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Case Study

April 2024

Respirator Fit Studies for 3M™ Aura 1870+ Filtering Facepiece Respirators

Executive Summary

For optimal respirator performance, choosing the right respirator for your face shape is essential.

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-respirator seal. To assist employer organizations and stockpile managers in understanding this important performance aspect of 3M filtering facepiece respirator models, 3M conducted a quantitative laboratory study to understand the possible range of fit test pass rates expected for two panels of 25 experienced respirator wearers using the 3M™ Aura 1870+.

To achieve an acceptable fit in the study, each participant needed to score a fit factor (FF) equal to or greater than 100 for eight exercises after they had properly donned the respirator and performed a user seal check. 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 in April-May 2021.

For this study's data analysis, pass rates were generated across the widest range of face sizes using the NIOSH bivariate grid. The 3M™ Aura 1870+ had the following pass rates: 91.2% (5th percentile), 92.4% (10th percentile), 96.4% (50th percentile), and 99.3% (95th percentile). Among participants with smaller faces (those with a size of 1 through 4 on the NIOSH bivariate grid), the pass rate were: 82.5% (5th percentile), 85.1% (10th percentile), 93.8% (50th percentile), and 99.6% (95th percentile).

Individual results may vary and there is no one-size-fit-all respirator. Employer organizations and stockpile managers should provide several different models of approved respirators to their employees to help them achieve a good fit.

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 with N95 enabled (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 1910.134 Appendix A Fit Testing Procedures (OSHA, 1974) 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.

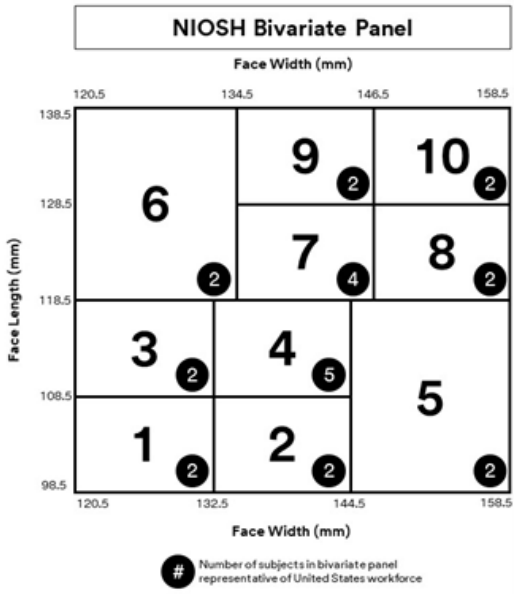
Male wearers were required to have shaven within the past 24 hours, and subjects were required to not have smoked within one half-hour of beginning the testing. Other head-worn PPE was not worn during the study.

Study Population

The study was approved by the 3M Institutional Review Board (comparable to an Ethics Committee). Fifty workers (30 male and 20 female) participated in the study. Data collection was conducted at the 3M United States fit testing laboratory in April-May 2021. Data collection occurred in two studies, separated by several weeks. Twenty-five 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: NIOSH Bivariate Panel



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. In this study, "smaller face sizes" are defined as grid cells 1 through 4 of the NIOSH bivariate panels.

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

Table 1: Subject Distribution

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.

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

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 bootstrap analysis was conducted with the Minitab® 20 Statistical Software (2021). For each simulated panel, Least Squares Estimate (LSE) of the percentage of passing fit factors (overall fit factor values equal to or greater than 100) was determined. The LSE 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 source dataset for the two bootstrap analysis was the overall fit factors for the 50 subjects participating in the two studies described above. 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. The results of the bootstrap analysis are shown in Figure 2.

Additionally, a subset of the source dataset was used for an analysis of smaller face sizes including 22 subjects in grid cells 1 through 4 from both studies. 5,000 simulated 11-member NIOSH bivariate panels were comprised of 2 subjects each from grid cells 1 through 3 and 5 subjects from grid cell 4. The result of the bootstrap analysis on smaller faces (NIOSH bivariate panel grid cells 1 through 4) is shown in Figure 3.

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.

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

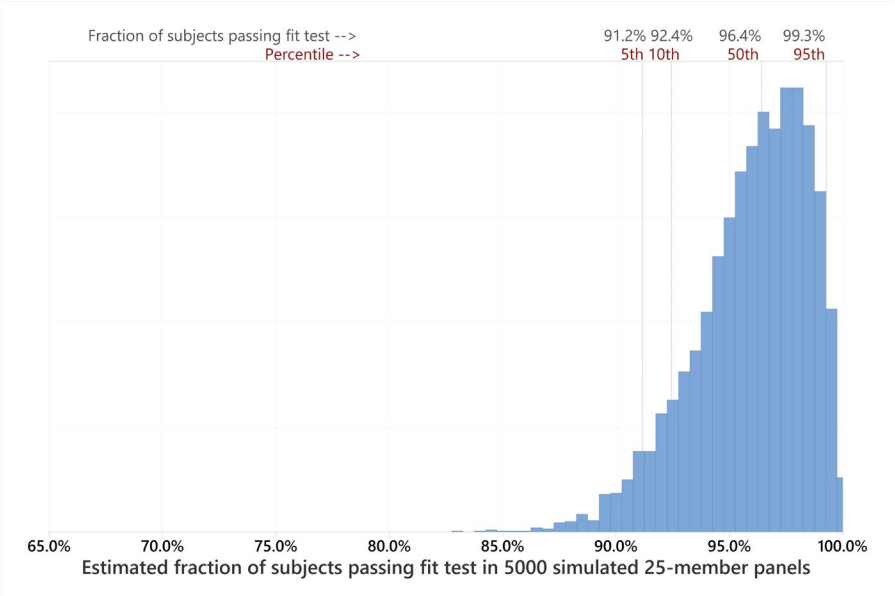
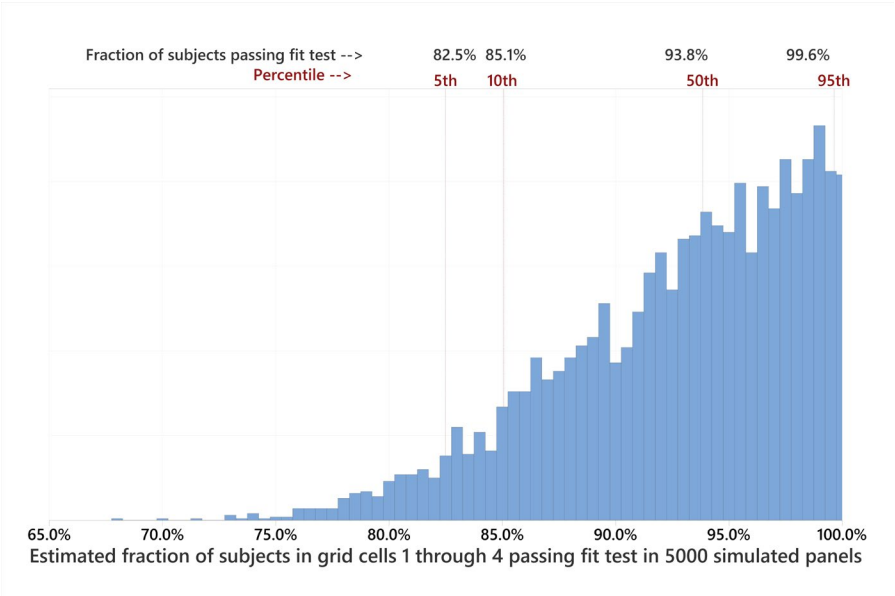


Figure 3: Histogram of 1870+ Small Faces Bootstrap Analysis with 5,000 Resamples



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