Nelson Labs
A Sotera Health company

Sponsor:
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CHINA

# Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Report

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|---|---|
| Test Article: | N95 TECT Respirator Style No: RM2020 MA-08 |
| Purchase Order: | 20-698A |
| Study Number: | 1338709-S01.2 Amended |
| Study Received Date: | 04 Sep 2020 |
| Study Completion Date: | 30 Sep 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>Salt Lake City, UT 84123 U.S.A. |
| Test Procedure(s): | Standard Test Protocol (STP) Number: STP0145 Rev 05 |
| Deviation(s): | None |

**Summary:** This procedure was performed to evaluate the differential pressure of non-powered air-purifying particulate respirators in accordance with 42 CFR Part 84.180. The air exchange differential or breathability of respirators was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003. The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

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.

The inhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial inhalation not exceeding 35 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

The exhalation resistance criteria as stated in 42 CFR Part 84.180 is an initial exhalation not exceeding 25 mm water column height pressure. The test articles submitted by the sponsor conform to this NIOSH criterion for airflow resistance.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

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Sean Shepherd electronically approved for Curtis Gerow
Study Director

15 Oct 2020 16:32 (+00:00)
Amended Report Date and Time

**Results:**

| Test Article Number | Inhalation Resistance (mm $H_2O$) | Exhalation Resistance (mm $H_2O$) |
|---|---|---|
| 1 | 13.4 | 14.0 |
| 2 | 13.7 | 14.2 |
| 3 | 13.1 | 13.6 |

**Test Method Acceptance Criteria:** The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

**Procedure:** A complete respirator was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).

**Amendment Justifications:**
.2 Amended: At the request of the sponsor, the test article was updated from "N95 TECT Respirator Model: RM220 MA-26" to "N95 TECT Respirator Style No: RM2020 MA-08" Additionally, the sponsor information was updated

.1 Amended: At the request of the sponsor, the test article was changed from "Particle Filtering Half Mask Model: RM2020 MA-26" to "N95 TECT Respirator Model: RM2020 MA-26"

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# Sodium Chloride (NaCl) Aerosol Test Final Report

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|---|---|
| Test Article: | N95 TECT Respirator Style No: RM2020 MA-08 |
| Purchase Order: | 20-698A |
| Study Number: | 1338708-S01 |
| Study Received Date: | 04 Sep 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>Salt Lake City, UT 84123 U.S.A. |
| Test Procedure(s): | Standard Test Protocol (STP) Number: STP0014 Rev 09 |
| Deviation(s): | None |

**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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

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| Natalie Brady electronically approved for | 28 Oct 2020 19:40 (+00:00) |
| Study Director Curtis Gerow | Study Completion Date and Time |

**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 | Corrected[a] Initial Airflow Resistance (mm $H_2O$) | Maximum Particle Penetration (%) | Filtration Efficiency (%) |
|---|---|---|---|
| 1 | 16.2 | 0.045 | 99.955 |
| 2 | 15.9 | 0.056 | 99.944 |
| 3 | 14.8 | 0.073 | 99.927 |
| 4 | 17.4 | 0.064 | 99.936 |
| 5 | 19.1 | 0.083 | 99.917 |
| 6 | 18.0 | 0.067 | 99.933 |
| 7 | 17.7 | 0.041 | 99.959 |
| 8 | 16.5 | 0.114 | 99.886 |
| 9 | 16.9 | 0.056 | 99.944 |
| 10 | 16.5 | 0.083 | 99.917 |
| 11 | 16.3 | 0.114 | 99.886 |
| 12 | 17.2 | 0.030 | 99.970 |
| 13 | 17.4 | 0.036 | 99.964 |
| 14 | 16.6 | 0.059 | 99.941 |
| 15 | 16.8 | 0.043 | 99.957 |
| 16 | 17.4 | 0.047 | 99.953 |
| 17 | 17.9 | 0.045 | 99.955 |
| 18 | 17.7 | 0.050 | 99.950 |
| 19 | 17.2 | 0.049 | 99.951 |
| 20 | 17.3 | 0.082 | 99.918 |

[a] The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

**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 hours.

The filter tester used in testing 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 microns (µm) and a geometric standard deviation not exceeding 1.86 µm. The mass median diameter was 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 minutes. 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 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 filter 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 each test article. Based upon the load pattern of NIOSH Type 2, the initial penetration reading of the remaining 17 respirators was recorded.