

Utility of an Optical Particle Counting Instrument for Quantitative Respirator Fit Testing with N95 Filtering Facepieces

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ABSTRACT

Currently, the aerosol-based quantitative respirator fit testing is primarily conducted using a PortaCount[®] (TSI Inc., Shoreview, MN, USA), which utilizes a condensation particle counting (CPC) technique and measures particles in a size range of $d_p \sim 0.02 - 1 \mu\text{m}$. A U.S. OSHA-accepted fit testing protocol or similar protocols approved by other countries' regulatory agencies shall be followed. We recently investigated a new instrument, MT-05U (Sibata Scientific Technologies, Ltd., Tokyo, Japan) utilizing an optical particle counting (OPC) technique, $d_p \geq 0.3 \mu\text{m}$, for the quantitative fit testing of three types of respirators with high-efficiency filters – the P100 filtering facepiece respirators (FFRs), and elastomeric half- and full-face respirators. Conducted with the PortaCount[®] as the reference instrument, good feasibility of the OPC method for fit testing of the above-mentioned types of respirators was demonstrated, according to the ANSI standard Z88.10-2010. The present effort is a follow-up study, in which the same fit testing instrument MT-05U was evaluated utilizing the same approach for N95 FFRs via the PortaCount[®] N95-Companion[™] as the reference instrument. It was found that the new instrument could identify inadequate fits of all tested N95 FFRs with sensitivity (probability of identifying inadequate fits) of 1.00, exceeding the ANSI mandatory requirement of ≥ 0.95 . The predictive value of a pass was 1.00 as well, exceeding the advisory criteria of ≥ 0.95 . Additionally, the specificity and predictive value of a fail were 0.59 and 0.69, respectively, both exceeding the advisory criteria of ≥ 0.5 . The value of the kappa statistic was 0.58 falling below the threshold of 0.7 (it is acknowledged though that the latter is optional as it is neither mandatory nor advised according to ANSI). In conclusion, the evaluated OPC-based fit tester could be successfully deployed as an alternative method for quantitative fit testing for N95 FFRs.

Keywords: N95 respirator, fit test, optical particle counter, condensation particle counter

INTRODUCTION

Respirators play an important role in preventing workers from inhalation overexposure at various workplaces. To ensure the proper protection by a respirator, fit testing must be performed following a U.S. OSHA-accepted protocol or similar protocols approved by regulatory agencies of other countries. Of the three accepted quantitative respirator fit testing methods, two are aerosol-based. To quantify the fit of a respirator, an aerosol measuring apparatus (typically a photometer or a condensation nuclei counter (CNC, also known as CPC)) is utilized to determine the particle concentrations outside (C_{out}) and inside (C_{in}) the respirator while the wearer is performing a standard set of exercises (ISO 16975-3:2017; OSHA 29 CFR Part 1910.134:1999). The ratio of C_{out} and C_{in} for each exercise is defined as a fit factor. The overall fit factor (FF) is calculated from these exercise-specific ratios (except grimace) (OSHA, 1999).

In the U.S., aerosol-based quantitative respirator fit testing is primarily conducted using the ambient aerosol method which is incorporated in a PortaCount® fit tester (TSI Inc., Shoreview, MN, USA) with an operational particle size range of $d_p \sim 0.02 - 1 \mu\text{m}$. In our recent study (Wu et al., 2017), we evaluated an alternative method based on optical particle counting (OPC) that is capable of measuring particles of $d_p \geq 0.3 \mu\text{m}$. A novel fit tester MT-05U (Sibata Scientific Technologies Ltd., Tokyo, Japan) was evaluated when operating in parallel with the PortaCount®, serving as the reference instrument. The evaluation was performed in accordance with the American National Standards Institute (ANSI) standard Z88.10-2010 (ANSI, 2010 - ANSI Z88.10 Annex A2) using three types of respirators with high-efficiency filters: the P100 filtering facepiece respirators (FFRs) and elastomeric half- and full-face respirators equipped with P100 filters. It was concluded that the OPC-based fit tester could be successfully deployed as an alternative method for quantitative respirator fit testing of the three above-mentioned respirator types.

Unlike high-efficiency filters such as P100, an N95 filter may allow the particle penetration as high as 5% when challenged by NaCl aerosols. The particle size distribution is supposed to have a count median diameter (CMD) of $0.075 \pm 0.020 \mu\text{m}$ (NIOSH, 2016). Aerosol-based quantitative respirator fit testing assumes that all particles detected inside the mask get through face seal leaks. However, the particle counter is not able to distinguish the source of the particles. Consequently, particles penetrating through the filter can be incorrectly attributed to a face seal leakage and thus, lead to a lower fit factor. To remove this possible miscounting, the PortaCount® is equipped with N95-Companion™ technology, which contains an electrostatic particle classifier to select and measure particles in a narrowed size range of $\sim 30 - 55 \text{ nm}$ (TSI Inc., 2010). The particle penetration through the N95 filter is considered negligible within this specific range. Hence N95-Companion™ deploys particles that come from face seal leakage for effective quantitative fit testing (TSI Inc., 2010).

The present effort is a follow-up study, aiming at extending the evaluation of the MT-05U Fit Tester to N95 FFRs. The same approach is utilized. In this study, the PortaCount® operates with the N95-Companion™ accessory.

METHODS

Overall Approach

The challenge aerosol (NaCl particles) was generated in a 24.3-m^3 test chamber with a Particle Generator (8026, TSI Inc, Shoreview, MN, USA). The size distribution of the challenge particles was obtained with a Mini Wide Range Aerosol Spectrometer (Mini-WRAS 1371, GRIMM Aerosol Technik Ainring GmbH & Co., Ainring, Germany). Each study subject was fit tested with MT-05U and PortaCount® N95-Companion™ running in parallel while the subject performed the eight standard OSHA fit test exercises, and the study followed OSHA-accepted generated aerosol quantitative fit testing protocol. The outcome of

each fit test was a pair of overall fit factors (FFs): the fit factor of the reference method (FF_{Ref}) obtained from the PortaCount® N95-Companion™ and the fit factor of the new method (FF_{New}) obtained from the MT-05U. Both instruments went through the daily check procedure as instructed by the manufacturer.

The data collection protocol was identical to the one deployed in our previous study (Wu et al., 2017), following four requirements stated in the ANSI standard Z88.10-2010 for evaluating new fit test methods. First, the new method shall never pass the fit test when FF_{Ref} is less than 10% of the required fit factor (RFF). Second, after the exclusion zone is applied (see details in the section entitled “Calculation of the exclusion zone”), the comparison dataset shall consist of a minimum of 100 paired fit tests from at least 25 different subjects. Third, among all the fit factor values measured by the PortaCount®, i.e., FF_{Ref} , there must be at least 50 FFs between 5% of the RFF and the lower bound of the exclusion zone. Last, FF_{Ref} values that are lower than RFF should be evenly distributed (ANSI, 2010 - ANSI Z88.10 Annex A2). There is a difference between the data collection process described by ANSI and the one used in this study and our previous investigation (Wu et al., 2017). Our approach is based on the paired fit tests performed with two methods *simultaneously* on the same donning, using one set of standard fit testing exercises; while the procedure described by ANSI as well as the study conducted by Richardson et al. (2014) involves *sequential* paired fit tests with two consecutive donnings. By performing measurements with the two methods simultaneously, we eliminated the variability arising from different donnings.

Test Respirators

N95 FFRs were represented by five different models and sizes (Table I) to achieve a variety of different air flow and leak patterns as required by ANSI. The required fit factor (RFF) is 100 for N95 FFRs according to 29 CFR 1910.134 (OSHA, 1999).

Table I. Respirators Used in the Study

Models and manufacturers	Sizes
3M model 1860, 3M Corp., St. Paul, MN, USA	Regular, Small
3M model 1870, 3M Corp., St. Paul, MN, USA	One size
3M model 8210, 3M Corp., St. Paul, MN, USA	Regular, Plus
Jackson Safety Model 64420 R20 with an exhalation valve, Kimberly-Clark Professional Worldwide, Inc., Roswell, GA, USA	One size
Moldex Model 2200, Moldex-Metric Inc. Culver City, CA, USA	Medium/Large

Study Participants

The University of Cincinnati Institutional Review Board (IRB) approved the study protocol before recruitment of the study subjects began. Twenty-five adult subjects, including 15 males and 10 females, participated in the study. The subjects were qualified for participation after obtaining medical clearance for wearing FFRs and providing a written consent form. Face width (bizygomatic breadth) and face length (menton-sellion length) data were collected from each subject and plotted in the NIOSH 25-member bivariate fit test panel (Zhuang et al., 2007). Although we did not aim at covering all facial dimension categories, the subjects largely represented the panel. All the data points, except one, fell inside of the panel boundaries. Since the panel was formed using the anthropometry data of the U.S. workforce, it showed our test subjects were representative.

Regardless of individual experience of using the tested respirators, each participant was trained on proper donning and doffing of respirators prior to the actual fit tests. During the testing, each participant was fit tested with different models of the respirators. A total of 4 – 8 replicate tests per subject were conducted. The number of replicated tests was designed in order to achieve the required amount of data points (≥ 100) with 25 subjects. In-mask particle concentration was measured with two instruments through tubing connected to two identical flush type sampling probes. The probes were placed in the center line (i.e., the breathing zone) of on each tested respirator. For respirators with center-mounted exhalation valves, the probes were installed to the left and right side of the valve.

Calculation of the Exclusion Zone

The uncertainty of measurement is unavoidable with any instrument; typical FF accuracy is $\pm 10\%$ of the reading for the reference PortaCount® (TSI, 2015). Thus, the unreliable pass/fail range (i.e., FFs that are too close to the RFF) should be determined first. ANSI (2010) defined this unreliable range as exclusion zone, which is \pm one coefficient of variation (CV) from the RFF. CV is the ratio of the standard deviation to the mean and can be estimated by making multiple measurements with a single respirator donning on a subject which produces an FF very close to the RFF. It is problematic to find a subject having the FF close to the RFF and, furthermore, generating almost the same FFs in the course of numerous fit tests. McKay and Bradley (2005) developed a so-called fixed leak approach to address this issue and determined the instrument-associated data variability near the RFF. However, altogether the variability is associated with PortaCount® instrument itself as well as the study protocol. For example, two separate sampling probes were needed for simultaneous measurements with two instruments, which is a source of variability. In this study, the exclusion zone was established in the same manner as in our previous study (Wu et al., 2017). Specifically, paired FFs covering a wide range were obtained using two identical PortaCount® N95-Companion™ units running in parallel. We believe that our approach adequately reflects the variabilities related to both the reference instrument N95-Companion™ itself and the study protocol.

The fit testing setup for the investigation of two N95-Companion™ instruments was established in the same way as the one utilized for comparing the MT-05U versus N95-Companion™, which included the same challenge aerosol, testing chamber, tested respirators, fit test exercises, and so forth. Particle concentration C_{out} recorded by PortaCount® N95-Companion™ ranged from 353 to 1158 particles/cm³ for the targeting particle sizes of $\sim 30 - 55$ nm.

Statistically, a large number of tests (rule of thumb $n \geq 20$) is adequate to make inference about the variability associated with the reference apparatus (Monrad et al., 2010). Thus, a minimum of 20 pairs of FF values measured with the two PortaCount® N95-Companion™ instruments operating side-by-side was needed.

The paired FFs collected from two N95-Companions™ were first log (base 10) transformed, then the log difference of FFs, $\log(FF_1) - \log(FF_2)$, was calculated for each fit test. Last, the standard deviation (SD) of all log differences was determined.

The boundaries of the exclusion zone were determined as follows:

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

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

Statistical Analysis

Once the data collection requirements were satisfied and the exclusion zone was applied, the paired FF dataset, generated from new and reference instruments, was examined for outliers using the statistical method – Tukey’s fences (Tukey, 1977). This method has wide applicability because it is independent of the distribution of the data. The outliers were identified from the ratios of the overall fit factors (i.e., $\text{FF}_{\text{Ref}}/\text{FF}_{\text{New}}$ and $\text{FF}_{\text{New}}/\text{FF}_{\text{Ref}}$), and the outliers were defined as observations outside the interquartile range. Two boundaries of the interquartile range were determined from the overall FF ratios as follows:

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

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

Here Q1 and Q3 are the first and third quartile of the data, respectively; k is a non-negative constant. Conventionally, a value of 1.5 for the constant k indicates a possible outlier and a value of 3 indicates the data is “far out” (Tukey, 1977). In this study, a very conservative k = 4 was used to scan for those extreme data points, which originated from instrument errors or sampling bias.

After outliers were excluded, the outcomes of failed and passed a fit test with both instruments formed four possible combinations (zone A – zone D) presented in Figure 1 (adopted from ANSI (2010)). Then using the counts of A, B, C, and D, one could calculate the test statistics – sensitivity, predictive value of a pass, specificity, predictive value of a fail, and kappa statistic as defined in ANSI (2010). Finally, those test statistics from this assessment were compared to the threshold values (specified in Table II) for passing a new fit testing method according to ANSI (2010).

Table II. Test Statistics Defined in 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

$$^a P_o = (B+C)/(A+B+C+D)$$

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

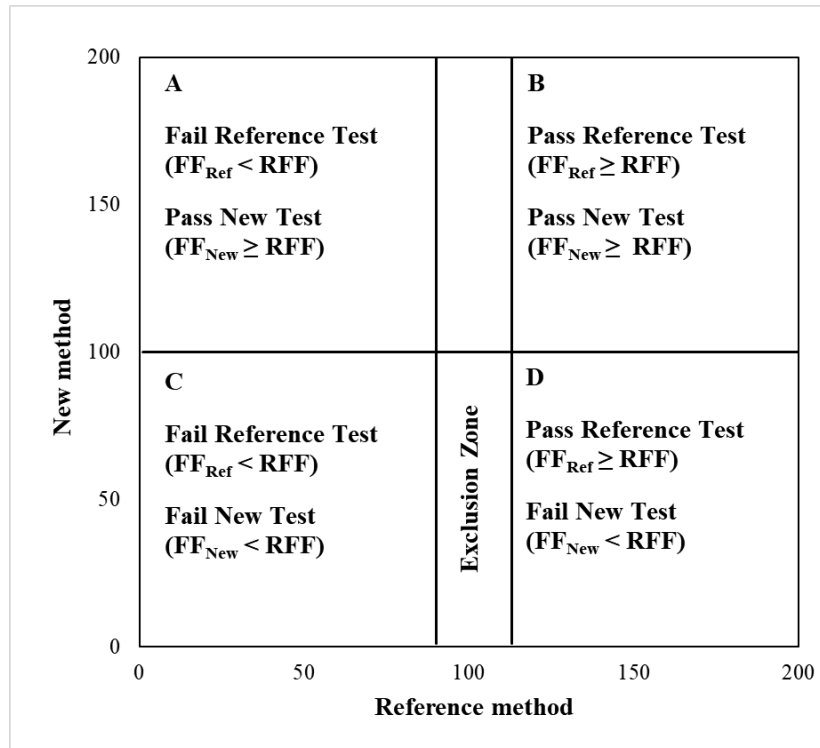


Figure 1. Definitions of zones A, B, C, and D used for test statistics calculation, adopted from ANSI (2010).

RESULTS AND DISCUSSION

Exclusion Zone

The paired FFs of N95 FFRs generated by the two PortaCounts[®] were evenly distributed from 13 to 200+ in this study (Figure 2). A decent agreement was observed between the two PortaCount[®] instruments operating with the N95-Companion[™]. The FFs of one PortaCount[®] can be estimated using the other one through a linear regression model: $y = 0.96x + 8.97$ (Figure 2). The regression coefficient k of 0.96 and the coefficient of determination R^2 of 0.985 revealed an almost perfect 1-1 linear fit, in which case both k and R^2 are equal to 1. Based on the data, the standard deviation of the log differences of the FF values was 0.095 resulting in the exclusion zone from 80 to 125 for PortaCount[®] N95-Companion[™]. The exclusion zone for FFRs established by Richardson et al. (2014), 78 – 128, was slightly wider, probably due to the consecutive donnings performed in the quoted study.

The differences in paired FF were brought by the instrument-to-instrument variation and testing protocol (for instance two separated sampling lines). Even though two PortaCounts[®] were assumed “identical” in this study, the instrument-to-instrument variation may still exist.

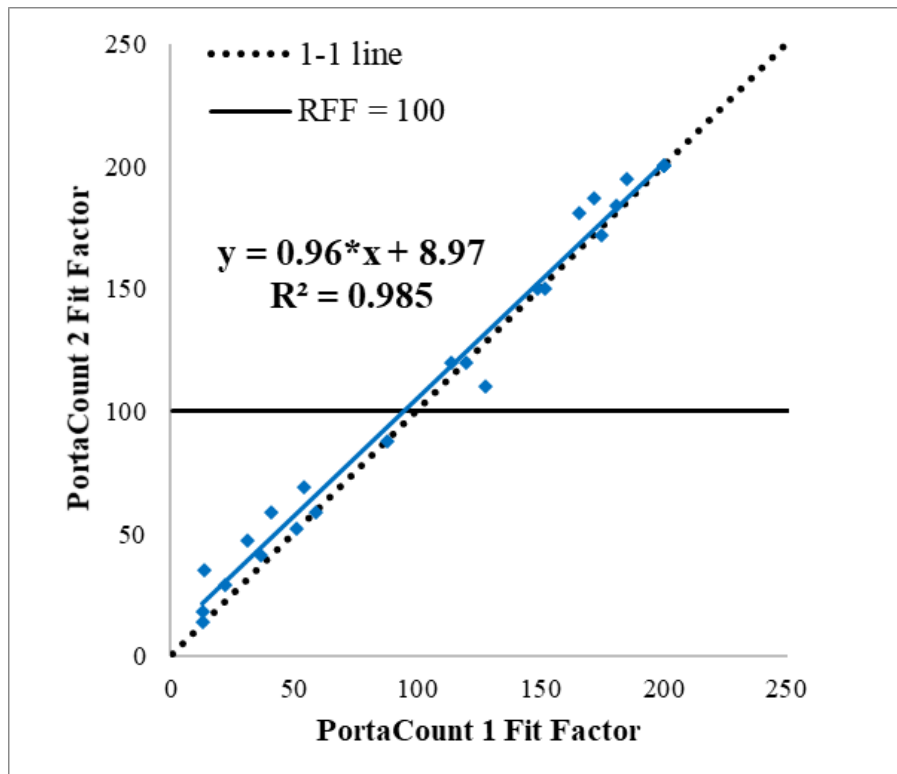


Figure 2. Comparison of the overall fit factors measured with two PortaCounts® N95-Companion™ for the determination of exclusion zone.

Comparison of the Two Fit Testing Methods

A total of 144 FF pairs were collected with MT-05U and PortaCount® N95-Companion™ from 25 subjects. Particle concentration C_{out} during testing ranged from 122 to 528 particles/cm³ and 142 to 1,155 particles/cm³ as determined by MT-05U and N95-Companion™, respectively. We found the number concentration of particles reported by N95-Companion™ slightly higher than that from MT-05U in general. The size distribution of test particles in the chamber is shown in Figure 3. The CMD of the distribution was typically within 75 – 85 nm.

All the ANSI requirements in the data collection procedure were fulfilled. First, when FF_{Ref} was less than 10 (i.e., 10% of RFF), the corresponding FF_{New} within the FF pair never reached the pass level. Second, after the exclusion zone had been applied, 127 fit tests from 25 subjects met the requirement for a minimum of 100 fit tests from 25 subjects. Third, 17 FFs generated by the N95-Companion™ fell within the exclusion zone; the rest constituted of 64 passes and 63 fails. While three fails had $FF \leq 5\%$ of the RFF, there were 60 fails between 5% of the RFF and the lower limit of the exclusion zone, thus meeting the requirement of ≥ 50 . Last, FF_{Ref} values lower than RFF were evenly distributed (Figure 4). Note that all the original FF data of 200+ from N95-Companion™ were plotted as 200. The N95-Companion™ does not provide more accurate FF measurement beyond 200 due to the lower particle concentration of the selected sizes.

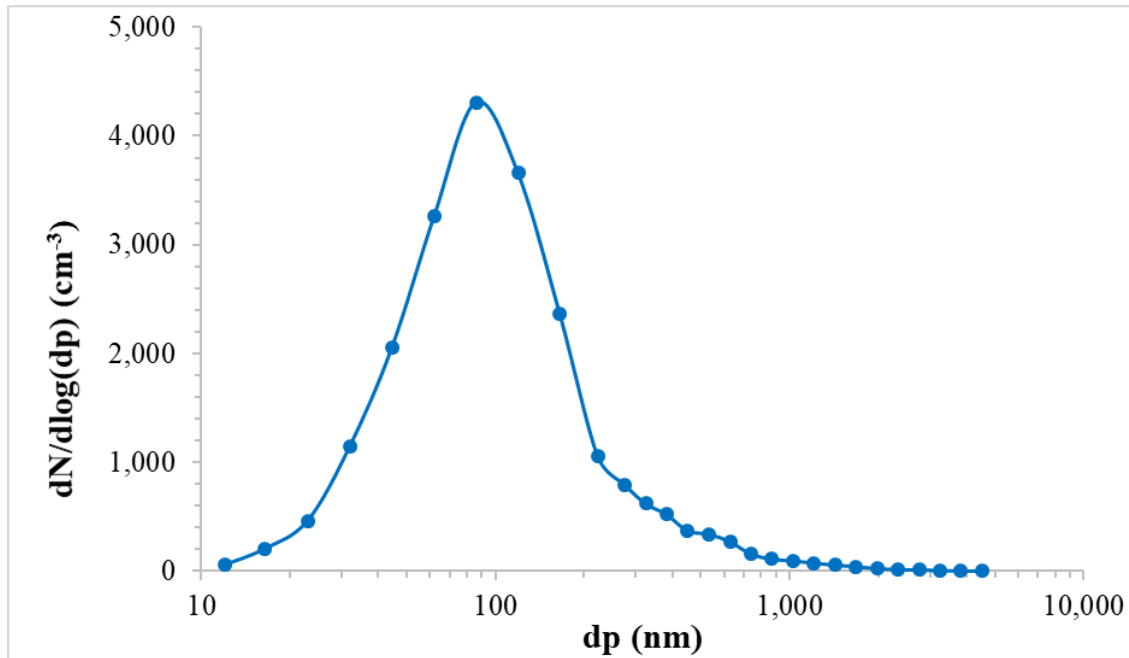


Figure 3. Typical particle size distribution measured in the chamber with a Mini-WRAS.

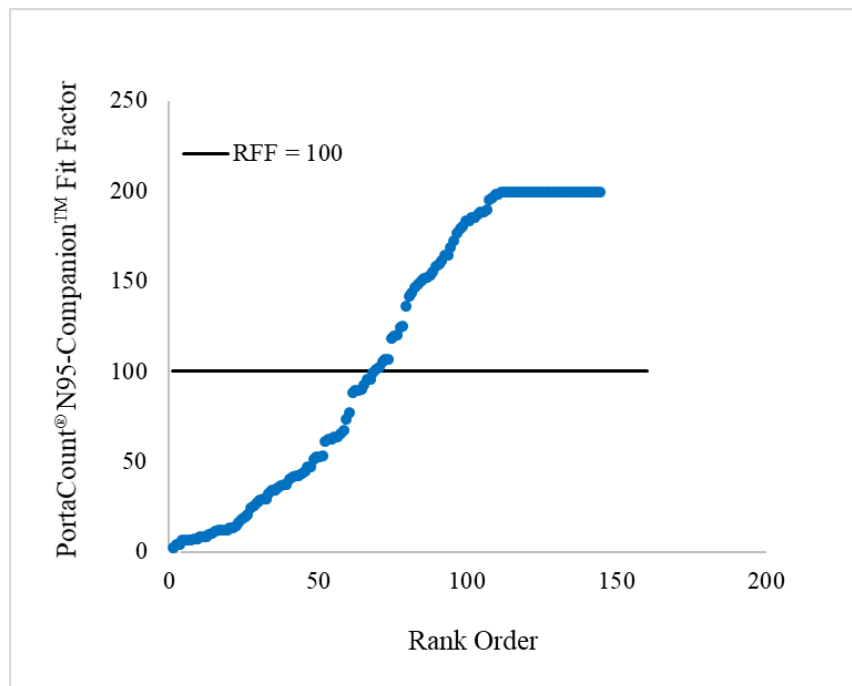


Figure 4. Distribution of the overall FFs obtained with the reference method (PortaCount® N95-Companion™). The black horizontal line represents the RFF (i.e., 100 for N95 FFR). Note the maximum FF displayed by the PortaCount® N95-Companion™ is 200.

All paired FFs were plotted to compare MT-05U and PortaCount® N95-Companion™ (Figure 5). Typically, the overall FFs generated by the two instruments were not equal so that their relationships did not follow the 1-1 dashed line in Figure 5. Most of FFs (101 out of 144) measured with the PortaCount® N95-Companion™ were higher than those measured with the MT-05U making the latter offering a more conservative assessment of the fit. This may be attributed to the following: It has been shown in several investigations that the use of the N95-Companion™ leads to generating higher FF comparing to other aerosol instruments, which do not deploy a differential mobility analyzer (DMA) or any other particle size-selective device (Clasphasm et al., 2000; Coffey et al., 2002; Lawrence et al., 2003; Coffey et al., 2004; Lawrence et al., 2006; Rengasamy et al., 2012, Rengasamy et al., 2013). In contrast to the PortaCount® N95-Companion™, the MT-05U does not measure FF particle size selectively and determines the overall fit over the entire size range of ambient aerosol particles.

Three outliers were identified, one located in the exclusion zone, one in zone C and one in zone D. There was no single FF pair in zone A, (i.e., failed the fit test with the reference method N95-Companion™, $FF_{Ref} < RFF$, and passed with the new method, $FF_{New} \geq RFF$). Thirty-nine FF pairs fell in zone B, where both methods passed the fit test, i.e., $FF_{Ref} \geq RFF$ and $FF_{New} \geq RFF$. A total of 59 FF pairs fell in zone C, where both methods failed the fit test, i.e., $FF_{Ref} < RFF$ and $FF_{New} < RFF$. It is noticed that there were 27 FF pairs in zone D, (i.e., passed the fit test with the reference method N95-Companion™, $FF_{Ref} \geq RFF$, but failed with the new method, $FF_{New} < RFF$).

The results of test statistics along with the corresponding ANSI requirements and recommendations are shown in Table III. The MT-05U instrument identified all inadequate fits of the tested respirators with sensitivity (probability of identifying inadequate fits) of 1.00, exceeding the ANSI mandatory requirement of ≥ 0.95 . The predictive value of a pass was 1.00 as well, exceeding the ANSI advisory criteria of ≥ 0.95 . Additionally, the specificity and predictive value of a fail were 0.59 and 0.69, respectively, both exceeding the ANSI advisory criteria of ≥ 0.5 . The only exception was the kappa statistic of 0.58, which was below the recommended, yet not mandatory ANSI's threshold of > 0.7 . The elimination of the two outliers had a trivial effect on the test statistics results.

Compared to our previous study with high efficiency (P100) respirators (Wu et al., 2017), test sensitivity and predictive value of a pass obtained in this effort with N95 FFRs were almost the same. However, the higher number of points that fell in zone D in this study lowered the test specificity and predictive value of a fail, and subsequently, the kappa statistics.

Table III. Statistics Summary along with the ANSI Requirements/Recommendations (Calculated after Excluding the Outliers)

Category	Test sensitivity	Predictive value of a pass	Test specificity	Predictive value of a fail	Kappa statistics
Value obtained in this study	1.00	1.00	0.59	0.69	0.58
ANSI requirement/recommendation	≥ 0.95	≥ 0.95	≥ 0.50	≥ 0.50	> 0.7
Level of endorsement	Mandatory	Advised	Advised	Advised	Recommended

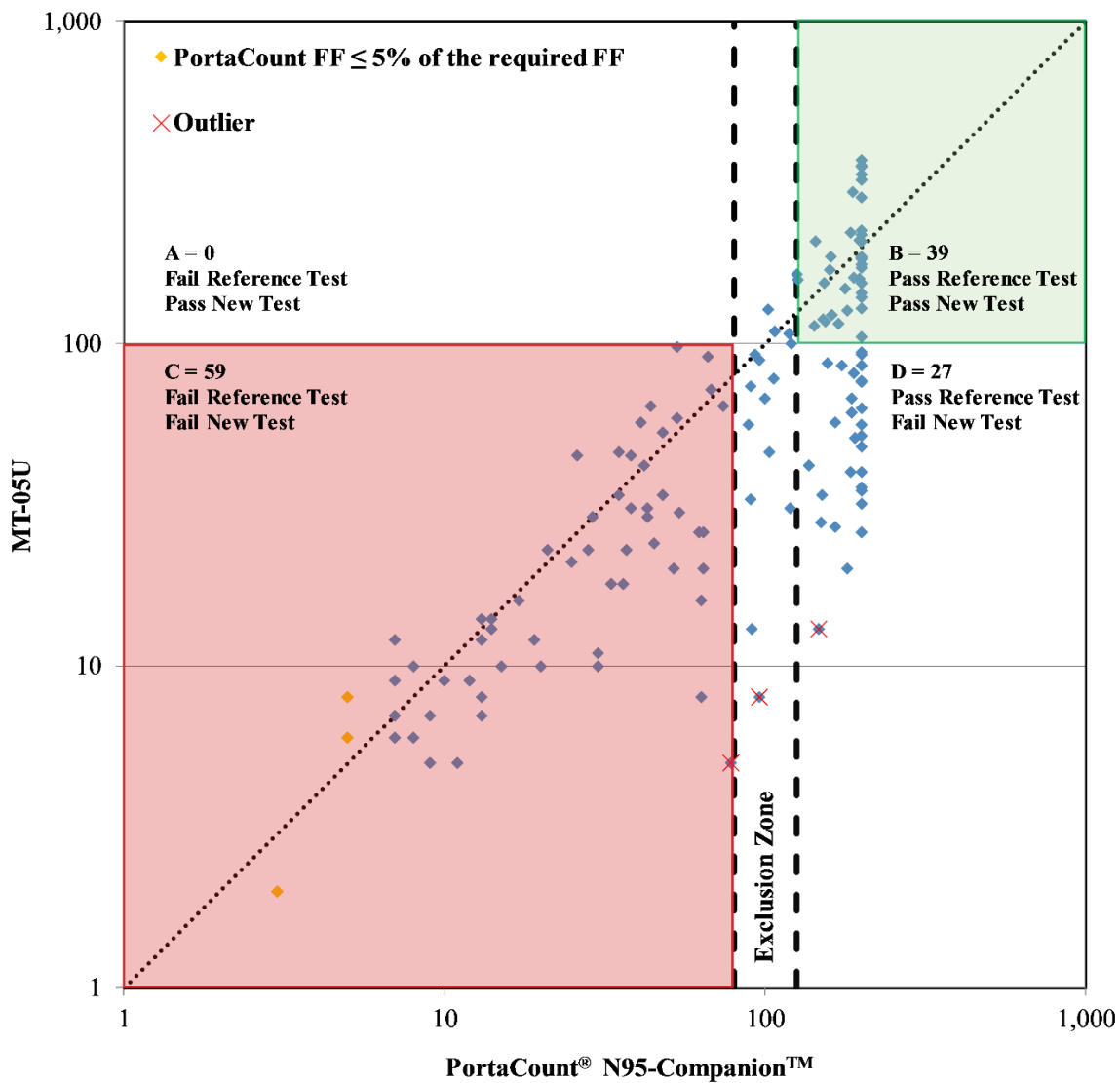


Figure 5. Comparison of overall FFs of N95 FFRs measured using the reference method (PortaCount® N95-Companion™) and the MT-05U instrument. Note the maximum FF displayed by the PortaCount® N95-Companion™ is 200.

Limitations

The findings of this study are affected by the accuracy of both new and reference instruments. First, the particle size detection range of MT-05U embraces 0.3 μm , which is at the lower edge capability of an optical particle counter. The increase of the counting threshold would result in lower in-mask particle concentration, which may negatively affect the sensitivity. A pilot study conducted with MT-05U operated at a different (optional) mode, $\geq 0.5 \mu\text{m}$, confirmed this possibility (Wu, 2018). Second, the reference instrument, PortaCount® N95-Companion™, may produce some instrumental errors (beyond the variability accounted for by establishing the exclusion zone). In fact, the manufacturer indicated the accuracy was up to $\pm 10\%$ of measured FF. Additionally, as stated earlier, several studies have reported that N95-

Companion™ does not necessarily identify correctly an improper fit of a respirator. For example, Coffee et al. (2002) reported a β error (the fraction of subjects with a respirator that provided inadequate protection but passed the fit test) of 9% for N95-Companion™. Rengasamy et al. (2012) reported that N95-Companion™ provided FFs well in excess of 100 for some of the tested respirators with artificially induced leaks.

Another concern is related to the sampling protocol utilizing two probes for N95 FFRs. This might have caused additional variability in the measured FFs, particularly from the model with an exhalation valve. Furthermore, some moisture condensation in the tubing could have affected the measurements.

CONCLUSIONS

The MT-05U Fit Tester has been shown to produce fit test results, which were comparable to those from the TSI PortaCount® N95-Companion™, with a perfect sensitivity of 1, meeting the mandatory ANSI criterion of ≥ 0.95 . Additionally, the specificity, predictive value of a pass and predictive value of a fail, all exceeded the ANSI advisory criteria. The kappa statistic of 0.58 obtained in this study was lower than ANSI criterion of ≥ 0.7 ; however, the latter is neither a mandatory nor advised level. Accordingly, it was concluded that the new fit tester, based on optical particle counting, could serve as an alternative method for effective quantitative fit testing of N95 FFRs and could readily be used in a manner similar to the TSI PortaCount®. Additionally, there are direct advantages of using the OPC method, e.g., no particle size-selective device (such as DMA, which is a part of the N95-Companion™ technology) is needed, and alcohol is not used (in contrast to CPC-based instruments).

These findings, as well as the results of our previous study conducted with higher efficiency respirators (Wu et al., 2017), were obtained under controlled laboratory conditions, inside a room-size test chamber. The conclusions appear to be fully applicable to the use of both instruments in the field. In other words, neither instrument would need to be used in a rigidly controlled environment (e.g., in a test chamber) nor would they necessarily require a particle generator as long as ambient particulate concentrations were adequate to meet each unit specified requirements. In general, both this and the previous (Wu et al., 2017) studies suggest that the fit testing results generated by the MT-05U are more conservative (i.e., produce higher fail rates) compared to those achieved by the TSI PortaCount® N95-Companion™. The new instrument, being more sensitive, may be less likely to result in false positive fit test pass results in the field, although this assertion would need to be demonstrated in an additional controlled study.

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