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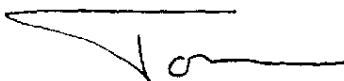
FROM: T. G. Grumbles
DATE: December 11, 1990

Interoffice
Communication

SUBJ: USE OF "PORTACOUNT" FOR QUANTITATIVE FIT TESTING

VISTA

The attached is a detailed study that further verifies the accuracy and utility of the Potacount device when compared to classical quantitative fit-testing methods.



T. G. Grumbles

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Attachment

SAFETY DIRECTORS

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A Comparison of Respirator Fit Factors Determined by Portable Condensation Nuclei Counting and Forward Light-Scattering Photometric Methods

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The purpose of this study was to compare fit factors determined by a recognized photometer quantitative fit test system (Model 264, Dynatech-Frontier Corp.) and a portable condensation nuclei counter respirator fit test instrument (Portacount, TSI, Inc.). The study was performed by conducting sequential fit tests with the two methods on human subjects wearing the same respirator at the same fitting. The fit factors obtained by the two methods were compared by several statistical tests. The results of these analyses indicated that there was good agreement in determining pass/fail at a critical fit factor. It was further concluded that fit factors for groups of wearers measured by the condensation nuclei counter instrument are comparable to those obtained by the photometer method. Rose, J.C.; Oestenstad, R.K.; Rose, V.E.: A Comparison of Respirator Fit Factors Determined by Portable Condensation Nuclei Counting and Forward Light-Scattering Photometric Methods. *Appl. Occup. Environ. Hyg.* 5:792-797; 1990.

Introduction

The quantitative measure of a respirator fit is generally expressed as a fit factor. This factor is an indication of the effectiveness of the respirator face seal. It is defined as the ratio of the concentration of the contaminant outside the respirator (C_o) to the concentration of the contaminant inside the respirator (C_i), or⁽¹⁾

$$\text{Fit Factor} = C_o/C_i \quad (1)$$

All measures of respirator performance are based on this ratio, with limitations and conditions that may be imposed on the measured concentrations, particularly C_i . When these concentrations are determined in the laboratory, the ratio is expressed as a fit factor. If the measurements are made in the workplace, the resulting value is called a protection factor or workplace protection factor.

In quantitative fit testing (QNFT) of respirators with aerosols, fit factor determination can be affected by a number

of factors, including particle size distribution and measurement methods.⁽²⁾ It has been demonstrated that there is a large variation in fit for individuals wearing the same respirator as well as for a population of respirator wearers.⁽³⁾ In both cases, the variation was best described by a lognormal distribution. Sampling bias can also be present as a result of sample probe location, leak site, and the interaction between leak site and breathing patterns.⁽⁴⁾ Studies have also indicated that laboratory fit factors do not correlate well with those determined in the workplace.^(5,6) Despite these problems, QNFT can be an effective tool in selecting the specific respirator that provides the best fit for a wearer.⁽⁷⁾ The use of QNFT for testing respirators has been included in the Occupational Safety and Health Administration (OSHA) comprehensive health standards for hazardous waste operations and emergency response, asbestos, lead, acrylonitrile, and formaldehyde.⁽⁸⁾

A widely accepted QNFT method which uses an oil aerosol as a test agent and forward light-scattering photometry as a measurement method was first reported in 1972.⁽⁹⁾ Since its development, the method has been used extensively in research and in industrial respirator programs. The aerosol size distribution, detection method, and test protocol have been incorporated into the American National Standards Institute's "Practices for Respirator Protection" (ANSI Z88.2-1980).⁽¹⁰⁾ This method requires the use of an exposure chamber and an accompanying aerosol generator. Therefore, the equipment is relatively expensive and must be set up and operated at a fixed location.

As an alternative to this method, a portable QNFT instrument has been developed. This light-weight, battery-operated instrument uses a constant flow condensation nuclei counter (CNC) as a sensor. It alternately measures aerosol concentrations from inside and outside the respirator by means of a solenoid valve. The instrument calculates the fit factor from average particle counts during

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90-second sampling intervals. This method allows the use of particles in the size range of about 0.2–1 micrometer (μm) in room air to be used as a test agent, thus eliminating the need for an aerosol generator and test chamber. Therefore, the CNC instrument can be used to perform QNFT in the workplace or at remote locations such as hazardous waste sites.

One of the initial studies involving a CNC for fit testing was conducted in 1981.⁽⁷⁾ Simultaneous measurement of respirator fit was conducted five times on two subjects using a continuous flow laboratory CNC instrument and a conventional light-scattering photometer. The subjects were exposed to an aerosol generated by the fit testing system. The researchers found that the fit factors determined by the photometer method were 1.64 times that for fit factors measured by the CNC. However, the correlation coefficient for the percent leakage measured by the two methods was 0.967. Respirator fit was also measured with the CNC alone using a variety of different aerosols, including ambient room particles. The researchers concluded that the CNC compared well with the photometer technique and that any fine particle cloud could be used as a test agent.

A study which used a portable CNC for fit testing was reported in 1987.⁽¹¹⁾ Comparative testing of the CNC and the standard photometer method was conducted in two stages. In the first comparison, the fit factors determined by the two instruments had correlation coefficients of 0.976–0.998 when sampling simultaneously in respirators with controlled leaks and mounted on mannequin head forms.

The second comparison in that study⁽¹¹⁾ involved sequential fit tests with the two methods on 100 human subjects wearing full facepiece respirators. The authors did not report direct correlation of these tests because of the effects of nonoverlapping sampling periods and the nonreproducible nature of leaks which occur at the face seal on the measurement of fit factors. However, the researchers did find that the two methods found 96 percent agreement in determining pass/fail fit at a critical fit factor of 6667.

Another study comparing respirator fit with ambient aerosols and the conventional photometer method was reported in 1988.⁽¹²⁾ The instrument used to measure fit factor with ambient aerosols was a laboratory particle counter. Both methods employed forward light-scattering photometers as sensors; however, the higher sensitivity of the particle counter allowed it to use room aerosols as a test agent. The methods were compared by sampling inside facepieces with controlled leaks and by sequential sampling of subjects wearing half-mask and full facepiece respirators.

The controlled leak comparison found significant differences between the two methods for 0.0075 and 0.55 percent leak levels but not at a 2.75 percent leak level on a half-face mask. The full-face mask analysis showed no significant difference for leak levels between 0.317 and 1.88 percent. While the difference of fit factors among subjects was significant, there was no significant difference between the means of five fit tests on 30 subjects deter-

mined by the two methods.

The purpose of the present study was to make a direct comparison of fit factors determined by the portable CNC instrument and the conventional photometer method rather than to determine the accuracy of fit factors determined by two methods of QNFT. This was accomplished by performing sequential measurements of fit factor with the two methods at the same fitting of the respirator. Since the measured fit factors were paired data, any difference in the fit factor could be attributed to the method. This design would also include the effects of nonoverlapping sampling periods and nonreproducible nature of leaks that occur at the face seal during the measurement of fit factors. It was intended to determine if fit factors obtained in the field with the CNC instrument could be expected to be similar to those obtained in the laboratory with the photometer method.

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Materials and Methods

The two instruments for determining fit factors compared in this study were the Model 264[®] polydispersed aerosol/photometer test system (Dynatech–Frontier Corp., Albuquerque, New Mexico) and the newly developed Portacount CNC Respirator Fit Tester[®] (TSI, Inc., St. Paul, Minnesota). The photometer system consisted of an aerosol generator, exposure chamber, and forward light-scattering photometer sensor. The mechanical generator produced a polydisperse oil aerosol with an aerodynamic mass median diameter between 0.5 and 0.7 μm with a geometric standard deviation of about 1.8. The aerosol was mixed with filtered air to produce an aerosol concentration in the range of 20–25 mg/m^3 in the test chamber. Measurement of the aerosol in the test chamber and inside the respirator was by forward light-scattering photometry.

The CNC is a compact, portable condensation nuclei counter. In this instrument, sampled air was first saturated with alcohol vapor while passing through a heated saturation tube. The air was then cooled in a condenser tube and the alcohol vapor condensed on particles causing them to increase in size so they would scatter light as they passed through a focused light beam.⁽¹¹⁾ Scattered light was focused onto a photodiode which in turn generated an electrical pulse for each aerosol particle that passed through the viewing volume. The CNC output only indicated the number of particles detected and did not account for differing size or mass of those particles. This technology allowed the device to count particles as small as 0.02 μm over a concentration range of 0.1 to 5×10^5 particles/ cm^3 .⁽¹⁰⁾ This measurement range allowed the determination of fit factors greater than 100,000.

The respirator used in this study was a 3M Easi-Air[®] (3M Corp., St. Paul, Minnesota) silicone half-mask respirator equipped with high efficiency filters. Two sizes were used: small/medium and medium/large. The respirators were cleaned and sanitized after each use to ensure sanitary conditions.

The study was conducted by fitting 24 subjects with a

respirator and then performing sequential quantitative fit tests, first in room air with the CNC instrument and then in the aerosol test chamber with the photometer method. During both tests, the subjects performed the following exercises: normal breathing, deep breathing, moving head side to side, moving head up and down, talking, and normal breathing. Care was taken not to disturb the fit of the respirator from the time of the initial fitting until after the conclusion of both fit tests.

Both instruments were operated in accordance with the manufacturers' operating instructions. The tests were conducted in separate locations so as not to expose the CNC instrument to the corn oil aerosol from the photometer method.

The CNC instrument measured three fit factors for each test exercise. The exercise fit factor was calculated as the average of the three values. The overall fit factor (FF) for the CNC test was then calculated by the following equation:⁽¹³⁾

$$\text{Overall FF} = 6 / [(1/\text{NB}_{1\text{FF}}) + (1/\text{DB}_{\text{FF}}) + (1/\text{SS}_{\text{FF}}) + (1/\text{UD}_{\text{FF}}) + (1/\text{TK}_{\text{FF}}) + (1/\text{NB}_{2\text{FF}})] \quad (2)$$

The photometer tests consisted of three 30-second integrated photometer values while sampling inside the respirator (C_i) during each exercise and integrated photometer values while sampling in the test chamber (C_o) between exercises. Fit factors for each exercise were calculated by dividing the average of the chamber values prior to and after that exercise by the average value of the three measurements inside the respirator during the exercise. The overall fit factor for the test was then calculated by Equation 2.⁽¹³⁾

It should be noted that both methods determined integrated values of aerosol concentration rather than peak values. Using integrated output while sampling inside the facepiece may overestimate fit factors by about 10–15 percent due to sampling exhaled air of the wearer.^(12,5) Measured fit factors were not corrected for this bias.

Data were entered into a computer spreadsheet, and appropriate transformations and statistical tests were performed using True Epistat Statistical Software.⁽¹⁴⁾ Two-tailed tests of hypothesis were performed at an alpha value of 0.05. With 24 pairs of measured fit factors, the study could detect a difference of 120 between the mean fit factors of the two methods at an alpha value of 0.05 and a power of 90 percent.⁽¹⁵⁾ This assumes a geometric standard deviation of 2.26 for mean difference between fit factors previously reported.⁽¹²⁾

Results

Exercise fit factors are shown in Tables I and II, and the paired overall fit factors are shown in Table III. The distributions of the fit factors for the two methods were found to be significantly different from the normal distribution.⁽¹⁴⁾ The natural logarithm transformed data were found not to be significantly different from the normal distribution⁽¹⁴⁾ and were used for subsequent parametric statistical analysis.

The range of measured fit factors by the CNC instrument method was 61–15,560 with a geometric mean of 1884 and a geometric standard deviation of 3.9. The range of fit factors measured by the photometer method was 30–52,130 with a geometric mean of 2092 and geometric standard deviation of 6.7. However, an inspection of the data in

TABLE I. CNC Instrument Exercise Fit Factors

Subject Number	Normal Breathing	Deep Breathing	Side to Side	Up and Down	Talking	Normal Breathing
1	245	163	177	177	585	610
2	34823	37567	85067	77167	3427	72767
3	63167	44100	25795	52256	2507	82533
4	3390	2533	1797	2580	1667	2857
5	3210	6170	4750	6867	4210	3423
6	2667	3113	2917	3720	2847	3297
7	512	351	281	315	359	301
8	889	1847	1620	3080	1250	2930
9	2993	4800	1663	1883	1409	2930
10	3969	3041	1391	84	124	99
11	1823	969	1897	3563	1029	4053
12	3357	2927	2977	3310	1960	3210
13	37	74	61	63	111	60
14	4590	4200	3780	2717	2137	2293
15	4450	3347	4120	4880	1873	2413
16	1060	1797	3673	3553	1713	2053
17	2740	2817	3293	2843	1204	1303
18	332	867	1203	116	258	221
19	3103	5333	7683	7573	1913	3879
20	14577	12447	11903	23600	6653	4627
21	3980	22200	5500	4350	4483	4510
22	3284	6903	3933	12433	1371	13867
23	33027	1337	3033	2833	1363	2250
24	3627	2243	2440	2897	2103	2180

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TABLE II. Photometer Instrument Exercise Fit Factors

Subject Number	Normal Breathing	Deep Breathing	Side to Side	Up and Down	Talking	Normal Breathing
1	296	312	221	398	761	637
2	38831	36738	92161	64676	44880	73938
3	98749	83425	101669	29438	12362	63214
4	1427	1514	1311	2018	1223	1398
5	4680	4538	1605	1529	4696	2826
6	3369	3414	4236	3084	3932	3587
7	243	330	217	201	371	230
8	1514	1544	1150	1634	1735	1266
9	5494	3286	2824	1602	6414	2422
10	516	52	109	146	125	136
11	3980	4789	4394	4904	1413	4775
12	2739	3491	2674	3806	1765	2508
13	23	27	24	44	31	51
14	2085	3007	1144	6152	1394	2492
15	10826	6120	5497	16662	5256	4499
16	59254	47368	85367	8971	97193	86783
17	9155	10571	17443	7761	14480	7715
18	42	81	32	31	37	36
19	1368	2968	2768	1627	1461	3001
20	12423	4309	26668	7496	12797	1831
21	3978	1871	927	1451	855	2049
22	7885	60485	26485	20449	31293	17998
23	900	1122	2123	2369	2147	2092
24	2020	1815	2348	2013	2274	1883

Table III indicates that fit factors for photometers were lower than for CNC in 14 of the 24 pairs.

A linear regression model with the photometer log fit factors as the independent variable and the CNC log fit factors as the dependent variable yielded a slope of 0.600 which was significantly different from a slope of zero ($p < 0.0001$).⁽¹⁴⁾ A plot of the regression with 95 percent confidence intervals for the curve is shown in Figure 1. The regression equation accounted for 73.9 percent of the variation in the dependent variable. Pearson's Correlation coefficient for the log fit factors by the two methods was 0.859 and was significantly different from zero ($p < 0.001$).⁽¹⁴⁾

Student's t-test for paired samples found that the mean difference between log fit factors determined by the two methods was 0.0454, which was not significantly different from zero ($p = 0.627$).⁽¹⁴⁾ The fit factor data were also compared by the Wilcoxon Signed Rank Test.⁽¹⁴⁾ That test found the median difference between fit factors obtained by the two methods not to be significantly different from zero ($p = 0.992$).

The two methods were also compared as to their agreement with regard to passing or failing a fit test rather than a direct comparison of fit factor values. Critical fit factor values of 100 and 1000 for pass/fail criteria and fit factors determined by the photometer as the standard were used for this comparison. These results were entered in a 2×2 table, and sensitivity, specificity, and predictive values were calculated. These results are shown in Table IV. It is noted that there was only one discordant pair in the 48 comparisons at the two critical fit factors. However, the statistical significance of these distributions cannot be tested because some cells have less than five observations.⁽¹⁴⁾

Discussion

Results of this study indicate that fit factors determined by the CNC instrument and the photometer method, on a

TABLE III. Overall Fit Factors

Subject Number	CNC Instrument		Photometer Method	
	Measured	Log	Measured	Log
1	241	5.486	364	5.896
2	15560	9.652	52130	10.862
3	11820	9.378	36890	10.516
4	2320	7.750	1450	7.278
5	4410	8.392	2630	7.876
6	3060	8.025	3560	8.179
7	340	5.829	252	5.531
8	1600	7.378	1440	7.275
9	2400	7.782	2950	7.900
10	191	5.254	114	4.738
11	1660	7.417	3320	8.107
12	2860	7.958	2660	7.887
13	61	4.110	30	3.417
14	3010	8.010	2020	7.612
15	3120	8.047	6590	8.794
16	1920	7.560	32790	10.398
17	2020	7.610	10190	9.229
18	272	5.608	39	3.610
19	3860	8.260	1960	7.581
20	9350	9.143	5420	8.597
21	5200	8.557	1420	7.262
22	3780	8.238	18880	9.846
23	2270	7.729	1560	7.354
24	2490	7.820	2040	7.621
GM ^a	1884		2092	
GSD ^b	3.9		6.7	

^aGM = geometric mean.

^bGSD = geometric standard deviation.

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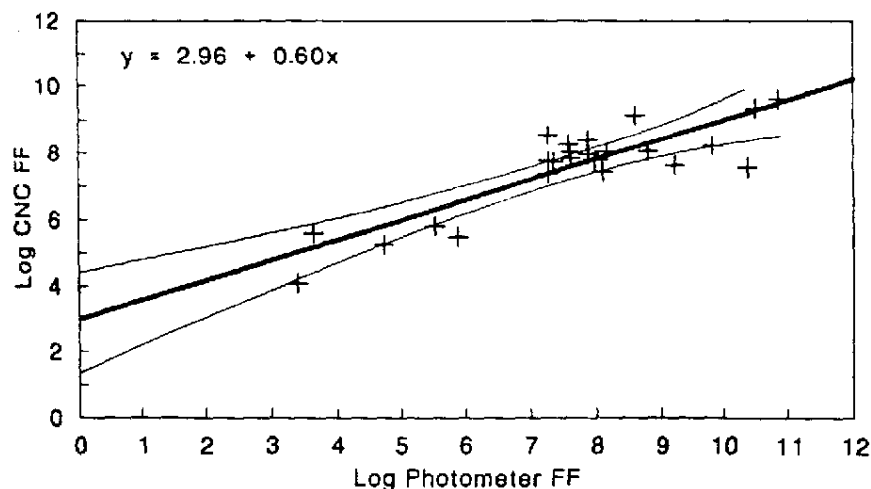


FIGURE 1. Regression of log photometer fit factor (FF) and log CNC fit factors.

group basis, are highly comparable. The results are in agreement with those reported in other studies.^(7,11,12) The range of fit factors obtained by both methods were extremely large and followed a lognormal distribution. These results correspond with those of a previous study on variability of respirator fit.⁽³⁾ The geometric standard deviation of 3.9 for the CNC instrument fit factors is almost the same as that found for half-mask respirators in the previous study. However, the geometric standard deviation of 6.7 for the photometer method was higher than those previously reported. The difference in variance between the two methods in this study was found not to be significantly different when tested by Bartlett's Test for Homogeneity of Variance ($p = 0.091$).⁽¹⁴⁾

The correlation coefficient for log fit factors by the two methods in testing 24 human subjects determined in this study was 0.859. One previous study found a correlation

coefficient of 0.967 from repeated, simultaneous tests on two subjects,⁽⁷⁾ and another found coefficients of 0.976–0.998 from testing respirators with controlled leaks and mounted on mannequin headforms.⁽¹¹⁾ The slightly lower value obtained in this study may be due to intersubject variation in leakage on a large sample of human subjects and/or the effects of nonoverlapping sampling periods and nonreproducible nature of face seal leaks.⁽⁵⁾ However, the coefficient obtained in this study was still not significantly different from 1.00.

The results of the regression analysis of the log fit factors from this study were also very similar to results reported in previous work.^(7,11) Those studies found slopes of 0.609 and 0.816–0.972 and correlation coefficients of 0.967 and 0.953–0.996, respectively, from simultaneous sampling by the two methods. The regression slope in this study was 0.600 with a correlation coefficient of 0.859. Again, the fact

TABLE IV. Pass/Fail Agreement

	Photometer			Photometer	
	FF* > 100	FF < 100		FF > 1000	FF < 1000
FF > 100	22	1	FF > 1000	19	0
CNC			CNC		
FF < 100	0	1	FF < 1000	0	5
			FF = 100	FF = 1000	
Sensitivity: A/(A + C)			1.00	1.00	
Specificity: D/(B + D)			0.50	1.00	
Positive Predictive Value: A/(A + B)			0.96	1.00	
Negative Predictive Value: D/(C + D)			1.00	1.00	
Sensitivity: The probability that the CNC FF will be greater than the critical value given that the photometer FF is greater than that value.					
Specificity: The probability that the CNC FF will be less than the critical FF given that the photometer FF is less than that value.					
Positive Predictive Value: The probability that a CNC FF greater than the critical value will reflect a photometer FF greater than that value.					
Negative Predictive Value: The probability that a CNC FF less than the critical value will reflect a photometer FF less than that value.					

*FF = fit factor.

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that the regression equation accounted for 73.9 percent of the variation in the dependent variable is probably due to intersubject variation in leakage and/or the effects of non-overlapping sampling periods.⁽¹¹⁾

The comparability of the two methods is further supported by results of the Student's *t*-test and Wilcoxon Sign Rank Test. The *t*-test found that the mean difference between the log fit factors for the two methods was not significantly different from zero, and the Sign Rank Test found the median difference between fit factors not to be significantly different from zero. These results are similar to those reported in a study of repeated measures of the same fit by a photometric method and a laboratory CNC.⁽¹²⁾

Finally, the two methods provided very good agreement in determining fit factor pass/fail criteria. Only one discordant pair was found in the set of 48 comparisons. This resulted in a specificity of 0.50 at a critical fit factor of 100 because of the small number of observations in the cells used to calculate that value. However, the two methods were found to be in complete agreement at a critical fit factor of 1000. These results are very similar to those found while testing full facepiece respirators with the two methods.⁽¹¹⁾

The study assumed any bias present as a result of facepiece sampling conditions would be the same during testing by the two techniques. Other possible sources of bias were the consistent sequence of test methods and facial exercises during the tests. These differences could be eliminated by randomizing the sequence of test methods and of exercises in the test. Also, simultaneous, as opposed to sequential, sampling of the two techniques could be considered.

Conclusions

The CNC instrument gave very similar results when tested in sequence with the photometer method. Fit factors determined by the two methods, compared on a group basis, were highly correlated. Both parametric and nonparametric statistical analysis of the data indicated no significant difference between the two methods, and the two methods were in good agreement in determining pass/fail at two critical fit factors. Differences in fit factors measured by the two methods could be attributed to intra- and intersubject variation in leakage on a large sample of human subjects and nonoverlapping sampling periods.

It was concluded that fit factors measured by the CNC instrument for the group of subjects are comparable to those measured by the photometer method. This would mean fit factors obtained for groups of wearers by users of the CNC instrument in the workplace or at remote locations could be expected to be equivalent to those measured by a photometer method at a laboratory location.

However, caution should be exercised when comparing fit factors on an individual basis. In applying the results of QNFT, the practicing industrial hygienist should keep in

mind the purpose of these tests. QNFT is performed to assist in selecting the respirator that provides the highest amount of protection for an individual wearer and to assure that an appropriate lower confidence limit of the measured fit factors exceeds the assigned fit factor for the type of respirator being used. This study indicates that the CNC instrument will provide similar results to the photometer in the performance of these tasks.

Acknowledgments

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References

1. Myers, W.R.; Lenhart, S.W.; Campbell, D.; Provost, G.: The Forum. *Am. Ind. Hyg. Assoc. J.* 44:B25-B26 (1983).
2. Holton, P.M.; Willeke, K.: The Effect of Aerosol Size Distribution and Measurement on Respirator Fit. *Am. Ind. Hyg. Assoc. J.* 48:855-860 (1987).
3. daRozza, R.A.; Cadena-Fix, C.A.; Carlson, G.J.; et al.: Reproducibility of Respirator Fit Tests as Measured by Quantitative Fit Tests. *Am. Ind. Hyg. Assoc. J.* 44:788-794 (1983).
4. Myers, W.R.; Allender, J.; Plummer, R.; Stobbe, T.: Parameters That Bias the Measurement of Airborne Concentrations Within a Respirator. *Am. Ind. Hyg. Assoc. J.* 47:106-114 (1986).
5. Dixon, S.W.; Nelson, T.J.: Workplace Protection Factors for Negative Pressure, Half-Mask Facepiece Respirators. *J. Int. Soc. Respir. Prot.* 2:347-361 (1984).
6. Myers, W.R.; Peach, M.J.; Cutright, K.; Iskander, W.: Workplace Protection Factor Measurements on Powered Air-Purifying Respirators at a Secondary Lead Smelter. Results and Discussion. *Am. Ind. Hyg. Assoc. J.* 45:681-688 (1984).
7. Willeke, K.; Ayer, H.E.; Blanchard, J.D.: New Methods for Quantitative Respirator Fit Testing with Aerosols. *Am. Ind. Hyg. Assoc. J.* 42:121-135 (1981).
8. General Industry Standards, Code of Federal Regulations Title 29, Part 1910, Subpart Z, pp. 676-957. U.S. Government Printing Office, Washington, DC (1987).
9. Hyatt, E.C.; Pritchard, J.A.; Richards, C.P.: Respirator Efficiency Measurements Using Quantitative DOP Man Tests. *Am. Ind. Hyg. Assoc. J.* 33:635-643 (1972).
10. American National Standards Institute: American National Standard for Respirators, Protection, Z88.2-1980. ANSI, New York (1980).
11. Laye, R.: Evaluation of a Miniaturized Condensation Nucleus Counter for Measurement of Respirator Fit Factors. *J. Int. Soc. Respir. Prot.* 5:1-7 (July/September 1987).
12. Ernstberger, H.G.; Gall, R.B.; Turok, C.W.: Experiments Supporting the Use of Ambient Aerosols for Quantitative Respirator Fit Testing. *Am. Ind. Hyg. Assoc. J.* 49:613-619 (1988).
13. American National Standards Institute: American National Standard for Respiratory Protection, Respirator Fit Methods: Draft ANSI-Z88.10. ANSI, New York (1989).
14. Gustafson, T.L.: True Epistat, 2nd ed. Epistat Services, Richardson, TX (1987).
15. Lachin, J.M.: Introduction to Sample Size Determination and Power Analysis for Clinical Trials. *Control. Clin. Trials* 2:93-113 (1981).

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