Performance Evaluation of a New Respirator Fit Testing Apparatus (Sibata MT-11D) against the Established PortaCount Fit Tester (TSI 8048)

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ABSTRACT

Efficiency of respiratory protective equipment (RPE), which is essential for protecting workers and the general public from various airborne hazards, largely relies on the quality of the faceseal. The faceseal is typically assessed using a US OSHA-accepted quantitative fit testing (QNFT). This study aimed at evaluating the performance of a newly developed respirator fit testing apparatus, the Sibata MT-11D, by comparing it with the reference TSI PortaCount® 8048 across three respirator types: N95 filtering facepiece respirators (FFRs), P100 FFRs, and half-face elastomeric respirators. Twenty-six adult participants, representing a diverse range of facial dimensions but not specially to match the NIOSH bivariate fit test panel, were recruited and trained in proper donning and doffing procedures to ensure standardized use of the respirators. Overall fit factors (FFs) were determined using the MT-11D and PortaCount® operating in simultaneously. The collected data were analyzed in accordance with American National Standards Institute (ANSI) guidelines to ensure statistical validity, including the application of exclusion zones and evaluation of test sensitivity, specificity, predictive values, and Kappa coefficients. Strong correlations were observed between the MT-11D and PortaCount® across all respirator types, with R^2 values of 0.93, 0.99, and 0.94 for N95 FFR, P100 FFR, and half-face elastomeric respirators, respectively. The test statistics met or exceeded ANSI thresholds, demonstrating the accuracy, reliability, and reproducibility of the MT-11D. These findings demonstrate that the MT-11D is a suitable device to other quantitative fit testers, capable of providing robust fit assessment for a variety of respirators in occupational and public health applications, thereby contributing to improved respiratory protection.

Keywords: Respiratory protective equipment, Quantitative fit testing, Filtering facepiece respirator, Half-face elastomeric respirator.

INTRODUCTION

Respiratory protective equipment (RPE) is employed to protect individuals from hazardous airborne contaminants. It is commonly used by occupational groups, such as healthcare workers (HCWs) and first responders, and may also be extensively used by the general public, especially during major disease outbreaks, like the recent COVID-19 pandemic. The performance of RPE depends critically on the quality of the faceseal between the respirator and the wearer's face. Therefore, respirator fit testing – either quantitative fit testing (QNFT) or qualitative fit testing (QLFT) – is conducted (generally for occupational use of respirators) to verify an adequate fit and ensure the intended sustainable level of protection. According to the U.S. Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.134, the respirator fit testing must be performed for occupational respirator users prior to initial use and periodically thereafter, typically annually or biannually (OSHA, 1998; Clayton and Vaughan, 2005). While both QLFT and QNFT are acceptable for occupational use, QNFT provides objective, numerical data on the degree of faceseal and overall fit, which allows for precise evaluation and comparison of respirator performance.

The QNFT has evolved over several decades and is recognized as the international gold standard for objectively assessing respirator fit (Bałazy et al., 2006; Lam et al., 2011). Early efforts from the 1970s through the 1990s focused on improving respirator evaluation by moving beyond subjective qualitative methods that relied on a wearer's ability to detect taste or odor. QNFT became formally standardized with OSHA's 1998 Respiratory Protection Standard (29 CFR 1910.134), which established both qualitative and quantitative fit testing as acceptable approaches for occupational use. Since then, OSHA has continued expanding and refining QNFT protocols.

For many years, QNFT has been conducted using the PortaCount® fit testing system (TSI Inc., Shoreview, MN, USA), which has long served as the standard instrument for quantitative respirator fit assessment. The PortaCount® operates on the principle of condensation nuclei counter (CNC), also referred to as a condensation particle counter (CPC), in which aerosol particles are enlarged within an isopropyl alcohol–saturated environment to sizes detectable by optical means (OSHA, 2004). During testing, the instrument continuously measures aerosol particle concentrations outside (C_{out}) and inside (C_{in}) the respirator while the wearer performs a prescribed sequence of exercises to assess robustness of respirator fit. The original QNFT protocol included 8 exercises: normal breathing, deep breathing, turning the head side-to-side, moving the head up-and-down, talking, grimacing, bending over, and normal breathing again (OSHA, 2004). The fit factor (FF) for each exercise is calculated as the ratio of C_{out} and C_{in}, and the overall FF is determined as the harmonic mean of the exercise-specific values, excluding the grimace exercise (OSHA, 2004). The PortaCount® detects particles across a size range of approximately 0.02 to > 1 µm. Using these particle counts, the instrument calculates fit factors, spanning from 1 up to greater than 10,000 (TSI Inc., 2022).

In recent years, several alternatives to the PortaCount® have been developed. For example, Kanomax-Japan Inc. (Suita-city, Osaka, Japan) introduced a novel apparatus AccuFIT-9000, which, like PortaCount®, utilizes the CPC principle, but features several advancements in the design of the saturation chamber and the flow control system. The AccuFIT-9000 was evaluated with 25 subjects and three types of respirators, including an N95 filtering facepiece respirator (FFR), P100 FFR, and half-mask elastomeric facepiece produced by different manufacturers (Grinshpun et al., 2021). The comparative testing and analysis showed that the AccuFIT 9000 is capable of identifying an inadequate fit of a tested respirator with a sensitivity 0.95 and specificity of 0.97. Overall, the test statistics results meet the American National Standards Institute (ANSI) guidelines (ANSI, 2010) – for all three endorsement levels: mandatory (sensitivity ≥ 0.95), advised (predictive value of a pass ≥ 0.95, specificity ≥ 0.50, and predictive value of a fail ≥ 0.50), and recommended (kappa statistics >0.70).

More recently, a new respirator fit testing apparatus, an MT-11D quantitative fit tester, was developed by Sibata Scientific Technology Ltd. (Soka, Saitama, Japan). The MT-11D employs the same CPC-based particle counting principle as the PortaCount® but incorporates several engineering and operational enhancements. It includes an air pump configuration and a proprietary software platform that allows customization of fit testing protocols, including exercise sequences and durations, to accommodate specific research or regulatory requirements. The MT-11D is capable of quantifying and displaying fit factors exceeding 200 when operating in N95 mode, enabling more precise quantification of FFRs. Such resolution is valuable in research and validation studies, as it allows for differentiation among respirators and facilitates comparative assessment of incremental improvements in fit.

In this study, the performance of the MT-11D was evaluated against the PortaCount® fit tester serving as the reference instrument. The evaluation followed the OSHA 8-exercise, quantitative fit testing protocol and adhered to ANSI guidelines (ANSI, 2010), consistent with methods used in the studies quoted above (Grinshpun et al., 2021). Similar to the previous study, the present effort aimed at determining whether the MT-11D could provide fit factor measurements comparable to the PortaCount®.

METHODS

Study Participants and Tested Respirators

Prior to the beginning of the study, the University of Cincinnati Institutional Review Board (IRB) approved the study protocol. Twenty-six adult subjects, including fifteen males and eleven females, were recruited for this study. All participants had completed OSHA-required respirator medical clearance prior to testing. The subjects received standardized training in proper respirator donning and doffing prior to testing. The cohort consisted of eight Caucasian, sixteen Asian, and two African American individuals, representing a wide range of facial dimensions. Each participant's face width (bizygomatic breadth) and face length (menton-sellion length) were measured using a spreading caliper (Fabrication Enterprises Inc., White Plains, NY, USA) and plotted on the NIOSH bivariate fit test panel (Zhuang et al., 2007). Most participants' facial dimensions fell within those of the NIOSH panel while five participants were identified outside the panel boundaries. The cohort spanned all facial size categories defined by the NIOSH panel – small, medium, and large. While the cohort was designed to include a diverse range of facial dimensions, it should be noted that participants were not recruited strictly according to the NIOSH bivariate panel proportions, which represents a limitation of the study.

Three types of respirators were evaluated in the study: N95 FFRs, P100 FFRs, and half-face elastomeric respirators equipped with two P100 filters (Model 2091, 3M Corp., St. Paul, MN, USA). For each type of respirator, three models produced by different manufacturers were selected for testing, as summarized in Table I. All respirators used in this study were certified for occupational use. For N95 FFR testing, both the PortaCount® (Model 8048, TSI Inc.) and Sibata's MT-11D instruments were operated in N95 mode with the N95-Companion accessory. The latter establishes a narrow particle size range by excluding the particles capable of penetrating the filter material. P100 FFRs and half-face elastomeric respirators were tested without the N95-Companion. To enable in-mask particle measurements, each respirator was fitted with a probe kit (Model 8025-N95, TSI Inc.) positioned within the breathing zone, which was connected to the fit tester during testing. A Y-splitter connected the respirator probe to both instruments, and identical sampling tubes with the same material, length, and internal diameter were used to ensure equivalence of measurements. This setup produced paired fit factor data for each exercise and overall fit factor, with one value obtained from the reference PortaCount® ($FF_{TSI\_PortaCount\ 8048}$) and one from the MT-11D ($FF_{Sibata\_MT\text{-}11D}$).

Table I. Respirators Tested in the Study.

Respirator type	Models and manufacturers	Sizes
N95 FFR	3M Model 1860, 3M Corp., St. Paul, MN, USA	One size
	3M Model 8210, 3M Corp., St. Paul, MN, USA	One size
	MODLEX Model 2200, Moldex-Metric, Inc., Culver City, CA, USA	One size
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
	SPERIAN Model P1130, Honeywell Inc., Charlotte, NC, USA	M/L
Half-face elastomeric respirator	3M Model 6200, 3M Corp., St. Paul, MN, USA	S/M; M/L
	Breath Buddy Model 750P3, Minor Miracle Home Solution, Coral Springs, FL, USA	M
	North 7700 Series, Honeywell Safety Products, Smithfield, RI, USA	L

Fit Testing Procedures

Respirator fit testing was performed at two locations: eleven subjects were tested in a room-size chamber at the University of Cincinnati, USA, and fifteen subjects were tested in a similar facility in Japan. Sodium chloride (NaCl) was used as the challenge aerosol. It was generated by a particle generator (Model 8026, TSI Inc.) to maintain an adequate particle concentration for quantitative fit testing. The ambient concentration range in the chamber was approximately in a range of 8,000 to 12,000 particles/cm³. It is noted that the TSI PortaCount® 8048 requires different ambient particle concentration levels for different types of respirators, e.g., while operating in N99 vs. N95 Mode. The recruited subjects randomly selected a respirator and performed the standard OSHA 8-exercise protocol while fit factors were measured simultaneously by the MT-11D and PortaCount® instruments. Both instruments were verified through daily calibration checks before fit testing.

The number of donnings and doffings was selected to satisfy the ANSI standards for evaluating fit testing methods, ensuring at least 100 data points across the cohort (ANSI, 2010). A total of 168 respirator donnings per respirator type resulted 504 donnings across the three respirator types. The study design also conformed to ANSI criteria for distribution of fit factors, including appropriate handling of the exclusion zone for $FF_{TSI\_PortaCount\ 8048}$ values between 90 and 110, sufficient representation of measurements near the required fit factor, and even distribution of $FF_{TSI\_Portacount\ 8048}$ values below the required fit factor. While the ANSI performance criteria provide benchmarks for accuracy, reliability, and reproducibility aiming for standardized comparison, they were originally developed for evaluating fit testing protocols rather than fit testing devices. The complete data collection and analysis procedures, adapted from ANSI (2010), has been detailed and discussed in previous publications (Wu et al., 2017, 2018; Grinshpun et al., 2021).

RESULTS AND DISCUSSION

The FF values measured by the MT-11D and PortaCount® instruments were widely distributed, spanning from 1 to 100,000 across all respirator types, as illustrated in Figure 1. This figure presents a comprehensive plot of all collected FF data for the different respirator types tested. The FF values were log-transformed to normalize the distribution and stabilize variance across the wide measurement range. It is noticed that when employing the N95-Companion, the MT-11D always provided specific FF values, including the situations when FF-value exceeded 200. On the other hand, the PortaCount® does not display the fit factor values above 200 and designated all values above this threshold as “200+.” To ensure consistency in data visualization and comparison, all “200+” readings from both instruments were standardized to 200 and the data points were plotted accordingly.

Correlation analysis revealed a strong agreement between the two instruments across all respirator types. For half-face elastomeric respirators, the overall FFs from both instruments fell well along a slope of 1.0, indicating near-perfect concordance. Although the slopes for N95 and P100 FFRs were slightly below unity (0.93 and 0.99, respectively), the correlations are strong. The P100 FFRs exhibited the highest correlation, with an R^2 of 0.99 based on the power regression model. N95 FFRs and half-face elastomeric respirators also showed high correlations, with R^2 values of 0.93 and 0.94, respectively, so that the MT-11D provides the overall FF values that closely align with those generated by the reference PortaCount®.

Application of the ANSI exclusion criteria resulted in the removal of fifteen N95 FFR measurement data points, eighteen P100 FFR data points, and six half-face elastomeric respirator data points, which fall within the exclusion zone ($FF \leq 10$ and $90 \leq FF \leq 110$). After these exclusions, a total of 463 donnings were considered for the statistical analysis: 151 for N95 FFRs, 150 for P100 FFRs, and 162 for half-face elastomeric respirators. As summarized in Table II, all calculated test statistics, including sensitivity, specificity, predictive value of a pass, predictive value of a failure, and the Kappa coefficient, satisfied the mandatory, advised, and recommended thresholds specified by ANSI (2010). These findings confirm that the MT-11D demonstrated consistent and reliable performance under the evaluated testing conditions.

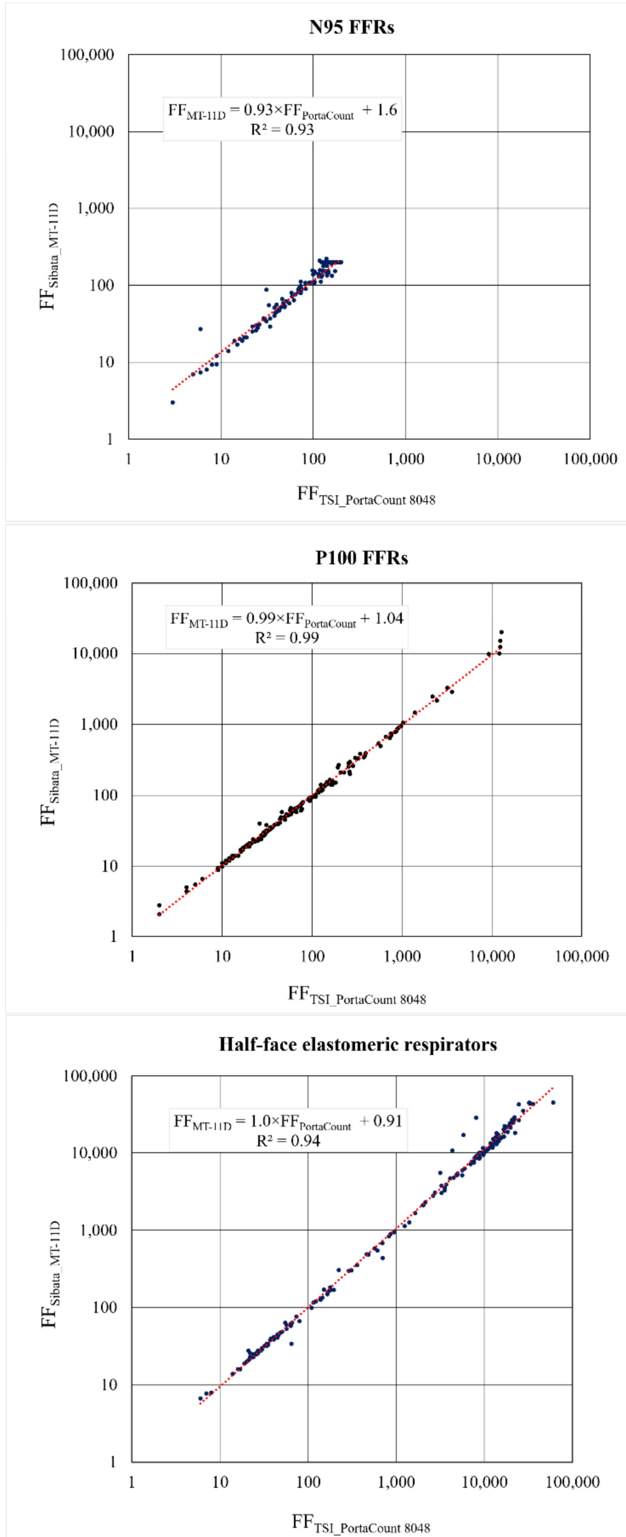

Figure 1. Comparison of FFs of N95 FFRs, P100 FFRs, and half-face elastomeric respirators measured using the reference PortaCount® and the new MT-11D. All data points, included and excluded, are plotted.

In summary, the findings highlight the MT-11D as a robust instrument for quantitative fit testing across multiple respirator types.

Table II. Statistics Summary along with the ANSI Requirements/Recommendations for Different Respirator Types.

Statistics	N95 FFRs	P100 FFRs	Half-face elastomeric respirators	ANSI requirement/ recommendation	Level of endorsement
Test sensitivity	0.96	1.00	1.00	≥ 0.95	Mandatory
Predictive value of a pass	0.98	1.00	1.00	≥ 0.95	Advised
Test specificity	1.00	1.00	1.00	≥ 0.50	Advised
Predictive value of a fail	1.00	1.00	1.00	≥ 0.50	Advised
Kappa statistics	1.00	1.00	1.00	> 0.70	Recommended

Limitations

While we have made every effort to recruit subjects with the greatest possible variety of facial dimensions, the 26 study subjects were not recruited specifically to match the NIOSH bivariate fit test panel representing 8 out of 10 cells). Additionally, although we examined a large variety of widely-used respirators, they belong to three types which feature the same assigned protection factor of 10. At the same time, several other types of respirators were beyond the scope of this study; among them are the full-facepiece air-purifying respirators with an assigned protection of 50. Future studies are being planned to address these limitations.

CONCLUSIONS

This study systematically evaluated the performance of the new MT-11D quantitative fit testing apparatus, including its N95-Companion module, in comparison with the reference PortaCount® instrument across three respirator types. The findings demonstrated strong correlations between the measurement results obtained with the MT-11D and PortaCount®, with correlation coefficients (R^2) ranging from 0.93 to 0.99, indicating a high degree of agreement. Application of the ANSI (2010) standard criteria further confirmed the validity of MT-11D as a reliable respirator fit testing device. All five key statistical performance indicators met the ANSI mandatory, advised and recommended thresholds.

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