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

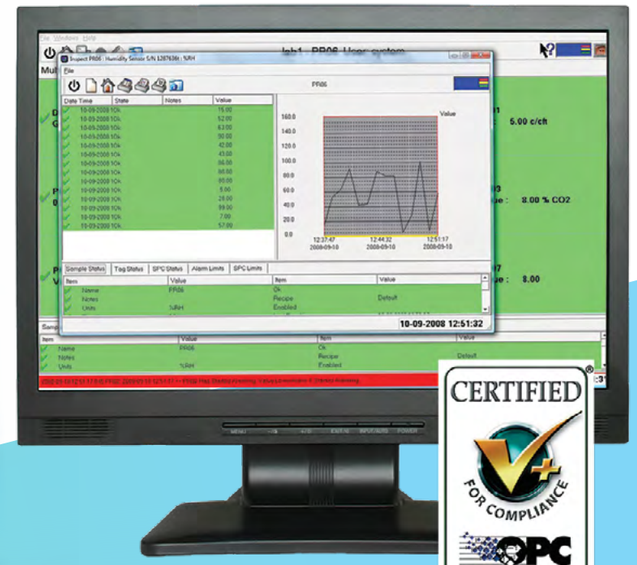
RELIABLE. CONFIDENT.
ENVIRONMENTAL MONITORING.

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

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



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

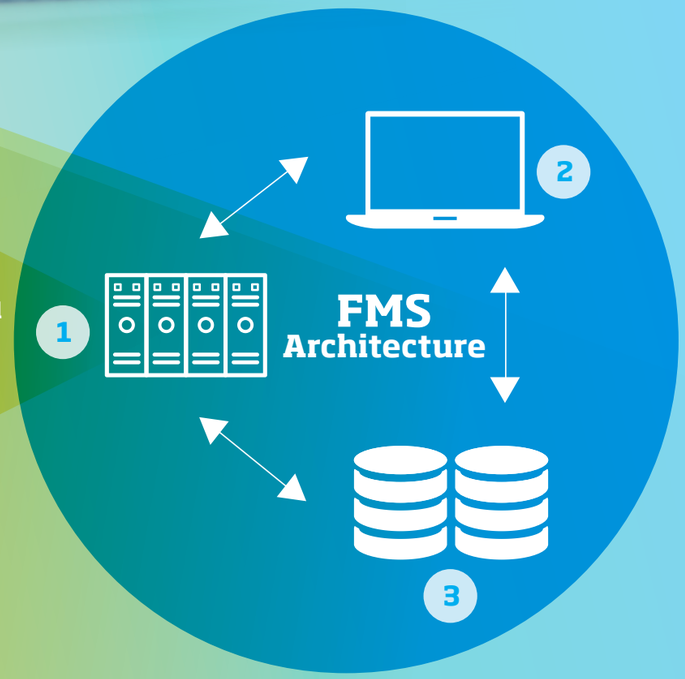
+ Intermittent sampling improves knowledge of conditions during a production run without interventions.
+ Protect against network failures with local data storage

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

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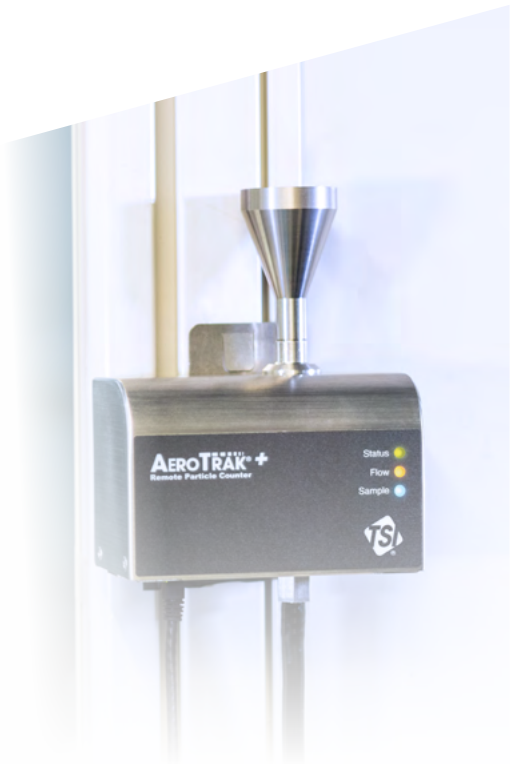
Environmental Monitoring Products for Pharmaceutical Manufacturing & Life Sciences

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
Remote Particle Counters Designed for continuous monitoring with a facility monitoring system		
AeroTrak®+ 7510	1 CFM (28.3 L/min)	0.5, 5.0 µm (VHP resistant models available; Wi-Fi® option)
AeroTrak® 6510	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		
AeroTrak® 9510	1 CFM (28.3 LPM)	0.5, 0.7, 1.0, 3.0, 5.0, 10.0 µm
High Flow Portable Particle Counters For faster periodic monitoring		
AeroTrak 9350	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
AeroTrak 9500	3.53 CFM (100 LPM)	0.5, 0.7, 1.0, 3.0, 5.0, 10.0 µm
AeroTrak 9550	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		
AeroTrak 9306	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		
BioTrak® 9510-BD	1 CFM (28.3 LPM)	0.5, 0.7, 1.0, 3.0, 5.0, 10.0 µm (and viable particle detection)
Active Air Sampler		
AeroTrak+ 7010	1 CFM (28.3 LPM)	d_{50} = 0.8 µm



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

UNDERSTANDING, ACCELERATED

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