QUANTITATIVE RESPIRATOR FIT TESTING

AN ANALYSIS OF UTILIZING CONDENSATION NUCLEI COUNTER (CNC) VS. OPTICAL PARTICLE COUNTER (OPC)

APPLICATION NOTE RFT-023 (A4)

Introduction

Particle counters (both CNCs and OPCs) directly count individual particles one at a time. While this seems obvious, it is important to state this up front because counting particles is a simple process of taking a random sample of particles in the air. This means that simple sample statistics are important in evaluating different techniques for their applicability to Respirator Fit Testing. The evaluation of these statistics is oftentimes referred to as (particle) counting statistics.

A particle counter pulls in a continuous sample of air and counts the particles. The number of particles measured (sampled) is a function of concentration in the ambient air, the flow rate pulling particles into the particle counting device, and the length of time the sample is taken. From simple statistics, the following equation is used to calculate the margin of error, in percentage (%):

$$\text{Margin of Error at 95\% confidence} \sim 0.98 / \sqrt{n},$$

Where, n is the number of particles sampled

For the purposes of this paper, we will use the following equation to simplify the math:

$$\text{Margin of Error at 95\% confidence} \sim 1 / \sqrt{n},$$

a commonly accepted approach in statistical calculations.

Here is a simple example. If a Particle Counter counts 100 particles in a given period of time, what is the margin of error?

$$\text{Margin of Error at 95\% confidence} = 1 / \sqrt{n} = 1 / \sqrt{100} = \pm 1 / 10 = \pm 0.1 = \pm 10\%$$

A user wearing a safety device like a respirator might want a higher degree of safety.

Basics of Masks

For Respirator Fit Testing, the definition of Fit Factor (FF) is:

$$FF = C_{out} / C_{in}, \text{ where}$$

- C_{out} is the concentration of particles outside the mask (ambient concentration)
- C_{in} is the concentration of particles inside the mask

The concentration inside the mask can come from:

- Particles leaking through the face seal
- Particles penetrating through a filter
- Particles generated by a person (i.e., coughing, breathing, and smoking)
- Particles generated by shedding (i.e., from inside of respirator or tubing)

This will become important later.

Statistics for a Pass/Fail Level of 500 (Typical for a Full Face Mask)

CNC (TSI PortaCount® Respirator Fit Tester)

TSI specifies that a minimum ambient concentration of 1000 particles (pt)/cm^3 is needed to properly conduct a fit test. Typical ambient concentrations can vary considerably, but for illustrative purposes, we will first use the *worst-case* scenario minimum of 1000 pt/cm^3. The pass/fail level for a full-face mask is 500 as defined in CSA Z94.4-11.

$$\text{Pass/Fail (min) Level FF} = C_{out} / C_{in}$$

$$C_{out} = \text{Minimum Ambient Concentration} = 1000 \text{ pt/cm}^3$$

$$\text{Substituting, } 500 = 1000 \text{ pt / cm}^3 / C_{in}$$

$$\text{Therefore, } C_{in} = 2.0 \text{ pt / cm}^3$$

The error at 95% confidence for counting particles is as follows:

Total particles = (C_{in}) x (flow rate) x (time conversion) x (time of exercise in Canadian Protocol), where the flow rate is the flow rate of the particle counter going through the particle counting optics.

Substituting,

Total Particles = (2.0 pt / cm^3) x (350 cm^3 / 1 min) x (1 min / 60 Sec) x (70 second total mask sample in 7 exercises) = 816 particles

Error at 95% confidence = $1 / \sqrt{n} = 1 / \sqrt{816} = \pm 3.5\%$ (again, this is a worst case scenario)

In some recent tests with a CNC, we experienced an ambient concentration of 7000 pt/ cm^3. If you perform similar calculations you will see the following:

$$\text{Pass/Fail (min) Level FF} = C_{out} / C_{in}$$

$$C_{out} = \text{actual Ambient Concentration} = 7000 \text{ pt / cm}^3$$

$$\text{Substituting, } 500 = 7000 \text{ pt/cm}^3 / C_{in}$$

$$\text{Therefore, } C_{in} = 14 \text{ pt / cm}^3$$

Total Particles for Canadian Protocol = (14 pt / cm³) x (350 cm³ / 1 min) x (1 min / 60 Sec) x (70 second total mask sample) = 5717 particles

Error at 95% confidence = $1 / \sqrt{n} = 1 / \sqrt{5717} = \pm 1.3\%$

OPC (New Fit Testers on the Market)

In some recent tests with an OPC-based Fit Tester that has a minimum ambient concentration of 10,000 pt/ft³, ambient particle counts (with an aerosol generator) were at about 75,000 pt/ft³. This corresponds to about 3 pt/cm³ (**Note**: 1 ft³ = 28,316.8 cm³). So, in a real situation (best-case scenario with aerosol generator for an OPC-based Fit Tester):

$$\text{Pass/Fail (min) Level FF} = C_{out} / C_{in}$$

$$C_{out} = \text{Minimum Ambient Concentration} = 3 \text{ pt / cm}^3$$

$$\text{Substituting, } 500 = 3 \text{ pt / cm}^3 / C_{in}$$

$$\text{Therefore, } C_{in} = 0.006 \text{ pt / cm}^3$$

Total Particles for Canadian Protocol = (0.006 pt / cm³) x (1000 cm³ / 1 min) x (1 min / 60 Sec) x (70 second total mask sample) = 7 particles

Error at 95% confidence = $1 / \sqrt{n} = 1 / \sqrt{7} = \pm 37.8\%$ (a large margin of error!)

In this realistic example, over 37.8% of the time, a user does not know if they are measuring a good fit or not with an OPC.

Actual Test Data

Performing fit tests with the Sibata MT-05C OPC-based Fit Tester and the TSI 8030 PortaCount CNC-based Fit Tester, testing supported the statistical analysis. Actual results are presented below.

Paired Fit Test Results using Sibata MT-05C and PortaCount Pro Model 8030						
MFG	Model	Type	Pass/Fail	MT-05C Overall Fit Factor	8030 Overall Fit Factor	Notes
3M	Ultimate FX; FF-402	Full Face	500	**594/Pass**	**6648/Pass**	Barely passed; questionable
3M	6898B	Full Face	500	**339/Fail**	**4342/Pass**	Failed a Good Fit
North	5400	Full Face	500	**257/Fail**	**737/Pass**	Failed a Good Fit; possibly poor fit
North	76009A	Full Face	500	**190/Fail**	**3998/Pass**	Failed a Good Fit

These tests were performed on one person conducting real-life, paired, same donning fit tests using the Canadian protocol in a typical room.

Because OPC-based fit testers do not have enough particles for good counting statistics, they falsely failed 3 of 4 fit tests that should have passed, with one other test close to failing as well. These false failures will put a fit test administrator in the challenging position of looking for different masks, spending more time (re-)fit testing, and potentially purchasing additional masks that very well might fail again due to counting statistics. At some point, this whole situation might bring about an unneeded safety concern.

Regarding the OPC technology, note that, at the Pass/Fail level for full-face masks (500), with an aerosol generator running, the OPC only "sees" 7 particles in 70 seconds. This averages out to 1 particle per 10 second mask sample. Noting from earlier in this document that one-way particles can get inside the mask is to be generated from inside the mask from people breathing or from residual particles. If a few particles are generated from inside the mask and get measured, it has a huge impact on the fit factor calculation. The OPC technology cannot determine signal (enough particles) from noise.

Conversely, in the worst-case scenario, the CNC technology "sees" 204 particles in 70 seconds. A couple of additional particles does not significantly change the fit factor calculation.

Proper Application of Technology

Typical commercial OPCs (like Sibata MT-O5C, MT-05, MT-O5U, and MT-03) can only measure down to 0.3 µm diameter particles, or 300 nanometers. Conversely CNCs (like TSI PortaCount 8030) measure down to 0.020 µm or about 20 nanometers. While ambient air conditions vary in every situation, there are typically at least 100 times or more particles in the measurement range of a CNC compared to an OPC. This makes the CNC a much better technology for fit testing using the Ambient Aerosol method as defined by regulatory bodies.

It should be noted that there is currently no existing "Ambient Aerosol Optical Particle Counter (OPC) Quantitative Fit Test Method/Protocol that has been validated and accepted for use by any regulatory body (e.g., OSHA, CSA, HSE, ANSI, ISO, etc.).

OPCs are the typical technology used for cleanroom measurements, where there should be a small number of particles. In fact, many OPCs for clean rooms have flow rates of up to 100 liter/min (100 times that of Sibata MT-05C). Why? Because you need to pull a significant amount of air through the measurement optics to 'see' enough particles to ensure the clean room classification test is statistically significant.

CNCs are used for a variety of applications, including fit testing, and ambient air studies, looking for environmental impacts of particles in the atmosphere. Why? Because there are a lot of small particles in the environment and scientists apply the best technology to 'see' the particles of interest.

Conclusion

From a statistical and real-world testing point of view, OPCs are not an appropriate measurement technology for fit testing. To be statistically appropriate, OPCs like the Sibata MT-05C, MT-05U, MT-05, and MT-03 would need to measure significantly more particles. To do this, fit test mask sample times would need to increase to an unrealistically long sample period.

CNCs are appropriate technology for modern fit testing.

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