

Evaluation of a Miniaturized Condensation Nucleus Counter for Measurement of Respirator Fit Factor

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INTRODUCTION

U.S. Army Chemical Research, Development and Engineering Center (CRDEC), in conjunction with TSI Inc., has developed a Mask Fit Validation Device (MFVD) which is based on the miniaturization of a continuous flow Condensation Nucleus Counter (CNC) sensor. The MFVD is a portable, battery operated instrument which is approximately 6" L x 5 1/2" W x 3" H and weighs three pounds. The device is used to assess the degree of protection that a respirator is providing the wearer. This measurement is commonly referred to as a fit factor (FF).

The MFVD determines FFs by alternately measuring aerosol particle concentrations from outside and inside the protective mask. This is accomplished by means of a solenoid valve located inside the instrument which directs the sample flow to the CNC sensor from either inside or outside the respirator. Mask fit is determined by dividing the particle concentration measured outside the mask by the particle concentration measured inside the mask. All functions of the instrument including sampling periods, solenoid valve actuation, particle measurement and determination and display of FF's are controlled by a single-chip microprocessor.

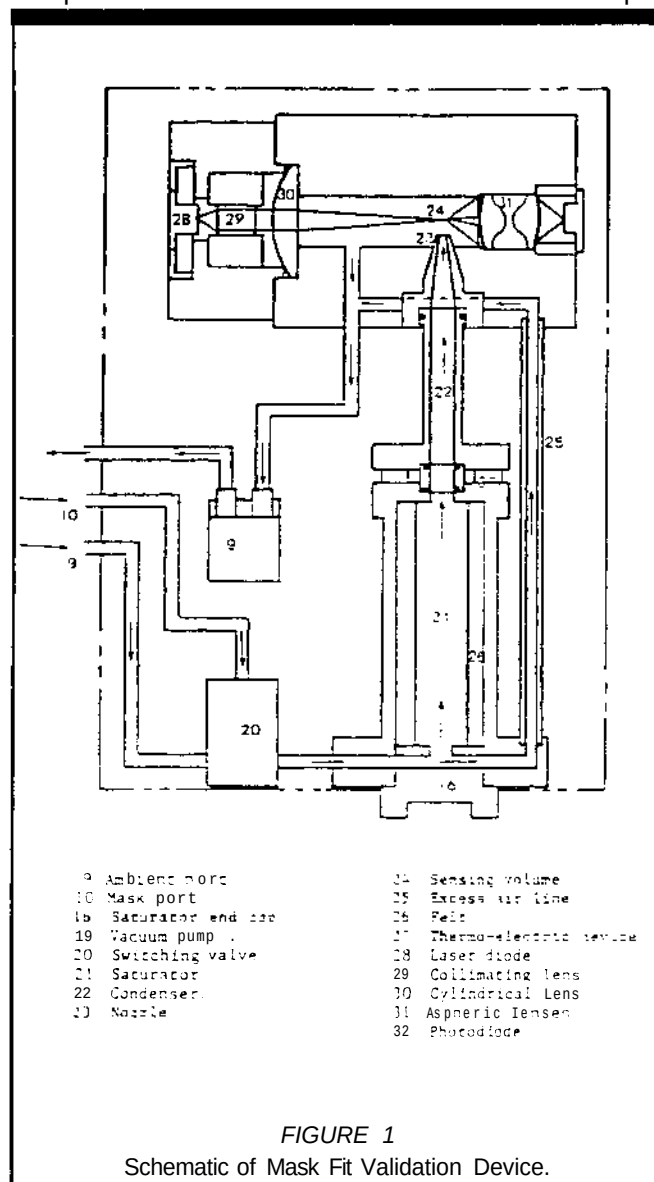
The MFVD is intended to provide a quick and easy method to quantitatively assess the fit of a protective mask on an individual. It will potentially be a valuable tool to aid in the proper sizing and fitting of protective masks as well as allow periodic checks to ensure the mask is providing adequate protection to the individual.

BACKGROUND

The Army's standard method of quantitatively assessing the performance of a respirator is to surround the mask with an oil aerosol and use a forward-light-scattering photometer to detect the amount of aerosol that leaks into the mask interior. The Army data base on mask performance, (both quality assurance tests which validate mask integrity alone, and quantitative fit testing, which tests the fit of

the mask on man) has been generated by utilizing photometer-based detection systems. Although the photometer and the CNC are both aerosol measuring instruments, the methods by which they detect and determine particle concentrations are quite different.

In the MFVD's continuous flow CNC (Figure 1) the sampled aerosol is first saturated with alcohol vapor

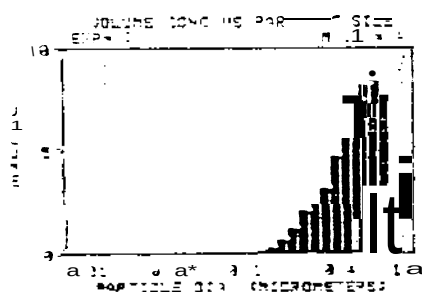
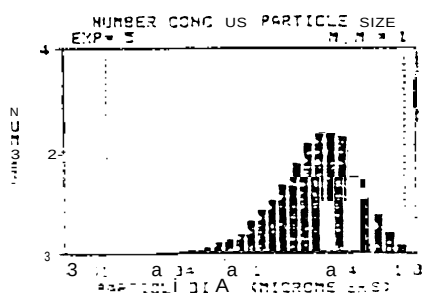


A schematic diagram of the Phase I test set-up can be seen in figure 3. The respirator is mounted on a headform containing a pneumatic bladder, which when inflated, seals the mask periphery to the headform. The mask/headform assembly is enclosed in a plastic hood where a corn oil aerosol challenge is introduced. Air samples are selectively obtained from either the hood volume or the cavity between the protective mask and headform (both eye and nose cup areas). A variable output bellows-type breather pump is also interfaced to the mask/headform assembly, which when activated simulates human respiration. By allowing the respirator to "breathe," air exchange and flow patterns within the mask are more representative of those found during actual fit testing of human subjects.

Sample lines are arranged to allow parallel sampling of aerosol by both the photometer and MFVD. The sample lines to each detector were of identical length and material composition so as to equalize particle loss. A 8 ml mixing chamber was added to the sample flow system of both the photometer and MFVD. This mixing chamber helped insure uniform distribution of the sampled aerosol to each detector.

Immediately upstream of the MFVD, a diluter, consisting of a capillary and a by-pass HEPA filter, was utilized to reduce the aerosol concentration to the MFVD. The dilution ratio obtained was approximately 65:1. This was necessary because the concentration of aerosol needed to produce a valid measurement from the photometer is above the calibration range of the MFVD. However, since a FF is a rationed value, as

MFVD/FIS COMPARISON TEST (CORN OIL)
AEROSOL FLOW RATE: .1 LPM
MAXIMUM DIA. MEASURED: .886 UM
MINIMUM DIA. MEASURED: .017 UM

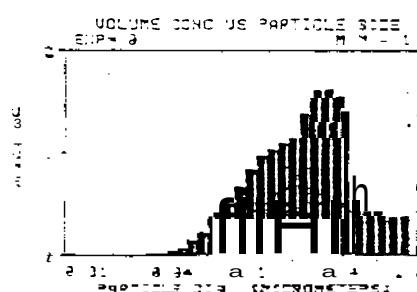
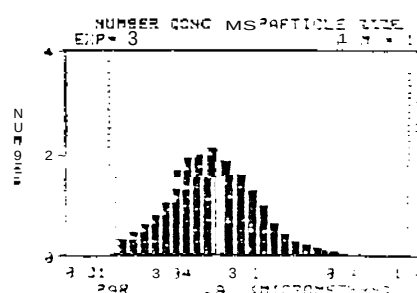


DIA	CONCENTRATION			
	DIA	NUMBER	SURFACE	VOLUME
CH#	MIDPOINT (UM)	(#/CC)	(UM ² /CC)	(UM ³ /CC)
TOTALS:	2.206E4	7.318E3	3.337E4	
FOR MEASURED DATA ONLY				
GEO. MEAN	.255	.408	.674	
SPREAD FACTOR:	1.739	1.523	1.444	

FIGURE 4

Corn Oil Characterization Data

MFVD/FIS COMPARISON TEST (ROOM AIR)
AEROSOL FLOW RATE: .3 LPM
MAXIMUM DIA. MEASURED: .886 UM
MINIMUM DIA. MEASURED: .017 UM



DIA	CONCENTRATION			
	DIA	NUMBER	SURFACE	VOLUME
CH#	MIDPOINT (UM)	(#/CC)	(UM ² /CC)	(UM ³ /CC)
TOTALS:	2.006E4	576.292	17.493	
FOR MEASURED DATA ONLY				
GEO. MEAN:	4.512E-2	.146	.226	
SPREAD FACTOR:	1.798	1.953	1.903	

FIGURE 5

Ambient Particulate Characterization Data

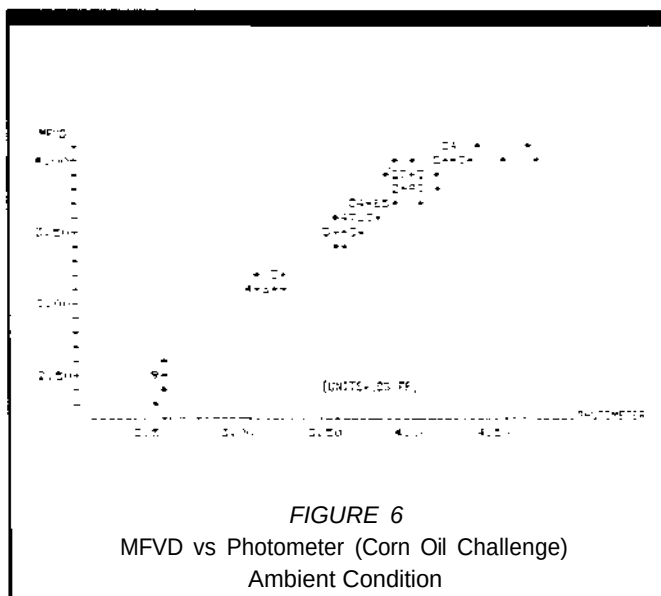


FIGURE 6
MFVD vs Photometer (Corn Oil Challenge)
Ambient Condition

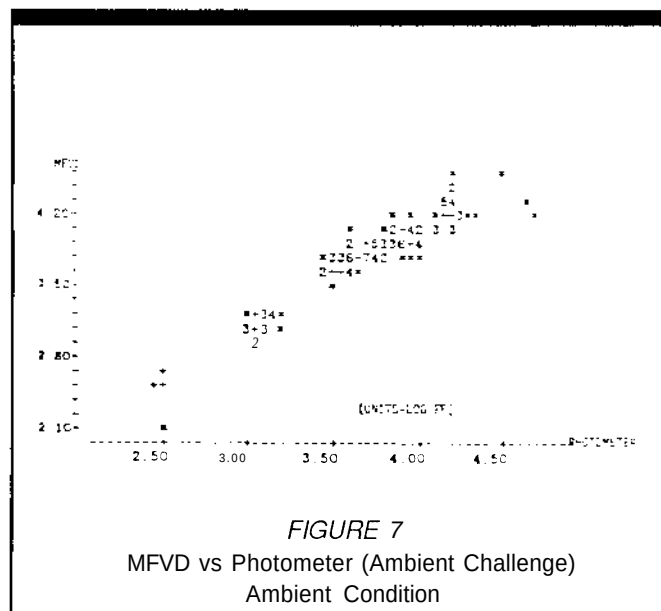


FIGURE 7
MFVD vs Photometer (Ambient Challenge)
Ambient Condition

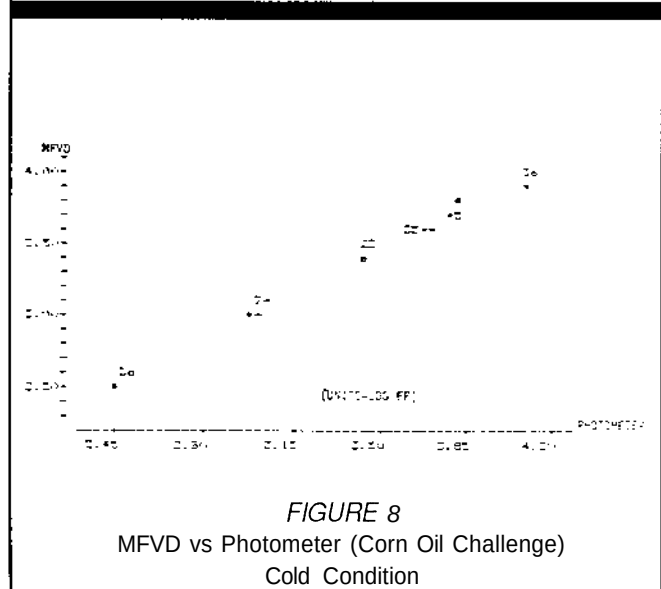


FIGURE 8
MFVD vs Photometer (Corn Oil Challenge)
Cold Condition

long as the dilution is constant for both upstream and downstream measurements, there is no effect on the final FF value.

The photometer chosen for use in Phase I is available commercially from Air Techniques Inc. (Model TDA 9A). The Erasable Programmable Read Only Memory (EPROM) chip that normally controls all the MFVD functions was replaced by a surrogate processor, which simply outputs the concentration of aerosol being sampled at a rate of one reading per second.

A Data Handling System (DHS) is linked to both the photometer and MFVD. Its function is to simultaneously read and store data from both detectors at a rate of one reading per second. In the case of the photometer, a digitized voltage response from the photomultiplier tube is received, while the MFVD serial port transmits data in the form of number concentrations. The DHS also controls the entire test sequence, including actuation of solenoid valves, activation as well as selection of air volume output of the breather simulator and conversion of fractional penetration measurements to FF values. The percent difference between FF values as measured by the photometer and MFVD is also calculated and all data is outputted to a printer for subsequent analysis.

PHASE I TEST METHOD

Testing was conducted to determine which hypodermic needles, produced fractional penetration values over a desired range. Ultimately, six leak levels were selected, ranging from approximately 0.3 percent to 0.005 percent (FF values of 300 to 20K).

When all test preparation had been completed, the previously prepared test respirator was carefully mounted on the headform and, the pneumatic bladder was inflated. The entire mask/headform assembly was then probed with corn oil aerosol to ensure a no-leak status of the set-up prior to insertion of the first capillary.

Each leak was tested in both a corn oil aerosol and an ambient particulate challenge. The corn oil aerosol and the ambient aerosol were both characterized on several occasions during each test day using a Differential Mobility Particle Sizer (TSI Model 3932C) and a Aerodynamic Particle Sizer (TSI Model 3300). Throughout the study, both aerosol challenges were very consistent with respect to mean size and standard deviation. Generally, the mean size of the ambient particulate was slightly less than an order of magnitude smaller than the corn oil aerosol. Typical size distribution data can be seen in Figures 4 and 5. In ambient temperature conditions (75°F/50 percent RH), each leak was tested over ten trials, with five

repetitions conducted per trial. Additionally, the order of the leaks tested and the challenge aerosols used were randomized to prevent biasing of data.

During corn oil testing, the following sequence of events occurred. The hypodermic needle is inserted through the rubber septum. The plastic hood is then closed and the aerosol generator is activated which fills the hood with corn oil aerosol. Both the photometer and MFVD simultaneously sample the challenge aerosol for a period of 15 seconds. The detectors are then purged, and the DHS establishes the photometer baseline while sampling through a HEPA filter. The photometer and MFVD then begin sampling through the mask/headform assembly at a flow rate of 2 lpm. This static test mode continues for a 30 second period. Following the static sampling, the breather simulator is activated which exercises the mask components at 4.5 lpm and 30 lpm respectively. Each of these dynamic modes also lasts for 30 seconds. Finally, a second hood sample is taken by both detectors to verify the stability of the challenge aerosol during the test period. The DHS compiles all data from both the photometer and the MFVD and calculates the results in terms of a FF value. The FF is determined by rationing the average concentrations of challenge aerosol with the integrated amount of aerosol penetrating through the capillary over the 90 second sampling period.

In The case of ambient aerosol testing, the plastic hood remained open allowing the test apparatus to be surrounded by naturally occurring particulate. The test sequence was identical to that of the corn oil testing. However, the ambient aerosol was not of sufficient quantity or size for the photometer to produce a valid measurement, therefore only MFVD data was recorded. Because of the lower aerosol concentration found in the room air, the diluter used upstream of the MFVD sample port during corn oil testing was removed.

Following testing in ambient conditions, the entire set-up was placed in an environmental chamber. A remote switch was wired to the DHS so that the tests could be controlled from outside the test chamber. Testing was conducted in the following conditions: cold (20°F), hot-dry (100°F/20 percent RH) and hot humid (100°F/69 percent RH). The test apparatus was conditioned in each environment for 16 hours prior to leak testing. Only the corn oil challenge was utilized during environment testing. Each orifice size was tested over ten repetitions.

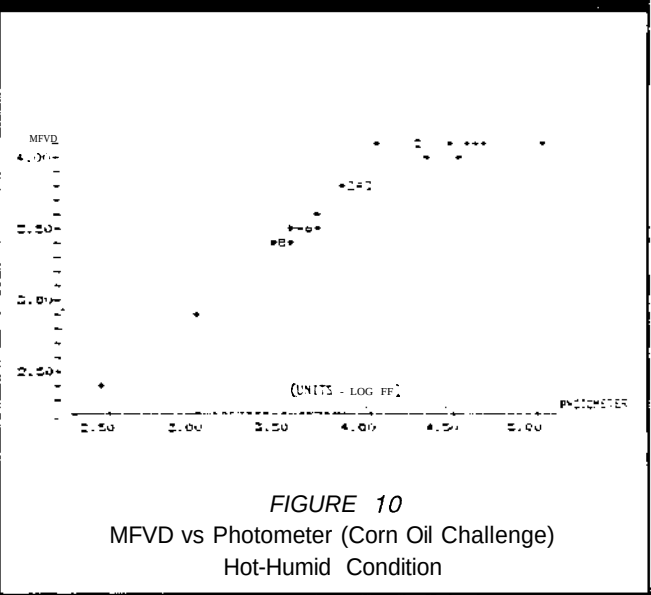
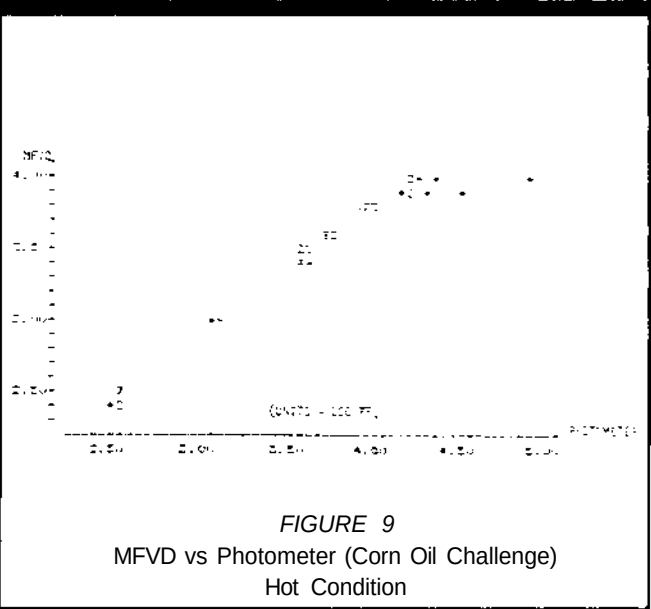
PHASE I
TEST RESULTS

Means and standard deviations in terms of FF's are shown in Table 1. Results are presented for the four different environmental conditions. It is observed from

Table 1 that the standard deviation for FF measurements made in the corn oil challenge by the MFVD was significantly lower than that of the photometer in range of 4,000 to 20,000. Therefore, it is concluded that in this study, the MFVD was more repeatable than the photometer when corn oil aerosol was used as the challenge medium.

It is also observed that the standard deviations were higher when the MFVD sampled naturally occurring aerosol found in the ambient room air as compared to MFVD measurements made in corn oil aerosol. This can be attributed to a higher variability of particle size as well as fluctuation in challenge concentration during test periods. Repeatability of measurements from the MFVD utilizing the ambient particulate challenge was roughly equal to those of the photometer with the corn oil challenge.

The data also indicates that higher penetration values were measured by the MFVD with corn oil



aerosol as compared to those taken in ambient particulate. This is not surprising, as the mean size of the naturally occurring aerosol is much smaller than that of the corn oil and is in the size range that is susceptible to diffusional loss during transport. This phenomenon is particularly apparent in the smallest orifice, where residence time of the aerosol traveling through the capillary is greatly increased, therefore allowing a greater number of particles to be lost. Additionally, as the capillary size increases along with flow rate through the orifice, diffusional losses are minimized. The data supports this hypothesis, as the FF's measured by the MFVD in both corn oil and ambient challenge become more similar as orifice size

increases.

Fit factors as determined by the MFVD and photometer were plotted to determine whether a linear relationship exists between them. Inspection of the graphs indicated significant curvature, particularly in the higher FF range (i.e. 10K). The FF data were then transformed to base ten logarithms and plotted in Figures 6 through 10. Since the plots appear linear, regression equations were developed to describe the relationship between the detectors.

Computer software was used to determine slopes and intercepts of linear regression equations. The equations relating the detectors and conditions are shown in Table 2. The correlation coefficients (R^2) are

Orifice #	PHOTOMETER		A. Ambient Condition MFVD [Corn Oil]		MFVD (Ambient Particulate)	
	$\bar{x}$	s	$\bar{x}$	s	$\bar{x}$	s
1	15382	2330	10897	492	16982	2348
2	8687	1162	7170	424	9463	1497
3	5181	984	4725	290	7122	981
4	3404	344	3233	270	4690	502
5	1173	115	1222	85.4	1415	196
6	309	9.72	340	30.7	375	45.3
B. Cold Condition (Corn Oil Only)						
1	13235	563	9442	517		
2	6465	191	5624	213		
3	4333	319	4041	131		
4	2733	76.3	2910	94.2		
5	1015	34.1	1142	25.2		
6	313	9.43	377	9.55		
C. Hot Condition (Corn Oil Only)						
1	22334	13217	9141	439		
2	8139	362	6424	124		
3	4573	174	3827	124		
4	3339	147	2822	90.5		
5	1090	12.3	1045	16.7		
6	305	6.54	233	17.7		
D. Hot-Humid Condition (Corn Oil Only)						
1	37301	27006	11233	725		
2	8677	923	6155	313		
3	4425	403	3359	125		
4	3182	122	2622	110		
5	999	11.5	529	13.5		
6	254	5.41	245	8.72		

TABLE 1
Summary of Photometer and MFVD Fit Factors
Phase I-Controlled Leak Data

also shown. The correlation coefficient is the proportion of the total sum of squares variation that is explained by the linear relationship. A value close to one indicates a high positive correlation, while a value of zero indicates that the two sets of data are not related. In all environmental conditions tested, the R^2 values are close to 1, therefore signifying a strong relationship between measurements made by the two detectors.

Given the regression equations, one can predict the FF reading of one detector within a certain range for a specific FF reading of the other detector. Table 3 shows equivalent FF readings for the special case in which the photometer reads of FF of 6667. (A FF of 6667 is the Army pass/fail level.) The 95 percent prediction intervals means that the probability is 95 percent that a specified data point will fall within that interval. The 95 percent confidence intervals shown only apply to the mean y' value corresponding to a specified x' value.

PHASE II TEST SET-UP

The Army Standard Fit Test Apparatus (SFTA) consists of 8' X 5' X 7' fiberglass test booths produced by Frontier Enterprises Inc., Laskin Nozzle aerosol generators which were fabricated by Los Alamos National Laboratory, and five decade forward-light-scattering photometers which were also assembled at Los Alamos. The scattering chambers used in the photometers are also marketed by Frontier Enterprise Inc. and used in their model 260B. The Laskin Nozzle generator produces 25 mg/m³ corn oil aerosol

challenge with a mass mean aerodynamic diameter of 0.5 μ m and a standard deviation of 1.6. The SFTA is driven by a portable technical computer (Hewlett-Packard Model 9816, Series 200). The workhorse of the system is the data acquisition and control unit (Hewlett-Packard, Model 3947A). The data acquisition unit is essentially a digital voltmeter. It interfaces directly with the photometer and processes the output signal of the photomultiplier tube at a rate of two actuation and second. The entire test sequence which includes solenoid valve actuation and FF calculation upon completion of each test is software controlled.

The MFVD was operated in the "as-used" mode, i.e., ambient particulate found in the room air served as the challenge medium and the instrument alternately sampled inside and outside the protective mask and determined a FF value approximately every 30 seconds. The standard MFVD EPROM controlled all instrument functions.

PHASE II TEST METHOD

Test subjects donned a variety of full-face protective masks and performed an abbreviated fit test routine while concentrations inside and outside the mask were being monitored. Each test was approximately 0 seconds in length and consisted of three 30 second exercises - normal breathing, head movement, side-to-side and up and down. At the conclusion of the 90 second period, the average FF for that test was recorded and the subject then proceeded to the second fit test apparatus and

A. Ambient Condition

		Regression Equation	R^2
PHOTOMETER FF	MFVD FF (corn oil)	$y' = .376 + .881x'$	.982
PHOTOMETER FF	MFVD FF (ambient part.)	$y' = -.182 + .972x'$	.968

B. Cold Condition

PHOTOMETER FF	MFVD FF (corn oil)	$y' = .420 + 0.969x'$	.996
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C. Hot Condition

PHOTOMETER FF	MFVD FF (corn oil)	$y' = .429 + 0.944x'$	.964
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D. Hot-humid Condition

PHOTOMETER FF	MFVD FF (corn oil)	$y' = .490 + 0.916x'$	.953
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Notes:

$$x' = \log_{10}(x)$$

$$y' = \log_{10}(y)$$

TABLE 2
Regression Equations

performed the same exercises. For the MFVD the average FF was determined over three 30-second sampling cycles. Each sampling cycle consists of four operation, sample cycles. Each sampling interior, and purge. For the SFTA the average FF was determined over one sampling cycle lasting approximately 0 seconds. A total of 100 sequential comparison tests were conducted.

PHASE II RESULTS

Some discrepancy in FF measurements between MFVD and SFTA results are expected due to (1) non-overlapping sampling periods and (2) the somewhat non-reproducible nature of leaks which occur at the man-mask interface and outlet valve. As a result, emphasis was placed on agreements or disagreements with regard to passing or failing a particular fit test rather than a comparison of FF values. Tests achieving FF's greater than or equal to 6667 were considered passed trials.

For nine of the 100 masks tested, induced leaks were created by piercing the mask with a hypodermic needle. This increased the size of the triple digit Ff data base near the critical FF of 6667. Table 4 summarizes the proportion of masks which yielded the same pass/fail result. The overall percentage of masks which gave the same pass/fail result was 96 percent for 100 masks. It was observed that all of the disagreeing pass/fail results were caused by temporary seal breakage during the up and down head movement that occurred while being tested by one system but not while being evaluated by the other.

CONCLUSIONS

Regression analysis of controlled leak data from Phase I of this study indicates a strong relationship between measurements made by the photometer and MFVD. Using the developed regression equations, for the critical Ff value of 6667, the photometer and MFVD measurements agree to within less than 20 percent. This holds true for MFVD measurements made with ambient particulate as well as corn oil aerosol.

The MFVD demonstrated a significantly higher degree of repeatability in the FF range of 4K to 20K when using corn oil aerosol as the challenge medium. The standard deviation of measurements made by the MFVD in the ambient particulate challenge was approximately equal to those of the photometer using the corn oil challenge.

Phase II of this study assessed the comparability of fit test measurements made by the MFVD in its "as used" mode and the Army's standard photometer-based fit test system. Again, the MFVD showed good correlation with the photometer system by attaining a 96 percent pass/fail agreement over 100 fit tests.

Test data indicates that in the range of penetration values that were evaluated in this study, the resulting fit factor measurements as determined by the MFVD were comparable to those made by the forward-light-scattering photometer. It is therefore concluded, that within this range, the MFVD is a suitable alternative to conventional photo-meter based quantitative fit testing systems.

Ease of use, portability, and the unique ability to make use of the ever present, naturally occurring airborne particulate, make the development of the MFVD an important first step to taking quantitative fit testing out of the laboratory and into the workplace.

FROM FF =6667	To	Best Fit	95% C.I.	95% P.I.
PHOTOMETER FF	MFVD FF (corn oil)	5575	5463-5692	4101-7582
PHOTOMETER FF	MFVD FF (ambient part.)	7952	7713-8197	5042-12541

TABLE 3
Special Case Equivalent FFs
Ambient Condition

Leak	Proportion of Agreement	Percentage
Induced	9/g	100
Non-Induced	87/91	95.6
Total	96/100	96.0

TABLE 4
Proportion of MFVD and SFTA FFs
With Same Pass/Fail Results