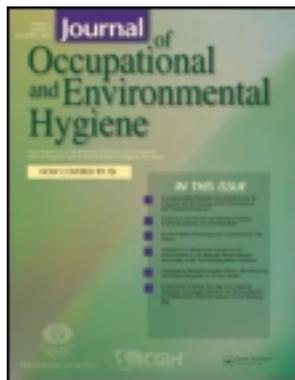


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# N95-Companion Measurement of $C_{out}/C_{in}$ Ratios for Two N95 Filtering Facepiece Respirators and One Surgical Mask

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*A previous study in our laboratory measured the ratio of particle concentration outside ( $C_{out}$ )/inside ( $C_{in}$ ) of three N95 filtering facepiece respirator (FFR) models with an N95-Companion and other aerosol instruments using a breathing manikin. Results showed that the Companion measured  $C_{in}$  was contributed by particle penetration through face seal leakage and not through filter media suggesting that the  $C_{out}/C_{in}$  ratio should be similar for different N95 models at any given leak size. To better understand the phenomenon, the current study analyzed the influence of factors, including filter penetration, resistance, and flow rate on the Companion ratios for two N95 FFR (N1 and N2) and one surgical mask (SM1) models using a manikin.  $C_{out}/C_{in}$  ratios were measured at 10 and 40 L breathing minute volumes with sealed condition and at artificially introduced leaks. Filter efficiency and resistance were measured at 10 and 40 L/min constant flow rates. Results showed that filter efficiency and resistance were higher for N1 than for N2 and SM1. The ratio for N1 was also higher than those of N2 and SM1 at sealed condition at both breathing rates. The result can be due to the higher filtration efficiency of N1. With increasing leak sizes, however, the ratios were higher for N2 than for N1 at 10 and 40 L breathing rates. Higher ratios for N2 can be attributed to the lower resistance that allowed higher aerosol flow through the filter media and captured more negatively charged particles to produce lesser  $C_{in}$  or greater  $C_{out}/C_{in}$  ratio. Ratios obtained for SM1 at different leak sizes were higher than the ratios of N1 at 10 L. SM1 ratios, however, decreased dramatically at 40 L indicating that high flow rate may adversely affect the ratios. Further studies are needed to better understand the influence of filter media characteristics on the Companion measured  $C_{out}/C_{in}$  ratios.*

**Keywords** N95 filtering facepiece respirator, surgical mask, filter penetration, face seal leakage, N95-Companion

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## INTRODUCTION

The use of a tight-fitting air purifying respirator may not provide appropriate protection in the absence of a good fit on the face of a worker. To address this issue, fit-testing was mandated by the Occupational Safety and Health Administration (OSHA) to test the acceptability of the fit of a respirator on a worker using a specific protocol periods.<sup>(1)</sup> The fit of a respirator can be measured by qualitative or quantitative methods. The TSI N95-Companion (TSI, Inc. Shoreview, Minn.) is commonly used for the quantitative fit-testing of tight fitting respirators with class 95 filters, and the PortaCount<sup>®</sup> Plus (TSI, Inc. Shoreview, Minn.) for respirators with class 99 and 100 filters. These instruments measure the concentrations of particles outside ( $C_{out}$ , ambient) and inside ( $C_{in}$ , breathing zone) of a respirator to produce a fit factor (FF), which is defined as a ratio of  $C_{out}/C_{in}$  and a measure of the fit of that respirator for that individual for the donning. A FF of 100 or above is considered acceptable for half-facepiece respirators.

The Companion has been designed to measure only 40–60 nm (electrical mobility diameter) negatively charged particles.<sup>(2)</sup> Because charged particles in the 40–60 nm range are effectively captured by the filter media, the Companion measured  $C_{in}$  represents particle penetration through face seal leaks alone and not through filter media. The  $C_{out}/C_{in}$  ratio results obtained in our recent study<sup>(3)</sup> supported the Companion measurement of  $C_{in}$  due to only particle leakage through face seal leaks.

The Companion has been widely used for fit-testing N95 filtering facepiece respirators (FFRs). Some studies have reported that the Companion fit-test was not adequately identifying poorly performing N95 FFRs.<sup>(4–8)</sup> One study compared the FFs for N95 FFRs obtained using the Companion and the Bitrex qualitative method.<sup>(8)</sup> Seventy-nine paired fit-tests were performed on human subjects. The Bitrex method

identified a high number of failures where acceptable fits were obtained by the Companion method.<sup>(8)</sup> The authors suggested that the Companion may not be useful in identifying poorly fitting N95 FFRs. Subsequently, five different test methods were employed to identify poorly fitting N95 FFRs.<sup>(5)</sup> Eighteen models of N95 FFRs were tested on human subjects using a Companion, a PortaCount, saccharin, “generated aerosol,” and Bitrex methods. The results showed that the PortaCount and the “generated aerosol” methods identified the poorly fitting respirators more often than the Companion method.<sup>(5)</sup> None of the above studies explained how the Companion obtained higher FFs than the other methods.

The concept that the Companion measures only negatively charged 40–60 nm range particles indicates that the  $C_{out}/C_{in}$  ratios for different N95 FFR models should be similar at a given leak size, because a similar concentration of particles will pass through the leak. In our previous study, the Companion ratios for three N95 models at different leak sizes were measured.<sup>(3)</sup> The ratios were lower for the relatively higher-efficiency N95 model (M2) compared to two lower-efficiency models (M1 and M3) at many leak sizes. Similar results were obtained for additional N95 models indicating that factors including filter efficiency, pressure drop, and flow rate can influence the Companion ratios at different leak sizes.<sup>(3)</sup> Comprehensive information on the Companion ratios for different N95 models at different leak sizes is lacking.

To better understand why the Companion measures different ratios for N95 FFR models at a given leak size, the influence of parameters including filter efficiency, resistance, and breathing minute volume was evaluated. In the present study, a Companion was used to measure the  $C_{out}/C_{in}$  ratios for two N95 models designated N1 and N2, respectively, with a manikin under different breathing minute volumes and leak sizes. The ratios at sealed condition as well as with different leak sizes for the two N95 FFR models were compared. A surgical mask (SM1) was included in the study for comparative purposes even though it is not recommended in workplaces when respiratory protection is required.<sup>(1)</sup>

## MATERIALS AND METHODS

### Filtering Facepiece Respirators (FFRs) and Surgical Mask (SM1)

In this study, two N95 model FFRs (NIOSH-approved) with no exhalation valves and one SM1 model (FDA-cleared) were selected for  $C_{out}/C_{in}$  ratio measurements. These models were selected based on the ease of fit to the two manikin head forms available in the laboratory. The manufacturers and models (in parentheses) of the N95 FFRs are Willson (N1105), Gerson (1730N), and the SM1 model is Barrier (4228) which have been assigned labels N1, N2, and SM1, respectively.

### Polydisperse Aerosol Penetration Test Method

Filter penetration of the N95 FFR and SM1 models was measured using NaCl aerosol. Three samples of N95 FFR

and SM1 models were tested with polydisperse NaCl aerosol ( $75 \pm 20$  nm, count median diameter) using an Automated Filter Tester (Model 8130, TSI, Inc.). Initial penetration of NaCl aerosol and resistance were measured simultaneously for 1 min using a Plexiglas box set up as described previously.<sup>(9)</sup> Penetration and resistance were measured at 10 and 40 L/min constant flow rates.

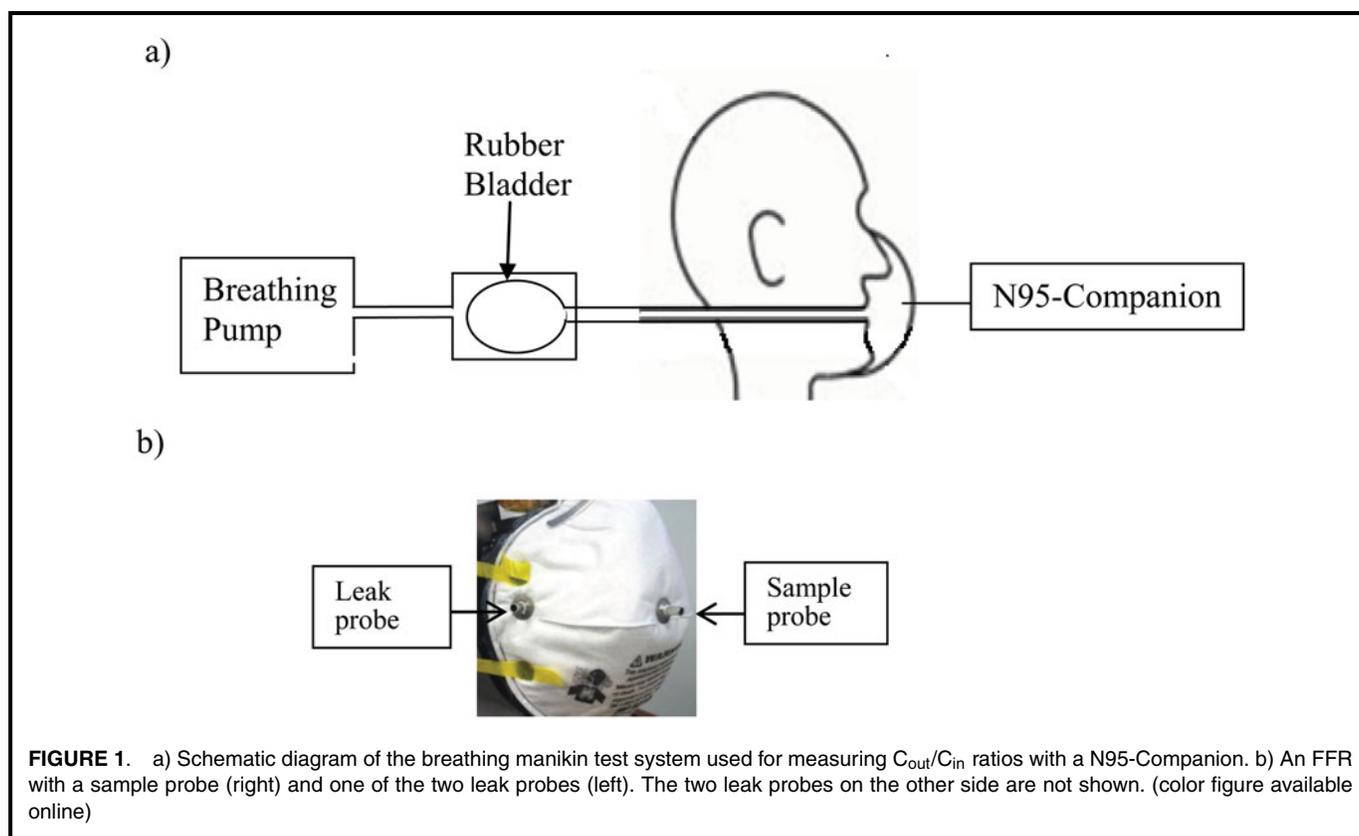
### $C_{out}/C_{in}$ Ratio Measurement

Figure 1a shows a manikin setup used for the measurement of  $C_{out}/C_{in}$  ratio for the N95 FFR and the SM1 models tested with ambient (laboratory) aerosol using a Companion. The manikin setup was similar to the one used previously,<sup>(3)</sup> with some modifications. Each N95 FFR and SM1 sample was equipped with one sampling probe and two additional probes on the sides for introducing artificial leaks as shown in Figure 1b. The probe was similar to the one used for fit-testing respirators with a PortaCount. The sample probe was inserted in the N95 FFR and SM1 along the centerline to eliminate effects of asymmetry. Two leak probes were fixed on either side of the N95 FFR 1.5 cm from the seal with the manikin. Figure 1b shows only one probe on one side and does not show the two probes on the opposite side. The leak probes were filled with non-hardening putty.

An N95 FFR or a SM1 equipped with sampling and leak probes was sealed to a manikin without any leaks around the face seal area. The head form was placed on the work bench and connected to a breathing simulator (Hans Rudolph, Inc., Shawnee, Kans.) through an isolation chamber to keep particles generated by the pump out of the test chamber. The breathing simulator produced sinusoidal wave form at two breathing rates for each model; 10 L and 40 L minute volumes with tidal volumes of 0.5 L and 1.5 L, representing realistic breathing conditions unlike the cam-driven piston pump with a tidal volume of 1.67 L at all flow rates used previously.<sup>(3)</sup> These two breathing minute volumes were selected representing sedentary and moderate work activities. The breathing flow rates and tidal volumes are comparable to the values reported for test subjects.<sup>(10)</sup>

Face seal leaks were introduced through the leak probes as described previously,<sup>(3)</sup> with some modifications. Increasing leak sizes were introduced using hypodermic needles (20-, 18-, and 16-gauge needles with inner diameters of 0.60, 0.84, and 1.18 mm, respectively, ~25 mm long) by inserting them through the putty and leaving them in place. Care was taken to ensure that the needle was kept open after inserting it into the putty. Each leak size was created by one to four needles introduced in the leak probes. Increasing leak sizes from 1.18 mm (Leak 1) to 3.7 mm (Leak 9) were obtained using different gauge needles.

The Companion recorded the  $C_{out}/C_{in}$  ratios at sealed condition and at different leak sizes while the manikin was breathing at the flow rates described above. The outlet of the sampling probe was connected to the Companion to measure  $C_{in}$ . The Companion also sampled the ambient air to obtain



$C_{out}$ . From the  $C_{out}$  and  $C_{in}$ , the Companion provided the fit factor. Fit-test exercises were not simulated, but the Companion measured the fit factor for 258 sec, equivalent to the time required to complete the first three exercises prescribed by OSHA.<sup>(1)</sup> The Companion calculated a harmonic average of the fit factors ( $1/[1/FF1+1/FF2+1/FF3]$ ) for three exercises.

It is possible that aerosol may deposit in the test system similar to that of the breathing human lung.<sup>(11)</sup> No attempt was made to measure the percentage of particle deposition in the test system or its effect on the  $C_{out}/C_{in}$  ratio measurement. Particle deposition or resuspension can be assumed to be negligible, because the ambient aerosol in the test system is under stirred state during the breathing condition.

## RESULTS

### Polydisperse NaCl Aerosol Penetration and Pressure Drop Measurements

Table I shows polydisperse aerosol penetration and resistance at 10 and 40 L/min constant flow rates. Percentage penetration of the N1 model was lower than the values obtained for N2 and SM1 models at both 10 and 40 L/min constant flow. Based on the filter penetration, N1 is described as a higher-efficiency model whereas N2 is termed a lower-efficiency model in the manuscript. The filtration efficiency of the SM1 model was several-fold lower than the two N95 models (N1 and N2) tested in the study. Table I shows that resistance was directly related to the filter efficiency of the N95 FFR and SM1 models at both flow rates.

**TABLE I. Filter Penetration and Resistance for Two N95 (N1 and N2) FFR and One Surgical Mask (SM1) Models for Polydisperse NaCl Aerosols Using a TSI 8130. Average for Three Samples ( $n = 3$ ) and Error (1 SD) Are Presented**

Flow Rate	Penetration (%)			Resistance (mm water)		
	N1	N2	SM1	N1	N2	SM1
10 L/min	$0.014 \pm 0.01$	$0.079 \pm 0.06$	$0.75 \pm 0.09$	$1.03 \pm 0.11$	$1.00 \pm 0.12$	$0.45 \pm 0.11$
40 L/min	$0.104 \pm 0.03$	$0.614 \pm 0.06$	$9.04 \pm 0.91$	$4.17 \pm 0.29$	$4.00 \pm 0.41$	$1.90 \pm 0.12$

**TABLE II. Measurement of  $C_{out}/C_{in}$  Ratios by the N95-Companion for Two N95 (N1 and N2) FFR and One Surgical Mask (SM1) Models at Different Leak Sizes and Breathing Minute Volumes**

Test Condition	$C_{out}/C_{in}$ Ratio		
	N1	N2	SM1
<b>Breathing Minute Volume 10 L, Tidal Volume 0.5 L</b>			
Sealed	10783 ± 10085	9280 ± 8308	1360 ± 1023
Leak 1	228 ± 53	322 ± 60	418 ± 365
Leak 2	182 ± 16	239 ± 21	281 ± 160
Leak 3	143 ± 21	199 ± 18	268 ± 167
Leak 4	128 ± 11	198 ± 77	243 ± 154
Leak 5	128 ± 17	183 ± 83	228 ± 130
Leak 6	115 ± 20	166 ± 26	216 ± 11
Leak 7	104 ± 18	150 ± 52	199 ± 94
Leak 8	84 ± 10	128 ± 68	187 ± 83
Leak 9	79 ± 12	109 ± 40	171 ± 82
<b>Breathing Minute Volume 40 L, Tidal Volume 1.5 L</b>			
Sealed	1390 ± 1171	1256 ± 1060	109 ± 15
Leak 1	313 ± 157	484 ± 83	89 ± 28
Leak 2	285 ± 163	400 ± 207	84 ± 30
Leak 3	239 ± 101	351 ± 133	76 ± 22
Leak 4	209 ± 63	345 ± 97	63 ± 26
Leak 5	198 ± 61	339 ± 160	60 ± 26
Leak 6	184 ± 41	304 ± 128	57 ± 27
Leak 7	165 ± 33	256 ± 104	54 ± 28
Leak 8	143 ± 15	209 ± 119	48 ± 22
Leak 9	138 ± 16	207 ± 132	46 ± 24

### $C_{out}/C_{in}$ Ratio Measurement

Table II shows the  $C_{out}/C_{in}$  ratios for the N1, N2, and SM1 models were greater at sealed condition than with different leak sizes introduced at both 10 L and 40 L breathing minute volumes. The ratios at sealed condition were greater at 10 L than at 40 L breathing minute volume. With increasing leak sizes, the ratios decreased gradually for the N95 and SM1 models at both 10 L and 40 L breathing minute volumes (Table II). The ratio for the lower-efficiency N2 at each leak size was greater than the ratio for the higher-efficiency N1. Similarly, the SM1 model ratios were also greater than the ratios for the N1 model at 10 L breathing minute volume. However, the SM1 ratio at each leak size was lower than the ratio for the N1 at 40 L breathing minute volume. The ratios for the two N95 models showed an increase with increasing breathing minute volume from 10 L to 40 L.

### DISCUSSION

As expected, the Companion  $C_{out}/C_{in}$  ratios for the N1, N2, and SM1 models sealed to the manikin were greater

than the ratios obtained with artificial leaks at both 10 L and 40 L breathing minute volumes. The  $C_{out}/C_{in}$  ratio was greater for N1 than for N2 and SM1 models. This can be explained by the difference in the filtration efficiency of the FFRs and SM1 models. When the FFR or SM1 is sealed to a manikin, the concentrations of particles inside and outside are the same as at no breathing condition. Once the manikin breaths, aerosols go in and out of the FFR or SM1 alternately. During this process, charged particles including the negatively charged 40–60 nm particles are captured by the filter medium followed by a decrease in the  $C_{in}$  and a greater  $C_{out}/C_{in}$  ratio. The higher-efficiency model N1 would capture negatively charged particles more efficiently to produce a greater ratio than the lower-efficiency N2 as well as the SM1. The results obtained in the study are supported by the greater ratio obtained for the higher-efficiency N95 model (M2) than the two lower-efficiency models (M1 and M3) at different breathing minute volumes for the sealed facepiece condition.<sup>(3)</sup>

With artificially introduced leaks in the N95 FFR and SM1 models, the Companion measured  $C_{out}/C_{in}$  ratios decreased with increasing leak size at the two breathing minute volumes tested in the study. This can be expected because ambient aerosols enter through the leaks during breathing and increase the concentration of negatively charged particles inside the respirator. In general, the ratios obtained for the higher-efficiency (N1) model at different leak sizes were lower than the ratios obtained for the lower-efficiency N2 model. This can be explained partly by the difference in the resistance offered by the two N95 models. Results showed that the resistance values for N1 were higher than for N2 at constant flow rates, which can be applied to breathing flow conditions. During breathing, the airflow through the filter media of both FFR models with leaks will be lower than the airflow at sealed condition. The airflow through the filter media of the two N95 FFR models at a given leak size is expected to vary because of their difference in resistance. The relationship between filter resistance and airflow velocity is shown below.

$$\text{Resistance} = \text{Pressure drop}/\text{Velocity} \quad (1)$$

where

$$\text{Velocity} = \text{Flow rate}/\text{Area}$$

Equation (1) becomes

$$\text{Resistance} = \text{Pressure drop} * \text{Area}/\text{Flow rate} \quad (2)$$

The areas of the two FFR models can be assumed to be similar for practical purposes. Then, equation (2) becomes

$$\text{Resistance} = \text{Pressure drop}/\text{Flow rate} \quad (3)$$

The inverse relationship between resistance and flow rate indicates that the percent of the total airflow through the filter media of lower resistance N2 would be greater than the airflow through the filter media of higher resistance N1 for a fixed leak size and a fixed breathing rate because of the difference in the percent of the total airflow through the filter media

versus the induced leak. A higher airflow resistance for the filter medium would drive a greater percent of the air through the leak paths. Therefore, N2 filter media would capture more negatively charged particles than by N1 filter media at different leak sizes under breathing conditions. The  $C_{in}$  for N2 would be relatively lower than for N1 and would produce a greater ratio. The results are consistent with the relatively greater ratios obtained for two lower-efficiency N95 models (M1 and M3) than a higher-efficiency model (M2).<sup>(3)</sup> The resistance measured for M2, M1, and M3 were  $4.29 \pm 0.32$ ,  $3.67 \pm 31$ , and  $2.85 \pm 0.25$  mm of water, respectively, at 40 L/min constant flow rate.

The results obtained in the study are indirectly supported by the increase in face seal leak caused by an increase in breathing resistance for half-mask elastomeric respirators tested on human subjects.<sup>(12)</sup> A subsequent study, however, showed no increase in face seal leak with increased pressure drop for subjects with acceptable fit.<sup>(13)</sup> The results obtained in the above studies for the half-mask elastomeric respirators with exhalation valves cannot be directly compared to the results obtained for FFRs in the current study, which had no exhalation valves.

The effect of breathing minute volume on the Companion  $C_{out}/C_{in}$  ratios can be seen from the data at the two flow rates tested. An increase in the flow from 10 to 40 L decreased the ratios at sealed condition for all test samples, which may be partly because of the penetration of some negatively charged 40–60 nm size particles inside the respirator at 40 L breathing rate. Contrary to this, the ratios were greater for both N1 and N2 at a breathing minute volume of 40 L than at 10 L at different leak sizes. The reason for the increase in the ratio at a higher flow rate may possibly be due to the difference in the relative volume of airflow through the filter media with leaks. With artificial leaks under continuous breathing, particles traverse through the leaks as well as through the filter media. The relative volume of aerosol going through the filter media may be greater at 40 L/min than at 10 L/min. Greater volume of airflow through the filter would favor the capture of relatively more negatively charged particles and decrease the concentration of negatively charged particles or increase the ratio.

Whether a loss of negatively charged 40–60 nm size particles occurred with leak conditions remains to be investigated. Despite the discrepancy described above, the ratios were consistently greater for N2 than for N1 at both breathing flow rates. At many leak sizes, the SM1 model showed  $C_{out}/C_{in}$  ratios greater than N1 at a breathing minute volume of 10 L. However, the Companion ratios for the SM1 measured at 40 L were lower than for N1 as well as N2 models. The decrease in the  $C_{out}/C_{in}$  ratios for the SM1 at the high breathing minute volume may be explained partly by the following.

The breathing minute volume 40 L exceeded a threshold flow rate for the SM1 model, which markedly decreased the particle capturing ability of the filter media. The threshold flow rate can be defined as the flow rate that drastically decreases

particle capturing by the filter media and is directly dependent on the filter efficiency of the test respirator. Among the two N95 FFR models N1 and N2, the threshold flow rate for N1 is expected to be higher than the threshold value for N2. It is also possible that at high flow rates the penetration of charged particles through the respirator may become significant. The results indicate that flow rates above the threshold value of respirators may adversely affect the Companion measurement of the  $C_{out}/C_{in}$  ratios.

Artificial leaks introduced in the experiments may influence the  $C_{out}/C_{in}$  ratios obtained in the study. Leak length is known to affect the pressure drop and aerosol penetration.<sup>(14)</sup> The authors of the above study showed that longer leak length decreased the aerosol penetration at low flow rates than at high flow rates. In the current study, the  $C_{out}/C_{in}$  ratios with different leak sizes were measured with a fixed length (~25 mm) hole of different diameters at 10 and 40 L breathing minute volumes. Results at both flow rates showed a consistent pattern of lower  $C_{out}/C_{in}$  ratios for the higher-efficiency respirator at different diameter holes. The use of a shorter leak hole length (~10 mm) also produced similar results for a higher-efficiency model (M2) and two lower-efficiency N95 models (M1 and M3).<sup>(3)</sup> The difference in the length of the leak holes used in the above studies showed no substantial change in the overall pattern of  $C_{out}/C_{in}$  ratios at different leak sizes. The results are supported by another line of evidence that came from the total inward leakage (TIL), representing filter penetration and face seal leakage of nanoparticles, measured with two scanning mobility particle size equipment using a similar experimental setup and leak hole length (~25 mm).<sup>(15)</sup> TIL value was obtained for ~45 nm size particles, the size range covered by the Companion measurement. Two lower-efficiency N95 FFR models showed TIL values higher (i.e., higher  $C_{in}$  or lower  $C_{out}/C_{in}$  ratios) than the TIL values (lower  $C_{in}$  or higher  $C_{out}/C_{in}$  ratios) for two higher-efficiency models at smaller leak sizes.

The opposing trend in  $C_{in}$  and TIL values with the same length leak indicates that leak hole length had minimal or no effect on the  $C_{out}/C_{in}$  ratios measured in the experiments. The TIL values represent both charged and uncharged ~45 nm size particles whereas the Companion ratios were obtained only for the negatively charged 40–60 nm size particles. The results obtained in the current study indicate that the difference in the  $C_{out}/C_{in}$  ratios obtained for the higher and the lower-efficiency N95 FFRs may be due partly to the design of the Companion to measure only the negatively charged 40–60 nm size aerosols.

The overestimation of the Companion ratios for some respirators may have implications for FF measurement. The Companion method produced acceptable FFs where other methods failed<sup>(5,6,8)</sup> as well as a higher “fit-test passing rate.”<sup>(4,7,8)</sup> The discrepancy with the Companion measurement is not well understood. The results obtained in our study also did not address the cause(s) of the fit-test results obtained in the above studies. However, the greater  $C_{out}/C_{in}$  ratios obtained for the

lower-efficiency N95 models may be related to the higher FFs measured by the Companion in the previous studies. This remains to be investigated in detail.

## LIMITATIONS AND/OR RECOMMENDATIONS FOR FUTURE INVESTIGATION

Limitations of the study include that the results obtained in the study are from a limited number of N95 model FFRs. Additional N95 models with different filter efficiency and pressure drop need to be tested for confirmation of the results. Pressure drop should be monitored during the manikin breathing and  $C_{out}/C_{in}$  ratio measurements to validate the results obtained in the study. The use of shorter leak probes may provide more realistic ratios. In this study, only  $C_{out}/C_{in}$  ratio and not the fit factor was measured at different leak sizes. Further studies are needed to compare the relevance of Companion ratios obtained with the manikin to FF measurement on test subjects.

## CONCLUSION

The Companion measured  $C_{out}/C_{in}$  ratio for the higher-efficiency N95 model was greater than the lower-efficiency model at sealed condition because of the difference in filter efficiency. With different leak sizes, however, the Companion ratios were greater for the lower-efficiency N95 FFR model at both 10 and 40 L breathing minute volumes. The greater ratio for the lower-efficiency model maybe due partly to the lower resistance, which allows higher aerosol flow through the filter media that captures more negatively charged particles to produce smaller  $C_{in}$  or greater  $C_{out}/C_{in}$  ratio. Increasing the breathing minute volume from 10 to 40 L, decreased the ratios for all models at sealed condition. With increasing leak sizes, the SM1 ratios decreased dramatically at 40 L indicating that high breathing flow rates may adversely affect the ratios. The greater ratios on lower-efficiency N95 model with leaks indicate that Companion may yield higher fit factors for some N95 models. Further studies are needed to better understand the Companion measurement of  $C_{out}/C_{in}$  ratios.

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