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Technical Bulletin

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Disinfection of Filtering Facepiece Respirators

Description

Filtering facepiece respirators (FFRs) 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.[2,3]

Based on currently available data, 3M does not recommend or support attempts to sanitize, disinfect, or sterilize 3M 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. It is critically important that such methods NOT compromise the respirator's filtration performance or the ability of the respirator to seal to the wearer's face as intended. The methods must also not create any new hazards for the wearer. We continue to conduct internal research into the viability of applying disinfection methods to our FFR products, but, we do not recommend or support any specific FFR disinfection method at this time. 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

A study from the University of Nebraska Medical Center 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 stream (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)s 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, 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.**

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_2O	Metal nose clip and staples melted surrounding plastic; nosefoams delaminted; 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 delaminted; straps on 1870 lost elasticity

A study published in the Journal of Engineered Fibers and Fabrics (JEFF) 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.

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. **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% H2O2, 45°C-50°C	Filter penetration exceeded 5% on multiple samples
Hydrogen Peroxide vapor15-min dwell, 125-min total cycle time, 8 g/m3 concentration	No observable physical changes
MGS 2-min @ 1,100 W full power, 50 mL H2O	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 peroxide30-min @ 6% hydrogen peroxide solution	Staples oxidized to varying degrees

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
Moist heat 30-min @ 60°C, 80% RH	Seperation of nose foam from FFR; melting of head straps

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) 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.
3) 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.

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