

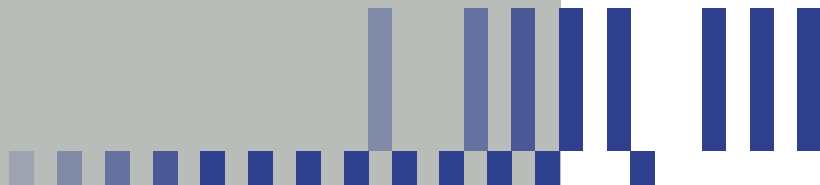


® Knowledge
Beyond
Measure.



Microbial Monitoring Continuous & Intervention-Free

The Biotrak® Real-Time Viable Particle Counter



Innovation for a Changing Industry

Aseptic manufacturing is changing. Regulations like the EU GMP Annex 1 encourage modernization. Technologies such as gloveless isolators and single-use systems that automate processes and limit human interventions are becoming the norm. Regulators and manufacturers alike recognize that highly-automating manufacturing leads to improved quality, safety, and efficiency.

This new paradigm demands in-depth process understanding, fewer interruptions, and no operator intervention. After decades of reliable service, traditional microbial monitoring techniques (i.e. growth-based detection methods) are not capable of meeting these demands.

Annex 1 ready, the BioTrak® Real-Time Viable Particle Counter (a biofluorescent particle counter) provides real-time viable and total particle monitoring of critical environments, including the aseptic core, without the need for operator intervention. The BioTrak® Real-Time Viable Particle Counter complements manufacturing innovations to maximize process understanding and efficiency without introducing any risk to product



Annex 1 Compliance Checklist

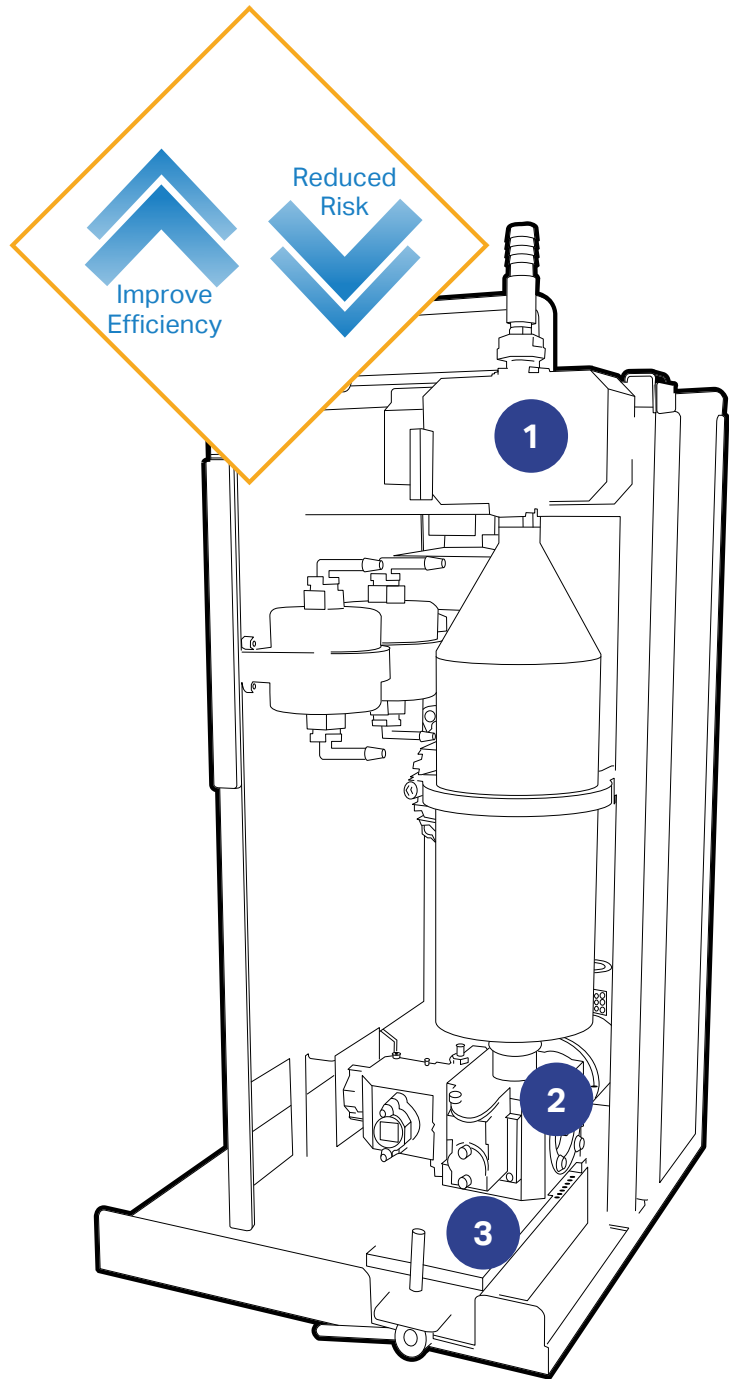
- Samples Continuously
- Expedites Detection
- Reduces Risk



A Complete Solution for Environmental Air Monitoring

- Viable Particles
- Non-Viable Particles
- Microbial Collection

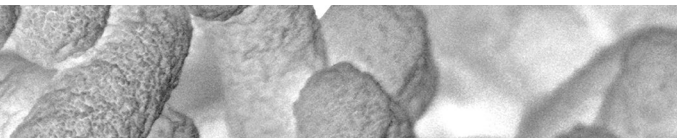
BioTrak® Real-Time Viable Particle Counter provides complete environmental monitoring of air in cleanroom spaces. Monitoring for both total and viable particles can be performed with this one instrument using a single isokinetic probe located within the test area.



1 Total Particle Counter
A 1 CFM (28.3 LPM) total particle counter provides the same trusted measurements users expect from all TSI particle counting instruments. Fully compliant to ISO 21501-4, it is suitable for use in all GMP applications.

2 Biofluorescent Particle Counter (BFPC)
Viable particles, also referred to as autofluorescence units (AFU), are detected using laser induced fluorescence (LIF). LIF works by detecting the fluoresce of metabolites in viable microorganisms that are excited as they pass through a laser beam. This requires no growth or reagents and makes viable results available in real-time.

3 Particle Filter
A highly efficient gelatin filter can be installed to capture the particles that pass through the BFPC. The filter can be transferred to growth media for an opportunity to identify culturable contaminants that were present in the sample



Improve Efficiency & Reduce Risk

Key Applications

Continuous Process Monitoring

BioTrak® Real-Time Viable Particle Counter is the ideal instrument for continuous microbial monitoring in the aseptic manufacturing core. Real-time, interruption-free monitoring unlocks process efficiencies and improves quality. Seamless integration with TSI Facility Monitoring System enables complete environmental monitoring automation.

Non-Compliance Based Applications

These applications, such as root-cause investigation, room release, and gowning training/verification, offer immediate benefit for any manufacturing facility. BioTrak® Real Time Viable Particle Counter has features and accessories designed for easy operation and data analysis

Validation

TSI® has a dedicated team of professionals with knowledge and experience to help users confidently implement the BioTrak® Real Time Viable Particle Counter in a compliant manner.

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- TSI® has submitted a Type V Drug Master File with the FDA. It includes rigorous performance qualification studies. A summary is available upon request or via the website.





Unmatched Benefits

Regulations such as Annex 1 recognize that manufacturers need to move past traditional growth-based monitoring methods to better assure product quality. These methods are also incompatible with efforts to modernize and to make Pharma 4.0 a reality. BioTrak® Real-Time Viable Particle Counter is ready to meet these demands in ways that are not possible with historically used microbiological methods.

Improve Process Understanding

Continuous monitoring reveals where and when microbial excursions occur. Time-resolved data demonstrates continuous control during normal operation. In the event an excursion does occur, immediate actions can be taken to resolve the issues with immediate feedback on action effectiveness. This allows for greatly improved, real-time, process control for improved quality.

Reduce Risk by Eliminating Operator Interventions

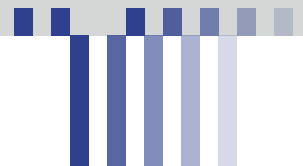
People are a primary source of viable contamination. Fully automating the air sampling within the aseptic core removes the need for operator interventions for microbial monitoring.

Reduce Loss of Product from Line Stoppages

Not only do line stoppages require interventions that increase risk, they often result in loss of product when the line is restarted. By eliminating the need to change plates, BioTrak® Real-Time Viable Particle Counter allows continuous operation during fill/finish operations.

Achieve High Level of Data Integrity

Data integrity is critical. BioTrak Real-Time Viable Particle Counter seamlessly interfaces with TSI Facility Monitoring Software (FMS). FMS is a fully compliant continuous monitoring software package that trends data, triggers alarms, and easily makes data available where and when it is needed.



Better Discrimination

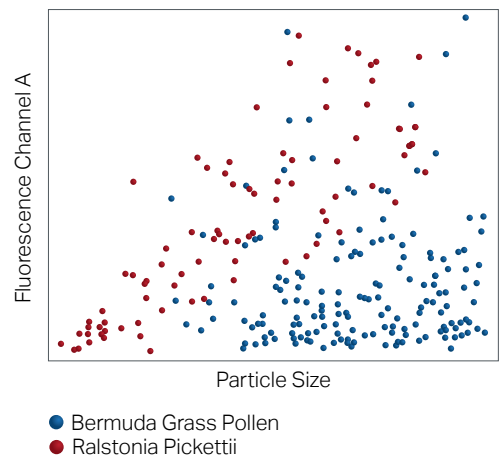
Dual-Channel Laser Induced Fluorescence (LIF)

Microorganisms contain fluorescent molecules that produce unique optical signatures. By measuring the size and fluorescent properties of individual particles, TSI's BioTrak® Real-Time Viable Particle Counter effectively distinguishes viable particles from non-viable particles.

At the heart of the BioTrak® Real-Time Viable Particle Counter is LIF technology. Simply stated, when microbial particles are exposed to ultra-violet laser light, they absorb and re-emit light at higher wavelengths; a process called fluorescence. Fluorescent cell metabolites associated with viability, such as nucleotides, flavins, lipids, and amino acids, are the primary markers targeted by the LIF technique.

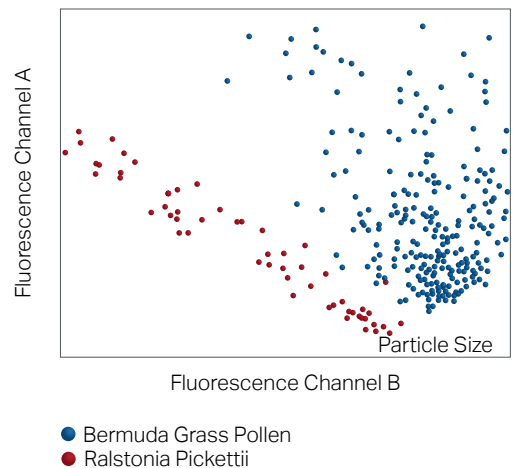
Unlike products with just one channel of fluorescence detection, TSI's BioTrak® Real-Time Viable Particle Counter has two channels for better discrimination. In the example shown, it is impossible to differentiate the pollen particles from the microorganisms using a single fluorescence channel. But, when a second channel of detection is added, the differentiation becomes clear. By collecting and processing more optical data than other instruments, TSI® has produced the most discriminating measurement on the market today.

FIGURE 1: Single Channel



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

FIGURE 2: Dual Channel

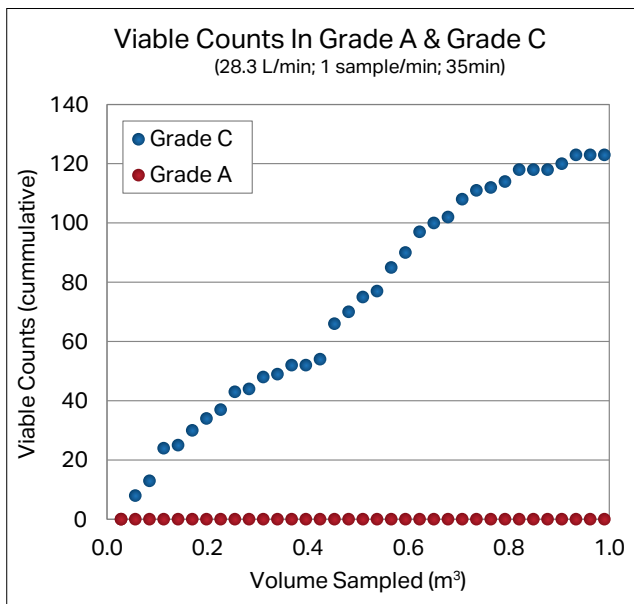


TSI's two channels of fluorescence detection provides the better measurement by clearly discriminating the viable particles.



Better Results

Specificity



A viable particle count in the absence of a microorganism is considered a false-positive. In critical environments, such as the aseptic core, false-positives can adversely impact processes. With dual-channel LIF and sophisticated discrimination algorithms, the BioTrak® Real-Time Viable Particle Counter reliably delivers essentially zero viable particle counts in rigorously hygienic spaces such as Grade A / ISO 5. The graph shows actual data from real-world manufacturing spaces. The BioTrak® Real-Time Viable Particle Counter shows little or no signal in extremely clean environments for as long as aseptic conditions are maintained.



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 suite of AeroTrak® Particle Counters, including handhelds, portables, and remotes, are designed to meet the rigid requirements for life science cleanroom 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



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