VALIDATION OF SAMPLE TUBING TO ENSURE COMPLIANCE WITH ISO/TR 14644-21

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Overview

ISO/TR 14644-21 is a technical report that supplements the ISO 14644 series, which provides standards for cleanroom technology and controlled environments. While the main ISO 14644 standards focus on classification of air cleanliness and methods for testing and monitoring, ISO/TR 14644-21 specifically deals with the measurement of efficiency of particle removal in cleanrooms and associated controlled environments.

This technical report provides guidance on evaluating the performance of systems designed to reduce particulate contamination. It covers methods for assessing the removal efficiency of particle contaminants, which is crucial in maintaining the required cleanliness levels in cleanrooms. The focus is on techniques and practices to ensure that cleanroom environments meet the necessary standards for particle removal efficiency, which is essential in industries like semiconductor manufacturing, pharmaceuticals, biotechnology, and others where high levels of cleanliness are required.

In summary, ISO/TR 14644-21 is an important reference for professionals in industries that rely on cleanrooms, offering guidelines on how to effectively measure and maintain the particle removal efficiency of these controlled environments.

Fig 1.0 Photo Caption

When to validate particle Losses in sample tubing?

According to ISO/TR 14644-21 the sample system must be evaluated based on certain criteria.

The following outlines the criteria where a sampling system will need to be validated to estimate the particle losses in the system:

- **Airflow = Unidirectional**
- **Sample Probe orientation: Into the airflow**
- **Particle Size: ≥5µm**
- **Sample tubing length: >2m**
- **Tubing bends: >3**

An evaluation of the impact of particle loss in the sample tubing must be performed.

How is the sample tubing validated?

In order to validate the particle losses, the sample system needs to be evaluated. The sample system can be evaluated in-situ, or a replica of the sample system can be made up which will represent exactly the tubing length, number of bends and sample probe orientation.

Two tests will be performed to validate the tubing arrangement. Each test will use two particle counters.

In the first test both counters will have the same short length of tubing. In the second test one counter will have sample tubing applied, and the other will not.

The goal of the tubing validation process is to establish what percentage of the difference in counts between the two instruments is due to the tubing, rather than the instruments themselves.

Establishing a baseline

A baseline needs to be established between the two particle counters so the difference in counts can be correctly attributed to tubing. Note: No two particle counters count exactly the same. They take different samples, and each sample volume is unique to the particle counter taking the sample. In other words, the sample volume cannot be in two particle counters at the same time, but we must establish what the % difference is between the two particle counters used the tubing evaluation. The first test will determine the average difference in counts between the two counters used. The second test will determine how the tubing contributes to these differences.

Testing Environment

The test can be done within the cleanroom in-situ, however we would recommend to replicate the sample system and conduct the test in a room or lab to reduce risk of human. Conducting the testing outside the cleanroom provides a more flexible test environment is more flexible, allowing the necessary tubing connections and movement of the two particle counters. As long as the number of particles exceed 100 in each channel on both instruments there will be sufficient count data to get a meaningful result.

Particle Counters

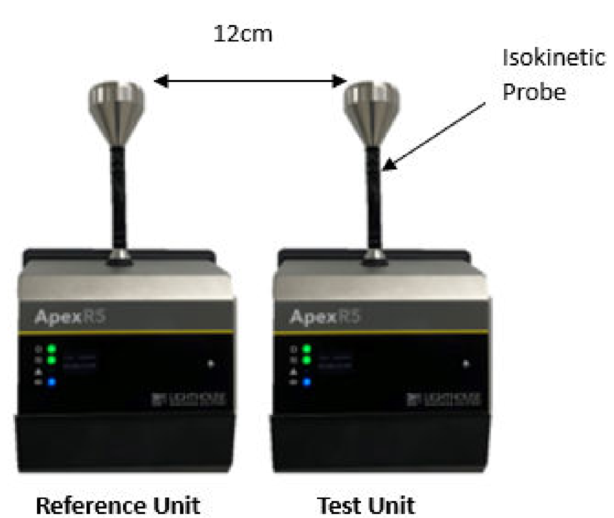
It is recommended to use particle counters which are the same model, have the same flowrate and are calibrated to ISO 21501-4.

Test 1 - Baseline Comparison of Particle Counters

1. Choose a test environment. This can be in a laboratory, or an unclassified room if the concentration of particles in the air is not too high where coincidence errors may occur. Typically, an office room with HVAC air is sufficient to have enough particles for a robust test.

2. Connect each particle counter to an isokinetic sample probe (ISP) with identical, short lengths of tubing, or directly mount to the sample inlet (preferred method).

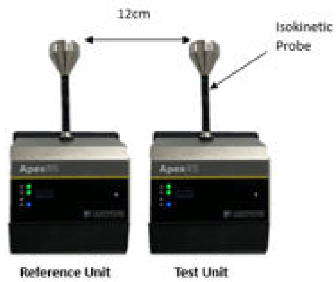
3. Label one unit as the Reference Unit and the other as the Test Unit. These labels will not change for the second test.



Baseline Setup 1 using remote particle counters

Baseline Setup 2 using portable particle counters

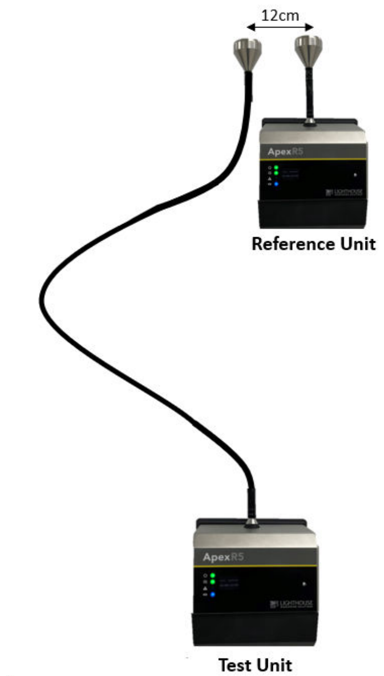
4. **Place the counters near each other so their isokinetic sampling probes are no more than 12cm apart.**
5. **Set each unit to capture 10 one-minute samples. Ensure both counters are set to one of the following count display modes: counts per cubic foot, counts per cubic meter, or raw counts.**
6. **Fill in the details of the baseline testing in the test form titled Baseline testing. Ensure that remote particle counters are connected to software where the data can be recorded, and data reports can be generated.**
7. **Start each particle counter sample at the same time. After the 10 one-minute's samples are completed, record the data into the Baseline Comparison Test Data form.**
8. **Calculate the average counts for each particle size determined by each particle counter.**
9. **Calculate the Baseline Error Factor for each particle size using the average count data. These values will be used in Test 2.**

Test Name: Particle Counter Baseline Testing Setup - Test Form 1					
Test Particle Counter ID	Model:	Serial No.	Flowrate:	Calibration Date:	Tester Initial & Date
Ref Particle Counter	Model:	Serial No.	Flowrate:	Calibration Date:	
ISP Connection	Connected directly to Inlet. Yes [ ] No [ ]		Are ISP's within 12cm. Yes [ ] No [ ]		
Sample Setup #1 Using Remote Particle Counters	Is the sample setup as below: Yes [ ] No [ ] N/A [ ] 				
Sample Setup #2 Using Portable Particle Counters	Is the sample setup as below: Yes [ ] No [ ] N/A [ ] 				
Tester Signature:		Date:			
Reviewed By:		Date:			

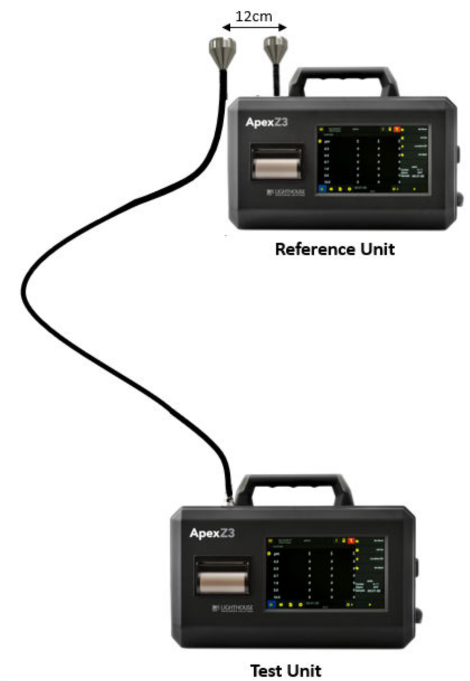
Test 1: Baseline Comparison Test Data					
Test Run #	Ref Unit Data Counts ≥0.5µm	Ref Unit Data Counts ≥5.0µm	Test Unit Data Counts ≥0.5µm	Test Unit Data Counts ≥5.0µm	Tester Initial & Date
Test Run 1					
Test Run 2					
Test Run 3					
Test Run 4					
Test Run 5					
Test Run 6					
Test Run 7					
Test Run 8					
Test Run 9					
Test Run 10					
Average Counts Baseline Error Factor $\frac{ref\ counts}{test\ counts}$					
Tester Signature:			Date:		
Reviewed By:			Date:		

Test 2 - Sample Tubing Particle Loss

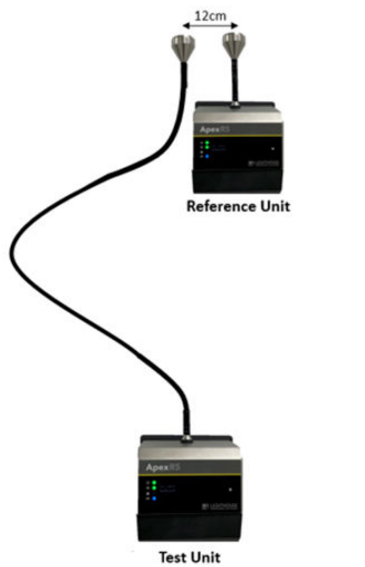
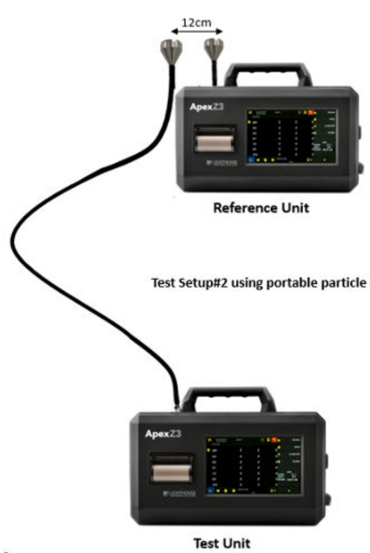
1. Detach the short tube from the Test Unit. Attach the long tubing to that unit with an isokinetic probe on the end. Ensure that the sample setup represents the actual tubing length and bends that are in the cleanroom.
2. Leave the short length of tubing used in Test 1 attached to the Reference Unit.
3. Move the Reference Unit so its ISP is within 12cm of the Test Unit's ISP. See test setup example below.
4. Complete the Test Setup 2 table.
5. Start both particle counters at the same time. After the 10 one-minute samples are completed, record the data into the Sample Tubing Particle Loss Data table.
6. Calculate the average counts for each particle size determined by each particle counter.
7. Calculate the Average Tubing Error % for each particle size using the averages from this test and the Baseline Error Factor from Test 1.



Test Setup 2 using remote particle counters.



Test Setup 2 using portable particle counters.

Test Setup 2: Sample Tubing Particle Loss Setup		
Sample Point Name:	Cleanroom Name, Location of sample point:	Tester Initials & Date:
Tubing length:		
Number of bends:		
Bend Radi:		
Sample Setup #1 Using Remote Particle Counters	Is the sample setup as below: Yes [ ] No [ ] N/A [ ]  Test Setup#2 using remote particle counters.	
Sample Setup #2 Using Portable Particle Counters	Is the sample setup as below: Yes [ ] No [ ] N/A [ ]  Test Setup#2 using portable particle counters.	
Tester Signature:	Date:	
Reviewed By:	Date:	

Test 2: Sample Tubing Particle Loss Data					
Test Run #	Ref Unit Data Counts ≥0.5μm	Ref Unit Data Counts ≥5.0μm	Test Unit Data Counts ≥0.5μm	Test Unit Data Counts ≥5.0μm	Tester Initial & Date
Test Run 1					
Test Run 2					
Test Run 3					
Test Run 4					
Test Run 5					
Test Run 6					
Test Run 7					
Test Run 8					
Test Run 9					
Test Run 10					
Average Counts					
Average Tubing Particle Loss % $\frac{ref\ counts - test\ counts * Baseline\ Error\ Factor}{ref\ counts} * 100$	0.5um Calculation		5.0um calculation		
Tester Signature:			Date:		
Reviewed By:			Date:		