THESIS

RESPIRATORY FIT TESTING: A COMPARATIVE STUDY ON THE AEROFIT® VS. THE PORTACOUNT™ PRO PLUS

Submitted by

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ABSTRACT

RESPIRATORY FIT TESTING: A COMPARATIVE STUDY ON THE AEROFIT® VS. THE PORTACOUNT™ PRO PLUS

Respirator fit testing is a critical component of respiratory protection programs and is required to ensure that respirators provide adequate protection in accordance with Occupational Safety and Health Administration (OSHA) standards (29 CFR 1910.134). This study focused on quantitative fit-testing methods, which evaluate respirator fit by comparing particle concentrations outside the respirator to those measured inside the facepiece to generate a fit factor. An emerging quantitative fit-testing technology, the AeroFit®, was compared against the reference device, the PortaCount™ Pro+.

Firefighters represent an occupational group with frequent and high-risk respirator use, making proper respirator fit essential during active-duty operations. Thirty-eight firefighters from a fire agency in Northern Colorado volunteered to participate in this study. Each participant completed fit testing on both devices, allowing for direct comparison of overall fit factor values, pass/fail outcomes, testing efficiency, and user experience.

Results showed substantial differences in fit factor magnitude between the two devices, with the AeroFit® generally producing higher overall fit factor values than the PortaCount™ Pro+. Equivalence between device fit factor measurements was not demonstrated. Despite these differences, pass/fail outcomes showed a high level of agreement between devices, with only one

observed discrepancy. In addition, participants perceived the AeroFit® as faster to complete, more efficient, and it was the most frequently preferred device overall.

Overall, these findings indicate that while quantitative fit factor values may vary across fit-testing technologies, both devices can provide fit-testing outcomes that align with regulatory requirements. This study contributes to a clearer understanding of how emerging fit-testing technologies compare to an established reference device and highlights the importance of interpreting fit-testing results within a regulatory and practical context.

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CHAPTER 1: INTRODUCTION

Respiratory hazards are a major concern across many workplaces, ranging from construction to laboratories and industrial settings. These hazards include contaminants such as bioaerosols, dust and chemical vapors. Respiratory hazards can lead to acute and chronic health effects including cancer, lung impairment, serious pulmonary diseases, cardiac events and death. Exposure to these hazards without adequate controls or respiratory protection leaves workers potentially susceptible to life-changing diseases (OSHA, 2012).

To mitigate these risks, the use of National Institute for Occupational Safety and Health (NIOSH)-approved respirators is essential, along with ensuring an adequate seal between the respirator and the user's face. NIOSH is responsible for testing and certifying respirators, while the Occupational Safety and Health Administration (OSHA) establishes requirements for respirator use and fit testing in the workplace (NIOSH, 2025; OSHA, 29 CFR 1910.134). Respirator fit testing is performed in one of two ways - qualitative or quantitative. Qualitative fit testing (QLFT) is subjective and relies on the user's ability to detect a test agent through taste, smell, nasal or throat irritation through the seal of the respirator. By contrast, quantitative fit testing (QNFT) is objective and relies on a computed value called the fit factor, which indicates the amount of respirator leakage. This numerical indicator can also be used to compare different manufactured fit testing devices (Balkhyour, 2013). These quantitative tests are primarily used when the worker has the potential to be exposed to a more toxic atmosphere, when compared to qualitative fit testing (Balkhyour, 2013).

The PortaCount™, also known as the "gold standard" in quantitative fit testing, has long been used to verify that respirators provide adequate protection for workers. The condensation

nuclei counter (CNC) PortaCount™ protocol uses a probe for particle detection inside the respirator, which is necessary to conduct a quantitative fit test. A fit-factor of at least 100 is required to pass for a half-mask respirator, while a fit-factor of at least 500 is required for a full-facepiece elastomeric respirator (OSHA, 29 CFR 1910.134). These fit factor thresholds ensure that the wearer is provided with a proper seal to protect against airborne contaminants. Understanding the PortaCount™'s role and the established fit-factor thresholds provides a benchmark for the current study by evaluating how emerging fit-testing systems compare when it comes to protecting respiratory health.

With the development of newer technologies such as the AeroFit® by Occupational Health Dynamics (OHD), there has been a surge of innovation as it relates to the world of respiratory protection. The AeroFit® system was designed to streamline the respirator fit-testing process by incorporating advanced CNC technology and delivering precise, reliable measurements that align with global standards. The researchers of the current study use the AeroFit® to investigate a new system in advancing occupational respiratory health protection. Additionally, perception surveys evaluate the AeroFit®, as comfort, ease of use, and confidence influence participation and complement quantitative fit testing.

In the current study, the researchers evaluate the performance of the AeroFit® against the established PortaCount™+ device among active-duty firefighters. The goal of this research is to inform the occupational safety community about the AeroFit® by assessing accuracy, efficiency, and user preference. The aims of this study are to 1) Compare fit-factor accuracy and usability of the AeroFit® to PortaCount™+, and 2) Assess pass/fail concordance, testing time, user experience, and practicality in field settings.

CHAPTER 2: LITERATURE REVIEW

Historic Development of Respiratory Protection

The concept of respiratory protection has existed for centuries. The earliest recorded use of any type of respirator dates back to Pliny the Elder (23-79 A.D.), who used loose bladder skins to act as a barrier to protect workers from exposure to cinnabar, a mercuric sulfide mineral which was used as a pigment in decorations during that time (Balkhyour, 2013).

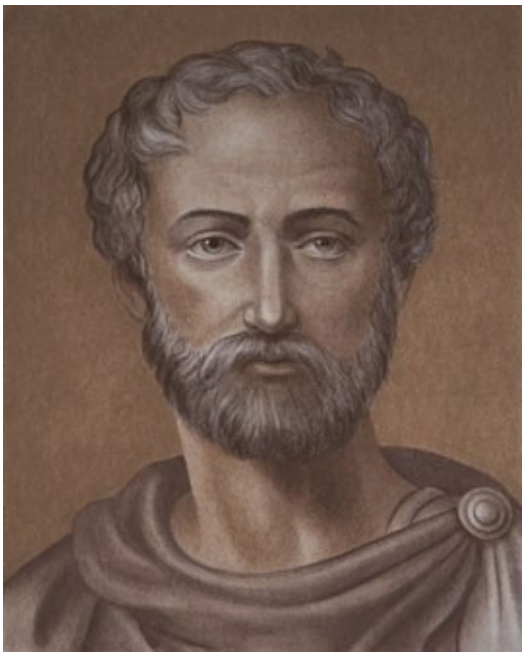

Figure 1.1: Pliny the Elder Pliny the Elder (23–79 AD), (Centers for Disease Control and Prevention [CDC], 2019)

While many others have been noted as contributors to the development of modern respiratory protection, including early concepts from Leonardo da Vinci, Julius Pollock, and Bernardo Ramazzini, it should also be noted that some 1800 years later, Dr. John Stenhouse created a charcoal respirator that was built using a perforated zinc case that was filled with granular wood charcoal. This respirator was designed to fit over the nose and mouth and used in hospital settings

(Tilden, 1919). Additionally, early accounts of respiratory protection even describe firefighters using wet beards as primitive filtration during smoke exposure (Held, 1974).

Building on centuries of research and innovation in respiratory protection, in June of 1995, the U.S. National Institute for Occupational Safety and Health (NIOSH) introduced the N95 respirator certification standard (42 CFR Part 84), which paved the way for continuous improvement in the protection of workers in every field (U.S. National Institute for Occupational Safety and Health [NIOSH], 1995).

Figure 1.2: Dr. Stenhouse's respirator featuring hollow wire gauze (Youmans, 1863)

Respirator fit may be influenced by several factors including facial anthropometry, donning technique, speaking or movement during use, and other user-related variables that can affect the seal between the respirator and the face (Zhuang & Bradtmiller, 2005). Most recently, in October, 2020, the American Society for Testing and Materials (ASTM) International released the ASTM F3407-20 Standard Test Method for Respirator Fit Capability (RFC) for Negative-Pressure Half-Facepiece Particulate Respirators. Respiratory protection programs may include several types of

respirators such as negative-pressure air-purifying respirators, powered air-purifying respirators, and atmosphere-supplying respirators including supplied-air and self-contained breathing apparatus (NIOSH, 2025). The purpose of the ASTM F3407-20 Standard Test Method was to ensure that companies that manufactured particulate respirators be held to a standard that ensured proper fit of the respirator no matter the size or shape of the user's face. Additionally, it was stressed that while this standard ensured accurate respirator fit, it did not negate the need for personal respirator fit tests as required by the OSHA (Coffey et al., 2021).

While the most commonly known respirator users are healthcare workers, there is also a need for respirators in other industries such as construction, oil and gas and emergency response workers, such as fire fighters. Despite regulatory requirements promulgated by NIOSH and OSHA, it was reported in a 2001 survey of approximately 40,000 private sector workplaces that only 57% of those workplaces performed fit testing (See Table 1.1), leaving more than 40% of respirator-using workplaces without required fit testing procedures (Coffey et al., 2021). In addition to workplace-level compliance, individual worker compliance with respirator requirements is influenced by factors such as comfort, communication limitations, perceived risk, and training within respiratory protection programs (Baig et al., 2010).The survey's reported lack of required respirator fit testing reinforces why fit testing is so critical in the continuous protection of the workforce. Addressing the issue of required respirator fit testing requires not only greater enforcement but also a clear understanding of how fit testing can be conducted effectively and efficiently.

Table 1.1: BLS 2001 survey results showing 57% of establishments performed fit testing.

Respirator Use Practices	Private Industry	Goods Producing				Service Producing				
		Agriculture, Forestry and Fishing	Mining	Construction	Manufacturing	Transportation and Public Utilities	Wholesale Trade	Retail Trade	Finance, Insurance and Real Estate	Services
Percent of Establishments (%)										
Total Tight-Fitting Respirators	100	100	100	100	100	100	100	100	100	100
Fit Testing for Employees who wear Tight Fitting Respirators (%)										
Yes	57.3	45.3	78.8	53.1	72.5	69.2	66.2	49.2	76.4	49.4
No	19.6	26.5	7.9	22.3	13.1	6.9	18.9	33.0	-	20.8
Not Needed	4.6	7.4	2.0	1.2	3.1	2.5	5.6	10.3	-	6.6
Don't Know	2.1	6.6	-	2.2	2.9	1.6	2.2	2.0	-	1.0

Note: Table adapted from data published by the U.S. Bureau of Labor Statistics (BLS, 2003)

Respirator Fit-Testing Comparative Studies

While there have not been any comparative studies on the effectiveness of the AeroFit® compared to the PortaCount™+, the PortaCount™+ has been used for comparison for other fit-testing systems. In 2022, a comparative study was conducted that involved the PortaCount™ and the MT-05U, a quantitative respirator fit tester developed by the Japanese company SIBATA Scientific Technology (Han et al., 2022).

In QNFT studies such as this, respirator performance is evaluated using the fit factor metric. Fit factor is a measurement used during QNFT to compare the concentration of aerosols inside and outside of a respirator and is a relative measure of respirator leakage. A fit factor greater than or equal to 100 is designated as a pass for half masks, while a fit factor of 500 is designated as a pass for full face pieces (OSHA, 29 CFR 1910.134). To determine fit-factor, the PortaCount™ passes fine aerosols through an infused isopropyl alcohol vapor. The aerosol nuclei enlarge through the condensation process to a microscopic particle size that the instrument can then detect

(Han et al., 2022). This process is called condensation nuclei counting (CNC). By contrast, the MT-05U uses the optical counting method by shining laser light to dried particulates in the air and counting the scattered light. Wu et al., compared fit factors between the PortaCount™ and the SIBATA MT-05U, finding that MT-05U generally displayed lower fit factors but showed very high consistency with the PortaCount™, with sensitivities of 0.98 for P100 filtering facepiece respirators — particulate air-purifying respirators certified by NIOSH to filter at least 99.97% of airborne particles — and 1.00 for full facepieces (Han et al., 2022; NIOSH, 2025).

Additional studies with the MT-05U and PortaCount™ confirmed strong agreement in pass/fail match rates (93% for N95 and 95% for full facepieces), which underscored the need to understand fit factor differences between the two devices, especially given their widespread use during the COVID-19 pandemic in Korean hospitals (Han et al., 2022). Using OSHA's QNFT protocol found in 29 CFR 1910.134, fit tests were performed on a randomized group of college students. They wore full facepiece respirators, half masks and N95 masks (Han et al., 2022).

Figure 1.3: Sibata MT-05U quantitative respirator fit tester (Sibata Scientific Technology, n.d.)

Further, Han et al. (2022) found that fit factors of the MT-05U device were lower than those found using the PortaCount™ in all masks. The researchers attributed this discrepancy to the observation that the MT-05U device can only count aerosols greater than roughly 0.3 µm (>0.5 µm in N95 test), while the PortaCount™ can count particles in the range of 20-1000 nm. This resulted in the number of particles counted outside of the mask being much higher for the PortaCount™ compared to the MT-05U (Han et al., 2022). Moreover, the differences in fit factor between the two devices were not found to be statistically significant.

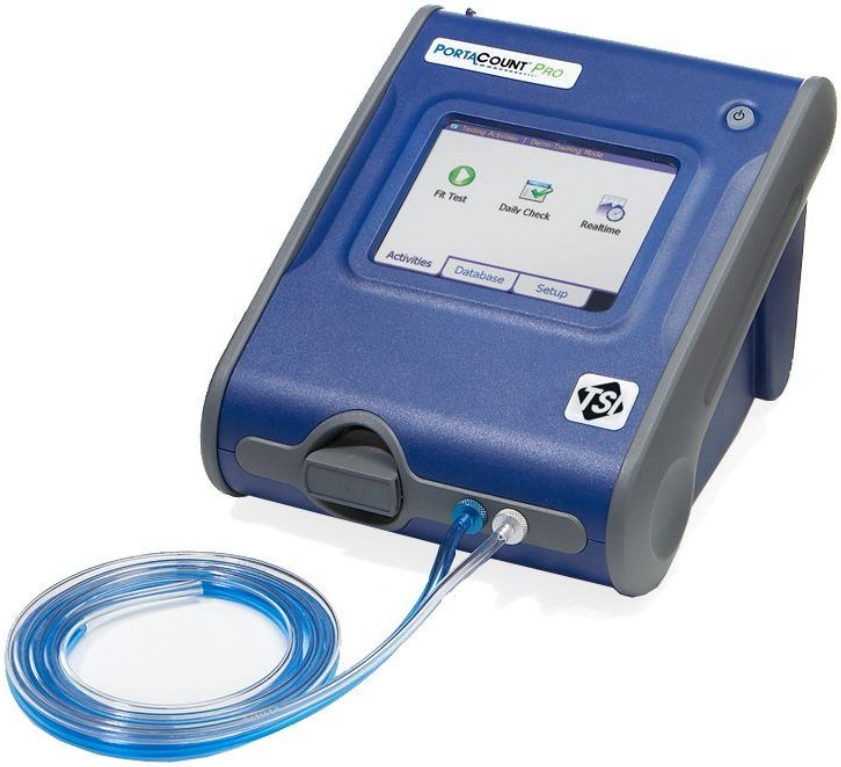

Figure 1.4: TSI PortaCount respirator fit tester (TSI Incorporated, n.d.)

However, it should be noted that overall, the MT-05U device consistently produced lower fit factor results compared to the PortaCount™ with the difference being significant for half-mask and full-facepiece respirators and especially shown in full-facepieces (Han et al., 2022).

A similar study by Coffey et al., (2006) randomly selected 38 individuals representing a range of facial sizes. Precautions were taken to avoid any exhaled particles due to smoking for the quantitative testing; while other precautions such as avoiding eating, chewing gum and drinking were implemented for the qualitative testing aspect of the study. Additionally, test subjects were

not trained on how to properly don and wear the respirators in order to generate a broad range of fit factor results.

The researchers followed the QLFT (Bitrex and saccharin) and QNFT protocols mandated by OSHA (OSHA, 29 CFR 1910.134). The qualitative methods relied on the test subjects' ability to detect aerosols through taste, while the primary quantitative method used was the TSI PortaCount™ Plus with the N95-Companion method, which measured particle leakage around the respirator seal. The N95-Companion selects particles in the size range of 0.03–0.06 μm, and only a very small fraction of these particles (maximum 0.3%) penetrate the N95 filter media itself. The 0.03–0.06 μm particle size range ensured that nearly 100% of the particles found inside the respirator facepiece were attributed to a lack of proper sealing. Fit factors were also compared to the Simulated Workplace Protection Factor (SWPF). This comparison of fit factors and SWPF values was conducted to demonstrate that SWPF values were calculated in the same way as the N95-Companion method, thereby confirming a strong correlation between fit test results and real-world protection (Coffey et al., 2006).

Coffey et al. (2006) demonstrated that for all respirators combined, the three fit test methods produced about the same rate of false passes (8–9%). However, the two QLFTs (Bitrex and saccharin) showed much higher false fails (68–71%) compared to the quantitative N95 Companion method (40%). Elastomeric respirators had consistently fewer false fails than those of the filtering facepiece respirators. However, the filtering facepiece respirators had fewer false passes. The results indicated that the N95 companion method outperformed both qualitative methods and provided data on identifying true adequate fits, whereas the qualitative methods often failed acceptable respirators fits (Coffey et al., 2006).

Overall, prior comparative studies indicate that quantitative fit-testing devices can produce different fit factor magnitudes, while pass and fail outcomes were often consistent across devices and in accordance with OSHA criteria. Existing research has focused on comparisons between the PortaCount™ and other established quantitative fit-testing systems, with findings emphasizing differences in particle counting methods and sensitivity ranges that influence measured fit factor values. However, there is limited independent evaluation of newer quantitative fit-testing technologies in applied occupational settings, particularly with respect to testing efficiency and user experience. This gap in the literature supports the need for the present study, which compares the AeroFit® to the PortaCount™ Pro+ in an active-duty firefighter population.

CHAPTER 3: PURPOSE AND SCOPE

Purpose

The purpose of this study was to evaluate and compare the performance of two quantitative respirator fit-testing devices — PortaCount™ Pro+ and AeroFit®— in an occupational setting, specifically among active-duty firefighters. These respirator fit-testing devices were essential in ensuring that tight-fitting respirators form an effective seal on the wearer's face, thereby offering critical protection from hazardous airborne contaminants commonly encountered in firefighting environments. This study provided a comprehensive comparison of established and emerging fit-testing technologies and helped to inform best practices for respirator fit testing in high-risk occupational environments.

Objective 1: Evaluate respirator fit-testing device accuracy

This objective was accomplished by comparing the respirator fit-factors obtained from respirator fit-tests across both fit-testing devices. The investigators assessed whether the fit factor results produced by AeroFit® are significantly different than those of the PortaCount™ Pro+.

Objective 2: Evaluate respirator fit-test pass/fail outcomes

This objective was accomplished by determining if pass/fail outcomes for the AeroFit® respirator fit-testing device were significantly different than the outcomes for the PortaCount™ Pro+.

Objective 3: Assess the respirator fit-testing time and efficiency

This objective was accomplished by measuring and comparing the duration of fit testing procedures across both devices to evaluate operational efficiency.

Objective 4: Evaluate respirator fit-testing subject experience and preference

This objective was accomplished by collecting qualitative feedback from firefighters regarding comfort, usability, and overall preference for each fit-testing method through post-test surveys.

Objective 5: Determine the practicality of the respirator fit-testing devices in an occupational setting

This objective was accomplished by analyzing the device setup time, calibration requirements, portability, and usability of each device under field conditions to assess their practicality in real-world occupational settings.

Hypotheses and Research Questions

To meet the study objectives, four hypotheses were posed and tested addressing differences in quantitative fit factor performance, agreement in pass/fail outcomes, testing time and efficiency, and user experience and device preference.

Compare Fit Factor Performance Across Devices

H_{01}: There is no significant difference in fit factor results between the AeroFit® and the PortaCount™ Pro+.

H_{11}: There is a significant difference in fit factor results between the AeroFit® and the PortaCount™ Pro+.

Evaluate Agreement in Pass/Fail Outcomes

H_{02}: There is a low level of agreement in pass/fail outcomes between the AeroFit® and the PortaCount™ Pro+.

H_{12}: There is a high level of agreement in pass/fail outcomes between the compared devices.

Assess Testing Time and Efficiency

H_{03}: There is no significant difference in testing time between the devices.

H_{13}: There is a significant difference in testing time between the devices.

Evaluate User Experience and Preference

H_{04}: A majority of participants prefer the PortaCount™ Pro+ over the AeroFit®.

H_{14}: A majority of participants prefer an alternative device (AeroFit®) over the PortaCount™ Pro+.

CHAPTER 4: METHODS AND MATERIALS

Study Site and Subject Recruitment

For this study, the investigators visited six fire stations that are part of a fire agency in Northern Colorado. The stations visited included Fire Stations 1, 2, 3, 5, 6, and 7. A total of 38 subjects were recruited and participated in the study. The sample was a convenience sample based on participant availability during scheduled station visits and work shifts. A minimum sample size of 34 participants was determined during study planning to provide sufficient observations for statistical comparison between devices.

Selection criteria were used to ensure that study participants were eligible and able to safely complete the respirator fit-testing procedures. Additionally, informed consent was obtained from participants by having participants read and sign the Consent to Participate in Research form. A prepared script was also read aloud to participants prior to testing, covering all information included in the consent form. All aspects of the research were reviewed and approved by Colorado State University's (CSU) Institutional Review Board (IRB).

Following recruitment and consent, participants completed a series of respirator fit tests during the station visits. Multiple QNFT devices were used during these testing sessions as part of the broader research project. The present study focuses specifically on the procedures and outcomes associated with the AeroFit® and PortaCount™ Pro+ systems.

Methods of Use: AeroFit®

For AeroFit® testing, participants donned their personal MSA G1 full-face elastomeric respirators, and investigators verified proper donning and strap adjustment to ensure an adequate

initial fit. Each respirator was fitted with an AeroFit®-specific adapter and a P100 filter to permit sampling of air from inside the facepiece. Tygon tubing was connected from the respirator to the AeroFit® system.

Prior to initiating the fit test, participants were given one to two minutes to assess respirator comfort and make minor adjustments as needed. Participants were also instructed not to smoke, eat, or chew gum prior to testing in order to avoid potential interference with the fit-testing procedures. Participants then completed a standardized series of exercises, each lasting approximately 30 seconds, including normal breathing, jogging in place, turning the head left and right with two breaths released at each extreme, and moving the head up and down with two breaths released at each extreme.

During each exercise, the AeroFit® system measured particle concentrations inside and outside the respirator to calculate individual exercise fit factors. Upon completion of the protocol, the system software displayed fit factors for each exercise, an overall fit factor, and a final pass/fail determination. Following testing, the respirator was reset for future use, investigators had the option to add notes, retest the participant if issues with the respirator seal or test setup were suspected, or proceed to the next subject in the database.

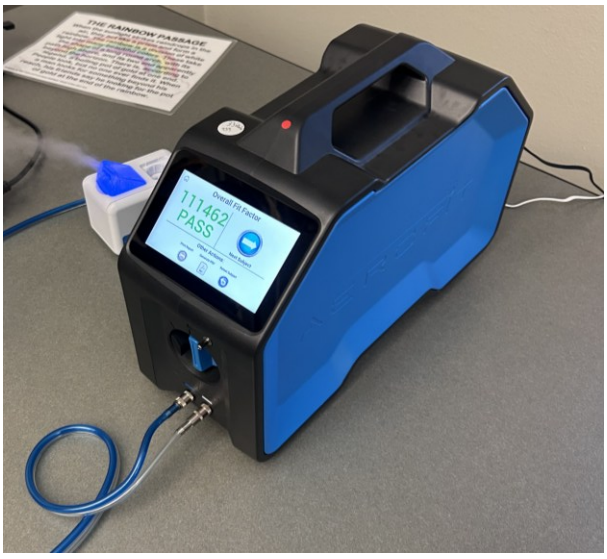

Figure 1.5: AeroFit® fit-testing setup used in this study, including the AeroFit® device and the particle generator.

Methods of Use: PortaCount™ Pro+

For PortaCount™ Pro+ testing, participants donned their personal MSA G1 full-face elastomeric respirators, with investigators ensuring proper fit and adjustment prior to testing. The respirator was connected to the PortaCount™ Pro+ using tygon tubing that allowed continuous measurement of particle concentrations inside the facepiece.

Participants were again allowed one to two minutes to assess respirator comfort before beginning the test protocol. Participants were also instructed not to smoke, eat, or chew gum prior to testing in order to avoid potential interference with the fit-testing procedures. The exercise protocol for the PortaCount™ Pro+ followed the manufacturer's standardized quantitative fit-testing procedure, which differs slightly from the exercise sequence used by the AeroFit® system. The PortaCount™ Pro+ fit test consisted of a series of exercises, each lasting approximately 60 seconds, including normal breathing, deep breathing, head movements (side-to-side and up-and-

down), talking by reading the Rainbow Passage as specified by OSHA fit-testing protocols, bending over, and a final normal breathing exercise.

Fit factors were calculated for each exercise by comparing particle concentrations inside and outside the respirator. An overall fit factor was then computed across the full test sequence, and a pass or fail determination was assigned based on whether the overall fit factor met or exceeded the OSHA-required minimum fit factor of 500 for full-face respirators as specified in 29 CFR 1910.134, Appendix A.

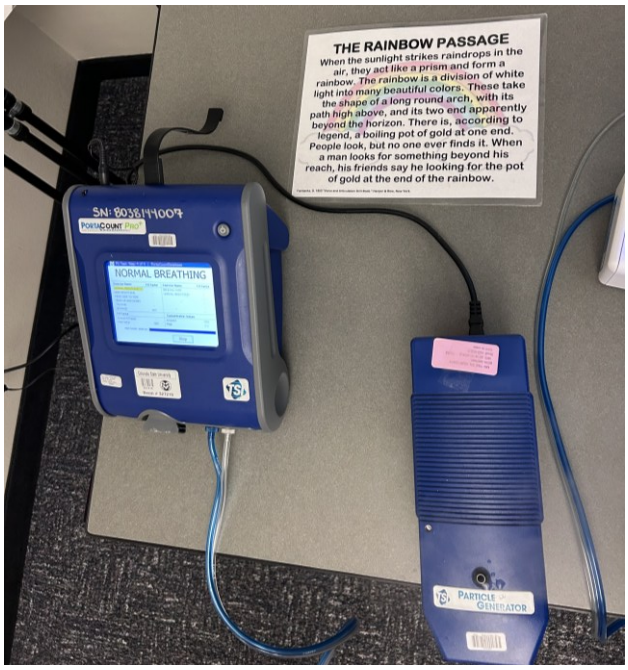

Figure 1.6: PortaCount™ Pro+ fit-testing setup used in this study, including the PortaCount™ Pro+ device, particle generator, and the Rainbow Passage as required by the OSHA fit-testing standard.

Table 1.2: Methodological Comparison of the AeroFit® and the PortaCount™ Pro+

Testing Methodology	AeroFit®	PortaCount™ Pro+
Respirator Used	MSA G1 full-face elastomeric	MSA G1 full-face elastomeric
Sampling Configuration	AeroFit® adapter with P100 filter and sampling line	Sampling line directly connected to device
Pre-Test Comfort Period	1-2 minutes	1-2 minutes
Exercise Duration	~ 30 seconds per exercise	~60 seconds per exercise
Exercise Protocol	Normal breathing, jogging in place, head movements (left/right and up/down)	Normal breathing, deep breathing, head movements, talking, bending, normal breathing
Fit Factor (FF) Calculation	Particle counts inside and outside the respirator measured during each exercise, with an overall fit factor calculated at test completion.	Particle counts inside and outside the respirator measured throughout the test exercises, with an overall fit factor calculated at test completion.
Output	Software-generated summary with step FFs, overall FF, and pass/fail	Fit test report with exercise FFs, overall FF, and pass/fail
Post-Test Actions	Reset respirator; option to retest or annotate results	End of Test

Employee Recruitment Screening Method

Participants were recruited and screened using a standardized health and eligibility checklist prior to fit testing. Screening included verification of age, visual inspection for facial hair that could interfere with the respirator seal, confirmation of medical clearance for respirator use, and completion of informed consent. The full screening questionnaire and is provided in Appendix A.

Testing Interruptions and Protocol Deviations

Fit testing was conducted during active-duty work shifts at each fire station. During data collection, fit testing was interrupted temporarily on two occasions when participating firefighters were required to respond to emergency calls. In these instances, testing was paused for that participant and subsequently restarted upon the participant's return to the station. Testing continued for firefighters that were still present at each station. Interrupted tests were repeated in full to ensure completion of the standardized fit-testing protocols for each device. No partial test results from interrupted sessions were included in the final analysis.

Randomization Method

Device testing order was not formally randomized. Devices were selected as first or second without a predetermined or systematic order (e.g., PortaCount™ Pro+ followed by AeroFit®, or AeroFit® followed by PortaCount™ Pro+).

Figure 1.7: PortaCount™ Pro+ and AeroFit® fit-testing lineup used in this study.

Blinding (Masking)

This study was unblinded due to the visible nature of the fit-testing devices, interfaces, and testing procedures. Although an attempt was made to blind data analysts to device identity during result review, complete blinding was not feasible because device-specific output formats made the testing system identifiable. To minimize potential bias, standardized analysis procedures were applied uniformly to results from both devices.

Source Records Used

Multiple source records were used to support data collection, documentation, and analysis throughout the study. These records included consent forms, pre-screening checklists, device-generated quantitative fit factor reports, post-test survey, and study logs containing de-identified participant codes.

Participant-reported comfort, usability, perceived efficiency, and overall device preference were evaluated using a post-test questionnaire completed following respirator fit testing. The post-test questionnaire was administered to assess participant perceptions of comfort, usability, testing efficiency, and overall device preference. The questionnaire included Likert-scale items using a five-point response scale (1 = strongly disagree to 5 = strongly agree) to evaluate comfort during testing, clarity of fit-testing exercises, and confidence in test accuracy for each device. Additional multiple-choice questions were used to assess perceived test duration and device efficiency, as well as overall device preference for future fit testing. Free response questions were included to capture qualitative feedback related to discomfort, anxiety, or suggestions for improving the fit-testing process. The full post-test questionnaire is provided in Appendix B.

Inclusion Criteria

Participants were eligible for inclusion if they met all of the following criteria:

- Active-duty firefighter
- Aged 18 years or older
- Medically cleared for respirator use
- Clean-shaven face with no facial hair interfering with the respirator seal
- Willing and able to provide informed consent

Exclusion Criteria

Individuals were excluded from participation if any of the following conditions were present:

- Self-reported acute respiratory symptoms on day of testing (e.g., allergies, cold, bronchitis)
- Visible facial scarring or conditions impairing respirator seal
- Under 18 years of age
- Unable or unwilling to complete testing steps

Special Populations

This study did not target special populations outside of active-duty firefighters. Adults unable to provide consent, children under 18 years of age, and prisoners were excluded from

participation. Pregnant women were not specifically excluded; however, they were not actively recruited as part of the study population.

Number of Subjects

A total of 38 subjects were enrolled in the study. All enrolled participants were expected to complete study procedures, with an estimated question-specific response rate of 90–95%.

Data Analyses

QNFT data were analyzed to compare fit factor performance and pass/fail outcomes between the AeroFit® and the PortaCount™ Pro+ devices. Overall fit factor values obtained from each device were summarized using descriptive statistics, including means, medians, interval ranges, and standard deviations. Because fit factor values were widely varied for each device, ratios of overall fit factors were calculated for paired observations, and log-transformed ratios were used for comparative analysis.

Equivalence testing was conducted to evaluate whether fit factor measurements from the two devices could be considered comparable within a predefined relative equivalence range of 0.80 to 1.25. The geometric mean ratio and corresponding 90% confidence interval were calculated and compared to the predefined equivalence range. Results that fell outside the equivalence range indicated that the two devices did not produce comparable fit factor measurements.

Pass and fail outcomes were determined using the OSHA minimum fit factor criterion of 500 for full-facepiece respirators. Agreement in pass/fail classifications between devices was evaluated using Fisher's exact test.

User experience data collected through post-test questionnaires were analyzed descriptively. Likert-scale responses assessing comfort and usability were summarized using means and standard deviations, with analyses conducted using available responses. Participant perceptions of testing efficiency and overall device preference were summarized using frequency counts and percentages. All statistical analyses were conducted using R (RStudio), and results were reported using descriptive or comparative summaries.

CHAPTER 5: RESULTS

Participant Characteristics

A total of 38 active-duty firefighters were enrolled in the study and completed quantitative respirator fit testing and 30 participants (79%) completed the user experience questionnaire. All participants met the predefined inclusion criteria, including being 18 years of age or older, medically cleared for respirator use, free of facial hair that would interfere with the respirator face seal (e.g., no beards), and willing and able provide informed consent at the time of testing. Participants were instructed to refrain from eating, smoking, or chewing gum prior to testing. However, if this occurred, those participants were scheduled to complete fit testing last in the testing sequence. Each participant completed fit testing using both QNFT devices evaluated in this study. No participants were excluded after enrollment due to incomplete testing procedures or missing fit-test data.

Table 1.3: Participant Characteristics

Participant Characteristic	n
Male	34
Female	4
Declined to participate	3

**Note: Demographic data collection was limited to gender.*

All 38 participants completed at least one item on the post-test questionnaire. Items related to perceived testing efficiency and overall device preference were completed by all participants (n

= 38), while Likert-scale items assessing comfort during fit testing were completed by 30 participants (79%). Survey results were analyzed using available responses for each item

Comparison of Fit Factor Performance Across Devices

Fit factor results from the AeroFit® and PortaCount™ Pro+ were compared to evaluate differences in QNFT performance. As shown in Table 1.4, overall fit factor values were higher for the AeroFit® than the PortaCount™ Pro+, based on higher mean and median values. OSHA requires a minimum fit factor of 500 to pass a quantitative fit test for full-facepiece respirators. The lowest overall fit factor observed for the PortaCount™ Pro+ (288) was below the 500 fit factor threshold, but overall pass and fail outcomes were largely consistent between devices, with only one observed discrepancy. This suggests that despite differences in fit factor magnitude, the devices generally supported the same compliance decisions.

Table 1.4: Comparison of Overall Fit Factor Summary Statistics for the AeroFit® and PortaCount™ Pro+ Devices

Device	Mean	Median	Min	Max
AeroFit®	62,835	41,196	637	179,771
PortaCount™ Pro+	28,536	28,050	288	80,150

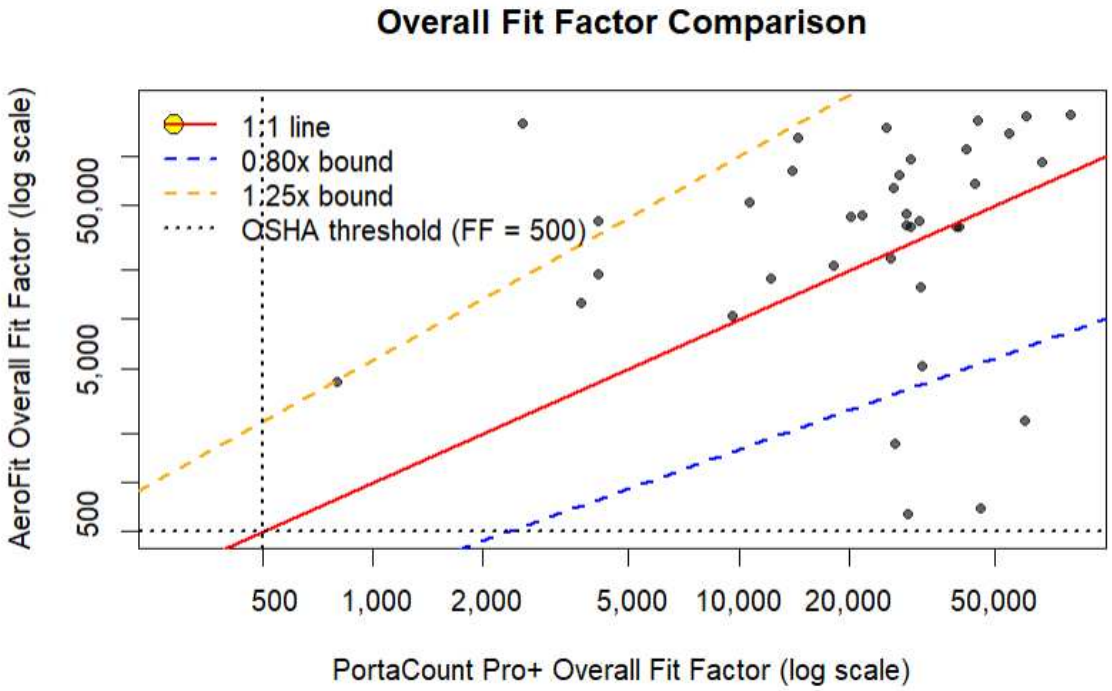

Figure 1.8: Overall Fit Factor Comparison Between the AeroFit® and the PortaCount™ Pro+

Figure 1.8 presents a scatter plot comparing overall fit factors measured using the AeroFit® and the PortaCountTM Pro+ with both axes shown on a logarithmic scale. To compare fit factor performance between devices, log-transformed ratios of overall fit factors for the AeroFit® and the PortaCount™ Pro+ were analyzed. A relative equivalence range of 0.80 to 1.25 was used to evaluate whether the devices produced comparable fit factor measurements. The geometric mean ratio was 1.69, and the 90% confidence interval for the ratio ranged from 1.00 to 2.85. Both the geometric mean ratio and the upper limit of the 90% confidence interval exceeded the predefined equivalence range. As a result, the fit factor measurements from the two devices were not considered equivalent within the selected bounds, supporting the alternative hypothesis (H11) that

there was significant difference in fit factor results between the AeroFit® and the PortaCount™ Pro+.

Agreement in Pass/Fail Fit Test Outcomes

Pass/fail fit test outcomes from the AeroFit® and PortaCount™ Pro+ devices were compared to evaluate agreement between devices. Table 1.5 summarizes pass and fail outcomes for each device.

Table 1.5: Agreement in pass/fail fit test outcomes between the AeroFit® and PortaCount™ Pro+

Fit Test Outcome	PortaCount™ Pro+ Pass	PortaCount™ Pro+ Fail
AeroFit® Pass	37	1
AeroFit® Fail	0	0

Fit test outcomes were compared between the AeroFit® and PortaCount™ Pro+ devices to evaluate agreement based on the OSHA QNFT criterion (overall fit factor ≥ 500). Of the 38 participants tested, 37 received the same pass/fail outcome on both devices, resulting in an overall agreement of 97.4%. One participant passed the fit test using the AeroFit®, however, failed when tested using the PortaCount™ Pro+. Fisher's exact test did not detect a statistically significant association between device type and fit test outcome ($p = 1.00$). Based on this high level of agreement, the alternative hypothesis (H12) was supported, indicating strong agreement in pass/fail outcomes between the two devices.

Testing Time and Efficiency

Testing time was not consistently recorded during data collection, and device-generated reports did not include time stamps or duration metrics. As a result, statistical comparison of testing time between devices could not be performed. A singular timed observation was conducted to estimate approximate testing duration. During this observation, the PortaCount™ Pro+ required 7 minutes and 57.10 seconds, while the AeroFit® required 2 minutes and 32.13 seconds to complete testing. These values are presented for context only and should not be interpreted as representative of typical testing time across participants. As a result of this, Hypothesis 3 (H03/H13) could not be evaluated using the available data.

User Experience and Device Preference

Participant perceptions of comfort, usability, testing efficiency, and overall device preference were assessed using a post-test questionnaire that was administered after respirator fit testing. The following sections summarize the participants' perceptions.

Comfort and Usability

Table 1.6 presents descriptive statistics for participant ratings of comfort and usability during fit testing. As shown below, participants reported high comfort and usability ratings during fit testing, reflecting participant experience with respirator fit and testing procedures rather than the devices themselves. Comfort scores were similar for the AeroFit® (mean = 4.60, SD = 0.93) and the PortaCount™ Pro+ (mean = 4.57, SD = 0.94). Participants also rated the fit-testing exercises as clear and easy to follow for both devices, with slightly higher mean clarity scores reported for the AeroFit® compared to the PortaCount™ Pro+.

Table 1.6: Participant-reported comfort and usability ratings during respirator fit testing using the AeroFit® and PortaCount™ Pro+

Measure	AeroFit® Mean	AeroFit® Standard Deviation	PortaCount™ Pro+ Mean	PortaCount™ Pro+ Standard Deviation
Comfort During Fit Testing	4.60	0.93	4.57	0.94
Clarity of Fit-Testing Exercises	4.58	0.79	4.45	0.89

**Ratings were collected using a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). Comfort ratings were available for 30 participants due to incomplete survey responses, while clarity ratings were available for all 38 participants. Ratings reflect participants' experience with respirator fit and testing procedures.*

Perceived Test Efficiency

Participant responses regarding perceived testing efficiency are shown in Table 1.7. Perceptions of testing efficiency are summarized below. When asked which device felt fastest or most efficient to complete, 44.7% of participants selected the AeroFit®, while 7.9% selected the PortaCount™ Pro+. The remaining participants identified another device evaluated in the testing session as the fastest.

Table 1.7: Participant perception of the fastest fit-testing device

Fastest Perceived Device	Participants (n)	Percentage (%)
AeroFit®	17	44.7
PortaCount™ Pro+	3	7.9
Other Device	18	47.4

**"Other Device" includes responses indicating the third device evaluated in the study.*

Table 1.8 presents participant responses regarding overall device preference for future respirator fit testing. When asked which device they would choose for a future annual fit test, 47.4% of participants selected the AeroFit®, compared to 5.3% who selected the PortaCount™ Pro+. The remaining participants either preferred another device or reported no preference. Based on these findings, the alternative hypothesis (H14) was supported, indicating that a greater proportion of participants preferred the AeroFit® over the PortaCount™ Pro+.

Table 1.8: Participant-reported device preference for future respirator fit testing

Preferred Device	Participants (n)	Percentage (%)
AeroFit®	18	47.4
PortaCount™ Pro+	2	5.3
Other Device	13	34.2
No Preference	5	13.2

CHAPTER 6: DISCUSSION

Overview of Key Findings

The purpose of this study was to compare the emerging AeroFit® device with the established PortaCount™ Pro+ in order to evaluate quantitative fit factor performance, pass/fail outcomes, testing efficiency, and user experience. Overall, the findings showed that the two devices differed in the magnitude of fit factor values, with the AeroFit® consistently producing higher overall fit factors than the PortaCount™ Pro+. Despite these differences, pass/fail outcomes were largely consistent between devices, with only a single discrepancy observed across all tests.

Differences were also observed in testing efficiency. Although a complete statistical analysis of testing time could not be performed, the AeroFit® required less time to initiate and complete a fit test, with the PortaCount™ Pro+ taking approximately four times longer under a singular observed condition. In addition, results from the post-test questionnaire indicated that participants more frequently preferred the AeroFit® over the PortaCount™ Pro+. Together, these findings suggest that while both devices met regulatory fit-testing requirements, meaningful differences exist in fit factor magnitude, testing efficiency, and user preference.

Fit Factor Performance Across Devices

Fit factor performance differed between devices. Equivalence testing indicated that overall fit factor values produced by the AeroFit® and the PortaCount™ Pro+ did not fall within the predefined equivalence range. To allow for more meaningful comparison, fit factor values were evaluated as ratios rather than as raw values. Even with this approach, the AeroFit® consistently produced higher overall fit factor values on average. Similar differences in fit factor magnitude

across QNFT devices have been reported in prior comparative studies, where variations were attributed to differences in particle detection methods and sensitivity ranges, rather than true differences in respirator seal performance (Han et al., 2022; Coffey et al., 2006).

It is important to note that these findings do not indicate that the PortaCount™ Pro+ performed poorly or failed to meet regulatory requirements. Both devices produced fit factor values well above the minimum criteria for acceptable respirator fit as defined by the Occupational Safety and Health Administration (OSHA, 29 CFR 1910.134). Rather, the results suggest that the AeroFit® evaluates fit factor on a higher numerical scale compared to the PortaCount™ Pro+. Higher fit factor values may reflect increased sensitivity to particulate concentrations or differences in device calculation methods, rather than a meaningful difference in device performance.

In addition to differences in particle detection and device methodology, the interpretation of results in this study may also be influenced by the implicit use of the PortaCount™ Pro+ as a reference method, or the "gold standard." Prior research has shown that agreement between fit-testing methods can vary depending on the reference standard used, and no single method consistently demonstrates superior performance (Janssen et al., 2002). This suggests that observed differences between devices may reflect methodological variation rather than true differences in respirator fit, which may help explain why differences in fit factor magnitude were observed despite strong agreement in pass/fail outcomes.

Pass and Fail Agreement Between Devices

Pass and fail agreement between the two devices was high, with only a single discrepancy observed in reporting. This high level of agreement is consistent with prior comparative studies of

QNFT systems, which have demonstrated strong concordance in pass and fail outcomes despite differences in measured fit factor magnitudes when devices are evaluated using OSHA protocols (Han et al., 2022; Coffey et al., 2006). This finding is important because it demonstrates that both devices consistently met the OSHA pass criterion of a fit factor greater than or equal to 500 for full-facepiece respirators (OSHA, 29 CFR 1910.134). The high level of agreement in pass and fail outcomes was further supported by Fisher's exact test, which indicated consistency in compliance classifications between devices.

Notably, this agreement was observed despite differences in the magnitude of overall fit factor values. In practice, both devices led to the same regulatory compliance decisions, reinforcing that numerical differences in fit factor values do not necessarily translate to different pass or fail outcomes. Overall, these results indicate that although the devices differed in the magnitude of fit factor values, both produced nearly the same pass/fail compliance determinations based on established fit-testing criteria, consistent with NIOSH guidance on QNFT (CDC, 2025).

Testing Time and Efficiency

Testing time and efficiency were evaluated, but these measurements were limited to a single observed trial and the absence of device-generated time stamps in the fit-testing reports. Based on this observation, the AeroFit® required substantially less time to complete a fit test compared to the PortaCount™ Pro+.

Differences in testing duration may be explained by the structure of the test protocols used by each device. The PortaCount™ Pro+ required participants to complete a greater number of exercises, including normal breathing, deep breathing, head movements (side-to-side and up-and-down), talking, bending over, and a final normal breathing exercise, with a longer duration of

approximately 60 seconds. In contrast, the AeroFit® included fewer exercises which included normal breathing, jogging in place, and head movements, with each exercise lasting approximately 30 seconds. The greater number and longer duration of exercises required by the PortaCount™ Pro+ (seven exercises lasting approximately 60 seconds each) compared to the AeroFit® (four exercises lasting approximately 30 seconds each) likely contributed to the longer overall testing time observed.

Although these findings suggest a potential efficiency advantage for the AeroFit®, they should be interpreted cautiously due to the limited availability of timed data. Additionally, the use of the standard PortaCount™ Pro+ protocol in this study, rather than the Fast Fit protocol, may have contributed to longer observed testing times. Use of the Fast Fit protocol could have reduced testing duration and influenced the observed differences in efficiency between devices. Nevertheless, differences in testing duration may have contributed to participants' perceptions of testing efficiency, as reflected in the user experience results.

User Experience and Device Preference

User experience and device preference were assessed using post-test questionnaires completed following fit testing. Overall, both the AeroFit® and the PortaCount™ Pro+ were rated highly for comfort during the testing process and for clarity of the fit-testing exercises. These results indicate that participants generally found the testing procedures for both devices easy to follow and the exercise instructions clear, reducing the potential for confusion during testing.

Despite similar comfort and clarity ratings, the AeroFit® was perceived as faster by many participants and was the most frequently preferred device when compared to the PortaCount™ Pro+. These preferences do not indicate reduced accuracy or diminished value of the PortaCount™

Pro+, nor do they challenge its role as a reference device in quantitative fit testing. Rather, participant preference appears to reflect practical aspects of the testing process, including shorter test duration, perceived ease of completing the test, and overall testing flow. It is important to note that if the PortaCount™ Pro+ Fast Fit protocol had been used, the reduced testing time may have influenced participants' perceptions of speed and, consequently, device preference.

User experience is an important consideration alongside quantitative performance metrics, as it can influence acceptance, compliance, and operational efficiency during fit-testing programs. Prior research has emphasized the importance of effective and efficient respirator fit-testing programs to support regulatory compliance, particularly given historically low fit-testing implementation rates across workplaces (Coffey et al., 2021). In applied settings such as fire departments, testing conditions may be interrupted by emergency response calls. During this study, firefighters were called away during the fit-testing process, requiring the tests to be paused and later repeated. In this context, differences in testing duration, with the PortaCount™ Pro+ requiring substantially more time than the AeroFit®, had practical implications for completing fit testing efficiently in a real-world occupational environment.

Practical and Regulatory Implications

The findings of this study have several practical and regulatory implications for respirator fit-testing programs. Although differences were observed in the magnitude of fit factor values produced by the AeroFit® and the PortaCount™ Pro+, both devices consistently met the Occupational Safety and Health Administration minimum fit factor requirement for full-facepiece respirators. This suggests that, from a regulatory compliance standpoint, either device can be used to support required fit-testing determinations when implemented correctly.

Importantly, the results demonstrate that higher numerical fit factor values do not necessarily translate to different compliance outcomes. While fit factor magnitude varied substantially between devices, pass and fail classifications were largely consistent. This highlights the importance of focusing on regulatory thresholds and pass/fail determinations rather than relying solely on absolute fit factor values when evaluating respirator fit-testing results across different technologies. Whether higher fit factor magnitudes beyond established OSHA criteria provide additional practical or protective benefit remains unclear and an area for future investigation.

Overall, the results suggest that although quantitative fit factor magnitudes differed between devices, both the AeroFit® and the PortaCount™ Pro+ produced consistent pass/fail outcomes when evaluated against OSHA requirements (OSHA, 29 CFR 1910.134).

Study Limitations

Several limitations should be considered when interpreting the findings of this study. The first important limitation found during this study was that testing time and efficiency measurements were limited to a single observed trial, as neither device generated time stamps within the fit-testing reports. Because of this, formal statistical comparisons of testing duration could not be conducted, and observed differences should be cautiously interpreted.

Another limitation was that operational constraints also influenced data collection. Only one adaptor was available for testing, which slowed the overall testing process. Additionally, fit testing was conducted across multiple fire stations and on different days, resulting in variability in testing environments and conditions. Due to the nature of the participants' work, testing was

sometimes interrupted by emergency response calls, requiring tests to be paused and repeated. These factors reflect real-world conditions but may have introduced variability into the data.

Several methodological factors should also be noted. The order in which devices were tested was not formally randomized; instead, devices were selected to be tested first, second, or third without a predetermined sequence. In addition, at times, the particle generator associated with the PortaCount™ Pro+ did not provide sufficient particles for calibration, and the AeroFit® particle generator was used for both devices. While this allowed testing to continue, it may have influenced particle concentrations during sampling. Furthermore, fit testing was conducted by two investigators, which may have resulted in minor differences in how testing instructions were delivered to participants.

Additionally, some participants had facial hair, specifically mustaches or facial features that may have affected respirator seal quality, and variation in age may have contributed to differences in fit factor values, even when overall pass criteria were met. Participation in the study was voluntary, and some firefighters chose not to participate, which may have reduced the overall sample size. In addition, not all participants completed every post-test questionnaire item, resulting in incomplete data for certain user experience measures.

Lastly, a major limitation of this study was that all participants were active-duty firefighters. While this population represents an important occupational group who engage in routine respirator use, their familiarity with fit-testing procedures and respirator donning may have influenced study outcomes. This experience could contribute to more consistent pass and fail results compared to populations with less exposure to fit testing. As a result, the findings may not be fully generalizable to other worker populations, such as healthcare or industrial workers.

Despite these limitations, the study provides meaningful insight into differences in fit factor magnitude, pass/fail agreement, testing efficiency, and user experience between fit-testing devices when evaluated under realistic occupational conditions.

CHAPTER 7: CONCLUSION AND FUTURE WORK

Recommendations for Future Research

Future research should expand on the findings of this study by addressing several identified limitations and exploring additional factors that may influence respirator fit-testing outcomes. Repeating testing time measurements across all participants would allow for a more robust statistical comparison of testing efficiency between devices. Specifically, by recording start and end times for each fit-testing exercise across multiple participants, researchers could determine whether observed differences in testing duration are consistent across users and devices. Incorporating device-generated timestamps or standardized timing protocols would allow for more accurate comparisons of testing efficiency. Future studies should also consider utilizing the PortaCount™ Pro+ Fast Fit protocol to allow for a more comparable assessment of testing duration and efficiency between devices, as differences in exercise structure and protocol length may influence observed testing times.

Additional studies should also evaluate multiple respirator models and sizes, as this study was limited to a single full-facepiece respirator. Expanding the participant population beyond firefighters and including other occupational groups may provide insight into whether similar results would be observed in other occupational settings. Further investigation into the effects of participant characteristics, such as age, facial features, and facial hair, on fit factor variability may also provide valuable insight (CDC, 2025).

Moreover, future research could explore whether differences in fit factor values above the OSHA pass criterion of 500 translate to meaningful differences in respiratory protection. Current fit-testing standards are based on pass and fail outcomes, and there is limited information on

whether or not higher fit factor values provide added protection in real-world occupational settings. Examining this relationship could help clarify how fit factor magnitude should be interpreted beyond meeting regulatory requirements and whether it should play a role in device selection or general fit-testing practices.

Additionally, future work could examine user experience more comprehensively by refining survey instruments and ensuring consistent response completion. Studies that evaluate device preference and usability across repeated annual fit tests may help determine whether initial preferences persist over time. Finally, evaluating additional fit-testing devices under standardized conditions would further inform device selection decisions in occupational health and safety programs.

Conclusion

This study compared quantitative fit-testing performance, pass/fail outcomes, testing efficiency, and user experience between the AeroFit® and the PortaCount™ Pro+ devices. While the two devices differed in the magnitude of reported fit factor values, both consistently met Occupational Safety and Health Administration pass criteria for full-facepiece respirators (OSHA, 29 CFR 1910.134). Equivalence testing demonstrated that the devices were not equivalent in terms of fit factor magnitude; however, these differences did not translate into differences in regulatory compliance decisions.

Pass and fail agreement between devices was high, reinforcing the importance of evaluating fit-testing results within established regulatory thresholds rather than relying solely on absolute fit factor values. Differences in testing duration were observed, with the AeroFit® requiring substantially less time to complete testing under the conditions evaluated. Although

timing data were limited, these findings suggest potential operational advantages that may be relevant in applied occupational settings.

User experience results indicated that both devices were rated highly for comfort during testing and clarity of fit-testing exercises. Participants more frequently perceived the AeroFit® as faster and preferred it over the PortaCount™ Pro+, reflecting practical aspects of the testing process rather than differences in compliance or accuracy. Overall, these findings show that evaluating respirator fit-testing devices should involve not only quantitative performance measures but also testing efficiency and user experience.

Overall, this study demonstrates that fit-testing devices may differ analytically while still producing consistent compliance outcomes. Evaluating fit-testing technologies across multiple dimensions, including performance, regulatory compliance, efficiency, and user experience, can support informed decision-making and effective implementation of respirator fit-testing programs in real-world occupational environments.

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APPENDIX A

MAJOR REQUIREMENTS OF OSHA'S RESPIRATORY PROTECTION STANDARD

CFR 1910.134

This document discusses the major requirements of OSHA's Respiratory Protection Standard, 29 CFR 1910.134.

No attempt has been made to discuss every detail of the standard. Readers are encouraged to consult OSHA's Respiratory Protection web page for the complete text.

MAJOR REQUIREMENTS OF 29 CFR 1910.134

Introduction

- This standard applies to General Industry (Part 1910), Shipyards (Part 1915), Marine Terminals (Part 1917), Longshoring (Part 1918), and Construction (Part 1926).

(a) Permissible Practice

- Paragraph (a)(1) establishes OSHA's **hierarchy of controls** by requiring the use of **feasible engineering controls** as the primary means to control air contaminants. Respirators are required when "effective engineering controls are not feasible, or while they are being instituted."

- Paragraph (a)(2) requires employers to provide employees with respirators that are "applicable and suitable" for the purpose intended "when such equipment is necessary to protect the health of the employee."

(b) Definitions

This paragraph contains definitions of important terms used in the regulatory text.

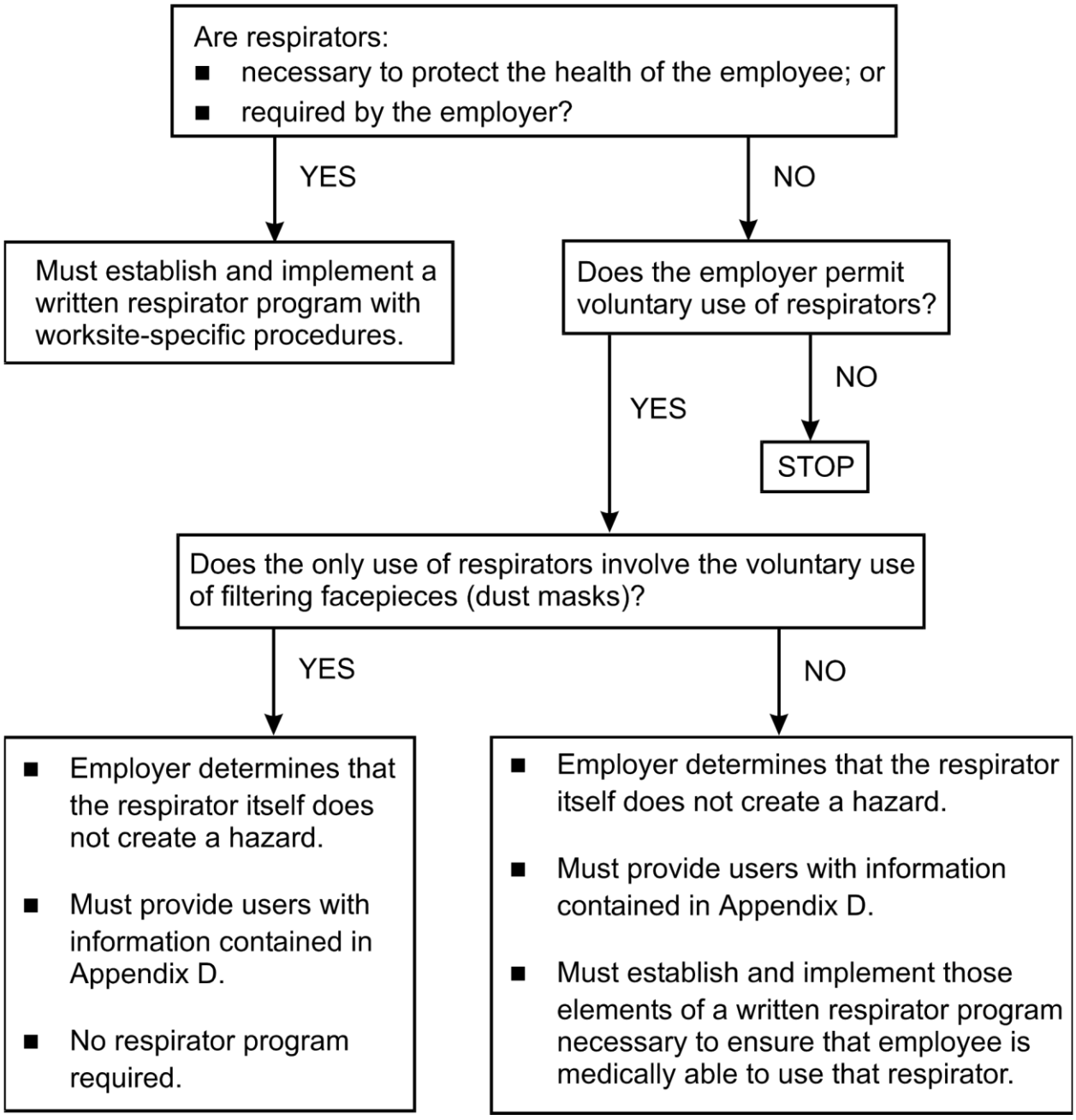
(c) Respiratory Protection Program

- Must designate a **qualified program administrator** to oversee the program.

- Must provide respirators, training, and medical evaluations **at no cost to the employee**.

- OSHA has prepared a *Small Entity Compliance Guide* that contains criteria for selection of a program administrator and a sample program.

Respirator-Use Requirements Flow Chart
29 CFR 1910.134(c)



(d) Selection of Respirators

④ Must select a respirator **certified by the National Institute for Occupational Safety and Health (NIOSH)** which must be used in compliance with the conditions of its certification.

④ Must identify and evaluate the respiratory hazards in the workplace, including a reasonable estimate of employee exposures and identification of the contaminant's chemical state and physical form.

- Where exposure cannot be identified or reasonably estimated, the atmosphere shall be considered immediately dangerous to life or health (IDLH).

- Respirators for IDLH atmospheres:
  - Approved respirators:
    - full facepiece pressure demand self-contained breathing apparatus (SCBA) certified by NIOSH for a minimum service life of thirty minutes, or
    - combination full facepiece pressure demand supplied-air respirator (SAR) with auxiliary self-contained air supply.
  - All **oxygen-deficient atmospheres (less than 19.5% O_2 by volume)** shall be considered IDLH.
    Exception: If the employer can demonstrate that, under all foreseeable conditions, oxygen levels in the work area can be maintained within the ranges specified in Table II (i.e., between 19.5% and a lower value that corresponds to an altitude-adjusted oxygen partial pressure equivalent to 16% oxygen at sea level), then *any* atmosphere supplying respirator may be used.

- Respirators for non-IDLH atmospheres:
  - Employers must use the **assigned protection factors (APFs)** listed in Table 1 to select a respirator that meets or exceeds the required level of employee protection.
    - When using a combination respirator (e.g., airline respirators with an air purifying filter), employers must ensure that the assigned protection factor is appropriate to the mode of operation in which the respirator is being used.
  - Must select a respirator for employee use that maintains the employee's exposure to the hazardous substance, when measured outside the respirator, at or below the **maximum use concentration (MUC)**.
    - Must not apply MUCs to conditions that are IDLH; instead must use respirators listed for IDLH conditions in paragraph (d)(2) of this standard.
    - When the calculated MUC exceeds the IDLH level or the performance limits of the cartridge or canister, then employers must set the maximum MUC at that lower limit.
    - The respirator selected shall be appropriate for the chemical state and physical form of the contaminant.

  - For protection against gases and vapors, the employer shall provide:
    - an atmosphere-supplying respirator, or
    - an air-purifying respirator, provided that:
      - the respirator is equipped with an **end-of-service-life indicator (ESLI)** certified by NIOSH for the contaminant; or
      - if there is no ESLI appropriate for conditions of the employer's workplace, the employer implements a **change schedule** for canisters and cartridges that will ensure that they are changed before the end of their service life and

describes in the respirator program the information and data relied upon and basis for the change schedule and reliance on the data.

- For protection against particulates, the employer shall provide:
  - an atmosphere-supplying respirator; or
  - an air-purifying respirator equipped with high efficiency particulate air (HEPA) filters certified by NIOSH under 30 CFR Part 11 or with filters certified for particulates under 42 CFR Part 84; or
  - an air-purifying respirator equipped with any filter certified for particulates by NIOSH for contaminants consisting primarily of particles with mass median aerodynamic diameters of at least 2 micrometers.

(e) Medical Evaluation

- Must provide a medical evaluation to determine employee's ability to use a respirator, **before fit testing and use**.

- Must identify a **physician or other licensed health care professional (PLHCP)** to perform medical evaluations using a medical questionnaire or an initial medical examination that obtains the same information as the medical questionnaire (information required is contained in mandatory Appendix C).

- Must obtain a **written recommendation** regarding the employee's ability to use the respirator from the PLHCP.

- Additional medical evaluations are required under certain circumstances, e.g.:
  - employee reports medical signs or symptoms related to ability to use respirator;
  - PLHCP, program administrator, or supervisor recommends reevaluation;
  - information from the respirator program, including observations made during fit testing and program evaluation, indicates a need; or
  - change occurs in workplace conditions that may substantially increase the physiological burden on an employee.

- Annual review of medical status is not required.

(f) Fit Testing

- All employees using a **negative or positive pressure tight-fitting facepiece** respirator must pass an appropriate **qualitative fit test (QLFT**) or **quantitative fit test (QNFT).**

- Fit testing is required prior to initial use, whenever a different respirator facepiece is used, and **at least annually thereafter**. An additional fit test is required whenever the employee reports, or the employer or PLHCP makes visual observations of, changes in the employee's physical condition that could affect respirator fit (e.g., facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight).

- The fit test shall be administered using an OSHA-accepted QLFT or QNFT protocol, as contained in mandatory Appendix A. QLFT Protocols: • Isoamyl acetate
  - Saccharin
  - Bitrex
  - Irritant smoke

  QNFT Protocols: • Generated Aerosol (corn oil, salt, DEHP)

  - Condensation Nuclei Counter (PortaCount)

- Controlled Negative Pressure (Dynatech FitTester 3000)
- Controlled Negative Pressure (CNP) REDON

④ QLFT may only be used to fit test negative pressure air-purifying respirators (APRs) that must achieve a fit factor of 100 or less.

④ If the fit factor determined through QNFT is ≥100 for tight-fitting half facepieces, or ≥500 for tight-fitting full facepieces, the QNFT has been passed with that respirator.

Note: If a particular OSHA standard (e.g., 29 CFR 1910.1001 Asbestos) requires the use of a full facepiece APR capable of providing protection in concentrations up to 50 times the Permissible Exposure Limit (PEL), this respirator must be QNFT. This is because a protection factor of 50 (50 X PEL) multiplied by a standard safety factor of 10 is equivalent to a fit factor of 500.

The safety factor of 10 is used because protection factors in the workplace tend to be much lower than the fit factors achieved during fit testing. The use of a safety factor is a standard practice supported by most experts to offset this limitation. This is discussed in the record at 63 FR 1225.

(g) Use of Respirators

④ Tight-fitting respirators shall not be worn by employees who have facial hair or any condition that interferes with the face-to-facepiece seal or valve function.

④ Personal protective equipment shall be worn in such a manner that does not interfere with the seal of the facepiece to the face of the user.

④ Employees shall perform a user seal check **each time they put on a tight-fitting respirator** using the procedures in mandatory Appendix B-1 or equally effective manufacturer's procedures.

④ Procedures for respirator use in IDLH atmospheres are stated. In addition to these requirements, interior structural firefighting requires the use of SCBAs and a protective practice known as "2-in/2-out" — at least two employees must enter and remain in visual or voice contact with one another at all times, and at least two employees must be located outside. (Note that this is not meant to preclude firefighters from performing emergency rescue activities before an entire team has assembled.)

(h) Maintenance and Care of Respirators

Must clean and disinfect respirators using the procedures in Appendix B-2, or equally effective manufacturer's procedures at the following intervals:

- as often as necessary to maintain a sanitary condition for exclusive use respirators,
- before being worn by different individuals when issued to more than one employee, and
- after each use for emergency use respirators **and those used in fit testing and training**.

(i) Breathing Air Quality and Use

Compressed breathing air shall meet the requirements for Type 1-Grade D breathing air as described in ANSI/CGA *Commodity Specification for Air*, G-7.1-1989.

(j) Identification of Filters, Cartridges, and Canisters

- All filters, cartridges, and canisters used in the workplace must be labeled and color coded with the NIOSH approval label.
- The label must not be removed and must remain legible.

(k) Training and Information

- Must provide effective training to respirator users, including:
  - why the respirator is necessary and how improper fit, use, or maintenance can compromise the protective effect of the respirator
  - limitations and capabilities of the respirator
  - use in emergency situations
  - how to inspect, put on and remove, use and check the seals
  - procedures for maintenance and storage
  - recognition of medical signs and symptoms that may limit or prevent effective use
  - general requirements of this standard
- Training required prior to initial use, unless acceptable training has been provided by another employer within the past 12 months.
- **Retraining required annually** and when:

- workplace conditions change,
- new types of respirator are used, or
- inadequacies in the employee's knowledge or use indicates need.

④ The basic advisory information in Appendix D shall be provided to employees who wear respirators when their use is not required.

(l) Program Evaluation

Employer must conduct evaluations of the workplace as necessary to ensure proper implementation of the program, and consult with employees to ensure proper use.

(m) Recordkeeping

④ Records of medical evaluations must be retained and made available per 29 CFR 1910.1020.

④ A record of fit tests must be established and retained until the next fit test.

④ A written copy of the current program must be retained.

Evaluation of the QuantiFit2 and AeroFit Respirator Fit-Testing Devices

Screening Questionnaire

Study Title: *Evaluation of the QuantiFit2 and AeroFit Respirator Fit-Testing Devices*
Principal Investigator: William Brazile
Participant ID (Study Code): _____

Instructions: Please answer the following questions honestly and to the best of your knowledge. Your responses will help determine your eligibility for participation in the study.

SECTION 1: ELIGIBILITY

1. **Are you currently an active-duty firefighter?**
   ☐ Yes ☐ No
2. **Are you 18 years of age or older?**
   ☐ Yes ☐ No
3. **Have you been medically cleared by your employer to wear respiratory protection?**
   ☐ Yes ☐ No ☐ Unsure
4. **Are you required to undergo an annual respirator fit test as part of your job duties?**
   ☐ Yes ☐ No
5. **Do you currently have any facial hair that may interfere with the sealing surface of a respirator (e.g., beard, stubble)?**
   ☐ Yes ☐ No
6. **Are you currently experiencing any of the following symptoms?** *(Check all that apply)*
   ☐ Cough ☐ Shortness of breath ☐ Congestion
   ☐ Runny nose ☐ Sore throat ☐ None of the above
7. **Do you have any visible facial scars, conditions, or injuries that could affect respirator seal?**
   ☐ Yes ☐ No
8. **Are you physically able and willing to:**
   - Wear a respirator for approximately 30 minutes?
     ☐ Yes ☐ No
   - Perform light physical movements (e.g., head movements, bending)?
     ☐ Yes ☐ No
   - Briefly hold your breath (up to 8 seconds) during fit testing?
     ☐ Yes ☐ No
9. **Have you experienced dizziness, anxiety, or shortness of breath during previous respirator fit tests?**
   ☐ Yes ☐ No ☐ Not applicable / never been fit tested

SECTION 2: CONSENT & AVAILABILITY

10. **Are you willing and able to provide written informed consent to participate in this research study?**
    ☐ Yes ☐ No
11. **Do you understand that participation is voluntary and that you can withdraw at any time without any consequences?**
    ☐ Yes ☐ No
12. **Are you available to complete a 30–45 minute session at your fire station during the study period (October 2025)?**
    ☐ Yes ☐ No ☐ Not sure

SECTION 3: INVESTIGATOR USE ONLY

- **Screening Outcome**:
  ☐ Eligible ☐ Not Eligible ☐ Requires Follow-Up
- **Notes**:

- **Reviewed by (Initials / Date)**: _____

APPENDIX B

Evaluation of the QuantiFit2 and AeroFit Respirator Fit-Testing Devices

Post Fit-Testing Questionnaire

Study Title: *Evaluation of the QuantiFit2 and AeroFit Respirator Fit-Testing Devices*
Participant Study Code: _____
Date: _____

Instructions: Please complete the following questions after completing all three respirator fit tests. Your responses will help us understand your comfort, experience, and preferences with each device.

SECTION 1: COMFORT AND USABILITY

Please rate your level of agreement with the following statements for each device.
(1 = Strongly Disagree, 2 = Disagree, 3 = Don't Agree or Disagree (Neutral), 4 = Agree, 5 = Strongly Agree)

Statement	PortaCount+	QuantiFit2	AeroFit
The respirator had the same level of comfort before and during the fit test. .	1 - 5	1 - 5	1 - 5
The fit-testing exercises were clear and easy to follow.	1 - 5	1 - 5	1 - 5
I felt confident in the accuracy of the test results.	1 - 5	1 - 5	1 - 5
The device and/or exercises made breathing more difficult during testing.	1 - 5	1 - 5	1 - 5
The device and/or exercises made the respirator more uncomfortable during this test.	1 - 5	1 - 5	1 - 5
I felt comfortable during the fit-testing.			

SECTION 2: PERCEPTION OF TEST DURATION

1. **Which device took the longest time to complete?**
   ☐ PortaCount+ ☐ QuantiFit2 ☐ AeroFit ☐ Not Sure

2. **Which device felt the fastest or most efficient to complete?**
   ☐ PortaCount+ ☐ QuantiFit2 ☐ AeroFit ☐ Not Sure

SECTION 3: DEVICE PREFERENCE

3. **If you had to use one of these devices for your next annual fit test, which would you choose?**
   ☐ PortaCount+ ☐ QuantiFit2 ☐ AeroFit ☐ No Preference

4. **Why did you select this device?**

   _____

   _____

SECTION 4: GENERAL FEEDBACK

5. **Did you experience any discomfort, anxiety, or difficulty during any of the tests?**
   ☐ Yes ☐ No
   If yes, please describe:

   _____

6. **Do you have any comments, concerns, or suggestions for improving the respirator fit testing process?**

   _____

   _____

Thank you for your participation! Your feedback is valuable to the success of this research.