

# 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

 $0.5, 0.7, 1.0, 3.0, 5.0, 10 \, \mu m$ 

channel for discrimination

@ 10% coincidence loss

NIST traceable using TSI®

Recommended minimum of

ISO 21501-4, CE, JIS B9921

calibration system

once per year

<1 count per 5 minutes

diameter filters

<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

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

Integrated filter holder for 37-mm

(per ISO 21501-4 and JIS B9921)

1.0 CFM (28.3 L/min) ±5% accuracy

(meets ISO 21501-4 and 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 contact closure rated

for 0 to 60 V AC/DC at 1.5A peak, 0.5A

insulation. Relay contact closes under

user configurable alarm conditions.

Dry contacts, closed when alarm

VGA 5.7-in. (14.5-cm) touch

19 in. x 10.5 in. x 11.7 in.

41° to 86°F (5° to 30°C),\*\*

Optional built-in thermal printer

(48.3 cm x 26.7 cm x 29.7 cm)

110 to 240 VAC universal power supply

20% to 85% RH non-condensing\*\*\*

Internal HEPA filter

Internal pump

is engaged

screen display

37 lbs (16.8 ka)

continuous. Alarm output rated for 60 V

0.5 to 25 um

Model 9510-BD

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Size Range 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

Viable 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

\*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.

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

USA Tet +1 800 874 2811 UK Tet +44 149 4 459200 Tet +33 1 41 19 21 99 Tet +49 241 523030

India China Singapore Tel: +91 80 67877200 Tel: +86 10 8219 7688 Tel: +65 6595 6388

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** 

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

Included: Software

TrakPro™ Lite Secure Software

• FMS Software (OPC UA Bridge 5SP)

FMS Software (full version)

Prints in all available languages with optional Printer Output

integrated printer

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, hard-sided carrying case and printer paper



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