



Respiratory Protection and Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Frequently Asked Questions (FAQs)

4 June 2013

3M has received a number of inquiries regarding the appropriate respirator recommendations for potential exposures to the Middle East respiratory syndrome coronavirus (MERS-CoV) (previously referred to as a novel coronavirus (nCoV)). Following are responses to many of the most commonly asked questions. It is important to note this FAQ is not a substitute for the guidance of the United States Centers for Disease Control and Prevention (CDC), World Health Organization (WHO) and your local health authority. Please frequently consult their websites for the most current information and infection control procedures regarding MERS-CoV.

US CDC <http://www.cdc.gov/coronavirus/ncv/>

WHO http://www.who.int/csr/disease/coronavirus_infections/en/index.html

For further information on 3M personal protective equipment please contact 3M Technical Service in the US at 1-800-243-4630 or consult the website at www.3M.com/PPEsafety.

What is the MERS coronavirus (MERS-CoV)?

Coronaviruses can cause illness in humans and animals. In people, coronaviruses can cause illnesses ranging from the common cold to Severe Acute Respiratory Syndrome (SARS). This novel coronavirus is a new strain that has not been seen before. The name “Middle East respiratory syndrome CoV” has been adopted by the WHO for this virus.

What do the United States CDC and WHO recommend for respiratory protection against MERS-CoV?

Both the United States (US) CDC and WHO have issued guidance for *individuals in health care settings* who may be potentially exposed to MERS-CoV. Users should monitor the US CDC, WHO and their local health authority websites in order to ensure that they receive the latest guidance from those organizations.

As of May 23, 2013, the US CDC states that “Until the transmission characteristics of the novel coronavirus are better understood, patients under investigation and probable and confirmed cases should be managed according to CDC’s infection control recommendations for the coronavirus that caused SARS.” The CDC guidance with respect to severe acute respiratory syndrome (SARS) recommended that a US National Institute for Occupational Safety and Health (NIOSH)-certified particulate respirator should be used to help reduce exposure. (<http://www.cdc.gov/sars/guidance/infection/healthcare.html>).

As of May 23, 2013, WHO states that at a minimum a NIOSH-certified N95, EU FFP2 or equivalent particulate respirator is required for health care workers performing aerosol-generating procedures on suspect or confirmed MERS-CoV patients.

Please be advised that most surgical masks are not approved as respirators and are not designed to prevent the wearer from inhaling airborne hazards.

Can the general public use respirators to help reduce exposure to MERS-CoV?

At this time, 3M is not aware of any recommendations for respiratory protection to help reduce exposure to MERS-CoV outside of health care and laboratory settings. Therefore the choice to use a respirator is a personal one. A respirator is just one of several preventative measures that can be used to help reduce exposure to the MERS-CoV. In general, thorough and frequent hand washing, close attention to hygiene and not sharing food utensils or towels with others is recommended to help reduce exposures to viruses.

Can respirators protect you from biological agents such as bacteria or viruses?

Bacteria and viruses may be spread from person to person in different ways. Therefore, a respirator is just one of several preventative measures that can be used to help reduce exposure to biological agents. Specifically, respirators are designed to help reduce exposures of the wearer to airborne hazards. Biological agents, such as bacteria or viruses, are particles and can be filtered by particulate filters with the same efficiency as non-biological particles having the same physical characteristics (size, shape, etc.). However, unlike many industrial particles, there are no exposure limits, such as Occupational Exposure Limits (OELs) Permissible Exposure Limits (PELs) or Threshold Limit Values (TLVs), established for biological agents. Respirators may help reduce exposures to airborne biological contaminants such as MERS-CoV, but they don't eliminate the risk of exposure, infection, illness, or death.

What is a type N95 respirator?

N95 is the simplest of the US NIOSH classifications of negative pressure particulate respirators.

What do N, R, and P stand for?

NIOSH designates negative pressure particulate respirators as N (Not Resistant to oil), R (Resistant to oil) or P (oil Proof).

Can medical facemasks be used to help reduce exposures to biological agents?

Medical, surgical and patient care masks are not designed to protect the wearer from inhaling airborne hazards; therefore 3M recommends that they not be used for this purpose, or in place of an approved respirator.

What is the difference between a government-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 facemask is to help prevent biological particles from being expelled by the wearer into the environment. Surgical masks are also typically designed to be fluid resistant to splash and splatter of blood and other infectious materials and not necessarily for filtration efficiency. Surgical facemasks are not necessarily designed to seal tightly to the face, and therefore the potential of air leakage around the edges exists. Even some masks that appear similar to respirators may have not been designed to protect the wearer from airborne hazards; therefore, they should not be considered an equivalent substitute to government-approved respirators.

Some approved respirators are designed to have the characteristics of both an approved respirator and a surgical mask. In the U.S., these products, typically referred to as "Surgical Respirators" are both approved by NIOSH and cleared by the U.S. Food and Drug Administration (FDA) for use in surgery.

Are there any medical restrictions for wearing a respirator?

Individuals with a compromised respiratory system, such as asthma or emphysema, or people with a history of heart disease should consult a physician before wearing a respirator. When personal protective equipment, including respirators, is used in a professional environment, its use must comply with applicable workplace standards, regulations and policies including medical clearance where required.

Can a European or Australian/New Zealand "P1" respirator be used for SARS in a healthcare setting?

Certain respirators, such as those approved as a European or Australian/New Zealand "P1" respirator, are not considered equivalent to those specified in the CDC and WHO guidances. Therefore, 3M does not recommend "P1" respirator use in health care settings to reduce exposures to MERS-CoV.

What are the limitations of using respirators for potential exposures to MERS-CoV?

Respirators are not a guarantee that the user will not develop infection with MERS-CoV. If you choose respirators as part of your efforts to help reduce exposures to MERS-CoV, the following items need to be carefully read and understood.

- Respirators must be used in the proper manner, in accordance with all manufacturer instructions and directions and local regulations.
- Respirators may help reduce exposure to airborne biological contaminants, but they don't eliminate the risk of exposure, infection, illness, or death.
- For greatest effectiveness respirators need to be worn before and during the entire exposure period.
- Respirators may help protect your lungs; however, some biological contaminants may be absorbed through the skin or eyes, and other protective equipment may be required.

- Fit of the respirator to the face is very important. If it does not fit properly, airborne contaminants will penetrate (enter underneath) the facepiece seal.
- 3M respirators are not designed for children. 3M respirators are designed for use by adults who are properly trained in their use and limitations.
- All users must perform a user seal check (fit check). In the US and certain other countries workers are required to pass a fit test, prior to use of the respirator in a contaminated area. Where not required by law, 3M recommends that all workers pass a fit test prior to use of a respirator in a contaminated area.
- The wearer must be clean-shaven to wear tight-fitting respirators that seal tightly to the face (such as an N95, FFP2 or FFP3 filtering facepiece respirator). Beard, stubble or long mustaches may cause large leaks into the respirator. Respirator users with facial hair must use powered air purifying respirators with loose fitting facepieces, hoods or helmets.
- Training on proper use and limitations, including practice putting the respirator on and wearing it, is required.
- Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician before wearing a respirator.

Each facility or individual should use the best available information to determine appropriate respiratory protection for exposures to MERS-CoV.

Can children wear respirators?

3M respirators are not designed for children. 3M respirators are designed for use by adults who are properly trained in their use and limitations.

Are multiple sizes of respirators needed?

Multiple sizes of respirators are not mandatory. Multiple sizes or alternative facepiece designs can provide the individual with additional options for obtaining a good fit and seal. What is important is that the respirator fit the wearer. As a result, all users must follow the manufacturer's instructions and directions, and perform a user seal check (fit check). In the U.S. 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.

How important is fit?

Fit is very important. If a respirator does not seal tightly to the face, airborne hazards can penetrate or enter underneath the facepiece seal and into the breathing zone. It is very important to always follow the donning instructions and do a user seal check (fit-check) before entering the contaminated environment. With a tight-fitting respirator, such as an N95, FFP2 or FFP3, a good fit can only be obtained if the face is clean-shaven in the area where the respirator seals against the face. Beards, long mustaches, and stubble may cause leaks into the respirator.

For workplace environments, such as health care facilities, you must follow local government standards and regulations concerning respirator use such as training and fit testing. In the U.S., the Occupational Safety and Health Administration (OSHA) requirements for respiratory protection (1910.134) must be followed including medical evaluation, training, and fit testing for employees

required to use respirators in the workplace. Fit testing must be done before wearing a tight fitting respirator for the first time, and repeated at least annually or sooner if changes to facial structure occur that may affect respirator fit. A user seal check cannot be used as a substitute for the fit test.

In countries where the OSHA standards do not apply, health care workers and other employees required to wear a respirator should follow applicable national workplace standards, regulations and policies concerning use, fit-testing/checking and training.

What if I have a beard or stubble and want to wear a respirator for MERS-CoV exposures?

As noted above, at this time 3M is not aware of any recommendations for respiratory protection to help reduce exposure to MERS-CoV outside of health care settings. Therefore the choice to use a respirator is a personal one, with a respirator serving as just one of several preventative measures that can be used to help reduce exposure to the MERS-CoV. If you do choose to use a respirator to help reduce exposure to MERS-CoV, you should be aware that a tight sealing respirator (one where the sealing surface contacts the face) will not provide an adequate seal when placed over facial hair. A bearded worker will typically require a powered air-purifying respirator (PAPR) or supplied air respirator with a loose-fitting facepiece, hood or helmet in order to attain a proper seal.

How do I put on the respirator and check for proper fit?

The user instructions for a 3M respirator contain the proper 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 (fit check) every time the respirator is put on. The user instructions are provided with the original packaging of the respirator. If you need instructions or have questions, please contact 3M Technical Service in the US at 1-800-243-4630 or consult the website at www.3M.com/PPESafety.

How is a user seal check/fit check performed on a disposable respirator?

To perform a user seal check on a 3M non-valved, cup shaped disposable filtering facepiece respirator, place both hands completely over the respirator and exhale. The respirator should bulge slightly. If air leaks between the face and the faceseal of the respirator, reposition it and readjust the nose clip for a more secure seal. If air leaks around the respirator edges, adjust the position on the face and the straps along the sides of the head and recheck fit. If a proper fit cannot be achieved, do not enter the area requiring respiratory protection. See specific product user instructions for the most current user seal check/fit check instructions.

To perform a user seal check on a 3M valved, cup shaped disposable respirator, place both hands completely over the respirator and inhale. The respirator should collapse slightly. If air leaks between the face and the faceseal of the respirator reposition it and readjust the nose clip for a more secure seal. If air leaks around the respirator edges, adjust the position on the face and the straps along the sides of the head and recheck fit. If a proper fit cannot be achieved, do not enter the area requiring respiratory protection. See specific product user instructions for the most current user seal check/fit check instructions.

What if I notice air leaking in during the user seal check?

If, during the user seal check (fit check), you notice air leakage around the edges of the respirator you should readjust the respirator. If you still notice air leakage, you should remove the respirator (in a clean area only). Review the instructions if necessary to make sure that you are putting it on correctly. Inspect the respirator to make sure that there is no damage to the respirator. You must be clean-shaven. Be sure that there is no hair, clothing or jewelry between your skin and the edge of the respirator. Put the respirator on again, according to the manufacturer's directions. Do a user seal check (fit check). If you still cannot achieve a proper seal, do not enter the contaminated area. You may need to obtain a different size, make or model respirator.

In the U.S. and certain other countries, workers need to pass a fit test before wearing a tight-fitting respirator for the first time. In countries where fit testing is not required, 3M recommends that workers pass a fit test prior to use of a respirator in a contaminated environment. If you do not pass a fit test on the first try, you should remove the respirator. Reread the instructions and put it on again. Conduct a user seal check (fit check). If you do not feel any air leakage around the respirator edges, then you should try the fit test again. If you fail the fit test on the second try, do not enter the contaminated area. You should obtain a different size, make or model of respirator and conduct a fit test on that respirator.

Can disposable respirators be shared between people?

Disposable respirators should never be shared.

What is BFE, and what does it measure?

BFE stands for Bacterial Filtration Efficiency. This test evaluates how well a surgical or medical respirator or surgical mask can prevent biological particles from being expelled by the wearer into the environment. Bioaerosol particles generated during the BFE test are "large," on the order of 1 to 5 microns in size. For comparison, particles used for respirator filter efficiency tests are much smaller, approximately 0.3 microns in size. The BFE test is a relative indicator of the performance of a medical, surgical or patient care mask but the results cannot be compared to respirator certification filtration efficiency.

Are government-certified respirators tested for BFE?

Particulate respirators are not necessarily tested for Bacterial Filtration Efficiency (BFE). The BFE result has little meaning for particulate respirators because more stringent filter efficiency tests are used for government certification. The manufacturers of combination approved respirator/surgical masks may publish BFE results. However, BFE results are not necessarily useful for applications outside of the health care industry.

Which 3M government certified respirators have been tested for BFE?

The following 3M respirators have been tested for Bacterial Filtration Efficiency (BFE). These 3M products all provide greater than 99% BFE against wearer-generated microorganisms.

3M™ N95 Health Care Particulate Respirator and Surgical Mask 1860 and 1860S
 3M™ N95 Health Care Particulate Respirator and Surgical Mask 1870
 3M™ Particulate Respirator 8210, N95
 3M™ Particulate Respirator 9210, N95
 3M™ Particulate Respirator 9210+*, N95
 3M™ EN149:2001 FFP2 Respirators 9320+*, 1862+ (Type IIR), 1802 (Type II) and 1802S (Type II).
 3M™ EN149:2001 FFP3 Respirators 1863+ (Type IIR), 1883+ (Type IIR).

* Testing conducted on a model with similar construction.

Can a valved respirator be used by health care workers to help reduce exposures to the MERS-CoV?

A valved respirator is designed to allow for easy exhalation through a one-way exhalation valve. However, use must be in accordance with national guidelines. For example, in some countries such as the U.S. and Canada, it is not recommended that healthcare workers wear a valved respirator in a situation requiring a sterile environment, such as the operating room.

Should a patient with MERS-CoV infection wear a respirator?

Typically respirators should not be worn by a person whose respiratory system has been compromised or who may have trouble breathing through a respirator, unless otherwise advised by their personal physician.

Is fluid resistance in a surgical respirator important?

It is up to the health care facility to determine the need to provide fluid resistant respirators or masks to their health care workers. In the U.S., OSHA has specific provisions under the Bloodborne Pathogen Standard that specifically details the “appropriateness” of personal protective equipment used by health care workers. Fluid resistance is the ability of a respirator’s or mask’s material construction to minimize fluids from traveling through the material and potentially coming in contact with the user of the facemask. Fluid resistance helps reduce exposure to blood or bodily fluids caused from splash, spray or splatter. If the mask or respirator comes in contact with blood or body fluids of a patient, it is recommended the respirator be changed as soon as possible. Respirators should only be removed when the wearer is in an area that is considered free of airborne hazards, including patients with confirmed or suspected infection with MERS-CoV .

What precautions should visitors take when visiting facilities with suspect or confirmed patients infected with MERS-CoV?

Prior to entering a healthcare setting, visitors should consult with the facility’s Infection Control Practitioner regarding visitor policies. As of May 23, 2013, the US CDC states that “Until the transmission characteristics of the novel coronavirus are better understood, patients under investigation and probable and confirmed cases should be managed according to CDC’s infection control recommendations for the coronavirus that caused SARS.” In other words, individuals in

healthcare settings who may be exposed to MERS-CoV (including everyone who enters the patient's room) should use a NIOSH approved particulate respirator to help reduce exposure.

Can I clean or wash a disposable respirator?

Under no circumstances should an attempt be made to clean or wash a disposable respirator.

If I use the disposable respirator in areas (i.e. healthcare settings) with suspect or confirmed patients with MERS-CoV infection should I discard the respirator after use?

As of May 23, 2013, the US CDC states that "Until the transmission characteristics of the novel coronavirus are better understood, patients under investigation and probable and confirmed cases should be managed according to CDC's infection control recommendations for the coronavirus that caused SARS." (<http://www.cdc.gov/sars/guidance/i-infection/healthcare.html>). In other words, a respirator worn in an area with a suspect or confirmed patient is considered potentially contaminated with infectious material. Therefore disposable respirators should be removed and discarded upon leaving the patient's room.

What is the risk of inhaling biological particles that have been collected by the respirator filter?

The risk of inhaling particles that have been collected by a filter is low, particularly in very clean areas (such as a patient care setting or a home). When particles are collected on a filter they are strongly held to the filter. Breathing through a filter has not been shown to dislodge the particles collected in that filter. However, it is important to note viruses may be spread by touching contaminated objects. Based on the US CDC recommendations for SARS, a respirator worn in an area with a suspect or confirmed patient is considered potentially contaminated with infectious material.

Can particles, such as bacteria or viruses, be reaerosolized from the respirator filter?

Particles are collected on a filter are strongly held to the filter. Proper and normal use of a respirator has not been shown to reaerosolize the particles collected in that filter. However, just because particles may not reaerosolize, does not mean that a respirator can be reused. It is important to note that some viruses may be spread by touching contaminated objects. Based on the US CDC recommendations for SARS, a respirator worn in an area with a suspect or confirmed patient is considered potentially contaminated with infectious material.

Do 3M disposable respirators contain natural rubber latex?

None of 3M's NIOSH approved N95, N100, R95, P95, or P100 disposable respirators contain components made from natural rubber latex. Many other 3M respirators sold outside the U.S. do not contain components made from latex. However, there are some that contain natural rubber latex components, and these respirators carry a statement on the primary packaging similar to the following: "This product contains components which contain natural rubber latex which may cause allergic reaction." If you require information on which 3M products contain natural rubber latex components, please contact your local 3M office.

Do any of 3M's disposable respirators contain fiberglass material?

No. All 3M disposable respirators have filter media made from polypropylene and coverings made from a combination of polypropylene and polyester.

Is a fit test hood system safe from contamination?

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

1. All individuals with suspect or confirmed infection with MERS-CoV should be eliminated from fit testing.
2. All subjects should thoroughly wash their hands.
3. 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. The test administrator handles the placement of the hood.
4. If the subject coughs or sneezes during the test, the hood should be disinfected with typical disinfectant such as dilute solution of common bleach. (The US CDC has made recommendations with regards to the SARS virus. They recommend that EPA-registered disinfectants or 1:100 dilution of household bleach and water should be used for surface disinfection and disinfection on noncritical patient-care equipment.
http://www.cdc.gov/hicpac/Disinfection_Sterilization/3_2contaminatedDevices.html)