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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. However, in crisis or contingency situations, decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability to the health care personnel available, vulnerable generalized population, responders and critical infrastructure workers. This page provides information on FFR decontamination methods, decontamination research about decontamination of FFRs, before reuse.

Introduction

Wearing disposable filtering facepiece respirators (FFRs) has been suggested as a contingency strategy to extend the supply of respiratory protection supplies for healthcare personnel during pandemic influenza. Strategies for FFR extended use and reuse before decontamination of the respirator are currently available from CDC/NIOSH.

The surface of an FFR may become contaminated while filtering the inhalation air of the wearer and/or during donning and doffing. Contamination of the surface of an FFR may also occur if the respirator is worn in environments where there are contaminants in the environment. Contamination of an FFR may increase the risk of transmitting infectious agents to the wearer, if the respirator is used beyond its recommended limits, or when performing a non-sterile task (e.g., wound care, or other contaminated environmental exposure). Reuse of an FFR may increase the risk of transmitting infectious agents to the wearer, if the respirator is used beyond its recommended limits, or when performing a non-sterile task (e.g., wound care, or other contaminated environmental exposure). Decontamination of an FFR may be a crisis capacity strategy to extend the supply of FFRs, if the respirator is not damaged by the decontamination process. Decontamination of an FFR may also be a crisis capacity strategy to extend the supply of FFRs, if the respirator is not damaged by the decontamination process and if the respirator is used beyond its recommended limits, or when performing a non-sterile task (e.g., wound care, or other contaminated environmental exposure). Decontamination and subsequent reuse of FFRs should only be considered when the FFR is decontaminated prior to reuse. On March 28, 2020, FDA issued an Emergency Use Authorization (EUA) for certain decontamination methods for certain models of FFRs. This page provides information about the EUA and other decontamination methods with respirators. The Guidance 21 details the checklist to determine if an FFR's EUA has been issued since the posting of this crisis capacity strategy. Healthcare facilities should follow their own internal procedures for decontamination of respirators, their specific models of FFRs, in absence of specific recommendations from their respirator manufacturer, provided guidance or procedures on how to decontaminate respirators without impacting respirator fit, filtration, or other performance characteristics. Healthcare facilities should follow their own internal procedures for decontamination of respirators, their specific models of FFRs, in absence of specific recommendations from their respirator manufacturer, provided guidance or procedures on how to decontaminate respirators without impacting respirator fit, filtration, or other performance characteristics. **Decontamination of respirators should only be considered when the FFR is decontaminated prior to reuse, if the respirator is not damaged by the decontamination process, and their reused as standard use. This practice would be inconsistent with their approved use, but may be considered in times of crisis, this option may need to be considered when FFR supply is at risk.**

An effective FFR decontamination method should reduce the pathogen burden, maintain the function of the FFR, and preserve its material integrity and fit. Fit test results should be the same before and after decontamination. The ability of the respirator filter media to withstand cleaning and decontamination is critical to maintaining respirator performance. Research has been conducted to investigate the impact of various decontamination methods on the filtration performance of the 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 promising pathogen reduction results in decontamination, these methods are the decontamination contingency healthcare systems, or individual healthcare providers may consider in crisis or contingency. Table 1 provides a summary of these methods. Healthcare facilities should follow their own internal procedures for decontamination of respirators, provided guidance or procedures on how to decontaminate respirators without impacting respirator fit, filtration, or other performance characteristics. Healthcare facilities should be consulted about the impact of the method on their respirator prior to considering the use of any method.

When information from the manufacturer or a third party is available showing that respirators can be safely decontaminated without impacting their performance, the use of that method should be considered following crisis considerations can be given for any pathogen (see Table).

In the absence of guidance or when information is available that a respirator cannot be safely decontaminated without impacting its performance, healthcare providers may consider the decontamination methods given in the following table on the impact of decontamination on respirator performance. Many 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 novel coronavirus. The data on the effectiveness of these methods against SARS-CoV-2 is based on data available for other pathogens. Further work is needed to confirm the effectiveness of SARS-CoV-2 and other pathogens are inactivated. Therefore, even after decontamination, these FFRs should be handled as contaminated.

FFRs should not be following decontamination treatment prior to the next use if they show any of the following:

- Cracks both wide and deep and/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 latex-free gloves when donning and performing a user seal check.
- Visually inspect the FFR to ensure it is in good condition before donning.
- If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR.
- Check that components such as straps and nosepiece are still in place and firmly attached. If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR.
- 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 decontaminations recommendations

Method	Manufacturer or third party decontamination for reuse	Decontamination for reuse of other decontamination	Additional use considerations
Ultraviolet germicidal irradiation (UVGI)	Yes, if	Can be used for any patient care activities	• Cracks both wide and deep and/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 latex-free gloves when donning and performing a user seal check. • Visually inspect the FFR to ensure it is in good condition before donning. • If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR. • Check that components such as straps and nosepiece are still in place and firmly attached. If the integrity of any part of the FFR is compromised, or if a successful user seal check cannot be performed, discard the FFR.
Vaporous hydrogen peroxide (VHP)			
Moist heat			
Ultraviolet germicidal irradiation (UVGI)	No	Can be used for patient care activities	
Vaporous hydrogen peroxide (VHP)			
Moist heat			

Table 1 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 time	FFR filtration performance	FFR fit performance	Other performance	References
Vaporous hydrogen peroxide (VHP)	**Battelle report:** Bioquest Clean VHP generator: The VPH cycle consisted of a conditioning phase, 20 min exposure phase at 12 g/min, 2 hour aeration phase at 50 cfm and a 30 min aeration phase.	Passed	FFR fit was shown to be unaffected by up to 20 VHP exposures.	Degradation of straps after 20 VHP exposures (Battelle report)	1, 4
	Bergman et. al.: from the Bioconversion Service (BIOSTY) generator, Model 1000, Kistler, LLC, which utilizes flue portable generator with a 30 kW generator cutting 30% H2O2 the Clarus® 500 sterilization instrumentation module and a control computer. Exposure phase 1 gram/min, 5 min dwell, 120 min total cycle time.	95-100% passing with exposure, depending on respirator model	95-100% passing with exposure, depending on respirator model		1, 3, 7, 8, 9, 10, 11
	Fontana personal communication: Bioquest Clean VHP generator: The VPH cycle consisted of a conditioning phase, 45 min, 40 min gaining phase at 2 g/min, 2 hour aeration phase.	100% passing after 1 and 20 VHP exposures	100% passing after 1 and 20 VHP exposures		5, 10, 14
Ultraviolet germicidal irradiation (UVGI)	0.5-1.0J/cm2	Passed	Passed		1, 3, 7, 8, 9, 10, 11
	1100-1200W microwave oven	30 minutes tested filtration performance after 1 and 20 VHP exposures	Passed	Not evaluated	15
Microwave (oven)	1100 W, 30 sec (per side) 85-145 (up water)	Passed	Not evaluated		15
Moist heat incubation	70 min, 85 min at 158°F, 90% RH	1 of 8 models passed after 3 cycles	Passed		2, 6, 10
Liquid hydrogen peroxide	1 hour at 50°C, conc. range: 250-6000	Passed	Not evaluated		2, 7
Ethylene oxide (EtO)	1 hour at 50°C, conc. range: 250-6000	Passed	Not evaluated		2, 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:** Bioquest Clean VHP generator: The VPH cycle consisted of a conditioning phase, 20 min exposure phase at 12 g/min, 2 hour aeration phase at 50 cfm and a 30 min aeration phase.	clostridium sporogenes(ATCC 19404) bacterial spores	>99.999%	1, 4, 5
	Bergman et. al.: from the Bioconversion Service (BIOSTY) generator, Model 1000, Kistler, LLC, which utilizes flue portable generator with a 30 kW generator cutting 30% H2O2 the Clarus® 500 sterilization instrumentation module and a control computer. Exposure phase 1 gram/min, 5 min dwell, 120 min total cycle time.	influenza A(H1N1) Aichi strain (ATCC VR-1735), influenza A(H3N2) Wyoming/03/2003 (ATCC VR-810), influenza B(ATCC VR-1738), SARS-CoV(ATCC VR-1756), influenza A(PR8)(ATCC VR-1469)	99.9% for all tested viruses	1, 3, 7, 8, 9, 10, 11
Ultraviolet germicidal irradiation	0.5-1.0J/cm2	influenza A (H1N1) Aichi strain (ATCC VR-1735), influenza A(H3N2) Wyoming/03/2003 (ATCC VR-810), influenza B(ATCC VR-1738), SARS-CoV(ATCC VR-1756), influenza A(PR8)(ATCC VR-1469)	99.9% for all tested viruses	1, 3, 7, 8, 9, 10, 11
Microwave (oven)	1100-1200W microwave oven	H1N1 influenza virus (ATCC VR-1469)	99.9%	15
Microwave (oven)	1100 W, 30 sec (begin Steam and 30 sec. rest)	MS2 bacteriophage	99.9%	15
Moist heat incubation	70, 85 min (85°C, 80% RH)	H1N1 influenza (A/PR/8/34)	99.99%	16
Liquid hydrogen peroxide	1 sec to 30 min (range 250-6000)	Not evaluated		Not evaluated
Ethylene oxide (EtO)	1 hour at 50°C, conc. range: 250-450 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 methods for decontamination of FFRs. Other methods have been studied but research has not appear to break down filtration or performance for FFR. However, many of these methods can only be used for limited cycles.

Vaporous hydrogen peroxide

Investigations into VHP decontamination of FFRs provide evidence of minimal effects to filtration and fit while demonstrating 99.999% efficacy in killing bacterial spores. VHP did not degrade the filtration performance of the (10) N95 FFR models tested while showing a big reduction in viable bacterial spores. Battelle found that the filtration performance of two models of respirators (one of 3M 1860 the other an unknown model) showed no significant difference between the filters tested before and after exposure (1 cycle) as well as 20 VHP decontamination cycles (manufacturers, using the Clarus® VPH sterilization system). Fit was not affected by 20 VHP cycles. Bergman et al. found that filtration was not affected by up to 20 VHP treatments using VHP's (1 hour). Advanced Healthcare's, 30 min dwell time, occurred after 20 treatments cycle. Fontana et. al., (a contaminated 3M 1870 N95 with three layers of filter media) found that the filtration performance was not affected after 1 and 20 VHP treatments (99.2% efficiency). The VHP treatment was when inactivated >99.999% of all pathogens and no loss in fit of the respirator. Fit was not affected by 20 VHP treatments. Vaporous hydrogen peroxide was tested against influenza A(H1N1) Aichi strain (ATCC VR-1735), influenza A(H3N2) Wyoming/03/2003 (ATCC VR-810), influenza B(ATCC VR-1738), SARS-CoV(ATCC VR-1756), influenza A(PR8)(ATCC VR-1469) and achieved 99.9% reduction in viable virus. Bacterial spores were tested against three cycles of VHP treatment (1 hour, 30 min, and 20 min) and achieved greater than 99.999% (5 log). Vaporous hydrogen peroxide was

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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.pdf

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