

The Effect of Ambient Aerosol Concentration and Exercise on PortaCount® Quantitative Fit Factors

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ABSTRACT

The PortaCount® Plus Model 8020 is a quantitative fit test instrument that uses ambient aerosol to estimate respirator fit. Ambient aerosol concentration levels vary greatly among workplaces. The purpose of this study was to determine: (1) if PortaCount Plus fit factors are affected by ambient aerosol concentration; and (2) if any of the exercises are the most critical in determining the overall fit factor. Fit test data for 30 elastomeric and filtering-facepiece respirator models from a companion study were analyzed. Each respirator model was tested on a 25-subject panel using the PortaCount Plus and seven exercises. The analyses were conducted to determine: (1) if fit factor varies among five levels of ambient aerosol concentration; (2) the frequency of each exercise having the lowest within-fit-test fit factor among all exercises; and (3) the mean ratio of each exercise fit factor to the highest within-fit-test fit factor. Ambient aerosol concentration had no practical effect on fit factor. "Talking out loud," "bending," and "moving head up/down" exercises had the lowest fit factor in approximately 66% of the tests. They also had the lowest average within-fit-test ratios of exercise fit factor to the highest fit factor (0.56, 0.62, and 0.67, respectively). Fit factors for each exercise were found to be highly correlated with fit factors for each of the other six exercises. There was no significant fit-factor difference between the first and second normal breathing exercises. We conclude that the fit test pass/fail criterion need not be adjusted for ambient aerosol concentration level and that "talking out loud," "bending," and "moving head up/down" are the three most critical exercises in determining the overall fit factor. These three exercises could be considered for development of a multi-donning protocol using fewer and/or shorter exercises to keep the length of a fit test the same as the current fit test protocol.

Keywords: Quantitative Fit test, Fit Factor, Ambient Aerosol, PortaCount® Plus, Exercise

INTRODUCTION

The purpose of the movements (exercises) used in quantitative fit tests is to simulate the type of head and facial movements made during the course of normal respirator use in the workplace. Different sequences of exercises have been used by both researchers and regulatory agencies. The most common sequence of movements prior to the standardization of fit test exercises in 1998 by the Occupational Safety and Health Administration (OSHA) was: 1) normal breathing while the head remains motionless, 2) deep breathing while the head remains motionless, 3) moving the head side to side, 4) moving the head up and down, 5) talking out loud (e.g., reading a prepared passage or reciting the alphabet, etc.), and 6) a second normal breathing (Hyatt, 1976; Murata et al., 1979).

In some studies, subjects performed these movements while walking on a treadmill or exercising on a bicycle ergometer (Bentley et al., 1984; Longson, 1982; Manninen et al., 1988). Other researchers added extra movements such as smiling/frowning, coughing, running in place, sand blaster movements, reaching overhead, bending and touching toes, and deep knee bends (Hyatt et al., 1972; Lowry et al., 1979; Hyatt et al., 1974; Brown, 1992). The purpose of the smiling/frowning movement was to break the seal and see if the respirator reseated itself during subsequent movements (Brown, 1992). The reseating usually occurred during the second normal breathing period. Questions about including smiling and coughing to simulate work movements in a standardized fit test have been raised since they are difficult to duplicate (Hyatt et al., 1974).

The first fit test protocol promulgated by OSHA was in the Code of Federal Regulations (CFR) lead standard [29 CFR 1910.1025 (1996)]. This protocol called for the same sequence of six movements described previously each lasting for one minute. When OSHA promulgated other substance specific standards, other exercises were added such as grimacing, bending over, and jogging in place [29 CFR 1910.1001 (1996); 29 CFR 1910.1026 (1996); 29 CFR 1910.1028 (1996); 29 CFR 1910.1048 (1996)]. The current OSHA regulation for quantitative fit testing requires the six exercises from the lead standard with the addition of grimacing and bending (or jogging in place) being performed between the talking out loud and the second normal breathing exercises [29 CFR 1910.134 (1998)]. The fit factor from the grimacing exercise is not used in the calculation of the overall fit factor due to its being designed to break the face seal which results in a lower fit factor. If the seal does not reseat during the subsequent exercises, the subsequent fit factors will also be lower.

Ambient aerosol concentration levels vary greatly among workplaces, but OSHA does not stipulate a specific concentration. A data set of 20,974 PortaCount[®] Plus (TSI Inc., St. Paul, MN) fit tests conducted at various workplaces was obtained and analyzed by Zhuang et al. (1999). The ambient aerosol concentrations were divided into five levels and Duncan's multiple-range test was performed to determine if fit factors varied among the five levels (Montgomery, 1984). Overall fit factors were found to be significantly dependent on the ambient aerosol concentration in both the half- and full-facepiece fit test data (p -value < 0.01). The overall fit factor increased as ambient aerosol concentration increased. However, the data set only contained fit test data with overall fit factors exceeding the pass/fail criteria. When the PortaCount Plus indicated a fit test failure, the test was usually stopped and test data was not recorded. Further investigation of both passing and failing fit test data is needed to determine if the fit test pass/fail criteria should be adjusted for ambient aerosol concentration level. No laboratory studies have been reported to investigate the effect of ambient aerosol concentration on PortaCount Plus fit factors. Due to the time required to conduct a fit test, considerable time and financial commitments must be made by employers to select a properly fitting respirator for a given worker. A recent study indicated the need to improve fit test accuracy (Coffey et al., 2002). A multi-donning approach is suggested as a method to improve fit test accuracy. The number of exercises in a multi-donning protocol will need to be reduced and/or shortened in order to keep the length of a fit test the same as the current fit test. Thus, the purpose of this study was to determine: (1) if PortaCount Plus fit factors are affected by ambient aerosol concentration; (2) if any of the exercises are the most critical in determining the overall fit factor or if any exercise consistently provides the lowest fit factor.

Fit test data from a companion study by the National Institute for Occupational Safety and Health (NIOSH) were used for the analyses in this study. The companion study evaluated three fit test methods (Bitrex, saccharin, and modified ambient aerosol condensation nuclei counter using the TSI PortaCount Plus with the N95-COMPANION[®]) for their ability to identify poorly fitting N95 respirators.

MATERIAL AND METHODS

Subjects

A total of 39 people (21 females and 18 males) participated in this study. A panel of 25 subjects tested each respirator model. Panel members were recruited from respondents to an advertisement placed in a

local city newspaper, word of mouth, and from participants in previous NIOSH fit testing studies. Panel members were selected to provide a variety of facial sizes without regard to any particular facial size distribution.

Respirators

The 30 models of NIOSH-certified N95 respirators used in this study are listed in Table I. The 15 filtering-facepiece respirators were selected at random from approximately 33 models which were commercially available at the beginning of the study and had not been tested in previous NIOSH studies (Coffey et al., 1999; Coffey et al., 2004). The 15 N95 elastomeric facepiece respirators were randomly chosen from approximately 40 models available at the time the study started in 2001.

TABLE I. List of Respirator Manufacturers and Models

Manufacturer	Model	Facepiece Size(s)	Facepiece Type
3M	8511	OSFA ¹	Filtering
3M	8515	OSFA	Filtering
3M	9210	OSFA	Filtering
3M	9211	OSFA	Filtering
3M	7000 with 7N11 filter	Small/Medium, Medium/Large	Elastomeric
AlphaProtech	695	OSFA	Filtering
AO Safety	5Star with 9500R filter	Small/Medium/Large	Elastomeric
Aswan	M-12	OSFA	Filtering
Draeger	Piccola	OSFA	Filtering
Gerson	1730	OSFA	Filtering
Gerson	2747	OSFA	Filtering
Gerson	3945	OSFA	Filtering
Lab Safety	11291 with 30638 filter	Small/Medium/Large	Elastomeric
Makrite	910-N95	OSFA	Filtering
Moldex-Metrics	2600	Small, Medium/Large	Filtering
Moldex-Metrics	8000 with 8910 filter	Small/Medium/Large	Elastomeric
MSA	AffinityFR200	OSFA	Elastomeric
MSA	Comfo Elite	Small/Medium/Large	Elastomeric
MSA	COMFO with 816291 filter	Small/Medium/Large	Elastomeric
North	7700-30 with 7506N95 filter	Small/Medium/Large	Elastomeric
Pro-Tech	1590 with F200 filter	Small/Medium/Large	Elastomeric
San-M	TN01	Small, Medium/Large	Filtering
Scott	66	Small/Medium/Large	Elastomeric
Sellstrom	Econ-Air	Small/Medium/Large	Elastomeric
Survivair	1913	Small/Medium/Large	Filtering
Survivair	2000 with 1060 filter	Small/Medium/Large	Elastomeric
Survivair	7000 with 7860 filter	Small/Medium/Large	Elastomeric
Willson	1200with GN95	Small/Medium/Large	Elastomeric
Willson	6100	Small/Medium/Large	Elastomeric
Willson	6800	Small/Medium, Medium/Large	Elastomeric

¹OSFA – One Size Fits All

Fit Test Procedures

Fit testing was done with the ambient aerosol condensation nuclei counter (CNC) quantitative fit testing method. It was done without a chamber and the ambient aerosols present in the fit test area were measured with a TSI Portacount Plus inside and outside of the respirator to determine the fit factor. The six-exercise fit test procedure similar to the procedure used in this study has been demonstrated, in a simulated health-care workplace test, to provide fit factors that have a high correlation with a wearer's actual exposure (Coffey et al., 1998). Before starting a fit test, a subject donned the respirator per the respirator manufacturer's instructions including performing a user-seal check. After the respirator was donned, fit testing began.

A fit test consisted of a test subject performing the following seven exercises for one minute each: (1) normal breathing, (2) deep breathing, (3) turning head side to side, (4) moving head up and down, (5) reading the rainbow passage out loud, (6) bending at waist, and (7) normal breathing. An overall fit factor was obtained. A fit factor is a measure of the protection received from a respirator and includes both filter penetration and face seal leakage. After completing the first test, the subject removed the respirator and gave it to the test operator. The test operator returned the respirator to its original configuration (e.g., loosening head straps, flattening nosepiece). The subject then donned and user-seal checked the same respirator again per the manufacturer's instructions. A second test, identical to the first, was conducted. This procedure was repeated four additional times for a total of six tests for each subject and respirator combination.

This study uses a different protocol than the one-donning eight-exercise OSHA fit test protocol even though both protocols use the TSI PortaCount Plus. For the OSHA protocol, fit factors are determined only from face seal leakage. A high efficiency filter, i.e., class 100, is used to minimize the amount of aerosol that penetrates the filter. For the fit test protocol in this study, the fit factors were determined from total inward leakage (i.e., both filter penetration and face seal leakage). Since these fit factors were not used to determine if a respirator fits a wearer and were used to answer the research questions in this study, the term "fit factor" is used throughout this paper. In addition, the penetration of ambient aerosol through N95 filters is usually less than 10% of total inward leakage. The geometric mean filter penetration of five N95 respirator models was 0.3% which was significantly smaller than the corresponding total inward leakage of 3.8% (Zhuang et al., 1998).

Statistical Analyses

Ambient aerosol concentrations were divided into five levels (i.e., <5000; 5,000 to 6,500; 6,500 to 8,500; 8,500 to 12,000; and >12,000 particles/cm³). The fit factors were analyzed using a two-factor, analysis of variance model. Log-transformed fit factor was the response variable. Fit factors were log-transformed because they were not normally distributed and the log-transformed fit factors were close to normal distribution. Ambient aerosol concentration level and respirator type were the predictor variables. A Duncan's multiple-range test was performed to determine if fit factors varied among the five ambient aerosol concentration levels. A significance level of 0.05 was used for all tests.

The analyses of the data also involved determining the frequency at which each exercise had the lowest fit factor for each fit test. The fit factors for each exercise were also normalized to the highest fit factor among all exercises in each test and the mean ratio was determined for each exercise. Correlations between fit factors for one exercise and fit factors for the other exercises were determined as well.

RESULTS

The results of analysis of variance for all respirator models are summarized in Table II. The p-values for the two main effects, i.e., ambient aerosol concentration level and respiratory type were 0.0072 and <0.0001, respectively. Thus, significant differences (p-value < 0.05) in overall fit factors were found

among different ambient aerosol concentration levels and between the two different respirator types. The geometric mean (GM) overall fit factor (35.0) for elastomeric respirators was significantly higher than the GM overall fit factor (20.2) for filtering facepiece respirators. The interaction between ambient aerosol concentration and respirator type was not significant (p -value > 0.05). The geometric mean (GM) fit factors are summarized by ambient level and respirator type in Table III. With the exception of one ambient aerosol concentration level (i.e., >12000 particles/cm³), the GM fit factor was not significantly different among ambient aerosol concentration levels. No trends such as the GM fit factor increasing with ambient aerosol concentration were observed in the data.

TABLE II. Analysis of Variance Table for Log-Transformed Overall Simulated Workplace Protection Factors Using a Two-Factor Statistical Model

Source of Variation	Degrees of Freedom	Mean Square	F-ratio	p-value
Ambient Aerosol Concentration Level (AACL)	4	0.697	3.51	0.0072
Respirator Type (RT)	1	61.8	311.56	< 0.0001
AACL x RT	4	0.317	1.60	0.1718
Errors	4324	0.198		
Total	4333			

TABLE III. Summary of Geometric Mean FFs by Ambient Aerosol Concentration Level and Respirator Type

Respirator Type		Ambient Aerosol Concentration Level (particles/cm ³)				
		< 5000	5000 - 6500	6500 - 8500	8500 - 12000	> 12000
Elastomeric	N	503	408	451	356	466
	GM	31.1 ^B	35.3 ^B	35.1 ^B	33.8 ^B	40.3 ^A
	GSD	2.4	2.6	2.4	2.7	2.9
Filtering Facepiece	N	377	411	446	460	456
	GM	20.8 ^A	19.5 ^A	19.7 ^A	19.5 ^A	21.5 ^A
	GSD	2.8	3.2	3.1	3.0	2.8
Both	N	880	819	897	816	922
	GM	26.2 ^B	26.2 ^B	26.4 ^B	24.8 ^B	29.6 ^A
	GSD	2.6	3.0	2.9	3.0	3.0

Note: Statistical comparisons were made for each respirator type and both respirator types combined, and means with the same superscript letter (A or B) are not significantly different among different ambient aerosol concentration levels (p -value > 0.05).

The percentages of observations with the smallest fit factor among all exercises are summarized in Table IV by the individual exercise. The fit factors for the talking out loud, bending, and moving head up and down exercises were found to account for 39.9%, 13.7%, and 12.7% of the lowest fit factors among all exercises in each test, respectively. Each of the other four exercises had about 8% of the lowest fit factors.

The mean ratios of exercise fit factor to the highest fit factor among all exercises are summarized in Table V by all respirators or each respirator type. The mean ratio ranged from 0.556 to 0.716. The talking out loud, bending, and moving head up and down exercises had the smallest, second smallest and third smallest ratio, respectively.

TABLE IV. Summary of Percent of Observations with the Lowest Fit Factor among All Exercises by Exercise Regime and Individual Exercise

Exercise	Frequency	Percent	Cumulative	Cumulative
			Frequency	Percent
Normal Breathing	348	8.0%	348	8.0%
Deep Breathing	320	7.4%	668	15.4%
Turning Head Side to Side	423	9.8%	1091	25.2%
Moving Head up and down	550	12.7%	1641	37.9%
Talking out loud	1731	39.9%	3372	77.8%
Bending	593	13.7%	3965	91.5%
Normal Breathing	369	8.5%	4334	100.0%

The correlation coefficient matrix for the log-transformed fit factors for one exercise and log-transformed fit factors for the other exercises is shown in Table VI for all respirators. The correlation coefficients for the log-transformed overall fit factors and log-transformed exercise fit factors are also shown in Table VI. The correlation coefficients ranged from 0.87 to 0.95. Similar correlation analyses were conducted for each type of respirator. The correlation coefficients were similar to those for combined half-facepiece respirators, and thus they are not reported.

DISCUSSION

This study investigated data for 4,334 fit tests and found that the GM fit factor was not significantly different among ambient aerosol concentration levels with one exception. The ambient aerosol concentration >12000 particles/cm³ had the largest GM fit factor of 29.6. Although it was significantly different from the GM fit factors for the other four ambient aerosol concentration levels (range=24.8-26.2), the differences were smaller than the intra- and inter-subject variations. Therefore, the differences were not of practical importance. In addition, no trends such as the GM fit factor increasing with ambient aerosol concentration were observed. In contrast, a previous study investigated data for more than 20,000 fit tests obtained from more than 16,000 subjects at various locations in the United States and found that the GM quantitative fit factors increased significantly as ambient aerosol concentration level increased. However, the data set only contained fit test data with overall fit factors exceeding the pass/fail criteria. It was impossible to determine the effect for fit factors around the pass/fail criterion of 100 for half-facepiece respirators. The fit factors in this current study ranged from less than 10 to greater than 6,000.

Thus, it can be concluded that fit factors around the pass/fail criterion of 100 for half-facepiece respirators are not affected by ambient aerosol concentration.

TABLE V. Summary of Mean Ratio of Exercise Fit Factor to the Highest Fit Factor by Exercise Regime and Individual Exercise

Exercise	Mean Ratio	Standard Deviation	Standard Error
All Respirators (n=4334)			
Normal Breathing	0.715	0.235	0.0036
Deep Breathing	0.701	0.236	0.0036
Turning Head Side to Side	0.716	0.249	0.0038
Moving Head up and down	0.666	0.251	0.0038
Talking out loud	0.556	0.275	0.0042
Bending	0.622	0.230	0.0035
Normal Breathing	0.706	0.238	0.0036
Elastomeric (n=2184)			
Normal Breathing	0.723	0.232	0.0050
Deep Breathing	0.699	0.236	0.0050
Turning Head Side to Side	0.777	0.235	0.0050
Moving Head up and down	0.735	0.231	0.0049
Talking out loud	0.486	0.259	0.0055
Bending	0.662	0.225	0.0048
Normal Breathing	0.711	0.238	0.0051
Filtering Facepiece (n=2150)			
Normal Breathing	0.706	0.238	0.0051
Deep Breathing	0.703	0.237	0.0051
Turning Head Side to Side	0.654	0.246	0.0053
Moving Head up and down	0.596	0.252	0.0054
Talking out loud	0.627	0.272	0.0059
Bending	0.582	0.228	0.0049
Normal Breathing	0.701	0.238	0.0051

TABLE VI. Correlation Coefficients of Log-Transformed Fit Factors for Each Exercise and Other Exercises (Half-Facepiece Respirators)

Exercise	Overall	NB	DB	SS	UD	TOL	BD	NB2
Overall	1.00							
Normal Breathing (NB)	0.94	1.00						
Deep Breathing (DB)	0.94	0.92	1.00					
Turning Head Side to Side (SS)	0.95	0.89	0.90	1.00				
Moving Head up and down (UD)	0.94	0.86	0.85	0.92	1.00			
Talking out loud (TOL)	0.87	0.80	0.81	0.79	0.77	1.00		
Bending (BD)	0.94	0.86	0.86	0.89	0.90	0.82	1.00	
Normal Breathing (NB2)	0.94	0.88	0.88	0.89	0.87	0.85	0.89	1.00

Exercises that have the lowest fit factor frequently are considered more critical in determining the overall fit factor. The ratio of exercise fit factor to the highest fit factor among all exercises provides a measure of the variation among exercise fit factors in each test. The smaller the ratio, the larger the variation among exercise fit factors in each test. Exercises that have small ratios are considered more critical in determining the overall fit factor. Exercises that are less critical may be eliminated from the fit test protocol without affecting the selection of properly-fitting respirators. Talking out loud had the largest percentage of the lowest fit factors and smallest ratio of exercise fit factor to the highest fit factor in each test. Thus, talking out loud exercise can be generally considered to produce more leak than other exercises. However, test subjects can sometimes generate particles while talking and the PortaCount Plus cannot distinguish these particles from the ambient aerosol particles.

The difference in the first and second normal breathing exercise fit factors was examined since both exercises are performed in the same way. A paired t-test showed that the fit factors for the first normal breathing were not significantly larger than fit factors for the second normal breathing (p -value > 0.05). This is consistent with the observation that the first normal breathing and second normal breathing exercises had similar percentage of observations with the lowest fit factor among all exercises (Table IV). The mean ratio of exercise fit factor to the highest fit factor for the first normal breathing was also similar to the mean ratio for the second normal breathing (Table V). These findings indicate that the second normal breathing may not be needed.

There have been several other studies that investigated the relationship of exercise fit factors. Direct comparisons are difficult since the exercises were different from those used in this study. Murata et al. fit tested 44 subjects using four exercises: normal breathing, smiling, moving the head, and talking. They found smiling had a higher face-seal leakage (i.e., lower fit factor) than talking and in general movements of the mouth resulted in lower fit factors than head movements (Murata et al., 1980). These results are similar to those of the current study in that talking out loud, a movement of the mouth, produced lower fit factors than head movements did. Manninen et al. used five exercises (counting aloud slowly, moving head side to side, moving head up and down, exercising with a bicycle ergometer, and sitting on a bicycle ergometer) to fit test 53 subjects (Manninen et al., 1988). They analyzed the fit test data by respirator model and subject gender. The exercise producing the highest leakage was dependent on these two factors. Some models had consistent fit factors regardless of subject gender. For those models having variation in the leakage, three exercises (sitting on the ergometer, moving the head up and down, and counting) had the highest leakage depending on the model and subject gender. These results were somewhat different from the Murata study and current study. A study by Bentley et al. (1983) found

that talking was the most critical exercise even for air-fed helmets and powered air-purifying respirators. These results are consistent with those from the current study.

Crutchfield and Van Ert (1993) stated that the fundamental or basic fit of a respirator is best described by the normal breathing fit factor. The purpose of the other exercises is to measure the change in fit due to facial or head movements. To prove this, they looked at eleven studies which reported complete fit test data sets: four using the generated aerosol method; four using the ambient aerosol method; and three using the controlled negative pressure (CNP) method.

It should be noted that the exercises are conducted differently for the CNP test since the test subject has to hold his breath and remain motionless while the measurement is being taken. During the CNP test, the subject performs the exercise for one minute, takes a deep breath, and holds the head still in the appropriate position. For example, if the exercise was turning the head side to side, the subject would do this for one minute and then hold his head still while looking left. A measurement would be taken at this time. Then, the subject would look to the right and another measurement would be taken. In the CNP studies, the talking out loud and deep breathing exercises were not done.

Their analysis of the data found 80 to 96% of the total test variation was due to the first normal breathing alone in the generated aerosol tests, 70 to 89% for the ambient aerosol tests, and 65 to 93% for the CNP tests (Crutchfield and Van Ert, 1993). In general for all three methods, there was either no significant difference between the first normal breathing and the rest of the exercise fit factors or the first normal breathing was significantly lower than the rest of the exercises. For the ambient aerosol method, the talking exercise was the exception. In the three studies in which talking exercise was performed, it was found to be significantly lower than the first normal breathing. This is consistent with the findings of this current study. The only exception for the CNP method was found in one study that used induced leakages on a half-facepiece. In this study, the fit factor measured with the head in the down position was lower than the first normal breathing. A 0.05 level of significance was used for all comparisons. The results of the current study generally agree with those from previous studies.

CONCLUSIONS

Fit factor was found to be independent of ambient aerosol concentration. "Talking out loud," "bending," and "moving head up/down" exercises had the lowest fit factor in about 66% of the tests. They also had the lowest average within-fit-test ratios of exercise fit factor to the highest fit factor (0.56, 0.62, and 0.67, respectively). Fit factors for each exercise were found to be highly correlated with fit factors for each of the other six exercises. There was no significant fit-factor difference between the first and second normal breathing exercises. We conclude that the fit test pass/fail criterion need not be adjusted for ambient aerosol concentration level and that "talking out loud," "bending," and "moving head up/down" are the three most critical exercises in determining the overall fit factor. These three exercises could be considered for development of a multi-donning protocol using fewer and/or shorter exercises to keep the length of a fit test the same as the current fit test protocol.

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