**Knowledge Beyond Measure.**

# 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— detecting total and viable particle counts in real time. It incorporates TSI® field-proven, patented laser induced fluorescence (LIF) technology to determine particle viability.

The TSI® 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.

### 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

### Features and Benefits
- Particulate size range: 0.5 to 25 µm
- 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

## Particle Counting

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| 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 (twice per year for fluorescence) |
| Standards | ISO 21501-4, CE, JIS B9921 |

## Hardware

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| 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) |
| 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 |
| 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 non-condensing*** |

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| 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 non-condensing |
| 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

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| 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<br>999 Locations<br>10,000 sample records |
| 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 | Included:<br>▪ TrakPro™ Lite Secure Software<br>▪ FMS Software (OPC UA Bridge 5SP)<br>Optional:<br>▪ FMS Software (full version) |
| 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 | Manual data transfer:<br>▪ Export .xml file to USB drive<br>▪ To TrakPro™ Lite Secure over Ethernet or USB<br><br>Automatic data transfer:<br>▪ To FMS over ethernet<br>▪ To external software via FMS with OPC UA |

## Accessories

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| Included Accessories | Printed QuickStart guide, power supply, isokinetic probe, tubing, 1/2" barb inlet adapter, zero count filter, USB cable, gelatin filter holder, gelatin filters, cleaning swabs, calibration certificate, and insert card with instructions on how to download manuals and software |
| Optional Accessories | Electronic filter scanning probe, basic filter scanning probe, BioTrak™ aerosol generator, TSI velocity probes, temp/RH probe, isokinetic probes, sample tubing, and hard-sided carrying case |

*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.
****Size setting at 0.5 and 5.0 µm per ISO 21501-4.

Specifications are subject to change without notice.

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