

## Comparing Particle Loss in Transport Tubing for Instruments with Different Flowrates

Particle counters are used in many applications ranging from cleanroom and clean air device classification in accordance with specified standards, testing of filter installation, portable environmental monitoring programs, in-situ environmental monitoring systems and the fault diagnosis of specific processes. Historically there has been a single volume flow rate of 1 Cubic Foot per Minute chosen for many of these applications, which is equal to 28.3 Liters Per Minute (1 CFM = 28.3 LPM).

Manufacturers of particle counters found that as regulations changed and higher volume flow rates were preferred for the classification of cleanrooms to either ISO14644-1<sup>1</sup> or EU GMP Annex 1<sup>2</sup> standards. Originally 50 liters per minute (50 LPM) instruments were designed and Particle Measuring Systems' led

the market with a true 100 liter per minute (100 LPM) instrument, thus enabling the sampling of a cubic meter of air (1 m<sup>3</sup>), required for the classification of a cleanroom either to ISO 4 or cleaner, or an EU GMP Grade A aseptic zone. The requirement for monitoring a process using a 'standard' 1 CFM device however, continues to prove the most suitable method of gaining data at a suitable rate and with sufficient confidence that a process can be measured economically.

### Particle Counter Types

The three (3) current instruments available from Particle Measuring Systems that satisfy all current needs of the room classification and environmental monitoring programs are described in the table below.

**Table 1 Features of Lasair III Particle Counters, Models 310C, 350L, and 5100**

Model	Lasair III 310C	Lasair III 350L	Lasair III 5100
Channel sizes (µm)	0.3, 0.5, 1.0, 5.0, 10.0, 25.0	0.3, 0.5, 1.0, 5.0, 10.0, 25.0	0.3, 0.5, 1.0, 5.0, 10.0, 25.0
Flow rate (LPM)	28.3 50		100
Counting efficiency	50% ±10% @0.3 µm	50% ±10% @0.3 µm	50% ±10% @0.5 µm
Maximum concentration (ft <sup>3</sup> )	1,200,000 700,0	00	575,000
ISO 21505-4	Yes Yes Yes		
Display	8.4 inch IR touch screen	8.4 inch IR touch screen	8.4 inch IR touch screen
Printer	Thermal Printer	Thermal Printer	Thermal Printer
Reports	ISO, EU GMP, Printouts	ISO, EU GMP, Printouts	ISO, EU GMP, Printouts
Weight w/o battery (kg)	6 6 6		
Dimensions (cm)	30 x 33x 26	30 x 33x 26	30 x 33x 26
Tube ID (inch)	3/8 1/2	3/4	
Battery type	Li-Ion Li-Ion	Li-Ion	
Battery life hours	4 hours single battery 8 hour dual battery continuous operation	3 hours single battery 6 hour dual battery continuous operation	3 hour dual battery continuous operation



**Figure 1** Three Lasair III particle counters with different flow rates

As there are different types of instruments available, each with a different flow rate, a concern arises in the industry of suitable transit of particles down tubing lengths associated with different instruments. Particle Measuring Systems has previously released information regarding the maximum suitable length of transport tubing<sup>3</sup> and this has been reinforced by the recent release of the draft World Health Organization requirements for vaccine manufacture which recommends that no more than 2.0 meters of tubing should be used<sup>4</sup>.

### Particle Loss Mechanisms

There are several factors affecting particle loss in transport tubing and these have been discussed in Application Note 81<sup>3</sup>. A function of these factors is to ensure that turbulent flow is maintained, thus ensuring that particles are transported with maximum efficiency. The Reynolds number is a function of turbulence and it is widely recognized that turbulent flow exists where the Reynolds number is greater than 4000<sup>5</sup>.

The flowing Reynolds numbers are calculated for the three Lasair III counters under review.

It can be seen in **Table 2** that in all but the low, 0.1 CFM (2.83 l/min), flow devices, turbulent flow exists in the transport tubing to the Lasair III particle counter, irrespective of flow rate chosen. This verifies that the losses due to particle transport are minimized. It does not mitigate from all losses however, and therefore further testing is required to demonstrate empirically what those losses are.

$$R = \frac{\rho VD}{\mu}$$

V = fluid velocity  
 D = Tube Diameter  
 ρ = Fluid density  
 μ = Fluid Viscosity

At 20 °C and 101.325 kPa, dry air has a density of 1.2041 kg/m<sup>3</sup>  
 At 15.0 °C, the viscosity of air is 1.78 × 10<sup>-5</sup> kg/(m·s)

Laminar flow occurs when ReD < 2300 and turbulent flow occurs when ReD > 4000 (J.P. Holman. *Heat Transfer*, McGraw-Hill, 2002, p. 207).

**Table 2 Flowing Reynolds numbers for the particle counters**

Instrument	Flow Rate L/min	Tubing ID mm	Flow Rate m <sup>3</sup> /sec	Tubing Area m <sup>2</sup>	Tube Velocity m/sec	Fluid Density kg / m <sup>3</sup>	Fluid Viscosity Kg m·s	Reynolds
Lasair III 310C	28.3	9.525	0.000471667	7.1265E-05	6.61849	1.2041	0.0000178	4264
Lasair III 350L	50	12.700	0.000833333	0.000126693	6.57756	1.2041	0.0000178	5651
Lasair III 5100	100	19.050	0.001666667	0.00028506	5.84672	1.2041	0.0000178	7534
AirNet 501	2.83	3.175	4.71667E-05	7.91833E-06	5.95664	1.2041	0.0000178	1279
AirNet-II 510	28.3	6.350	0.000471667	3.16733E-05	14.89161	1.2041	0.0000178	6397
AirNet-II 501	2.83	6.350	4.71667E-05	3.16733E-05	1.48916	1.2041	0.0000178	640

### Testing to Demonstrate Losses in 2 m Long Tubing

The following section (**Results of Testing**) describes the test method and results from testing each of the above flow rate instruments against a reference Lasair III 5100 particle counter. This reference unit has the highest volume and flow rate and therefore improves statistical significance due to the number of particles measured in a single sample period. Prior to testing, all Lasair III's were calibrated in accordance to the ISO 21501-4 standard for the calibration of aerosol particle counters<sup>6</sup>. This base-lined all particle counters such that no significant instrument-to-instrument error existed.



**Figure 2** Lasair III 5100 reference unit beneath a HEPA air supply

The reference unit was placed directly beneath the outlet of the HEPA filtered air supply and had no sample tubing attached (**Figure 2**). Each of the units under test: Lasair III-310C, Lasair III-350L and the Lasair III-5100, had 2 meters (2 m) of tubing attached and the inlet of this tubing was located adjacent to the reference unit input. This minimized any sample errors and ensured that the same number of particles was delivered to each transport mechanism, tubing, or directly to the sample inlet.

To minimize the particle sizing error, only NIST traceable PSL (Polystyrene Latex Spheres) and DRI-CAL particle size standards were used. Three particles were chosen for testing: 0.5 µm, 1.0 µm and 5.0 µm. The aerosol mist of size standard was generated using the PMS PG-100 Particle Generator, which nebulizes and dries the particles prior to delivery into the HEPA filtered air flow and supplies the particles to the test instruments. The larger 5.0 µm DRI-CAL particles were generated using the

PMS Large Particle Generator, which uses shear forces to deliver individual particles to the test instruments, also via the HEPA filtered air.

The 2 m sample tubing selected was Excelon Bev-A-Line XX. Bev-A-Line tubing is preferred as it is semi-rigid tubing, thus minimizing the risk of kinks in the tubing, and the inner surface is lined with a HYTREL polymer that offers a very low friction surface suitable for the transportation of particles.

### Results of Testing

**Table 3** shows the particle counts from each instrument for each of the duplicated test runs. This data is normalized to counts per cubic meter (n/m<sup>3</sup>). The results presented also show the % losses of each test run for the instruments relative to the reference Lasair III-5100.

A summary of average losses is given in **Table 4**.

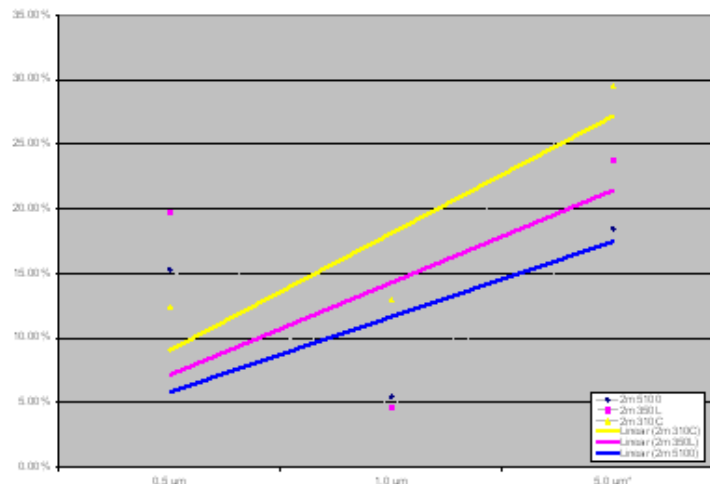
**Table 3** Test results

Challenge	REF 5100	2 m 5100	2 m 350L	2 m 310C	% LOSSES		
					2 m 5100	2 m 350L	2 m 310C
0.5 µm	34847	27995 290	26 312	88	19.67%	16.71%	10.21%
0.5 µm	56560	50361 436	48 482	79	10.96%	22.83%	14.64%
1.0 µm	47635	45180 446	80 417	28	5.15%	6.20%	12.40%
1.0 µm	46679	44011	45291	40351	5.72%	2.97%	13.56%
5.0 µm*	26692	21746	20878	19115	18.53%	21.78%	28.39%
5.0 µm*	29056	23703	21596	20149	18.42%	25.67%	30.65%

**Table 4** Average losses of particles relative to reference

Challenge	AVE %LOSSES		
	2 m 5100	2 m 350L	2 m 310C
0.5 µm	15.31%	19.77%	12.43%
1.0 µm	5.44%	4.59%	12.98%
5.0 µm*	18.47%	23.73%	29.52%

The plot in **Figure 3** shows the data of % loss verses particle size.



**Figure 3** Particle loss vs. particle size

## Conclusions

From the theoretical data, all instruments achieved turbulent flow conditions, as all instruments have a Reynolds number > 4000. Therefore the transportation of particles is maximized. However it is a known function of adding tubing to a particle counter that one will experience losses in tubing. The test data showed that these losses are measurable. The following conclusions can be made:

- Particle losses increase as particle size increases. Each of the instruments demonstrates lower losses in 2 m of tubing for the smallest particles (0.5 µm) than is apparent for the large particles (5.0 µm).
- The instruments with the higher Reynolds number transport particles more efficiently. The % loss of particles for the higher flow rate instrument, the Lasair III 5100, is less than the % loss of particles for the lowest flow rate, Lasair III-310C.

- Average losses for particles in 2 m of transport tubing for large (5.0 µm) particles are between 17% and 27%. This is reflective of previously published data from Particle Measuring Systems<sup>3</sup>.

Therefore, when choosing a particle counter for different applications, remember that there is a difference between instrument flow rate and potential data, relative to particle losses of the larger particles. For room classification, to either ISO14644-1 or EU GMP Annex 1, where a single measurement per year is made and that measurement is both of a large sample volume and a critical measurement, the high flow rate Lasair III-5100 is preferred as it both transports particles more effectively and samples the 1 m<sup>3</sup> faster.

## References

1. EN ISO 14644-1, Cleanrooms and associated controlled environments – Part 1: Classification of air Cleanliness, 1999.
2. EU Guidelines to Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use, Annex 1 – Manufacture of Sterile Medicinal Product, 2008.
3. An Analysis of Acceptable Particle Losses in Transport Tubing, PMS Application Note 81 (2007).
4. Environmental Monitoring of Cleanrooms in Vaccine Manufacturing Facilities, World Health Organization, Final Draft March 2010.
5. J P Holman, Heat Transfer, McGraw-Hill, 2002, p 207.
6. ISO 21501-4 Determination of particle size distribution, single particle light interaction methods - Light scattering airborne particle counter for clean spaces, 2007.

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