

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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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

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

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

Data

• Pharma 4.0 ready - communication via OPC UA Client/Server



Monitor: Data Collection

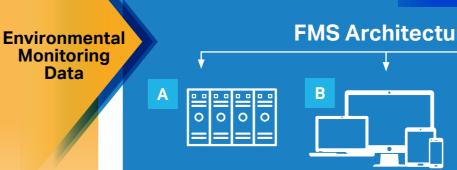
- Fault-tolerant design
- Protects against network failures
- Hot-standby options

Client: Interface

- Turn data into knowledge with alarming, reports, and trending
- Access anywhere with FMS Web Client

Database: **Secure Storage**

- Valuable data is safe and secureRedundancy 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

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

Model	Flow Rate	Benefits and Features
Pomoto Particle Counters		

Designed for continuous monitorinig as part of the Facility Monitoring System

VHP resistant models available, Wi-Fi® capable AeroTrak™+ 7510 1 CFM (28.3 LPM)

with optional module

Built-in pump, VHP resistant models available AeroTrak™ 6510 1 CFM (28.3 LPM)

Portable Particle Counters

Versatile instruments suitable for classification and monitoring

1 CFM (28.3 LPM), 1.77 CFM (50 LPM), and 3.53 CFM AeroTrak™+ A100 Series (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

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

Active Air Sampler

Designed specifically for use in aseptic environments

Meets ISO 14698 and EN 17141 requirements with a d_{50} = 0.8 μm AeroTrak™+ 7010 1 CFM (28.3 LPM)



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