

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

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 μ m; 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/ft3 (29,000,000/m3)

@ 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 660 nm laser diode for MIE particle sizing Light Source

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

Dry contacts, closed when alarm Alarm Output

is engaged

VGA 5.7-in. (14.5-cm) touch Display

screen display

Dimension

 $(H \times W \times D)$ 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

41° to 86°F (5° to 30°C),** Operating Range

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

Programmable for all particle channels Alarm Limits

(both total and viable)

English, German, French, Spanish, Japanese, Languages

Chinese (simplified), Italian

Software

TrakPro™ Lite Secure Software FMS Software (OPC UA Bridge 5SP)

 FMS Software (full version) Configurable IP address

Unit ID Security 2-level password protection to lock out usage

and configuration

Provides Pass/Fail on ISO 14644-1, EU GMP, Reports

and FS209E reports

Communication

Mode

Manual data transfer:

Export .xml file to USB drive

To TrakPro™ Lite Secure over Ethernet or USB

Automatic data transfer: To FMS over ethernet

To 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



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*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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