Evaluation of a New Instrument for Aerosol Quantitative Fit Testing

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ABSTRACT

Millions of workers exposed to various hazards perform fit testing to assure anticipated protection of their respirators. This testing has been conducted for about two decades mainly with a TSI PortaCount®, an instrument that measures the aerosol concentrations inside and outside the respirator using a condensation nuclei counting principle. Recently, a new fit testing instrument, Fit Tester (MT-05U) was developed for quantitative fit testing based on the optical particle counting (OPC). The objective of this study was to explore if this type of particle counter can be used for quantitative respirator fit testing. The study was performed in accordance with the American National Standards Institute (ANSI) and the American Industrial Hygiene Association Z88.10-2010 criteria for evaluating new fit test methods with the TSI PortaCount® as the reference apparatus. The overall fit factors were measured with the two instruments operating in parallel with respirators donned by 26 subjects performing the standard OSHA exercises during fit testing. The experiments were conducted with three types of high-efficiency particulate filtering respirators: P100 filtering facepiece, and two elastomeric respirators, half facepiece and full facepiece. The results showed that the MT-05U can correctly identify an inadequate fit of the tested respirators as compared with the reference instrument (with a sensitivity between 0.98 and 1.00, exceeding the ANSI requirement of ≥ 0.95). The other advisory ANSI requirements/recommendations for statistics (i.e., predictive value of a pass, specificity, predictive value of a fail, and kappa statistics) were also met. Due to the difference in operational particle size ranges of the two instruments, fit factors within pair comparison measured by MT-05U were generally lower than fit factors measured by PortaCount®. In conclusion, the new OPC-based MT-05U showed an acceptable performance in quantifying a respirator fit and, thus, can serve as an alternative method for respirators equipped with high-efficiency filters.

Keywords: quantitative respirator fit testing, optical particle counter (OPC), condensation nuclei/particle counter (CNC/CPC), filtering facepiece respirator, elastomeric half facepiece respirator, elastomeric full facepiece respirator.

INTRODUCTION

The purpose of the respirator fit testing is to assure that the selected make, model, and size of a tight-fitting respirator adequately fit the wearer, and that the wearer dons the respirator properly, which is a key issue for achieving the anticipated protection during use (ANSI, 2010). Fit testing has a significant role in protecting workers' respiratory health. Workers wearing respirators in the United States, Canada and Australia are required to perform fit testing prior to the first-time use, and at least annually or biannually (OSHA 1999, Clayton and Vaughan, 2005). A widely-used US OSHA-accepted quantitative fit testing protocol [29 CFR 1910.134 (OSHA, 1999)] is based on the "ambient aerosol condensation nuclei counter" (CNC, also known as condensation particle counter CPC), which is incorporated in the PortaCount® instrument (PortaCount Pro+ 8038, TSI Inc., Shoreview, MN, USA). The instrument measures particle concentrations outside the respirator, (C_{out}) and inside the respirator (C_{in}) while the subject is performing a standard set of head and breathing maneuvers, and records the exercise-specific ratio, C_{out}/C_{in}. The overall fit factor (FF) is calculated from these exercise-specific ratios (except grimace) (OSHA, 1999).

A PortaCount® fit tester includes a miniature, continuous-flow CNC, in which aerosol particles that are too small to be easily detected by optical means, are grown to a larger, easily detectable size in a chamber saturated with isopropyl alcohol, and then enumerated using a photodetector. The PortaCount®'s operational particle size range is approximately from 0.02 to > 1 µm, and the particle concentration range is approximately from 0.01 (for C_{in}) to 2.5 x10^5 (for both C_{in} and C_{out}) particles/cm^3. It is capable of measuring FFs from 1 to greater than 10,000 (TSI Inc., 2015).

Recently, a new instrument, Fit Tester (MT-05U, Sibata Scientific Technologies Ltd., Nakane Soka-City, Saitama, Japan), was developed for quantitative fit testing. Unlike the PortaCount®, the MT-05U utilizes an optical particle counting (OPC) principle, based on the light scattering from aerosol particles. With MT-05U, there is no need to use alcohol to grow particles. The instrument is capable of measuring particles of approximately 0.3 µm and above, and operates at concentrations of up to 10^4 particles/cm^3. It can measure FFs approximately between 1 and 10,000.

The aim of this study was to examine the use of an OPC for the purpose of quantitative respirator fit testing and determine if it meets the ANSI/AIHA Z88.10 criteria for a new fit testing method. It was accomplished by comparing the new instrument to the PortaCount® serving as the reference fit testing apparatus. In the present comparative study, we followed Criteria for Evaluating New Fit Test Methods established by the American National Standards Institute (ANSI) developed to ensure that a new fit test method identifies poorly fitting respirators as effectively as the reference method (ANSI, 2010 - ANSI Z88.10 Annex A2).

MATERIALS AND METHODS

Overall Approach

For this study, the data were collected according to the flow chart presented in Figure 1. There are two fundamental issues that must be emphasized: (i) the ANSI criteria as well as some previous investigations (Richardson et al., 2013, 2014a, 2014b) concerned with comparison of two fit testing methods, and (ii) the test design required by the ANSI is based on the sequential paired fit testing. In contrast, in this study, we compared two instruments (not methods) and the two fit tests were performed with these instruments operating simultaneously on the same subject. This eliminated "donning" as a source of variability.

Test Participants and Respirators

The study protocol was approved by University of Cincinnati Institutional Review Board (IRB). Before the fit testing, each subject obtained the OSHA medical clearance for wearing respirators that were used in the investigation, and signed the informed consent form. There were 26 participants in this study, of which 18 were males and 8 were females. The subjects represented different occupations, including medical professionals, firefighters, laboratory workers, etc. Each participant was fit tested wearing each respirator type with a number of replicates ranging from 1 to 15, except for one subject, who was tested only with the P100 filtering facepiece respirator (FFR). Face width (bizygomatic breadth) and face length (menton-sellion length) were measured for each subject to identify his/her facial dimension category in accordance with the National Institute for Occupational Safety and Health (NIOSH) bivariate fit test panel (Zhuang et al., 2007). Figure 2 shows that while the recruited subjects were well distributed across the panel, the majority of the participants' face dimensions fell in cell 6, and there were no subjects in cells 1, 5, 8, and 10. Two subjects had facial dimensions outside the NIOSH bivariate chart.

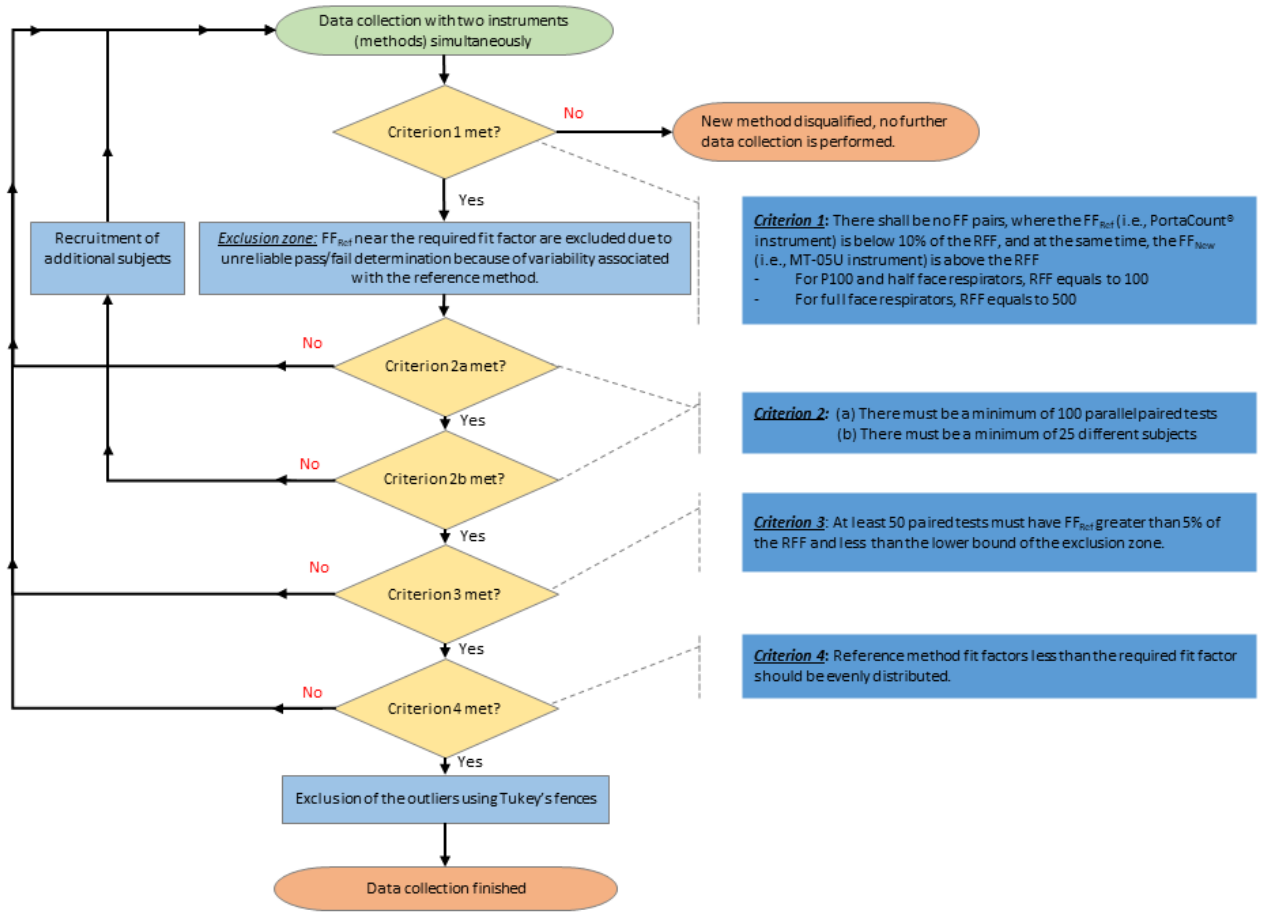


Figure 1. Data collection flow chart. FF = fit factor: FF_{New} = fit factor of the new method; FF_{Ref} = fit factor of the reference method; RFF = required fit factor.

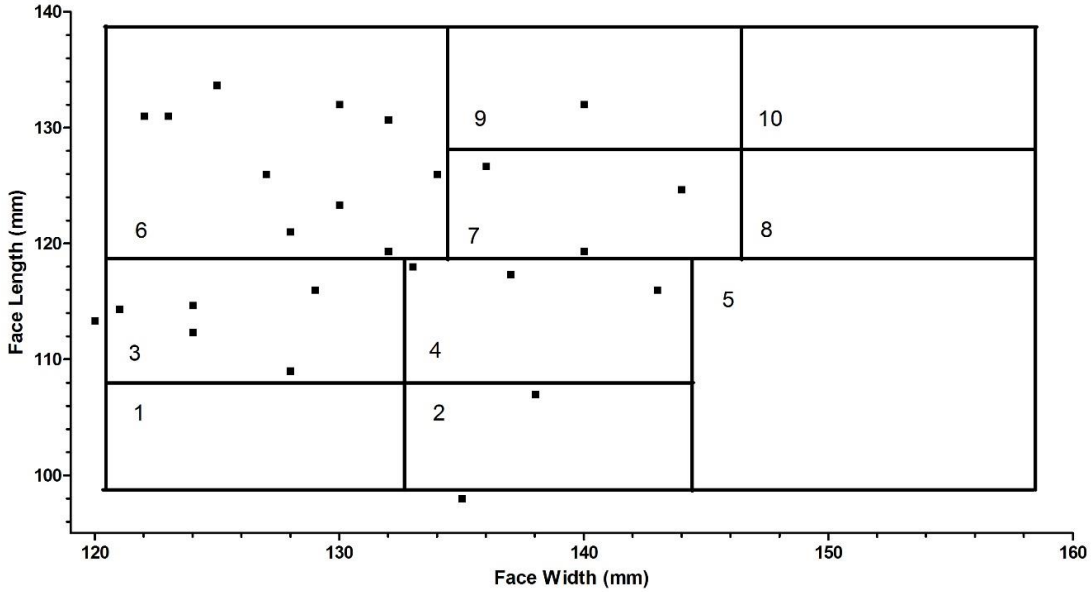


Figure 2. Distribution of facial dimensions of the participants overlaid on the NIOSH bivariate chart.

Three types of respiratory protective devices were used in this study: a P100 FFR, as well as elastomeric half facepiece and full facepiece respirators. Four different respirator models were used for each respirator type (Table I) to achieve a variety of different air flow and leak patterns as required by ANSI. All tested elastomeric respirators were equipped with high-efficiency P100 filters. The respirators selected for the testing are known to cover a wide range of fit factors. Individuals wearing P100 FFRs have been reported to have FFs from 4.7 to over 200 (Kim et al., 2016). Elastomeric respirators typically offer much better fit (He et al., 2013): The required fit factor, RFF is 100 for the half facepiece and 500 for the full facepiece respirators according to 29 CFR 1910.134 (OSHA, 1999).

Table I. Respirators Used in the Study

Respirator type	Models and manufacturers	Sizes
P100 FFR	3M model 8293, 3M Corp., St. Paul, MN, USA	One size
	SAS model 8641, SAS Safety Corp., Long Beach, CA, USA	One size
	Gateway P100 TruAir, Gateway Safety Inc., Cleveland, OH, USA	One size
	Sperian P1130, Sperian Protection, Basingstoke, UK	S
Half facepiece	3M 6000 series, 3M Corp., St. Paul, MN, USA	S, M, L
	North 7700 series, Honeywell Safety Products, Smithfield, RI, USA	L
	Breath Buddy, Minor Miracle Home Solution, Coral Springs, FL, USA	M
	Moldex 8000 series, Moldex, Culver City, CA, USA	M
Full facepiece	3M 6000 series, 3M Corp., St. Paul, MN, USA	S, M, L
	Strong ST-S100 series, Jingzhou Strong Scientific & Technological Development Co., Ltd., Jingzhou, Hubei, China	N/I[a]
	Dawei, China	N/I[a]
	Sansido, SJL, China	N/I[a]

[a] Not identified.

Some of the participants were profoundly experienced in wearing respirators; others were trained prior to this study but had little or no experience of using the three tested respirators at the workplace.

Every participant was advised on donning of respirators with the two fit testing instruments connected and observed throughout the test.

The ANSI comparison protocol requires that at least 50 fit test pairs produced by the reference method FFs (i.e., measured by the PortaCount®) in a range between 5% of the RFF and the lower bound of the exclusion zone (see the exclusion zone determination later in the paper). Achieving low FFs is difficult for all respiratory types used by trained subjects, and especially for elastomeric respirators, which have tight fit. Therefore, the number of failed fit tests is naturally low. In order to better simulate "failures" and achieve the required number of failed tests with a reasonable amount of test subjects, the following measures were implemented: participants were sometimes provided mis-sized respirators, respirators were not properly tightened, and the user seal check was not performed by the wearer.

Fit Factor Measurements

The testing was performed in a 24.3 m^3 exposure test chamber to assure an adequate and stable aerosol concentration for measuring a wide range of FFs. Sodium chloride (NaCl) was aerosolized in the chamber from a liquid suspension with a particle generator (model 8026, TSI Inc., Shoreview, MN, USA). The aerosol concentration in the chamber was in a range of 4,000 to 16,000 particles/cm^3 as measured with a P-Trak (model 8525 TSI Inc., Shoreview, MN, USA) with an operating size range of 20 nm to above 1 µm while MT-05U recorded C_{out} of approximately 60 – 760 particles/cm^3. The latter concentration levels are much lower because the MT-05U does not detect particles below the lower OPC threshold of approximately 0.3 µm, and the majority of particles were in this size range. The concentrations C_{out} and C_{in} were measured by the PortaCount® and MT-05U operating in parallel while the subject was performing the standard fit testing exercises. Thus, two FFs were generated with each donning: one by the reference instrument (FF_{Ref}) and the other by the new instrument (FF_{New}). The daily check tests of both instruments were performed following manufacturer's instructions.

The in-mask samples were collected as follows. With elastomeric half facepiece and full facepiece respirators, a removable fit test adaptor obtained from the manufacturer was used. A sampling tube was inserted inside the mask between nose and mouth, and the in-mask sample was split into the two instruments. The adapter could not be used for the in-mask sample collection from a P100 FFR. Furthermore, the exhalation valve in the center of the P100 FFR introduced additional challenges. Therefore, two flush type sample probes (acquired from TSI Inc.) were inserted into the P100 FFR providing separate sampling points for the two fit testing instruments. The probes located to the left and right of the exhalation valve, approximately 2.5 cm apart from each other. Identical sampling lines (with respect to the material, length, and internal diameter) were used for both instruments.

For this study, the standard OSHA exercises were used, consisting of eight exercises: normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, grimace (FF excluded from calculation), bending over, and normal breathing. The duration of each exercise was 1 min, except for grimace, which lasted for 15 s. The calculated overall fit factors were used for data analysis.

FF data were collected until Criteria 1-4 (Figure 1) were met. The most important issue in conducting a "test versus reference" comparison is to determine whether the new method can correctly identify an inadequate fit of the tested respirators. Therefore, within any FF pair, if the FF_{Ref} is < 10% of the RFF, but $FF_{New} \geq$ RFF (Criterion 1, Figure 1), the MT-05U instrument would have been disqualified for fit testing and the data collection would have been aborted. Other ANSI criteria require that, after applying the exclusion zone (see the following section), there must be a minimum of 100 paired tests from at least 25 different subjects in the analysis data set, of which at least 50 must have FF_{Ref} greater than 5% of the RFF and less than the lower bound of the exclusion zone. Additionally, FF_{Ref} that are lower than RFF, should have an even distribution.

Calculation of the Exclusion Zone

According to ANSI (2010), the FF-values generated by the reference method, which are too close to the RFF value (either below or above it), i.e., within one coefficient of variation (CV) from the RFF, should be excluded due to unreliable pass/fail determination within this range. CV for the reference method can be approximated by making multiple measurements with a single respirator donning on a subject generating an FF near RFF. However, it may be difficult to identify such a subject, especially when testing with full facepiece respirators because they, if properly donned, provide a very tight face seal, and typically generate FF values much greater than RFF. In the meantime, the exclusion zone calculation requires FF-values being both below and above RFF. The so-called fixed leak approach (McKay and Bradley, 2005) helps address this issue and determine the instrument-associated data variability around RFF. However, in order to capture the overall variability – arising from PortaCount® instrument as well as related to the study protocol based on simultaneous measurement with two instruments – a different way for the exclusion zone determination was adopted in this study: The exclusion zone establishment was based on parallel FF measurements with two identical PortaCount® instruments across a wide FF range. The authors believe that parallel fit testing with two identical PortaCount® instruments adequately reflects the uncertainties related to our study protocol, including the variability caused by two separate sampling probes utilized when testing with P100 FFR.

Similar to Richardson et al. (2013, 2014a, 2014b), the FFs were log (base 10) transformed, their differences, $\log(FF_1)-\log(FF_2)$, was calculated, and the standard deviation (sd) was determined from the log differences across all trials. Consequently, the boundaries of the exclusion zone were determined as follows:

$$\text{Lower Bound FF of the Exclusion zone} = 10^{(\log(RFF) - sd)}$$

$$\text{Upper Bound FF of the Exclusion zone} = 10^{(\log(RFF) + sd)}$$

Regardless of the distribution of $\log(FF_1)-\log(FF_2)$ associated with the reference method, a large sample (rule of thumb $n > 20$) is sufficient to generalize the findings from this sample to the entire database (Monrad et al., 2010). Thus, to estimate the reference method's variability, we had to collect >20 samples (each sample produces a pair of FF values obtained with the two PortaCount® instruments operating side-by-side). Altogether, 24 PortaCount®'s FF pairs were collected for P100 FFR and 22 FF pairs were collected for each the elastomeric respirators (half and full facepieces).

Statistical Analysis

The database collected for each respirator type was examined for statistical outliers. First, the ratios of the overall fit factors (i.e., FF_{Ref}/FF_{New} and FF_{New}/FF_{Ref}) were calculated, and outliers were identified from the ratios using Tukey's fences (Tukey, 1977). This method has a wide applicability because it is not dependent on distributional assumptions. The outliers are defined as observations outside the interquartile range. The boundaries of the interquartile range were determined from the overall FF ratios as follows:

$$\text{Lower Bound of the interquartile range} = Q1 - k(Q3 - Q1)$$

$$\text{Upper Bound of the interquartile range} = Q3 + k(Q3 - Q1)$$

Q1 and Q3 are the first and third quartile, and k is a non-negative constant. Conventionally, a value of 1.5 for constant k indicates an outlier and a value of 3 indicates data that is "far out" (Tukey, 1977). In this

study, a rather conservative value (k = 5) was used to exclude outliers to ensure that only extreme data pairs, originated from instrument errors or sampling bias, would be omitted.

After excluding the outliers, the number of failed and passed fit tests with both instruments were counted and recorded as four possible combinations presented in Table II [contingency table adopted from ANSI (2010)]. Test statistics, i.e., sensitivity, predictive value of a pass, specificity, predictive value of a fail, and kappa statistic were calculated and compared to the thresholds as specified in Table III.

Table II. Contingency Table from ANSI (2010)

Result	Failed Reference Test (FF_{Ref} < RFF)	Passed Reference Test (FF_{Ref} > RFF)
Passed New Test (FF_{New} > RFF)	A	B
Failed New Test (FF_{New} < RFF)	C	D

Table III. Test Statistics from ANSI (2010)

Statistics	**Equation**	**Value**	**Level of endorsement**
Test sensitivity	C/(A+C)	≥ 0.95	Mandatory
Predictive value of a pass	B/(A+B)	≥ 0.95	Advised
Test specificity	B/(B+D)	≥ 0.50	Advised
Predictive value of a fail	C/(C+D)	≥ 0.50	Advised
Kappa statistics	$(P_o^a-P_e^b)/(1-P_e^b)$	> 0.7	Recommended

$^aP_o = (B+C)/(A+B+C+D)$

$^bP_e = [(A+B)(B+D)+(C+D)(A+C)]/(A+B+C+D)^2$

RESULTS AND DISCUSSION

Exclusion Zone

The fit factors measured with the two PortaCounts® were widely distributed, covering the FF range approximately from 10 to 10,000 for all respirator types examined in this study (Figure 3). A very good agreement was observed between the two PortaCount® instruments, especially when testing with elastomeric half facepiece and full facepiece respirators (R^2 > 0.99 for the power regression model). For P100 FFR, the correlation remained high (R^2 = 0.98) with slightly greater data variability, which was possibly associated with two separate sampling probes installed inside the FFR. Alternatively, if a simple linear regression model were used to compare FFs from two PortaCounts®, the values of R^2 would still be in excess of 0.99 for both the elastomeric half facepiece and full facepiece masks; however, R^2 would decrease to 0.92 for P100 FFR. A lower linearity for P100 FFR pointed to an additional source of data variability (other than the instrument-to-instrument one). It is acknowledged that a power regression was also used in the studies of Richardson et al. (2013, 2014a, 2014b).

The standard deviation of the log differences of the FF values ranged from 0.02 to 0.14 resulting in the exclusion zones of 73 – 137, 85 – 118 and 472 – 529 for P100 FFR, elastomeric half facepiece, and full facepiece respirators, respectively (Table IV). Previous studies reported both wider and narrower

exclusion zones when testing with elastomeric respirators. McKay and Bradley (2005) determined exclusion zones (they referred to it as instrument noise) by repeatedly running the fit testing procedure on a high-efficiency filter with a fixed leak that provided FFs near the RFF (i.e., 100 for half facepiece and 500 for full facepiece respirators). In their study, the exclusion zones were approximately 94 – 106 and 475 – 525 for elastomeric half facepiece and full facepiece respirators, respectively. Compared to exclusion zones established in this study, the above ranges are narrower (for half facepiece) and similar (for full facepiece). Richardson et al. (2013, 2014a) collected overall FF pairs (two reference method tests done sequentially during the same donning) across multiple subjects, and determined the exclusion zone similarly to this study, which resulted in wider ranges such as 82 – 123 and 345 – 726 for half-mask and full-mask, respectively (Richardson et al., 2013, 2014a). These wider exclusion zones probably reflected the variability induced by the instrument and multiple subjects, along with the within-person variability performing exercises (one probably cannot perform the exercises exactly the same manner from one fit test to another), whereas the narrower exclusion zones determined by McKay and Bradley (2005) captured only the variability of the PortaCount® instrument.

Table IV. Exclusion Zones Calculated for Different Respirators

Respirator type	Measured sd from the log differences	Lower bound of the exclusion zone	Upper bound of the exclusion zone
P100 FFR	0.14	73	137
Half facepiece	0.07	85	118
Full facepiece	0.02	472	529

The widest exclusion zone was determined for P100 FFR. The tested P100 respirators were equipped with an exhalation valve in the middle. This did not allow placing the two in-mask sampling probes (one to PortaCount® and one to MT-05U) very close to each other. Although the distance between the probes was relatively small, some spatial non-uniformity associated with a poor particle mixing in the respirator cavity might have been present causing an additional variability in the measured FF (Myers et al., 1988).

Comparison of the Two Fit Testing Instruments

A total of 148 FF pairs were collected with PortaCount® and MT-05U instruments from 26 subjects with P100 FFR; a total of 122 and 135 FF pairs were collected from 25 subjects wearing elastomeric half facepiece and full facepiece respirators, respectively (Table V). In the collected data sets, there occurred no single pair in which the FF_{Ref} (PortaCount®) was below 10% of RFF, and at the same time, the FF obtained with the new method (MT-05U) was above RFF (Criterion 1, Figure 1). By applying the exclusion zone to the data sets, we excluded 15 FF pairs for P100 FFR, 8 for half facepiece, and 2 for full facepiece respirators. After this exclusion, the ANSI (2010) requirements stated in Criteria 2a, 2b, and 3 (Figure 1) appeared still fulfilled (Table V).

Figure 4 shows that FF_{Ref} values, which fell below the corresponding RFF, were evenly distributed for each of the three tested respirator types (Criterion 4, Figure 1), and that the entire FF data set bracketed the RFF value for each respirator type, thus meeting the ANSI criteria.

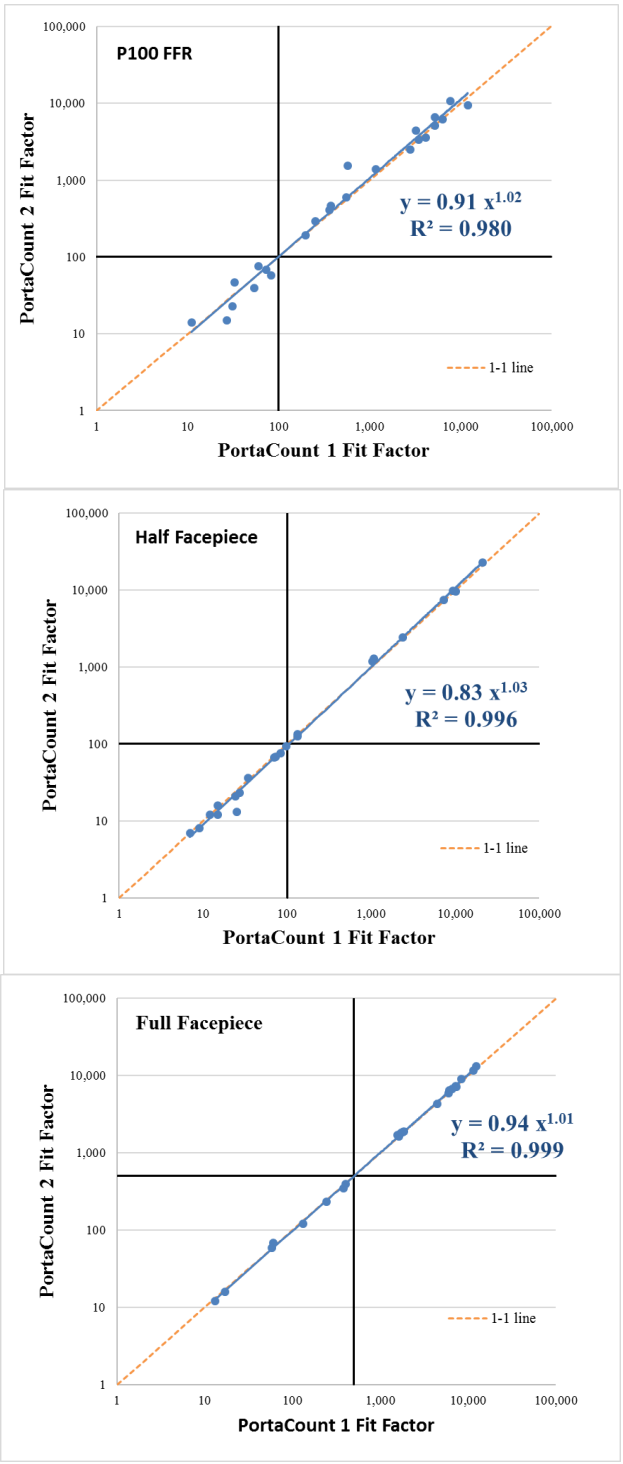


Figure 3. Comparison of the overall fit factors measured with two PortaCounts® for the determination of exclusion zone when testing with P100 FFR, elastomeric half facepiece, and full facepiece respirators.

Table V. The numbers of Paired Tests: Result of Application of the Exclusion Zone and Correction of FF_{Ref} for Outliers.

Respirator type	No. of completed paired tests	No. of cases that fall into EZ[a]	After EZ has been applied				No. of outliers	After EZ has been applied and outliers have been excluded		
			No. of paired tests[b]	No. of Passes	No. of Fails			No. of paired tests	No. of Passes	No. of Fails
					No. of Fails: Lower bound of the EZ > FF > 5% of the RFF[c]	No. of Fails: FF ≤ 5% of the RFF				
P100 FFR	148	15	133	72	54	7	3	130	70	60
Half facepiece	122	8	114	45	65	4	10	104	36	68
Full facepiece	135	2	133	59	58	16	13	120	53	67

[a] Exclusion zone
[b] 100 required by ANSI (2010)
[c] 50 required by ANSI (2010)

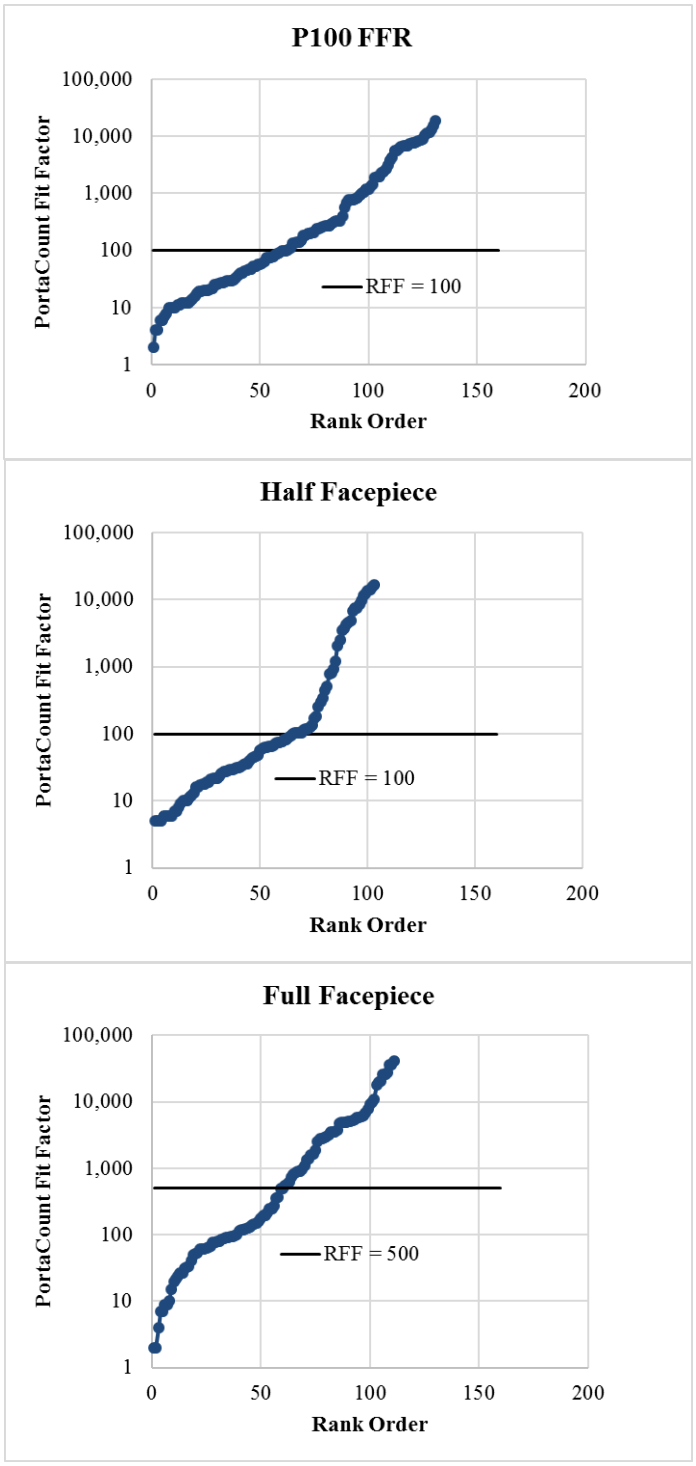


Figure 4. Distribution of the overall FFs obtained with the reference method for P100 FFR, elastomeric half facepiece, and full facepiece respirators. Horizontal black lines represent the RFF (i.e., 100 for FFR and half facepiece, and 500 for full facepiece respirator).

Figure 5 presents the comparison of PortaCount® versus MT-05U FFs. Typically, FFs measured with the PortaCount® were higher than those measured with the MT-05U, especially when the respirator was well fitting, and the seal was intact (green zones in Figure 5). This can be explained by the difference in the operational particle size ranges of the instruments. As indicated above, MT-05U is capable of detecting only particles with the optical size range (above approximately 0.3 µm), whereas PortaCount® measures particles in a size range of approximately 20 nm to above 1 µm. The latter particle size range is represented by much larger overall particle number concentration than the former. Therefore, MT-05U may not be able to measure FF values as high as PortaCount®, especially when the respirator is well fit and there are very few particles detected inside. Although the overall FFs generated by of the two instruments are not equal (their relationships do not fit to the 1:1 dashed line in Figure 5), the correlation between the data sets is satisfactory for all three respirators, with the slope varying from 1.29 to 1.96 and R^2 varying from 0.865 to 0.924.

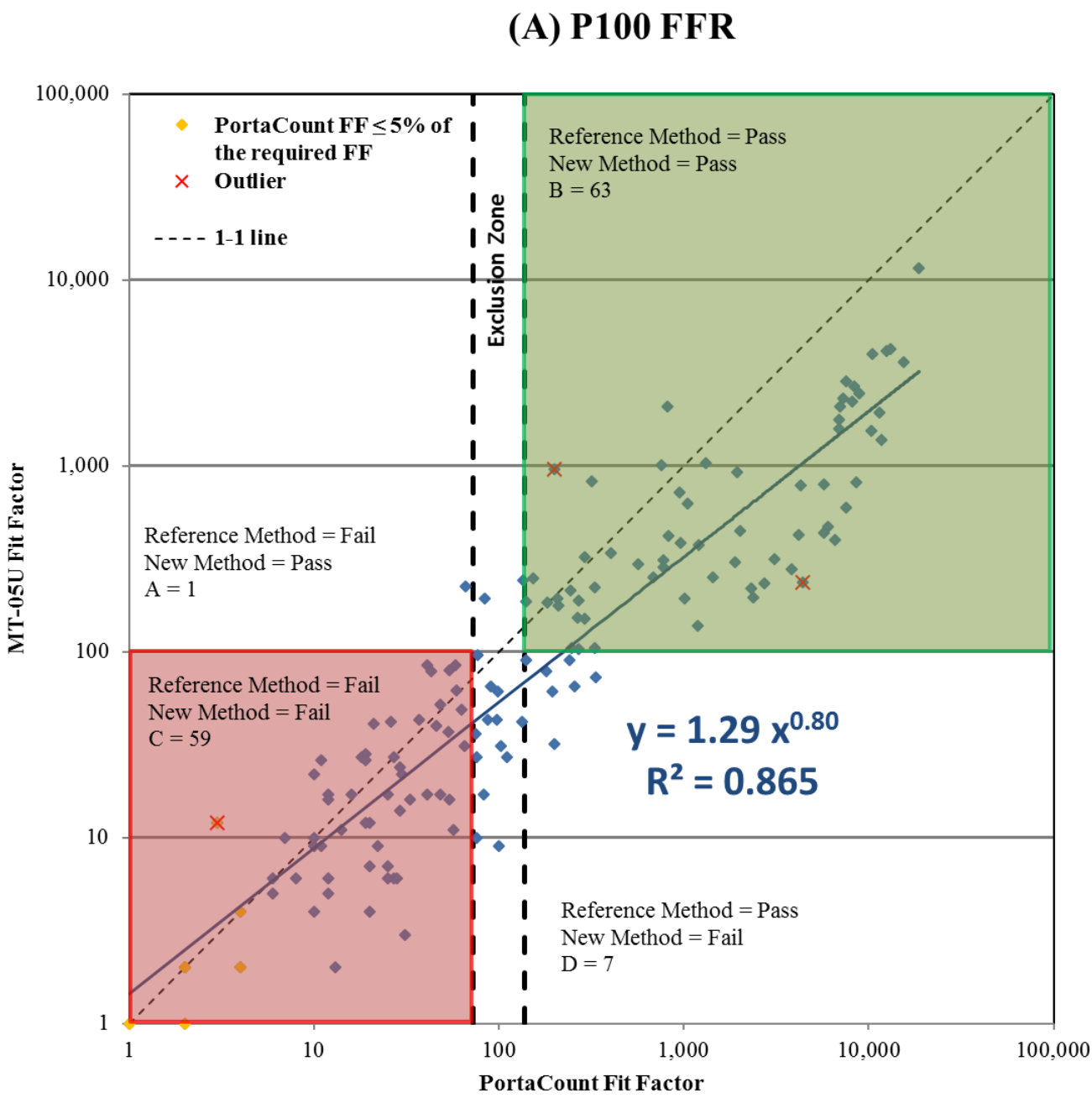
The number of outliers ranged from 3 for the P100 FFR to 13 for full facepiece respirator (Table V). For P100 FFR, two of the outliers were categorized as “Pass” by both instruments (i.e., they were located in the green quadrant in Figure 5A) and one was categorized as “Fail” by both instruments. For half facepiece respirators, all outliers, except for one, were located in the green quadrant (Figure 5B). For full facepiece respirators, outliers were distributed throughout all quadrants (Figure 5C).

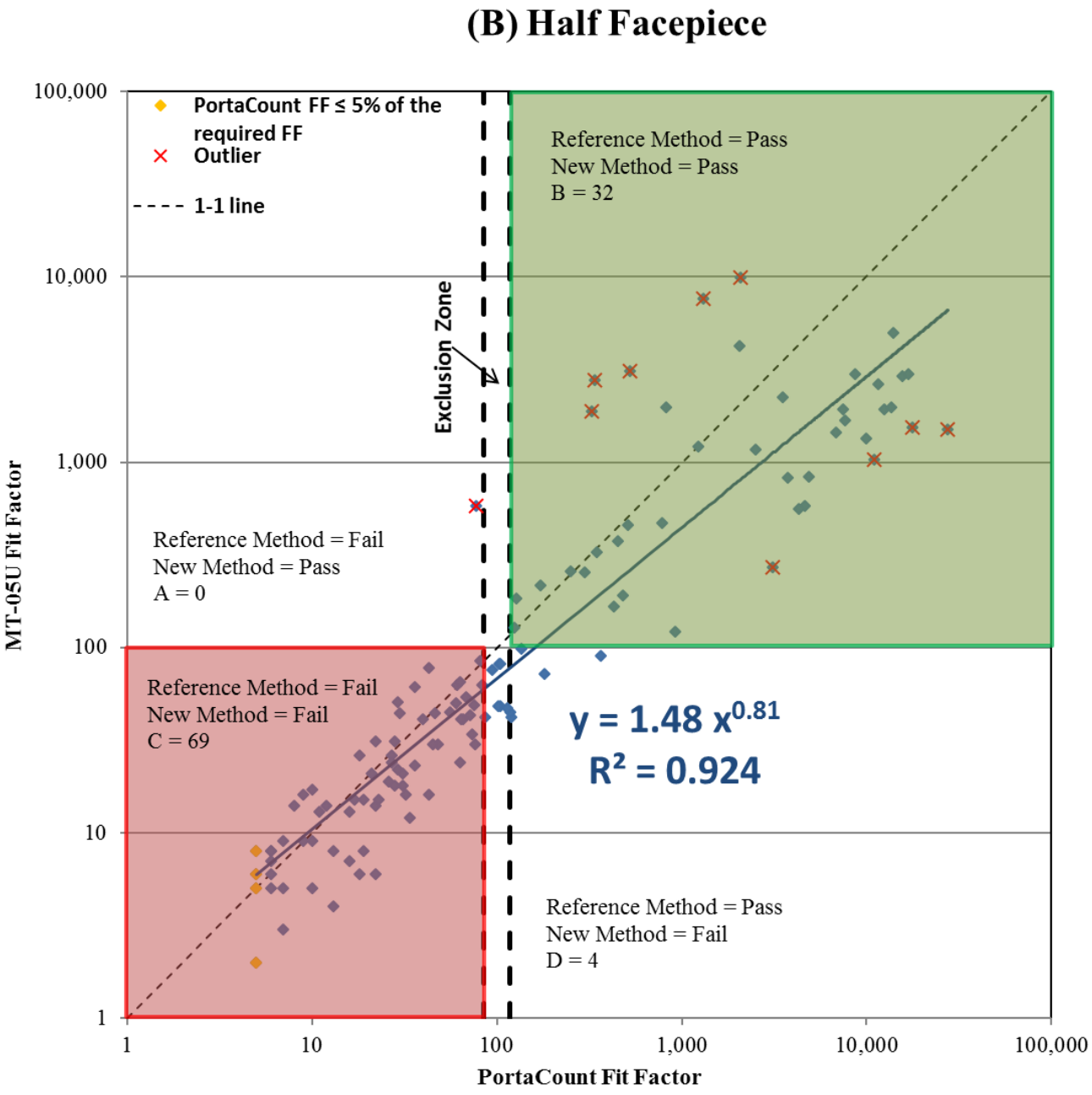
The results from statistical analysis along with the corresponding ANSI requirements and recommendations are presented in Table VI. The ANSI requirements/recommendations were fulfilled for all three respirator types. Exclusion of outliers affected some of the outcomes. For instance, it helped the case with respect to “sensitivity” and “predictive value of a pass” when testing with the full facepiece respirator. The results obtained with the P100 FFR and half facepiece respirator satisfied all the ANSI requirements/recommendations even before the outliers were excluded. Some of the outliers likely occurred due to instrumental errors. Other outliers were associated with specific subjects: six individuals, which account for about 25% of the subjects tested, produced 73% of all outliers. When testing with these subjects, we observed an excessive amount of water condensed in sampling lines, which was apparently related to the humidity of air exhaled by these subjects.

Table VI. Statistics Summary along with the ANSI Requirements/Recommendations for Different Respirator Types (calculated after excluding the outliers)

Respirator	Sensitivity	Predictive value of a pass	Test specificity	Predictive value of a fail	Kappa statistics
P100 FFR	0.98	0.98	0.90	0.89	0.88
Half facepiece	1.00	1.00	0.89	0.94	0.91
Full facepiece	1.00	1.00	0.81	0.87	0.83
ANSI requirement/ recommendation	≥ 0.95	≥ 0.95	≥ 0.50	≥ 0.50	> 0.7

The limitations of this study are primarily concerned with the sampling protocol. We used two sampling probes for P100 FFRs, which might have caused an additional variability in the measured FFs. When testing with elastomeric half facepiece and full facepiece respirators, we used a removable fit test adaptor, which could have caused particle losses. Finally, some moisture condensation in the tubings could have affected the measurement results.


(A) P100 FFR
PortaCount FF ≤ 5% of the required FF
Outlier
1-1 line
Exclusion Zone
Reference Method = Pass
New Method = Pass
B = 63
Reference Method = Fail
New Method = Pass
A = 1
Reference Method = Fail
New Method = Fail
C = 59
Reference Method = Pass
New Method = Fail
D = 7
y = 1.29 x^0.80
R² = 0.865
MT-05U Fit Factor
PortaCount Fit Factor
100,000
10,000
1,000
100
10
1
1
10
100
1,000
10,000
100,000


(B) Half Facepiece
PortaCount FF ≤ 5% of the required FF
Outlier
1-1 line
Exclusion Zone
Reference Method = Pass
New Method = Pass
B = 32
Reference Method = Fail
New Method = Pass
A = 0
Reference Method = Fail
New Method = Fail
C = 69
Reference Method = Pass
New Method = Fail
D = 4
y = 1.48 x^0.81
R² = 0.924
MT-05U Fit Factor
PortaCount Fit Factor
100,000
10,000
1,000
100
10
1
1
10
100
1,000
10,000
100,000

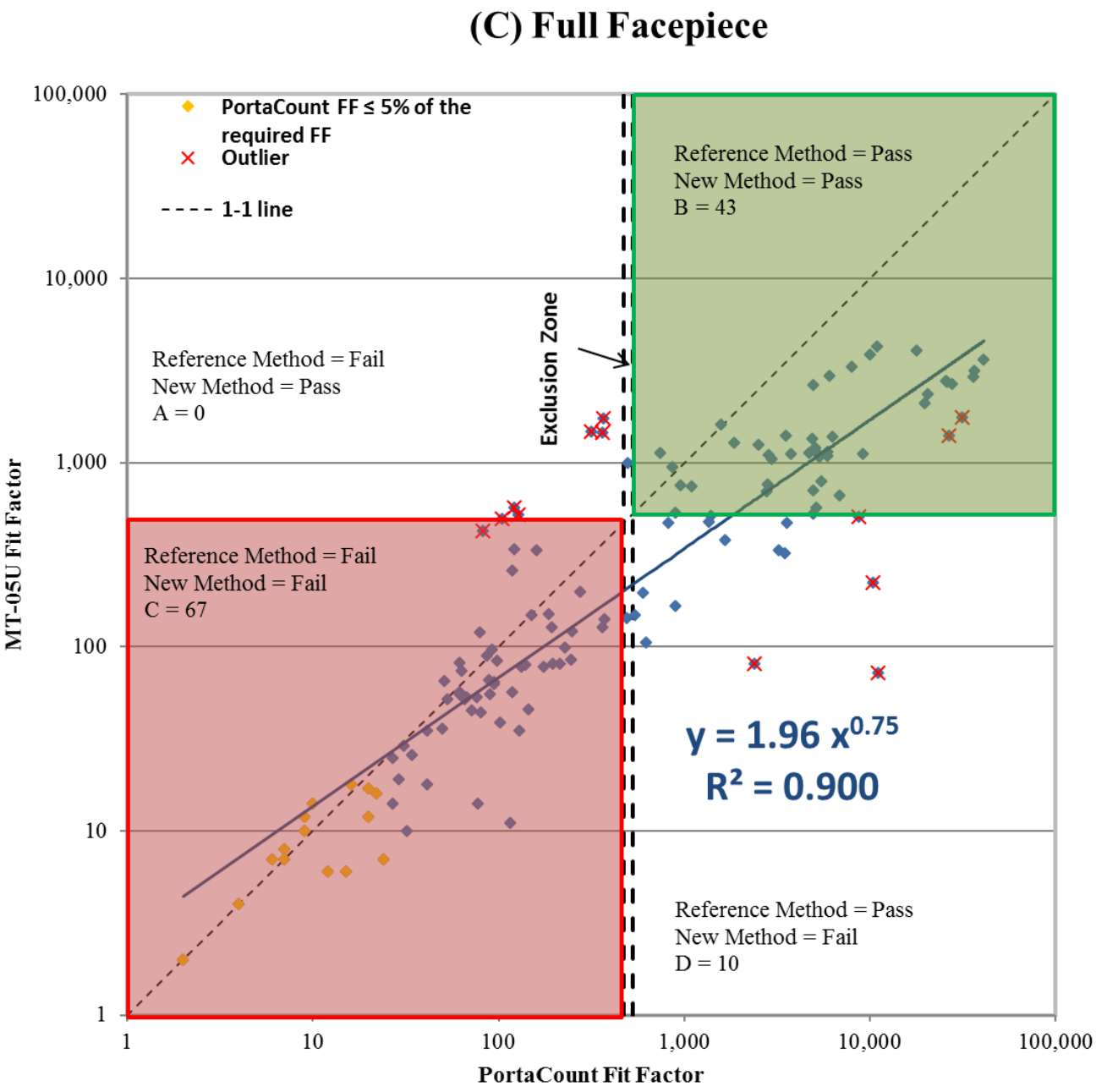


Figure 5. Comparison of overall FFs measured using the reference method and the MT-05U instrument for (A) P100 FFR, (B) half facepiece, and (C) full facepiece respirators.

CONCLUSIONS

The new fit testing instrument MT-05U was found capable of identifying the poorly fitting respirators. Most of the subjects who passed a fit test with the MT-05U instrument, actually have acceptable fits, and those who failed, actually have unacceptable fits (based on the data obtained with the reference PortaCount® operated in parallel). High specificity found for all the tested respirator types ensures that most wearers with a proper fit measured by the reference instrument would also pass the fit test performed with the new MT-05U. An agreement between the data generated with the MT-05U and PortaCount® was obtained for each of the three respirator types, although MT-05U revealed lower fit factors due to the difference in operational particle size ranges. It was concluded that the OPC-based MT-05U is a feasible alternative for fit testing.

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