

Evaluation of a Faster Fit Testing Method for Full-Facepiece 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 full-facepiece 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 0.98 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, full-facepiece 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. For example, an Institute of Medicine (IOM) report indicates that "fit testing is a critical requirement for ensuring the efficacy of respirators" but that "it may not always be complied with for various reasons, including time and cost" and recommends more efficient fit test methods should be explored (IOM, 2008). Less burdensome fit test methods for tight-fitting respirators may help increase compliance (NIOSH, 2013). 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 full-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-Full method. All testing was performed on full-facepiece 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 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. At least one participant was within each cell with exception of the two extremes (cells 1 and 10). 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 secure. 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., 500 for a full-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 cause 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. In addition, consistent with observations by Janssen et al. (2002), the wearer did not perform a seal check to increase the potential for “poor” fits. The test administrator assisted with donning to ensure that the respirator was tight to the face to minimize the potential for slippage. Artificial leak paths were not used because the objective was to evaluate the Fast-Full 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.

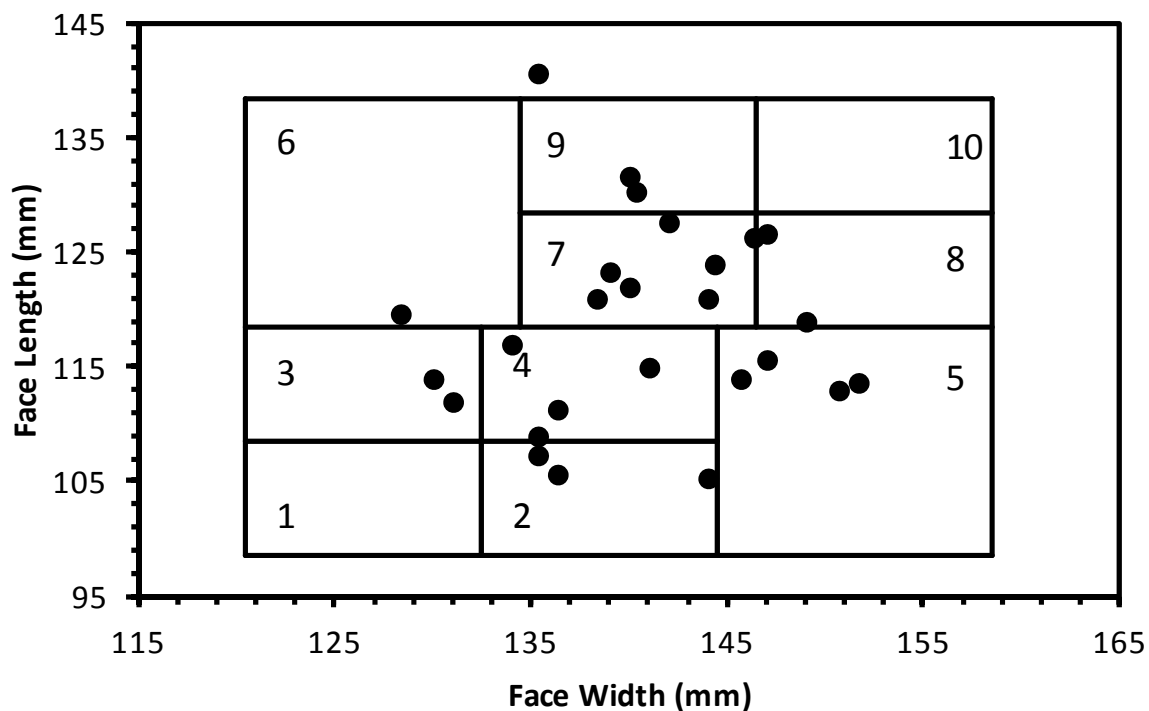


Figure 1. Distribution of Participant Facial Sizes Overlaid on the NIOSH Bivariate Chart.

Three different models of NIOSH-approved, full-face air-purifying respirators from leading U.S. mask manufacturers were used and each was tested in three different sizes. 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 non-flush sample probe that was permanently installed inside the nose cup. The probes generally extended about 0.6 cm into the breathing zone. Bergman et al. (2012) observed no practical differences in measured fit factors using flush versus deep probes.

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-Full 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 instructed 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-Full 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-Full method reduced the fit test time by about 65% relative to the Reference method (2.5 min vs. 7.2 min).

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-Full 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-Full 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-Full 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-Full 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 475 to 525 for fit testing of full-facepiece 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., 500 for a full-facepiece 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 0.05. 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., $\log(\text{FF}_1) - \log(\text{FF}_2)$) 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:

$$\text{Upper Bound Fit Factor of Exclusion Zone} = 10^{(\log(500) + \sigma)}$$

$$\text{Lower Bound Fit Factor of Exclusion Zone} = 10^{(\log(500) - \sigma)}$$

where σ is the standard deviation of the log-transformed difference and 500 is the pass/fail criterion for a full-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-Full 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-Full 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-Full method and one with the Reference method. The order was randomized with respect to whether the Fast-Full 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 to have 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-Full 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-Full 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-Full Test	A	B
Failed Fast-Full 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 62 fit factor pairs across 17 participants (7 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. Five 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 three 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 data points tightened the exclusion zone around the pass/fail criterion of 500, ultimately making it more difficult for the Fast-Full method to meet the ANSI criteria.

Good correlation (>0.95) was observed between the two Reference fit factors within each pair as shown in Figure 3. The best-fit regression nearly coincides with the 1:1 line shown as a dashed line. All of the fit factors within each individual pair were within a factor of three. The average log difference was 0.026 with a standard deviation of 0.16. Based on this standard deviation, the exclusion zone for the Reference method was 345 to 726.

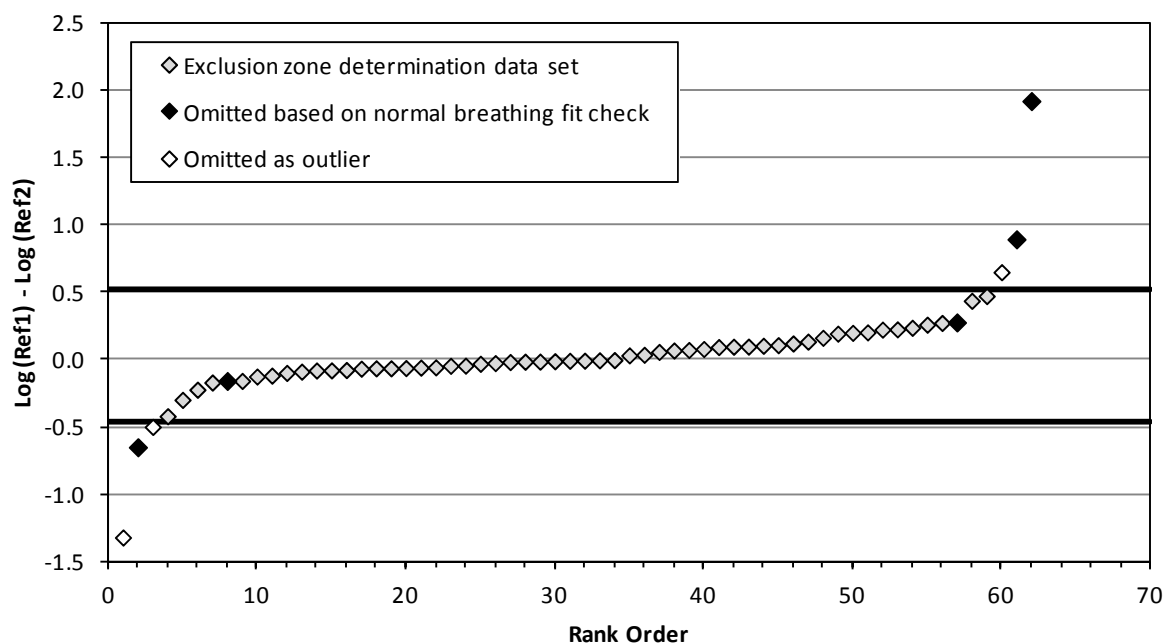


Figure 2. Distribution of Log Differences in Overall Reference Fit Factors Used in Determination of the Exclusion Zone.

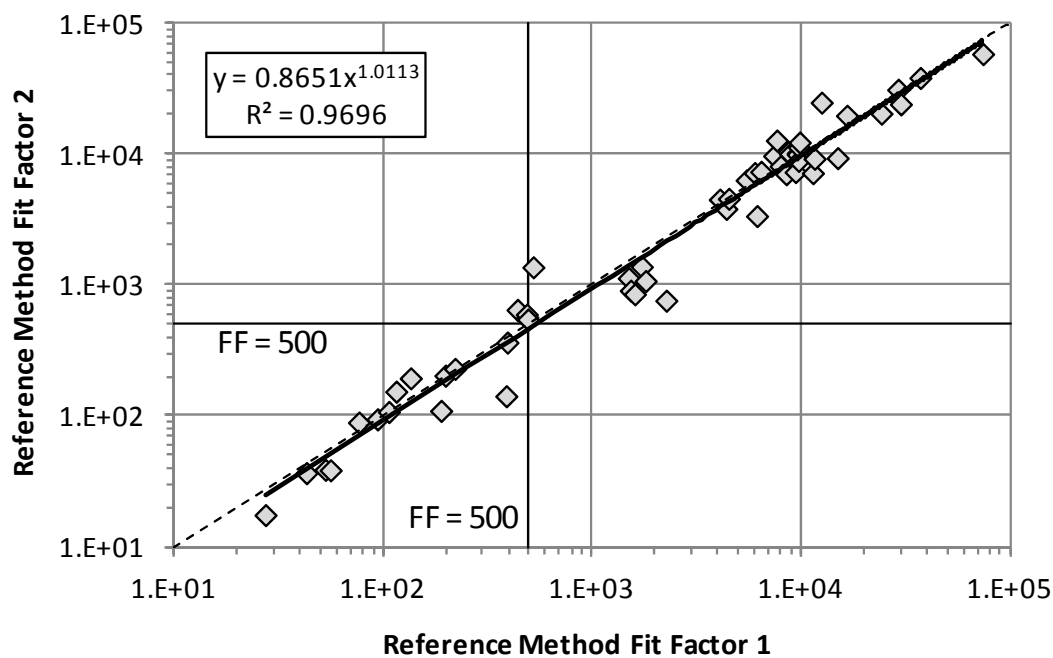


Figure 3. Comparison of Reference Overall Fit Factors Used in Determination of Exclusion Zone.

Comparison of Fast-Full and Reference Method

A total of 148 fit factor pairs across 27 participants including 11 females (41%) and 16 males (59%) were collected to compare the Reference and Fast-Full 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.

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 (a torn piece of a cleaning wipe was observed in the respirator during the test). Thus, the data set for the comparison included 136 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 25 (5% of the pass/fail criterion) and 345 (lower bound of the exclusion zone). These Reference method fails were evenly distributed as shown in Figure 4 and not weighted toward the lowest fit factors. Figure 4 also demonstrates that the Reference method fit factors bracketed the pass/fail criteria (500 for full-face respirator).

Figure 5 compares the measured Reference and Fast-Full 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 (89%) of the fit factors within each pair were within a factor of three. The average magnitude of the log difference was -0.067 with a standard deviation of 0.38.

Table VI. Distribution of Reference Fit Factors in ANSI Comparison

Reference Fit Factor Range	Number of Observations (ANSI Requirement)
Total Number of Tests	136 (N/A)
12 < FF < 25	5 (N/A)
25 < FF < 345	54 (50)
345 < FF < 726 (Exclusion Zone)	12 (N/A)
726 < FF < 51,261	65 (N/A)
Total Number of Tests Outside of Exclusion Zone	124 (100)

There was a single instance outside of the exclusion zone where the Reference fit factor failed and the Fast-Full method passed (upper left quadrant in Figure 5). In this instance, the measured Reference fit factor was 131 which is greater than 10% of the pass/fail criterion. Thus, there were no instances where the Reference fit factor was below 10% of the pass/fail criterion (i.e., 50) and was passed by the Fast-Full method, which would have disqualified the method per ANSI.

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-Full method met the requirement in all cases indicating excellent agreement between the Fast-Full and the Reference method. From a safety perspective, the test sensitivity demonstrates that the Fast-Full method can identify poorly fitting respirators as well as the Reference method.

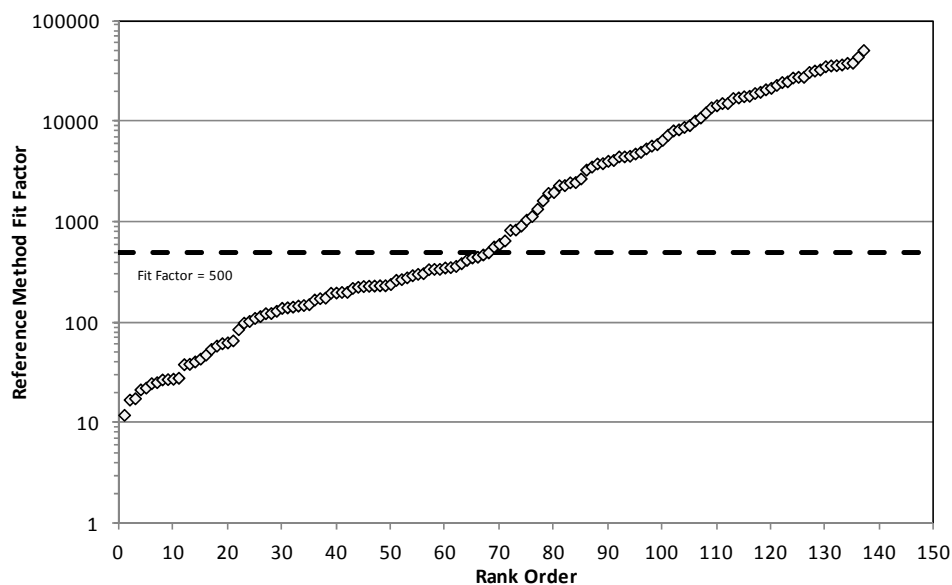


Figure 4. Distribution Reference Overall Fit Factors in ANSI Comparison.

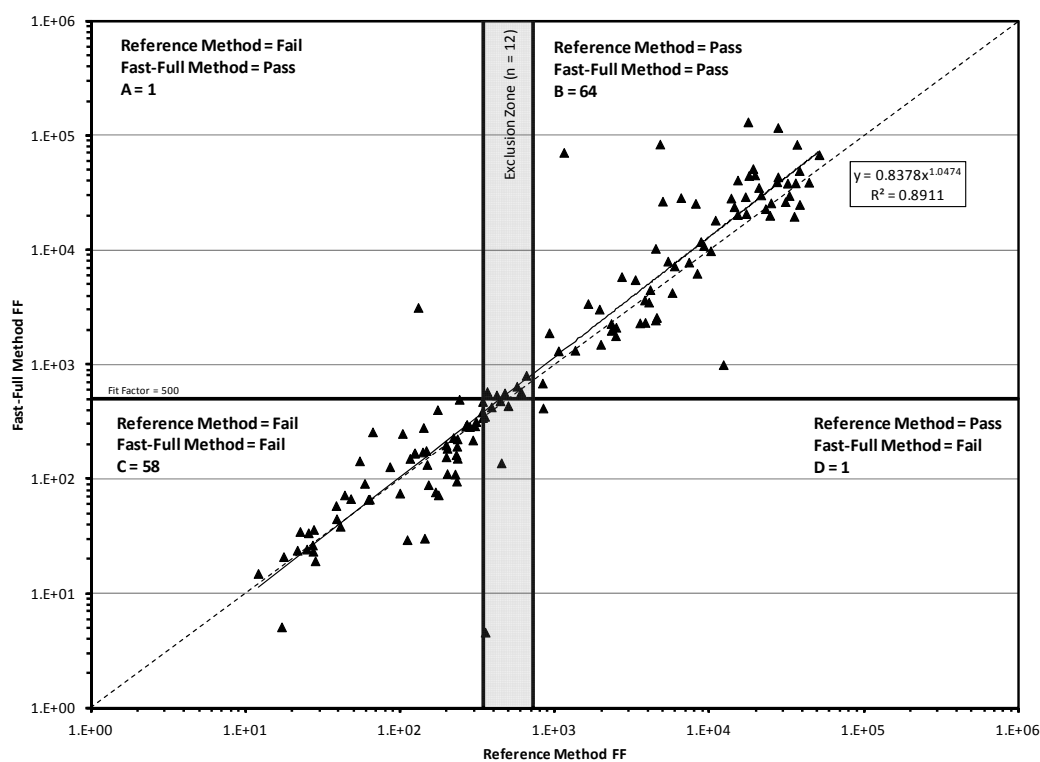


Figure 5. Comparison of Overall Fit Factors Measured Using Reference and Fast-Full Fit Test Methods.

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

Criterion	ANSI Requirement	Measured
Sensitivity	≥ 0.95	0.98
Predictive Value of a Pass	≥ 0.95	0.98
Test Specificity	> 0.50	0.98
Predictive Value of a Fail	> 0.50	0.98
Kappa Statistic	> 0.70	0.97

Analysis of the data indicates that the Fast-Full method would have passed the test sensitivity requirement until the lower bound of the exclusion zone exceeded 473. It is also important that the Fast-Full method exceeded the target for test specificity (0.98). This statistic represents the fraction of passing fit factors with the Fast-Full method that also passed the Reference method. Thus, use of the Fast-Full method will not cause the false rejection of adequately fitting respirators and subsequent unnecessary retesting.

CONCLUSIONS

A new fit test method (termed the Fast-Full fit test method) for full-face respirators based on the PortaCount[®], a CNC-based instrument, that reduces the test duration from 7.2 min to 2.5 min (~65% reduction relative to the Reference method) 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-Full method can identify poorly fitting respirators as well as the Reference method, as the test sensitivity of 0.98 was greater than the requirement (≥ 0.95) as defined by ANSI Z88.10-2010. The Fast-Full 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-Full 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 half-face respirators and filtering facepiece respirators.

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