CLIMET INSTRUMENTS COMPANY

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SUMMARY TEST REPORT – LIGHT BLOCKER COLLECTION EFFICIENCY

APPLICATION NOTE: 20230206-A
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INTRODUCTION

This is a reprint and adaptation of a Summary Test Report dated February 14, 2011; additional testing conducted in 2013; and an application note dated 9 November 2015. These articles were written by Randy Grater (Service/Quality Manager), and testing by Dave Chandler (Engineering Manager). It includes information pertinent to current ISO 14644-1:2015.

APPLICATION

It has been called a "horn," "megaphone," "funnel," and even a "big sucky thing." Occasionally it is called a "sample probe." Officially, it is an isokinetic probe. "Isokinetic" means the air flows in and around the probe is laminar without creating any turbulence or loss of velocity.

When macroparticles of ≥ 5 µm are a size of interest, there can be loss using transport tubing. Some drug manufacturers have dispensed with isokinetic probes in non-laminar flow areas, sampling instead with a bare inlet in non-unidirectional flow areas. Climet's internal testing confirms that you are only exchanging > 5µm tubing loss with losses due to insufficient inlet size.

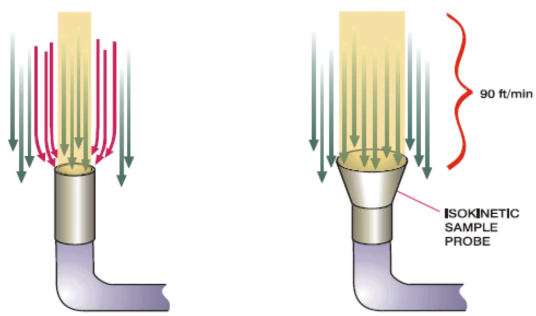

Figure 1: Sample without / with an Iso Probe

Another problem is turbulence. Per Figure 1 above (left image), the inner yellow-green and pink air flow is captured by the inlet at different velocities. Moreover, this often creates a vacuum below the rim of the inlet where the pink air flow is vacated by the suction of the particle counter. On the outer edges, the green air flow is pulled up into this vacuum, thus creating a donut shaped circular ring of turbulence around the inlet. This phenomenon can occur in both laminar and non-laminar flow areas, and may contribute to higher particle counts or particle loss depending on the severity of the turbulence. Subsequently, Climet recommends always sampling with an isokinetic probe.

Need for Light Blocker Probe

Climet uniquely has a wide-scatter optical sensor designed to measure a particle's light scatter from virtually every angle. This differs from other manufacturers who use front-scatter or side-scatter optical sensors, which measure light scatter from only the front or side, respectively.

The wide-scatter optical sensor, indeed, has pros and cons.

The primary advantage of a wide-scatter optical sensor is based on a basic law of physics. That is, the more light scatter captured in the measurement, the more accurate the measurement. It also mitigates the effect of particle orientation and morphology (or shape) on sizing. In short, the accuracy of measurement is significantly improved.

A disadvantage of a wide-scatter optical sensor is that it may be susceptible to false counts when placed directly under fluorescent light fixtures. Fluorescent lights flicker at a rate of 120 Hz (120 cycles per second), which is invisible to the eye. The flickering light can enter the sensor chamber and can clearly result in false counts well into the millions, typically in the lowest channel size (i.e., 0.3 µm or 0.5 µm channels).

LIGHT BLOCKING ISOKINETIC PROBE

While smaller-sized particles remain entrained in the airflow, a light blocking isokinetic probe mechanically mitigates fluorescent light flicker without interfering with macroparticle (≥ 5 µm) collection.

The light blocker has an internal bullet-shaped pitot that uses the counter's suction to aerodynamically pull large particles into the sensor chamber while concurrently maintaining laminar flow around the inlet. Unlike other light blocker designs, the Climet Light Blocker tapering of the pitot prevents surface impaction losses.

VALIDATION: In 2011 and again in 2013, a Climet light-blocker isokinetic probe was tested against a standard sample probe. Numerous tests were performed using extended sample times (16 to 25 hours) to minimize other variables, such as spatial variations in 5 µm concentrations. Tests were repeated with various flow rates and locations with half the tests using a standard sample probe, and half using a Climet Light Blocker sample probe. The testing determined use of the Climet Light Blocker Isokinetic probe was virtually indistinguishable from our standard sample probe. For macroparticles, and loss was less than 1%. These variances would be expected when sampling ambient air with two standard isokinetic probes. Thus, the testing demonstrated that there is no bias or consistent effect between a standard sample probe and Climet's light blocker iso probe. The Climet light-blocker is, therefore, neutral to the count efficiency of large macroparticles. Testing was conducted by Randy Grater (Technical Service/Quality Manager) and Dave Chandler (Engineering Manager).

TROUBLESHOOTING: While conducting sequential monitoring and using a light blocker, if counts are into the millions, press down to ensure the probe is properly seated over both o-rings. Then move the counter 12 inches in any direction and restart the sample. The problem should resolve immediately.

ALTERNATIVE: Use a standard sample probe and a large probe stand with a short length of sample tubing. Make sure the sample tubing has a slight bend to block any fluorescent light. Always sample from top to bottom with minimal bends in the sample tubing.

REFERENCES

- **EU GMP, Annex 1.**
- **ISO 14644-1:2015 Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness.**
- **ISO 14644-2:2015 Cleanrooms and associated controlled environments – Part 2:** Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration**.**
- **ISO 21501-4:2018 Determination of particle size distribution – Single particle light interaction methods – Part 4: Light scattering airborne particle counter for clean spaces.**

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