
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
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

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

REMOTES WITH PUMP

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

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

HANDHELDs
PORTABLEs
INTEGRATED ENVIRONMENTAL MONITORING PROBES

RELIEABLE. CONFIDENT. ENVIRONMENTAL MONITORING.

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

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
+ Multiple clients possible

DATABASE: SECURE STORAGE
+ Valuable data is safe and secure
+ Redundancy is standard with a mirror database
+ SQL for high availability and

FMS Architecture

Environmental Monitoring Data

1 2 3 4 5 6 7

1 2 3

1 2 3

1 2 3

1 2 3

1 2 3
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.

<table>
<thead>
<tr>
<th>Model</th>
<th>Flow Rate</th>
<th>Particle Size Ranges Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote Particle Counters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AeroTrak®+ 7510</td>
<td>1 CFM (28.3 L/min)</td>
<td>0.5, 5.0 μm (VHP resistant models available; Wi-Fi® option)</td>
</tr>
<tr>
<td>AeroTrak® 6510</td>
<td>1 CFM (28.3 LPM)</td>
<td>0.5, 0.7, 1.0, 5.0 μm (VHP resistant models available)</td>
</tr>
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**Portable Particle Counters**
For confident, compliant periodic monitoring.

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<th>Model</th>
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<tr>
<td>AeroTrak® 9510</td>
<td>1 CFM (28.3 LPM)</td>
<td>0.5, 0.7, 1.0, 3.0, 5.0, 10.0 μm</td>
</tr>
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**High Flow Portable Particle Counters**
For faster periodic monitoring.

<table>
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<tr>
<th>Model</th>
<th>Flow Rate</th>
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</tr>
</thead>
<tbody>
<tr>
<td>AeroTrak® 9550</td>
<td>1.77 CFM (50 LPM)</td>
<td>0.3, 0.5, 1.0, 2.0, 3.0, 5.0 μm</td>
</tr>
<tr>
<td>AeroTrak® 9500</td>
<td>3.53 CFM (100 LPM)</td>
<td>0.5, 0.7, 1.0, 3.0, 5.0, 10.0 μm</td>
</tr>
<tr>
<td>AeroTrak® 9550</td>
<td>1.77 CFM (50 LPM)</td>
<td>0.5, 0.7, 1.0, 3.0, 5.0, 10.0 μm</td>
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**Handheld Particle Counters**
Are convenient and compact for spot-checks and investigations.

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

**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.

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<tr>
<td>BioTrak® 9510-BD</td>
<td>1 CFM (28.3 LPM)</td>
<td>0.5, 0.7, 1.0, 3.0, 5.0, 10.0 μm (and viable particle detection)</td>
</tr>
</tbody>
</table>

**Active Air Sampler**

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<tr>
<td>AeroTrak+ 7010</td>
<td>1 CFM (28.3 LPM)</td>
<td>$d_{90} = 0.8\ \text{μm}$</td>
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</tbody>
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*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.