



# **BASICS OF PARTICLE COUNTING**

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Lighthouse Worldwide Solutions



## Overview

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Over the years, particle counters have earned themselves the honor of being a staple in cleanrooms for a variety of industries. They are a critical tool for early fault diagnosis of a cleanroom's air filtration integrity. Thus, knowing the basics about them is important for anyone who works in or around cleanrooms. This paper covers the basics of why they matter, how they work, frequently used terms, and how to handle them.

# Getting Started With Particle Counters: Why They Matter

## Cleanroom Certification

Portable particle counters have been designed specifically for cleanroom certification: they are the cornerstone of this process. Top of the line particle counters have advanced features to help you certify your cleanroom with ease. ISO14644-1 2015 is considered the international standard for cleanroom certification. To summarize the standard, a volume of air is sampled based on the cleanroom's classification and number of samples to be taken (derived from the area of the room using a reference table). The average counts of the sizes of particles of interest must agree with the ISO 14644-1 table.

For example, if your room classification is ISO 5 then you must not exceed more than 3520 particles at a size of  $\geq 0.5\mu\text{m}$  for a sample volume of  $1\text{m}^3$ . Therefore, the location sampled must have less than 3,520 particles  $\geq 0.5\mu\text{m}$  to consider the room to pass for that size range.

## GMP

GMP refers to the Good Manufacturing Practice regulations promulgated by the US Food and Drug Administration under the authority of the Federal Food, Drug, and Cosmetic Act. These regulations, which have the force of law, require that manufacturers, processors, and packagers of drugs, medical devices, some food, and blood take proactive steps to ensure that their products are safe, pure, and effective. GMP is one of the standards cleanrooms follow that require particle counters.

Particle counters have the ability for special programs to be setup within the particle counters firmware to make tracking for GMP easier. Most particle counters on today's market can be set up so a specific standard can be selected and based on the sampling completed a Pass/Fail report can be generated.

# Using Particle Counters: Anatomy & Functioning Technology

## Light Scattering

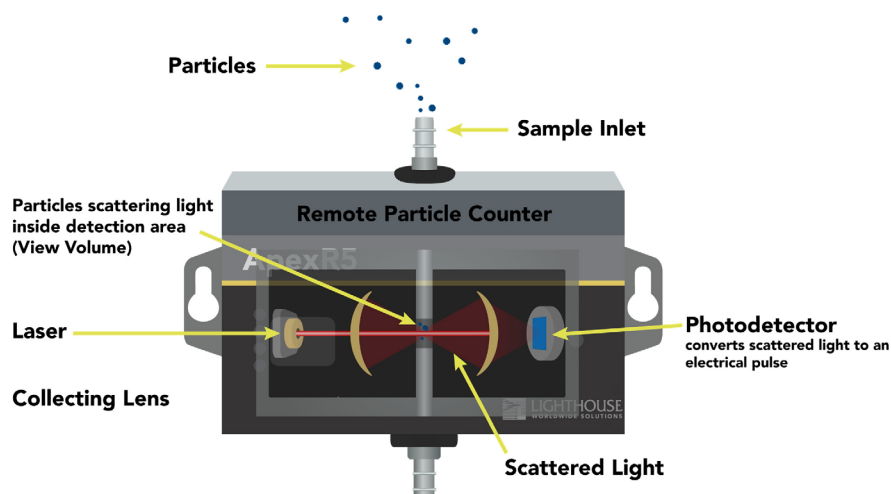
This is the technology that allows particle counters to determine the size and number of particles present. Essentially, particles pass in front of a laser and a photodetector determines the size of the particles based on how much the laser's light is offset. This is a simple physics phenomenon of displacement to determine volume (or size). For example, if you place a basketball in a half full bucket of water, the water level would rise. You could use that new water height to determine the volume of the basketball. The sample principle applies to light scattering: the photodetector determines the size of the particle based on how the laser's light changes.

## Sample Inlet

The sample inlet is where the air sample is taking from. In cleanrooms where the airflow is non-linear an iso-kinetic sample probe must be used. Current GMP standards recommend that the distance between the sample inlet and the iso-kinetic sample probe is as short as possible. The sample probe must also face towards the airflow. When not sampling the sample inlet must always be capped to ensure no contamination can fall inside the sensor.

## Particle Counter Sensor

The sensor of a particle counter is susceptible to contamination which can inhibit the sensor performance and the data integrity. It is important to follow the operating instructions and to avoid any ingress of cleaning solution spray or liquids or any other such kind of contamination into the sensor including any product being manufactured in powder or liquid form.





# Understanding Particle Counters: Important Terms & Functionalities

## Particle Counter Resolution

When selecting a particle counter, it is important to consider the smallest size that needs to be recorded. The resolution is basically the ability to distinguish particle sizes. It should be defined in the instruments calibration certificate. In the pharmaceutical industry, 0.5µm is typically the smallest size (sensitivity) that is required to be recorded GMP purposes; there for it is common for manufactures to test the ability to distinguish 0.5µm from 0.6µm as per ISO 21501-4 so particles are counted and sized accurately.

## How big is 1µm?

1µm is a relatively small size. The average human hair diameter is about 100µm. A grain of salt can be as small as 60µm. The types of particles to be monitored in a cleanroom range from 0.1µm up to over 20µm or in some cases, as in the automotive industry, larger particles up to 100 µm can affect the spray paint process causing defects and costly reworks.

## Zero Count Filter & Zero Counting

In terms of particle counting, a zero count filter is your best friend. This is a filter that attaches onto the sample inlet of the particle counter and enables the user to determine that the sensor is clean. Sometimes referred to as a purge filter, which should, when attached and the particle counter is operational, clean up the sensor.

You may get a few counts in some channels, but in general the expectation is to see zero counts. Your SOP should include the use of the zero count filter. It verifies the sensor is clean and eliminates false positives.

This filter should be used when transporting the particle counter between rooms to prevent cross contamination. It is also a great troubleshooting tool and can also validate sample tubing to verify the tubing is particle free and eliminate false positives.

If you have any doubts surrounding your particle counters sensor and the particle counts you are getting seems higher than what you are expecting, then place the filter onto the sensor and wait for the sensor to clean up.

Don't forget to take it off before you sample your process or environment.

## Flowrate

The flowrate is how quickly the air flows through the particle counter and it is a critical parameter for a couple of reasons. Accurate flow is tied into the sizing precision of the particle counter. The particle counter is designed and calibrated for particles to be moving at a certain rate. If a particle moves through the laser too quickly, it might appear smaller than it actually is. Inversely, if a particle lingers in the laser, it might appear larger than actuality.

# Maintaining Particle Counters: How To Handle Them

## Determining Robustness

Particle counters require careful handling and should be treated with care. The laser and optic are critical to the counting and sizing accuracy of the data, so they should be treated respectfully due to their sensitivity.

Excessive vibration, heavy handling, and any mishandling can result in laser misalignment. If the sample inlet was to take a knock or if liquid contamination, like aerosol cleaning solution sprays, or even liquid product splashes enter the sensor the risk of bad data is high.

## Sensor Calibration

Manufacturers of particle counters recommend at least annual calibrations and GMP requirements for calibrations are nominally every 12 months. However, it is worth considering based on the usage of a sensor and how often a sensor is used to consider calibration intervals of 6 monthly to avoid the impact of out of tolerance calibrations. Mitigation of data integrity is important in a GMP environment, and the cost of a calibration compared to the costs and impact of an out tolerance excursion are negligible.

# In Conclusion

Particle counters are complex but critical tools. They don't have to be difficult or cumbersome to use, though. Here at Lighthouse, our goal is to make your experience with particle counters simple and useful. For example, our ApexZ line has set the standard for particle counters on the market. It has a range of the latest features and technology. For example, it offers a GRID VIEW that makes it much easier for the user see what locations have been sampled and whether or not that location is in compliance with ISO 14644-1. This innovative way to review the sampled data in real time enables the user to work their way through each room and mitigate from any operator errors which could result in the work having to be redone. The ApexZ line of particle counters can also print certificates easily.

The ApexZ line boasts an impressive array of technological innovations and advancements designed to make your life easier in your cleanroom.

**Visit our Knowledge Center for more information on Cleanroom Technology and its applications.**

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