Applied Occupational and Environmental Hygiene
Volume 14(12):827-837,1999

Effect of Test Exercises and Mask Donning on Measured Respirator Fit

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Quantitative respirator fit test protocols are typically defined by a series of fit test exercises. A rationale for the protocols that have been developed is generally not available. There is also little information available that describes the effect or effectiveness of the fit test exercises currently specified in respiratory protection standards. This study was designed to assess the relative impact of fit test exercises and mask donning on respirator fit as measured by a controlled negative pressure and an ambient aerosol fit test system. Multiple donnings of two different sizes of identical respirator models by each of 14 test subjects showed that donning affects respirator fit to a greater degree than fit test exercises. Currently specified fit test protocols emphasize test exercises, while the determination of fit is based on a single mask donning. A rationale for a modified fit test protocol based on fewer, more targeted test exercises and multiple mask donnings is presented. The modified protocol identified inadequately fitting respirators as effectively as the currently specified OSHA quantitative fit test protocol. The controlled negative pressure system measured significantly ($p < 0.0001$) more respirator leakage than the ambient aerosol fit test system. The bend over fit test exercise was found to be predictive of poor respirator fit by both fit test systems. For the better fitting respirators, only the talking exercise generated aerosol fit factors that were significantly lower ($p < 0.0001$) than corresponding donning fit factors.

Key words: respiratory protection, fit test, fit test protocols, fit test exercises, respirator donning

The fit of a respirator can have a profound effect on the level of protection it provides when worn in a contaminated environment. Determining respirator fit is an essential part of a respiratory protection program. A number of test methods and protocols for determining respirator fit have evolved over the past three decades. Although many of the test protocols include post-donning seal checks and fairly elaborate sets of fit test exercises, there is little information in the literature that provides a rationale for the fit test exercises that have been adopted, or that documents their effectiveness. This paper presents the results of an assessment of the relative importance of fit test exercises and mask donning techniques on measured respirator fit. A condensed fit test protocol designed to target specific elements of respirator fit is compared to the current standard fit test protocol. The relative ability of a controlled negative pressure and an ambient aerosol fit test system to differentiate the fit of different sized respirators on the same subject over multiple mask donnings is also assessed.

Background

Techniques developed for determining respirator fit include both qualitative and quantitative fit test methods. Qualitative (QLFT) fit test methods are based on generating a sensible challenge agent outside the respirator and determining whether a detectable amount of the agent penetrates (leaks) into the respirator during a fit test. Current QLFT protocols are based on subjective agent detection by odor, taste, or irritation, and yield a pass/fail determination of respirator fit.[1] Quantitative (QNFT) respirator fit testing involves the physical measurement of challenge agent penetration or leakage into the respirator facepiece. The term fit factor, which is the reciprocal of measured penetration, has been derived to express the fit of a respirator measured during the fit test.[2] For aerosol-based QNFT systems, the fit factor is derived as the ratio of measured outside challenge agent concentration to measured in-mask agent concentration. For pressure-based QNFT systems, air is used as the test challenge agent and the fit factor represents the ratio of measured leakage flow to total airflow into the respirator.[3]

Quantitative respirator fit test protocols are characterized by a series of fit test exercises. The first published protocols generally included the following six fit test exercises (see Table I for descriptions): NB1, DB, SS, UD, TK, NB2.[4,5] An overall fit factor is calculated as the harmonic mean of individual fit test exercise results. Decisions regarding the adequacy of respirator fit are generally based on comparing the overall fit factor to a pass/fail criterion value that is established as a multiple of the test respirator's assigned protection factor.

Table I.
Fit Test Exercises Included in OSHA Fit Test Protocol

Test Exercise	Symbol	Description
Normal Breathing 1 [A]	NB1	Breathe normally
Deep Breathing [A]	DB	Breathe deeply
Side-to-Side [A]	SS	Turn head side to side, pausing to inhale at each extreme
Up-Down [A]	UD	Nod head up and down, pausing to inhale at each extreme
Talking [A]	TK	Talk out loud or read a standard passage
Grimace [B]	GR	Contort the face using facial muscles
Bend Over [B]	BO	Bend over as if to touch the toes
Jog in Place [C]	Jog	Jog in place
Normal Breathing 2 [A]	NB2	Breathe normally
Overall Fit Factor	OA	Calculated harmonic mean of individual exercise fit factors

[A] Originally recommended by NIOSH[4], ANSI[5]
[B] Added in OSHA Benzene, Cadmium, Formaldehyde Standards
[C] Added in OSHA Asbestos, Methylenedianiline Standards

As shown in Table I, more physically rigorous exercises involving bending over, jogging in place, and grimacing have been added to the original protocols. Although it is generally assumed that fit test exercises are meant to be representative of the ways in which respirator face seals are stressed in the work place, a published rationale for specific exercises could not be found. A requirement for each test exercise to last for at least one minute has also been included in fit test protocols currently specified by OSHA.[6] A scientific basis or rationale for specified exercise durations is also not evident in the literature.

Another aspect of QNFT protocols that has changed over the past two decades is the requirement to base mask fit decisions on the results of single versus multiple fit tests. A requirement to complete three fit tests and base the respirator fit decision on the most conservative result can be traced to the 1980 ANSI Respiratory Protection Standard.[4] The same requirement can be found in OSHA's substance specific standards for asbestos[7] and cadmium.[8] The rationale provided for requiring multiple fit tests primarily addressed the variability that has historically been associated with QNFT results.[9] The issue of mask donning was not addressed in the standards. Procedures for conducting multiple fit tests did not specify that the respirator had be removed and redonned between each test. The requirement to conduct multiple fit tests was dropped in the most recent ANSI Standard,[1] and is not included in the recent update of OSHA's Respiratory Protection Standard.[6]

A minimum of 15 minutes are required for a worker to complete the QNFT protocols currently specified by OSHA. If multiple fit tests are conducted in an attempt to identify the best fit among an array of different respirator models or sizes, a substantial fit test time burden can accrue. Mask fit decisions are also based on a single mask donning under the current protocols. Using the specified protocols to conduct multiple fit tests with a selected respirator, in an attempt to improve mask donning efficiency and increase training effectiveness, would impose an even greater time burden. One of the objectives for this study was to determine whether a modified fit test protocol with fewer, more specifically targeted fit test exercises and multiple mask donnings could identify poorly fitting respirators as effectively as currently specified QNFT protocols in less time.

Table II.
Modified Fit Test Exercise Protocol

Test Exercise	Symbol	System Specific Description[A]
Fundamental Fit	FF	AA – Equivalent to OSHA normal breathing exercise CNP – Measure leak rate while head held forward
Bend Over	BO	AA – Bend over as if touching toes, pausing for one inhalation; repeat for one minute CNP – Measure mask leak rate while subject bent over with face held parallel to floor
Shake Head	SH	AA – Shake head quickly[B] back and forth for 2-3 sec to try to shift the fundamental fit of the respirator; follow with FF measurement CNP – Same as AA
Overall Fit Factor	OA	Calculated harmonic mean of individual exercise fit factors

[A] AA – ambient aerosol system; CNP – controlled negative pressure system
[B] Test subjects with pre-existing neck problems should be cautioned to self-pace head Shake

Rationale for Modified Fit Test Protocol

The modified fit test protocol shown in Table II was derived from author experience and from a conceptual analysis of the fit test process. The fundamental fit exercise (identical to OSHA protocol normal breathing exercise) is designed to assess respirator leakage resulting from mask donning. The term fundamental fit refers to the fundamental relationship that is established between the facepiece and the wearer's face when a respirator is donned.

Depending on a number of factors including size and shape, facial morphology and condition, strap tension, and donning technique, the possibilities for fundamental fit range from “fits like a glove” to “leaks like a sieve”. It is important to note that the fundamental fit that is established when an air-purifying respirator is donned affects respiratory protection during every breath taken while the respirator is worn in a contaminated environment.

Once donned, fundamental respirator fit (or leakage) can theoretically change in two primary ways. A transient leak can result from a temporary break in the facepiece-to-face seal caused by face or mask movement. A mask seal break must be accompanied by a simultaneous inhalation for a transient leak to occur. As defined here, a transient leak would disappear when the movement that caused the faceseal to break ceases. It should be noted that only those workplace breaths taken while the faceseal is temporarily altered would affect the basic level of respiratory protection provided by the respirator. An alteration of the faceseal that does not reseat when movement ceases represents a shift in the fundamental fit of a respirator. Such a shift implies a new relationship between facepiece and face, and could theoretically affect respiratory protection during each subsequent breath taken while the respirator is worn.

Based upon the above analysis, the most important elements to assess during a fit test are: 1) fundamental respirator fit, 2) the tendency of the respirator to significantly shift its fundamental fit due to movements that are likely to occur in a work environment, and 3) the respirator’s tendency to develop transient leaks as a result of face or mask movement. Fundamental fit is directly related to respirator selection and donning. Since it has the potential to affect the level of protection provided during every breath taken in a contaminated environment, fundamental fit is the most important aspect of respirator fit assessed during the fit test. Based upon observation and experience, mask donning can have a dramatic effect on the fundamental fit of a respirator. Multiple mask donnings were therefore selected for analysis in this study.

Knowledge of fundamental fit alone is not sufficient to assure respiratory protection. A mask that significantly shifts its fundamental fit as a result of typical worker movements can substantially change our appreciation and expectation of mask performance in the workplace. Assessing the tendency of a mask to significantly shift its fit during wear is another important part of a fit test. The shake head exercise described in Table II involves a quick head shake designed to assess the potential for shifting the facepiece into a new fundamental fit relationship with the face.

Transient leaks are expected to have a lesser impact on respiratory protection since their effect is limited to those inhalations during which mask or facial movement causes a seal break. The bend over exercise included in Table II utilizes gravity to pull the respirator facepiece away from the face when it is held parallel to the ground. A faceseal leak that occurs with the head in this position that is not evident when the head is perpendicular to the ground is an example of a transient leak. Since many industrial jobs include activities that require looking down or bending over for periods of time involving multiple inhalations, the bend over exercise was selected for inclusion in the modified exercise protocol.

Study Objectives

The three major objectives of this study were to: 1) examine the effects of respirator donning and exercise protocols on measured fit factors, 2) assess the capability of a modified exercise protocol to effectively identify poor respirator fit, and 3) determine how effectively aerosol-based and pressure-based fit test systems can differentiate between respirators with different levels of fit.

Methods and Materials

A population of 14 Air Force personnel (11 males) previously assigned to a respiratory protection program volunteered to participate in the study. A range of respirator fit was generated within the population by assigning two different sizes of the same air purifying respirator model and type (elastomeric; half-mask or full-face) to each subject. The respirator size that had been selected and worn by each subject prior to their participation in the study was designated as his/her Mask 1. An identical respirator, except for a single-category size shift (i.e. next size larger or smaller), was assigned as each subject’s Mask 2. It was assumed that, in general, each subject’s Mask 1 would fit better than his/her assigned Mask 2. Half-mask and full-face respirator facepieces were equally represented in the study. Pass-fail levels for half-mask and full-face respirators were set at fit factors of 100 and 500 respectively.[6,10] The results of ambient aerosol fit tests were also analyzed relative to a pass/fail criterion of 1000, which has been recommended by the instrument manufacturer.[11]

A controlled negative pressure (FitTester 3000®, DNI Nevada, Inc., Carson City, NV) and an ambient aerosol (Portacount Plus®, TSI, Inc., St. Paul, MN) fit test system were used to conduct the study. Pressure and flowrate transducers of the FitTester device were calibrated against primary pressure (water manometer) and flowrate (Gilibrator, Gilian Instrument Corp., Caldwell, NJ) calibration standards prior to study initiation. Daily probe calibration checks were conducted to assure that the pressure drop across the instrument’s bypass orifice remained stable throughout the study.

A daily operational check of the Portacount device consisted of exposing both mask and ambient aerosol sample lines to room air and checking for a reported fit factor of one. The HEPA filter supplied with the Portacount was used to check detector zero each day. Ambient aerosol concentrations in the test room were monitored and recorded during each aerosol fit test.

Each subject completed three fit tests per day of both assigned respirators with each fit test system for a period of five consecutive days (ie. 2 fit test systems x 14 subjects x 2 masks/subject x 3 fit tests/mask/day x 5 days = 840 total fit tests.) The order of fit test system use was alternated between test days. Respirators were removed and redonned by the subject between each fit test. This study design allowed the fit of each subject's two assigned respirators to be assessed by two different fit test systems on the basis of 15 individual mask donnings over the course of one week.

The first ambient aerosol (AA) fit test conducted each day with each mask consisted of a full OSHA substance-specific exercise protocol as shown in Table I. The remaining two AA fit tests conducted each day with each mask utilized the modified exercise protocol described in Table II. No in-mask sampling was done during the shake head exercise, which was accomplished immediately after the completion of the bend over exercise. During the shake head exercise, the Portacount instrument collected a 10-sec ambient air sample. The effect of the shake head exercise was assessed by a second fundamental fit exercise measurement made immediately after the head shake. Both ambient aerosol protocols involved collection of a 60 sec in-mask sample for each exercise. An overall fit factor was calculated by the Portacount as the harmonic mean of the individual exercise fit factors measured during each fit test.

All controlled negative pressure (CNP) fit tests were accomplished using the modified exercise protocol described in Table II. The FitTester instrument required approximately 10 sec to acquire static measurements of respirator leakage at each specified head position.

Data Analysis

CNP and AA fit factors were log-transformed prior to statistical analyses, which were conducted using Number Cruncher Statistical Systems with $\alpha = 0.05$ for all tests.[12] A Martinez-Iglewicz test of the log-transformed fit factor distributions accepted normality of the CNP data (test value = 1.017), but rejected normality of the AA data (test value = 1.323). Therefore a Kruskal-Wallis One-Way Analysis of Variance on Ranks was used to test for significant differences between fit test exercise protocols, test systems, and assigned respirators. A Kruskal-Wallis Multiple Comparison Z-Value test was used to identify significantly different test exercises within a given fit test protocol.

Results

Summary fit test results are shown as a function of subject assigned mask number and fit test system in Table III. In general, each subject's Mask 1 fit better than his/her Mask 2. A Kruskal-Wallis One-Way Analysis of Variance found that log-transformed CNP median fit factors were significantly lower ($p < 0.0001$) than log-transformed AA median fit factors.

Table III.
Summary Fit Test Results by Assigned Mask and Fit Test System
(N = 210 fit tests for each mask/system combination)

Fit Test System	Mean OA[A] Fit Factor	Median OA Fit Factor	Geometric Mean OA Fit Factor	Geometric Standard Deviation
Mask 1				
CNP[B]	897	1115	808	3.1
AA[C]	4971	6490	4179	4.3
Mask 2				
CNP	422	461	364	3.5
AA	1809	3125	1329	6.7

[A] OA – Overall fit factor
[B] CNP – Controlled Negative Pressure
[C] AA – Ambient Aerosol

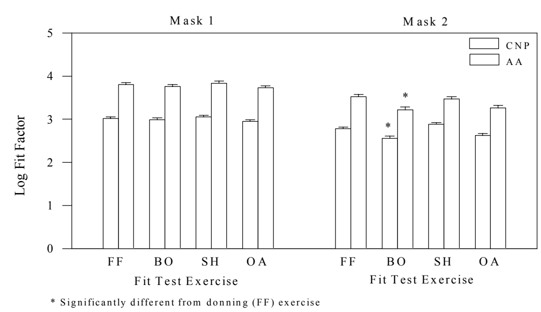


Figure 1. Mean Log-transformed Individual Exercise Fit Factors Measured with Ambient Aerosol Fit Test System using OSHA Protocol (N = 70 fit tests; error bars = 1.0 std. err.)

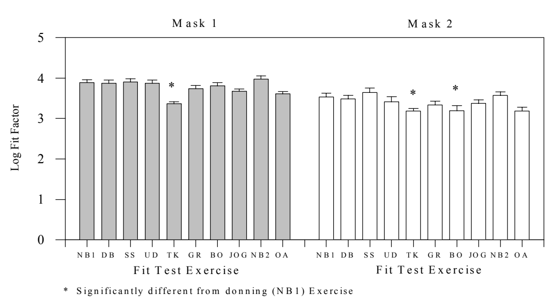
Means of log-transformed individual exercise fit factors for the fit test protocols and systems used in the study are shown in Figures 1 and 2. A Kruskal-Wallis Multiple Comparison Test of the OSHA protocol results for Mask 1 (see Figure 1) found that only the talking exercise generated fit factors that were significantly lower ($p < 0.0001$) than the donning (NB1) fit factors.

For Mask 2, both talking and bend over exercises were significantly lower ($p < 0.0009$) than donning fit factors.

Figure 2 shows fit test results obtained using the modified exercise protocol. No significant differences were detected between Mask 1 individual exercise median fit factors by either the CNP ($p > 0.612$) or ambient aerosol ($p > 0.389$) systems. For Mask 2 data, a Kruskal-Wallis Multiple Comparison Test found that bend over exercise fit factors were significantly lower than their corresponding donning (FF) fit factors for both CNP ($p < 0.0001$) and ambient aerosol ($p < 0.012$) systems.

The first of each subject's three daily ambient aerosol fit tests conducted with each mask included all of the exercises in the OSHA protocol. The remaining two fit tests were conducted using the modified protocol. A Kruskal-Wallis One-Way Analysis of Variance was used to examine differences between the two protocols. For Mask 1 data, log-transformed median overall fit factors measured with the OSHA protocol were significantly lower ($p < 0.023$) than those measured using the modified protocol. Mask 2 results were not significantly different ($p > 0.551$) as a function of fit test protocol.

Figure 2. Mean Log-transformed Individual Exercise Fit Factors Measured with Controlled Negative Pressure (CNP) and Ambient Aerosol (AA) Fit Test Systems using Modified Fit Test Protocol [N = 210 (CNP) and 140 (AA) fit tests; error bars = 1.0 std. err.]



A primary purpose of QNFT is to detect inadequately fitting respirators. An analysis of fit test results as a function of test failure rates by test exercise is presented in Table IV. Ambient aerosol results were analyzed relative to both OSHA and manufacturer recommended pass-fail criterion values.[6,11] The following logic was used to allocate mask failures to specific test exercises. A mask failure was defined as a fit test with an overall (OA) fit factor less than the applicable pass-fail criterion. If the NB1 or FF fit factor was less than the criterion value, the mask failure was attributed to mask donning. Otherwise, the mask failure was attributed to the lowest individual exercise fit factor recorded during the fit test. This logic was applied because the process used to calculate an overall QNFT fit factor as the harmonic mean of individual exercise fit factors assigns the greatest weighting to the lowest individual fit factor measured during the fit test.

In order to examine the effect of donning on measured respirator fit, overall fit factors were transformed into multiples of the OSHA pass-fail criterion value (MCV), with the criterion value established as ten times the test respirator's assigned protection factor. For example, a fit test with an MCV of 2.5 means that the overall fit factor was 2.5 times higher than the required minimum passing fit factor for the test respirator. Based on this logic, a respirator that just passes a fit test would have an MCV of 1.0 (i.e. an overall fit factor of 500 for a full-face respirator would be assigned an MCV = 1.0, as would an overall fit factor of 100 for a half-mask respirator). Tables V and VI show MCV values for all fifteen fit tests completed by each subject with his/her assigned Mask 1 and Mask 2. An MCV of less than 1.0 signifies a failed fit test, as indicated by bold values in the tables.

Discussion

The two OSHA fit test protocols completed with the ambient aerosol fit test system took a substantial portion of the approximate 75 min/day spent with each test subject during this study. Each OSHA protocol involved nine test exercises and required 12 min of test time to complete. The modified fit test protocol required four min test time to complete with the AA system, and approximately two min to complete with the CNP system. These test times do not include time devoted to respirator inspection and setup, donning, initial warm-up, user seal checks, or mask redonning.

The use of two different sizes of the same respirator model for each subject generated a wide range of fit factors over which to evaluate exercise protocol, donning, and fit test system effects on measured respirator fit. The wide range of fit factors was achieved without using artificially induced faceseal or facepiece leaks that may have interfered with mask re-donning. Assigning a second respirator (Mask 2) that differed only by a single size shift also allowed each subject to don both assigned respirators using standard donning techniques. As shown in Table III, each subject's Mask 1 generally fit better than his/her assigned Mask 2. The finding that CNP fit factors were significantly lower than AA fit factors is consistent with other comparison study results.[13-16]

Table IV. Fit Test Failure Rates as a Function of Test System, Mask, and Exercise

Ambient Aerosol Fit Test System						
Mask 1						
	OSHA Pass/Fail Criterion[A]			Pass/Fail Criterion = 1000		
Fit Test Exercise[B]	N[C]	% of Failing Fit Tests	% of Total Fit Tests	N	% of Failing Fit Tests	% of Total Fit Tests
OA	10	100.0	4.8	25	100.0	12.0
Donning	10	100.0	4.8	23	92.0	11.0
DB	---	---	---	1	4.0	0.5
SS	---	---	---	1	4.0	0.5
Mask 2						
	OSHA Pass/Fail Criterion			Pass/Fail Criterion = 1000		
Fit Test Exercise	N	% of Failing Fit Tests	% of Total Fit Tests	N	% of Failing Fit Tests	% of Total Fit Tests
OA	31	100.0	14.8	65	100.0	31.0
Donning	10	32.3	4.7	45	69.3	21.4
BO	18	58.1	8.6	16	24.6	7.6
SH	2	6.4	1.0	1	1.5	0.5
UD	1	3.2	0.5	2	3.1	1.0
Jog	---	---	---	1	1.5	0.5

Controlled Negative Pressure Fit Test System				
Mask 1				
	OSHA Pass/Fail Criterion			Pass/Fail Criterion = 1000 Not Applicable
Fit Test Exercise	N	% of Failing Fit Tests	% of Total Fit Tests	
OA	45	100.0	21.4	
Donning	39	86.7	18.6	
BO	5	11.1	2.3	
SH	1	2.2	0.5	
Mask 2				
	OSHA Pass/Fail Criterion			Pass/Fail Criterion = 1000 Not Applicable
Fit Test Exercise	N	% of Failing Fit Tests	% of Total Fit Tests	
OA	88	100.0	41.9	
Donning	63	71.6	30.0	
BO	22	25.0	10.5	
SH	3	3.4	1.4	

[A] Half-mask = fit factor of 100; full-face = fit factor of 500
[B] See Table II for description of exercises; Donning = NB1 or FF exercise
[C] N = number of fit test failures due to specified exercise out of 210 total fit tests

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Table V. Mask 1 Fit Test Results (Expressed as Multiple of Criterion Value[A]) by Subject, Fit Test System, Test Day, Mask Type, and Trial Number

Sub # / Type[B]	Test System	Test Day / Trial No. 1/1	1/2	1/3	2/1	2/2	2/3	3/1	3/2	3/3	4/1	4/2	4/3	5/1	5/2	5/3
		Multiple of Criterion (Pass/Fail) Value[A]														
1	CNP	4.06	0.30	1.86	2.78	3.34	7.56	0.57	1.42	0.52	3.44	2.39	1.96	1.79	7.28	0.71
FF	AA	13.48	7.44	9.08	15.80	14.96	6.56	16.98	24.60	12.90	12.92	6.04	7.46	13.84	6.02	1.62
2	CNP	7.36	3.90	3.67	8.02	12.68	6.56	17.89	3.12	8.87	20.02	15.10	31.42	24.34	26.05	27.52
HM	AA	26.20	27.40	21.70	85.30	69.90	79.50	30.80	16.80	19.20	47.70	39.50	44.20	128.0	84.10	78.20
3	CNP	0.63	0.65	1.81	0.84	1.31	1.34	3.20	2.75	4.01	1.52	1.38	0.93	2.37	1.97	1.09
FF	AA	14.82	22.80	13.72	8.28	5.68	7.92	9.72	7.84	3.94	5.52	6.14	6.22	17.44	13.78	19.48
4	CNP	21.41	12.32	0.49	19.18	1.39	0.82	0.42	5.95	13.76	34.43	26.05	41.54	17.20	18.70	19.85
HM	AA	35.40	261.0	0.08	88.10	19.60	322.0	3.84	3.80	8.23	53.70	0.07	157.0	233.0	523.0	476.0
5	CNP	3.34	3.45	3.22	3.68	2.61	1.67	0.31	0.29	0.28	2.26	2.61	2.35	4.39	4.86	4.94
FF	AA	19.94	37.00	41.20	7.22	35.20	20.00	13.94	25.40	34.00	3.24	32.60	2.94	9.08	21.20	15.48
6	CNP	0.42	1.81	1.48	1.03	1.50	1.13	0.67	0.69	0.67	2.31	2.26	2.19	2.20	1.00	2.06
FF	AA	10.24	42.60	18.06	7.42	19.36	23.80	1.92	2.20	2.20	11.02	16.36	12.36	12.60	19.44	10.74
7	CNP	18.44	0.32	23.83	31.55	16.24	54.90	19.13	22.44	14.56	10.78	22.85	23.60	22.44	22.53	26.83
HM	AA	16.70	65.20	86.50	38.90	123.00	158.00	8.95	11.80	12.80	30.70	61.70	53.50	73.80	86.60	171.0
8	CNP	4.22	24.57	19.53	11.92	14.76	21.50	15.20	12.92	43.74	30.48	17.61	13.69	16.88	9.22	3.30
HM	AA	28.20	63.80	5.85	83.30	676.0	538.0	100.0	254.0	198.0	147.0	926.0	344.0	58.20	91.30	370.0
9	CNP	37.75	24.59	21.18	43.47	36.98	26.44	21.48	19.76	19.62	20.97	17.83	11.91	27.66	26.50	26.80
HM	AA	54.20	181.0	230.0	29.30	42.80	102.0	3.14	365.0	385.0	107.0	23.10	438.0	83.70	88.60	251.0
10	CNP	3.80	2.74	2.49	37.95	77.13	269.0	56.93	77.41	107.0	1.82	2.63	5.42	32.56	29.60	33.47
HM	AA	226.0	121.0	404.0	12.20	19.50	12.90	26.90	88.30	124.0	12.60	171.00	55.60	5.22	4.54	4.04
11	CNP	0.29	0.15	0.36	2.80	2.45	2.84	0.71	0.93	1.38	0.52	0.54	0.56	0.91	0.52	0.60
FF	AA	5.20	45.40	28.80	11.76	48.20	42.00	19.94	58.80	32.40	7.00	6.90	11.40	15.38	28.00	10.80
12	CNP	17.26	13.03	17.79	19.39	9.46	6.43	1.06	1.10	1.10	6.60	7.30	5.30	22.37	27.52	24.26
HM	AA	133.0	163.0	169.0	24.10	101.0	172.0	38.40	406.0	245.00	91.40	196.0	93.20	9.34	9.68	9.47
13	CNP	2.27	0.86	0.81	2.85	1.77	7.80	0.23	0.09	2.49	0.68	0.75	0.71	2.02	1.30	1.87
FF	AA	25.60	42.20	34.40	7.02	13.78	13.84	22.00	30.20	33.60	20.00	17.22	4.30	5.88	6.56	4.40
14	CNP	1.55	1.66	1.79	1.78	1.00	0.74	0.56	0.05	0.23	0.91	1.20	1.38	0.56	0.23	0.41
FF	AA	0.89	1.20	1.11	12.08	0.58	5.66	4.00	0.45	0.47	7.16	0.37	0.06	0.43	0.05	4.46

[A] Overall fit factor ÷ criterion (pass/fail) fit factor
[B] Mask type: FF = full-face; HM = half-mask

Bold value indicates failed fit test

Table VI. Mask 2 Fit Test Results (Expressed as Multiple of Criterion Value[A]) by Subject, Fit Test System, Test Day, Mask Type, and Trial Number

Sub # Type[B]	Test System	Test Day / Trial No.														
		1/1	1/2	1/3	2/1	2/2	2/3	3/1	3/2	3/3	4/1	4/2	4/3	5/1	5/2	5/3
Multiple of Criterion (Pass/Fail) Value[A]																
1	CNP	1.20	0.56	0.61	0.63	1.02	0.76	0.99	0.40	1.29	0.71	0.50	0.51	0.39	0.23	0.24
FF[B]	AA	31.80	37.20	22.60	19.14	26.80	23.40	10.74	7.12	4.10	7.30	8.86	8.16	6.32	3.78	6.56
2	CNP	2.96	0.95	1.62	1.61	1.37	1.47	0.6	0.56	0.56	2.7	2.58	1.89	0.27	0.3	0.31
HM	AA	14.42	9.6	6.08	15.6	21.6	20.6	12.3	6.98	5.76	18.66	8.68	10.68	6.5	8.66	7.2
3	CNP	1.84	1.75	1.9	4.67	3.91	4.67	8.26	4.03	4.46	1.25	3.11	3.75	3.11	1.93	3.65
FF	AA	14.26	20	17.06	9.6	12.7	9.58	9.54	7.8	11.96	11.66	11.86	15.46	10.76	14.12	11.86
4	CNP	51.98	47.19	0.86	19.03	2.65	0.22	21.16	2.37	15.26	13.87	10.75	15.10	27.52	13.40	19.48
HM	AA	21.70	179.0	236.0	4.06	4.16	15.60	1.24	0.34	147.0	52.00	435.0	272.0	6.80	15.20	11.80
5	CNP	0.65	0.79	0.56	0.79	4.25	1.90	0.36	0.53	0.53	0.79	0.57	0.61	0.37	0.38	0.36
FF	AA	7.50	53.40	0.06	5.46	28.80	35.20	12.36	31.00	27.60	27.80	49.60	44.40	17.58	20.40	44.20
6	CNP	0.88	0.91	0.92	2.20	1.89	1.89	0.71	1.62	0.70	1.03	1.20	1.12	0.89	0.57	0.86
FF	AA	3.24	5.26	5.98	29.40	43.20	32.60	16.24	59.00	67.60	14.46	11.42	17.82	8.12	16.26	13.24
7	CNP	24.94	0.43	0.43	23.99	3.13	0.42	1.43	9.99	0.57	0.43	14.64	0.43	0.25	0.24	0.26
HM	AA	8.14	26.20	38.10	13.90	0.72	12.30	0.28	4.75	11.70	1.85	0.49	5.91	0.93	0.91	0.51
8	CNP	4.58	20.02	19.30	12.33	13.75	16.08	39.63	2.26	17.16	18.60	25.41	13.32	6.97	0.64	17.57
HM	AA	9.28	41.00	9.60	21.40	17.90	37.10	50.30	235.0	292.00	14.80	8.92	53.40	5.26	6.16	7.47
9	CNP	0.20	0.42	0.60	52.87	29.85	22.99	5.28	5.17	5.55	8.43	7.42	5.21	1.77	6.53	5.41
HM	AA	4.20	3.03	0.83	8.79	5.46	4.90	3.36	10.80	3.57	15.10	18.40	18.50	6.33	7.16	11.30
10	CNP	2.61	2.42	3.04	3.25	3.27	3.74	1.57	1.35	1.50	17.76	8.48	7.52	0.90	5.56	4.03
HM	AA	2.53	2.82	1.90	113.0	48.40	17.90	8.25	6.90	5.59	3.34	5.66	4.03	26.80	26.70	27.00
11	CNP	3.02	2.21	2.06	0.73	0.71	0.91	1.08	2.05	1.95	1.72	2.14	2.40	2.82	0.90	0.37
FF	AA	15.14	87.00	25.40	7.98	7.02	5.40	6.18	12.08	5.40	4.74	16.98	16.42	0.22	0.40	0.48
12	CNP	1.23	0.43	0.42	0.40	0.41	0.40	1.32	1.75	0.33	0.32	0.24	0.34	0.89	0.42	0.43
HM	AA	0.79	0.54	0.22	0.34	0.56	0.65	0.52	0.17	0.40	0.30	0.16	0.14	0.26	1.23	0.19
13	CNP	1.93	0.93	4.58	1.39	1.46	1.09	1.17	1.24	1.79	2.29	3.88	1.82	3.18	1.11	4.08
FF	AA	5.90	6.56	6.50	7.94	7.08	14.10	3.90	2.02	2.52	9.24	15.94	7.48	10.22	12.66	3.08
14	CNP	0.60	0.57	0.63	0.35	0.31	0.37	0.33	0.39	0.35	0.47	0.28	0.38	1.00	0.46	0.27
FF	AA	0.23	0.59	0.87	14.00	8.46	2.26	2.48	4.32	1.65	11.46	12.02	14.94	0.44	0.01	7.42

[A] Overall fit factor ÷ criterion (pass/fail) fit factor

[B] Mask type: FF = full-face; HM = half-mask

Bold value indicates failed fit test

Table VII.
Results of Kruskal-Wallis One-Way ANOVA of Log-Transformed Fit Factors

Response Variables	X^2 Value	Z-Value	Prob., p	Decision[A]
Overall Fit Factors measured by CNP and AA systems	226.9		0.0000	Reject
Mask 1 OSHA Protocol Individual Exercise AA Fit Factors	72.06		0.0000	Reject
Talking Exercise		6.14		
Mask 2 OSHA Protocol Individual Exercise AA Fit Factors	72.06		0.0008	Reject
Talking Exercise		4.02		
Bend over exercise		2.35		
Mask 1 Modified Exercise AA Fit Factors	3.01		0.389	Accept
Mask 2 Modified Exercise AA Fit Factors	10.87		0.012	Reject
Bend over exercise		2.70		
Mask 1 Modified Exercise CNP Fit Factors	1.81		0.612	Accept
Mask 2 Modified Exercise CNP Fit Factors	24.30		0.00002	Reject
Bend over exercise		2.33		
Mask 1 OSHA Protocol vs Modified Protocol OA Fit Factors	7.57		0.023	Reject
OSHA protocol		2.47		
Mask 2 OSHA Protocol vs Modified Protocol OA Fit Factors	1.19		0.551	Accept
Mask 1 OSHA (minus TK exercise) vs Modified Protocol AA Fit Factors	3.271		0.195	Accept

[A] Ho: All medians are equal; ∀ = 0.05 level of significance

Based upon the conceptual analysis of the fit test process presented earlier, and the specified manner in which test exercises are conducted, the nine exercises included in the OSHA fit test protocol appear to be designed to measure respirator leakage as follows. The NB1 exercise assesses the fundamental fit that is achieved when the respirator is donned. The DB exercise simulates an increased workrate, which increases the inspiratory pressure gradient across the respirator. The increased inspiratory pressure should increase the leak rate through existing respirator leakage paths. Since the flowrate through the respirator's filtration media also increases with pressure gradient, a substantial change in measured respirator fit would not be expected. The DB exercise fit factors measured during this study did not differ significantly from their corresponding NB1 donning fit factors.

The apparent purpose of the SS, UD, TK, and BO exercises is to assess transient respirator leakage associated with head, mouth, or mask movement during the fit test. Several of these exercises involve pausing at an extreme head position for a full breath cycle, so that any resulting seal break would be coupled with an inhalation to create a transient leak. The GR and Jog exercises seem to be aimed more towards assessing the tendency of the respirator to shift its fundamental fit. These exercises are followed by the NB2 exercise, which should pick up such shifts.

Of the nine OSHA protocol exercises measured with the ambient aerosol system, only the TK and BO exercises significantly reduced measured respirator fit below donning levels. The finding that the talking exercise generates significantly lower ambient aerosol fit factors has been reported in other studies.[14,17] The apparent logic of this finding is not consistent with the actual dynamics of the talking exercise. Talking, with its associated mouth movement, occurs only during periods of exhalation when the respirator facepiece is positively pressurized. Aerosol penetration into air-purifying respirators occurs during inhalation, when talking is difficult. Transient leakage associated with the talking exercise should therefore be out of, rather than into, the respirator.

An observation made prior to this study may explain the apparent paradox of the significantly lower ambient aerosol fit factors reported during talking, when transient leakage should be out of, not into, the respirator. When placed in count mode with its sampling time-lag factored out, the Portacount instrument typically reports higher particle counts during the exhalation portion of the breathing cycle. This observation is consistent with the concept of aerosol streamlining reported by other researchers.[18,19] Upon entering a respirator facepiece through a leakage path during inhalation, an ambient aerosol particle encounters two radically different airflow streams. The Portacount's in-mask sample flowrate is a nominal 700 ml/min.[20] The inhalation airflow stream into the nose and mouth typically ranges from 30,000-50,000 ml/min, depending on subject workrate.[3] Such differential flow rates create a strong tendency for penetrating particles to be carried into the lungs during inhalation, a phenomenon called streamlining. Particle migration to the aerosol sampling probe would be more probable during exhalation, when a more uniformly mixed exhaled flow is directed at the probe. Since the talking exercise involves exhalation periods that are substantially longer than corresponding inhalation periods, the significantly lower talking exercise fit factors reported by the Portacount may be a sampling artifact due to the apparent increased in-mask sampling efficiency during exhalation. This increased sampling efficiency is apparent even though some of the aerosol penetrating during inhalation is lost to lung deposition prior to exhalation. For these reasons, the talking exercise was not included in the modified exercise protocol used in this study.

In the Mask 1 OSHA protocol data (see Figure 1), only the talking exercise generated significantly lower fit factors. The Mask 1 overall fit factors measured using the OSHA protocol were significantly lower than the aerosol fit factors measured using the modified protocol. This finding seems to indicate that the OSHA protocol was more efficient than the modified protocol in detecting mask leakage. However, an examination of Table IV shows that the talking exercise was not responsible for aerosol fit test failures. Even at the more stringent pass/fail fit factor of 1000, none of the 25 Mask 1 or 65 Mask 2 failing aerosol fit tests had the talking exercise as the lowest measured exercise result. When the talking exercise results are factored out of the Mask 1 aerosol data, there is no significant difference ($p > 0.195$) between the OSHA and modified protocol results for Mask 1. Mask 2 aerosol results, which generally showed more respirator leakage, did not differ significantly ($p > 0.551$) as a function of fit test protocol. These findings seem to indicate that the increased in-mask sampling efficiency associated with the talking exercise is more apparent at relatively high fit factors. This finding is supported by the fact that the modified exercise protocol's aerosol fit test failure rates were the same or higher than the OSHA protocol's failure rates for both Mask 1 (5.8% vs. 2.9%) and Mask 2 (15.0% vs. 14.3%).

By contrast, the effect of the bend over exercise was more apparent at lower fit factors. For the better fitting respirators (Mask 1), bend over exercise fit factors did not differ significantly from the donning fit factors measured by both fit test systems. With Mask 2, the bend over exercise produced significantly lower fit factors with both fit test systems. Table IV shows that the bend over exercise produced the lowest fit factor in 58% of the 31 aerosol fit test failures, and 25% of the 88 CNP fit test failures reported for Mask 2. Based on these results, the BO exercise appears to be an effective indicator of poor mask fit.

Table IV shows that mask donning was the greatest single cause of the failing fit tests measured during this study. Much of the variation in test results that is apparent in Tables V and VI can be attributed to mask donning. The results of this study indicate that mask donning affects respirator fit much more than fit test exercises do. These findings are not consistent with the currently specified OSHA fit test protocol, which places a high emphasis on test exercises while requiring only a single mask donning. The number of fit test failures recorded during this study also indicates that the user seal checks accomplished by each subject after each donning were not preventive of mask failure.

Conclusions

Respirator donning has a greater effect on respirator fit than do fit test exercises. The only exercises that produced fit factors significantly lower than donning fit factors were the talking and bend over exercises. The lower fit factors produced by the talking exercise appear to be more consistent with sampling artifact than with actual exercise dynamics. The bend over exercise appears to be predictive of poor mask fit.

A modified aerosol fit test protocol made up of fewer, more targeted fit test exercises identified unacceptable respirator fit as effectively as the longer OSHA specified protocol. The controlled negative pressure fit test system, using the same modified test protocol, measured significantly more leakage in test respirators than the ambient aerosol system using either protocol. Actual test times for the modified fit test protocol were 18% (controlled negative pressure system) and 33% (ambient aerosol system) of the time required to complete the current OSHA protocol. The time saved by reducing the number of fit test exercises could be better utilized to test more than a single mask donning.

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