# Application Note

## 100 LPM Aerosol Particle Counters:

The Benefits of Sampling at Higher Flow Rates

Many current standards define airborne particle monitoring in units of particles per cubic meter of air (particles/$m^3$). Often, these standards require sampling an entire cubic meter (1 $m^3$) of air to provide an accurate measurement of airborne particulate levels. Sampling 1 $m^3$ of air is time consuming when using conventional aerosol particle counters that sample at 1 cubic-foot per minute (1 CFM), which is equal to 28.3 LPM. Now, Particle Measuring Systems offers the Lasair® III 5100 Particle Counter that samples volumetric flow rates of 100 LPM. This application note will discuss the benefits of sampling at higher flow rates.

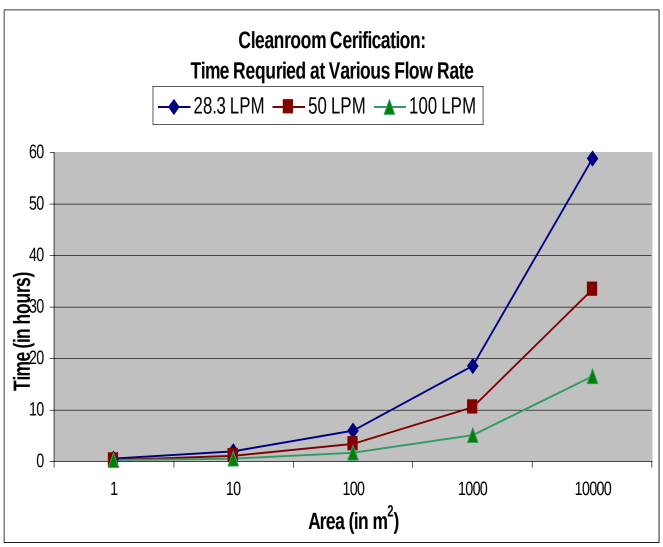


**Fig.1: Comparing time required to certify different size cleanrooms using particle counters with 28.3 LPM, 50 LPM, and 100 LPM sample flow rates.**

One of the primary benefits, as shown in Figure 1, is the reduction of time required to certify a cleanroom environment. In addition, Figure 1 illustrates that if the cleanroom area is very large, more sampling locations are required, which causes an exponential rise in sampling time. The time required to certify a cleanroom is extremely important, but depending upon the classification, the ISO standards require sampling a full meter of air. Using a particle counter with higher sampling flow rates will more quickly meet the ISO-specified volumes. Specifically, ISO 14644 standards for cleanroom classifications state the particle limits per $m^3$ of air. Sampling 1 $m^3$ of air requires 35.3 minutes at 28.3 LPM, 20 minutes at 50 LPM, and only 10 minutes at 100 LPM.

| Class | Number of Particles per $m^3$ | | | | | |
|---|---|---|---|---|---|---|
| | 0.1 um | 0.2 um | 0.3 um | 0.5 um | 1 um | 5 um |
| ISO 1 | 10 | 2 | | | | |
| ISO 2 | 100 | 24 | 10 | 4 | | |
| ISO 3 | 1,000 | 237 | 102 | 35 | 8 | |
| ISO 4 | 10,000 | 2,370 | 1,020 | 352 | 83 | |
| ISO 5 | 100,000 | 23,700 | 10,200 | 3,520 | 832 | 29 |
| ISO 6 | 1,000,000 | 237,000 | 102,000 | 35,200 | 8,320 | 293 |
| ISO 7 | | | | 352,000 | 83,200 | 2,930 |
| ISO 8 | | | | 3,520,000 | 832,000 | 29,300 |
| ISO 9 | | | | 35,200,000 | 8,320,000 | 293,000 |

**Table 1: ISO 14644 Cleanroom Classification Limits**

The ISO cleanroom classifications (Table 1) are a departure from the FS-209E standards that were based upon particles per cubic foot ($ft^3$). This is an important detail because it changes the way particle counters report data. Most particle counters operate at flow rates of 1 CFM, which is equal to 28.3 liters per minute (LPM). Then, to convert particles per $ft^3$ to particles per $m^3$, multiply the particles per $ft^3$ by 35.31 $ft^3/m^3$. This fact becomes extremely important when we consider particle sampling as a function of sample volumes and time.

### Sample Volume

Table 1 illustrates the challenges when certifying ISO Class 2 and lower. Specifically, we must consider the required *sample volume*, as well as, the *sampling time*. ISO 14644-1 Annex B requires sampling a sufficient volume of air, such that, a minimum of 20 particles are captured. The volume required for each ISO Class is derived from the equation:

$$V_S = \frac{20}{C_{n,m}} \times 1000$$

where

$V_s$ Minimum single sample volume per location (in liters)

20 Number of particles that could be counted if the particle concentration meets the class limit

$C_{n,m}$ The class limit (n) for the number of particles/$m^3$ and the particle size (m) for the specific class

Specific to the ISO Classes, we can derive the following equation:

*Min. Volume($m^3$) ≥ 20 particles / Max. Particle Concentration Allowed*

Then, to certify a cleanroom meets the standard, ISO requires collecting enough sample volume, at each location, so the volume includes at least 20 particles, which represents a statistically significant sample. Table 2 illustrates ISO 14644-1 requirements for the minimum sample volume per sample location.

| Class | Certification Particle Size | | | | | |
|---|---|---|---|---|---|---|
| | **0.1 um** | **0.2 um** | **0.3 um** | **0.5 um** | **1 um** | **5 um** |
| **ISO 1** | 2.000 | 10.000 | NA | NA | NA | NA |
| **ISO 2** | 0.200 | 0.834 | 2.000 | 5.000 | NA | NA |
| **ISO 3** | 0.028 | 0.085 | 0.196 | 0.572 | 2.500 | NA |
| **ISO 4** | 0.028 | 0.028 | 0.028 | 0.057 | 0.241 | NA |
| **ISO 5** | 0.028 | 0.028 | 0.028 | 0.028 | 0.028 | 0.690 |
| **ISO 6** | 0.028 | 0.028 | 0.028 | 0.028 | 0.028 | 0.028 |
| **ISO 7** | NA | NA | NA | 0.028 | 0.028 | 0.028 |
| **ISO 8** | NA | NA | NA | 0.028 | 0.028 | 0.028 |
| **ISO 9** | NA | NA | NA | 0.028 | 0.028 | 0.028 |

**Table 2: Minimum Sample Volume (in $m^3$) required per ISO Class**

Considering the sampling flow rate of a particle counter, we can develop a table that is based upon sampling time.

### Sampling Time

Performing any type of testing, saving time during those tests results in the highest return on investment. Airborne particle monitoring is no different, so employing a particle counter that samples at higher flow rates provides more data in less time. This time savings allows testing personnel to focus on process improvement—rather than process monitoring and room certifications. Table 3 illustrates the time, in minutes, to achieve statistically-significant data for the different ISO Classes

| Particle Counter | Flow Rate | Sensitivity | ISO Class | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Lasair III 5100 | 3.53 CFM (100 LPM) | 0.5 µm | NA * | 50 | 6 | 1 | 1 | 1 | 1 | 1 | 1 |
| Lasair II 510 | 1.00 CFM (28.3 LPM) | 0.5 µm | NA * | 177 | 20 | 2 | 1 | 1 | 1 | 1 | 1 |
| Lasair III 350L | 1.78 CFM (50 LPM) | 0.3 µm | NA * | 40 | 4 | 1 | 1 | 1 | NA * | NA * | NA ** |
| Lasair III 310C | 1.00 CFM (28.3 LPM) | 0.3 µm | NA * | 71 | 7 | 1 | 1 | 1 | NA * | NA * | NA ** |

**Table 3: Minutes Required to Sample Locations using Different Flow Rates.**

* ISO does not provide values for these room classifications
** Requires an aerosol diluter

Although the Lasair III 350 Particle Counter samples at half the rate (compared to the Lasair III 5100), it requires fewer minutes to sample ISO Class 2 & 3. The reason is the Lasair III 350's higher sensitivity, at 0.3 µm, which will count 20 particles sooner because within a standard environment, the concentrations of smaller particles greatly exceed those of larger particles. However, the Lasair III 350, without a diluter, cannot be used to certify ISO Class 7 and higher, so the Lasair III 5100's higher sample rate and versatility is the preferred choice for many cleanroom certifications.

#### EU GMP Annex 1

A common European standard in the pharmaceutical industry, EU GMP Annex 1, follows similar guidelines as defined in ISO 14644 with a few exceptions. The most significant addition requires bi-annual certifications of Grade A or B cleanrooms and sampling a complete cubic meter of air.

#### Pharmaceutical Approach to Volume & Time Savings

Performing a simple conversion, a 1 CFM particle counter samples at 28.3 LPM and requires 35.3 minutes to sample 1m$^3$ (1000 liters). Conversely, a 100 LPM particle counter requires only 10 minutes to sample 1m$^3$. This represents better data analysis, greater repeatability, and a significant cost saving in terms of labor hours.

| | Maximum particles per m$^3$ (≥ the stated particle size) | | | |
|---|---|---|---|---|
| | AT REST | | OPERATIONAL | |
| GRADE | 0.5 MM | 5.0 MM | 0.5 MM | 5.0 MM |
| A | 3,520 | 20 | 3,520 | 20 |
| B | 3,520 | 29 | 352,000 | 2,900 |
| C | 352,000 | 2,900 | 3,520,000 | 29,000 |
| D | 3,520,000 | 29,000 | not defined | not defined |

**Table 4: EU GMP Annex 1 Certification Requirements**

Example: Pharmaceutical Cleanroom

- The cleanroom is defined as Grade A
  - ≤ 3520 particles per m$^3$, measuring 0.5 µm and larger
- The cleanroom area equals 4600 m$^2$ (approx. 50000 ft$^2$)
- To determine the number of sampling locations, ISO suggests calculating the square root of the cleanroom's area (in m$^2$)
  - $\sqrt{4600} \cong 68$
  - This cleanroom requires 68 sampling locations for certification
- Certification performed with a 100 LPM particle counter:
  - All testing completed in 11.3 hours

- Certification performed with a 1 CFM (28.3 LPM) particle counter:
    - All testing completed in 40.7 hours (over 5 work days)!
- Grade A and Grade B cleanrooms require recertification every 6 months, so the total time, each year, spent certifying the cleanroom:
    - Using a 100 LPM particle counter: 23 hours
    - Using a 1 CFM particle counter: 81 hours

### Other Considerations

Excluding time savings, we must recognize the advantages of particle transport and statistical accuracy. Consider the following: If certification personnel need to collect 1 $m^3$ of airborne particle data, the time required is 35.3 minutes (sampling at 1 CFM). Consequently, the risk of data variability increases exponentially because during the longer period of sampling, other factors can influence data repeatability:

- Material processes can change
- Personnel can disrupt/influence air flow patterns
- Environmental conditions can change

These factors can adversely affect data integrity. In contrast, collecting airborne particle data for 10 minutes (100 LPM) provides more expedient particle capture, higher accuracy and repeatability with less variance. This is an important consideration because the various standards require calculation of standard deviation ($s$) and mean of the averages ($\bar{\bar{x}}$). If the data widely fluctuates, the allowable limits for $s$ and $\bar{\bar{x}}$ could actually cause the cleanroom classification to fail.

Therefore, sampling larger volumes of air produces more data, which result in significantly smaller ratios of standard deviation to the mean value. These ratios lead to tighter limits as the differences shrink between the allowed maximum and the mean of the averages, which provide statistical confidence at any cleanroom classification.

Finally, effective particle transportation through tubing has been debated for decades, but these points are certain: Higher flow rate particle counters collect more data per unit time and larger particles travel farther, which increases the probability of capture.

Particle Measuring Systems has conducted many particle transport studies. One study employed a 1 CFM particle counter, various lengths of 3/8" sample tubing, and 5.0 µm polystyrene latex spheres (PSL) particle standards. Here are the particle losses that occur with different lengths of horizontal sample tubing:

- 45% particle losses (3 meters of sample tubing at 1 CFM)
- 59% particle losses (4.5 meters of sample tubing at 1 CFM)

Decreasing particle losses is best achieved by sampling at higher flow rates. A separate study employed a 100 LPM particle counter, various lengths of ¾" sample tubing, and 5.0 µm PSLs. The larger tubing and higher sample flow rate greatly improves particle transportation, which significantly reduces particle losses and allows the freedom to choose longer sample tubing lengths. Here are the particle losses that occur with different lengths of horizontal sample tubing:

- 41% particle losses (3 meters of sample tubing at 100 LPM)
- 42% particle losses (4.5 meters of sample tubing at 100 LPM)
- 44% particle losses (8 meters of sample tubing at 100 LPM)

These particle transport efficiencies can be improved, if the tubing diameter is smaller (for straight tubing layouts) or if the tubing diameter is larger (for tubing layouts with bends).

### Summary

Sampling at higher flow rates provides more data, faster, which leads to shorter time to statistical significance. In addition, these advantages lead to lower labor costs, less chance for data variability, and better process improvements. The final benefit, particle transport, is greatly enhanced when using higher flow rates. This is especially important when analyzing particles larger than 1 µm, as those particles are the most difficult to transport. All of these factors should be considered before purchasing your next particle counter.

**Author**

**Steven Kochevar**
stevek@pmeasuring.com
303.443.7100 x372
Steve is a Senior Application Engineer at Particle Measuring Systems. He has worked for Particle Measuring Systems for 15 years. He has a B.S. in Electrical Engineering from the University of Colorado.