Comparison of Six Quantitative Fit Test Methods Using Full Facepiece Respirators with a Measurement of Exposure

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Abstract

A study is described comparing fit factors from six quantitative fit-tests for full facepiece respirators to the concentration of 1,1,2-trichloro-1,2,2-trifluoroethane (Freon®-113) in the wearer's end-exhaled breath during a 30-minute simulated workplace test. The methods were: (1) continuous high flow, deep probe, generated aerosol (CHD); (2) continuous low flow, flush probe, generated aerosol (CLF); (3) controlled negative pressure (CNP); (4) long duration (30 minute) ambient aerosol (AALong); (5) short duration (8 minute) ambient aerosol (AA); and (6) high-flow, deep probe, 8-minute duration ambient aerosol (HDAA). The first two methods utilized corn oil and a forward light scattering photometer. The CNP used the Occupational Health Dynamics Fit Tester 3000. The last three used the TSI PortaCount Plus.™ The method fit factors were then individually correlated with the Freon-113 exposures using the coefficient of determination, r^2. The potential for Freon-113 being absorbed through the skin and eliminated in the exhaled breath was also evaluated. The study found (1) for all methods except the controlled negative pressure method, a statistically significant correlation was found between total Freon-113 exposure dose and method fit factors (r^2 values were: AALong = 0.26, AA= 0.11, HDAA = 0.10, CHD = 0.09, CLF = 0.20, CNP =< 0.01); (2) the amount of Freon-113 in the exhaled breath due to skin absorption ranged from 0.03 to 0.52 parts per million (ppm) with a mean of 0.16 ppm; (3) approximately 24 percent of all end-exhaled air samples were less than the limit of detection.

Introduction

A recent study compared quantitative fit factors from half-mask respirators using high efficiency organic vapor cartridges to an actual measure of exposure using 1,1,2-trichloro-1,2,2-trifluoroethane (Freon®-113)(Coffey, et. al., 1998a). That study looked at six quantitative fit-test methods, and found the following coefficients of determination (r^2): 1.) 0.81 for the continuous high flow, deep probe, generated aerosol; 2.) 0.78 for the six exercise ambient aerosol; 3.) 0.70 for the 30 minute 17 exercise ambient aerosol; 4.) 0.41 for the continuous low flow flush probe generated aerosol; 5.) 0.36 for the controlled negative pressure; and 6.) 0.20 for the exhalation valve discharge generated aerosol. All of the models had slopes significantly different than zero ($p<0.05$). The first purpose of this study was to determine if it was feasible to correlate fit factors from these methods with the measured levels of Freon-113 in exhaled breath when full facepiece respirators were tested at the same level seen in the previous study. The exhalation valve discharge method was not included in this study ue to time and resource constraints, its having the lowest coefficient of determination, and its impracticability in the field (i.e., adapting the facepiece to collect the exhaled breath).

The ambient aerosol condensation nuclei method as commonly used employs a low sampling rate (approximately 0.7 Lpm) and a flush-mounted probe. The data from previous studies of in-facepiece sampling bias suggest this method may perform even better if the sampling probe was located deeper into the facepiece and a higher sampling rate was used (Myers and Hornung, 1993; Myers et al., 1986, Coffey, et. al., 1998a). The second purpose of this study was to determine the level of correlation between fit factors of a new facepiece fit-test method (high flow, deep probe, ambient aerosol) and the exhaled breath concentrations of Freon-113.

Materials and Methods

Respirators

The full facepiece respirators equipped with organic vapor/P100 cartridges listed in Table 1 were used in this study. The respirator model worn by a subject for a particular test was selected at random. If a facepiece model was available in multiple sizes, the subject was given a size based on his/her face size (Table 1).

Table 1. List of respirators, sizes, and corresponding facial sizes

Manufacturer	Facepiece Model	Available Sizes	Face Width (mm)	Face Length (mm)
Mine Safety Appliances (MSA, Pittsburgh, PA)	Ultra-Twin	Small	93.5 to 113.5	117.5 to 126.5
MSA	Ultra-Twin	Medium	103.5 to 123.5	126.5 to 144.5
MSA	Ultra-Twin	Large	113.5 to 133.5	144.5 to 153.5
North Safety Products (Cranston, RI)	7600-8AS	Small	113.5 to 133.5	1175 to 135.5
North	7600-8A	Medium/Large	103.5 to 133.5	136.5 to 153.5
Scott Aviation (Lancaster, NY)	652-S	Small	93.5 to 113.5	117.5 to 126.5
Scott	652-L	Large	103.5 to 123.5	126.5 to 144.5
Scott	652-XL	Extra large	113.5 to 133.5	144.5 to 153.5
Willson Safety Products (Snow Hill, NC)	1600 Basic Tite-Seal	One size fits all	93.5 to 133.5	117.5 to 153.5
3M (St. Paul, MN)	7800S	Small	93.5 to 113.5	117.5 to 126.5
3M	7800M	Medium	103.5 to 123.5	126.5 to 144.5

3M	7800L	Large	113.5 to 133.5	144.5 to 153.5
Survivair, Inc. (Santa Ana, CA)	Series 4000	Small	93.5 to 113.5	117.5 to 135.5
Survivair	Series 4000	Large	103.5 to 113.5	126.5 to 153.5
Cabot Safety Corp. (Southbridge, MA)	7 Star	One size fits all	93.5 to 133.5	117.5 to 153.5
Lab Safety Supply, Inc. (Janesville, WI)	24734	One size fits all	93.5 to 133.5	117.5 to 153.5
Glendale Protective Technology (Lakeland, FL)	F710	Small/Medium	93.5 to 113.5	117.5 to 135.5
Glendale	F710	Medium/Large	103.5 to 113.5	126.5 to 153.5
United States Navy (Washington, DC)	MCU-2P	Small	93.5 to 113.5	117.5 to 126.5
Navy	MCU-2P	Medium	103.5 to 123.5	126.5 to 144.5
Navy	MCU-2P	Large	113.5 to 133.5	144.5 to 153.5

Subjects

A total of 37 subjects participated in this study. The subjects had face lengths ranging from 93.5 millimeters (mm) to 133.5 mm and face widths ranging from 117.5 mm to 153.5 mm. Nineteen of the subjects were females and 18 were males. Included among the subjects were one African-American male, and one African-American female. The majority of the test subjects were experienced in wearing respirators and performing fit tests. Each subject was provided with the manufacturer's instructions on the proper donning and use of the respirator. Verbal instructions were given to the subjects regarding their performance of the quantitative fit tests and simulated workplace tests. Each subject performed each of the six quantitative fit-test methods at least 3 times. When time and resource constraints permitted, additional tests were performed using some methods. Every subject did not perform every quantitative fit-test method with every respirator model.

Subject Characterization

In order to determine if a correlation existed between fit factors and total Freon-113 exposure dose (i.e., the amount of Freon-113 in part per million- minutes (ppm-min) which a subject breathed over the 30-minute simulated workplace test), a relationship between end-exhaled breath samples and exposure concentrations had to be established. This was done by developing a straight-line characterization curve for each subject (Coffey et al., 1998b). A characterization test consisted of a subject wearing a flexible cup covering the nose and mouth (nose cup) connected to a system that supplied either pure Grade D (Compressed Gas Association, 1989) quality breathing air or Grade D quality breathing air containing 500 parts per million (ppm) of Freon-113 and 15 to 20 milligram per cubic meter (mg/m^3) of corn oil aerosol (Figure 1). For the first two

minutes, the subject breathed Grade D air containing 500 ppm Freon-113 and 15 to 20 mg/m^3 corn oil. For the next twelve minutes, the subject breathed Grade D quality air. At fourteen minutes into the test, the subject started to breathe the Grade D air containing 500 ppm Freon-113 and 15 to 20 mg/m^3 corn oil and continued to do so for two minutes. For the next twelve minutes, the subject again breathed Grade D air. At twenty-eight minutes into the test, the subject breathed the Grade D air containing 500 ppm Freon-113 and 15 to 20 mg/m^3 corn oil and continued to do so until the end of the 30 minute test. This protocol is summarized in Table 2. The three 2-minute 500 ppm exposure periods used in this protocol resulted in the subject receiving a 100 ppm 30-minute time-weighted exposure. This exposure was the highest possible exposure that a subject would receive since the chamber contained 1,000 ppm Freon-113 and the respirator was required to have a minimum fit factor of 10.

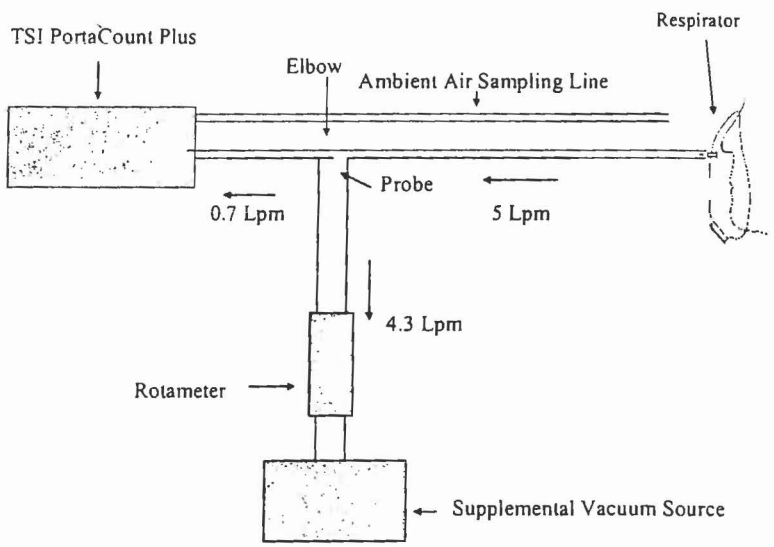

Figure 1. Schematic of High-flow Deep Probe PortaCount Plus test system.

Throughout each characterization test, the subject performed the simulated workplace movements listed in Table 2. After each test the subject provided an end-exhaled air sample as described below. Three replicates of the characterization test were done on each subject on different days to compute the individual exhaled breath characterization curves and equations.

Skin Absorption

Previous research has demonstrated that Freon-113 can be absorbed into the blood through the skin and eliminated through the exhaled breath (Decker and Crutchfield, 1993; Coffey et al., 1998b). Since this project involved full facepiece respirators and possibly fairly high protection factors, the amount of Freon-113 being absorbed through the skin during the simulated workplace testing had to be reduced to the fullest extent possible to allow low concentrations of Freon-113 from respiratory exposure to be analyzed. To achieve this, it was decided to examine the ability of a Tyvek®/Saranex® 23-P suit, with elastic respirator hood and boots (Tyvek® suit) (Mar Mac Manufacturing Company, Inc., model number 42124, McBee, SC) and natural lined latex gloves (Best Manufacturing Company, model VM, Menlo, GA), to minimize or eliminate the contribution

of skin absorption to the end-exhaled breath concentration of Freon-113. The Tyvek® suits were available in five sizes (small, medium, large, extra large and XX-large) and the gloves were available in three sizes (small, medium, and large). The subject selected the size of each item which was the most comfortable for him/her. The suits and gloves were permeation tested against 1,000 ppm Freon-113 (Aldrich Chemical Company, catalog number 24,281-0, Milwaukee, WI) vapor. No permeation was found after 48 hours of exposure.

Table 2. Exposure scenario for characterization tests

Time into Simulated Workplace Test (min)	Exposure
0 to 2	Freon-113 (500 ppm) and Corn Oil (15 -20 mg/^{3})
2 to 14	Grade D air
14 to 16	Freon-113 (500 ppm) and Corn Oil (15 -20 mg/^{3})
16 to 28	Grade D air
28 to 30	Freon-113 (500 ppm) and Corn Oil (15 -20 mg/^{3})

Due to time and resource restrictions, only six out of the 37 subjects were selected at random to participate in the skin absorption testing. The skin absorption test procedure consisted of the subject donning a suit, gloves, and a Survivair (Survivair, Inc., Santa Ana, CA) 9685 Series Sigma Hip-pac™ Pressure-demand Supplied-Air Respirator with 15-minute escape cylinder in a clean area. The subject then entered a 4' x 6' x 7' laboratory chamber (Dynatach Frontier Corporation, Series 200, Albuquerque, NM) containing a spatially and temporally uniform concentration of 1,000 ppm of Freon-113. The subject remained in the chamber for 30 minutes and performed the exercises listed in Table 3.

Table 3. Simulated workplace movements.

Movement	Duration (Minutes)	Movement	Duration (Minutes)
Bending	2	Reaching from side to side	2
Hanging IV bag	1	Reaching from waist to over head	2
Inserting syringe	1	Talking out loud	2
Picking up 15 lb. weight	2	Nodding and turning head	2
Twisting body	2	Stand and talk out loud	2
Simulating opening and closing doors	1	Reach over head	1
Sitting and talking out loud	3	Work on simulated waist high control panel	1
Bending at waist	3	Walking in place	1
Looking left and right	2		

After 30 minutes, the subject left the chamber and proceeded to a clean area where he/she removed the respirator, suit, and gloves. The subject provided an end-exhaled air sample as described under the end exhaled air sampling procedure section. The skin absorption test was conducted three times on different days for each subject.

Fit-test Methods

Thirty subjects performed each method at least three times for a minimum of 90 tests per method. Some subjects performed more than three replicates per method. The subjects wore the respirators in the laboratory chamber containing a spatially and temporally uniform concentration 1,000 ppm Freon-113 and either 15 to 20 mg/m^3 corn oil aerosol (specified mass median aerodynamic diameter of 0.5 - 0.7 micrometers) for the continuous high flow deep probe (CHD) and continuous low flow, flush probe (CLF) tests or ambient aerosol for the 30-minute duration ambient aerosol (AALong) tests. The concentration of Freon-113 inside was monitored continuously during the time the subject was in the chamber. The fit factors from each of these methods were then compared to the subjects' Freon-113 exposure. The controlled negative pressure (CNP); the high-flow, deep probe ambient aerosol (HDAA); and short-duration (6 minute) ambient aerosol (AA) methods entailed performing a fit-test before and after entering the laboratory chamber. This was done to see if the degree of correlation between fit factors obtained and exposure would increase by adding a post-chamber fit-test because the fit of the respirator could have changed during the simulated workplace test. Based on service life testing, the respirator cartridges were changed after every other test.

CHD Method

The in-facepiece sampling flowrate for the CHD method was 5 L/min. The method of detection for the corn oil was a light scattering photometer. The throat of the probe was located ½ – ¾ inch away from the subject's mouth. This method lasted thirty minutes with the subject inside the laboratory chamber executing the movements listed in Table 3. A total of 185 CHD tests were conducted.

AA Method

The AA method was done outside the chamber and measured the ambient aerosols inside and outside of the respirator to determine the fit factor. A condensation nuclei counter inside the TSI PortaCount Plus™ detected the aerosols, with the probe location flush against the respirator wall, halfway between the subject's nose and mouth. The method entailed the subjects performing six movements for approximately one minute each: 1) normal breathing while holding the head forward and motionless, 2) deep breathing, 3) normal breathing while turning the head side to side, 4) normal breathing while moving the head up and down, 5) reading the rainbow passage (TSI, Inc., 1991), and 6) normal breathing while holding the head forward and motionless. Two procedures were used for the AA method. In the first procedure used in the half-facepiece study, the AA method was performed only prior to a chamber fit-test (i.e., a CHD, CLF, or AALong test). Performing the AA method only before a chamber fit-test could have put the method at a disadvantage because it would not be able to measure a change in the fit of a facepiece while the subject was in the chamber. To determine if this was the case, the AA method was performed prior to and immediately after a chamber fit-test in the second procedure. In this procedure, the average of the two AA tests was used in the analysis. A total of 88 AA tests were conducted. Two of the AA tests had to be deleted from the data set due to equipment malfunction and could not be repeated.

CLF Method

The CLF method used an in-facepiece sampling flowrate of 1.1 L/min. The probe location was flush

against the respirator wall, halfway between the subject's nose and mouth. The method of detection for the corn oil was a light scattering photometer. This method lasted 30 minutes with the subject inside the chamber performing the movements listed in Table 3. A total of 111 CLF methods were conducted.

CNP Method

The CNP method used the FitTester 3000 NPS™(Occupational Health Dynamics, Birmingham, AL). This method was conducted by sealing the air-purifying paths into the respirator through the use of special test adapter manifold(s) installed into the respirator, which replaced the normal air-purifying element(s). The manifold(s) had a valve which provided a breathing path for the test subject between tests and ports for the measurements of flow and pressure. The inhalation valve(s) of the respirator was either propped open or removed. To start a test, the subject closed his/her mouth and the manifold valve and held his/her breath (for approximately 10 seconds); which temporarily sealed the back of the respirator. A pump and a control valve were used to exhaust air from the temporarily sealed facepiece at a rate that was controlled to generate and maintain a selected negative pressure inside the respirator. With the pressure held constant, the exhaust flow equaled the mask leakage flow rate, which was used as an index of respirator face seal fit. This leak rate was determined with the subject facing forward (both before and after vigorously shaking his/her head while yelling for approximately 3 seconds) and bent over. This was done in accordance with directions provided by Dr. Clifford Crutchfield, the developer of the CNP (Crutchfield, 1997 e-mail). At the conclusion of the method the adapter(s) was removed and replaced by an organic vapor/P100 air purifying element(s). A total of 116 CNP methods were conducted. The CNP method was performed before and after a chamber test and the average of the two tests was used in the analysis.

AALong Method

The AALong method used the TSI PortaCount Plus quantitative fit-test system (TSI Incorporated, St. Paul, MN) in the chamber with a concentration of 1,000 ppm Freon-113. Ambient aerosols inside and outside of the respirator were measured to determine the fit factor. A condensation nuclei counter inside the PortaCount Plus was used to detect the aerosols, with the probe location flush against the respirator wall, halfway between the subject's nose and mouth. This method lasted 30 minutes with the subject executing the movements listed in Table 3. A total of 183 AALong tests were conducted.

HDAA Method

For the HDAA method, a TSI PortaCount Plus, an in-mask sampling flowrate of 5 L/min., and a probe depth of approximately one-half inch were chosen. The TSI PortaCount Plus has a non-adjustable sample flowrate of 0.7 L/min. (TSI, 1991). Therefore, an additional 4.3 liters of sample flow had to be combined with the 0.7 L/min. from the PortaCount Plus to obtain the total in-facepiece sampling rate of 5 L/min.

The additional 4.3 L/min. flowrate was obtained by using a supplemental vacuum source that was connected to a flowmeter (Cole-Parmer Instrument Company, catalog number P-32460-46, Vernon Hills, IL) and the PortaCount Plus, as shown in Figure 1. The ¼-inch white polypropylene elbow (Cole-Parmer, catalog number P-06383-10) connecting the supplemental vacuum source to the facepiece was modified in such a way as to also hold the probe for the in-facepiece sampling tube of the PortaCount Plus. In consultation with TSI, it was determined that the inlet of the probe did not have to be designed for isokinetic sampling.

The HDAA method was performed prior to and immediately after a chamber fit-test in the second

procedure. In this procedure, the average of the two AA tests was used in the analysis. A total of 88 HDAA tests were conducted. Two of the HDAA tests had to be deleted from the data set due to equipment malfunction and could not be repeated.

Method Comparison Test Procedure

Prior to beginning a simulated workplace test, each subject entered a clean area and donned a randomly selected respirator model. The subject then performed one of the following testing regimens:

Testing Regimen 1

Subject performed the AA method mentioned above. If the subject did not attain a fit factor of at least 10, he/she was given a different size of the same respirator model or another brand selected at random. This was repeated until the required fit factor was achieved. The subject then put on a Tyvek suit and latex gloves and proceeded to the testing chamber. Once inside the chamber, the subject did either the CHD or the CLF method. After thirty minutes, the subject exited the chamber, removed the suit and gloves, proceeded to a clean area. The subject continued to wear the respirator for at least two minutes before removing it to allow any possible off-gassing of Freon-113 from their clothes to cease. The subject then provided an end-exhaled air sample as described under the end exhaled air sampling procedure section.

Testing Regimen 2

Subject performed the AA method mentioned above. If the subject did not attain a fit factor of at least 10, he/she was given a different size of the same respirator model, or another brand selected at random. This was repeated until the required fit factor was achieved. The subject then put on a Tyvek suit and latex gloves and proceeded to the testing chamber. Once inside the chamber, an AALong method was done. After thirty minutes, the subject exited the chamber, removed the suit and gloves, and proceeded to a clean area. Without disturbing the fit of the respirator, a second AA method was performed. The subject then removed the respirator, and provided an end-exhaled air sample as described under the end exhaled air sampling procedure section.

Testing Regimen 3

Subject performed the CNP method mentioned above. If the subject did not attain a fit factor of at least 10, he/she was given a different size of the same respirator model, or another brand selected at random. This was repeated until the required fit factor was achieved. The subject then put on a Tyvek suit and latex gloves and proceeded to the testing chamber. Once inside the chamber, either a CLF or CHD method was done. After thirty minutes, the subject exited the chamber and removed the suit and gloves, proceeded to a clean area. Without disturbing the fit of the respirator, a second CNP method was performed. The subject then removed the respirator, and provided an end-exhaled air sample as described under the end exhaled air sampling procedure section.

Testing Regimen 4

Subject performed the HDAA method mentioned above. If the subject did not attain a fit factor of at least 10, he/she was given a different size of the same respirator model, or another brand selected at random. This was repeated until the required fit factor was achieved. The subject then put on a Tyvek suit and latex gloves and proceeded to the testing chamber. Once inside the chamber, the subject performed the simulated workplace test. After thirty minutes the subject exited the chamber, removed the suit and

gloves, and proceeded to a clean area. Without disturbing the fit of the respirator, a second HDAA method was performed. The subject then removed the respirator, and provided an end-exhaled air sample as described under the end exhaled air sampling procedure section. Each subject performed the HDAA test in triplicate. Table 4 is a description summary of the methods.

Table 4. Description of Fit-Test Methods

Fit-test	Description
CLF[A] (continuous low flow with flush probe)	Challenge was an oil aerosol with 0.6 mass median aerodynamic diameter (MMAD) generated in a test chamber. Detector was light scattering photometer. Aerosol was sampled from facepiece cavity at 1 liter/minute from a probe mounted flush with inside wall.
CHD[A] (continuous high flow with deep probe)	Challenge was an oil aerosol with 0.6 MMAD generated in test chamber. Detector was light scattering photometer. Aerosol was sampled from facepiece cavity at 5 liter/minute using a probe deeply inserted into facepiece above upper lip. Incorporates the deep probe and high sampling rates to minimize sampling bias.[(8)]
CNP[B] (controlled negative pressure)	Based on the principle of controlled negative pressure in which the volumetric leak rate of air into the facepiece was measured while subject held breath.
AA[C] (short duration ambient aerosol)	Ambient aerosol was used as challenge. Aerosol was sampled from facepiece cavity at 0.7 liter/minute from a probe mounted flush inside facepiece wall. Performed before and after a simulated workplace test in chamber.
AAlong[A,D] (30 minutes ambient aerosol)	Ambient aerosol was used as challenge. Aerosol was sampled from facepiece cavity at 0.7 liter/minute from a probe mounted flush inside facepiece wall. The AA test modified to be conducted in Freon-113 chamber simultaneously with the 30 minute exposure to Freon-113. Oil aerosol was not generated in the chamber during this test.
HDAA[B,D] (high flow deep probe ambient aerosol)	Ambient aerosol was used as challenge. Aerosol was sampled from facepiece cavity at 5 liter/minute using a probe deeply inserted into facepiece above upper lip. Incorporates the deep probe and high sampling rates to minimize sampling bias.[(Myers, 1986))] Performed before and after a simulated workplace test in chamber.

[A]Fit-testing was conducted simultaneously with Freon-113 challenge of respirator
[B]Fit-testing was conducted immediately before and after Freon-113 challenge of respirator without respirator being removed and redonned
[C]Available commercially as the FitTester 3000 NPS (Occupational Health Dynamics, 4518 Valleydale Road, Suite 102, Birmingham, AL 35242-4635)
[D]Available commerically as the PortaCount Plus (TSI Inc., P.O. Box 64394, St. Paul, MN 55164-4394)

End Exhaled Air Sampling Procedure

Thirty minutes after completing a chamber test, the subject provided an end-exhaled air sample. The end-exhaled air sample consisted of taking a deep breath through his/her nose, putting on a nose clip (Vacu•Med, catalog number 1008, Ventura, CA), and exhaling as long and as hard as possible into a sampling apparatus. The sampling apparatus consisted of a Vacu•Med 1026 cardboard mouthpiece; Vacu•Med 1084 adapter; Vacu•Med 1011 Clean Bor tubing; K270 K-valve, T-version; and a silicone stopper equipped with a fitting,

tubing, and clamp which fit into the K-valve. The design of the sampling apparatus allowed only the last 25 mL of expiration to be collected. Since the subject exhaled as long and as hard as possible, the last 25 mL of the exhaled breath sample is alveolar air. Alveolar air would contain the highest concentration of Freon-113 in the exhaled air. Analyzing alveolar air allows lower exposure levels of Freon-113 to be measured and provide more consistent results than using the entire exhaled breath.

The end-exhaled air samples were analyzed using a Hewlett®-Packard Model 5890 gas chromatograph (Agilent Technologies, Palo Alto, CA) equipped with a 5972A mass selective detector. The gas chromatograph was calibrated with standards of 0.05, 0.5, and 1.0 ppm. The limit of detection was 0.005 ppm , the limit of quantification was 0.015 ppm, and the coefficient of variation was 0.03. The coefficient of variation for the entire end-exhaled breath sampling method was determined to be 0.12, which was linear over the concentration range seen in the study.

Statistical Analysis

Subject Characterization Testing

End-exhaled air concentration (at 30 minutes post-exposure) was proportional to the Freon-113 exposure concentration and could be expressed by the relationship, $Y = k X$ where Y is the end-exhaled air concentration, X is the exposure concentration, and k is a proportionality constant that differs for each subject. The characterization equation was determined through simple linear regression. All end-exhaled breath samples found to be less than the limit of detection were set equal to one-half the limit of detection for analysis purposes.

Method Comparison Testing

The fit factors obtained from each of the six quantitative fit-test methods were correlated to the total Freon-113 exposure dose in ppm-min. As in the half-facepiece study, a correlation existed if the slope of the model was found to be different than zero (i.e., the total Freon-113 exposure dose systemically varied with differences in the method fit factor). A slope of zero would mean the slope of the line was horizontal and total Freon-113 exposure doses did not vary in a predictable manner with differences in the method fit factors. The value of the coefficient of determination did not determine if there was a significant correlation.

The total Freon-113 exposure dose was determined by the analysis of the end-exhaled air sample. First, the contribution of skin absorption was subtracted from the end-exhaled air sample Freon-113 concentration. For the six subjects who participated in the skin absorption testing, their individual values were used. For the 31 subjects who did not perform the skin absorption testing, the average (0.16 ppm) of the six who did was used. The adjusted end-exhaled breath concentration was converted into a Freon-113 exposure level through the use of the subject's characterization equation. The total Freon-113 exposure dose was calculated by multiplying this exposure level by 30 minutes (the time the subject was in the chamber). The maximum value for the total Freon-113 exposure dose was 30,000 ppm-min (1,000 ppm times 30 minutes). This would have occurred if the respirator did not provide any protection (protection factor = 1). This would be unlikely since the subject had to have a minimum fit factor of 10 with a particular respirator before being allowed to proceed with the method comparison testing in the chamber.

The correlation of the fit factors and total Freon-113 exposure dose was accomplished using simple linear regression. Six linear regression models (one each for AA, HDAA, CHD, AALong, CLF, and CNP methods) were developed from all the fit factor data for each method. In addition, eight different subsets of fit factors were correlated to the total Freon-113 exposure dose. They were: (1) fit factors <100,000; (2) fit factors <10,000; (3) fit factors <1,000; (4) fit factors <500; (5) fit factors <100; (6) 100<=fit factor<500; (7) 100<=fit factor<1,000; and (8) 500<=fit factor<1,000. The method having the highest

coefficient of determination and a slope closest to negative one using all the fit factors would be the one which best predicted the wearer's exposure.

Results and Discussion

Subject Characterization

The characterization curve for a typical subject is shown in Figure 2. This linear function was used to calculate each subject's exposure concentration from their end-exhaled air during the method comparison testing and the equivalent inhalation exposure for the skin absorption testing. Table 5 is a summary of the characterization equations. The proportionality constants ranged from 0.0076 to 0.0605 and the r^2 values ranged from 0.45 to >0.99. These ranges indicated significant differences in the proportionality constants among subjects. The ranges of the proportionality constants (0.0086 to 0.0256) and the coefficients of determination (0.79 to 0.99) for the half-facepiece study were narrower, (Coffey, 1998b). This may be due to the smaller number of test subjects in the half-facepiece study (11 versus 37).

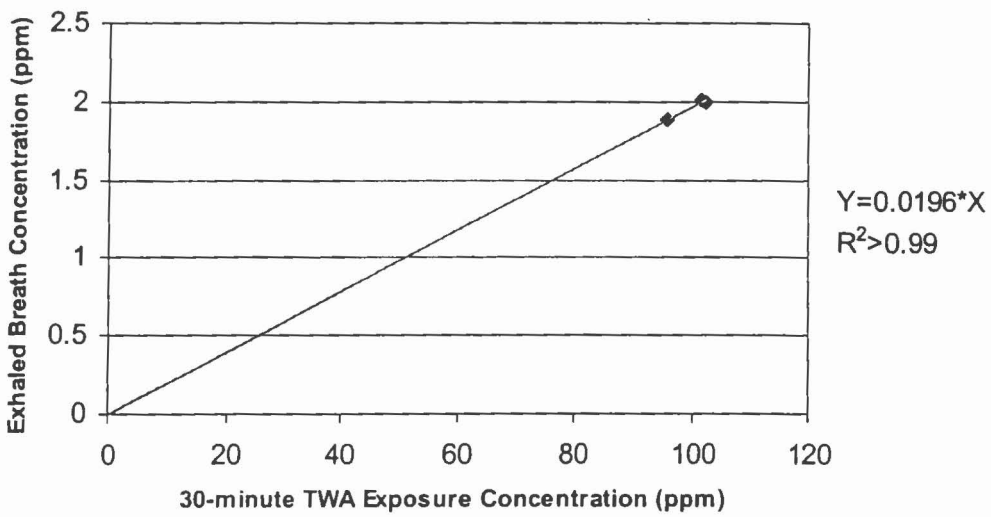

Figure 2. Typical subject characterization curve.

Skin Absorption

It was expected that for full facepiece testing, the contribution due to skin absorption would be less than that of the half-mask study even though the concentration was doubled because the subjects wore protective suits and gloves. The skin absorption results are contained in Table 6. The individual values ranged from the less than the limit of detection (these values were set equal to one-half the limit of detection) to 0.83 ppm with subject averages for the 3 trials ranging from 0.03 to 0.52 ppm. The overall mean for all six subjects combined was 0.16 ppm. Since the subjects were wearing pressure-demand supplied-air respirators, the Freon-113 in the end-exhaled breath can be attributed to skin absorption. The mean skin absorption value is 4 times higher than in the half-facepiece study (mean =0.04 ppm) (Coffey, 1998b). Further research is required to determine the cause(s) for the increased skin absorption.

Method Comparison Testing

The method comparison results using the fit factors for a particular method are contained in Table 7. Exhaled-breath samples having undetectable concentrations were set equal to 1/2 of the lower limit of detection (i.e., 0.0025ppm). The slope of the model for all methods except the CNP was significantly different from zero ($p<0.05$). The CNP method was the only method not to have a slope that was significantly different from zero ($p>0.76$). Figure 3 shows the correlation between the AALong fit factors and total Freon-113 exposure dose.

Table 5. Characterization Equation Summary

Subject Number	Characterization Equation[A]	r^2 Value
1	Y=0.0201*X	0.92
2	Y=0.0257*X	0.84
3	Y=0.0274*X	0.69
4	Y=0.0205*X	0.75
5	Y=0.0170*X	0.72
6	Y=0.0266*X	0.69
8	Y=0.0223*X	0.68
9	Y=0 .0312*X	0.99
10	Y=0.0187*X	>0.99
12	Y=0.0136*X	0.94
14	Y=0.0605*X	0.98
15	Y=0.0141*X	0.69
16	Y=0.0473*X	0.81
17	Y=0.0489*X	0.93
18	Y=0.0214*X	0.90
19	Y=0.0187*X	0.84
21	Y=0.0196*X	>0.99
22	Y=0.0315*X	0.91
23	Y=0.0463*X	0.99
25	Y=0.0333*X	0.87
26	Y=0.0269*X	0.45
27	Y=0.0317*X	0.82
28	Y=0.0363*X	0.94
29	Y=0.0287*X	0.78

30	Y=0.0194*X	0.85
32	Y=0.0347*X	0.99
42	Y=0.0255*X	0.88
43	Y=0.0489*X	0.96
44	Y=0.0566*X	0.75
46	Y=0.0263*X	0.89
47	Y=0.0130*X	0.98
48	Y=0.0136*X	0.98
49	Y=0.0072*X	>0.99
50	Y=0.0104*X	0.99
51	Y=0.0076*X	0.59
52	Y=0.0076*X	0.96

[A]Y = end-exhaled air Freon-113 concentration; X = Freon-113 exposure concentration

When the data from all six methods are considered, approximately 24 percent of all end-exhaled air samples are less than the limit of detection. These values were set equal to one-half the limit of detection. Breaking down the fit factors into the eight different subsets improved the correlation for some of the methods (Table 8). For the AA and CHD methods, the subsets of fit factors less than 1,000 had at least double the r^2 value as compared to all the fit factors. A slight improvement was seen for the AALong method. No improvement was seen for the HDAA, CLF, and CNP methods.

Table 6. Summary of Skin Absorption Data

Subject	Subject Mean Freon-113 Concentration in End-Exhaled Air Due to Skin Absorption (PPM) [A]	Inhalation Equivalent Exposure Concentration (PPM) [B]
3	0.52	19.01
8	0.03	1.34
17	0.16	3.27
18	0.05	2.34
22	0.06	1.91
23	0.13	2.81
Overall Mean	0.16	7.98
Standard Deviation	0.21	6.25

[A] End-exhaled air was measured at 30 minutes after exposure (n=3)

[B] The inhalation equivalent exposure concentration was calculated using the characterization equations in Table 5

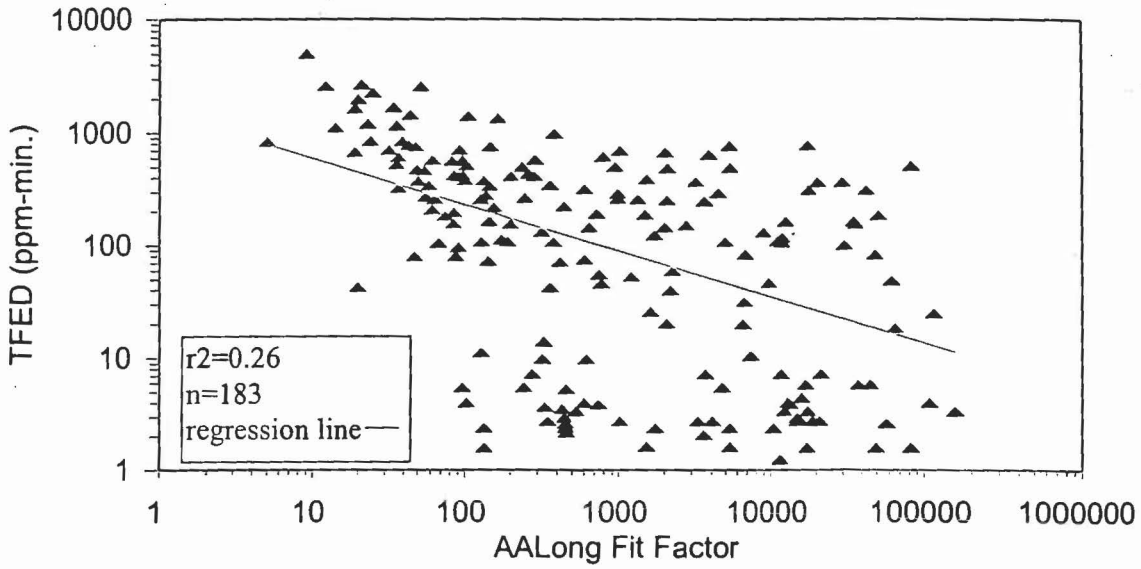

Figure 3. Total freon-113exposure dose (TFED) vs. AALong method quantitative fit factors.

These results are different from those of the half-facepiece study (Coffey, 1998a). Of the five methods used in both studies, all of the methods had higher coefficients of determination in the half-facepiece study (lowest =0.36) than the highest value in the full facepiece study (0.26). Not only were the coefficients of determination different between the two studies but also was the method order. In the half-facepiece study, the order was CHD>AA>AALong>CLF>CNP. In the full facepiece study, the order was AALong>CLF>AA>CHD>CNP.

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[A] End-exhaled air was measured at 30 minutes after exposure (n=3)

[B] The inhalation equivalent exposure concentration was calculated using the characterization equations in Table 5

Table 7. Summary of Correlation Results

Method	r^2	Linear Regression[A]
AALong	0.26	Y=3.20-0.46*X
CLF	0.20	Y=3.09-0.33*X
AA	0.11	Y=2.80-0.35*X
HDAA	0.10	Y=2.76-0.45X
CHD	0.09	Y=2.85-0.19*X
CNP	<0.01	Y=2.15+0.04*X

[A]Y=(Log total Freon-113 exposure dose); X=(Log of quantitative fit factor)

A question was raised after the half-mask study: do fit factors during the 30-minute test differ from the fit factors obtained before the 30-minute chamber test? To answer this question, fit factors were also obtained after the 30-minute chamber test using the AA, HDAA, and CNP methods in this study. The geometric mean of all 88 fit factors obtained from the ambient aerosol, 6-exercise method before the 30-minute chamber test was 510 with a geometric standard deviation of 6.8. The geometric mean of all 89 fit factors obtained from the corresponding AA method after the 30-minute chamber test was 390 with a GSD of 10.9. The p-value of the paired-sample t-test of the log-transformed fit factors was 0.07. Thus, the difference in fit factors obtained from the AA method before and after the 30-minute chamber tests was barely insignificant. This supported the use of the averages of the two tests in the analysis.

There were several problem areas associated with this study. The first was the high number of end-exhaled breath samples that did not have detectable levels of Freon-113 (approximately 24%). The high skin absorption values contributed greatly to the large number of undetectable samples which could be a cause of the poor correlation between method fit factors and the end-exhaled breath Freon-113 concentrations. Another problem area associated with the skin absorption was that only six of the 37 subjects were tested for skin absorption due to time and resource constraints. Using the average skin absorption to adjust the end-exhaled breath concentrations for the other 31 subjects contributes to the uncertainty of the correlation. The average skin absorption value may have been much higher or lower than the actual value for each subject. It is suggested that in future studies, skin absorption be measured on each individual subject and those values used to adjust the end-exhaled breath concentrations.

Another problem area was the high intra-subject characterization variability which introduced uncertainty in the total Freon-113 exposure dose. The Freon-113 delivery method used in the characterization phase may have caused this variability. When the apparatus was switched from Grade D to Freon-113 and corn oil, all subjects may not have received a consistent exposure of 500 ppm each time. The Freon-113 delivery system needs to be examined to determine if this occurred. If so, then another system needs to be developed.

Another possible explanation for the variability may involve the characterization procedure. The exercises during the three periods of Freon-113 exposure did not have the same metabolic or breathing patterns. The first exposure period consisted of the subject bending the entire time. The second exposure period consisted of the subject bending for a minute and standing still and moving his/her head left and right. The third period entailed the subject simulating working on a control panel for a minute and walking for a minute.

Some of these movements (i.e., bending and walking) are more strenuous than the other movements. The difference in metabolic and/or breathing patterns may have caused the subject's uptake and elimination of Freon-113 to vary between replicates of the characterization test and the method comparison testing.

Another potential problem with the characterization procedure was only one exposure level (i.e., 100 ppm 30-

minute time-weighted average) was used. This was the only level used because the limited pharmacokinetic testing done in the half-facepiece study showed that the subject characterization curve was a straight line (Coffey et. al, 1998b). Since this assumption was based on limited data, it may not be correct. Future studies should be carried out with a multi-level subject characterization procedure. These problem areas may have contributed to the low coefficients of correlation found between the method fit factors and the total Freon-113 exposure dose and the change in the rank order in the methods between the half- and full-facepiece studies.

Conclusions

This study has demonstrated that it is feasible to use full facepiece respirators in an investigation of the correlation of quantitative fit-test method fit factors to total Freon-113 exposure dose levels which are a measure of a respirator wearer's exposure. In the study, the models correlating quantitative fit factors to total Freon-113 exposure dose had slopes which were significant ly different than zero for all methods except the CNP. The correlation of fit factors and total Freon-113 exposure dose in this study was not as high as in the half-facepiece study. Using various subsets of the fit factors did not significantly improve the correlation.

The method correlation order was different between the studies. In the half-facepiece study, the CHD method had the highest coefficient of determination (0.81), followed by the AA (0.78), the AALong (0.70), the CLF (0.41), and the CNP (0.36) methods. In this full facepiece study, the AALong had the highest value (0.25), followed by the CLF (0.18), the AA (0.14), the CHD (0.07), and the CNP(<0.1) methods. Since the AA method had a high correlation in the half-facepiece study and ranked third in the full facepiece, the AA method should continue to be used for both half- and full facepiece respirators until the necessary research can be conducted to explain the difference in the order and determine whether it is significant.

It was believed by combining the two highest correlating methods from the half-facepiece study (i.e., the CHD and AA methods) the resulting HDAA method would have a higher correlation than either of the two methods. The HDAA method had a lower coefficient of determination (0.09) than the AA method (0.14) and only slightly higher than the CHD method (0.07). Further research is required to determine why the HDAA did not correlate better than the AA method.

Possible explanations for lower coefficients of determination in the full facepiece study are high skin absorption values, the limit of detection of the gas chromatograph was too high resulting in a high number of samples being non-detectable, and high intra-subject variability. Further research is needed to determine if these are the causes of the low correlations and to find solutions.

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