

Confidence comes with a higher caliber of data

BioTrak® Real-Time Viable Particle Counter offers bestin-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 um

Particle Channel Sizes

Size Resolution Total Particulate

Counting Efficiency

Viable Detection

Sample Collection

Concentration Limit

Zero Count

Flow Rate

Calibration

Calibration Frequency

Standards

Hardware

Total Particulate Light Source

Flow Rate Control

Audible Alarm

External Alarm Relay

Exhaust Vacuum Source

Alarm Output

Display

Printer

Dimension $(H \times W \times D)$

Weight

Power

Operating Range

0.5, 0.7, 1.0, 3.0, 5.0, 10 μm

<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

Integrated filter holder for 37-mm

diameter filters

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

@ 10% coincidence loss

channel for discrimination

<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®

calibration system

Recommended minimum of

once per year

ISO 21501-4, CE, JIS B9921

Viable Particulate 405 nm laser diode for laser induced Light Source

fluorescence viability detection

660 nm laser diode for MIE particle sizing

Electronic, automatic closed loop (patented* flow control technology) Built-in; >85 dB at 1 meter (adjustable)

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.

Internal pump Dry contacts, closed when alarm

is engaged

Internal HEPA filter

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***

Specifications are subject to change without notice.

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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

Stainless steel Housing

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

Manual, automatic, beep; cumulative/differential; Sampling Modes

count or concentration

Sampling Time 1 second to 99 hours

Sampling

Frequency

Data Storage

1 to 9,999 cycles or continuous 250 Zones

999 Locations 10,000 sample records

Status Indicators Flow Instrument

Alarm Limits Programmable for all particle channels

(both total and viable)

English, German, French, Spanish, Japanese, Languages

Chinese (simplified), Italian

Software Included:

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

FMS Software (full version)

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

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, hard-sided carrying case and printer paper

*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

