

Evaluation of a Shortened Fit Test Protocol for Elastomeric Half-Mask 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 a shortened fit test protocol for elastomeric half-mask respirators using Controlled Negative Pressure (CNP) technology. The new protocol is a modification of the OSHA-accepted CNP REDON protocol and would reduce the test duration to 1.9 minutes. The overall fit factor measured using the new method 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 shortened method (0.98) was greater than the requirement (>0.95) defined in ANSI Z88.10-2010. The new method also met the test specificity, predictive value of a pass, predictive value of a failure, and kappa statistic recommended by ANSI. This study also evaluated the effect of reducing the number of redon exercises from two to one, further decreasing the test duration to 1.2 minutes. The results demonstrated the sensitivity (0.98) remained 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, elastomeric half-mask respirator, OHD Quantifit, controlled negative pressure.

INTRODUCTION

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). Controlled Negative Pressure (CNP) is an OSHA-approved fit test method which provides a direct measure of respirator leakage by maintaining a constant negative pressure inside the facepiece (Crutchfield et al., 1991a; OHD, 2013). The Quantifit®, manufactured by Occupational Health Dynamics (OHD), is the most widely used CNP instrument to date. 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*), which consists of two 30-second exercises, one 3-second exercise and two respirator redonnings exercises (total of 5-exercises). Fit testing is an integral part of a respirator protection program and 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 this study was to investigate whether a modified REDON method with a shortened protocol was as effective and accurate compared to the existing CNP reference method. 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 new method was a shortened REDON method and will be referred to as the modified-REDON method. The methods differed by exercise sets and exercise duration. All testing was performed on elastomeric half-mask 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

Twenty-five (25) 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, 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 elastomeric half-mask air-purifying respirators. Three different models of NIOSH-approved respirators from U.S. mask manufacturers were used. Two masks were tested in three different sizes (small, medium, large) and one mask was tested in two different sizes (small-medium and medium-large) for a total of eight respirators. The respirator models were used approximately the same number of times in the study.

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 H₂O) 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 H₂O) 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 the 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 modified-REDON 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 on 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.

Exercise Sets

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.

ANSI Standard Criteria

The ANSI standard (2010) stipulates a minimum of 100 fit test pairs be conducted 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 < 100 for half-mask 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, because the Quantifit® is highly sensitive and measures leak rate directly, mis-sizing resulted in termination of the test. Previous studies have shown 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., 2010; Kuo et al., 2005; Snyder and McKay, 2003). Three damaged/dirty exhalation valve configurations were utilized approximately the same number of times in the study. The first configuration had one slit cut into the valve using scissors. The second configuration had two slits cut into the valve using scissors, and the third configuration had a thin layer of tape placed on the side of the valve that normally makes contact with the valve seat. 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.

Table I. Reference Method

Exercises	Exercise procedure	Duration (seconds)
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

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 ^a
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 ^a

^a estimate based on inexperienced users with assisted donnings

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, 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., 100 for a half-mask respirator).

Comparison of Methods

The reference method and modified-REDON method 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 100 for half-mask 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 ($\bar{X}_c = 122.95$, $s_c = 23.3$). The resulting coefficient of variation (CV = 0.19) resulted in an exclusion range between 81 and 119.

Although not a direct comparison, Richardson and colleagues (2014a) determined an exclusion range between 82 and 123 for fit testing of elastomeric half-mask 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 94 and 106. 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

A total of 147 fit test pairs across 25 participants (19 female and 6 male) were 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 (100 for half-mask respirators) as required by ANSI (2010). Ten fit test pairs were omitted from the analysis because the reference method fit factor was within the exclusion range ($81 \leq FF \leq 119$). Thus, the data set for comparison included 137 fit test pairs. As required by ANSI, a minimum of 50 Reference method fit factors were between 5 (5% of the required

fit factor) and 81 (lower bound of the exclusion range) and were not weighted towards the lowest fit factors, as shown in Figure 2.

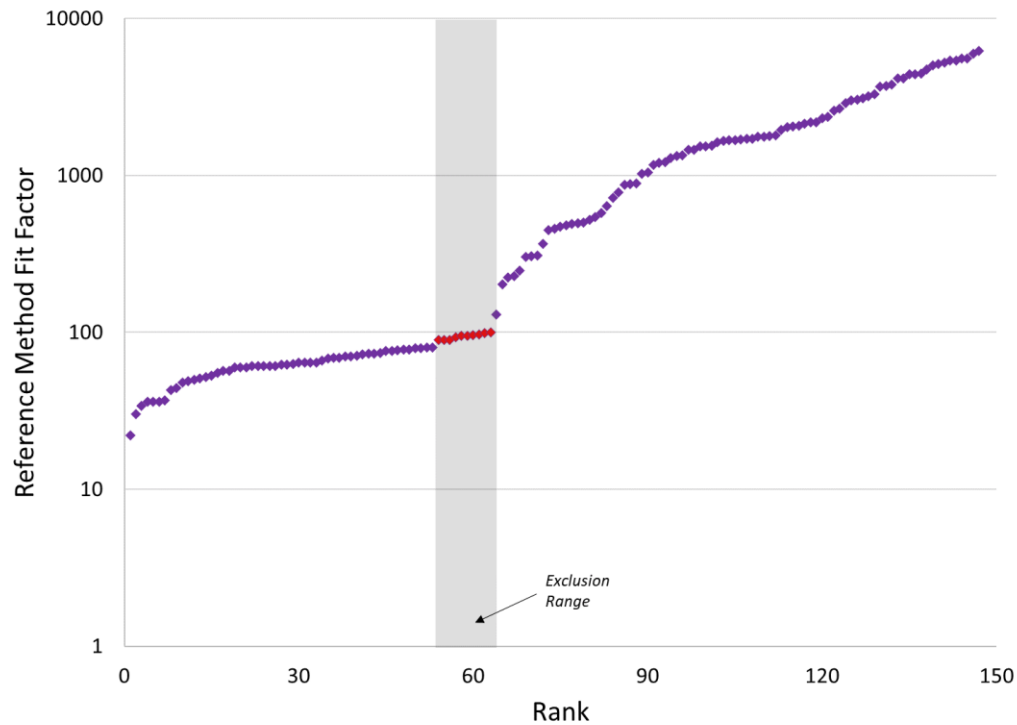


Figure 1. Distribution of Reference Method Overall Fit Factors.

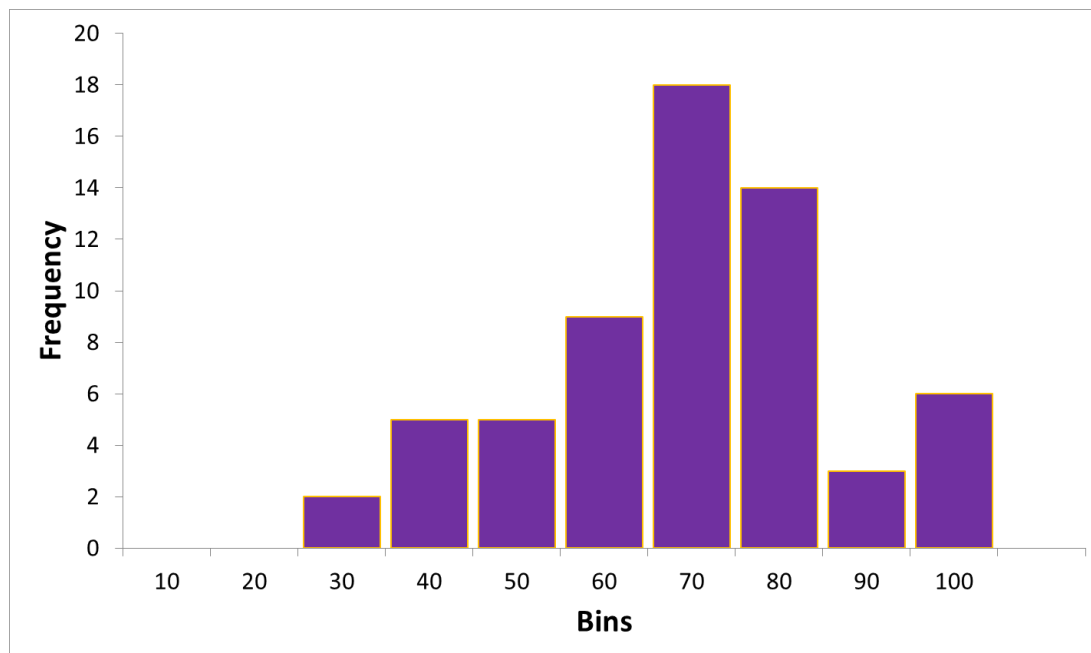


Figure 2. Histogram of Reference Method Fails.

Fit test pairs (reference method vs. modified-REDON method) are shown in Table III and depicted graphically in Figure 3. Good agreement was observed between the pairs given that data points tend to lie near the linear regression line ($r(135)=0.71$, $p<0.001$), and ninety-three percent (128 of 137) of the fit factors within each pair were within a factor of three (Richardson et al., 2013, 2014a, 2014b). There was only one instance outside of the exclusion range where the reference method fit factor failed (FF = 77) and the modified-REDON method fit factor (FF = 121) passed.

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

	Failed Reference Test	Passed Reference Test
Passed Modified-REDON Test	1	82
Failed Modified-REDON Test	52	2

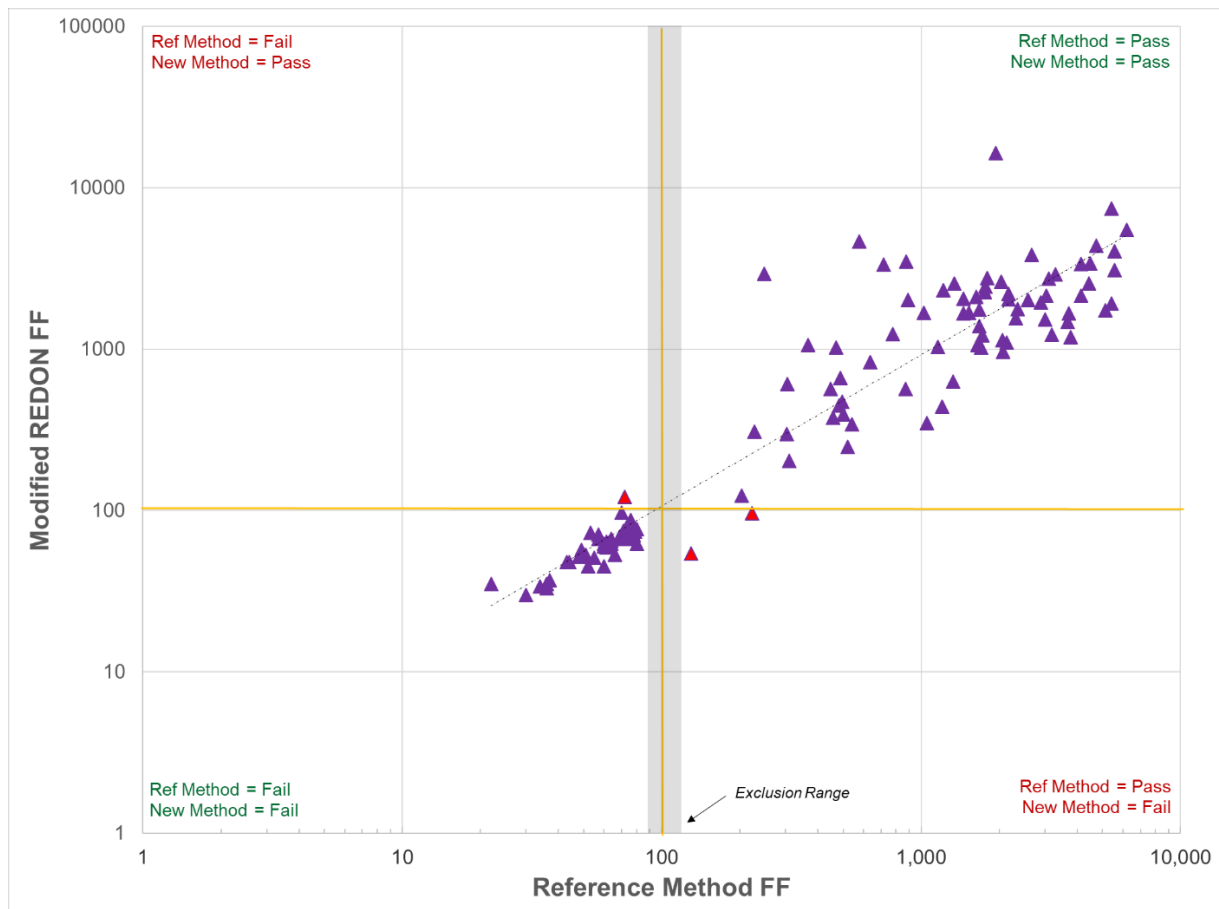


Figure 3. Comparison of Overall Fit Factors: Reference Method vs. Modified-REDON Method.

The measured descriptive statistics for the modified-REDON method compared to the requirements of the ANSI standard (2010) are shown in Table IV. 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 98%, 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 IV. ANSI Z88.10-2010 Statistics for Modified-REDON Method

Statistic	Definition	ANSI Criterion	Measured Value
Sensitivity	Probability the new test will correctly detect a fail	≥ 0.95	0.98
Test Specificity	Probability the new test will correctly detect a pass	> 0.50	0.98
Predictive Value of a Pass	Probability of passing the reference method when the new fit test passed	≥ 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

Comparison of Brief-REDON and Reference Method

The CNP Redon fit test protocol 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 CNP Redon protocol assesses three separate mask donnings during the fit test. To evaluate the impact of reducing the number of redon exercises from two to one (i.e., omitting the final redon step in Table II), the ANSI analysis was repeated. Measured fit factors for each exercise were used to re-calculate the harmonic mean, omitting results from the second redon step. The re-calculated harmonic mean and shortened method were termed the brief-REDON method. The fit test pairs (reference Method vs. brief-REDON Method) are shown in Table V. The exclusion criteria remained unchanged; thus the data set for comparison included the same 137 fit test pairs.

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

	Failed Reference Test	Passed Reference Test
Passed Brief-REDON Test	1	81
Failed Brief-REDON Test	52	3

Good agreement was observed between the fit test pairs given that data points tend to lie near the linear regression line ($r(135)=0.72$, $p<0.001$), and ninety-four percent of the fit factors within each pair were within a factor of three (Richardson et al., 2013, 2014a, 2014b). There was only one instance

outside of the exclusion range where the reference method fit factor failed (FF = 72) and the brief-REDON method fit factor (FF = 120) passed.

The test sensitivity for the brief-REDON method was 0.98, which met the primary ANSI requirement (≥ 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 (Kappa statistics = 0.94).

CONCLUSIONS

A shortened fit test method (termed the modified-REDON) for elastomeric half-mask respirators based on the Quantifit®, a CNP-based instrument, has been developed and assessed. The modified-REDON method would reduce the fit test duration to 1.9 minutes. This reduced time requirement has the potential to benefit industry considering the large number of fit tests performed annually. The modified-REDON method has a test sensitivity of 0.98 (ANSI Z88.10-2010 requirement ≥ 0.95), indicating the method can identify poorly fitting respirators as well as the reference method. The method also met the ANSI criteria for test specificity, predictive value of a pass, predictive value of a fail, and the kappa statistics. In addition, this study evaluated the effect of reducing the number of redon exercises from two to one, further decreasing the test duration to 1.2 minutes. The results demonstrated the sensitivity (0.98) remained unchanged indicating removal of the second redon step would not negatively impact the ability of the new method to effectively identify poorly fitting respirators. One limitation of the current study is the modified-REDON protocol was only evaluated using elastomeric half-mask respirators; thus, all conclusions from the current study are limited to elastomeric half-mask respirators. Further study involving full facepiece respirators will be completed prior to drawing definitive conclusions about the new shortened REDON protocols. In addition, these shortened REDON protocols will require acceptance by OSHA prior to implementation in industry.

Acknowledgments

This study was supported by Grant 5T03OH008624-17 from the National Institute for Occupational Safety and Health (NIOSH). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of NIOSH.

Several companies donated to this project. We would like to thank 3M, Draeger and Dentec for respirators as well as OHD, LLLP for calibration services and support.

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