

## Evaluation of a Shortened Fit Test Protocol for Full-Facepiece Respirators Using the OHD Quantifit®

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### ABSTRACT

Annual fit testing, as mandated by the Occupational Safety and Health Administration (OSHA), is required for every employee in the United States who wears a tight-fitting respirator. Considering the volume of fit tests performed annually, a reduced test duration would prove advantageous. This study evaluated two shortened fit test protocols for full-facepiece respirators using Controlled Negative Pressure (CNP) technology. This study is a continuation of a previous study that evaluated the effectiveness and accuracy of the same shortened protocols for elastomeric half-mask respirators. The new protocols are a modification of the OSHA-accepted CNP REDON protocol, titled modified-REDON and brief-REDON, and would reduce the test duration to 1.9 and 1.2 minutes, respectively. The overall fit factor measured using the new methods was compared to that of a reference method following the "Criteria for Evaluating New Fit Test Methods" outlined in American National Standards Institute (ANSI) publication Z88.10-2010, Annex A2. Sequential paired fit tests were performed on human test participants during the same respirator donning. Fit factors were measured using the Quantifit® CNP instrument. The exercise set for the reference method was the standard OSHA 8-exercise protocol for CNP-based instruments. The exercise set for the modified-REDON method included facing forward, facing parallel to the floor, head shaking, and two redon exercises. The results demonstrated that the sensitivity of the modified-REDON method (1.00) was greater than the requirement ( $>0.95$ ) defined in ANSI Z88.10-2010. The modified-REDON method also met the test specificity, predictive value of a pass, predictive value of a fail, and kappa statistic recommended by ANSI. The brief-REDON method evaluated the effect of reducing the number of redon exercises from two to one. The results demonstrated the sensitivity (0.99) remained essentially unchanged indicating removal of the second redon step would not negatively impact the ability of the new method to effectively identify poorly fitting respirators.

**Keywords:** respirator fit testing, quantitative fit test, full-face respirator, OHD Quantifit, controlled negative pressure.

### INTRODUCTION

A respirator is designed to protect an individual from inhaling harmful gases, vapors or particulates. Quantitative fit testing is an important component of a respiratory protection program. In the United States, employees required to wear a respirator in the workplace must be fit tested annually using an Occupational Safety and Health Administration (OSHA) accepted protocol published in Title 29 of the Code of Federal Regulations (CFR) Part 1910.134, Appendix A (OSHA, 1998). The Quantifit® respirator fit test instrument, manufactured by Occupational Health Dynamics (OHD), uses controlled negative pressure (CNP) to provide a direct measure of leak rate. The instrument creates a fixed vacuum on the facepiece by temporarily cutting off the breathing air with special adapters. The airflow, or leak rate, needed to maintain the vacuum on the mask is then measured by the instrument. A fit factor (FF) is computed by dividing an average breathing rate by the measured leak rate (Crutchfield et al., 1991a; OHD, 2013).

There are two OSHA-accepted fit test protocols using CNP technology: (1) the reference method (*duration: approximately 9 minutes*), which consists of seven one-minute exercises plus a 15-second grimace maneuver (total of 8-exercises) and (2) the REDON method (*duration: approximately 3 minutes*).

The REDON method was accepted by OSHA in 2004, based on research that indicated proper donning affects respirator fit to a greater degree than multiple test exercises (Crutchfield et al. 1999). The current CNP REDON protocol consists of two 30-second exercises, one 3-second exercise and two respirator redonning exercises (total of 5-exercises). Given that employers in the United States must perform annual fit tests on employees required to wear a respirator, industry would benefit if the time required to complete a fit test was reduced without sacrificing accuracy for the sake of speed.

Previous research has sought to develop faster, less burdensome methods to increase compliance (Crutchfield et al., 1999; McKay and Bradley, 2005; Richardson et al., 2013, 2014a, 2014b). The purpose of the current study was to evaluate whether modified REDON methods with shortened protocols were as effective and accurate compared to the existing CNP reference method for full-face respirators. This study is a continuation of a previous study which evaluated the effectiveness and accuracy of the same shortened REDON protocols for elastomeric half-mask respirators (Kimbrough et al. 2022).

The American National Standards Institute (ANSI) defines the approach required to evaluate new fit test methods in standard Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods" (2010). The approach involves conducting sequential paired fit tests during the same respirator donning using the new method and reference method. In the current study, the reference method was defined as the OSHA-accepted, CNP based protocol (8 exercises). The two new methods are modifications to the REDON method and will be referred to as the modified-REDON method and brief-REDON method. The methods differed by exercise sets and exercise duration. All testing was performed on full-face respirators using the OHD Quantifit® CNP instrument.

## MATERIALS AND METHODS

The study design was based on requirements established by ANSI Z88.10-2010 (Annex A2: Criteria for Evaluation New Fit Test Methods) and paralleled previous studies which evaluated faster fit test protocols using ambient aerosol condensation nuclei counter (CNC) technology (Richardson et al., 2013, 2014a, 2014b). The study was reviewed and approved by the Institutional Review Board (IRB) at the University of North Alabama (UNA).

### Participants and Respirators

Thirty (30) subjects participated in the study. Prior experience wearing a respirator was not a requirement for participation. The test administrator selected a properly fitting respirator based on observed facial characteristics of the test participant and professional experience. Assisted donning by the test administrator was performed to ensure proper fit, and the test participant was instructed on how to perform a user seal check. If a successful fit test was achieved, the respirator was used to satisfy the requirement of a fit factor greater than the pass/fail criterion. To satisfy the requirement of a fit factor less than the pass/fail criterion, mis-sized respirators and respirators with artificial leak paths were utilized. Test participants were trained on how to perform exercises correctly by the test administrator and were required to be clean shaven on the day of the fit test.

All fit tests were performed using full-face respirators. Three different models of NIOSH-approved respirators from U.S. mask manufacturers were used approximately the same number of times in the study. Two masks were commercially available in three different sizes (small, medium, large) and one mask was commercially available in two different sizes (small and medium-large) for a total of eight respirators. Each test participant was asked to complete a total of six sequential paired fit tests (*i.e. fit test with target FF < 500 and fit test with target FF > 500 for each respirator model*) for a total of 180 tests.

### Fit Factor Measurement

Fit factors were measured using the Quantifit® CNP instrument which uses air as the challenge agent. A constant negative challenge pressure (15 mm H<sub>2</sub>O) was maintained in the respirator for the duration of the fit test measurement by exhausting air at a controlled rate. The challenge pressure applied replicates

the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Thus, the measured exhausted flow rate represents a direct measure of leakage flow rate into the respirator. The CNP fit factor is calculated as the ratio of the inspiratory flow rate (53.8 liters per minute) associated with the challenge pressure (15 mm H<sub>2</sub>O) to the mean measured leakage flow rate as shown in Equation 1 (OHD, 2013).

$$CNP\ FF = \frac{IFR}{LFR} \quad (1)$$

where:

- IFR = inspiratory flow rate associated with CNP challenge pressure
- LFR = mean leakage flow rate measured with the head held in a motionless position at the end of each test exercise

Sampling manifolds were attached to the respirator mask inlet and inhalation valves were removed. Test participants donned the respirator and waited 5-minutes before beginning each fit test as required by OSHA (1998). Following the acclimation period, adjustments to the respirator were not made. Exercise sets were performed for the reference method followed by the new method without pause. Although the ANSI standard recommends the order of sequential fit tests be randomized with respect to test method, the reference method was administered first to avoid altering the initial fit during respirator re-donning exercises. The test administrator instructed participants which exercises to perform and ensured they were performed correctly. After each exercise, the test participant was instructed to take a breath and hold it for 10 seconds. The instrument removed air from the facepiece until the challenge pressure was reached and then measured the mean leakage flow rate. FitTrack Gold software, developed and supplied by OHD Global, was used to execute the sampling sequences and collect data during each trial. Measured fit factors for each exercise were captured electronically and the overall fit factor, which is the harmonic mean of the fit factors measured for each exercise, was calculated by the software. Each trial generated a fit test pair consisting of two overall fit factors. The overall fit factor was used to compare the methods in accordance with the ANSI standard. Data were exported into Microsoft Excel® and the specified statistical parameters were calculated.

### Proposed New Fit Test Methods

The reference method used the standard OSHA CNP test exercises shown in Table I. The modified-REDON method is an adaptation of the OSHA-accepted REDON method. It substitutes two static positions (face forward, face parallel to the floor) for two 30-second exercises (facing forward, bending over). The head shaking exercise and two respirator redonning exercises remained unchanged. The modified-REDON method is shown in Table II. Note that the duration (40 seconds) allotted for each REDON exercise is an estimate provided by the authors based on inexperienced users with assisted donnings.

**Table I. Reference Method**

| <b>Exercises</b>  | <b>Exercise procedure</b>                                                                                                                                                              | <b>Duration (seconds)</b> |
|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Normal Breathing  | Stand and breathe normally, without talking, for 60 seconds; face forward, while holding breath for 10 seconds                                                                         | 70                        |
| Deep Breathing    | Stand and breathe slowly and deeply for 60 seconds; face forward, while holding breath for 10 seconds                                                                                  | 70                        |
| Head Side-to-Side | While standing, slowly turn head from side to side for 60 seconds; hold head full right, while holding breath for 10 seconds; hold head full left, while holding breath for 10 seconds | 80                        |
| Head Up-and-Down  | While standing, slowly move head up and down for 60 seconds; hold head full up, while holding breath for 10 seconds; hold head full down, while holding breath for 10 seconds          | 80                        |
| Talking           | Talk slowly and loud enough to be heard for 60 seconds; face forward, while holding breath for 10 seconds                                                                              | 70                        |
| Grimace           | Smile or frown for 15 seconds                                                                                                                                                          | 15                        |
| Bending Over      | Bend at the waist, as if going to touch toes for 60 seconds; face forward, while holding breath for 10 seconds                                                                         | 70                        |
| Normal Breathing  | Stand and breathe normally, without talking, for 60 seconds; face forward, while holding breath for 10 seconds                                                                         | 70                        |

**Table II. Modified-REDON Method**

| <b>Exercises</b> | <b>Exercise procedure</b>                                                                                                                            | <b>Duration (seconds)</b> |
|------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|
| Facing Forward   | Face forward, while holding breath for 10 seconds                                                                                                    | 10                        |
| Bending Over     | Face parallel to the floor, while holding breath for 10 seconds                                                                                      | 10                        |
| Head Shaking     | For about three seconds, shake head back and forth vigorously several times while shouting; face forward, while holding breath for 10 seconds        | 13                        |
| REDON 1          | Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask; face forward, while holding breath for 10 seconds       | 40 <sup>a</sup>           |
| REDON 2          | Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again; face forward, while holding breath for 10 seconds | 40 <sup>a</sup>           |

<sup>a</sup> estimate based on inexperienced users with assisted donnings

The current CNP REDON method places a strong emphasis on mask re-donning since previous studies have emphasized that proper donning affects respirator fit to an even greater degree than multiple test

exercises (Crutchfield et al. 1999). The current REDON method assesses three separate mask donnings. To evaluate the impact of reducing the number of redon exercises from two to one (i.e., omitting the final redon step), measured fit factors from the modified-REDON exercises were used to re-calculate the harmonic mean, omitting results from the second redon step. This shortened protocol, shown in Table III, was termed the brief-REDON method.

**Table III. Brief-REDON Method**

| Exercises      | Exercise procedure                                                                                                                             | Duration (seconds) |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Facing Forward | Face forward, while holding breath for 10 seconds                                                                                              | 10                 |
| Bending Over   | Face parallel to the floor, while holding breath for 10 seconds                                                                                | 10                 |
| Head Shaking   | For about three seconds, shake head back and forth vigorously several times while shouting; face forward, while holding breath for 10 seconds  | 13                 |
| REDON 1        | Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask; face forward, while holding breath for 10 seconds | 40 <sup>a</sup>    |

<sup>a</sup> estimate based on inexperienced users with assisted donnings

### ANSI Standard Criteria

The ANSI standard (2010) stipulates a minimum of 100 fit test pairs be included in the data analysis with at least 50 of the fit test pairs in the data set for analysis having a reference method fit factor below the required fit factor (i.e. fit factor < 500 for full-face respirators). To obtain fit factors below the required fit factor, participants were first provided mis-sized respirators, as was done in previous studies (Richardson et al., 2013, 2014a, 2014b; McKay and Bradley, 2005). However, mis-sizing almost always resulted in an aborted test due to large leakage. The Quantifit®, which measures leak rate directly, is programmed to terminate the measurement when the leak rate is too great. Previous studies have demonstrated CNP fit test methods yield more conservative estimates of respirator fit than aerosol systems (Crutchfield et al., 1991b; Crutchfield et al., 1993; Crutchfield et al., 1995; Burnis, 1991; Graffeo, 1992). Thus, similar to the approach taken by Crutchfield and colleagues (1994), artificial leaks were used to achieve a failed fit test. In the current study, artificial leaks were created by altering the integrity of the exhalation valve. A properly functioning exhalation valve will close during inspiration to prevent unfiltered air from entering the respirator facepiece. It is well documented that damaged, dirty, and improperly seated exhalation valves can result in sizable inward leakage (Brueck et al., 1992; Delaney et al., 2003; Kuo et al., 2005; Snyder and McKay, 2003). Three altered exhalation valve configurations were used approximately the same number of times in the study. Exhalation valves were improperly seated by placing tape on the side of the valve that contacts with the valve seat. The first configuration interfered with valve seating at two points of contact. The second configuration interfered with valve seating at four points of contact, and the third configuration interfered with valve seating at 5 or more points of contact. During typical respirator usage and fit testing, total respirator inward leakage occurs through various means including the filter, face-seal, and secondary paths (i.e. reduced mask-integrity due to holes or tears, improperly functioning exhalation valves, etc.) (Delaney et al., 2003; Grinshpun, 2018). Given that the fit test instrument is designed to measure overall fit and does not differentiate among leak sources, the use of artificial leaks in the study was a reasonable alternative to dynamic leaks induced through mis-sizing.

### Quantification of Exclusion Criteria

The ANSI standard (2010) recommends that reference method fit factors within one coefficient of variation (CV) of the required fit factor be excluded from the analysis. Fit factors that fall within this range are considered unreliable due to the observed variability of the method. The approach to determine the CV is not mandated by ANSI; however, a recommended approach is to perform repeated measurements on a subject having a fit factor near the required fit factor during a single facepiece donning. Thus, twenty repeated measurements were made by performing the reference fit test method on a single subject with an artificial leak path which provided an overall fit factor near the required fit factor (i.e., 500 for a full-face respirator).

### Comparison of Methods

The reference method and new methods were compared using the approach outlined by ANSI (2010). Sequential paired fit tests performed during the same respirator donning resulted in a fit test pair for each trial. Per the standard, a minimum of 100 fit test pairs were collected and a minimum of 25 participants were used. At least 50 of the fit test pairs had reference fit factors between 5% of the required fit factor of 500 for full-face respirators and the lower bound of the exclusion range.

ANSI (2010) specifies data analysis using a 2x2 contingency table. To meet the standard requirements, the new method must achieve a minimum test sensitivity of 0.95. The test sensitivity is defined as the probability that the new test will correctly identify an inadequate fit. The standard also advises meeting the criteria for three additional test statistics (specificity, predictive value of a pass, and predictive value of a fail) and recommends a Kappa statistics greater than 0.70. Collectively these test statistics provide a comprehensive comparison of the two methods.

## RESULTS

### Exclusion Range Determination

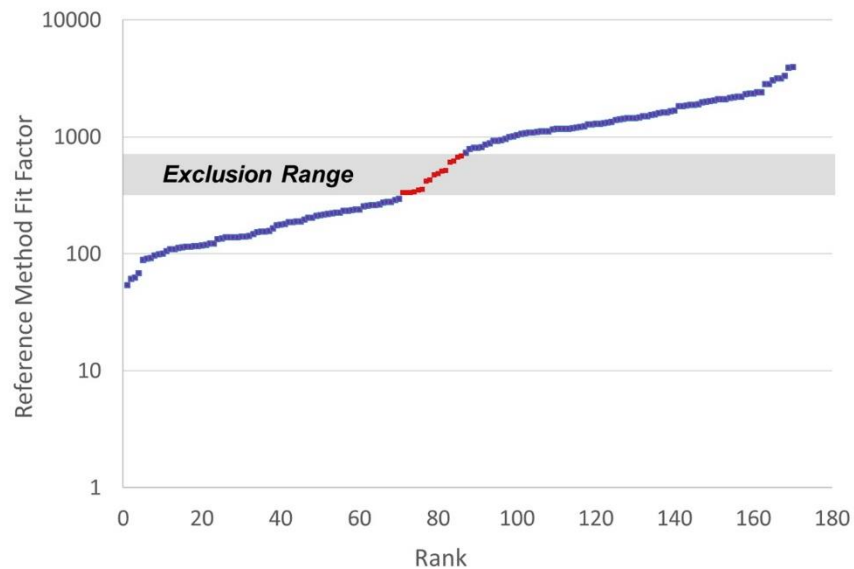
Four separate trials consisting of five sequential fit tests were performed during a single respirator donning ( $n_T=20$ ) to determine the exclusion range. The mean and standard deviation for each trial were used to calculate the combined mean and combined standard deviation ( $\bar{x}_c = 375.15$ ,  $s_c = 131.80$ ). The coefficient of variation (CV = 0.35) resulted in an exclusion range between 324 and 676.

Although not a direct comparison, Richardson and colleagues (2014b) determined an exclusion range between 345 and 726 for fit testing of full-facepiece respirators with the TSI Portacount® Plus Model 8020, an ambient aerosol fit test instrument. In a separate study utilizing the TSI Portacount®, McKay and Bradley (2005) defined the exclusion range between 475 and 525. According to ANSI (2010), previous studies associated with generated aerosol quantitative fit test methods yielded CV's ranging from 0.23 to 0.82. The exclusion range determined for the CNP method was found to be similar to the exclusion range determined for ambient and generated aerosol methods in previous studies.

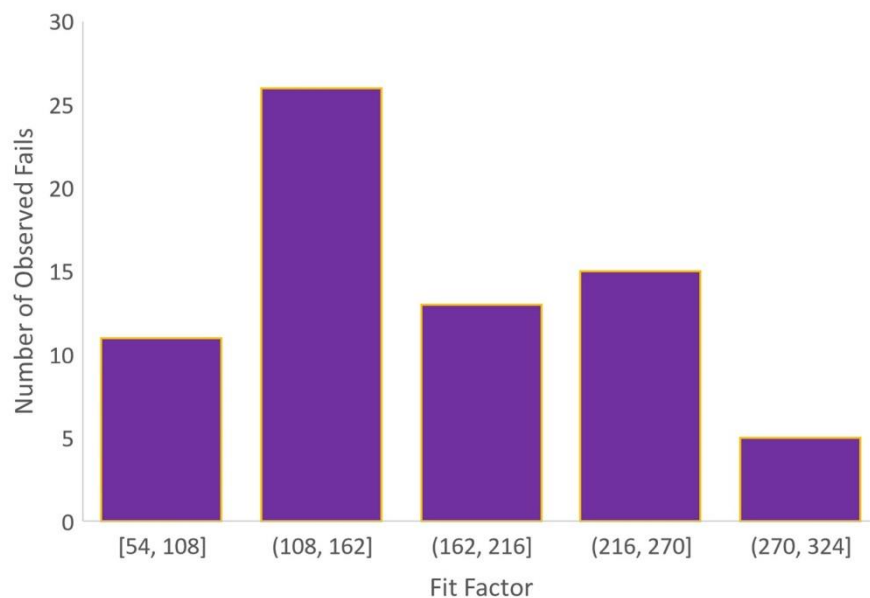
### Comparison of Modified-REDON and Reference Method

Twenty-seven of the 30 test participants completed all six sequential paired fit tests and three participants elected to exit the study early. Thus, a total of 173 fit test pairs across 30 participants (19 female and 11 male) was collected to compare the reference and modified-REDON methods. The distribution of reference method fit factors, as shown in Figure 1, bracketed the required fit factor (500 for full-face respirators) as required by ANSI (2010). Three fit test pairs were omitted from the analysis because the reference method fit factor was less than 5% of the required fit factor ( $FF < 25$ ). Fifteen fit test pairs were omitted from the analysis because the reference method fit factor was within the exclusion zone ( $324 \leq FF \leq 676$ ). Thus, the data set for comparison included 155 fit test pairs. As required by ANSI, a minimum of 50 Reference method fit factors were between 25 (5% of the required fit factor) and 324 (lower bound

of the exclusion range) and distributed across the range of possible fit factors (i.e., not weighted towards the lowest fit factor), as shown in Figure 2.



**Figure 1. Distribution of Reference Method Overall Fit Factors**



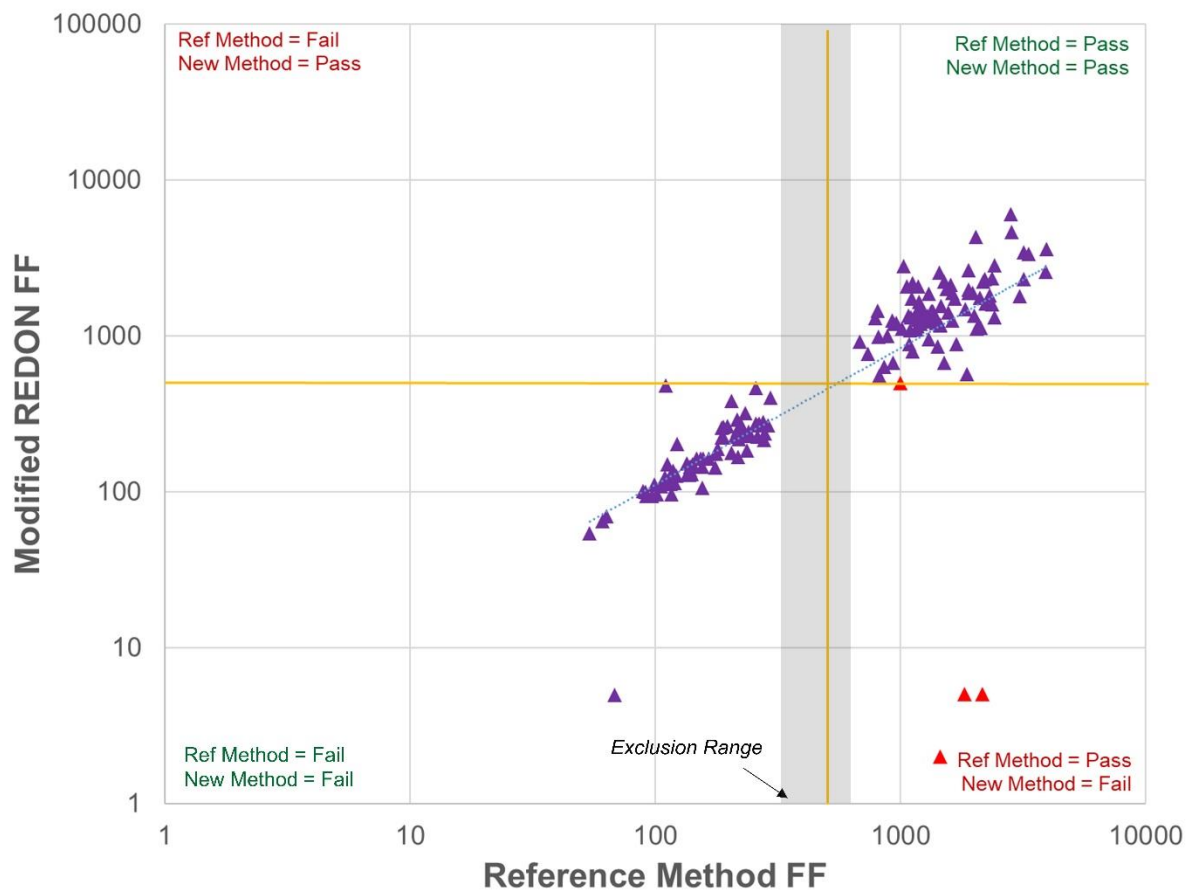
**Figure 2. Histogram of Reference Method Fails**

Fit test pairs (reference method vs. modified-REDON method) are shown in Table IV and depicted graphically in Figure 3. Good agreement was observed between the fit test pairs given that the data

points tend to lie near the linear regression line ( $r(153)=0.81$ ,  $P<0.001$ ) and ninety-seven percent (151 of 155) of the fit factors in each pair were within a factor of three (Richardson et al., 2013, 2014a, 2014b). There was no instance outside of the exclusion zone where the reference method fit factor failed and the modified-REDON method fit factor passed.

**Table IV. ANSI 2x2 Contingency Table (Evaluation of Modified-REDON Method)**

|                            | Failed Reference Test | Passed Reference Test |
|----------------------------|-----------------------|-----------------------|
| Passed Modified-REDON Test | 0                     | 81                    |
| Failed Modified-REDON Test | 70                    | 4                     |



**Figure 3. Comparison of Overall Fit Factors: Reference Method vs. Modified-REDON Method**

The measured descriptive statistics for the modified-REDON method compared to the requirements of the ANSI standard (2010) are shown in Table V. The modified-REDON method met the primary requirement for test sensitivity indicating the modified-REDON method can identify poorly fitting respirators as well as the reference method. In addition, the modified-REDON method met all other recommended ANSI criteria indicating excellent agreement between the modified-REDON method and reference method. The modified-REDON method had a test specificity of 95%, meaning the new method will also consistently identify correctly fitting respirators. The measured test specificity was much higher than the recommended ANSI criterion ( $>0.50$ ), reducing the likelihood of a false rejection that would result in needless retesting.

**Table V. ANSI Z88.10-2010 Statistics for Modified-REDON Method**

| <b>Statistic</b>           | <b>Definition</b>                                                                 | <b>ANSI Criterion</b> | <b>Measured Value</b> |
|----------------------------|-----------------------------------------------------------------------------------|-----------------------|-----------------------|
| Sensitivity                | Probability the new test will correctly detect a fail                             | $\geq 0.95$           | 1.00                  |
| Test Specificity           | Probability the new test will correctly detect a pass                             | $> 0.50$              | 0.95                  |
| Predictive Value of a Pass | Probability of passing the reference method when the new fit test passed          | $\geq 0.95$           | 1.00                  |
| Predictive Value of a Fail | Probability of failing the reference fit test method when the new fit test failed | $> 0.50$              | 0.95                  |
| Kappa Statistics           | Measure of the degree of agreement between two fit tests                          | $> 0.70$              | 0.95                  |

**Comparison of Brief-REDON and Reference Method**

Fit test pairs comparing the reference Method and brief-REDON Method are shown in Table VI and depicted graphically in Figure 4. Good agreement was observed between the fit test pairs given that the data points tend to lie near the linear regression line ( $r(153)=0.81$ ,  $P<0.001$ ) and ninety-eight percent (152 of 155) of the fit factors in each pair were within a factor of three (Richardson et al., 2013, 2014a, 2014b). There was only one instance outside of the exclusion zone where the reference method fit factor failed (FF = 257) and the shortened-REDON method fit factor (FF = 1304) passed.

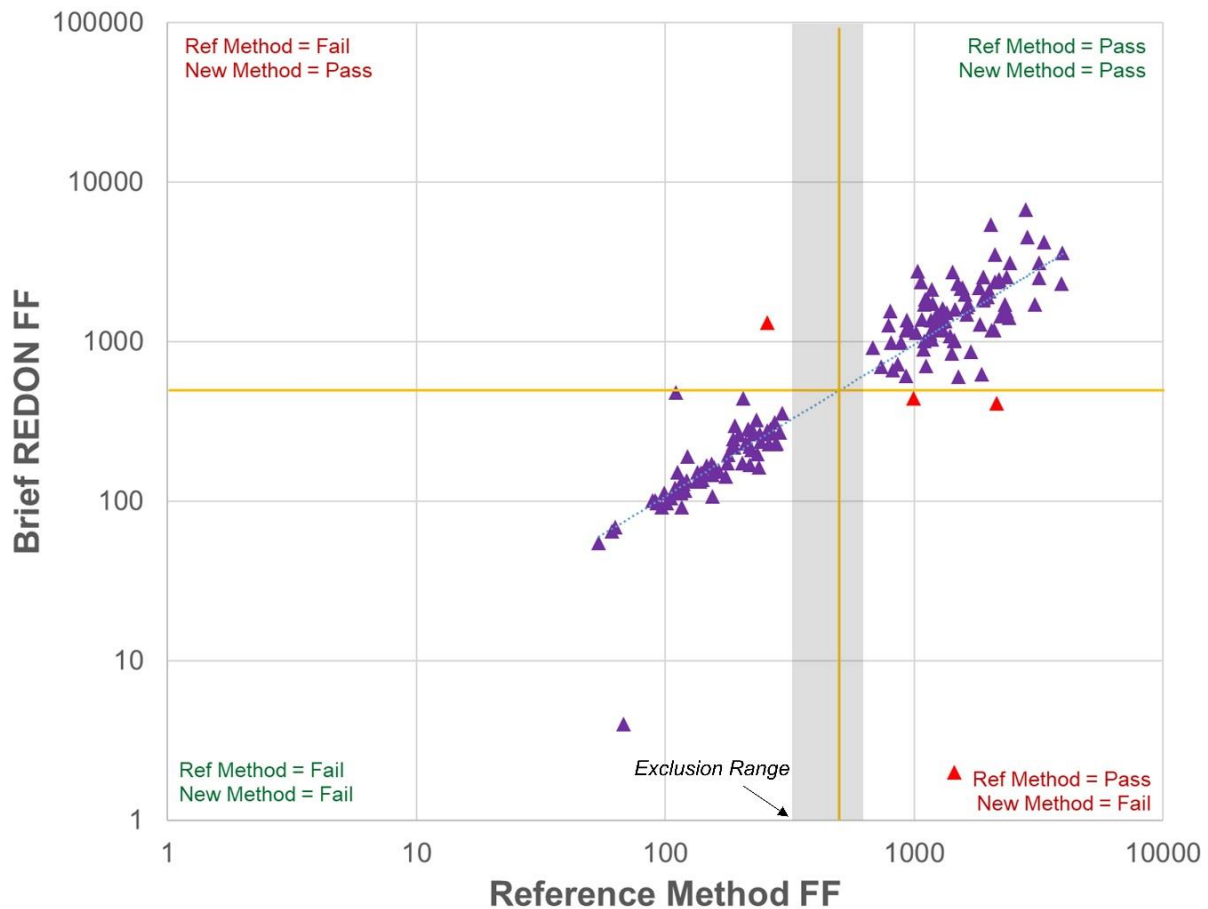
The test sensitivity for the brief-REDON method was 0.99, which met the primary ANSI requirement ( $\geq 0.95$ ) indicating the brief-REDON method can identify poorly fitting respirators as well as the reference method. In addition, the brief-REDON method had a test specificity of 0.96, meaning the method will also consistently identify correctly fitting respirators. The brief-REDON method met all other recommended ANSI criteria indicating excellent agreement between the brief-REDON and reference method (Table VII).

**Table VI. ANSI 2x2 contingency table (Evaluation of Brief-REDON Method)**

|                                | <b>Failed Reference Test</b> | <b>Passed Reference Test</b> |
|--------------------------------|------------------------------|------------------------------|
| <b>Passed Brief-REDON Test</b> | 1                            | 82                           |
| <b>Failed Brief-REDON Test</b> | 69                           | 3                            |

**Table VII. ANSI Z88.10-2010 Statistics for Brief-REDON Method**

| Statistic                  | Definition                                                                        | ANSI Criterion | Measured Value |
|----------------------------|-----------------------------------------------------------------------------------|----------------|----------------|
| Sensitivity                | Probability the new test will correctly detect a fail                             | $\geq 0.95$    | 0.99           |
| Test Specificity           | Probability the new test will correctly detect a pass                             | $> 0.50$       | 0.96           |
| Predictive Value of a Pass | Probability of passing the reference method when the new fit test passed          | $\geq 0.95$    | 0.99           |
| Predictive Value of a Fail | Probability of failing the reference fit test method when the new fit test failed | $> 0.50$       | 0.96           |
| Kappa Statistics           | Measure of the degree of agreement between two fit tests                          | $> 0.70$       | 0.95           |

**Figure 4. Comparison of Overall Fit Factors: Reference Method vs. Brief-REDON Method**

## CONCLUSIONS

Two shortened fit test methods (termed the modified-REDON and brief-REDON) based on the Quantifit®, a CNP-based instrument, have been evaluated for full-facepiece respirators and elastomeric half-mask respirators (Kimbrough et al. 2022). The modified-REDON method has a test sensitivity of 1.00 (ANSI Z88.10-2010 requirement  $\geq 0.95$ ), indicating the method can identify poorly fitting respirators as well as the reference method. The brief-REDON method, which reduces the number of redon exercises from two to one, has a test sensitivity of 0.99, indicating removal of the second redon step would not negatively impact the ability of the method to effectively identify poorly fitting respirators. Both new methods also met the ANSI criteria for test specificity, predictive value of a pass, predictive value of a fail, and the kappa statistics. The modified-REDON and brief-REDON methods would reduce the fit test duration to 1.9 and 1.2 minutes, respectively. This reduced time requirement has the potential to benefit industry considering the large number of fit tests performed annually. These shortened REDON protocols will require acceptance by OSHA prior to implementation in industry.

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