



® 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

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

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



Distributed by:

Kenelec Scientific Pty Ltd  
1300 73 22 33  
sales@kenelec.com.au  
www.kenelec.com.au

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](http://www.tsi.com) for more information.

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



Unmatched  
5 Year Laser  
Warranty