

Disinfection of Filtering Facepiece Respirators

Considerations for healthcare organizations and occupational health professionals

Description

We at 3M have been studying ways to sterilize or disinfect filtering facepiece respirators for years. There are at least four key aspects of successful disinfection of respirators, and most studies do not take all four into consideration. The disinfection method must:

- be effective against 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 (e.g. no off-gassing of chemicals into the breathing zone).

If 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.

As of March 27, 2020, no disinfection method has met all four of these key criteria, and without all four, the method is not acceptable. 3M is now working with several major sterilization and disinfection companies and consulting with external experts to develop an effective disinfection method. We are working as quickly as possible and are hopeful that we will find an effective method soon.

Background

Filtering facepiece respirators (FFRs), such as those that meet the filtration efficiency requirements for classification as such as N95, FFP2, KN95, and similar, are commonly used to help provide respiratory protection in a variety of workplaces, including healthcare settings. A common infection prevention practice employed by healthcare organizations is to utilize FFRs as one-time-use items when worn in the presence of infected patients.¹ In the face of a global pandemic and associated FFR shortage, 3M has received numerous questions concerning potential methods to disinfect FFRs, including questions relating to studies that have evaluated the effectiveness of various disinfection methods on FFRs. In an attempt to respond to urgent requests we are receiving from customers and organizations around the world, we have prepared this bulletin to provide information concerning a few methods that have been suggested to potentially help disinfect FFRs.

Based on currently available data, 3M does not recommend or support attempts to sanitize, disinfect, or sterilize 3M FFRs.

We note, however, that the U.S. Centers for Disease Control and Prevention (CDC) has published guidance on managing respirators during pandemics including the reuse and extended use of respirators at:

<https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

Disinfection Methods Often Considered for FFR

IONIZING RADIATION

Ionizing radiation has the potential to significantly impact the performance and/or integrity of 3M filtering facepiece respirators. The effect of ionizing radiation on the filtration performance will not be apparent by visible inspection or noticeable when wearing the respirator. Therefore, as with any research regarding sterilization, disinfection and reprocessing, it is especially important to have the filtering facepiece respirators evaluated in a test laboratory using equipment designed to evaluate filtration of particulate respirators. In past research, 3M has found that attempts to sterilize respirators with ionizing radiation (e.g. e-beam, x-ray) have significantly damaged the filter media and are, therefore, not acceptable methods.

ETHYLENE OXIDE

3M does not support the use of ethylene oxide to sterilize, disinfect or reprocess filtering facepiece respirators. Ethylene oxide (EtO) has been determined to be carcinogenic to humans by the inhalation route of exposure, and the U.S. National Institute for Occupational Safety and Health (NIOSH) and the CDC recommend that worker's exposures be kept as low as possible.² Since filtering facepiece respirators are designed to fit over a worker's breathing zone and workers breathe through them for hours every day, as well as the particulate filter media not being intended or effective to reduce exposure to EtO, we cannot rule out the possibility that filtering facepiece respirators sterilized with EtO will continue to off-gas into the worker's breathing zone, exposing the worker to EtO. To the best of our knowledge there has not been sufficient research done, at this time, to demonstrate that sterilization of filtering facepiece respirators with EtO is safe for the wearer.

According to the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System and the Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile for Ethylene Oxide³, the acute (short-term) effects of ethylene oxide in humans include mainly central nervous system depression and irritation of the eyes and mucous membranes. Chronic (long-term) exposure to ethylene oxide in humans can cause irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. There also is some evidence linking ethylene oxide exposure to reproductive effects. EPA has concluded that ethylene oxide is carcinogenic to humans by the inhalation route of exposure. Evidence in humans indicates that exposure to ethylene oxide increases the risk of lymphoid cancer and, for females, breast cancer.

MGS, UBGI, and MOIST HEAT

A study from the University of Nebraska Medical Center⁴ evaluated the effectiveness of three disinfection methods on two 3M FFR models: the 3M™ Health Care Particulate Respirator and Surgical Mask 1860 and the 3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870 (the latter of which has since been discontinued and replaced in the 3M FFR product line by the 3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870+). Each of these FFRs was subjected to only 1-cycle (1X) of one of three disinfection methods tested: ultraviolet germicidal irradiation (UVGI), microwave-generated steam (MGS), and moist heat. The study found that UVGI, MGS, and moist heat effectively reduced viral load of H5N1 virus by > 4 log median tissue culture infective dose. It also found <5% filter penetration on each FFR following subjection to one of the three disinfection methods.² However, this study did not investigate the effect of these disinfection treatments on respirator fit.

3M has conducted a similar study to better understand how these disinfection methods might affect fit and filtration of the 3M™ Healthcare Particulate Respirator and Surgical Mask 1860 and 3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870. In the 3M study, one of the three disinfection methods (UVGI, MGS, and moist heat) was performed between 5-10 cycles (5X-10X) on a small sample of FFRs (N = 3 of each model). The 3M study found the filtration performance was not affected, in that the respirators continued to provide at least the minimum filtration efficiency required for the N95 designation. However, all three disinfection methods caused damage to at least one respirator in each sample. Observed damage included: delamination or compression of the respirator's nosefoam, a strong burnt odor, the respirator straps on the 1870 lost elasticity, and the MGS and moist heat methods melted the respirator material surrounding the metal noseclip and staples. This damage compromised the fit of these respirators and made them not suitable for use. Table 1 summarizes the

results found in the 3M study. **Sanitization, disinfection, or sterilization of FFRs utilizing these specific methods is, therefore, not recommended or supported by 3M at this time.**

Decontamination Methods and Impact on Facepiece Materials

Table 1: 3M Study of Damage Due to Attempted Disinfection of Models 1860 and 1870

Disinfection Method Tested by 3M (repeated 5X-10X per FFR)	Results on 3M 1860 and 1870
Microwave Generated Steam 2-min @ full power, 50ml H ₂ O	Metal nose clip and staples melted surrounding plastic; nosefoams delaminated; straps on 1870 lost elasticity
Ultraviolet germicidal irradiation (UVGI) 30-min @ 254nm (15-min per side)	Straps on 1870 lost elasticity; strong burnt odor; nosefoam compressed on 1860
Moist Heat 30 mins, 60°C, 80%RH oven	Metal nose clip and staples melted surrounding plastic; nosefoam delaminated; straps on 1870 lost elasticity

HPV, MGS, BLEACH, LHP, and MOIST HEAT

A study published in the Journal of Engineered Fibers and Fabrics (JEFF)⁵ evaluated 3-cycle (3X) processing of eight disinfection methods: UVGI, ethylene oxide (EtO), hydrogen peroxide gas plasma (HPGP), hydrogen peroxide vapor (HPV), MGS, bleach, liquid hydrogen peroxide (LHP), and moist heat. This study did not assess the efficiency of the disinfection method to inactivate microorganisms. Appearance, odor, and filtration performance were evaluated. The specific FFRs evaluated in the study were not disclosed so it is unclear if 3M FFRs were included. The study found four methods caused visible damage/changes to the FFRs: MGS, bleach, LHP, and moist heat. Hydrogen peroxide gas plasma treatment was the only disinfection method resulting in high penetration levels (> 5%). EtO, HPV, and UVGI disinfection did not cause any observable physical changes to the FFRs and did not negatively affect filter penetration.³ This study did not evaluate respirator fit. Table 2 summarizes the results found in the JEFF study.

UVGI, EtO, and HPGP

Although the JEFF study found three disinfection methods (EtO, HPV, and UVGI) caused no visible changes to the FFRs, it is unclear what specific FFR models were evaluated or what effect was achieved with regard to microorganism deactivation. **At this time sanitization, disinfection, or sterilization of 3M FFRs utilizing these specific methods is, therefore, not recommended or supported by 3M.**

Table 2: Results of various disinfection methods on FFRs found in JEFF study (Sheet 1 of 2)

Disinfection Method Utilized in JEFF Study (repeated 3X per FFR)	Results on Various Unknown FFR Makes and Models
Ultraviolet germicidal irradiation (UVGI) 15-min @ 254nm (only one side of FFR faced lamp, not straps)	No observable physical change
Ethylene oxide 1-hr 100% EtO Sterilizer	No observable physical changes
Hydrogen Peroxide Gas Plasma ~55-min, 59% H ₂ O ₂ , 45°C-50°C	Filter penetration exceeded 5% on multiple samples
Hydrogen Peroxide vapor 15-min dwell, 125-min total cycle time, 8 g/m ³ concentration	No observable physical changes

Table 2: Results of various disinfection methods on FFRs found in JEFF study (Continued) (Sheet 2 of 2)

Disinfection Method Utilized in JEFF Study (repeated 3X per FFR)	Results on Various Unknown FFR Makes and Models
MGS 2-min @ 1,100 W full power, 50 mL H ₂ O	Separation of nosefoam from FFR; melting of head straps
Bleach 30-min @ 0.6% sodium hypochlorite solution	Nosefoam slightly tarnished; staples oxidized to varying degrees; discolored or dissolved inner nose pad
Liquid hydrogen peroxide 30-min @ 6% hydrogen peroxide solution	Staples oxidized to varying degrees
Moist heat 30-min @ 60°C, 80% RH	Separation of nose foam from FFR; melting of head straps

Summary

If organizations choose to attempt to disinfect filtering facepiece respirators, using any of the methods described above or any other methods, then such organization should carefully consider the findings described in this document and 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 protection for this type of respirator.

References

- 1) U.S. Centers for Disease Control and Prevention, "Pandemic Planning: Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings," March 2018, <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>.
- 2) U.S. National Institute for Occupational Health and Safety (NIOSH), Worker Health Study Summaries - Sterilization of Medical Instruments and Treatment of Spices (Ethylene Oxide). <https://www.cdc.gov/niosh/pgms/worknotify/ethyleneoxide.html>, April 2017.
- 3) U.S. Environmental Protection Agency, Hazard Summary, Ethylene Oxide. <https://www.epa.gov/sites/production/files/2016-09/documents/ethylene-oxide.pdf>, December 2018.
- 4) Lore, M.B., Heimbuch, B.K., Brown, T.L., Wander, J.D. and Hinrichs, S.H. Effectiveness of Three Decontamination Treatments against Influenza Virus Applied to Filtering Facepiece Respirators. *Ann. Occup. Hygiene* 2011;1-10.
- 5) Bergman, M.S., Viscusi, D.J., Heimbuch B.K., Wander, J.D., Sambol, A.RI, Shaffer, R.E. Evaluation of Multiple (3-cycle) Decontamination Processing for Filtering Facepiece Respirators. *J Engineered Fibers Fabrics* 2010;5:33-41.