

## Confidence comes with a higher caliber of data

BioTrak® Real-Time Viable Particle Counter best-in-class features and versatility in the exciting new field of real-time airborne viable particle detectiondetecting total and viable particle counts in real time. It incorporates TSI® field-proven, patented laser induced fluoroscence (LIF) technology to determine particle viability.

The TSI<sup>®</sup> BioTrak<sup>®</sup> Real-Time Viable Particle Counter combines real-time viable particle detection, 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 intergrate into a facility monitoring system
- Displays up to three environmental paramaters
- · Stainless steel enclosure





## **Specifications**

# BioTrak<sup>®</sup> Real-Time Viable Particle Counter

Model 9510-BD

Size Range

**Particle Channel Sizes** 

**Size Resolution** 

**Total Particulate Counting Efficiency** 

**Viable Detection** 

Sample Collection

**Concentration Limit** 

**Zero Count** 

Flow Rate

Calibration

Calibration Frequency Recommended minimum of once per year

**Standards** 

**Hardware** 

**Total Particulate Light Source** 

**Viable Particulate** 

**Light Source** 

Flow Rate Control

Audible Alarm **External Alarm** 

Relay

**Exhaust Vacuum Source** 

**Alarm Output** 

**Display** 

**Printer** 

**Dimension** (HxWxD)

Weight

**Power** 

**Operating Range** 

0.5 to 25 um

0.5, 0.7, 1.0, 3.0, 5.0, 10µm

<15% @ 0.5 µm (per ISO 21501-4)

50% at 0.5 μm; 100% for particles >0.75 μm, (per ISO 21501-4 and JIS)

2 fluorescent channels and 1 sizing channel for discrimination

Integrated filter holder for 37mm diameter

filters

820,000 particles/ft3 (29,000,000/m3)

@ 10% coincidence loss

<1 count per 5 minutes

(per ISO 21501-4 and JIS B9921)

1.0 CFM (28.3 L/min) ± 5% accuracy (meets ISO 21501-4 and JIS B9921)

NIST traceable using TSI<sup>®</sup> calibration system

ISO 21501-4, CE, JIS B9921

660 nm laser diode for MIE

particle sizing

405 nm laser diode for laser induced fluorescence viability detection

Electronic, automatic closed loop (patented flow control technology)

Built-in: >85 dB at 1 meter (adjustable)

Normally open contract closure rated for 0 to 60V AC/DC at 1.5A peak, 0.5A continuous. Alarm output rated for 60V

insulation. Relay contact closes under user configurable alarm conditions.

Internal HEPA filter

Internal pump

Dry contacts, closed when alarm is

engaged

VGA 5.7 in. (14.5 cm) touch screen

display

Optional built-in thermal printer

19 in. x 10.5 in. x 11.7 in. (48.3 cm x 26.7 cm x 29.7 cm)

37 lbs (16.8 kg)

110 to 240 VAC universal power supply

41° to 86°F (5° to 30°C). 20% to 85% RH non-condensing **Operating Elevation** 

Housing **External Chemical** Resistance

**Environmental** Sensor Interface

Storage Range

0 to 10,000 ft (0 to 3,000 m) 32° to 122°F (0° to 50°C) up to 98% RH non-condensing

Stainless steel

Isopropyl alcohol, chlorinated solution, hydrogen peroxide

Support TSI®air velocity, temperature and relative humidity probes

### **User Interface and Communication**

Sampling Modes

Sampling Time Sampling Frequency

**Data Storage** 

**Status Indicators Alarm Limits** 

Languages

Software

**Printer Output** 

**Unit ID** Security

Reports

Communication Mode

Manual, automatic, beep; cumulative /differential: count or concentration

1 second to 99 hours

1 to 9,999 cycles or continuous

250 Zones, 999 locations, 10,000

sample records

Flow Instrument

Programmable for all particles channels (both total and viable)

English, German, French, Spanish, Japanese, Chinese(Simplified), Italian

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

•FMS Software (full version)

Prints in all available languages with

optional integrated printer

Configurable IP address 2-level password protection to lock out

usage and configuration Provides Pass/Fail on ISO 14644-1 EU

GMP, and FS209E reports 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 IJΑ

#### **Accessories**

Included **Accessories** 

**Optional 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

Electronic filter scanning probe, basic filter scanning probe, BioTrak aerosol generator, TSI velocity probes, temp/RH isokinetic probes, sample probe, tubing, hard-sided carrying case and printer paper

