Nelson Labs™
A Sotera Health company

Sponsor:

SleepNet Corporation
5 Merrill Industrial Dr.
Hampton, NH 03842

Determination of Valve Leakage for Air-Purifying Respirators Final Report

Test Article:	envo valves - cut from mask
Purchase Order:	16008
Study Number:	1026767-S01
Study Received Date:	01 Mar 2018
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0143 Rev 03
Deviation(s):	None

Summary: This procedure was performed to measure the level of exhalation valve leakage on an air-purifying respirator. Testing was conducted in accordance with 42 CFR Part 84.182 and NIOSH standard procedure TEB-APR-STP-0004. The exhalation valve was sealed into a valve holder and suction applied. Leakage between the valve and valve seat was measured.

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.

According to 42 CFR Part 84.182 the leakage between the valve and valve seat shall not exceed 30 mL/min. The test articles submitted by the sponsor conform to the NIOSH criteria for exhalation valve leakage.

Results:

Test Article Number	Exhalation Valve Leakage (mL/min)
1	5.66
2	9.41
3	3.37

Study Director Brandon L. Williams

14 Mar 2018
Study Completion Date

1026767-S01

Test Method Acceptance Criteria: The test system must have no leaks prior to examination of each test article as determined by passing the "Leak Check of Test system." The manometer must have current calibration. Suction on the valve assembly must be set at 25 mm of water as determined by the manometer display. The leakage rate on the reference standard must be within ± 3 standard deviations of the mean established in the control chart.

Procedure: The valve assembly was carefully removed from the respirator and sealed into a small funnel. Care was taken during sealing not to block the valve assembly's function but provide an airtight seal. A larger funnel was sealed to the smaller funnel to create a test article holder for the valve assembly.

Prior to each analysis, the test system was checked for leaks. This included a series of steps that checked for leaks at the manometer connection, the "T" connector, and around the test article holder.

The flow cell for the Gilibrator® primary flow system was pre-wet, then a valve assembly was attached to the Gilibrator®. A suction of 25 mm ± 5% water column height (1 inch vacuum of water) was applied and the flow reading recorded with the bubble generator.

A reference control was included at the beginning and end of each day of testing to demonstrate the test system was within normal operating parameters. The reference consisted of a control with a known leakage rate prepared in the same manner as the test articles and housed in a test article holder.