TSI ® Knowledge Beyond Measure.

Reliable. Confident. Environmental Monitoring.

Pharmaceuticals | Life Sciences

Global Good Manufacturing Practices
- Annex 1 (EU, PIC/S, WHO): Manufacture of Sterile Medicinal Products
- FDA Guidance for Industry - Sterile Drug Products Produced by Aseptic Processing

ISO 14644-1:2015, 14644-2:2015 & 21501-4:2018

Reliable. Confident.
Environmental Monitoring.

Airborne Particle Counters

Confident Results Matter
- Models for every pharmaceutical environment and application
- ALCOA+ data integrity principles for no-hassle 21 CFR Part 11 compliance
- Leading the way in real-time viable particle detection

TSI® Facility Monitoring Software: Reliable Monitoring Systems

Distributed. Flexible. Redundant.
- No single point of failure
- Data available where and when you need it
- Easily scalable
- Pharma 4.0 ready - communication via OPC UA Client/Server

A **Monitor: Data Collection**
- Fault-tolerant design
- Protects against network failures
- Hot-standby options

B **Client: Interface**
- Turn data into knowledge with alarming, reports, and trending
- Does not effect monitor or database functions
- Multiple clients possible

C **Database: Secure Storage**
- Valuable data is safe and secure
- Redundancy is standard with a mirror database
- SQL for high availability and fast access

1 **BioTrak® Real-Time Viable Particle Counter**
The Future of Viable Monitoring
- Reduce or eliminate interventions in Grade A
- Achieve truly continuous viable monitoring
- Accelerate investigations with real-time data

2 **AeroTrak®+ Remote Particle Counters***
Ultra-Reliable Data Collection
- Protect against network failures with six months of data storage
- Worry-free cleaning with sealed inlets and VHP resistant options
- Flexible environmental monitoring system with Wi-Fi® communication

3 **Remotes with Pump**

4 **AeroTrak® Handheld Particle Counters**

5 **AeroTrak®+ Portable Particle Counters***
- Different sample modes for monitoring, classifying, and root cause investigation
- Built-in monitoring and classification reports

6 **Active Air Sampler for Aseptic Environments**
- Intermittent sampling improves knowledge of conditions during a production run without interventions
- Protect against network failures with local data storage

7 **Integrated Environmental Monitoring Probes**
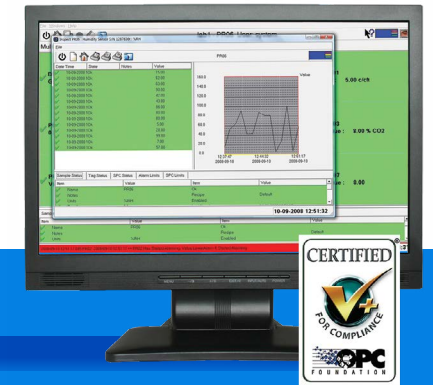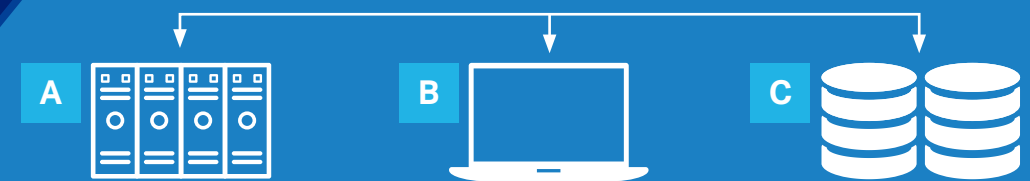
* Unmatched 5 Year Laser Warranty

Pressure   Temperature   Humidity

Environmental Monitoring Data

FMS Architecture

A   B   C

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Environmental Monitoring Products for Pharmaceutical Manufacturing & Life Sciences

Facility Monitoring System
A reliable monitoring system that ensures environmental control and decreases downtime — Pharma 4.0 plug and play functionality via OPC UA Client/Server

Model	Flow Rate	Benefits and Features
Remote Particle Counters Designed for continuous monitorinig as part of the Facility Monitoring System		
AeroTrak®+ 7510	1 CFM (28.3 LPM)	VHP resistant models available, Wi-Fi® capable with optional module
AeroTrak® 6510	1 CFM (28.3 LPM)	Built-in pump, VHP resistant models available
Portable Particle Counters Versatile instruments suitable for classification and monitoring		
AeroTrak®+ A100 Series	1 CFM (28.3 LPM), 1.77 CFM (50 LPM), and 3.53 CFM (100 LPM) models available	Intuitive interface, manages sampling with workflows, built-in classification and monitoring reporting capabilities
Handheld Particle Counters Economical choice for higher class cleanrooms and investigations		
AeroTrak® 9306	0.1 CFM (2.83 LPM)	Small and lightweight
Real-Time Viable Particle Counter A bioflourescent particle counter (BFPC) that provides total and viable particle counts in real-time		
BioTrak® 9510-BD	1 CFM (28.3 LPM)	Alternative method to meet Annex 1 requirement for continuous viable air monitoring
Active Air Sampler Designed specifically for use in aseptic environments		
AeroTrak®+ 7010	1 CFM (28.3 LPM)	Meets ISO 14698 and EN 17141 requirements with a d_{50} = 0.8 µm

Compliance
Data Integrity
Ease of Use
Profitability

Risk
Downtime
Cost
Waste

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Unmatched 5 Year Laser Warranty

TSI

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