



BEST PRACTICES IN PARTICLE COUNTER MANAGEMENT TO INCREASE DATA INTEGRITY RELIABILITY

Lighthouse Worldwide Solutions



Particle Counter Management

Particle Counter management is a critical process in ensuring particle counter health and data integrity. The accuracy of the data from particle counters is critical in regulated industries. Particle Counters should be calibrated regularly based on their use. Manufacturers recommend that Particle Counters are calibrated at a minimum on an annual basis.

In the case of remote Particle counters used in continuous real-time monitoring systems, some end users turn in their instruments for calibration on a more frequent basis. More frequent calibrations are driven by data and having fewer intervals between calibration verification that the sensor is within tolerance.

These steps manage the impact of a Particle Counter when not found to be within tolerance during calibration. The problem with an out-of-tolerance event is the impact of the reliability of the data produced by the Particle Counter when it was in service. That impact needs to be evaluated, and the product safety and quality needs to be addressed. All of this process takes time and a lot of resources. The end result could be loss of product and loss of hundreds of thousands of dollars and can even impact product shortages.



Mitigate Out-of-tolerance Issues

So how can you mitigate out-of-tolerance issues when your Particle Counter is sent in for routine calibration? The best advice we can provide is to manage your processes, especially around locations where particle counters are used. These critical locations are where the product has been deemed most at risk. That is the reason remote Particle Counters are in those locations. When we look at a Grade A (ISO 5) location, this is a critical location, and any activity in these locations should be managed appropriately.

Most cleanroom operators or even managers do not understand how particle counters operate and the sensor's sensitivity to outside contamination. The number one issue we see for failed calibration as found data is sensor contamination from aerosol solutions that are sprayed during cleaning processes near the particle counter.

These cleaning agents and the aerosol solutions are pulled into the particle counter sensor, where they coat the mirrors and optics of the sensor. This has an immediate impact on the accuracy of the data. The particles counted after being contaminated with an aerosolized cleaning solution can be sized inaccurately. Therefore, during the calibration, we check the data for the sizing accuracy of the particle counter. The sizing test is based on ISO 21501-4, an internationally recognized particle counter calibration standard. So how could the contamination issue have been mitigated? The answer is simple. Manage your process by keeping in mind the sensitivity of the particle counter sensor.



Stop spraying cleaning solutions around the locations where particle counters are in use. If that practice is managed correctly, you will significantly reduce the instances of failed as found calibrations. If the practice cannot be changed, put a cap on the particle counter while the cleaning agent is being sprayed.

The ApexR was designed to be able to be wiped down externally in conjunction with the smart Bracket technology. The ApexR offers the best seal-ability and ingress protection on the market.

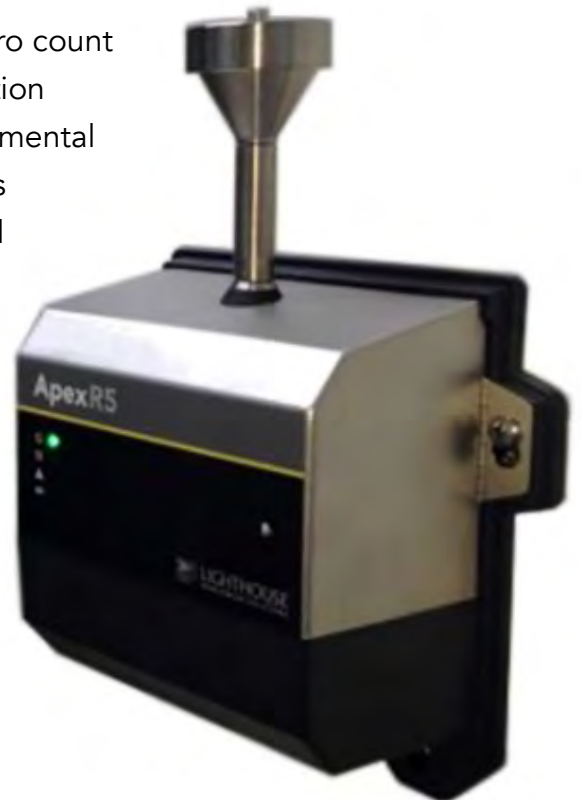


- 1** Sealed sample inlet base - avoids buildup of wipe down excess and potential particle traps and difficult area to keep free from ingress debris and potential home for bacteria.
- 2** Sealed housing seam. Waterproof sealed housing seam without any crevices where cleaning solution can build up and moisture accumulate.
- 3** Sealed smart bracket that can actually withstand low pressure water shower.
- 4** Concealed tubing and cables that normally hang out at the bottom of the unit and create particle traps and are difficult to clean.

However, care still needs to be taken to prevent contamination from entering the sensor. End-users need to understand that this type of particle counter does not work correctly when contamination, such as an aerosol solution, is inside the sensor. An aerosol will stick to and coat the sensor internally, leading to inaccurate data, particularly in particle sizing. We strongly recommend that the practice of spraying aerosols near an operating particle counter is stopped, or at least a cap is put onto the sensor during that operation. Your Data Integrity relies on this.

“By managing your processes around critical locations, you can make a major impact on Data Integrity and reliability.”

Particle Counter accessories such as stainless-steel caps or zero count filters can be used to close off the sensor to avoid contamination issues. Training of cleanroom operators and updating Environmental Monitoring and process SOPs should also be considered. This common-sense approach will work and mitigate against failed calibration as found data which puts the data from that particle counter into question.



“Since implementing a ban on spraying cleaning agents near our particle counters and requiring a zero count filter on the particle counter inlet during cleanroom sanitization operations, our failed calibrations have dropped from 58% to under 2%, and we now have a better understanding of protecting our data integrity.”
-Pharma Customer quote after implementing recommendations