

Response to Letter to the Editor

RE: Papers “Evaluation of a New Instrument for Aerosol Quantitative Fit Testing” and “Utility of an Optical Particle Counting Instrument for Quantitative Respirator Fit Testing with N95 Filtering Facepieces”

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We appreciate the opportunity to respond to the Letter to the Editor, which was submitted by Andrew Viner, Craig Colton, and Ginny Agresti of the 3M Personal Safety Division regarding our two papers, Wu et al. (2017) and Wu et al. (2018), recently published in the *Journal of ISRP*. The referred papers present our studies on the evaluation of a new instrument for respirator fit testing, MT-05U. We are grateful to the authors of this Letter for their interest in our research and for taking the time to share their thoughts. Our responses are presented below.

The main concern voiced in the Letter is that our studies might have reached an incorrect conclusion at least in one case. The authors seem to attribute it to our possible misunderstanding of the requirements of the evaluation protocol specified in ANSI Z88.10-2010, Annex A2 (ANSI, 2010) as well as to an alleged “weakness” of the ANSI standard.

First, the Letter questioned whether an appropriate reference fit test method (required by the ANSI standard) was used in our evaluation of the new MT-05U. We fully acknowledge that the generated aerosol method described in Clause 7.1 “Generated Aerosol Quantitative Fit Test Procedure” (QNFT) of the ANSI standard is the one to be used, and indeed implemented this very method in our studies. Our investigation was designed as a comparative study involving the new OPC-based fit testing instrument and the reference instrument (PortaCount®, TSI Inc., Shoreview, MN). The latter is overwhelmingly used in the field. The PortaCount® design allows using not only generated aerosol but also the ambient aerosol as the challenge. The PortaCount® fits in the Clause 7.2 (“Particle-counting Instrument Quantitative Fit Test Procedure”) of the ANSI standard that suggests utilizing the ambient aerosol. It is to note that in our studies the PortaCount® served as the “aerosol detection system” and “device for recording fit test results” as listed in the “Equipment” section of Clause 7.1. The procedures required by Clause 7.1 for the generated aerosol QNFT were carefully followed in our study design. Finally, the concentration of aerosol generated in our tests (4,000 – 16,000 particles/cm³) was always within the operational concentration range of the PortaCount®: 0.01 – 25,000 particles/cm³ (TSI Inc., 2015).

The Letter points out to a “weakness” in the ANSI standard associated with the definition of the aerosol detection system in the generated aerosol method. Apparently, the authors of the Letter would like to see a standard specifying a single detection method, e.g., photometry. First of all, even if the ANSI standard had some shortcomings or “weaknesses”, this is the only one providing guidelines for evaluating a new fit testing method. In absence of alternatives, it was utilized in our studies. We acknowledge that ANSI (2010) does not define a specific aerosol detection system. Typically, it is a flame or forward light scattering photometry utilized in the frameworks of the generated aerosol method, described in Han, Willeke, and Colton (1997) as well as in the International Organization for Standardization (ISO) standard 16975-3 (ISO, 2017). We believe that it is an advantage of the ANSI standard, not its “weakness,” that it is not limited to a specific aerosol detection system. This leaves a niche for measurement devices other than photometers to be deployed for respirator fit testing.

Second, the Letter implies that the treatment of outliers in our data analysis was not sufficiently justified, which could have affected the final conclusion of the study. It is stated in the Letter that there was no sufficient explanation as to how the outliers were identified and what the causes of the outliers are. We agree that eliminating an outlier requires a proper explanation, and should probably have provided more details in our papers. We are using this Response as an opportunity to elucidate the justification of the outlier treatment. The Letter specifically questioned the five outliers marked in zone A, Figure 5C of Wu et al. (2017). In these, the reference fit factor (FF_{ref}) was below the required fit factor (RFF) while the new method produced FF_{new} in excess of RFF. These data points were indeed critical to the validation of the new method because if they were not eliminated but included in calculations, the comparison statistics sensitivity would have dropped to 93.2%, which is below the mandatory requirement of $\geq 95\%$.

It was observed that the five points, which later were identified as outliers, presented a subject-specific pattern. Having come from two subjects, three from X and two from Y, these five data points formed two clusters shown in the graph (Figure 5C of Wu et al., 2017). The exercise-specific and overall FF-values representing these data points are listed in Table I below. In all cases obtained with these two subjects, the exercise-specific FF values recorded by the MT-05U were considerably greater than those recorded by the PortaCount®. It was reported in Wu et al. (2017) that when testing these individuals, we observed an excessive amount of water condensed in sampling lines. This must have resulted from the high humidity of air exhaled by these subjects. The block or kink in a sampling tube impedes the normal performance of the instrument, and the MT-05U was found to be particularly sensitive to the humidity effect, which made the MT-measured FF values higher. One value, 14,657, generated during exercise 3 by subject X, was even above the upper operating limit of MT-05U (10,000).

The Letter also made an inference that if there was any instrument error, it would probably come from MT-05U. This judgement was based on the readings from the two identical PortaCounts® that were tested in parallel that showed an excellent agreement (Figure 3 of Wu et al., 2017). We are hesitant to come to this conclusion because the sample sizes were fairly different. For the comparison of two PortaCounts®, the sample size was 22 for half facepiece and full facepiece respirators and 24 for P100 FFR; for the comparison of MT-05U versus PortaCount®, the sample size was 122 for half facepiece, 135 for full facepiece, and 148 for P100 FFR. In other words, while no direct instrumental error was discovered in the course of the tests involving two PortaCounts®, can one be assured that, likewise, no instrumental error occurred also in a much larger set of experiments?

The Letter referred to the screening approach for validating a consistent fit during the two tests (Richardson et al., 2013). While we acknowledge the features of the approach and its ability to check whether the respirator fit changed between sequential tests involving different fit testers (each requiring a separate donning), we do not believe that this approach is applicable to our study design. The reason is that, unlike the sequential fit testing conducted by Richardson et al. (2013), we performed the simultaneous measurement with two fit testing instruments operating in parallel (during the same donning). This design eliminates the need in “screening.”

Table I. Original Fit Factor Data Representing the Outliers in Zone A, Figure 5C of Wu et al. (2017)

Subject code	Instrument	Fit factor							Overall
		Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Exercise 7	Exercise 8	
X	PortaCount®	368	623	462	387	215	287	509	365
X	MT-05U	1335	4108	14657	2727	595	1560	3386	1731
X	PortaCount®	291	359	341	384	258	474	606	361
X	MT-05U	1180	9542	4899	929	538	1691	7838	1455
X	PortaCount®	189	312	335	347	248	572	518	317
X	MT-05U	855	3993	3904	1301	880	1858	1638	1480
Y	PortaCount®	137	200	122	125	184	100	73	121
Y	MT-05U	602	778	507	443	738	596	485	570
Y	PortaCount®	86	223	110	109	168	150	129	128
Y	MT-05U	539	802	310	403	688	756	525	519

The authors of the Letter were not sure whether we were able to disqualify the new method when a statistical test identified an outlier point in case

$$FF_{Ref} < 0.1 \times RFF \text{ and } FF_{New} > RFF \quad (1)$$

following ANSI (2010). This concern is probably rooted in a lack of understanding of our protocol with respect to the data collection order (Figure 1 of Wu et al., 2017). In our studies, the data analysis always started with checking for conditions described in Eq. (1) (see Criterion 1 of the protocol presented in Figure 1 of Wu et al., 2017). Therefore, we are confident that our study design provided a full capability to disqualify the new method in case the data would fit Eq. (1).

Last, the Letter suggested us to define an acceptable margin of error for a fit factor of $FF_{New} = 500$ (e.g., $\pm 5\%$) and then work backward to establish a minimum required chamber concentration C_{out} to achieve that margin of error, as discussed by TSI Inc. (2018). We appreciate the suggestion, but in our experiments, the aerosol concentration C_{out} was sufficiently high to assure a reasonable margin of error. The calculation in the referred TSI document was conducted for a very low level of $C_{out} = 3$ particles/cm³ while in our tests involving MT-05U the C_{out} level was much greater: 60 – 760 particles/cm³ in Wu et al. (2017) and 122 – 528 particles/cm³ in Wu et al. (2018). We determined that even in the worst-case scenario the margin of error generated in our studies was within $\pm 8.45\%$, which is rather low. Below, we present the calculation that yields this value.

In our calculation, we conservatively used the lowest concentration measured in the fit tests performed with full facepiece respirators ($C_{out} = 60$ particles/cm³). For this type, the fit factor required for passing the fit test is $RFF = 500$ according to 29 CFR 1910.134 (OSHA, 1999). Consequently, $C_{in} = C_{out}/500 = 0.12$ particles/cm³. The margin of error for counting particles in the worst-case scenario at the 95% confidence level can be calculated according to the TSI Inc. (2018) algorithm as follows:

Total Particles (n) = (C_{in}) × (flow rate) × (time conversion) × (time of exercise) = (0.12 particles/cm³) × (1000 cm³/min) × (1 min / 60 sec) × (70 seconds total mask sample) = 140 particles. Note that the sampling flow rate of MT-05U is 1000 cm³/min. In the worst-case scenario, the margin of error at 95% confidence level is

$$\pm \frac{1}{\sqrt{n}} = \pm \frac{1}{\sqrt{140}} = \pm 8.45\%$$

In case someone wants to achieve a lower margin of error, e.g., 5%, the minimum ambient aerosol concentration should be 171 particles/cm³. By reviewing the data obtained by Wu et al. (2017), we found that the ambient concentration fell below 171 particles/cm³ only on three occasions when the following paired fit factor values (FF_{Ref}, FF_{New}) were generated: (371, 142), (215, 81), and (2513, 1248). However, none of these pairs was identified as statistical outliers, contrary to the expectation articulated in the Letter.

To summarize, the studies of Wu et al. (2017) and Wu et al. (2018) did utilize the generated aerosol method as the reference, which we believe is appropriate. The outlier analysis included two steps: statistical screening and investigation of the causative factors. The testing was conducted in accordance with the ANSI (2010) standard for the evaluation of new methods.

We hope that this Response contains appropriate information to essentially eliminate the concerns expressed in the Letter. We sincerely appreciate this opportunity to discuss our findings and trust that this exchange will bring additional attention to the development and evaluation of alternative respirator fit testing methods.

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