Aerosol Mask Design in the Era of the COVID

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KEYWORDS: COVID-19, Bioaerosols, ASTM 3502-21 Barrier Face Coverings, PPE, NIOSH Anthropometric Data, Thermoplastic Elastomer Compounds (TPE), Polyvinyl

INTRODUCTION

In the era of COVID-19 there has been great concern with nebulized aerosol treatments in regard to bioaerosols contamination to caregivers. This concern has changed the manner in which aerosol medications are delivered in the clinical setting. It is believed that MDI treatments for repertory conditions offer less possibility of bioaerosols contamination than nebulizer treatments. Although there is no evidence that nebulizer treatments cause any additional contamination as compared to MDI treatments [1], better aerosol containment during aerosol treatments helps reduce the possibility of caregiver contamination along with the use of Personal Protection Equipment (PPE) by caregivers. Current mask designs were reviewed and found to be ineffective in filtering aerosol and were only intended as a reservoir for aerosol containment near the mouth and nasal area of patients who could not use standard mouthpieces. The need for new mask designs with filter capability has now become necessary to allow for standard nebulized aerosol treatments in the clinical setting while offering additional protection from bioaerosols contamination.

METHOD

MVD reviewed all current aerosol masks to determine if an existing mask could be utilized along with filter material to contain exhalation. It was determined that none of the existing masks could be retrofitted with filter material for this purpose. The new design would have to take into consideration different facial shapes in order to accommodate all faces. Anthropometric face cover data from the National Institute for Occupational Safety (NIOSH) was used for this purpose. NIOSH data divides face-size into five categories that cover 95% of US workers that require respirators. From this data, it was determined that we would need to use a soft polyvinyl material that would flex to conform to the various face sizes while maintaining a seal around the nose and mouth. In addition to the mask material, a filter material was needed that would meet ASTM F3502-21 barrier face coverings standard and have a high filter efficiency $\geq$ 50% while having a breathability $\geq$10 mm H_2O. Intertek Cortland, New York conducted the filter material testing on Aries, USA 3502 green and 3502 white to ASTM standard 3502-21 barrier face coverings.

RESULTS

The X-Hale design took into consideration facial characteristics and filter capability with regard to fit and function. Thermoplastic Elastomer Compounds (TPE) polyvinyl was selected for the mask material due to its flexibility and resilience, providing protection from flex fatigue and tear resistance while creating a form fit to the contour of the face. The filter test fixtures were designed to ISO 16900-5-2016 (Picture #1). The filter

material tested was Aries USA 3502 white (Picture #2). Mask material was mounted to test fixture (Picture #3) and test setup for filtration and breathability (Picture #4). After reviewing the test results found on page 5, the filter material selected was Aries USA 3502 white due to its 80% submicron particulate filtration efficiency and 5 mm H_2O flow residence rating.

Total Quality. Assured.

TEST REPORT

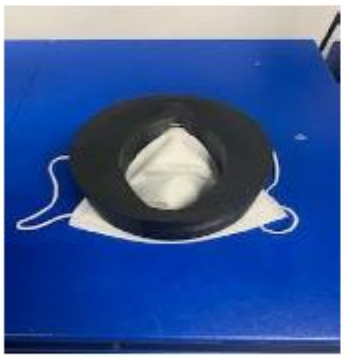
SECTION 4

PHOTOS

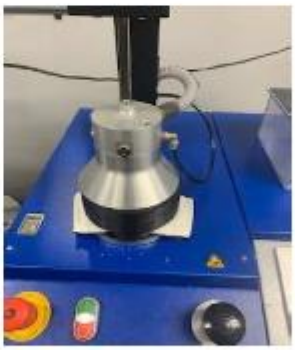
White 3502

1. Printed Adult Medium Face Form ISO # 16900-5-2016

2. Mask Under Test



3. Mounting of Mask



4. Test Set up

Total Quality. Assured.

TEST REPORT

SECTION 2

REPORT OF TESTING AND OTHER INFORMATION REQUIRED BY ASTM F3502-21SPECIFICATION ON BARRIER FACE COVERINGS	
Manufacturer Name	ARIES USA, INC.
Product Name or Model number	White 3502
Laboratory Name/Address	Intertek Testing Services NA, Inc./Cortland, NY 13045
Flow Rate Tested at to Achieve 10 ±0.5 cm/s (LPM)	45.6
Laboratory Accreditation Credentials	Lab Accreditation

Sub-micron Particulate Filtration Efficiency (Section 8 .1)							Test Date:			20-Mar-21	
Test Values(%) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value
Pristine*	87.8	87.3	87.3	83.9	85.4	86.8	84.3	84.0	84.1	84.6	83
After Wash**	Not Tested										

Air Flow Resistance (Section 8.2)							Test Date:			20-Mar-21	
Test Values (mm H2O) by Specimen											
Condition	1	2	3	4	5	6	7	8	9	10	Report Value
Pristine*	3.7	4.3	4.6	4.8	4.9	4.3	4.7	4.7	4.9	4.5	5
After Wash**	Not Tested										

* Description of Condition if Other than Pristine (identify where performed)	Pre Conditioning according to section 8.1.1.5 of the ASTM 3502 Standard.
** Description of Laundering or Cleaning Conditions Applied (identify where performed)	Not tested
Description of Approach Applied as Part of Product Design Analysis (provide supporting documentation, as needed)	Evaluated By Client
Results of quantitative leakage assessment with leakage ration (if applicable Document full findings in separate report)	N/A

Overall Performance Classification	Sub-micron Particulate Filtration Efficiency	Level 2	Air Flow Resistance	Level 2

ASTM Filter

8 exhalation ports

CONCLUSION

The current aerosol facemasks for solution nebulization do not offer a seal fit or filtration for aerosol exhalation during treatment. Their design was for an inexpensive mask used in a pre-COVID environment. We can present a design that includes a sealed fit and meets a standard for filtration as well as airflow. Combining NIOSH facial assisted design and ASTM 3502-21 Barrier Face Coverings testing, the X-Hale filtered aerosol mask is designed with the current needs of both end user and caregiver when nebulizing solution medication in the clinical setting. In the post COVID era, more attention will be given to nebulized aerosol treatments with the use of PPE by caregivers during treatments, contained isolation areas and the use of filtration masks. The X-Hale mask design offers a “best practices” approach for nebulized aerosol treatments in the COVID and post COVID era.

REFERENCES

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Reducing Aerosol-Related Risk of Transmission
in the Era of COVID-19: An Interim Guidance Endorsed
by the International Society of Aerosols in Medicine

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