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Technical Bulletin

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Revision 3

Decontamination Methods for 3M N95 Respirators

Description

During this public health emergency of the COVID-19 pandemic outbreak, many healthcare institutions are experiencing shortages of 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 recommendations for PPE Optimization, including 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: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html and has published new 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."**

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.

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 Crisis Standards of Care Decontamination Recommendations. 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, 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. 3M remains committed to providing data to the health care community as soon as possible. 3M is not evaluating the efficacy of these methods with regards to deactivation of the virus that cause COVID-19.

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.

1. These conclusions apply to all 3M filtering facepiece respirators including those approved in countries and regions other than the United States.

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.

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

Please revisit this bulletin often for frequent updates.

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	U.S. FDA EUA Issued
Vaporized Hydrogen Peroxide (VHP)						
VHP – Steris	1860, 8210	V-PRO 1 Plus, V-PRO Max, V-PRO Max2, Non-Lumen Cycle	10	Pass	Pass	Link
VHP –ASP, STERRAD®	1860, 8210	100S-Short NX-Standard 100NX-Express	2	Pass	Pass	No
VHP – Ecolab, Bioquell	Under evaluation	Under evaluation		Under evaluation	Under evaluation	No
VHP- Battelle	1860, 8210, 1804	Under evaluation	3 - tested, 20 - under evaluation	3 cycles: Pass 20 cycles: Under evaluation	Under evaluation	Link
VHP - Sterilucent	1860, 8210	Sterilucent™ HC 80TT - Flexible Cycle	10	Pass	Pass	No
Ultraviolet Radiation						
UV Lamp 254nm	1860, 8210, 1804	Under evaluation		Under evaluation	Under evaluation	No
Moist Heat						
Steris - Moist Heat, Environment Chamber	1860, 8210	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 and 1805S.
b. Per NIOSH requirements applicable to N95 respirators.

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