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EFFECT OF PARTICLE SIZE ON RESPIRATOR FACESEAL LEAKAGE

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This report has been reviewed and is approved for publication.

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13. ABSTRACT *(Maximum 200 words)*

The objective of this research was to study the effect of aerosol size on measurement of respirator faceseal leakage. Penetration of aerosols through fixed diameter capillaries, positioned at the respirator-face junction to simulate faceseal leakage, were measured on a dynamic laboratory test system as a function of challenge aerosol size and breathing tidal volume. Four sizes of polystyrene latex (PSL) spheres were used to generate the challenge aerosols. In addition to PSL aerosols, acetone vapor was used as a challenge agent. Penetration measurements made using the vapor challenge agents resulted, in all instances, in higher values than measurements made using aerosols. Vapor penetration was found to be a function of tidal volume. Higher capillary penetration by both vapor and aerosol occurred with the 1,500-ml tidal volume as compared to the 600-ml tidal volume. All PSL aerosols, regardless of particle size or tidal volume used, provided the same order of ranking of the leak sizes. Results of this evaluation suggest that for measuring a fit factor of greater than 1,000 a gas or vapor fit test produces a more accurate test than a fit test assessment using aerosols and a data reduction technique based upon particle number counts.

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LIST OF ACRONYMS AND DEFINITIONS

ACFM - absolute cubic feet per minute

AFF - apparent fit factor - 1/(mean PRPEN)

ANOVA - analysis of variance - a statistical test

CBWA - chemical and biological warfare agents

CMD - count mean diameter - particle size which defines the 50th percentile of the cumulative number of an aerosol when arrayed by size

CTD - Crew Technology Division

DEHP - di-2-ethylhexyl phthalate - an oil

DEHS - di-2-ethylhexyl sebacate - an oil

fit factor - a measure of mask protection defined as the dimensionless ratio of the concentration (or count) of a challenge to a mask to the concentration (or count) of the challenge measured inside the mask

MMD (or MMAD) - mass median diameter - particle size which defines the 50th percentile of the cumulative mass of an aerosol when arrayed by size

NaCl - sodium chloride - salt

ppm - parts per million

PRC - particle range counts - the count of a particular size range of aerosol particles

PRPEN - particle range penetration - ratio of inside concentration (or count) to outside (challenge concentration (or count) - the inverse of fit factor

PSL - polystyrene latex - used to generate mono-dispersed aerosols

QLFT - qualitative fit testing - mask leak testing based on subjective criteria

QNFT - quantitative fit testing - mask leak testing based on objective criteria which generates fit factors

USAFSAM - United States Air Force School of Aerospace Medicine

VMD - volume median diameter - particle size which defines the 50th percentile of the cumulative aerosol volume when arrayed by size

µm - micrometer - 10^{-8} meter

EFFECTS OF PARTICLE SIZE ON RESPIRATOR FACESEAL LEAKAGE

INTRODUCTION

The Crew Technology Division (CTD) of the United States Air Force School of Aerospace Medicine (USAFSAM) tests and evaluates service respirators against the penetration of vapors and aerosol particles. The service respirator selected for and assigned to Air Force servicemen is designed to provide adequate protection against chemical and biological warfare agents (CBWA). These agents can be in the physical form of a solid or liquid aerosol or a gas/vapor. These physical forms of CBWA may be present at the same time.

A very important part of the evaluation process used by CTD is to determine how well the respirator fits individual servicemen. Fit-test methods generally use an aerosol as the physical form of choice for the challenge agent in the fit tests. The CTD has reported on studies of fit-test methods using particulate aerosols of sodium chloride (NaCl) and various oil mists (1-4). The oils used by CTD to generate aerosol include corn oil, di-2-ethylhexyl phthalate (DEHP), and di-2-ethylhexyl sebacate (DEHS) (3)[*].

The importance of how well a respirator achieves protection is obvious and will not be emphasized. However, not obvious is how the reliability and validity of the results of the fit test may be influenced by the test methodology. For example, sampling biases associated with obtaining in-facepiece samples may affect the results (5-8). Other aspects of the test methodology, particularly those associated with the use of aerosol, are also of interest.

The objective of this research was to study the influence that the particle size of the fit test aerosol has on estimates of faceseal leakage. This investigation evaluated quantitative assessments of faceseal leakage as a function of leak size, particle size, physical state of the test material (vapor vs. particulate), and tidal volume. The results of the study provided information on the conditions which may influence estimates of fit.

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[*] This report does not contain any sensitive information from referenced limited distribution publications or presentations.

LITERATURE REVIEW AND BACKGROUND

The history and development of fit testing has been recently reviewed and only limited aspects of fit testing will be reviewed here (5). Generally a fit test is performed to assess whether a respirator adequately fits the wearer. Two basic approaches have been developed for conducting fit testing, namely qualitative and quantitative fit testing. Qualitative fit testing (QLFT) methods have been developed that use many challenge materials. Some of the more widely used challenge materials are irritant smoke, sodium saccharin, and isoamyl acetate vapors. Qualitative methods, regardless of the material used, rely on the ability of the person being fit tested to sense the presence of leakage. Because of the subjective nature of sensory responses, qualitative methods suffer from a common lack of quantification. The problem of quantification can be eliminated by adopting quantitative fit testing (QNFT) methods. Quantitative fit test methods use instrumentation to measure the concentration of a test agent surrounding the respirator wearer and the concentration of that same substance inside the respirator.

Many different test agents, both gases and particulates, have been used over the years in QNFT methods. Gases that have been used include helium (9), freon (10), argon (11), and radon (12). Aerosols that have been used in various QNFT procedures include bacteria (13), uranine (14), sodium chloride (15,16), and oil mists of di-2-ethylhexyl phthalate (17), di-2-ethylhexyl sebacate (3), and corn oil (18). These aerosols are generated by a number of different techniques and are usually considered to represent a poly-dispersed aerosol. The reported mass median diameter of these aerosols typically range from roughly 0.14 µm to 2.5 µm with geometric standard deviations generally between 1.9 to 2.3.

Recent research studies, first reported in the United States (5) and later in the United Kingdom (19), have shown that in-facepiece sampling will not provide representative samples of faceseal leakage. These studies demonstrated that faceseal leakage doesn't mix rapidly or uniformly within the respirator. As a result, concentration or penetration measurements made by in-facepiece sampling are subject to large, variable sampling biases. Variations in several parameters of the person-respirator system have been identified to cause significant changes in the sampling bias (5-7). These changes are: (1) location of the sampling probe on the respirator; (2) depth at which the probe is inserted into the facepiece cavity; (3) breathing through the mouth or through the nose; and (4) area of the faceseal leakage. Based upon these results, it is now hypothesized that faceseal leakage can form localized flow patterns of contaminated air within the facepiece cavity. Because of these flow patterns, in-facepiece sampling can produce biased and highly variable concentration measurements. These findings have been corroborated by other investigators (20,21).

Another issue with QNFT is the use and interpretation of the fit-test results. This issue is currently under considerable debate within the respirator community. Research studies have indicated that a correlation has not been shown to exist between the level of fit ascribed to a respirator-person combination by QNFT and the level of protection achieved in use when the respirator is properly used and conscientiously worn (22-24). Therefore, QNFT results do not appear to be good predictors of "in-use" protection even when the respirator is used conscientiously. Results of QNFT are now being referred to as fit factor and not protection factor. This change is noteworthy and is based on the understanding that fit test results may not indicate protection as use of the term protection factor implies.

A number of studies have been conducted to evaluate the effect of gas and aerosol test agents on measuring faceseal penetration. Hounam et al. (16) evaluated faceseal leakage using a particulate test agent, sodium chloride, and a gaseous test agent, difluorodichloromethane. For faceseal penetrations equivalent to fit factors up to 500, he noted similar estimates of faceseal leakage with both agents (16). Griffin and Webb, cited by Schwabe (25), obtained similar results using sodium chloride and argon. In 1980, Schwabe investigated the differences between gases and aerosols in the measurement of faceseal leakage using three different types of military respirators (25). Test agents he used were gases of methane, penthrane, and amyl acetate and aerosols of sodium chloride and oil aerosols. He concluded that no exceptional differences exist between gases and aerosols in the measurement of faceseal leakage over the concentration range 0.1 to 5,000 mg/m^3 and for leakages in the range 0.05% to 10% (FF from 10 to 2,000). Schwabe also observed in faceseal leakage tests using different aerosols that the dimension of the leak path had an influence on the deposition mechanism of the oil mist.

The quantitative assessment of respirator fit using a gas as a test agent appears to be rather straightforward since the amount of gas entering through the facial seal leak is equal to the product of the leak flow and the concentration of the gas outside the respirator (5). In the case of aerosol exposure, however, the assessment appears to be more complicated. There are a limited number of studies dealing with the effects of particle size on assessment of respirator faceseal leaks. Tuomi (26) found that the effects of particle size on faceseal leakage performance were significant. He evaluated the performance of half-mask respirator as a function of particle size using a corn oil aerosol over the size range of 0.35 to 9 μm. He reported that the measured aerosol penetration was approximately constant for particle sizes below 2 μm but decreases for larger particles.

Hinds and Kraske investigated the facial seal leak performance of half-mask and single-use respirators which were mounted on a manikin in a chamber (27). The test aerosols they used were mono- and poly-dispersed oleic acid aerosol in the size range of 0.1 to 11.34 μm. Three configurations of facial leak were used: (1) metal tubes inserted between the faceseal lip of the respirator and the manikin; (2)

wires inserted between the faceseal lip and the manikin without caulking, and (3) natural leaks. Respirators were operated at seven steady flow rates over the range of 2 to 150 l/min. Their results indicated that aerosol penetration in the size range of 0.1 to 1 μm was approximately 100% regardless of size of the leak or pressure drop across the respirator. In the size range from 1 to 12 μm, however, penetration first increased as pressure drop increased and then decreased with further increases in pressure drop. They suggested that the initial increase in penetration is due to decreased sedimentation losses in the leaks. The noted decrease in penetration with further increase in pressure drop was attributed to increased inlet losses and impaction losses against the face at the leak inlet.

Similar results were obtained by Holton et al. who investigated the leakage into the half-mask negative-pressure respirator with particle sizes ranging from 0.07 to 4.4 μm using a human subject (20). Test aerosols were generated from a mixture of a smoke, nebulized corn oil aerosol, and limestone dust. The leakage into a respirator was through 3 holes punched into the body of the respirator. These leaks were not located between the sealing lip of the respirator and the face of the test subject. The aerosol penetrations were measured using various optical particle size or count instruments. Their results showed that as the particle size increased from 1 to 4.4 μm, the percent aerosol inside the mask decreased for all 3 hole sizes. Furthermore, as particle size decreased from 0.22 to 0.07 μm the percent aerosol inside the mask once again decreased. However, for particles between 0.2 to 1.0 μm there was little difference in the penetration of aerosol into the respirator. The higher penetration of certain particle sizes appeared to be independent of the 3 leak sizes used in the study.

The geometry of the faceseal leak has also been observed to influence the measurement of faceseal leakage when aerosols are used to assess penetration. Holton et al. observed that a slit or narrow gap in the faceseal, as compared to a circular hole, decreases the total aerosol leakage and reduces the entry of larger particles through the leaks (20). This finding is in contrast to studies by Myers et al. which found no effect of faceseal leak geometry on penetration of a vapor test agent into the respirator (6,7).

Based upon the reported studies in the literature, aerosol penetration into a respirator through faceseal leaks appears to be dependent on particle size and leak geometry and less so on leak size or pressure drop.

METHODS AND MATERIALS

Test System

The configuration of the test system, used in the study, is presented in Figure 1. The test chamber is approximately 2 ft. x 2 ft. x 2 ft. and is constructed of 1/2-inch Plexiglas. The aerosol or vapor enters the test chamber through 4 inlets uniformly positioned on top of the chamber. The top and bottom diffusing plates are constructed from 1/4-in. Plexiglas with 3/8-in. holes on 1-in. centers. The top plate distributes the aerosol or vapor evenly over the entire cross-section of the chamber after it has been discharged from the 4 inlets. The bottom plate supports the head form and helps facilitate a more uniform discharge of the air from the chamber. One wall of the chamber is equipped with two 8 in. diameter circular openings which are located opposite the head form during testing. The shoulder-end of heavy-walled, rubber, glove-box sleeves are attached to these openings. During testing, the wrist-end of the sleeve(s) can be attached to the air-purifying element on the facepiece. This setup allows acetone-free or polystyrene latex (PSL)-free air to be drawn through the air-purifying elements during operation of the breathing machine. This movement provides enhanced test reliability. Concerns about vapor or PSL penetration through the air-purifying element of the respirator are greatly reduced. Ports are provided in the walls of the chamber for the test operator to manually open and close the capillary leaks. Ports are also provided for determining the chamber concentrations of vapor and PSL aerosol.

The plumbing between the chamber and the breathing simulator was designed so that the entire inspired tidal volume could be drawn through the aerosol detector. To complement this design an aerosol detector was required that could handle sampling rates of at least 32 lpm. This design feature was critical to the assurance of obtaining aerosol measurements that would have a minimum of bias associated with sample collection, since all the inspired air volume was drawn through the detector. This test system design helped minimize sampling errors associated with the uniformity of the aerosol within the tidal volume.

Aerosol Generation

Polystyrene latex spheres having diameters of .36, .62, 1.0 and 2.56 μm were chosen for use in the study. The dilution ratio used for generating the PSL aerosol was approximated from the following relationship proposed by Raabe:

$$y = \frac{F(vmd^3) \cdot \exp(4.5\ln^2 \cdot T_g) \cdot [\,1-((\exp \ln^2 T_g)/2)\,]}{(1-R)D^3} \qquad (1)$$

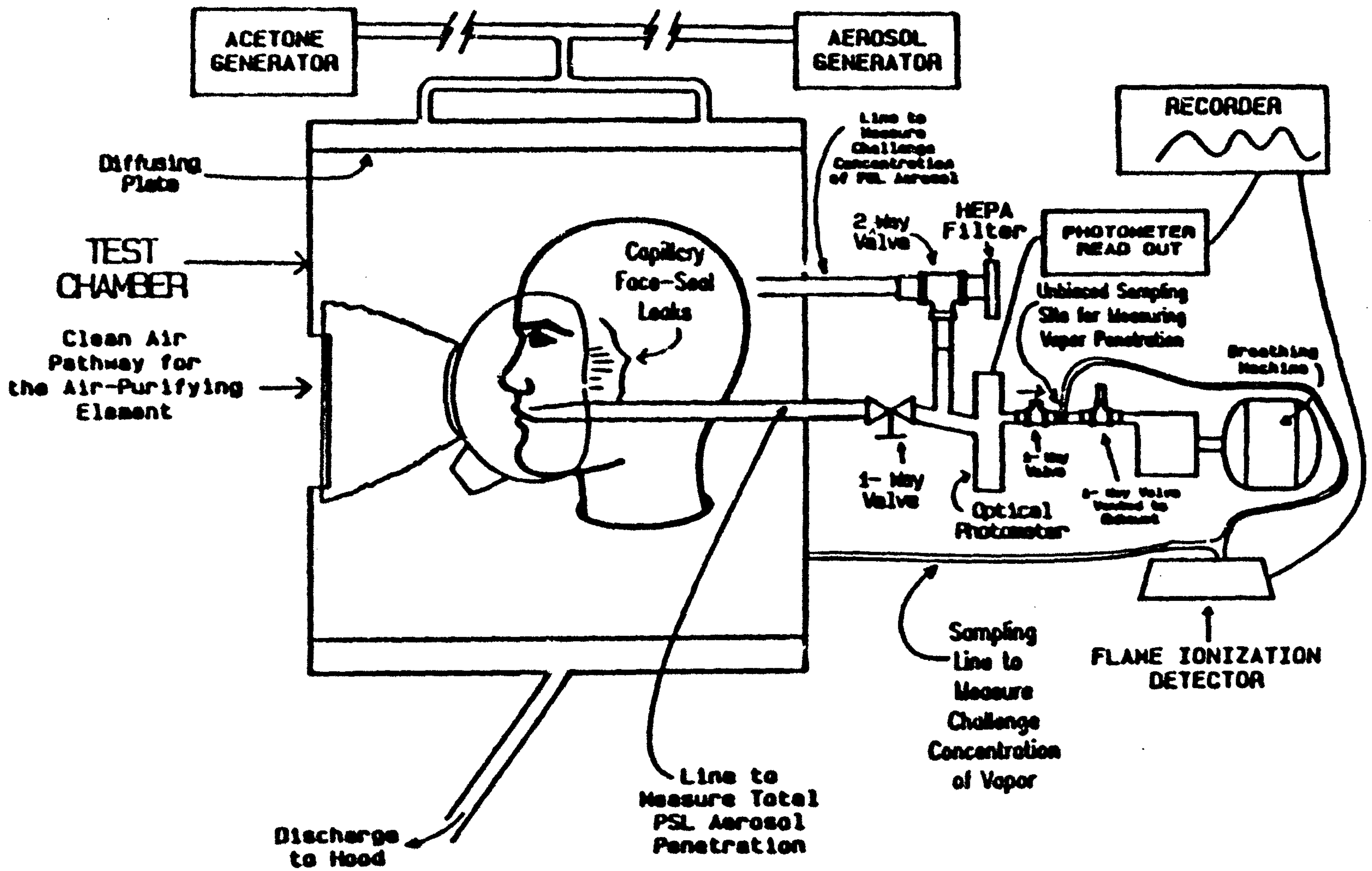

Figure 1. Aerosol and vapor test system.

where y = approximate dilution ratio
R = singlet ratio, chosen to be 0.95
D = diameter of PSL particle
vmd = volume median diameter of the output of the atomizer
T_g = geometric standard deviation of the output particle distribution
F = fraction by volume of the particles in the original PSL stock solution.

A singlet ratio of 0.95 was chosen to estimate the dilution ratio. This ratio indicates that 95% of generated PSL particles will be singlets and 5% will be doublets, triplets, etc. The dilution ratio is a function of the volume median diameter (VMD) of the generator's output. The output of the TSI generator is stated by the manufacturer to have a geometric mean (GM) of 2 µm and a geometric standard deviation of < 2. For purposes of calculations it was assumed to be 1.9. Size characteristics of the generated aerosol distributions are given in Table 1.

TABLE 1. PARTICLE SIZE CHARACTERISTICS

PSL Size (µm)	CMD* (µm)	MMD** (µm)	S_g
0.36	0.55	0.62	1.23
0.62	0.58	0.65	1.21
1.01	0.62	0.73	1.26
2.52 (Vol=600 ml)	0.82	1.06	1.34
2.52 (Vol=1500 ml)	0.94	1.23	1.35

*Count Median Diameter
**Mass Median Diameter

Aerosol Measurement

Measurement of PSL aerosol was made using a parts per million (ppm) Incorporated Aerosol Scanner® Model S-0.2/2. The detection size range of the instrument is from <0.2 µm to >5.0 µm. The range is divided into 8 different channels, <0.2; 0.2-0.3; 0.3-0.5; 0.5-0.7; 0.7-1.0; 1.0-2.0; 2.0-5.0; >5.0 µm. The Scanner can handle flow rates from 0.2 to 2.1 absolute cubic feet per minute (ACFM). The operating temperature for the instrument is between 0-40 °C. The maximum particle count rate is 12,000 particles per minute.

The Scanner® sensor layout is shown in Figure 2. The Scanner® uses a laser beam that oscillates across the aerosol flow path. Light scattered at 90 degrees is collected on the receiver optics for further electronic processing. The calibration of the Scanner® was performed by the manufacturer using monodispersed PSL spheres.

Before beginning experimentation, the Scanner® was checked using aerosols of 0.6 and 1-µm PSL. Figure 3 illustrates particle count assignments made for 1-µm PSL under both constant and cyclic flow rates of 10.8 lpm. Under constant flow conditions, approximately 60% of the particles counted by the instrument were assigned to the 1-2 µm range and 20% to the .7-1 µm range. Under cyclic flow conditions, apparently a higher number of the 1-µm particles are misassigned.

Figure 4 illustrates particle count assignments made for 0.6-µm PSL. With this size particle there appears to be little effect of flow condition on particle range assignment. Approximately 70% of the particles counted were correctly assigned to the .5-.7 µm size range.

Apparently misassignment of particles counted to wrong channels does occur. However, the form of the count distribution was stable during the period of the experiment. This allowed data from a given size range to be used for the type of proportional data reduction needed to calculate a fit factor.

Vapor Generation

Acetone vapor generation was accomplished using a syringe pump, a calibrated dilution air source, and an evaporation column. The generated vapor was routed into the chamber from the evaporation column. Syringe flow rates and dilution air volumes were selected to produce roughly 15,000 ppm of acetone in the chamber. Samples to determine the chamber concentration of acetone and the concentration of acetone vapor leaking into the respirator were collected from a sampling site located in the plumbing between the test chamber and breathing machine (Fig. 1). A similar sampling location has been evaluated and reported on in the literature (5).

Vapor Measurement

A Beckman Industrial Model 400A Hydrocarbon Analyzer was used for acetone vapor measurement. This analyzer automatically and continuously measures the concentration of the

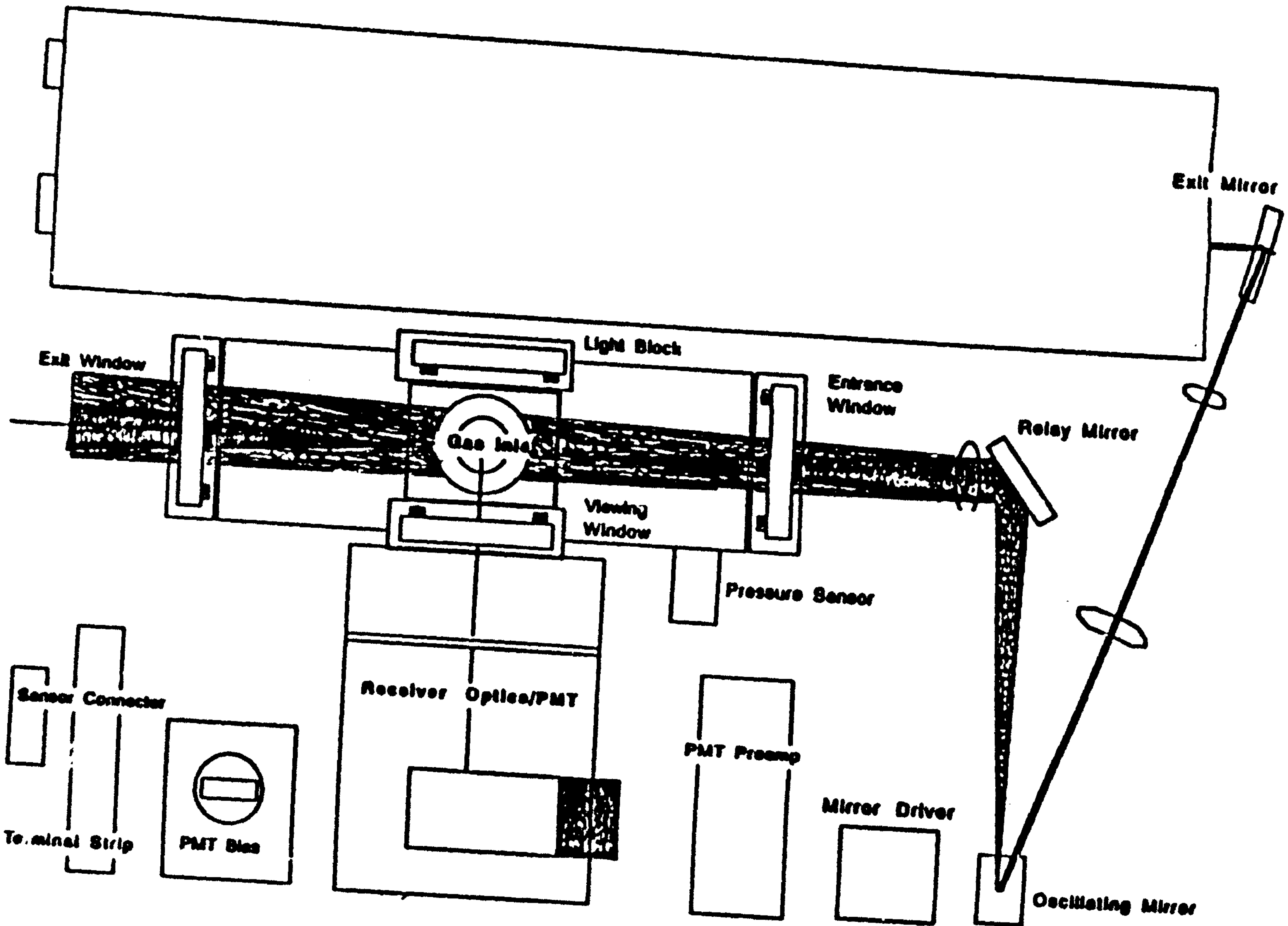

Figure 2. Schematic of the aerosol detector.

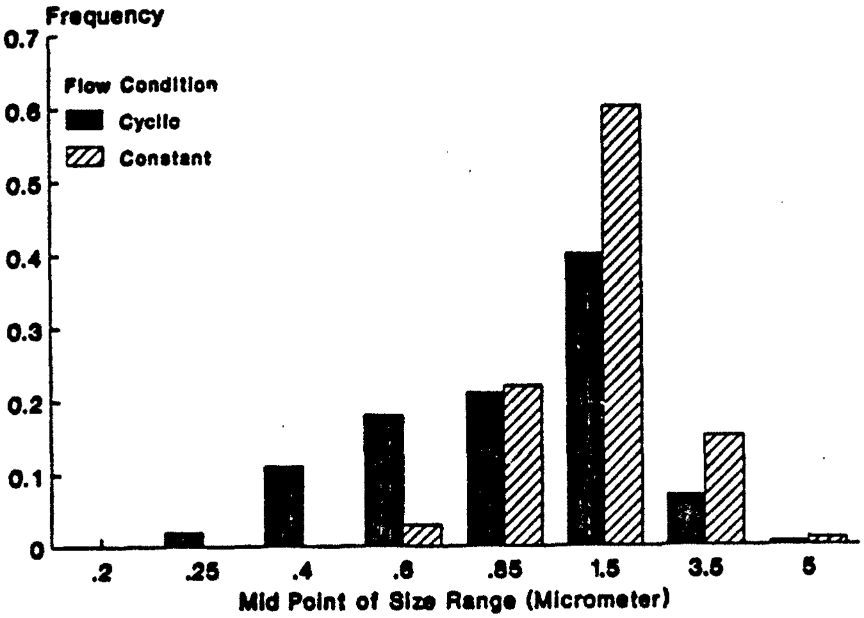

Figure 3. Frequency of particle counts in all Scanner® size ranges for a 1.0-µm PSL aerosol with a cyclic and constant flow of 10.8 LPM.

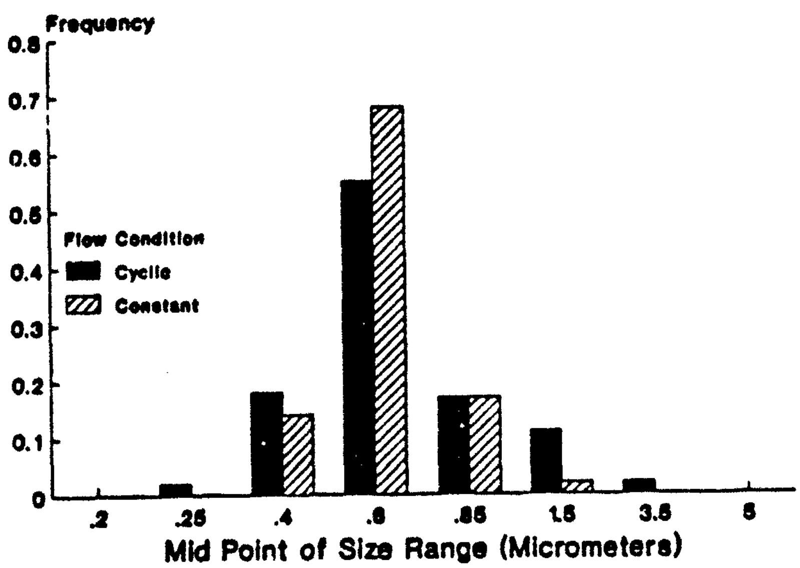

Figure 4. Frequency of particle counts in all Scanner® size ranges for a 0.6-µm PSL aerosol with a cyclic and constant flow of 10.8 LPM.

hydrocarbons in a gas stream. It has a lower-limit of detection of approximately 0.5 ppm of acetone. Flame ionization is used as the method of detection. The analyzer was calibrated with certified mixtures of acetone in ultra-pure air (hydrocarbon content < 0.5 ppm). With a chamber concentration of approximately 16,500 ppm acetone, fit factors up to approximately 33,000 could be measured.

Automated Breathing Simulator

Breathing simulation was produced with a TSI Model 8091 breathing simulator. This simulator uses a moving rubber bellows. The bellows is operated by a stepper motor with a lead screen, which is controlled by a microprocessor. The stepper motor provides continuous control over the movement of the bellows; hence, many breathing rates and minute volumes could be produced. The instrument operates under either start or stop mode, where selection of different breathing curves, breathing rates, and minute volumes can be made. Once set the simulator will produce breathing patterns based on the 3 parameters selected.

The breathing curve used in the experiment was representative of a watt (622 kg-m/min) work rate. The parameter ranges for the instrument are as follows:

	MINIMUM	MAXIMUM
1. Breathing rate (breaths/minute)	2.0	30.0
2. Minute volume (liters/minute)	1.0	54.0
3. Tidal volume (liters/breath)	-	1.8

The breathing rate used in the experiments was held constant at 18 per minute. The tidal volume was varied between 0.6 and 1.5 liters to simulate rest and moderate workload breathing conditions. The 600-ml tidal volume produced a maximum pressure drop of .6 in. of water and the 1,500 ml-tidal volume 2.1 in. of water.

Facepiece and Faceseal Leaks

In preparation for testing, the test facepiece was mounted on a manikin head form. Five capillary tubes of various diameters were inserted between the facial surface of the manikin and the sealing lip of the respirator. The leak capillary diameters and length-to-width ratios are given in Table 2. Faceseal leaks are generally believed to have a circular or slit geometry. Oestenstad reported that approximately 27% of the faceseal leaks could be represented by a circular geometry (28).

TABLE 2. CAPILLARY DIAMETERS AND LENGTH-TO-DIAMETER RATIOS

Internal Diameter (mm)	L/D Ratio
.25	76.0
.275	69.1
.3	63.3
.33	57.6
.51	37.3

Length = 19 mm for all capillaries

After the capillary tubes were positioned an air-tight seal was made around the entire perimeter of the sealing-lip surface. The air-tight seal was produced by using silicone adhesive. The air-tight seal was very important to assure that no leakage occurred, other than through one of the open capillary tubes. This air-tight integrity was also conditional upon no leakage occurring at any other site on the facepiece, for example around the exhalation valve or the speaking diaphragm housing.

To evaluate the air-tight integrity of the facepiece seal, a slight negative pressure was created in the cavity of the facepiece. Evidence of air-tightness was demonstrated by maintaining 2 in. of water negative or positive pressure over a long period (approximately 1 h). Attempts to produce air-tight integrity with the mask provided by CTD were at first extremely frustrating. Many attempts were made to seal and/or reseal the sealing lip in such a way as to achieve air tightness. It became apparent that relatively large amounts of air were leaking into the respirator from other sites on the facepiece. This finding initiated a systematic investigation to determine where those sites were and then seal them. As a result of this investigation, leakage was found to be occurring around both the exhalation valve and the speaking diaphragm housing of the respirator. The only remedy found to adequately correct the leakage was to seal those openings.

After the air-tight integrity of the mounted respirator was assured it was placed in the test chamber and attached to plumbing connecting the head form to the breathing machine.

Test Procedure

The test procedure used in the experiment to collect experimental data was as follows. The procedure was repeated for each treatment setup for each different particle size and the acetone vapor.

1. The in-facepiece line valve was opened to measure the in-facepiece background concentration. The chamber line valve and all the leaks were closed and sealed. The breathing apparatus was turned on. Three 2-min in-facepiece background values were recorded. The first sample was discarded and the last two were used for further data analysis.

2. The chamber line valve and the in-facepiece line valve were opened and closed respectively to obtain four 2-min samples of the chamber concentration. The first of the four 2-min samples was discarded. The last three samples were used for further data analysis.

3. The in-facepiece line valve and the chamber line valve were opened and closed again. The system was given 1 min to equilibrate, then the aerosol measurement was started. The value obtained should verify the initial background reading.

4. A specific leak was opened and four 2-min samples were recorded. The first one was discarded and the last three were used for data analysis.

5. The chamber line valve and the in-facepiece line were opened and closed respectively, to obtain a second set of four 2-min samples of the chamber concentration. These samples were treated as identified in Step 2.

The data collected by the aerosol scanner was expressed as particle counts, for an appropriate size range, per unit volume. The 0.36-μm particles counts were taken from the channel having a size interval of 0.3-0.5. The .62-μm particles counts were taken from the 0.5-0.7 channel, the 1.0-μm particles from the 0.7-1.0 and the 1.0-2.0 channels since the PSL size overlapped both channels, and the 2.56-μm particles from the 2.0-5.0 channel. All count data were corrected for background. When a background value exceeded its corresponding C_i value, it was replaced with the average background calculated from all the background observations made for the 30 test cells involving that particle size. When C_i=0 or when (C_i-background)=0, the apparent fit factor (AFF) cannot be estimated. In these cases, the average background for the particle size range involved was again used to estimate C_i.

These count data are subsequently referred to as particle range counts (PRC). The PRC data was used directly to calculate the particle range penetration (PRPEN), the ratio of inside concentration (or counts) to outside concentration (or counts). The count data could be used directly to calculate penetration because the inside and outside minute sampling volumes were the same.

The acetone concentration data were expressed as ppm. Penetration was calculated using a ratio of the ppm data. The inverse of the penetration can be expressed as the AFF achieved under the contrived conditions of our test equipment, experimental setup, and test procedure. Statistical analysis was done using the penetration data. Relative humidity, barometric pressure, and temperature were recorded during each experimental test setup but not used in the statistical analysis.

Experimental Design and Data Analysis

The experiment considered 3 main parameters, leak size (LS), particle size (PS), and tidal volume (vol) as independent variables and penetration of a particular particle size (PRPEN) as the dependent variable. Five levels of leak size, 5 levels of particle size, and 2 levels of tidal volume were evaluated. For the experiment, acetone vapor was considered as a level of particle size. Three replications were run on each of the 50 (5*5*2) test cells.

The experimental design adopted for the study was a split-plot design. This design was necessary because the 150 treatment cells (50 test configuration*3 replications) could not be randomly evaluated. Generation of the PSL aerosol required significant time to set up the generation equipment and, once generation started, for the aerosol concentration to stabilize. As a result, it was not practical to generate multiple size PSL aerosols in the same day. Therefore, the size of PSL to be generated on a given day was randomly selected and then all combinations of the other test variables were randomly tested. With this test scheme particle sizes were the whole plots in the split-plot design.

The null hypotheses to be tested are:

1. The mean penetration estimates made for a given leak size are not different for different size PSL and the vapor.

2. The mean penetration estimates made for different tidal volumes are not different.

3. The mean penetration estimates made for different leak sizes are not different. NOTE: This null hypothesis should be rejected given the physical principles involved.

The linear model for the split-plot design is:

$$Y_{ijkl}=U+P_i+R_j+e_{ij}+V_k+(PV)_{ik}+L_l+(PL)_{il}+(VL)_{kl}+(PVL)_{ikl}+e_{ijkl} \qquad (2)$$

Where:

U = the true mean,

P_i= the effect of the i^{th} particle size (i=1,2...5),
R_j= the effect of the j^{th} replication (j=1,2,3),
V_k= the effect of the k^{th} tidal volume (k=1,2),
L_l= the effect of the l^{th} leak size (l=1,2...5),
e_{ij}= the whole-plot error term, and
e_{ijkl}= the subplot error term

The penetration data in each treatment combination were checked for normality using the Shapiro-Wilks test. Of the 50 test cells in the test matrix, 45 of the penetration data sets could be considered normally distributed and 5 were not. Based upon these test results the complete data were considered to be normally distributed. Tests on means were done with a Duncan's Multiple Range Test with an alpha = 0.05. The AFF values were not used as a dependent variable in the analysis of variance (ANOVA) but were subsequently calculated from the penetration values for inclusion into the report.

RESULTS AND DISCUSSION

The results of the ANOVA are given in Table 3. Leak size, particle size, and tidal volume were all found to be significant effects on faceseal penetration as well as a leak size•tidal volume interaction. The effect of leak size on PSL and acetone penetration was entirely expected and the explanation is simple, the bigger the leak the greater the flow through the leak and, therefore, the greater the measured penetration.

The effect of tidal volume on PSL and acetone penetration was also significant. The mean penetration and apparent fit factor data are summarized in Tables 4 through 9. The higher pressure drop in the facepiece associated with the higher tidal volume caused increased flow through the leaks. The relationship between leak flow Q and pressure drop P is given by:

$$Q = aPb \tag{3}$$

where "a" and "b" are constants for a given leak (29). The exponent "b" is a function of the length -to-diameter ratio. For ratios greater than 18 "b" approaches unity indicating laminar flow through the capillaries (30). The L/D ratios used on this experiment were all greater than 18 suggesting laminar flow conditions existed within the capillaries. The leak size•tidal volume interaction is thought to be due to the unique linear flow vs. pressure drop relationship which existed for each different L/D ratio.

As a result of these volume effects, for any leak size - particle size combination a lower AFF was measured for the 1,500-ml tidal volume than for the 600-ml tidal volume. This observation is similar to

TABLE 3. ANALYSIS OF VARIANCE TABLE

SOURCE	DF	ANOVA SS	F VALUE	Critical $F_{.95}$
REP	2	2.66E-09		
PS	4	3.52E-07	4.7	$F_{4,8}$=3.8
Error	8	1.49E-07		
VOL	1	8.59E-08	8.1	$F_{1,90}$=3.96
PS*VOL	4	6.37E-08	1.5	$F_{4,90}$=2.49
LS	4	3.87E-06	91.3	$F_{4,90}$=2.49
PS*LS	16	2.45E-07	1.45	$F_{16,90}$=1.79
VOL*LS	4	1.20E-07	2.8	$F_{4,90}$=2.49
PS*VOL*LS	16	1.98E-07	1.2	$F_{16,90}$=1.79
ERROR	90	9.54E-07		

REP = replication

PS = particle size generated

VOL = minute volume

LS = leak size

TABLE 4. GAS PENETRATION DATA AND APPARENT FIT FACTORS AS A FUNCTION OF LEAK SIZE AND TIDAL VOLUME

Leak Size (mm)	Tidal Volume (ml)	Mean	Standard Deviation	Minimum Penetration	Maximum Penetration	Apparent Fit Factor
0.51	600	4.43E-04	4.57E-04	1.78E-04	9.70E-04	2,256
0.33	600	1.92E-04	1.42E-05	1.80E-04	2.08E-04	5,200
0.3	600	1.20E-04	7.45E-06	1.13E-04	1.28E-04	8,321
0.28	600	6.30E-05	3.53E-06	5.94E-05	6.65E-05	15,873
0.25	600	4.54E-05	5.50E-07	4.49E-05	4.60E-05	22,046
0.51	1,500	9.38E-04	2.79E-04	6.17E-04	1.12E-03	1,067
0.33	1,500	2.25E-04	2.33E-05	2.04E-04	2.50E-04	4,441
0.3	1,500	1.38E-04	5.49E-06	1.33E-04	1.44E-04	7,258
0.28	1,500	7.75R-05	4.21E-06	7.64E-05	8.24E-05	12,897
0.25	1,500	7.19E-05	3.01E-06	6.98E-05	7.53E-05	13,910

TABLE 5. MEAN PENETRATION FRACTION AND APPARENT FIT FACTOR FOR A 0.36-μm-DIAMETER PSL AEROSOL AS A FUNCTION OF LEAK SIZE AND TIDAL VOLUME

Leak Size (mm)	Tidal Volume (ml)	Mean	Standard Deviation	Minimum Penetration	Maximum Penetration	Apparent Fit Factor
0.51	600	3.52E-04	1.51E-04	2.13E-04	5.12E-04	2,843
0.33	600	8.18E-05	2.12E-05	5.76E-05	9.72E-05	12,228
0.3	600	3.88E-05	1.90E-05	1.69E-05	5.02E-05	25,747
0.28	600	3.09E-05	1.86E-05	1.03E-05	4.64E-05	32,404
0.25	600	1.62E-05	7.53E-05	1.09E-05	2.48E-05	61,483
0.51	1,500	3.07E-04	9.11E-05	2.41E-04	4.11E-04	3,260
0.33	1,500	8.58E-05	3.58E-05	4.63E-05	1.16E-04	11,652
0.3	1,500	5.83E-05	1.58E-05	4.01E-05	6.81E-05	17,144
0.28	1,500	2.43E-05	1.95E-05	9.71E-06	4.65E-05	41,118
0.25	1,500	2.42E-05	1.02E-05	1.78E-05	3.60E-05	41,254

TABLE 6. MEAN PENETRATION FRACTION AND APPARENT FIT FACTOR FOR A 0.62-μm-DIAMETER PSL AEROSOL AS A FUNCTION OF LEAK SIZE AND TIDAL VOLUME

Leak Size (mm)	Tidal Volume (ml)	Mean	Standard Deviation	Minimum Penetration	Maximum Penetration	Apparent Fit Factor
0.51	600	3.63E-04	9.11E-05	2.95E-04	4.67E-04	2,753
0.33	600	6.02E-05	1.69E-05	4.08E-05	7.18E-05	16,606
0.3	600	3.46E-05	4.55E-06	3.20E-05	3.99E-05	28.868
0.28	600	2.83E-05	4.69E-05	2.37E-05	3.30E-05	35,398
0.25	600	1.95E-05	5.70E-06	1.60E-05	2.61E-05	51,282
0.51	1,500	4.78E-04	6.92E-05	4.04E-04	5.41E-04	2,091
0.33	1,500	9.94E-05	1.60E-05	8,79E-05	1.18E-04	10,065
0.3	1,500	7.80E-05	2.27E-05	6.04E-05	1.04E-04	12,827
0.28	1,500	1.93E-05	4.04E-06	1.56E-05	2.36E-05	51,894
0.25	1,500	2.62E-05	9.82E-06	1.94E-05	3.68E-05	38,183

TABLE 7. MEAN PENETRATION FRACTION AND APPARENT FIT FACTOR DATA FOR A 1-µm-DIAMETER PSL AEROSOL AS A FUNCTION OF LEAK SIZE AND TIDAL VOLUME

Leak Size (mm)	Tidal Volume (ml)	Mean	Standard Deviation	Minimum Penetration	Maximum Penetration	Apparent Fit Factor
0.51	600	3.17E-04	1.07E-04	2.20E-04	4.31E-04	3.152
0.33	600	7.11E-05	5.26E-05	4.05E-05	1.32E-04	14,055
0.3	600	1.24E-05	1.18E-05	1.07E-06	2.46E-05	80,972
0.28	600	1.51E-05	6.79E-06	7.87E-06	2.13E-05	66,050
0.25	600	1.49E-05	1.27E-05	2.06E-06	2.74E-05	67,340
0.51	1,500	4.99E-04	2.26E-04	3.32E-04	7.56E-04	2,002
0.33	1,500	1.09E-04	4.61E-05	5.61E-05	1.40E-04	9,163
0.3	1,500	9.09E-05	1.83E-05	7.11E-05	1.07E-04	11,004
0.28	1,500	4.24E-05	3.70E-05	2.74E-06	7.59E-05	23,602
0.25	1,500	1.16E-05	7.81E-06	2.58E-06	1.66E-05	86,430

TABLE 8. MEAN PENETRATION FRACTION AND APPARENT FIT FACTOR DATA FOR A 2.5-µm-DIAMETER PSL AEROSOL AS A FUNCTION OF LEAK SIZE AND TIDAL VOLUME

Leak Size (mm)	Tidal Volume (ml)	Mean	Standard Deviation	Minimum Penetration	Maximum Penetration	Apparent Fit Factor
0.51	600	3.87E-04	2.91E-04	2.01E-04	7.22E-04	2,583
0.33	600	4.89E-05	1.95E-05	2.69E-05	6.39E-05	20,471
0.3	600	3.04E-05	3.34E-05	4.00E-07	6.65E-05	32,884
0.28	600	7.10E-07	2.60E-07	4.30E-07	9.30E-07	1,840,451
0.25	600	1.14E-06	7.80E-07	4.60E-07	1.99E-06	877,193
0.51	1,500	4.31E-04	2.40E-04	2.90E-04	7.08E-04	2,318
0.33	1,500	7.46E-05	1.44E-05	6.05E-05	8,92E-05	13,412
0.3	1,500	7.30E-05	5.50E-05	3.52E-05	1.36E-04	13,704
0.28	1,500	3.81E-06	3.55E-06	6.80E-07	7.66E-06	262,467
0.25	1,500	4.03E-06	6.43E-06	3.00E-07	1.15E-05	248,139

TABLE 9. MEAN FIT FACTORS AS A FUNCTION OF LEAK SIZE AND PARTICLE SIZE FOR A TIDAL VOLUME OF 600 ML

Challenge Agent	Leak Size 1	2	3	4	5
GAS	$8{,}300^{A}$	$5{,}200^{A}$	$15{,}900^{A}$	$2{,}300^{A}$	$22{,}000^{A}$
0.36 mm PSL	$25{,}700^{B}$	$12{,}200^{B}$	$32{,}400^{B}$	$2{,}800^{A}$	$61{,}800^{C}$
0.62 mm PSL	$28{,}900^{B}$	$16{,}600^{B}$	$35{,}400^{B}$	$2{,}800^{A}$	$51{,}300^{BC}$
1.01 mm PSL	$81{,}000^{B}$	$14{,}100^{B}$	$66{,}100^{BC}$	$3{,}200^{A}$	$67{,}300^{C}$
2.52 mm PSL	$32{,}000^{B}$	$20{,}300^{B}$	$1.408 \times 10^{6\ C}$	$2{,}600^{A}$	$2.48 \times 10^{5\ C}$

n=3

Values rounded to hundreds

Values within a leak size with different superscripts are significantly different ($p<.05$)

other pressure drop effects on aerosol flow into a respirator reported by Hinds and Bellin (30) and Campbell (31). This observation suggests that use of an "at rest condition" which translates into smaller tidal volumes in a fit test will tend to produce inflated estimates of fit as compared to estimates of fit made with larger tidal volumes, i.e., under conditions of exercise which increase pulmonary tidal volumes. In a fit-test scenario where the goal of the testing is to select a better fitting respirator (brand and/or size) and the in-facepiece sampling biases are similar (between brands and/or sizes) the importance of the measured fit's dependence on tidal volume is small because a relative comparison is being made. While the difference in AFF determined by this study was significantly different ($P<0.05$) for the 600-ml vs. the 1,500-ml tidal volume, the data in Tables 4 through 9 show that the same relative order of size ranking of the leak is obtained with either tidal volume. The degree to which tidal volume will remain somewhat consistent for a given individual or group of individuals undergoing fit testing is unknown. What is more certain, however, is that the tidal volume exhibited by an individual who is basically "at rest" in a fit test, will be substantially higher during actual use of the respirator. Even if the respirator "fits" him identically as when he was fit tested, he will experience greater faceseal penetration (i.e., lower protection) than what he experienced during fit testing. This fact will be true given the increased pressure differential does not change the leak size. While it is often stated that naturally occurring faceseal leaks will seal better at higher pressures, the literature searched by these authors revealed no published data upon which such conclusions can be substantiated.

Another significant determinant on penetration was particle size. The mean values of the apparent fit factor, AFF, calculated as 1/(mean PRPEN), for different size aerosol, different leak sizes and different tidal volumes are given in Tables 4 through 9.

It should be noted that very high AFF values were measured for the largest particle size - smallest leak diameter treatment combinations (Tables 7 and 9). All of the AFF values determined with the 4 PSL aerosols, for both tidal volumes on the 0.25-mm capillary were greater than 35,000, 5 of 8 AFF values determined on the 0.275-mm capillary were greater than 35,000, and 1 of 8 AFF values on the 0.3-mm capillary was greater than 35,000. With the test system and test procedures used, the reliability of measured AFF values above 35,000 must be cautioned. Only small numbers of particles were counted with these high AFF values even with test times of 20 min. However, the data do suggest that very high AFF values were being measured even if it is not believed that they could be reliability quantified with the test equipment and methodology used. The mean penetration values measured with the 2.5-μm PSL on the 0.25 and 0.275-mm capillaries were significantly different ($P<0.05$) from the mean penetration data obtained with the other PSL aerosols and the acetone vapor.

Another observation arising from the data is that regardless of which particle size or tidal volume was used the order of the leak size rankings based upon the AFF rankings were all the same 0.51 > 0.33 > 0.3 > 0.275 > 0.25 (if AFF values equal to or greater than 35,000 were excluded from the rankings). Relatively speaking, the correct order of capillary size (or degree of fit by analogy) could be determined with gas or particles at either 600 or 1,500-ml tidal volumes.

Perhaps the most interesting observation is the finding that the mean penetration values measured with a vapor, for all leak sizes, were larger than those mean penetration values measured with any of the different size PSL aerosols. Duncan's Multiple Range Test indicated that acetone vapor penetration was significantly higher than the penetration measured with any of the aerosol sizes tested. Tables 9 and 10 contain mean penetration data for a vapor challenge agent and each PSL particle size as a function of leak size for tidal volumes of 600 and 1,500 ml respectively. These mean penetration data expressed as AFF are plotted in Figures 5 and 6 for tidal volumes of 600 ml and 1,500 ml respectively and in Figure 7 for the pooled tidal volume data. With the largest leak size (0.51 mm), the AFF determined with the vapor challenge was significantly ($P<0.05$) less than the AFF determined with the 0.36-μm particle range penetration data. None of the AFFs determined by the particle range penetration data on the 0.51 mm capillary leak were significantly different from one another. For the larger leak sizes (0.3 mm, 0.33 mm, and 0.51 mm), the penetration for acetone vapor was 1.6 to 3.4 times higher than the penetration calculated by particle size range data.

TABLE 10. MEAN FIT FACTORS AS A FUNCTION OF LEAK SIZE AND PARTICLE SIZE FOR A TIDAL VOLUME OF 1,500 ML

Challenge Agent	Leak Size 1	2	3	4	5
GAS	7,300^{A}	4,400^{A}	12,900^{A}	1,100^{A}	13,900^{A}
0.36-MM PSL	17,100^{B}	11,700^{B}	41,100^{B}	3,300^{B}	41,300^{C}
0.62-MM PSL	12,800^{B}	10,100^{B}	52,900^{B}	2,100^{B}	38,200^{BC}
1.01-MM PSL	11,000^{AB}	9,200^{B}	23,600^{AB}	2,000^{B}	86,400^{CD}
2.52-MM PSL	13,700^{B}	13,400^{B}	2.625×10^{5} ^{B}	2,300^{B}	8.772×10^{5} ^{D}

FF = (mean penetration)$^{-1}$

n = 3

Values rounded to hundreds

Values within a leak size with different superscripts are significantly different ($p<.05$)

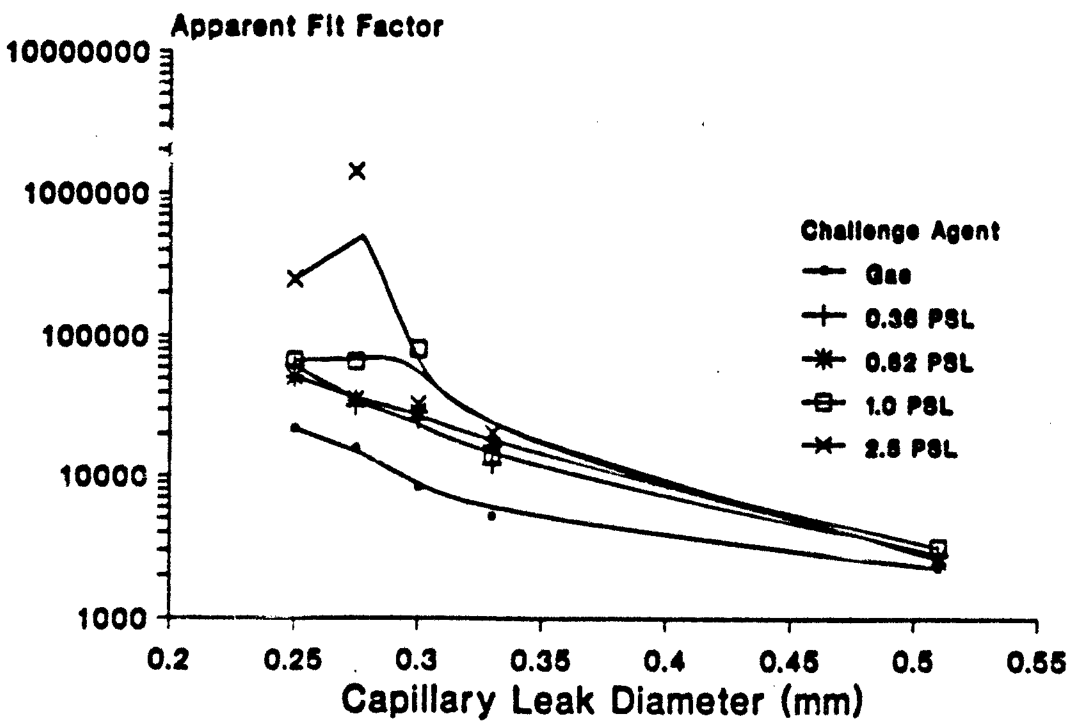

Figure 5. Apparent fit factor measured with a 600-ml tidal volume plotted for various PSL aerosols and a vapor as a function of leak diameter.

With the two small diameter leaks (.25mm and .275mm) the AFF measured with the 2.5-μm aerosol was also significantly higher than those obtained with the other PSL size range penetration data. For these leak sizes, the acetone vapor penetration was approximately two times higher than that determined with particle size range data up to 1 μm and 22 to 30 times higher for particles above 1 μm. Figure 5 illustrates the marked increase in AFF that occurs with the 1 and 2.5-μm particle range data for the 0.25 mm and 0.275 mm diameter leaks. The 0.36- and 0.62- particle range data seem to parallel each other (as well as the vapor data) very nicely over the range of leak diameters studied.

Significantly lower penetration ratios by particles over 1 μm may be attributed to the particles' inability to penetrate the smaller leaks. This penetration ratio may be due either to insufficient capture velocity of the leak inlets or possibly inlet losses of the larger particles. In comparison with earlier results, these penetration ratios are much higher than reported by Schwabe who compared the penetration by methane with that of salt aerosol (25). He reported that the average leakage measured by methane was 50% greater than the same leakage measured by salt aerosol. Considering the differences in the number of leaks (9 vs. 5) and sizes of leaks (0.1 mm vs. 0.25 to 0.51 mm), studied and the sizes of particle used (0.2 μm Mass Median Aerosol Diameter (MMAD) vs. 0.27 to 2.5 μm) the ratios obtained by this study appear to be comparable to Schwabe's results for the smaller particle sizes. In contrast, the results obtained by Hounam (16) who compared the penetration by sodium chloride with difluorodichloromethane, and by Griffin and Webb (cited by Schwabe (25)) who used sodium chloride and argon, showed no difference between gas and particulates in terms of penetration. These data clearly do not support such an observation.

These findings suggest that the aerosol sizes used in the study did not provide the same measurement of penetration obtained with the acetone vapor. Given the test system setup this result is not likely caused by sampling errors. We conclude that the difference is real and one that must be recognized by CTD in developing fit test techniques and comparing measurements of penetration made with different challenge agents (size and physical state) and different methods of quantifying penetration (count data vs. scatter data vs. mass data). Based upon this experimental data, we feel that for fit determinations above 1,000 a vapor or gas fit test agent provides a more realistic assessment of the true faceseal penetration. The difference between penetration measurements made by vapor and particle size range penetration data implies that fit test assessments, made with aerosols and subsequently used in considerations that involve a gas or vapor CBWA, may underestimate the penetration of these CBWAs. Correlations appear to be evident in the data. Further research to clarify and further define this correlation is needed.

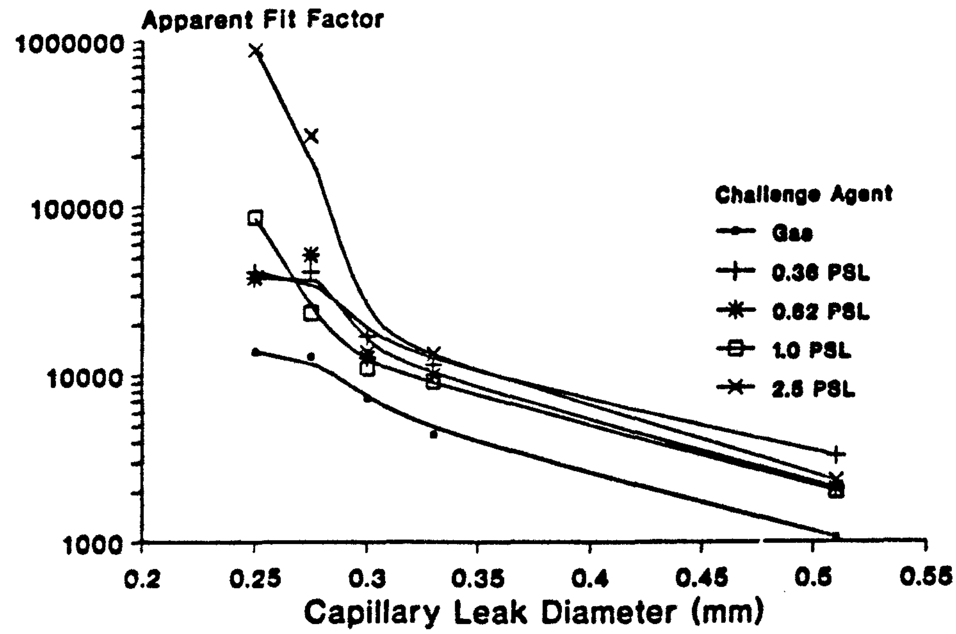

Figure 6. Apparent fit factors measured with a 1,500-ml tidal volume plotted for various PSL aerosols and a vapor as a function of leak diameter.

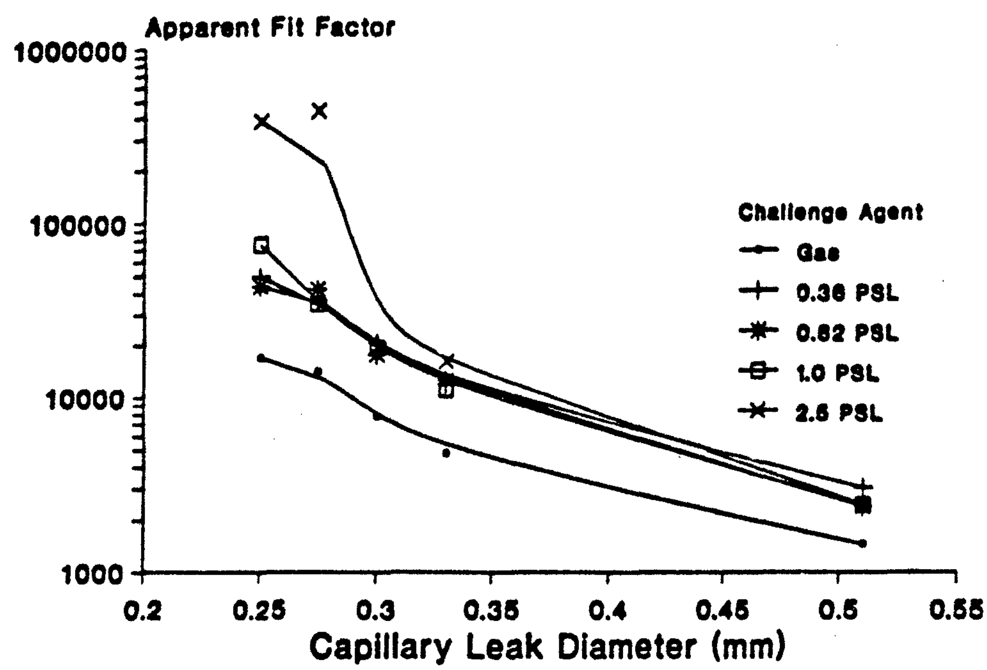

Figure 7. Apparent fit factors averaged for 600-ml and 1,500-ml tidal volumes plotted for various PSL aerosols and a vapor as a function of leak diameter.

In Figures 8 and 9 the mean penetration is plotted as a function of particle size for 3 of the 5 leak sizes. For the 1,500-ml tidal volume measurements the features of the penetration curves appear to be similar to those reported by Holton et al. (20). That is, a maximum in penetration appears to occur in the particle size range of roughly 1 μm. This penetration is evident with both the 0.3-mm and 0.51-mm diameter leaks. Our range of particle sizes was insufficient to confirm Holton's observation that penetration begins to again decrease with increasing particle sizes. For the 600-ml tidal volume the features of the penetration curves are quite different from those obtained with the 1,500-ml tidal volume and those reported by Holton et al. (20). With the 0.51-mm diameter leak no variation appears to be present in the mean penetration values measured over the range of particle sizes used in this study. With both the 0.3-mm and 0.33-mm diameter leaks a minimum in penetration occurs at roughly the 1-μm particle size range rather than a maximum in penetration. The reason for this apparent discrepancy is not known. The 0.25-mm and 0.275-mm diameter leaks were not plotted with these data because of the small particle counts measured with these leaks.

CONCLUSION AND RECOMMENDATIONS

As mentioned in the Section on Methods and Materials in-board leakage was observed to occur with the respirator provided by CTD for evaluation at locations other than the faceseal lip. When the faceseal lip was sealed, the air-tight integrity of the respirator could not be maintained without sealing the speaking diaphragm and exhalation valve.

The air-tight integrity of completely assembled facepieces should be evaluated if it has not already been done. Leakage through speaking diaphragm, etc. may not in many cases be evident from a fit test. Such leaks could be assessed as a quality assurance (QA) check using a setup to seal the facepiece to a head-form, create a set pressure differential within the mask and either measure the pressure decay over time or the amount of flow required to maintain the pressure differential. The development and occurrence of this type of leakage after the facepiece has been fit tested could cause a major decrement in the level of protection provided by the respirator even when perfectly donned and used.

Once these measures were undertaken, preliminary testing with acetone vapor revealed that considerable quantities of acetone vapor were diffusing through the silicone material of the facepiece. This problem forced us to abandon using the respirator CTD provided. In its place was selected a commercially available full facepiece respirator made of a butyl rubber compound.

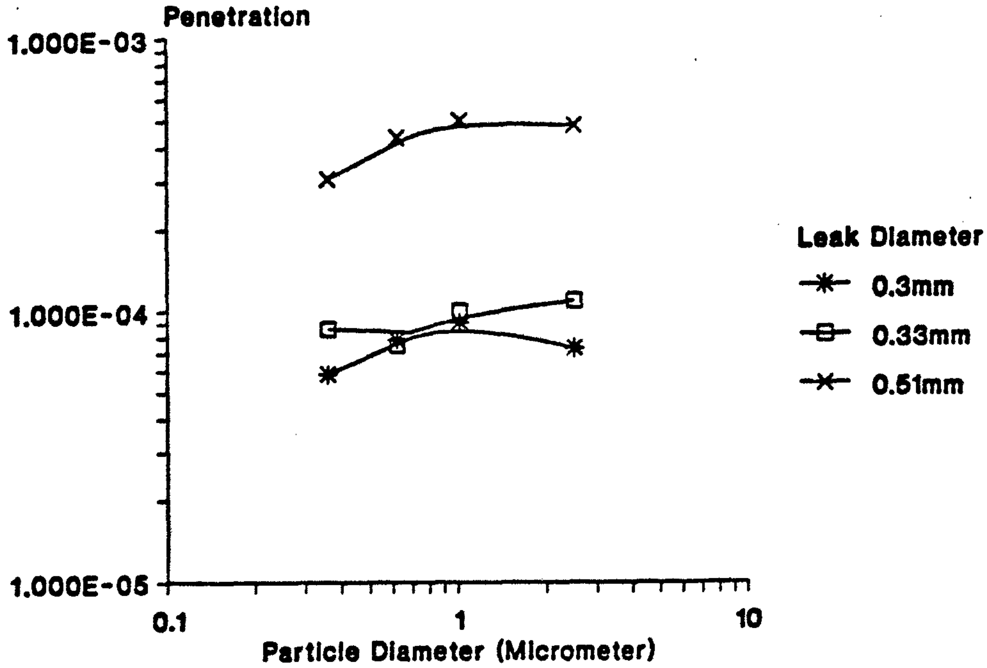

Figure 8. Penetration measured with a 1,500-ml tidal volume plotted as a function of particle size and leak diameter.

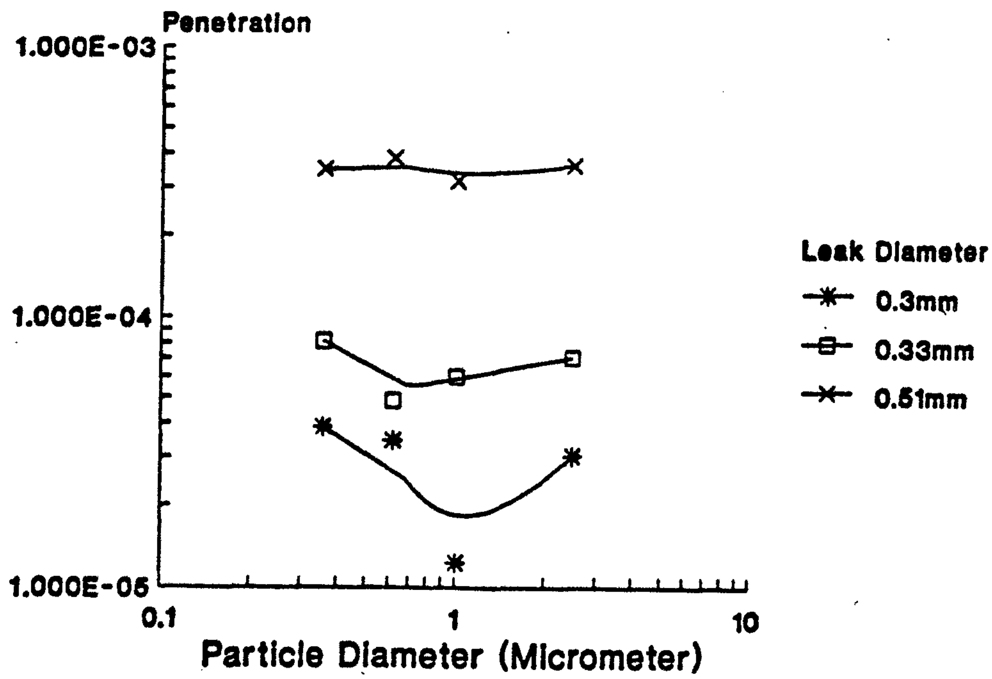

Figure 9. Penetration measured with a 600-ml tidal volume plotted as a function of particle size and leak diameter.

The permeability of the facepiece material appears to have the potential to be a significant component of overall in-board leakage for respirators required to provide high protection performance. For devices requiring high levels of performance the permeability of the facepiece material must be evaluated and factored into the overall assessment of protection. We recognized such in-board leakage is not fit related. However, attempts must be made to quantify it so that it can be considered.

Findings that measurement of faceseal leakage is affected by particle size and tidal volume are in agreement with the few studies that have evaluated such relationships. The difference in the calculated fit factors arising from using aerosol count concentration data vs. vapor mass concentration is a significantly new observation. The test results suggest that a fit test using a vapor or gas challenge agent may be a more critical test, in terms of penetration than fit tests using an aerosol. Efforts need to be undertaken to evaluate the feasibility of such test systems.

Such systems should also consider means for increasing the tidal volume of test subjects. This recommendation is based on the significant difference in measured faceseal penetration that was observed when a low or high tidal volume was used.

The differences in penetration, noted particularly with the smaller leaks (i.e., vapor determined AFF > 7,000) as a function of particle size is an important observation to consider when attempting to compare fit factors measures with a sodium chloride aerosol of 0.28 µm (3)and an oil mist aerosol of 0.5 µm MMAD (3). The results of this study indicate that for constant leak size, two different fits will be measured making it appear that different fits are being measured. In truth, the same fit could exist and the observed difference could be due to differences in the fit test methodologies.

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