



® 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



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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

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

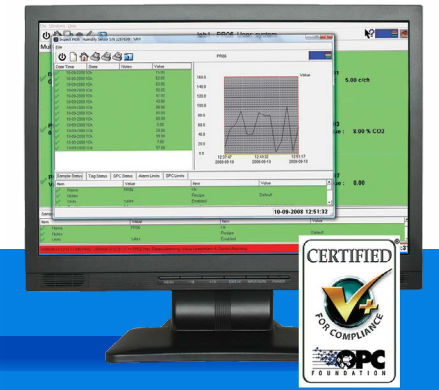
* Unmatched 5 Year Laser Warranty



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

Environmental
Monitoring
Data

FMS Architecture



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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
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Remote Particle Counters

Designed for continuous monitoring 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
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Handheld Particle Counters

Economical choice for higher class cleanrooms and investigations

AeroTrak® 9306	0.1 CFM (2.83 LPM)	Small and lightweight
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Real-Time Viable Particle Counter

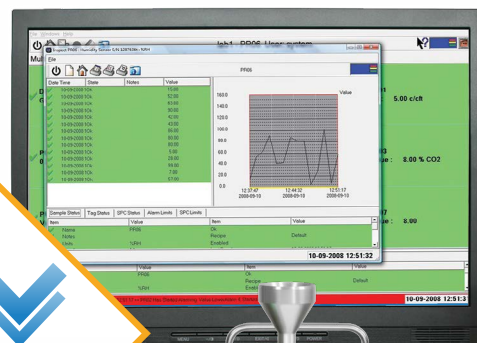
A biofluorescent particle counter (BFPC) that provides total and viable particle counts in real-time

BioTrak® 9510-BD	1 CFM (28.3 LPM)	Alternative method to meet Annex 1 requirement for continuous viable air monitoring
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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 $d_{50} = 0.8 \mu\text{m}$
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Compliance
Data Integrity
Ease of Use
Profitability

Risk
Downtime
Cost
Waste



**Unmatched
5 Year Laser
Warranty**

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Knowledge Beyond Measure.

TSI Incorporated - Visit our website www.tsi.com for more information.

USA	Tel: +1 800 874 2811	India	Tel: +91 80 67877200
UK	Tel: +44 149 4 459200	China	Tel: +86 10 8219 7688
France	Tel: +33 1 41 19 21 99	Singapore	Tel: +65 6595 6388
Germany	Tel: +49 241 523030		