[47] However, the respirators in that study were made primarily of polyesters and polyolefins, so the reason the device aborted was not clear. These devices are expensive for both chamber and open-room systems ($40 000-$130 000).[48,49]

## Moist-Heat Incubation

Heat inactivates viruses by denaturing the proteins involved in attachment and replication within a host cell. However, concerns exist regarding the deleterious effects dry heat may have on certain materials, including those that comprise N95 respirators. Moist heat, on the other hand, is more effective at killing microorganisms, it distributes homogeneously across the surface being sterilized, and the lower temperature is less likely to degrade materials.

#### Effectiveness of Decontamination and Sterilization Processes

Nine studies evaluated infectious and mask integrity outcomes after MHI on 15 contaminated N95 respirators (**Table 3**). Three studies used a Caron model 6010 laboratory incubator, 2 used preheated 6-L sealable containers filled with 1 L of water, 2 used a heated cabinet, and 2 used a preheated chamber. In 5 of the 7 studies, moist heat was generated at 60 °C to 70 °C, relative humidity of 50% to 90%, and incubation times lasting 15 minutes to 30 minutes, with outcomes evaluated after 1 to 3 treatment cycles. Moist-heat decontamination was also evaluated using heated cabinets at 70 °C to 90 °C, with 0% to 70% relative humidity, and a 60-minute incubation cycle for up to 15 cycles,[27,50] and in another study, a preheated chamber at 85 °C, with 30% and 100% relative humidity, was evaluated using a 20-minute incubation cycle for up to 20 cycles.[28]

Of these studies, 1 reported infectious outcomes for N95 respirators contaminated with SARS-CoV-2 and *E coli*, 1 reported infectious outcomes for N95 respirators contaminated with SARS-CoV-2 and vesicular stomatitis virus, and 2 reported infectious outcomes for FFRs contaminated with influenza virus using a preheated 6-L water filled container. Moist-heat incubation effectively reduced SARS-CoV-2, *E coli*, and vesicular stomatitis virus after 60-minute incubation periods[27,50] and effectively reduced influenza A(H5N1) and influenza A(H1N1) viruses to undetectable limits after 20-minute[6] and 30-minute[7] incubation periods, respectively. The infectious outcomes for contaminated straps were not reported.

#### FFR Damage, Process Time, Scalability, and Cost

No signs of damage were found when FFR filter efficiency and facial fit were tested after 1 cycle or 50 cycles of container/chamber incubation.[6,7,28] Filter performance was not reduced following 10 or 15 cycles of treatment in a heated cabinet.[26,50] Similarly, there was no reduction in facial fit and comfort after 10 cycles.[26,50] In contrast, when FFRs were decontaminated in Caron incubators, 1 to 3 cycles of 15- to 30-minute treatment did not alter filter performance or fit testing, but significant physical degradation was observed with 3M 1870 N95 respirators. The 3M devices had partial separation of the inner foam nose cushion from the FFR body and melting of head straps.[8,23,51] The 3M devices did not degrade when treated by preheated container incubatation.[6] In the same study, one 30-minute incubation cycle resulted in significantly impaired fit in 2 of 6 N95 respirators (3M 8210 and Moldex-Metric 2200) tested; however, the quantitative fit factors (measuring particle leakage around the face seal) for these masks were still greater than 100, suggesting that the masks provided adequate protection against infection.[23]

Treatment with MHI uses readily available equipment, requires short exposure times, and can be easily implemented in most health care settings. The commercially available Caron incubator device for MHI treatment is expensive (approximately $9000-$23 000),[52,53] the processing volume of its incubation chamber is small, long preheating times are required, and physical damage to the FFRs can occur.[8,23]

## Microwave-Generated Steam

Steam treatment is a known method for inactivating viruses on surfaces. Microwave-generated steam is an alternative to standard steam treatment, as much of the energy formed from microwave radiofrequency can be absorbed by water, reducing the potential of damaging N95 respirator materials.[54] A single N95 respirator is

Table 3. Moist-Heat Incubation (MHI): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators

| Source | Mask (make and model/type) | MHI device, volume | MHI temperature, humidity, time, surface tested | Decontamination results | Mask integrity outcome | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Bergman et al,[8] 2010 | 3M 1860S, 3M 1870, 3M 8000, 3M 8210, Moldex-Metric 2201, Kimberly-Clark PFR95-174 | Caron 6010 laboratory incubator | Temperature: 60 °C<br>Relative humidity: 80%<br>Time: 30-min incubation (3 cycles)<br>Surface tested: N95 samples removed from incubator and air dried overnight; 3 masks from each make/model, 18 total masks | Not assessed | Three-cycle processing caused no change in filter aerosol penetration or airflow resistance | Facial fit not assessed<br>All 3M 1870 samples had partial separation of inner foam nose cushion from the N95<br>Two had melting of head straps |
| Lore et al,[6] 2012 | 3M 1860S, 3M 1870 | Thermo Fisher Scientific 6-L sealable container filled with 1 L of tap water | Temperature: 65 °C ± 5 °C<br>Relative humidity: 80%<br>Time: Preheated in oven for 3 h, 20-min incubation in oven<br>Surface tested: single N95 placed on oven rack with convex surface pointed toward water layer; 9 masks from each make/model; experiments run in triplicate (18 total masks) | No viable influenza virus detectable on facepiece (>$10^4$ reduction)<br>Greater detectable viral RNA levels than UV germicidal irradiation<br>Results similar to 2-min treatment with microwave-generated steam<br>Straps and nose clip not assessed | No reduction in filtration performance | Facial fit not assessed<br>No gross physical damage[a] |
| Heimbuch et al,[7] 2011 | 3 particulate (P1-P3), 3 surgical (S1-S3) | 6-L sealable container filled with 1 L of tap water | Temperature: 65 °C ± 5 °C<br>Relative humidity: 85% ± 5%<br>Time: Preheated in oven for 3 h, 30-min incubation in oven<br>Surface tested: N95 placed on plastic support rack in water to isolate N95 from liquid; 1 mask from each make/model); experiments run in 6 replicates (36 total masks) | >$10^4$ reduction in viable influenza A(H1N1) virus | Filtration efficacy not assessed | Facial fit not assessed<br>No gross physical damage |
| Bergman et al,[51] 2011 | 3M 1860, 3M 1870, Kimberly-Clark PFR95-270 | Caron 6010 laboratory incubator | Temperature: 60 °C<br>Relative humidity: 80%<br>Time: 15-min incubation (3 cycles)<br>Surface tested: 10 masks from each make/model for 4 donning trials; experiments run in duplicate (60 total masks) | Not assessed | Filtration efficacy not assessed | Mean face-seal leakage <1%<br>Fit test passing rate (fit factor >100) ranged from 90% to 100% and varied by N95 model<br>3M 1870 had slight separation of inner foam nose cushion |
| Viscusi et al,[23] 2011 | 3M 1860, 3M 1870, 3M 8000, 3M 8210, Moldex-Metric 2200, Kimberly-Clark PFR95-270 | Caron 6010 laboratory incubator | Temperature: 60 °C<br>Relative humidity: 80%<br>Time: 30-min incubation<br>Surface tested: following treatment, N95s dried overnight on laboratory benchtop; 10 masks from each make/model: experiments run in duplicate (120 total masks) | Not assessed | Filtration efficacy not assessed | Two of 6 N95s had statistically significant reduction in fit but fit factor still ≥100<br>One N95 demonstrated statistically significant increase median odor response; not clinically significant<br>3M 1870 masks had slight separation of inner foam nose cushion |
| Daeschler et al,[50] 2020 | 3M 1860S, 3M 8110S, 3M 8210, 3M 9105S | BevLes heated holding cabinet | Temperature: 70 °C<br>Relative humidity: 0%-70%<br>Time: 60-min incubation<br>Surface tested: N95s dried overnight on laboratory benchtop; 1 mask coupon (1 $cm^2$) from each make/model; experiments run in triplicate (12 total coupons) | No infectious SARS-CoV-2 detected after dry-heat treatment (70 °C for 60 min)<br>No infectious *Escherichia coli* detected after 70 °C at 50% relative humidity or 90 °C at 70% relative humidity | No effect on mean overall fiber diameter on scanning electron microscopy after 10 cycles<br>No reduction in filtration performance after 15 cycles (0% and 50% relative humidity) | Subjective fit and wearing comfort did not differ from new masks (rated 0 [no issues] on Comfort Assessment Score) after 10 cycles |

(*continued*)

Table 3. Moist-Heat Incubation (MHI): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | MHI device, volume | MHI temperature, humidity, time, surface tested | Decontamination results | Mask integrity outcome | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Kumar et al,[27] 2020 | 3M VFlex 1804, 3M 1860, 3M Aura 1870, 3M 8210, 3M 9210, AOSafety 10545 | Imperial Surgical/SurgMed Group OR-7854 warming cabinet | Temperature: 70 °C and 75 °C<br>Relative humidity: 22%<br>Time: 1 h and 3 h incubation<br>Surface tested: 1 mask coupon from each make/model; experiments run in triplicate (18 total coupons) | Complete inactivation (>$10^6$) of vesicular stomatitis virus<br>Complete inactivation of SARS-CoV-2 with 3 h at 75 °C and 22% relative humidity | No significant effects on filtration efficiency for 10 cycles | Fit factor >100 for 10 cycles<br>No qualitative damage observed |
| Grillet et al,[26] 2020 | 3M 1860, 3M 1870+ Aura | Memmert HCP 150 chamber | Temperature: 60 °C<br>Relative humidity: 85%<br>Time: 40 min in chamber and then dried<br>Surface tested: 25 masks | Not assessed | No significant effects on filtration efficiency | Manikin fit factor testing >100 (3M 1870+) |
| Liao et al,[28] 2020 | Melt-blown fabric: Guangdong Meltblown Technology[b]; N95-grade FFRs: 3M 8210 | ESPEC SH-642 preheated 5-sided heating chamber | Temperature: 85 °C<br>Relative humidity: 30%, 70%, 100%<br>Time: 20-min incubation (10-min resting time between cycles)<br>Surface tested: 30 melt-blown fabric samples | Not assessed | No reduction in filtration performance after 50 cycles on melt-blown fabric at any humidity[b]<br>No reduction in filter performance at 30% and 100% relative humidity after 20 cycles on N95-grade FFRs | No qualitative change in fit or strap elasticity |

Abbreviation: FFR, filtering facepiece respirator.

[a] Melt-blown fabric represents the most critical filtering layer of an N95 respirator with initial efficiency ≥95%, representative of how the filtration efficiency in an N95 respirator may change given exposure to these treatments in a worst-case scenario (no protective layer of the FFR). Used because of the shortage of FFRs during the study period.

[b] Visible damage on an FFR may not translate to a change in facial fit.

placed outer side down on top of a reservoir filled with 50 mL to 100 mL of room-temperature tap water and then placed on a rotating glass plate in the microwave to allow generated steam to distribute over the respirator surface. The operator uses a respirator holder placed above the water source to generate the steam needed to reduce the risk of degradation when using dry heat.[54,55]

### Effectiveness of Decontamination and Sterilization Processes

Ten studies evaluated decontamination and filter performance for various pathogens following MGS decontamination of at least 10 FFR models (**Table 4**), but none studied SARS-CoV-2. A commercially available microwave was used in 9 of 10 studies. Devices ranged from 1100 W to 1800 W and were run at high power for various time ranging from 15 seconds to 3 minutes. In these studies, MGS effectively decontaminated FFRs for influenza virus (2 studies), MS2 bacteriophage (3 studies), and *S aureus* (1 study). Steam generated in 1100-W to 1800-W devices for 40 seconds to 3 minutes reduced MS2 bacteriophage, influenza A(H5N1), and influenza A (H1N1) virus counts by a factor of $10^3$ to $10^4$ and *S aureus* by $10^6$.[6,7,56-58] Microwave-generated steam was effective even when proteins such as those found in saliva or skin oil were present that tend to protect pathogens from decontamination.[56,59] Contaminated FFR straps had a $10^5$ reduction in viable MS2 bacteriophage following exposure to 2 minutes of MGS.[57]

### FFR Damage, Process Time, Scalability, and Cost

Filter performance, respirator fit, and comfort were not affected by 1 to 3 cycles of MGS treatment in 5 studies[6,8,23,51,58] and for up to 20 cycles in 1 study.[57] However, FFR damage was observed in 4 studies. In 3 of these, 3M 1870 respirators had partial separation of the inner foam nose cushion from the FFR,[8,23,51] and in 2 studies, the 3M 1870 and Kimberly-Clark PFR95-270 respirator head straps melted.[8,51] Deformation of the FFR foam nose cushion was observed in a study evaluating an N95 respirator after a 2-minute MGS cycle using a 1250-W microwave oven, yet the elastic straps were unaffected.[7] In a study using a commercially available 1250-W Panasonic microwave to generate steam, a single 2-minute treatment of the 3M 1860 and 3M 1870 N95 respirator models did not result in any gross physical damage.[6] No microwave sparking from the metallic noseband material was observed in any studies.

Microwave-generated steam as a means of FFR decontamination is advantageous because of short exposure times and uses inexpensive, readily available equipment.[60,61] However, if greater water reservoir volume is used to generate steam, more time is needed to produce the adequate amount of steam. Only 1 FFR can be processed at a time because of the small interior space of commercially available microwaves.

## Ethylene Oxide

Ethylene oxide is a sterilant gas with bactericidal, sporicidal, and viricidal activity commonly used in health care for medical equipment and supplies.[62] The broad material compatibility of ethylene oxide makes it compelling when considering N95 respirator decontamination, but risks are present involving safety and handling of a flammable and hazardous gas and residue control following sterilization.[47] Furthermore, these processing systems may not be present at or close to many health care centers.

Table 4. Microwave-Generated Steam (MGS): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators

| Source | Mask (make and model/type) | Device | Power, time, surface tested | Decontamination results | Mask integrity outcome | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Fisher et al,[56] 2009 | NIOSH-approved N95 | Sharp Electronics R-305KS commercially available microwave oven, 2450 MHz | Power: 1100 W<br>Time: 0, 15, 30, 45, 60, 75 s at high power<br>Surface tested: N95 coupons placed over pipette tip boxes with 50 mL of room-temperature tap water; 6 mask coupons | Steam treatments of >45 s resulted in >$10^4$ reduction of MS2 bacteriophage in the presence of organic protective factors | Filtration efficacy not assessed | Facial fit not assessed |
| Fisher and Shaffer,[59] 2010 | 3M 1860 | Sharp Electronics R-305KS commercially available microwave oven, 2450 MHz | Power: 1100 W<br>Time: 40 s at high power (3 cycles)<br>Surface tested: coupons (5 $cm^2$) 2.5 cm above water placed over pipette tip box with 50 mL of room-temperature tap water; 6 mask coupons | MS2 bacteriophage inactivation efficacy was similar for all 3 cycles regardless of soil accumulation | Filtration efficacy not assessed | Facial fit not assessed |
| Bergman et al,[8] 2010 | 3M 1860S, 3M 1870, 3M 8000, 3M 8210, Moldex-Metric 2201, Kimberly-Clark PFR95-174 | Sharp Electronics R-305KS commercially available microwave oven, 2450 MHz | Power: 1100 W<br>Time: 2 min total exposure at power setting of 10 (maximum) (3 cycles)<br>Surface tested: N95 placed outer side down on top of pipette tip boxes filled with 50 mL of room-temperature tap water (approximately 20 °C); N95s dried 1 h between each exposure; 3 masks from each make/model, 18 total masks | Not assessed | Three-cycle processing caused no change in filter aerosol penetration or airflow resistance | Facial fit not assessed<br>All 3M 1870 samples had partial separation of inner foam nose cushion from N95 and 2 had melting of head straps following first cycle<br>No sparking from metallic noseband |
| Fisher et al,[75] 2011 | 3M 1870, 3M 1860, Kimberly-Clark PFR95, 3M 8210, Cardinal Health, Moldex-Metric 2200 | Sharp Electronics R-305KS commercially available microwave oven, 2450 MHz | Power: 1100 W<br>Time: 90 s at high power<br>Surface tested: individual N95s placed inside separate sealed bags filled with 60 mL of tap water; 9 masks tested for filtration; 6 masks tested for decontamination | $10^3$-$10^4$ reduction in surrogate MS2 bacteriophage virus | Filtration performance not affected after 3 cycles (>95%) | Facial fit not assessed |
| Heimbuch et al[7] 2011 | 3 particulate (P1-P3), 3 surgical (S1-S3) | Microwave oven (make/model not specified) | Power: 1250 W<br>Time: 2-min exposure<br>Surface tested: N95s placed outer-side down on the surface on top of 2 reservoirs with perforated tops (each filled with 50 mL of tap water at 22 °C to 25 °C); 1 mask from each make/model; experiments run in 6 replicates (36 total masks) | >$10^4$ reduction in viable influenza A(H1N1) virus-contaminated N95s | Filtration efficacy not assessed | Facial fit not assessed<br>Slight deformation of foam nose cushion in type S2<br>No sparking from metallic noseband |
| Bergman et al,[51] 2011 | 3M 1860, 3M 1870, Kimberly-Clark PFR95-270 | Sharp Electronics R-305KS commercially available microwave oven, 2450 MHz | Power: 1100 W (manufacturer rated); 750 W/$ft^3$<br>Time: 2-min exposure at power setting of 10 (maximum) (3 cycles)<br>Surface tested: N95s placed outer side down on top of 2 pipette tip boxes filled with 50 mL of room- temperature tap water (approximately 20 °C); 10 masks from each make/model for 4 donning trials; experiments run in duplicate (60 total masks) | Not assessed | Filtration efficacy not assessed | Fit test pass rate (fit factor >100) ranged from 90% to 100% and varied by N95 model; mean face-seal leakage <1%<br>3M 1870 samples had slight separation of inner foam nose cushion<br>One head strap melted in a Kimberly-Clark PFR95-270 sample during third cycle<br>No sparking from metallic noseband |

(continued)

Table 4. Microwave-Generated Steam (MGS): Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators (continued)

| Source | Mask (make and model/type) | Device | Power, time, surface tested | Decontamination results | Mask integrity outcome | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficacy | Facial fit |
| Viscusi et al,[23] 2011 | 3M 1860, 3M 1870, 3M 8000, 3M 8210, Moldex-Metric 2200, Kimberly-Clark PFR95-270 | Sharp Electronics R-305KS commercially available microwave oven, 2450 MHz | Power: 1100 W; 750 W/ft$^3$ experimentally measured<br>Time: 2-min total exposure at a power setting of 10 (maximum)<br>Surface tested: N95s placed outer side down on top of 2 side-by-side pipette tip boxes with 50 mL of room-temperature tap water (20 °C); 10 masks from each make/model; experiments run in duplicate (120 total masks) | Not assessed | Filtration efficacy not assessed | No clinically meaningful reduction in fit, increase in odor, increase in discomfort, or increased difficulty in donning<br>3M 1870 samples had slight separation of inner foam nose cushion<br>No sparking |
| Lore et al,[6] 2012 | 3M 1860S, 3M 1870 | Panasonic commercially available microwave oven, 2450 MHz | Power: 1250 W<br>Time: 2 min at full power<br>Surface tested: N95s placed outer side down toward steam source in a plastic box filled with 50 mL of room-temperature tap water; 9 masks from each make/model; experiments run in triplicate (18 total masks) | No viable virus detectable<br>>$10^4$ reduction of influenza A(H5N1) virus<br>Straps and nose clip not assessed | No reduction in filtration performance | Facial fit not assessed<br>No gross physical damage[a]<br>No sparking from metallic noseband |
| Pascoe et al,[58] 2020 | Kimberly-Clark, Fluidshield (N95 model not specified) | Panasonic NE-1853 commercially available microwave oven, 2450 MHz | Power: 900 W, 1800 W<br>Time: 60-120 s<br>Surface tested: 100-200 mL deionized water in reservoir; 4 total masks tested for filtration, 9 samples tested for decontamination | $10^6$ reduction in *Staphylococcus aureus* with 1800 W within 60-90 s | Filtration performance not affected after 3 cycles | Facial fit not assessed |
| Zulauf et al,[57] 2020 | 3M 1860 | Microwave oven with turntable (make/model not specified) | Power: 1100 W, 1150 W<br>Time: 1-min, 2-min, and 3-min exposure<br>Surface tested: N95s placed outer side down suspended directly above a 10-cm-diameter ceramic mug and a 17 × 17 × 7.5-cm glass container filled with 60 mL of distilled water, both covered with mesh secured with a rubber band; 1 mask coupon, tested in triplicate | Mug: no detectable MS2 bacteriophage after 3 min on single N95 coupon; >$10^4$ reduction in MS2 bacteriophage on entire N95 except elastic straps ($10^1$-$10^3$ reduction) after 3 min<br>Glass container: no detectable viable MS2 bacteriophage after 2 min on all N95 coupons; >$10^5$ reduction in MS2 bacteriophage on entire N95<br>Average $10^6$ viral load reduction | Filtration efficacy not assessed | No degradation of respirator fit and filtration performance (fit factor >100) for up to 20 three-minute cycles<br>No odor or water retention detected after treatment<br>No sparking from metallic noseband |

Abbreviation: NIOSH, National Institute for Occupational Safety and Health.

[a] Visible damage on a filtering facepiece respirator may not translate to a change in facial fit.

### Effectiveness of Decontamination and Sterilization Processes

Seven studies evaluated ethylene oxide use on 15 different FFR models (**Table 5**). In 2 studies, the Steris AMSCO Eagle 3017 ethylene oxide sterilizer was used, and in 3 studies the 3M Steri-Vac (4XL and 5XL) gas sterilizer/aerator was examined. The systems operated at 54 °C to 55 °C with chamber volumes of 0.13 $m^3$ to 0.14 $m^3$. The ethylene oxide concentration ranged from 725 mg/L to 883 mg/L and treatment timed varied among 1 hour,[8,54,55] 3 hours,[47] and 12 hours.[29] Among these studies, 1 reported infectious outcomes for N95 respirators contaminated with vesicular stomatitis virus. Ethylene oxide effectively reduced vesicular stomatitis virus to undetectable limits after 1 hour of treatment.[27]

### FFR Damage, Process Time, Scalability, and Cost

In the 6 studies assessing the effect of ethylene oxide on FFR filter performance, no significant changes were observed.[8,27,29,54,55,63] While 1 to 3 cycles of processing caused no damage or change in physical appearance to the facepieces of the respirators, 725 mg/L to 883 mg/L of ethylene oxide concentrations caused the P100 (make/model unspecified) respirator straps to darken after 1 hour of treatment followed by 4 hours of aeration using the 3M Steri-Vac 4XL and 5XL ethylene oxide devices.[54]

The ability of high-volume reprocessing of FFRs with ethylene oxide for FFR decontamination has not been published in the peer reviewed literature. Ethylene oxide reprocessing of FFRs is limited by a lack of studies showing the safety and efficacy of this approach, the need for long aeration periods (>4 to 12 hours) to reliably remove hazardous ethylene oxide gas from FFR devices,[8,27,29,47,54,55,63] and the need for expensive equipment.[64] Ethylene oxide is a flammable, hazardous gas with known toxic by-products.[47,65] The CDC recommends against the use of ethylene oxide for personal protective equipment reprocessing because of the potential for harm to the wearer. Detailed results on toxicity are available in eAppendix 4 in the Supplement.

## Discussion

The COVID-19 pandemic resulted in a critical shortage of FFRs that has persisted for nearly a year. Inadequate FFR supply has resulted in widespread reprocessing of these devices. N95 respirators are designed for single use, and there are few studies of the effectiveness of reprocessing them for repeated use. The CDC recommends FFR reprocessing only in extreme circumstances, which, unfortunately, have existed for the entire duration of the COVID-19 pandemic. Out of necessity, many clinicians and institutions have adopted protocols for FFR reprocessing, but many of these have not been studied. This review summarizes the available evidence regarding FFR reprocessing. Despite a modest body of available literature, only a few studies examined the effectiveness of FFR reprocessing on SARS-CoV-2 contamination, with the remaining studies evaluating the effect of decontamination procedures on other viruses and bacteria.

Ultraviolet germicidal irradiation, VHP, MHI, and MGS processing effectively sterilize FFRs and retain filtration performance (**Box**). Ultraviolet germicidal irradiation and VHP are advantageous because they have a low risk of damaging mask components. Physical degradation and changes to the mask may occur, depending on the FFR make and model and decontamination method,[22,66] that may affect fit and decrease filter performance.[21,63,67] When clinicians use a reprocessed N95 respirator, they should inspect the entire mask for visual damage and the elastic function of the straps, ensuring a proper seal and facial fit before using the mask (Box). They should ensure that whatever process is used to reprocess the mask has been tested to confirm that adequate filtration efficiency is maintained.[30,68] Because FFR devices are made of a variety of materials and constructed in different ways, clinicians should establish that the reprocessing system in use at their facility has been tested for the specific make and model of the N95 respirator. The CDC recommends that the manufacturer be consulted about the effect of the chosen decontamination process method for the specific respirator model before reprocessing is attempted in the clinical setting. If the manufacturer cannot provide this information, the methods used to test the efficacy of reprocessing systems reported in the literature summarized in this review should be implemented by local facilities to ensure the safe operation of reprocessed FFR devices.

Ultraviolet germicidal irradiation may be one of the most practical methods for reprocessing N95 respirators. Commercially available UV light boxes and laboratory hoods are currently used in health care systems and are readily accessible.[31,32] Many health care systems have adopted whole-room UVGI decontamination systems. To date, there are limited peer-reviewed reports of this method's efficacy.[24,27,30] Closed box systems are simple to construct and may provide more reliable and reproducible UVGI dosage than whole-room decontamination systems.[69] When using UVGI for FFR decontamination, the FFR material type, design, and location of contamination on the mask should be considered to determine the optimal means for exposing the mask to UV light.[14,15] Ultraviolet light primarily decontaminates surfaces and is more effective when directed at inoculum dispersed over larger surface areas as opposed to droplets, in which clumping or stacking of organisms may occur.[18] Hydrophilic and irregular surfaces, such as occur in Gerson 1730, Sperian HC-NB095, Dentec Safety AD2N95A, 3M 1860S, and Moldex-Metric 1517 N95 respirators, may not be amenable to uniform light exposure of critical surfaces, resulting in inadequate decontamination of FFR devices by UVGI.[14,15,20,27]

Ultraviolet doses of 1 to 2 J/$cm^2$ effectively sterilize N95 respirators for most pathogens without causing degradation of mask components.[6,20-22] However, in the 3 studies specifically assessing SARS-CoV-2, higher UV doses were necessary or used,[13,14] so higher doses of UV energy might be needed for reprocessing FFRs during the COVID-19 pandemic. When reprocessing FFR using a UV box, both the interior and exterior mask surfaces must be exposed to the UV light to address potential contamination from either the external environment or the wearer. Mask material should be directly exposed to UV light and the amount of UV light delivered measured using a radiometer or colorimetric indicator. Because UV decontamination depends on exposure of the mask material to UV light energy, N95 respirators should not be stacked during the process.

Recently, the US Food and Drug Administration approved the use of VHP decontamination that is performed in either sterilization/aeration chambers or by mobile generators placed in large room spaces.[70] Vaporized hydrogen peroxide effectively decontaminated FFRs impregnated with virus including SARS-CoV-2, bacteria, and spores.[8,13,16,27,41] Filtering facepiece respirator mask integrity was maintained for up to 20 to 30 cycles of VHP open-room

Table 5. Ethylene Oxide: Decontamination Results, Filtration Efficiency, and Facial Fit Outcomes for Decontamination of Specific Makes/Models and Types of N95 Respirators

| Source | Mask (make and model/type) | Ethylene oxide device, chamber volume | Ethylene oxide concentration, temperature, time, surface tested | Decontamination results | Mask integrity outcomes | |
|---|---|---|---|---|---|---|
| | | | | | Filtration efficiency | Facial fit |
| Viscusi et al,[54] 2007 | N95 class, P100 class | 3M Steri-Vac 4XL and 5XL<br>Volume: 4.5 $ft^3$ (0.13 $m^3$), 141.5 L<br>Single warm cycle | Concentration: 725 mg/L (4XL), 883 mg/L (5XL)<br>Temperature: 55 °C (4XL), 55 °C (5XL)<br>Time: 1 h followed by 4-h aeration interval<br>Surface tested: 1 mask from each make/model; experiments run in quadruplicate (8 total masks) | Not assessed | Average penetration increased, but within NIOSH limits (<5%) | No facial fit studies<br>P100 class straps darkened[a]<br>5XL model slightly less degrading |
| Viscusi et al,[55] 2009 | 3M 1860, 3M 1870, 3M 8000, 3M 8210, 3M 8293, Moldex-Metric 2200, Moldex-Metric 2360, Kimberly-Clark PFR95-270, North 8150 | 3M Steri-Vac 5XL<br>Volume: 4.5 $ft^3$ (0.13 $m^3$), 141.5 L<br>Single warm cycle | Concentration: 725 mg/L 100% ethylene oxide gas<br>Temperature: 55 °C at 50% relative humidity<br>Time: 1 h followed by 4-h aeration interval<br>Surface tested: 3 masks from each make/model, 27 total masks | Not assessed | No significant changes to filter aerosol penetration and filter airflow resistance | No facial fit studies<br>No observable physical changes with ethylene oxide[a] |
| Bergman et al,[8] 2010 | 3M 1860S, 3M 1870, 3M 8000, 3M 8210, Moldex-Metric 2201, Kimberly-Clark PFR95-174 | Steris AMSCO Eagle 3017<br>Volume: 4.8 $ft^3$ (0.14 $m^3$)<br>High-temperature setting | Concentration: 736.4 mg/L<br>Temperature: 55 °C<br>Time: 1 h followed by 12-h aeration interval<br>Surface tested: 6 masks per pouch with a chemical indicator strip; 6 masks from each make/model, 36 total masks | Not assessed | Three-cycle processing caused no change in filter performance | No facial fit studies<br>Three-cycle processing caused no change in physical appearance |
| Salter et al,[47] 2010 | NIOSH- or FDA-approved N95s (surgical [S1-S3], particulate [P1-P3]) | Steris AMSCO Eagle 3017<br>Volume: 4.8 $ft^3$ (0.14 $m^3$) | Temperature: 54 °C<br>Time: 3 h followed by 12-h aeration interval<br>Surface tested: exposed individually in sterilization pouches with indicator strip; 3 masks from each make/model, 18 total masks | Not assessed | No filtration efficiency studies | No facial fit studies<br>Toxic residue analysis: no ethylene oxide detected on any masks, but several models contained possibly hazardous by-products (diacetone alcohol and traces of 2-hydroxyethyl acetate), possibly due to reaction with rubber[b]<br>Quantitative measurements necessary |
| Kumar et al,[27] 2020 | 3M VFlex 1804, 3M 1860, 3M Aura 1870, 3M 8210, 3M 9210, AOSafety 1054S | 3M Steri-Vac 5XL | Time: 1-h exposure followed by 12-h aeration interval<br>Surface tested: 1 mask coupon from each make/model; experiments run in triplicate (18 total coupons) | Complete inactivation (>$10^6$) of vesicular stomatitis virus<br>SARS-CoV-2 decontamination not evaluated | No significant effects on filtration efficiency through 3 cycles | Fit factor >100 for 3 cycles<br>No qualitative damage observed |
| Rohit et al,[29] 2020 | Not specified | 3M (model not specified) | Time: 12-h exposure followed by 12-h aeration interval<br>Surface tested: 6 masks from each make/model; experiments run in triplicate (54 total masks) | Not assessed | No significant effects on filtration efficiency for 1 cycle | Facial fit not assessed |
| Sickbert-Bennett et al,[63] 2020 | 3M 1860 | Device not specified | Concentration: 500 mg/L-hours<br>Temperature: 50 °C<br>Time: 16-hour cycle<br>Surface tested: 1 mask | Not assessed | No significant effects on filtration efficiency for 1 cycle | Poor facial fit led to reduced filter efficiency (90%-95%) |

Abbreviations: FDA, US Food and Drug Administration; NIOSH, National Institute for Occupational Safety and Health.

[a] Visible damage on a filtering facepiece respirator may not translate to a change in facial fit.

[b] All 15 occurrences of 2-hydroxyethyl acetate were on straps and were measured qualitatively in trace amounts.

processing.[41,43] Physical degradation and reduction in N95 respirator filter performance was observed using the STERRAD VHP system that uses small chamber sizes and higher fractions of $H_2O_2$,[8,27,30] and early fit test failure was observed with extended clinical FFR use and decontamination with the Steris V-PRO maX VHP system.[40] The use of self-seal pouches protects against VHP absorption of cellulose-based material when using small chambers. Throughput challenges using the Bioquell Clarus C hydrogen peroxide vapor generator and, in more recent studies, using VHP chamber systems have not been reported.[13,30,39] Open-room sterilization and aeration may limit cycle abortion and FFR damage while maximizing the volume of N95 respirators that can be decontaminated during a single cycle. Low levels of residual oxidant may be present on FFRs after treatment, so residual hydrogen peroxide levels should be assessed[41,47] and/or confirmed with the manufacturer to be below the established residue limit after treatment. Although this technology may support large-volume FFR decontamination efforts, scalability is limited by long treatment and aeration times and expense.

Moist-heat incubation and MGS effectively kill microorganisms by heating them. When generating moist heat using a water-filled container in an oven, preheating allows the liquid to reach the desired temperature prior to decontamination, whereas incubator and heated cabinets can be set to the desired temperature and relative humidity. These modalities distribute heat evenly across the surface being sterilized, facilitating the use of lower temperatures than otherwise needed for sterile processing and reducing the risk of damaging polymer fibers in N95 respirators. Sterilization and retention of FFR filtration and integrity are optimized by MHI performed with a relative humidity of 80% to 100% at 60 °C to 85 °C for 15 to 30 minutes or by MGS in an 1100-W to 1800-W device (the power range of commercially available microwave devices) with treatment times ranging from 40 seconds to 3 minutes.[6,50,57,58] These techniques are useful for small-scale decontamination because the equipment is readily available and the treatment times are short. However, preheating time as long as 3 hours is required for MHI, and physical damage to the N95 respirator can occur from both techniques.[8,23]

Ethylene oxide was a common means for processing equipment not amenable to steam sterilization. It fell out of favor because of risks with the handling of flammable and hazardous gases and residual potential toxic by-products.[47,65] Nevertheless, it can be used to reprocess N95 respirators. Studies show that ethylene oxide effectively sterilizes bacteria and viruses from FFRs and surfaces,[27,62] and filter performance is preserved after 1 to 3 cycles of ethylene oxide treatment.[8,27,29,63] Lengthy aeration cycles lasting more than 4 hours are needed to vent toxic ethylene oxide, limiting how many masks can be processed in a timely manner. The CDC's guidance recommends against the use of ethylene oxide due to the risk of inhalation by the wearer, as its carcinogenic and potentially teratogenic toxicity are unresolved concerns.

N95 respirators are highly effective at reducing the transmission of viral infection.[2] However, when the demand for these devices is unusually high, as has occurred during the COVID-19 pandemic, there may be a need to reuse these devices that were originally intended for single use. Fortunately, research performed to date has shown that as a general proposition, N95 respirator decontamination processes are feasible. Ultraviolet germicidal irradiation, VHP, MHI, and MGS processing can sterilize N95 respirators while retaining filtration performance and fit. Ultraviolet germicidal irradiation and VHP

**Box. How to Choose a Filtering Facepiece Respirator (FFR) Decontamination Method During Critical Shortages**

**What Are the Best Large-Scale Decontamination Methods?**
Ultraviolet germicidal irradiation (UVGI) is cost-effective and should be considered when equipment (UV lamps or bulbs, biosafety cabinets/laboratory hoods, or whole-room decontamination systems) are available. Vaporized hydrogen peroxide (VHP) is a comparable method and its equipment is often available because it is used for sterilizing other medical equipment (but cost is higher).

**What Is the Evidence Supporting High-Volume FFR Reprocessing in a Large Room With UV lights?**
Filtration performance of FFRs is maintained with up to 9 to 10 cycles of whole-room UVGI decontamination (3 studies). The efficacy of pathogen decontamination has been demonstrated in 1 study.

**What Are the Best Small-Scale Decontamination Methods?**
Consider UVGI box reprocessing, as it appears to damage FFRs the least. If UVGI is unavailable, moist-heat incubation (MHI) using preheated containers/chambers and microwave-generated steam (MGS) are comparable options. With MHI, the Caron incubator should be avoided because of the greatest risk of mask damage. With MGS, efficacy is dependent on volume of water used in the reservoir to produce adequate amount of steam (50-100 mL).

**Is FFR Reprocessing Using Ethylene Oxide Safe?**
No reduction in FFR filtration performance with ethylene oxide has been reported. However, ethylene oxide is a human carcinogen and its chemical residue is an unresolved concern; this method has not been proven safe.

**How Should FFRs Be Evaluated After Reprocessing?**
Systematic evaluation of reprocessed FFRs should occur after decontamination methods are implemented. The FFR should be visually inspected for damage, filtration performance and facial fit assessed, and a proper seal ensured. Reprocessed FFRs should not be used for aerosol-generating procedures, such as intubation or bronchoscopy.

Visual Inspection
Decontaminated FFRs should be examined for visible signs of deterioration/damage such as changes in texture (softness, pliability, coarseness) and separation of inner foam nose cushion from FFR body.

Mask Filtration Performance and Facial Fit
The integrity of FFRs should be assessed (elastic function and breathing resistance) and qualitative fit testing performed. Filtering facepiece respirators donned more than 5 times should undergo qualitative FFR fit performance evaluation. Fit testing should be performed for new FFR models or change in decontamination protocol.

User Seal Check
A user seal check should be performed by the wearer to ensure an adequate seal is achieved. If air leaks around the nose, the user should readjust the nose piece and straps. If air leaks between the facial seal, the FFR should be discarded.

**When Should Reprocessed Respirators Be Discarded?**
Reprocessed FFRs should be discarded when soiled or damaged, if the mask creates more difficulty breathing through it, or if there is failure to achieve a proper fit/seal during user seal check. The Centers for Disease Control and Prevention limits donnings to 5, then disposing of the reused FFRs, unless the manufacturer states otherwise.

**When Should Reprocessing Be Discontinued?**
Normal operations should resume when supplies meet projected FFR demand.

appear to cause the least physical damage to the respirator components. Of these modalities, UVGI might be the most feasible approach for FFR reprocessing because UV bulbs are ubiquitous in the medical environment, the required equipment is readily available, and the process is safe. Vaporized hydrogen peroxide is a suitable alternative for high-throughput processing but requires relatively expensive equipment and may be difficult to implement. Although decontamination can be achieved with these techniques, FFRs were not designed for reuse and should be processed as few times as necessary until unused FFR devices can be obtained.

## Limitations

This review has several limitations. First, the included studies were experimental, laboratory-based studies, with the exception of 2 studies that evaluated respirator performance in clinical use.[13,40] Second, only 5 studies demonstrated adequate reduction of infectivity for SARS-CoV-2. Most of the studies examined other viral and bacterial pathogens. Third, there are more than 530 types of NIOSH-approved N95 respirators, and findings may not generalize to all of them. The lack of evidence pertaining to decontamination for specific types of N95 respirators suggests that individual institutions should test their specific FFRs to ensure pathogen removal and retained mask filtration efficiency and facial fit. A hospital's health and safety and infection control office should be consulted.

The COVID-19 pandemic has been characterized by persistent shortages of personal protective equipment, especially N95 respirators. As the supply of these masks has remained limited throughout the duration of the pandemic, it can be assumed that in future pandemics, reprocessing of FFRs will be necessary. Health care institutions should have plans in place to implement one of the FFR reprocessing systems described in this review. They should be prepared to test the effectiveness of the chosen reprocessing method for the specific pathogens of concern and masks used at their institution before implementing large-scale reprocessing programs. Given the inevitability of the need for reprocessing in emergency systems, FFR manufacturers should provide guidance for how to best reprocess their FFR devices when emergency conditions exist.

## Conclusions

Ultraviolet germicidal irradiation, vaporized hydrogen peroxide, moist heat, and microwave-generated steam processing effectively sterilized FFRs and retained filtration performance. Ultraviolet irradiation and vaporized hydrogen peroxide damaged masks the least. More research is needed on decontamination effectiveness for SARS-CoV-2 because few studies specifically examined this pathogen.


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