

Technical Bulletin

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Respiratory Protection FAQ – First Responder Respirator (FRR)

Introduction

During outbreaks of coronaviruses, some Military and First Responder organizations may assign reusable respirators to workers providing care for persons with suspected cases of infection by coronaviruses. This document contains considerations related to the performance of certain 3M Scott respirators that will be used for protection against potential exposure to coronaviruses.

When used correctly, respirators can help reduce wearers' exposures to airborne particulate hazards, including both bioaerosols and nonbiological aerosols. Respirators contain filter material and are designed to form a seal with the wearer's face, so that air passes through the filter (instead of around the edges) before it is inhaled. A common choice for Military and First Responder organizations is to use a Reusable Full Facepiece Respirators (RR), such as the 3M[™] Scott[™] First Responder Respirator (FRR)¹ illustrated below.



The 3M[™] Scott[™] First Responder Respirator (FRR)¹ is an Air Purifying Respirator (APR) system designed to meet the requirements for defense against current Chemical, Biological, Radiological and Nuclear (CBRN) threat levels and for all other operational requirements. For example, tight-fitting full-facepiece respirators designed for CBRN applications, can be used in combination with appropriately certified CBRN filters to provide respiratory protection against solid and liquid micro-organisms, e.g. viruses such as SARS-CoV-2, the virus that causes COVID-19. BS8468-2:2006 or NIOSH 42 CFR 84 CBRN APR certified CBRN filters, when worn in conjunction with a correctly fitted full facepiece respirator, will deliver a minimum P3 or P100 particulate protection respectively, thereby exceeding the current WHO/CDC recommendations² for COVID-19 protection.

No matter how well a respirator seals to the face and how efficient the filter media is, wearers should expect a small amount of leakage inside any respirator. No respirators will eliminate exposures entirely. Please read the questions and answers below to give you a better understanding of how the FRR respirator works. If you have additional questions about the use of 3M respirators, please consult our website or contact your local 3M office. For more information on many of these topics, see <u>3M Technical Bulletin - Respiratory Protection for Airborne Exposures to Biohazards.</u>

It is important to note that guidance from any applicable occupational health authority, the World Health Organization (WHO), United States National Institute for Occupational Safety and Health (NIOSH), United States Centers for Disease Control and Prevention (CDC), United States Environmental Protection Agency (EPA), and Health Canada or your local health authority should be followed in any health emergency. This document is not a substitute for that guidance.

The following are generalized responses to some frequently asked questions, to help provide clarity around the following topics:

- 1. Will the First Responder Respirator (FRR) offer protection in connection with COVID-19?
- 2. What is the FRR secondary filter designed for?
- 3. What is the FRR secondary filter made from?
- 4. Can the FRR secondary particulate filter be removed and reinstalled?
- 5. Can the secondary filter be cleaned and reused?
- 6. How can the secondary filter be cleaned?
- 7. What is the recommended service life or when should it be changed out?
- 8. What is the efficiency of the secondary filter?

1. Will the First Responder Respirator (FRR) offer protection in connection with COVID-19?

Several questions have been raised regarding the use of respirators to help protect against biological agents. The primary question is whether particulate respirators can filter small particles such as fungal spores (2 to 5 μ m), bacteria (0.3 to 10 μ m), or viruses (0.02 to 0.3 μ m)³. The physical size of various organisms is shown in Table A^{3,4,5}. As noted previously, biological organisms may be carried on other particles including dust, blood, saliva, etc

Microorganism (common name or disease)	Physical Size (µm)	
Hepatitis virus (Hepatitis B)	0.042 - 0.047	
Adenovirus (respiratory infections)	0.07 - 0.09	
Filoviruses (Ebola)	0.08 diameter	
	0.79 - 0.97 length	
Bunyaviridae (Hantavirus)	0.08 - 0.012	
Orthomyxoviridae (Influenza A, B, & C)	0.08 - 0.012	
Coronaviridae (SARS - CoV & MERS - CoV)	0.125	
Variola Virus (Smallpox)	0.14 - 0.26 diameter	
	0.22 - 0.45 length	
Mycobacterium tuberculosis (TB)	< 1 to > 5 diameter	
Bacillus anthracis spore (Anthrax infection)	1.0 - 1.5 diameter	

Droplets generated from coughing, sneezing or talking will quickly dry in the air to form droplet nuclei. Droplet nuclei generated from coughs, sneezes, or speaking have been found to range from submicron to over 20 microns.⁴⁻⁵ Influenza viruses, and other viruses, have been collected from exhaled breath.⁶ It is thought that droplet nuclei that contain Mycobacterium tuberculosis may range from less than 1 μ m to greater than 5 microns.⁷⁻⁸ Airborne particles containing influenza viruses have been sampled from the air of hospital rooms containing influenza patients and found to be in the size range from less than 1 μ m to greater than 4 μ m.⁹ Understanding filtration mechanisms can help answer whether or not these particles can be filtered by particulate respirators.

Many particulate or combination filters use a non-woven fibrous filter media to capture particles. Fibers from less than 1 μ m to 100 μ m in size crisscross to form a web of many layers which is mostly air due to the spaces between the fibers. It is these spaces between fibers that allow for breathability. Particles are trapped, or captured, when flowing through the layers of filter media, and a particle becomes attached to a fiber due to a number of different mechanisms. The most common of these are inertial impaction, interception, diffusion, and electrostatic attraction.¹⁰

To understand how a particle is captured, one must first consider the movement of air through the filter media. The path of the air around a fiber may be described in terms of imaginary streamlines. Any particle carried by the air may or may not stay within the streamlines depending largely upon the particle's size (aerodynamic diameter). Respirable particles above 0.6 µm in diameter are typically captured efficiently by interception and inertial impaction.¹¹ Inertial impaction occurs when a particle cannot follow an air streamline around a fiber because of its inertia and instead impacts into the fiber. In the interception mechanism, the particle holds to the streamline, but that streamline will naturally bring the particle close enough to come in contact with the fiber.

In contrast, diffusion is typically very efficient for particles smaller than 0.1 μ m. Random movements of air molecules collide with these very small particles and cause them to wander across streamlines until they come in contact with a fiber. Because of the various mechanisms by which particulate filtration occurs, the smallest particles are typically not the most difficult to filter. Most particulate filters have a region of lower filtration efficiency somewhere between 0.05-0.5 μ m.¹⁰ Particles in this range are large enough to be less effectively pushed around by diffusion, but small enough to be less effectively captured by interception or impaction. The most penetrating particle size (MPPS) will depend on the filter media, air flow, and electrostatic charge on the particle. Filters that use electrostatic attraction may have a MPPS shifted to a slightly smaller size range.

Filtration claims, especially regarding bioaerosols, can be complex to understand. To help maximize the level of protection, make sure to use a respirator that has been tested and approved per all applicable local regulations. And, as mentioned above, filtration efficiency is just one of the required components that needs to be considered when selecting and using a respirator. An often-expressed question is whether biological aerosols are removed by respirator filters the same as non-biological aerosols. Due to concerns on the efficacy of respirator filters for Mycobacterium tuberculosis (TB), many studies have been conducted using bioaerosols. These filter evaluations were conducted over a range of test conditions (flow, humidity), biological species representing various shapes (spheres, rod, and rod/sphere shape) and sizes, filter performance levels and varying filter media (mechanical and electret; polypropylene and fiberglass).

These experiments¹²⁻¹⁷ found no significant difference in the filtration of biological aerosols and non-biological aerosols with similar physical properties – in other words, filtration efficiency is based on particle size rather than the nature of the particle's origin.¹⁸⁻²¹ Spherical particles were found to be usually more penetrating than rod-shaped particles with equivalent aerodynamic diameter over a range of particle sizes.

Studies in which researchers challenged NIOSH-certified N95 and P100 filtering facepiece respirators and filter cartridges with viable virus aerosols – including H1N1 influenza aerosols – indicated that respirators capture viable H1N1 influenza and other virus aerosols as well as or better than the filtration efficiency required by their respective N95 or P100 rating.¹⁸⁻¹⁹ Other studies have investigated the filtration efficiency of respirator filters challenged with nanometer-sized particles. These studies have found that NIOSH certified respirators show filtration efficiencies similar to what would be expected based on their approval category.²²⁻²³ Where penetrations have slightly exceeded 5%, the results were not statistically significant.²³

Tight-fitting full-facepiece respirators designed for CBRN applications can be used in combination with appropriately certified filters to help provide respiratory protection against solid and liquid micro-organisms, e.g. coronaviruses. Full facepiece CBRN respirators with a P3 or P100 filter exceed the current WHO/CDC recommendations² for respiratory protection in connection with COVID-19. Therefore, respirators such as the 3M[™] Scott[™] First Responder Respirator (FRR) with its combined "*mask within a mask design architecture*", help provide effective protection against coronaviruses when properly fitted and worn. And its patented secondary filtration technology allows for increased levels of protection against biological & radiological particulates and facilitates the unique sweat removal system greatly increasing overall comfort.

2. What is the FRR secondary filter designed for?

In addition to the filtering capability of the primary canister (e.g. CBRN Cap1 Canister or Tac-1), the FRR's "mask within a mask" concept incorporates a patented secondary filter system that provides additional particulate protection against biological and radiological material hazard. Because the inner oro-nasal mask of an FRR, provides a separate seal (not just an air guide), the Respirator filters the air between the ocular (eye space) and breathing zones through the secondary filter. Integrated into the internal oro-nasal inner cavity, this secondary filter is a particulate filter only because biological agents are particulate in nature.



3. What is the FRR secondary filter made from?

The secondary filter particulate media is made from a durable hydrophobic polytetrafluoroethylene membrane which is water repellant and can therefore be easily disinfected. The porous PTFE membrane provides a low pressure drop particulate filter with a minimum 98% particulate efficiency (See section 8 for further details).



4. Can the FRR secondary particulate filter be removed and reinstalled?

Yes. The secondary filter can be easily removed and refitted by the user for cleaning and inspection purposes. Inspect and reassemble the respirator as described in the Operation and Maintenance Instructions.

5. Can the secondary filter be cleaned and reused?

Yes. The secondary filter can be easily removed and refitted by the user for cleaning and inspection purposes. Air dry in a non-contaminated area or follow the directions provided in the Operating and Maintenance Instructions provided with the full facepiece

6. How can the secondary filter be cleaned?

The secondary particulate filter can be cleaned and reused using the following procedure:

- Visually inspect secondary filter for signs of damage and contamination
- o Wash secondary filter in 1% solution of Trigene or similar non-abrasive detergent and rinse THOROUGHLY
- o Shake excess water from filter
- o Visually check by-pass micro tube is clear and uncontaminated
- Allow secondary filter to dry naturally.

Secondary filters that are wet, from sweating or immersion in water / cleaning fluid, can be air dried and re-used once dry. They **should not** be dried using artificially heated or forced volume air sources (e.g. hair/ hand dryers). Post cleaning of the FRR and prior to re-assembly, the secondary filter moisture clearance tube must be visually inspected to be clear of any contamination or blockage. If grossly contaminated and/or blocked, replace with a new assembly. Air dry in a non-contaminated area or follow the directions provided in the Operating and Maintenance Instructions provided with the full facepiece

7. What is the recommended service life or when should it be changed out?

As per the 3M[™] Scott[™] FRR User Instructions the secondary filter should be changed on the following occasions:

- o If deploying to an operational environment after a confirmed pathogen release
- o If inspection reveals that the filter is damaged or beyond effective cleaning
- o After 5 years of issue

8. What is the filtration efficiency of the secondary filter?

The FRR secondary particulate filter membrane material offers particulate protection that is 98% efficient, passing both the N95 (NIOSH42 CFR, Part 84) or P2 (EN143) particulate filter standard requirements as a standalone item (Table B). The particle filter removes aerosols and solid particulates which makes it effective for protection against a range of radiological and biological agents."

Standard	Classification	Filter Efficiency
NIOSH 42 CFR 84 Subpart K	N95	≥ 95%
EN 143:2000	P2 (elastomeric facepiece)	≥ 94%
EN136 Conditions	FRR Secondary Particulate Filter	98%

Table B. Filtration Requirements Per U.S and European Standards

When fitted with the secondary particulate filter and appropriate BS8468-2:2006 (P3) or NIOSH 42 CFR 84 CBRN APR (P100) certified filter, a correctly fitted FRR will deliver a respiratory protection exceeding the current WHO/CDC recommendations² for COVID-19. Please note that penetration of particles through the filter is only one of the possible sources of exposure to contaminants. Other potential sources such as face seal leakage, leakage as a result of improper maintenance, or not wearing the respirator when necessary may contribute more to exposure than filter penetration. Each of these factors must be addressed and controlled. For example, to ensure proper fit, all Reusable Full Facepiece Respirators (RR) must be fitted to their wearer using an appropriate fit test method such as the ambient particle counting method using the TSI® PortaCount®. Wearers must be trained how to properly use and maintain their respirators and the importance of wearing them all the time during potential exposure.

Please also note that respirators help reduce exposure to airborne contaminants but do not prevent the inhalation of all particles. As a result, when properly selected, used and maintained, respirators can lower exposures to concentrations considered safe for most non-biological particles. However, they do not eliminate the risk of exposure, infection, or illness since safe exposure levels have not been established for biological particles. In many countries, types or classes of respirators are given an "assigned protection factor," or APF. APF is the expected ability of the respirator to reduce exposure when used according to an effective respiratory protection program. For example, an APF of 10 means that a respirator may reduce exposure by a factor of 10 (or 90%) when properly selected, used, and maintained. Therefore, even if a filter could be hypothetically 100% efficient, the expected amount of exposure reduction would be limited by the APF. Because no respirator will prevent the inhalation of all particles, none can entirely eliminate the risk of exposure, infection, and illness.

For more information on the proper selection, use, and maintenance of respiratory protection, please see the United States (US) OSHA standard for respiratory protection (29 CFR 1910.134), EN 529 Respiratory protective devices: Recommendations for selection, use, care and maintenance — Guidance document^{24,} or any applicable local standards and guidance.

Additional Resources

- WHO: https://www.who.int/health-topics/coronavirus
- CDC: https://www.cdc.gov/coronavirus/index.html
- OSHA: https://www.osha.gov/SLTC/novel_coronavirus/
- ECDC: https://www.ecdc.europa.eu/sites/default/files/documents/Risk-assessment-pneumonia-Wuhan-China-22-Jan-2020.pdf

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