

# AmSafe Filtering Facepiece Respirator P/N 506478-1, Rev A

### Standard Face Mask versus Respirator Mask

In day to day language we often say mask, when referring to what are technically called respirators.

#### **Uses for Standard Masks:**

- Mask are loose fitting, covering the nose and mouth.
- Designed for one way protection, to capture bodily fluid leaving the wearer.
- Example worn during surgery to prevent coughing, sneezing, etc on the vulnerable patient.
- Contrary to belief, masks are NOT designed to protect the wearer.
- The vast majority of masks do not have a safety rating assigned to them (e.g. NIOSH or EN).

#### **Uses for Respirator Masks:**

- Respirators are tight fitting masks, designed to create a facial seal.
- Non-valved respirators provide good two way protection, by filtering both inflow and outflow of air.
- These are designed to protect the wearer (when worn properly), up to the safety rating of the mask.
- Available as disposable, half face or full face.

## **Intended Use of AmSafe Respirator**

The AmSafe respirator is intended to be worn in an occupational setting under a respiratory protection program as a way to mitigate exchange of airborne particles.

#### **Design Overview**

The basis of the design is a variation of one published by the University of Florida.

#### **Respirator shape**

The shape lends itself well to properly sealing all the way around the face as compared to a simple surgical mask design which tends to have a larger opening at the sides.

# **Respirator material**

The innovative mask uses Halyard H600 two-ply spun polypropylene made by Halyard Health. The use of the material was inspired by the research at the University of Florida.

N95 respirator masks have been in high demand worldwide since the outbreak of COVID-19. That led a UF Health anesthesiology professor to create a simple respirator mask from the sterile wrapping that is normally used to surround surgical instrument trays before they pass through gas sterilization or an autoclave.

#### **Respirator attachment**

The AmSafe respirator uses elastic bands that go over the head (as depicted below) rather than behind the ear. This design provides better long-duration comfort versus behind-the-ear designs.



# **Respirator Donning, Doffing and Fit Guidance**

Before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the local government requirements. In the United States, employers must comply with OSHA 29 CFR 1910.134 which includes medical evaluation, training and fit testing.

#### **IMPORTANT**

Before use, the wearer must read and understand these *User Instructions*. Keep these instructions for reference.

#### **Donning the Respirator**

- 1. Place the respirator in the palm of your hand with the straps going around the back of your hand. Ensure that the side with the formable nose piece is facing up (Fig 1).
- 2. Place your face in the respirator such that it covers the nose at the top and the chin at the bottom.
- 3. While holding the respirator in place with one hand, use the other hand to pull one strap over your head and to the back of your neck (Fig 2).
- 4. Next, pull the second strap over your head and place it at the top of your head (Fig 3).
- 5. With the respirator in place, form the nose piece by pressing the down on the top edge of the respirator over the bridge of your nose (Fig 4).
- 6. Perform a User Seal Check prior to each wearing. To check the respirator-to-face seal, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 5. If air leaks at the respirator edges, work the straps back along the sides of your head.











# **Doffing the Respirator**

1. Pull the bottom strap over back of head, followed by the top strap, without touching the respirator (Fig 5). Discard in waste container.



# **Respirator Fit**

A well-fitting respirator:

- Should cover the nose
- Should cover the chin
- Should stay in place when looking side-to-side or up and down
- Should have proper strap tension. It should not be uncomfortably tight.
- Should stay in place when bending over
- Should allow for the use of eye protection if needed



# **Record of Revisions**

Rev.	Changed By	Revisions	Approved	Release Date
-	C.Arnold	New document Release: ECO05190	MR	9/01/20
A	C.Arnold	Updated to remove respirator photo, remove approval label per ECO05258	MB	9/21/20