

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

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

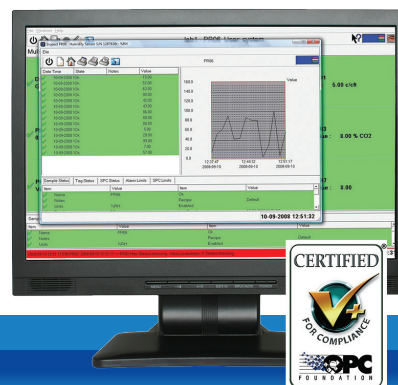
6

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



A

Monitor: Data Collection

- Fault-tolerant design
- Protects against network failures
- Hot-standby options

B

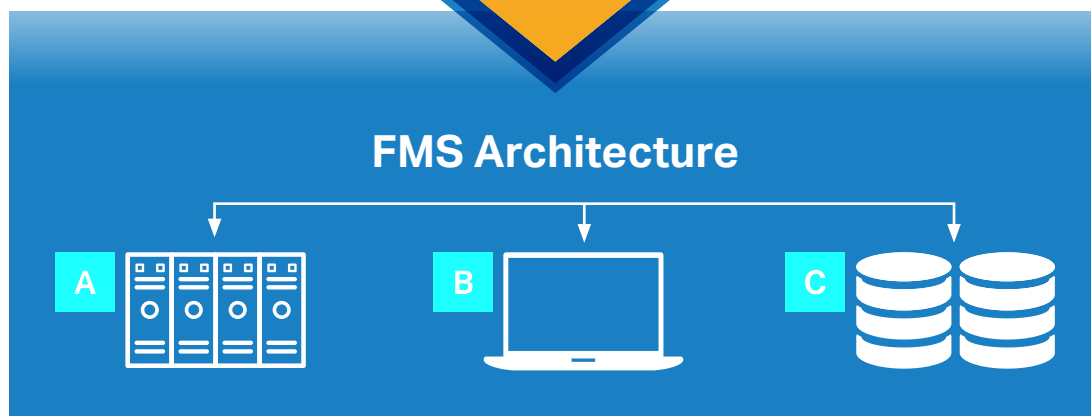
Client: Interface

- 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



Reliable. Confident. Environmental Monitoring.

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 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
-----------------------	--	---

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

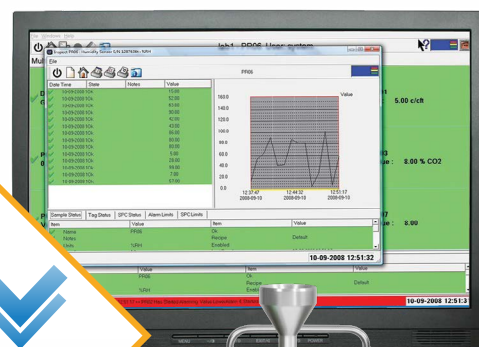
A biofluorescent particle counter (BFPC) that provides total and viable particle counts in real-time

BioTrak® 9510-BD	1 CFM (28.3 LPM)	Alternative method to meet Annex 1 requirement for continuous viable air monitoring
------------------	------------------	---

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 $d_{50} = 0.8 \mu m$
----------------	------------------	---



Compliance
Data Integrity
Ease of Use
Profitability

Risk
Downtime
Cost
Waste



AeroTrak, BioTrak, TSI and the TSI logo are registered trademarks of TSI Incorporated in the United States and may be protected under other country's trademark registrations.

Wi-Fi is a registered trademark of the Wi-Fi Alliance.



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		

Unmatched
5 Year Laser
Warranty