

# Respiratory Protection FAQ: Healthcare

### Introduction

When respiratory protection is required or recommended for healthcare professionals to help reduce their exposures to airborne particles, including bacteria and viruses that may cause disease, most often the requirement is for them to use an "N95, FFP2 or equivalent" filtering facepiece respirator.

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 is a disposable filtering facepiece respirator (FFR), such as those shown below.







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 respirators. No respirator will eliminate exposures entirely. Please read the questions and answers below to give you a better understanding of how respirators work. If you have additional questions about the use of 3M respirators, please consult our website or your local 3M office.

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

- 1) Respirator vs. Masks
- 2) Types of Respirators
- 3) How Respirators Work
- 4) How to Use Respirators
- 5) Comfort Considerations
- 6) Other Questions

For more information on many of these topics, see 3M Technical Bulletin - Respiratory Protection for Airborne Exposures to Biohazards. Additionally, the Hospital Respiratory Protection Program Toolkit, co-authored by the Occupational Safety & Health Administration (OSHA) and other U.S. agencies, provides guidance on developing and implementing effective respiratory protection programs, focusing on prevention of transmission of aerosol transmissible diseases to healthcare professionals.

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), and the United States Environmental Protection Agency (EPA), or your local health authority should be followed in any health emergency and that this document is not a substitute for that guidance.

### Respirators vs. Masks

What should healthcare and hospital infection control practitioners and occupational health and safety teams look for when selecting a respirator during public health emergencies?

- 1) Check to confirm that the product you are considering is certified as a respirator (such as an N95, FFP2, or KN95). Certified respirators contain filtration material capable of capturing particles including ones that are too small to see with your eyes. Certified particulate respirators can filter all types of particles, including bacteria and viruses.
- 2) Be sure to select a respirator that can seal against your face without any gaps. To provide respiratory protection, a respirator must fit snugly on the users face to ensure there are no gaps between the face and the respirator seal. Even very small gaps between the face and the edge of the respirator allow air, and particles, to go around the filter media.

Surgical gauze masks or uncertified "dust" masks typically do not have adequate filtration material and may not be designed to form a seal against the face and therefore may not provide the expected protection to your lungs. Note that some uncertified masks look very similar to certified respirators. It is important to carefully read the information printed on packaging before you purchase a product.

For more information, see 3M Technical Bulletin: What is an N95 Respirator?

### What is the difference between a certified respirator and a surgical mask?

Respirators are designed to help reduce the wearer's exposure to airborne particles. The primary purpose of a surgical mask is to help prevent biological particles (e.g. bacteria and viruses) from being expelled by the wearer into the environment. Surgical masks are not necessarily designed to seal tightly to the face, so air might leak around the edges.

Many surgical masks are also designed to be fluid-resistant to splash and splatter of blood and other bodily fluids.

Surgical masks may be provided to patients by healthcare organizations to help protect healthcare professionals and other patients from particles being introduced into the room as a patient talks, sneezes or coughs.

Some approved respirators are designed to have the characteristics of both a respirator and a surgical mask. These products are often called "healthcare or medical respirators." In the U.S., surgical N95 respirators are both approved by the U.S. National Institute of Safety and Health (NIOSH) and cleared by the U.S. Food and Drug Administration (FDA) for use in surgery. In other countries, these products are often approved by two equivalent or similar agencies.

For more information, see 3M Technical Bulletin: Respirators and Surgical Masks — A Contrast

## Types of Respirators

#### Do I need a surgical respirator?

Surgical respirators are typically designed to be fluid-resistant to splash and splatter of blood and other bodily fluids. They are intended to be worn by healthcare professionals during procedures in which a blood vessel might be punctured resulting in a high velocity stream of blood. In contrast, liquid-droplet aerosols, such as those generated by coughs and sneezes, are capturable by the particulate filter in certified filtering facepiece respirators. Surgical respirators also do not have exhalation

valves or have specially designed shrouded exhalation valves. Surgical respirators are designed without exhalation valves because there is concern that any bacteria or viruses expelled from the wearer may travel through the exhalation valve and enter the surrounding environment, such as a sterile field during surgery, potentially exposing other people.

Many tasks performed by healthcare professionals – such as patient intake and non-emergency patient evaluation – are highly unlikely to generate high-pressure streams of liquid or be conducted in a sterile field. For workers performing such tasks, a primary potential hazard to consider is airborne viruses and bacteria, such as those generated by coughs and sneezes, which are effectively filtered by N95 respirators. Therefore, if a healthcare facility is prioritizing respirator use, they may want to consider prioritizing use of surgical respirators for those healthcare professionals performing surgery or other tasks that may expose them to high pressure streams of bodily fluid or conduct work in a sterile field. In times of limited supply healthcare facilities may want to consider use of non-medical N95 respirators for other tasks.

For more information, see 3M Technical Bulletin - Surgical vs. Standard N95 - Which to Consider? and 3M Technical Bulletin - Possible Alternatives to Surgical Filtering Facepiece Respirators: Healthcare.

#### What is the difference between different countries' respirator approvals? (N95 vs. FFPS vs. KN95, etc.)

Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an "N95, FFP2, or equivalent" respirator.

Most regulatory standards for FFRs have similar, but not identical, test methods and respirator classes. The most commonly used respirator class descriptor is filtration efficiency. This is the ability of a respirator to filter a specific particle in a controlled laboratory test. Because of similarities in standard requirements, the following respirator classes, from various countries and regions, all have approximately 94-95% filtration efficiency, are designed to form a seal with the face, and may be considered to be functionally similar for most uses against non-oil airborne particles:

- Australia/New Zealand P2
- Brazil P2
- China KN95, KP95
- Europe FFP2
- Japan DS2, DL2
- India BIS P2
- Korea 1st class
- US NIOSH N95, R95, P95

For more information, see 3M Technical Bulletin: Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator Classes

## How Respirators Work

#### Can a respirator help protect against very small particles like bacteria and viruses?

A certified FFR is one way to help reduce exposure to small particles like patient-generated aerosols that might contain bacteria and viruses.

Droplets generated from talking, coughing or sneezing will quickly dry in the air to form droplet nuclei – which may contain bacteria and viruses. Potentially infectious particles have been found to range in size from submicron to over 20 microns. <sup>12</sup>

<sup>123</sup> Particles, including bioaerosols, in this size range have been found to be effectively captured by most particulate respirator filters. <sup>45</sup>

For more information about filtration of bioaerosols by respirators, see Respiratory Protection for Airborne Exposures to Biohazards.

#### Can a surgical mask help protect against small particles?

Surgical/procedure or "medical" facemasks are designed to help keep spit and mucous generated by the wearer from reaching a patient or medical equipment. Some surgical/procedure masks do contain filter media but as they may not be designed to form a seal to the face, and have not been certified to meet all of the performance standards of a respirator, they should not be used to help reduce exposures to airborne particles. To better understand the difference between respirators and surgical/procedure masks, see 3M Technical Bulletin - Respirators and Surgical Masks - A Contrast.

#### Can a respirator with a valve be effective against bioaerosols?

The purpose of a respirator's exhalation valve is to reduce the breathing resistance during exhalation; it does not impact a respirator's ability to provide respiratory protection. The valve is designed to open during exhalation to allow exhaled air to exit the respirator and then close tightly during inhalation, so inhaled air is not permitted to enter the respirator through the valve. Most countries do not permit valves on surgical respirators because wearer-generated droplets, exhaled through the valve, might contaminate a sterile field. While a valve does not change a respirator's ability to help reduce a wearer's exposure to bioaerosols, it is not recommended that a person who is exhibiting symptoms of illness wear a valved respirator, because there is a possibility that exhaled particles may leave the respirator via the valve and enter the surrounding environment, potentially contaminating the sterile field. In summary:

- Healthcare workers may wear valved or unvalved respirators to help reduce their exposure to potentially infectious aerosols
- Healthcare workers should wear a surgical respirator (which usually do not have valves) if they require respiratory
  protection while performing patient care tasks that might generate a high-pressure stream of liquid such as arterial spray
  or are working in a sterile field.

#### Will filtering facepiece respirators remove odors?

Some FFRs are available with a carbon layer that will provide relief against low levels of odors (also called "nuisance" odors). For higher-concentration levels of gases and vapors or for areas with low oxygen, different types of respirators should be used. Contact your occupational health and safety department, local health authority and hire a professional to deal with these types of situations, as they can be very dangerous.

#### Does 95% efficient mean that 5% of the particles get through the filter?

- 1. Cole, E.C. and C.E. Cook: Characterization of Infectious Aerosols in Health Care Facilities: An aid to Effective Engineering Controls and Preventive Strategies. American Journal of Infection Control. 26:453-64; 1998.
- 2. Morawska L, Johnson GR, Ristovski ZD, Hargreaves, M, Mengersen K, Corbett S, Chao CYH, Li Y, and D. Katoshevski. Size distribution and sites of origin of droplets expelled from the human respiratory tract during expiratory activities. J Aerosol Sci 40:256–269; 2009.
- 1. Stelzer-Braid, S., Oliver, B.G., Blazey, A.J., Argent, E., Newsome T.P., Rawlinson, W.D., and E. R. Tovey. 2009. Exhalation of Respiratory Viruses by Breathing, Coughing, and Talking. J Med Virol. 81:1674-1679; 2009.
- 2. Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Heath-care Facilities. MMWR Morb. Mortal Wkly. Rep. 43 (RR-1—RR-13); 1994.
- 3. Fennelly, K.P. et al.: Cough-Generated Aerosols of Mycobacterium Tuberculosis: A New Method to Study Infectiousness. Am. J. Resp. Crit. Care. 169:604-609; 2004.
- 4. Qian, Y., Willeke, K., Grinshpun, S.A., Donnelly, J. and C.C. Coffey. Performance of N95 respirators: Filtration efficiency for airborne microbial and inert particles. AIHA Journal. 59:128-132; 1998.
- 5. Heim, M., Mullins, B.J., Wild, M., Meyer, J., and G. Kasper: Filtration Efficiency of Aerosol Particles Below 20 Nanometers. Aerosol Science & Technology 39(8): 782 –789; 2005.

All respirators are designed to help reduce, not eliminate, exposures to airborne hazards. For example, N95-rated FFRs have a filtration efficiency of at least 95% against non-oily particles when tested using the NIOSH criteria. The particles used to test the filtration are in a size range that are considered the most penetrating. Therefore, the test methods ensure that the filter media can filter particles of all sizes with at least 95% efficiency.

It's important to remember that the filter efficiency alone does not determine the overall reduction in airborne hazards provided by a respirator. There are two other key determinants in reducing exposure: fit and wear time, both of which are addressed in the How to Use Respirators section of this document.

#### Can I wear a filtering facepiece respirator if I have facial hair?

FFRs are considered tight-fitting respirators, meaning they must seal to the wearer's skin to work correctly. Therefore, wearers should be cleanshaven if they will wear an FFR. If a worker is unable to shave than powered air purifying respirators (PAPRs) may be considered as an alternative to FFRs. Some PAPR headtops, called loose-fitting headtops, do not need to seal to the wearer's skin to work correctly; they instead are designed to cinch under the wearer's chin or at their neck. These loose-fitting headtops can accommodate some facial hair styles (see 3M Technical Bulletin - 3M™ Versaflo™ Loose Fitting Facepieces, Hoods, and Helmets: Use with Facial Hair).

#### Will a filtering facepiece respirator still work if I am not fit tested?

Possibly. When worn correctly, government-certified respirators, such as N95 respirators, can help reduce the number of airborne particles you breathe. If you do not receive formal training or a fit test (as a medical or industrial worker typically would), you may not receive the full benefit of the respirator. Fit testing is required in some countries and considered a best practice. However, studies have shown that people can still receive a reduction in exposure if they do the following:

- Follow the instructions on how to put on the respirator (i.e., donning)
- Perform the user seal check (fit check) described in the user instructions
- Make sure that they are clean-shaven where the respirator touches the face
- Make sure no clothing or jewelry gets between the respirator and the face

It is important to remember that respirators cannot eliminate the breathing in of all particles in the air and cannot eliminate the possibility of becoming sick. For your respirator to help reduce the number of particles you breathe, you must read and follow the user instructions that come with each respirator.

#### Can respirators without fluid resistance testing help protect against sneezes and coughs?

Filtering facepiece respirators do help protect against liquid droplets that are generated due to sneezes and coughs. When such droplets strike the surface of a respirator, they are captured like other airborne contaminants

Fluid resistance testing for surgical respirators involve a high-pressure jet of liquid sprayed directly at the respirator. A droplet from a sneeze or cough has far less momentum than a jet of liquid.

### How to Use Respirators

#### What should I do to become familiar with respirators and how to use them?

Occupational health and safety standards – and best practice – indicate that a complete and effective respiratory protection program should be in place whenever workers are required to wear respirators, including proper respirator selection, medical

Brian Rembialkowski, Margaret Sietsema & Lisa Brosseau (2017) Impact of time and assisted donning on respirator fit, Journal of Occupational and Environmental Hygiene, 14:9, 669-673.

evaluations, fit testing, and training. It is the employer's responsibility to ensure that all regulatory requirements are met and that workers are prepared to use their respirators safely and effectively. In certain countries respiratory protection programs are mandatory when respirators are used in occupational settings. Please be sure to review local respirator regulations when starting respirator use in your facility.

For more information about respiratory protection programs, see the 3M Center for Respiratory Protection.

The Hospital Respiratory Protection Program Toolkit (OSHA, CDC, Department of Health and Human Services) provides guidance on developing and implementing effective respiratory protection programs.

#### How important is the fit of the respirator?

It is very important that your respirator be able to seal completely to your face. Your respirator should be well-sized for your face, so no gaps or leaks are detectable around the edge of the respirator. If a respirator does not seal well to your face, airborne hazards can enter through the gaps in the faceseal. If you cannot achieve a good seal with your respirator, you should try a different model until you find one that is well sized and seals well to your face. The respirator should not be so large that it is very close to your eyes or impacting your vision.

It is very important to always follow the user instructions and do a user seal check (fit check) before entering a contaminated environment. Remember, the better the seal, the more of the air you breathe goes through the filter.

Your face should be cleanshaven in the area where the respirator seals to your skin. Beards, long mustaches, and stubble may cause leaks into the respirator.

If you are not able to obtain a good seal, please consult the user instructions and/or your supervisor.

#### How do I put on the respirator and check for an effective seal?

The user instructions for 3M respirators contain the model-specific procedures for putting on the respirator and checking for fit and seal. It is very important to read and follow the donning instructions very carefully and to conduct a user seal check (or fit check) every time the respirator is put on. The instructions are provided with the original packaging of the respirator.

#### Is a fit test hood system subject to contamination during an infectious disease outbreak?

The fit test hood used in the 3M™ Qualitative Fit Test Apparatus FT-10 and 3M™ Qualitative Fit Test Apparatus FT-30 is a closed environment. The following precautions apply:

- 1) All individuals with suspected or confirmed illness (cold, influenza, etc.) should be eliminated from fit testing.
- 2) All subjects should thoroughly wash their hands.
- 3) The test administrator handles the placement of the hood. The subject should not touch the test hood with his or her hands and should wear protective gloves and/or practice proper hand hygiene following any contact with the fit test hood.
- 4) If the subject coughs or sneezes during the test, the hood should be disinfected with typical disinfectant, such as adilute solution of common bleach.

#### Can filtering facepiece respirators be decontaminated?

FFRs are not approved for routine decontamination and reuse as standard of care. However, the US CDC indicates FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability of FFRs, during certain pandemic events. The CDC has published guidance on the Decontamination and Reuse of Filtering Facepiece Respirators.

3M has evaluated the compatibility of certain decontamination methods with 3M FFRs. For more information, see 3M Technical Bulletin – Decontamination Methods for 3M N95 Respirators.

#### Can filtering facepiece respirators be re-used?

Strategies for FFR extended use and reuse (without decontamination of the respirator) are currently available from CDC's National Institute for Occupational Safety and Health (NIOSH). In this document the following definitions are provided:

- **Extended** use refers to the practice of wearing the same N95 respirator for repeated close contact encounters with several patients, without removing the respirator between patient encounters.
- **Reuse** refers to the practice of using the same N95 respirator for multiple encounters with patients but removing it ('doffing') after each encounter. The respirator is stored in between encounters to be put on again ('donned') prior to the next encounter with a patient. Thus, N95 respirator reuse is often referred to as "limited reuse".

If extended use of N95 respirators is permitted, refer to the document linked above for guidance on implementation of this practice.

#### Is there a time limitation for wearing an FFR?

There is no time limit to wearing an FFR. Generally, respirators can be worn until they are dirty, damaged or difficult to breathe through. Note that if an FFR is used to filter bioaerosols, those potentially infectious particles will remain on the filter fibers, and therefore the respirator could become a potential source of contact contamination after use. The National Institute for Occupational Safety & Health (NIOSH) has Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings.

#### Can filtering facepiece respirators be shared?

FFRs are not intended to be decontaminated and are therefore assigned to only one person.

#### How should I store my respirator before use?

FFRs are carefully designed to both filter particles and seal to the face. To help protect the condition of respirators so they can function correctly, it's important to store them according to the specified storage requirements.

Until they are needed for use, respirators must be stored:

- In the original packaging
- In a hazard-free environment (clean air)
- Away from direct sunlight
- In a climate-controlled area, with humidity and temperature within the acceptable range specified on the packaging

This means that respirators should be stored indoors, in their original packaging, in a structured storage space where they can't become crushed or distorted.

#### Do filtering facepiece respirators have a shelf life?

Yes, many filtering facepieces do have shelf lives. The shelf life and storage information is usually found on the side or bottom of the package. Shelf life is usually shown as a "use by" or "use before" date. Please refer to the respirator packaging, as shelf life is specific to each model.

For more information see 3M Healthcare Particulate Respirator and Surgical Masks Storage Conditions and Shelf Life.

### Should the respirator be disposed of after the shelf life has expired?

3M's recommendation is that the respirator be disposed of after the stated use by date has expired.

The CDC has published guidelines, Strategies for Optimizing the Supply of N95 Respirators, in which CDC states the following about the use of respirators after the end of their shelf life: "In times of increased demand and decreased supply, consideration can be made to use N95 respirators past their intended shelf life. However, the potential exists that the respirator will not perform to the requirements for which it was certified. Over time, components such as the strap and material may degrade, which can affect the quality of the fit and seal. Prior to use of N95 respirators, the HCP [healthcare professional] should inspect the respirator and perform a seal check. Additionally, expired respirators may potentially no longer meet the certification requirements set by NIOSH."

CDC also published information regarding research NIOSH has performed on five stockpiled 3M respirator models that are past their shelf life: Release of Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response. Based on the research findings, CDC and NIOSH state that they believe the listed products, "despite being past their manufacturer-designated shelf life, should provide the expected level of protection to the user if the stockpile conditions have generally been in accordance with the manufacturer-recommended storage conditions and an OSHA-compliant respiratory protection program is used by employees." In the document linked above, CDC/NIOSH recommend thorough inspection procedures and conducting user seal checks before using those stockpiled respirators included in the study. Organizations who have been issued stockpiled respirators past their shelf lives should review the information published by CDC and NIOSH, to aid in decision-making regarding how to use those respirators.

For additional considerations in understanding shelf lives, these 3M resources may be helpful:

- 3M Blog Post: Why Do Disposable Respirators Have a Defined Shelf Life?
- 3M Filtering Facepiece/Disposable Respirator Storage Conditions and Shelf Life FAQs
- 3M Healthcare Particulate Respirator and Surgical Masks Storage Conditions and Shelf Life FAQs

### Are multiple sizes/models of respirators needed?

Multiple sizes or alternative facepiece designs can provide the individual with additional options for obtaining a good fit and seal. It is important that the respirator fit the wearer. In the U.S., UK and certain other countries, workers must pass a fit test prior to use of a respirator in a contaminated area. Where not required by law, 3M recommends that workers pass a fit test prior to use of a respirator in a contaminated area.

### **Comfort Considerations**

#### I'm looking for a comfortable respirator - what should I know?

Many FFR models include a variety of comfort features, such as exhalation valves, nose foam, and small-sized options. You might take note of listed comfort features, in addition to whether a product holds a certification from an approval authority.

It may also be helpful to note that reusable elastomeric respirators offer a different wearer experience from FFRs, for those applications where an exhalation valve is acceptable. The sealing surfaces of elastomeric facepieces are rubber or silicone instead of the "nonwoven" materials that line the insides of FFRs. Due to the nature of elastomeric respirator design, exhaled air exits the facepiece through an exhalation valve, rather than through the filter material, as it does with unvalved FFRs. Some wearers may prefer this experience.

### Other Questions

#### How can I help determine whether a 3M respirator is authentic or a counterfeit?

3M recommends purchasing 3M respirators from 3M authorized distributors or dealers, which will increase the likelihood that you will receive authentic 3M products.

3M does not recommend purchasing respirators from unknown sellers on multi-party internet e-commerce platforms. Here are some tips to help avoid counterfeit products:

- 3M respirators will be sold in 3M packaging, with model-specific user instructions accompanying the product
- 3M respirators should not be sold individually, or without packaging (including User Instructions)
- 3M has strict quality standards, and therefore products that have missing straps, strange odors, blocked valves, misspelled words, etc. are likely not authentic 3M respirators

The 3M Safe Guard™ product authentication process can be used to help ensure your 3M products are authentic. It is available only for the following models:

- 3M™ Particulate Respirator 8210
- 3M<sup>™</sup> Particulate Respirator 8210Plus

#### Does carbon dioxide from exhaled breath affect health?

Carbon dioxide from exhaled breath inside of certified filtering facepiece respirator has not been shown to affect health. A 2010 study indicated that although CO<sub>2</sub> levels increase inside filtering facepiece respirators (such as N95s) during wear, health indicators do not change significantly, suggesting that there is no effect on health.<sup>1</sup>

In addition, some regulatory standards – such as Europe EN 149, China GB2626, Korea KMEOL 2017-64, Australia/New Zealand standard 1716, and Japan JMHLW notification 299 – require CO<sub>2</sub> levels inside the respirators to be less than 1%.



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<sup>1.</sup> Williams et al. (2010) Physiological response to alterations in O2 and CO2 - relevance to RPD. J Intl Soc Respiratory Protection. 11: 269–281.