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Russell R Willis

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Determining Leak Percentage at Known Leak Locations for Full-Mask Respirators Using TSI PortaCount™ and OHD Quantifit™

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Thesis submitted to the Statler College of Engineering and Mineral Resources at West Virginia University

In partial fulfillment of the requirements for the degree of
Master of Science
In
Industrial Hygiene

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Keywords: Leak Rate (LR), Penetration, Fit Factor (FF), Leak Percentage

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Abstract

Determining Leak Percentage at Known Leak Locations for Full-Mask Respirators Using TSI PortaCount™ and OHD Quantifit™

Russell R. Willis

The purpose of the study was to determine the percentage of known leakage introduced into a full-face respirator and a half-face respirator. The instruments employed were the OHD Quantifit™ and a TSI PortaCount Pro+ Model 8038™. This study introduced three known leak sites into a full-face respirator and a half-face respirator. The PortaCount Pro+ 8038™ was attached to a breathing simulator to simulate a working moderate breathing flow rate of 40L/min, and also attached to a vacuum to simulate a negative pressure continuous breathing scenario at 40L/min. The Quantifit™ is a Controlled Negative Pressure (CNP) system that has all of its functions built within. The Quantifit™ doesn't rely on a breathing machine, instead it applies a negative pressure and modeled breathing rate.

The study was completed over the course of 21 days. There were seven fit tests that were conducted at each known leak location for each system, and the results were recorded for analysis. The PortaCount Pro+ 8038™ had a series of seven tests that were conducted for a continuous breathing cycle and a cyclic breathing cycle. That equals a total of 42 fit tests for the PortaCount Pro+ 8038™, because there are three needles, seven tests per needle, equaling 21, and then that was repeated for the cyclic breathing cycle with the PortaCount Pro+ 8038™. A total of 21 fit tests were conducted with the Quantifit™, 7 fit tests at each of the three needles.

When using the paired two t-tests, there were many results that proved to be statistically significant ($p < .05$) while comparing the Quantifit™ to the PortaCount Pro+ 8038™ and comparing each machine to its own baseline results. When using the full-face respirator, the overall average leak percentage for the PortaCount Pro+ 8038™ during continuous breathing at 40L/min was 2.24%, and the overall average leak percentage for the PortaCount Pro+ 8038™ on cyclic breathing at 40L/min was 20.43%. The Quantifit™ detected an overall average leak percentage of 22.25%.

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List of Abbreviations

CA,CB	Concentration A, Concentration B
CNC	Condensation Nucleus Counter
CNP	Controlled Negative Pressure
CPC	Condensation Particle Counter
CSA	Canadian Standard Association
FF	Fit Factor
HEPA	High Efficiency Particulate Air filter
Leak%	Leak Percentage
LR	Leak Rate
LS	Leak Site
MDC	4-methyl-7-diethyl-aminocoumarin
NIOSH	National Institute for Occupational Safety and Health
OHD	Occupational Health Dynamics
OSHA	Occupational Safety and Health Administration
PAPR	Powered-Air Purifying Respirator
PD	Probe Depth
Pen%	Penetration Percentage
PL	Probe Location
QLFT	Qualitative Fit Test
QNFT	Quantitative Fit Test
SCBA	Self-Contained Breathing Apparatus
SR	Sample Rate

Chapter 1: Introduction

The motivation for this study is technological advancements. It has been over twenty years since that last comparison of an aerosol based fit testing system, and a Controlled Negative Pressure (CNP) based fit testing system. Employee protection is the number one concern of a company's safety team and the safety programs that are implemented. Respirator protection is one of the many focal points for a company's safety department. The Occupational Safety and Health Administration (OSHA) requires either a Qualitative Fit Test (QLFT) or Quantitative Fit Test (QNFT) method for fit testing workers (1910 Occupational Safety and Health Standards). QNFT and QLFT methods are quite different, in that the QNFT method relies on the use of an instrument to detect and measure the face seal leakage, while the QLFT method relies on the individual wearing the respirator being able to detect the test agent enter the mask (Craig E. Colton, 1996). There's a misunderstanding that QNFT is more accurate than QLFT methods, but actually it has more precision (Stearns, 2004; Colton, 1996). The QNFT methods ability to generate a fit factor is what leads some people to believe that the QNFT method is the best fit testing method, but there is no data to support QNFT methods as having a greater protection in the workplace compared to QLFT methods. OSHA established general industry respiratory protection standard, 29 CFR 1910.134 in the 1970s (Craig E. Colton). The standard wasn't made valid until the late 1970s and early 1980s, and the OSHA general industry respiratory protection standard, 29 CFR 1910.134 was made effective on April 8, 1998 (Stearns, 2004; Colton, 1996).

Two commonly used methods for fit testing are the Aerosol/Particle based fit testing method, and Controlled Negative Pressure (CNP) fit testing method. Both methods are capable of producing a fit factor score for the wearer. Quantitative fit testing uses non-harmful aerosols or test agents (sodium chloride, corn oil, polyethylene glycol 400, and di-2-ethyl hexyl sebacate) generated in a testing chamber, with a condensation nuclei counter to quantify the respirator fit (1910 Occupational Safety and Health Standard). QNFT can also use CNP and the appropriate instruments needed to measure the volumetric leak rate of a face piece to quantify a respirators fit.

The personnel that are conducting the fit testing procedures are aiming to produce a fit factor of the individual that the fit test is being performed upon. Fit factor is the term used to express the results of a QNFT (Craig E. Colton 1996). The fit factor is a ratio of the test agent concentration outside the facepiece to the test agent concentration inside the facepiece (Craig E. Colton 1996). Half-face masks and full-face mask have different pass or fail parameters. The Half-face respirator has to meet a passing score of 100 overall on its fit tests, while the full-face mask respirator has to meet an overall score of 500 on fit tests (1910 Occupational Safety and Health Standard) . This allows the operator to know that the face seal is secure for the wearer and they can wear the mask in those designated contaminated work zones as personal protective equipment (PPE).

Chapter 2: Literature Review

2.1 PortaCount and Quantifit

The PortaCount^{TM} by TSI^{TM} and the Quantifit^{TM} by Occupational Health Dynamics^{TM} are two fit testing instruments that have been studied and compared side-by-side quite a few times to analyze the effectiveness of both machines' ability to detect face seal leakages in respirators. The PortaCount^{TM} is an ambient aerosol/particle based fit testing method that determines the fit factor by measuring the aerosol concentration inside the mask and outside the mask, while the Quantifit^{TM} is a CNP based fit testing system that determines the fit factor of a respirator by introducing a challenge pressure to the inside of the face mask, and detecting the leakage. CNP and ambient aerosol systems are designed with different measurement principles, but they are both designed to provide quantitative measurements of respirator fit based on the penetration of a challenge agent into the respirator (Crutchfield, C.D., D.L. Parker, 1995). A CNP system is designed to measure the air leakage into a respirator (Delaney, L.J, et al 2003 and Crutchfield, C.D., D.L. Parker, 1995), while the ambient aerosol system is designed to determine leakage by a ratio of inside-to-outside aerosol concentrations (Crutchfield, C.D., D.L. Parker 1995). Another significant difference between the ambient aerosol system and the CNP system is the exercise

protocol employed while fit testing, being that the ambient aerosol system conducts exercises for at least one minute durations to establish a proper fit, and the CNP makes five second measurements to detect leakage at various static head positions to determine if a change has occurred in the fit of the respirator. In comparative studies, CNP systems have proved to be more efficient in detecting known leakage than ambient aerosol systems, reporting lower fit factors and more respirator leakage (Crutchfield, C.D., D.L. Parker 1995).

2.2 Portacount

The PortaCount Pro+ Model 8038^{TM} produces a fit factor, which is a ratio of two concentrations by measuring microscopic particles outside the respirator and the concentration of particles that exist inside the respirator. Fit factors can be interpreted as such, a fit factor measurement of 100 means that the air inside the respirator is 100 times cleaner than the air outside the respirator. Two sampling tubes are used during the sampling process. One tube is used to measure the ambient air concentration and the other tube is connected to the respirator to measure the in-mask concentration.

Figure 1 Example of TSI PortaCount 8038 (Source: TSI)

The foundation of the PortaCount Pro+ Model 8038^{TM} is a Condensation Nucleus Counter (CNC), which is also known as a Condensation Particle Counter (CPC). The CNC has the capability of detecting particles that are very small in size, and makes them grow to a size that is easily detected so that they can be counted. The particles that can be detected by the PortaCount^{TM} are as small as 0.015 microns. The PortaCount^{TM} is insensitive to variations in particle size, shape, composition, and refractive index.

The PortaCount^{TM} is equipped with a diaphragm vacuum pump that pulls aerosols in at a flow rate of 1 liter/min. As the flow enters the system through the sampling port or ambient port, a switch valve determines which port to use. The switch valve has an outlet that leads to the saturator end cap, where the flow splits. The saturator receives a flow rate of .35 liters/min which passes through the condenser, nozzle, and sensing volume. Any remaining flow is combined with the sampling flow further downstream of the sensing volume.

The PortaCount^{TM} sensor is equipped with a saturator and condenser. There is an alcohol soaked wick which lines the saturator, and works by creating vapor that condenses on particles, causing them to grow into droplets, and they pass through the nozzle and into the sensing volume.

The particles that pass through the sensing volume scatter light, and then that light is collected by a receiving optic and focused onto a photodetector. The photodetector and scattered light work together to generate an electric pulse as the droplets continue to pass through the sensing volume.

The PortaCount^{TM} calculates a fit factor (FF) score by dividing the concentration of particles outside the respirator by the concentration of particles inside the respirator. The factors that make up the numerator of the ratio are particle concentration in the ambient sample before the respirator sample (CB), added to the particle concentration in the ambient sample after the respirator sample (CA). The denominator of the ratio is determined by the particle concentration in the respirator sample (CR), and is multiplied by 2. The formula looks as such: $FF = (CB + CA) / 2CR$. Also, if the in-mask concentration is 0, the PortaCount^{TM} will add 1 to the concentration so that the outside mask concentration isn't divided by zero.

The overall FF is calculated by dividing the total number of test cycles (n) by the fit factor for test cycle (FFX). The formula looks as such: $Overall\ FF = n / (1/FF1 + 1/FF2 + 1/FF3 + \dots +$

1/FFn1 + 1/FFn). The information in the above section, titled PortaCount™, was derived from the PortaCount Pro 8030™ and PortaCount Pro+ 8038™ Respirator Fit Testers Operation and Service Manual.

2.3 Quantifit

The Quantifit™ is a respirator fit test instrument that uses Controlled Negative Pressure (CNP) technology to determine how well a respirator is fitting an individual. While the Quantifit™ is conducting fit tests, it uses a special adapter in the place of a filter or cartridge, and at least one inhalation valve flap has to be removed so that the Quantifit™ can apply negative pressure to the inside of the respirator.

Figure 2 Example of OHD Qunatifit™ (Source: Wilner-Greene Associates)

Once the operator is ready to begin the fit test the individual has to hold his or her breath before the trigger is pressed. The trigger functions by closing the valve on the adapter, and this causes the respirator to be sealed, removing air from the respirator until the desired challenge pressure is reached within the mask. While the trigger is being held the exercise lasts for 8 seconds and the individual under test has to hold his or her breathe for that 8 second duration.

Once the Quantifit™ reaches its challenge pressure it stops removing air from the respirator cavity and attempts to sustain the pressure for the duration of the 8 seconds exercise. If there happens to be a leak in the respirator, air will enter the respirator, causing the pressure

within the respirator to become unstable. The Quantifit™ works to remove that unwanted air from the respirator until the desired challenge pressure is reached. The Quantifit™ will continue to go through this process until the 8 second fit test is completed.

The Quantifit™ conducts fit tests under a standard protocol or a custom protocol. These are the five standard protocol settings that are preprogrammed within the Quantifit™. The Redon Protocol, which is approved by OSHA, and applies a challenge pressure of .58 in H₂O, and a modeled breathing rate of 53.8 L/min. The Redon Protocol should be used with half-mask, air purifying, gas/escape, and PAPR respirators. The MIL (Militray) Protocol applies a challenge pressure of 1.0 in H₂O, and a modeled breathing rate of 55.8 L/min. The MIL Protocol should be used with military grade respirators. The Self Contained Breathing Apparatus (SCBA) Protocol applies a negative pressure of 1.5 in H₂O, and has a modeled breathing rate of 93.1 L/min. The SCBA Protocol should be used with SCBAs. With the last two protocols the internal configuration is setup as though the wearer is under more duress on a consistent basis. The Canadian Standards Association (CSA) SCBA Protocol has a stricter guideline, in that it requires for a minimum fit factor of 1,000. The CSA SCBA Protocol applies a challenge pressure of 1.5 in H₂O, a modeled breathing rate of 53.8 L/min, and should be used with Canada SCBA respirators. The CBRN Protocol is similar to the MIL Protocol, but it differs due to the desired fit factor being 2,000. The CBRN Protocol applies a challenge pressure of 1.50 in H₂O, a modeled breathing rate of 55.8 L/min, and should be used with Military grade, and CBRN respirators.

When using the Quantifit™ the fit factor is calculated as ratio of the modeled breathing rate divided by the measured leak rate. The unit of measurement is cubic centimeter per minute. The equation is as follows: $FF = \text{Modeled Breathing Rate} / \text{Measured Leak Rate}$. The information in the Quantifit™ section above was derived the OHD Operator's Manual

2.4 Respirators

What is a respirator? A respirator is a device that is worn covering the nose and mouth region of the individual, and serves as an air filtering/air-purifying or atmosphere-supplying

device for the user. Air-purifying respirators use filters, cartridges, and canisters to remove contaminants from the air that is inhaled by the user. Atmosphere-supplying respirators provide the user with clean air from an uncontaminated source. Respirators are classified as tight fitting or loose fitting, and they can either be half-mask respirators or full-face mask respirators. Under these two categories there are several types of respirators that are purposed for certain job functions. Some of the types of respirators that are being used in various industries today are as follows, filtering facepiece respirators, elastomeric respirators, Self-Contained Breathing Apparatus (SCBA), and Powered Air-Purifying Respirator (PAPR).

2.4.1 N95 Respirator

Filtering facepiece respirators are tight-fitting, air-purifying respirators that are sometimes referred to as N95 respirators. These respirators cover the nose and mouth (half-mask), and the whole mask acts as a filter. Filtering facepiece respirators do not protect against non-particulate airborne contaminants such as gases and vapors. It is required that an individual is fit tested before using a filtering facepiece respirator in the workplace, but if the use or the facepiece is completely voluntary and the job function does not require the use of a respirator, the user does not need to be fit tested. The N95 filtering facepiece respirator is typically disposed of after one use.

Figure 3 Example of N95 Respirator (Source: 3M)

An elastomeric respirator are tight-fitting, air-purifying, and are manufactured as half-mask or full-face mask respirator. Elastomeric respirators are not typically disposed of after one use, and can be cleaned with disinfectant solution and properly store to be reused. The user has to be fit tested before using the facepiece in the work environment. The facepiece has a rubber or silicon that covers the nose and mouth, and rests against the face of the user. The soft rubber or silicon region can interchange filters, canisters, and cartridges. The half and full-face elastomeric respirators are every similar, but they differ if design, being that the full-face mask cover the users entire face and can also be used in situations where the worker is prone to encounter splashes, irritant vapors or anything that could cause harm to someone's eyes.

2.4.2 Self-Contained Breathing Apparatus (SCBA)

The SCBA is a type of atmosphere-supplying respirator that supplies the user with a clean air source, and considered by OSHA to provide the highest level of respiratory protection. The air “is supplied from a cylinder of compressed breathing air that is designed to be carried by the respirator user”. The SCBA is a tight-fitting respirator with an elastomeric facepiece, and the user must be fit tested before the respirator is worn in the hazardous conditions within the workplace.

Figure 4 Example of SCBA (Source: SCBA Sales Co)

2.4.3 Powered Air Purifying Respirator (PAPR)

The PAPR is designed as loose-fitting or tight-fitting, half-mask, full-mask, and some have helmets or hoods. Loose-fitting PAPR do not have to be fit tested. They work by allowing a blower to pull air through a filter, and then the filtered air flows into the facepiece of the respirator. The tight-fitting PAPR has an elastomeric facepiece and the user must be fit tested before the respirator is worn in the hazardous conditions of the workplace. Tight-fitting PAPRs are the respirator of choice for many, if not all airlines. They are equipped with a long hose that supplies air to a hood or facepiece from a clean air source such as a cylinder or compressed air. The information in the Respirator section above is derived from the Occupational Safety and Health Administration website under the section labeled Respirator Type.

Figure 5 Example of Full-face PAPR (Source: Honeywell)

There are various types of filters for respirators that are in circulation. The National Institute for Occupational Safety and Health (NIOSH) has approved seven classes of filters for facepiece respirators that are currently in use. The approved classes are N95, N99, N100, R95, P95, P99 and P100. The prefix before each number on the respirators represents if the respirator is or isn't oil resistant. **N** means not oil resistant, **R** means somewhat oil resistant/resistant to oil, and **P** means strongly oil resistant. The minimum filtration of particulates that is approved by NIOSH is 95%.

2.5.1 Three Categories of Resistance to Filter Efficiency Degradation

There are three categories for N-series filters, and they are N95, N99 and N100. N95 filter is a filter that is not oil resistant, and is capable of filtering a minimum of 95% of airborne particulates. The N95 filter is also the most commonly used filter of the seven types. Some N95 respirators are approved by NIOSH and cleared by the Food and Drug Administration (FDA). These filter facepiece respirators are called surgical N95 respirators. “The FDA is the U.S. Government agency that oversees most medical products, foods, and cosmetics. Within the FDA, the Center for Devices and Radiological Health (CDRH) oversees the safety and effectiveness of medical devices. Medical devices intended for use in preventing and treating the disease is subject to regulation under the device provisions of the Federal Food, Drug, and Cosmetic ACT. This includes surgical masks and surgical N95 respirators. The FDA has no role in the approval or clearance of N95 respirators not intended for use as a medical device”. Surgical masks are not N95 respirators. Surgical masks prevent exposure to large respiratory particles, but do not effectively filter smaller particles from the air or prevent leakage around the edge of the respirator where the seal meets the face when the wearer inhales. “Surgical masks are not designed for use as particulate respirators and do not provide as much respiratory protection as an N95 respirator”. The N99 filter protects the user from at least 99% of airborne particulates, while the N100 filter protects the user from 99.97% of airborne particulates.

NIOSH ratings for particulate filtering respirators

N95 — Filters at least 95% of airborne particles. Not resistant to oil.

Surgical

N95 — A NIOSH-approved N95 respirator that has also been cleared by the Food and Drug Administration (FDA) as a surgical mask.

N99 — Filters at least 99% of airborne particles. Not resistant to oil.

N100 — Filters at least 99.97% of airborne particles. Not resistant to oil.

R95 — Filters at least 95% of airborne particles. Somewhat resistant to oil.

P95 — Filters at least 95% of airborne particles. Strongly resistant to oil.

P99 — Filters at least 99% of airborne particles. Strongly resistant to oil.

P100 — Filters at least 99.97% of airborne particles. Strongly resistant to oil.

Figure 6 NIOSH Respirator Ratings (Source: Canadian Metal Working) When determining if the N-series filters should be reused it is important to consider hygiene, damage, and increased breathing resistance. In a situation of high filter loading (200mg), which could be due to dirty workplace conditions, the N-series filter should only be extended beyond the use of continuous or intermittent eight hour use if an evaluation is performed under those same workplace conditions. This evaluation must prove that the extended use will not degrade the filter efficiency below the efficiency level specified in 42 Code of Federal Regulations (CFR) Part 84, or the total mass loading of the filter is less than 200mg. This evaluation process must be repeated if the workplace conditions change or if modifications are made to the process that could potentially lead to alterations in the type of particles that are generated in the workplace.

There are three categories of R-series filters, and they are R95, R99, and R100. R-series respirators are resistant to airborne particulates, and resistant to oil. Of the three R-series respirator models certified under 42 CFR Part 84, only the R95 model appears to be listed as an approved model by NIOSH. The R-series filters should only be used during a continuous or intermittent eight hour shift when oil is present in the workplace. It is necessary to follow the same evaluation protocol as listed above for the N-series filters. This evaluation process must be repeated if the workplace conditions change or if modifications are made to the process that could potentially lead to alterations in the type of particles that are generated in the workplace.

There are three categories of P-series filters, and they are P95, P99, and P100. P-series filters are resistant to airborne particulates, and strongly resistant to oil. When oil is present, the P-series filter can only be used or reused according to the guidelines that are established by the manufacturer. Also, when determining if the P-series filter should be used or reused it is important to consider hygiene, damage, and increased breathing resistance if oil aerosols are not present. The information in the Respirator Filter section above is derived from the Centers for Disease Control and Prevention website under the sections labeled The National Personal Protective Technology Laboratory, and The National Institute for Occupational Safety and Health.

2.6 Current Discoveries

In a study addressing effects of leak location on respirators (Crutchfield, et al., 1997) known leak locations were established along with known leak rates through each leak location so that a leak percent can be established at each known leak location. When calculating the leak percent (Leak%), baseline leakage was measured with all leak locations capped (R), the measured leakage at each individual leak site ($R+L_M$), and the calibrated known leakage at each leak location (L_k). All of these variables were established while conducting this study so that the Leak%, which is the percentage of the known leakage accounted for by the difference between L_M and R leak measurements. The Leak% is calculated as follows, $\text{Leak}\% = 100\% [((R+L_M) - R)/L_k]$ (Crutchfield, et al., 1995; Crutchfield, et al., 1997).

In that same study there was a significant difference between the ambient aerosol system and the CNP system. The ambient aerosol system was able to detect 37.2% of the average overall leakage from designated known leak locations within the respirator, and was able to establish a coefficient of variation of 44.7%. They discovered that the CNP system was able to detect 97.9% of the average overall leakage from the designated know leak locations within the respirator, and were able to establish a coefficient of variation of 4.3%. The ambient aerosol system detected less than 50% of the know leakage into the respirator while the CNP system detected nearly 100% of the known leakage.

In a study done by Crutchfield et al, (1995) where known leakage was determined using controlled negative pressure and ambient aerosol systems, measurements were taken over the

course of ten day at two separate known leak locations. When calculating leakage associated with the aerosol system, particle penetration was the concern. The percentage of penetration was calculated by dividing 100 by the measured FF, $\text{Pen\%} = 100/\text{FF}$ (Crutchfield et al., 1995). The CNP system exhibited a coefficient of variation of less than 2%, while the ambient aerosol system displayed a coefficient of variation of up to 15% during precision tests with a fixed leak assembly. The controlled negative pressure system resulted in measuring an average of 105% of the known leakage through the designated leak sources, with a coefficient of variation of 10%. Furthermore, the ambient aerosol system resulted in measuring an average of 21% of the known leakage through the known leak location, with a coefficient of variation of 62%.

In an article addressing the comparison of the portable condensation nucleus counter (PortaCount model 8010 by TSI) to an aerosol photometer (Biermann et al., 1991), they used an oil mist aerosol and an ambient room aerosol. While using the full-face respirator for the experimental data collection, a moderate breathing work rate of 40L/min was established, which is 23.6 respirations/min. They noted that a photometer measures that amount of particles by scattering light, and historically has been used to measure the performance of high-efficiency particulate air filters (HEPA), and respirators. Biermann et al., (1991) also informs the reader that a Condensation Nucleus Counter (CNC) such as the PortaCount^{TM} is much more sensitive to smaller aerosol particles and individual particles than a photometer, due to its ability to introduce vapor to the detected particles, which can cause particle growth, making them more detectable by the scattering light. This allows for particles as small as <0.1 micrometer in diameter to be detected. In workplace environments, aerosol concentrations have been reported as high as 2,000-30,000 particles/cm³, and in environments as these barring any technical difficulties, the PortaCount^{TM} can perform to the best of its ability because it is internally configured not to produce a fit factor score when the particle concentration is less than 1500 particles/cm³ (Biermann et al., 1991). Biermann, et al, (1991) also observed that although CNC instrument have been used to assess the performance of protection devices, they have always been used in conjunction with other aerosol instruments so that the relationships between aerosol penetration and aerosol particle size can be thoroughly investigated.

In the study comparing the PortaCount^{TM} and photometer (Biermann et al., 1991), measured fit factors by the two instruments agree at scores below 1000 when using the oil mist

aerosol and the PortaCount™ performed as well as the photometer in the one hour stability tests of fit factors. As the leak rate decreases the PortaCount™ measures significantly lower fit factor scores than the photometer. When using the room aerosol challenge agent, fit factor score using the PortaCount™ measured 2 to 7 time higher than those measured with the oil mist aerosol agent at the same leak rate conditions. The results can be attributed to the differences in particle size of the challenge aerosols.

The lack of awareness as it pertains to air quality and respirator use can be detrimental to those individuals in hazardous environments. Sometimes, occupational diseases that are caused by contaminated air can only be avoided through the use of engineering controls to prevent atmospheric contamination (Klaus et al., 1990). In an article addressing the present quantitative fit testing procedures (Klaus et al., 1990), the reader is informed that the proper fit of a respirator can be determined by qualitative or quantitative methods, and expressed in a ratio of the agent outside the mask to the agent inside the mask. The result of this ratio is known as a fit factor. They also state that the National Standards Institute provides the proper guidance on respirator selection based on the hazards, and the respirator that is chosen should provide the user with a certain minimum fit according to federal regulations for respirator types. Half-mask respirators have a minimum fit requirement of 100, while full-face respirators have a minimum fit requirement of 500. Typically, these minimum fit scores are exceeded. By doing a quantitative fit test it actually allows the user to select a respirator that gives them the desired minimum fit or exceeds the established minimum score; Fit factors are determined for each exercise of the fit factor test, and those score are calculated into an overall fit factor score to be compared to the standards so that it can be determined if this respirator is an acceptable fit (Klaus et al., 1990).

The use of a HEPA filter is very important in test where a challenge aerosol agent has been introduced to the mask. This HEPA filter has the ability to block extremely small particles. With this being so, it can be assumed that leakage into the respirator cavity was caused by imperfections in the faceseal, and not by penetration through the filter (Klaus et al., 1990).

Klaus et al, (1990) concludes by mentioning the importance of having a respirator fit test method that is reliable, but fast. If this particular test was quick, it would allow for work to be momentarily interrupted to check for dust build up on the respirator and sweat. Dust and sweat are two elements that can actually negatively affect the ability of a respirator to perform

properly. Sweating can cause slippage of the respirator, or potentially eliminate or reduce leakage by filling them with liquid (Klaus et al., 1990). Dust particles may even become trapped in the sweat, causing a buildup of grime.

Being able to properly don a respirator is something that all personnel should be thoroughly trained on. Wearing a respirator improperly can lead to leakage around the faceseal of the respirator, and typically these leak locations will be invisible to the naked eye, but some agents that contaminate the air are capable of penetrating the smallest incisions. In an article addressing methods of identifying faceseal leaks (Oestenstad et al., 1990), which would identify the location of the leak along with the size of the leak site, they mention previous methods such as a qualitative fit test which sprayed coal powder around the facepiece and the leakage was able to be determined by observing the coal deposited at each leak site. They also mentioned methods that used Freon gas as a testing agent, and light as a test agent. In the case of the Freon gas, a halide meter was used to measure the leakage. In this method a tube was attached to the Freon supply, and moved around the respirator. When the tube reached a leak site a strong deflection of the meter was observed. In the case of the light being used as the testing agent, photosensitive paper was placed under the facepiece in a darkroom setting. After the paper was properly positioned under the respirator, a high intensity light was moved around the facepiece. The photo paper would later be developed and the appearance of leakage could be determined by the observation of gray and black areas on the photo paper.

Oestenstad et al, (1990) experiments with a method of observing and locating leakage within and around the seal of a respirator the involved the use of a fluorescent trace agent being introduced to the facepiece. 4-methyl-7-diethyl-aminocoumarin (MDC) was chosen as a fluorescent whitening agent for the study, because its nontoxic, very small quantities are visible on the skin, and it could be generated in concentrations and particle size be used in current quantitative fit test methods which employ aerosols. The study involved the use of high efficiency cartridges attached to a half-mask respirator, pre-exposure and post exposure photographs under ultraviolet light, and introduction of MDC aerosol. They were able to observe the fluorescent tracer agent around the nostril of the subject, which confirmed that the phenomenon occurred within the respirator of the subject. This method of determining a leak could be used to determine the distribution of the leak site and shapes for groups of wearers,

types of respirators, various breathing rates, and interactions of these variables (Oestenstad, et al., 1990). This study may also help to identify an association of critical facial dimensions with respirator fit or facial shapes which might be accommodated by a specific respirator type or configuration (Oestenstad, et al., 1990).

In an article that addresses the theoretical basis upon which a test system has been set up to evaluate the sampling error associated with in-facepiece sampling on half-mask respirator (Myers, et al., 1986), the author focuses on test variables associated with sampling probe location (PL), sampling probe depth (PD), leak site on face seal perimeter (LS), breathing distribution patterns (BP), and measurement sample rate (SR). The factor PL represents where the sampling probe is located along the midline of the respirator. PD as it pertains to this study is the depth at which a probe is inserted into the respirator (1/2 inch, 1/4 inch, and flush < or = 1/8 inch). LS represents the location of the leak on the face seal perimeter. The nose, chin and cheek are areas that are more likely to have face seal leaks to occur (Myers, et al., 1986). Myers, et al., (1986) didn't fail to include that they questioned a number of respirator wearers, and were informed that most respirator wearers would breathe through their nose during quantitative fit testing, and would breathe through their mouth while working. BP represents the ratio of inhalation flow volume through the nose and mouth. SR represents the volumetric rate of sample through the sampling probe. SR is significant because it allows the experimenters to view the sampling probe as an open duct. This duct would then have a "capture zone" that could be defined by velocity contours.

For any in-facepiece sampling measurements to be considered valid it depends upon how well or closely the collected sample represents the environment from which it was extracted from (Meyers et al., 1986). They also mention that the validity of recovered samples is heavily based upon accuracy, precision, sensitivity, and sample recovery associated with the analytical method(s).

When negative pressure respirators are the safety equipment of choice, it's vital to understand that the environment the wearer of the respirator is operating within is subject to instantaneous flow rates, minute volumes and inboard contaminant leakage (Meyers et al., 1986). Sampling using half-mask respirators requires the sampling probe to be attached to the wall of the respirator, and the technique is to position the probe between the nose and mouth region

along the midline of the respirator (Meyers et al., 1986). Respirator sampling techniques have not been developed in the area of making strict guidelines for sampling probe diameter size or sampling flow rates (Meyers et al., 1986). Meyers, et al., (1986) was able to demonstrate that face seal leakage within a respirator is not mixing instantaneously or uniformly. They believe that the variability in quantitative fit testing results can potentially be attributed to sample bias centered around inhalation (Meyers et al., 1986).

In an article addressing the causes of in-facepiece sampling bias associated with half-mask respirators (Meyers, et al., 1988), they suggest that the leak location of a facepiece are subject to change randomly during a fit test exercises involving head-face movements, and it is believed that the variability that is caused by these facial movements could be reduced by simply have the wearer of the respirator breath through his or her mouth rather than their nose. If leak locations are changing during movement, then it's acceptable to assume that the size of the leak(s) are changing as well, causing more or less penetration of particles as the individual shifts. The acceptable particle penetration for half-mask respirators and full-face respirators is 1% - 2%, and .02% - .1% respectively (Meyers, et al., 1988).

In general, it is observed that respirator fit factor is a factor of several varying factors (Meyers, et al., 1988). The results from Meyers, et al., (1988) suggests that different magnitudes of sampling errors can be attributed to sampling probe location, area of leakage, and breathing pattern interaction. They concluded by suggesting that the bias related to in-facepiece sampling may not be easily defined, and as different parameters are set, degrees of bias will vary on different facepieces.

Chapter 3: Materials and Experimental Methods

In this comparative study of the aerosol detecting PortaCount Pro+ 8038^{TM} (particle detecting) and controlled negative pressure (CNP) Quantifit^{TM} (pressure detecting), the aim is to compare both devices' ability to fit test full-face respirator model 6800 by 3M^{TM} on subjects (mannequins) with known leak location. The Occupational Safety and Health Administration (OSHA) requires all workers (male or female) pass a qualitative (QLFT) or quantitative (QNFT) fit test before wearing a respirator (Delaney, et al., 2003). The study is taking place in a controlled environment, and the subject of choice for the experiment is a mannequin. A full-face

respirator was used in a series of seven fit tests at each known leak location, and baseline with all leak locations capped. This study is designed to assess the efficacy of both the PortaCount Pro+ 8038^{TM} and Quantifit^{TM} under the same conditions. A full-face respirator will be donned on the mannequin and a series of seven fit tests will be performed to assess the efficacy of the PortaCount^{TM} and the Quantifit^{TM} to detect the penetration, and percentage of leak.

Data collection took place over the course of 21 days. Before fit tests could begin with the PortaCount Pro+ 8038^{TM} or the Quantifit^{TM} a daily check was done with the PortaCount^{TM} and a daily calibration was performed with the Quantifit^{TM}. The daily check and daily calibration prepares each system to effectively conduct fit tests for that day.

When the half-face respirator is donned onto the mannequin and properly fitted the mask will not be removed until all fit tests are completed for both the PortaCount and the Quantifit. This means both instruments will run their fit tests using the same masks, under the same conditions. After these tests are completed the full-face mask will be removed. The full-face mask isn't being removed until each fit testing system has conducted its perspective fit tests so that the conditions remain exactly the same within the cavity of the mask, and face seal.

3.1 Materials and Instruments Used

The materials and instruments for this study are as follows:

1. TSI PortaCount Pro+ 8038^{TM}
  - a. Particle detecting instrument used to fit test respirators
2. OHD Quantifit^{TM}
  - a. Negative pressure instrument used to fit test respirators
3. Series 1101 Breathing Simulator by
  - a. Breathing simulator equipped with a bellows, used to simulate various breathing rates
4. Full-face Respirator 3M^{TM} 6800
5. House Vacuum
  - a. Used to create continuous flow rates for the PortaCount^{TM}
6. Mannequin

- a. Used as the subject to conduct various fit tests
- 7. TSI P-Trak 8525
  - a. A particle-detecting instrument used to monitor the particle concentration within the room when needed.
  - b. Can detect between 0 to 500,000 particles per cubic centimeter.
- 8. Airflow PVM 100 Micro manometer
  - a. An airflow instrument that can be used to record flow rates and pressures
- 9. TSI Particle Generator
  - a. Used to generate particles if the particle concentration isn't high enough for the PortaCount™ to conduct fit testing
- 10. Hypodermic Needles
  - a. 3 hypodermic needles
  - b. 22G, 23G, and 21G needle

3.2 Calibration

For both devices, the PortaCount Pro+ 8038™ and the Quantifit™, manufacturer calibrations are to be done on a yearly basis. The Quantifit™ has to undergo daily calibrations before fit testing, which consists of a zero check, and dual tube calibration. The PortaCount Pro+ 8038™ has to undergo a daily check that consists of a minimum particle check, classifier check, zero check and a maximum fit factor check. Before the PortaCount Pro+ 8038™ can be used for fit testing it has to achieve a minimum particle check reading that's greater than or equal to 30, a classifier reading of PASSED, a zero check reading of less than or equal to 30, and a maximum fit factor check reading of greater than or equal to 200.

3.3 Probing Masks and Seal Leak Checks

The full-face respirator will be probed in various locations so that there can be known leak locations throughout the respirator. There will be a series of fit tests that are run while the probed locations are all capped, and uncapped individually. The purpose of conducting a fit test

while all locations are capped is to achieve a baseline reading that will serve as a point of reference throughout the study.

3M^{TM} full-face mask respirator Model 6800 was probed in three locations by needles of different sizes. The full-face mask has a very large lens that covers majority of the respirator. It was very risky to attempt to probe through the lens due to the possibility of the lens cracking, causing the respirator to be useless for the study. Due to the chances of the lens cracking, the respirator was probed through the softer rubber region of the mask. Probes are positioned at the left cheek, right cheek, and chin.

When using both the PortaCount and the Quantifit, before the tests are conducted a test for leaks was conducted with all known sources capped to allow for establishing baseline leak data according to a study by Crutchfield and Park (1997).

3.4 The Study/ Experiment

In this study a series of seven fit tests were conducted with the PortaCount Pro+ 8038^{TM} and Quantifit^{TM} using a 3M^{TM} full-face mask model 6800 to determine the leak percentage at each of the three known leak locations in the full-face mask. The leak percentage was established by using formulas that have been previously proven valid in earlier research (Crutchfield et al., 1997; Crutchfield et al., 1995). The baseline measurements were taken by conducting seven fit tests with all leak locations capped. Each known leak location underwent a series of seven fit tests. These fit tests will take place under cyclic and continuous flow rate parameters when the PortaCount Pro+ 8038^{TM} is being used. The PortaCount Pro+ 8038^{TM} was setup on the continuous and cyclic breathing system at a moderate flow rate of 40L/min, which is approximately 23.6 respirations/min (Biermann et al., 1991).

The Quantifit^{TM} is a negative pressure system that operates by applying a negative pressure to the inside of the facepiece without the help of an external source. This means the Quantifit^{TM} creates its own flow rate using the settings that are available for selection within its operating system. Fit tests with the Quantifit^{TM} will be conducted using the Redon Protocol. The Redon Protocol applies a challenge pressure of .58 in H₂O, and a moderate modeled breathing flow rate of 53.8 L/min. The challenge pressure essentially creates a vacuum, causing a

continuous negative pressure within the respirator. Modeling a continuous flow rate for the PortaCount™ allows for the opportunity to compare the PortaCount™ to the Quantifit™ using a negative pressure scenario. This makes the conditions even similar, and intern decreasing the differences.

Table 1 Experimental Steps

*Calibrate Quantifit and perform Daily Check on Portacount each day

*Be able to close air flow passage to the nose and mouth when needed

*Be able to attaché breathing machine and vacuum supply when needed

1. Establish desired leak locations (insert needles)
2. Probe respirator so that Portacount can be properly connected so that fit tests can be conducted
3. Probe respirator so that internal mask pressures can be measured during Portacount and Quantifit testing
4. Don respirator on mannequin
5. Caulk respirator onto mannequin head form to eliminate unwanted leakage and stabilize respirator on head form
6. Caulk any other suspicious leak locations that may exist

*These are the setup steps that were conducted. These steps were not necessarily conducted in this order

Table 2 Steps for Conducting Testing

1. Seven baseline measurements with all leak locations capped
2. Seven measurements with leak location 1 uncapped and all other locations capped
3. Recap leak location 1
4. Seven measurements with leak location 2 uncapped and all other location capped
5. Recap leak location 2
6. Seven measurements with leak location 3 uncapped and all other locations capped
7. Seven measurements with all leak locations uncapped
8. Remove mask and repeat steps 1-7 for the next face mask

*Measurements were always conducted with the Quantifit first

Table 3 PortaCount Exercises

Quantifit Exercises

1. Normal Breathing
2. Deep Breathing
3. Head side-to-side
4. Head Down
5. Talking
6. Grimace

1. Face Forward
2. Bend Over
3. Shake Head
4. Redon 1
5. Redon 2

*One inhalation valve flap must remain opened

7. Bend Over

*Hold breath/Close valve that allows air into the head form

8. Normal Breathing

*Each exercise has an 8 sec duration

*Each exercise has a 64 sec duration

The ambient aerosol concentration was monitored using the P-Trak Model 8525 by TSI™. The P-Trak 8525™ has the ability to measure between 0 to 500,000 particles per cubic centimeter. Aerosol concentration was maintained between 1,500-3,000particles/cm³, due to the PortaCount™ having difficulty producing a fit factor score if the particle concentration is lower than 1,500particles/cm³ (Biermann et al., 1991). If it was hard to reach the desired aerosol concentration of 1,500-3,000particles/cm³, the particle generator along with sodium chloride (NaCl) salt tablets was employed to increase particle concentration in the lab.

With the Quantifit™ being a controlled negative pressure system, I will not be able to simulate breathing while conducting the fit testing. In contrast, I will simulate breathing when testing the PortaCount™, using the vacuum (constant flow) and breathing simulator (cyclic flow). The Quantifit™ has built-in settings that can simulate different work rates to meet the desired needs of those individuals that will be wearing the respirator and performing tasks, by applying what is called a challenge pressure. The desired moderate work flow rate is 40L/min

(Biermann et al., 1991). By using the in-lab vacuum system, the PortaCount^{TM} was configured to the desired 40L/min flow rate, while the Quantifit^{TM} was adjusted to the Redon Protocol setting that applies challenge pressure on .58 in H₂O accompanied by a moderate modeled breathing flow rate of 53.8 L/min. The two flow rates are very close to one another and both within the moderate breathing range.

3.4.1 Quantifit and PortaCount Measurements with Full-Mask

When conducting the first fit tests, before the known leak locations were inserted into the respirator, the full-face respirator was donned onto the mannequin head form for testing. This was done without caulk sealant, which is used to create a seal that minimizes or eliminates leakage around the seal of the respirator. The fit test score results were completely different for the Quantifit^{TM} and the PortaCount^{TM}. The PortaCount^{TM} and the Quantifit^{TM} were examined once again under the same respirator condition. The Quantifit^{TM} produced a fit factor score of 363 with a leak rate of 148.1cc/min. The displayed results showed that the Quantifit^{TM} has not reached the minimum fit factor score of 500 for a full face respirator and that there was too large of a leak in the respirator. The Quantifit^{TM} does reach its desired challenge pressure of .58 in H₂O, but reaching the challenge pressure doesn't necessarily allow the Quantifit^{TM} to meet the minimum full-face respirator requirement of 500. The PortaCount^{TM} produced an overall fit factor score of 114,821. The PortaCount^{TM} passes the minimum fit factor score of 500.

Figure 7 PortaCount Scores on Full-Face Respirator

Figure 8 Portacount™ Scores on Full-Face Respirator

Figure 9 Quantifit™ Scores on Full-Face Respirator

Figure 10 Quantifit™ Scores on Full-Face Respirator

Next, the caulk sealer was applied to the full-face respirator to provide a tighter seal. The three leak locations were established at the chin (21G needle), right cheek (23G needle), and left cheek (22G needle). The needles were inserted along the rubber of the respirator due to the lens being so hard. Trying to penetrate the lens without the proper tools could lead to the lens cracking, and destroying the respirator. It was observed that the Quantifit™ reaches the desired challenge pressure of .58 in H₂O, but

even with the caulk sealer the Quantifit™ didn't reach the minimum full-face mask required score of 500. The Portacount™ reports an overall fit factor score of 2,418, and meets the minimum full-face mask required scored of 500. I was expecting the scores to be much higher after the caulk sealer was applied to the facepiece. The low scores could be attributed to the slight buckle in the rubber of the respirator. If you look through the lens you can see how the rubber buckles a little.

Figure 11 Full-Face Respirator with Buckle on inner rim

Under these mask conditions the PortaCount™ is displaying that the respirator has a good seal on the mannequin head form, while the Quantifit™ is showing the complete opposite. Even with the caulk sealer the Quantifit™ displays that the seal on the mannequin needs to be significantly tighter. During fit tests, it was observed that if the mask was pressed while on the mannequin while fit testing with the Quantifit™, the respirator would pass the fit test with scores as high as 1201.

3.4.2. Reaching the Minimum Fit

I noticed that there could be a potential leak where the copper pipe exits the mannequin head and connects to the rubber tubing, which is attached to a valve that can be opened or closed. This valve is significant because it allow for the flow of air to be restricted, which simulates

someone holding their breath. I sealed the suspicious leak site where the copper pipe is connected to the rubber hose with caulk sealer, allowed it to dry, then resumed testing. It was observed that the Quantifit™ was reaching FF scores as high as 416, which is still lower than the desired FF score of 500 for a full-face respirator, but closer to the desired goal than previously observed. I later used a spray bottle with soap and water to locate any more leaks that may still exist around the seal of the mask and also at the copper pipe and rubber hose connection.

While a fit test is being conducted, the soap and water solution will create bubbles in the areas where leaks exist. When the soap water solution was sprayed onto the suspected leak location, scores for the Quantifit™ jumped as high as 559 and 603. At this time the mask had not been moved, and the condition remained the same. I was unable to determine how the FF score could jump to and above the desired passing score for a full-face respirator after simply spraying the soap water solution onto suspected leak locations.

Later, the caulk was removed from the copper pipe and rubber hose connection site. The copper was then inserted farther into the rubber tubing. After that change was made, I started to observe FF scores as high as 1400+. The Pre-Test was conducted several times with the Quantifit™ for a baseline reading to assure that passing FF scores could be consistently achieved, and they were. Each known leak location was given a Pre-Test as well, and the FF scores were maintained above 10000+ with leak rates as low as 6.0 cc/min. The tubing was detached and reconnected for final check to assure that the leak was sealed and the method of sealing the leak could be duplicated. After reconnecting the tubing to the copper pipe the FF score dropped below 500, showing that the leak wasn't resolved. The FF scores were as low as 270 accompanied by leak rates as large as 243 cc/min.

Figure 12 Copper Pipe Without Caulk to Eliminate Leaks

Figure 13 Copper Pipe With Caulk to Eliminate Leaks

Practice fit tests were conducted with the PortaCount™ after the tests were complete with the Quantifit™. The caulk sealer remained removed keeping the conditions the same for both systems while testing the mannequin head form to determine whether the PortaCount™ would pass or fail under the same conditions. The PortaCount™ reached fit factor scores as high as 99000+ under the same mask conditions as the Quantifit™.

With the Quantifit™ and PortaCount™ being based upon completely different foundations as it pertains to Fit-testing subjects, it is very important to understand that each system is performing at a high level. Low FF scores and high leak rates from the Quantifit™ are informing the operator that the system is sensing an air leak that is too large, so adjustments need to be made. The Quantifit™ applies its standard pressure of .58 in H₂O creating a flow rate of 53.8 L/min to establish a negative pressure within the cavity of the respirator, and if there is an air leak that is too large it will be detected by the Quantifit™. Unlike the Quantifit™, the PortaCount™ producing consistently high scores due to its foundation of detecting particles in the air is not alarming. The PortaCount™ is creating a FF by using a ratio of the in-mask particle concentration to the ambient air concentration, which is completely different from the way we reach a FF score when using the Quantifit™. So, if the conditions in a room remain the same during a fit test with the PortaCount™ and Quantifit™, with a facepiece on a subject, without removing the facepiece when switching between fit testing systems, the FF scores that are produced will be different. This is because one system bases its measurement upon the particle concentration in the mask and ambient air concentration outside the mask, while the other system bases its measurement upon negative pressure applied to the respirator and escaping air. Each fit-testing system is unique in its own way, and performs at exceptionally high levels.

The mannequin was later reset, and caulk sealer was reapplied to the copper pipe and rubber hose connection site. This time I also made adjustments to the copper pipe that extends through the mannequin head that represents the nose. The piping was previously caulked and taped, but as I covered the pipe with my hand during a Fit Test I observed that the Quantifit™ produce a FF of 10519 with a leak rate of 6.4 cc/min. I proceeded to caulk and tape the copper pipe until it appeared leak tight.

Figure 14 Quantifit™ FF Score of 10519

Figure 15 PortaCount™ FF Score of 94701

I proceeded to conduct several Pre-Tests with the Quantifit™, like before to assure that the current setup was able to consistently repeat passing FF scores. The conditions allowed for consistently passing FF scores, and repeatability. The PortaCount™ was connected to the full-face respirator under

that same respirator conditions to conduct a practice Fit Test, and the overall FF score was 94701. With the current results, I was ready to proceed to data collection on the full-face respirator.

Chapter 4: Data Analysis and Results

By using a paired t-Test to analyze the results, it allows the opportunity to assume that the means are equal, having a difference with very little statistical significance, and lastly it allows to assume that the means are not equal, having a difference that's statistically significant ($H_0: \mu \neq 0$, and $H_A: \mu = 0$). The H_0 is that the Quantifit^{TM} will detect the same amount of leakage as the PortaCount^{TM} ($H_0: \text{Quantifit} = \text{PortaCount}$). The H_A is that the Quantifit^{TM} will detect a different amount of leakage than the PortaCount^{TM} ($H_A: \text{Quantifit} \neq \text{PortaCount}$).

The leak percentage was determined by using the formula $\text{Leak\%} = 100 * ((R+N)-R)/L$, which was proven valid by Crutchfield et al (1997). The Leak rates that are detected by the PortaCount^{TM} are achieved by converting the FF score into Penetration ($\text{Penetration} = 1 / \text{FF}$), and converting Penetration to an Estimated Leakage flow rate ($\text{Estimated Leakage flow rate} = \text{Penetration} * \text{Modeled Breathing rate}$) (Crutchfield et al., 1997). Penetration percentage for the PortaCount^{TM} is achieved by calculating $100/\text{FF}$.

Table 4 PortaCount™ Measurements during Continuous Breathing

	Portacount Full-Mask Continuous Cycle (40 L/min)									
	Baseline (Needles Capped)		Needle #1 22G		Needle #2 23G		Needle #3 21G		All Uncapped	
Fit Tests	FF	Penetration%	FF	Penetration%	FF	Penetration%	FF	Penetration%	FF	Penetration%
1	1602	0.062421973	2364	0.042301184	3382	0.029568303	631	0.158478605	1337	0.074794316
2	2649	0.037750094	2790	0.035842294	3433	0.029129042	1678	0.059594756	1205	0.082987552
3	2558	0.039093041	2470	0.04048583	2979	0.033568312	1254	0.079744817	1028	0.097276265
4	2125	0.047058824	2180	0.04587156	2701	0.037023325	1398	0.071530758	1175	0.085106383
5	2218	0.045085663	2393	0.04178855	2728	0.036656891	1089	0.091827365	1081	0.092506938
6	1999	0.050025013	2201	0.045433894	2300	0.043478261	1328	0.075301205	1139	0.087796313
7	1947	0.051361068	1945	0.051413882	2459	0.040666938	1211	0.082576383	1051	0.095147479
Mean	2156.85714	0.047542239	2334.714	0.043305313	2854.571	0.035727296	1227	0.08843627	1145.143	0.087945035
COV,%		17.50787718		11.30559326		15.03622782		36.69149894		8.873015562
Variance		6.92829E-05		2.39701E-05		2.88588E-05		0.001052911		6.08927E-05
Stdev		0.008323637		0.004895923		0.005372038		0.032448593		0.007803377
Penetration	0.00046364		0.000428		0.00035		0.000815		0.000873	
Leak Rate L	0.0185455		0.017133		0.014013		0.0326		0.03493	
Leak Rate mL	18.5455027		17.13272		14.01261		32.59984		34.93014	
Leak %			-2.927		-1.421		11.075			
Avg Leak%	2.242									

*FF means Fit Factor

*LR means Leak Rate

*Penetration = $1/FF$

*Penetration% = $100/FF$

In the graph above displaying the continuous breathing cycle data for the PortaCount™, the focal point is the Leak% and Avg Leak% rows, which are highlighted in red. As the gauges for the needles increase, the leak rate and leak percentage increases. The needle sizes increases from 23G, 22G, and 21G, gauge size has an inverse relationship. The negative values for leak needles 1, and 2 can potentially be attributed to the continuous breathing cycle, and the small diameters of the 22G and 23G needles. During the continuous cycle the PortaCount™ is attached to the lab vacuum system, which is applying a modeled breathing rate of 40L/min along with an average internal mask pressure of .53in H₂O. The PortaCount™ is not designed for the wearers of the respirator to hold his or her breathe while a negative pressure is created within the respirator cavity. The PortaCount's inability to detect leakage can potentially be attributed to the continuous breathing cycle having a negative effect on the PortaCount™.

Table 5 PortaCount™ Measurements during Cyclic Breathing

Portacount Full-Mask Cyclic (40 L/min) Measurements										
Baseline (Needles Capped)			Needle #1 22G		Needle #2 23G		Needle #3 21G		All Uncapped	
Fit Test	FF	Penetration%	FF	Penetration%	FF	Penetration%	FF	Penetration%	FF	penetration%
1	2039	0.049043649	2026	0.049358342	1576	0.063451777	965	0.103626943	973	0.102774923
2	1993	0.050175615	2310	0.043290043	1783	0.05608525	924	0.108225108	1103	0.090661831
3	2434	0.041084634	2230	0.044843049	1816	0.055066079	817	0.122399021	1056	0.09469697
4	1800	0.055555556	1823	0.054854635	1728	0.05787037	935	0.106951872	837	0.119474313
5	1660	0.060240964	1595	0.062695925	1822	0.054884742	852	0.117370892	946	0.105708245
6	3079	0.032478077	1766	0.056625142	1660	0.060240964	848	0.117924528	1024	0.09765625
7	2534	0.039463299	1600	0.0625	1600	0.0625	759	0.131752306	802	0.124688279
Mean	2219.857	0.046863113	1907.143	0.053452448	1712.143	0.058585597	871.4286	0.115464381	963	0.105094402
COV, %		20.7130626		14.7603386		6.018263992		8.574128482		12.08718561
Variance		9.42217E-05		6.22483E-05		1.24315E-05		9.80113E-05		0.000161365
Stdev		0.009706786		0.007889762		0.003525836		0.009900064		0.012702955
Penetration	0.00045		0.000524		0.000584		0.001148		0.001038	
Leak Rate	0.018019		0.020974		0.023363		0.045902		0.041537	
Leak Rate mL	18.01918		20.97378		23.36254		45.90164		41.53686	
Leak %			6.8776		3.664		50.769			
Avg Leak%	20.437									

*FF means Fit Factor

*LR means Leak Rate

*Penetration = 1/ FF

*Penetration% = 100/FF

In the graph above displaying the cyclic breathing cycle data for the PortaCount™, the focal point is the Leak% and Avg Leak% rows, which are highlighted in red. The results show that the leak rates and leak% increase as the gauge size increases. There is an inverse relationship between the gauge size and leak rate. There is adverse relationship between the leak rate and leak%, as expected. The average leak percentage for the cyclic breathing cycle at a modeled breathing rate of 40L/min was 20%. The PortaCount™ produces positive values for leak percentages, as expected under the cyclic breathing parameters. The difference in scores in comparison to the scores during the continuous breathing cycle can potentially be attributed to the cyclic breathing cycle allowing for inhalation and exhalation. The PortaCount™ works at its best when the subject inhales and exhales as the fit testing exercises desire.

Table 6 Quantifit™ Measurements during Redon Protocol

Quantifit Redon Protocol Full-Mask (.58 in H2O, 53.8L/min) Measurements											
		Baseline (Needles Capped)		Needle #1 22G		Needle #2 23G		Needle #3 21G		All Uncapped	
Fit Tests		FF	LR	FF	LR	FF	LR	FF	LR	FF	LR
1	9539	5.64	4622	11.62	5134	10.48	852	63.16	735	73.22	
2	11956	4.5	3904	13.78	5028	10.7	973	55.3	735	73.2	
3	9817	5.48	4402	12.22	4936	10.9	963	55.86	731	73.6	
4	9505	5.66	3848	13.98	5028	10.7	1005	53.52	739	72.82	
5	10591	5.08	2989	18	5028	10.7	1002	53.7	735	73.2	
6	8907	6.04	2076	25.92	3606	14.92	991	54.3	735	73.22	
7	9212	5.84	2061	26.1	2360	22.8	973	55.28	738	73.2	
Mean	9932.429	5.463	3414.571	17.374	4445.714	13.029	965.571	55.874	735.429	73.209	
COV,%		9.510443147		35.91912		35.22225		5.958911		0.307814	
Variance		0.27		38.95		21.06		11.09		0.05	
Stdev		0.519541923		6.240691		4.588956		3.329499		0.225346	
Leak%				24.68178		2.372441		39.72532			
R				5.463		5.463		5.463			
R+N				17.374		13.029		55.874			
L				48.26		318.9		126.9			
Penetration	0.000101		0.000293		0.000225		0.001036		0.00136		
Leak Rate L	0.005417		0.015756		0.012102		0.055718		0.073155		
Leak Rate mL	5.416601		15.756		12.10154		55.7183		73.15462		
Avg Leak%	22.25985										

*FF means Fit Factor

*LR means Leak Rate

*R is the average baseline LR

*R+N is the measured LR at leak needle

*L is the calibrated needle flow rate

*Leak% = $100 * ((R + N) - R) / L$

In the graph above displaying the Quantifit™ results during the Redon Protocol, the focal point is the Leak% and Avg Leak% rows, which are highlighted in red. The results show that the leak rates and leak% increase as the gauge size increases. There is an inverse relationship between the gauge size and leak rate. There is an adverse relationship between the leak rate and

leak%, as expected. The average leak percentage for the Quantifit™ using the Redon Protocol, applying .58in H₂O along with a modeled breathing rate of 53.8 L/min, was 22%.

4.1 Summary

In summary, the data retrieved from sampling with the PortaCount™ on both the continuous breathing cycle and cyclic breathing cycle, and Quantifit™ was compared and simplified. Detailed figures for p-value information are provided in Appendix B.

Table 7 PortaCount™ on Continuous Breathing Cycle Vs. Quantifit™

Full-Face Respirator: Portacount Continuous Breathing Vs. Quantifit				
	P- value	Hypothesis	Quantifit LR (mL)	Portacount LR (mL)
Baseline	p < .05	reject Ho	5.46	19.01
Needle #1 22G	p > .05	accept Ho	17.37	17.32
Needle #2 23G	p > .05	accept Ho	13.02	14.29
Needle #3 21G	p < .05	reject Ho	55.87	35.37
All Uncapped	p < .05	reject Ho	73.2	35.117

*LR means Leak Rate

The area that is highlighted in red shows a comparison between the Quantifit™ and PortaCount™ at leak needle 1 (22G), and leak needle 2 (23G). The data at these two locations accepts the Ho, that states the leakage detected by the Quantifit™ and PortaCount™ are equal, having a statistical difference that isn't significant. The p-value for the comparison of leak needle 1 for the PortaCount™ and Quantifit™ can be found in Appendix B on Table 5. The p-value for the comparison of leak needle 2 for the PortaCount™ and Quantifit™ can be found in Appendix B on Table 6. The comparison of data at baseline, needle 3, and also with all locations uncapped, displays data that rejects the Ho, and in favor of the H_A, stating that the Quantifit™ and PortaCount™ are not equal, having a difference in leakage that is statistically significant.

Table 8 PotaCount™ on Cyclic Breathing Cycle Vs. Quantifit™

Full-Face Respirator: Portacount Cyclic Breathing Vs. Quantifit				
	P- value	Hypothesis	Quantifit LR (mL)	Portacount LR (mL)
Baseline	p < .05	reject Ho	5.46	18.74
Needle #1 22G	p > .05	accept Ho	17.37	21.38
Needle #2 23G	p < .05	reject Ho	13.02	23.43
Needle #3 21G	p < .05	reject Ho	55.87	46.18
All Uncapped	p < .05	reject Ho	73.2	42.03

*LR means Leak Rate

The area that is highlighted in red shows a comparison between the Quantifit™ and PortaCount™ at leak needle 1 (22G). The data at this location accepts the Ho, that states the leakage detected by the Quantifit™ and PortaCount™ are equal, having a statistical difference that isn't significant. The p-value for the comparison of leak needle 1 for the PortaCount™ and Quantifit™ can be found in Appendix B on table 10. The comparison of data at baseline, needle 2, needle 3, and also with all locations uncapped, displays data that rejects the Ho, and is in favor of the HA, stating that the Quantifit™ and PortaCount™ are not equal, having a difference in leakage that is statistically significant.

Chapter 6: Discussion and Conclusion

The overall leak percentage was achieved by taking the average of the leak percentages from leak needle 1, 2, and 3, excluding the leak percentage when all leak needles were uncapped.

Table 9 PortaCount™ and Quantifit™ Overall Leak Percentage

Portacount Vs. Quantifit Overall Leak Percentage			
	Quantifit Leak %	Portacount Continuous Breathing Leak %	Portacount Cyclic Breathing Leak %
Full-Face Respirator	22.25%	2.24%	20.43%

When comparing the Quantifit™ and the PortaCount™, the PortaCount™ operating under the cyclic breathing rate of 40L/min compared to the Quantifit™ Redon Protocol .58in H₂O

and a modeled breathing rate of 53.8 L/min yields the greatest findings. The measurements exhibit the Quantifit™ and the ProtaCount™ nearly evenly yoked with overall leak percentages being 22%, and 20% respectively. The results show that the PortaCount™ works best when the wearer of the respirator breaths (inhales and exhales) during the designated exercises as one should during PortaCount™ fit testing. While operating under the cyclic breathing, the PortaCount™ detected an overall average leakage of 20%. It is also observed that the PortaCount™ doesn't detect as much leakage when the continuous breathing parameters are applied, only detecting 2% of the known leakage.

When observing baseline leakage compared to the leakage at each known leak location, it is expected to have the least amount of leakage at baseline, and leakage should increase as the gauge size of the needles become larger. When conducting studies with the Quantifit™ the results are as expected and easier to understand, since they increase from baseline to the largest needle as expected to do so in the study. On the other hand, the PortaCount™ results aren't as easy to give reason to during certain samples. For example, looking at Table 7 during the continuous breathing cycle with the PortaCount™, the baseline reading is 19.01mL/min. From that measurement it would be expected for the measurements to increase, with the 23G needle having the second lowest leak rate, and the 21G needle having the greatest leak rate, but when all leak locations are uncapped it is expected for the leak rate to be much higher than all leak locations. The Quantifit™ exhibits data increasing in increments, as expected throughout the experiment. The consistency of the Quantifit™ could potentially be attributed to the CNP system that's built within, and the measurements achieved by the PortaCount™ can be potentially attributed to the mechanics of its aerosol detecting system.

While comparing the Quantifit™ with the PortaCount™ operating with cyclic breathing parameter at 40L/min, data displays the two system competing very well side-by-side. With the cyclic parameters applied, the PortaCount™ continues to exhibit numerical leak rate results that aren't ideal, unlike the Quantifit™, as mentioned in the paragraph above. For example, Table 8 displays the PortaCount™ with a baseline leak rate that's lower than the other expected measurements, but as the measurements for leak needle 1 (22G), and leak needle 2 (23G) are observed the measurements read 21.38mL/min, and 23.43mL/min respectively. Ideally it would

be expected for the 22G needle to have a greater leak rate than the 23G needle due to it having a larger diameter.

There isn't an established standard that allows the PortaCount and Quantifit to be compared to one another. The Quantifit has an internal mechanism that computes a leak rate, while the PortaCount doesn't. These are limiting factor to the study. By converting the PortaCount's FF score to Penetration ($\text{Penetration} = 1/\text{FF}$), and converting Penetration to Estimated leak rate ($\text{Penetration} * \text{Modeled breathing rate}$) (Crutchfield et al., 1997). The calculation produces an estimate value for the PortaCount.

In conclusion, the data shows that each system can detect leak rates that are very similar, and some that have slight statistical differences. With the same in-mask and external mask conditions applied to each fit testing system (PortaCount^{TM} and Quantifit^{TM}), it is observed that the PortaCount's need to detect aerosols inside and outside the mask verses the Quantifit's need to create a negative pressure and detect escaping air into the cavity of the facepiece, play a major role in the output results. The findings direct me to believe that the PortaCount's ability to produce a FF score is based more largely on the room/atmosphere conditions than the Quantifit's FF score. The overall leak percentage results from the PortaCount^{TM} (20%) during cyclic breathing compared to the Quantifit^{TM} (22%) during the Redon Protocol supports Crutchfield et al (1997) belief that aerosol penetration rates equal air penetration rates. The findings give reason to believe that aerosol penetration into a respirator is the same as air being detected escaping into a respirator, with very little difference between to two.

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Appendix A: Raw Data

Table 1 PortaCount™ Full-Mask Continuous Breathing Measurements

	Portacount Full-Mask Continuous Cycle (40 L/min)									
	Baseline (Needles Capped)		Needle #1 22G		Needle #2 23G		Needle #3 21G		All Uncapped	
Fit Tests	FF	Penetration%	FF	Penetration%	FF	Penetration%	FF	Penetration%	FF	Penetration%
1	1602	0.062421973	2364	0.042301184	3382	0.029568303	631	0.158478605	1337	0.074794316
2	2649	0.037750094	2790	0.035842294	3433	0.029129042	1678	0.059594756	1205	0.082987552
3	2558	0.039093041	2470	0.04048583	2979	0.033568312	1254	0.079744817	1028	0.097276265
4	2125	0.047058824	2180	0.04587156	2701	0.037023325	1398	0.071530758	1175	0.085106383
5	2218	0.045085663	2393	0.04178855	2728	0.036656891	1089	0.091827365	1081	0.092506938
6	1999	0.050025013	2201	0.045433894	2300	0.043478261	1328	0.075301205	1139	0.087796313
7	1947	0.051361068	1945	0.051413882	2459	0.040666938	1211	0.082576383	1051	0.095147479
Mean	2156.85714	0.047542239	2334.714	0.043305313	2854.571	0.035727296	1227	0.08843627	1145.143	0.087945035
COV,%		17.50787718		11.30559326		15.03622782		36.69149894		8.873015562
Variance		6.92829E-05		2.39701E-05		2.88588E-05		0.001052911		6.08927E-05
Stddev		0.008323637		0.004895923		0.005372038		0.032448593		0.007803377
Penetration	0.00046364		0.000428		0.00035		0.000815		0.000873	
Leak Rate L	0.0185455		0.017133		0.014013		0.0326		0.03493	
Leak Rate mL	18.5455027		17.13272		14.01261		32.59984		34.93014	

*FF means Fit Factor

*LR means Leak Rate

*Penetration = 1/ FF

*Penetration% = 100/FF

Table 2 Full-Mask PortaCount™ Cyclic Breathing Measurements

Portacount Full-Mask Cyclic (40 L/min) Measurements										
Baseline (Needles Capped)			Needle #1 22G		Needle #2 23G		Needle #3 21G		All Uncapped	
Fit Test	ff	Penetration%	ff	Penetration%	ff	Penetration%	ff	Penetration%	ff	penetration%
1	2039	0.049043649	2026	0.049358342	1576	0.063451777	965	0.103626943	973	0.102774923
2	1993	0.050175615	2310	0.043290043	1783	0.05608525	924	0.108225108	1103	0.090661831
3	2434	0.041084634	2230	0.044843049	1816	0.055066079	817	0.122399021	1056	0.09469697
4	1800	0.055555556	1823	0.054854635	1728	0.05787037	935	0.106951872	837	0.119474313
5	1660	0.060240964	1595	0.062695925	1822	0.054884742	852	0.117370892	946	0.105708245
6	3079	0.032478077	1766	0.056625142	1660	0.060240964	848	0.117924528	1024	0.09765625
7	2534	0.039463299	1600	0.0625	1600	0.0625	759	0.131752306	802	0.124688279
Mean	2219.857	0.046863113	1907.143	0.053452448	1712.143	0.058585597	871.4286	0.115464381	963	0.105094402
COV, %		20.7130626		14.7603386		6.018263992		8.574128482		12.08718561
Variance		9.42217E-05		6.22483E-05		1.24315E-05		9.80113E-05		0.000161365
Stdev		0.009706786		0.007889762		0.003525836		0.009900064		0.012702955
Penetration	0.00045		0.000524		0.000584		0.001148		0.001038	
Leak Rate	0.018019		0.020974		0.023363		0.045902		0.041537	
Leak Rate mL	18.01918		20.97378		23.36254		45.90164		41.53686	

*FF means Fit Factor

*LR means Leak Rate

*Penetration = 1/ FF

*Penetration% = 100/FF

Table 3 Full-Mask Quantifit™ Measurements Redon Protocol

Quantifit Redon Protocol Full-Mask (.58 in H2O, 53.8L/min) Measurements										
	Baseline (Needles Capped)		Needle #1 22G		Needle #2 23G		Needle #3 21G		All Uncapped	
Fit Tests	FF	LR	FF	LR	FF	LR	FF	LR	FF	LR
1	9539	5.64	4622	11.62	5134	10.48	852	63.16	735	73.22
2	11956	4.5	3904	13.78	5028	10.7	973	55.3	735	73.2
3	9817	5.48	4402	12.22	4936	10.9	963	55.86	731	73.6
4	9505	5.66	3848	13.98	5028	10.7	1005	53.52	739	72.82
5	10591	5.08	2989	18	5028	10.7	1002	53.7	735	73.2
6	8907	6.04	2076	25.92	3606	14.92	991	54.3	735	73.22
7	9212	5.84	2061	26.1	2360	22.8	973	55.28	738	73.2
Mean	9932.429	5.463	3414.571	17.374	4445.714	13.029	965.571	55.874	735.429	73.209
COV,%		9.510443147		35.91912		35.22225		5.958911		0.307814
Variance		0.27		38.95		21.06		11.09		0.05
Stdev		0.519541923		6.240691		4.588956		3.329499		0.225346
Leak%				24.68178		2.372441		39.72532		41.13613
R				5.463		5.463		5.463		5.463
R+N				17.374		13.029		55.874		73.209
L				48.26		318.9		126.9		164.687
Penetration	0.000101		0.000293		0.000225		0.001036		0.00136	
Leak Rate L	0.005417		0.015756		0.012102		0.055718		0.073155	
Leak Rate mL	5.416601		15.756		12.10154		55.7183		73.15462	

*FF means Fit Factor

*LR means Leak Rate

*R is the average baseline LR

*R+N is the measured LR at leak needle

*L is the calibrated needle flow rate

*Leak% = $100 * ((R + N) - R) / L$

Appendix B: Raw Data

Table 4 Paired t-Test PortaCount™ Continuous Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Portacount Baseline	Quantifit Baseline
Mean	19.01689574	5.462857143
Variance	11.08526893	0.26992381
Observations	7	7
Pearson Correlation	0.602685668	
Hypothesized Mean Difference	0	
df	6	
t Stat	11.77807495	
P(T<=t) one-tail	1.13118E-05	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	2.26236E-05	
t Critical two-tail	2.446911851	

	LR at base	pen baseline	difference		
1	5.64	24.96878901	19.32878901	mean difference	13.55404
2	4.5	15.10003775	10.60003775	stdev of diff	3.044692
3	5.48	15.63721658	10.15721658	sdt error of diff	1.150786
4	5.66	18.82352941	13.16352941	tAlpha half 95% CI	2.446912
5	5.08	18.0342651	12.9542651	LCL	10.73817
6	6.04	20.010005	13.970005	UCL	16.36991
7	5.84	20.54442732	14.70442732		
mean	5.462857	19.01689574	13.5540386		

*LR means Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring 11.778 standard deviations from the mean. The t-statistic is greater than the t-critical two-tail value of 2.446, which is in favor of rejecting the H_0 , and accepting the H_A ($H_A: \mu \neq 0$) stating there is a difference in baseline measurements for the Quantifit and Portacount during baseline measurements that are

statistically significant. The p-value is 2.26E-5, which is less than the alpha value of .05 ($p < .05$), and in favor of rejecting the H_0 . The UCL is 16.369, LCL is 10.738, and the mean difference is 13.554, there is 95% confidence that the mean difference in leak rate at baseline for the Quantifit and Portacount is between UCL and LCL.

Table 5 Paired t-Test PortaCount™ Continuous Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Quantifit needle 1	Portacount needle 1
Mean	17.37428571	17.32212533
Variance	38.94622857	3.83520927
Observations	7	7
Pearson Correlation	0.689591051	
Hypothesized Mean Difference	0	
df	6	
t Stat	0.02710347	
P(T<=t) one-tail	0.489628095	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	0.979256191	
t Critical two-tail	2.446911851	

	LR needle 1	Pen needle 1	difference		
1	11.62	16.92047377	-5.300473773	mean difference	0.05216
2	13.78	14.33691756	-0.556917563	stdev of diff	5.091724
3	12.22	16.19433198	-3.974331984	sdt error of diff	1.924491
4	13.98	18.34862385	-4.368623853	tAlpha half 95% CI	2.446912
5	18	16.71541997	1.284580025	LCL	-4.6569
6	25.92	18.17355747	7.746442526	UCL	4.76122
7	26.1	20.5655527	5.534447301		
mean	17.37428571	17.32212533	0.052160383		

*LR means Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring .027 standard deviations from the mean. The t-statistic is less than the t-critical two-tail value of 2.446, which is in favor of accepting the Ho (Ho: $\mu = 0$) stating there isn't a difference in Quantifit measurements at leak location 1, and Portacount measurements at leak location 1 that are statistically significant. The p-value is .979, which is greater than the alpha value of .05 ($p > .05$), and in favor of accepting the Ho. The UCL is 4.761, LCL is -4.656, and the mean difference is .052, there is 95% confidence that the mean difference in leak rate for the Portacount and Quantifit at leak location 1 is between UCL and LCL.

Table 6 Paired t-Test PortaCount™ Continuous Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Portacount needle 2	Quantifit needle 2
Mean	14.29091833	13.02857143
Variance	4.617406064	21.05851429
Observations	7	7
Pearson Correlation	0.631468447	
Hypothesized Mean Difference	0	
df	6	
t Stat	0.918488514	
P(T<=t) one-tail	0.196893765	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	0.393787529	
t Critical two-tail	2.446911851	

	LR needle 2	Pen needle 2	difference		
1	10.48	11.82732111	1.347321112	mean difference	1.262347
2	10.7	11.65161666	0.951616662	stdev of diff	3.636252
3	10.9	13.42732461	2.527324606	sdt error of diff	1.374374
4	10.7	14.80932988	4.109329878	tAlpha half 95% CI	2.446912
5	10.7	14.6627566	3.962756598	LCL	-2.10063
6	14.92	17.39130435	2.471304348	UCL	4.625319
7	22.8	16.26677511	-6.533224888		
mean	13.02857143	14.29091833	1.262346902		

*LR means Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring .918 standard deviations from the mean. The t-statistic is less than the t-critical two-tail value of 2.446, which is in favor of accepting the Ho (Ho: $\mu = 0$) stating there isn't a difference in Quantifit measurements at leak location 2, and Portacount measurements at leak location 2 that are statistically significant. The p-value is .393, which is greater than the alpha value of .05 ($p > .05$), and in favor of accepting the Ho. The UCL is 4.625, LCL is -2.100, and the mean difference is 1.262, there is 95% confidence that the mean difference in leak rate for the Portacount and Quantifit at leak location 2 is between UCL and LCL.

Table 7 Paired t-Test PortaCount™ Continuous Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Quantifit needle 3	Portacount needle 3
Mean	55.87428571	35.37450791
Variance	11.0855619	168.4657899
Observations	7	7
Pearson Correlation	0.900279374	
Hypothesized Mean Difference	0	
df	6	
t Stat	5.377147442	
P(T<=t) one-tail	0.000850121	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	0.001700242	
t Critical two-tail	2.446911851	

	LR needle 3	Pen needle 3	difference		
1	63.16	63.39144216	-0.231442155	mean difference	20.49978
2	55.3	23.83790226	31.46209774	stdev of diff	10.08663
3	55.86	31.89792663	23.96207337	sdt error of diff	3.812389
4	53.52	28.61230329	24.90769671	tAlpha half 95% CI	2.446912
5	53.7	36.73094582	16.96905418	LCL	11.1712
6	54.3	30.12048193	24.17951807	UCL	29.82836
7	55.28	33.03055326	22.24944674		
mean	55.87428571	35.37450791	20.49977781		

*LR mean Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring 5.377 standard deviations from the mean. The t-statistic is greater than the t-critical two-tail value of 2.446, which is in favor of rejecting the H_0 , and accepting the H_A ($H_A: \mu \neq 0$) stating there is a difference in measurements for the Quantifit and Portacount during measurements at leak location 3 that are statistically significant. The p-value is .0017, which is less than the alpha value of .05 ($p < .05$), and in favor of rejecting the H_0 . The UCL is 29.828, LCL is 11.171, and the mean difference is 20.499, there is 95% confidence that the mean difference in leak rate at leak location 3 for the Quantifit and Portacount is between UCL and LCL.

Table 8 Paired t-Test PortaCount™ Continuous Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Quantifit All Uncapped	Portacount All Uncapped
Mean	73.20857143	35.17801396
Variance	0.050780952	9.742829897
Observations	7	7
Pearson Correlation	0.430792245	
Hypothesized Mean Difference	0	
df	6	
t Stat	33.19563776	
P(T<=t) one-tail	2.48655E-08	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	4.9731E-08	
t Critical two-tail	2.446911851	

	LR All Uncapped	Pen All Uncapped	difference		
1	73.22	29.91772625	43.30227375	mean difference	38.03056
2	73.2	33.19502075	40.00497925	stdev of diff	3.031103
3	73.6	38.91050584	34.68949416	sdt error of diff	1.145649
4	72.82	34.04255319	38.77744681	tAlpha half 95% CI	2.446912
5	73.2	37.00277521	36.19722479	LCL	35.22725
6	73.22	35.11852502	38.10147498	UCL	40.83386
7	73.2	38.05899144	35.14100856		
mean	73.20857143	35.17801396	38.03055747		

*LR means Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring 33.195 standard deviations from the mean. The t-statistic is greater than the t-critical two-tail value of 2.446, which is in favor of rejecting the H_0 , and accepting the H_A ($H_A: \mu \neq 0$), stating there is a difference in measurements for the Quantifit and Portacount with all leak locations uncapped that is statistically significant. The p-value is 4.973E-8, which is less than the alpha value of .05 ($p < .05$), and in favor of rejecting the H_0 . The UCL is 40.833, LCL is 35.227, and the mean difference is 38.030, there is

95% confidence that the mean difference in leak rate with all leak location uncapped for the Quantifit and Portacount is between UCL and LCL.

Table 9 Paired t-Test PortaCount™ Cyclic Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Portacount baseline	Quantifit baseline
Mean	18.74524535	5.462857143
Variance	15.07547114	0.26992381
Observations	7	7
Pearson Correlation	-0.57515816	
Hypothesized Mean Difference	0	
df	6	
t Stat	8.360993952	
P(T<=t) one-tail	7.9571E-05	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	0.000159142	
t Critical two-tail	2.446911851	

	LR at baseline	Pen baseline	difference		
1	5.64	19.61745954	13.97746	mean difference	13.28239
2	4.5	20.07024586	15.57025	stdev of diff	4.203076
3	5.48	16.43385374	10.95385	sdt error of diff	1.588614
4	5.66	22.22222222	16.56222	tAlpha half 95% CI	2.446912
5	5.08	24.09638554	19.01639	LCL	9.395191
6	6.04	12.99123092	6.951231	UCL	17.16959
7	5.84	15.78531965	9.94532		
mean	5.462857143	18.74524535	13.28239		

*LR means Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring 8.360 standard deviations from the mean. The t-statistic is greater than the t-critical two-tail value of 2.446, which is in favor of rejecting the Ho, and accepting the HA (HA: $\mu \neq 0$), stating there is a difference in measurements for the Quantifit at baseline and the Portacount using cyclic breathing at baseline that is

statistically significant. The p-value is .000159, which is less than the alpha value of .05 ($p < .05$), and in favor of rejecting the H_0 . The UCL is 17.169, LCL is 9.395, and the mean difference is 13.282, there is 95% confidence that the mean difference in leak rates at baseline for the Quantifit and Portacount is between UCL and LCL.

Table 10 Paired t-Test PortaCount™ Cyclic Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Portacount needle 1	Quantifit needle 1
Mean	21.38097918	17.37428571
Variance	9.95973589	38.94622857
Observations	7	7
Pearson Correlation	0.716066263	
Hypothesized Mean Difference	0	
df	6	
t Stat	2.329963916	
P(T<=t) one-tail	0.029321813	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	0.058643626	
t Critical two-tail	2.446911851	

	LR needle 1	Pen needle 1	difference		
1	11.62	19.74333662	8.123337	mean difference	4.006693
2	13.78	17.31601732	3.536017	stdev of diff	4.549733
3	12.22	17.93721973	5.71722	sdt error of diff	1.719638
4	13.98	21.94185409	7.961854	tAlpha half 95% CI	2.446912
5	18	25.07836991	7.07837	LCL	-0.20111
6	25.92	22.65005663	-3.26994	UCL	8.214495
7	26.1	25	-1.1		
mean	17.37428571	21.38097918	4.006693		

*LR means Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring 2.329 standard deviations from the mean. The t-statistic is less than the t-critical two-tail value of 2.446, which is in favor of

accepting the Ho ($H_0: \mu = 0$) stating there isn't a difference in Quantifit measurements at leak location 1, and Portacount measurements at leak location 1 that are statistically significant. The p-value is .058, which is slightly greater than the alpha value of .05 ($p > .05$), and in favor of accepting the Ho. The UCL is 8.214, LCL is -.201, and the mean difference is 4.006, there is 95% confidence that the mean difference in leak rate for the Portacount and Quantifit at leak location 1 is between UCL and LCL.

Table 11 Paired t-Test PortaCount™ Cyclic Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Portaconut needle 2	Quantifit needle 2
Mean	23.43423896	13.02857143
Variance	1.989043022	21.05851429
Observations	7	7
Pearson Correlation	0.541571532	
Hypothesized Mean Difference	0	
df	6	
t Stat	6.874651328	
P(T<=t) one-tail	0.000233512	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	0.000467024	
t Critical two-tail	2.446911851	

	LR needle 2	Pen needle 2	difference		
1	10.48	25.38071066	14.90071	mean difference	11.77328
2	10.7	22.43409983	11.7341	stdev of diff	4.004684
3	10.9	22.02643172	11.12643	sdt error of diff	1.513628
4	10.7	23.14814815	12.44815	tAlpha half 95% CI	2.446912
5	10.7	21.95389682	11.2539	LCL	8.069564
6	14.92	24.09638554	9.176386	UCL	15.47699
7	22.8	25	2.2		
mean	13.02857143	23.43423896	11.77328		

*LR mean Leak Rate, and is referring to Quantifit™ measurements

*Pen mean penetration (Pen = 1/FF), and refers to PortaCount™ measurements

The t-statistic shows that the results are occurring 6.874 standard deviations from the mean. The t-statistic is greater than the t-critical two-tail value of 2.446, which is in favor of rejecting the H_0 , and accepting the H_A ($H_A: \mu \neq 0$), stating there is a difference in measurements for the Quantifit at leak location 2 and the Portacount using cyclic breathing at leak location 2 that is statistically significant. The p-value is .000467, which is less than the alpha value of .05 ($p < .05$), and in favor of rejecting the H_0 . The UCL is 15.476, LCL is 8.069, and the mean difference is 11.773, there is 95% confidence that the mean difference in leak rates at needle 2 for the Quantifit and Portacount is between UCL and LCL.

Table 12 Paired t-Test PortaCount^{TM} Cyclic Breathing Vs. Quantifit^{TM}

t-Test: Paired Two Sample for Means		
	Quantifit needle 3 Portacount needle 3	
Mean	55.87428571	46.18575255
Variance	11.0855619	15.68180406
Observations	7	7
Pearson Correlation	-0.403708878	
Hypothesized Mean Difference	0	
df	6	
t Stat	4.190783898	
P(T<=t) one-tail	0.002872126	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	0.005744252	
t Critical two-tail	2.446911851	

	LR needle 3	Pen needle 3	difference		
1	63.16	41.4507772	21.70922	mean difference	9.688533
2	55.3	43.29004329	12.00996	stdev of diff	6.116624
3	55.86	48.95960832	6.900392	sdt error of diff	2.311867
4	53.52	42.78074866	10.73925	tAlpha half 95% CI	2.446912
5	53.7	46.94835681	6.751643	LCL	4.031599
6	54.3	47.16981132	7.130189	UCL	15.34547
7	55.28	52.70092227	2.579078		
mean	55.87428571	46.18575255	9.688533		

The t-statistic shows that the results are occurring 4.190 standard deviations from the mean. The t-statistic is greater than the t-critical two-tail value of 2.446, which is in favor of rejecting the H_0 , and accepting the H_A ($H_A: \mu \neq 0$), stating there is a difference in measurements for the Quantifit at leak location 3 and the Portacount using cyclic breathing at leak location 3 that is statistically significant. The p-value is .000574, which is less than the alpha value of .05 ($p < .05$), and in favor of rejecting the H_0 . The UCL is 15.345, LCL is 4.031, and the mean difference is 9.688, there is 95% confidence that the mean difference in leak rates at needle 3 for the Quantifit and Portacount is between UCL and LCL.

Table 13 Paired t-Test PortaCount™ Cyclic Breathing Vs. Quantifit™

t-Test: Paired Two Sample for Means		
	Quantifit All Uncapped	Portacount All Uncapped
Mean	73.20857143	42.03776066
Variance	0.050780952	25.81841211
Observations	7	7
Pearson Correlation	-0.571660696	
Hypothesized Mean Difference	0	
df	6	
t Stat	15.81924574	
P(T<=t) one-tail	2.02367E-06	
t Critical one-tail	1.943180281	
P(T<=t) two-tail	4.04735E-06	
t Critical two-tail	2.446911851	

	LR All Uncapped	Pen All Uncapped	difference		
1	73.22	41.10996917	32.11003	mean difference	31.17081
2	73.2	36.26473255	36.93527	stdev of diff	5.213284
3	73.6	37.87878788	35.72121	sdt error of diff	1.970436
4	72.82	47.78972521	25.03027	tAlpha half 95% CI	2.446912
5	73.2	42.2832981	30.9167	LCL	26.34933
6	73.22	39.0625	34.1575	UCL	35.99229
7	73.2	49.87531172	23.32469		
mean	73.20857143	42.03776066	31.17081		

The t-statistic shows that the results are occurring 15.819 standard deviations from the mean. The t-statistic is greater than the t-critical two-tail value of 2.446, which is in favor of rejecting the H_0 , and accepting the H_A ($H_A: \mu \neq 0$), stating there is a difference in measurements for the Quantifit with all leak locations uncapped and the Portacount with all leak locations uncapped using cyclic breathing that is statistically significant. The p-value is 4.047E-6, which is less than the alpha value of .05 ($p < .05$), and in favor of rejecting the H_0 . The UCL is 35.99, LCL is 26.349, and the mean difference is 31.170, there is 95% confidence that the mean difference in leak rates with all leak locations uncapped for the Quantifit and Portacount is between UCL and LCL.