

Evaluation of a Faster Fit Testing Method for Elastomeric Half-Mask Respirators Based on the TSI PortaCount[®]

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ABSTRACT

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. Given the large number of fit tests performed annually, industry would benefit if the time required to complete a fit test was reduced. TSI, Inc. (Shoreview, MN) has developed a method for elastomeric half-mask respirators that is a modification of the OSHA-accepted 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces the test duration from about 7.2 min to 2.5 min. The objective of this study was to compare the fit factors measured with the TSI modified method to that of a reference method. The method comparison approach was based on American National Standards Institute (ANSI) Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods". Sequential, paired fit tests were performed on test participants with the modified (i.e., faster) method and a reference method during the same respirator donning. The fit factors for both methods were measured using the PortaCount[®] Model 8030, a CNC-based instrument. The exercises for the reference method were the standard OSHA exercise set without the grimace. The exercise set for the modified method included bending, jogging, head side-to-side, and head up-and-down. The results demonstrated that the new faster method can identify poorly fitting respirators as well as the reference method, as the test sensitivity of 0.96 was greater than the requirement (≥ 0.95) defined in ANSI Z88.10-2010. This new method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard.

Keywords: respirator fit, quantitative fit test, elastomeric half-mask respirators

INTRODUCTION

In the United States, employees that wear tight-fitting respirators in the workplace are required to be fit tested annually using an Occupational Safety and Health Administration (OSHA)-accepted protocol. The OSHA-accepted fit test protocols are defined in Title 29 Code of Federal Regulations (CFR) Part 1910.134 (OSHA, 1998). One of these OSHA-accepted protocols is the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol', which takes over 7 min to execute for each respirator wearer. Given the large number of fit tests performed annually, industry would benefit if this time were reduced. Fit testing is an important part of a respirator program and less burdensome fit test methods for tight-fitting respirators may help increase compliance (NIOSH, 2013; IOM, 2008). TSI, Inc. (Shoreview, MN) has developed a modified method to the 'Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol' that reduces this test duration to about 2.5 min. The objective of this study was to assess whether the modified, faster fit test method was comparably effective as an existing method at identifying poorly fitting half-face respirators.

The American National Standards Institute (ANSI) standard Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods" (ANSI, 2010) defines an approach to evaluate new fit test methods to ensure they can identify poorly fitting respirators as effectively as an accepted method. The standard recommends performing sequential paired fit tests with the new method and a reference method during the same respirator donning for comparison. In the current study, the Reference method was defined as the OSHA-accepted, CNC-based protocol except the grimace was not included in the exercise set. The new method was the faster CNC method and will be referred to as the Fast-Half method. All testing was performed on elastomeric half-mask respirators. An ambient aerosol challenge augmented with sodium chloride (NaCl) aerosol was used for both methods. In addition, both methods were based on the TSI PortaCount[®] Model 8030, a CNC-based fit-testing device. The methods differed by the exercise sets, exercise duration, and sampling sequence.

METHODS

Test Participants and Respirators

The study plan was reviewed and approved by Battelle's Institutional Review Board (IRB). All participants were non-smokers and clean shaven in the areas where the respirator sealed against the face. Anthropometric measurements, specifically face width (bizygomatic breadth) and face length (menton-sellion length), of the participant's faces (except for one due to subject unavailability at the time of measurement) were made and are compared with the National Institute for Occupational Safety and Health (NIOSH) bivariate fit test panel in Figure 1. As shown, the test participants were distributed across the panel and thus represented a wide range of the respirator-wearing population. Note, there was not a requirement to meet a specific distribution of face size. Test participants were not required to have any prior experience wearing a respirator. The participants were trained to perform the exercises properly and consistently by viewing a video created for that purpose.

The test administrator selected the respirator and assisted the participant with donning to ensure that it was properly donned. The ANSI comparison requires at least 50 fit test pairs in the data set for analysis where the Reference method has a fit factor below the pass/fail criteria (i.e., 100 for a half-face respirator). Modern elastomeric respirators are constantly improving as manufacturers take advantage of new technologies and materials to improve the facial seal. Anecdotally, the percentage of failed fit tests for these respirators is low which would require a large number of trials to collect at least 50 failures. Thus, participants were sometimes provided mis-sized respirators to obtain fit factors below the pass/fail criterion. The wearer did not perform a user seal check to increase the potential for "poor" fits that are

needed for the ANSI comparison (OSHA, 2010; Janssen et al., 2002; McKay and Bradley, 2005). The test administrator assisted with donning to ensure that the respirator was properly donned to minimize the potential for slippage. Artificial leak paths were not used because the objective was to evaluate the Fast-Half method in its entirety including the exercise set used to produce real-world, dynamic leaks between the respirator and wearer's faces. The use of artificial leak paths (e.g., capillary tubes, etc.) would not have allowed evaluation of dynamic leaks that are caused by exercising.

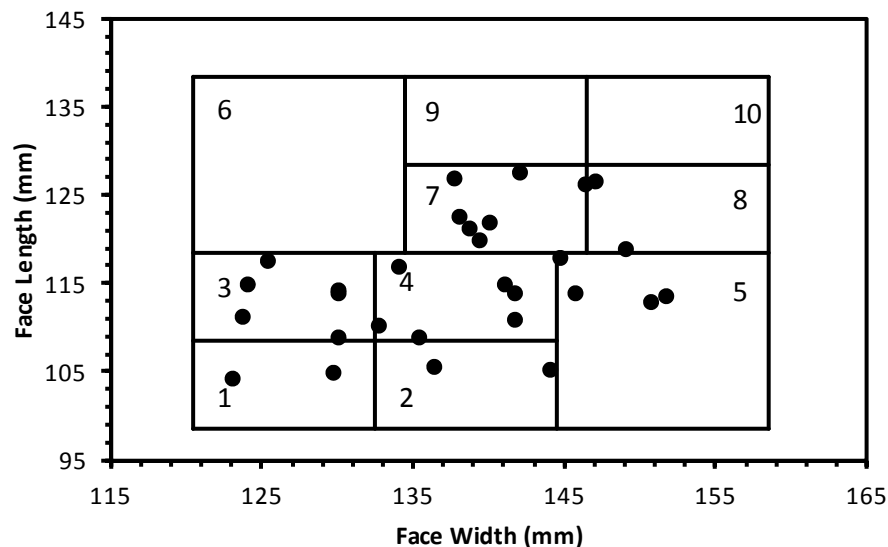


Figure 1. Distribution of Participant Facial Sizes Overlaid on the NIOSH Bivariate Chart.

Three different models of NIOSH-approved, half-face air-purifying respirators from leading U.S. mask manufacturers were used and each was tested in three different sizes for a total of nine respirators). The respirators models/sizes were used approximately the same number of times in the study. The specific respirators will not be identified because the intentional mis-sizing and lack of performing a user seal check would misrepresent performance of these respirators when used as part of a proper respiratory protection program. The respirators were equipped with P100 filters. In-mask samples were collected from the breathing zone between the nose and mouth using a flush sample probe that was permanently installed.

Fit Factor Measurements

The system used to measure the fit factors included a chamber (~3 x 2 x 2.5 m) that was large enough to test two participants simultaneously. Large, clear plastic windows allowed the test administrator to observe the test participants. The chamber contained the ambient laboratory aerosol which was augmented with NaCl aerosol generated using a Model 8026 Particle Generator (TSI, Inc.). A mixing fan was used to distribute the aerosol throughout the chamber. The target aerosol concentration was 10,000 particles/cm³ with an acceptable range of 5,000 to 20,000 particles/cm³. Zhuang et al. (2004) concluded that the ambient aerosol concentration did not affect the measured fit factor. The challenge and in-mask aerosol concentrations were measured using the PortaCount[®] Model 8030. Aerosol sampling lines of equal length and internal diameter were used for the challenge and in-mask samples. Laptop computers with custom software developed and supplied by TSI, Inc. were used to execute scripts that controlled the instrument sampling sequences and data collection during each trial. The measured in-mask and challenge aerosol concentrations were captured electronically and imported into Microsoft[®]

Excel® for calculation of the fit factors and to determine the statistical values defined in the ANSI standard.

After donning the respirator, the test participants entered the chamber and began a 5-minute “comfort assessment period” to allow the respirator to settle on the face and to purge ambient aerosol from the mask. The comfort assessment period is an OSHA requirement for all fit test methods. During this time, adjustments could be made to the respirator and the test participants breathed normally. The respirator was not adjusted after this period (i.e., once the fit test initiated). After the 5-minute acclimation period, the participants performed exercise sets for two fit test methods in succession, without pause in between. The test administrator instructed them on the exercises to perform and observed them to ensure the exercises were performed properly. Any anomalies were recorded. Prior to this study, the test administrator had extensive experience performing quantitative respirator fit tests in industry.

Exercise Sets

The Reference method used the standard OSHA exercises with grimace omitted. The set consisted of seven exercises performed while standing: normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, bending over, and normal breathing. The eighth exercise, grimacing, required per 29 CFR 1910.134 is intended to break the respirator seal to the face. This potentially results in a shift of the respirator and, thus, was not used. A shift in the respirator may confound comparison of the two fit test methods. Each of the seven exercises was performed for one minute. Test participants were instructed to take a single breath at each extreme during the head side-to-side exercise, at the bottom of the bend during the bending exercise, and when looking up during the head up-and-down exercise. It was optional for the test participants to take breaths at other times during these exercises. The sample timing of the PortaCount® used for the Reference method is summarized in Table I.

The Fast-Half method included four exercises: bending, jogging in place, head side-to-side, and head up-and-down. The duration of each exercise was 30 sec. This is the minimum exercise duration recommended in ANSI Z88.10-2010 and CSA Z94.4-11. Test participants were required to take two breaths at each extreme during the head side-to-side and head up-and-down exercises and at the bottom of the bend during the bending exercise. It was optional for the test participants to take breaths at other times during these exercises. The PortaCount® sample timing for the Fast-Half method is summarized in Table II. The PortaCount® sampled the ambient aerosol at the start and end of the fit test rather than in between each exercise. This is acceptable because the shorter method leaves less time for the ambient concentration to drift during the test. The ambient measurements were separated by only 2.3 min. The Fast-Half method reduced the fit test time by about 65% relative to the Reference method (2.5 min vs. 7.2 min).

The most strenuous exercises were generally selected for the Fast-Half fit test method. Zhuang et al. (2004) recommends talking, bending, and moving head up-and-down for protocols that use fewer and/or shorter exercises. Of these, the Fast-Half method included bending and head up-and-down. In addition, it included two other exercises that are aggressive in terms of evaluating the respirator seal, head side-to-side and jogging.

Table I. Exercise Set and PortaCount® Sampling Sequence for the Reference Fit Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Normal Breathing	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	40
2	Deep Breathing	Challenge Purge	4
		Challenge Sample 2	5
		Mask Purge	11
		Mask Sample	40
3	Head Side-to-Side	Challenge Purge	4
		Challenge Sample 3	5
		Mask Purge	11
		Mask Sample	40
4	Head Up-and-Down	Challenge Purge	4
		Challenge Sample 4	5
		Mask Purge	11
		Mask Sample	40
5	Talking	Challenge Purge	4
		Challenge Sample 5	5
		Mask Purge	11
		Mask Sample	40
6	Bending	Challenge Purge	4
		Challenge Sample 6	5
		Mask Purge	11
		Mask Sample	40
7	Normal Breathing	Challenge Purge	4
		Challenge Sample 7	5
		Mask Purge	11
		Mask Sample	40
		Challenge Purge	4
		Challenge Sample 8	5
		Total Test Time	429 sec = 7:09 min

Table II. Exercise Set and PortaCount® Sampling Sequence for the Fast-Half Test Method

Exercise Number	Exercise	PortaCount® Sample	Time (s)
1	Bending	Challenge Purge	4
		Challenge Sample 1	5
		Mask Purge	11
		Mask Sample	30
2	Jogging-in-Place	Mask Sample	30
3	Head Side-to-Side	Mask Sample	30
4	Head Up-and-Down	Mask Sample	30
		Challenge Purge	4
		Challenge Sample 2	5
		Total Test Time	149 sec = 2:29 min

Fit Factor Vetting

The fundamental premise of the ANSI approach to compare the Reference and Fast-Half methods in the same respirator donning is that the baseline fit of the respirator remains the same throughout the procedure. The baseline fit was defined as the fit factor measured during normal breathing. To quantify undesirable changes in the baseline fit, a 5-second normal breathing fit factor check was added to the beginning, middle (i.e. after the first exercise set and before start of the second), and end of each fit test pair. A fit test pair was omitted from analysis if the ratio of the maximum to minimum normal breathing fit factor check was greater than 100, signifying that the baseline fit of the respirator changed during the trial. When comparing the Fast-Half and Reference methods, the order was randomized with respect to which method occurred first in the test pair. The test administrator noted any observed anomalies that may be indicative of respirator slippage or other problems. Following each trial, the test participants were queried regarding whether they felt the respirator slip or any sudden sensations of air rushing into the respirator from around the peripheral seal that may also be indicative of respirator slippage. All comments/observations were recorded on the trial data sheet.

Calculation of Fit Factors

Fit factors were calculated for the individual exercises and represented the ratio of the measured challenge to in-mask aerosol concentration. For the Reference method, the challenge concentration was based on the average of the measurements made immediately before and after the in-mask sample for that specific exercise (Refer to Table I for PortaCount® sample timing), which is consistent with the scheme currently used for OSHA-compliant fit testing. For the Fast-Half method, the challenge concentration was based on the average measured at the start and finish of the entire fit test. The overall fit factor for both methods was the harmonic mean of the fit factors measured for each exercise. Each trial generated two overall fit factors per test participant, referred to as a fit test pair. It was this overall fit factor that was used for the ANSI analysis to compare test methods.

Calculation of the Exclusion Zone

The study was comprised of two parts; key study design parameters/requirements for each part are summarized in Table III. The first part characterized the variability of the Reference method. The ANSI standard specifies 'exclusion criteria', one of which is that "Reference method fit factors within one (1) Coefficient of Variation (CV) of the required fit factor should be excluded". In the current study, an "exclusion zone" was defined as the range of Reference fit factors that bracketed the pass/fail fit factor criterion inside which the pass/fail determination was deemed to be unreliable due to the observed variability. The ANSI standard does not mandate the approach to determine the CV for the reference method but suggests making multiple fit factor measurements on a subject during a single facepiece donning. The subject should have a fit factor near the required fit factor. McKay and Bradley (2005) previously determined an exclusion range of about 94 to 106 for fit testing of elastomeric half-mask respirators by determining the variability associated with the TSI PortaCount® Plus Model 8020. Repeated measurements were made by performing the fit test procedure on a high efficiency filter with a fixed leak that provided fit factors near the pass/fail requirement (i.e., 100 for a half-mask respirator). This approach only accounted for the variability of the instrument and not the overall fit test method as specified in the ANSI standard. This approach resulted in a CV of about 0.06. The CV associated with generated aerosol quantitative fit test methods can range from 0.23 to 0.82 (ANSI, 2010).

A different approach was used in the current study to determine the variability associated with the overall Reference method. Fit test pairs were collected across multiple subjects that consisted of two Reference method fit tests performed sequentially during the same respirator donning, without any adjustment between the two. The measured overall fit factors as determined for both Reference methods

in each pair were log (base 10) transformed and their difference (i.e, $\log(FF_1) - \log(FF_2)$) was determined. The standard deviation (σ) of the log differences across all trials was calculated. The high and low fit factors defining the boundaries of the Reference method exclusion zone were calculated as follows:

Upper Bound Fit Factor of Exclusion Zone = $10^{(\log(100) + \sigma)}$

Lower Bound Fit Factor of Exclusion Zone = $10^{(\log(100) - \sigma)}$

where σ is the standard deviation of the log-transformed difference and 100 is the pass/fail criterion for a half-face respirator. This has the effect of defining the exclusion zone as the range within one standard deviation of the pass/fail criterion.

Table III. Summary of Key Study Design Parameters

Task	Study Design
1	• Objective: Establish exclusion zone of the Reference fit test method • Number of Fit Test Pairs: 50 (target minimum) • Number of Participants: 15 (target minimum) • Number of Fit Test Pairs Below Pass/Fail Criterion: N/A • Respirator models/sizes: 3 models each with 3 sizes, Use each equally
2	• Objective: Use ANSI Z88.10-2010 method to compare fit factors measured using the Reference and Fast-Half method during same respirator donning • Number of Fit Test Pairs: 100 (ANSI minimum requirement) • Number of Participants: 25 (ANSI minimum requirement) • Number of Fit Test Pairs Below Pass/Fail Criterion: At least 50 measured Reference fit factors need to be between 5% of the pass/fail and the lower bound of the exclusion zone (ANSI requirement) • Respirator models/sizes: 3 models each with 3 sizes, Use each equally

ANSI Comparison

The second part of the study compared the Reference and Fast-Half fit test methods using the approach described in the ANSI standard. Again, fit test pairs were collected during the same respirator donning, without any adjustment between the two sequential fit tests. In each fit test pair, one fit factor was measured using the Fast-Half method and one with the Reference method. The order was randomized with respect to whether the Fast-Half or Reference method occurred first in the test pair. Per the ANSI standard, a minimum of 100 fit test pairs were collected and at least 25 different participants were used. At least 50 of these fit test pairs had Reference fit factors between 5% of the pass/fail criterion and the lower bound of the exclusion zone.

The ANSI standard specifies the 2x2 contingency table shown in Table IV where A, B, C, and D represent the number of observations in each cell. To meet the requirement in the ANSI standard, the Fast-Half method needs to achieve a test sensitivity of at least 0.95. The test sensitivity is defined in Table V and provides the probability that the Fast-Half test method will correctly identify an inadequate fit (as determined by the Reference method). The ANSI standard recommends, but does not require, meeting the criteria for the other four statistics defined in Table V: (1) predictive value of a pass, (2) test specificity, (3) predictive value of a fail, and (4) Kappa statistic. The Kappa statistic is a measure of the agreement between the two methods. It is the ratio of the proportion of times the two methods provided the same outcome to the proportion of times that the two methods would agree by chance if independent (ANSI, 2010).

Table IV. 2 x 2 Contingency Table Specified by ANSI Z88.10-2010 Standard

	Failed Reference Test	Passed Reference Test
Passed Fast-Half Test	A	B
Failed Fast-Half Test	C	D

Table V. Test Statistics Defined in ANSI Z88.10-2010 Standard

Statistic	Equation	Criterion
Test Sensitivity	$C / (A + C)$	≥ 0.95
Predictive Value of a Pass	$B / (A + B)$	≥ 0.95
Test Specificity	$B / (B + D)$	≥ 0.50
Predictive Value of a Fail	$C / (C + D)$	≥ 0.50
Kappa Statistic ^(a, b)	$(P_o - P_e) / (1 - P_e)$	> 0.7

$$^{(a)} P_o = (B + C) / (A + B + C + D)$$

$$^{(b)} P_e = [(A + B)(B + D) + (C + D)(A + C)] / (A + B + C + D)^2$$

RESULTS AND DISCUSSION

Exclusion Zone Determination

A total of 59 fit factor pairs across 16 participants (6 female and 10 male) were collected to determine the exclusion zone. The log difference between the two overall Reference fit factors (i.e., $\log(FF_1) - \log(FF_2)$) within each pair are plotted by rank in Figure 2. Six of these pairs were omitted as the ratio of the maximum to minimum fit factor during the normal breathing check was greater than 100. The symbols for these omitted data are filled in black in Figure 2 and tend to lie at the two extremes (i.e., largest log differences) which is consistent with a shift in respirator fit during the test. An additional five points (the symbols filled in white in Figure 2) were omitted as outliers because they were more than three (3) standard deviations from the mean of the remaining data points. After exclusion, the log differences were found to be normally distributed based on a Shapiro-Wilk test. Note that excluding these 11 data points tightened the exclusion zone around the pass/fail criterion of 100, ultimately making it more difficult for the Fast-Half method to meet the ANSI criteria.

Good correlation (>0.95) was observed between the fit factors within each pair as shown in Figure 3. The best-fit regression, shown as a dashed line, nearly coincides with the 1:1 line (not shown). All of the fit factors within each individual pair were within a factor of three. The average log difference was -0.0001 with a standard deviation of 0.09. Based on this standard deviation, the exclusion zone for the Reference method was 82 to 123.

Comparison of Fast-Half and Reference Method

A total of 134 fit factor pairs across 25 participants (9 female and 16 male) were collected to compare the Reference and Fast-Half fit test methods. The ANSI standard requires a minimum of 25 participants. As was shown in Figure 1, the participants were well-distributed across the NIOSH Bivariate Fit Test Panel. The respirator models and sizes were used in nearly equal proportion.

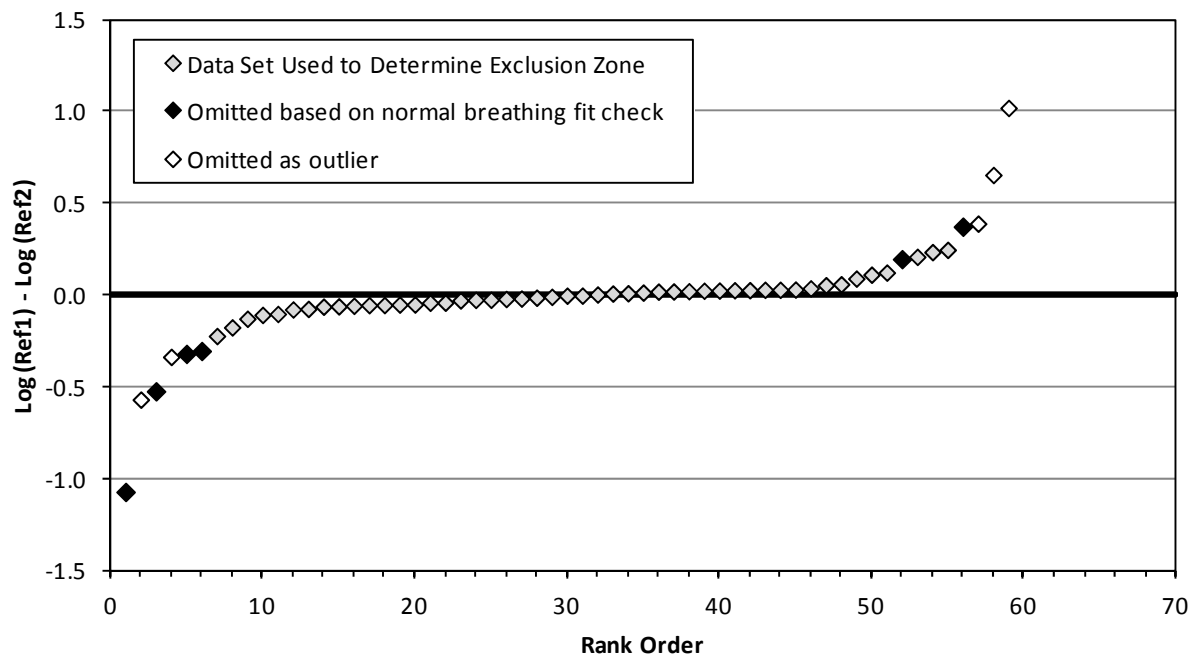


Figure 2. Distribution of Log Differences in Overall Reference Fit Factors Used in Determination of the Exclusion Zone.

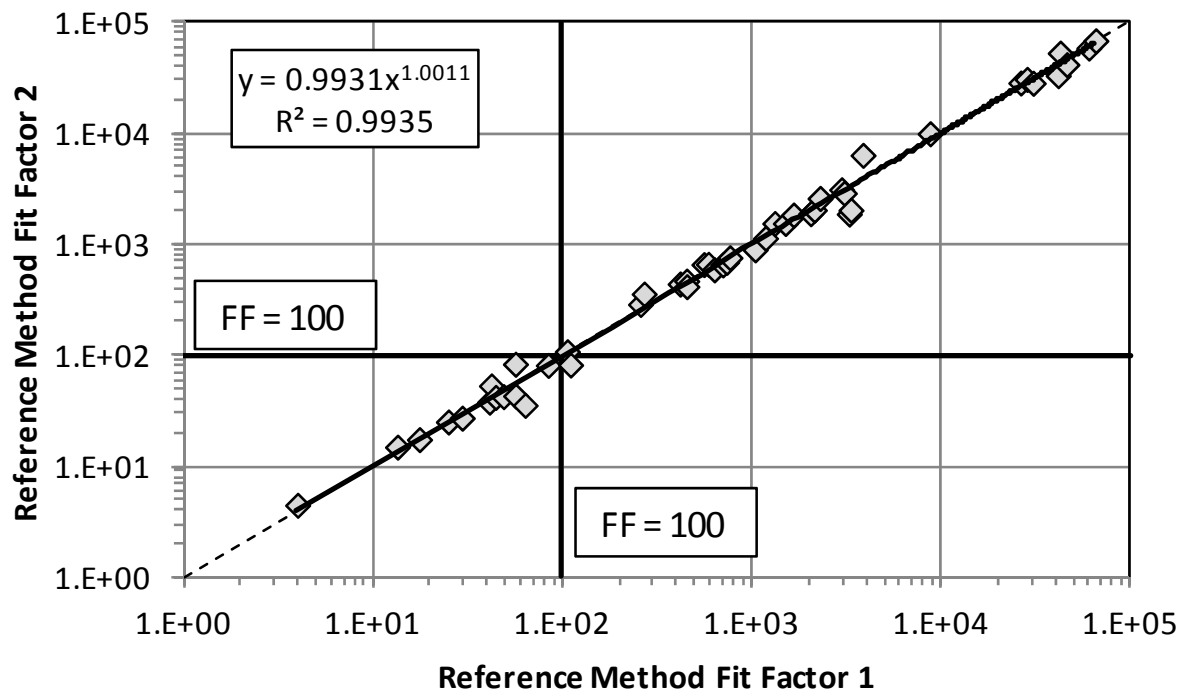


Figure 3. Comparison of Reference Overall Fit Factors Used in Determination of Exclusion Zone.

Eleven fit factor pairs were omitted from the analysis because the ratio of the maximum to minimum fit factor during the normal breathing checks was greater than 100 indicating a shift in the baseline fit. One additional fit factor pair was omitted due to an anomaly (sample line detached from respirator during test). Thus, the data set for the comparison included 122 fit factor pairs. The distribution of Reference fit factors is summarized in Table VI and shown graphically in Figure 4. As required by the ANSI standard, at least 50 Reference fit factors were between 5 (5% of the pass/fail criterion) and 82 (lower bound of the exclusion zone). These Reference method fails were evenly distributed as shown in Figure 3 and not weighted toward the lowest fit factors. Figure 4 also demonstrates that the Reference method fit factors bracketed the pass/fail criteria (100 for half-mask respirators).

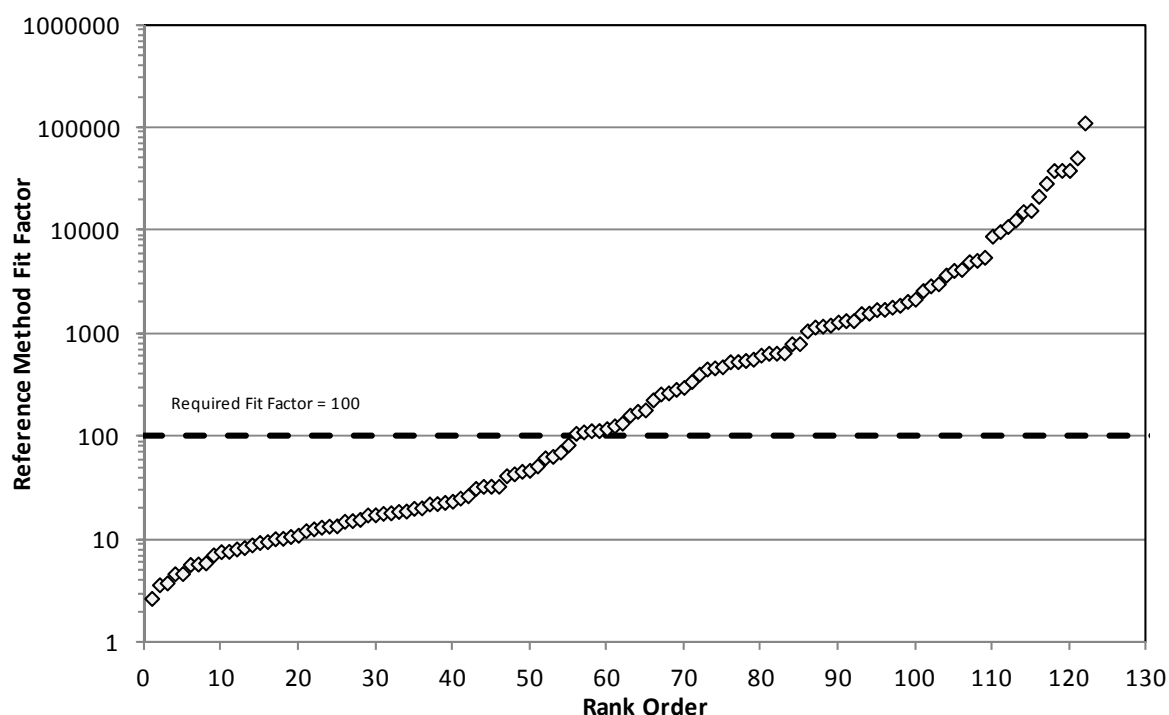


Figure 4. Distribution Reference Overall Fit Factors in ANSI Comparison.

Table VI. Distribution of Reference Fit Factors in ANSI Comparison

Reference Fit Factor Range	Number of Observations (ANSI Requirement)
Total Number of Tests	122 (N/A)
$3 \leq FF < 5$	3 (N/A)
$5 \leq FF < 82$	51 (50)
$82 \leq FF \leq 123$ (Exclusion Zone)	6 (N/A)
$123 < FF \leq 112,000$	62 (N/A)
Total Number of Tests Outside of Exclusion Zone	116 (100)

Figure 5 compares the measured Reference and Fast-Half fit factors within each pair. Good agreement was observed between the pairs as the data points tend to lie near the 1:1 line (dotted black line). The majority (93%) of the fit factors within each pair were within a factor of three. The average magnitude of the log difference was 0.030 with a standard deviation of 0.44.

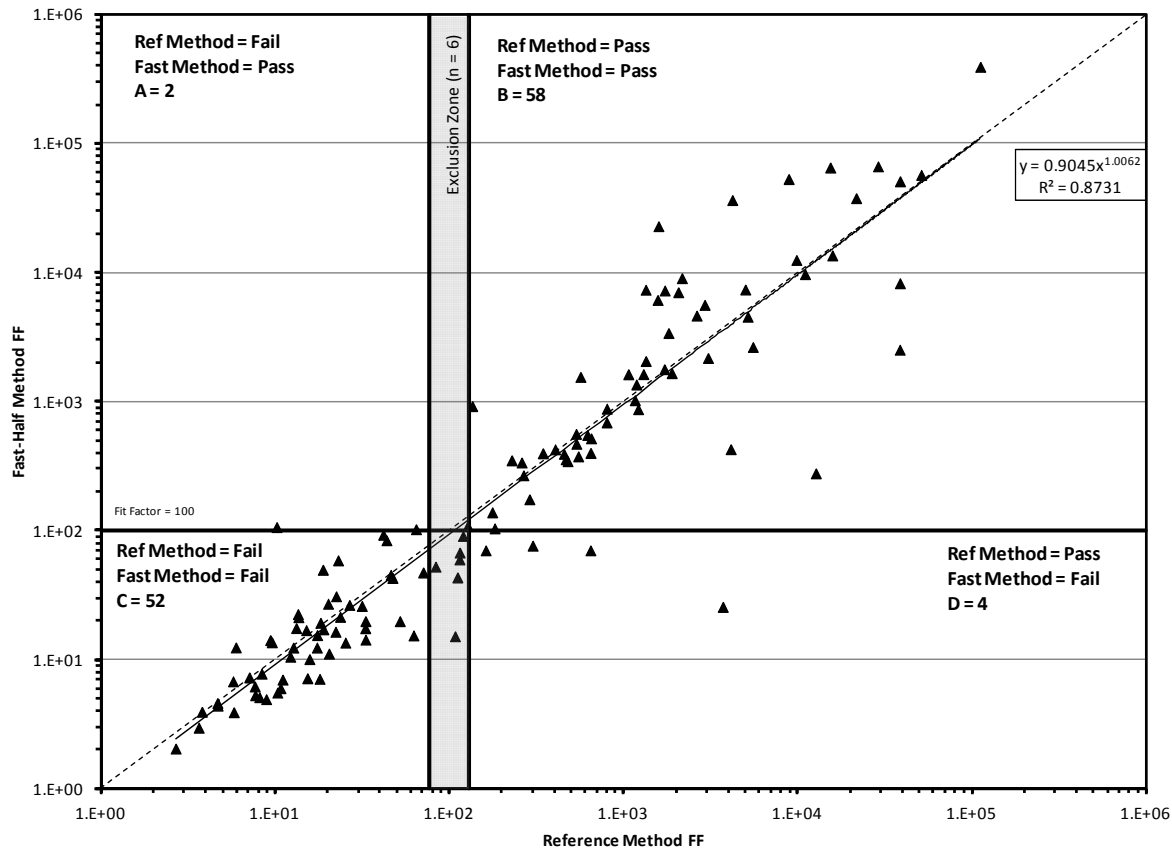


Figure 5. Comparison of Overall Fit Factors Measured Using Reference and Fast-Half Fit Test Methods.

There were two instances outside of the exclusion zone where the Reference method fit factor failed and the Fast-Half method fit factor passed (upper left quadrant in Figure 5). In both instances, the Fast-Half method was very nearly a fail (fit factors of 102 and 106). The Reference fit factors were 64 and 10, respectively, in these two fit test pairs. The Reference fit factor of 10 is 10% of the pass/fail criterion (i.e., 10% of 100). The ANSI standard states that “any reference fit factor below 10% of the required fit factor accepted by the new fit test method shall disqualify the method.” It should be noted that the measured Reference fit factor was rounded down to 10 and, thus, was not less than 10% of the pass/fail criterion. It should also be noted that the test participant commented that the respirator shifted during the fit test, specifically during the jogging exercise of the Fast-Half method. In this fit test pair, the Fast-Half method was performed first so it was the second exercise. Review of the fit factor data by exercise supports that a shift in the respirator occurred as a high fit factor (greater than 2,000) was observed during the first exercise (bending) and then dropped during the jogging to below 100. The fit factor was below 100 for all remaining exercises in that fit test pair. The normal breathing fit factor check at the start of the test was 142 and at the end of the test was only 8 (a ratio of 18) further supporting the occurrence

of a shift. Despite the convincing evidence of respirator shift, the data pair was retained in the final data set because the normal breathing ratio check did not exceed the study criterion of 100.

Table VII compares the measured descriptive statistics with the requirements from the ANSI standard. The primary requirement is the test sensitivity and the other statistics are for comparison purposes. The Fast-Half method met the requirement in all cases indicating excellent agreement between the Fast-Half and the Reference method. From a safety perspective, the test sensitivity demonstrates that the Fast-Half method can identify poorly fitting respirators as well as the Reference method.

Table VII. Comparison of Measured ANSI Analysis Statistics with ANSI Criteria for Fast-Half Method to be Acceptable

Criterion	ANSI Requirement	Measured
Sensitivity	≥ 0.95	0.96
Predictive Value of a Pass	≥ 0.95	0.97
Test Specificity	> 0.50	0.94
Predictive Value of a Fail	> 0.50	0.93
Kappa Statistic	> 0.70	0.90

It is also significant that the Fast-Half method exceeded the target for test specificity (0.94 as compared to a target of > 0.50). This statistic represents the fraction of passing fit factors with the Fast-Half method that also passed the Reference method. Thus, use of the Fast-Half method will not cause the false rejection of adequately fitting respirators and subsequent unnecessary retesting.

It was important in this study to have dynamic leak paths to evaluate the exercise sets selected for the Fast-Half method. The ratios of the maximum to minimum fit factors measured across the exercises within each fit test were determined. A frequency distribution of the magnitude of this ratio is summarized in Table VIII. A ratio of one would indicate that the maximum and minimum fit factors within the fit test were the same. As shown in Table VIII for the Reference method, the highest fit factors were greater than 9 times the lowest fit factors (nearly an order-of-magnitude) in over 50% of the fit factor measurements. Similarly, this ratio exceeded 9 in about 35% of the measurements with the Fast-Half method.

Table VIII. Summary of Observed Ratios of Maximum to Minimum Fit Factors within Each Exercise Set

Ratio of Maximum to Minimum Fit Factor	Reference Method (n=218)			Fast-Half Method (n=122)		
	Frequency	Percent	Cumulative Percent	Frequency	Percent	Cumulative Percent
< 3	57	26.2%	26.2%	46	37.7%	37.7%
$3 \leq \text{Ratio} < 9$	40	18.3%	44.5%	34	27.9%	65.6%
$9 \leq \text{Ratio} < 27$	44	20.2%	64.7%	16	13.1%	78.7%
$27 \leq \text{Ratio} < 81$	34	15.6%	80.3%	15	12.3%	91.0%
$81 \leq \text{Ratio} < 243$	17	7.8%	88.1%	6	4.9%	95.9%
$243 \leq \text{Ratio} < 729$	14	6.4%	94.5%	4	3.3%	99.2%
≥ 729	12	5.5%	100.0%	1	0.8%	100.0%

Zhuang et al. (2004) previously evaluated the affect of exercise on quantitative fit factors measured with the PortaCount[®] by calculating the mean ratios of individual exercise fit factors to the high fit factor among all exercises within each fit test. Leakage was associated with dynamic leaks and not fixed leak pathways. For comparison, the mean ratios calculated are summarized in Table IX. The values ranged from 0.38 to 0.63. These ratios were similar to those measured by Zhuang et al. and are another indication that the test method was not inducing fixed leak paths.

Table IX. Summary of Mean Ratio of Exercise Fit Factor to the Highest Fit Factor within Each Exercise Set

Exercise	Mean Ratio	Standard Deviation
Reference Method (n = 218)		
Normal Breathing	0.56	0.34
Deep Breathing	0.55	0.33
Head Side-to-Side	0.46	0.36
Head Up-and-Down	0.43	0.37
Talking	0.53	0.38
Bending	0.38	0.33
Normal Breathing	0.49	0.36
Fast-Half Method (n = 122)		
Bending	0.56	0.38
Jogging	0.59	0.33
Head Side-to-Side	0.62	0.33
Head Up-and-Down	0.63	0.36

CONCLUSIONS

A new fit test method (termed the Fast-Half fit test method) for elastomeric half-mask respirators based on the PortaCount[®], a CNC-based instrument, that reduces the test duration from 7.2 min to 2.5 min has been successfully developed and assessed. Given the large number of fit tests performed annually, this reduction in time would benefit industry given the reduced time and burden. The Fast-Half method can identify poorly fitting respirators as well as the Reference method, as the test sensitivity of 0.96 was greater than the requirement (≥ 0.95) as defined by ANSI Z88.10-2010. The Fast-Half method also met the requirements for the predictive value of a pass, test specificity, predictive value of a fail, and the kappa statistic contained in the ANSI standard. The Fast-Half method requires acceptance by OSHA prior to implementation in industry. It is planned to submit this method to OSHA for consideration. Future testing is recommended to develop and evaluate faster fit test methods for use with filtering facepiece respirators.

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