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Filtration Efficiency of Surgical Masks

Erin Sanchez
University of South Florida

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by

Erin Sanchez

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Co-Major Professor: Yehia Y. Hammad, Sc.D.
Co-Major Professor: Steve Mlynarek, Ph.D.
Yangxin Huang, Ph. D.

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Dedication

Firstly, I dedicate this thesis to God, for providing the opportunity to attend graduate school, giving me the strength to complete this program, and blessing my family with patience and understanding.

Secondly, I dedicate this thesis to my wife Flor and my children, Alyssa, Destiny, and Elijah who supported and loved me throughout this process.

Thirdly, I dedicate this thesis to my mom who has always encouraged me, loved me, and supported me.

I love you all and thank you for being there for me.

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ABSTRACT

Surgical masks are intended to be used to prevent transmission of disease from a health care worker to a patient. Often times, they are relied upon by health care workers for their own protection. In light of recent developments regarding preparation for health care worker response to global infectious diseases such as H1N1 Influenza, health care workers may experience a false sense of security when wearing surgical masks. The goal of this study was to evaluate the filtration efficiency of a double strap tie-on surgical mask. The manufacturer asserts a >95% efficiency with a 0.1 um challenge aerosol under FDA testing procedures. The NIOSH Title 42 CFR Part 84 certification criteria call for testing at a rate of 85 lpm representing a human moderate to heavy work load breathing rate. Three sizes of monodispersed aerosols (polystyrene latex beads: 0.5 um, 1.0 um, 2.0 um) were used.

The specific aims were to measure the collection efficiencies of this mask for the various particle sizes. Two tests were performed. In the first, masks were affixed to a dummy head and the edges of the mask were not sealed. In the second, the edges of the masks were sealed to the head using silicone sealant, so all penetration was through the filtering material of the mask. Differences in upstream and downstream particle concentrations were measured. Thus, penetration by leakage around the mask and through the filtering material was measured. The experimental set up involved passing

the aerosol from the nebulizer through a diffusion dryer and Kr-85 charge equilibrator ensuring a dry charge neutralized aerosol cloud for detection by a LASAIR particle counter. The analysis revealed that the filtration efficiency for 0.5 um particles ranged from 3% to 43% for the unsealed masks and 42% to 51% for the sealed. For 1.0 um particles, the efficiency was 58% to 75% for unsealed and 71% to 84% for sealed masks. For 2.0 um, the efficiency was 58% to 79% for unsealed masks and 69% to 85% for the sealed masks. The data were statistically significant and indicated that surgical masks were associated with very low filtration efficiency. This suggests that they may be inadequate against airborne viruses and bacteria.

Introduction

Background

Surgical masks are not designed to protect health care workers from airborne particulates and will not provide as much protection as N-95 respirators. Smaller particulates are less effectively filtered by most surgical masks. In addition to relatively poor filtration efficiency, these masks permit leakage around the edges upon inhalation, and they cannot be fit tested. For healthcare workers dealing with patients ill with infectious agents like the Swine Flu (H1N1 influenza virus), surgical masks have been recommended by the Center for Disease Control and Prevention (CDC) as a last resort, when no National Institute of Occupational Safety and Health (NIOSH) approved respirator is available. Using surgical masks as a form of personal protective equipment (PPE) may lead to adverse health effects.

Literature Review Studies Associated with Efficiency Testing

Surgical masks have been used since the early 1900s in the health care setting to prevent transmission of infectious diseases, via large droplets, from the worker to the patient. The masks are also used to prevent splashes of blood and body fluids from the patient to the mucous membranes of the healthcare worker. In 2008, the Institute of Medicine reported that during an influenza pandemic, it may be necessary to protect more than 13 million health care workers from illness or from infecting their families or patients (Grinshpun, 2009).

Early surgical masks were constructed from layers of cotton gauze and were designed to protect the mucous membranes of the nose, eyes and mouth where patient handling may have resulted in splashes or sprays of blood and body fluids. Health care workers have used and continue to use surgical masks as a form of personal protective equipment against airborne infectious diseases. In a Toronto hospital, all attending health care workers reported wearing "respirators" contracted severe acute respiratory syndrome (SARS) during patient intubation. Closer examination revealed that employees were wearing surgical masks (Oberg, 2008). While some surgical masks look similar to respirators, they are not, and do not offer the same protection as respiratory protection devices. Respiratory protection devices are certified by NIOSH and are used to protect the wearer from inhaling contaminants suspended in the air. NIOSH approved respirators have a filtering medium capable of removing at least 95% of airborne particulates > 0.3 um in diameter. Respirators have been used in the health care setting when the workforce was concerned with the spread of tuberculosis. Surgical masks are not equipped with such filtering material to reduce particle penetration by 95%. An aerosol is a liquid droplet or solid particle dispersed in air. Bioaerosols are aerosols of biological origin and include viruses, living organisms, such as bacteria and fungi. Bacteria are usually spherical or rod shaped, but may occur in clusters or chains. The adverse health affects of the biologic particles, particularly pathogenicity, depend not on the mass of the inhaled particles but on the number of particles. There are more than 17,000 species of bacteria and those that cause human disease are called human pathogens. Viral particles, called virions, are one of the smallest known bioaerosol agents, with a particle diameter ranging from 20 to 300 nm (Balazy, 2006a). Aerosol particles attach firmly to any surface they

contact and this is what separates them from gas molecules and from millimeter size particles. When aerosol particles contact each other they adhere and form agglomerates. (Hinds, 1999)

Filtration relies on the adhesion of the particles. Although surgical masks are not as efficient as air purifying NIOSH respirators they too operate by mechanical filtration. A mechanical respirator traps the particulate matter that passes through the filter material. Surgical masks and respirator filters are constructed of flat, non-woven mats of fine fibers (NIOSH Science Blog, 2009). The fiber is laid so the long section of the fiber is perpendicular to the air crossing the path, therefore allowing several particles to be captured along the axis. The efficiency with which a fiber removes particles from an aerosol stream is called Single Fiber Efficiency. The assumption is that the particle adheres to the fiber and is permanently removed from the airflow. An examination of the Reynolds number ($Re_{f)}$ that characterizes the flow around a fiber having a diameter d_f reveals that, under most conditions, the flow inside a filter will be laminar. (Hinds, 1999). Flow is distorted and influenced by other fibers, even when they are several fiber diameters away. The efficiency is considered the number of particles collected on a unit length of fiber divided by the number of particles that would have passed by the fiber in one second (Hinds, 1999). There are five mechanisms for particles to be deposited on a filter and in the lungs: interception, inertial impaction, diffusion, gravitational settling, and electrostatic attraction. The first four mechanisms are called mechanical mechanisms. Interception and impaction are responsible for collecting the relatively larger particles while diffusion is responsible for capturing the smaller particles. Interception occurs when the particle follows a streamline and the particle comes within one radius particle

of the fiber and adheres to it. The particle is assumed to follow its streamline perfectly and is not affected by inertia, settling, and Brownian motion. Inertial impaction occurs when the particle, due to inertia, is unable to adjust quickly enough to the change in the air stream near the fiber and collides into the fiber. Impaction is the most important mechanism for large particles. Diffusion is a mechanism in which the particles wander in a random motion (known as Brownian Motion) and leave the airflow streams and adhere to the collection surface and are effectively removed from the air. Diffusion is negligible for particles greater than 5 um; and is predominately important for particles less than 0.1 – 0.25 um (Fleeger, 2002). Gravitational settling is simply the particle settling due to gravitational forces and adhering to the filter material. Electrostatic deposition can be extremely important but difficult to quantify because it requires knowing the charge on the particles and on the fibers. Charged particles are attracted to oppositely charged fibers by Coulombic attraction (Hinds, 1999). Once the particles are adhered to the filter they are difficult to remove.

The challenge aerosols in this test were 0.5 um, 1.0 um, and 2.0 um, and these sizes are generally captured through impaction and interception, but 0.5 um particles also diffuse to some degree by diffusion. Particles that are 0.3um, the most penetrating particle size (MPPS), are dominated by diffusion and interception, while particles below 0.1 um are affected only by diffusion. When the filter demonstrates high efficiency at 0.3 um, then the filter will be more effective against smaller and larger particle sizes.

With the recent development of infectious diseases such as SARS, Avian influenza, and the threat posed by the H1N1 Influenza virus, the world has a renewed emphasis on infectious agents. The health care industry has an increased risk of

occupational exposure based on the likelihood of encountering patients with the H1N1 virus. SARS developed in Asia and spread across more than 20 countries. Surgical masks became the staple image associated with respiratory protection for swine flu. Air, water and ground transportation have played a significant role in the spread of the diseases. People are capable of traveling from one country to another country half way across the world in less than 48 hrs. The CDC states the H1N1 virus was first detected in the United Stated in April 2009. The virus is spread in the same way as the seasonal flu. The flu is spread from person to person by inhalation of the large droplets spread though coughing and sneezing, and sometimes by contact with contaminated surfaces and touching their face and mouth. The symptoms of H1N1 and seasonal flu are very similar; therefore, infected persons continue to spread the disease without being diagnosed. The H1N1 virus has been associated with several deaths throughout the United States. Local Department of Public Health organizations, such as Florida, are tracking and posting confirmed cases and deaths, along with the county location on the internet.

Viruses are intracellular parasites that can reproduce only inside a host cell. Infectious diseases vary in size with viruses at 0.02 to 0.3 um diameters, bacteria with 0.5 to 5.0 um diameters and droplets with 1 to 100 um in diameter (Grinshpun, 2009). The physical size of a SARS causing coronavirus was about 0.08 – 0.12 um (Lee, 2007). Surgical masks will provide a barrier protection against large droplets that are considered to be the primary route of SARS and H1N1 transmission; however, smaller particulates are less effectively filtered. Close contact, generally less than 3 ft, is required for transmission. Surgical masks may also be placed on patients with communicable diseases to contain respiratory droplets. Surgical masks cover the nose and mouth of the health

care provider and are held in place by double straps. The masks are generally worn during medical procedures with the intent of reducing the spread of disease from the worker to the patient. The mask will provide a barrier for the worker against larger droplets, such as sneezes and coughs; however, it is not uncommon to find workers using surgical masks for protection against smaller airborne aerosols. Under 29 CFR 1910.134 the Occupational Safety and Health Administration (OSHA) require use of NIOSH approved respirators for protection against airborne diseases such as Tuberculosis (TB) when engineering controls are not adequate. NIOSH respirators are at least 95% efficient for particles > 0.3 um. Surgical masks continue to be used as a form of respiratory protection. Surgical masks are not tested under the NIOSH certification however, the Food and Drug Administration (FDA) is responsible for regulating medical devices and requires manufacturers to demonstrate efficiency with regards to fluid resistance, filter efficiency, differential pressure, and flammability. The manufacturer provides data and proposed claims to FDA for review and the FDA reviews the provided data and clears the mask for sale (3M, 2005). The two filter efficiency tests recommended include particulate filtration efficiency (PFE) using a non-neutralized aerosol of 0.1 um latex spheres at a challenge velocity of 28 lpm. PFE is a quality indicator for surgical masks and is not an indicator of protection performance. It measures how well the mask filters out particles such as viruses and other submicron particles. The filter media of a surgical mask with a very high (> 95%) PFE may be less than 70% efficiency under NIOSH certification test methods. Bacterial filtration efficiency (BFE) testing uses a non-neutralized 3+/- 0.3 um staphylococcus aureus aerosol and a flow rate of 28.3 lpm. BFE measures how well the mask filters out bacteria when challenged with an aersosol

containing bacteria. It assesses the ability of the mask to provide a barrier to large particles expelled by the wearer. The FDA does not have a minimum filtration efficiency (Oberg, 2008). The pressure differential is a measure of the air flow resistance of the mask and is an objective measure of breathability. The higher the pressure differential, the harder it is for the wearer to breathe. The fluid resistance test reflects the mask's ability to minimize the amount of fluid that could transfer from the outer layers through to the inner layer as a result of splash or spray (Marusyk, R., 2009). The surgical masks tested in this study claimed 99% BFE and 95% PFE.

Respirators are evaluated using the NIOSH certification testing method in accordance with Title 42 CFR Part 84. The new certification test was implemented in June 1995 outlining the procedures for testing and certifying air purifying and particulate respirators. The certification test identifies nine classes of filter with efficiencies of 95%, 99% and 99.97%. The filters also have a resistance to degradation and are labeled as N, R and P series. The rating for "N" series respirators is given when the filters are not oil resistant. The "R" rating is given when the filter is resistant to oil and "P" rating is given when the filter is oil proof. The testing parameters call for using NaCl particle sizes with a count median diameter in the range of 0.075 +/- 0.02 um (0.3 um Mass median diameter) and a geometric standard deviation not exceeding 1.86 at a challenge flow rate of 85 lpm (+/- 5%), which represents a moderately to high work rate. Sodium chloride (NaCl) particles are used when testing N-series filters, and dioctyl phthalate (DOP) oil are used for testing R and P series filters. The challenge aerosols are charge neutralized.

Manikin based and live human studies have been conducted under various circumstances to determine filtration efficiency of masks. One study tested two chambers

and determined that a small chamber (0.096 m^3) was just as effective as a large walk in chamber (24.3 m^3) for testing of masks, suggesting that laboratory based evaluations have a good potential to adequately represent the respirator field performance (Balazy, 2006b). Overall, surgical masks tests revealed penetration in the range of 4 – 90%. The aerosol concentration outside and inside the mask were measured to determine filtration efficiency. Tests concluded that penetration occurs mainly at the faceseal and the manufacturing of masks should focus on improving the faceseal efficiency instead of the filter medium. Several studies used aerosol generating jet nebulizers, charge neutralizers, aerosol sampling chambers and silicone to seal the mask. Electrostatic filter properties play a significant role in capture efficiency. Table 1 provides a summary of similar studies identifying the specifics parameters used and specific aims.

Table 1. Summary of Similar Studies

Study	Study Description	Study Specifics	Results	Comments
AIJC Major Study; Anna Balazy; 2006a	Efficiency test of N-95 and surgical masks	Equipment used include: HEPA filter used to filter air, Kr-85 charge neutralizer, silicone sealant, aerosol chamber, flow rate at 85 lpm & 30 lpm, aerosol particle counter	Penetration of virions exceeded 5%for N-95, Surgical masks 25 – 84.5% penetration	6-jet nebulizer, Silicone leak tested, MS2 virions used 0.01 to 0.08 um, Diffusion dryer not used
Tara Oberg, 2008	Evaluate filter performance and facial fit of surgical masks	Nine surgical masks were tested using monodispersed aerosols (0.895, 2.0, 3.1 um) – represent Bitrex size, Kr-85 charge neutralizer, HEPA filtered air, light scattering photometer, also used 0.075 um NaCl at 84 lpm	Latex challenge: 0 - 84% penetration was 16% for 0.895 um, 15% for 2.0 um, 11% for 3.1 um; NaCl: 4 - 90% penetration	Flow rate at 6 lpm (resting human breathing rate), mask sealed to metal plate; human subjects also used and fit tests conducted
Sergey Grinshpun, 2009	Efficiency testing of N-95 and surgical masks using human subjects and manikins	Test penetration under normal breathing conditions for N-95 and surgical masks under 0.3 – 1.0 um, 25 subjects used; breathing rate was recorded with breathing simulation system, masks sealed to manikin with glue, leak check, Kr-85 neutralizer, Dryer	Surgical Penetration -Faceseal: 48%, Filter medium: 9%	Electrical Low Pressure Impactor with an air diluter, leak check conducted
3M, 2005	N-95 and surgical mask comparison	Compared N-95 and surgical masks, described PFE, BFE	None	None
Anna Balazy, 2006b	Manikin evaluation N-95 w/ challenge aerosols	Aerosol concentration inside and outside at 85 lpm & 30 lpm, NaCl challenge aerosol , 0.01 – 0.6 um aerosols, small and large test chamber used & showed no difference, Dryer, HEPA filter, Kr-85 neutralizer, particle counter, silicone sealants	Penetration exceeded 5% for 9 of 10 masks at 85 lpm for N-95 respirators	6 –jet nebulizer, leak check
JT Huang, 2007	Evaluation of Efficiency of masks	Human subjects, masks were sealed to the face by using sticky tape to determine breathing resistance	Greater resistance when sealed, observations indicated bacteria from cough was at least 1000 times more than generated by regular breathing or talking	Idea for future human testing
Byung Lee, 2005	Filtering Efficiency of N95 & R-95, surgical masks	Room size indoor test chamber, real time aerosol size cascade impactor reports concentration and size every minute, mask sealed to face, Manikin, Bioaerosol target diameter of 0.04 – 1.3 um, neutralizer	Surgical masks > 20% penetration for 0.04 um and < 15% for 1.3 um	Neutralizer used after aerosols through filter, poly test aerosol, leak test
Shu-an Lee, 2008	Respiratory Performance Offered by N95 Respirators and Surgical Masks	Determine protection factor of N-95 and surgical masks against particles representing bacterial and viral sizes of 0.04 to 1.3 um, Walk in test chamber and human subjects performed OSHA fit testing exercises, Dryer, HEPA filter	About 29% of N-95 and 100% of surgical masks had protection factor < 10, surgical average PF was 2.4	Human test subjects

Study Purpose and Hypothesis

The purpose of this study was to assess filtration efficiency resulting from leakage around the surgical mask and determine if the efficiency was different for sealed and unsealed masks using NIOSH certification methods. The filtration efficiency was then compared to FDA methods. In this study monodispersed polystyrene latex (PSL) beads were used. These are aerosols composed of airborne particulates of a single size or a small size range as opposed to polydispersed particulates composed of airborne particulates of many different sizes.

The first hypothesis was that the filtration efficiencies were not different between sealed and unsealed surgical masks. The second hypothesis was that surgical mask efficiencies for the particle sizes tested were greater than the 95% efficiency specified by NIOSH.

Research Methods

Materials and Methods

The filtration efficiency of the double tie strap surgical masks was measured using a protocol that included using a manikin head, in which the masks were affixed and tested with and without being sealed to the head. Sealing the masks prevented leakage between the mask edges and the face; therefore aerosol concentrations detected in the masks were those which passed through the filtering medium. The experiment was conducted in the USF College of Public Health Student lab where the average temperature was 74 °F.

An aerosol sampling chamber (see figure 1) was constructed by converting a 50 gallon aquarium into a tightly sealed testing chamber. The volume of the aerosol chamber is 190 liters. The chamber was used in a standing position at a height of 48". Two wood door panels (see figure 2) were modified to enable testing within the chamber. A tight seal was created by applying weather stripping along the inside door edges. The top panel was designed to include an aerosol entry port at the top section and to allow for clean make up air through the middle section (see figure 3). A high efficiency particulate air (HEPA) filter capable of filtering 99.97% of particles 0.3 um particles was installed and secured by wire mesh screen in between an 8" x 11" wood panel which was secured to the panel by metal screws and washers. Weather stripping was also placed along the edges of the wood frame and wood panel to reduce leakage. A magnahelic gauge (Dwyer

Instruments, Inc, Michigan City, IN) was installed for indication of pressure inside the chamber and to reveal potential air leaks.

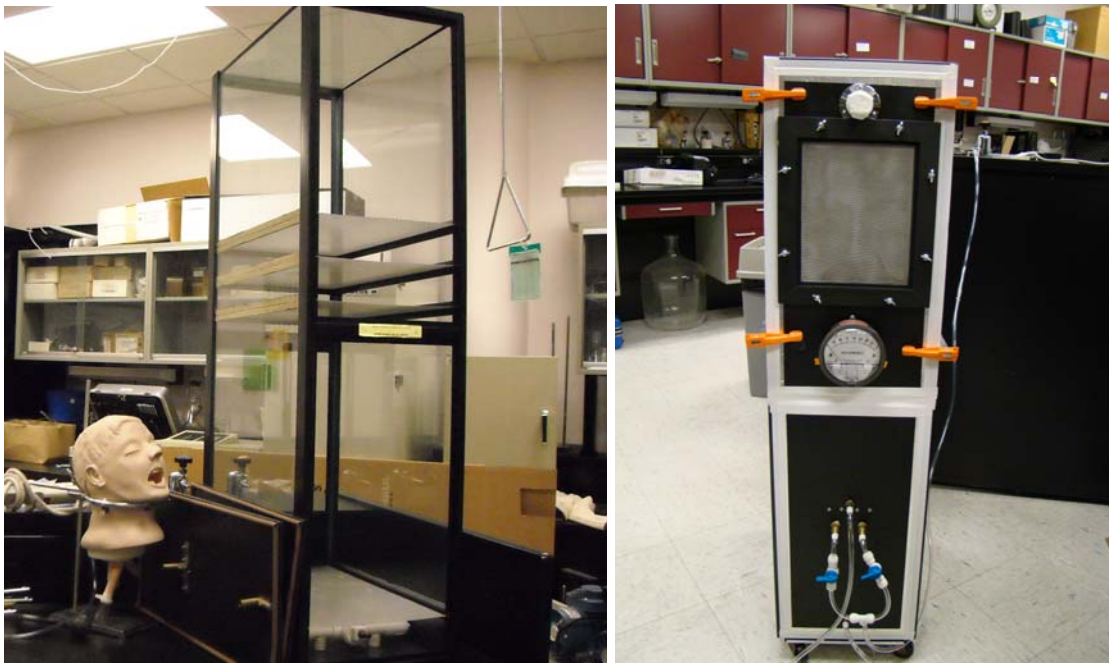


Figure 1. Aerosol Chamber

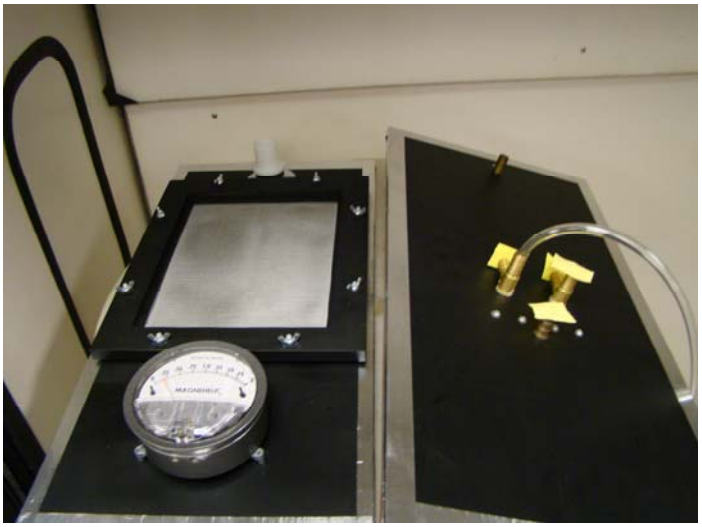


Figure 2. (left) top panel, (right) bottom panel

Figure 3. Make up air entry with magnehelic gauge, aerosol entry port, weather stripping

The bottom wood panel (see figure 4) was equipped with brass “T” entry ports to allow for the passage of Tygon tubing (see figure 5). Teflon tape was applied to the edges of the port openings to seal around the Tygon tubing. Two polyvinyl chloride (PVC) bypass valves and a PVC “T” connector were used to enable the operator to switch from inside to outside the mask and measure the aerosol concentration levels.

Figure 4. Bottom Panel

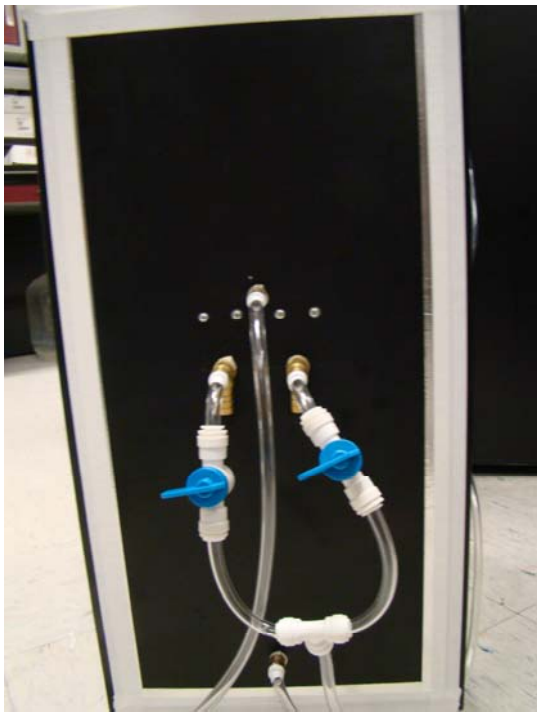


Figure 5. PVC Bypass Valves with "T" Connection

The chamber contained three stainless steel baffles with 1/8 inch diameter holes spaced uniformly on 1/4 inch centers located in the middle of the chamber (see figure 6). Baffles were spaced three inches apart with the top baffle located 16" from the top of the chamber. The fourth baffle (see figure 7) was located 3 ½" from the bottom of the chamber and was installed over the PVC plenum (see figure 8) used to exhaust the air out of the chamber.

Figure 6. Center diffusion baffles

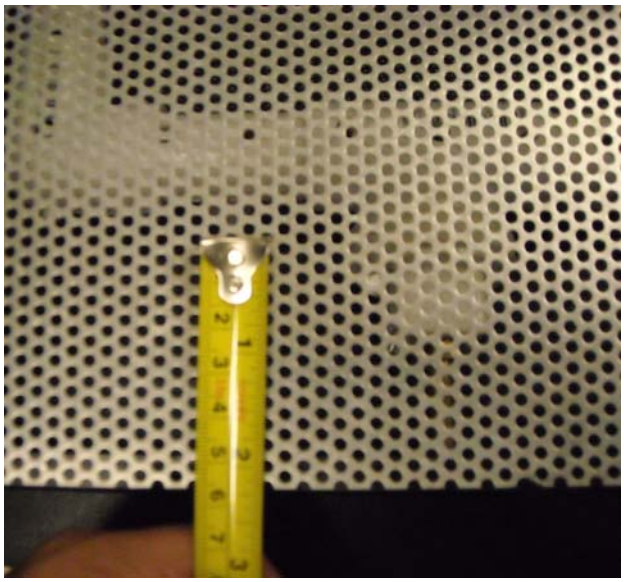


Figure 7. Exhaust baffles

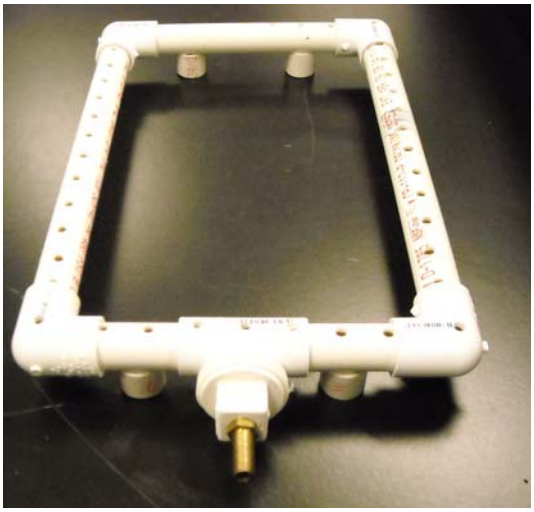


Figure 8. PVC Exhaust

The manikin head used for the experiment was an Airway Larry Management Trainer (Nasco: Life Form Products, Fort Atkinson, WI). The manikin was installed in the aerosol sampling chamber for every test (see figure 9 & 10). The head exhibited a nose and a mouth opening through which aerosols were passed. To achieve 85 lpm of air through the surgical mask two pieces of Tygon tubing were inserted through the mouth opening with one tube connected to the LASAIR and the other tube to an electric pump.

Figure 9. Manikin head on mounting bracket

Figure 10. Manikin inside chamber

The masks used in this experiment were double strap tie on surgical masks (see figure 11a). They consisted of a pleated three layer filter medium. The pleated filter provided more surface area for ease of breathing through the filter. The mask also contained a metal forming nose clip (see figure 11b) which allows the user to adjust the nose clip according to the dimensions of the individual's facial features. The nose clip was formed to the manikin's head and nasal features. In respirator test #1 the straps were secured as it would be in real life and actual use. The lower strap was tied behind the neck and the top strap was tied on the top portion of the skull. Crossing the straps provided a tighter fit and this configuration was used for all tests thereafter.

Figure 11a. Pleated Double Strap Tie on Surgical Mask

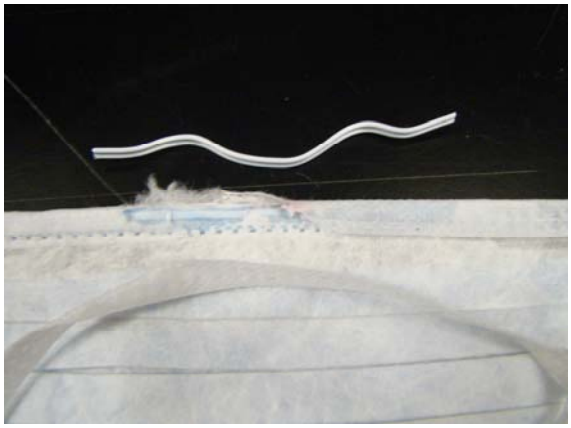


Figure 11b. Nose Clip

The experimental design called for generating monodispered PSL particles of three sizes: 0.5 um, 1.0 um, and 2.0 um. The PSL was received in 15 ml bottles. Before use, the bottles were slightly shaken to mix the particles and reduce clumping. For each trial, two drops of the PSL suspension were added to 40 ml of distilled water measured by a graduated cylinder. The suspension in the jar was swirled slightly to ensure mixing.

Table 2. Polystyrene latex spheres parameters

Nominal Size (um)	Actual Size (um)	Standard Deviation (um)	Solids-Latex (%)
0.5	0.465	0.01	2.62
1.0	0.989	0.02	2.59
2.0	1.826	0.046	2.70

In this experiment, generation of monodispersed PSL was achieved by using a CN-24J 3-jet Collison Nebulizer (BGI, Inc, Waltham, MA) (see figure 12) with a 1.9" diameter glass jar. The nebulizer jet stem was placed inside the jar ensuring the bottom of the stem was in the water while keeping the jet ports above the liquid level. The house air supply was not used. Rather, nitrogen (see fig 13) contained in an AIRGAS compressed gas cylinder was used to generate the aerosols. Nitrogen pressure was maintained at 20 PSI as directed in the manual. The nitrogen provided a steady, consistent gas which was controlled and monitored using a regulator pressure gauge. The nitrogen was relatively inexpensive. Maintaining a steady flow of compressed air when using house air is difficult due to the unpredictable pattern of use by other personnel and equipment in the facility. Therefore, pressure in the facility fluctuates considerably. Besides, house compressed air usually contains condensed water. The Collison nebulizer manual indicated that a 3- jet unit running at 20 PSI resulted in a flow of 6 liters per minute of nitrogen. The nitrogen gas was filtered using fiber glass HEPA filter. The filter was placed in line prior to connecting to the nebulizer's port. As the gas passed through the nebulizer the PSL aerosols were sprayed against the jar walls which acted as a barrier and allowed the aerosol particles to atomize at the appropriate particle diameter. The mist inside the jar exited the nebulizer where the connection port was fitted tightly into the diffusion dryer (ATI, Inc, Ownings Mills, MD).

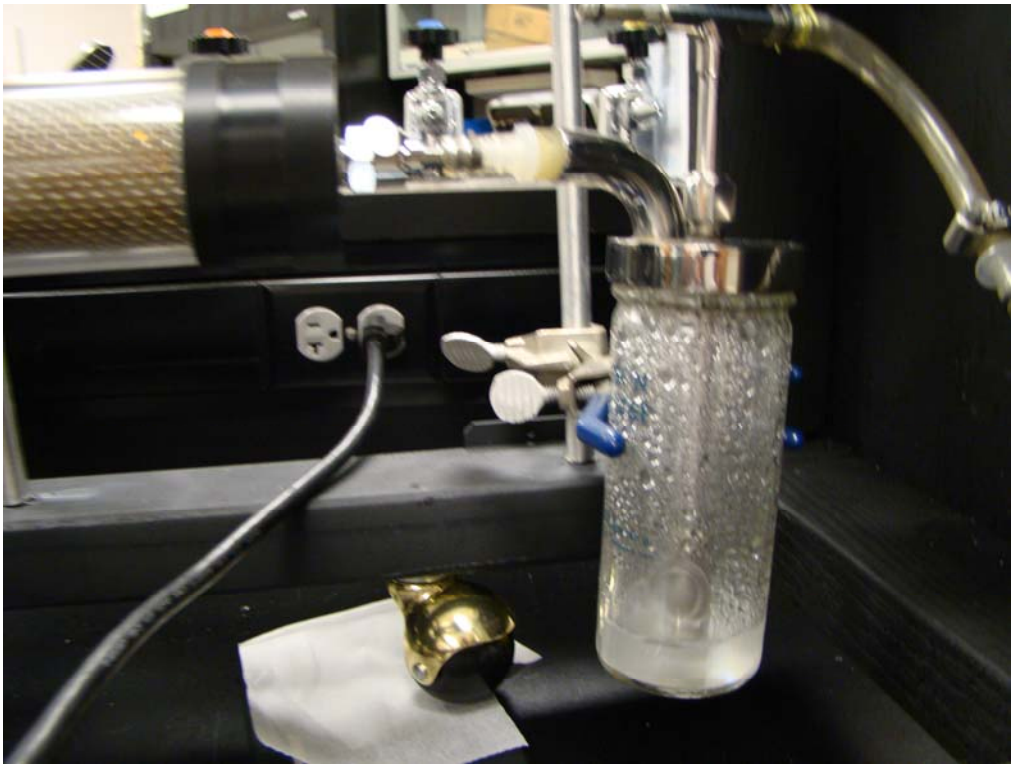


Figure 12. Collison Nebulizer

Figure 13. Nitrogen Tank

The utilization of the diffusion dryer (see figure 14) resulted in producing dry aerosol particles prior to entering the chamber. Reducing the amount of water reduced the relative humidity build up within the test chamber. The dryer allowed for the particles to enter the chamber dry and the particle counter appropriately determined the size, count, and concentration outside and inside the surgical mask. The silica gel beads were yellow (see figure 15) within the container and visible with the naked eye. The silica gel changed color from yellow to green when saturated (see figure 16). The silica gel did not change color instantaneously. Rather, the individual gel beads gradually changed color as the aerosols were generated and partial saturation occurred. The diffusion dryer was monitored continuously throughout the testing to prevent saturation. An additional dryer was available and as a result a dry chamber was used for each test. While one dryer was being used for testing the second dryer was placed in an oven set at 120 °C indicated in the operator's manual. The particles were dried as they passed through the silica gel chamber and allowed to enter the Kr-85 charge equilibrator. Partial saturation of the dryer was evident; however, the full saturation did not occur prior to completing the testing procedures. A test to determine relative humidity (RH) within the chamber was conducted and measured every 5 minutes for 3 ½ hrs during aerosol generation. The RH in the chamber prior to testing was equal to the RH in the room which was 51.22% and the highest level achieved during testing was 51.06%. The results indicate that the particles entering the chamber are dry.

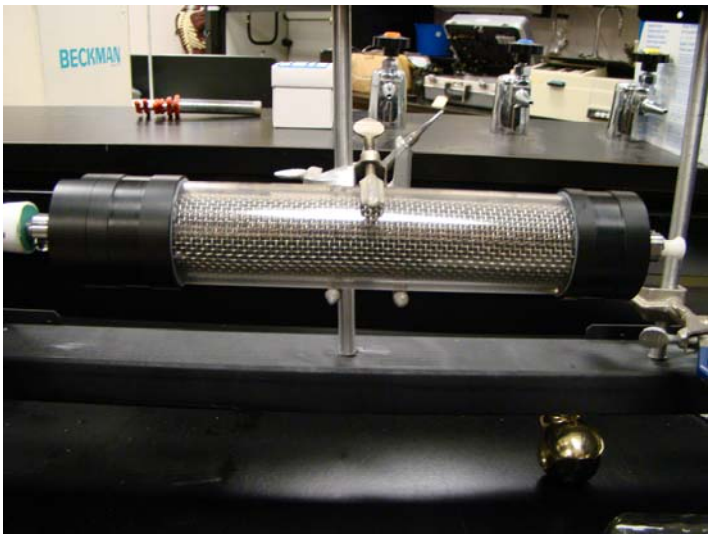


Figure 14. Diffusion Dryer

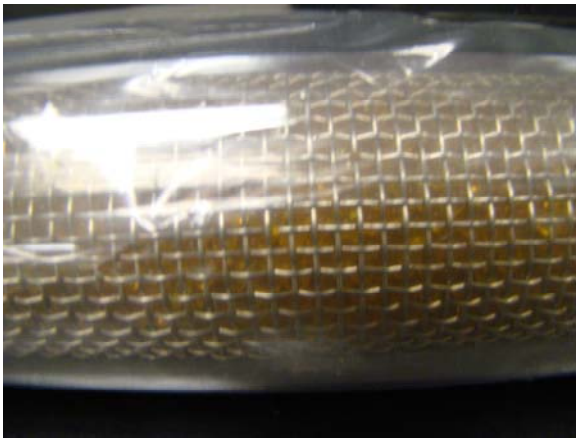


Figure 15. Unsaturated (yellow)

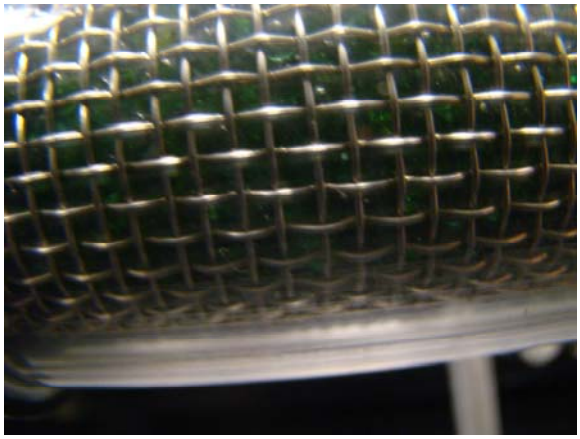


Figure 16. Saturated (green)

It should be noted that NIOSH certification tests were carried out using charge neutralized particles. The Kr-85 charge equilibrator (TSI Isotope Products Laboratories, Valencia, CA) (see figure 17) was the radioactive source used to neutralize the aerosol cloud prior to dispersion into the chamber. Kr-85 was a beta emitter. The aerosols naturally acquire electrostatic charge as they are released into the environment. The charged particles have a tendency to migrate to the Tygon tube walls, chamber walls, manikin head and to the surgical mask itself. The neutralization therefore permits the particles to provide for more dependable testing results.

Figure 17. Kr-85 charge equilibrator

Aerosol particles entering the chamber were measured using a LASAIR Particle Counter (Particle Measuring Systems, Inc, Boulder, CO) (see figure 18), Model 210, inside and outside the mask. The LASAIR sized and counted particles by measuring the amount of light scattered by each particle. The source of illumination is an internal 10 milliwatt HeNe laser. The instrument sampled air at 1 CFM (28.32 lpm). There were eight channels in the instrument which included the particle sizes of interest: 0.5 um, 1.0 um, and 2.0 um. The average outside and inside particle concentrations were displayed and recorded every 10 mins. The maximum concentration the instrument was capable of reading was 750,000 ft^3. Prior to testing, the instrument was zeroed using manufacturer Ultipor N66 0.2 um rated zero calibration filters. The LASAIR was configured to provide six 10 minute samples and the results were displayed in real time.

Figure 18. LASAIR Model 210 Particle Counter

The airflow into the chamber included: the nebulizer's 6 lpm of nitrogen when operated at 20 PSI; the airflow through the surgical mask at 85 lpm as required by NIOSH, this flow is divided into two parts: 28.3 lpm for the particle counter and the balance, 56.7 lpm to the air pump and finally, 9 lpm in the plenum at the bottom of the chamber. Therefore, the total airflow in the chamber is 100 lpm (see figure 19). A TSI mass-flow meter was used to measure the airflow in the various system components. The system components were set up as depicted in figure 20.

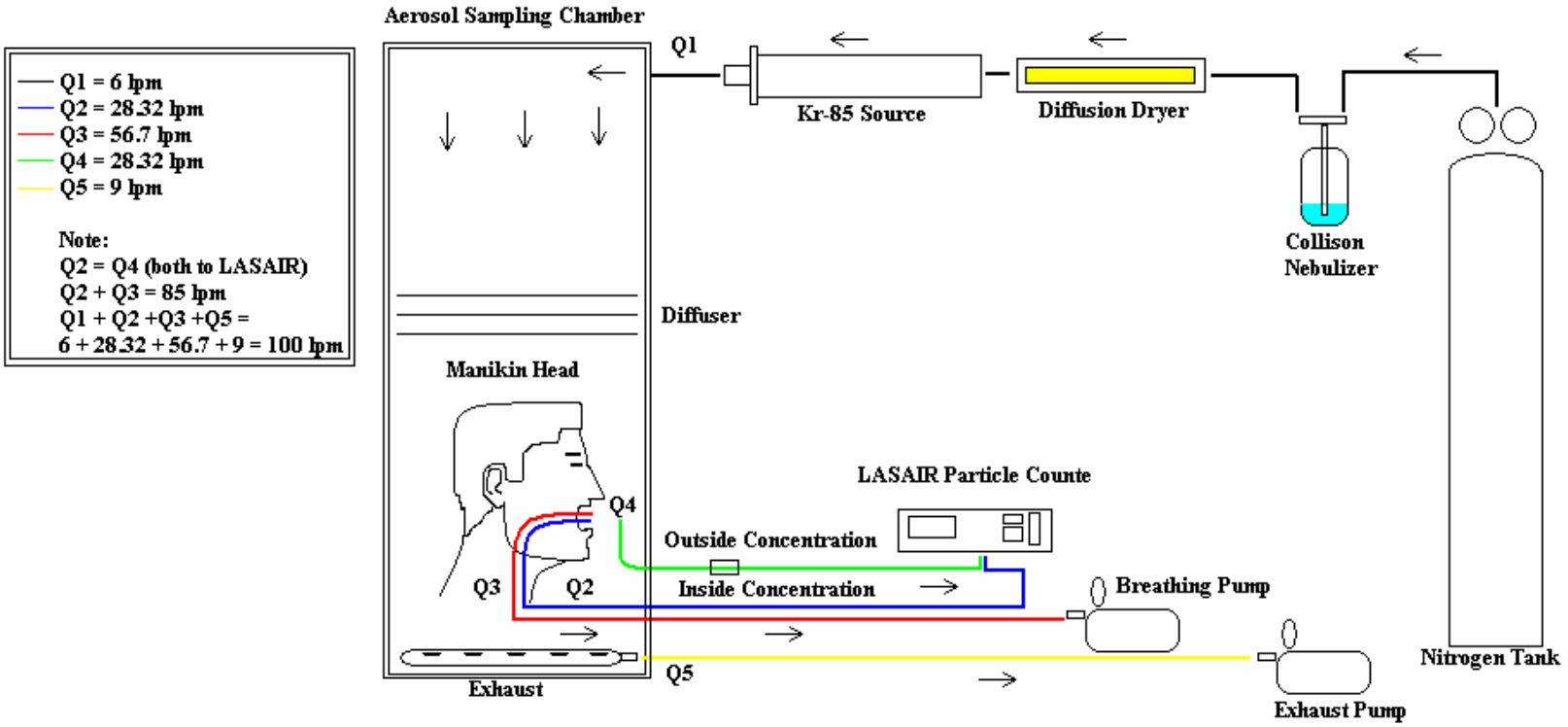


Figure 19. Aerosol Sampling Air Flow Diagram

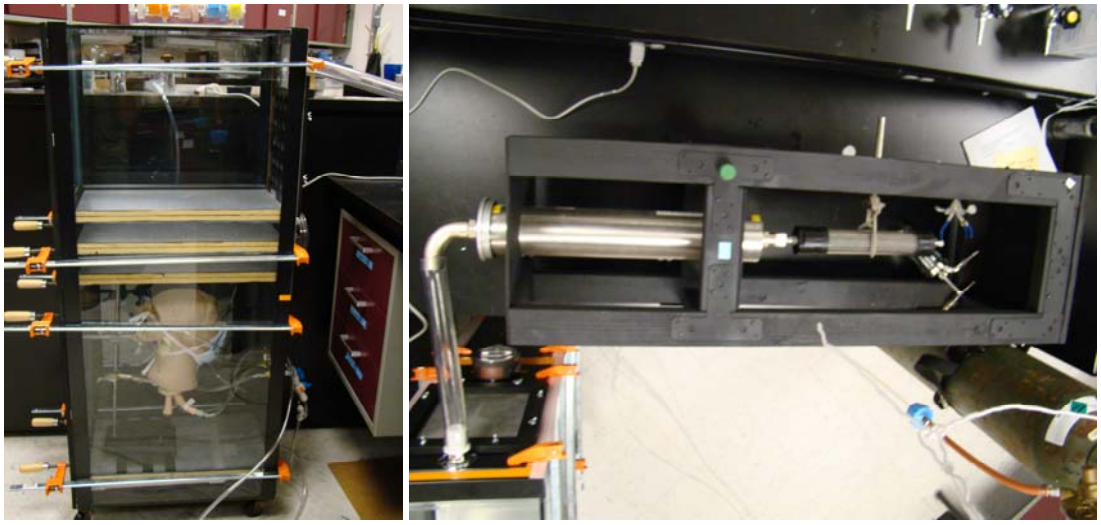


Figure 20. Aerosol Sampling Chamber System Set Up

To determine the period of time required to reach the maximum (equilibrium) concentration in the chamber, the following equation was used:

$C = (G/Q) * (1- e^{(-Qt/V)})$, note: G/Q is equal to C_{max}

$C/ C_{max} = (1- e^{(-Qt/V)})$, note: $C/ C_{max} = 0.99 = 1 - e^{(-Qt/V)}$

$0.01 = e^{(-Qt/V)}$, this is 1% because the concentration can't reach zero

$\ln (0.01) = \ln (e^{(-Qt/V)})$

4.6 = Qt/V, desired Q = 100 lpm (assume Q = V), the volume of tank is 190 liters

t = 4.6 * V/Q

t = 4.6 * 190 liters/ 100 lpm

t = 8.74 mins ≈ 9 mins

Six individual surgical masks were tested during the experiment. Three masks were unsealed and three masks were sealed. After the mask was secured on the manikin head and placed in the chamber, testing of the three different size aerosols was conducted until the filtration efficiency for each size was determined. An unsaturated diffusion dryer was used for each particle size test.

Protocol

Each trial was conducted using the following procedures:

1. Unsealed testing – the nose clip was formed to the nose. The surgical mask was secured to the manikin by tying the double tie straps behind the head.
2. Sealed testing – silicone sealant was applied to the inner edge of the surgical mask. The nose clip was formed to the nose and the mask was secured to the head by tying the double straps. A second layer of silicone was applied to the outside edge of the mask and to the face contact point to provide a complete seal.
3. Once the manikin was in the chamber the bottom door panel was installed (top panel in place). Eight clamps were used to tightly secure the panel in place, and they were sealed with tape along the edges to prevent leakage.
4. The magnahelic gauge was monitored throughout the experiment to ensure that there was no air leakage in the chamber.
5. The brass "T" connection ports with Tygon tubing running through were sealed with Teflon tape. The Tygon tube connecting the Kr-85 and chamber was also sealed with Teflon tape.
6. A 30 minute background check was conducted by operating the lower exhaust pump (9 lpm), the mask pump (56.7 lpm) and the LASAIR pump (28.32 lpm). Background readings were conducted with all components in place except the nebulizer.
7. After the 30 minutes were complete an additional 10 mins were monitored to determine and record background levels outside the mask.

8. Once completed, the bypass valves were switched to conduct and record the inside concentration levels after an additional 10 minutes of monitoring.
9. The nebulizer was then turned on and allowed to generate PSL aerosols for 15 minutes to reach maximum concentration. Once maximum concentration was reached, 10 min samples were conducted to determine concentration levels outside the mask.
10. The bypass valves were switched to record inside concentration levels and the instrument was allowed to run for 1 minute to clean out residual particles in the line.
11. After 1 minute, a 10 minute sample was taken to determine inside concentration.
12. Measuring the inside and outside concentration levels continued in this fashion until five tests were completed for each trial. Alternating from inside to outside measurements provided a good and consistent concentration ratio throughout the experiment.
13. These procedures were repeated for each particle size and for each mask. If back to back particle size tests were run, the background levels were measured for one hour prior to testing.
14. At the conclusion of each trial the nebulizer was shut off, disassembled and cleansed using soapy water, distilled water, and a wire brush.

The efficiency of the surgical mask was determined by first subtracting the background levels from the resulting concentrations inside and outside the mask. The following equation was used to calculate the efficiency:

Efficiency = ((Concentration out – Concentration in)/ Concentration out) * 100

The resulting value is the efficiency of the mask. An efficiency of 20% indicated that there was 80% penetration through the mask. The major materials and components of the experiment are presented in Appendix 1.

Results

The results of the six respirator tests are presented separately and the filtration efficiencies are analyzed for each individual mask, by aerosol particle size, and sealing status. The results of the individual tests are listed in Tables 3 - 8. Table 3 lists the efficiencies per trial for the unsealed surgical masks along with the standard deviation and average efficiencies. Table 4 lists the efficiencies per trial for the sealed surgical masks along with the standard deviation and average efficiencies. Figure 21 is a graph illustrating the efficiency per trial at 0.5 um unsealed and Figure 22 illustrates the efficiency with a sealed mask.

Table 3. Efficiency (%) for Unsealed Mask at 0.5 um

Respirator #	Trial I	Trial II	Trial III	Trial IV	Trial V	SD	Avg
1	2.80	4.95	2.39	4.71	4.30	1.16	3.83
2	18.55	23.17	17.63	26.85	26.85	4.40	22.61
3	40.68	33.27	48.44	47.57	49.13	6.80	43.82

Table 4. Efficiency (%) for Sealed Mask at 0.5 um

Respirator #	Trial I	Trial II	Trial III	Trial IV	Trial V	SD	Avg
4	46.94	47.80	45.69	45.69	52.83	2.96	47.79
5	43.47	43.27	52.30	34.41	37.92	6.78	42.27
6	30.16	54.50	51.01	55.20	64.47	12.70	51.07

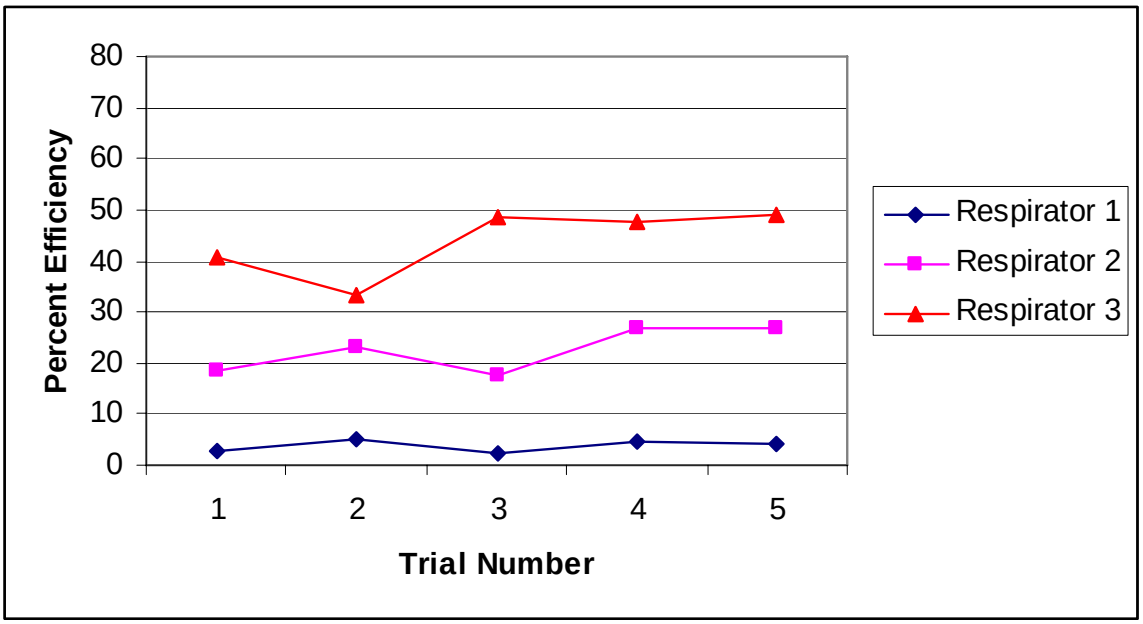


Figure 21. Efficiency comparison of 0.5 um particles by unsealed mask

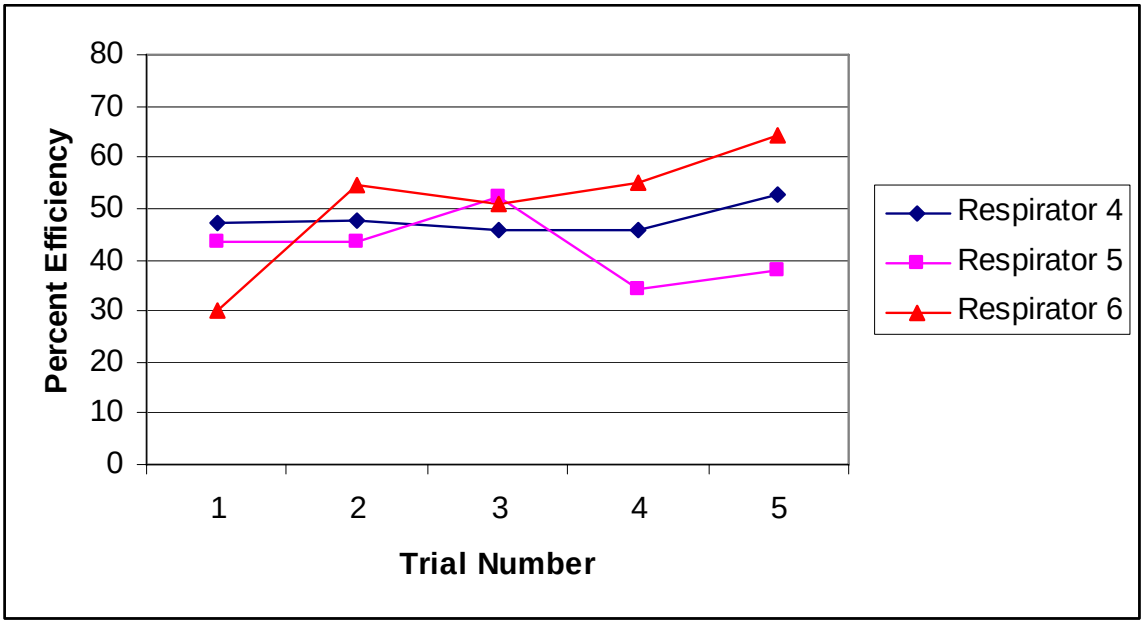


Figure 22. Efficiency comparison of 0.5 um particles by sealed mask

Tables 5 and 6 list the efficiencies per trial for the unsealed and sealed surgical masks along with the standard deviation and average efficiencies for 1.0 um. Figure 23 is a graph illustrating the efficiency per trial at 1.0 um unsealed and Figure 24 illustrates the efficiency with a sealed mask.

Table 5. Efficiency (%) for Unsealed Mask at 1.0 um

Respirator #	Trial I	Trial II	Trial III	Trial IV	Trial V	SD	Avg
1	50.00	57.14	61.37	59.79	63.19	5.15	58.30
2	74.42	73.34	70.84	68.00	69.23	2.70	71.17
3	71.65	75.92	75.67	77.71	76.98	2.35	75.58

Table 6. Efficiency (%) for Sealed Mask at 1.0 um

Respirator #	Trial I	Trial II	Trial III	Trial IV	Trial V	SD	Avg
4	73.68	68.70	70.00	72.34	70.59	1.96	71.06
5	81.34	85.50	80.36	86.01	87.89	3.22	84.22
6	68.09	73.85	73.84	77.05	77.40	3.74	74.05

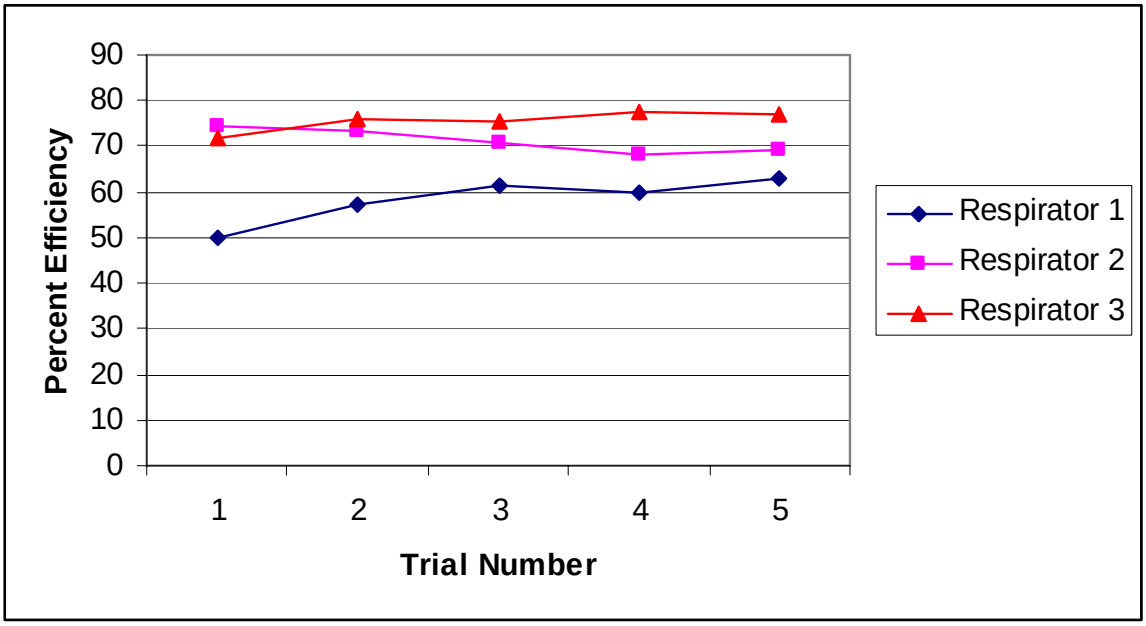


Figure 23. Efficiency comparison of 1.0 um particles by unsealed mask

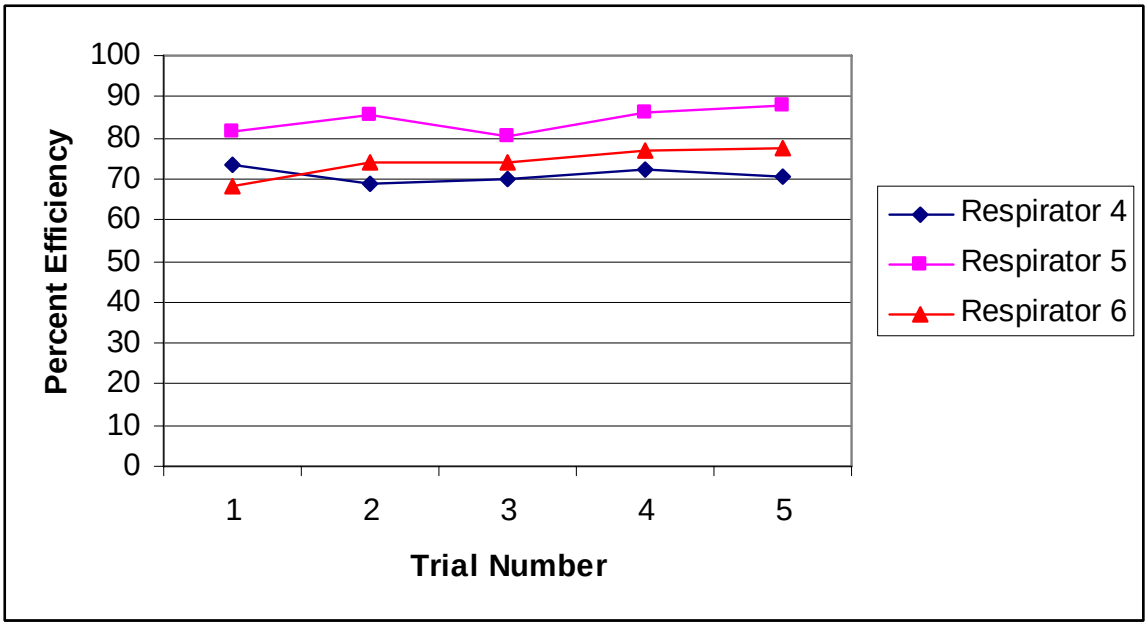


Figure 24. Efficiency comparison of 1.0 um particles by sealed mask

Tables 7 and 8 list the efficiencies per trial for the unsealed and sealed surgical masks along with the standard deviation and average efficiencies. Figure 25 is a graph illustrating the efficiency per trial at 2.0 um unsealed and Figure 26 illustrates the efficiency with a sealed mask.

Table 7. Efficiency (%) for Unsealed Mask at 2.0 um

Respirator #	Trial I	Trial II	Trial III	Trial IV	Trial V	SD	Avg
1	45.67	55.34	59.28	70.01	64.07	9.19	58.87
2	77.88	79.75	74.90	82.48	83.33	3.43	79.67
3	68.71	66.12	67.16	66.25	67.58	1.06	67.16

Table 8. Efficiency (%) for Sealed Mask at 2.0 um

Respirator #	Trial I	Trial II	Trial III	Trial IV	Trial V	SD	Avg
4	67.94	69.29	71.80	64.77	74.97	3.86	69.76
5	80.25	81.67	81.70	80.83	81.76	0.68	81.24
6	83.60	85.14	84.80	86.09	86.66	1.19	85.26

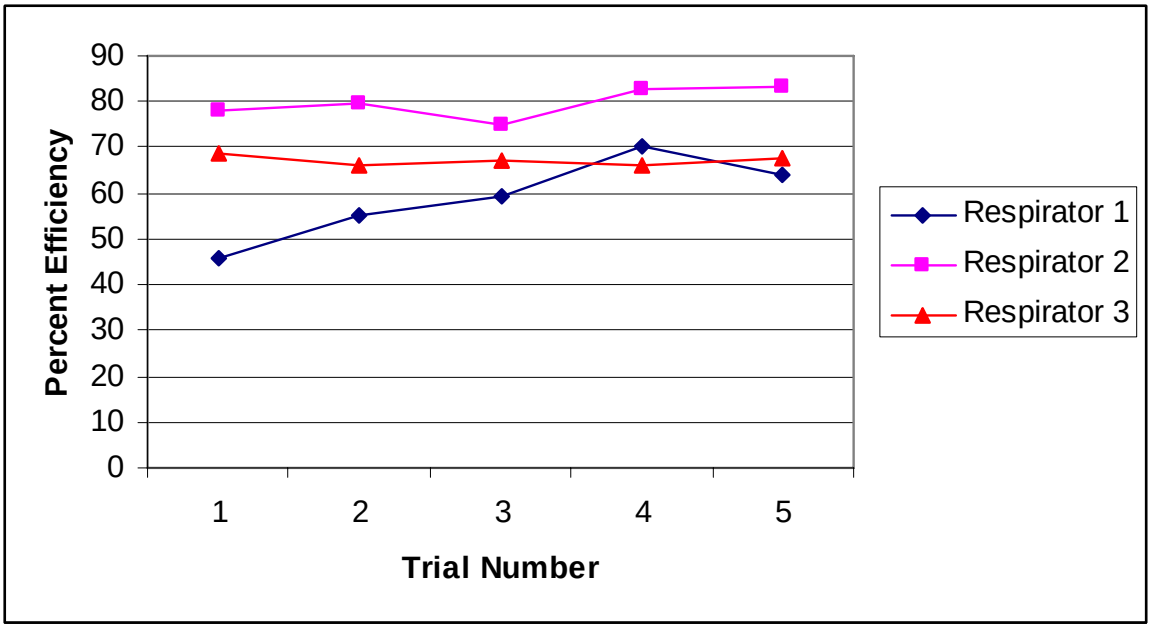


Figure 25. Efficiency comparison of 2.0 um particles by unsealed mask

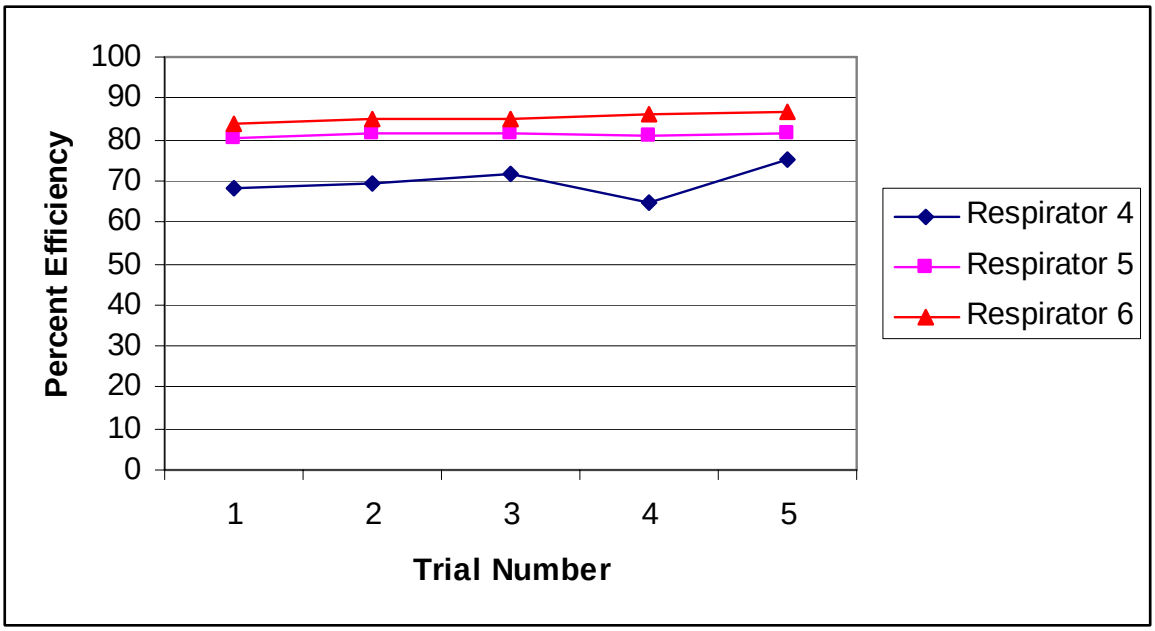


Figure 26. Efficiency comparison of 2.0 um by sealed mask

Discussion

The purpose of this experiment was to assess filtration efficiency resulting from leakage around the surgical mask and to determine if the efficiency was different for sealed and unsealed masks using 85 lpm from the NIOSH certification methods. The filtration efficiency was then compared to FDA methods.

A JMP statistical software program was used to generate a General Linear Model that was used to analyze the data. The analysis evaluated the effects for the following: seal vs unsealed, particle size, and trials. The independent variable was efficiency. The fixed effects were the seal, particle size, and trial. The random effects were the masks themselves. We also examined the interaction between particle sizes and seal status. The fixed effect tests revealed that for sealed vs unsealed the results were statistically significant ($p < 0.0001$). Tests for particle size also were statistically significant ($p < 0.0001$). The random effects indicate that there was a statistically significant difference between mask #1 as compared to masks #2 and # 3. Masks #2 and #3 were not significantly different. The test for interaction of seal status and particle size were statistically significant ($p = 0.0006$). The test for trials indicated that there was no statistical difference among trials ($p = 0.2213$).

Tukey's Honestly Significant Difference (HSD) test is a multiple comparison test and was conducted to compare each of the particle sizes to each other. The test revealed that efficiencies of the 1um and 2um particle sizes were not statistically different from each other. The test revealed that there is a statistical difference with the 0.5 um as

compared to the 1 and 2 um sizes. A Tukey HSD test was also conducted to analyze the interaction of particle size and seal status. The results revealed that 1 and 2 um were similar when sealed and 1 and 2 um were similar when unsealed. For both sealed and unsealed conditions there was a significant difference for 0.5 um compared to 1 and 2 um particles.

The manufacturer of the tested surgical mask claimed that the mask provided a PFE of >95% for 0.1 um particles sizes. The manufacturer indicated that the test was conducted using a particle challenge study based on filtration efficiency measured using the mass median aerodynamic diameter of particles and using the 28 lpm flow rate. This research experiment was conducted using 85 lpm air flow rate that is specified in the NIOSH certification testing method. It represents the breathing rate at moderate to heavy work load conditions. Trials were conducted with the surgical masks unsealed to the manikin head and tested using three monodispersed PSL particle sizes with diameters of 0.5 um, 1.0 um and 2.0 um. Trials were also conducted with the surgical masks secured to the manikin head and sealed with silicone along the edges of the mask and face. During each trial five tests were conducted and monitored to identify the concentration levels during the trial and to indicate the efficiency throughout the trial. The standard deviation and average concentrations for the trials were determined. As expected the results were quite consistent throughout the trials indicating that the sealed masks were 23% more efficient than unsealed masks at 0.5 um, 8% at 1.0 um and 10% at 2.0 um. The results of the 0.5 um unsealed masks tests were associated with the widest variability and the highest potential for leakage. The average efficiency ranged from 3.8% to 43.8%. However, the results were remarkably consistent when the sealed mask efficiency was

evaluated at 0.5 um, where the efficiency ranged from 42.3% to 51%. The 0.5 um particles had the ability to follow the air flow patterns and enter the mask through gaps left by a non-tight fitting mask. The surgical masks had tie straps that were tightened based on an individuals comfort level as opposed to a person donning a NIOSH approved filtering facepiece device where the straps are elastic and self tightening. An evaluation of respirator test # 1 revealed the mask was tightened as it would be in real life and actual use. The lower strap was tied behind the neck and the top strap was tied on the top portion of the skull. The results under this configuration were 3% efficiency; that is, 97% penetration of 0.5 um diameter particles. The head was slightly smaller than an average sized head and this securing method provided a loose fit and there were visible gaps on the top section and under the chin. Crossing the straps provided a tighter fit and this configuration was used for all tests thereafter. Sealing the mask resulted in improvement of the efficiency by up to 40%. The faceseal edges were sealed and the aerosols were forced to enter the mask through the filter instead around the edges. Figure 27 was the configuration for respirator #1 and Figure 28 was the configuration for the other testing.

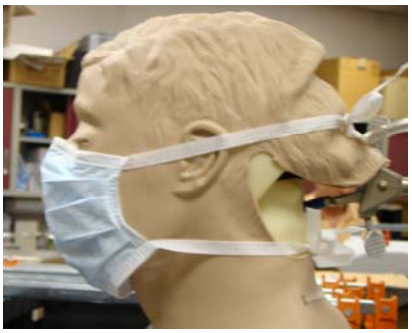


Figure 27. Unsealed mask under normal use

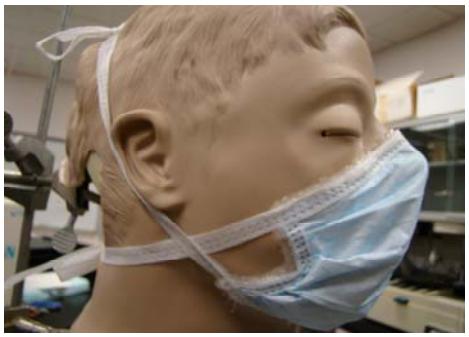
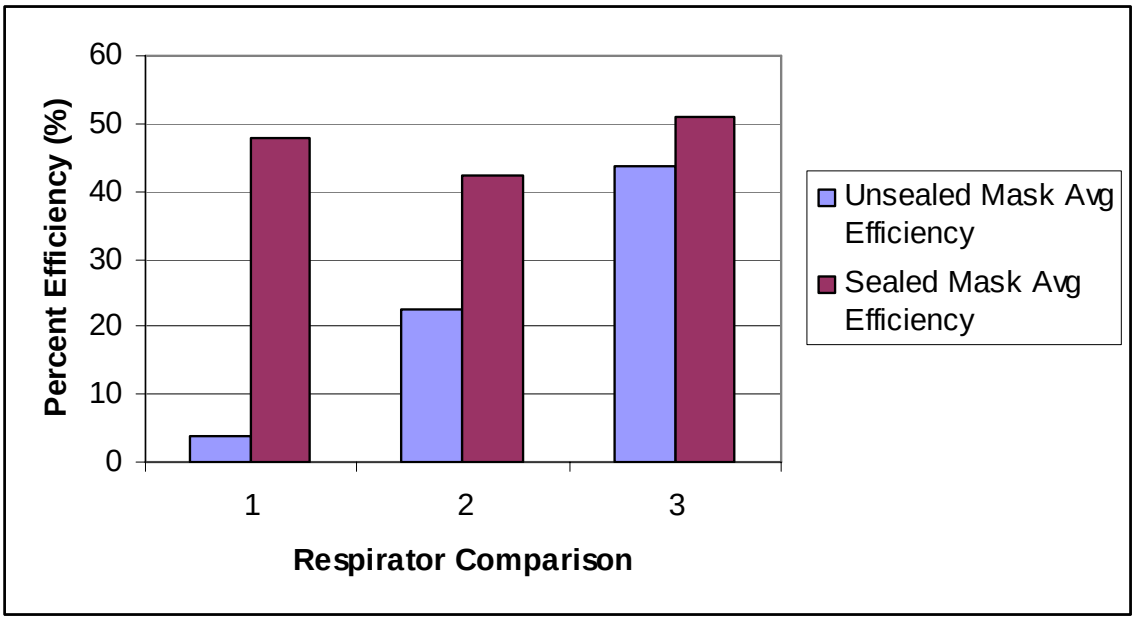


Figure 28. Sealed mask with crossed straps

Table 9. Average Efficiency Comparison of Unsealed and Sealed Mask at 0.5 um

Surgical Masks	Unsealed Mask % Efficiency	Sealed Mask % Efficiency
Respirator # 1 vs 4	3.83	47.78
Respirator # 2 vs 5	22.6	42.27
Respirator # 3 vs 6	43.81	51



Section 1: respirator 1 vs 4; Section 2: respirator 2 vs 5; Section 3: respirator 3 vs 6
Figure 29. Unsealed vs. Sealed Mask Comparison at 0.5 um

Table 10. Average Percent Difference for Unsealed vs. Sealed Mask at 0.5 um

0.5 um Comparison	Percent
Avg % unsealed	23.41
Avg % sealed	47.02
Difference of efficiencies	23.61

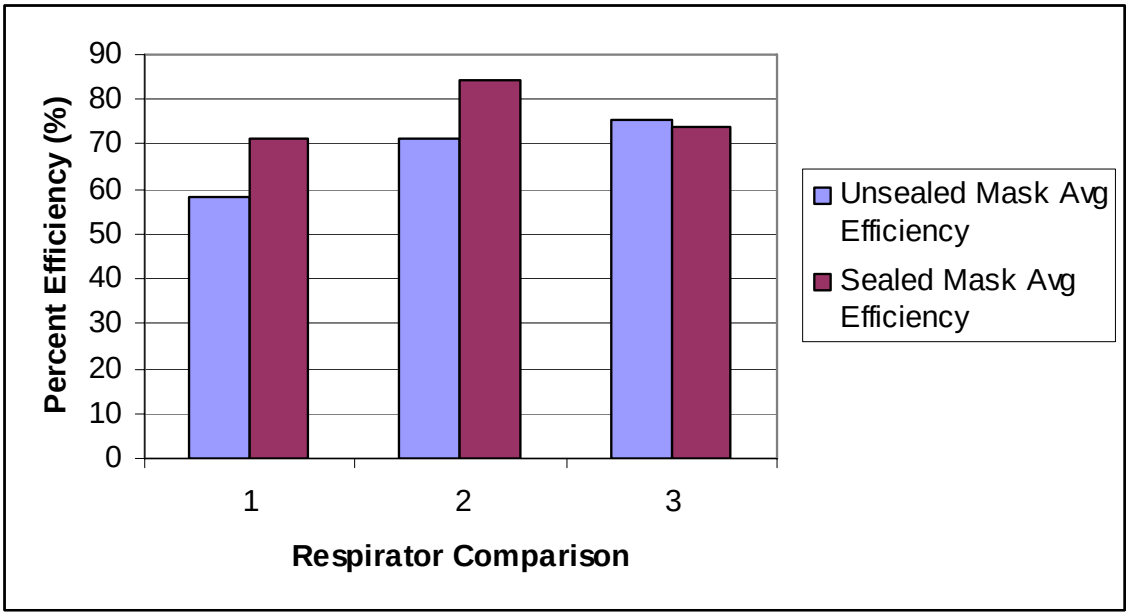
Figures 21 through 26 plot the efficiencies when the masks were sealed and unsealed. The results clearly show the high variability in efficiency when the masks were unsealed and also indicated that the best efficiency through the filter medium was 51%. This efficiency is 44% less efficient than claimed by the manufacturer when using challenge particles that were 0.1 um under PFE testing methods. The smaller particles,

0.5 um, were able to enter the breaks in the mask at a higher rate because these particles tend to follow the air movement very closely. They were too small for collection by impaction and too large for collection by diffusion. Figure 30 indicated that the sealed masks were 23% more efficient on average than unsealed masks.

While the 0.5 um particles followed the airflow patterns the larger 1.0 um and 2.0 um particles were more affected by inertia. The particles impact on the filter more readily because they do not follow the air flow as easily and in turn are captured by the filter medium. The sealing of the mask allowed for determination of the actual efficiency of filtering material. The average efficiency increased approximately 8% from unsealed to sealed masks at 1.0 um and 10% at 2.0 um.

Table 11. Average Efficiency Comparison of Unsealed and Sealed Mask at 1.0 um

Surgical Masks	Unsealed Mask % Efficiency	Sealed Mask % Efficiency
Respirator # 1 vs 4	58.29	71.06
Respirator # 2 vs 5	71.16	84.22
Respirator # 3 vs 6	75.58	74.04



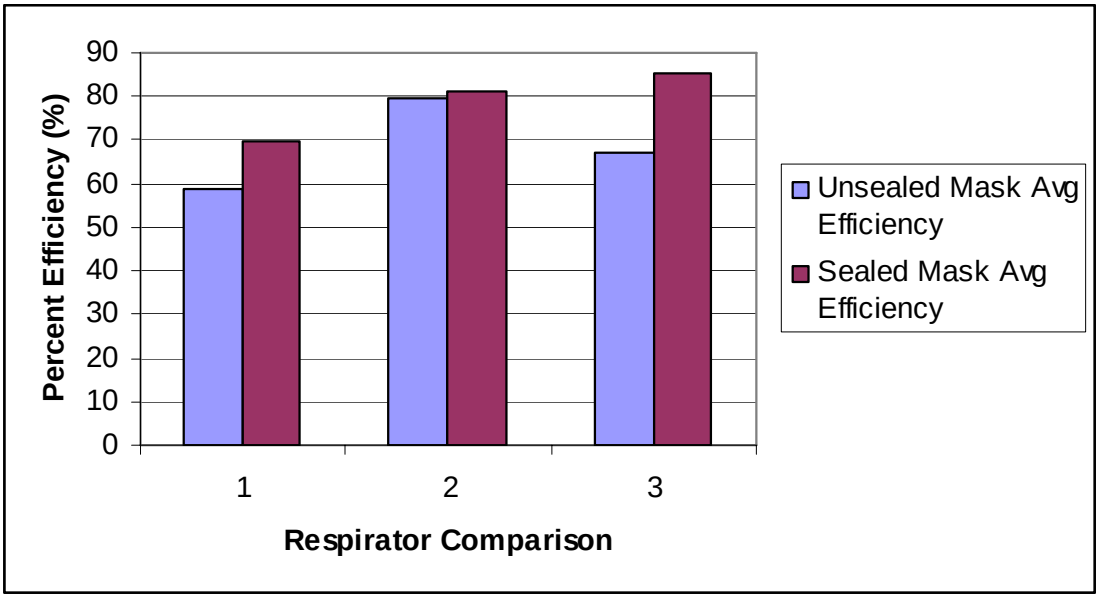
Section 1: respirator 1 vs 4; Section 2: respirator 2 vs 5; Section 3: respirator 3 vs 6
Figure 30. Unsealed vs. Sealed Mask Comparison at 1.0 um

Table 12. Average Efficiency Comparison of Unsealed and Sealed Mask at 1.0 um

1.0 um Comparison	Percent
Avg % unsealed	68.34
Avg % sealed	76.44
Difference of efficiencies	8.10

Table 13. Average Efficiency Comparison of Unsealed and Sealed Mask at 2.0 um

Surgical Masks	Unsealed Mask % Efficiency	Sealed Mask % Efficiency
Respirator # 1 vs 4	58.87	69.75
Respirator # 2 vs 5	79.66	81.24
Respirator # 3 vs 6	67.16	85.26



Section 1: respirator 1 vs 4; Section 2: respirator 2 vs 5; Section 3: respirator 3 vs 6
Figure 31. Unsealed vs. Sealed Mask Comparison at 2.0 um

Table 14. Average Efficiency Comparison of Unsealed and Sealed Mask at 2.0 um

2.0 um Comparison	Percent
Avg % unsealed	68.56
Avg % sealed	78.75
Difference of efficiencies	10.19

The data presented in table 14 show the average efficiencies for all particle sizes and for sealed and unsealed configurations. For unsealed masks the data indicated the surgical masks were approximately 45% more efficient for particles with a diameter of 1.0 & 2.0 um as compared to 0.5 um diameter. For sealed masks the data indicated the surgical masks were approximately 30% more efficient for particles with a diameter of 1.0 um and 2.0 um as compared to particles of 5.0 um diameter.

Table 15. Average efficiency compared to particle diameter

Diameter um	Unsealed Avg % Efficiency	Sealed Avg % Efficiency
0.5	23.41	47.02
1	68.34	76.74
2	68.56	78.75

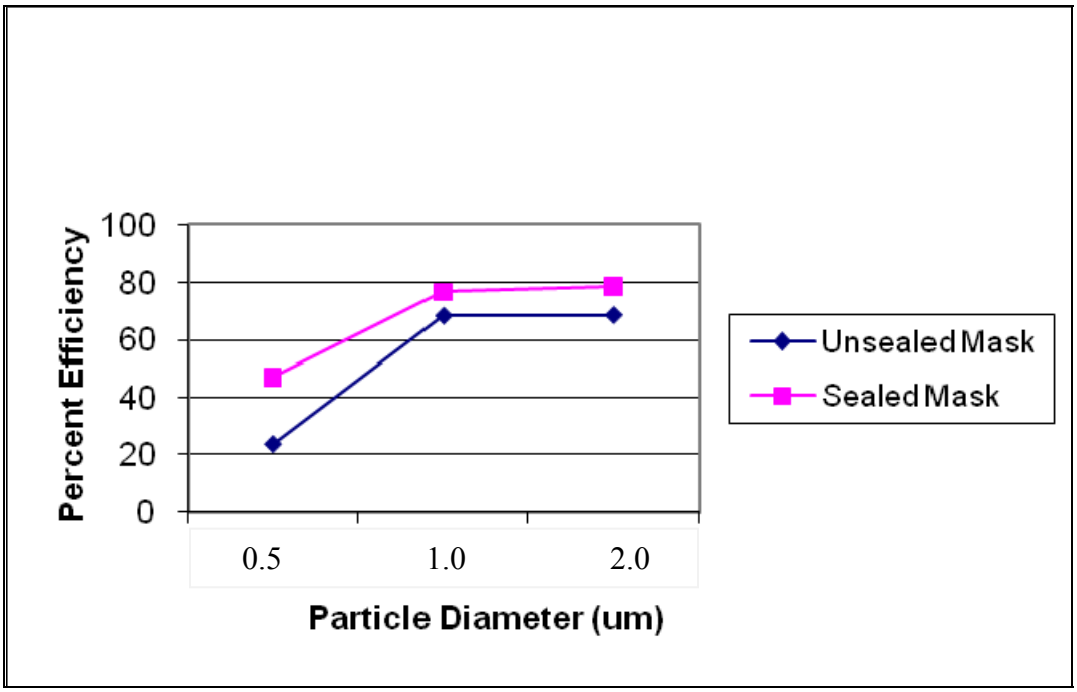


Figure 32. Average Efficiency for Unsealed vs Sealed Masks Compared by Particle Size

Conclusions

Analysis of the data indicated that the first hypothesis, which stated that the filtration efficiencies were not different between sealed and unsealed surgical masks, is rejected. Analysis indicates that the second hypothesis, which stated that the filtration efficiencies of surgical masks were greater than those approved by NIOSH for N-95 respirators, is also rejected.

Surgical masks are more appropriate for droplets of larger size such as droplets resulting from sneezing and coughing. Respirators require a >95% filtration efficiency and the surgical mask maximum average efficiencies while sealed were 47% for 0.5um, 76% for 1.0 um and 78% for 2.0 um. The FDA PFE testing methods can not be compared to NIOSH testing methods. Based on the data healthcare workers should not use surgical masks as personal protective equipment, instead NIOSH approved respirators, such as the N-95 filtering face piece device, are more appropriate for protection against viruses as recommended by the CDC and OSHA. Providing a patient with a surgical mask to capture the larger droplets is a good practice.

The limitations of this study include the fact that the air flow was constant instead of a pulsating flow rate simulating natural breathing rate. A constant air flow provides consistent results. Under NIOSH testing methods 20 respirators are tested. Systematic errors associated with this test include aerosol wall losses and instrument calibration.

Based on the results of this study, recommendations for future research include:

- Conduct human testing of the surgical masks in the USF Breathing Lab.

- Study and compare the efficiencies of various manufactured surgical masks such as, but not limited to, ear loop masks, masks without formable nose clips, and different double strap tie-on surgical masks.
- Conduct a similar study with particles ranging from 0.1 um to 0.3 um PSL aerosol. These particle sizes are closer to the sizes of droplet nuclei containing viruses.
- Conduct studies using a manikin head of normal size and shape.

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3M Occupational Health and Environmental Safety Division: "Regulation Update – 42 CFR 84". , Number 18, August 1995.

Appendices

Appendix 1: Major Materials and Components of the Experiment

Component	Manufacturer	Specifications	Comments
Double Strap Tie-On Surgical Mask	----------	Three layer fabric, metal nose clip	Six independent masks used
Manikin Head	Nasco: Life Form Products, Fort Atkinson, WI	"Airway Larry" Airway Management Trainer LF03699U	Contains Dry Natural Rubber
Nitrogen Compressed Air	AIRGAS (www.airgas.com)	Operated at 20 PSI, 0.2 um fiberglass filter in 45 mm holder in line	Equipped with Harris Regulator, Model 92-250
Collison Nebulizer	BGI Inc., Waltham, MA	3-Jet stainless steel	Q = 6 LPM; Operated at 20 PSI
Polystyrene Latex Beads (0.05 um)	Polyscientific, Inc Warrington, PA	Geometric mean: 0.465 um, std deviation: 0.01 um	Monodispersed
Polystyrene Latex Beads (1.0 um)	Polyscientific, Inc Warrington, PA	Geometric mean: 0.989 um, std deviation: 0.01 um	Monodispersed
Polystyrene Latex Beads(2.0 um)	Polyscientific, Inc Warrington, PA	Geometric mean: 1.826 um, std deviation: 0.01 um	Monodispersed
Diffusion Dryer	ATI, Inc Owings Mills, MD Length - 11.1 in Diameter: 2.23 in	Model DD250; Manufactured April 2008	Changed out for every test size
Kr-85 (Krypton)	TSI Isotope Products Laboratories Valencia, CA	10 mCi Activity: 370 mBq Source # 54-0018	Half life: 11 yrs Decay Mode: Beta
Aerosol Sampling Chamber	50 gallon tank; Approx. 48" x 12.5" x 20.75"	N/A	Volume = 190 liters
LASAIR	Particle Measuring Systems, Inc; Size: 14" x 17" x 6.75" Boulder, CO	Model 210 Serial #: 36071	Operates at 1 CFM Eight Channels with thresholds at: 0.2, 0.3, 0.5, 0.7, 1.0, 2.0, 3.0, 5.0
Bypass Valves		Made of PVC	
Magnahelic Gauge	Dwyer Instruments, Inc Michigan City, IN	0 – 2" H_20	
Exhaust Pump	Environmental Monitoring Systems	Model: 905CA23-097G	Bottom Exhaust operated at 9 LPM
Breathing Pump	Emerson Electric Co.	MFG # A007; Phase 1, HP 1/3; Pump #2 LR39793	Mouth port through mask operated at 57 LPM

Appendix 2: NIOSH Title 42 CFR Part 84 Requirements

National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236		
Procedure No. TEB-APR-STP-0059	Revision: 2.0	Date: 5 October 2007

DETERMINATION OF PARTICULATE FILTER EFFICIENCY LEVEL FOR N95 SERIES FILTERS AGAINST SOLID PARTICULATES FOR NON-POWERED, AIR-PURIFYING RESPIRATORS
STANDARD TESTING PROCEDURE (STP)

1. PURPOSE

This test establishes the procedure for ensuring that the level of protection determined by the particulate filter efficiency level test for N95 series filters used on non-powered respirators submitted for Approval, Extension of Approval, or examined during Certified Product Audits meet the minimum certification standards set forth in 42 CFR, Part 84, Subpart G, Section 84.181. These filters and filter cartridges may be integral components; mounted individually; used in conjunction with cartridges and canisters for chin-style, front-mounted, and back-mounted gas masks; or used in combination with gas-and-vapor or supplied-air respirators.

2. GENERAL

This STP describes the Determination of Particulate Filter Efficiency Level for N95 Series Filters Against Solid Particulates For Non-Powered, Air-Purifying Respirators test in sufficient detail that a person knowledgeable in the appropriate technical field can conduct the test and determine whether or not the product passes the test.

3. EQUIPMENT/MATERIAL

3.1. The list of necessary test equipment and materials follows:

3.1.1. TSI Model 8130 Automated Filter Tester or equivalent instrument. Air flow control accuracy is 2% of full scale. Pressure measurement accuracy is 2% of full scale. Penetrations can be measured to 0.001%, efficiencies to 99.999%.

Approvals:			
First Level	Second Level	Third Level	Fourth Level

3.1.2. Particle sizing instrument (such as TSI Model 3936 Scanning Mobility Particle Size Spectrometer or equivalent) that is capable of determining submicrometer particles according to count median diameter (CMD).

3.1.3. Microbalance accurate to 0.0001 grams (g).

3.1.4. Gelman 102 mm diameter, type A/E glass filters or equivalent high efficiency filters with a 1 micron pore size.

3.1.5. Timer (accurate to 0.01 second).

3.1.6. 2% sodium chloride solution in distilled water (NaCl).

3.1.7. Temperature and humidity chamber capable of maintaining 38 ±2.5°C and 85 ± 5% relative humidity.

3.1.8. Respirator filter holder supplied for specific manufacturer type which is compatible with TSI filter tester. NIOSH will not be obligated to use these holders for actual certification testing. All manufacturer test fixtures must be correlated with the NIOSH test method (see Work Instruction WI- 1605).

3.1.9. Thermal printer (supplied) or optional data acquisition system.

3.2. Refer to the following Work Instructions for further information on performing this test:
TEB-RCT-APR-WI-1005 – Laboratory Safety Procedures for Particulate Tests for Non-Powered Respirators
TEB-RCT-APR-WI-1105 – Calibration Procedures for Particulate Tests for Non-Powered Respirators
TEB-RCT-APR-WI-1205 – Start–Up and Shut–Down Procedures for Particulate Tests for Non-Powered Respirators
TEB-RCT-APR-WI-1405 – Reporting Results for Particulate Tests for Non-Powered Respirators
TEB-RCT-APR-WI-1505 – Checking System Performance and Calculating Test Duration for Particulate Tests for Non-Powered Respirators
TEB-RCT-APR-WI-1605 – Correlating Manufacturer – Supplied Test Fixtures for Particulate Tests for Non-Powered Respirators

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the testing laboratory's calibration procedure and schedule. All measuring equipment utilized for this testing must have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST) when available.

4.2. Any laboratory using this procedure to supply certification test data as a contractor to NIOSH will be subject to the provisions of the NIOSH Supplier Qualification Program

(SQP). This program is based on the tenets of *ISO/IEC 17025, the NIOSH Manual of Analytical Methods* and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the program. Additional details of the Program and its requirements can be obtained directly from the Institute.*

***Note** 4.2 does not apply to Pretest data from applicants as required under 42 CFR 84.64.

4.3. Precision and accuracy (P&A) must be determined for each instrument in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under *NIOSH Manual of Analytical Methods*, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.

4.4. The precision and accuracy of this method is monitored by the validation method which is incorporated in the automated filter tester procedure. This procedure is performed on a daily basis when testing is performed. This procedure is designed to test many aspects of the method, for proper photometer and general system operation. The validation technique uses "green line" filter media discs, 6 inch diameter, HE 1071 grade, H & V brand, P/N 813010, with a known penetration range, which are tested at least once in each 8 hour test period (see 5.2.5).

4.4.1. Two sheets of unused filter media are stacked together and the penetration, flow rate and pressure drop are measured to evaluate the higher range of penetration values. Five unused sheets are stacked together to evaluate the lower range of penetration values.

4.4.2. The analysis of these readings over the long term was used to examine the precision and accuracy of this test method. The table below summarizes the data.

	Two Sheets	Five Sheets
Mean	2.692%	0.033%
Std. Dev.	0.318	0.007
Range	1.89 – 3.56%	0.015 – 0.058%
N	182	182

4.5. Normal laboratory safety practices must be observed. Please refer to Material Safety Data Sheets and the current NIOSH Pittsburgh Health and Safety Program for the proper protection and care in handling, storing, and disposing of the chemicals used in this procedure.

5. PROCEDURE

Note: Reference Section 3 for equipment, model numbers and manufacturers.
Work Instructions are to be used in conjunction with standard NIOSH test apparatus.

5.1. Respirator filters and filter cartridges will be tested as follows:

5.1.1. The filtering elements of the respirator, including the filter holders and gaskets will be tested for particle penetration.

5.1.2. When filters are not separable from the respirator body, the exhalation valves will be sealed to ensure that any leakage due to the exhalation valve is not included in the filter penetration measurement.

5.1.3. Filters used in conjunction with gas mask canisters and odd or unusually shaped filters may be tested on a headform assembly or assembly provided by manufacturer.

5.2. Respirator filters will be challenged by a NaCl aerosol at 25 ±5°C and a relative humidity of 30 ±10% that has been neutralized to the Boltzmann equilibrium state. The particle size distribution will be a count median diameter of 0.075 ± 0.020 micrometer and a geometric standard deviation not exceeding 1.86. Each respirator filter unit will be challenged with an aerosol concentration not exceeding 200 mg/m³.

5.2.1. The NaCl aerosol concentration will be determined daily by the following gravimetric method and calculated as milligrams per cubic meter (mg/m³).

5.2.2. Weigh a Gelman 102 mm filter to the nearest 0.1 mg., mount in the gravimetric filter holder, subject it to the generated aerosol at 30 Lpm for 40 minutes , and reweigh the filter. Use a timer to monitor the duration of the test. Record the pre- and post-weights, time, and average flow rate on the data sheet and calculate the aerosol concentration in mg/m³ by the following formula:

$$\text{Concentration in mg/m}^3 = \frac{W2 - W1}{(Q / 1000)(T)}$$

Where:
W1 = Initial filter weight in mgs.
W2 = Final filter weight in mgs.
Q = Flowrate in liters per minute
T = Elapsed time in minutes

With a flowrate of 30 Lpm for 40 minutes, the above formula simplifies to:

$$C = \frac{W2 - W1}{1.2}$$

5.2.3. Use the following formula to calculate the test duration:

$$\text{T in minutes} = \frac{(\text{mg load})(1000\ L / m^3)}{(C)(Q)}$$

Where:
C = Concentration in mg/m³ from 5.2.2.
Q = Flow rate for test in Lpm
Follow the procedure in Work Instruction WI- 1505.

5.2.4. The upstream and downstream photometer readings are used for monitoring stability and for calculating a photometer correlation factor (CF). The correlation factor is determined with an empty filter holder and is calculated internally as shown below:

$$CF = \frac{\text{Downstream Photometer Voltage} - \text{Downstream Background Voltage}}{\text{Upstream Photometer Voltage} - \text{Downstream Background Voltage}}$$

The correlation factor is used by the software to express the upstream photometer signal in terms of the downstream photometer signal. Follow Work Instruction WI- 1505 for determining, monitoring and recording the CF.

5.2.5. The NaCl particle size distribution shall be verified using "green line" filter discs supplied by TSI with a known penetration range. Graphs of penetration vs. resistance for two sheets and five sheets of stacked filter discs are supplied with each lot of the standard filters, with a central line and upper and lower lines representing the expected penetration range at a given resistance. The test data should fall within an acceptance zone having boundaries defined by the upper and lower curves on the graphs. Follow the procedure in Work Instruction WI-1505. The standard filter test using both 2 sheets and 5 sheets will be run at least once in each 8 hour test period to verify that the aerosol distribution is within the acceptance zone.

5.2.6. If the instantaneous filter penetration is not within the acceptance zone for any sample, abort testing and add 100 mL of distilled water to the NaCl generator. Run another standard filter set; if the results are acceptable continue running tests. If the results are not acceptable, check the aerosol particle size with the Scanning Mobility Particle Size (SMPS) Spectrometer.

5.3. The NaCl particle size will be monitored at least once every three months (quarterly) with the SMPS spectrometer to ensure the particle size distribution count median diameter remains in the range of 0.075 ± 0.020 micrometer and a geometric standard deviation not exceeding 1.86.

5.4. Respirator filters will be pre-conditioned at 85 ± 5% relative humidity and 38 ±2.5°C for 25 ±1 hours. After conditioning, the filters shall be sealed in a gas tight container and tested within 10 hours.

5.5. Filters will be mounted and sealed on holders to prevent leakage around the filter holder. Single air purifying respirator filters will be tested at a challenge flow rate of 85 ± 4 Lpm. Filters used as pairs on a respirator are tested using a single filter of the pair at 42.5 ± 2 Lpm challenge flow rate. Filters used in threes are tested using a single filter of the set at 28.3 ± 1 Lpm challenge flow rate.

5.5.1. The challenge flow rate must be checked for stability for at least 30 seconds prior to testing.

5.6. A sample of 20 filter units will be tested against the NaCl aerosol. Three filters will be loaded until the aerosol mass loading levels as shown in the table below are reached and evaluated to determine the method for the remaining 17 filters. This is the mass amount of NaCl aerosol that has contacted the filter.

NUMBER OF FILTERS IN RESPIRATOR CONFIGURATION	AEROSOL MASS LOADING LEVEL
SINGLE	200 ± 5 mg.
DOUBLE	100 ± 5 mg.
TRIPLE	66.7 ± 5 mg.

5.6.1. Type 1. If preliminary testing of all three initial test filters consistently results in a straight line (Figure 1), for the remaining 17 filters, record the initial penetration reading.

5.6.2. Type 2. If filter testing of all three initial test filters consistently results in a curve which indicates increased efficiency during the complete run (Figure 1), for the remaining 17 filters, record the initial penetration reading.

5.6.3. Type 3. If filter testing of all three initial test filters consistently results in decreased efficiency over time (Figure 1), load the remaining 17 filters with NaCl to the level specified in the table above and record the maximum penetration reading.

5.6.4. Type 4. If filter testing of all three initial test filters consistently results in increased efficiency, then a decrease in efficiency, and then flattens out during the remainder of the complete run (Figure 1), for the remaining 17 filters, record the maximum penetration reading after reaching and maintaining a flat line for a period of 20 minutes following the decreasing segment in efficiency.

5.6.5. For any other filter type, determine loading at which maximum penetration consistently occurs and test at that loading value for the remaining 17 filters.

5.6.6. If any one of the 20 filters has a penetration greater than 5.0%, further testing of that filter will be terminated. Any filter that exceeds the specified limit shall be remounted and retested to ensure that leakage was not caused by a mounting leak. If retesting eliminates the excessive leakage, that sample will be considered an invalid sample and another tested in its place.

5.7. The penetration of the first three filters will be measured, recorded, and printed at approximately 1 minute intervals during the test period. The highest penetration observed throughout the test of each filter will be recorded as the maximum penetration of that filter.

5.8. Determine and record on the data sheet the maximum filter penetration for each of the 20 filters.

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6. PASS/FAIL CRITERIA

6.1. The legal basis for passing this test is set forth in 42 CFR, Part 84, Subpart K, Section 84.181.

6.2. The minimum efficiency for each of the 20 filters shall be determined and recorded and shall be equal to or greater than 95 %.

6.3. For the sample of 20 filters or filter cartridges to demonstrate acceptable performance, each filter shall meet or exceed the specified minimum efficiency level at the end point of the test.

7. RECORDS/TEST SHEETS

7.1. Record the test data in a format that shall be stored and retrievable.

8. ATTACHMENTS

8.1. Fig. 1

8.2. Data Sheet

8.3. Test Setup

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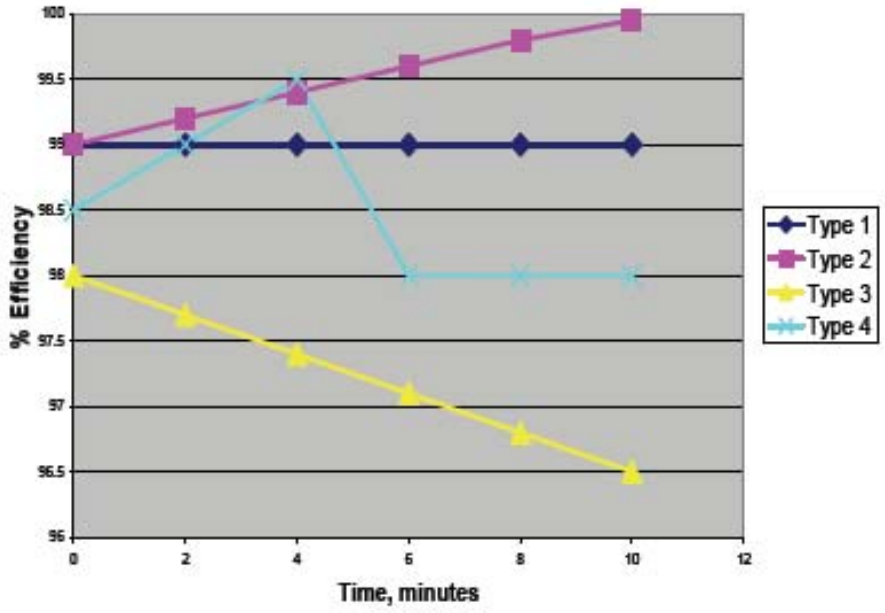
8.1 Figure 1

Figure 1



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8.2 Data Sheet

National Institute for Occupational Safety and Health
Certification and Quality Assurance Branch
Air-Purifying Respirator Section
Test Data Sheet

Task Number: TN-2000 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N100 **STP No.:** 57
Manufacturer:
Item Tested:

Filter	Flow Rate	Maximum Allowable Percent Leakage	Actual Percent Leakage	Result
A	85	0.03	0.030	PASS
B	85	0.03	0.030	PASS
C	85	0.03	0.030	PASS
D	85	0.03	0.030	PASS
E	42.5	0.03	0.030	PASS
F	42.5	0.03	0.030	PASS
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		
		0.03		

Overall Result: PASS

All test equipment within calibration: Yes
Comments:
TESTING

Signature: Jeffrey A. Robinson **Date:** 4/5/04

Engineering Technician

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8.3 Test Setup

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Revision History

Revision	Date	Reason for Revision
1.0	7 March 2002	Historic document
1.1	24 August 2005	Update header and format to reflect lab move from Morgantown, WV No changes to method
2.0	05 October 2007	Significant rewrite of RCT-APR-STP-0051-56. Changes affect form and provide clarification of technical content.

Appendix 3: Respirator #1 Concentration Levels

Background Air

Size (µm)	Out	In
0.5	379.6	158.8

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
0.5	**2.80**	**4.95**	**2.39**	**4.71**	**4.30**	**1.16**	**3.83**

Outside Concentration w/ 0.5 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
0.5	350000	400000	410000	420000	460000

True Outside: PSL Concentration - Background

I	II	III	IV	V
349620.4	399620.4	409620.4	419620.4	459620.4

Inside Concentration w/ 0.5 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
0.5	340000	380000	400000	400000	440000

True Inside: PSL Concentration - Background

I	II	III	IV	V
339841.2	379841.2	399841.2	399841.2	439841.2

Background Air

Size (µm)	Out	In
1	33.9	7.53333

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
1	**50.00**	**57.14**	**61.37**	**59.80**	**63.19**	**5.15**	**58.30**

Outside Concentration w/ 1.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
1	240000	280000	250000	190000	150000

True Outside: PSL Concentration - Background

I	II	III	IV	V
239966.1	279966.1	249966.1	189966.1	149966.1

Inside Concentration w/ 1.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
1	120000	120000	96573.8	76383.9	55204.8

True Inside: PSL Concentration - Background

I	II	III	IV	V
119992.47	119992.5	96566.27	76376.37	55197.27

Appendix 3: Respirator #1 Concentration Levels (Continued)

Background Air

Size (µm)	Out	In
2	1.3	0.6

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
2	**45.67**	**55.34**	**59.28**	**70.00**	**64.07**	**9.19**	**58.87**

Outside Concentration w/ 2.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
2	5640	7909.7	9000.2	11046.6	11548.9

True Outside: PSL Concentration - Background

I	II	III	IV	V
5638.7	7908.4	8998.9	11045.3	11547.6

Inside Concentration w/ 2.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
2	3064	3532.4	3664.9	3313.6	4149.1

True Inside: PSL Concentration - Background

I	II	III	IV	V
3063.4	3531.8	3664.3	3313	4148.5

Appendix 4: Respirator #2 Concentration Levels

Background Air

Size (µm)	Out	In
0.5	229.2	48.1

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
0.5	18.55	23.17	17.63	26.85	26.85	4.40	22.61

Outside Concentration w/ 0.5 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
0.5	700000	690000	680000	670000	670000

True Outside: PSL Concentration - Background

I	II	III	IV	V
699770.8	689770.8	679770.8	669770.8	669770.8

Inside Concentration w/ 0.5 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
0.5	570000	530000	560000	490000	490000

True Inside: PSL Concentration - Background

I	II	III	IV	V
569951.9	529951.9	559951.9	489951.9	489951.9

Background Air

Size (µm)	Out	In
1	19.6	14.6

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
1	**74.42**	**73.34**	**70.84**	**68.00**	**69.23**	**2.70**	**71.17**

Outside Concentration w/ 1.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
1	430000	450000	480000	500000	520000

True Outside: PSL Concentration - Background

I	II	III	IV	V
429980.4	449980.4	479980.4	499980.4	519980.4

Inside Concentration w/ 1.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
1	110000	120000	140000	160000	160000

True Inside: PSL Concentration - Background

I	II	III	IV	V
109985.4	119985.4	139985.4	159985.4	159985.4

Appendix 4: Respirator #2 Concentration Levels (Continued)

Background Air

Size (µm)	Out	In
2	1.2	2.9

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
2	**77.88**	**79.75**	**74.90**	**82.48**	**83.33**	**3.43**	**79.67**

Outside Concentration w/ 2.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
2	2090.9	3128.3	3290.3	3947.2	3831

True Outside: PSL Concentration - Background

I	II	III	IV	V
2089.7	3127.1	3289.1	3946	3829.8

Inside Concentration w/ 2.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
2	465.1	636	828.3	694.3	641.5

True Inside: PSL Concentration - Background

I	II	III	IV	V
462.2	633.1	825.4	691.4	638.6

Appendix 5: Respirator # 3 Concentration Levels

Background Air

Size (µm)	Out	In
0.5	686.3	52.3

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
0.5	**40.68**	**33.27**	**48.44**	**47.57**	**49.13**	**6.80**	**43.82**

Outside Concentration w/ 0.5 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
0.5	540000	600000	660000	630000	610000

True Outside: PSL Concentration - Background

I	II	III	IV	V
539313.7	599313.7	659313.7	629313.7	609313.7

Inside Concentration w/ 0.5 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
0.5	320000	400000	340000	330000	310000

True Inside: PSL Concentration - Background

I	II	III	IV	V
319947.7	399947.7	339947.7	329947.7	309947.7

Background Air

Size (µm)	Out	In
1	28.4	9.8

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
1	**71.65**	**75.92**	**75.67**	**77.71**	**76.98**	**2.35**	**75.59**

Outside Concentration w/ 1.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
1	99740.7	160000	180000	200000	160000

True Outside: PSL Concentration - Background

I	II	III	IV	V
99712.3	159971.6	179971.6	199971.6	159971.6

Inside Concentration w/ 1.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
1	28283.1	38531	43788.4	44588	36837.2

True Inside: PSL Concentration - Background

I	II	III	IV	V
28273.3	38521.2	43778.6	44578.2	36827.4

Appendix 5: Respirator # 3 Concentration Levels (Continued)

Background Air

Size (µm)	Out	In
2	1.5	4.4

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
2	**68.71**	**66.12**	**67.16**	**66.25**	**67.58**	**1.06**	**67.16**

Outside Concentration w/ 2.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
2	2383	3536.8	4491.1	5173.3	6197.8

True Outside: PSL Concentration - Background

I	II	III	IV	V
2381.5	3535.3	4489.6	5171.8	6196.3

Inside Concentration w/ 2.0 um PSL Mask not Sealed

Size (µm)	I	II	III	IV	V
2	749.6	1202	1478.9	1749.8	2013.1

True Inside: PSL Concentration - Background

I	II	III	IV	V
745.2	1197.6	1474.5	1745.4	2008.7

Appendix 6: Respirator # 4 Concentration Levels

Background Air

Size (µm)	Out	In
0.5	440.83	41.43

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
0.5	**46.94**	**47.80**	**45.69**	**45.69**	**52.83**	**2.96**	**47.79**

Outside Concentration w/ 0.5 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
0.5	660000	690000	700000	700000	700000

True Outside: PSL Concentration - Background

I	II	III	IV	V
659559.17	689559.2	699559.2	699559.2	699559.2

Inside Concentration w/ 0.5 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
0.5	350000	360000	380000	380000	330000

True Inside: PSL Concentration - Background

I	II	III	IV	V
349958.57	359958.6	379958.6	379958.6	329958.6

Background Air

Size (µm)	Out	In
1	11.2	2.4

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
1	**73.68**	**68.70**	**70.00**	**72.34**	**70.59**	**1.96**	**71.06**

Outside Concentration w/ 1.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
1	230000	310000	400000	470000	510000

True Outside: PSL Concentration - Background

I	II	III	IV	V
229988.8	309988.8	399988.8	469988.8	509988.8

Inside Concentration w/ 1.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
1	60545.4	97014.7	120000	130000	150000

True Inside: PSL Concentration - Background

I	II	III	IV	V
60543	97012.3	119997.6	129997.6	149997.6

Appendix 6: Respirator # 4 Concentration Levels (Continued)

Background Air

Size (µm)	Out	In
2	0.9	0

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
2	**67.94**	**69.29**	**71.80**	**64.77**	**74.97**	**3.86**	**69.76**

Outside Concentration w/ 2.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
2	3354.1	3947.8	4482.4	5488.6	7274.4

True Outside: PSL Concentration - Background

I	II	III	IV	V
3353.2	3946.9	4481.5	5487.7	7273.5

Inside Concentration w/ 2.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
2	1075	1211.9	1263.8	1933.1	1820.3

True Inside: PSL Concentration - Background

I	II	III	IV	V
1075	1211.9	1263.8	1933.1	1820.3

Appendix 7: Respirator # 5 Concentration Levels

Background Air

Size (µm)	Out	In
0.5	160.8	18

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
0.5	**43.47**	**43.27**	**52.30**	**34.41**	**37.92**	**6.78**	**42.27**

Outside Concentration w/ 0.5 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
0.5	690000	670000	650000	610000	580000

True Outside: PSL Concentration - Background

I	II	III	IV	V
689839.2	669839.2	649839.2	609839.2	579839.2

Inside Concentration w/ 0.5 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
0.5	390000	380000	310000	400000	360000

True Inside: PSL Concentration - Background

I	II	III	IV	V
389982	379982	309982	399982	359982

Background Air

Size (µm)	Out	In
1	28.9	5.3

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
1	**81.34**	**85.50**	**80.36**	**86.01**	**87.89**	**3.22**	**84.22**

Outside Concentration w/ 1.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
1	99699.2	170000	190000	190000	200000

True Outside: PSL Concentration - Background

I	II	III	IV	V
99670.3	169971.1	189971.1	189971.1	199971.1

Inside Concentration w/ 1.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
1	18607.3	24645.5	37308.8	26579.9	24217.5

True Inside: PSL Concentration - Background

I	II	III	IV	V
18602	24640.2	37303.5	26574.6	24212.2

Appendix 7: Respirator # 5 Concentration Levels (Continued)

Background Air

Size (µm)	Out	In
2	0.7	0.4

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
2	**80.25**	**81.67**	**81.70**	**80.83**	**81.76**	**0.68**	**81.24**

Outside Concentration w/ 2.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
2	2696.3	3381.4	4684.8	4890.2	5860.4

True Outside: PSL Concentration - Background

I	II	III	IV	V
2695.6	3380.7	4684.1	4889.5	5859.7

Inside Concentration w/ 2.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
2	532.8	620	857.5	937.8	1069

True Inside: PSL Concentration - Background

I	II	III	IV	V
532.4	619.6	857.1	937.4	1068.6

Appendix 8: Respirator # 6 Concentration Levels

Background Air

Size (µm)	Out	In
0.5	891	162.9

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
0.5	**30.16**	**54.50**	**51.01**	**55.20**	**64.47**	**12.70**	**51.07**

Outside Concentration w/ 0.5 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
0.5	330000	550000	470000	380000	310000

True Outside: PSL Concentration - Background

I	II	III	IV	V
329109	549109	469109	379109	309109

Inside Concentration w/ 0.5 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
0.5	230000	250000	230000	170000	110000

True Inside: PSL Concentration - Background

I	II	III	IV	V
229837.1	249837.1	229837.1	169837.1	109837.1

Background Air

Size (µm)	Out	In
1	38.8	11.4

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
1	**68.09**	**73.85**	**73.84**	**77.05**	**77.40**	**3.74**	**74.05**

Outside Concentration w/ 1.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
1	46319.4	69612	94226.6	100000	100000

True Outside: PSL Concentration - Background

I	II	III	IV	V
46280.6	69573.2	94187.8	99961.2	99961.2

Inside Concentration w/ 1.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
1	14779.2	18201.8	24651.8	22949.3	22600.8

True Inside: PSL Concentration - Background

I	II	III	IV	V
14767.8	18190.4	24640.4	22937.9	22589.4

Appendix 8: Respirator # 6 Concentration Levels (Continued)

Background Air

Size (µm)	Out	In
2	4.4	3.2

Efficiency: ((Conc $_{out}$- Conc $_{in}$)/Conc $_{out}$) x 100

Size (µm)	I	II	III	IV	V	SD	Avg
2	**83.60**	**85.14**	**84.80**	**86.09**	**86.67**	**1.19**	**85.26**

Outside Concentration w/ 2.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
2	1995.7	2628	2987	3341.2	3091

True Outside: PSL Concentration - Background

I	II	III	IV	V
1991.3	2623.6	2982.6	3336.8	3086.6

Inside Concentration w/ 2.0 um PSL Mask Sealed

Size (µm)	I	II	III	IV	V
2	329.7	393	456.5	467.5	414.8

True Inside: PSL Concentration - Background

I	II	III	IV	V
326.5	389.8	453.3	464.3	411.6

Appendix 9: General Linear Model Statistics

Sheet 1: Fit Least Squares					
Response Efficiency					
Summary of Fit					
R Square	0.881843				
R Square Adj	0.86855				
Root Mean Square Error	8.07964				
Mean of Response	60.42867				
Observations (or Sum Wgts)	90				
Fixed Effect Tests					
Source	**Nparm**	**DF**	**DFDen**	**F Ratio**	**Prob > F**
Sealed	1	1	78	67.2418	<0.0001*
Particle Size	2	2	78	219.0141	<0.0001*
Sealed*Particle Size	2	2	78	8.1600	0.0006*
Trial	4	4	78	1.4637	0.2213
Effect Details					
Sealed					
Least Square Means Table					
Level	**Least Sq Mean**	**Std Error**			
N	53.444889	4.5587992			
Y	67.412444	4.5587992			
Particle Size					
Least Square Means Table					
Level	**Least Sq Mean**	**Std Error**			
0.5	35.231333	4.6376708			
1.0	72.395000	4.6376708			
2.0	73.659667	4.6376708			
LSMeans Differences Tukey HSD					
α = 0.05					
Level		**Least Sq Mean**			
2	A	73.659667			
1	A	72.395000			
0.5	B	35.231333			
Levels not connected by same letter are significantly different					

Sheet 1: Fit Least Squares					
Response Efficiency					
Effect Details					
Sealed*Particle Size					
Least Square Means Table					
Level	**Least Sq Mean**	**Std Error**			
N, 0.5	23.419333	4.8666220			
N, 1.0	68.347333	4.8666220			
N, 2.0	68.568000	4.8666220			
Y, 0.5	47.043333	4.8666220			
Y, 1.0	76.442667	4.8666220			
Y, 2.0	78.751333	4.8666220			
LSMeans Differences Tukey HSD					
α = 0.05					
Level		**Least Sq Mean**			
Y, 2.0	A	78.751333			
Y, 1.0	A B	76.442667			
N, 2.0	B	68.568000			
N, 1.0	B	68.347333			
Y, 0.5	C	47.043333			
N, 0.5	D	23.419333			
Levels not connected by same letter are significantly different					
Trial					
Least Square Means Table					
Level	**Least Sq Mean**	**Std Error**			
1	56.990556	4.7915206			
2	59.928889	4.7915206			
3	60.509444	4.7915206			
4	61.430556	4.7915206			
5	63.283889	4.7915206			

Sheet 1: Fit Least Squares					
Response Efficiency					
Effect Details					
Respirator					
Least Square Means Table					
Level	**Least Sq Mean**	**Std Error**			
1	51.920238	1.4572433			
2	63.416560	1.4572433			
3	65.949202	1.4572433			
LSMeans Differences Student's t					
α = 0.05					
Level		**Least Sq Mean**			
3	A	65.949202			
2	A	63.416560			
1	B	51.920238			
Levels not connected by same letter are significantly different					