TECHNICAL PAPER

ApexR5 Remote Particle Counter Addressing Risks in Airborne Particle Counting

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The Apex R5 Remote Particle Counter: Addressing Risks in Airborne Particle Counting

A frustrating problem facing quality and calibration managers in healthcare manufacturing facilities is finding out an instrument is out of tolerance or broken at the time of calibration. This automatically requires a time-consuming and costly investigation that may lead to product re-call. As airborne particle counters are an important tool used in the environmental monitoring of pharmaceutical, bio-pharmaceutical and healthcare facilities worldwide, in tolerance calibration is critical in addressing the risk of airborne contamination to the final product. In addition to determining air quality as part of the facility qualification, particle counters are required tools used in confirming air cleanliness in critical areas where high-risk operations are carried out. Airborne particle counters address the risk of airborne environmental contamination by monitoring and providing proof that critical environments are in control before and during manufacturing operations.

When airborne particle counters are recalibrated, “as received” data establishes if the particle counter is within tolerance since the previous calibration. If a particle counter’s as found data is out of tolerance, ISO 9001 requires consideration that the environment that the product was produced in, suspect. If there is no other way to determine that the environment was suitable for manufacturing then the product produced is at risk of contamination. This can become a very expensive and time-consuming process as ultimately the patient is at risk of using contaminated product. Calibration and quality managers in the pharmaceutical industry have to evaluate the as found (as received) data and evaluate the risk of contamination.

The calibration data must then be reviewed to assess the confidence that the product was not exposed to dangerous levels of contamination during the manufacturing process the particle counter was monitoring.

Questions that have to be addressed are:

- Does the calibration data suggest the equipment was broken, minimally out of tolerance, or grossly out of tolerance?
- Was it out of tolerance in the range in which it was used?
- How much product was produced in the environment that was monitored by the particle counter?
- How much product that passed inspection was sent to inventory or was shipped to the customer?

If confidence is low that the out-of-tolerance particle counter was capable of producing good results, then the product produced in this environment may be handled as suspect product. This can include segregation, quarantine, recall, re-inspection or retesting the product produced for contamination.

The Apex R5 Remote Particle Counter addresses the risks of out of tolerance calibration by providing advanced self-diagnostics and communication to external computer systems such as “Facility Monitoring Systems” (FMS) or more specifically “Non-Viable Particle Monitoring Systems” (NVPMS). These systems can notify operating personnel that the specific instrument is either non-operational or calibration is out of tolerance.

Laser Diode Life

A common problem with airborne particle counters is laser diode life. Laser diodes have a finite life that can be reduced by heat and high operational current. In pharmaceutical manufacturing external heat from process tools or internal heat from lack of sample air can reduce laser diode life. These conditions may occur during cleaning and decontamination cycles that shut down the vacuum source eliminating sample air that may be factored into the particle counter design to reduce heat. To reduce costs many particle counter manufactures utilize Consumer Grade Laser Diodes. These are the same laser diodes used in mass produced consumer electronics such as Blue-Ray players and laser pointers. The Apex R5 addresses this issue by the using a Communications Grade Laser Diode that was designed to operate under elevated temperature conditions with a laser life span far exceeding that of Consumer Grade Laser Diodes.

Laser Diode Self Diagnostics:

In addition to an extreme life laser diode the Apex R5 monitors and reports laser current and output power to the external system. As laser current and output power are an important diagnostic to the life of the laser diode. This data record can be included in the environmental report for batch release. In the unlikely event, that a laser diode should start to fail the external system is notified immediately so that operating personnel may take corrective action and reduce product risk of contamination that would otherwise be undetected.

Sample Air Flow Monitoring:

An additional requirement for particle counter calibration is the monitoring of sample airflow. Remote particle counters rely on external vacuum systems and use a critical orifice for flow control. Reduced cost particle counters may offer no flow monitoring or rely on monitoring the presence of vacuum to address sample air flow. This may be particularly problematic as the calibration of the particle counter at the factory may be at a different altitude then the altitude it is used in monitoring. As particle counter accuracy is greatly affected by air flow, the difference in altitude can affect the accuracy of the particle counter. The Apex R5

reduces this risk by utilizing an altitude and pressure compensated flow monitor and reports it's status to the external system.

Reduced Risk of Contamination:

Another problem facing users is contamination of the particle counter. This can occur from exposure to the product itself (power filling operations) or poorly implemented cleaning and decontamination process. The Apex R5 addresses this risk in several ways. The first is the superior design of the internal airflow path using Computational Fluid Dynamics (CFD) in the design process to eliminate turbulence and particle recirculation within the sensing zone of the particle counter. This reduces the possibility of contamination of particles settling on optical components. Additionally the Apex R5 monitors the photo detector for increased background voltage that may indicate the presence of contamination. More on background monitoring in the following section.

Comprehensive Photo Detector Monitoring:

A common problem facing users of remote particle counters besides laser diode failure is the failure of the photo detector itself. Most particle counters monitor laser diode current in terms of determining if the particle counter is working. This reports that the light source for illuminating the particle is working. However if the photo detector (the component that actually receives the scattered light) is broken no particles will be detected. This problem is particularly insidious as most particle counters operate in an environment that is by design as having low particle levels. Where a particle counter consistently reporting zero particles is not uncommon. While the operating personnel who are focused on producing product and reliant on the FMS or NVPMS to indicate when particle counts exceed limits or the particle monitoring system has a problem. Often a broken photo detector is not noticed until calibration and this presents a significant risk.

An additional risk is contamination of the sensing optical components. When contamination is present small amounts of stray laser light are

scattered within the optical sensing zone. This can affect the photo detector in terms of background light and influence particle counter accuracy.

The Apex R5 addresses these risks by monitoring the status of the photo detector and reports it's status to the external system. The photo detector power, background and health is part of the data record that can be included in the environmental report for batch release or reviewed at calibration to determine it's operational history.

Particle Counter Suitability:

Another risk to the operational life of a Remote Particle Counter is it's suitability for the environment it is used to monitor. In cleanroom environments frequent cleaning and decontamination may involve the use of various chemicals in liquid and vapor states. Any particle counter and associated isokinetic sample probe, data cables and tubing will be exposed to the same cleaning and decontamination chemicals used in these environments. The particle counter should be designed to withstand these processes. A particle counter with a sheet metal shell and exposed data connectors may allow cleaning fluid to enter and risk corrosion of internal components. This may create an undetected failure that may not be detected until calibration. Chemical compatibility for the variety of cleaning, sterilization and antifungal agents should be considered. The Apex R5 address this risk as it is a stainless steel enclosure with a sealed inlet that prevents any cleaning fluids from entering. Additionally the Apex R5 is designed for vapor Hydrogen Peroxide decontamination cycles.

Reinstallation Errors and Incorrect Particle Counter Sensor Addressing:

Reinstallation error is one particular risk associated with particle counter recalibration that is all too commonly reported. This common complaint associated with Network based particle counters (Ethernet and RS-485 communication) is that the sensor's address on the network is not

physically associated with sample location. Even with well written SOPs the reinstallation of particle counters into the manufacturing environment has often resulted in the incorrectly addressed particle counters reporting data from the wrong location. This is catastrophic if this incorrect address/location goes undetected and operations resume. The Apex R5 addresses this risk with a Validation mode and with the optional SmartBracket™.

Validation Mode:

Validation mode is a special mode that is only utilized in installation and re-installation of the Apex R5. This special mode is used to confirm the physical location of the particle counter and confirm expected data is received by the external system. This greatly improves validation by confirming the actual location via a light on the front of the particle counter once validation mode is activated by the external system. Additionally data records received from the specific particle counter in validation mode confirm that the specific instrument is transmitting as expected.

SmartBracket™

Another way the Apex R5 addresses the risk of improperly addressed and installed particle counters is with the optional SmartBracket™. The SmartBracket™ greatly reduces operator error and installation/reinstallation efforts. The SmartBracket™ allows for easy installation and re-installation and removes particle sensor addressing as the SmartBracket™ has an EEPROM that is factory programmed with a globally unique IEEE EUI-48 node address. The SmartBracket™ physically remains at the installed location and provides sensor location addressing to the external system. If a particle counter has to be replaced any sensor can be easily reattached to the SmartBracket™ without having to worry about setting a network address avoiding addressing mistakes.

ISO 21501-4

Airborne particle counter calibration standard ISO 21501-4 is the only acceptable calibration standard for light scattering airborne particle counters used in cleanrooms. Any calibration and re-calibration should be referenced for further information as to the requirements for calibration. However, every calibration report per ISO 21501-4 should include at a minimum:

ISO 21501-4 Test report

a) Date of calibration;

b) Calibration particle sizes;

c) Flow rate;

d) Size resolution (with the particle size used);

e) Counting efficiency;

f) False count rate;

g) Voltage limit or channel of an internal pulse height analyzer (PHA).

In addition re-calibration should include the as found, as received_ data.

End of Technical Paper