

# Contamination Control for Life Science Applications



CONTROLLED ENVIRONMENTS

Contamination Control



TRUST. SCIENCE. INNOVATION.

# TSI Sets the Standard



## Regulatory Compliance

Pharmaceutical companies, medical device manufacturers, biotech companies, healthcare facilities and other regulated organizations are subject to a variety of laws and regulations regarding the production, storage and testing of their products. For example, sterile drugs produced by aseptic processing are subject to FDA Aseptic Guidelines and EU GMP Annex 1, and are classified using ISO 14644-1 standards. Strict regulations help ensure safety and consistency for end consumers.

## Patient Safety

The manufacture of sterile products has special requirements to minimize the risk of particle and microbiological contamination. Whether manufacturing pharmaceutical drugs or medical devices, these are ultimately intended for use with ill patients. Patient safety is of paramount importance. Life science professionals are required to demonstrate that critical product manufacturing environments are within specified control limits. TSI's AERO TRAK™ Particle Counters and FMS 5 software continuously monitor these vital processes for particle contamination, temperature, relative humidity and differential pressure, minimizing risk while enabling regulatory compliance.

## Process Control

Continuous improvement tools such as TSI's FMS software, are an important part of the US FDA Process Analytical Technology (PAT) initiative. The objective is to define process weaknesses and to implement process improvement initiatives. TSI's FMS software collects data in real time, resulting in immediate user response to out-of-specification events, enhanced root cause investigations, and improved processes.



# for Particle Counting



## TSI – a Leader in Particle Counting

For over 40 years, TSI has been a recognized leader in accurate particle measurements. TSI is considered the leader in aerosol and particle instrumentation for many applications, including:

- Filter testing
- Ambient air monitoring
- Dust monitoring
- Engine emissions
- Clean room certification
- Atmospheric and climate studies
- Nanoparticle measurements
- Respirator fit testing
- Aerosol research
- Biodetection

## AERO TRAK Particle Counters – Where Research meets Reality

The AERO TRAK line of Particle Counters, including handhelds, portables, and remotes, are designed to meet the rigid requirements for life science clean room applications. AERO TRAK Particle Counters comply with the stringent requirements set forth in ISO 21501-4. These particle counters are calibrated to NIST traceable PSLs using TSI's world-class Classifier and Condensation Particle Counters, the recognized standard for particle measurements. Backed with TSI's long-standing reputation for high quality and accuracy, AERO TRAK Particle Counters provide the best measurement and data to help keep your processes in control.

## Certification and Monitoring – Made Simple

Whether you periodically certify your clean areas, continuously monitor them, or both, TSI products help you simplify your task, while staying in compliance. AERO TRAK Portable Particle Counters offer a simple icon driven touch screen interface, making it easy to set up tests. Accurate data is securely output in a variety of formats, which is perfect for reports.

FMS 5 Facility Monitoring Software is the backbone of a fully compliant, continuous monitoring system. AERO TRAK Remote Particle Counters and other environmental sensors seamlessly integrate into FMS 5 to collect information needed to monitor your processes. FMS 5 is simple to configure and enables you to easily comply with 21 CFR part 11.

## Setting the Standard for Your Everyday Measurements

When it comes to measuring particles, TSI's instrumentation is called on time and again to provide accurate measurements and information for the most challenging applications. Hundreds of studies have been performed using TSI products and have been published in renowned technical journals.



## AEROtrak Portable Particle Counters

TSI offers a complete line of Portable Particle Counters, including 1 CFM, 50 LPM, and 100 LPM versions. The 100 LPM version allows you to sample 1 m<sup>3</sup> of air in just 10 minutes, shortening the time needed to perform ISO 14644-1 and EU GMP classifications. Professional certifiers prefer AEROtrak's easy icon-driven touch screen interface when measured against comparable products. Additional unique features of these Particle Counters include:

- Lightest products on the market, making it easy to transport from location to location
- Most sample points (10,000) and locations (999) available, allowing you to store more information in the instrument
- Easy set-up and recall of specific tests and recipes
- Instant Pass/Fail reporting on ISO 14644-1 and EU GMP Annex 1
- Draws samples through long sample tubing, making it easy to perform tests at multiple locations, to conduct filter testing, and to take surface particle samples
- Plug and play with TSI's industry leading, accurate, low velocity probes to certify critical air flows in clean rooms
- Loudest audible alarm, easy to hear in even the noisiest environments...and it's user adjustable
- Interfaces with TRAKPRO™ Lite and FMS 5 Software

AEROtrak Portable Particle Counters set a new standard for your everyday certification needs.



# Certification Solutions



## AEROTrAK Handheld Particle Counters

TSI's Handheld Particle Counters are an excellent choice for tracking down particle contamination sources, classifying clean areas, looking for filter leaks, and conducting IAQ investigations. When used as survey tools, these products are a great place to start when looking for early identification of problem areas, helping you save time and money.

The Model 9303 is a cost-effective, basic 3-channel, 0.1 CFM (2.83 L/min) particle counter. The Model 9306 is a best-in-class 6-channel, 0.1 CFM (2.83 L/min) particle counter with some unique features, including:

- Integrated handle for one hand operation
- Icon-driven color touch screen for simple configuration
- Unique variable binning option
- 10,000 sample record storage, 250 locations
- Pass/Fail reporting for ISO 14644-1 and EU GMP Annex 1
- Interfaces with TSI's TRAKPRO™ Lite and FMS 5 Software



Model 9303

Model 9306

## ISO 21501-4 Compliant

TSI's AeroTrak Particle Counters are fully ISO 21501-4 compliant, ensuring accurate and repeatable measurements. Classify clean rooms with confidence using products from TSI.

## Air Flow Products for Clean Room Certification

TSI air flow products are the recognized worldwide standard for accurate, low velocity instruments used to certify clean rooms and other clean devices. Products include:

- VELOCICALC® Air Velocity Meters
- ACCUBALANCE® Air Capture Hoods
- Air Velocity Transducers
- DP-CALC™ Micromanometers



# Ensure Compliance and Validation



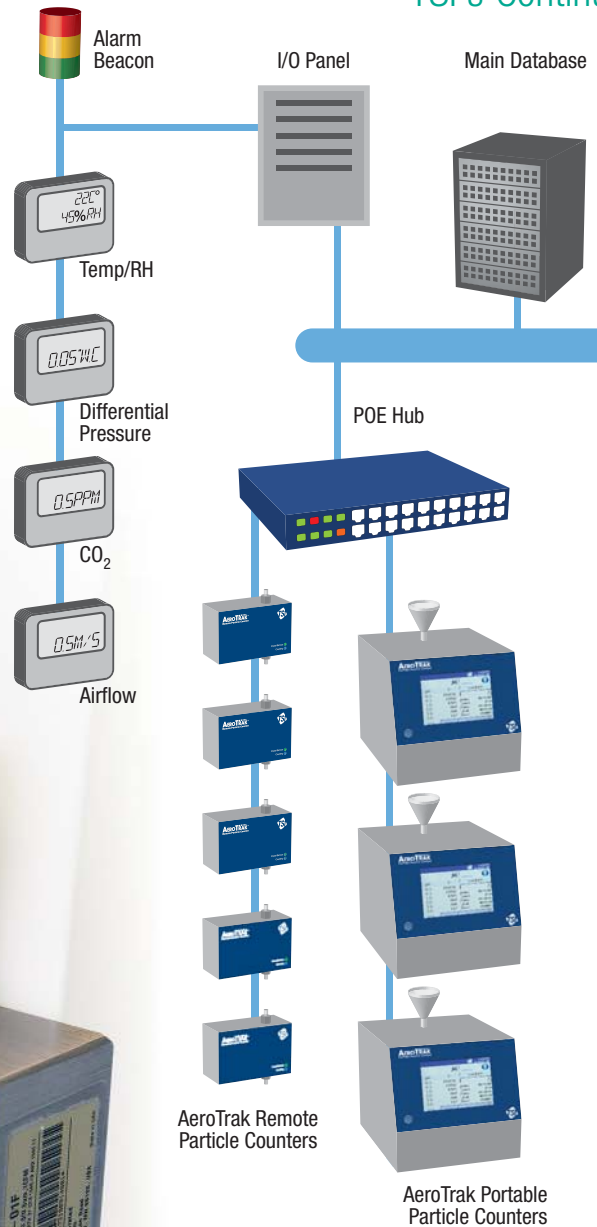
## AERO TRAK Remote Particle Counters

TSI's AERO TRAK Remote Particle Counters provide a continuous stream of data that integrates directly into TSI's FMS 5. These particle counters can easily be mounted in critical locations to ensure your processes are properly monitored. These products can be powered over its Ethernet connection (Power-over-Ethernet) to simplify installation, or via a local power supply.

Integration is easy using Ethernet (TCP/IP) or serial Modbus RTU communications. Configuration is easily completed locally with a PC or via a web browser. These particle counters come with data redundancy in the form of a 3000 sample point buffer. If the system goes down, these particle counters continue to collect and store valuable data.

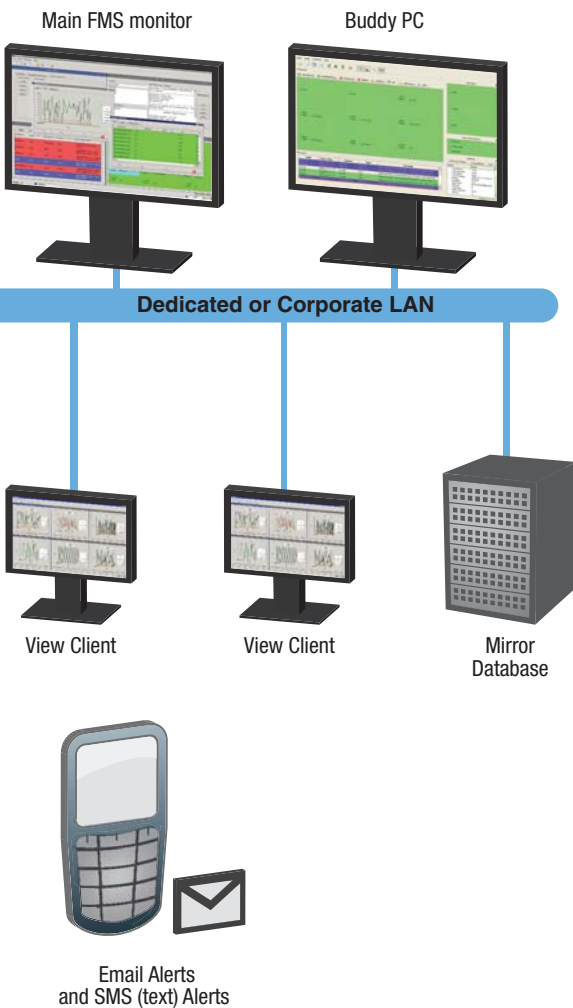


## TSI's Continuous



# with Continuous Monitoring

## Monitoring System



## Facility Monitoring Has Never Been So Easy

FMS 5 is a compliant environmental monitoring system software for the Pharmaceutical, Medical Device and Life Science industries. All software development activities at TSI follow the ISPE GAMP® lifecycle model. FMS 5 is assigned current GAMP® as a configurable software. It is specifically intended for use where compliance to EU GMP Annex 1 and the aseptic processing FDA cGMP is required.

FMS 5 enables compliance with the FDA 21 CFR Part 11 ruling. Full audit trail, password aging and lockout after failed logins, ensures secure, tamper proof data archiving and reporting. System security is easily configurable. User groups allow users and managers appropriate levels of system access.

Open architecture makes it easy to integrate any sensor with standard outputs. This includes TSI's AERO TRAK Particle Counters, temperature and humidity sensors, differential pressure gauges, and more. FMS 5 comes with built-in redundancy via a mirror database and unique Buddy automatic hot standby option. FMS 5 comes with a variety of alarm options that provide immediate notification of any out-of-specification event. User defined and automatic reporting options make it easy to get valuable timely information. FMS 5 has all the tools you need to ensure full compliance in your rigorously regulated environment.

## Validation

Full project based validation lifecycle documentation based on the latest ISPE GAMP® guidelines is available and tailored to meet your requirements.

- User Requirement Specification (URS)
- Functional Specification (FS)
- Configuration Statement (CS)
- Factory Acceptance Test (FAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)

# Parameters and Features Chart

The chart below is a guide for selecting the products that best fit your needs.

		Sensitivity	Flow Rate	# of Channels	ISO 21501-4	Modbus RTU	Alarm Contact	Audible Alarm	Filter Scanning Probe	Velocity Probes	Temp/ Humidity Sensor	Manifold Compatible	Printer	TrakPro Lite Software	Integrates with FMS 5
Handhelds	9303	0.3 µm	0.1 CFM (2.83 L/min)	3	•									•	
	9306	0.3 µm	0.1 CFM (2.83 L/min)	6	•	•		•			0		0	•	•
Portables	9110	0.100 µm	1.0 CFM (28.3 L/min)	8	•	•	•	•	0	0	0	•	•	•	•
	9310	0.3 µm	1.0 CFM (28.3 L/min)	6	•	•	•	•	0	0	0	•	•	•	•
	9510	0.5 µm	1.0 CFM (28.3 L/min)	6	•	•	•	•	0	0	0	•	•	•	•
	9350	0.3 µm	50 LPM	6	•	•	•	•	0	0	0		•	•	•
	9550	0.5 µm	50 LPM	6	•	•	•	•	0	0	0		•	•	•
	9500	0.5 µm	100 LPM	6	•	•	•	•	0	0	0		•	•	•
	9500	0.5 µm	100 LPM	6	•	•	•	•	0	0	0		•	•	•
Remotes	7110	0.100 µm	1.0 CFM (28.3 L/min)	8	•	•	0				0				•
	7201	0.2 µm	0.1 CFM (2.83 L/min)	2, 4	•	•	0				0				•
	7301	0.3 µm	0.1 CFM (2.83 L/min)	2, 4	•	•	0				0				•
	7501	0.5 µm	0.1 CFM (2.83 L/min)	2, 4	•	•	0				0				•
	7310	0.3 µm	1.0 CFM (28.3 L/min)	2, 4	•	•	0				0				•
	7510	0.5 µm	1.0 CFM (28.3 L/min)	2, 4	•	•	0				0				•
	7301-P	0.3 µm	0.1 CFM (2.83 L/min)	3	•	•									•

• = Feature of Instrument    0 = Optional accessories available

TSI Incorporated serves a global market by investigating, identifying and solving measurement problems. As an industry leader in the design and production of precision instruments, TSI partners with research institutions and customers around the world to set the standard for measurements relating to aerosol science, air flow, health and safety, indoor air quality, fluid dynamics and biohazard detection. With headquarters based in the U.S. and field offices throughout Europe and Asia, TSI has established a worldwide presence in the markets we serve. Every day, our dedicated employees turn research into reality.

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