THESIS

EVALUATION OF THE QUANTIFIT2™ COMPARED TO THE PORTACOUNT™ PRO+ FOR RESPIRATOR FIT TESTING IN A FIREFIGHTER POPULATION: A PERFORMANCE AND USER PREFERENCE STUDY

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In partial fulfillment of the requirements

For the Degree of Master of Science

Colorado State University

Fort Collins, Colorado

Summer 2026

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ABSTRACT

EVALUATION OF THE QUANTIFIT2™ COMPARED TO THE PORTACOUNT™ PRO+ FOR RESPIRATOR FIT TESTING IN A FIREFIGHTER POPULATION: A PERFORMANCE AND USER PREFERENCE STUDY

Firefighters are routinely exposed to hazardous airborne contaminants and rely on tight-fitted self-contained breathing apparatus (SCBA) for respiratory protection. The effectiveness of these respirators depends on proper seal and fit, which are mandated for fit-testing annually under the Occupational Safety and Health Administration (OSHA) Standard 29 CFR 1910.134. Researchers have found that different fit-testing devices result in significantly different fit-testing results. Specifically, in a 2018 study, the author noted that fit factors were "not equal" and that the PortaCount™ Pro+ typically resulted in higher fit factor values (Wu 2018). The current study compared the performance and user preference of two OSHA-approved quantitative fit testing (QNFT) devices: the PortaCount™ Pro+, that uses condensation nuclei counting (CNC) technology, and the QuantiFit2™, which uses controlled negative pressure (CNP) technology, in a firefighter population.

Limited research exists comparing both technologies, even less related to firefighter populations. This study involved thirty-eight (38) active-duty firefighters from a northern Colorado fire department who were fit-tested on both devices during the same testing session using their personally-issued SCBA facepieces. Quantitative results, such as fit factors and pass/fail outcomes, were based on the OSHA minimum fit factor requirement of ≥ 500 for full-face

respirators. Qualitative results were collected via a post fit-test survey to evaluate metrics such as clarity of fit-testing instructions, comfort, perceived efficiency, and overall device preference.

Fit-testing pass rates did not differ significantly between the two devices ($P > 0.05$). Both devices yielded pass rates exceeding 94%, indicating comparable compliance performance. However, $\log_{10}$-transformed overall fit factors differed significantly between devices (paired t-test, $p < 0.001$). These discrepancies in fit factor values were interpreted as differences in measurement technology and reporting scales rather than regulatory performance equivalency. The linear association between fit factor values on both devices was analyzed using Pearson correlation analysis, which resulted in a slightly negative association. This means that a participant who scored high on the fit factor scale of one device, did not necessarily score high on the other device.

Analysis of qualitative data from the post fit-test survey supported that there was no significant difference in clarity of instructions or comfort ratings between the devices. However, in terms of overall preference based on device test duration, 47.4% (18/38) of participants selected other fit-testing devices, 34.2% (13/38) selected the QuantiFit2™, 13.2% (5/38) reported no preference, and 5.3% (2/38) selected the PortaCount™ Pro+ (binomial exact test, $p<0.05$).

It was concluded that both the QuantiFit2™ and the PortaCount™ Pro+ provided reliable and comparable pass/fail rates for regulatory compliance. It should be noted that the PortaCount™ Pro+ fit-testing procedure used in this study followed the standard OSHA ambient aerosol CNC protocol, requiring approximately 8 minutes. However, OSHA also recognizes a modified ambient aerosol (“fast fit”) protocol for CNC technology, which reduces test duration to 2.5 minutes (OSHA 2019). Given that perceived test duration was the primary factor influencing device preference among study subjects, use of the “fast fit” protocol may have affected the outcomes of this study.

ACKNOWLEDGMENTS

The author would like to express sincere appreciation to Dr. William Brazile for his guidance, support, and mentorship throughout this research. Appreciation is also extended to the committee members, Dr. Mike VanDyke, Professor Tiffany Lipsey, and Dr. Daniel Autenrieth, for their valuable feedback and contributions.

The author gratefully acknowledges the participating fire department and firefighters for their time, cooperation, and commitment to this study.

The author also acknowledges Colorado State University (CSU) for providing the resources and support necessary to complete this research, including access to the PortaCount™ Pro+ device. Finally, the author acknowledges Occupational Health Dynamics (OHD) for providing the QuantiFit2™ used in this research to CSU for educational purposes.

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1. INTRODUCTION

Firefighters are routinely exposed to combustion byproducts, particulate matter, toxic gases, and other airborne contaminants that pose significant risks to respiratory health. Researchers have demonstrated that repeated and continuous exposure to such contaminants is associated with acute and chronic respiratory effects on firefighters (Nicola Cherry, James Barrie, Jeremy Beach, Jean-Michel Galarneau, Trish Mhonde, Eric Wong 2021) (Joana Barbosa 2022). To mitigate these occupational hazards, employees in the fire service are mandated to use tight-fitting respirators.

The effectiveness of any respirator depends mainly on its ability to form a proper seal with the user's face. Due to the variation in facial anthropometrics, respirator users must undergo fit testing as mandated by the Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134, Respiratory Protection. OSHA requires individuals who are required to wear tight-fitting respirators to pass an annual fit test. Fit-testing is performed to ensure that respirators provide an adequate level of seal against hazardous airborne contaminants.

OSHA recognizes two methods for fit testing: qualitative fit testing (QLFT) and quantitative fit testing (QNFT). Qualitative fit testing determines mask leakages by relying on the user's sensory response; thus, it introduces the possibility of subject bias and variability (A. Regli 2021). In contrast, QNFT uses a fit-testing device to objectively measure face-mask leakages and calculates a "fit factor" that represents the effectiveness of the respirator seal.

According to the American National Standards Institute (ANSI) and the American Industrial Hygiene Association (AIHA) Standard ANSI/AIHA Z88.10-2010, a fit factor is a unitless number that expresses "how well a tight-fitting respirator fits a wearer during a quantitative fit test. It is the ratio of the measured challenge agent concentration outside the respirator (C_{out}) to its concentration inside the respirator" (ANSI/AIHA 2010). In general, higher

fit factor values represent a better seal and less leakage into the mask. QNFT devices are scientifically engineered to calculate fit factors and assign pass/fail and are generally preferred when evaluating full-face respirators including Self-Contained Breathing Apparatuses (SCBA).

The American National Standards Institute (ANSI) and the American Industrial Hygiene Association (AIHA) recognize multiple QNFT technologies in ANSI/AIHA Z88.10-2010, including condensation nuclei counting (CNC) and controlled negative pressure (CNP). The PortaCount™ Pro+ uses CNC technology, which measures aerosol concentrations inside and outside the facemask to calculate fit factor values. The PortaCount™ Pro+, and previous variations of this technology, are widely used, OSHA-accepted, and are considered the "gold standard" for quantitative fit testing benchmarking (Or P 2014) (A. Regli 2021).

Figure 1: PortaCount™ Pro+ Device (TSI 2015)

In contrast, the QuantiFit2™, the device evaluated in this research, uses a controlled negative pressure (CNP) technology to assess respirator seal integrity, rather than relying on ambient aerosol concentration. The CNP method does not require ambient particle levels or a

particle generator and uses shorter testing exercises; hence, fit-testing can be completed more efficiently in field or station environments where time and space are of normally of the essence (OHD, LLLP 2024).

Figure 2: QuantiFit2^{TM} Device (OHD, LLLP 2024)

Although there have been multiple studies evaluating QNFT device performance in healthcare and other industries, limited research has examined both device performance and user experience in firefighter populations using SCBA facepieces (Or P 2014) (A. Regli 2021). Firefighters operate in high physical and psychological stressful environments that may cause other issues such as fatigue and stress. Thus, it is critical to evaluate their respirator comfort to ensure full compliance and protection from airborne contaminants while on duty (Mari-Amanda Dyal 2021).

When comparing two respirator fit-testing devices, it is important to study both performance (fit factor and pass rate) and user experience. In this study, user experience was evaluated using metrics such as clarity of instructions, perceived comfort, efficiency (defined in this study as the overall time to complete the fit-testing procedure), and device preference. These

factors are often overlooked; yet they may substantially influence user acceptance, respiratory protection programs compliance, and success.

The purpose of the current study was to compare the performance and user experience of two respirator fit-testing devices: QuantiFit2™ and PortaCount™ Pro+ in a firefighter population. The study included a sample of 38 firefighters (n=38) from a northern Colorado fire department. The researchers aimed to: (1) compare quantitative outcomes obtained from each fit-testing device such as fit factors and pass rates, and (2) compare qualitative feedback from the participants including clarity of instructions, perceived comfort, efficiency, and overall preference. The current study results will allow researchers to determine whether the QuantiFit2™ (CNP-based) is indeed a reliable and accurate fit-testing device alternative for fire departments.

2. LITERATURE REVIEW

2.1. Overview of Respirator Fit-Testing

Respiratory protective devices are life-saving equipment meant to safeguard workers from hazardous airborne contaminants, especially in high-risk occupations such as firefighting. Firefighters have been recognized by the Centers for Disease Control and Prevention (CDC) to be exposed to a "variety of toxic, irritating, and carcinogenic compounds in the by-products of combustion and other chemicals encountered while on the fire scene" (Xiaodan Xu 2023) (A. Regli 2021). Because a respirator's protective capability depends on achieving and maintaining a tight seal on the user's face, fit-testing is essential to verify that seal for each user.

Under the Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134, fitting masks of any variety must undergo annual fit-testing. According to this standard, employees "using a tight-fitting facepiece respirator is fit tested prior to initial use of the respirator, whenever a different respirator facepiece (size, style, model or mask) is used, and at least annually thereafter" (OSHA, 29 CFR 1910.134). The success of fit-testing is directly related to the proper respirator selection and seal. Fit testing is critical in determining if a respirator meets the intended assigned protection factor (APF) (Xiaodan Xu 2023). The APF is a numerical value set by OSHA that represents the level of protection of a respirator, or class of respirators, that is expected to be provided to the wearers (OSHA 2009). For example, a tight-fitting full-face respirator has an APF of 50.

2.2. Qualitative Fit-Testing (QLFT) vs. Quantitative Fit-Testing (QNFT)

OSHA recognizes two main methods for fit-testing: qualitative fit-testing (QLFT) and quantitative fit-testing (QNFT). The key differences between the two fit-testing methods are summarized in Table 1.

Table 1. Comparison of QLFT and QNFT Methods

Method	Description	Advantage	Limitation
QLFT	Pass/fail test based on the user's sensory response of a test agent.	Requires less instrumentation.	Subjective, human bias, cannot be used for all respirators.
QNFT	Objective measurement of leakage (fit factor) based on an instrument reading.	Objective, accurate, reliable, provides a numeric fit factor.	Requires special equipment, expensive.

*Information in Table 1 is adapted from OSHA (29 CFR 1910.134) and ANSI/AIHA Z88.10-2010. QLFT = qualitative fit test, QNFT = quantitative fit test.

Qualitative fit-testing relies solely on the user's sensory detection of a testing agent and provides only a pass or fail outcome. This reliance on subjective perception introduces potential bias and variability into the fit-testing process (A. Regli 2021). The quantitative fit-testing method, in contrast, uses a testing device to objectively measure air leakage into the facepiece, via particle counting or pressure, and calculates a numerical fit factor. ANSI/AIHA Z88.10-2010 recognizes multiple QNFT technologies including condensation nuclei counting (CNC) and controlled negative pressure (CNP). Although they differ in measurement technology, both are accepted by OSHA (ANSI/AIHA 2010).

According to ANSI/AIHA Z88.10-2010, the fit factor can be mathematically expressed as: fit factor = C_{out}/C_{in}, and interpreted as the concentration outside the respirator divided by the concentration inside the respirator (ANSI/AIHA 2010). A better seal translates to less leakage; thus, the seal can be accurately quantified by a higher fit factor. In the fire service, QNFT is generally preferred for SCBA use due to its objectivity and higher assigned protection factors (ANSI/AIHA 2010) (OSHA 2024). This was supported by early regulatory guidance where

firefighters were expected to use SCBAs in structural firefighting and immediately dangerous to life or health (IDLH) environments (Jr. 1999).

2.3. PortaCount™ Pro+

The PortaCount™ Pro+ uses condensation nuclei counting (CNC) technology to measure particle concentration inside and outside the respirator. The device then calculates a fit factor that represents the respirator's level of protection. The PortaCount™ Pro+ is widely recognized, due to its compatibility with most respirator types, thoroughly validated in literature across various industries, and regarded as the "gold standard" for QNFT (Or P 2014) (A. Regli 2021).

Despite its global recognition, the PortaCount™ Pro+ has some limitations. The PortaCount™ Pro+ requires a minimum aerosol concentration in the testing environment to start the test. If "the minimum ambient particle concentration needed for the PortaCount™ Pro+ fit tester to do a fit test" is not achieved, the "particle generator supplements naturally occurring room concentration with non-toxic salt (NaCl)" (TSI 2015). Additionally, the standard PortaCount™ Pro+ testing protocol involves relatively time-consuming exercises. According to OSHA and the PortaCount™ Pro+ testing protocol, seven (7) exercises are required to be completed on the PortaCount™ Pro+ to comply with the QNFT requirements, with each exercise lasting 60 seconds excluding setup, donning, doffing, and administrative procedures (OSHA 2024). OSHA also recognizes modified ambient aerosol CNC fit-testing protocol ("fast fit"), which includes only three of the seven standard fit-test exercises reducing test duration to 2.5 minutes (OSHA 2019). However, the PortaCount™ Pro+ used in this study followed the standard ambient aerosol CNC protocol.

Figure 3: TSI Particle Generator (Supplemental to PortaCount™ Devices) (TSI 2015)

2.4. QuantiFit2™

The QuantiFit2™ uses a different testing method that involves Controlled Negative Pressure (CNP) technology. Instead of measuring particle concentrations, QuantiFit2™ "functions by creating and maintaining a negative pressure in the respirator. Once the adapter valve is closed, sealing the respirator, the QuantiFit2™ removes air from the respirator until the challenge pressure is reached" (OHD, LLLP 2024). Thus, measuring the rate of air leakage and seal integrity in eight (8) seconds per exercise, for five (5) exercises total, without requiring a specific ambient aerosol concentration (OHD, LLLP 2024).

The QuantiFit2™ uses a Respirator Evaluation Determined by Objective Negative Pressure (REDON) protocol, which involves multiple donnings and doffings of the respirator. The protocol was designed to mimic real-life occupational situations, particularly firefighting. According to the QuantiFit2™ manual, a standard fit-test can be completed in less than five

minutes, which may offer operational advantages compared to PortaCount™ Pro+ (OHD, LLLP 2024).

As displayed in Figure 4, the QuantiFit2™ is set up to test in a closed circuit to ensure a constant negative pressure within the respirator mask.

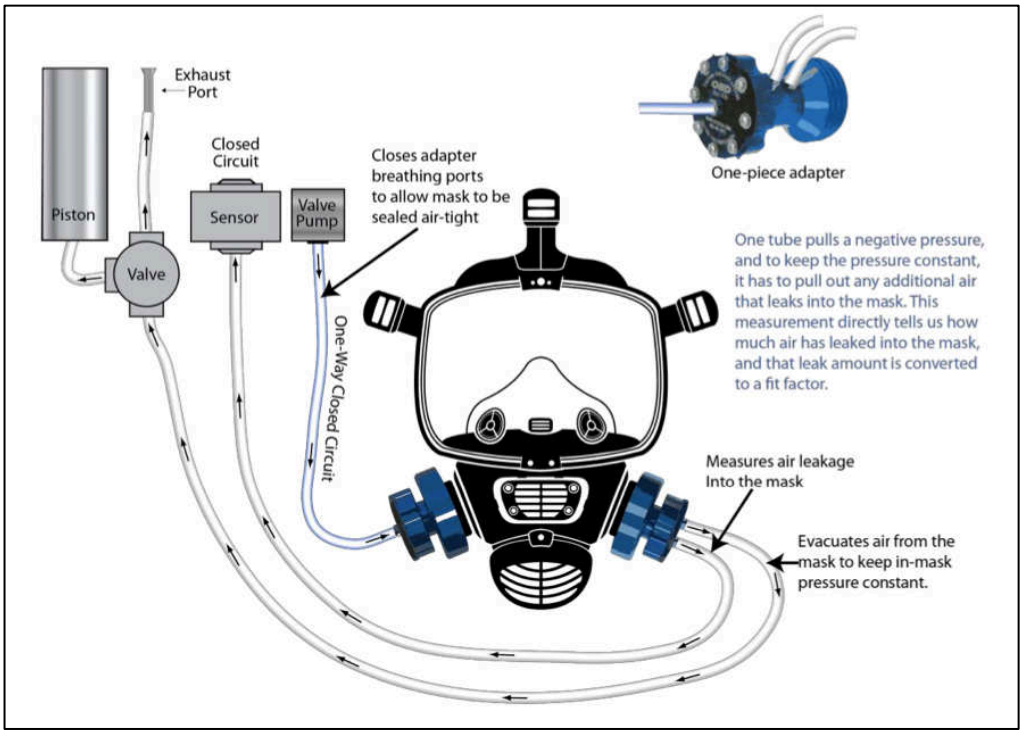

Figure 4: Overview of QuantiFit2™ Setup and Components (OHD, LLLP 2024)

A side-by-side comparison of the key features of PortaCount™ Pro+ vs. QuantiFit2™ is listed in Table 2.

Table 2. Key Features of PortaCount™ Pro+ vs. QuantiFit2™

Feature	PortaCount™ Pro+	QuantiFit2™
Recognized by OSHA	Yes	Yes
Technology	CNC	CNP

Output	Numerical Fit Factor (overall and exercise-specific) & Pass or Fail	Numerical Fit Factor (overall and exercise-specific) & Pass or Fail
Minimum Active Test Time	Appox. 8 minutes	<5 minutes
SCBA Compatibility	Yes	Yes
Primary Measurement Principle	Aerosol particle counting	Pressure decay (leak rate)
Ambient Aerosols Requirement	Yes (may require a particle generator)	No
Environmental Sensitivity (Field Portability)	Affected by low background particle concentration	Not affected by ambient particle concentration

*Information on Table 2 has been adapted from ANSI/AIHA Z88.10-2010, OSHA 29 CFR 1910.134, PortaCount™ Pro+ Manual, TSI, and QuantiFit2™ Manual, OHD (ANSI/AIHA 2010) (OSHA 2024) (TSI 2015) (OHD, LLLP 2024). OSHA = Occupational Safety and Health Administration, CNC = Condensation Nuclei Counting, CNP = Controlled Negative Pressure, SCBA = Self-Contained Breathing Apparatuses.

The two major distinctions that can be derived from Table 2 are that: (1) fit-testing on QuantiFit2™ generally requires less time compared to the PortaCount™ Pro+'s standard fit-testing procedure, and (2) unlike PortaCount™ Pro+, the QuantiFit2™ does not require an ambient aerosol, which is critical for firefighters when conducting fit-testing in uncontrolled environments.

2.5. Prior Fit-Testing Comparison Studies

Since the COVID-19 pandemic, researchers have primarily focused on studying respirator fit-testing in the healthcare industry using the N95 respirator, a filtering facepiece respirator (A. Regli 2021). However, firefighters rely on elastomeric full-face SCBA facepieces that require a

minimum fit factor of 500, which differ significantly in design and sealing mechanics compared to disposable N95 respirators, that require a fit factor of 100, used in healthcare (ANSI/AIHA 2010) (OSHA 2024). Firefighters also operate in high-stress environments, physically and psychologically, which have been proven to be associated with an increase in occupational stress and fatigue, and a decrease in respiratory function (A. Regli 2021). As a result, findings from healthcare-based studies may not be directly generalizable to firefighter populations or other populations that use elastomeric, full-facepiece masks.

Several studies have compared QNFT devices to evaluate agreement between fit-testing technologies. In a 2022 study comparing two QNFT devices, the authors evaluated fit factor values obtained from the PortaCount™ Pro+ and another aerosol-based device (MT-05U) across multiple respirator types (half and full-facepiece respirators). The authors reported that fit factor magnitudes differed substantially between devices due to differences in particle-counting methodologies. However, pass/fail rates were consistent between the two devices (Don-Hee Han 2022). These findings emphasize that absolute fit factor values commonly vary between fit-testing devices while still result in comparable pass/fail rates.

Similarly, another comparison study conducted in 2010 comparing three commercially available fit-testing devices highlighted that fit factor values varied between different technologies, even when respirator type, user, and testing conditions were constant. The authors noted that differences in fit factor values were due to the variability in measurement principles and testing procedures (Larry Janssen 2010). These findings reinforce the importance of focusing on pass/fail results and device practicality rather than focusing solely on absolute fit factor values when comparing technologies.

In a 2023 study comparing CNC and CNP methodologies, the authors noted that CNC was "more practical and comprehensive" due to the high failure rates related to CNP's breath-holding exercises (Xiaodan Xu 2023). Specifically, the researchers compared QuantiFit™ (different from QuantiFit2™) to the PortaCount™ Pro+ and were focused on fit-testing using half mask and full mask respirators.

In a 1997 study, researchers compared leak detection performance in CNC compared to CNP technology-based fit-testing devices. In a laboratory setting, CNP has demonstrated approximately 98% of known leakage and was not affected by leak location; whereas CNC detected only 37% of known introduced leakage and was significantly influenced by leak location (Clifton Crutchfield 1997).

Prior fit-testing comparison studies highlight that differences in technology and measurement principles can lead to significant differences in fit factor values while still producing comparable pass/fail rates. However, given the paucity of fire service respirator fit-testing studies using new technologies, additional research is necessary to determine whether newer technologies, such as QuantiFit2™, perform comparably to the widely recognized PortaCount™ Pro+.

2.6. Device Practicality and User Preference

In addition to technical performance, user experience and preference are crucial factors in successfully implementing respiratory protection programs. Parameters such as comfort, clarity of instructions, efficiency (test duration), and perceived practicality must be taken into consideration as they can significantly influence program compliance. According to a study conducted by Balkhyour (2013), "fit test exercises can be costly, sometimes taking up to 75 min to complete, during which time an employee is away from the job" (Balkhyour 2013). The authors of

ANSI/AIHA Z88.10-2010 also note that complex or uncomfortable procedures can negatively affect compliance with respiratory protection programs (ANSI/AIHA 2010).

In fire departments, where time and operational efficiency are vital, selecting a fit-testing device that meets performance, efficiency, and user preference may improve participation and overall program success. Therefore, it is necessary to evaluate both quantitative performance outcomes (pass/fail rates and fit factors) and quantitative user experience outcomes when comparing fit-testing devices.

2.7. Summary

While the PortaCount™ Pro+ has been extensively validated and regarded as the benchmark fit-testing device, newer alternatives such as QuantiFit2™ may carry operational advantages worthy of evaluation. In areas of research involving SCBA facepieces and qualitative user experience data, firefighter-specific studies are few. Therefore, the researchers designed the current study to bridge the gap by comparing both performance and user preference of the QuantiFit2™ and PortaCount™ Pro+ in a real-life firefighter population.

3. PURPOSE AND SCOPE

3.1. Purpose

The purpose of this research was to compare the performance and user preference of two quantitative fit-testing devices: QuantiFit2™ and PortaCount™ Pro+. Both fit-testing devices are compatible with the personally-issued SCBA facepieces used in the firefighting population.

The research was designed to address a gap in the literature, namely the comparison of fit-testing devices for elastomeric respirators, as most previous researchers have focused primarily on healthcare applications with the fit of N95 respirators. Limited research has evaluated both performance and user experience of fit-testing technologies in firefighting settings using SCBA facepieces.

Specifically, researchers designed the current study to evaluate whether the QuantiFit2™, which uses CNP technology and a REDON procedure, is a viable and accurate alternative to PortaCount™ Pro+, which uses CNC technology and is widely recognized as the benchmarking device for QNFT.

3.2. Scope

This research included 38 firefighters from a northern Colorado fire department. All participants used their personally-issued SCBA facepieces and had prior experience with respirator fit testing annually as required by OSHA. Data collection was conducted over four testing days, during which a total of 12 fire stations were visited.

During each testing session, each participant underwent fit testing on both the QuantiFit2™ and PortaCount™ Pro+ devices. The order of the devices was randomized to minimize potential bias. Both quantitative and qualitative data were collected. Quantitative data included fit factors

and pass/fail results. Qualitative data were collected via a post-test survey and focused on assessing comfort, clarity of instructions, efficiency (test duration), and overall device preference.

3.3. Hypothesis and Research Questions

The following three research questions and hypotheses were used to guide this research:

1. In the firefighter study population, is there a significant difference in pass rates between the QuantiFit2™ and PortaCount™ Pro+ devices?
    - H01: There is no significant difference in pass rates between the two fit-testing devices.
    - HA1: There is a significant difference in pass rates between the two fit-testing devices.
2. In the firefighter study population, is there a significant difference in fit-test results (fit factors) between the QuantiFit2™ and PortaCount™ Pro+ devices?
    - H02: There is no significant difference in fit factors between the two fit-testing devices.
    - HA2: There is a significant difference in fit factors between the two fit-testing devices.
3. Do the firefighter study subjects prefer one fit-testing device over another?
    - H03: There is no significant difference in firefighter preference between the QuantiFit2™ and PortaCount™ Pro+.
    - HA3: There is a significant difference in firefighter preference between the QuantiFit2™ and PortaCount™ Pro+.

These hypotheses and research questions allow for a comprehensive evaluation of devices, quantitatively and qualitatively. At the end of this study, researchers are expected to answer whether the QuantiFit2™ is a viable and accurate alternative to the current gold standard, PortaCount™ Pro+.

4. METHODS AND MATERIALS

4.1. Study Design

The researchers of the current study employed a randomized, paired-subject design to compare the performance and user preference of the QuantiFit2™ and PortaCount™ Pro+. Both quantitative (fit factor, pass/fail outcomes) and qualitative data were collected. Qualitative data were collected via a post-test survey (Appendix A), which assessed comfort, clarity of instructions, perceived efficiency (test duration) and overall device preference. Each participant completed quantitative fit-testing using both devices during the same fit-testing session using their personally-issued SCBA facepiece.

4.2. Site Selection

The study was conducted at several fire stations all under the jurisdiction of a Northern Colorado fire department due to its operational relevance, accessibility to the researchers, and availability of a sufficient number of participants meeting the inclusion criteria. Each fire station provided the required facilities and space for fit-testing using both devices.

4.3. Participants Recruitment

All aspects of the current study were performed in accordance with a human subjects study protocol approved by the researchers' Institutional Review Board (IRB#6699). Researchers solicited collaboration with the Fire Chief to explain the study objectives and eligibility requirements. A Recruitment Information Sheet (RIS) detailing the study purpose, procedures, risks, benefits, and confidentiality measures was distributed to firefighters at the fire stations.

A sample size calculation was conducted, based on previous research, to determine a minimum required sample of 34 participants for this study. However, a total of 38 participants were ultimately recruited, all of whom were issued and used SCBA facepieces as part of their job duties. Inclusion criteria included: (1) active-duty firefighter, (2) eighteen (18) years of age or older, (3) no interfering facial hair, and (4) medically cleared to wear a SCBA. Exclusion criteria include: (1) facial hair interfering with respirator seal, (2) existing respiratory medical condition, or (3) less than eighteen (18) years of age. Participation was voluntary and an informed consent was shared and signed by participants before any data collection.

4.4. Instruments and Equipment

Two QNFT devices were used in this research: PortaCount™ Pro+ [Thermo Systems Incorporated (TSI), Minnesota, USA, Serial number 8038144007] and QuantiFit2™ [Occupational Health Dynamics (OHD), Alabama, USA, serial number 86112754].

Each device was within factory calibration and verified daily per manufacturer's instructions before testing. Participants were asked to use their personally issued SCBA facepieces, which were connected to the fit-testing devices via an adapter and sampling probes provided by devices manufacturers.

4.5. Procedures

Informed consent was obtained from each participant prior to fit-testing (Appendix B), and then each subject was asked to complete a pre-test screening form (Appendix C). Following OSHA and the fit-testing device manufacturers' guidance, participants were instructed to avoid eating, drinking, chewing gum, or smoking at least 30 minutes before fit-testing to ensure consistent pre-

test conditions. Each eligible participant was then fit-tested individually, in a dedicated testing room, on both fit-testing devices using their personally issued SCBA facepiece. The order of fit-testing device (PortaCount™ Pro+ and QuantiFit2™) was randomized for each participant to minimize potential order effects. Randomization was achieved by assigning participants to one of two testing sequences (PortaCount™ Pro+ first or QuantiFit2™ first).

Daily verification tests were conducted on each fit-testing device to ensure proper device-operation prior to testing. Participants were instructed to perform the required fit-testing exercises for each device according to the procedures listed in the following sections. The automated daily verification tests confirmed that the devices are operating within acceptable performance limits, including checks for internal leaks, flow rate, pressure, and other system diagnostics.

4.5.1. Fit Testing with PortaCount™ Pro+

Participants donned their SCBA facepiece and the proper fit was verified by the researchers. The respirator was then attached to the PortaCount™ Pro+ via Tygon® tubing. Participants were allowed at least five minutes to assess comfort before starting the test.

Each participant performed a series of exercises while wearing the respirator following the standard OSHA ambient aerosol CNC fit-testing protocol (OSHA 2024). Each of the seven exercises required at least 60 seconds, including:

1. Normal breathing
2. Deep breathing
3. Head movements – side to side
4. Head movements – up and down
5. Talking

6. Bending over
7. Normal breathing

The PortaCount™ Pro+ issued a pass or fail for each subject's fit-test and calculated both an overall fit factor and exercise-specific fit factor.

4.5.2. Fit Testing with QuantiFit2™

Participants donned the respirator and the proper fit was verified by the researchers. The respirator was connected to the QuantiFit2™ device via a manufacturer-provided adapter and sampling probes. Fit-testing was performed following the CNP REDON protocol (OHD, LLLP 2024). Each of the five exercises required at least 8 seconds, including:

1. Faced forward and held breath
2. Bent over and held breath
3. Shook head side to side, then held breath
4. Re-don 1: Removed mask completely and redonned; faced forward and held breath
5. Re-don 2: Removed mask completely and redonned; faced forward and held breath

The QuantiFit2™ issued a pass or fail for each subject's fit-test and calculated both an overall fit factor and exercise-specific fit factor.

4.6. Post-Test Survey

After completing fit-testing on both devices, participants completed a post-test survey (Appendix A) to collect qualitative opinions on the metrics listed below. The survey metrics followed a 1-5 Likert-type scale and categorical preference response. Selection options such as "other devices" and "no preference" were added where applicable as firefighters are experienced in fit-testing and might have used a more preferred device in the past.

1. Clarity of instructions: The fit-testing exercises were clear and easy to follow
2. Comfort: The device and/or exercises made the respirator more uncomfortable during this test.
3. Perceived Fastest: Which device felt the fastest or most efficient?
4. Device Preference: If you had to use one of these devices for your next annual fit test, which would you choose?

4.7. Data Collection

Quantitative data (fit factors and pass/fail results) were automatically saved by each device and then exported into a password protected laptop for analysis. All quantitative data were erased from both fit-testing devices daily. Qualitative data were collected via the hard-copy post-test survey and later entered into a secured electronic datasheet on a password protected laptop for analysis.

4.8. Data Analysis

Both descriptive and inferential statistical analyses were conducted using R statistical software (RStudio, Posit PBC, Version 2025.05.1+513) and using a statistical significance of alpha = 0.05. After collecting data from all 38 participants, the data were cleaned and filtered into one protected spreadsheet. Descriptive statistical analyses for the following parameters were conducted as a starting point, then inferential analysis was applied where applicable: (1) overall fit factor means, standard deviation, and median, (2) pass/fail proportions, (3) survey response medians and interquartile ranges, and (4) preference frequencies.

Different inferential statistical analyses were conducted based on the hypothesis questions. For question one (1) concerning significant difference in pass rates between the devices, McNemar's test for paired binary data was conducted. McNemmar's test was selected because each participant was tested twice (once on each device), producing a dependent pass/fail outcome.

For question two (2) concerning significant difference in overall fit factors between the devices, conducting a direct raw value comparison was not statistically beneficial. For a full-face SCBA respirator, a minimum overall fit factor of 500 was required to pass, as per OSHA and ANSI/AIHA Z88.10-2010 standards (ANSI/AIHA 2010) (OSHA 2024). The two devices use different measurement technologies and fit factor scales, which resulted in highly skewed data. Specifically, PortaCount™ Pro+ fit factor values were relatively larger than the QuantiFit2™ fit factor values.

To reduce skewness of the data and stabilize variance, overall fit factor data were $\log_{10}$-transformed prior to analyses. Then, a paired t-test was conducted on the $\log_{10}$-transformed data to compare the mean difference between QuantiFit2™ and PortaCount™ Pro+. A paired t-test was used as the data were paired for the same participant (i.e., same participant on both devices). The assumption of normality improved after $\log_{10}$ transformation.

Pearson correlation analysis was also conducted to evaluate the strength of association between fit factor values from each device. Pearson correlation does not assess agreement; rather, it evaluates whether participants who scored a high fit factor on one device also scored relatively high on the other device (i.e., linear association).

Participants with a fit factor value of zero (failed on either devices) were excluded only from data-transformation because $\log_{10}$-transformation of zero is undefined (all participant data were included in other tests and analyses).

For question three (3) concerning significant difference in device preference in the study population, a chi-squared test was conducted. The chi-squared test was selected because in the survey, participants were presented with categorical outcomes including: QuantiFit2™, PortaCount™ Pro+, other devices, or no preference. Using the chi-squared test enabled the

researchers to assess whether there was a statistical difference in preference between the fit-testing devices.

For the Likert-scale survey metrics (comfort, clarity of instructions, and efficiency), Wilcoxon signed-rank tests were conducted. The Wilcoxon signed-rank test was selected because it compares paired ordinal data without assuming normality of the data.

5. RESULTS

5.1. Study Population

A total of 38 firefighters (males and females) completed quantitative fit-testing using the QuantiFit2™ and PortaCount™ Pro+. Each participant completed both fit tests during the same fit-testing session. All participants were tested using their personally-issued SCBA full-face respirators. Participant experience, feedback, and device preference were documented using a post fit-testing survey.

5.2. Quantitative Fit Factor Results

- Research Question 1: In the firefighter study population, is there a significant difference in **pass rates** between the QuantiFit2™ and PortaCount™ Pro+ devices?

Of the 38 participants, one participant failed using the PortaCount™ Pro+ device, and two participants failed the QuantiFit2™ device. Notably, the participant who failed on the PortaCount™ Pro+ was also one of the participants who failed on the QuantiFit2™, indicating that one failure was common between the two devices. Pass/fail was assigned using the OSHA minimum fit factor requirement of ≥ 500 for full-face respirators. The number of passed and failed fit tests and the pass/fail rates for both devices are presented in Table 3 with the McNemar Chi-squared test p-value (alpha=0.05).

Table 3: Research Question 1 Statistical Analysis Results (n=38)

Device	#Passed / #Failed	Pass Rate (%) n=38	McNemar's Chi-squared Test p-value
QuantiFit2™	36/2*	94.7%	0.99

PortaCount™ Pro+	37/1	97.4%	

*One participant failed on QuantiFit2™ but passed on PortaCount™ Pro+

The McNemar's Chi-squared test was conducted to examine whether there was a statistically significant difference between pass rates between devices. Based on the p-value at 0.05 (alpha), it was concluded that there is no statistically significant difference in pass rates between the two devices. That is, both devices produced comparable pass/fail outcomes in this firefighter population. Therefore, there was not sufficient evidence to reject H01 (i.e., there is no significant difference in pass rates between the two fit-testing devices).

- Research Question 2: In the firefighter study population, is there a significant difference in fit-test results (**fit factors**) between the QuantiFit2™ and PortaCount™ Pro+ devices?

Descriptive statistics of the overall fit factors obtained from each device (n=38) are listed in Table 4.

Table 4: Research Question 2 Fit Factor Descriptive Statistics (n=38)

Device	Fit Factor (n=38)		
	Mean	Median	Standard Deviation
QuantiFit2™	2049	1781	1554
PortaCount™ Pro+	28533	28050	19284

Based on the results in Table 4, it was concluded that fit factor values differed substantially in magnitudes between the two devices. The differences in device technologies, measurement principles, and fit factor reporting scales contributed to the noted differences in fit factor values between the devices.

Additionally, a scatterplot of the overall fit factor values (raw data) is shown in Figure 5. The two data points that scored a fit factor value of zero are visible on the far left of the scatterplot figure (same participant who failed on both devices and one participant who failed on the QuantiFit2™). The dashed line on the scatterplot figure is linear regression line of best fit, which represents the relationship between the two devices' overall fit factor values.

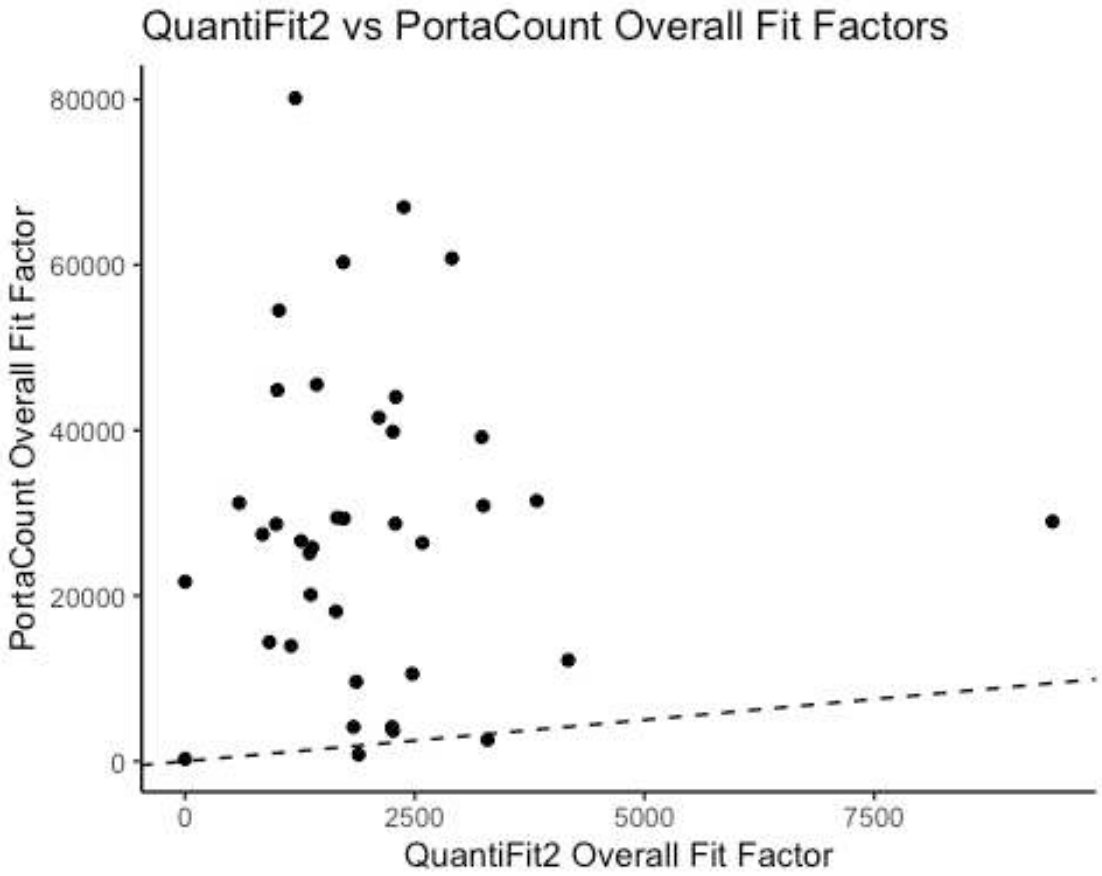

Figure 5: Scatterplot of the Relationship Between the Overall Fit Factor Values of the QuantiFit2™ vs. PortaCount™ Pro+

When plotting the raw fit factor values in a boxplot (Figure 6), clear differences in the distribution between the two devices are observed. The PortaCount™ Pro+ results show higher median fit factor and a wider interquartile range, which reflect high variability in measured values. In contrast, the QuantiFit2™ results are clustered within a much lower range and a smaller

interquartile spread. Outliers were observed on both devices. The findings from the Scatterplot (Figure 5) and the Boxplot (Figure 6) confirm that fit factor values differed substantially in magnitudes between the two devices, which is due to differences in measurement technologies.

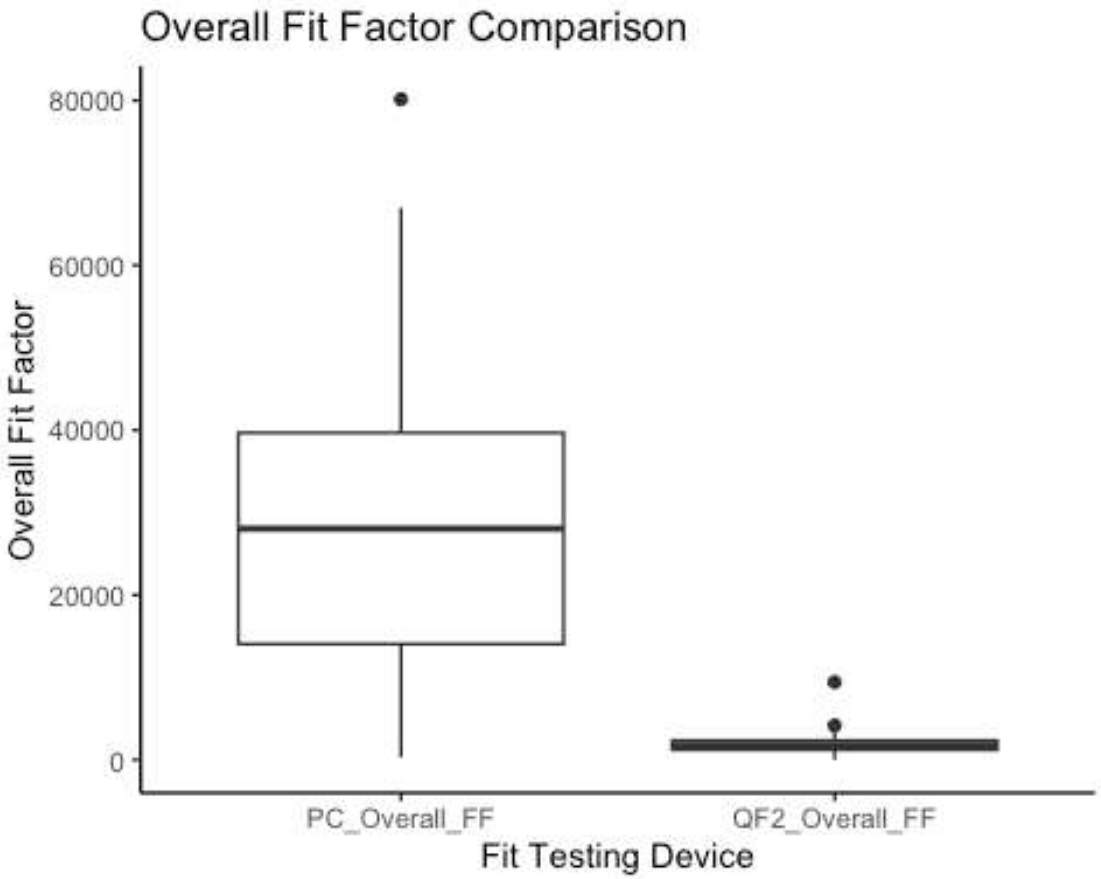

Figure 6: Distribution of Fit Factor Values of the QuantiFit2™ vs. PortaCount™ Pro+

To account for the differences in fit factor magnitudes, the overall fit factor raw data were $\log_{10}$-transformed prior to inferential analysis. Only the 36 participant fit factors with valid results (i.e., passing & non-zero fit factors), were included in the $\log_{10}$ transformation as $\log_{10}$ of zero is undefined.

A paired t-test was conducted on the log_{10}-transformed data, which resulted in a p-value<0.05. Test value (t) and other parameters such as degrees of freedom (df), 95% confidence interval, and mean difference are shown in Table 5.

Table 5: Fit factor paired t-test results (n=36)

Test Statistic (t)	df	P-value	95% Confidence Interval	Mean difference (log_{10})
-12.18	35	3.8e-14	(-1.23, -0.88)	-1.06

df = degrees of freedom

Since the p-value was less than alpha (p<0.001), it was concluded that there is a statistically significant difference in log_{10}-transformed fit factors between the two devices. On average, PortaCount™ Pro+ fit factor values were still significantly higher than QuantiFit2™ values in the log_{10}-transformed data.

Since a significant difference in log_{10}-transformed fit factors was found between the two devices, the association between the two devices' fit factors was analyzed. Specifically, the data were analyzed to determine if a subject who scored a relatively higher fit factor value on one device also scored a relatively high fit factor on the other device. To investigate, a Pearson correlation analysis was conducted using the same log_{10}-transformed overall fit factor data of both devices (n=36). Test statistic value (t) and other parameters such as degrees of freedom (df), 95% confidence interval, and estimated correlation (r) are shown in Table 6.

Table 6: Pearson Correlation of Log_{10}-Transformed Fit Factors (n=36)

Correlation Test Statistic (t)	df	P-value	95% Confidence Interval	Estimated Correlation (r)
-0.76	34	0.45	(-0.44, 0.21)	-0.13

df = degrees of freedom

The Pearson correlation coefficient (r) was -0.13, which reflects a relatively weak negative correlation between the two devices' log_{10}-transformed fit factor values. Additionally, the p-value ($p = 0.45$) exceeded the alpha value of 0.05, meaning that there was no statistically significant linear association in log_{10}-transformed fit factors between the two devices. That is, a participant who scored a high fit factor value on one device did not necessarily score a correspondingly high fit factor value on the other device. A scatterplot of the association between the log_{10}-transformed overall fit factors between PortaCount™ Pro+ and QuantiFit2™ is shown in Figure 7. On Figure 7, the solid blue line represents the fitted linear regression line, which reflects the estimated relationship between the two devices. The surrounding gray shaded region represents the 95% confidence interval for the regression estimate.

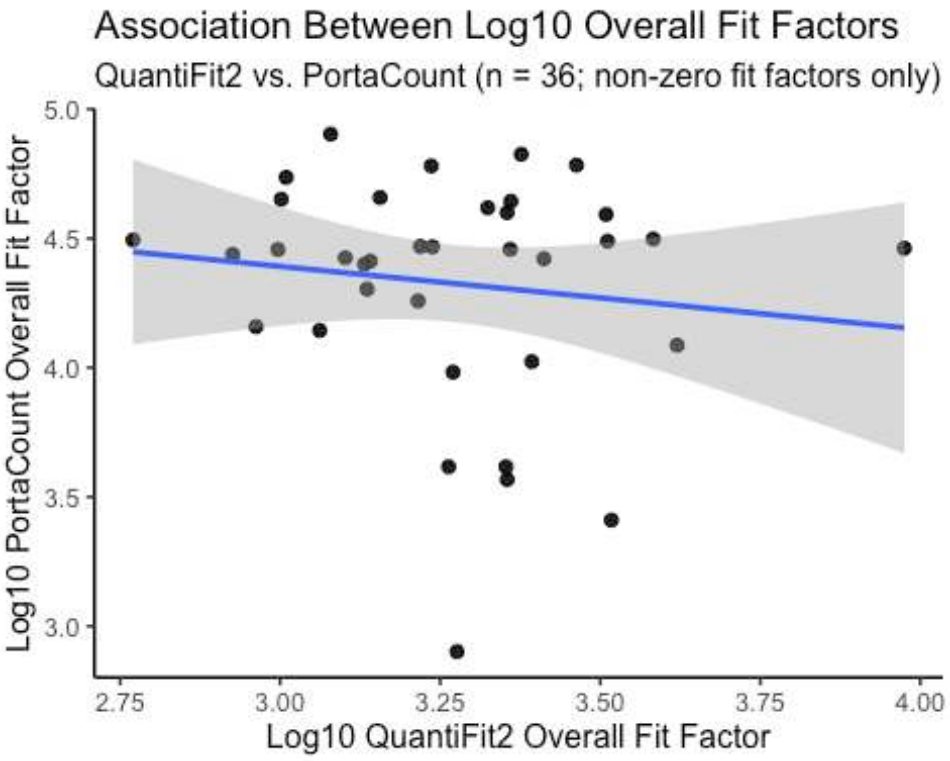

Figure 7: Scatterplot of the Association Between the Log_{10}-transformed Overall Fit Factor Values of the QuantiFit2™ vs. PortaCount™ Pro+

- Research Question 3: Do the firefighter study subjects prefer one fit-testing device over another?

Data on four metrics were solicited from study participants to determine their preferences of one fit testing device over another through a post fit-testing survey. The metrics were: clarity of fit-testing exercises, comfort, perceived efficiency (fastest test duration), and overall device preference. Participants' survey ratings were recorded categorically on all metrics for both devices on a 1-5 Likert-type scale. The summary of the survey results that were used to answer research question #3 are found in Table 7, including the metric studied, test name, test statistic, p-value, and a brief conclusion.

Table 7: Statistical Summary of User Experience Results (n=38)

Metric	Test	Test Statistic	p-value	Conclusion (alpha = 0.05)
Clarity of Instructions	Wilcoxon Signed-Rank	V = 41.5	0.80	No statistically significant difference in clarity ratings between devices
Comfort	Wilcoxon Signed-Rank	V =10	0.09	No statistically significant difference in comfort ratings between devices
Perceived Efficiency	Chi-Squared	$X^2 = 11.1$ df=2	0.004	Statistically significant difference in perceived efficiency ratings between devices
Overall Device Preference	Exact Binomial	---	0.007	Statistically significant preference for "other devices"

V= Wilcoxon Signed-Rank test statistic, X^2= Chi-Squared test statistic.

3.1. Clarity of Fit-Testing Instructions

Clarity of fit-testing instruction ratings were analyzed using a Wilcoxon signed-rank test. There was no statistically significant difference in the clarity of instruction rating medians between the PortaCount™ Pro+, QuantiFit2™, or "Other device" (V=41.5, p=0.80). Based on the clarity of instruction findings, it was concluded that clarity of instructions did not influence device preference in this study population. Additionally, based on the boxplot in Figure 8 (showing clarity ratings by device), the median clarity ratings for all devices were high, meaning that participants found instructions generally easy to follow.

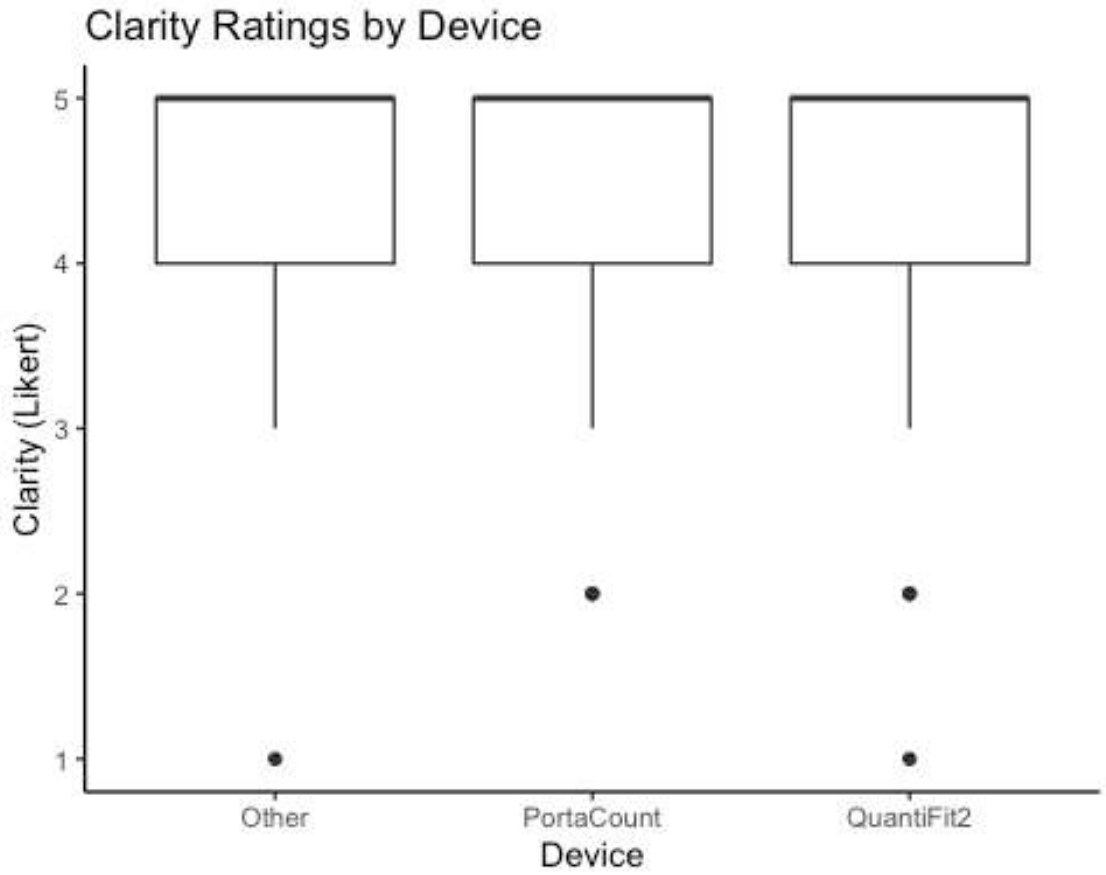

Figure 8: Boxplot of Clarity Ratings by Device

3.2. Comfort

Comfort ratings to determine if the device and/or exercises made the respirator more uncomfortable during the fit test were analyzed using a Wilcoxon signed-rank test. There was no statistically significant difference in comfort median ratings between the PortaCount™ Pro+ and QuantiFit2™ (V=10, p=0.09).

3.3. Perceived efficiency

Efficiency ratings to determine which device felt the fastest or most efficient was determined by using a Chi-squared test on the survey data. Based on the results presented in Figure 9, it was determined that the QuantiFit2™ was most frequently selected as the fastest device (X^2 = 11.1, p-value=0.004).

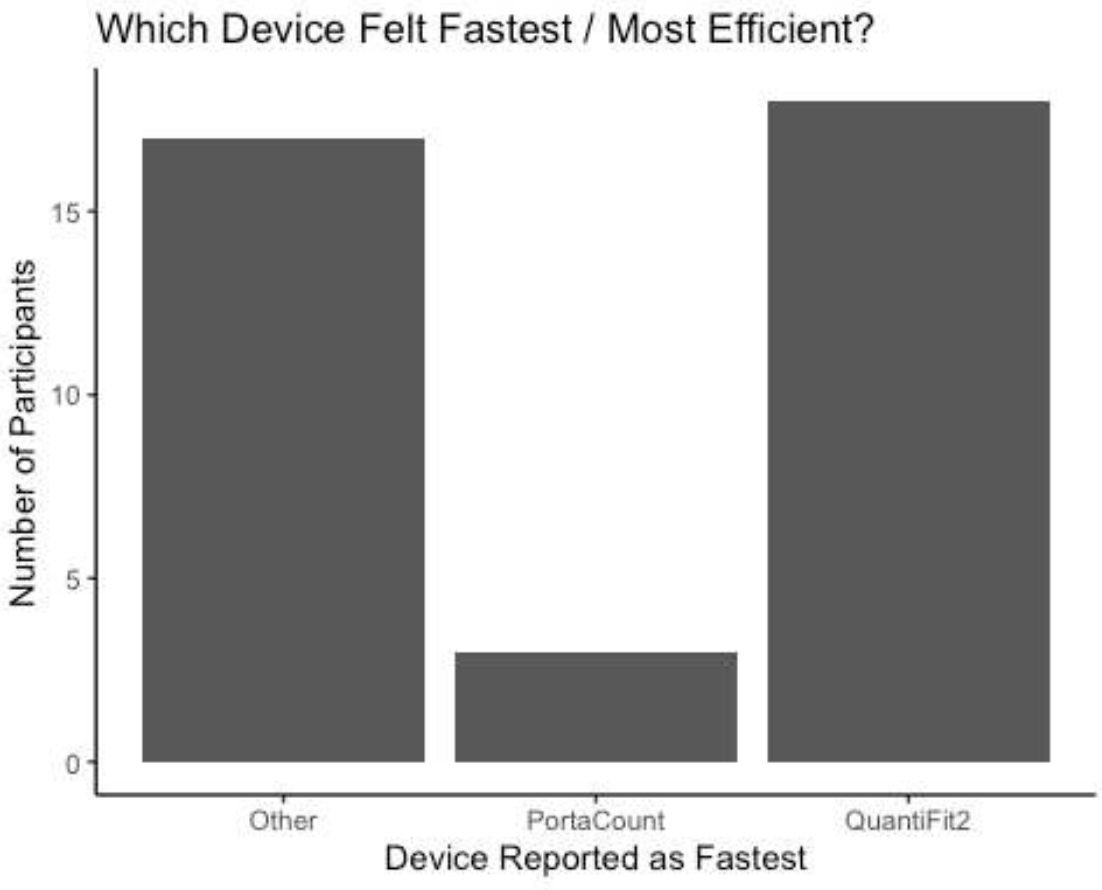

Figure 9: Bar Chart of Perceived Efficiency Among Fit-Testing Devices

3.3. Overall Device Preference

When participants were asked which device they would choose for their next annual fit-test, responses included PortaCount™ Pro+, QuantiFit2™, “other devices”, and “no preference”. Among the 38 participants, 47.4% (18/38) of participants selected other fit-testing devices, 34.2% (13/38) selected the QuantiFit2™, 13.2% (5/38) reported no preference, and 5.3% (2/38) selected the PortaCount™ Pro+.

To specifically evaluate device preference among QuantiFit2™ and PortaCount™ Pro+ (n=15), 2 participants selected PortaCount™ Pro+, and 13 participants selected QuantiFit2™. An exact binomial test was conducted to statistically confirm the results. With a p-value = 0.007, a bar chart of device preference distribution is shown in Figure 10.

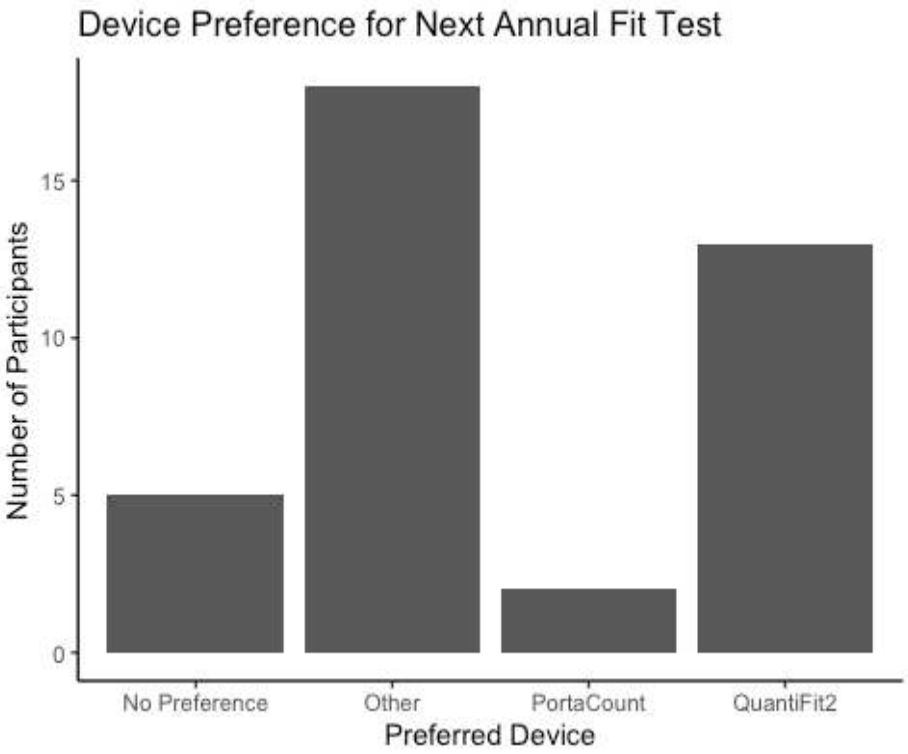

Figure 10: Bar Chart of Fit-Testing Devices Preference Distribution

6. DISCUSSION

The researchers of the current study evaluated quantitative and qualitative differences between the PortaCount™ Pro+ and QuantiFit2™ fit-testing devices in a sample of 38 firefighters. The research addressed three research questions: (1) differences in pass/fail rates, (2) differences in fit factor measurements, and (3) participant fit-testing device preference. Quantitative fit-test data were complemented by participant post fit-test survey feedback to yield a more comprehensive evaluation of fit-testing device performance, efficiency, and practicality.

6.1. Pass/Fail Results (research question 1)

Despite the difference in technologies and fit-factor scales among the PortaCount™ Pro+ and QuantiFit2™, pass rates did not differ significantly between the two devices. Among the 38 participants, both devices resulted in passing rates above 94% (using the OSHA minimum fit factor criteria for full-face respirators of ≥ 500). These findings align with outcomes reported in prior studies involving elastomeric respirators, where different quantitative methods produced high pass rates despite differences in measurement technologies and fit factor magnitudes. Specifically, in a 2010 study comparing three commercially available fit testing methods, all three different measurement principles generally produced comparable pass/fail rates (75% agreement) using the OSHA passing criteria (Larry Janssen 2010). Similarly, in another study conducted in 1997, leakage rates measured using CNC and CNP technologies were compared in a laboratory-controlled setting. Although the research did not focus primarily on pass/fail rates, rather it focused on leakage rates, both technologies effectively detected respirator leakage despite the different measurement approaches (Clifton Crutchfield 1997). Both studies support the current study's pass/fail findings when evaluating compliance outcomes.

The results from research question 1 (is there a significant difference in **pass rates** between the QuantiFit2™ and PortaCount™ Pro+ devices?) allowed the researchers of the current study to conclude that both devices are capable of reliably verifying the fit of a respirator from a compliance perspective. The lack of a statistically significant difference in pass rates supports this research in going further into studying the user experience (research question three). If both devices function similarly from a compliance perspective, factors such as user acceptance, preference, and operational efficiency become relevant considerations when evaluating fit-testing devices.

6.2. Fit Factor Results (research question 2)

Based on the overall fit factor results, it was concluded that a statistically significant difference ($p<0.001$) existed between the two devices. After $\log_{10}$-transforming the raw fit factor data to address skewness and fit factor scale differences, the paired t-test analysis still resulted in lower fit factor values for QuantiFit2™ compared to the PortaCount™ Pro+. As the two devices use different fit factor scales, this finding was anticipated and does not indicate negative performance of either device. The PortaCount™ Pro+ uses CNC technology, which reports fit factors based on ambient particle concentration. The QuantiFit2™ uses CNP technology, which directly measures air leakage into the respirator. Thus, exact fit factor values resulting from using both devices are not directly interchangeable. Similar findings have been reported when comparing different QNFT technologies, where CNC methods often result in higher numerical fit factors compared to alternative methods (optical particle counter technology) due to difference in particle size detection ranges and measurement technologies (Wu 2018).

Additional statistical analysis was conducted using Pearson correlation analysis to evaluate the linear association between fit factor outcomes of both devices. The test produced no

statistically significant association between the fit factor values. The lack of a statistical significant association means that a relatively high fit factor on one device does not predict a relatively high fit factor on the other device.

Regulatory bodies such as OSHA and ANSI do not specify equivalency between CNC-based and CNP-based fit factor values beyond pass/fail criteria; they only specify a minimum acceptable fit factor. As long as the respirator users meet the minimum acceptable fit factor value of 500 for SCBA full face respirators, they should be in compliance with the OSHA requirement.

6.3. Preference and User Experience (research question 3)

Analysis of the four metrics from the post fit-testing survey [clarity of instructions, comfort, perceived efficiency (test duration), and overall preference] provided additional insight into participant perceptions of the fit-testing devices. Although comfort ratings were not significantly different between devices, researchers observed that some participants experienced difficulty performing breath-holding exercises required by the QuantiFit2™. The QuantiFit2™ protocol requires participants to draw a "comfortable breath and hold as if going under water", which was observed in this study to resemble a sharp-short inhalation followed by breath-holding (OHD, LLLP 2024). However, firefighters are generally trained to control their breathing while using SCBA, which may have contributed to the discomfort observed during the breath-holding exercises. This finding is consistent with a 2023 study that noted that CNP-based technology introduced challenges related to breath-holding exercises (Xiaodan Xu 2023).

In terms of overall preference, the largest portion of participants (47.4%) selected "other devices", indicating prior experience with various fit-testing technologies. Specifically, 18 participants selected "other devices" as their preferred fit-testing device, while 13 selected

QuantiFit2™, and 2 selected PortaCount™ Pro+. However, based on the qualitative survey responses, the observed preference of the QuantiFit2™ over the PortaCount™ Pro+ appeared to be primarily driven by perceived test duration. This finding was interpreted in the context of the standard PortaCount™ Pro+ protocol, rather than the modified ("fast fit") protocol.

From a practical standpoint, selection of both the fit-testing device and protocol has important implications for the success of respiratory protection programs, including potential improvements in compliance, testing fatigue, and willingness to participate in annual fit testing.

6.4. Study Limitations

In this study, the PortaCount™ Pro+ was operated using the standard OSHA ambient aerosol CNC protocol, which includes seven exercises and requires approximately eight minutes. However, OSHA also recognizes a modified ambient aerosol ("fast fit") protocol that reduces the number of exercises to three (3) and total test duration to 2.5 minutes (OSHA 2019). Therefore, differences in perceived efficiency and overall device preference may have been influenced if the PortaCount™ Pro+ has been operated using the modified "fast fit" protocol.

It is critical to emphasize that the current study was conducted within a single firefighter study population, which may limit generalizability to other occupational sectors since the study subjects were accustomed to respirator use and fit testing. Additionally, all qualitative data were self-reported on a survey, which may be influenced by subjective perception, familiarity with a specific device, and participant recollection of devices and exercises.

The study was conducted in active fire stations; hence, some tests were interrupted by emergency calls. Although firefighters were given time to rest after emergency calls, researchers

acknowledge fatigue was a potential bias. Finally, while QuantiFit2™ and PortaCount™ Pro+ fit factor data were $\log_{10}$-transformed to facilitate statistical comparison, equivalency between measurement scales remains inappropriate.

7. CONCLUSION AND FUTURE WORK

7.1. Conclusion

The researchers of the current study evaluated qualitative and quantitative differences between the QuantiFit2™ and PortaCount™ Pro+ fit-testing devices in a study population of 38 firefighters. The research addressed three research questions related to pass rates, fit factor results, and device preference.

1. In the firefighter study population, is there a significant difference in pass rates between the QuantiFit2™ and PortaCount™ Pro+ devices?
    - H01: There is no significant difference in pass rates between the two fit-testing devices.
    - HA1: There is a significant difference in pass rates between the two fit-testing devices.

Pass rates were evaluated using the OSHA full-face respirator criteria of ≥ 500. Using statistical analysis (McNemar's test), there was no evidence of a statistically significant difference in pass/fail results between QuantiFit2™ and PortaCount™ Pro+ (fail to reject H01). Both devices resulted in high pass rates, indicating that each device effectively measured and identified acceptable respirator fit within this study population.

2. In the firefighter study population, is there a significant difference in fit-test results (fit factors) between the QuantiFit2™ and PortaCount™ Pro+ devices?
    - H02: There is no significant difference in fit factors between the two fit-testing devices.
    - HA2: There is a significant difference in fit factors between the two fit-testing devices.

Despite the agreement in pass/fail rate, fit factor results were different in magnitude. To better analyze the fit factor results, QuantiFit2™ and PortaCount™ Pro+ data were $\log_{10}$-

transformed. Using statistical analysis (paired t-test), there was evidence of a statistically significant difference in the $\log_{10}$-transformed overall fit factors between the devices (reject H02). Fit factor values produced by the PortaCount™ Pro+ were consistently higher.

This finding was anticipated due to the devices' differences in technologies and measurement principles. PortaCount™ Pro+ uses CNC technology and reports fit factors based on particle concentration ratios, whereas QuantiFit2™ uses CNP, directly quantifying respirator air leakage. Therefore, absolute fit factor values from using both devices are not directly comparable.

3. Do the firefighter study subjects prefer one fit-testing device over another?
    - H03: There is no significant difference in firefighter preference between the QuantiFit2™ and PortaCount™ Pro+.
    - HA3: There is a significant difference in firefighter preference between the QuantiFit2™ and PortaCount™ Pro+.

Post-test survey results were analyzed to evaluate four metrics: clarity of instructions, fit-testing level of comfort, duration to complete the fit-test exercises (efficiency), and overall device preference. As the firefighters are accustomed to fit-tests and complex routine training instructions, there was no evidence of a significant preference in clarity of instructions and level of comfort in one device over another (Wilcoxon signed-rank test p-value > 0.05).

When analyzing overall device preference, the largest proportion of participants selected "other devices" as their preferred device (47.4%), followed by QuantiFit2™ (34.2%), "no preference" (13.2%), and PortaCount™ Pro+ (5.3%). When restricting the analysis to participants who selected either QuantiFit2™ or PortaCount™ Pro+ (n=15), a statistically significant preference for QuantiFit2™ was observed (binomial exact test, p-value < 0.05). Therefore, H03

was rejected; there is a significant difference in firefighter preference between the QuantiFit2™ and PortaCount™ Pro+.

While QuantiFit2™ and PortaCount™ Pro+ produced statistically different fit factor magnitudes; they yielded comparable pass/fail results within a firefighter study population. Participants generally favored devices with shorter test duration, despite the observed discomfort associated with the breath-holding exercises required by the QuantiFit2™.

The findings of this study support the continued use of either device for regulatory compliance. However, the results highlight the importance of incorporating user experience – particularly test duration – into respiratory protection program decisions. The PortaCount™ Pro+ was evaluated using the standard OSHA ambient aerosol protocol; therefore, differences in perceived efficiency may have been reduced if the modified ("fast fit") protocol had been used.

7.2. Future Work

Future research may include the modified CNC ("fast fit") protocol to evaluate the impact on perceived efficiency and user preference outcomes. Overall, the findings from this study highlight the importance of considering both device performance and test duration when selecting fit-testing methods in occupational settings.

To generalize findings from this research, researchers may include multiple sites, and diverse occupational groups from various work sectors. The current research focused on one type of respirator; thus, future research should include different respirator types to better evaluate device performance.

The current research focused solely on testing participants once on each device. Future research may emphasize on test-retest reliability and results reproduction. Reproducing consistent

results on both technologies within the same participants over multiple testing sessions may help ensure device precision and consistency.

Finally, future work may include facial anthropometric measurements to study the implication of scars, face shapes, and facial hair on fit factors and pass/fail rates between fit-testing devices.

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APPENDIX A (Post Fit-Test Survey)

Study Title: *Evaluation of the QuantiFit2TM Fit Testing Device Against the PortaCountTM Pro+ for Respirator Fit Testing Among Firefighters*
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	Other Devices
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 ☐ Other ☐ Not Sure

2. **Which device felt the fastest or most efficient to complete?**
   ☐ PortaCount+ ☐ QuantiFit2 ☐ Other ☐ 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 ☐ Other ☐ No Preference

APPENDIX B (Consent Form)

Consent to Participate in Research

Project Title:	**Evaluation of the QuantiFit2 and AeroFit Respirator Fit Testing Devices**
Principal Investigator:	**William J. Brazile, Professor** **970-491-4272** **William.brazile@colostate.edu**
IRB Study #:	**6699**
Sponsor:	**N/A**

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to evaluate the performance of the QuantiFit2 and AeroFit devices compared to the established PortaCount device for respirator fit testing.
- **Duration.** It is expected that your participation will last 30-45 minutes.
- **Procedures and Activities.** You will be asked to participate in three respirator fit tests and complete a brief questionnaire.
- **Risks.** Some of the foreseeable risks or discomforts of your participation include (1) minor discomfort while wearing the respirator and performing the exercises, and (2) minor breathing resistance while wearing the respirator.
- **Benefits**. One of the direct benefits that may be expected is a determination of how well your respirator fits you and if it will protect you against airborne contamination. An indirect benefit is that the researchers hope to learn if the QuantiFit2 and AeroFit perform as well as the PortaCount fit-testing device.
- **Alternatives.** Participation is voluntary, and the only alternative is to not participate.

Who is conducting this research?

Mr. Othman Alkubaisi (Toomy) and Ms. Kenya Campbell are conducting this research as their Master's research theses.

What is the Purpose of this study?
The purpose of this study is to evaluate and compare the performance of three quantitative respirator fit-testing devices—PortaCount+, QuantiFit2, and AeroFit—in an occupational setting, specifically among active-duty firefighters. Proper fit testing of respirators is critical to ensure adequate protection against airborne contaminants, and the researchers aim to determine if the QuantiFit2 and AeroFit are viable alternatives to the PortaCount.
Why Am I Being Invited to Take Part in this research? You are being asked to participate in the study because you fit these criteria: (1) You are an active-duty firefighter who is greater than 18 years old and (2) you are mandated to undergo annual respirator fit testing as part of your normal job.
What will I be asked to do?
The study is designed to include the following activities; however, the participant may refuse to answer any question or item in any test, questionnaire, or interview:

1. Consent and Pre-Test Screening – 10 minutes:
   - You will be asked to provide written consent and answer a few screening questions about your age and facial hair; and you have to be medically cleared to wear a respirator.

2. Fit Testing with PortaCount – 10 minutes:
   - You will don a respirator and perform a series of exercises while the PortaCount device measures the fit factor of your respirator; these include:
     1. Normal breathing.
     2. Deep breathing.
     3. Head movements (side to side, up and down).
     4. Talking.
     5. Bending over.
     6. Normal breathing.

3. Fit Testing with QuantiFit2 – 10 minutes:
   - You will don a respirator and perform a series of exercises while the Quantifit2 device measures the fit factor of your respirator; these include:
     1. Face forward and hold breath.
     2. Bend over and hold breath.
     3. Head shake side to side while talking, then hold breath.
     4. Re-don 1: Remove mask completely and redon. Face forward and hold breath.
     5. Re-don 2: Remove mask completely and redon. Face forward and hold breath.

4. Fit Testing with the AeroFit – 10 minutes
   - You will don a respirator and perform a series of exercises while the PortaCount device measures the fit factor of your respirator; these include:
     1. Normal breathing.

2. Deep breathing.
3. Head movements (side to side, up and down).
4. Talking.
5. Bending over.
6. Normal breathing.

5. Post-Test Feedback – 5 minutes:

You will be asked to complete a brief survey about your demographic background, years of employment, type of respirator, and your feedback on the testing procedures for both devices.
Where is the study going to take place and how long will it last? The data collection part of this study will take place at your fire department. The entire process, including consent, pre-testing screening, fit testing with both devices, and post-test feedback, will take approximately 45 minutes per participant.
Data analysis, interpretation, and report building for the thesis will continue for up to 1 ½ years.
What are the possible risks and discomforts?
Potential risks, stress, and/or discomforts of participation may **include:** (1) minor physical and/or psychological discomfort while wearing the respirator and performing the exercises, and (2) minor breathing resistance while wearing the respirator. However, the testing procedures are designed to be safe and non-invasive following Occupational Safety and Health Administration (OSHA) Fit Testing Procedures standard number 1910.134 App A: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA. However, if at any point you feel uncomfortable, you may stop the test.
WHAT SHOULD I DO IF I BECOME INJURED?
If you are injured because of participation in this study, you should call the study principal investigator immediately (if it is a medical emergency, first call 911). Study contact numbers are listed in the Questions section below. If you require medical care, go to your local or primary care hospital.
How will my privacy and data confidentiality be protected?
We will take measures to protect your privacy. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. Measures we will take include:
All information gathered in this study will be kept as confidential as possible. Your identity will not be revealed in the study results, and no reference will be made in written materials that could link you to this study. Your data will be assigned a code, and only the research team will have access to the link between you, your code, and your data. All records will be stored on a locked server that is only accessed by the research team, and the link between your identifiers and the research data will be destroyed after the records retention period required by state and/or federal law.
However, your fit test results using QuantiFit2 will be shared with your employer to satisfy your mandatory annual respirator fit testing, but your name will not be linked to the results in any published materials. Additionally, if you choose to take part in this study, your private information collected for this study will not be used or distributed for future studies.

Confidentiality of Information

Individuals and organizations that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information such as name, age, demographic background, and years of employment. These individuals and organizations include:

• The Institutional Review Board (IRB) that reviewed this research
• Employer (Quantifit2 Results only to satisfy your mandatory annual respirator fit testing requirement)

Limits to confidentiality

All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, including, but not limited to child or elder abuse/neglect, suicide ideation, or threats against others, we must report that to the authorities as required by law.

Who Will See the Information that I give?

Other people may learn that you participated in this study but the information you provide will be kept confidential to the extent permitted by law. We may be asked to share the research files with the sponsor or the CSU Institutional Review Board ethics committee for auditing purposes.

Are There Any Benefits from Taking Part in the Study?

Direct benefits that may be expected is a determination of how well your respirator fits you and if it will protect you against airborne contamination. An indirect benefit is that the researchers hope to learn if the QuantiFit2 and AeroFit perform as well as the PortaCount fit-testing device.

Will I Receive Compensation? You will not be compensated for participating in this research. Your employer will pay you for your time while you are taking part in this study.

Data Sharing/Future Research:

Your information collected as part of the research, even if identifiers are removed, **WILL NOT** be used or distributed for future research studies.

Use of your information for future research [

All identifiable information (e.g., your name, age) will be removed from the information or samples collected in this project. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information (e.g., your name, age) that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information or samples we share. Despite these measures, we cannot guarantee the anonymity of your personal data.

Incentives to participate

No incentives will be provided to participate in this research.

Questions

For questions, concerns, or complaints about the study you may contact William Brazile, Professor, at William.brazile@colostate.edu, 970-491-4272.
If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the CSU Institutional Review Board at: CSU_IRB@colostate.edu.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.
I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of participant	**Signature of participant**	**Date**

Printed name of person obtaining consent	***Signature of person obtain consent***	***Date***

APPENDIX C (Pre-Test Screening Form)

Study Title: *Evaluation of the QuantiFit2 vs. PortaCount 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 (August–October 2025)?**
    ☐ Yes ☐ No ☐ Not sure

SECTION 3: INVESTIGATOR USE ONLY

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

Reviewed by (Initials / Date): _____