

Respirator Fit Study for 3M™ Aura™ 1870+, 9205+, and 9210+ Filtering Facepiece Respirators

Introduction

Tight-fitting respirators, such as filtering facepiece respirators, are designed to seal tightly to a wearer's face. The better the seal, the more inhaled air will pass through the respirator's filter. A poor seal can result in air and particles bypassing the filter and entering the breathing zone. Fit testing helps confirm that each wearer has achieved a good face-to-facepiece seal. To assist employer organizations and stockpile managers in understanding this important performance aspect of 3M filtering facepiece respirator models 1870+, 9205+, and 9210+, 3M conducted a quantitative laboratory study to estimate the likelihood of passing a fit test for an individual in a population similar to the study population.

The study described here involved a population of people that were experienced respirator wearers. It is always important that wearers are trained to wear respirators correctly, are fit tested when and where required, and follow the model-specific user instructions each time the respirator is worn. The testing was conducted in the United States at 3M's fit test laboratory.

Based on analysis of the data collected during the study described in this publication, 3M estimated (based on the 10th percentile of a bootstrap analysis) the pass rate to be 93% based on this study population. The purpose of this 3M study report is to convey the data collection and analysis methods which substantiate the following statements. Please be aware that fit test pass rates will vary in each workplace.

- **3M Aura 1870+ has up to a 93% fit test pass rate across a broad range of face sizes and shapes.***
- **3M Aura 9205+ has up to a 93% fit test pass rate across a broad range of face sizes and shapes.***
- **3M Aura 9210+ has up to a 93% fit test pass rate across a broad range of face sizes and shapes.***

*Based on quantitative fit testing in 3M's United States Fit Test Laboratory in April-May 2021 of subjects with a range of face sizes 1 through 10 on the [NIOSH bivariate grid](#). A passing fit factor is defined as 100, based on OSHA 1910.134. Aura 1870+ was tested, 9205+ and 9210+ pass rates are based on these test outcomes, as further described in the [Similar-Fit Model Pairings of 3M Filtering Facepiece Respirators](#). Individual results may vary.

Background

Based on 3M's experience supporting stockpiling organizations over several decades, stockpile managers often have questions about the fit characteristics of 3M filtering facepiece respirators. Understanding pass rates for specific respirator models can help respirator program managers and stockpile planners anticipate what percentage of a given population the respirator is expected to generally fit. 3M's intention in sharing this information is to help respirator program managers and stockpilers of filtering facepiece respirators make purchase decisions.

Some key concepts to understand are:

- **No single respirator model fits every face. It is likely that multiple respirator models will be needed in order to achieve a good fit on every single face in a large population of wearers.**

- **Every wearer population may yield different respirator fit test pass rates. Fit test pass rates for any given respirator model will vary depending on population demographics, such as gender distribution, ethnicity, and age, and on the fit test methodology used.**
- **Because each face is different and each worker group is different, every fit testing session may yield a different pass rate.**
- **3M recommends fit testing each individual on any respirator model they will wear.**
- **In occupational settings, fit testers may need to deliver some training to the person being fit tested.**

Equipment and Setup

Fit tests were conducted in a fit test chamber measuring 72 in x 156 in x 108 in, with an airlock measuring 72 in x 60 in x 108 in. Approximately 150 cfm airflow of filtered air was maintained through the chamber, and both the airlock and the chamber were kept under slight negative pressure relative to the laboratory.

Quantitative fit tests were conducted using the TSI PortaCount® Pro+ Respirator Fit Tester Model 8038 (TSI Incorporated, Shoreview, Minnesota), which measures ambient particle concentrations of diameter 0.03–0.06 µm using a condensation particle counter and electrostatic classifier. NaCl particles were generated inside the chamber using a modified TSI 5-jet particle atomizer, loaded with 2% NaCl solution (ACS-grade NaCl crystals dissolved in deionized water). During fit tests, the particle concentration in the chamber was maintained at about 500 to 1500 particles/cc.

Respirators were probed in the lateral center of the respirator, with vertical placement about halfway between the nose and the upper lip. Double polymeric tubing was used to collect in-respirator samples and ambient samples from each subject's breathing zone. To support the weight of the tube, the tubing was clipped to a lanyard worn around the subject's neck, with enough slack to accommodate the subject's range of motion as the subject completed the eight exercises included in the Occupational Safety and Health Administration (OSHA) [1910.134 Appendix A Fit Testing Procedures](#) with the exception that the duration of the exercises were 86 seconds instead of 60 seconds and subjects sat instead of stood.

The study was performed using 3M's simulated field fit test data collection laboratory procedure. Subjects were provided an 1870+ respirator, with the tubing already attached. A brief (55-second) model-specific training video was shown to the subject, and if necessary, the staff member reinforced key donning actions through demonstration. After it was completed the subject was provided the model-specific User Instructions. The subject was instructed to don the respirator and complete a user seal check before entering the chamber for the fit test. Each subject then completed a fit test following the specified eight exercises (OSHA, 1974) as noted. The fit factor (FF) for each of the eight exercises and the overall fit factor were recorded automatically using software and were also manually logged in test records. If the FF was equal to or greater than 100, the session was complete. If the FF was less than 100, the staff member verbally instructed the subject on adjustments they could make that may help to improve the fit. Common instructions included: noseclip formation, headband positioning, centering of respirator, and fully opening the respirator. If any significant adjustments were made, the staff member noted them. After adjustments, the subject completed a user seal check and entered the chamber for a second time and completed the eight exercises again. Regardless of the outcome after the second fit test, the session was complete.

Male wearers were required to have shaven within the past 24 hours, and subjects were required to not have smoked within one half-hour of beginning the testing. Other head-worn PPE was not worn during the study.

The respirator model fit tested during the study was the 1870+. Per the 3M publication [Similar-Fit Model Pairings of 3M Filtering Facepiece Respirators](#), fit test outcomes for the 1870+ can help predict a fit test outcome for the 9205+ and 9210+.

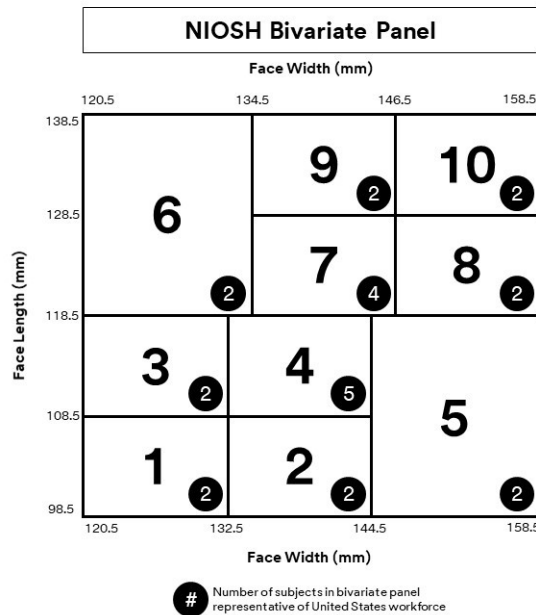
Study Population

The study was approved by the 3M Institutional Review Board (comparable to an Ethics Committee). 50 workers (30 male and 20 female) participated in the study. Data collection was conducted at the 3M United States fit testing laboratory. Data

collection occurred in two studies, separated by several weeks. 25 subjects participated in each study, for a total of 50 unique subjects.

It was important for the subject population to represent a wide range of face sizes and shapes. One well-established way to compose a study population of diverse face sizes and shapes is to reference a bivariate grid – a grid of face sizes, designed to represent a population of people, based on measurements of people’s faces. The U.S. National Institute for Occupational Safety and Health (NIOSH) bivariate grid defines 10 cells, with face sizes 1 through 10, where face size 1 is shortest and narrowest, and face size 10 is longest and widest. The [NIOSH bivariate panel \(NIOSH, 2019\)](#) represents the range of face sizes and the distribution of face sizes found in the U.S. workforce, [based on 3,997 face measurements in 2003 \(Zhuang, 2007\)](#) (Figure 1).

Figure 1



In order to represent the distribution of face sizes in the United States, the study population was composed according to the NIOSH bivariate panel. The first study completed followed the NIOSH bivariate panel face size distribution as shown in Figure 1. During the second study, there was only one subject in grid cell 10 and three subjects in grid cell 9.

The distribution of the entire 50-subject study is below:

Grid Number	# of subjects
1	4
2	4
3	4
4	10
5	4

6	4
7	8
8	4
9	5
10	3
Total	50 subjects

Data Collection

Fit factors were measured for each exercise (ratio of ambient concentration to the concentration inside the respirator), and the overall fit factor for each test was determined by calculating the harmonic mean of the fit testing exercises.

$$Overall\ Fit\ Factor = \frac{N}{\left[\frac{1}{FF_1} + \frac{1}{FF_2} + \dots + \frac{1}{FF_N}\right]}$$

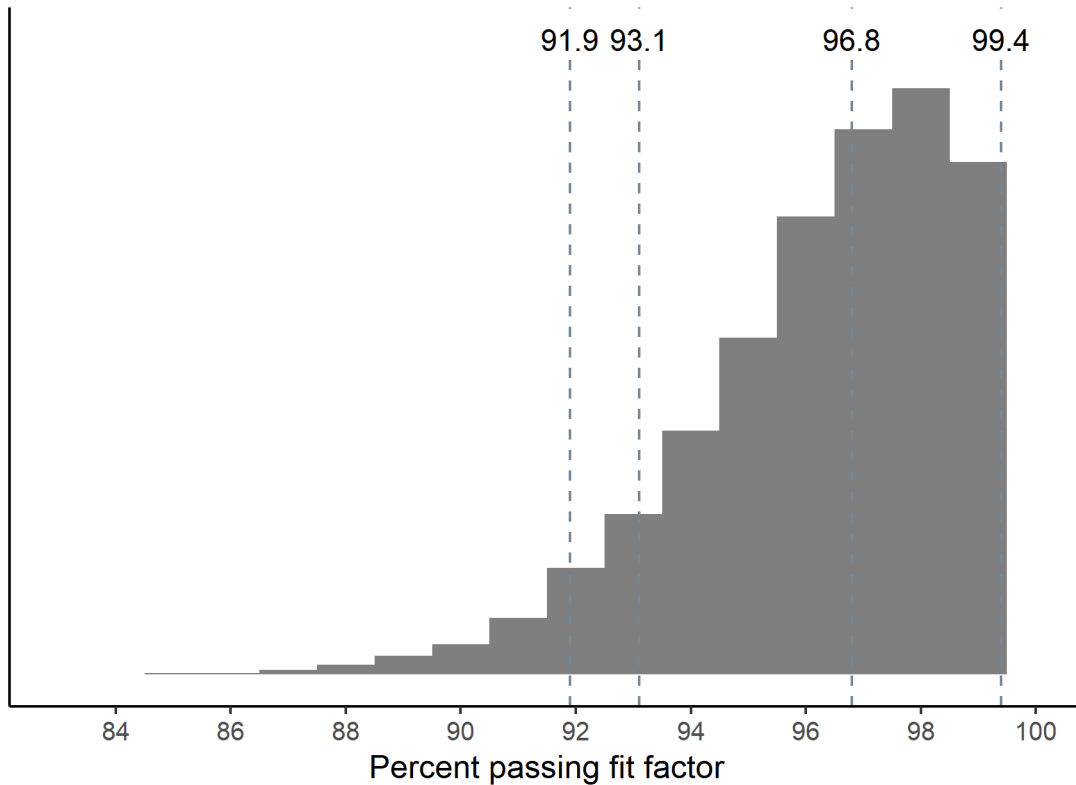
Data Analysis

To gain insight into the expected distribution of estimated fit pass rates for 25-member NIOSH bivariate panels, a bootstrap analysis was conducted. Bootstrap analyses can be used to construct confidence intervals for statistics that may be difficult or impossible to determine using more standard statistical methods (Bootstrapping, 2021). An FDA guidance document related to use of filtering facepiece respirators by the general public suggests that the bootstrap technique can be used to generate confidence intervals for respirator fit test pass rates (U.S. FDA, 2007).

The source dataset for the bootstrap analysis was the overall fit factors for the 50 subjects participating in the two studies described above. The bootstrap analysis was conducted with the R software package (R Core Team, 2021). 5,000 simulated 25-member NIOSH bivariate panels were constructed by randomly selecting the appropriate number of subjects from each grid cell defined for a NIOSH bivariate panel. The random selection of subjects was done with replacement, as is generally defined for bootstrap analyses. For each simulated panel, a Maximum Likelihood Estimate (MLE) of the percentage of passing fit factors (overall fit factor values equal to or greater than 100) was determined. The MLE of the percent passing fit factor for each simulated panel was based on the assumption of a lognormal distribution of overall fit factors within the panel.

The results of the bootstrap analysis are shown in Figure 2. The dashed vertical lines in the figure represent the 5th, 10th, 50th and 95th percentile values of percent passing fit factors for the 5,000 simulated panels. The 10th percentile of the distribution of percent passing fit factors is 93%, the value published as the pass rate in the study.

Figure 2: Histogram of 1870+ Bootstrap Analysis with 5,000 resamples



References

- 1) Bootstrapping (statistics). (2021, May 7). Wikipedia. Retrieved from [https://en.wikipedia.org/wiki/Bootstrapping_\(statistics\)](https://en.wikipedia.org/wiki/Bootstrapping_(statistics))
- 2) NIOSH. (2019, January 15). NIOSH Respirator Approval Program's use of the NIOSH Bivariate Panel during Isoamyl Acetate Fit Testing beginning February 1, 2019. Conformity Assessment Notices. National Institute of Occupational Safety and Health. Retrieved from <https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformityin-terp/CA-2019-1011.html>
- 3) OSHA. (1974). OSHA 1910.134 Appendix A. Fit Testing Procedures (Mandatory). Occupational Safety and Health Administration. Retrieved from <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA>
- 4) R Core Team. (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing. Retrieved from <http://www.r-project.org/>
- 5) U.S. FDA. (2007, July 3). Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies - Class II Special Controls Guidance for Industry and FDA Staff. Guidance Documents. U.S. Food and Drug Administration. Retrieved from <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/filtering-facepiece-respirator-use-general-public-public-health-medical-emergencies-class-ii-special>
- 6) Zhuang, Z. (2007, October). New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. Journal of Occupational and Environmental Hygiene (4 (9)), 647-59. Retrieved from https://www.researchgate.net/publication/6223633_New_Respirator_Fit_Test_Panels_Representing_the_Current_US_Civilian_Work_Force



Personal Safety Division

3M Center, Building 235-2W-70
St. Paul, MN 55144-1000

3M PSD products are
occupational use only.

3M Canada

P.O. Box 5757
London, Ontario
N6A 4T1

In United States of America

Technical Service: 1-800-243-4630

Customer Service: 1-800-328-1667

3M.com/workersafety

In Canada

Technical Service: 1-800-267-4414

Customer Service: 1-800-364-3577

3M.ca/Safety

3M is a trademark of 3M. Used under
license in Canada. © 2021, 3M. All rights
reserved. Please recycle.

