



® 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

- 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
- 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
- Remotes with Pump**
- AeroTrak™ Handheld Particle Counters**
- AeroTrak™+ Portable Particle Counters***
 - Different sample modes for monitoring, classifying, and root cause investigation
 - Built-in monitoring and classification reports
- 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
- Integrated Environmental Monitoring Probes**

* Unmatched 5 Year Laser Warranty



Environmental
Monitoring
Data

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



OPC UA

- Monitor: Data Collection**
 - Fault-tolerant design
 - Protects against network failures
 - Hot-standby options
- Client: Interface**
 - Turn data into knowledge with alarming, reports, and trending
 - Does not effect monitor or database functions
 - Access anywhere with FMS Web Client
- Database: Secure Storage**
 - Valuable data is safe and secure
 - Redundancy is standard with a mirror database
 - SQL for high availability and fast access

FMS Architecture



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 with accessibility anywhere using FMS Web Client.

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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Distributed by:

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Knowledge Beyond Measure.

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