USING PARTICLE COUNTERS - THE DIFFERENCE BETWEEN ZERO COUNTS AND FALSE COUNTS

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Overview

This tech paper delves into the critical aspects of ensuring accurate and reliable particle count data in cleanroom environments. The understanding of distinguishing between zero counts and false counts, alongside adherence to appropriate calibration procedures and standards, plays a pivotal role in achieving precise measurements. Acknowledging the limitations of particle counting technology, particularly in attaining absolute zero counts, the paper explores the application of the Poisson distribution to make informed decisions based on dependable data. By addressing these fundamental principles, this study aims to empower users in maintaining desired cleanliness levels within their cleanrooms while optimizing efficiency and safety.

A zero-count filter on an ApexZ particle counter.

Particle Counters

Particle Counters play a critical role in maintaining cleanroom environments by providing data that verifies whether the rooms meet the design criteria for sterile and aseptic conditions. These controlled environments are crucial for industries such as pharmaceuticals, semiconductors, healthcare, and aerospace, where the presence of airborne particles can compromise product quality and safety. Particle counters measure and monitor the concentration of airborne particles in cleanrooms, enabling operators to assess air cleanliness and take appropriate actions to uphold the required standards.

ISO 14644-1:2015

The International Organization for Standardization (ISO) provides guidelines for air cleanliness classification in cleanrooms and controlled environments through ISO 14644-1:2015. This standard categorizes cleanrooms into nine different classes, ranging from ISO Class 1 (the cleanest) to ISO Class 9 (the least clean). Each class has specific particle concentration limits for different particle sizes. To adhere to ISO 14644-1:2015, cleanrooms utilize High Efficiency Particulate Air (HEPA) filters or Ultra Low Particulate Air (ULPA) filters installed in the HVAC systems to supply filtered air.

Particle Counter Functionality and Calibration

Particle counters typically utilize laser-based or light scattering technologies to detect and count particles in the air. These instruments provide real-time data on particle counts in different size ranges, typically ranging from 0.1 to 5 micrometers, as these particle sizes are considered most critical in cleanroom environments. For instance, most HEPA filters used in cleanrooms are specified at 0.3 microns with 99.97% efficiency. In semiconductor cleanrooms, even finer filtration is required, and ULPA filters are used to filter air down to 0.12 microns with a 99.999% efficiency.

A crucial aspect of particle counters' accuracy is the calibration process. Before the publication of ISO 21501-4 in 2007, calibration of particle counters varied between industries, manufacturers, and regions. The ISO 21501-4 standard, published in 2007, provided a globally accepted calibration procedure for light scattering airborne particle counters, unifying calibration practices worldwide. Following the latest version of ISO 14644-1:2015, particle counters must be calibrated according to ISO 21501-4:2018.

Zero Count Test

One of the essential tests performed during particle counter calibration is the Zero Count test. Historically, this term has been used to describe the test where a filter is placed on the sample inlet, and the particle counter is expected to display zero counts across all channels. However, this terminology is somewhat outdated and misleading, as the test is actually designed to capture False Counts. False Counts can occur due to various factors, such as particle drop-out, electronic noise, and dark noise, which make it challenging to achieve a true zero count.

Particle drop-out can occur downstream of the filter, in the sample tubing, or within the sensor itself. Electronic noise, caused by bad grounding or other electrical issues, can be erroneously detected as particles.

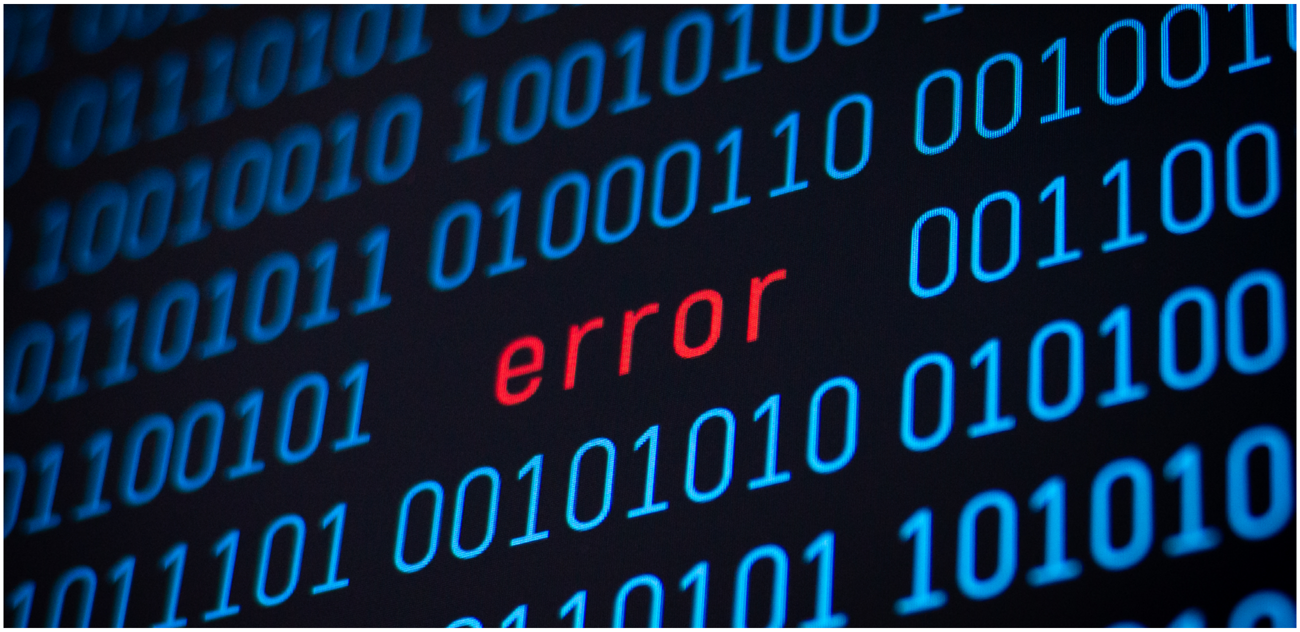
Zero count test in progress

Dark noise, originating from solar radiation, can also be picked up by the photodetector of the particle counter. Consequently, obtaining an absolute zero count result all the time is practically impossible.

False Count Test

To address this, ISO 21501-4:2018 introduced the concept of the False Count test. This test uses the Poisson distribution, a probability distribution, to calculate the expected variability in particle counts when a known concentration of particles is being measured, even with a zero count filter. The Poisson distribution describes the probability of obtaining a certain number of events (in this case, particle counts) in a fixed interval of time or space.

False Count Representation



To better understand the Poisson distribution's application, let's consider a few examples from different fields:

1. **Insurance: The Poisson distribution can model the number of insurance claims in a given time period, helping insurance companies estimate risks and set premiums accordingly.**
2. **Manufacturing: It can be applied to model the number of defective products produced during a specific production run, aiding manufacturers in assessing quality control processes.**

3. **Traffic Analysis: Traffic engineers use the Poisson distribution to model the number of vehicles arriving at a specific intersection within a given time frame, assisting in designing efficient traffic systems.**
4. **Website Traffic: Website owners can use the Poisson distribution to model the number of website visits per unit of time, helping in capacity planning and server allocation.**

Returning to the particle counting context, the Poisson distribution allows users to determine the probability of false counts even with a zero count filter. Annex C of ISO 21501-4:2018 provides the mathematical formula for the False Count test based on a sample volume of 1 cubic meter.

When calibrating particle counters, it is essential to follow ISO 21501-4:2018 and adjust expectations to meet the false count standard. Training the team to understand the limitations of particle counting technology and the effects of environmental conditions will help interpret data accurately. By using the zero count filter regularly and understanding the influences of flow rates on false counts, users can ensure the reliability and data integrity of their particle counters.

The recommendation for different models of particle counters includes performing a quick 10-minute sensor purge by attaching the zero-count filter before sampling. By observing the count results and comparing them with the 95% upper confidence limits based on different flow rates, users can assess the performance of their particle counters and detect any system failures or sensor contamination issues.

Reccommendations

Based on the information provided about the difference between Zero Counts and False Counts in particle counters, here are the key recommendations for the readers:

1. **Embrace the False Count Test Approach: Understand that the term "Zero Count" is somewhat outdated and misleading. Instead, adopt the False Count test approach based on the Poisson distribution as detailed in ISO 21501-4:2018. This will provide a more accurate assessment of particle counts and help you better interpret the data.**

2. **Adjust Expectations: Recognize that achieving an absolute zero count result all the time is not always possible due to various factors like particle drop-out, electronic noise, and dark noise. Be aware of the limitations of particle counting technology and understand that false counts can occur even with a zero count filter.**

3. **Ensure Proper Calibration: Ensure that your particle counters are calibrated following ISO 21501-4:2018 standards. Calibration is critical for maintaining accurate and reliable data, and adherence to the global calibration procedure helps ensure consistency and standardization across industries.**

4. **Regularly Use Zero Count Filters: Regularly perform a sensor purge by attaching the zero count filter to the particle counter. This will help ensure the sensor is clean before sampling and reduce the chances of cross-contamination from previous samples, which can lead to false counts.**
5. **Train Your Team: Educate your team members about the False Count test approach and the limitations of particle counting technology. Train them to interpret the data accurately and make informed decisions based on reliable information.**
6. **Monitor System Performance: Observe the counts in a 10-minute sample and compare them with the 95% upper confidence limits based on different flow rates. This will allow you to assess the performance of your particle counters and detect any potential system failures or sensor contamination issues.**
7. **Consult Relevant Standards: Stay updated with the latest standards and recommendations in the particle counting field, especially ISO 21501-4:2018 and ISO 14644-1:2015. Always consult the most recent and relevant standards for your particular application.**
8. **Follow Good Housekeeping Practices: Ensure good housekeeping practices when using particle counters. Use the zero count filter regularly, purge the sensor before sampling in each new room, and be mindful of cross-contamination between different cleanroom environments.**

By following these recommendations, you can enhance the accuracy and reliability of your particle counting data, thereby improving the effectiveness of your cleanroom operations. Understanding the difference between Zero Counts and False Counts and implementing the appropriate calibration procedures will lead to better decisions regarding the cleanliness of your cleanroom and the integrity of your particle counter data.

Conclusion

In conclusion, understanding the difference between zero counts and false counts and adhering to appropriate calibration procedures and standards is crucial for ensuring accurate and reliable particle count data in cleanroom environments. By embracing the Poisson distribution and accepting that absolute zero counts may not always be achievable due to inherent limitations of particle counting technology, users can make informed decisions based on reliable data and maintain the desired cleanliness levels in their cleanrooms.