Characterization of the Particle Reduction Efficiency of The MyAirHat by Clean Air Hats Inc. & N95 Mask

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Compliance:

This study was conducted in compliance with FDA Good Laboratory Practices (GLP) as defined in 21 CFR Part 58

Conflict of Interest:

Aerosol Research and Engineering Laboratories Inc. has no affiliations with, or involvement in any capacity with Clean Air Hats Inc. financial interests such as: membership, employment, stock ownership or other equity interest.

ABSTRACT

***Objective*:** To evaluate the efficacy of the MyAirHat by Clean Air Hats Inc. at reducing exposure to airborne particulate matter to the wearer using a ventilated mannequin system.

***Background*:** The MyAirHat is headwear intended for use as PPE for protection against airborne particulates such as smoke. The MyAirHat provides a layer of protection to keep the breathing area of the device wearer as particulate-free as possible. Testing was conducted in a 300-liter primary containment chamber that was housed within a 16m3 custom bioaerosol exposure chamber to keep background particulate concentrations low. In addition a NIOSH certified AccuMed N95 mask was tested for comparative performance.

Methods: Particulate generation was performed by running an airline of purified, house-supplied air through a sample port in the chamber to the nebulizer, which was operated at 30 psi for testing. The PBS with 5% glycol solution was nebulized for a total of 20 seconds to attain an adequate concentration of particulates within the primary containment chamber. The ventilated mannequin system was turned on for the duration of each test, including the nebulization phase. After background concentrations were taken, the technician then nebulized the PBS solution into the primary containment chamber and then allowed thirty (30) seconds for the internal mixing fan to operate and ensure a homogenous concentration of particulates throughout the test chamber. After the mixing period, the technician sampled the chamber particulate concentration with both instruments, which were integrated into the same sample line. The initial chamber measurement was taken for thirty (30) seconds. The technician then opened the check valve leading to the sample probe located internally within the MyAirHat and sampled for thirty (30) seconds. The technician then switched the sampling location back to the chamber sampling location, and this location-switching process was repeated a total of five (5) times over the test period for each hat tested. The N95 mask was tested in the same manner.

***Results*:** The MyAirHat showed reasonable efficacy at reducing inert particulate matter in all the size groups tested, with the device being most effective against larger particulate matter. When looking at all particulates below 5 µm in size, the average reduction was 80.77% +/- 2.85% compared to the N95 mask which showed an overall average reduction of 43.44% +/- 3.42%. Under simulated real-world conditions the MyAirHat showed greater reduction of particulates in all size categories when compared to the N95 mask.

STUDY OVERVIEW

This study evaluated the efficacy of the MyAirHat at reducing exposure to airborne particulate matter to the wearer using a ventilated mannequin system. The MyAirHat is headwear intended for use as PPE for protection against airborne particulates such as smoke. The MyAirHat provides a layer of protection to keep the breathing area of the device wearer as particulate-free as possible. Testing was conducted in a 300-liter primary containment chamber that was housed within a 16m³ custom bioaerosol exposure chamber to keep background particulate concentrations low.

Test Matrix For MyAirHat Particulate Testing

Test Device	Replicates	Breathing Parameters	Instrumentation	Sampling Locations	Aerosol Challenge
MyAirHat 1	3	Tidal Volume Of 0.55 Liters, Frequency 16 Breaths Per Minute	*TSI Optical Particle Sizer (OPS) 3330*	Primary Containment Chamber & Inside MyAirHat/Inhalation Path for N95 Testing	Phosphate Buffered Saline (PBS) Mixture With 5% Propolyene Glycol
MyAirHat 2	3				
MyAirHat 3	3				
AccuMed N95 Mask	3				

Figure 1. *Test matrix for the MyAirHat study.*

TEST SETUP

A full test matrix can be found in **Figure 1.** Testing was conducted in a 300-liter aerosol test chamber as primary containment. This chamber was housed within an environmentally controlled bioaerosol test chamber constructed from 304 stainless steel and designed to simulate a small room environment (10' L x 10' W x 7' H). The testing environment was maintained at a temperature of 25°C ± 3°C with a relative humidity of approximately 60% ± 5%. The humidity and temperature were controlled with a ceramic heater and humidifier connected to an electronic PID controller inside the testing chamber.

Testing was performed at a minimum of triplicate test trials with each of the three (3) tested hats, each hat was identical. All testing and instrumentation are listed in the test matrix. Particulate concentrations were sampled utilizing a TSI Optical Particle Sizer (OPS) which measures particulate concentrations between 300 nanometers and 5 microns.

This study measured the reduction seen in particulate concentrations within the MyAirHat versus particulate concentrations within the 300-liter test chamber. Challenge particulates consisted of Phosphate buffer saline solution (PBS) with a concentration of 5% propylene glycol, which was nebulized from a Collison 6-jet nebulizer. A flow diagram of the testing setup can be seen in **Figure 2.**

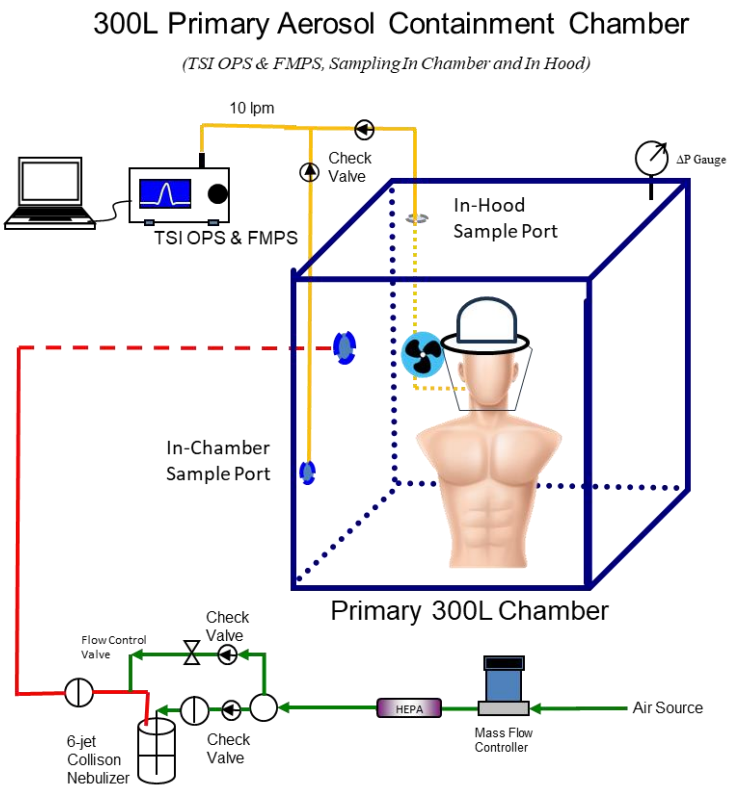

Figure 2. *Flow Diagram for the primary 300-liter test chamber used for the MyAirHat & N95 Mask testing.*

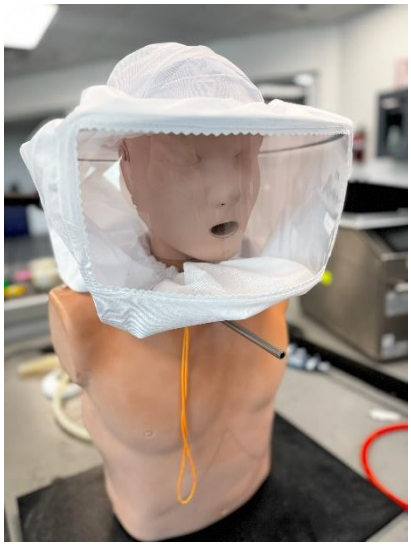

Figure 3. *Image of the MyAirHat on The Ventilated Mannequin.*

PRODUCT TESTED: MyAirHat & AccuMed N95 Mask

The MyAirHat is like a beekeeper's hat where the netting is replaced with a fabric that has been selected to have an appropriate porosity, or "breathability." A clear plastic window in the front of the hat allows visibility. The objective is to protect the air you breathe from particulates in the air in the surrounding room. Just as your lungs exchange oxygen molecules you inhale with carbon dioxide molecules in your blood using molecular diffusion, so the MyAirHat uses molecular diffusion to exchange carbon dioxide molecules you exhale with oxygen molecules outside the fabric wall of the MyAirHat. A picture of the MyAirHat fitted to the ventilated mannequin can be found in **Figure 3.** In addition, an AccuMed NIOSH certified headband style N95 mask was tested for comparative analysis. A picture of the AccuMed N95 mask fitted to the ventilated mannequin can be found in **Figure 4.**

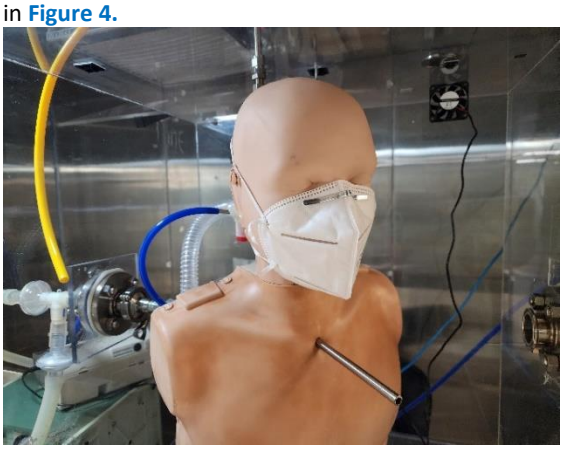

Figure 4. *Image of the AccuMed NIOSH certified N95 Mask on The Ventilated Mannequin.*

EQUIPMENT

Testing Chamber

The primary aerosol exposure chamber containing the MyAirHat was a sealed 300 L environmental chamber constructed of 3/8" Lexan and outfitted with all necessary pass-though and sub-systems sampling ports. The chamber is equipped with HEPA-filtered house air to maintain a clean background environment before all testing and to allow rapid air flushing through the chamber after the completion of each trial to ensure a clean background before conducting subsequent trials.

Nebulization of the aerosol challenge occurred at the beginning of each trial. The chamber is outfitted with aerosol sample ports located on the sides and back of the chamber.

A large, sealed aerosol test chamber was used as secondary containment for the primary aerosol exposure chamber in order to maintain a low background of aerosol particulates at the onset of each test. The secondary containment chamber is constructed of 304 stainless steel and is equipped with three viewing windows and an air-tight lockable chamber door for system setup and general ingress and egress. The secondary containment chamber (**Figure 5)** is equipped with two high-flow HEPA filters to introduce filtered, purified air into the test chamber during aerosol evacuation/purging of the system. It also has a HEPA-filtered exhaust blower, with a 500 ft^3/min rated flow capability, to evacuate remaining particulates rapidly.

Figure 5. *Stainless steel secondary aerosol containment chamber, which housed the 300-liter primary aerosol test chamber.*

Aerosol Sampling and Monitoring Instrumentation

The TSI Optical Particle Sizer (OPS) 3330 (**Figure 6)** is a portable device manufactured by TSI that measures the

concentration and size distribution of airborne particles using single particle counting technology, typically ranging from 0.3 to 10 micrometers in size. The OPS and FMPS were used simultaneously to monitor particles between 5 nanometers and 5 microns both within the MyAirHat as well as within the primary aerosol exposure chamber.

Figure 6. *TSI Optical Particle Sizer (OPS) 3330 measures particulate concentrations within the primary exposure chamber of particles greater than 300 nanometers.*

Breathing Circuit

The breathing circuit used in the testing consisted of a custom trachea breathing and sampling manifold, a respiratory particle filter, connecting tubing, and a Lifecare® PLV-100 mechanical piston ventilator (Respironics, Inc. Murrysville, PA). The Lifecare® mechanical piston ventilator was used during each test to control the mannequin's respiration/exhalation frequency and tidal volumes. The breathing and aerosol sampling manifold, connected to the Lifecare® mechanical piston ventilator, is equipped with a circuit incorporating two check valves to capture inhaled aerosols and prevent exhalation of previously inhaled/captured aerosols. A flow diagram of the breathing circuit can be found in **Figure 8.**

Aerosol Generation System

Test aerosol challenges were disseminated using a Collison 6-jet nebulizer, **Figure 7**, driven by a purified, filtered house air supply. A pressure regulator allowed control of the disseminated particle size, use rate, and sheer force generated within the nebulizer. Before testing, the nebulizer flow and use rates were characterized by an air supply pressure of approximately 30 psi. This obtained an output volumetric flow rate of 25-40 LPM with a fluid dissemination rate of approximately 0.50 mL/min. The nebulizer was flow characterized using a calibrated TSI model 4040 mass flow meter (TSI Inc., St Paul, MN).

Figure 7. *A 6-jet Collison nebulizer was used to nebulize the PBS solution into the primary exposure chamber for all trials.*

Respiratory Parameters

The Lifecare® PLV-100 mechanical piston ventilator was set to mimic a typical adult's respiration frequency, tidal volume, and minute volume at a resting rate for all trials. The ventilator test operation settings were controlled and set as follows: Tidal volume was set at 0.55 Liters. The breaths per minute were set to 16 bpm. The Inspiration-to-Expiration (I:E) ratio was set to 1:1.2.

Testing Method

To accurately assess the MyAirHat while trying to keep the background particulate concentration as low as possible, the primary aerosol containment chamber was housed within the secondary HEPA-filtered containment chamber. Before beginning each trial, background particulate measurements were taken for 20 seconds with both the FMPS and OPS for subtraction from test results.

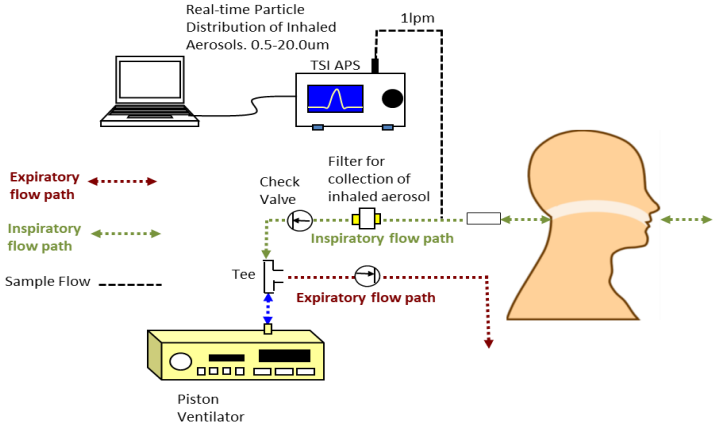

Figure 8. *Flow Diagram of the Breathing Circuit for The Ventilated Mannequin System Used During Testing.*

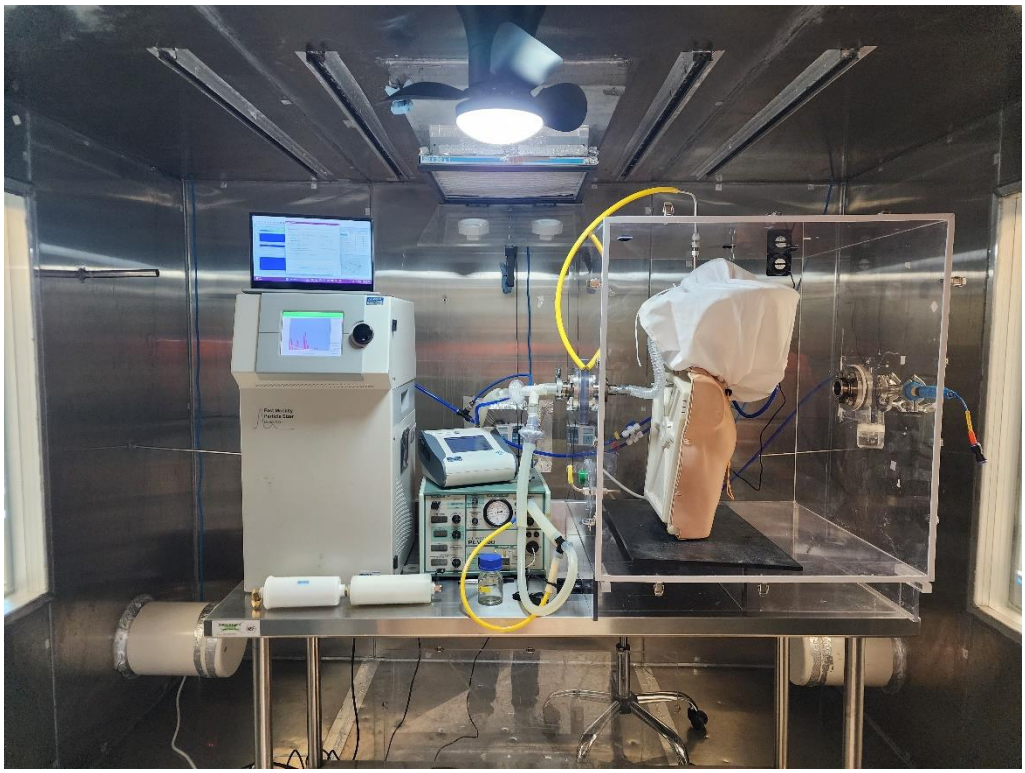

Figure 9. *A picture of the full test setup used for MyAirHat testing shows the instrumentation and the 300-liter primary containment chamber used during testing.*

Particulate generation was performed by running an air line of purified house-supplied air through a sample port in the chamber, and the nebulizer was operated at 30psi for testing. The PBS with 5% glycol solution was nebulized for a total of 20 seconds to attain an adequate concentration of particulates within the primary containment chamber. The ventilated mannequin system was turned on for the duration of each test, including the nebulization phase.

After background concentrations were taken, the technician then nebulized the PBS solution into the primary containment chamber and then allowed thirty (30) seconds for the internal mixing fan to operate and ensure a homogenous concentration of particulates throughout the test chamber.

After the mixing period, the technician sampled the chamber particulate concentration with both instruments, which were integrated into the same sample line. The initial chamber measurement was taken for thirty (30) seconds. The technician then opened the check valve leading to the sample probe located internally within the MyAirHat and sampled for thirty (30) seconds. The technician then switched the sampling location back to the chamber sampling location, and this location-switching process was repeated a total of five (5) times over the test period for each hat tested. Testing conducted with the N95 mask followed the same procedure with the only variation being the internal sampling location which was located within the breathing circuit for N95 testing. The full test setup is pictured in **Figure 9.**

Data Analysis

The data was averaged to show a percentage reduction comparing particulate concentrations within the hat versus the primary exposure chamber. The particulate concentrations inside the hat were compared to the particulate concentrations within the primary exposure chamber during the same time period. Graphs in this report display the averages of the triplicate trials for comparison as well as the overall average between all three (3) hats that were tested.

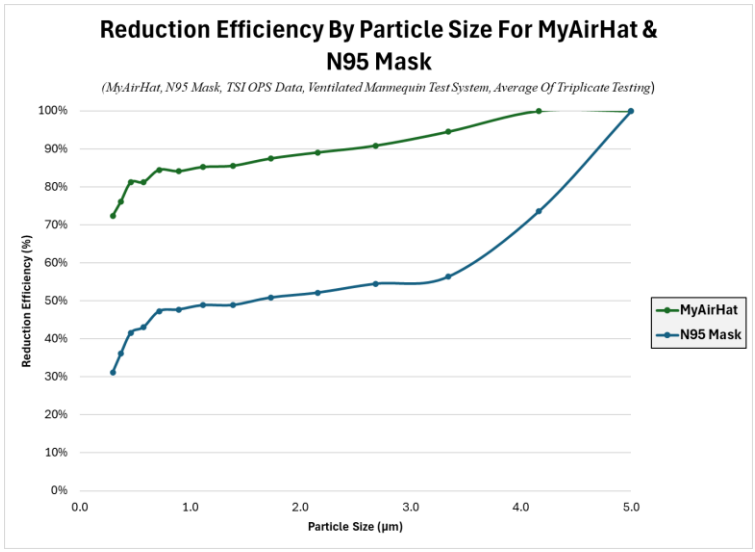

Figure 10. *The reduction efficacy of the MyAirHat & N95 mask between 300 nanometers and 5 microns, shows % reduction for each size range measured during testing.*

Summary of Results

Results showed that the MyAirHat showed an average reduction of 72.41% +/- 4.05% of ultra-fine particles, which were defined as 0.3µm (300 nm). Particles in the ultra-fine size range would primarily consist of biological contaminants and some ultrafine smoke particulates. The N95 mask by comparison showed an average reduction of 31.18% +/- 3.83%. **Figure 10** shows the reduction efficiency for the MyAirHat and N95 mask over the entire size range tested.

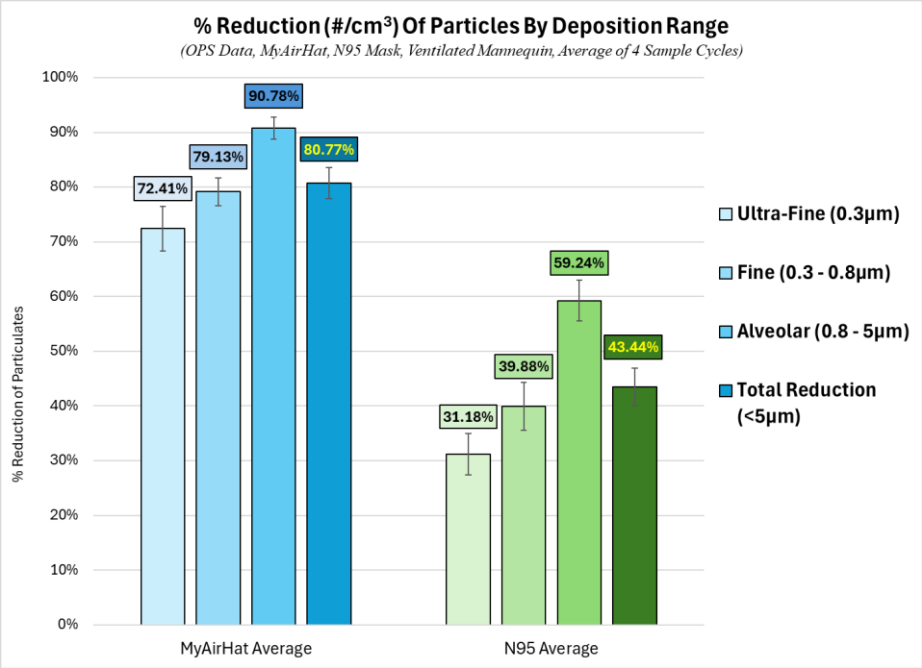

Figure 11. *Summary of all triplicate trial sets conducted during the MyAirHat study. Reduction is based on % reduction between particulate concentrations within the hat or N95 mask vs. the primary exposure chamber.*

MyAirHat & N95 Mask Summary Data

Hat ID	Ultra-Fine (0.3µm) % Reduction	Fine (0.3 - 0.8µm) % Reduction	Alveolar (0.8 - 5µm) % Reduction	Total % Reduction (<5µm)
Hat 1	68.29%	76.49%	88.51%	77.76%
Hat 2	72.55%	79.33%	91.50%	81.13%
Hat 3	76.38%	81.57%	92.32%	83.42%
MyAirHat Average	**72.41%**	**79.13%**	**90.78%**	**80.77%**
Std. Deviation	4.05%	2.55%	2.00%	2.85%
N95 T1	34.67%	42.46%	57.50%	44.88%
N95 T2	31.81%	42.35%	63.55%	45.90%
N95 T3	27.08%	34.83%	56.68%	39.53%
N95 Average	**31.18%**	**39.88%**	**59.24%**	**43.44%**
Std. Deviation	3.83%	4.37%	3.75%	3.42%

Figure 12. *Summary of all triplicate trial sets conducted during the MyAirHat Study. Reduction is based on the average of triplicate trials.*

In the fine particulate range (0.3 – 0.8 µm), the MyAirHat showed an average reduction of 79.13% +/- 2.55%. Fine particulates would include a mixture of biological contaminants such as viruses as well as some particulate contamination such as smoke. By comparison the N95 mask showed a 39.88% +/- 4.37% reduction of fine particulates.

In the Alveolar size range (0.8 – 5 µm), the MyAirHat showed an average reduction of 90.78% +/- 2.00%. The Alveolar size range represents respirable particulates that are in the appropriate size range for inhalation and alveolar deposition. These particulates represent the primary exposure risk for users as this size range is primed for Alveolar deposition, leading to a greater risk of negative side effects or biological exposures. The N95 mask when tested showed an average reduction of 59.24% +/- 3.75% in the same size range. These results are shown for the overall average of all three (3) hats tested as well as the overall average for the N95 mask in **Figure 11.**

Conclusion

The MyAirHat showed reasonable efficacy at reducing inert particulate matter in all of the size groups tested, with the device being most effective against larger particulate matter. When looking at all particulates below 5 µm in size, the average reduction was 80.77% +/- 2.85% compared to the N95 mask which showed an overall average reduction of 43.44% +/- 3.42%. When compared to the NIOSH certified N95 mask the MyAirHat showed greater particulate reduction in all size ranges tested. A summary table with all these values can be found in **Figure 12.**

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11024.10

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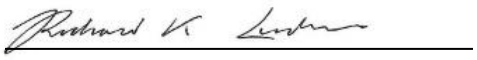

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