



12.28.05

## Respirators and Surgical Masks: A Comparison

Because certain disposable respirators are similar in appearance to many surgical/procedure masks, their differences are not always well understood. However, respirators and surgical masks are very different in intended use, fit against the face, wear time, testing and approval. The purpose of this document is to highlight some of these differences.

The biggest difference between a respirator and a surgical mask is the intended use. Respirators are designed to help reduce the **wearer's** respiratory exposure to airborne contaminants such as particles, gases or vapors. Particulate respirators may be used to reduce exposure to particles that are small enough to be inhaled - particles less than 100 microns ( $\mu\text{m}$ ) in size. This includes airborne particles that may contain biological material, e.g. mold, *Bacillus anthracis*, *Mycobacterium tuberculosis*, the virus that causes Severe Acute Respiratory Syndrome (SARS), etc.

Surgical masks do not have either adequate filtering or fitting attributes to provide respiratory protection for the wearer. They are designed to help prevent contamination of the work **environment or sterile field** from large particles generated by the wearer (e.g. spit, mucous). Surgical masks may also be used to help reduce the risk of splashes or sprays of blood, body fluids, secretions and excretions from reaching the wearer's mouth and nose.

Fit against the face is also an important differentiator. Respirators such as N95 filtering facepieces are designed to seal to the face of the wearer. Therefore most of the inhaled air is drawn through the filter media and not through gaps between the respirator and the wearer's face. To determine proper fit, wearers must be fit tested to make sure they have selected the appropriate model and size. The wearer must also perform a "user seal check" each time the respirator is worn prior to entering the contaminated environment to check the respirator-to-face seal. Surgical masks are not designed to seal against the face and are not fit tested since the main goal is to help capture large particles expelled by the wearer and to help reduce the wearer's exposure to splashes. During inhalation, much of the air passes through gaps between the face and the surgical mask.

Respirators must be carefully donned and worn properly the entire time the wearer is in the contaminated area. Surgical masks are frequently worn for specific procedures and then removed.

Government requirements for testing and certifying respirators and surgical masks are substantially different. Respirators must be tested and certified by the National Institute for Occupational Safety and Health (NIOSH). NIOSH tests particulate respirators under "worst case" conditions to help ensure adequate performance in the work place. The test protocol includes high flow rate, most penetrating particle size, aerosols that may degrade filter material, etc. Filtering facepiece respirators that are approved under these tests must have "NIOSH" and the filter classification printed on them.

The Food and Drug Administration (FDA) does not test surgical masks. Rather, the manufacturer provides data and proposed claims to FDA for review. The FDA reviews manufacturer's test data and "clears" the mask for sale. Tests include particle filtration efficiency (PFE), bacterial filtration efficiency, fluid resistance, flammability testing, etc. The results of the surgical mask PFE testing and the NIOSH filtration testing should not be compared. The PFE test is a quality indicator for healthcare surgical masks. The PFE test is not an indicator of respirator protection performance and is not comparable to the government mandated filtration testing required for NIOSH approved respirators, such as the N95 filtering facepiece respirator. The filter media of a surgical mask with a very high PFE (>95%) may be less than 70% efficient when tested with the NIOSH N95 test method. Additionally, because surgical masks do not seal against the face when worn much of the inhaled air passes through gaps between the mask and the face rather than through the filter media. The bacterial filtration efficiency and fluid resistance tests measure the masks ability to capture large particles expelled by the wearer and to help reduce the wearer's exposure to splashes respectively.

In conclusion, surgical masks in effect put a barrier between the wearer and the work environment or sterile field. They may help keep spit and mucous generated by the wearer from reaching a patient or medical equipment. They can also be used as a fluid barrier to help keep blood splatter from reaching the wearer's mouth and nose. However, surgical masks cannot provide respiratory protection unless they are also designed, tested and NIOSH approved as a respirator. If a wearer wants to reduce inhalation of smaller, inhalable particles (those smaller than 100 microns), they need to obtain and properly use a NIOSH-certified respirator. If the wearer needs a combination surgical mask and a particulate respirator, they should use a product that is both cleared by FDA as a surgical mask and tested by NIOSH as a particulate respirator. An in-depth comparison of surgical masks and respirators is outlined in table 1.

**Table 1: A comparison of respirators and surgical masks.**

	<b>Respirators</b>	<b>Surgical Masks/Procedure Masks</b>
<b>Intended Use</b>	The intended use of a respirator is to help reduce the wearer's exposure to certain airborne particles. Airborne particles are those that are 100 microns ( $\mu\text{m}$ ) in size or smaller (measured by aerodynamic diameter). Extensive research has shown that particles < 100 $\mu\text{m}$ can be inhaled through the nose or mouth and into the human respiratory system. Approximately 50% of particles 30 to 100 $\mu\text{m}$ in size will be inhaled into the respiratory system. Up to 100% of particles smaller than 30 microns can be inhaled into the respiratory system.	The intended use of a surgical / procedure mask is to help prevent large particles expelled by the wearer (e.g. spit, mucous) from reaching the patient or work environment. Some surgical masks also have fluid resistant properties to help reduce the risk of splashes or sprays of blood, body fluids, secretions and excretions from reaching the wearer's mouth and nose. Fluids contacting the outer surface of the surgical mask will not immediately soak through to the interior of the surgical mask and contact the wearer's lips or skin.
<b>Fit</b>	Respirators are designed to fit tightly to the face and create a seal between the face and the respirator. This helps ensure that most of the inhaled air is drawn through the filter media rather than through leaks between the respirator and the wearer's face. In the United States, workers, which includes health care providers, are required by OSHA to be fit tested prior to use and must conduct user seal checks before each use of the respirator in a contaminated area. There are two types of fit tests: qualitative and quantitative. In qualitative fit testing, taste, smell or irritation is used as a sign of an improperly fitting respirator. Quantitative fit testing uses a direct reading instrument to evaluate the fit of the respirator, such as one that counts the number of particles inside and outside the respirator.	Surgical masks are not designed to pass a fit test. Flat surgical masks fit loosely over the face leaving large gaps between the mask and the wearer. It is unlikely that most of the air will pass through the mask material. The air (and any airborne particles) will go through the gaps. Cup or Cone shaped surgical masks appear to fit tighter to the face, but they are not designed to seal to the face and cannot be relied upon to provide respiratory protection.
<b>Wear Time</b>	Respirators must be put on and taken off in a clean area and worn the entire time in the contaminated area to have a significant effect on reducing exposure. Having the respirator off even 10% of the time in a contaminated area significantly reduces the effectiveness of the respirator.	Surgical masks are typically donned for a specific procedure. For infection control purposes masks are typically disposed of after each procedure/patient activity.
<b>Approval / Certification</b>	In the United States respirators are tested /certified by NIOSH. Respirators must meet stringent test criteria stated in 42 CFR Part 84. As part of the approval process, NIOSH reviews test data submitted by the manufacturer and also conducts testing. A NIOSH-approved respirator will have the following text printed on the respirator: NIOSH, the type of approval (e.g. N95), and the manufacturer's name.	In the United States, surgical masks are cleared for sale by the Food and Drug Administration (FDA). The FDA reviews data submitted by the manufacturer but does not test the surgical mask. The FDA only allows the sale of products that meet their minimum requirements based on the data supplied.

<p><b>Testing</b></p>	<p><b>Filtration Efficiency:</b> In the United States respirators must meet test criteria stated in the Code of Federal Regulations 42CFR Part 84. For a complete understanding of all the test criteria the reader will need to review the standard. Respirators with N95 filter media are tested using criteria that reflect “worst-case” conditions. The test criteria for respirators with “N95” filter media include:</p> <ul style="list-style-type: none"> <li>• Sodium chloride test aerosol with a mass median aerodynamic diameter (MMAD) particle of about 0.3 µm;</li> <li>• Airflow rate of 85 liters per minute (lpm);</li> <li>• Charge neutralized test aerosol</li> <li>• Preconditioning at 85% relative humidity (RH) and 38°C for 24 hours before testing.</li> </ul> <p>The 0.3 µm particle diameter was selected because, for filters, it lies within the most penetrating particle size range. Smaller and larger particles will be trapped in the filter at higher rates due to the physics of filtration. By using this most penetrating particle size, particulate filters certified under these procedures can be used regardless of aerosol size in the workplace. Filter efficiency is affected by the flow rate of air through the filter. Higher flow rates tend to reduce filter efficiency measurements for smaller particles. The specified flow rate of 85 liters per minute (lpm) represents a very high work rate, equivalent to the breathing rate of an individual running at 10 miles an hour.</p>	<p>Common tests for surgical masks include: particle filtration efficiency (PFE), bacterial filtration efficiency (BFE), fluid resistance, differential pressure and flammability.</p> <p><b>PFE:</b> The PFE test is a quality indicator for healthcare surgical masks. The PFE test is not an indicator of respirator protection performance. The filter media of a surgical mask with a very high (&gt;95%) PFE may be less than 70% efficient when tested with the NIOSH N95 test method. The results of the surgical mask PFE testing and NIOSH filtration efficiency testing should not be compared. Conditions of the PFE test include:</p> <ul style="list-style-type: none"> <li>• Polystyrene latex sphere test aerosol approximately 0.1 µm in size;</li> <li>• Airflow rate of 28 liters per minute (lpm).</li> <li>• Unneutralized test aerosol.</li> <li>• No preconditioning</li> </ul> <p><b>BFE:</b> This test assesses the ability of a mask to provide a barrier to large particles expelled by the wearer. It is not a filtration efficiency test and it does not evaluate the mask’s ability to provide any protection to the wearer. Two methodologies are available: the “Modified Greene and Vesley Test or ASTM method F2101-01.</p> <p><b>Fluid Resistance:</b> The fluid resistance test is typically conducted based on the American Society of Testing and Materials (ASTM) Test Method F 1862 “Resistance to Penetration by Synthetic Blood” which determines the mask’s resistance to synthetic blood squirted at it under varying pressures.</p>
-----------------------	--	--