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Case Study

October 2024

Respirator Fit Study for 3M™ Aura™ 9320+, 9322+, 9330+, and 9332+ 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-facepiece seal. To assist employer organisations 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 following 3M™ Aura™: 9320+, 9322+, 9330+, 9332+.

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 United Kingdom at 3M's main European fit test laboratory.

For this study's data analysis, pass rates were generated across the widest range of face sizes using the NIOSH/ISO bivariate grid. Below lists the pass rates for each product tested.

3M™ Aura™ Particulate Respirator, FFP2, Unvalved 9320+

The 3M™ Aura 9320+ had the following pass rates based on ISO 16975-3: 95.4% (5th percentile), 96% (10th percentile), 98.1% (50th percentile), and 99.7 % (95th percentile). The pass rates based on UK HSE criteria included in INDG479: 98%. Testing was conducted during February-March 2022.

3M™ Aura™ Particulate Respirator, FFP2, Valved, 9322+

The 3M™ Aura 9322+ had the following pass rates based on ISO 16975-3: 93.3% (5th percentile), 94.1% (10th percentile), 96.8% (50th percentile), and 99.1% (95th percentile). The pass rate based on UK HSE criteria included in INDG479: 96%. Testing was conducted during November 2022.

3M™ Aura™ Particulate Respirator, FFP3, Unvalved, 9330+

The 3M™ Aura 9330+ had the following pass rates based on ISO 16975-3: 97.4% (5th percentile), 97.8% (10th percentile), 99% (50th percentile), and 99.8% (95th percentile). The pass rates based on UK HSE criteria included in INDG479: 95%. Testing was conducted during January 2023.

3M™ Aura™ Particulate Respirator, FFP3, Valved, 9332+

The 3M™ Aura 9332+ had the following pass rates based on ISO 16975-3: 96.6% (5th percentile), 97.2% (10th percentile), 98.7% (50th percentile), and 99.8% (95th percentile). The pass rates based on UK HSE criteria included in INDG479: 89%. Testing was conducted during November 2021.

Individual results may vary and there is no known 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 organisations 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 and should be repeated regularly according to applicable guidance.**
- **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 1.83 m x 2.12 m x 2.45 m, with an airlock measuring 1.05 m x 2.14 m x 2.45 m. 85 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 TSI Six-Jet Particle Atomizer model 9306, 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 centre 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 seven exercises required per the Health and Safety Executive's (HSE) INDG479 Ambient Particle Counting protocol in accordance with the fit test exercise. The seven exercises required per INDG479 are equivalent to the ISO 16975-3 fit test exercises.

The study was performed using 3M's simulated field fit test data collection laboratory procedure. Subjects were provided a respirator, with the tubing already attached. A brief (4 minute) respirator-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 seven- exercise regimen. The fit factor (FF) for each of the seven 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,

centring 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 re-entered the chamber for a second time and completed the seven 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

3M™ Aura™ 9320+

The study was approved by the 3M Institutional Review Board (comparable to an Ethics Committee). 49 workers (28 male and 21 female) participated in the study. Data collection was conducted in a United Kingdom ISO 9001:2015 accredited laboratory, by a Fit2Fit accredited fit tester. Data collection occurred in two studies, that were completed in consecutive weeks. The study was composed of two panels (25 subjects and 24 subjects) for a total of 49 unique subjects.

3M™ Aura™ 9322+

The study was approved by the 3M Institutional Review Board (comparable to an Ethics Committee). 48 workers (31 male and 17 female) participated in the study. Data collection was conducted in a United Kingdom ISO 9001:2015 accredited laboratory, by a Fit2Fit accredited fit tester. Data collection occurred in two studies, that were completed in consecutive weeks. The study was composed of two panels (25 subjects and 23 subjects) for a total of 48 unique subjects.

3M™ Aura™ 9330+

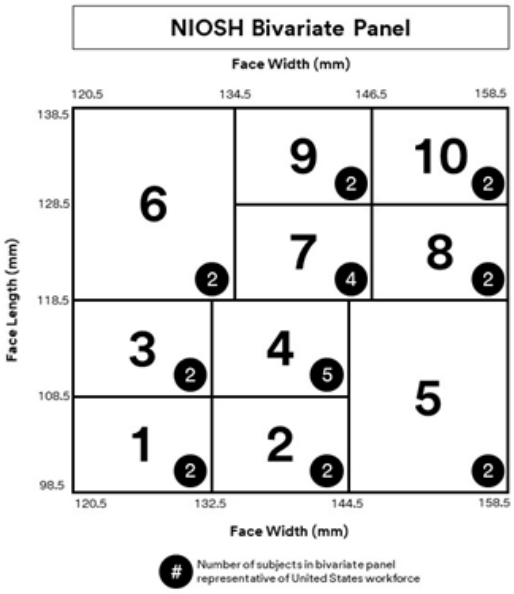
The study was approved by the 3M Institutional Review Board (comparable to an Ethics Committee). 47 workers (29 male and 18 female) participated in the study. Data collection was conducted in a United Kingdom ISO 9001:2015 accredited laboratory, by a Fit2Fit accredited fit tester. Data collection occurred in two studies, that were completed in consecutive weeks. The study was composed of two panels (25 subjects and 22 subjects) for a total of 47 unique subjects.

3M™ Aura™ 9332+

The study was approved by the 3M Institutional Review Board (comparable to an Ethics Committee). 47 workers (27 male and 20 female) participated in the study. Data collection was conducted in a United Kingdom ISO 9001:2015 accredited laboratory, by a Fit2Fit accredited fit tester. Data collection occurred in two studies, that were completed in consecutive weeks. The study was composed of two panels (25 subjects and 22 subjects) for a total of 47 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. As of the publication date of this paper, three such grids are commonly used: the U.S. National Institute for Occupational Safety and Health (NIOSH) bivariate grid (NIOSH, 2019), the International Organization for Standardization (ISO) bivariate grid (ISO, 2022), and the China bivariate grid (Chen, 2009). The NIOSH bivariate grid represents the range of face sizes found in the U.S. workforce, based on 3,997 face measurements in 2003 (Zhuang, 2007). The 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 (Figure 1). The NIOSH and ISO bivariate grids have identical face length and width parameters however they differ in the suggested distribution of the test subjects to complete a test panel.

Figure 1:



The NIOSH/ISO bivariate grid was selected for use in this study because it is presumed to be more representative of the workforce of the Europe, Middle East, and Africa region than the China bivariate grid. The face sizes of the study population spanned the entire grid, from size 1 to size 10. Each study aimed to follow the NIOSH bivariate panel face size distribution as shown in Figure 1.

The distribution of the entire subject study for each product is below:

Table 1: Subject Distribution

Grid Number	9320+ # of subjects	9322+ # of subjects	9330+ # of subjects	9332+ # of subjects
1	4	4	4	4
2	4	3	3	3
3	4	4	4	3
4	9	9	8	9
5	4	4	4	4
6	5	4	4	4
7	8	8	8	8
8	3	4	4	4
9	4	4	4	4
10	4	4	4	4
Total	**49 subjects**	**48 subjects**	**47 subjects**	**47 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 for each product study. 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). A United States 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.

3M™ Aura™ 9320+

The source dataset for the two bootstrap analysis was the overall fit factors for the 49 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.

3M™ Aura™ 9322+

The source dataset for the two bootstrap analysis was the overall fit factors for the 48 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 3.

3M™ Aura™ 9330+

The source dataset for the two bootstrap analysis was the overall fit factors for the 47 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 4.

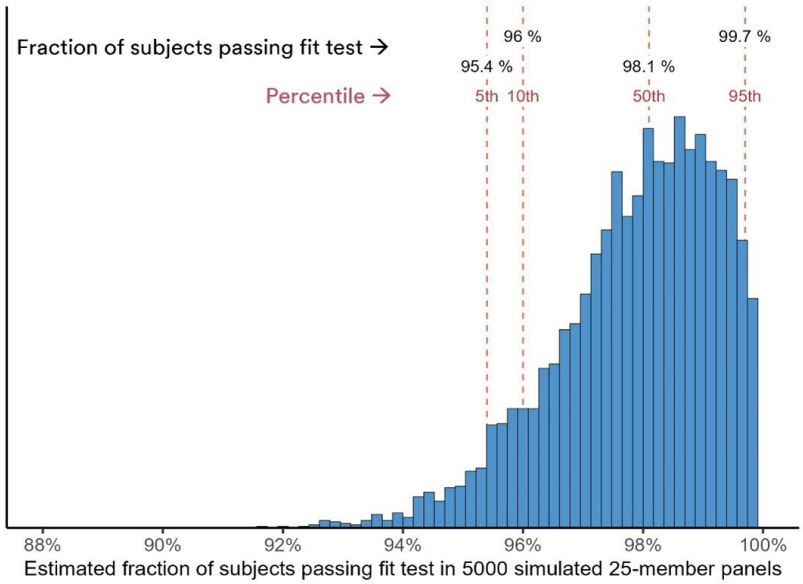
3M™ Aura™ 9332+

The source dataset for the two bootstrap analysis was the overall fit factors for the 47 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 5.

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.

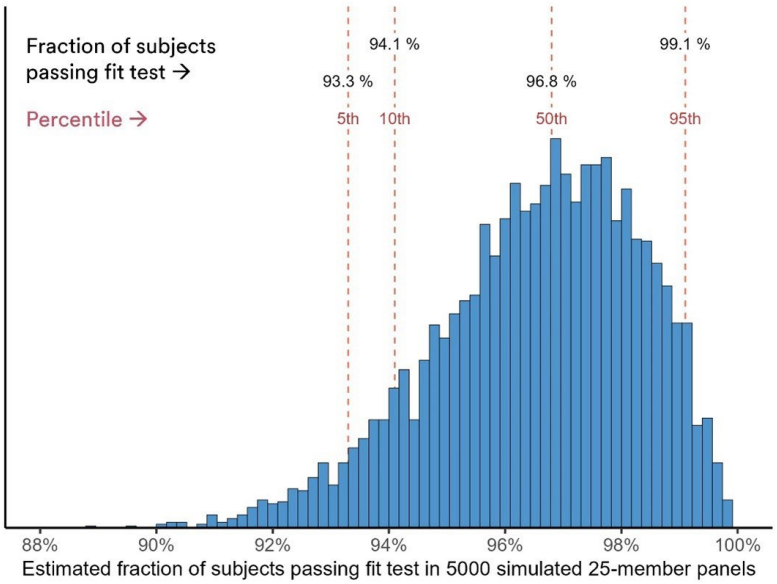
The 3M™ Aura 9320+ had the following pass rates based on ISO 16975-3: 95.4% (5th percentile), 96% (10th percentile), 98.1% (50th percentile), and 99.7 % (95th percentile). The pass rates based on UK HSE criteria included in INDG479: 98%. Testing was conducted during February-March 2022.

Figure 2: Histogram of 9320+ Bootstrap Analysis with 5,000 Resamples



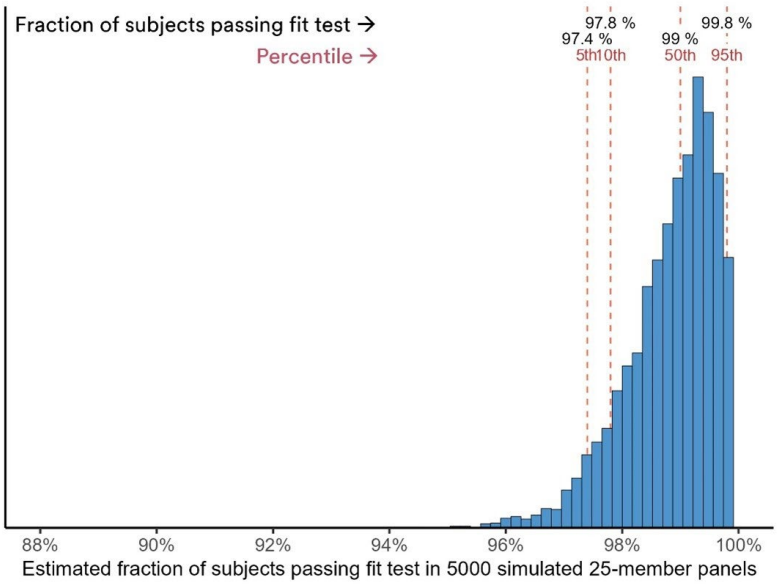
The 3M™ Aura 9322+ had the following pass rates based on ISO 16975-3: 93.3% (5th percentile), 94.1% (10th percentile), 96.8% (50th percentile), and 99.1% (95th percentile). The pass rate based on UK HSE criteria included in INDG479: 96%.

Figure 3: Histogram of 9322+ Bootstrap Analysis with 5,000 Resamples



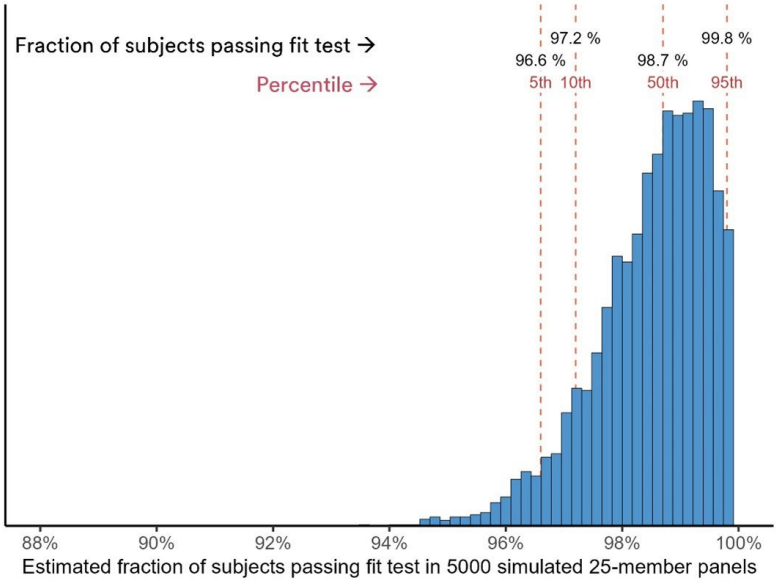
The 3M™ Aura 9330+ had the following pass rates based on ISO 16975-3: 97.4% (5th percentile), 97.8% (10th percentile), 99% (50th percentile), and 99.8% (95th percentile). The pass rates based on UK HSE criteria included in INDG479: 95%.

Figure 4: Histogram of 9330+ Bootstrap Analysis with 5,000 Resamples



The 3M™ Aura 9332+ had the following pass rates based on ISO 16975-3: 96.6% (5th percentile), 97.2% (10th percentile), 98.7% (50th percentile), and 99.8% (95th percentile). The pass rates based on UK HSE criteria included in INDG479: 89%.

Figure 5: Histogram of 9332+ Bootstrap Analysis with 5,000 Resamples



More About Fit Test Outcomes

Readers should keep in mind that there are two different methodologies for determining whether the outcome of a fit test is a pass or a fail. One approach is to determine that a test is passed or failed based on whether the overall fit factor is higher or lower than 100. This methodology of determining pass or fail based on the overall fit factor is one that is accepted by many researchers and ISO (ISO, 2017). Respirators are utilized to reduce wearer exposure to airborne contaminants over a

period of time to an acceptable level; therefore, small temporary leaks are acceptable, as long as the average protection is maintained at the acceptable level. This methodology corresponds to most quantitative fit testing and is the approach used in this study.

However, the United Kingdom (HSE, 2019) and France (INRS, 2021) use a different methodology for determining the outcome of quantitative fit tests, which considers an entire fit test failed if one exercise is failed, even if the overall fit factor is higher than 100 – corresponding to results if qualitative fit testing was used and possibly resulting in a lower pass rate. For example, several of the data points for this study returned overall fit factors that were higher than 100 but included individual exercise fit factors that were lower than 100. If the United Kingdom methodology of determining pass or fail were followed, those fit tests would be considered failures despite having an overall fit factor higher than 100, and the measured pass rate (passes/total tests) would have been 98% (9320+), 96% (9322+), 95% (9330+), or 89% (9332+).

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