

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

Test Article: envo masks  
Purchase Order: 15997  
Study Number: 1018869-S01  
Study Received Date: 02 Feb 2018  
Testing Facility: Nelson Laboratories, LLC, a Business Unit of Sterigenics International  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0145 Rev 04  
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.

### Results:

Test Article Number	Inhalation Resistance (mm H <sub>2</sub> O)	Exhalation Resistance (mm H <sub>2</sub> O)
1	15.7	8.8
2	16.0	8.4
3	15.9	8.5



Study Director

Brandon L. Williams



12 Feb 2018  
Study Completion Date



1018869-S01



**Test Method Acceptance Criteria:** The resistance measurement for the reference plate must be within  $\pm 3$  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  $85 \pm 2$  liters per minute (L/min).