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Technical Bulletin

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Revision 10

Decontamination of 3M Filtering Facepiece Respirators, such as N95 Respirators, in the United States - Considerations

Introduction

NOTE: Please revisit this document often for frequent updates.

The purpose of this document is to communicate information related to the impact of decontamination methods on certain 3M filtering facepiece respirator (FFR) models – the purpose is **not** to recommend the practice of decontamination or to comment on the efficacy of the decontamination method on the virus that causes COVID-19 or the safety of the decontamination methods for FFR wearers.

During this COVID-19 pandemic, several governmental agencies have recommended that decontamination may be part of a reuse approach to optimize the use of available FFRs. 3M cannot recommend decontamination of FFRs, because FFRs are not designed to be decontaminated, and doing so voids the regulatory approval (see details in the Background section). However, since certain decontamination methods have been recommended by United States Centers for Disease Control and Prevention (CDC), US Occupational Health and Safety Administration (OSHA), and US Food and Drug Administration (FDA), 3M has evaluated the impact of select decontamination methods on certain 3M FFR models, and is publishing this information to help customers who choose to implement decontamination to do so in such a way that they are unlikely to damage FFRs, as such damage may result in the FFRs not providing the indicated level of exposure reduction, such as N95.

Background

During this public health emergency of the COVID-19 pandemic outbreak, many healthcare institutions are experiencing shortages of FFRs such as N95 respirators.

The CDC has issued Strategies for Optimizing the Supply of N95 Respirators. In this document the CDC recommends conventional capacity strategies, contingency capacity strategies (during expected shortages) and crisis strategies (during known shortages). Contingency and crisis strategies include use of N95s past their shelf life, extended use of N95s, use of other types of respirators, use of respirators from other countries, and re-use of respirators, ahead of decontamination of respirators.

The CDC discusses reuse and extended use of N95s as a crisis strategy at Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings and has published guidelines on Decontamination and Reuse of Filtering Facepiece Respirators. CDC is recommending a wait and reuse approach before consideration of other decontamination approaches.

Key excerpt from CDC guidelines: **“One strategy to reduce the risk of contact transfer of pathogens from the FFR to the wearer during FFR reuse is to issue five N95 FFRs to each healthcare staff member who care for patients with suspected or confirmed COVID-19. The healthcare staff member can wear one N95 FFR each day and store it in a breathable paper bag at the end of each shift with a minimum of five days between each N95 FFR use, rotating the use each day between N95 FFRs. This will provide some time for pathogens on it to “die off” during storage.”**

According to OSHA, decontaminating FFRs voids the respirators' NIOSH approval. However, OSHA has published an enforcement memorandum indicating that during the COVID-19 pandemic, U.S. employers may consider using certain decontaminating methods in their procedures for reusing N95s. This dispensation stands only if employers have exhausted many other options – such as the strategies recommended by the CDC – to reduce the need for respiratory protection and/or manage the use of respirators to try to ensure adequate supply. OSHA emphasizes that employers should look to respirator manufacturers for guidance regarding which decontamination methods are compatible with specific respirator models.

Evaluating Decontamination Methods for Filtering Facepiece Respirators

Per the CDC guidelines, a number of companies which manufacture decontamination equipment are assessing decontamination processes for FFRs. The U.S. Food and Drug Administration (FDA) is evaluating and granting Emergency Use Authorizations (EUAs) for such decontamination systems during the COVID-19 outbreak. Issued EUAs for Personal Protective Equipment with regards to COVID-19 are available on the FDA website: Personal Protective Equipment EUAs.

3M is collaborating with several equipment manufacturers and institutions that are investigating ways for hospitals to safely decontaminate 3M's N95 FFRs in line with the CDC guidance on Decontamination and Reuse of Filtering Facepiece Respirators. 3M has been studying ways to decontaminate filtering facepiece respirators for years.

There are at least four key aspects of successful decontamination of respirators. Many published studies do not take all four into consideration. The method must:

- inactivate the target organism, such as the virus that causes COVID-19;
- not damage the respirator's filtration;
- not affect the respirator's fit;
- and be safe for the person wearing the respirator.

If, as a result of decontaminating a respirator, the filtration is damaged or the respirator does not fit, it will not help reduce exposure to airborne particles at the level indicated, such as N95, FFP2, etc. In 3M's work with external manufacturers of decontamination equipment, 3M relies upon the method developer to confirm the germicidal efficacy of the decontamination method and to provide information on potential hazards to the respirator user.[1] 3M evaluates the effect of the method on filtration efficiency and integrity of our respiratory protection products.

To that effect, 3M is testing certain 3M N95 FFRs regarding the effect of the decontamination processes on fit and filtration performance. We are in the process of testing treated 3M respirators from multiple equipment manufacturers and institutions. Methods under evaluation include Vaporized Hydrogen Peroxide, UV, and Low Temperature Moist Heat, amongst others, as reflected in the CDC Guidance. Other methods of decontamination are being discussed in public forums, including liquid chemical decontamination and time-based methods, but 3M is not prioritizing investigation of these methods at this time. Additional information about many decontamination methods can be found in the CDC guidance on Decontamination and Reuse of Filtering Facepiece Respirators, but again, many published studies have not considered all four key aspects listed above. 3M remains committed to providing data to the health care community as soon as possible.

Note that this document discusses decontamination, not sterilization or disinfection of FFRs. For the purposes of this document, decontamination is defined as "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item..." (U.S. OSHA Bloodborne Pathogens Standard, §29 CFR §1910.1030).

Note these 3M recommendations:

1. Note that 3M has established the firm exclusion of ethylene oxide and formaldehyde decontamination methods for use with 3M FFRs, because ethylene oxide and formaldehyde are inhalation-route carcinogens, and any potential off-gassed residuals would be directly inhaled by the wearer.

- FFRs should be assigned to one single wearer, even when reused. During wear, headbands and noseclips adjust to the face of the wearer, and these products are only designed to be worn by one wearer.
- Respirators should be thoroughly inspected each time they are put on, according to the model-specific User Instructions. Filtering facepiece respirators that are reused should be assessed for any signs of damage or fatigue, including such points as headband elasticity, nosefoam compression, pinholes near the staples, or deformation. User seal checks should also be performed. If the wearer cannot achieve an effective seal, the respirator should be discarded.

Current Findings on Decontamination Methods

Current information supports the following conclusions for all 3M filtering facepiece particulate respirators[1]:

- 3M **does not** recommend the use of Ethylene Oxide or formaldehyde for respirator decontamination due to potential for repeat inhalation exposure to residual ethylene oxide or formaldehyde, known human airborne respiratory carcinogens.[1] Ethylene oxide is an accepted sterilant for many device types, but given that the respirator is directly in line with a person's breathing zone, it is not recommended for respirator decontamination.
- 3M **does not** recommend the use of Ionizing Radiation due to degradation in filter performance.
- 3M **does not** recommend the use of Microwave due to melting of the respirator near metal components resulting in compromise of fit.
- 3M **does not** recommend the use of High Temperatures above 75°C, such as Autoclave or Steam, unless specifically listed in the tables below due to significant filter degradation and fit degradation.
- 3M **does not** recommend the use of ethanol, isopropanol[2], quat solutions, soaps, or detergents due to degradation in filter performance.
- 3M **does not** recommend the use of Ozone due to degradation of headband and nosefoam materials.

Table 1 shows the status of ongoing and completed filtration and fit tests by 3M for decontamination methods which have been issued EUAs. We do anticipate that additional information will be available as this work is completed and reviewed with regulatory agencies. Please note that for information on efficacy of decontamination, please refer to the decontamination equipment manufacturers.

Considering the many variables involved in the processes, decontamination of FFRs in the US should follow all requirements of the current EUA issued for each specific decontamination system. If organizations choose to attempt to decontaminate filtering facepiece respirators using any of the methods described within this document or any other methods, then such organization should understand that doing so may impact the filtration performance and/or the respirator materials in such a way that may reduce the respirator's ability to seal to the wearer's face and provide the expected respiratory protection.

Note that respirators should be thoroughly inspected each time they are put on, according to the model-specific User Instructions. Filtering facepiece respirators that are reused should be assessed for any signs of damage or fatigue, including such points as headband elasticity, nosefoam compression, pinholes near the staples, or deformation. User seal checks should also be performed. If the wearer cannot achieve an effective seal, the respirator should be discarded.

1. These conclusions apply to all 3M filtering facepiece respirators including those approved in countries and regions other than the United States.
2. The filter degradation caused by isopropanol would also be seen from a method which combines an alcohol with other physical or chemical treatments, such as an ethanol-vacuum method.

Table 1: Decontamination methods which have received EUAs – Effect on Certain 3M Filtering Facepiece Particulate Respirators (3M does not recommend decontaminating FFRs.)

Decontamination Method	3M FFR Models[a]	Cycle[b]	Number of Reprocess Cycles Tested[c]	Filtration Efficiency[d]	Fit Related Evaluation	U.S. FDA EUA Information
Vaporized Hydrogen Peroxide (VHP) Systems for Decontamination [e]						
VHP – Steris V-PRO, V-PRO 60	**1860**, 1860S, **1870+**, 8110S, **8210**, **9205+**, 9210+ Models not covered by EUA: **8511, 8801H, 9820+BR, 9920H**	V-PRO 1 Plus, V-PRO maX, V-PRO maX2,V-PRO 60, V-PRO s2 Non- Lumen Cycle	10	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
VHP –ASP, STERRAD®	**1860**, **1860S**, 8110S, **8210**	100S-Short NX-Standard, 100NX-Express	2	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
VHP - Sterilucent	**1860**, 1860S, **1870+**, 8110S, **8210**, 9205+, 9210+ Models not covered EUA:**1804**, 1804S, 1805, 1805S, 8210V, **8511**, 9105, 9105S, 9211+	Sterilucent™ HC 80TT - Flexible Cycle	10	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
Vaporized Hydrogen Peroxide Environmental Decontamination Systems						
VHP- Battelle	**1860**, 1860S, 1870+, 8110S, **8210, 9205+**, 9210+ Models not covered by EUA:**8511**, 9211+	Battelle CCDS	20	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
Moist Heat						

Table 1: Decontamination methods which have received EUAs – Effect on Certain 3M Filtering Facepiece Particulate Respirators (3M does not recommend decontaminating FFRs.)

Decontamination Method	3M FFR Models[a]	Cycle[b]	Number of Reprocess Cycles Tested[c]	Filtration Efficiency[d]	Fit Related Evaluation	U.S. FDA EUA Information
Steris - AMSCO Medium Steam Sterilizers	1804, 1804S, 1805, 1805S, **1860**, 1860S, 8110S, **8210**, 9105, 9105S	Steris Steam Decon Cycle (Temperature = 65°C, Pressure = 21 inHg, time = 30 min.)	10	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
Other						
NovaSterilis - NovaClean 2200	Not recommended for any 3M models. Tested: 1804, 1860, 8210	-	-	Failed - degraded filtration efficiency	-	EUA granted, but not recommended since filtration efficiency is degraded.

a. Bold font indicates respirator models that were tested. Other listed respirator models are included based on similarity to the tested models. Models that have been evaluated by 3M but are not authorized for decontamination by the U.S. FDA – such as models that contain cellulose, exhalation valves, or KN95 – are listed as "Models not covered by EUA."
b. Cycle parameters are determined by the equipment manufacturer. Further details need to be provided by the decontamination equipment manufacturer.
c. This column represents the number of cycles tested and is intended as the maximum number of cycles that should be attempted. The number of cycles that a particular respirator will withstand will depend on how many times it has been donned, how it has been stored and the duration and conditions of use.
d. Tested per applicable regulatory respirator performance standards.
e. Per manufacturers of VHP equipment, most VHP methods are not to be used with cellulose-based materials. See the 3M Technical Bulletin - Cellulose Certification - Filtering Facepiece Respirators for information about which 3M respirators contain cellulose.

Table 2 shows the status of ongoing and completed filtration and fit tests by 3M for crisis strategy decontamination methods which have been recommended by CDC and are identified in OSHA's enforcement memorandum as methods that may be acceptable for use with filtering facepiece respirators BUT which have NOT been issued EUAsAUs. As such, no government authority has expressly established oversight over how these methods should be implemented to ensure efficacy and safety.

The table below provides certain key details regarding the methods that were used to treat the samples 3M evaluated. However, unlike the methods that have EUAs, there may not be static, detailed implementation procedures published for these methods. Considering the many variables involved in the processes, it may be difficult to implement these decontamination methods exactly as they were performed to treat the samples that 3M evaluated for compatibility with the respirator models listed below. Contact the manufacturer of the equipment used in each method for information about procedures, efficacy, and safety.

Table 2: Decontamination methods which DO NOT have EUAs – Effect on certain 3M Filtering Facepiece Particulate Respirators (3M does not recommend decontaminating FFRs.)

Decontamination Method	3M FFR Models[a]	Cycle[b]	Number of Reprocess Cycles Tested[c]	Filtration Efficiency[d]	Fit Related Evaluation	U.S. FDA EUA Information
Vaporized Hydrogen Peroxide (VHP) Systems for Decontamination [e]						
VHP - Canon	**1860**, 1860S, **1870+**, 8110S, **8210**, **8210J**, 9205+, 9210+	ES-1400/Short cycle ES-700i/Short cycle ES-700/Short cycle	10	Pass	Pass	No
Vaporized Hydrogen Peroxide Environmental Decontamination Systems						
VHP – Ecolab, Bioquell	**1860**, 1860S, 1862+, 1863+, **1870+**, 8110S, **8210**, 9205+, 9210+, **9320+**, **9330+**	10 g/m^3	20	Pass	Pass	No
VHP – Steris - Victory™, 1000 ED, ARD, and M100 Biodecontamination Unit	**1860, 1860S**, **1870+**, 8110S, **8210**, 9205+, 9210+	STERIS Atmospheric VHP Process	20	Pass	Pass	No
VHP – The Nocospray® Disinfection System	**1804**, 1804S, 1805, 1805S, **1860**, 1860S, 1870+, 8110S, **8210**, 9105, 9105S, **9205+**, 9210+	Sporicidal dose – 7x room volume	20	Pass	Pass	No
Ultraviolet Light Environmental Decontamination Systems						
UV-C (254 nm)	**1804**, 1804S, 1805, 1805S, **1860**, 1860S, 8110S, **8210**, 9105, 9105S	Refer to CDC guidance or UV OEM	Maximum 100 J/cm^2 cumulative lifetime exposure	Pass	Pass	No

Table 2: Decontamination methods which DO NOT have EUAs – Effect on certain 3M Filtering Facepiece Particulate Respirators (3M does not recommend decontaminating FFRs.)

Decontamination Method	3M FFR Models[a]	Cycle[b]	Number of Reprocess Cycles Tested[c]	Filtration Efficiency[d]	Fit Related Evaluation	U.S. FDA EUA Information
Xenex Lightstrike™ System	**1804**, 1804S, 1805, 1805S, **1860**, 1860S, 8110S, **8210**, 9105, 9105S	Pulsed xenon, 200 – 280 nm for 5 minutes on each side	10	Pass	Pass	No
UVDI (UV-C, 254 nm)	**1804**, 1804S, 1805, 1805S, **1860**, 1860S, 8110S, **8210**, 9105, 9105S	1 J/cm^2 on each side	10 (cumulative exposure of 10 J/cm^2 on each side)	Pass	Pass	No
Surfacide Helios System	1860, 1860S, 8110S, 8210	15 min exposure of ≥ 1 J/cm^2 on each side	5	Pass	Pass	No
AquiSense Technologies PearlSurface ™ (UV-C LED, 280nm)	**1804**, 1804S, 1805, 1805S, **1860**, 1860S, 8110S, **8210**, **8511**, 9105, 9105S	Maximum 2 J/cm^2, dual sided treatment with N95 insert	20	Pass	Pass	No
Heat						
Steris - Moist Heat Method using Vis-U-All High-Temperature Self-Seal Pouches	**1804**, 1804S, 1805, 1805S, **1860**, 1860S, **1870+**, 8110S, **8210**, 9105, 9105S, 9205+, 9210+	In High Temperature Self-Seal Pouches (1 FFR per pouch) Temperature = 65±5°C, Humidity = 50-80% RH, 30 min	10	Pass	Pass	No
Belimed	**1804**, 1804S, 1805, 1805S, 1862+, 1863+, 1870+, **9205+**, 9210+, **9320 +**, **9330+**	US: Mask 250 Cycle Intl: Prevac 121° cycle (Temperature = 121°C, time = 20 min.)	1	Pass	Pass	No

Table 2: Decontamination methods which DO NOT have EUAs – Effect on certain 3M Filtering Facepiece Particulate Respirators (3M does not recommend decontaminating FFRs.)

Decontamination Method	3M FFR Models[a]	Cycle[b]	Number of Reprocess Cycles Tested[c]	Filtration Efficiency[d]	Fit Related Evaluation	U.S. FDA EUA Information
Hybrid Systems						
Clean Works Medical	**1804**, 1804S, 1805, 1805S, **1860**, 1860S, **1870+**, 8110S, **8210**, 9105, 9105S, 9205+, 9210+	Clean Flow Healthcare Mini	10	Pass	Pass	No (IO approval in Canada)

a. Bold font indicates respirator models that were tested. Other listed respirator models are included based on similarity to the tested models.
b. Cycle parameters are determined by the equipment manufacturer. Further details need to be provided by the decontamination equipment manufacturer.
c. This column represents the number of cycles tested and is intended as the maximum number of cycles that should be attempted. The number of cycles that a particular respirator will withstand will depend on how many times it has been donned, how it has been stored and the duration and conditions of use.
d. Tested per applicable regulatory respirator performance standards.
e. Per manufacturers of VHP equipment, most VHP methods are not to be used with cellulose-based materials. See the 3M Technical Bulletin - Cellulose Certification - Filtering Facepiece Respirators for information about which 3M respirators contain cellulose.

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