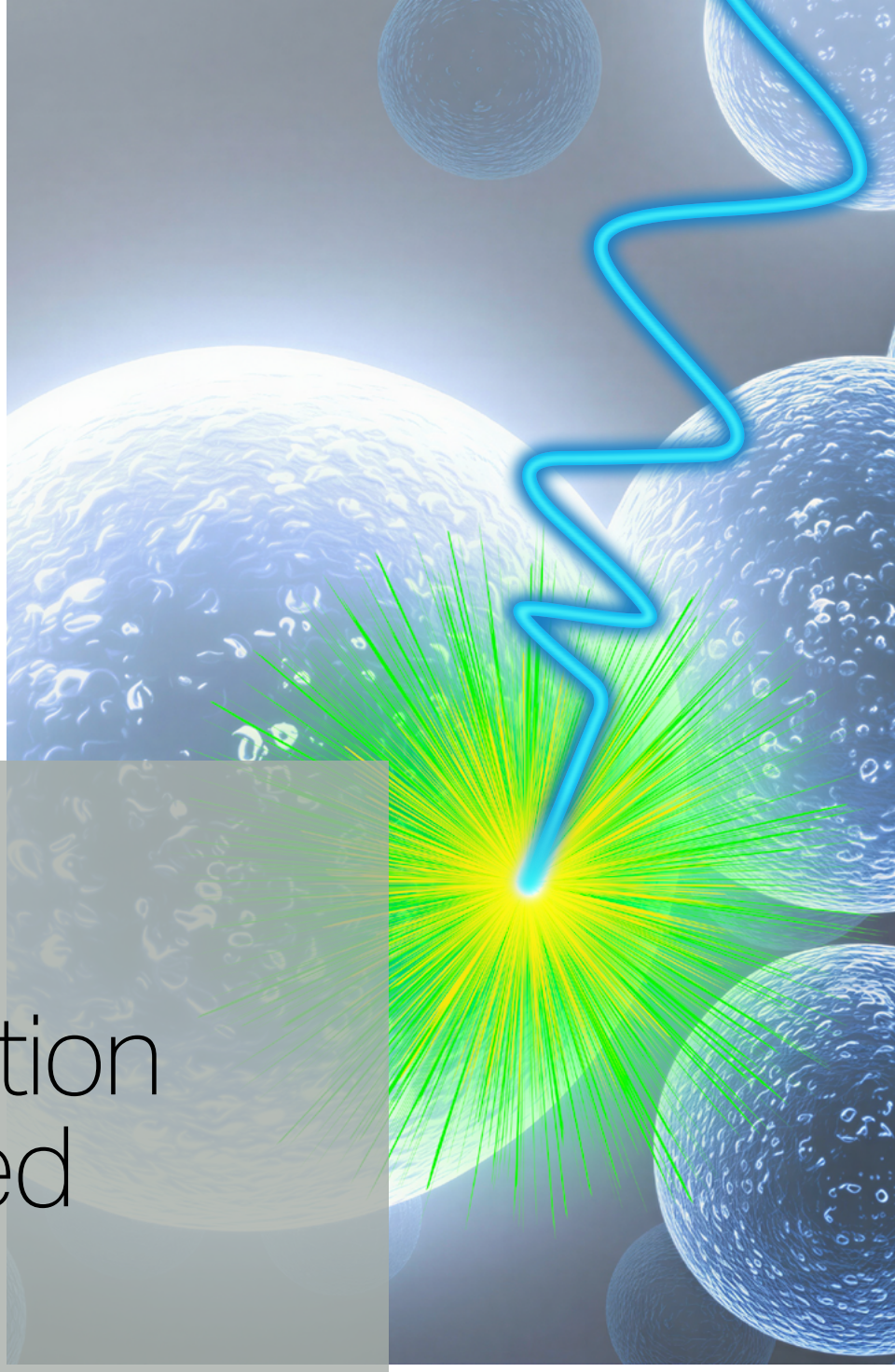
Knowledge
Beyond
Measure.



Catching Contamination at the Speed of Light

Accepted BFPC. Engineered for Grade A.
Introducing the ***BioTrak***® II BFPC



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***® II BFPC (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***® II BFPC 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® II BFPC 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.

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.

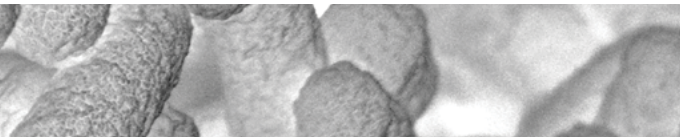
Biofluorescent Particle Counter (BFPC)

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.

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® II BFPC 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*® II BFPC has features and accessories designed for easy operation and data analysis.

Validation

TSI® BFPCs have been in use for routine monitoring for years. TSI® brings this knowledge and experience to help confidently validate and implement the *BioTrak*® II BFPC today.

TSI® has performed an extensive primary validation per the guidance of USP <1223> and EP 5.1.6.





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*® II BFPC 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*® II BFPC allows continuous operation during fill/finish operations.

Achieve High Level of Data Integrity

Data integrity is critical. *BioTrak*® II BFPC 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.

Benefits of High Flow

Annex 1 states that particle counters used for total particle monitoring in Grade A must have a suitable sample flow rate of at least 28 lpm. BFPCs need a much slower flow rate to reliably detect AFUs. So, while many BFPCs report total particle counts, most do not meet Annex 1 requirements. To overcome this issue, the ***BioTrak***® II BFPC utilizes a unique solution to make it suitable for use for both total particle and viable air monitoring.

The ***BioTrak***® II BFPC uses a particle concentrator located between the total particle counter and the BFPC. The concentrator operates on the same principles used by impaction air samplers to collect particles. It forces the sampled air to make a tight turn, causing particles with sufficient inertia to fall out of the air stream with smaller particles being exhausted. Instead of the particles that fall out impacting on a plate, they are concentrated and pass through the BFPC at a reduced flow rate of 1 lpm.

Any loss of small particles that result from the use of the concentrator is more than made up for by the significant benefits provided by a flow rate of 28.3 lpm:

- A larger sample volume provides more opportunity to detect a contamination risk if present in Grade A
  - Sample volume is 5.66 times larger than if sampling at 5 lpm
- A second particle counter is not needed for total particle counting
  - Less equipment to manage
  - Only a single sampling probe in Grade A



Trusted Measurement

Introduced in 2012, the ***BioTrak***® BFPC was based on robust biological threat detection technology used by the United States (U.S.) military. Pharmaceutical manufacturers adopted the ***BioTrak***® BFPC for numerous applications, most notable as an extremely valuable tool for root cause investigations. The first Grade A monitoring installation, which fully replaced traditional active and passive viable testing methods, was implemented in 2022. Given the criticality of this testing, a high degree of trust in the measurement was required. This trust was gained through the following:

- Over a decade of experience in using the instrument, including several evaluations performed by industry working groups
- A comprehensive primary validation performed by TSI at the U.S. Army Edgewood Chemical and Biological Center, a global leader in bioaerosol testing
- A robust calibration process where all optical sensors are evaluated and calibrated. Important note: as-found results are quantitatively related to the performance of the instrument — this is the only way to ensure the instrument operates in a validated state

While much has technically evolved with the ***BioTrak***® II BFPC, the trust in the measurement has not. It uses the same detection components as the first revision, thus making it an established measurement device with years of proven performance in the field.



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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Knowledge Beyond Measure.

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