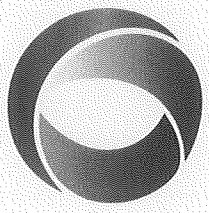
A 12th Man Technologies, Inc. Engineering Report



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3D Filter Mask, Sodium Chloride Aerosol GLP Report

Document Number	Revision	Released Date		Page
ER016-1324	*A*	9/29/2016		*1 of 3*

Approval Signatures

Written By: _____ 9/29/2016
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Approved By: _____ 9/29/16
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Released By: _____ 9/29/16
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Document Revision History

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

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/m^3. 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.

Appendix A

NELSON LABORATORIES

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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/m^3. 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_2O)	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

23 Sep 2016
Study Completion Date

915434-S01

Test Article Number	Initial Airflow Resistance (mm H_2O)	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/m^3 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

26 Sep 2016
Date