

BIOTRAK[®] REAL-TIME VIABLE PARTICLE COUNTER MODEL 9510-BD

CONFIDENCE COMES WITH
A HIGHER CALIBER OF DATA



BioTrak[®] Real-Time Viable Particle Counter offers best-in-class features and versatility in the exciting new field of real-time airborne viable particle detection. The BioTrak particle counter detects total and viable particle counts in real time and incorporates TSI field-proven, patented Laser Induced Fluorescence (LIF) technology to determine particle viability.

Real-time viable particle detection enables:

- + Immediate notification of contamination events allowing
 - Segregation of product potentially exposed to contamination
 - Initiation of root cause investigations
 - Initiation of control measures
- + Trending of biological particulate levels
- + Information for process improvement (PAT)
- + Information for process risk management (ICH Q9)
- + Feedback for gowning and aseptic process training

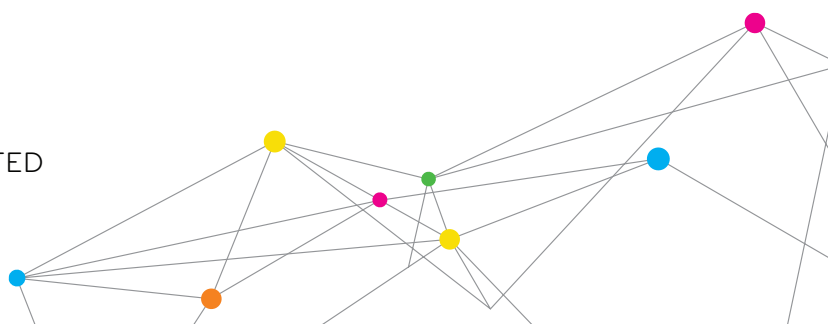
TSI's BioTrak Real-Time Viable Particle Counter combines real-time viable particle detection, total particulate detection, and integrated particle collection functionality into a single portable instrument.

Features and Benefits

- + Particulate size range: 0.5 to 25 μ m
- + Up to six channels of simultaneous total and viable particle data
- + Patented Laser Induced Fluorescence viability detection
- + Integrated particle collection filter for offline speciation analysis
- + Complies with all requirements of ISO 21501-4
- + 1.0 CFM (28.3 L/min) sample flow rate
- + Full optical particle counter functionality
 - Intuitive icon-driven touch screen Graphical User Interface
 - Recipe-based storage and recall of sampling protocols
 - Reports for ISO-14644-1, EU GMP Annex 1, and FS209E
 - 10,000 sample record storage, 999 locations
 - Ethernet and USB outputs
 - Stand-alone operation or integrate into a facility monitoring system
 - Displays up to three environmental parameters
 - Stainless steel enclosure



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SPECIFICATIONS

BIOTRAK® REAL-TIME VIABLE PARTICLE COUNTER MODEL 9510-BD

Particle Counting	
Size Range	0.5 to 25 µm
Particle Channel Sizes	0.5, 0.7, 1.0, 3.0, 5.0, 10 µm
Size Resolution	<15% @ 0.5 µm (per ISO 21501-4)
Total Particulate Counting Efficiency	50% at 0.5 µm; 100% for particles >0.75 µm, (per ISO 21501-4 and JIS)
Viable Detection	2 fluorescent channels and 1 sizing channel for discrimination
Sample Collection	Integrated filter holder for 37-mm diameter filters
Concentration Limit	820,000 particles/ft ³ (29,000,000/m ³) @ 10% coincidence loss
Zero Count	<1 count per 5 minutes (per ISO 21501-4 and JIS B9921)
Flow Rate	1.0 CFM (28.3 L/min) ±5% accuracy (meets ISO 21501-4 and JIS B9921)
Calibration	NIST traceable using TSI calibration system
Calibration Frequency	Recommended minimum of once per year
Standards	ISO 21501-4, CE, JIS B9921
Hardware	
Total Particulate Light Source	660 nm laser diode for MIE particle sizing
Viable Particulate Light Source	405 nm laser diode for Laser Induced Fluorescence viability detection
Flow Rate Control	Electronic, automatic closed loop (patented* flow control technology)
Sample Tube Extension	Up to 10 ft (3 m)
Audible Alarm	Built-in; >85 dB at 1 meter (adjustable)
External Alarm Relay	Normally open contact closure rated for 0 to 60 V AC/DC at 1.5A peak, 0.5A continuous. Alarm output rated for 60 V insulation. Relay contact closes under user configurable alarm conditions.
Exhaust	Internal HEPA filter
Vacuum Source	Internal pump
Alarm Output	Dry contacts, closed when alarm is engaged
Display	VGA 5.7-in. (14.5-cm) touch screen display
Printer	Optional built-in thermal printer
Dimension (H x W x D)	19 in. x 10.5 in. x 11.7 in. (48.3 cm x 26.7 cm x 29.7 cm)
Weight	37 lbs (16.8 kg)
Power	110 to 240 VAC universal power supply
Operating Range	41° to 86°F (5° to 30°C),** 20% to 85% RH noncondensing***
Operating Elevation	0 to 10,000 ft (0 to 3,000 m)
Storage Range	32° to 122°F (0° to 50°C), up to 98% RH noncondensing
Housing	Stainless Steel
External Chemical Resistance	Isopropyl alcohol, chlorinated solution, hydrogen peroxide
Environmental Sensor Interface	Supports TSI air velocity, temperature and relative humidity probes

User Interface and Communication	
Sampling Modes	Manual, automatic, beep; cumulative/differential; count or concentration
Sampling Time	1 second to 99 hours
Sampling Frequency	1 to 9,999 cycles or continuous
Data Storage	250 Zones 999 Locations 10,000 sample records including: Date, time, six total viable particulate size channels, flow status, instrument status; transferable via USB storage device, TrakPro™ Lite Secure software, Modbus® TCP over Ethernet or USB, and optional TSI FMS software.
Status Indicators	Flow, Instrument
Alarm Limits	Programmable for all particle channels (both total and viable)
Languages	English, German, French, Spanish, Japanese, Chinese (simplified), Italian
Software	TrakPro Lite Secure, optional FMS software
Printer Output	Prints in all available languages with optional integrated printer
Unit ID	Configurable IP address
Security	2-level password protection to lock out usage and configuration
Reports	Provides Pass/Fail on ISO 14644-1, EU GMP, and FS209E reports
Communication Mode	Modbus® TCP over Ethernet or USB
Accessories	
Included Accessories	Printed QuickStart guide, operating manual on CD, power supply, isokinetic probe, tubing, zero count filter, USB cable, TrakPro Lite Secure software, viable filter holder, viable collection filters, cleaning swabs, and calibration certificate
Optional Accessories	Electronic filter scanning probe, basic filter scanning probe, TSI velocity probes, Temp/RH probe, isokinetic probes, sample tubing, hard-sided carrying case, printer paper, and FMS Software

*The BioTrak 9510-BD incorporates the following patented technologies:
Patent Numbers 6,167,107; 5,701,012; 5,895,922; 6,831,279; 7,261,007.
**Maximum temperature limited by gel collection filter.
***See TSI Application Note CC-104 for operation above 50% RH.

Specifications are subject to change without notice.

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