

# CONFIDENCE COMES WITH A HIGHER CALIBER OF DATA

INTRODUCING THE BIOTRAK® REAL-TIME VIABLE PARTICLE COUNTER



UNDERSTANDING, ACCELERATED

# WHY COUNT VIABLE PARTICLES IN REAL-TIME?



Traditional microbial active air sampling and compendial culture-based count methods have been used for decades, providing invaluable microbial contamination information. However, they typically require a delay of 2-4 days for incubation and analysis – which could result in production of potentially contaminated product.

In addition, regulatory bodies are interested in knowing that your process is understood and in control. By knowing when excursions happen, immediate action can be taken to minimize potentially impacted product. Root cause investigations and remediation efforts are more effective with instant notification. Real-time data uncovers another layer of valuable information toward identifying root causes and addressing particle contamination sources.

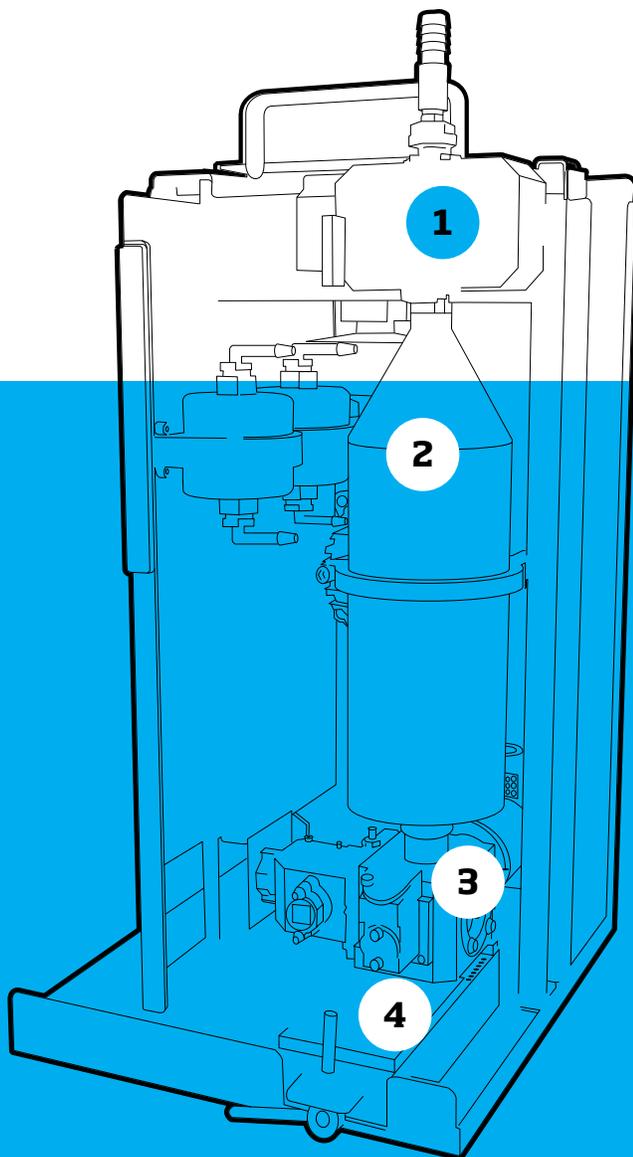
A new generation of products, like TSI's BioTrak® Real-Time Viable Particle Counter, provides information on when contamination excursions occur, as they happen. Meaning you can respond to an event right away by segregating potentially contaminated products and immediately locating the source of potential contamination. This minimizes product loss and enhances product safety.

## **PUT YOUR TRUST IN TSI'S BIOTRAK**

The BioTrak Real-Time Viable Particle Counter delivers airborne viable particle count data you can trust, moving you towards real-time quality assurance and process control.



# THE INNOVATIVE SOLUTION FOR VIABLE PARTICLE COUNTING DETECTION



With over 40 years of particle counting experience and 20 years of viable particle detection in the defense and threat detection field, TSI delivers confidence with the BioTrak Real-Time Viable Particle Counter. The patented Laser Induced Fluorescence (LIF) technology provides the best viable measurements for any real-time Rapid Microbial Method (RMM) available on the market today. And, with TSI, you will be working with a trusted, knowledgeable partner in regulated life science contamination control markets.

#### **1. Particle Counter**

Built-in 1 CFM (28.3 LPM), ISO 21501-4 compliant Particle Counter measures Total Particle Count (T-CNT). This component is used to classify cleanrooms to ISO 14644-1 and EU GMP standards.

#### **2. Particle Concentrator**

Patented\* high efficiency Particle Concentrator reduces flow rate for entrance to Viability Detector, maintaining majority of particles in the biological range of 2-10  $\mu\text{m}$ .

#### **3. Viability Detector**

Real-time single particle viability detector utilizes TSI's patented\* fluorescence technology for the best discrimination available between viable particles and potential interferents.

#### **4. Collection Filter**

Industry standard 37 mm integrated collection filter captures optically analyzed particles for laboratory analysis.

# BETTER MEASUREMENTS

## DISCRIMINATION

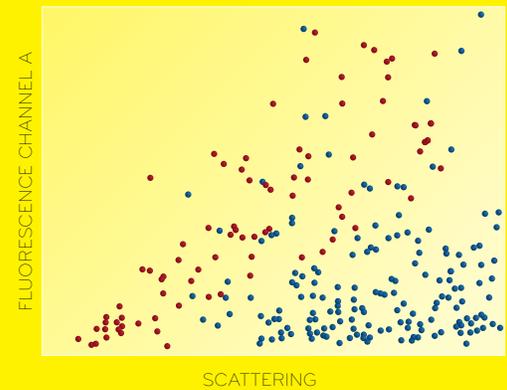
Measuring viable microbial particles is complex. In any given sample of particles, there are non-viable, viable organisms, non-viable particles, fluorescing non-viable particles such as pollen and paper, and Viable But Not Culturable (VBNC) organisms. TSI's BioTrak Real-Time Viable Particle Counter, along with extensive characterization via our unique discrimination algorithms, has produced the most discriminating measurement on the market today.

At the heart of the BioTrak Particle Counter is our Laser Induced Fluorescence (LIF) technology. Simply stated, when microbial particles are exposed to ultra-violet laser light, they become excited, meaning the particles start to 'glow' or emit light at different frequencies. Various cell metabolites like NADH, flavins (Riboflavin) and Tryptophan are associated with cell viability and are the primary markers targeted by the LIF technique.

Unlike products with just one channel of fluorescence detection, TSI's BioTrak Particle Counter has two channels for better discrimination. In the example shown, it is impossible to differentiate the pollen from the microorganism using a single fluorescence channel. But, when a second channel of detection is added, the differentiation becomes clear. TSI understands the technology and limitations of viable detection.

TSI understands LIF technology, along with its limitations, and is ready to assist you in applying it to your microbial environmental monitoring program.

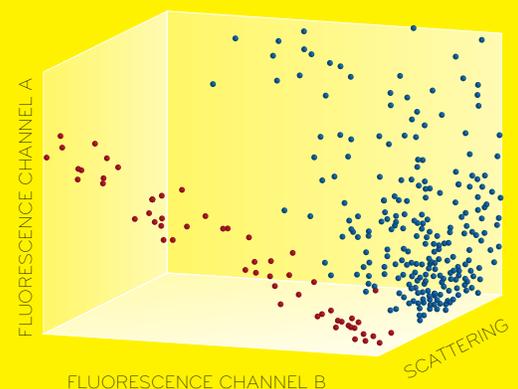
FIGURE 1: Single Channel



● BERMUDA GRASS POLLEN ● RALSTONIA PICKETTII

A single channel of fluorescence makes it very difficult to discriminate viable from non-viable particles.

FIGURE 2: Dual Channel

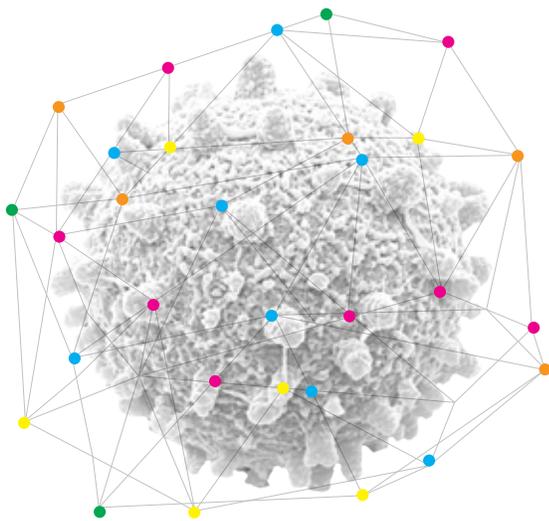


● BERMUDA GRASS POLLEN ● RALSTONIA PICKETTII

TSI's two channels of fluorescence detection provides the better measurement by clearly discriminating the viable particles.

# BETTER RESULTS

## SENSITIVITY



---

A particle that is determined to be viable when it is not is called a False Positive. With multiple parameter optical detection and discrimination algorithms, the BioTrak Particle Counter allows you to choose one of two instrument sensitivity settings.

Each sensitivity setting is appropriate for the cleanliness of the area you wish to monitor.

---

The most sensitive setting is for critical process monitoring Grade A/B and ISO5/6 areas where there are very clean particle backgrounds and no viable particle can be missed.

A less sensitive setting for Grade C/D and ISO 7/8 areas where the particle backgrounds are more likely to contain interferences. This setting will minimize false positives.

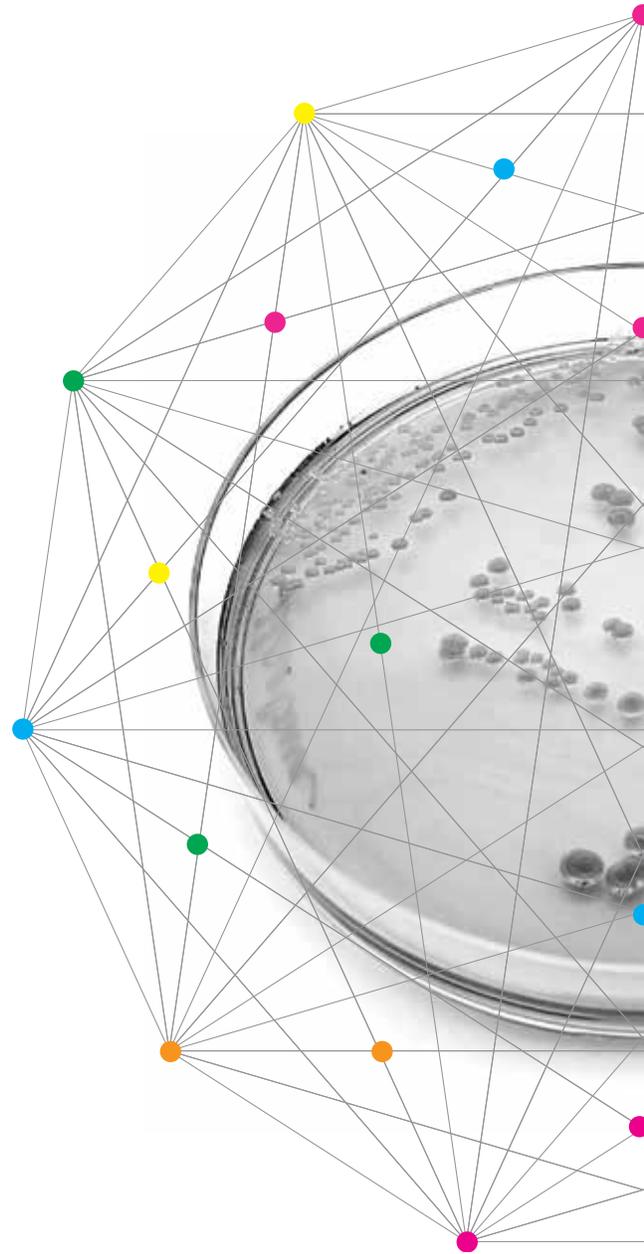
## SAMPLE COLLECTION

The BioTrak Particle Counter includes an integrated sample collection filter. And, unlike side-by-side measurements of separate particle counters and active air samplers, the BioTrak Particle Counter collects the same particles that were optically interrogated during viability detection. The gelatin filter can be transferred to growth media, analyzed using standard compendial methods, and provide speciation of the microorganisms that caused a contamination event. Rapid Microbiological Methods (RMM) identification techniques can also be used to facilitate fast response.

## VALIDATION

Regulatory authorities have published guidance related to Alternative Microbiological Methods, commonly referred to as Rapid Microbiological Methods (RMM) in USP <1223>, EP 5.1.6, PDA TR33. This guidance focuses on evaluation of laboratory-based equipment operating on previously collected environmental samples, and does not include the aerosol efficiency of the instrument. Aerosol efficiency testing and validation guidance for active air samplers is given in ISO 14698-1.

In addition, TSI has the knowledge and experience needed to help you utilize the BioTrak Particle Counter in a validated manner.



### TSI Understands Particles

The BioTrak Particle Counter has been characterized using the latest in aerosol techniques by TSI scientists and engineers. TSI is committed to help you fully understand how the BioTrak Particle Counter operates, and assist you in utilizing it for your application. With TSI as your partner, you can be confident in knowing what is happening, when it happens.

# TE SOLUTION



## ONE PRODUCT DOES IT ALL

---

### **Particle Counter**

Perform ISO 14644 and EU GMP classifications, just like TSI AeroTrak Portable Particle Counters.

### **Viability Detector**

Two fluorescence channels for simply the best measurement available.

### **Collection Filter**

Analyze the same microorganisms detected by the viability detector.

### **User Interface**

Intuitive airborne particle counter interface provides sampling setup, alarm settings, data organization, and notification of excursions as they happen.

### **Ties into FMS**

The BioTrak Particle Counter seamlessly interfaces with TSI's FMS Facility Monitoring Software, a fully compliant continuous monitoring software package that trends data and records alarms - great for process control and root cause investigations.

# TSI – A LEADER IN PARTICLE COUNTING

For over 40 years, TSI has been a recognized leader in accurate particle measurements. In fact, TSI is considered the leader in aerosol and particle instrumentation for many applications, including: filter testing, atmospheric and climate studies, ambient air monitoring, nanoparticle measurements, dust monitoring, respirator fit testing, engine emissions, aerosol research, clean room certification, and bio detection.

## **AeroTrak Particle Counters - Where Research Meets Reality**

The AeroTrak line of Particle Counters, including handhelds, portables, and remotes, are designed to meet the rigid requirements for life science clean room applications. AeroTrak Particle Counters comply with the stringent requirements set forth in ISO 21501-4. These particle counters are calibrated to NIST traceable PSLs using TSI's world-class Classifier and Condensation Particle Counters, the recognized standard for particle measurements. Backed with TSI's long-standing reputation for high quality and accuracy, AeroTrak Particle Counters provide the best measurement and data to help keep your processes in control.

\*Patents: 5,701,012; 5,895,922; 6,831,279



UNDERSTANDING, ACCELERATED

**TSI Incorporated** - Visit our website [www.tsi.com](http://www.tsi.com) for more information.

<b>USA</b>	<b>Tel:</b> +1 800 874 2811	<b>India</b>	<b>Tel:</b> +91 80 67877200
<b>UK</b>	<b>Tel:</b> +44 149 4 459200	<b>China</b>	<b>Tel:</b> +86 10 8251 6588
<b>France</b>	<b>Tel:</b> +33 4 91 11 87 64	<b>Singapore</b>	<b>Tel:</b> +65 6595 6388
<b>Germany</b>	<b>Tel:</b> +49 241 523030		