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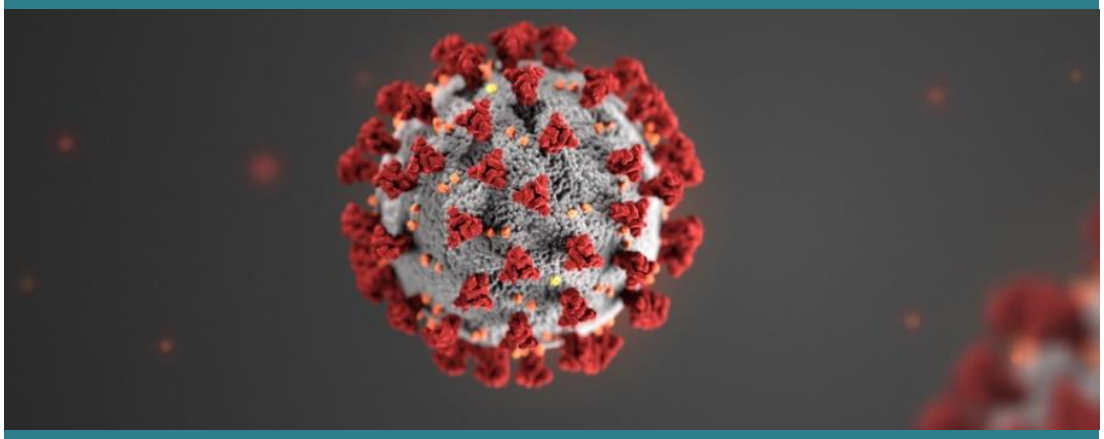

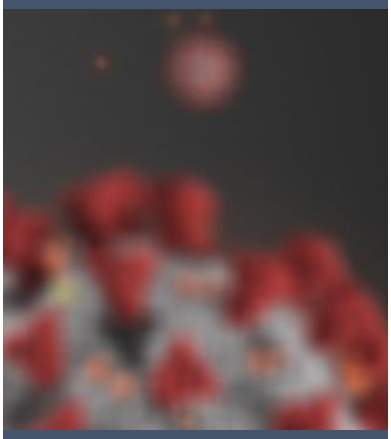

DECONTAMINATION AND REUSE OF FILTERING FACEPIECE RESPIRATORS USING CONTINGENCY AND CRISIS CAPACITY STRATEGIES

Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. This document summarizes research about decontamination of FFRs before reuse.

Introduction

Reusing disposable filtering facepiece respirators (FFRs) has been suggested as a contingency capacity strategy to conserve available supplies for healthcare environments during a pandemic. Strategies for FFR extended use and reuse (without decontamination of the respirator) are currently available from CDC's National Institute for Occupational Safety and Health (NIOSH).

The surfaces of an FFR may become contaminated while filtering the inhalation air of the wearer during exposures to pathogen-laden aerosols. The pathogens on the filter materials of the FFR may be transferred to the wearer upon contact with the FFR during activities such as adjusting the FFR, improper doffing of the FFR, or when performing a user-seal check when redoffing a previously worn FFR. A study evaluating the persistence of SARS-CoV-2 (the virus that causes COVID-19) on plastic, stainless steel, and carboard surfaces showed that the virus is able to survive for up to 72-hours [1]. One strategy to mitigate the contact transfer of pathogens from the FFR to the wearer during reuse is to issue five respirators to each healthcare worker who may care for patients with suspected or confirmed COVID-19. The healthcare worker will wear one respirator each day and store it in a breathable paper bag at the end of each shift. The order of FFR use should be repeated with a minimum of five days between each FFR use. This will result in each worker requiring a minimum of five FFRs, providing that they put on, take off, care for them, and store them properly each day. Healthcare workers should treat the FFRs as though the y are still contaminated and follow the precautions outlined in our reuse recommendations. If supplies are even more constrained and five respirators are not available for each worker who needs them, FFR decontamination may be necessary.

Decontamination and subsequent reuse of FFRs should only be practiced as a crisis capacity strategy. At present, FFRs are considered one time use and there are no manufacturer authorized methods for FFR decontamination prior to reuse. On March 28, 2020, FDA issued an Emergency Use Authorization (EUA) permitting the Battelle Decontamination Systemexternal icon at Battelle Memorial Institute to be authorized for use in decontaminating "compatible N95 respirators." The FDA websiteexternal icon should be checked to determine if other EUAs have

been issued since the posting of this crisis capacity strategy guidance. Only respirator manufacturers can reliably provide guidance on how to decontaminate their specific models of FFRs. In absence of manufacturer's recommendations, third parties may also provide guidance or procedures on how to decontaminate respirators without impacting respirator performance. Decontamination might cause poorer fit, filtration efficiency, and breathability of disposable FFRs as a result of changes to the filtering material, straps, nose bridge material, or strap attachments of the FFR. **CDC and NIOSH do not recommend that FFRs be decontaminated and then reused as standard care. This practice would be inconsistent with their approved use, but we understand in times of crisis, this option may need to be considered when FFR shortages exist.**

An effective FFR decontamination method should reduce the pathogen burden, maintain the function of the FFR, and present no residual chemical hazard. The filter media in NIOSH-approved respirators varies by manufacturer. The ability of the respirator filter media to withstand cleaning and disinfection are not NIOSH performance requirements. The NIOSH's National Personal Protective Technology Laboratory (NPPTL) and other researchers have investigated the impact of various decontamination methods on filtration efficiency, facepiece fit of FFRs, and the ability to reduce viable virus or bacteria on the FFRs. This research is summarized below.

Crisis Standards of Care Decontamination Recommendations

Because ultraviolet germicidal irradiation (UVGI), vaporous hydrogen peroxide (VHP), and moist heat showed the most promise as potential methods to decontaminate FFRs, researchers, decontamination companies, healthcare systems, or individual hospitals should focus current efforts on these technologies. Specifically, the effectiveness of using these methods should be explored further with specific FFR models based on the manufacturers' support to better understand the impact on the respirator performance, including filtration and fit. The respirator manufacturer should be consulted about the impact of the method on their respirators prior to considering the use of any method.

When information from the manufacturer or a third-party is available showing that respirators can be successfully decontaminated without impacting respirator performance, then FFRs decontaminated following those recommendations can be worn for any patient care activities.

In the absence of guidance or when information is available that a respirator cannot be decontaminated without negatively impacting the performance, respirators may still be decontaminated. However, given the uncertainties on the

impact of decontamination on respirator performance, these FFRs should not be worn by HCPs when performing or present for an aerosol-generating procedure.

No current data exists supporting the effectiveness of these decontamination methods specifically against SARS-CoV-2 on an FFR. Other pathogens may also be present on FFRs and there is only limited data available for other pathogens. Further work is needed to assure SARS-CoV-2 and other pathogens are inactivated. Therefore, even after decontamination, these FFRs should be handled carefully.

HCPs should take the following precautionary measures prior to using a decontaminated FFR:

- Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the FFR.
- Avoid touching the inside of the FFR.
- Use a pair of clean (non-sterile) gloves when donning and performing a user seal check.
- Visually inspect the FFR to determine if its integrity has been compromised.
- Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit, and seal.
- If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR and try another FFR.
- Users should perform a user seal check immediately after they don each FFR and should not use an FFR on which they cannot perform a successful user seal check.

Table 1 provides a summary of the crisis standards of care decontamination recommendations.

Table 1. Summary of crisis standards of care decontamination recommendations

Method	Manufacturer or third-party guidance or procedures available	Recommendation for use after decontamination	Additional use considerations
Ultraviolet germicidal irradiation (UVGI)	Yes	Can be worn for any patient care activities	• Clean hands with soap and water or an alcohol-based hand sanitizer before and after touching or adjusting the FFR. • Avoid touching the inside of the FFR. • Use a pair of clean (non-sterile) gloves when donning and performing a user seal check. • Visually inspect the FFR to determine if its integrity has been compromised. • Check that components such as the straps, nose bridge, and nose foam material did not degrade, which can affect the quality of the fit, and seal. • If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR and try another FFR. • Users should perform a user seal check immediately after they don each FFR and should not use an FFR on which they cannot perform a successful user seal check.
Vaporous hydrogen peroxide (VHP)			
Moist heat			
Ultraviolet germicidal irradiation (UVGI)	No	Can be worn for patient care activities except when performing or present for an aerosol generating procedure	
Vaporous hydrogen peroxide (VHP)			
Moist heat			

Table 2 provides a summary of the decontamination methods evaluated in the referenced literature and the reported effect of each method on FFR performance.

Table 2. Summary of the decontamination method and effect on FFR performance

Method	Treatment level	FFR filtration performance	FFR fit performance	Other observations	References
Vaporous hydrogen peroxide (VHP)	**Battelle report:** Bioquell Clarus C HPV generator: The HPV cycle included a 10 min conditioning phase, 20 min gassing phase at 2 g/min, 150 min dwell phase at 0.5 g/min, and 300 min of aeration. **Bergman et. al.:** Room Bio-Decontamination Service (RBDS™, BIOQUELL UK Ltd, Andover, UK), which utilizes four portable modules: the Clarus® R HPV generator (utilizing 30% H_2O_2), the Clarus R20 aeration unit, an instrumentation module and a control computer. Room concentration = 8 g/m^3, 15 min dwell, 125 min total cycle time.	Passed	FFR fit was shown to be unaffected for up to 20 VHP treatments cycles using a head form	Degradation of straps after 30 cycles (Battelle report)	3, 4
Ultraviolet germicidal irradiation (UVGI)	0.5–950 J/cm^2	Passed	90–100% passing rate after 3 cycles depending on model		2, 3, 7, 8, 9, 10
Microwave generated steam	1100–1250 W microwave models (range: 40 sec to 2 min)	All models passed filtration evaluation for 1 or 20 treatment cycles as per test	95–100% passing rate after 3 and 20 cycles for all models tested		9, 10, 14
Microwave steam bags	1100 W, 90 sec (bags filled with 60 mL tap water)	Passed	Not evaluated		15
Moist heat incubation	15 min–30 min (60°C, 80% RH)	6 of 6 models passed after 3 cycles of contamination	Passed		3, 9, 10
Liquid hydrogen peroxide	1 sec to 30 min (range: 3–6%)	Passed	Not evaluated		3, 7
Ethylene oxide	1 hour at 55°C; conc. range: 725–833/L	Passed	Not evaluated		2, 3, 7

Table 3 provides a summary of the decontamination methods used, the treatment levels assessed, the microbes tested, and the antimicrobial efficacy as reported in the literature.

Table 3. Summary of decontamination method antimicrobial efficacy

Method	Treatment level	Microbe tested	Antimicrobial efficacy	References
Vaporous hydrogen peroxide (VHP)	**Battelle report:** Bioquell Clarus C HPV generator: The HPV cycle included a 10 min conditioning phase, 20 min gassing phase at 2 g/min, 150 min dwell phase at 0.5 g/min, and 300 min of aeration. **Bergman et. al.:** Room Bio-Decontamination Service (RBDS™, BIOQUELL UK Ltd, Andover, UK), which utilizes four portable modules: the Clarus® R HPV generator (utilizing 30% H_2O_2), the Clarus R20 aeration unit, an instrumentation module and a control computer. Room concentration = 8 g/m^3, 15 min dwell, 125-min total cycle time. **Kenney personal communication:** Bioquell BQ-50 generator: The HPV cycle included a 10 minute conditioning phase, 30–40 min gassing phase at 16 g/min, 25 min dwell phase, and a 150 min aeration phase.	*Geobacillus stearothermophilus spores* T1, T7, and phi-6 bacteriophages	>99.999%	3, 4, 6
Ultraviolet germicidal irradiation (UVGI)	0.5–950 J/cm^2	Influenza A (H1N1) Avian influenza A virus (H5N1), low pathogenic Influenza A (H7N9), A/Anhui/1/2013 Influenza A (H7N9), A/Shanghai/1/2013 MERS-CoV SARS-CoV H1N1 Influenza A/PR/8/34 MS2 bacteriophage	99.9% for all tested viruses	12, 13, 14
Microwave generated steam	1100–1250 W microwave models (range: 40 sec to 2 min)	H1N1 influenza A/PR/8/34	99.9%	14
Microwave steam bags	1100 W, 90 sec (bags filled with 60 mL tap water)	MS2 bacteriophage	99.9%	15
Moist heat incubation	15–30 min (60°C, 80% RH)	H1N1 influenza A/PR/8/34	99.99%	14
Liquid hydrogen peroxide	1 sec to 30 min (range: 3–6%)	Not evaluated	Not evaluated	
Ethylene oxide	1 hour at 55°C; conc. range: 725–833 mg/L	Not evaluated	Not evaluated	

Vaporous hydrogen peroxide, ultraviolet germicidal irradiation, and moist heat are the most promising FFR decontamination methods

Vaporous hydrogen peroxide, ultraviolet germicidal irradiation, and moist heat are the most promising decontamination methods. If FFR decontamination is considered, these methods do not appear to break down filtration or compromise the FFR; however, many of these methods can only be used for limited times.

Vaporous hydrogen peroxide

Investigations into VHP decontamination of FFRs provides evidence of minimal effect to filtration and fit while demonstrating 99.9999% efficiency in killing bacterial spores. VHP did not reduce the filtration performance of the ten N95 FFR models tested while showing a 6-log reduction in *Geobacillus stearothermophilus* spores [2-4]. In a report prepared by Battelle Memorial Institute, the 3M 1860 FFR was shown to maintain filtration performance for 50 treatment cycles of VHP, also referred to as HPV by some decontamination system manufacturers, using the Clarus® R HPV generator form Bioquell (utilizing 30% H_2O_2). Additionally, FFR fit was shown to be unaffected for up to 20 VHP treatments cycles using NPPTL's Static Advanced Headform [4, 5]. Strap degradation occurred after 20 treatment cycles. Kenney et al., co-contaminated 3M 1870 FFRs with three bacteriophages, T1, T7, and Phi 6, and decontaminated the FFRs using VHP generated from the Bioquell's BQ-50 system. The VHP treatment was shown inactivate >99.999% of all phages which was below the limit of detection [6]. Viscusi et al. found that 9 FFR models (three particulate N95, three surgical N95 FFRs and three P100) exposed to one cycle of VHP treatment using the STERRAD 100S H_2O_2 Gas Plasma Sterilizer (Advanced Sterilization Products, Irvine, CA) had filter aerosol penetration and filter airflow resistance levels similar to untreated models; however, Bergman et al. found that three cycles of VHP treatment using the STERRAD 100S H_2O_2 Gas Plasma Sterilizer negatively affected filtration performance [2, 3]. Bergman et al. measured acceptable filtration performance for six FFR models (three particulate and three surgical FFRs) that received three cycles of VHP treatment using the Clarus® R HPV generator (utilizing 30% H_2O_2) [3]. VHP is a promising method with a potential for high capacity throughput, but certain VHP systems, such as the Clarus® R HPV generator, may be more compatible with FFR decontamination.

Ultraviolet germicidal irradiation

UVGI is a promising method but the disinfection efficacy is dependent on dose. Not all UV lamps provide the same intensity thus treatment times would have to be adjusted accordingly. Moreover, UVGI is unlikely to kill all the viruses and bacteria on an FFR due to shadow effects produced by the multiple layers of the FFR's construction. Acceptable filtration performance was recorded for eleven FFR models exposed to various UV doses ranging from roughly 0.5–950 J/cm^2 and UVGI was shown to have minimal effect on fit [2, 3, 7, 8, 9, 10]. Heimbuch et al. tested filtration and fit of 15 FFRs and found no adverse effects to FFR performance [11]. Lindsley et al. reported a reduction of the durability of materials of the FFRs for doses ranging from 120–950 J/cm^2; however, an approximate inactivation of 99.9% of bacteriophage MS2, a non-enveloped virus, and H1N1 influenza A/PR/8/34 were achieved with much lower doses of approximately 1 J/cm^2 [12–14]. Heimbuch et al. tested the performance of 1 J/cm^2 of UVGI against Influenza A (H1N1), Avian influenza A virus (H5N1), Influenza A (H7N9) A/Anhui/1/2013, Influenza A (H7N9) A/Shanghai/1/2013, MERS-CoV, and SARS-CoV and reported virus inactivation from 99.9% to greater than 99.999% [11]. UVGI is harmful. Proper precautions are required to avoid UVGI exposure to skin or the eyes.

Moist heat

Moist heat, consisting of 60°C and 80% RH caused minimal degradation in the filtration and fit performance of the tested FFRs [3, 9, 10]. Heimbuch et al. disinfected FFRs contaminated with H1N1 using moist heat, of 65°C and 85% RH, and achieved a minimal of 99.99% reduction in virus [14]. One limitation of the moist heat method is the uncertainty of the disinfection efficacy for various pathogens.

Steam treatment and liquid hydrogen peroxide are promising methods with some limitations

Steam treatment

Steam treatment may be a suitable approach for decontaminating FFRs. The limited number of studies for steam report minimal effect on FFR filtration and fit performance and a minimum 99.9% reduction in H1N1 and bacteriophage MS2 [14, 15]. Fisher et al. used microwave steam bags, designed for disinfecting infant feeding equipment, to decontaminate six FFR models and achieved 99.9% inactivation of MS2 bacteriophage. Filtration performance of all tested FFRs scored above NIOSH certification requirements. Three FFRs were further evaluated for three cycles of steam exposure and demonstrated no change in filtration performance [15]. Bergman et al. also demonstrated acceptable filtration performance after three cycles of exposure to microwave generated steam [3]. Microwave generated steam had little effect on FFR fit after exposure to up to three cycles of steam [9, 10]. Using microwaves to produce steam to decontaminate FFRs is not without limitations. Not all microwaves are constructed the same and some are more powerful than others. The effect of higher power microwaves on FFRs is unknown. Furthermore, the metal nosebands of FFRs may cause arcing, sparks inside the microwave oven, during exposure to microwaves.

Liquid hydrogen peroxide

Liquid hydrogen peroxide showed no effect of FFR filtration performance [3, 7]. Bergman et al. evaluated six FFRs for filtration performance after a 30-minute submersion in 6% hydrogen peroxide. All six FFR models tested demonstrated no changes in filter performance after three cycles of decontamination. FFR fit and disinfection efficacy were not assessed for this method.

Table 4 provides a summary of the decontamination methods evaluated for each FFR model.

Table 4. Decontamination methods evaluated for each FFR model

FFR Model	Type	VHP	UVGI	EtO	Steam	Moist heat	Hydrogen peroxide
3M 1860	N95	x	x	x	x	x	x
3M 1870	N95	x	x	x	x	x	x
3M 8000	N95	x	x	x	x	x	x
3M 8210	N95	x	x	x	x	x	x
3M 9210	N95		x				
3M Vflex 1805	N95		x				
Alpha protech	N95		x				
Cardinal Health	N95				x		
Gerson 1730	N95		x				
Kimberly Clark PFR-95	N95	x	x	x	x	x	x
Moldex 1512	N95		x				
Moldex 1712	N95		x				
Moldex 2200	N95	x	x	x	x	x	
Moldex 2201	N95	x	x	x	x	x	x
Precept 65-3395	N95		x				
Prestige Ameritech RP88020	N95		x				
Sperian HC-NB095	N95		x				
Sperian HC-NB295	N95		x				
U.S. Safety AD2N95A	N95		x				
U.S. Safety AD4N95A	N95		x				
3M 8293	P100	x	x	x			
Moldex 2360	P100	x	x				
North 8150	P100	x	x				

Decontamination methods that changed FFR performance or function

Autoclaving and the use of disinfectant wipes are not recommended as crisis strategies as they may alter FFR performance.

Autoclave, dry heat, isopropyl alcohol, soap, dry microwave irradiation and bleach

Decontamination using an autoclave, 160°C dry heat, 70% isopropyl alcohol, microwave irradiation and soap and water caused significant filter degradation to both FFRs and particle penetration levels did not meet the levels that NIOSH would allow for approval. Decontamination with bleach caused slight degradation in filtration performance and created an odor that would not be suitable for use [2, 7].

Disinfectant wipes

Heimbuch et al. evaluated biological decontamination efficacy and filtration penetration following aerosol exposure of mucin or viable *Staphylococcus aureus* [18]. Following aerosol exposure, respirators were cleaned with three types of wipes: hypochlorite, benzalkonium chloride (BAC), or nonantimicrobial. Particle penetration following cleaning yielded mean values <5%. The highest penetrations were observed in FFRs cleaned with BAC wipes. The BAC wipe caused one sample of FFRs to exceed 5% penetration. Filter penetration following various decontamination methods was shown in this study to vary based on the decontamination method and the model of FFR.

Ethylene oxide as a promising method with serious limitation

Ethylene oxide is not recommended as a crisis strategy as it may be harmful to the wearer.

Ethylene oxide (EtO) was shown to not harm filtration performance for the nine tested FFR models [2, 3, 7]. All tests were conducted for one hour at 55˚C with EtO gas concentrations ranging from 725 to 833 g/L. Six models that were exposed to three cycles of 736 mg/L EtO all passed the filtration performance assessment [3]. Data is not available for the effect that EtO treatment may have on FFR fit. However, EtO treatment does not cause visible physical changes to the appearance of FFRs [2, 3]. A serious concern about using EtO for decontamination of large numbers of FFRs is throughput, since relatively long aeration cycles are needed to ensure removal of highly toxic EtO gas [2]. Any use of ethylene oxide (EtO) should be accompanied by studies to ensure no off-gassing into the breathing zone of the wearer as EtO is carcinogenic and teratogenic. Chronic inhalation of EtO has been linked to neurologic dysfunction and may cause other harmful effects to the wearer [16]. EtO should be used in accordance with Occupational Safety and Health Administration standard 29 CFR 1910.1047 [17].

Other methods for consideration which have not been tested

Hospitals may have other decontamination capabilities on-hand that may be feasible. For example, photodynamic inactivation of pathogens using methylene blue plus visible light exposure is used to treat blood products and there is interest in using the method to decontaminate PPE. There is currently no data to evaluate the effect of this method on FFR filtration and fit [19].

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Other resources

Lowe, J.J. *N95 Filtering Facemask Respirator Ultraviolet Germicidal Irradiation (UVGI) Process for Decontamination and Reuse*. 2020; Available from: https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdfpdf iconexternal icon.