FIT TESTING USING SIZE-SELECTED AEROSOL

APPLICATION NOTE ITI-062

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Editor's Note: The "Standard CNC" referred to throughout this document is the TSI Model 8020 PortaCount® Plus Respirator Fit Tester. The "CNC with Size Selection" is the Model 8020 PortaCount Plus used along with the TSI Model 8095 N95-Companion™.

Introduction

Various regulatory agencies have established standards that specify the required goodness of fit of a mask respirator, as determined by either qualitative or quantitative methods. A common method of quantitative fit-testing involves the measurement of particle concentration both inside and outside the respirator mask[1]. The particle detector commonly used (a condensation particle counter, known as a "CPC" or "CNC"[2,3,4]) is capable of measuring nearly all the particles typically found in an ambient atmosphere. If one assumes the respirator filter is nearly 100% efficient in removing particles from the breathing air, then the goodness of face-seal fit (fit factor) is simply calculated by taking a ratio of the particle concentration outside the mask to the concentration inside. This assumption is valid when fit testing is done using high efficiency particle air (HEPA) grade filters, which are at least 99.97% efficient at 0.3 micron particle size.

It is sometimes desirable to perform fit testing using respirators with filters that are less efficient than HEPA grade. One common class of respirators of this type is known as Class-95. The most popular style within this class is an N95 filtering facepiece. When exposed to a polydisperse challenge aerosol, these filters remove most of the large particles and most of the very small particles, but allow a percentage of particles in the mid-range to pass through the filter[5] (in certain cases, this percentage can be as high as 5%). This phenomenon is known as the "most penetrating particle size". All filters exhibit this characteristic; that is, they have a filtration efficiency, based upon particle size, which reaches a minimum value at some midpoint on a size spectrum (typically 0.1 to 0.3 micrometers) and rises on both sides of that midpoint. Figure 1 shows a fractional filtration curve representative of these low efficiency filters (the actual curve will vary depending upon the filter class and/or brand).

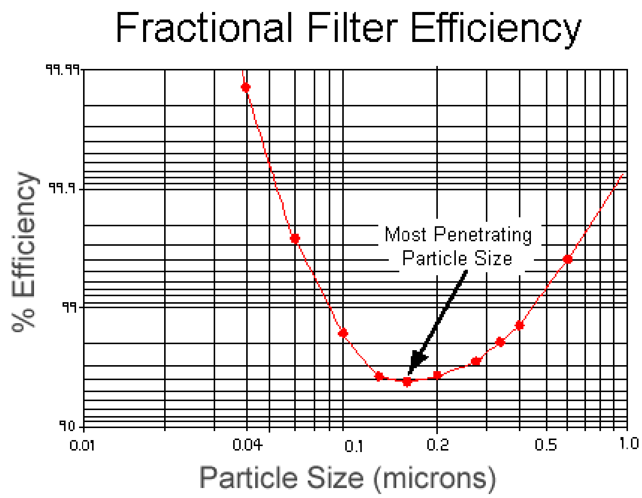

Figure 1

When performing a quantitative fit test on a class-95 respirator using polydisperse aerosol as the challenge agent (such as the particles found in ambient air), a relatively large number of particles of the most penetrating size pass through the filter and are detected inside the respirator mask[6]. These particles mix with those that entered the mask through face-seal leaks. The resulting inside-mask particle concentration, and calculated fit factor, do not fairly represent the true fit factor of the respirator. In actual practice, the particles entering the mask through the filter often overwhelm those coming into the mask from face-seal leaks. The large number of particles counted inside the mask result in a poor fit factor calculation, when in fact the respirator may be properly fitted.

Prior Work

Various techniques have been employed to overcome the limitations of standard quantitative aerosol fit test methods for dust/mist respirators (these techniques apply by extension to class-95 respirators as well). Iverson et al.[7] used a monodisperse aerosol generator to create a challenge aerosol of 2.5 micron particles for testing dust/mist respirators. The high filtration efficiency at this large particle size allowed her to successfully perform fit tests on this class of respirator using monodisperse aerosol.

A commercially available instrument does exist, which determines fit factor using ambient aerosol and an optical particle counter (OPC)[8]. The relatively small number of large sized particles that occur naturally in ambient aerosol, however, severely limits the ability of this instrument to perform fit tests with statistical accuracy. These alternate methods have important limitations that have prevented their widespread acceptance and use in the market. There is a demonstrated need for a new method which retains the ease, simplicity and speed of the aerosol/CNC method while adding a novel method for eliminating the cross contaminating aerosol that penetrates through the filter.

Search for a New Method

The search for a simple, practical and commercially viable method of fit testing class-95 respirators led to a re-examination of the fractional efficiency characteristics of these respirators. Figure 1 reveals that typical class-95 respirators become very efficient when the particle size reaches approximately 0.04 micron diameter. It can therefore be assumed that particles of this size range that are detected inside the respirator entered through face-seal leaks and did not penetrate the media. If a method could be found whereby the particles of interest (the 0.04 micron "leak particles") could be separated from the entire range of particles found inside a respirator mask, then a valid fit test could be performed on class-95 respirators.

Inertial methods of particle separation (such as impaction or centrifugal separation) were examined but were discarded as impractical. The electrical mobility method of particle separation showed much promise for this application. Utilizing naturally occurring electrical charge, the particles of interest could be separated from the ambient polydisperse distribution. When performing a fit test on a class-95 respirator, the mask concentration of 0.04 micron particles would be compared to the ambient concentration at this same size. The resulting fit factor would be free from the bias caused by penetrating particles.

In practice, this method utilizes a differential mobility analyzer[9,10] (DMA) in series between the aerosol sampling point and a CNC. The DMA operates at 1000 volts and is specifically designed to sample particles at the size of interest. The mask sample tube is connected to a sampling probe located on the respirator mask under test. The ambient sample tube is placed in close proximity to the respirator. Both sample tubes are connected to the two inlet ports of a three-way solenoid valve. The CNC sequentially samples first the ambient aerosol and then the mask. In both cases, only the particles of interest are extracted from all particles present and end up being counted by the CNC. The resulting fit factor is a ratio of the 0.04 micron particles outside the mask to those inside the mask.

Comparative Advantages and Disadvantages

This new method is in fact a minor adaptation of a well-proven, existing method. Besides the primary benefit of yielding unbiased fit factor measurements, this technique also has numerous other advantages:

1. it incorporates two well known and reliable aerosol technologies, condensation particle counting and differential mobility analysis;
2. it allows the use of existing instrumentation with only minor modifications
3. it retains all of the inherent advantages of quantitative fit testing.

The one important limitation of this technique is related to count statistics. The DMA acts like a band-pass filter for particles, selecting particles from a narrow size range around the nominal diameter (0.04 micron). This results in approximately 1.5 to 3% of the ambient particles being separated and counted by the CNC. For example, in a typical ambient environment with 4,000 particles/cc., the DMA will separate out approximately 90 particles/cc. To compensate for these low count statistics, several techniques were implemented:

1. the reported fit factor measurement has been limited to a maximum of 200
2. the mask sampling time has been slightly increased
3. the naturally occurring ambient aerosol has been supplemented using a portable salt aerosol generator.

Validation Testing

A variety of tests have been performed to validate this new technique, including: 1) controlled leak tests, 2) class-100 comparative respirator fit tests and 3) class-95 comparative fit tests. All of the tests performed to date have demonstrated the validity of this method.

Validation Testing: Controlled Leak Test

A simulated fit test was conducted using a sharp-edged orifice. A carefully controlled concentration of ambient particles was drawn through an orifice into a mixing chamber and diluted with filtered air. Simultaneous, comparative "fit tests" were conducted using the standard CNC method and a CNC with the size-selection accessory. The test was repeated with a variety of orifice sizes to simulate a range of fit factors. The results are shown in Figure 2.

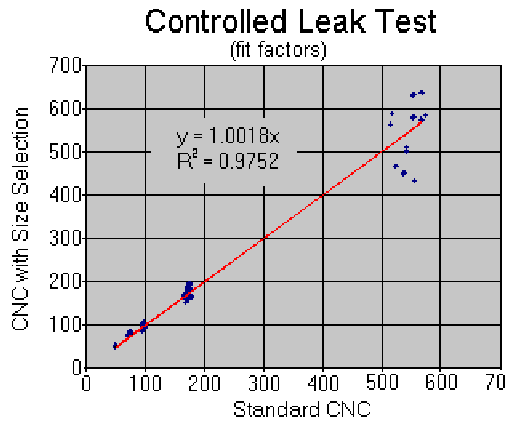

Figure 2

The two methods show very good agreement in the measured fit factor, as evidenced by the linear regression slope of 1.0 and the high correlation value. The data points exhibit greater variability, however, with higher fit factors.

Validation Testing: Class 100 Respirator Test

A second validation test involved comparative fit tests conducted on a class-100 respirator. Since no class-100 respirators were available at the time of testing, a HEPA filtering facepiece was substituted. The respirator was placed on a head form and a flow rate of 30 L/min was generated using a vacuum pump. The respirator straps and nosepiece were adjusted in order to obtain a representative range of fit factors. Once again, simultaneous, comparative fit tests were conducted using the standard CNC method and a CNC with the size-selection accessory. For this high efficiency respirator, one would expect identical fit test results using the two methods (none of the ambient particles should penetrate the respirator media, to bias the results). The results are shown in Figure 3.

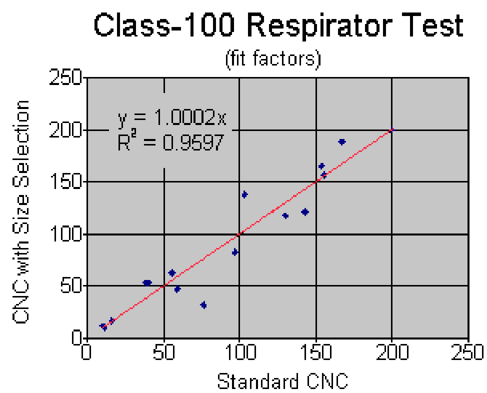

Figure 3

The two methods again show very good agreement in the measured fit factor, as evidenced by the linear regression slope of 1.0 and the high correlation value. From these two tests, one can assume that the CNC with size selection accessory is making the same measurement as the CNC alone.

Validation Testing: Class-95 Respirator Test

A final validation test involved comparative fit tests conducted on a class-95 respirator. The test method was the same as for the class-100 respirator. It is expected that the two methods will yield substantially different results. The CNC with the size selection accessory should give a higher fit factor measurement. Figure 4 shows the results graphed two ways: Figure 4A has a linear regression and Figure 4B has a power function regression.

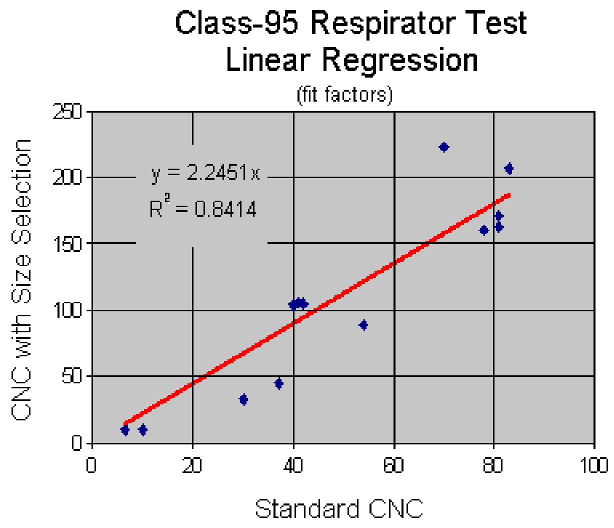

Figure 4A

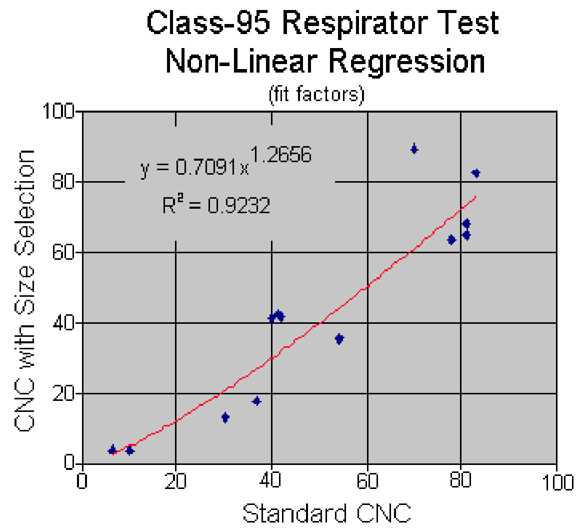

Figure 4B

The results are consistent with expectations; the CNC with the size selection accessory yielded significantly higher fit factors. A non-linear regression model appeared to provide a better fit for the data. Upon closer examination, this result is also consistent with expectations. When there is a large face-seal leak (low fit factor), the "leak" particles predominate the measurement, with the penetration particles adding little to the calculation. The relationship between the two methods is largely linear. As the leak becomes smaller (higher fit factors) the penetration particles begin to dominate the calculation and the relationship between the two methods becomes non-linear.

A comparison of the fit test decision logic when using N95 respirators, shows the clear advantage of using the size-selection accessory. With the standard CNC method, fit tests are often artificially low, sometimes causing the fit test to fail (fit factor below 100) when it should pass. In Figure 5, notice the simultaneous fit test comparisons between the standard CNC method and the CNC with size selection. For example, in tests 3 and 4, the standard CNC method yielded a fit factor of approximately 40. The unbiased fit factor, as measured using the size-selection accessory, was actually over 100.

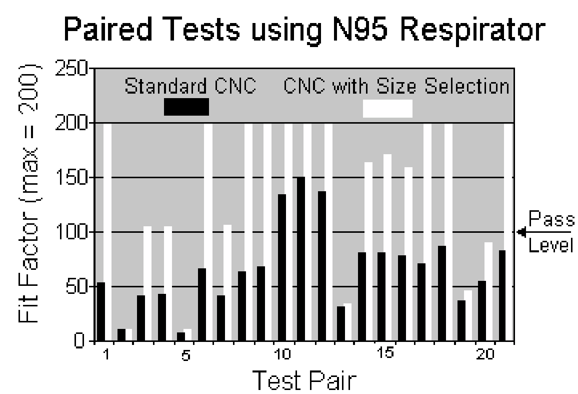

Figure 5

In tests where the actual fit factor is poor, both methods yield similar results (tests 2, 5, 13 and 19). Where the fit factor is excellent, both methods will result in a pass (tests 10, 11 and 12). In the middle ground, where the fit factor is close to the pass/fail level of 100 (test 3, 4, 7 and 20) the biased measurement using the standard CNC method results in an unfairly low fit factor. The size selecting device is necessary to provide accurate results.

Conclusions

A new technique allows for unbiased fit testing of class-95 respirators. The method uses a size selection accessory upstream of a standard CNC quantitative fit tester, to select out only certain particles of interest. This technique has been validated using several methods, including controlled leak tests, class-100 and class-95 respirator fit tests.

Notes

1. "New Methods for Quantitative Respirator Fit Testing with Aerosols", Willeke, Klaus; Ayer, Howard; Blanchard, James; *American Industrial Hygiene Association Journal*, **(42)** 2/81, pp. 121-125

2. Madelaine, Guy and Reiss, Philippe; French Patent # 1422188

3. Keady, Patricia B.; U.S. Patent # 4,790,650

4. Sinclair, David; U.S. Patent # 3,806,248

5. "Aerosol Penetration Through Filtering Facepiece and Respirator Cartridges", Chen, C.C.; Lehtimaki, M.; Willeke, K.; *American Industrial Hygiene Association Journal*, (**53**), September, 1992, pp. 566-574

6. It should be noted that a majority of class-95 filtering-facepiece respirators exhibit this phenomenon. However, some brands of class-95 respirators are, in fact, greater than 95% efficient. These respirators may only allow 1 to 2% of the particles to penetrate the media.

7. "Validation of a Quantitative Fit Test for Dust/Fume/Mist Respirators: Part I", Iverson, Sandra; Danisch, Susan; Mullins, Haskell; Rudolph, Shelly; *Applied Occupational Environmental Hygiene*, March 1992, pp. 161-167

8. Sibata Model MT-02

9. "A Submicron Aerosol Standard and the Primary, Absolute Calibration of the Condensation Nuclei Counter", Liu, Benjamin and Pui, David; *Journal of Colloid and Interface Science*, Vol. **47**, No. 1, April 1974, p. 155-171

10. "Aerosol Classification by Electric Mobility: Apparatus, Theory and Applications", Knutson, E.O., and Whitby, K.T.; *Journal of Aerosol Science*, Vol. **6**, pp. 443-451

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