



MEETING DATA INTEGRITY REQUIREMENTS WHEN SAMPLING WITH TSI AEROTRAK PORTABLE PARTICLE COUNTERS

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Introduction—Contamination Data is Critical in Cleanrooms

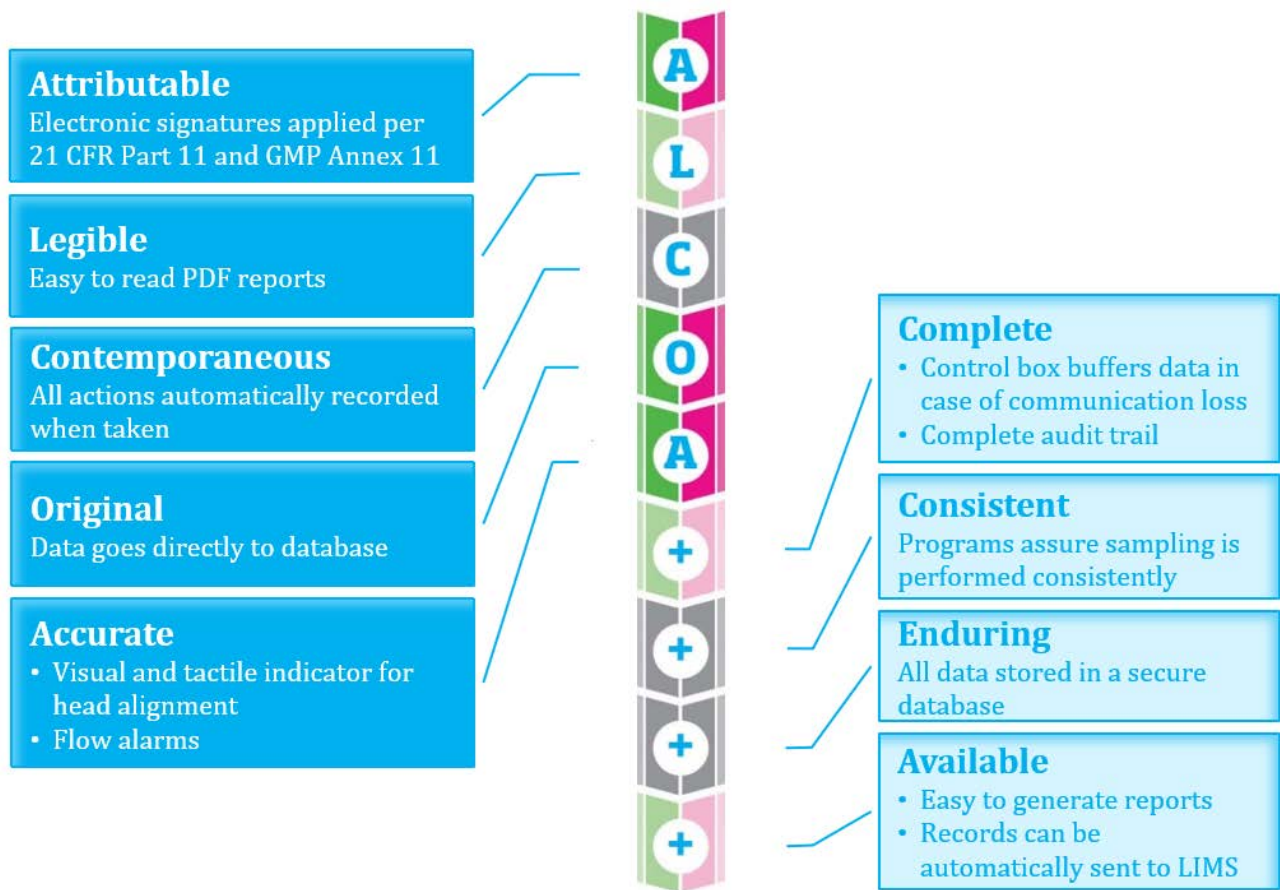
Portable particle counters serve an important function in demonstrating that the concentration of particles in a cleanroom are being controlled to acceptable levels. This critical contamination control data is used to help assure the quality of the product being manufactured. Therefore, this data must have a high level of integrity to meet internal quality requirements and the expectations of regulatory inspectors. This document demonstrates how the TSI AeroTrak® Portable Particle Counter can be used to deliver a high level of data integrity with two different use cases.



What is Data Integrity?

Data integrity is defined by the U.S. Food and Drug Administration (FDA) as the completeness, consistency, and accuracy of data. Deficiencies related to data integrity has become one of the most frequently cited findings in recent years. It is easy to believe this increased scrutiny is a result of a change in the good manufacturing practices (GMPs), but the basic requirements have always been an integral part of the regulations.

What has changed however, is the regulatory agencies have made evaluating data integrity a key component of routine GMP inspections. This has resulted in a rapid increase in findings associated with records and recordkeeping which has subsequently led to the publication of numerous data integrity guidance documents. From these guidance documents, the acronym ALCOA+ has become a popular reference tool for manufacturing companies to use when evaluating their data integrity compliance. ALCOA+ requires data be:



What Does Data Integrity Effect Particle Counting?

Like any other GMP testing, particle count testing must follow ALCOA+ principles to comply with data integrity requirements. This is achieved by using a particle counter designed for GMP use in combination with good test procedures. These procedures can vary between users based on risk.

Risk factors may include, but are not limited to, the number and experience of monitoring technicians, the type of product being manufactured in the area, the number of monitoring locations, and the frequency of testing. For example, a small quality control (QC) department with experienced monitoring technicians performing weekly monitoring of a small cleanroom used for the manufacture of a non-sterile product may be able to satisfactorily meet all data integrity requirements using printouts and paper forms. In turn, a large manufacturer with a sizeable staff of technicians with varying degrees of experience monitoring a cleanroom used for the manufacture of an aseptically manufactured product may view that level of manual recordkeeping as a considerable risk and require a more automated solution.

Regardless of the chosen recordkeeping procedures, there are some steps all users should include to help assure the accuracy of particle counts.

- Calibrate particle counters as per ISO 21501-4 on a regularly scheduled frequency—generally, at least once per year.
- Qualify each particle counter to verify that it operates as expected for its intended use.
- Perform a zero-count for each particle counter on a routine basis.
- Purge each particle counter as needed to assure residual particles do not significantly affect counts.

Achieving Data Integrity Using AeroTrak Portable Particle Counters

TSI AeroTrak® Portable Particle Counters offer the flexibility needed to meet the needs of a variety of GMP customers. They come integrated with a built-in printer that can be used in a simple and straightforward manner where paper records are acceptable. Environments that require a more automated process to minimize risk to data, while improving efficiency, can configure these particle counters to operate in data integrity mode working in conjunction with the included TrakPro™ Lite Secure (TPLS) Software. Both use cases presented in this application note provide examples of how these two different types of users can meet their specific data integrity needs with the AeroTrak Portable Particle Counters.



Printout Use Case

Printing out data requires the use of an AeroTrak Particle Counter with a built-in printer.

Configuration

Configuration of the particle counter for sampling and printing is outlined below.

- Create Zones and Recipes per approved sampling plans to ensure testing is performed consistently.
- Set a Power On Password and Setup Password to limit unauthorized use of the particle counter.
- Set the Print Schedule to Automatic Printing On Sample to automatically print test results at the end of each sample to create the original record.
- In Print Setup, at minimum, check the boxes next to Serial Number and Last Calibration to ensure this critical equipment metadata is included on the printout for completeness of the record.
- In Configuration, check Store Partial Samples to ensure a sample record will be printed even if sampling is manually stopped so a complete record of all sampling is obtained.

Sampling

Selecting a preconfigured Zone and Location is necessary. This can be done via manual selection or, to ensure additional accuracy and consistency, selection can be done by scanning barcodes posted at the sample locations using a barcode scanner. Press the Start button to begin sampling. Once sampling is complete, a printout will be generated. Initial and date each record as it is printed so that the responsible person is attributed contemporaneously on the original record. Continue to sample the remaining locations.

The AeroTrak Portable Particle Counter uses a thermal printer instead of an ink printer to prevent the generation of ink particles that could contaminate the cleanroom. Unfortunately, thermal printouts fade over time and can also become illegible by such things as being sprayed with isopropyl alcohol. Therefore, at the end of testing, a true copy of the original printout should be generated to create an enduring record that will not fade and remains legible over time. Attach the original and true copy to the applicable paper test record to ensure they are available for future reference.

Data Integrity Mode and TPLS Software Use Case

Using the AeroTrak Portable Particle Counter in data integrity mode and TPLS Software for instrument configuration, logging into the particle counter for sampling, and report generation ensures error-proof Part 11 compliance with flexible user configuration capabilities and easy access audit trail.

Configuration

With data integrity mode enabled, configuration of the particle counter functionality is no longer available. Therefore, prepping of the particle counter as outlined below is required prior to enabling data integrity mode so that it will function properly for its intended use.

- Configure functional settings—e.g. alarm volume, IP address, language settings, etc.
- Delete any Zones and Recipes currently loaded on the particle counter. These are created using TPLS Software after data integrity mode is enabled, so their creation will be recorded and attributed to the logged in user on the TPLS Software audit log.

Due to the high degree of integration with TPLS Software when using the particle counter in data integrity mode, users must be created in the software prior to enabling data integrity mode. Users should only be granted the specific privileges required for their role to ensure testing is performed consistently.

With the AeroTrak Particle Counter prepped, and users created in TPLS Software, connect the particle counter to TPLS Software and enable data integrity mode. Once in data integrity mode, the option to print data using the particle counter's built-in printer or exporting it to a USB drive will no longer be available. This ensures the accuracy of the original record will be maintained by preventing the creation of multiple copies of the same record, possibly resulting in the creation of conflicting records. In addition, the store partial samples function is always enabled in data integrity mode to ensure there will always be a complete record of all sampling. Create Zones and Recipes per approved sampling plans in TPLS Software and upload them to the particle counter to ensure testing is performed consistently.

Sampling

Login to the particle counter via TPLS Software to unlock it for testing. The User Id and Password of the logged in user will transfer to the particle counter. All sampling will be attributed to that user in the sample records until the user logs out of the particle counter.

Attempt to start sampling by selecting a preconfigured Zone and Location and a prompt for the logged in user to enter their password will appear. Before any samples can be taken, the logged in user must enter their password to ensure the user attributed in the sample record is the one who performs the sampling. Enter the password and the Zone and Location can be selected. The Start button will appear and sampling can begin. At the end of a sample, the Start button will disappear until a new location is selected. This prevents a common error of the user forgetting to select a new location when the particle counter is moved from one location to another, thus resulting in an incorrect sample location in the sample record. The risk of having an inaccurate sample location in the record can be further reduced by using a barcode with a barcode scanner to input the particle counter location.

Once all sampling is complete, import the records into TPLS Software and generate the original record in the form of a report. The report can be printed or exported only in the format that was defined during configuration. Printing provides a legible and enduring document (not a thermal printout that fades over time) that can be attached to paper records. Exporting electronics files provides the report in a legible and enduring format that can be imported into an electronic record system.

After the report is generated, logout of the particle counter or disconnect via TPLS Software (either of these actions will result in the records being deleted from the particle counter data buffer). Logging out of TPLS Software will result in the records no longer being present when a user logs back in. If any data remained in either of these locations and manual edits were made to the original record, the stored data would no longer be accurate. Automatic deletion of these records from the particle counter and the software prevent the generation of a new report that is neither accurate nor a true copy.

Conclusions—Data Integrity is Easy with TSI

The integrity of particle count data must be assured to provide confidence in the control of the manufacturing environment and to meet regulatory requirements. How that is achieved can vary for different users based on their assessment of the risks involved. AeroTrak Portable Particle Counters offer the flexibility needed to meet these requirements, whether it is for a manual process using the built-in printer or a more automated method utilizing data integrity mode and TPLS Software.

Learn More

Visit www.tsi.com/data-integrity

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