Particle Data Collection and Interpretation for ISO Cleanrooms

Abstract

Facility Monitoring Systems (FMS) (or Environmental Monitoring Systems – EMS) gather data from a variety of sensors, including particle, microbial or environmental. Once all the data is gathered it must be correctly interpreted to be useful and effective. This paper addresses how to set up the FMS collection settings to support effective interpretation of the particle data to ensure effective cleanroom monitoring and particle management.

FACILITYPRO® ENVIRONMENTAL MONITORING SYSTEM

Introduction

ISO standards for cleanroom certification (ISO 14644-1:2015) and monitoring (ISO 14644-2:2015) are separate. In fact, ISO instructs that both certification and monitoring should be performed individually, and should not use identical values. General guidance in ISO 14644-2 Annex B states:

> **"Statistical process control principles can be used to set alert and action levels based on analysis of historical data."**

When performing a certification, there is a specific formula to determine where to take the sample, in addition to sampling time and volume. There are also pass/fail criteria for the certification. For monitoring, the values for alarm or alert should be based on historical information as well as what will affect the product quality.

As an example, if you are doing a room certification for ISO class 5 with a particle size of 0.5 microns, the limits are 3,520 particles per cubic meter. However, this number should not be used as the alarm limit, as a very clean room would have a significantly lower average, such as 100 particles, and never trigger it. In this case, it is advisable to set the alarm limits to 150 or 200 particles, enabling a more active monitoring of the room's environment. Ensure the limit is reflective of the entire room, which is typically much lower than the certification value.

The intervals between samples is an important decision – cleanroom

managers don't want to miss events, but too much data can be difficult to manage. One minute samples taken by FMS systems contain valuable details revealing what is occurring in the cleanroom, providing an immediate indication and response if something is out of control, without producing an overwhelming amount of data. Ten second sampling can provide a higher quantity of data without impacting data quality.

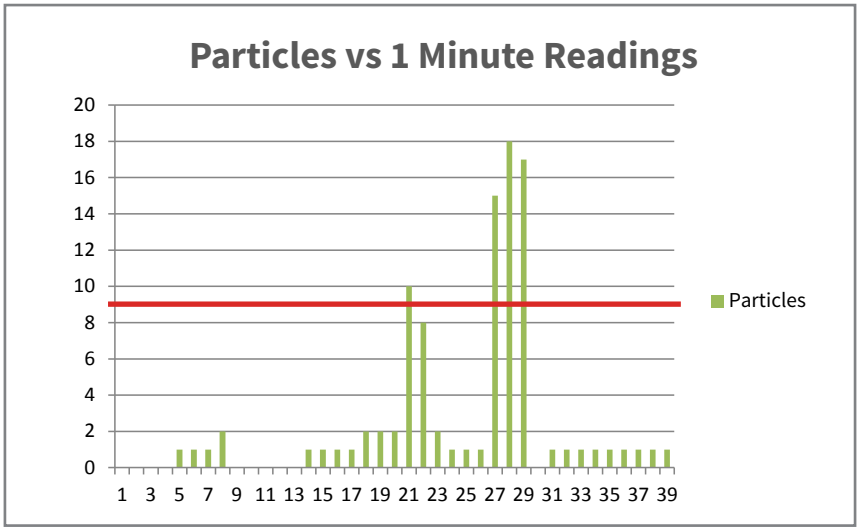
LASAIR® III PARTICLE COUNTER FOR CLEANROOM CERTIFICATION

Methods

Based on their likelihood of occurrence, it may be necessary to view data for 0.5 micron particles and 5.0 micron particles differently. There is a greater chance that a large volume of smaller particles will be present, with a smaller volume of larger sizes. In most cases, a larger particle's low occurrence frequency prevents the use of traditional statistical modeling.

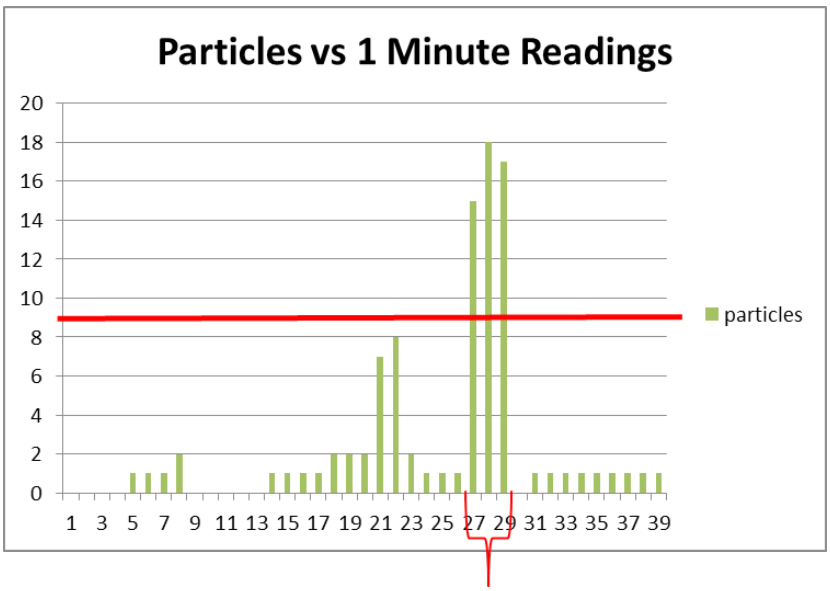
There are several different ways that one minute samples can be viewed including:

1. **Trigger the threshold value based on out of limit readings.** Each reading triggers an alert or alarm after exceeding the threshold. In the example below, the alarm limit is set at nine particles or higher. Four of the readings are higher than the nine particle alarm limit and each would cause an alarm to be activated. The rest of the readings are below that value and would not cause an alarm to occur.

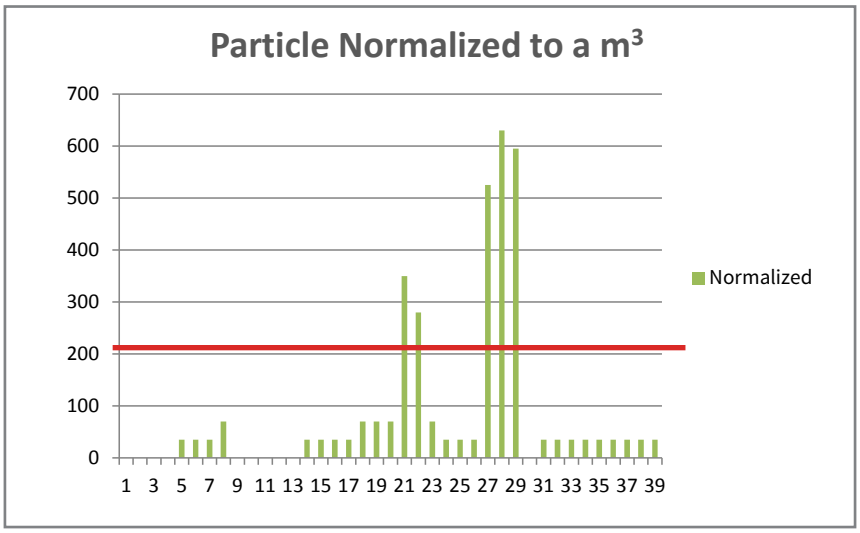


2. View one minute data and provide an alarm if you have N number of samples above a threshold

value out of X samples. In the below example, 3 samples out of 10 are above the defined threshold value (consecutively in samples 27, 28 and 29). An alarm occurred each time the past 10 samples contained 3 samples that exceeded the threshold. There were a total of 7 alarms created for the below data set.

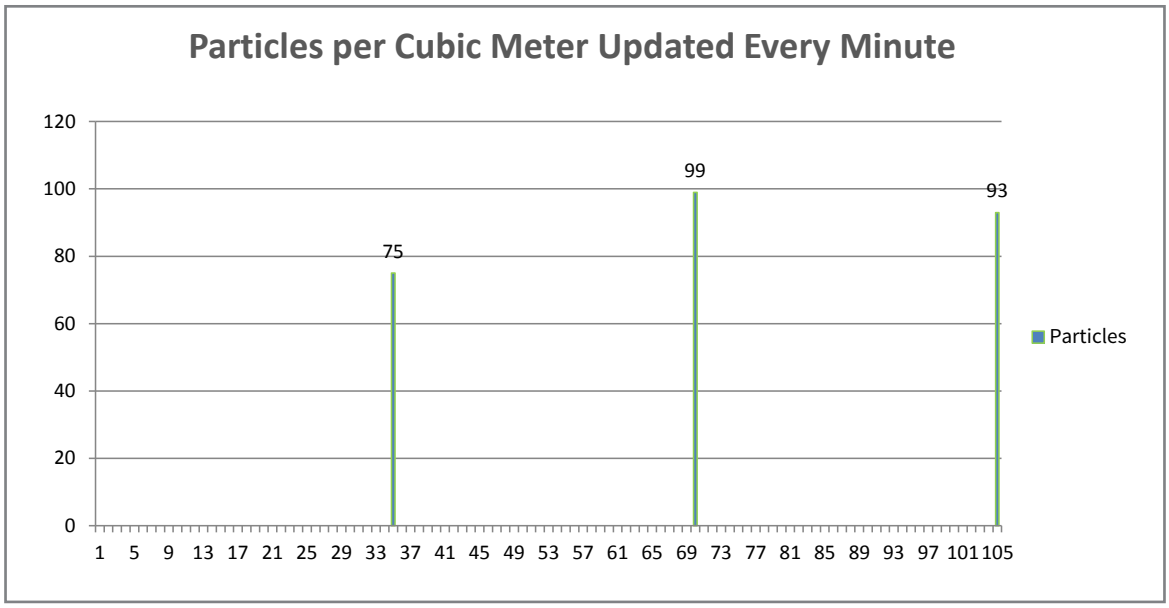


3. **Multiply the particle readings by 35.3 to obtain normalized cubic meter values.** This provides a reference back to the certification data and normalizes the data to cubic meters. The alarm should have a set threshold based on exceeding a specific count value. The below data set makes it easier to identify a small number of counts on a larger scale.

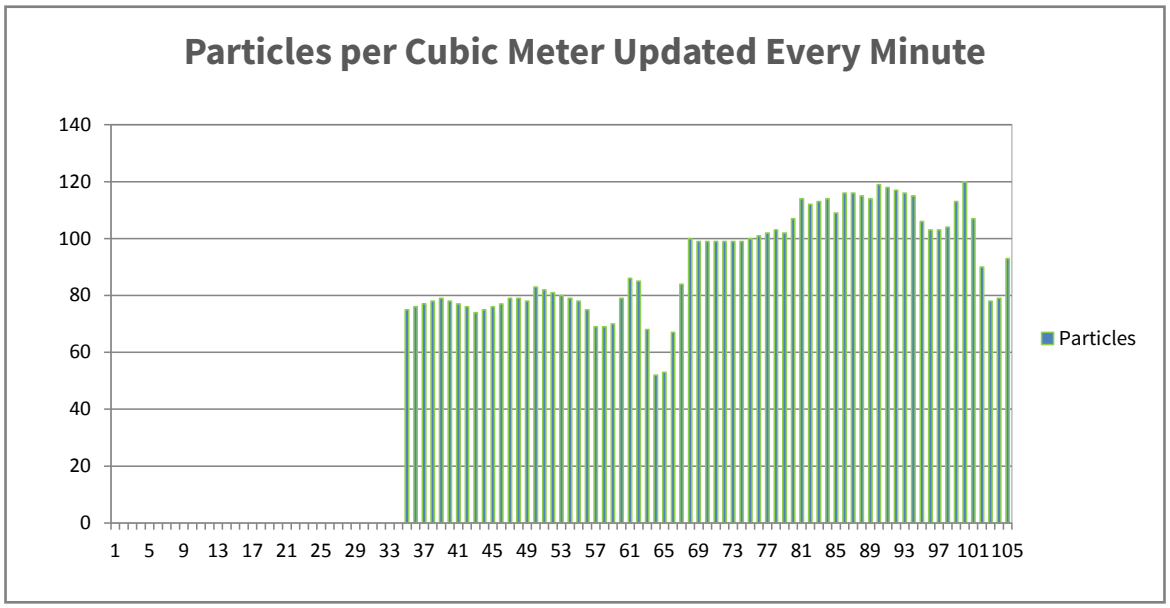


4. **Average the last 35 minutes and provide it as cubic meter data, then begin the next sample.** This provides an update every 35 minutes, but the ability to act is delayed by 35 minutes. This is not a

common approach but has been used in the past. Alarms would occur if a predetermined value is exceeded. For example, if there are more the 90 counts per cubic meter.



5. Average the last 35 minutes, update every minute, drop the oldest one minute sample and add back the newest one. This takes out the peaks or spikes that might occur due to a single excursion. This is a running average value.



These are some of the most common ways to view particle data in an environmental monitoring system, every one of these ways, plus more, are ways to look at the data. The actual alarm and action limits need to be set

AIRNET® II PARTICLE COUNTER

based on the data from the system. When a completely new system is installed the ISO standards are used for the initial alarm limits if there is no other data available. However, after a period of time of sufficient data gathering it needs to be reviewed and updated. That period of time needs to be long enough to have seen the room in operation over a variety of conditions. How the data should be viewed is determined based on the type and quantities of data obtained, the individual values and the risk to the product. Sometimes this can be done in 30 days, and sometimes it takes 90 days or longer of data collection to review depending upon the process's consistency.

For example, if the room always runs at 100 particles per minute with small excursions to 110 or down to 90, then one minute samples with an alarm at 120 might be reasonable. But if the room runs at 100 particles on average but fluctuates up to 140 once every 10 minutes due to personnel actions in the room, it might be more reasonable to have an action set at 150 if it happens 3 times in 10 minutes. The alarm notifies personnel that they are doing something wrong, with the instigation of a single corrective action over 200.

Conclusion

There is no specific rule regarding where to set an alarm limit. However, in order to ensure a quality product and identify where action and alert limits should be set, limits should be based on a careful review of the data and the process.

Author

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Paul Hartigan has been involved in product management, engineering development and marketing for over 25 years. He has held a variety of product management positions covering most PMS products over his last 8 years with PMS. His background includes work for a variety of instrumentation companies serving pharmaceutical, oil and gas industry, industrial manufacturing, utilities, and municipal water industries. He has a Bachelor's Degree in Electrical Engineering Technology as well as a MBA in Marketing. He has published numerous application papers as well as presented at seminars around the world.

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