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Technical Bulletin

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Release 1

Decontamination Methods for 3M N95 Respirators

Description

N95 respirators are designed and regulated as disposable devices. Due to the current shortage of Personal Protective Equipment (PPE) associated with the COVID-19 outbreak, 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.

3M is collaborating with several sterilization companies and institutions that are investigating ways for hospitals to safely decontaminate N95 FFRs. To that effect, 3M is committed to **testing 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. The table below (Table 1) shows the status of ongoing and completed tests and issued EUAs. We do anticipate that additional information will be available as this work is completed and reviewed with regulatory agencies.

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

- 3M **does not** recommend the use of Ethylene Oxide due to significant concerns associated with off-gassing.
- 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 Temperature, Autoclave, or Steam due to significant filter degradation.

3M is working to quickly evaluate other decontamination methods on 3M respirator fit and filtration performance, such as Vaporized Hydrogen Peroxide, UV, Low Temperature Moist Heat, amongst others, as reflected in the CDC guidance on Crisis Standards of Care Decontamination Recommendations. 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. 3M remains committed to providing data to the health care community as soon as possible.

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 method.

Please revisit this bulletin often for frequent updates. Additional background information can be found in the data bulletin: Disinfection of Filtering Facepiece Respirators.

1. 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

Decontamination Method	3M N95 Models Evaluated [a]	Cycle	Number of Reprocess Cycles Tested	Filtration Efficiency[b]	Fit Related Evaluation	Conclusion	EUA Issued
Vaporized Hydrogen Peroxide							
VHP – Steris	1860, 8210	VPro Max nonLumens	10	Pass	Pass	Pending EUA	
VHP –ASP, STERRAD®	1860, 8210, 1804	Under eval	2	Under eval	Under eval	Test ongoing	
VHP – Ecolab, Bioquell	Under eval	Under eval		Under eval	Under eval	Test ongoing	
VHP- Battelle	1860, 8210, 1804	Under eval	20	Under eval	Under eval	Waiting on samples from Battelle	Link
Ultraviolet Radiation							
UV Lamp 254nm	1860, 8210, 1804	Under eval		Under eval	Under eval	Test ongoing	

a. The results on the 1860 are applicable to the 1860S.The results on the 1804 are applicable to the 1804S, 1805 and 1805S.
b. Per NIOSH requirements applicable to N95 respirators.

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