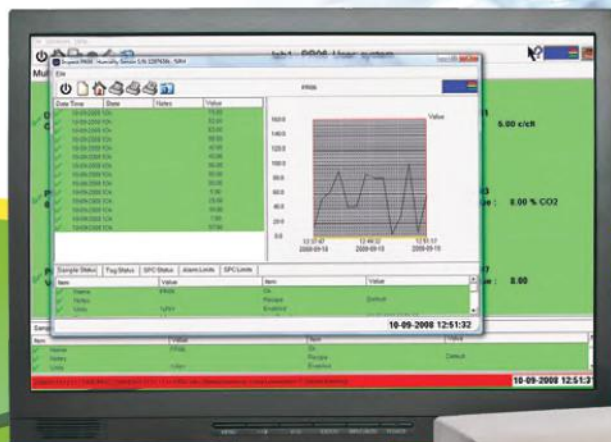




# Reliable. Confident. Environmental Monitoring.

PHARMACEUTICALS | LIFE SCIENCES

**Instruments and Systems for Compliance**  
+ FDA cGMP - Sterile Drug Products Produced by Aseptic Processing  
+ EU GMP - Annex 1: Manufacture of Sterile Medicinal Products  
+ ISO 14644-1:2018 & 14644-2:2018



Compliance  
Data Integrity  
Ease of Use  
Profitability



Risk  
Downtime  
Cost  
Waste



# 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

### 1 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

#### When Every Second Counts, Count Every Second

Particle data updated every second allows instant action when excursions occur

### 2 REMOTES WITH PUMP

### 3 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

### 4 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

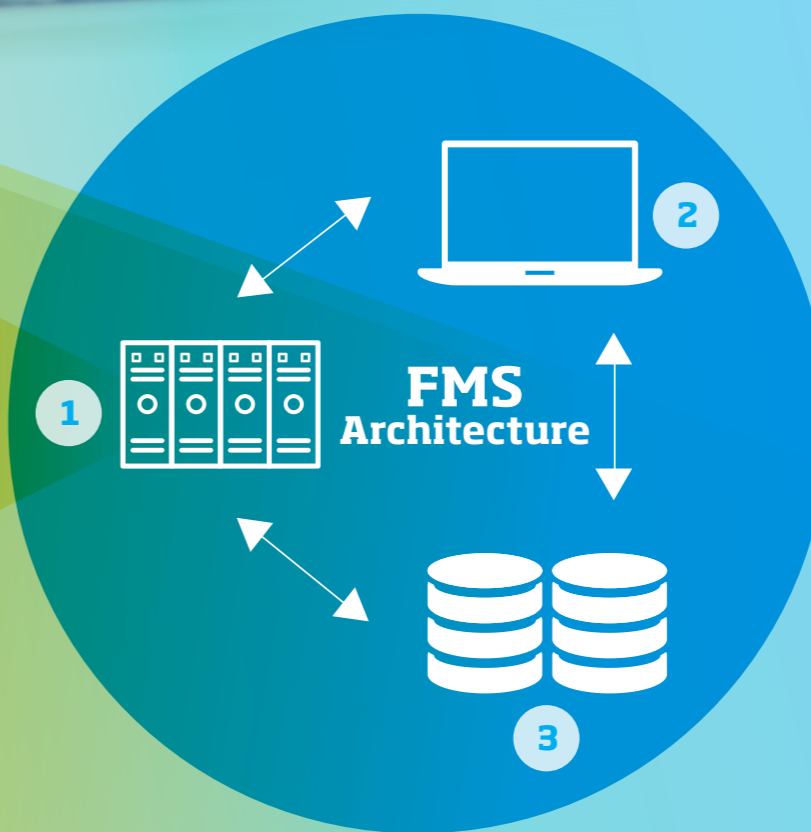
### 5 HANDHELDS

### 6 PORTABLES

### 7 INTEGRATED ENVIRONMENTAL MONITORING PROBES



Environmental Monitoring Data



### 1 MONITOR: DATA COLLECTION

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

### 2 CLIENT: INTERFACE

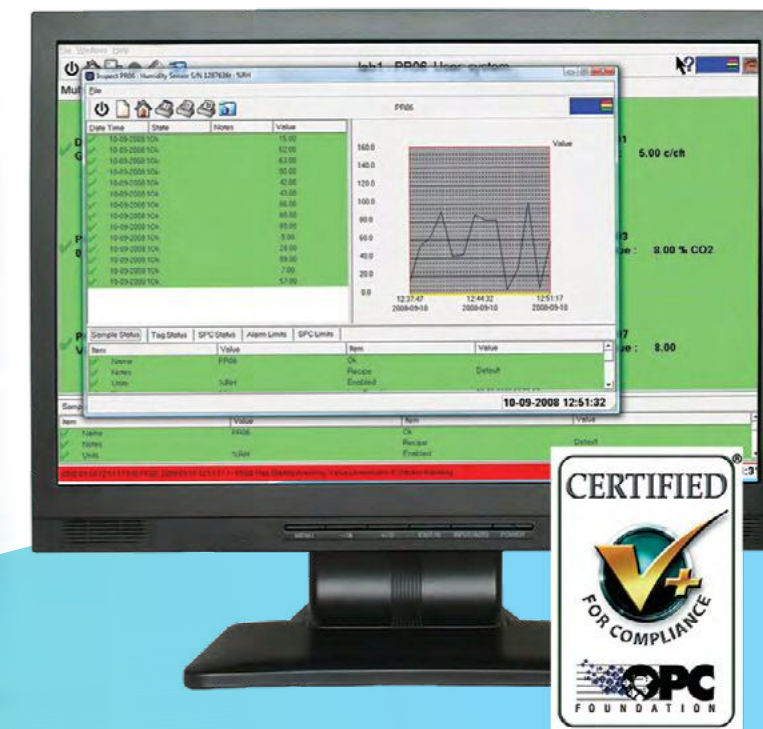
- + Turn data into knowledge with alarming, reports, and trending
- + Does not effect monitor or database functions
- + Multiple clients possible

### 3 DATABASE: SECURE STORAGE

- + Valuable data is safe and secure
- + Redundancy is standard with a mirror database
- + SQL for high availability and

## TSI FMS SOFTWARE: RELIABLE MONITORING SYSTEMS DISTRIBUTED. FLEXIBLE. REDUNDANT.

- + No single point of failure with a distributed design
- + Fault-tolerant and redundant
- + Communicate with virtually any other platform via OPC UA Client/Server



# RELIABLE. CONFIDENT. ENVIRONMENTAL MONITORING.

Environmental Monitoring Products for Pharmaceutical Manufacturing & Life Sciences

## FMS Software

Is a reliable monitoring system that reduces waste and increases yield, quality and profits—OPC UA Foundation compliant

Model	Flow Rate	Particle Size Ranges Available
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### Remote Particle Counters

Designed for continuous monitoring with a facility monitoring system

<u>AeroTrak®+ 7510</u>	1 CFM (28.3 L/min)	0.5, 5.0 µm (VHP resistant models available; Wi-Fi® option)
<u>AeroTrak® 6510</u>	1 CFM (28.3 LPM)	0.5, 0.7, 1.0, 5.0 µm (VHP resistant models available)

### Portable Particle Counters

For confident, compliant periodic monitoring

<u>AeroTrak® 9510</u>	1 CFM (28.3 LPM)	0.5, 0.7, 1.0, 3.0, 5.0, 10.0 µm
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### High Flow Portable Particle Counters

For faster periodic monitoring

<u>AeroTrak 9350</u>	1.77 CFM (50 LPM)	0.3, 0.5, 1.0, 2.0, 3.0, 5.0 µm
		0.3, 0.5, 1.0, 3.0, 5.0, 10.0 µm
<u>AeroTrak 9500</u>	3.53 CFM (100 LPM)	0.5, 0.7, 1.0, 3.0, 5.0, 10.0 µm
<u>AeroTrak 9550</u>	1.77 CFM (50 LPM)	0.5, 0.7, 1.0, 3.0, 5.0, 10.0 µm

### Handheld Particle Counters

Are convenient and compact for spot-checks and investigations

<u>AeroTrak 9306</u>	0.1 CFM (2.83 LPM)	0.3, 0.5, 0.7, 1.0, 2.0, 5.0 µm
		0.3, 0.5, 1.0, 3.0, 5.0, 10.0 µm
		0.3 to 10 µm, user-selectable
		Factory calibrated at 0.3, 0.5, 1.0, 3.0, 5.0, 10.0 µm

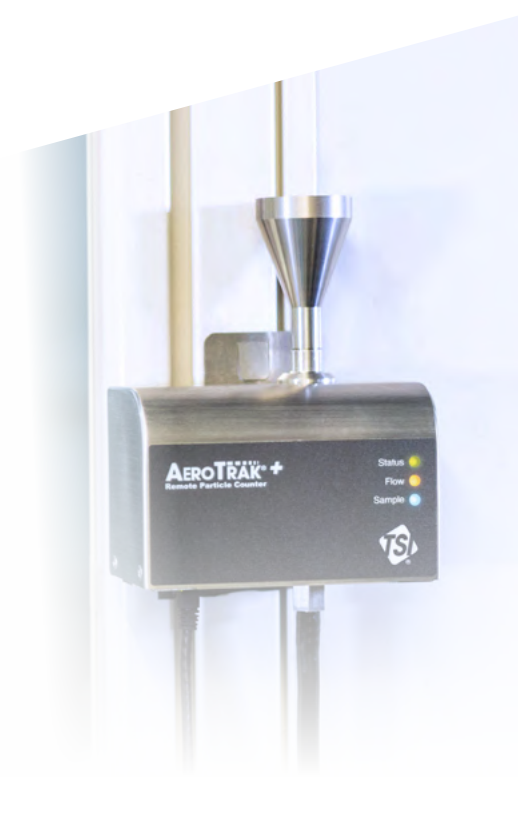
### Real-Time Viable Particle Counter (also known as biofluorescent particle detector)

An alternative and rapid microbiological method (ARMM) for viable air testing that offers proactive risk mitigation, continuous viable monitoring, improved process knowledge and investigations

<u>BioTrak® 9510-BD</u>	1 CFM (28.3 LPM)	0.5, 0.7, 1.0, 3.0, 5.0, 10.0 µm (and viable particle detection)
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### Active Air Sampler

<u>AeroTrak+ 7010</u>	1 CFM (28.3 LPM)	d <sub>50</sub> = 0.8 µm
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Wi-Fi is a registered trademark of the Wi-Fi Alliance.



UNDERSTANDING, ACCELERATED

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