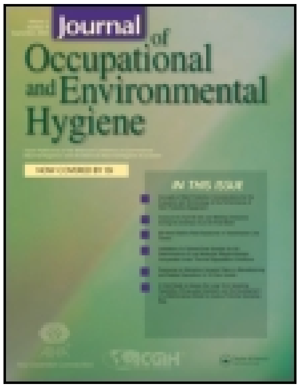

Journal of Occupational and Environmental Hygiene
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/uoeh20

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Available online: 29 May 2012

Journal of Occupational and Environmental Hygiene, 9: 417–426
ISSN: 1545-9624 print / 1545-9632 online

DOI: 10.1080/15459624.2012.685838

Evaluation of the Performance of the N95-Companion: Effects of Filter Penetration and Comparison with Other Aerosol Instruments

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Fit factor is the ratio of the particle concentration outside (C_{out}) to the inside (C_{in}) of the respirator and assumes that filter penetration is negligible. For Class-95 respirators, concerns were raised that filter penetration could bias fit test measurements. The TSI N95-Companion was designed to overcome this limitation by measuring only 40–60 nm size particles. Recent research has shown that particles in this size range are the most penetrating for respirators containing electrostic filter media. The goal of this study was to better understand the performance of the N95-Companion by assessing the impact of filter penetration and by comparing C_{out}/C_{in} ratios measured by other aerosol instruments (nano-Differential Mobility Analyzer/Ultrafine Condensation Particle Counter (nano-DMA/UCPC) and the TSI PortaCount Plus) using N95 filtering facepiece respirators sealed to a manikin and with intentionally created leaks. Results confirmed that 40–60 nm-diameter size room air particles were most penetrating for the respirators tested. A nonlinear relationship was found between the N95-Companion-measured C_{out}/C_{in} ratios and the other instruments at the sealed condition and at the small leak sizes because the N95-Companion measures only charged particles that are preferentially captured by the electrostic filter media, while the other instrument configurations also measure uncharged particles, which are captured less efficiently. The C_{out}/C_{in} ratios from the N95-Companion for experiments conducted under sealed condition suggest that filter penetration of negatively charged 40–60 nm size particles was less than 0.05%. Thus, the N95-Companion measured C_{out}/C_{in} ratios are due primarily to particle penetration through leakage, not through filter media, while the C_{out}/C_{in} ratios for the PortaCount, nano-DMA/UCPC, and UCPC result from a combination of face seal leakage and filter penetration.

Keywords face seal leakage, filter penetration, fit testing, N95-Companion, N95 filtering facepiece respirators, PortaCount Plus

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INTRODUCTION

Fit testing of tight fitting respirators is a required component of an Occupational Safety and Health Administration (OSHA)-compliant respiratory protection program.(1) Fit testing of respirators is necessary to ensure that the respirators are capable of providing expected levels of protection to the user when working in hazardous environments. The importance of fit testing to enhance respiratory protection in workplaces has been described.(2–4) Both quantitative and qualitative fit tests have been employed to measure the fit factor.(5) Among the quantitative methods, a PortaCount Plus (TSI, Inc. Shoreview, Minn.) and an N95-Companion (TSI, Inc.) have been used in several studies.(2–4,6)

The PortaCount and the N95-Companion measure the concentrations of ambient particles outside (C_{out}) and inside (C_{in}) particulate respirators to produce a fit factor, which is defined as a ratio of (C_{out}/C_{in}), a measure of the fit of that respirator for that individual for the donning. The fit factor of the National Institute for Occupational Safety and Health (NIOSH)-approved

N, R, and P series filtering facepiece respirators (FFRs) can be obtained using a PortaCount.[7] The PortaCount measures the fit factor of a respirator using a miniature condensation nuclei or particle counter (CNC or CPC).

The number of ambient particles that are present inside the respirator can come from two major sources: (1) penetration through the filter media, or (2) leakage around the face seal area. Inward leakage can also arise from the exhalation valve of a respirator but for the purposes of this article will be considered minor. For NIOSH-approved Class-99 and Class-100 FFRs, particle concentration measured by the PortaCount in the breathing zone results mostly from face seal leakage because filter penetration is considered negligible ($<1\%$) as prescribed by NIOSH particulate filter penetration test requirements.

However, fit testing for Class-95 respirators was not deemed possible originally because of particle penetration through filter media up to 5%.[8] This problem was overcome by the development of the N95-Companion, which works in conjunction with a PortaCount, to measure particles in a size range that were thought to not readily penetrate the filter.[9] The N95-Companion has an electrostatic classifier that is designed to separate negatively charged particles in the 40–60 nm size range from the other particles, and only those charged particles get counted. As originally designed, the N95-Companion measured the negatively charged particles of 40–60 nm size as these were considered to be the least penetrating particles for NIOSH-approved Class-95 filters including N95, R95, and P95.[10] By selecting a particle size range with minimal penetration, fit test measurements with the N95-Companion were thought to be mainly the result of face seal leakage, as in fit testing of Class-99 and Class-100 respirators.

Some studies have reported a most penetrating particle size (MPPS) of ~300 nm (electrical mobility diameter) for fibrous filters.[11,12] However, recent studies have shown that 40–60 nm range particles were the MPPS for Class-95 as well as for Class-99 and Class-100 of NIOSH-approved FFRs containing electrostatic filter media, rather than 300 nm as originally thought.[13–17] Many of these studies measured initial penetration levels at 85 L/min flow rate using charge neutralized aerosol particles. For example, Martin and Moyer[13] investigated the penetration of 30–400 nm size particles for N95 FFR models and N99, R95, and P100 filter media. Their results showed that the MPPS was in the 50 to 100 nm size range for N95 FFRs and other classes of electrostic respirator filter media.[13]

Further studies with additional N95 FFR models confirmed that the MPPS was in the 40–60 range[15,17] when challenged at 85 L/min flow rates. However, many factors affect the MPPS including flow rate and particle charge.[18] For example, electrostic filters challenged with charged aerosol particles showed several-fold decrease in penetration levels for 50 nm size range particles with a shift in the MPPS from 50 nm to ~200 nm size range.[14,19,20]

Unfortunately, none of these laboratory filtration studies were done with room air particles at flow rates similar to those found during fit testing. Furthermore, given the ubiquitous application of the N95-Companion for fit testing Class-95 FFRs, it is surprising that no studies exist to fully evaluate the performance characteristics and possible limitations of the N95-Companion. The goal of this study was to better understand the performance of the N95-Companion by assessing the impact of filter penetration (at conditions similar to those found during fit testing) and by comparing C_{out}/C_{in} ratios measured by other aerosol instruments (nano-Differential Mobility Analyzer/Ultrafine Condensation Particle Counter (nano-DMA/UCPC) and the TSI PortaCount Plus) using three N95 FFR models sealed to a manikin and with intentionally created different size leaks.

METHODS

Filtering Facepieces

Three N95 FFR models, with no exhalation valves, were selected for particle penetration and C_{out}/C_{in} ratio measurements. These models were selected based on the ease of fit to the two manikin head forms used in the study. Three samples from each model were used in each test.

Equipment

Major equipment employed in the study includes a Scanning Mobility Particle Sizer (SMPS), a PortaCount, an N95-Companion, and a UCPC.

PortaCount Plus (TSI 8020)

The PortaCount consists of a miniature condensation particle counter (mini-CPC) and measures the concentration of aerosol particles in the samples inside and outside of the FFR. In this study, a PortaCount was used to measure C_{out}/C_{in} ratios of N95 FFR samples sealed to a manikin head with different leak sizes and at various breathing flow rates.

N95-Companion (N95-Companion, TSI 8095)

An N95-Companion consists of an electrostatic classifier[21,22] and is paired with a PortaCount, so that they work together. For the rest of the article, the N95-Companion with a PortaCount will be referred to as the N95-Companion. An N95-Companion measures fit factors of Class-95 FFR by selecting 40–60 nm range size particles from air samples taken inside and outside the respirator using an electrostatic classifier and transporting only the negatively charged particles to the PortaCount for measuring particle concentration. The N95-Companion normally provides fit factor values up to 200. Fit factors above 200 are displayed as 200+ (200 plus) because they exceed the manufacturers' recommended operating range. For this work, special software without the 200 limit was provided by the manufacturer. This adjustment allowed for the measurement of actual C_{out}/C_{in} ratios to compare to those ratios from other aerosol instruments. Ratios of C_{out}/C_{in} were measured for an N95 FFR sample sealed to a manikin head with different leak sizes and at different breathing flow rates.

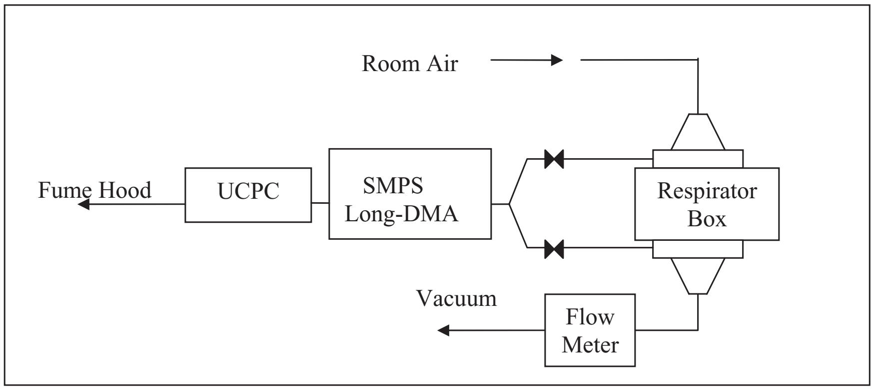

FIGURE 1. Schematic diagram of the room-air particle penetration test system

Nano-Differential Mobility Analyzer (TSI 3085)

The SMPS contains a nano-DMA and a bipolar charger. The bipolar charger neutralizes the charge on particles first and then transports them to the nano-DMA. The nano-DMA consists of an electrostatic classifier that allows for particles in the sub-100 nm range to be size classified according to their electrical mobility. In this study, the nano-DMA was adjusted to select 40–60 nm particles (95% of particles) with the distribution centered at 55 nm for measuring particles inside and outside the FFR.

Ultrafine Condensation Particle Counter (TSI 3776)

An UCPC was used for measuring aerosol particle concentration inside and outside of the FFR in combination with a nano-DMA for 40–60 nm size range particles. When the UCPC was used in the absence of the nano-DMA/UCPC, a 1-L airtight glass bottle with an inlet for FFR sample entry and an outlet for the UCPC sampling was employed for measuring particle concentration to reduce pressure fluctuations.

EXPERIMENTAL

Room Air Particle Penetration Through FFRs

Room air particle (20–1000 nm range) penetration through each N95 FFR was measured as a function of particle size using the SMPS (Figure 1). To supplement aerosol concentration in the test laboratory, an aerosol generator (TSI 9302) was placed 2 m from the test chamber. This allowed the generated aerosol to mix well before entering the respirator test box. Room

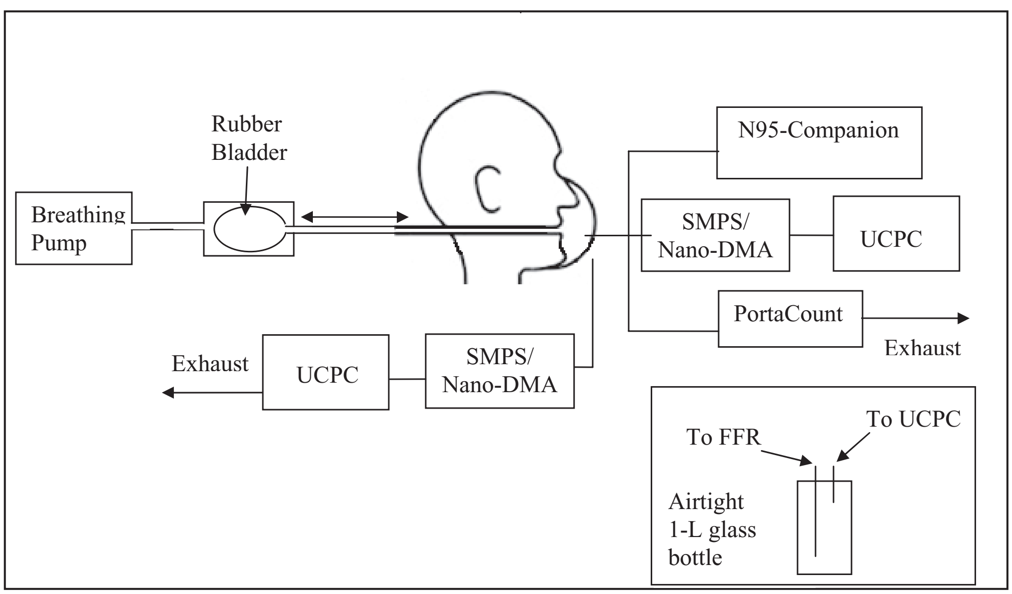

FIGURE 2. Schematic diagram of the breathing manikin test system. Insert: A sample pressure dampening glass bottle was used in place of the nano-DMA for UCPC measurements

aerosol was passed through the test box fixed with an FFR, and the flow rate was regulated by a vacuum line as described previously.[15] Particle size distributions over the size range of 20–1000 nm were measured upstream and downstream of each test FFR alternately for 3 min. From three such measurements, the average penetration value was obtained.

Manikin Test Setup

An experimental setup was designed to measure C_{out} and C_{in} of an FFR fitted to a manikin head using four different particle counting equipment, including an N95-Companion, a PortaCount, a nano-DMA/UCPC, and a UCPC (Figure 2). An FFR was sealed to a manikin face using a silicone sealant and allowed to set overnight. No attempts were made to measure any micro leaks at the manikin face and FFR interface. For measuring C_{in}, aerosol samples from inside the mask were collected through a sample probe inserted into the FFR along the centerline to eliminate effects of asymmetry. The sample probe was similar to the one used for fit testing FFRs with a PortaCount.

Two probes were placed on either side of the FFR at the same height as the sample probe. These probes were placed approximately 1.5 cm from the seal with the manikin face on each side. The leak probes were filled with non-hardening putty, and the mask was then sealed to the manikin face. Different leak sizes were obtained by carefully inserting hypodermic needles (20-, 18-, 16-, and 13-gauge needles) through the putty and removing them to produce leaks of increasing size with diameters of 0.90, 1.27, 1.65, and 2.41 mm, respectively. For each test, leaks were introduced on both side probes simultaneously. Two similar or different gauge size needles were used to obtain 10–11 leak states. The sampling probe was split using a y-connector, and the two resulting lines were then connected to two particle counting instruments for simultaneous measurement—either an N95-Companion, a PortaCount, a nano-DMA/UCPC, or a UCPC. For measuring C_{out}, samples 10 cm from the FFR sealed to the manikin were analyzed by the N95-Companion, the PortaCount, the nano-DMA/UCPC, or UCPC. The N95-Companion, the PortaCount, nano-DMA, and the UCPC used were randomly selected from the units available in our laboratory. No specific unit was always dedicated to this project. All units were calibrated as per manufacturer's specifications.

A physically isolated breathing pump was placed on the laboratory work bench and connected to the manikin head as shown in Figure 2. The outlet of the manikin mouth was connected to an inflatable rubber bladder inside an airtight glass bottle connected to the breathing pump. This prevented any particles generated by the pump entering the breathing zone of the manikin. The breathing pump was a cam-driven piston pump with a displacement of 1.65 L per breath. Measurements were made randomly at three different breathing rates 12, 18, and 24 breaths per minute, equivalent to minute volumes of approximately 20, 30, and 40 L/min, respectively.

Aerosol Sampling

Aerosol sampling with the PortaCount and the N95-Companion were carried out according to the manufacturer's instructions. Care was taken to ensure the concentration of aerosol measured with the N95-Companion remained at the optimal range of 100–300 particles/cm^3 as recommended by the manufacturer. This was done by supplying aerosol produced from the aerosol generator (TSI 8026) when needed. No additional measures were taken to minimize variations in the ambient aerosol levels as long as they were maintained within this range.

Aerosol Concentration Measurements Inside and Outside FFRs

The PortaCount and the N95-Companion give a ratio of C_{out}/C_{in} by alternately measuring the particle concentrations outside and inside the FFR. In the case of the nano-DMA/UCPC as well as the UCPC, particle concentrations inside and outside the respirator were measured simultaneously using two identical nano-DMA/UCPC or UCPC units, and then the ratio of C_{out}/C_{in} was calculated. In each test, two aerosol samples were withdrawn from the inside of the FFR simultaneously for particle concentration measurements using two instruments.

C_{out}/C_{in} Ratio Measurements with a N95-Companion and a Nano-DMA/UCPC

The N95-Companion measures particles in the 40–60 nm range to give the C_{out}/C_{in} ratio using the equipment software. To mimic the size range, a nano-DMA was adjusted for these experiments to select particles in the 40–60 nm size range for the nano-DMA/UCPC measurement of particle concentration. This was done by setting the sheath flow rate of nano-DMA to 2.0 L/min and centering the peak particle size at 55 nm, which provided a particle distribution across the target size range (95% particles in the 40–60 nm range). The UCPC was operated in high flow mode (1.3 L/min). A needle valve upstream of a HEPA filter was used to allow 0.6 L/min of make-up air to the sample inlet. This was used to limit the sample flow from the FFR to 0.7 L/min, identical to the inlet flow of the PortaCount. The C_{out}/C_{in} ratio was calculated from the concentrations outside and inside the FFR measured by the nano-DMA/UCPC.

Sampling was done during the first three "exercises" from the OSHA fit testing protocol.[1] For the N95-Companion, an exercise consisted of sampling for 15 sec outside the FFR, and 50 sec inside the FFR with a 21-sec period used for sampling line purging time, to bring the total time of each exercise to 86 sec. For the three exercises (258 sec), the N95-Companion gives a harmonic average value of the C_{out}/C_{in} ratio. In the case of nano-DMA/UCPC, two setups were employed for measuring outside and inside aerosol concentrations simultaneously for 60 sec during each exercise. The upstream concentration divided by the downstream concentration gives the C_{out}/C_{in} ratio. Average ratio for three exercises was calculated.

Measurements with an N95-Companion and a PortaCount

In these experiments, both the N95-Companion and PortaCount were used to measure the C_{out}/C_{in} ratio for each FFR was measured with an N95-Companion and a PortaCount simultaneously. Sampling was performed during the first three exercises from the OSHA fit testing protocol[1] for 180 sec. Measurement with a PortaCount provided the C_{out}/C_{in} ratio for three exercises directly using the software in the equipment. The sampling time of each exercise for the PortaCount was 5 and 40 sec for outside and inside the FFR, respectively. Each exercise also had 15 sec of purge time.

Measurements with a PortaCount and a UCPC

In these experiments, both the PortaCount and UCPC were used to measure the C_{out}/C_{in} ratio simultaneously. The use of a breathing pump rapidly changes the pressure inside the FFR, cyclically causing unstable data output from the UCPC, which relies on critical orifice for flow control. To mitigate the pressure changes at the UCPC, the FFR inside sample was passed through an airtight glass bottle (1-L) with two probes placed in line with a UCPC as shown in the Figure 2 insert. Aerosol flow rates were maintained at 0.7 L/min for both instruments. For the UCPC, the C_{out}/C_{in} ratio was calculated from the concentrations outside and inside the FFR. Two UCPCs (with <5% variation in counting efficiency) sampled outside and inside FFR simultaneously for 60 sec, and the C_{out}/C_{in} ratio during each exercise was obtained. The average ratio for three exercises was calculated.

Data Analysis

The C_{out}/C_{in} ratios were linear with the different size leaks for the PortaCount and the UCPC. The association between the data for the PortaCount and the UCPC was analyzed by the Pearson Product Correlation Coefficient (r) using the Microsoft Excel 2003. Because the relationship between the Companion C_{out}/C_{in} ratios to the nano-DMA/UCPC ratios was nonlinear, a comparison between those ratios relative to different leak states was standardized by applying the same nonlinear function (exponential) for the purpose of developing the coefficient of determination (R^2) that could be compared across the leaks. The same was true for the N95-Companion ratios relative to the PortaCount ratios. R^2 in the above analyses was obtained using SigmaPlot version 11.2 (Systat Software, Inc., San Jose, Calif.).

RESULTS

Room Aerosol Penetration by Size

Penetration levels for 20–1000 nm range particles showed that the MPPS was in the 50 nm range for all three N95 FFR models at both 20 and 40 L/min flow rates (Figure 3). Average penetration levels for 50 nm size particles were 0.113% and 0.602% for Model 1, 0.046% and 0.236% for Model 2, and 0.252% and 0.675% for Model 3, at 20 and 40 L flow rates, respectively. Overall, penetration levels at 40 L/min were higher than the penetration levels at 20 L/min.

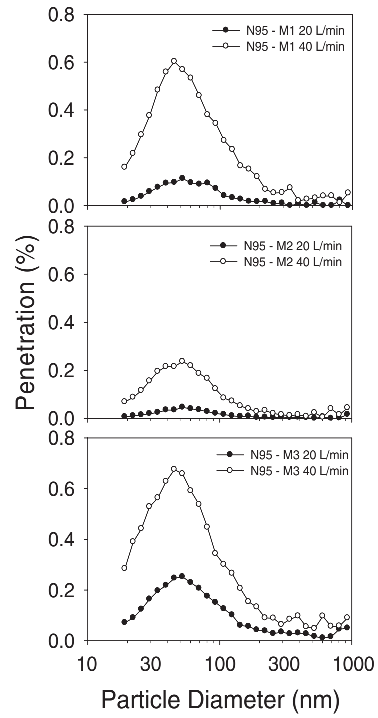

FIGURE 3. Average percentage penetration curves for three representative FFR samples from three N95 models (M1, M2, and M3) as measured by a Scanning Mobility Particle Sizer (SMPS). Penetration was determined at constant flow rates of 20 and 40 L/min.

Comparison of C_{out}/C_{in} Ratios by an N95-Companion to a Nano-DMA/UCPC

C_{out}/C_{in} ratios for each of the three different FFR models sealed to a manikin were obtained with an N95-Companion and a nano-DMA/UCPC simultaneously. The ratios were measured for sealed FFR and at different leak sizes at three different breathing flow rates. The C_{out}/C_{in} ratio decreased gradually with increasing leak sizes by both methods at 20, 30, and 40 L/min flow rates for M1 model (Figure 4, left panel, top to bottom). The N95-Companion-measured C_{out}/C_{in} ratios were several-fold higher than the ratios obtained by nano-DMA/UCPC at sealed conditions in all tests, while similar C_{out}/C_{in} ratios were obtained at larger leak sizes. A similar trend in the C_{out}/C_{in} ratios was obtained for FFR Models M2 and M3 (Figure 4, center and right panels, top to bottom, respectively).

The maximum C_{out}/C_{in} ratio under sealed condition for the three FFR samples reached 3950–20,000, and 113–174 by the N95-Companion and nano-DMA/UCPC, respectively, at 20 L/min flow rate. Ratios of C_{out}/C_{in} >400 were excluded in Figure 4 to prevent skewing of majority of the data. A nonlinear regression analysis showed that the coefficient of determination (R^2) for the C_{out}/C_{in} ratio data was in the range

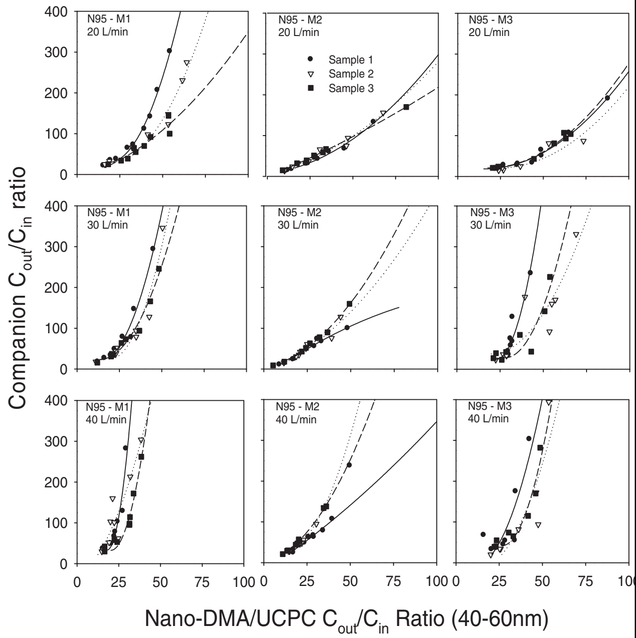

FIGURE 4. Nonlinear regression plot for the C_{out}/C_{in} ratios measured with the N95-Companion and the nano-DMA/UCPC at different leak sizes. C_{out}/C_{in} ratios for N95 FFR models M1 (left column), M2 (center column), and M3 (right column) are shown under three breathing rates: 20 L/min (top row), 30 L/min (middle row), and 40 L/min (bottom row).

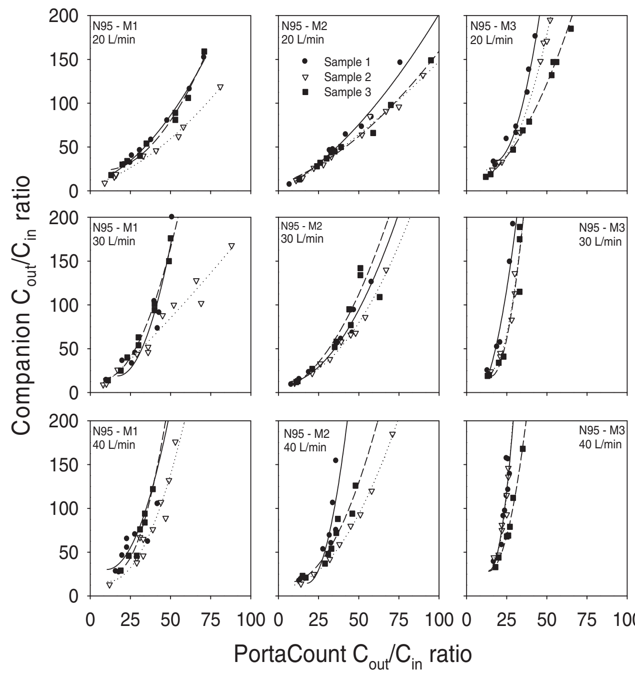

FIGURE 5. Nonlinear regression plot for the C_{out}/C_{in} ratios measured with the N95-Companion and the PortaCount at different leak sizes. C_{out}/C_{in} ratios for N95 FFR models M1 (left column), M2 (center column), and M3 (right column) are shown under three breathing rates: 20 L/min (top row), 30 L/min (middle row), and 40 L/min (bottom row).

of 0.76–0.96, 0.81–0.99, and 0.51–0.89 at 20, 30, and 40 L/min flow rates, respectively, for the three N95 FFR models.

Comparison of C_{out}/C_{in} Ratios by an N95-Companion to a PortaCount

The N95-Companion and the PortaCount measured C_{out}/C_{in} ratios were compared for the three N95 models employed in the study (Figure 5). Maximum C_{out}/C_{in} ratios ranged from 2220–6880 and 93–280 for the N95-Companion and the PortaCount, respectively, at sealed conditions for the three N95 model FFRs. The N95-Companion measured C_{out}/C_{in} ratios were several-fold higher than the ratios obtained by the PortaCount at sealed conditions in all tests. In general, the C_{out}/C_{in} ratios decreased with increasing leak sizes for both instruments. Similar C_{out}/C_{in} ratios were obtained for both the N95-Companion and the PortaCount at larger leak sizes. The curves shifted toward the left with an increase in flow rate from 20 to 40 L/min for each FFR model (Figure 5, left, center and right panels, top to bottom). A nonlinear regression analysis showed that R^2 for the C_{out}/C_{in} ratio data was between 0.70–0.97, 0.33–0.87, and 0.47–0.95 at 20, 30, and 40 L/min flow rates, respectively, for all three N95 FFR models.

Comparison of a C_{out}/C_{in} Ratios by PortaCount with a UCPC

The PortaCount and the UCPC ratio showed comparable C_{out}/C_{in} ratios showing a linear relationship among all three samples of Models M1, M2, and M3 at 20, 30, and 40 L/min breathing flow rates (Figure 6). Maximum C_{out}/C_{in} ratios were obtained for sealed FFR for both PortaCount and UCPC and decreased linearly with increasing leak sizes in all tests. FFR Model M1 showed maximum values of C_{out}/C_{in} ratio of 150 and 140 for the PortaCount and the UCPC, respectively, at a 20 L/min breathing rate (Figure 6, left panel top). PortaCount and UCPC measured maximum C_{out}/C_{in} ratios were 135 and 113, respectively, for Model M2, while the ratios were 137 and 122 for Model M3 at 20 L/min flow rate (Figure 6, middle and right panels, top). Increase in breathing rates decreased the C_{out}/C_{in} ratios for both instruments for all three N95 FFR models (Figure 6, left, middle and right panels, top to bottom). A linear regression was used to analyze the association between the ratios by the two instruments. The r values for the C_{out}/C_{in} ratios data were between 0.95–0.99 at both the 20 and 30 L/min flow rates, for all three N95 FFR models. The r values were in the range of 0.83–0.99 at 40 L/min for the three models except two FFR samples (one sample each from model M1 and M3) with r values 0.30 and 0.61.

Summary

Table I shows typical C_{out}/C_{in} ratios measured by the nano-DMA/UCPC vs. the N95-Companion, and the UCPC vs. the PortaCount combinations for samples from the three FFR models. The nano-DMA/UCPC, UCPC, and the PortaCount C_{out}/C_{in} ratios were higher for Model M2 than for Models M1

TABLE I. Simultaneous Measurement of C_{out}/C_{in} Ratios by the Nano-DMA/UCPC vs. N95-Companion and the PortaCount vs. the N95-Companion for a Typical N95 FFR for Each Model at 20 L/min Breathing Flow

	M1		M2		M3	
N95 Model Method	**Nano-DMA /UCPC**	**N95-Companion**	**Nano-DMA /UCPC**	**N95-Companion**	**Nano-DMA /UCPC**	**N95-Companion**
Sealed	113	6040	139	16800	123	680
Leak 1	111	4000	130	23000	99	872
Leak 2	64	275	62	133	77	443
Leak 3	62	231	45	68	66	104
Leak 4	53	123	36	61	63	107
Leak 5	53	148	29	43	62	93
Leak 6	41	98	23	31	56	81
Leak 7	32	66	22	31	45	43
Leak 8	19	33	14	18	24	24
Leak 9	17	25	12	15	22	21
Leak 10	16	25	11	13	20	21
Magnitude decrease[A]	7	241	12	1292	6	32
	M1		**M2**		**M3**	
N95 Model Method	**PortaCount**	**N95-Companion**	**PortaCount**	**N95-Companion**	**PortaCount**	**N95-Companion**
Sealed	157	3730	280	3050	96	1800
Leak 1	132	6880	275	2490	93	2220
Leak 2	91	322	134	260	69	268
Leak 3	71	152	90	132	66	210
Leak 4	62	116	75	96	65	185
Leak 5	48	80	67	91	56	147
Leak 6	38	58	52	64	54	147
Leak 7	31	46	33	39	53	132
Leak 8	26	40	28	30	35	69
Leak 9	25	32	22	26	29	47
Leak 10	21	30	15	15	15	19
Leak 11	15	18	11	12	12	16
Magnitude decrease[A]	10	207	25	254	8	112

Note: Shaded areas show the N95-Companion C_{out}/C_{in} ratios exceeding 100 for ratios less than 100 obtained by the nano-DMA/UCPC (top) and the PortaCount (bottom) for FFR models tested in the study.

[A]The magnitude of C_{out}/C_{in} ratio decrease was calculated by dividing the ratio at sealed condition to the value at the largest size leak tested in that experiment.

and M3 at sealed condition and decreased with increasing leak sizes at 20 L/min. The N95-Companion ratios were higher than the nano-DMA/UCPC and the PortaCount ratios for all the three models. The nano-DMA/UCPC, UCPC, and PortaCount C_{out}/C_{in} ratios at sealed condition decreased with increasing leak sizes (Table I). The magnitude of the decrease in the C_{out}/C_{in} ratio was calculated by dividing the ratio at sealed condition by the ratio at the largest leak size employed in the experiment. The magnitude of decrease in the C_{out}/C_{in} ratio for the N95-Companion was larger than the nano-DMA/UCPC as well as the PortaCount for all three FFR models (M1, M2, and M3). Among the three models, the magnitude of decrease in the C_{out}/C_{in} ratio for Model M2 was larger than the other two models.

DISCUSSION

Penetration of room air particles in the 20–1000 nm range for N95 FFR from three different manufacturers showed that the MPPS was in the 50-nm range at the different breathing flow rates (20 and 40 L/min) tested in the study. The MPPS obtained for room air particles was consistent with the values reported in the literature for N95 FFRs challenged with charge neutralized aerosols at 30 L/min[14] as well as at 85 L/min flow rates.[13–17] The selection of the MPPS (40–60 nm) for the N95-Companion could present a potential limitation in accurately measuring the fit factor, if significant filter penetration was found. Recent studies from our laboratory showed negligible penetration (<0.024%) for negatively

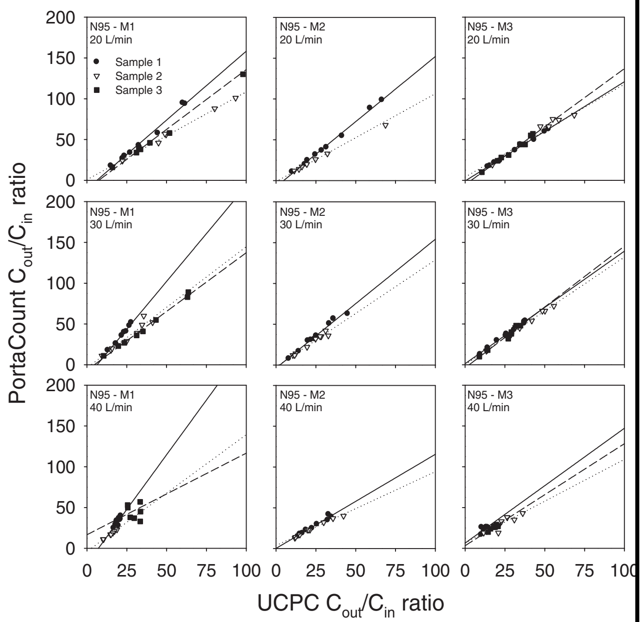

FIGURE 6. Linear regression plot for the C_{out}/C_{in} ratios measured with the PortaCount and the UCPC at different leak sizes. Ratios for FFR models M1 (left column), M2 (center column), and M3 (right column) are shown under three breathing rates: 20 L/min (top row), 30 L/min (middle row), and 40 L/min (bottom row).

charged ~50 nm size aerosols for five N95 models at 85 L/min.[23] Much lower penetration of the negatively charged 50 nm particles can be expected at 30 L/min, even though penetration values up to 0.67% were obtained for the charged and uncharged 50 nm size room particles at 40 L/min in the present study.

The above results indicate that negatively charged 40–60 nm did not significantly penetrate the filter media. This conclusion is supported by the penetration values ranging from 0.01% to 0.2% obtained for 18 N95 FFR models at 31.4 L/min previously using the N95-Companion.[24] Data collected in the present study confirm that earlier observation as filter penetration levels (i.e., C_{out}/C_{in} at the sealed condition) were all less than 0.05% (i.e., maximum C_{out}/C_{in} ratios for the N95-companion were > 2220). For comparison, C_{out}/C_{in} ratios measured by the PortaCount during the sealed experiments ranged from 93–280 and 135–150, indicating filter penetration > 0.4%.

Data collected comparing the C_{out}/C_{in} ratios measured by the various aerosol instrument configurations can further address this concern. In this study, C_{out}/C_{in} ratios were obtained by measuring similar size range of particle species with positive, negative, and/or neutral charges on both inside and outside the respirator. If the various instruments all measure C_{out}/C_{in} ratios, then values measured by the N95-Companion, the PortaCount, and the nano-DMA/UCPC should be similar.

However, results obtained in the study showed that the N95-Companion ratios were consistently higher than the ratios obtained by the PortaCount and the nano-DMA/UCPC. The discrepancy can be explained by the difference in how the C_{out}/C_{in} ratio is measured by these instruments. When a manikin sealed with a respirator breathes, aerosols go in and out of the respirator alternately. During this process, charged particles, including the negatively charged 40–60 nm particles that enter and exit the respirator, will be captured by the filter medium. The concentration of negatively charged 40–60 nm particles inside the respirator becomes considerably lower than in the ambient air. The N95-Companion measured C_{out}/C_{in} ratios are higher than those ratios obtained by the other instruments because they measure both neutral and charged particles inside and outside the respirator. The relatively high concentration of neutral particles in the ambient air and their high penetration produces a smaller ratio than the ratio obtained by the N95-Companion. When a leak is introduced, negatively charged 40–60 nm size ambient particles enter inside the respirator and decrease the N95-Companion ratio drastically (Table I). The other instruments produce a relatively small magnitude of decrease in the C_{out}/C_{in} ratio because they measure both neutral and charged particles that came through the leak.

To assess the appropriateness of the PortaCount for measuring C_{out}/C_{in} ratios for Class-95 FFR, parallel experiments were conducted with the UCPC and the ratios compared. Results showed a good correlation (r = 0.95 to 0.99) between the PortaCount and the UCPC ratios. In general, the PortaCount ratios were larger than the UCPC ratios. One possible explanation is that the mini-CPC in the PortaCount may not be as sensitive as the UCPC. The mini-CPC-measured particle number inside the FFR may be less than the value obtained by the UCPC, resulting in slightly higher ratios. In any case, the PortaCount-measured C_{out}/C_{in} ratios were more comparable to the UCPC ratios than the corresponding N95-Companion measured ratios. These results suggest that the PortaCount provides accurate C_{out}/C_{in} ratios measuring total inward leakage (i.e., they contain significant contributions from filter penetration) for Class-95 FFRs. Thus, it may be possible to subtract off the filter penetration value as was done by Coffey et al.[24]

Flow rate appears to influence the value of C_{out}/C_{in} ratios measured in this study. The N95-Companion vs. the nano-DMA/UCPC (40–60 nm) C_{out}/C_{in} ratio curves shifted toward left with increasing flow rates in the 20 to 40 L/min range (Figure 4, top to bottom). An increase in flow rate is expected to increase the particle number inside the FFR that will allow a reasonable counting by the N95-Companion and produce lower C_{out}/C_{in} ratios. On the other hand, the C_{out}/C_{in} ratios remained elevated at higher flow rates causing a leftward shift of the curve. One possible explanation is that the manikin breathing produces a pressure change in the sample entering the electrostatic classifier that could adversely affect the N95-Companion measurement of C_{out}/C_{in} ratios. At the same time, the PortaCount vs. UCPC C_{out}/C_{in} ratio comparison curves showed a linear relationship with no leftward shift, indicating that increased C_{in} levels were measured by both the PortaCount and the UCPC to decrease the C_{out}/C_{in} ratio with increasing flow rates. A breathing flow rate of 30 L/min was reported for test subjects during fit testing,[6] but it can vary between individuals. Previous studies reported that aerosol concentration inside the mask was highly dependent on flow rate,[25] indicating that the C_{out}/C_{in} ratio is not only dependent on the face mask leak but also on the breathing rate of the wearer.

Although, the data obtained in the current study indicates that the N95-Companion measured C_{in} is primarily due to the particles that pass through the leaks, a close look at the C_{out}/C_{in} ratios for the different N95 FFR models showed lower ratio for the relatively high efficiency model (M2) than the low efficiency models (M1 and M3) at many leak sizes tested. Further studies in our laboratory showed that factors including filter penetration, pressure drop, and flow rate can influence the N95-Companion measurement to produce dissimilar ratios on different N95 FFR models at a given leak size.

In this study, a limited number of N95-Companions and PortaCounts were used. Further studies using similar instruments in other laboratories are needed to confirm the results obtained in this work. In addition, a PortaCount with an N95-Companion is no longer commercially available but is replaced by a combination PortaCount Pro Respirator Fit Tester Model 8030 (TSI, Inc.). The use of this equipment for measuring C_{out}/C_{in} ratio may be important to confirm the results obtained in our studies. The large variation in the C_{out}/C_{in} ratios obtained in the N95 Companion data at sealed condition (3950–20,000 and 2280–6880) suggests that these C_{out}/C_{in} ratios (i.e., fit factors) should be interpreted cautiously, as these values are far outside the upper limit (200) of the operating range of the instrument as specified by the manufacturer.

CONCLUSION

Results obtained in this study showed that the MPPS for the three models of N95 FFRs studied was in the 40–60 nm range for room air particles at flow rates similar to those found during fit testing. A series of experiments was done with N95 FFRs under sealed conditions and with intentionally created leak sites on a manikin to compare C_{out}/C_{in} ratios obtained from the N95-Companion, the PortaCount, the nano-DMA/UCPC, and the UCPC. The data exhibited a nonlinear relationship with higher N95-Companion-measured C_{out}/C_{in} ratios at the sealed conditions and with small leak sizes, compared with the other two instrumental configurations. The nonlinear relationship was attributed to the detection system used in the N95-Companion. The N95-Companion measures only charged particles that are preferentially captured by the electrostic filter media, while the other instrument configurations also measure uncharged particles, which are captured less efficiently by electrostic filter media. C_{out}/C_{in} ratios from the N95-Companion for experiments conducted under sealed condition suggest that filter penetration for the negatively charged 40–60 nm particles was less than 0.05%. Thus, the C_{out}/C_{in} ratios measured by the N95-Companion are due primarily to particle penetration through leakage, not through filter penetration, while the C_{out}/C_{in} ratios for the PortaCount, the nano-DMA/UCPC, and the UCPC result from a combination of face seal leakage and filter penetration.

ACKNOWLEDGMENTS

The authors acknowledge NIOSH colleagues Ziqing Zhuang, Roland BerryAnn, William Newcomb, and Christopher Coffey for their critical review of the manuscript and suggestions. This research work was supported by NIOSH funding-CAN #927 Z1NT.

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