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- **ISPE BOSTON**
Foxboro, MA - October 5
- **PDA'S 6TH ANNUAL GLOBAL CONFERENCE ON PHARMACEUTICAL MICROBIOLOGY**
Bethesda, MD - October 17-18
- **ISPE ANNUAL MEETING**
Dallas/Ft. Worth, TX - November 6-9

CONTACT US

www.pmeasuring.com
info@pmeasuring.com
1.800.238.1801
1.303.443.7100

REGULATORY UPDATE

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USP <1788> Guidance for Testing Particulate Matter in Injections

USP <1788> became active on May 2011 and offers additional information relating to the selection of a particle counter suitable for use in testing finished injectable products. This guidance is supplemental to the general chapter <788> on testing of Particulate Matter in Injections. [Click here to learn more.](#)

Good Manufacturing Practices Outlined by China's SFDA

China's SFDA has published its Good Manufacturing Practices (GMP) for Pharmaceutical Products. The guidance essentially follows the PIC/S rules for manufacturing, including the requirements for environmental monitoring, along with the same limits identified for the different grades of pharmaceutical cleanrooms, A through D. [Click here to learn more.](#)

TECHNICAL PAPERS

Review of the PIC/S GMP Annex1 Interpretation Document, PI 032-2

There are two sections within the recent PIC/S document, GMP ANNEX 1 REVISION 2008, INTERPRETATION OF MOST IMPORTANT CHANGES FOR THE MANUFACTURE OF STERILE MEDICINAL PRODUCTS (PI 032-2), issued January 2010, which required further clarification from an industry perspective. Section 6 and 11 talk to particle counter performance and tubing length; it is only those two sections that are discussed in this review. [Click here to learn more.](#)

Comparing Particle Loss in Transport Tubing for Instruments with Different Flow Rates

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. [Click here to learn more.](#)

PRODUCT SPOTLIGHT

FacilityPro™ Environmental Monitoring System



The new FacilityPro system tightly integrates viable and non-viable automated sampling control and reporting. The module rack-mount system is designed to incorporate all necessary components of the environmental monitoring system, enabling faster installation and validation. Built-in redundancy and data buffering mitigates the risk of data or production loss. Designed specifically around the needs of aseptic fillers, the FacilityPro system has an intuitive iFix-based interface, saving time and minimizing the chances of operator error. [Click here to learn more.](#)

BioLaz™ Real-Time Microbial Monitor



The BioLaz was recently introduced to the Italian regulatory agency, Agenzia Italiana del Farmaco (AIFA), involving a half-day presentation and demonstration session. They were also interested in the validation proving compliance to USP <1223> Validation of Alternative Microbial Methods and EP 5.1.6. Subsequent validation testing has demonstrated the BioLaz's ability to detect single spore events down to 0.5 – 0.7 µm sizes using *Bacillus atrophaeus* spores. [Click here to watch a short video detailing the BioLaz.](#)

Lasair® III and MODA™ Paperless QC Micro System



Lonza in conjunction with Particle Measuring Systems has created a software driver to interface the Lasair II and Lasair III Particle Counters with the MODA paperless QC Micro System. MODA is a mobile data acquisition platform that eliminates inefficiencies and reduces error rates inherent with paper-based systems. [Click here to learn more.](#)

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REGULATORY UPDATE - USP <1788> OVERVIEW

USP <1788> became active in May 2011 and offers additional information relating to the selection of a particle counter suitable for use in testing finished injectable products. This guidance is supplemental to the general chapter <788> on testing of Particulate Matter in Injections. The following highlights are extracted from the guidance document:

Sample Volume Accuracy

The sample volume accuracy should be < 5% of the measured value using a mass method, based on a sample volume greater than the tare volume. Typically either a 5 ml or sample volume similar to what is typical for product should be used.

Sample Flow Rate

Sample flow rate should be tested against the manufacturer's requirements.

Calibration

Three methods described:

- Manual (using half count technique)
- Electronic (using a PHA)
- Automated (using a software based algorithm that is comparable to the manual method) with count values between 1000 and 5000 particles/ml.

Sensor Resolution

Sensor resolution is a particle counter's ability to differentiate between sizes. Again three methods are allowed: Manual, Electronic, and Automated. Resolution tests should be done using a solution of a 10 μ m suspension of PSL's with a distribution of no greater than 5%.

Particle Counting Accuracy

For multi-channel instruments such as the APSS-2000, a dilution of the standard USP test reference standard should be used such that a final concentration of between 50 and 200 particles/ml is made. Testing should give better than 20% of the diluted sample concentration when measured at > 10 μ m size.

Particle Measuring Systems APSS-2000 sampling system fully complies with the requirements of the new chapter. A technical paper is available upon request.

REGULATORY UPDATE - GOOD MANUFACTURING PRACTICES OUTLINED BY CHINA'S SFDA

China's SFDA has published its Good Manufacturing Practices (GMP) for Pharmaceutical Products. The guidance essentially follows the PIC/S rules for manufacturing, including the requirements for environmental monitoring, along with the same limits identified for the different grades of pharmaceutical cleanrooms, A through D.

It was recently issued and became active on March 1, 2011. It has been under development for some time and was drafted under support from the University of Beijing. More information can be found at the following site: <http://eng.sfda.gov.cn/cmsweb/webportal/W43879541/A64031585.html>



5475 Airport Boulevard, Boulder, Colorado 80301-2339
303.443.7100 1.800.238.1801 Fax: 303.546.7380
Customer Service Center 1.877.475.3317
Instrument Service 1.800.557.6363

Review of the PIC/S GMP Annex 1 Interpretation Document, PI 032-2

There are two sections within the PIC/S document, GMP ANNEX 1 REVISION 2008, INTERPRETATION OF MOST IMPORTANT CHANGES FOR THE MANUFACTURE OF STERILE MEDICINAL PRODUCTS (PI 032-2), issued January 2010, which require further clarification from an industry perspective. Section 6 and Section 11 both speak to particle counter performance and tubing length. It is only those two sections that are discussed in this review.

Section 6:

New EC-GMP text: Portable particle counters with a short length of sample tubing should be used for classification purposes because of the relatively higher rate of precipitation of particles $\geq 5 \mu\text{m}$ in remote sampling systems with long lengths of tubing.

PIC/S Interpretation: This section implies that old central particle counters with long tube lengths will no longer be acceptable for clean room classification, as they absorb too many particles (especially $5 \mu\text{m}$ particles). Therefore, modern portable particle counters with short tubes or (even preferable when possible) those without tubes should be used for classification purposes. The certificate of calibration of the particle counter should mention the tube length and nature of material (inox or polymer). When calibration of the particle counter is performed outside by an external laboratory, the particle counting system should be qualified on site with a comparative measurement with an isokinetic probe. For impact on monitoring, see also Section 11.

Section 11:

New EC_GMP text: Airborne particle monitoring systems may consist of independent particle counters; a network of sequentially accessed sampling points connected by manifold to a single particle counter; or a combination of the two. The system selected must be appropriate for the particle size considered. Where remote sampling systems are used, the length of tubing and radii of any bends in the tubing must be considered in the context of particle losses in the tubing.

PIC/S Interpretation: This section addresses concerns especially for the sedimentation of $5 \mu\text{m}$ particles in remote systems (as a rough example, s-shaped bent tubing of 1.5 m length can already absorb about 30% of the $5 \mu\text{m}$ particles.). The company must qualify their particle sampler and sampling system for both particle sizes, $0.5 \mu\text{m}$ and $5 \mu\text{m}$.

Particle Loss in Transport Tubing

Particle losses have been discussed at length in a number of Particle Measuring Systems technical papers (*Acceptable Loss of Particles in Transport Tubing*, May 2010). The following summarizes the mechanisms of how particles behave and will assist us in understanding of sampling difficulties and also assist in improving the efficiency of sampling.

- The *Stokes number* is the ratio of a particle's radius to the dimension of an obstacle, an important factor in determining when a particle in motion will be impacted by an obstacle (fiber or tube wall).
- The *drag coefficient* is the reflection of the particle's ability to change direction relative to size. Smaller particles have smaller drag coefficients and hence change direction more dynamically.
- The *Relaxation time* is the time for a particle initially in equilibrium with a moving fluid to match a change in fluid velocity. Large particles have a long relaxation time. Therefore, when an air stream moves through tubing that contains small-radius bends or elbows, the large particles will deposit on a tube wall because they cannot adapt easily to sudden velocity changes owing to tube curvature, but will continue in their original direction until they impact on the tube wall.
- The *Deposition velocity* or sedimentation velocity is the ratio of particle flux, the distance per unit time for sedimentation to occur, relative to the ambient particle concentration.
- *Reynolds number* describes the turbulent flow within tubing; ensuring turbulent flow improves particle transport as the factors above are overcome through moving particles off the tube walls post collision.

It can still be determined though that particle attrition does occur, especially with the larger $5 \mu\text{m}$ particles. Practical experimentation demonstrates that tubing lengths over 2 m should not be used whenever the quantification of $5 \mu\text{m}$ particles is required.

As the length of tubing is restricted to only 2 m and the particle burden in sample tubing is so low, many of the effects that impact particle transport in tubing are limited, such as orientation of sample tubing (lying flat, vertical etc.) and number of bends (providing they maintain at least a tube diameter*4 radius).

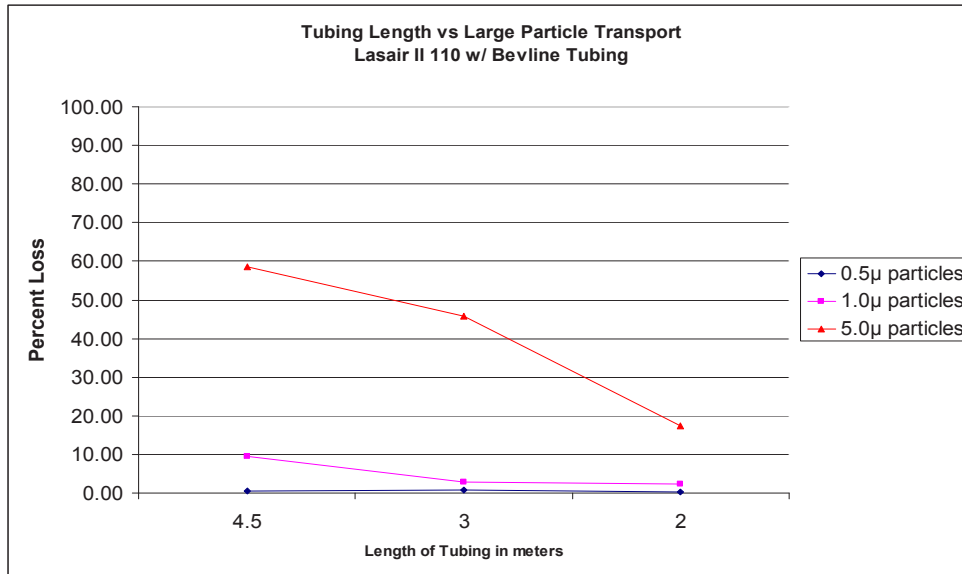


Figure 1 Particle loss in a portable particle counter (3/8" tubing at 28.3 liter/minute flow rate)

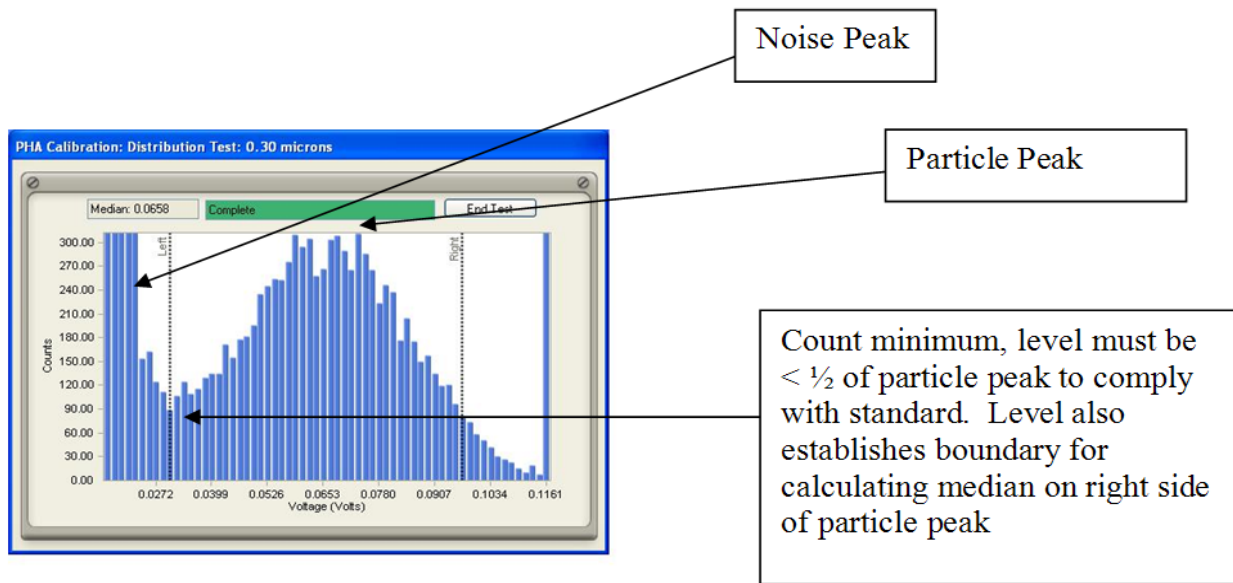


Figure 2 Particle counts for ISO 21501-4 testing

Particle Counter Calibration

EU GMP and therefore PIC/S suggests pharmaceutical manufacturers follow ISO 14644-1 for determining particle counts and classifying cleanrooms (based upon airborne particle data) and ISO 14644-2 for instrumentation guidelines that demonstrate continued compliance. They require that particle counters are calibrated in accordance with industry standards, ISO 21501-4 provides calibration methods to assure common calibration methods

among optical particle counters (OPC's) and to meet the requirements for ISO 14644-1.

The ISO 21501-4 Scope asserts: "Instruments that conform to this part of ISO 21501 are used for the classification of air cleanliness in cleanrooms and associated controlled environments in accordance with ISO 14644-1". Consequently, cleanroom users should look to ISO 21501-4 as a method to meet cGMP, EU GMP, and other requirements.

Overview of the ISO 21501-4 Test Method

- Calibration Particle: PSL particles traceable to an international standard with uncertainty $\leq 2.5\%$
- Sizing calibrated with a Pulse Height Analyzer (PHA) at median value for each size channel
- Pulse height distribution of PSL particle signals with noise must increase by 50% from the minimum to the peak

The ISO 21501-4 defines a particle size range from 0.1 – 10.0 μm . The particle counter is defined as an instrument used for classification of air cleanliness in cleanrooms and controlled environments in accordance with ISO 14644-1. Specific parameters defined within ISO 21501-4 include:

- Size calibration:
 - When calibrating a light-scattering airborne particle counter (LSAPC) with calibration particles of a known size, the median voltage (or internal PHA channel) corresponds to the particle size. The median voltage (or internal PHA channel) should be determined by using a particle counter with variable voltage limit (or internal PHA channel) settings. The median voltage is the voltage (or internal PHA channel) that equally divides the total number of pulses counted.
- Verification of size setting
- Counting efficiency:
 - 50% ($\pm 20\%$) for particles close to the minimum detectable size
 - 100% ($\pm 10\%$) for particles 1.5 – 2 times larger than the minimum detectable size
- Size resolution:
 - $\leq 15\%$ for calibration particles specified by the manufacturer
- False count rate:
 - When sampling clean air, the false count rate is a measure of particle concentration (counts per cubic meter) reported from the minimum size ranges.
- Maximum particle number concentration
- Sampling flow rate
- Sampling time
- Response rate
- Calibration interval

It must be noted that the critical component of particle counting is that no known concentration is delivered, only that the particle counter must accurately determine the size of a particle and that the instrument measures a known volume of air and that all particles ($100\% \pm 10\%$) are measured.

Therefore if particle loss occurs in sample tubing during the calibration of a particle counter and as such too few particles are measured to determine an accurate sizing calibration, the calibrating technician

will increase delivery of the nebulized particles to the units under test, overcoming any losses and increasing counts to such a level as a sample sufficiently large enough for calibration to occur. This is an independent function of the length of tubing used. For this reason it is not necessary that the particle counter be calibrated using the same tubing length as that used in operation.

Responses to PIC/S Interpretation

Section 6

- It is a known and documented component of particle transport in tubing that losses do occur in tubing, and particle loss manifests itself more pronouncedly in the larger sizes, 5 μm and above.
- The purpose of cleanroom classification is to demonstrate as scientifically as possible the status of the cleanroom or clean air device at a given point in time and as such the most accurate readings must be taken. This requires that either no tubing or as short a tubing as required for an individual test point be used.
- There is no correlation between the particle counter calibration and tubing length; the two are independent components of measurement. It is therefore not required to know the tube length during calibration and ideally during calibration no tubing should be used.

Section 11

- Particle losses in transport tubing are known and manufacturers such as Particle Measuring Systems are able to supply data showing particle losses with specific tubing lengths.
- A maximum length of 2 m is recommended for all point-of-use particle counters. Given this short distance, tubing bends (providing they meet specifications, no less than tube diameter *4), electrostatic forces etc. have a lower impact on transported particles and can essentially be removed from practical considerations.
- Evaluating particle losses on site requires the generation of particles within a controlled zone and testing is prone to multiple errors. To test effectively, either a simulation of the installed sample points for the shortest and longest points being designed in a test laboratory, or the particle counter manufacturer's own data should be used for validation. Particle Measuring Systems can supply data for losses for all portable instruments.
- Manufacturer's data can be used to determine what reduction in action and alert levels for monitoring is optimal. It is important to reduce action limits rather than increase particle values due to the nature of the distribution (log relationship as a function of diameter) of particle populations within cleanrooms.

Author: Mark Hallworth, Market Manager – Life Sciences Group

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Comparing Particle Loss in Transport Tubing for Instruments with Different Flow Rates

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 ISO14644-1¹ or EU GMP Annex 1² 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 faster sampling of a cubic meter of air (1 m³), 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 Specifications 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 ³)	1,380,270	832,599	688,495
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	3 hours single battery 6 hour dual battery continuous operation	2.5 hours single battery 5 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 tubing³ 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 used⁴.

Particle Loss Mechanisms

There are several factors affecting particle loss in transport tubing and these have been discussed in Application Note 81³. 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 4000⁵.

The flowing Reynolds numbers are calculated for the three Lasair III counters under review as well as fixed location sensors, the Airnet II particle sensors.

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/m³
 At 15.0 °C, the viscosity of air is 1.78 × 10⁻⁵ 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 ³ /sec	Tubing Area m ²	Tube Velocity m/sec	Fluid Density kg / m ³	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 counters⁶. 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/m³). 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	29026	31288	19.67%	16.71%	10.21%
0.5 μm	56560	50361	43648	48279	10.96%	22.83%	14.64%
1.0 μm	47635	45180	44680	41728	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 versus particle size.

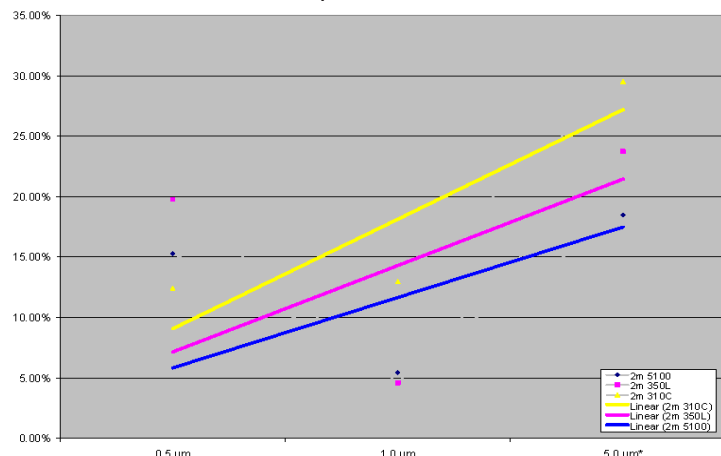


Figure 3 Particle loss vs. particle size

Conclusions

From the theoretical data, all Lasair III particle counters 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 5.0 μm 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 Systems³.

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 m³ faster.

References

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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.

Author: Mark Hallworth, Particle Measuring Systems, Life Science Market Manager
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