

IMPORTANT SAFETY INFORMATION

for

3M™ 8612F Respirator For Use by the General Public in Public Health Medical Emergencies

Keep these *User Instructions* for future reference.

WARNING

This respirator is intended to help reduce breathing in pathogenic biological airborne particulates or germs during public health medical emergencies, such as an influenza pandemic. If you do not follow all instructions and limitations on the use of this respirator and/or do not wear this respirator during all times of exposure to the airborne germs the respirator may not be as effective. The respirator cannot stop the breathing in of all germs in the air and does not eliminate the risk of disease or illness. For proper use of this respirator, see the box and *User Instructions* or call 3M in the U.S.A. at 1-888-436-3636.

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IMPORTANT:

If you have pre-existing lung disease such as asthma or emphysema, underlying heart disease such as heart failure or other health conditions, you may have difficulty breathing through respirators and should consult your healthcare provider (doctor) before use.

Standards regulating respirator training for the general public have not been established. For your respirator to help reduce the number of germs you breathe, you must read and follow these *User Instructions*.

Indications for Use

The 3M™ 8612F Respirator for Use by the General Public in Public Health Medical Emergencies is a filtering face piece respirator device. It is intended to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during public health medical emergencies, such as an influenza pandemic. The 3M™ 8612F Respirator for Use by the General Public in Public Health Medical Emergencies also protects the wearer from splash and spray of body fluids.

- This is a disposable, single use respirator.

1. SELECT THE RIGHT RESPIRATOR

- This is an adult size respirator. To determine if the respirator fits you, follow the instructions in Section 6. Always check your fit when you wear it.
- The U.S. Food and Drug Administration (FDA) has cleared this respirator (model 8612F) for use by the general public in public health medical emergencies, such as an influenza pandemic, to help reduce wearer exposures to airborne germs. This respirator is not intended for any other use. For more information see section 11, General Information.
- This respirator has been certified by the National Institute for Occupational Safety and Health (NIOSH) as an N95 for filtration efficiency. NIOSH does not evaluate respirators for use as medical devices. For more information on NIOSH certification see the NIOSH approval label in Section 11, General Information.
- Before use keep respirators in their original packaging. Store in a dry, clean area at room temperature.

2. WHEN TO WEAR YOUR RESPIRATOR

- To be most effective, use this respirator when you are directed by a public health authority or may be exposed to germs in the air during a public health medical emergency, such as an influenza pandemic.
- This respirator must be worn whenever you are exposed to germs during a public health medical emergency, such as an influenza pandemic.

3. USE IT CORRECTLY

- Although this respirator can help reduce the number of germs you breathe, it will not eliminate the risk of disease or illness. See Section 10, Additional Precautions To Take, for information on other things you can do to help reduce your risk of getting sick.
- Do not alter, abuse or use this respirator for any purpose other than those stated.

4. PREPARE YOURSELF

- Practice putting a model 8612F respirator on to make sure you are ready in the event of a public health medical emergency, such as an influenza pandemic.
- Anything that comes between the respirator and your face will make the respirator less effective by interfering with its fit. Men should shave every day that they may use the respirator. Hair, jewelry and clothing should not be between your face and the respirator.
- Wash your hands thoroughly with soap and water before handling the respirator.

5. INSPECT YOUR RESPIRATOR

- Inspect respirator for holes, tears or other damage to surfaces, straps, metal nose strip and nose foam. If your respirator has been damaged – DO NOT USE IT. Get a new one.

6. HOW TO WEAR

1. Prepare to use respirator



Wash your hands thoroughly with soap and water before handling the respirator.

Inspect the respirator for holes, tears or other damage to surfaces, straps, metal nose strip and nose foam. Get a new respirator if damaged.

If you wear glasses, **read steps 2 through 4** then remove your glasses before putting on the respirator.

2. Place respirator on face

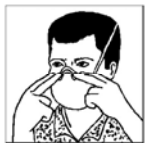


Place the respirator against your face, with the bottom under your chin and metal nose strip across bridge of your nose.

Pull the top elastic band over your head and place high at the top back of your head.

Next, **pull** the bottom elastic band over your head and place around the neck below your ears.

3. Adjust the metal nose strip

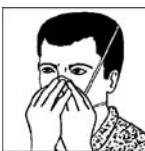


Use both hands to bend the metal nose strip to fit snugly against your nose and face. The respirator may not fit as well if you pinch the metal nose strip using one hand. Use two hands.

Slide fingers down both sides of the metal nose strip to seal it against your nose and face.

4. Check the respirator-to-face seal

REMEMBER: Putting the respirator on correctly means more of the air you breathe goes through the respirator filter.



Completely cover the outside of the respirator with both hands.

Do not push the respirator against your face.

With your hands in place on the surface of the respirator, exhale, or breathe out sharply.

If you feel air blowing on your face or eyes, the respirator needs to be adjusted. To adjust, **repeat steps 2 and 3. Repeat step 4.** When the respirator is a good fit, you will not feel any air blowing on your face or eyes. If you can't get a good fit, try a different model respirator.

Return eyewear to face, if applicable.

7. WHEN TO REPLACE

- Go to a clean, safe area away from other people, and replace your respirator if it is damaged, has been splashed or sprayed with body fluids, or if it becomes harder to breathe through.
- This is a single use respirator.
- Dispose of respirator after each use by carefully placing it in a closed waste container.
- **You should never wash, disinfect, reuse or share your respirator with others.**

8. RESPIRATOR REMOVAL & DISPOSAL

Important: Touch only the straps and not the surface of the respirator when removing.

1. Go to a clean, safe area away from other people.
2. Wash your hands thoroughly with soap and water.
3. Lift the bottom strap from around your neck up over your head.
4. To avoid snapping the respirator, SLOWLY lift off the top strap.
5. Properly dispose of your used respirator by carefully placing in a closed waste container. **You should never share respirators.**
6. Wash your hands after disposal.

You will also find additional assistance on how to fit this respirator by visiting 3M's web site at www.3M.com/OccSafety.

9. LIMITATIONS OF USE

This respirator will not protect you from all germs.

The U.S. Food and Drug Administration (FDA) has cleared this respirator (model 8612F) for use by the general public in public health medical emergencies, such as an influenza pandemic, to help reduce wearer exposures to airborne germs. This is not intended for any other use.

This respirator is designed to cover your nose and mouth. It can help reduce the number of airborne disease causing organisms (germs) you breathe. However, the respirator cannot eliminate the breathing in and all germs in the air and does not eliminate the possibility of contracting infection, illness, or disease.

Respirators can help reduce the number of germs you breathe. However, they will not prevent entry of germs through your skin, eyes, or other parts of your body.

If you experience dizziness, irritation or other distress while wearing this respirator, go to a clean, safe area away from other people, and remove your respirator. Consult your healthcare provider (doctor) to determine whether or not you should continue use of the respirator.

10. ADDITIONAL PRECAUTIONS TO TAKE

If a public health medical emergency occurs, a respirator should be used as part of a total personal protection system including hand washing, social distancing, etc. According to the CDC, precautions you can take to limit the spread of germs include:

- Wash your hands often with soap and water. Use an alcohol-based hand cleaner if soap and water are not available.
- Cover your mouth and nose with a tissue or your arm when you cough and sneeze.
- Put used tissues in waste basket.
- Clean your hands after coughing or sneezing
- Avoid crowded places and large gatherings as much as possible.
- Stay away from other people if you are ill.

- Stay at home if you are sick.

The use of waterless hand hygiene products may be an option when a sink is not accessible. For additional guidance you should refer to the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (DHHS), the World Health Organization (WHO), and your local health authority.

CDC Website: <http://www.cdc.gov>
DHHS Website: <http://pandemicflu.gov>
WHO Website: <http://www.who.int>



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11. GENERAL INFORMATION

The U.S. Food and Drug Administration (FDA) has cleared this respirator (model 8612F) for use by the general public in public health medical emergencies, such as an influenza pandemic, to help reduce wearer exposures to airborne germs. Public use of respirators is for contaminant or germ exposures that are generally intermittent or for short periods of time. In addition, users in the public setting cannot easily determine exposure levels nor do they have ready access to the type of training, medical evaluation, and fit testing needed to be in compliance with workplace respirator standards. Part of this product's evaluation shows that following the fitting instructions is important to help reduce wearer exposure to airborne germs. It is important to understand that no respirator will eliminate the inhalation of all particles and/or airborne organisms and will not eliminate the risk of disease, illness, or death.

This respirator's ability to help reduce wearer exposure to airborne germs depends on the filtration capabilities of the materials it is made of and on how well it fits the wearer. The filtration capability of this respirator meets FDA's requirement of being certified by NIOSH as an N95 respirator. In accordance with FDA recommendations, the facial fit of this respirator was tested on a group of healthy adults not previously trained on respirator use and representing a range of facial characteristics. The respirator fit test measured how many airborne test particles were able to get inside the respirator through small leaks between the edges of the respirator and the wearer's face. While individual results varied, all participants tested achieved some reduction in exposure to airborne test particles.

Performance testing for this respirator was not conducted during an actual public health medical emergency.

The 3M respirator model 8612F has been cleared by the FDA for use by the general public in public health medical emergencies to help reduce wearer exposures to airborne germs. It is important to follow the "How to Wear" section in these *User Instructions* to achieve a good fit. You will also find additional assistance on how to fit this respirator by visiting 3M's web site at www.3M.com/OccSafety.

This respirator is fluid resistant to splash and spray of body fluids. It has been tested according to the American Society for Testing and Materials (ASTM) test method F 1862.

This respirator has been tested according to fabric flammability regulations and standards. The test measures how easily the fabric catches fire and how fast the flame spreads. In the test, the fabric was exposed to a flame for one second and did not catch on fire. The fabric is classified as "Class 1". However, use caution near open flames or other sources of intense heat.

This N95 configuration is not intended for occupational use or applications.

NIOSH-Certified N95 Particulate Respirator

N95 Particulate Respirator

NIOSH Approved: N95

At least 95% filtration efficiency against solid and liquid aerosols that do not contain oil.

Insert approval label:

For more information and division signature