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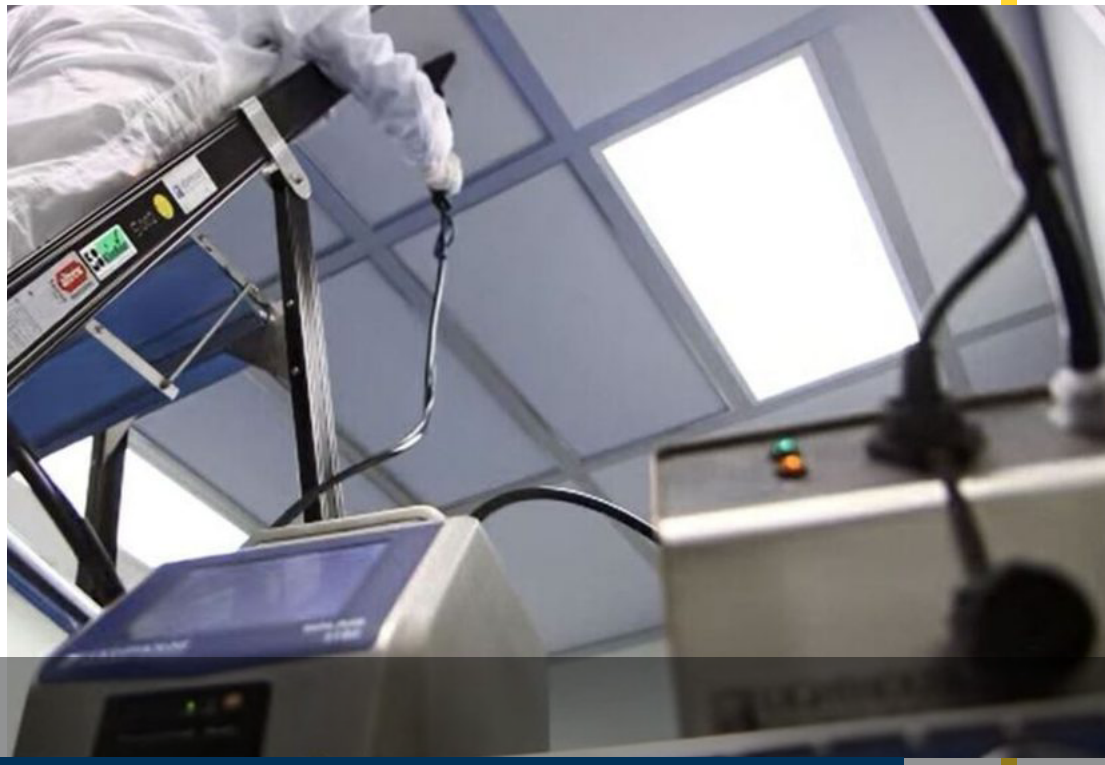

ADVANCEMENTS IN PARTICLE COUNTER-BASED TESTING AND MONITORING FOR CLEANROOMS, FILTERS, AND SEPARATIVE DEVICES:

A COMPREHENSIVE ANALYSIS OF ISO 14644-1, ISO 14644-2, AND ISO 14644-3

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Overview

Particle counters are a critical tool in the testing and monitoring of cleanrooms and clean air devices. They are used to measure the number and size distribution of particles in the air, which is an essential parameter for determining the air cleanliness level. When testing filters in cleanrooms and clean air devices, particle counters are used to measure the number and size distribution of particles upstream and downstream of the filter. This article provides specific ISO 14644-3 guidelines for using a particle counter to test filters.

Particle Counters detect, size and count the microscopic particles that we cannot see using a laser, optics, specific airflows and a photodetector. Particle Counters provide visibility in cleanrooms to ensure product quality.

Testing a Cleanroom using a Particle Counter following ISO 14644-1:2015

ISO 14644-1 is the international standard for classifying the cleanliness of air in cleanrooms and controlled environments. This standard establishes the limits for airborne particulate contamination and provides a methodology for classifying and certifying cleanrooms. Here is a detailed outline on how to certify a cleanroom using a particle counter following the ISO 14644-1 standard:

1. **Preparation:**
   a. Acquire the latest version of the ISO 14644-1 standard.
   b. Review the cleanroom design, specifications, and classification requirements.
   c. Obtain a calibrated particle counter appropriate for the required particle size range and sensitivity. Particle Counter must be calibrated to ISO 21501-4 standard.
   d. Ensure the cleanroom has been properly cleaned and the conditions are specified such as "as rest or "in operation".

2. **Sampling Locations:**
   a. Determine the minimum number of sampling locations based on the cleanroom area according to ISO 14644-1.
   b. Establish a uniform grid pattern for the sampling locations.
   c. Mark and document the sampling locations.

3. **Particle Counter Setup:**
   a. Set the particle counter to measure the required particle size ranges as per the cleanroom classification. These settings can be easily programmed into the unit.
   b. Set the sample volume and sampling time as per the standard (typically 1m3 or 2.83 L/min for a 35-minute duration). This is based on the cleanroom and particle size to report on.
   c. Calibrate the particle counter according to the manufacturer's instructions and ISO 21501-4 standard. (This should be done prior and typically the manufacturer provides this service annually).
4. **Sampling Procedure:**
   a. Turn on the cleanroom's air handling system and allow it to stabilize for a sufficient period.
   b. Position the particle counter at the first sampling location and start the sampling process.
   c. Record the particle count data for each size range at the end of the sampling duration.
   d. Repeat the sampling procedure for all predetermined sampling locations. Today's digital based particle counters will automatically do all of the recording and the operator only has to ensure that the samples are taken at the right locations. It is important to have a SOP developed which shows locations and defines the sampling configurations.

5. **Data Analysis:**
   a. Calculate the average particle concentration for each size range at each sampling location.
   b. Determine the maximum allowable concentration for each particle size range based on the cleanroom classification.
   c. Compare the measured concentrations with the allowable concentrations to verify if the cleanroom meets the specified classification requirements.
6. **Certification Report:**
   a. Prepare a detailed report documenting the certification process, including the cleanroom specifications, classification requirements, sampling locations, particle counter settings, and calibration information.
   b. Include the measured particle concentration data and the comparison with the classification limits.
   c. State the overall compliance or non-compliance of the cleanroom with the ISO 14644-1 standard.
   d. Include any recommendations for improving cleanroom performance, if necessary.
7. **Ongoing Monitoring and Recertification:**
   a. Establish a monitoring plan to ensure the cleanroom continues to meet the specified classification requirements.
   b. Perform regular maintenance and cleaning of the cleanroom as per the established procedures.
   c. Schedule periodic recertification to verify the cleanroom's compliance with the ISO 14644-1 standard.

By following these steps, you can successfully certify a cleanroom using a particle counter as per the ISO 14644-1 standard. Remember to adhere to the standard guidelines, maintain detailed documentation, and follow best practices for cleanroom operations to ensure ongoing compliance.

Following ISO 14644-2:2015 for Routine Monitoring applications

ISO 14644-2:2015 provides guidance on the selection and use of particle counters in cleanrooms. The standard outlines the criteria for selecting appropriate particle counters, including the measurement range, sensitivity, accuracy, and reproducibility. It also provides guidance on the frequency and location of particle monitoring, as well as the interpretation of particle count data. ISO 14644-2 emphasizes the need to consider a monitoring strategy in addition to the initial or periodic execution of the classification of a cleanroom or clean zone in accordance with ISO 14644-1:2015

1. **Routine Monitoring:**
   a. Routine monitoring is the regular assessment of a cleanroom's performance to ensure the cleanroom continues to meet the required classification.
   b. It involves measuring and analyzing the airborne particle concentrations within the cleanroom to detect any deviations from the specified limits.
   c. The frequency of routine monitoring depends on the cleanroom's classification, application, and risk assessment.

2. **Monitoring Plan:**
   a. A monitoring plan is a document that outlines the procedure and guidelines for routine monitoring of a cleanroom.
   b. It should be based on a risk assessment and include key elements such as sampling locations, sampling frequency, particle size ranges, equipment, and alert/action limits.

3. **Key Components of a Monitoring Plan:**
   a. Sampling Locations:
   i. Determine the number of sampling locations based on the cleanroom area and risk assessment.
   ii. Focus on high-risk areas such as critical process zones, transfer points, and material entry/exit points.
   iii. Ensure a representative distribution of sampling locations.
   b. Sampling Frequency:
   i. Establish a suitable sampling frequency based on the cleanroom classification, application, and risk assessment.
   ii. Higher-risk applications may require more frequent sampling, while lower-risk applications may require less frequent monitoring.
   c. Particle Size Ranges:
   i. Identify the relevant particle size ranges for the cleanroom classification and application.
   ii. Ensure the particle counter is set up to measure the required particle size ranges.
   d. Equipment:
   i. Use calibrated particle counters suitable for the required particle size range and sensitivity.
   ii. Ensure regular calibration and maintenance of the particle counting equipment as per the manufacturer's instructions and ISO 21501-4 standard.
   e. Alert/Action Limits:
   i. Establish alert limits, which are the warning levels indicating that the cleanroom may be approaching the specified classification limits.
   ii. Define action limits, which are the levels at which immediate corrective action must be taken to ensure the cleanroom's compliance.
   iii. Ensure that alert and action limits are documented and communicated to the relevant personnel.

4. **Documentation and Data Management:**
   a. Maintain detailed records of routine monitoring activities, including date, time, sampling location, particle count data, and any corrective actions taken.
   b. Regularly review and analyze the data to identify trends and assess the cleanroom's ongoing performance.
5. **Training and Personnel:**
   a. Ensure that personnel responsible for routine monitoring are adequately trained in the use of particle counters and the cleanroom's monitoring plan.
   b. Regularly update the training to reflect changes in procedures, equipment, or cleanroom requirements.
6. **Perform Periodic Reviews of the Monitoring Plan.**

Following ISO 14644-3:2019 to test HEPA filters using a Particle Counter.

ISO 14644-3:2019 provides detailed guidelines for the testing and monitoring of cleanrooms and clean air devices. The standard specifies the requirements for testing clean air devices to ensure that they meet the required air cleanliness levels. In the case of filter testing, the standard provides guidelines for using a particle counter to measure the number and size distribution of particles upstream and downstream of the filter.

Filter integrity testing typically refers to testing High-Efficiency Particulate Air (HEPA) or Ultra Low Particulate Air (ULPA) filters, which are commonly used in cleanrooms.

The installed filter system leakage test with a Particle Counter (LSAPC) listed in ISO 14644-3:2019 is a method to evaluate the efficiency and integrity of the installed filters in cleanrooms and associated controlled environments. This test helps detect any leaks in the filter system and ensures that the filters are operating at their optimal performance. By using a calibrated LSAPC to measure particle concentrations upstream and downstream of the filter system, organizations can calculate the filter efficiency, identify potential issues, and take corrective actions to maintain the desired cleanroom performance.

Test equipment used for testing filters includes a particle counter, aerosol generator, dilutor and scanning probe.

Installed filter system leakage tests with Particle Counter (LSAPC) Listed Test Apparatus in ISO 14644-3:2019

The LSAPC method may be used for testing:

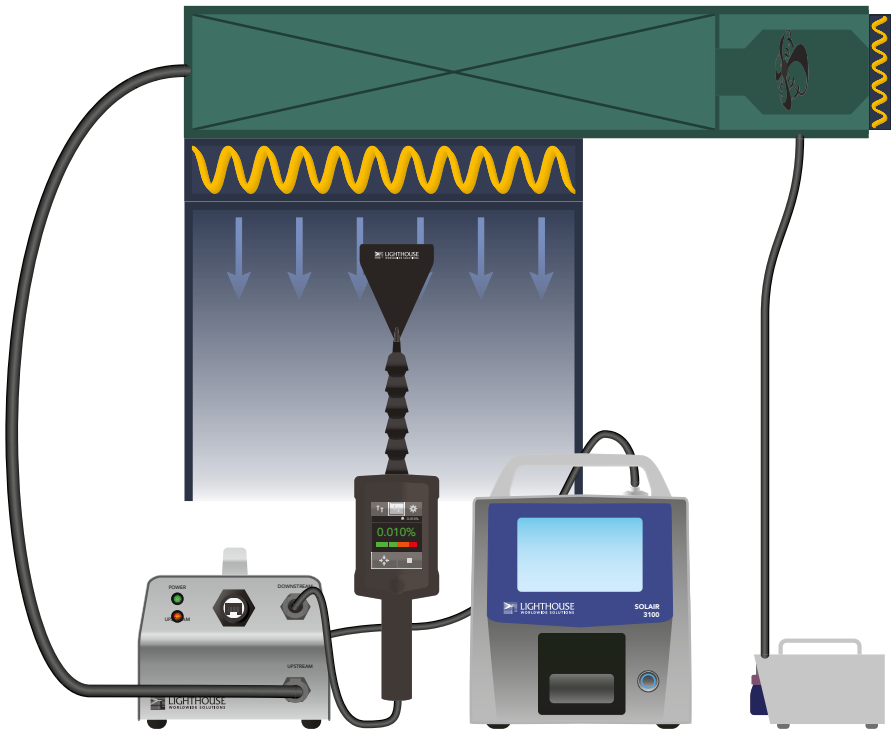
a) cleanrooms and clean zones with all types of air-handling systems;

b) installations where outgassing of oil-based volatile aerosol deposited on filters and ducts cannot be tolerated or where the use of solid aerosol is recommended.

NOTE 1: This method requires a series of calculations to set up the method and can also require the use of a diluter.
The calculations can be manual, through independent computers, instrument linked computers, or ***within automated adapted LSAPC*** *instruments.*

NOTE 2: This method can also be used with ***oil-based aerosol*** *where outgassing can be tolerated.*

Countries like Japan and Germany mostly use the method using polydisperse latex spheres. Below is a diagram of how the filter is challenged with a particle aerosol upstream and tested downstream to detect the leakage in a Laminar Flow Cabinet.



Testing a Laminar Airflow Cabinet HEPA Filter using poly dispersed particles with an upstream challenge.

The aerosol generator introduces particles into the topside of the HEPA filter. The concentration of particles and particle size are considered based on the type of filter. For most HEPA filters the particle size used is 0.3µm.

Choice of upstream aerosol challenge & Concentration

A polydisperse aerosol should be introduced into the upstream airflow to achieve the required homogeneous challenge concentration. The concentration of the aerosol challenge upstream of the filter should be sufficiently high to achieve acceptable practical scan rates.

In most cases, generated aerosol should be added to the upstream aerosol challenge to reach the necessary high challenge concentration. To verify such high concentrations, a dilution system can be required to avoid exceeding the concentration tolerance of the LSAPC (particle counter coincidence error).

Installed filter system leakage Test Method

This method has a two-stage approach:

Stage 1: the clean side of the filter should be scanned for a potential leak. During scanning with a LSAPC, detection of more than an acceptable count for given test conditions, Na, in sample acquisition time, Ts, indicates the potential presence of a leak. In this case, the second stage should be performed. If there are no indications of potential leaks, further investigations are not necessary.

Stage 2: the probe should be returned to the place of maximum particle count under each potential leak and a stationary re-measurement should be performed. During the stationary re-measurement with the LSAPC, detection of more than acceptable count for given test conditions, Nar, in sustained residence time, Tr, indicates the presence of a leak.

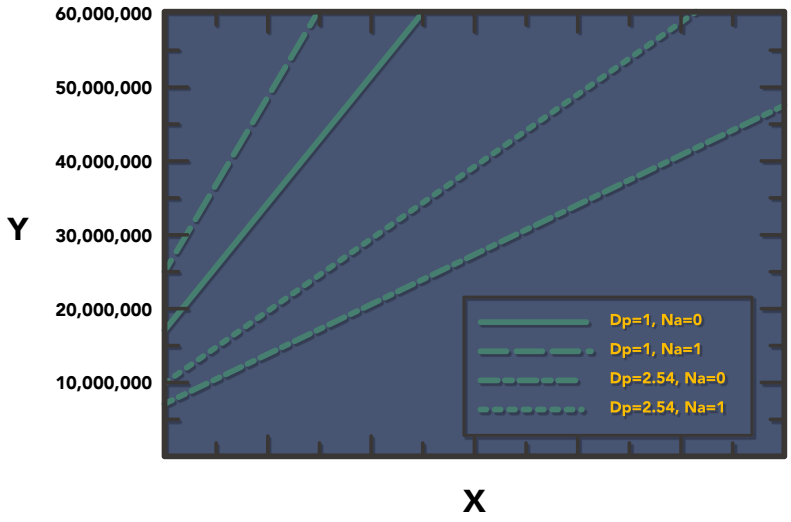
Testing Calculations

Np (Expected number of particle counts)

Na (Acceptable Count, Stage 1) and all others...

$$N_{pr} = C_c \times P_t \times Q_{vs} \times T_r$$

$$N_{ar} = N_{pr} - 2\sqrt{N_{pr}}$$

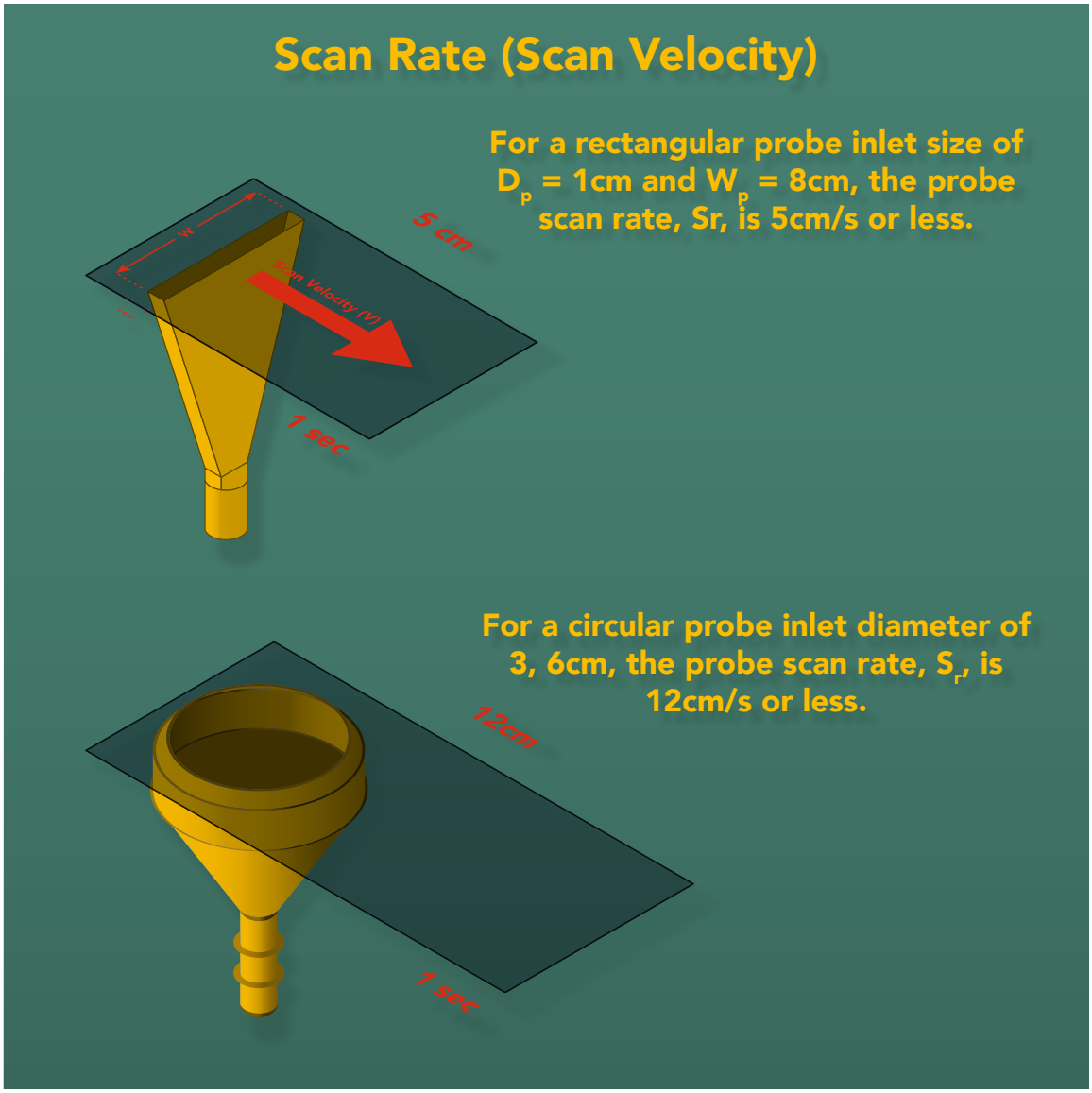


Key

X: probe transverse scan rate, S_r in cm/s
Y: challenge aerosol concentration. C_c in particles/m^3

C_c is the challenge aerosol concentration upstream of the filter in particles/m3
P_l is the maximum permitted penetration of the filter installation to be tested at 0.3µm
Q_{vs} is the actual sample flow rate of the measuring apparatus in m3/s
T_r is the recommended sustained residence time(s)
D_p is the probe dimension parallel to the scan direction in cm
N_{ar} is the acceptable count at stationary re-measuring
N_{pr} is the number of particle counts which characterize the designated leak

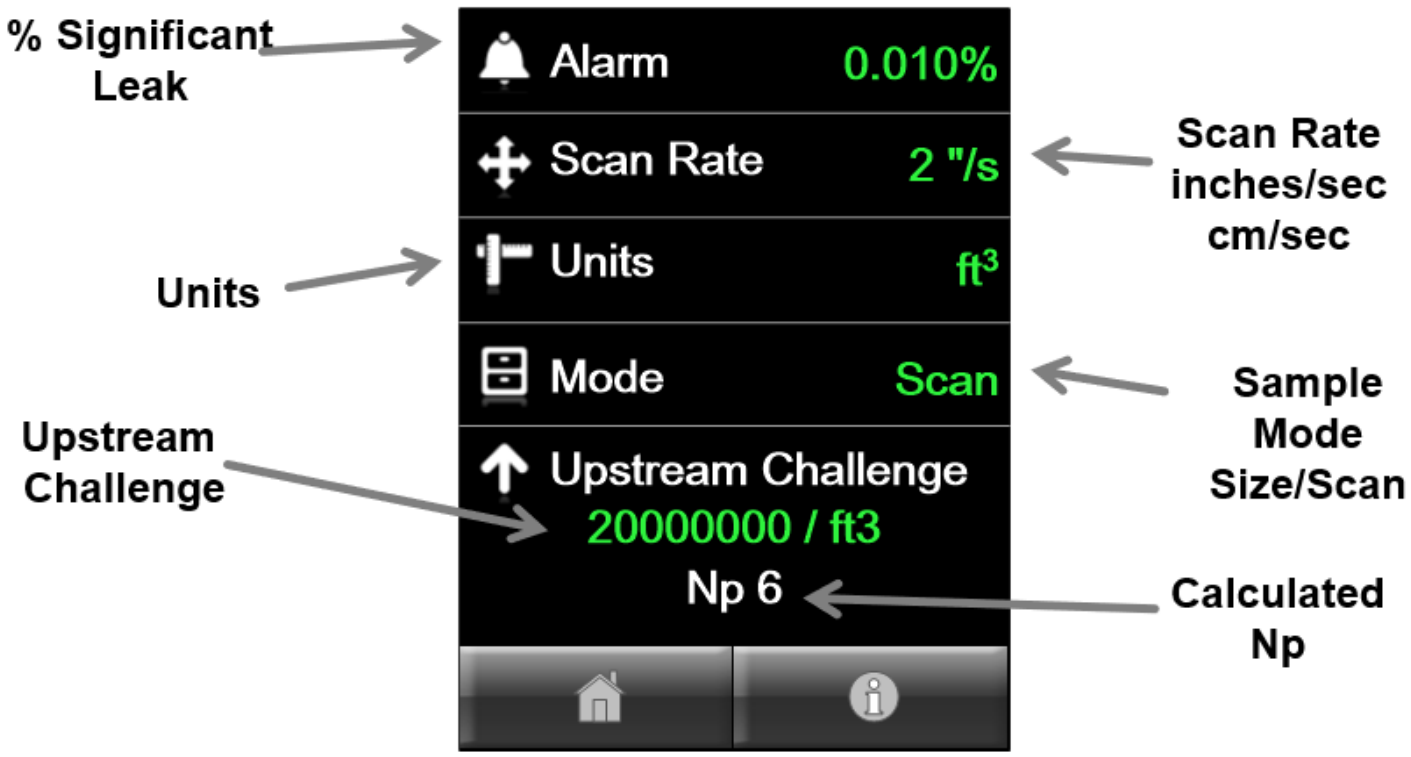
Example of the calculation to determine expected and acceptable number of particle counts.



Scan Rate (Scan Velocity)

Acceptance Criteria

- **The particle size to be counted should be equal to or greater than 0,3µm.**
- **While scanning, any indication of a leak should be cause for holding the probe at the leak location. The location of the leak should be identified by the position of the probe.**
- **A leak detected in excess of 0,01 % of the upstream number concentration is deemed to exceed the maximum allowable penetration. However, for filter systems of an integral efficiency at MPPS ≥ 99,95 % and less than 99,995 %, the acceptance criterion is 0,1 %.**
- **If filter systems of an integral efficiency lower than 99,95 % at MPPS are to be tested, a different acceptance criterion is necessary, based on agreement between customer and supplier.**



Example of scanning probe test data in real time.

Summary of Testing

- **Measure upstream challenge & record.**
- **Scan filter face within scan rate (5cm/s optimal) .**
- **Slightly overlapping strokes.**
- **Approximately 3 cm from the downstream filter face.**
- **Repeat upstream measurements between and after test.**

Advantages of using Particle Counters over Photometers

- **Photometer tests require 100 to 1,000 times the PAO aerosol mass as particle counters. Scan filter face within scan rate (5cm/s optimal) .**
- **Particle counter method requires small generators, no fire risk.Approximately 3 cm from the downstream filter face.**
- **Microspheres can be used with particle counters to eliminate PAO in small systems.**
- **PAO may degrade gel seals in filters.**
- **Only test available for PTFE filters**
- **Smart technology on particle counter method (concentration level verification and homogeneity testing) makes it easy and enhance testing quality.**
- **Real particle counts instead of relative % of concentration assumption in photometers.**
- **Test suitable for EN1822: MPPS efficiencies**
- **The same particle counter can be used to Certify your cleanroom so less equipment is required.**