

SOFTSEAL[®] PREMIUM RESPIRATOR+

FINE PARTICLE FILTRATION
WITH CoolTech™ Valve

**BETTER FIT for
BETTER PROTECTION and
INCREASED COMFORT**

UNIQUE PATENTED DESIGN
Seals NOSE, CHIN,
AND CHEEKS with
medical-grade silicone



**360 DEGREE SILICONE SEAL
MOLDS TO FACE**
Covers nose,
chin, and cheeks

**CRUSH PROOF
INTERNAL LAYER**
Prevents mask collapse
while breathing

**COARSE
PARTICULATE
FILTER**

**FLAME &
FLUID
PENETRATION
RESISTANT**



**ADJUSTABLE
TENSIONING**
For better fit

**4-POINT ATTACHMENT
HEAD STRAP**
Ultrasonically welded
without staple holes
that leak

FINE PARTICULATE FILTER
Filters: $\geq 99\%$ BFE,
 $\geq 99\%$ PFE @ 0.1 micron,
 $> 95\%$ NaCl @ 0.3 micron

**COOLTECH™
VALVE**
Reduces heat
and humidity

**FLAME RESISTANT LAYER
FOR WELDING**

- Stays sealed while you work, breathe, and speak
- Protection against airborne bacteria, molds, and viruses including H1N1 and Swine Flu
- Protects against allergens, smoke, ash, soot, and fine particle air pollution (PM2.5)
- Meets CDC guidelines for TB exposure control



SOFTSEAL[®]
The Difference is the Seal



SOFTSEAL[®] PREMIUM RESPIRATOR+



FINE PARTICLE FILTRATION WITH CoolTech™ Valve

UNIQUE PATENTED DESIGN
Seals NOSE, CHIN, AND CHEEKS with medical-grade silicone



Why other N95 masks may fail to protect you

If your N95 mask doesn't seal to your face and remain sealed, the simple fact is you are NOT protected. Anyone who has worn an N95 mask has experienced the substandard performance of many N95s — poor fit, poor seal, and uncomfortable to wear.

Particles in and around your nose after wearing an N95 mask indicate the seal around the edges of the mask has failed, allowing particles into your breathing zone. The facial seal is the single most important factor in protecting your lungs.

FLEXIBLE SILICONE SEAL
Gives you 360 degrees of protection



What makes SoftSeal masks better

SoftSeal masks are specifically designed to seal to your face, remain sealed so you stay protected, and be comfortable to wear for extended periods. Here's how:

SILICONE SEAL

- The 360 degree silicone seal molds to your face, maintaining the seal even while speaking or moving.
- As you inhale, the thin, feathered edge of the silicone seal tightens to your face.
- Molded-in adjustable nose clip can be shaped to your nose and won't peel off.

PERSONALIZED FIT FOR A TIGHT SEAL

- Three sizes ensure a personalized fit and tight seal.
- While most masks use staples that can leak, SoftSeal's 4-point, wide head straps are molded into the silicone face seal to help prevent leakage.
- Dual straps above and below the ears provide sealing forces in two directions.
- Tensioning clips in each head strap enable manual adjustment for an even better fit.

COMFORT

- No itchy material against your skin.
- An internal structure prevents mask collapse while breathing and improves the mask's durability.
- CoolTech™ Valve reduces heat and moisture in the mask.
- SoftSeal's no-fog design keeps goggles and glasses fog-free.



Available in 3 sizes for a personalized fit:

- Medium PN 16-90084
- Large PN 16-90083
- X-Large PN 16-90082

Also Available:
SoftSeal[®] N95+ VFold
Foldable protection.
Same seal. Same comfort.
4 sizes including small for children.



Distributed by:

DDME, Inc.
800.513.9337
www.softsealmask.com



SOFTSEAL[®]
The Difference is the Seal

WORKPLACE/OCCUPATIONAL USER INSTRUCTIONS**20180022V-L 3D N95 B Mask+ (With Valve): Large Size**

When fit testing or reordering, be aware that this is a large size mask and that other sized masks may fit better.

User Instructions

(IMPORTANT: Keep these instructions for reference)

This respirator contains no compounds from natural rubber latex.

⚠ WARNING

This respirator helps protect against certain particles.

Misuse may result in sickness or death. For proper use, see supervisor or instructions.

Respirator Use:

For protection against particles such as those from metal, wood, minerals, coal, iron ore, cotton, pollen, flour, and certain other substances as well as liquid or non-oil based particles from sprays that do not also emit oil aerosols or vapors.

Do Not Use For:

Gases and vapors, including those present in paint spraying operations, asbestos or sandblasting or for oil aerosols. This respirator does not supply oxygen.

Biological Particles

This respirator can help reduce inhalation exposures to certain airborne biological particles but cannot eliminate the risk of contracting infection, illness or disease. OSHA and other government agencies have not established safe exposure limits for these contaminants.

Additional Use Limitations

- Inspect the respirator for damage, check the integrity of breathing valve and valve leaf. If your respirator or breathing valve appears damaged, DO NOT USE IT. Replace it with a new one.
- Failure to follow all instructions and use limitations for this respirator and/or failure to wear this respirator during all times of exposure may result in sickness or death.
- Do not allow facial hair, hair, jewelry, glasses, clothing, or anything else to prevent proper placement or come between your face and the respirator.
- Do not alter, abuse or misuse the respirator.
- Leave the contaminated area immediately and contact supervisor if dizziness, irritation, or other distress occurs.
- This respirator is designed for use by adults who are properly trained in their use and limitations. This respirator is not designed to be used by children.
- Employers must comply with the OSHA Respiratory Protection Standard, 29 CFR 1910.134 and the requirement for fit testing the respirator if respirators are used by employees performing work-related duties.

Available Sizes:	Part Number
Extra Large	20180022V-XL
Large	20180022V-L
Medium	20180022V-M

Time Use Limitations

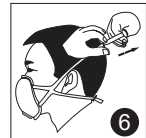
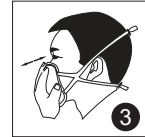
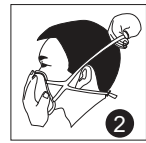
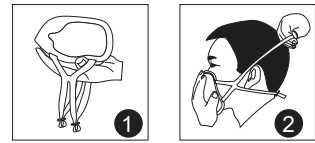
If the respirator becomes damaged, soiled, or breathing becomes difficult, leave the contaminated area immediately and replace the respirator.

WASH YOUR HANDS THOROUGHLY BEFORE PUTTING ON AND AFTER TAKING OFF THE RESPIRATOR**Instructions for Use:**

- Position the respirator in your hand with the nose piece at your fingertips (Figure 1).
- Cup the respirator in your hand allowing the headbands to hang below your hand. Hold the respirator under your chin with the nosepiece up and then pull both straps over your head and allow the mask to seat over your nose and mouth (Figure 2).
- Position the top strap high on the back of the head and the lower strap around your neck and below your ears.
- Adjust for a comfortable fit by pulling the mask away from your face and reseating it on the bridge of your nose and below your chin so that the rolled edges of the silicone seal against your skin (Figure 3).
- Place fingertips from both hands at the top of your nose and mold the nosepiece around your nose to achieve a secure seal (Figure 4).
- Take a quick breath in to check whether the respirator pulls tightly to the face. Failure to feel a negative pull of the mask against the skin suggests that there is air leakage.
- Place both hands completely over the respirator and exhale. If you feel leakage, there is not a proper seal (Figure 5).
- If you cannot achieve a proper seal due to air leakage, adjust tension by pulling strap loop through the tensioning bar or ask for help (Figure 6).

Removal Instructions:

- Cup respirator in hand to maintain position on face and pull bottom strap over your head.
- Hold respirator in position and pull top strap over your head and remove respirator.



Manufactured by:
AOK Tooling Limited
Shen Zhen, China



AOK Tooling Limited
Long Tian Village, Keng Zi Town
Pingshan District, Shen Zhen
China
TEL 86 0755 84111912



THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection ¹	Respirator	Cautions and Limitations ²
		20180022V-L	
84A-8128	N95	X	ABCJMNOP

1. PROTECTION

N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 % oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- J - Failure to properly use and maintain this product could result injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.

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

Care of SoftSeal Masks

Respirators (N95 masks) and Filter masks trap particles by having a tortuous path through the non-woven material of the mask. As they trap particles, the pathways get smaller actually improving the filter efficiency. At some point, the pathways get so small it becomes hard to breathe through the mask. When that happens, the mask should be discarded. You can imagine workers in dusty environments may need to change their masks daily. If you are using one of these masks for protection against small or invisible particles you might inhale while outside, or in a building like a store, these masks will last for months until they fill up with particles making them hard to breathe through.

However, you should take proper care of yourself and the mask to extend its usefulness. Remember you can't see what is trapped on the outside of the mask. Therefore, any time you touch the outside of the mask, you might transfer what is on it to your hands. Therefore, you should wash your hands every time you put the mask on or take it off. Washing your hands after contact with the mask will avoid transferring material from your fingers to your eyes. After taking it off, wash your hands again so that anything transferred to your hands won't be transferred to your nose, mouth or eyes.

When you take your mask off, you should place it in an open container/box/bag to let the humidity from your breath captured on the inside of your mask evaporate. Do not put it in a sealed container. We suggest always placing it in the container with the front of the mask facing up so the contaminated side of the mask is not against the container surface. Although we have performed no specific studies, recommendations in the literature suggest after 3-4 days, there is likely no living viruses on the surface. However, this does not suggest you do not wash your hands after every time you touch the mask. Also, using disinfecting solutions or wipes containing alcohol have been shown to damage the non-woven filter media and should not be used.



SoftSeal Mask Fitting

It is important that the SoftSeal mask you select is the correct size to get the best seal to protect your respiratory system. Below are instructions for determining the most likely size of mask to fit your face. While this estimated size should reduce the number of masks you may need to try on, you still may find that the overall shape of your face is sealed better by a different size.

Have someone measure the distance between the bridge of your nose to the point just below your chin (See Figure 1). Select a mask suggested from the table.

Bridge to Chin (mm)	FilterMask+ or N95 Mask Size
78-98	Small
90-108	Medium
95-118	Large
99-130	X-Large

Bridge to Chin (mm)	VFold+ Mask Size
74-100	Small
82-110	Medium
97-130	Large
100-138	X-Large



SoftSeal® Masks Frequently Asked Questions (FAQs)

DDME is bringing to market two types of vastly improved filtering facemask designs for the **N95 Respirator** and **Filter Mask** markets. DDME's new mask designs are for the construction, industrial, homeowner projects and the growing consumer market as part of a personal protection strategy.

What is a Filtering Facemask

A filtering facemask is a disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Facemasks are a cheaper, lighter, and possibly more comfortable alternative to cartridge or powered respirators, but may not provide as much protection, and may be more susceptible to misuse or poor fit. Facemasks are made in different thicknesses and with different abilities to protect you from contact with particles. These properties may also affect how easily a person can breathe through the facemask and how well the facemask provides protection. There are primarily two types of facemasks that offer two different levels of protection. One is called a Filter Mask and the other, with a higher level of protection, is called an N95 Mask.

What are the differences between a Filter Mask and an N95 Mask

By just looking at a filter mask or an N95 mask, it would be difficult to tell the difference between them. However there are real differences between how they protect your airways. What makes filter masks so effective is that there is no direct path through the fibers that make up the filtration material. Therefore the airflow and the particles it carries must turn and weave their way through the tortuous path of the filter media. Large particle greater than around 0.6 um in diameter are usually captured when the particle can't make the turn around a fiber due to its inertia and it impacts on a fiber. The random movement of very small particles (around 0.1 microns in diameter), because they are too small to be carried away in the airflow, cause them to accidentally come into contact with fibers and get trapped. Therefore it is not the largest or the smallest particles that are the hardest to trap but the particles that are greater than 0.1 micron and less than 0.6 micron. Particles of 0.3 microns are therefore considered to be the most difficult particles to trap. The N95 mask is certified by the National Institute for Occupational Safety and Health (NIOSH), an agency in the US government, to assure that the mask has been tested and manufactured to a standard that makes it capable of filtering particles that do not contain oil, including specifically around 0.3 micron in size. The period at the end of the last sentence is approximately 615 micron so you can appreciate that these particles cannot be seen with the naked eye. Filter masks, which offer less protection, typically filter down to 1 micron, and then down around 0.1 microns. Filtration efficiencies at those two ranges are at least 99% or better. So it's important to know what type of particle you may be exposed to and select the right mask for the right job.

Even N95 masks cannot guarantee that no particles will be inhaled, and even a properly fitted N95 mask does not completely eliminate the risk of illness or death. The N95 designation means that the mask will block at least 95% of particles around the 0.3 microns. Approximately 5% of particles that size will pass through the mask. Both types of masks will reduce the number of particles you breathe into your lungs but to a different degree. However, neither mask will protect your lungs if the mask doesn't seal to your face from particles that enter your breathing zone from around the edges.

Importance of the facial seal

The facial seal of facemasks is THE most important factor in protecting your lungs. Most filter masks are not designed to seal well to the face while N95 masks are required by design to seal to the faces of at least half of the people who use them. N95 masks are typically "fit" to each person and a wide selection from different manufacturers is usually required to find the right N95 mask for each individual when that level of filtering is critical. However, even a non-perfect fit of an N95 mask will increase your protection.

The reason that you find particles in your nose after using most very inexpensive filter masks and even unfitted N95 masks is that there is no seal around the edges to the face. Particles get drawn into the mask from the edges and into your breathing zone. You might as well not be wearing any mask when you consider how poorly they seal.

That's why some people chose N95 masks even when working with large particles. Because rarely do filter masks seal well enough to provide anything close to the protection you need.

Facial hair and jewelry can also affect the seal of both types of facemasks. If a good seal is important, facial hair should be shaved at the edges where the mask contacts the skin and any jewelry that interferes with the seal should be removed. It is important to follow the directions in the mask insert to assure a good seal and fit. **With SoftSeal masks, it is important that once the mask is placed in position over the nose and mouth, that the mask is pulled away from the face and reseated direct towards the face.**

To test the seal:

- Completely cover the outside of the mask with both hands.
- Do not press the mask against your face.
- With both hands on the surface of the mask, breathe in quickly. The mask should slightly collapse.
- When the mask is a good fit, you will not feel any air leaking in between the face and the seal.

What makes the SoftSeal® facemasks different

Other competitors like 3M, MSA, Survivair, and Moldex have some N95 Masks and Filter Masks similar to the SoftSeal facemasks, but they can never match their unique features. Recognizing the importance of a good fit and facial seal to make any facemask actually functional, both the SoftSeal N95 facemask and the SoftSeal Filter Masks have all of these features.

- ❖ Medical grade silicone seal that moves with your face and mouth to maintain the seal even when you are speaking
- ❖ The thin feathered edge of the silicone seals tighter to your face as you breathe in
- ❖ Extreme comfort with no itchy material against the skin
- ❖ You can read and see what you are working on without fogging up your glasses
- ❖ Internal skeleton or vertical structures prevent mask collapse while you breathe and gives it significantly improved durability
- ❖ A really unique head strap design for the best protection and comfort
 - Dual straps above and below the ears or ear loops to provide sealing forces in two directions
 - Almost half-inch wide head straps provide durable and comfortable support
 - Head straps are molded into the silicone face seal so there are no staples inside the mask or the potential for pinhole leaks
 - Tensioning clip in each head strap enables manual adjustment of the sealing force
- ❖ Molded-in adjustable nose clip that easily forms to your nose and can't peel off.

Choosing the right mask for the right job

Using the wrong mask for a job can present a significant and possibly deadly danger as many filter masks with widely varied levels of protection may look similar, and even masks that do not protect against dust at all, such as paint masks and surgical masks may look similar to filter masks. The SoftSeal N95 Mask can offer good protection against germs as well as airborne viruses including those that cause colds and the flu. It is the best protection for Swine Flu, Pig Flu, H1N1, Bird Flu and TB. It is also the mask of choice when working with fine particles, around 0.3 microns in diameter (see Appendix 1. Particle Table to determine what level of protection you need). So it is really important to use an N95

masks when working in those environments. However, N95 masks have a higher work of breathing due to the greater resistance to airflow, a result of their higher filtration capabilities. The higher work of breathing may cause fatigue and may present a risk to people with chronic or acute lung diseases such as COPD or asthma and should be used with caution unless the exposure environment is critical.

When particles are larger than around 1 micron, the SoftSeal Filter Mask may be a good choice of mask to use. It offers the same sealing protection of the SoftSeal N95 Mask while having a lower work of breathing and lower cost.

In addition, the SoftSeal masks have been tested by Nelson Laboratories in Utah, one of the most prestigious testing laboratories for barrier technology, and found to pass the same flammability resistance and fluid penetration tests that are required by the FDA for surgical masks to protect surgeons in the OR from blood spraying at their faces. So if you are working in environments where you want to protect yourself from even liquid spray or sparks, the SoftSeal Masks are your mask of choice.

Markets and Applications

The markets and applications for the SoftSeal Masks include the construction, homeowner projects, industry and personal health protection.

Market	Application	Mask Selection	
Construction	Sanding	Filter Mask	
	Grinding	Filter Mask	
	Demolition	Filter Mask	
	Installing Wallboard	Filter Mask	
	Working with Cement	Filter Mask	
	Fiberglass Insulation	Filter Mask	
	Mold Removal	Filter Mask	
		Fine Particles (<2.5 micron)	N95
		Smoke	N95
	Ash	N95	
	Soot	N95	
	Welding	N95	
	Ultra-Fine Metal Particles	Cartridge Respirator	
	Toxic Fumes	Cartridge Respirator	
	Oil	Cartridge Respirator	
	Vapors	Cartridge Respirator	
	Asbestos	Cartridge Respirator	
	Lead	Cartridge Respirator	
	Chemical Fumes	Cartridge Respirator	
Homeowner Projects	Sweeping	Filter Mask	
	Yard Work	Filter Mask	
	Woodwork	Filter Mask	
	Bagging	Filter Mask	
	Pesticides	N95	
Industrial	Laboratory Work	Filter Mask or N95	

	Manufacturing Cleanrooms	Filter Mask
Personal Health Protection	Swine Flu, H1N1	N95
	Protection for TB exposure control	N95
	Protecting others from your infection	N95
	Air travel*	N95

- ❖ An additional benefit of using the SoftSeal N95 Mask when traveling by air is its ability to capture the water vapor in your exhaled breath and release it again when you breathe in. This reduces the water loss from your airways and helps keep your breathing air moist when breathing the dry airplane cabin air.

Appendix 1. Particle Size Table

Particle	Particle Size (microns)
Glass Wool	1000
Spanish Moss Pollen	150 - 750
Beach Sand	100 - 10000
Mist	70 - 350
Fertilizer	10 - 1000
Pollens	10 - 1000
Cayenne Pepper	15 - 1000
Textile Fibers	10 - 1000
Fiberglass Insulation	1 - 1000
Grain Dusts	5 - 1000
Human Hair	40 - 300
Human Hair	60 - 600
Dust Mites	100 - 300
Saw Dust	30 - 600
Ground Limestone	10 - 1000
Tea Dust	8 - 300
Coffee	5 - 400
Bone Dust	3 - 300
Hair	5 - 200
Cement Dust	3 - 100
Ginger	25 - 40
Mold Spores	10-30
Starches	3 - 100
Red Blood Cells	5-10
Mold	3-12
Mustard	6-10
Antiperspirant	6-10
Textile Dust	6-20

Gelatin	5-90
Spider web	2-3
Spores	3-40
Combustion-related - motor vehicles, wood burning, open burning, industrial processes	up to 2.5
Fly Ash	1 - 1000
Milled Flour, Milled Corn	1 - 100
Coal Dust	1 - 100
Iron Dust	4-20
Smoke from Synthetic Materials	1-50
Lead Dust	2
Face Powder	0.1 - 30
Talcum Dust	0.5 - 50
Asbestos	0.7 - 90
Calcium Zinc Dust	0.7 - 20
Paint Pigments	0.1 - 5
Auto and Car Emission	1 - 150
Metallurgical Dust	0.1 - 1000
Metallurgical Fumes	0.1 - 1000
Clay	0.1 - 50
Humidifier	0.9 - 3
Copier Toner	0.5 - 15
Liquid Droplets	0.5 - 5
Insecticide Dusts	0.5 - 10
Anthrax	1-5
Yeast Cells	1-50
Carbon Black Dust	0.2 - 10
Atmospheric Dust	0.001 - 40
Smoldering or Flaming Cooking Oil	0.03 - 0.9
Corn Starch	0.1 - 0.8
Sea Salt	0.035 - 0.5
Bacteria	0.3 - 60
Bromine	0.1 - 0.7
Lead	0.1 - 0.7
Radioactive Fallout	0.1 - 10
Rosin Smoke	0.01 - 1
Combustion	0.01 - 0.1
Smoke from Natural Materials	0.01 - 0.1
Burning Wood	0.2 - 3
Coal Flue Gas	0.08 - 0.2
Oil Smoke	0.03 - 1
Tobacco Smoke	0.01 - 4

Viruses	0.005 - 0.3
Typical Atmospheric Dust	0.001 to 30
Sugars	0.0008 - 0.005
Pesticides & Herbicides	0.001

Source: www.engineeringtoolbox.com

A 12th Man Technologies, Inc. Engineering Report

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3D Filter Mask, Sodium Chloride Aerosol GLP Report


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ER016-1324	A	9/29/2016		1 of 3

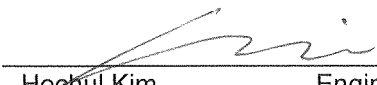
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Approval Signatures


Written By:  9/29/2016
Hochul Kim Engineering Intern Date

Approved By:  9/29/16
Steve Han VP of Engineering Date

Released By:  9/29/16
Hochul Kim Engineering Intern Date

Document Revision History

Date	Revision	Description of Change
09/27/2016	A	Initial Release

ER Report Number	Revision	Engineering Report Title		Page
ER016-1324	A	3D Filter Mask, Sodium Chloride Aerosol GLP Report		2 of 3

A 12th Man Technologies, Inc. Quality Documents

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1. Purpose

The purpose of this document is to release Nelson Lab's report on the study of Sodium Chloride (NaCl) Aerosol Test for 3D Filter Mask (Part Number:16-40348) GLP report to 12th Man Technologies document control.

2. Background

The test was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m³. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH.

3. Reference Document

Appendix A Sodium Chloride (NaCl) Aerosol GLP Report

4. Result


All test method acceptance criteria were met.

The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test results are attached in the appendix of this document.

5. Conclusion

The results of the Sodium Chloride Aerosol test for the 3D Filter Mask (Part Number:16-40348) are deemed acceptable.

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Appendix A

Sodium Chloride (NaCl) Aerosol Test GLP Report

Test Article: 3DXL0716
Purchase Order: TE2016090302
Study Number: 915434-S01
Study Received Date: 08 Sep 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0014 Rev 07

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m³. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

All test method acceptance criteria were met.

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test Article Number	Initial Airflow Resistance (mm H ₂ O)	Particle Penetration (%)	Filtration Efficiency (%)
1	10.0	3.02	96.98
2	10.5	2.69	97.31
3	11.0	2.27	97.73
4	10.6	1.86	98.14
5	10.7	2.27	97.73
6	11.0	1.43	98.57
7	10.5	1.21	98.79
8	11.2	3.02	96.98
9	11.0	2.79	97.21
10	10.2	1.95	98.05
11	10.5	1.43	98.57
12	10.8	2.11	97.89


Study Director _____ Brandon L. Williams


Study Completion Date



915434-S01

Test Article Number	Initial Airflow Resistance (mm H ₂ O)	Particle Penetration (%)	Filtration Efficiency (%)
13	10.3	1.94	98.06
14	10.2	1.20	98.80
15	10.8	2.51	97.49
16	10.8	3.91	96.09
17	10.3	1.36	98.64
18	10.5	2.17	97.83
19	10.2	2.26	97.74
20	11.2	1.37	98.63

Test Method Acceptance Criteria: The filter tester must pass the “Tester Set Up” procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Filter Test Procedure: Prior to testing, respirators were taken out of their packaging and placed in an environment of 85 ± 5% relative humidity (RH) and 38 ± 2.5°C for 25 ± 1 hrs.

The filter tester used in this procedure was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of 0.075 ± 0.020 µm and a geometric standard deviation not exceeding 1.86 µm. The mass median diameter is approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 min. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The neutralized NaCl test aerosol was verified to be at 25 ± 5°C and 30 ± 10% RH by the acceptance of the manufacturer’s reference material. The NaCl concentration of the test aerosol was determined in mg/m³ by a gravimetric method prior to the load test assessment.

An entire respirator was mounted on a test fixture, placed into the test article holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted the filter. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 filters was recorded.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	09 Sep 2016
Phase Inspected by Quality Assurance: Gravimetric Test	14 Sep 2016
Audit Results Reported to Study Director	22 Sep 2016
Audit Results Reported to Management	23 Sep 2016

Scientists	Title
Adam Meese	Supervisor
Brandon Williams	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

Date

Latex Particle Challenge GLP Report

Test Article: 16-40348/201603200-100
16-40345/201603200-400
20130040-002/201603200-416A
20130040-005/201603200-416B
Purchase Order: 16-000533
Study Number: 889570-S01
Study Received Date: 28 Apr 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 05
Protocol Detail Sheet (PDS) Number: 201601655 Rev 01


Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met.

Test Side: Outside (16-40348/201603200-100, 16-40345/201603200-400)
Inside (20130040-002/201603200-416A, 20130040-005/201603200-416B)
Area Tested: Entire Mask
Particle Size: 0.1 μ m
Laboratory Conditions: 11 May 2016: 21°C, 27% relative humidity (RH) at 0859;
21°C, 24% RH at 1341; 21°C, 24% RH at 1645
17 May 2016: 21°C, 30% RH at 0837; 21°C, 30% RH at 0911


Study Director _____ Brandon L. Williams


23 May 2016
Study Completion Date



Results:

16-40348/201603200-100:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	1	13,725	99.9951
2	<1	13,860	>99.9976
3	<1	13,272	>99.9975
4	1	12,391	99.989
5	1	11,456	99.9942

Average Filtration Efficiency: >99.9947%
Standard Deviation: 0.00341

16-40345/201603200-400:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	18	13,555	99.87
2	14	13,688	99.90
3	6	13,206	99.955
4	11	12,686	99.913
5	7	12,366	99.946

Average Filtration Efficiency: 99.915%
Standard Deviation: 0.0361

20130040-002/201603200-416A:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	5	12,060	99.961
2	122	11,117	98.9
3	20	13,300	99.85
4	2	13,114	99.987
5	12	13,440	99.908

Average Filtration Efficiency: 99.722%
Standard Deviation: 0.4597

20130040-005/201603200-416B:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	12	11,944	99.90
2	14	12,655	99.89
3	16	13,666	99.88
4	63	14,359	99.56
5 ^a	12	12,733	99.903
	39	12,849	99.70

Average Filtration Efficiency: 99.81%
Standard Deviation: 0.142

^a Additional testing was conducted for this sample as the original result was determined to be invalid. Only the additional testing results are reported.

Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <1 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The average number of particles being delivered to the test article was determined (no medium in air stream) as triplicate one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. Triplicate one-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

$$\% PFE = \frac{C - T}{C} \times 100$$

Where: C = Combined average of the control counts
T = Average test article counts

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

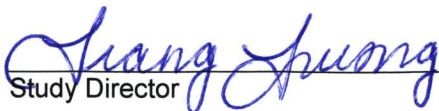
Test Article: 16-40348/201603200-100
16-40345/201603200-400
20130040-002/201603200-416A
20130040-005/201603200-416B
Purchase Order: 16-000533
Study Number: 889565-S01
Study Received Date: 28 Apr 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 13
Protocol Detail Sheet (PDS) Number: 201601653 Rev 01

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) at $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met.

BFE Area Tested: Entire Test Article (Samples glued to plates)
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours.
Negative Monitor Count: <1 CFU


Study Director

Trang Truong, B.S.




Study Completion Date



889565-S01

Results:

16-40348/201603200-100:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9	5.4 ^c	53.2 ^c
2	99.5	4.8 ^c	47.5 ^c
3	>99.9 ^{ab}	4.9 ^c	47.9 ^c
	>99.9 ^b		
4	>99.9 ^b	5.1 ^c	50.5 ^c
	>99.9 ^{ab}		
5	98.7	5.0 ^c	49.6 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^b The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
 Test Article Dimensions: ~120 mm x ~125 mm
 Positive Control Average: 2.4 x 10³ CFU, 2.1 x 10³ CFU (3, 4)
 MPS: 3.1 µm, 2.9 µm (3, 4)

16-40345/201603200-400:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9 ^a	3.7 ^c	36.1 ^c
2	99.6	3.3 ^c	32.0 ^c
3	>99.9 ^b	3.3 ^c	32.2 ^c
	>99.9 ^b		
4	>99.9	3.3 ^c	32.7 ^c
5	>99.9 ^a	3.9 ^c	37.9 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^b The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
 Test Article Dimensions: ~100 mm x ~100 mm
 Positive Control Average: 2.4 x 10³ CFU, 2.1 x 10³ CFU (3)
 MPS: 3.1 µm, 2.9 µm (3)

20130040-002/201603200-416A:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	99.8	7.7 ^b	75.2 ^b
2	>99.9 ^a	7.7 ^b	75.2 ^b
3	99.8	7.7 ^c	75.7 ^c
4	>99.9	7.8 ^b	75.2 ^b
5	98.6	7.8 ^b	76.8 ^b
		7.5 ^c	73.7 ^c
		7.0 ^c	68.8 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^b The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
 Test Article Dimensions: ~135 mm x ~135 mm
 Positive Control Average: 2.4 x 10³ CFU
 MPS: 3.1 µm

20130040-005/201603200-416B:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9 ^a	3.2 ^c	31.7 ^c
2	>99.9 ^a	3.3 ^c	32.4 ^c
3	>99.9 ^a	2.9 ^c	28.6 ^c
4	>99.9	4.0 ^c	39.0 ^c
5	99.5	4.0 ^c	39.1 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
 Test Article Dimensions: ~105 mm x ~100 mm
 Positive Control Average: 2.4 x 10³ CFU
 MPS: 3.1 µm

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
 T = Plate count total recovered downstream of the test article
 Note: The plate count total is available upon request

Latex Particle Challenge GLP Report

Test Article: 16-40348/201603200-100
16-40345/201603200-400
20130040-002/201603200-416A
20130040-005/201603200-416B
Purchase Order: 16-000533
Study Number: 889570-S01
Study Received Date: 28 Apr 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 05
Protocol Detail Sheet (PDS) Number: 201601655 Rev 01

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met.

Test Side: Outside (16-40348/201603200-100, 16-40345/201603200-400)
Inside (20130040-002/201603200-416A, 20130040-005/201603200-416B)
Area Tested: Entire Mask
Particle Size: 0.1 μ m
Laboratory Conditions: 11 May 2016: 21°C, 27% relative humidity (RH) at 0859;
21°C, 24% RH at 1341; 21°C, 24% RH at 1645
17 May 2016: 21°C, 30% RH at 0837; 21°C, 30% RH at 0911


Study Director _____ Brandon L. Williams


23 May 2016
Study Completion Date



Results:

16-40348/201603200-100:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	1	13,725	99.9951
2	<1	13,860	>99.9976
3	<1	13,272	>99.9975
4	1	12,391	99.989
5	1	11,456	99.9942

Average Filtration Efficiency: >99.9947%
Standard Deviation: 0.00341

16-40345/201603200-400:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	18	13,555	99.87
2	14	13,688	99.90
3	6	13,206	99.955
4	11	12,686	99.913
5	7	12,366	99.946

Average Filtration Efficiency: 99.915%
Standard Deviation: 0.0361

20130040-002/201603200-416A:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	5	12,060	99.961
2	122	11,117	98.9
3	20	13,300	99.85
4	2	13,114	99.987
5	12	13,440	99.908

Average Filtration Efficiency: 99.722%
Standard Deviation: 0.4597

20130040-005/201603200-416B:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	12	11,944	99.90
2	14	12,655	99.89
3	16	13,666	99.88
4	63	14,359	99.56
5 ^a	12	12,733	99.903
	39	12,849	99.70

Average Filtration Efficiency: 99.81%
Standard Deviation: 0.142

^a Additional testing was conducted for this sample as the original result was determined to be invalid. Only the additional testing results are reported.

Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <1 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The average number of particles being delivered to the test article was determined (no medium in air stream) as triplicate one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. Triplicate one-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

$$\% PFE = \frac{C - T}{C} \times 100$$

Where: C = Combined average of the control counts
T = Average test article counts

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	02 May 2016
Phase Inspected by Quality Assurance: Latex Test	11 May 2016
Audit Results Reported to Study Director	19 May 2016
Audit Results Reported to Management	20 May 2016

Scientists	Title
Adam Meese	Supervisor
Brandon Williams	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.



 Quality Assurance

24 May 2016

 Date

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

Test Article: 16-40348/201603200-100
16-40345/201603200-400
20130040-002/201603200-416A
20130040-005/201603200-416B
Purchase Order: 16-000533
Study Number: 889565-S01
Study Received Date: 28 Apr 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 13
Protocol Detail Sheet (PDS) Number: 201601653 Rev 01

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at $1.7 - 2.7 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) at $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met.

BFE Area Tested: Entire Test Article (Samples glued to plates)
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours.
Negative Monitor Count: <1 CFU


Study Director

Trang Truong, B.S.



26 May 2016
Study Completion Date



889565-S01

Results:

16-40348/201603200-100:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9	5.4 ^c	53.2 ^c
2	99.5	4.8 ^c	47.5 ^c
3	>99.9 ^{ab}	4.9 ^c	47.9 ^c
	>99.9 ^b		
4	>99.9 ^b	5.1 ^c	50.5 ^c
	>99.9 ^{ab}		
5	98.7	5.0 ^c	49.6 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^b The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
 Test Article Dimensions: ~120 mm x ~125 mm
 Positive Control Average: 2.4 x 10³ CFU, 2.1 x 10³ CFU (3, 4)
 MPS: 3.1 µm, 2.9 µm (3, 4)

16-40345/201603200-400:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9 ^a	3.7 ^c	36.1 ^c
2	99.6	3.3 ^c	32.0 ^c
3	>99.9 ^b	3.3 ^c	32.2 ^c
	>99.9 ^b		
4	>99.9	3.3 ^c	32.7 ^c
5	>99.9 ^a	3.9 ^c	37.9 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^b The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
 Test Article Dimensions: ~100 mm x ~100 mm
 Positive Control Average: 2.4 x 10³ CFU, 2.1 x 10³ CFU (3)
 MPS: 3.1 µm, 2.9 µm (3)

20130040-002/201603200-416A:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	99.8	7.7 ^b	75.2 ^b
2	>99.9 ^a	7.7 ^b	75.2 ^b
3	99.8	7.7 ^c	75.7 ^c
4	>99.9	7.8 ^b	75.2 ^b
5	98.6	7.5 ^c	76.8 ^b
		7.0 ^c	73.7 ^c
			68.8 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^b The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
 Test Article Dimensions: ~135 mm x ~135 mm
 Positive Control Average: 2.4 x 10³ CFU
 MPS: 3.1 µm

20130040-005/201603200-416B:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	>99.9 ^a	3.2 ^c	31.7 ^c
2	>99.9 ^a	3.3 ^c	32.4 ^c
3	>99.9 ^a	2.9 ^c	28.6 ^c
4	>99.9	4.0 ^c	39.0 ^c
5	99.5	4.0 ^c	39.1 ^c

^a There were no detected colonies on any of the Andersen sampler plates for this test article.

^c Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
 Test Article Dimensions: ~105 mm x ~100 mm
 Positive Control Average: 2.4 x 10³ CFU
 MPS: 3.1 µm

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
 T = Plate count total recovered downstream of the test article
 Note: The plate count total is available upon request

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at $21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average must be $1.7 - 2.7 \times 10^3$ CFU. Other positive control averages may be used as approved by the sponsor.

The average MPS of the challenge aerosol must be maintained at $3.0 \pm 0.3 \mu\text{m}$.

The Delta P test flow rate must be maintained at 8 liters per minute throughout the testing.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to a precise concentration to yield challenge level counts of $1.7 - 2.7 \times 10^3$ CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately $3.0 \mu\text{m}$. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at $37 \pm 2^\circ\text{C}$ for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of colonies for each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm² of test area and calculated using the following equation:

$$\text{Delta P} = \frac{\bar{M}}{\text{Test Area}}$$

Where: \bar{M} = Average mm water or Pa of test replicates.

The test article holder used in the Delta P test has a test area of 4.9 cm^2 .


Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	02 May 2016
Phase Inspected by Quality Assurance: BFE Challenge	06 May 2016
Audit Results Reported to Study Director	17 May 2016
Audit Results Reported to Management	17 May 2016

Scientists	Title
Adam Meese	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.



 Quality Assurance

26 May 2016

 Date

Flammability of Clothing Textiles GLP Report

Test Article: 20130040-003/201603200-416C
 Purchase Order: 16-000533
 Study Number: 889567-S01
 Study Received Date: 28 Apr 2016
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0073 Rev 06
 Protocol Detail Sheet (PDS) Number: 201601821 Rev 01

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. *Step 2 - Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met.

Test Article Side Tested: Outside Surface
 Orientation: Cross

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time \geq 3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time $<$ 3.5 seconds

16 CFR Part 1610 specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

Results:

Replicate Number	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

DNI = Test Article did not ignite


 Study Director Brandon L. Williams


 Study Completion Date



889567-S01

Acceptance Criteria: Flame length must be approximately 16 mm ($\sim\frac{5}{8}$ in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the side of the test article to test was performed. The side that burned the fastest was used to test the test articles. Testing in the machine direction was not performed, as the 150 mm length could not be achieved. Only the cross direction was tested. Each test article was clamped into the specimen holder and placed in an oven maintained at $105 \pm 3^\circ\text{C}$ for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

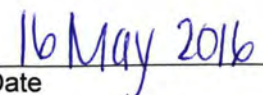
Activity	Date
Study Initiation	10 May 2016
Phase Inspected by Quality Assurance: Preliminary Test	11 May 2016
Audit Results Reported to Study Director	11 May 2016
Audit Results Reported to Management	11 May 2016

Scientists	Title
Adam Meese	Supervisor
Brandon Williams	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.



 Quality Assurance



 Date

Synthetic Blood Penetration Resistance GLP Report

Test Article: 20130040-002/201603200-416A
Purchase Order: 16-000533
Study Number: 889568-S01
Study Received Date: 28 Apr 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 06
Protocol Detail Sheet (PDS) Number: 201601657 Rev 01

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014) with the following exception. ISO 22609 requires testing to be performed in an environment with a temperature of $21 \pm 5^\circ \text{C}$ and a relative humidity of $85 \pm 10\%$. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 32
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at $21 \pm 5^\circ \text{C}$ and $85 \pm 5\%$ relative humidity (RH)
Test Conditions: 21.8°C and 22% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results.

Test Pressure: 120 mm Hg

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Note: All blood spurts were directed at the center seam of the masks.

Acceptance Criteria: The output of synthetic blood through the targeting hole before and after every 16 test articles must be within 2% ($\pm 0.04 \text{ g}$) of the theoretical output of 2 mL.


Study Director
Brandon L. Williams


Study Completion Date



889568-S01

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 specimens, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the specimen holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.


Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	02 May 2016
Phase Inspected by Quality Assurance: Penetration Test	10 May 2016
Audit Results Reported to Study Director	11 May 2016
Audit Results Reported to Management	11 May 2016

Scientists	Title
Adam Meese	Supervisor
Brandon Williams	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.


Quality Assurance

13 MAY 2016
Date



NIOSH Reference: TN-18877

Mfr. Reference: AOK07

National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051
March 21, 2013

Mr. Jerry Teng, President
AOK Tooling Limited
No.3 of Longtian 3 Road, Longtian Village
Kengzi Town, Longgang District
Shenzhen
China

Dear Mr. Teng:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted January 3, 2013. This request was for an approval of the part number 20100032-002 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix 20100032-002Assembly_Matrix_AMf.xlsx. In addition, the AOK Tooling Limited Quality Manual, (Reference Number FS-QM-2009, revision number D/7, with a validation date of Nov 30th 2011), was submitted for review.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. The approval number TC-84A-6269 has been assigned. This respirator is approved for protections against particulates at a N95 filter efficiency level.

NIOSH has also reviewed the quality manual presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, *Code of Federal Regulations (CFR)*, Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The CD enclosed with this letter contains the final respirator approval label. The abbreviated label has been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.


The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that the respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

A copy of the quality manual will be retained by NIOSH and incorporated into our files. Any future changes to this accepted quality document must be submitted to NIOSH for a modification of this accepted quality system.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Jeffrey Peterson', with a long horizontal flourish extending to the right.

Jeffrey Peterson

Acting Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures



TEST REPORT

Task Number: TN-18877

Manufacturer: AOK Tooling Limited

Prepared by: Jeremy Brannen

Tests Conducted by: Jeremy Brannen

Date: February 13, 2013

Respirator Tested: 20100032-002

Background Information

In an application accepted January 3, 2013 AOK Tooling requested an approval of the part number 20100032-002 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix 20100032-002Assembly_Matrix_AMf.xlsx. In addition, the AOK Tooling Limited Quality Manual, (Reference Number FS-QM-2009, revision number D/7, with a validation date of Nov 30th 2011), was submitted for review.

Tests Assigned

<u>Test Description</u>	<u>STP Number</u>	<u>Reference</u>
A. Exhalation Resistance Test	RCT-APR-STP-0003	84.180
B. Inhalation Resistance Test	TEB-APR-STP-0007	84.180
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059	84.181

Overall Results

The items tested passed laboratory testing.

Individual Test Results

See the attached test data sheets.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-18877
Test: Exhalation Resistance Test
Manufacturer: AOK Tooling Limited

Reference No.: CFR 84.180
STP No.: 3

Filter Type: Filter Only

Item Tested: 20100032-002

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Exhalation	Exhalation	
1	25	14.7	PASS
2	25	14.7	PASS
3	25	14.7	PASS

Overall Result: PASS

Comments:

Was all equipment verified to be in calibration throughout all testing? Yes No

Signature:

Engineering Technician

Date: 2/13/2013

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-18877
Test: Inhalation Resistance Test
Manufacturer: AOK Tooling Limited
Item Tested: 20100032-002

Reference No.: CFR 84.180
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H ₂ O)	Actual Resistance (MM of H ₂ O)	Result
	Inhalation	Inhalation	
1	35	15.5	PASS
2	35	15.2	PASS
3	35	16.0	PASS

Overall Result: PASS

Signature:

Engineering Technician

Date: 2/13/2013

Task Number: TN-18877
Test: Inhalation Resistance Test
Manufacturer: AOK Tooling Limited
Item Tested: 20100032-002

Reference No.: CFR 84.180
STP No.: 7

Comments:

Was all equipment verified to be in calibration throughout all testing?

Yes No

Signature:



Engineering Technician

Date: 2/13/2013

National Institute for Occupational Safety and Health
 Respirator Branch
 Test Data Sheet



Task Number: TN-18877 Reference No.: CFR 84.181
 Test: Sodium Chloride (NaCl) - N95 STP No.: 59
 Manufacturer: AOK Tooling Limited
 Item Tested: 20100032-002

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	18.6	5.00	1.120	1.120	PASS
2	85	19.3	5.00	1.750	1.750	PASS
3	85	18.5	5.00	1.170	1.170	PASS
4	85	18.6	5.00	1.810	1.810	PASS
5	85	18.2	5.00	1.470	1.470	PASS
6	85	17.6	5.00	1.650	1.650	PASS
7	85	17.6	5.00	1.230	1.230	PASS
8	85	20.0	5.00	1.280	1.280	PASS
9	85	17.8	5.00	2.090	2.090	PASS
10	85	18.5	5.00	0.988	0.988	PASS
11	85	17.6	5.00	1.890	1.890	PASS
12	85	18.6	5.00	0.740	0.774	PASS
13	85	17.5	5.00	1.500	1.500	PASS
14	85	17.0	5.00	1.220	1.220	PASS
15	85	19.9	5.00	1.370	1.370	PASS
16	85	19.6	5.00	2.210	2.210	PASS
17	85	18.4	5.00	2.220	2.220	PASS
18	85	18.7	5.00	1.750	1.750	PASS
19	85	18.7	5.00	1.630	1.630	PASS
20	85	19.0	5.00	1.420	1.660	PASS

Overall Result: PASS

Signature: 
 Engineering Technician

Date: 2/13/2013

Task Number: TN-18877

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: AOK Tooling Limited

Item Tested: 20100032-002

Comments:

Was all equipment verified to be in calibration throughout all testing?

Yes No

Signature:



Engineering Technician

Date: 2/13/2013

Harvey, Karen (CDC/NIOSH/NPPTL)

From: Peterson, Jeff (CDC/NIOSH/NPPTL)
Sent: Friday, March 22, 2013 3:26 PM
To: Harvey, Karen (CDC/NIOSH/NPPTL); Zubasic, Dawn (CDC/NIOSH/NPPTL)
Cc: Pouchot, Thomas D. (CDC/NIOSH/NPPTL); Stein, Robert (CDC/NIOSH/NPPTL)
Subject: FW: TN18877AOKnew.doc, TN18877 Approval Letter
Attachments: TN18877AOKnew.doc; 18877ApprovalConcurrence.xls; 18877rep.doc

Please finalize for signature

-----Original Message-----

From: Stein, Robert (CDC/NIOSH/NPPTL)
Sent: Friday, March 22, 2013 10:57 AM
To: Peterson, Jeff (CDC/NIOSH/NPPTL)
Cc: Harvey, Karen (CDC/NIOSH/NPPTL); Zubasic, Dawn (CDC/NIOSH/NPPTL); Pouchot, Thomas D. (CDC/NIOSH/NPPTL)
Subject: FW: TN18877AOKnew.doc, TN18877 Approval Letter

Jeff:

I concur with the draft letter as prepared by Tom.
Bob

-----Original Message-----

From: Pouchot, Thomas D. (CDC/NIOSH/NPPTL)
Sent: Tuesday, March 19, 2013 8:13 AM
To: Stein, Robert (CDC/NIOSH/NPPTL)
Subject: TN18877AOKnew.doc, TN18877 Approval Letter

Bob,

Attached are the approval letter, test report and concurrence sheet for TN18877 (AOK). The file will be in your office shortly.

Please review and concur as appropriate.

Any issues, please contact me.

Tom Pouchot
Ext 4036

The message is ready to be sent with the following file or link attachments:

TN18877AOKnew.doc
18877ApprovalConcurrence.xls
18877rep.doc

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

Approval - Concurrence

Concurrence - Process in order shown, sending the project to the next person on the list.

TN18877(AOK)

Author - be sure to complete the checklist to include all relevant information for the Program Assistant.

Author Date sent to peer review and MSHA (if applicable)
T Pouchot 3/19/2013

MSHA representative Date sent to Secretary- N/A

Certification Team Leader Date sent to Branch Chief (cc: Secretary)
RRS for J. Peterson 3/22/2013

Branch Chief Date sent to Secretary
JAP 3/22/2013

Secretary Date Ready for Signature
KH 3/25/2013

Secretary	Date Mailed	CD? Y/N	PDF? Y/N
KH	3/25/2013	Y	N

BOM

Adjustment Clip	EVA
Elastic Strip, L320mm	PTMG+MDI
Elastic Strip, L360mm	PTMG+MDI
Non-woven Fabric,42G	Polypropylene
Non-woven Fabric,70G	PET
Filter Fabric, 20G	Polypropylene
Needle punched cloth,120G	Polypropylene
Non-woven Fabric,50G	Polypropylene
Seal Oring	Silicone
Nose Piece	Aluminum,AL1100
Valve Base	Polypropylene
Valve	Silicone
Valve Cover	Polypropylene
Part Name	Material