Science. Applied to Life.™

Technical Bulletin

April, 2020
Revision 5

Decontamination Methods for 3M Filtering Facepiece Respirators such as N95 Respirators

Background

NOTE: Please revisit this document often for frequent updates.

During this public health emergency of the COVID-19 pandemic outbreak, many healthcare institutions are experiencing shortages of filtering facepiece respirators such as N95 respirators. The U.S. Center for Disease Control (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 says research indicates the virus survives for up to 72 hours on a variety of surfaces. Therefore, CDC is recommending a wait and reuse approach before consideration of other decontamination approaches.

Key excerpt from CDC guidelines: **"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 they 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."**

Evaluating Decontamination Methods for Filtering Facepiece Respirators

Per the CDC guidelines, a number of sterilization companies are assessing decontamination processes for N95 filtering facepiece respirators (FFRs). The U.S. Food and Drug Administration (FDA) is evaluating 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 will be available on the FDA website: Personal Protective Equipment EUAs

3M is collaborating with several sterilization companies 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 sterilize, disinfect or decontaminate filtering facepiece respirators for years. There are at least four key aspects of successful decontamination reprocessing of respirators, and 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 sterilization/decontamination equipment, 3M relies upon the method developer to confirm the germicidal efficacy of the 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 sterilization companies 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, ozone, 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.

Current Findings on Decontamination Methods

Current information supports the following conclusions for all 3M filtering facepiece particulate respirators[2]:

- 3M **does not** recommend the use of Ethylene Oxide due to the potential for repeat inhalation exposure to residual ethylene oxide, a known human airborne respiratory carcinogen.[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**, at this time, recommend the use of High Temperatures above 75°C, such as Autoclave or Steam due to significant filter degradation.

The table below (Table 1) shows the status of ongoing and completed filtration and fit tests by 3M and EUAs issued to sterilization equipment manufacturers. We do anticipate that additional information will be available as this work is completed and reviewed with regulatory agencies. For information on efficacy of decontamination, please refer to the sterilization equipment manufacturers.

Considering the many variables involved in the process, decontamination of FFRs in the US should follow all requirements of the current EUA issued for each specific decontamination system.

Please revisit this bulletin often for frequent updates.

1. Note that 3M has established the firm exclusion of ethylene oxide decontamination methods for use with 3M FFRs, because ethylene oxide is an inhalation-route carcinogen, and any potential off-gassed ethylene oxide residuals would be directly inhaled by the wearer.
2. These conclusions apply to all 3M filtering facepiece respirators including those approved in countries and regions other than the United States.

Table 1: Effect of decontamination methods on certain 3M N95 Filtering Facepiece Particulate Respirators (Sheet 1 of 2)

Decontamination Method	3M N95 Models Evaluated [a]	Cycle	Number of Reprocess Cycles Tested	Filtration Efficiency[b]	Fit Related Evaluation	U.S. FDA EUA Issued
Vaporized Hydrogen Peroxide (VHP) Sterilizer Systems for Decontamination [c]						
VHP – Steris V-Pro	1860, 8210, 1870+	V-PRO 1 Plus, V-PRO maX, V-PRO maX2, Non- Lumen Cycle	10	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
VHP – Steris V-PRO 60	1860, 8210	V-PRO 60 V-PRO s2 Non-Lumen cycle	10	Pass	Pass	No
VHP –ASP, STERRAD®	1860, 8210	100S-Short NX-Standard, 100NX-Express	2	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
VHP - Sterilucent	1804, 1860, 8210	Sterilucent™ HC 80TT - Flexible Cycle	10	Pass	Pass	EUA Facility Instructions HC Personnel Instructions
VHP - Stryker	1804, 1860, 8210, 1870+	STERIZONE VP4 N95 Respirator Decontamination Cycle	2	Under evaluation	Under evaluation	EUA Facility Instructions HC Personnel Instructions
Vaporized Hydrogen Peroxide Environmental Decontamination Systems						
VHP – Ecolab, Bioquell	Under evaluation	Under evaluation		Under evaluation	Under evaluation	No
VHP- Battelle	1860, 8210, 1804	Under evaluation	3 cycles: tested 20 cycles: Under evaluation	3 cycles: Pass 20 cycles: Under evaluation	3 cycles: Pass 20 cycles: Under evaluation	EUA Facility Instructions HC Personnel Instructions

Table 1: Effect of decontamination methods on certain 3M N95 Filtering Facepiece Particulate Respirators (Continued) (Sheet 2 of 2)

Decontamination Method	3M N95 Models Evaluated [a]	Cycle	Number of Reprocess Cycles Tested	Filtration Efficiency[b]	Fit Related Evaluation	U.S. FDA EUA Issued
VHP – Steris - Victory™, 1000 ED, ARD, and M100 Biodecontamination Unit	1860, 8210, 1804	STERIS Atmospheric VHP Process	20	Pass	Pass	No
Ultraviolet Light Environmental Decontamination Systems						
UV-C (254 nm)	1860, 8210, 1804	1-2 J/cm^2 per side		Under evaluation	Under evaluation	No
Xenex Lightstrike™ System	1860, 8210, 1804	Pulsed xenon, 200 – 280 nm for 5 minutes	10	Pass	Pass	No
Moist Heat						
Steris - Moist Heat Method using Vis-U-All High-Temperature Self-Seal Pouches	1860, 8210, 1804, 1870+	In High Temperature Self-Seal Pouches (1 FFR per pouch) Temperature = 65±5°C, Humidity = 50-80% RH, 30 min	10	Pass	Pass	No

a. The results on the 1860 are applicable to the 1860S.The results on the 1804 are applicable to the 1804S, 1805, 1805S, 9105, and 9105S.
b. Per NIOSH requirements applicable to N95 respirators.
c. Per manufacturers of VHP equipment, VHP methods are not to be used with items containing cellulose. See the 3M Technical Bulletin - Cellulose Certification - Filtering Facepiece Respirators for information about which 3M respirators contain cellulose.

3M Company
3M Center
St. Paul, MN 55144-1000

Customer Questions:
1-800-537-2191

In United States of America
Technical Service: 1-800-243-4630
Customer Service: 1-800-328-1667
3M.com/workersafety
In Canada
Technical Service: 1-800-267-4414
Customer Service: 1-800-364-3577
3M.ca/Safety