Introduction

3M’s assessments of decontamination methods and their compatibility with certain 3M filtering facepiece respirator (FFR) models, made available for end user consideration during the unprecedented respirator shortage associated with the COVID-19 pandemic, are detailed in these 3M Technical Bulletins:

- U.S. information: Decontamination of 3M Filtering Facepiece Respirators, such as N95 Respirators, in the United States - Considerations
- Global Information: Decontamination of 3M Filtering Facepiece Respirators: Global Considerations.

The purpose of this bulletin is to supplement those technical bulletins with answers to some frequently asked questions.

General FFR Decontamination Questions

Many general questions on filtering facepiece respirators (FFRs) have been answered in the 3M Technical Bulletin: Filtering Facepiece Respirators FAQ: Healthcare.

Should FFRs be decontaminated?

3M does not recommend decontaminating FFRs. FFRs are designed to be discarded at the end of their useful life. Governmental Agencies who have recommended decontamination of FFRs have identified several other ways that organizations can work to reduce their need for FFRs or extend the use of their available FFRs. As an example, the U.S. Centers for Disease Control and Prevention (CDC), in their guidelines on Strategies for Optimizing the Supply of N95 Respirators recommends a wait and reuse approach as part of a limited re-use crisis capacity strategy during known shortages. “One potentially effective strategy to mitigate the contact transfer of pathogens from the respirator to the wearer could be to issue each HCP who may be exposed to patients with SARS-CoV-2 infection a minimum of five respirators. Each respirator will be used on a particular day and stored in a breathable paper bag until the next week. This will result in each worker requiring a minimum of five N95 respirators if they put on, take off, care for them, and store them properly each day. This amount of time in between uses should exceed the 72 hour expected survival time for SARS-CoV-2 (the virus that causes COVID-19).”

For additional strategies on ways to reduce and extend the use of FFRs, consider consulting the following resources:

- Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19) (WHO)
- Strategies for Optimizing the Supply of N95 Respirators (U.S. CDC)

What methods did 3M use to evaluate the compatibility of specific decontamination methods with specific 3M FFR models?

To assess the compatibility of specific decontamination methods with specific 3M FFR models, 3M evaluated the impact of the decontamination methods on the filtration and fit performance of FFR models. The compatibility of decontamination methods is dependent on both of the following:

- The specific details of the decontamination procedure AND
- The specific construction and material composition of each FFR model
Filtration validation:

Filter performance validation should be conducted using an instrument such as the TSI Automated Filter Tester 8130, which is used in generating filter data for meeting the U.S. respirator performance standard, 42 CFR part 84.

Some journal articles that describe various decontamination methods for N95 respirators used the TSI model 8038 (also known as the PortaCount®) to validate filter performance of the respirator. This is not an appropriate method for measuring filtration performance, because the PortaCount is designed to measure the fit of a respirator.

The PortaCount measures fit while a respirator is worn by a person by comparing the concentration of particles in the ambient air to the concentration of the same size particles inside the respirator. It measures only a narrow range of particle sizes which is expected to be captured effectively by the filter. As a result, tests conducted in this way seek to detect particles in that size range inside the respirator that have entered through a leak in the seal. Given that the PortaCount 8038 measures only very small particles of a very narrow size range, it should not be used to assess filter performance.

Respirator fit evaluation:

Respirator fit can be evaluated by one of multiple methods, in accordance with applicable local regulations related to respirator fit testing. One option is quantitative fit testing using the TSI model 8038, for example. Such testing should be conducted by a person experienced in the method. If this type of device is not available, a qualitative fit test method can be used. See 3M Training Video - 3M Fit Test Kit for details.

Fit can also be assessed indirectly by examining the respirator for damage following decontamination process. The damage can be in the form of deformed components, compressed or delaminated nosefoam, or stretched or saggy headbands.

Does 3M evaluate or have data on residual off-gassing for decontamination methods evaluated?

3M is testing the fit and filtration performance of certain 3M filtering facepiece respirators following decontamination. The safety of the decontamination method is assessed by the manufacturer of the decontamination equipment. In the United States, there is a process for these equipment manufacturers to submit their decontamination data to the FDA and request an EUA. The FDA reviews safety and efficacy data before granting an EUA. The equipment manufacturer can be contacted to obtain relevant information specific to processing in their system with their specific chemical sterilant or high-level disinfectant under the process conditions they recommend.

Can a decontaminated respirator be shared by multiple users?

We strongly advise against sharing decontaminated respirators. Decontamination methods may be effective in deactivating certain pathogens such as COVID-19 but rarely clean the respirator. Skin oils, makeup and proteins excreted by the wearer may remain on the respirator post-decontamination. Therefore, it is not good hygiene practice to share FFRs, even after decontamination. Moreover, it is important to note that most decontamination methods do not sterilize the respirator, posing potential cross contamination risk to someone who is not the original wearer. In addition, FFRs typically conform to the shape of the face of the wearer and may not fit as effectively on the face of a subsequent wearer of the decontaminated respirator.

How do I decide if my FFR should be discarded instead of decontaminated?

FFRs are designed to be discarded after their useful life. If the respirator becomes difficult to breathe through, is visibly soiled, or damaged, then it should be discarded. The respirator should be examined before each donning and discarded if any components are damaged. If the wearer perceives at any time during wear that the respirator is not sealing well, the wearer should go to an area clear of the airborne hazard, remove the respirator, and discard it.
How many times can an FFR be decontaminated and reused?

The number of decontamination cycles that have been tested for filtration and fit after exposure to decontamination methods varies for each FFR model and the method of decontamination. Refer to Tables 1 and 2 in this 3M technical bulletin. The number of cycles specified in the table should be considered a maximum number of times an FFR can be decontaminated for each method. However, depending on wear times, handling, etc., an FFR may need to be discarded before it has been decontaminated the maximum number of times specified. FFRs should always be thoroughly inspected before each use. If an FFR becomes dirty, damaged, or difficult to breathe through, it should be discarded. See this 3M Instructional Video - Inspection and Redonning (putting on) of a FFR for tips for inspection and redonning for reuse.

Questions about Specific Decontamination Methods

Why is Ethylene Oxide not recommended for 3M FFR decontamination?

The U.S. CDC does not recommend Ethylene Oxide (EO) for decontamination and reuse of respirators because it may be harmful to the wearer and would require extensive studies to ensure that no off-gassing occurs into the breathing zone of the wearer. EO is a well-known inhalation risk, associated with chronic, long term health effects. During pandemics such as COVID-19, it is common for respirators to be worn by healthcare providers throughout long shifts for multiple days, with the potential for continuous exposure through inhalation and exhalation of breath. While EO is an acceptable sterilant for many device types, given the unique use conditions of respirators and the known inhalation risk of ethylene oxide, 3M is not recommending its use in decontamination of any 3M filtering facepiece respirators.

Why is gamma radiation or e-beam not recommended for decontamination?

Respirator decontamination using ionizing radiation methods (Gamma, Electron beam and X-rays) is not recommended because such methods are not compatible with polypropylene polymer. The filter in FFRs as well as in the reusable respirator filters is made of polypropylene. Gamma radiation is known to break down polypropylene, potentially causing reduced filter efficiency, which may increase the penetration of harmful particles such as pathogens through the respirator, thereby increasing potential exposure risk to the wearer. 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, decontamination, and reprocessing, it is especially important to have processed FFRs evaluated in a test laboratory using equipment designed to evaluate filtration of particulate respirators.

Why are high heat or steam treatments not recommended?

FFRs contain filter material made of fine polypropylene fibers. The fibers begin to melt between 90-100°C (194-212°F). As the fibers melt, they are distorted, affecting filtration performance. Therefore, exposing respirators to temperatures above about 85°C (185°F) will damage the filter, potentially causing reduced filter efficiency, which may increase the penetration of harmful particles, such as pathogens through the respirator, thereby increasing potential exposure risk to the wearer. The extent of filtration efficiency degradation is dependent upon the respirator model, temperature, and time at elevated temperature.

Steam treatment is typically conducted at temperatures above the boiling point of water (100°C or 212°F). Such temperatures can damage the filter fibers in the respirator as described above.

Decontamination methods using a consumer electronic cooker are not recommended due to temperature variations within the appliance, which can expose the respirator to high temperatures in excess of 100°C and degrade filtration performance.

Why is microwave not recommended?

Microwave oven heating is not compatible with adhesives and metal parts. FFRs typically have a nosefoam attached with an adhesive, and they contain metal noseclips and metal staples attaching the headbands to the respirator. Microwave energy heats the metal, causing it to melt the surrounding plastic of the respirator, potentially creating pinholes and distorting the shape of the respirator compromising its fit. Moreover, microwave energy melts the adhesive used to attach the nosefoam to the respirator, causing the nosefoam to delaminate and/or compress, which in turn can compromise the fit of the respirator.
Why are alcohol, soap and water, or quat-based disinfectants not recommended?

These chemicals degrade the respirator’s filtration performance.

Can ozone be used to decontaminate FFRs?

Ozone is known to degrade polyisoprene and other polymers. Ozone exposure degrades the integrity of the elastic headbands and nosefoam, which compromises respirator fit.

Can FFRs be stored for 5 days before reuse to help mitigate contact transfer?

The U.S. CDC suggests waiting for 5 days before reuse to allow for viral inactivation as a strategy to be employed to extend use of FFRs in a healthcare setting as part of a limited re-use crisis capacity strategy during known shortages. Other studies (Munster University School of Health (Fachbereich Gesundheit) discuss a “7 day drying indoors” method.

Why do some VHP methods say no cellulose-based products, but the cellulose-containing model 1804 respirator, available in some countries, appears under other methods?

The table indicates which respirators were tested for filtration and fit. The cellulose in 3M FFRs is bound in an elastomer. According to manufacturers of VHP equipment, most VHP methods are not to be used with cellulose-based materials. Regulations in some countries prohibit products that contain cellulose from being treated in VHP equipment, because of concerns regarding efficacy and safety. See the 3M Technical Bulletin Cellulose Certification - Filtering Facepiece Respirators for information about which 3M respirators contain cellulose.

Can I use appliances at home to decontaminate my respirator?

We do not recommend that frontline workers bring PPE home for decontamination.

Other Related Questions

What PPE can be used as alternatives to filtering facepiece respirators?

FFRs are particulate respirators. There are a variety of other types of respirators that employ the same particle capture technologies as FFRs. These include elastomeric half facepieces, elastomeric full facepieces, and powered air purifying respirators (PAPRs). For additional information, refer to the 3M Technical Bulletin - Possible Alternatives to Surgical Filtering Facepiece Respirators: Healthcare.

How can reusable respirators be decontaminated?

Many reusable respirators can be decontaminated and used multiple times. Refer to the equipment instructions.

3M Elastomeric Half & Full Facepiece Respirators:

Cleaning and Disinfecting 3M Reusable Elastomeric Half and Full Facepiece Respirators following Potential Exposure to Coronaviruses

3M PAPRs:

Cleaning and Disinfecting 3M™ Versaflo™ Powered Air Purifying Respirator Assemblies following Potential Exposure to Coronaviruses

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