



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



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 (twice per year for fluorescence) |
| 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) |
| 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*** |

| | |
|--------------------------------|--|
| 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

| | |
|--------------------|---|
| 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 |
| 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: <ul style="list-style-type: none">TrakPro™ Lite Secure SoftwareFMS Software (OPC UA Bridge 5SP) Optional: <ul style="list-style-type: none">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: <ul style="list-style-type: none">Export .xml file to USB driveTo TrakPro™ Lite Secure over Ethernet or USB Automatic data transfer: <ul style="list-style-type: none">To FMS over ethernetTo external software via FMS with OPC UA |

Accessories

| | |
|----------------------|---|
| 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 |



Knowledge Beyond Measure.

TSI Incorporated - Visit our website www.tsi.com for more information.

| | | | |
|---------|------------------------|-----------|-----------------------|
| USA | Tel: +1 800 874 2811 | India | Tel: +91 80 67877200 |
| UK | Tel: +44 149 4 459200 | China | Tel: +86 10 8219 7688 |
| France | Tel: +33 1 41 19 21 99 | Singapore | Tel: +65 6595 6388 |
| Germany | Tel: +49 241 523030 | | |

*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.

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.