Ann Work Expo Health. 2020 Dec 21 : wxaa116. PMCID: PMC7799224
Published online 2020 Dec 21. doi: 10.1093/annweh/wxaa116 PMID: 33345279

Evaluation of AccuFIT 9000: A Novel Apparatus for Quantitative Fit Testing of Particulate Respirators

Sergey A Grinshpun,[1] Michael Yermakov,[1] and Minoru Kano[2]

[1] Center for Health-Related Aerosol Studies, Department of Environmental and Public Health Sciences, University of Cincinnati, Cincinnati, OH, USA
[2] Kanomax-Japan Inc., Shimizu, Suita-city, Osaka, Japan
Author to whom correspondence should be addressed. Tel: +1-513-558-0504; fax: +1-513-558-2263; e-mail: sergey.grinshpun@uc.edu

Received 2020 Jul 23; Revised 2020 Sep 15; Accepted 2020 Oct 30.

Abstract

Various strategies developed for protecting frontline workers and the general public from the novel coronavirus, SARS-CoV-2, largely rely on respiratory protective devices (RPDs), especially considering recent evidence about the aerosol transmission route of COVID-19. Performance of an RPD primarily depends on how well the protective device fits the wearer. Therefore, quantitative fit testing of particulate respirators is crucial for achieving the intended protection level. Millions of fit tests are conducted every year using a US OSHA-accepted standard protocol involving a PortaCount® (TSI Inc., Shoreview, MN, USA) which measures a respirator fit factor. Recently, several alternative fit testing instruments have been developed and introduced to the market. Among them is an AccuFIT 9000 (Kanomax-Japan Inc., Suita-city, Osaka, Japan), which, like the PortaCount®, utilizes the condensation particle counting principle, but features an advanced saturation chamber design allowing

for a longer residence time and greater flow stability. It is also claimed to have a more cost-efficient assembly than its predecessors. In this study, the novel AccuFIT apparatus was extensively evaluated against the PortaCount® (the reference instrument) using the traditional standard fit testing protocol and following the American National Standards Institute (ANSI) standard (Z88.10-2010 Annex A2). The evaluation was performed with three types of respirators, N95 filtering facepiece respirator (FFR), P100 FFR, and half-mask elastomeric facepiece, of different models and manufacturers donned on 25 subjects. The comparative testing and analysis showed that the AccuFIT 9000 is capable of identifying an inadequate fit of the tested respirators with a sensitivity 0.95 and specificity of 0.97, which meets the ANSI requirement of ≥0.95. The other ANSI requirements/recommendations were also met. It was concluded that the novel fit testing apparatus demonstrated an acceptable performance and, thus, can be successfully deployed for the quantitative respirator fit testing.

Keywords: AccuFIT, fit testing, PortaCount, respirator

What's important about this paper

Performance of a respiratory protective device, such as those use to protect frontline workers from SARS-CoV-2 aerosols, primarily depends on how well the device fits the wearer. Millions of fit tests are conducted every year using a US OSHA-accepted standard protocol involving a PortaCount® (TSI Inc., Shoreview, MN, USA), but the AccuFIT 9000 (Kanomax-Japan Inc., Suita-city, Osaka, Japan) is a new instrument for fit testing. The AccuFIT measured fit factors similar to the PortaCount® and met the ANSI performance criteria. The AccuFIT can be successfully deployed for quantitative respirator fit testing.

Introduction

The strategies developed for protecting healthcare providers and other frontline workers as well as the general public from the novel coronavirus, SARS-CoV-2, essentially rely on respiratory protective devices (RPDs), especially in light of recent evidence about the aerosol transmission route of COVID-19. Performance of an RPD primarily depends on how well the protective device fits the wearer. Therefore, quantitative fit testing of particulate respirators, which assures that the device adequately fits the wearer, is crucial for achieving the intended protection level (ANSI, 2010). It is mandatory in certain countries/workplaces to conduct the respirator fit testing for first-time users and then annually or biannually (OSHA, 1998, Clayton and Vaughan, 2005). A US OSHA-accepted standard aerosol-based quantitative fit testing protocol, 29 CFR 1910.134 (OSHA, 1998), has been traditionally deployed for testing particulate respirators. The central component of this protocol is a PortaCount® instrument developed and manufactured by TSI Inc. (Shoreview, MN, USA). It measures aerosol particle concentrations outside the respirator (C_{out}) and inside the respirator (C_{in}) while the subject is performing a set of head and breathing maneuvers, and records the exercise-specific ratio, C_{out}/C_{in}. The traditional standard protocol includes exercises such as normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, grimace (excluded from calculating the exercise-specific ratio), bending over, and normal breathing. Additionally, the so-called 'faster', or abbreviated, protocol was recently accepted by OSHA (Final Rule of 26 September 2019); it utilizes a modified set of exercises described in Appendix A of the recently revised Respiratory Protection Standard (OSHA, 2019). The overall fit factor (FF) is calculated from exercise-specific ratios; the calculation procedures are different for the standard and abbreviated protocols as they are based on different sets of exercises (OSHA, 2019). The present study addresses only the traditional fit testing protocol.

A PortaCount® fit tester includes a continuous-flow condensation particle counter (CPC), in which particles grow in a chamber saturated with isopropyl alcohol to a size detectable by a photodetector and are then enumerated by a real-time optical particle counting (OPC) principle. The PortaCount® is capable of measuring FFs from 1 to >10 000 within the particle size range of approximately 0.02 to >1 μm (TSI Inc., 2015). The PortaCount® instrument has served the respiratory protection community well for decades, being essentially the only option available. Recently, several companies developed alternative respirator fit testing instruments. For example, Sibata Scientific Technologies Ltd. (Nakane Soka-City, Saitama, Japan) introduced a fit tester, which, unlike a PortaCount®, does not utilize a saturation chamber and alcohol for the particle growth, but counts the particles only within the 'optical' size range (the Sibata's instrument uses the OPC based on the light scattering). The latter limits the particle enumeration inside and outside the respirator to the 'optical' size range only (about 0.3 μm and above). The Sibata 'mask tester' (MT) has been extensively evaluated when operating in parallel with the PortaCount® that served as the reference instrument. The evaluation was performed for three types of high-efficiency particulate filtering facepiece respirators (FFRs), including P100 and elastomeric half-mask and full-mask (Wu *et al.*, 2017), as well as for N95 FFRs (Wu *et al.*, 2018). The comparative testing and analysis were conducted in accordance with the American National Standards Institute (ANSI) standard Z88.10-2010, Annex A2 (ANSI, 2010). It was concluded that the OPC-based fit tester could be successfully deployed as an alternative method for quantitative respirator fit testing.

The other alternative is a novel apparatus developed by Kanomax-Japan Inc. (Suita-city, Osaka, Japan). Utilizing the CPC principle, the AccuFIT features an advanced saturation chamber design allowing for a longer residence time and greater flow stability. The latter is achieved due to the precise flow control system that provides a flow stability as low as 1.6% by using a damper that was designed to reduce the flow pulsation. In addition, the AccuFIT ensures a fast response to a change in aerosol particle concentration inside and outside of a respirator by deploying a Fast CPC (Model 3650, Kanomax-FMT, White Bear Lake, MN, USA). The particles detected by the AccuFIT 9000 are as small as 0.015 μm, and the instrument can measure FFs in excess of 10 000.

The AccuFIT 9000 novel fit tester was evaluated in the present study against a Model 8038 PortaCount® using the traditional standard fit testing protocol and following the above ANSI standard, similar to our previous studies (Wu *et al.*, 2017, 2018).

Methodology

Following an extensive screening, 25 adult subjects, including 9 males and 16 females, were selected to participate in the study. The subjects were medically cleared for wearing respirators and provided a written consent approved by the University of Cincinnati Institutional Review Board (IRB). The face width (bizygomatic breadth) and face length (menton–sellion length) data were collected from each subject and compared with the facial dimensions of the NIOSH 25-member bivariate panel (Zhuang *et al.*, 2007). While it was not our intention to recruit subjects that would perfectly fit the NIOSH bivariate panel, the study subjects were within the frameworks of the NIOSH panel with respect to the ranges allocated for the bizygomatic breadth and menton–sellion length. The facial dimensions of the study participants occupied 7 out of 10 cells of the NIOSH panel (cell numbers 2, 3, 4, 5, 6, 7, and 9). Finally, the subjects represented all three categories identified in the NIOSH panel: small, medium, and large. Participants were trained on donning and doffing of respirators prior to the actual fit tests.

In each test, NaCl particles were aerosolized in a 24.3-m^3 exposure test chamber with a Particle Generator (Model 8026, TSI Inc., Shoreview, MN, USA). A study subject was fit tested with a AccuFIT 9000 and a Model 8038 PortaCount® operating in parallel while a respirator-wearing subject performed the eight fit test exercises of the standard OSHA-accepted generated aerosol quantitative fit testing protocol. Each of the two fit testing instruments was connected to two identical flush type

probes for measuring C_{in} and C_{out} to determine the exercise-specific ratios and ultimately the overall FF. The probes were placed in the center line (i.e. the breathing zone) of a tested respirator. For respirator models with center-mounted exhalation valves, the probes were installed to the left and right side of the valve. Preliminary testing was performed with different probe locations to ensure that the probe interinfluence was minimal. Thus, each test produced a pair of FFs: one of the reference method ($FF_{PortaCount}$) and the other of the method under evaluation ($FF_{AccuFIT}$). Both instruments were subjected to the daily check procedures as advised by the manufacturers.

Three types of respirators, N95 FFR, P100 FFR, and half-mask elastomeric facepiece equipped with two P100 filters (Model 2091, 3M Corp., St. Paul, MN, USA) were tested. These represented different models and were produced by different manufacturers (see Table 1). All the RPDs featured the same required fit factor (RFF) of 100.

Table 1.

Respirators used in the study.

Respirator type	Model and manufacturer	Sizes
N95 FFR	3M 1860 N95, 3M Corp., St. Paul, MN, USA	S/M
	3M 8210+ N95, 3M Corp., St. Paul, MN, USA	One size
	JACKSON SAFETY 64420 P95, SureWerx USA Inc., Elgin, IL, USA[a]	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
	Gateway 80902V TruAir, Gateway Safety Inc., Cleveland, OH, USA	One size
	DRAGEN XP1330, Dragen Inc., Minneapolis, MN, USA	One size
	Willson N99 SAF-T-FIT Plus N1139, Honeywell Inc., Charlotte, NC, USA[b]	M/L
Half facepiece with P100 filters (2000-series)	3M 6000 series, 3M Corp., St. Paul, MN, USA	S/M
	Breath Buddy, Minor Miracle Home Solution, Coral Springs, FL, USA	M
	North 7700 series, Honeywell Safety Products, Smithfield, RI, USA	L

[a]Used interchangeably with N95 FFRs.

[b]Used interchangeably with P100 FFRs.

Specifically for testing with N95 FFRs: a PortaCount® fit test is generally conducted with an N95-Companion; however, the AccuFIT 9000 is not equipped with the Companion. Thus, to be consistent, in this study the tests with N95 FFRs did not include the Companion.

A total of 4–8 replicate tests per subject were conducted to represent different respirator types, models, and sizes listed in Table 1. The number of subject–respirator combinations was determined based on the subject availability and other factors. The respirators were doffed and redonned between replicate tests. The number of replicated tests was chosen to be sufficient for achieving the ANSI data points' requirement (≥100) with 25 subjects. To meet other criteria stated in the ANSI standard for evaluating new fit test methods, we

- ensured that no test produced $FF_{PortaCount}$ <10 and at the same time $FF_{AccuFIT}$ >100,
- applied the exclusion zone of FF = 90–110 representing the uncertainty of measurements conducted with the reference instrument, PortaCount®,
- ensured that among all the FF values measured by the PortaCount® at least 50 fell between 5% of the RFF and the lower bound of the exclusion zone,
- verified that $FF_{PortaCount}$ values, which fell below RFF, were evenly distributed.

The full flow chart describing the data collection procedure adopted from ANSI (2010) was presented in our earlier publication (Wu *et al.*, 2017).

Results and discussion

Overall, 298 respirator donnings were performed before we applied the exclusions deriving from the ANSI (2010) criteria. Fig. 1 presents a plot with all the collected FF data displayed. Overall, the correlation is good with a slope of 1.06 and $R^2 = 0.80$. Application of the ANSI criteria resulted in exclusion of 28 points with $FF_{PortaCount}$ falling into the exclusion zone (from 90 to 110). Subsequently, we selected 270 donnings for further analysis. Out of those, the PortaCount® produced 163 passes and 107 failures. The AccuFIT produced the same numbers of passes and failures but not always in the same donnings.

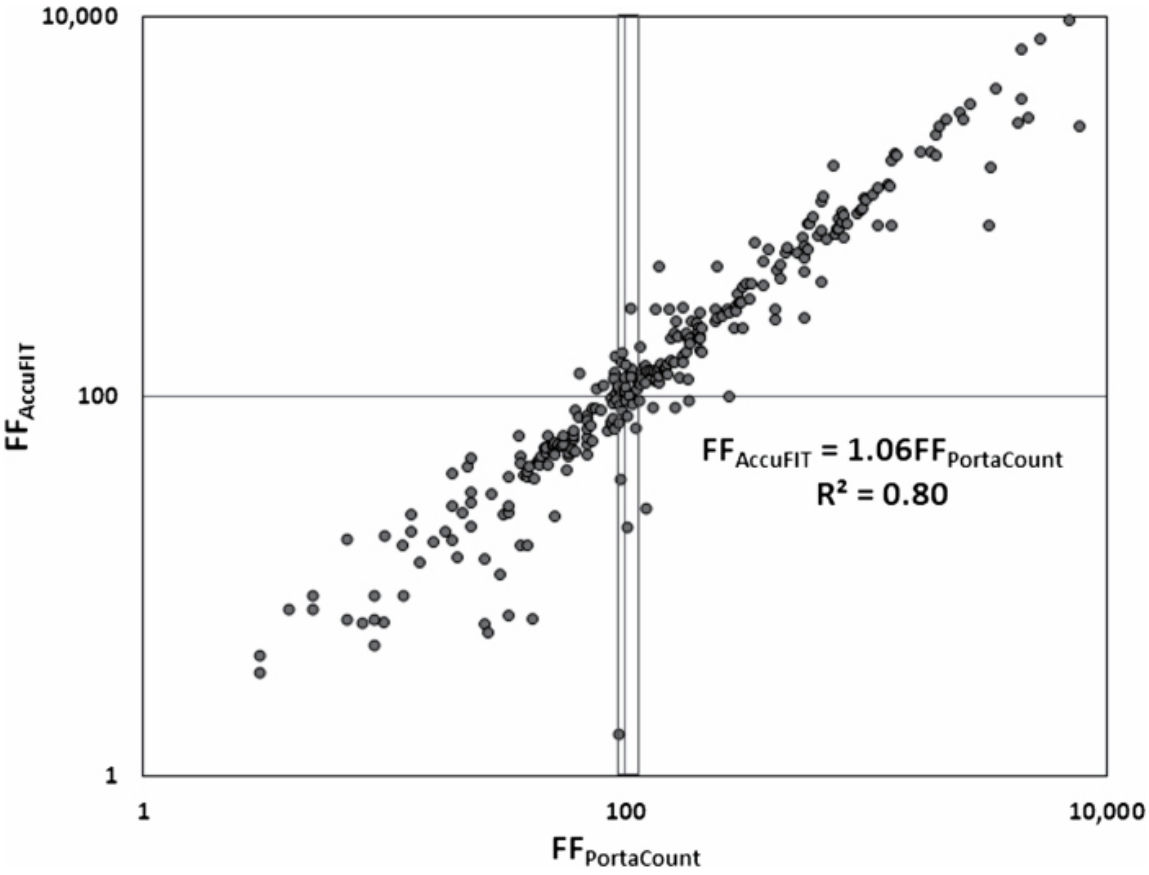

Figure 1.

Comparison of FFs of N95 FFRs, P100 FFRs, and half-mask facepiece measured using the reference method (PortaCount® without N95-Companion™) and the novel AccuFIT 9000. All data points—included and excluded—are plotted.

The results of the test statistics along with the corresponding ANSI requirements and recommendations are presented in Table 2. All statistical parameters, including the test sensitivity, predictive value of a pass, test specificity, predictive value of a fail, and Kappa statistics, met mandatory, advised, and recommended ANSI criteria. This provides evidence of adequate performance of the novel AccuFIT 9000 respirator fit testing apparatus within the set of conditions tested in this study. It is not surprising that the fit testing results produced by the AccuFIT match well the FFs generated by the PortaCount® considering that both utilize the same CPC principle and differ mainly by the design of the saturation chamber. Additionally, differences may be associated with locations of the in-mask sampling probes, movement of the probes and sampling lines connected to the reference and tested instruments during exercises, variability in the ambient particle concentration, and other factors.

Table 2.

Statistics summary along with the ANSI requirements/recommendations.

Category	Test sensitivity	Predictive value of a pass	Test specificity	Predictive value of a fail	Kappa statistics
Value obtained in this study	0.95	0.97	0.97	0.95	0.92
ANSI requirement/ recommendation	≥0.95	≥0.95	≥0.50	≥0.50	>0.7
Level of endorsement	Mandatory	Advised	Advised	Advised	Recommended

One limitation of this study concerns the data collected for N95 respirators. As stated above, these tests could not be conducted with an N95 Companion because the present AccuFIT model is not equipped with one. On a positive side, this approach allowed us to compare the two fit testing instruments over the same particle size range of the challenge aerosol (although it is noted that the AccuFIT is capable of counting slightly more particles than PortaCount® because its minimum detectable particle size is 0.015 μm against approximately 0.02 μm of the PortaCount®). With respect to the fit testing of N95 respirators, it is yet to be determined whether the currently available 'Companionless' AccuFIT will generate the same or appreciably different pass/failure rate as compared with the PortaCount® equipped with a Companion. This question, however, may lose its practical relevance if future AccuFIT models are manufactured with an N95 Companion.

Conclusion

The novel fit testing apparatus evaluated in this study demonstrated an acceptable performance in accordance with the ANSI criteria and, thus, can be successfully deployed for the quantitative respirator fit testing. The AccuFIT 9000 featuring an advanced saturation chamber and a cost-efficient assembly is believed to be a valuable addition to the existing fleet of fit testing instruments for particulate respirators (including the widely used PortaCount®). It appears to be a timely development given the rapidly growing demand for fit testing equipment due to the COVID-19 pandemic.

Acknowledgement

The authors of this paper wish to thank all the subjects participating in the study.

Funding

This effort was partially supported by Kanomax-Japan Inc. (Suita-city, Osaka, Japan).

Conflict of interest

The authors declare no conflict of interest.

References

1. ANSI (2010) *Respirator fit testing methods*. Fairfax, VA: American Industrial Hygiene Association. ANSI Z88.10-2010. [Google Scholar]
2. Clayton M, Vaughan N (2005) Fit for purpose? The role of fit testing in respiratory protection. *Ann Occup Hyg*; 49: 545–8. [PubMed] [Google Scholar]
3. OSHA (1998) *Respiratory protection. Title 29 Code of Federal Regulation, Part 1910.134*. p. 134. [Google Scholar]
4. OSHA (2019) *Additional ambient aerosol CNC quantitative fit testing protocols: respiratory protection standard. Title 29 Code of Federal Regulation, Part 1910.134; Appendix A*. [Google Scholar]
5. TSI Inc (2015) *PortaCount® Pro 8030 and PortaCount® Pro+ 8038 respirator fit testers. Operation and service manual. P/N 6001868, Revision P, March 2015*. Shoreview, MN: TSI Inc. [Google Scholar]
6. Wu B, Leppänen M, Yermakov M et al. (2017) Evaluation of a new instrument for aerosol quantitative fit testing. *J Int Soc Respir Prot*; 34: 111–27. [Google Scholar]
7. Wu B, Leppänen M, Yermakov M et al. (2018) Utility of an optical particle counting instrument for quantitative respirator fit testing with N95 filtering facepieces. *J Int Soc Respir Prot*; 35: 14–25. [Google Scholar]
8. Zhuang Z, Bradtmiller B, Shaffer RE (2007) New respirator fit test panels representing the current U.S. civilian work force. *J Occup Environ Hyg*; 4: 647–59. [PubMed] [Google Scholar]