Knowledge Beyond Measure.

BioTrak® II Biofluorescent Particle Counter (BFPC)

Implementation Roadmap



Equipped to Support You Every Step of the Way



Every project is unique, but once the decision is made to install *BioTrak*® II BFPCs for Grade A monitoring (after proof of concept and business case are finalized), the implementation process generally follows the four stages outlined below.

Backed by years of experience, TSI is equipped to support you every step of the way.

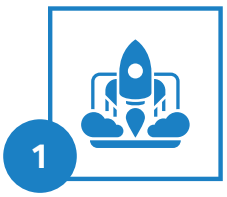
Project Initiation
Collaborate with the fill line manufacturer and authorities, and proceed with placing instrument orders.

System Design
Mechanically and digitally integrate the *BioTrak*® II BFPC with the fill line.

Validation
Qualify the *BioTrak*® II BFPC as part of the fill line, and perform secondary validation.

Routine Use
Begin Grade A monitoring, and establish a calibration regimen.



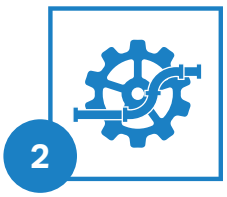


1 Project Initiation

Prior to purchase, users must be certain that the ***BioTrak®*** II BFPC aligns with their intended use and requirements. This preparation often includes training on its operation, reviewing prior studies, and conducting limited testing. Typically, a User Requirements Specification (URS) is created.

Additionally, many users may need to calculate the return on investment (ROI) to support and include in final business case. The project officially begins with the purchase of the ***BioTrak®*** II BFPC, at which point engagement with the fill line manufacturer and relevant authorities should also commence.

Key Actions	Support Resources
Instrument Operation Training	▪ Virtual and/or in-person training options available ▪ TSI Application Note CC-134: Gelatin Filter Handling Guide
Prior Study Review	▪ Primary validation documentation ▪ Published industry papers ▪ TSI Application Note CC-104: Sample and Collection Efficiency
Proof of Concept	▪ TSI Application Note CC-124: Evaluation Guidance
ROI Calculation	▪ ROI worksheet tool
URS Creation	▪ URS template document



2 System Design

System design consists of two key components:

- **Mechanical Design**
  Focuses on determining the optimal placement of the ***BioTrak®*** II BFPCs. Key considerations include minimizing particle loss in the sample tubing and ensuring easy access to the gelatin filter.
- **Digital Integration**
  Addresses how the ***BioTrak®*** II BFPC works with the filling system and manages data handling.

For filling lines where the ***BioTrak®*** II BFPC is offered as a standard feature, the required design work may be significantly reduced.

Key Actions	Support Resources
Physical Integration	▪ Instrument specification sheet ▪ Detailed CAD drawing ▪ Inlet/Outlet specifications
Tubing Configuration	▪ Recommended 3-way valve configuration ▪ Particle loss modeling analysis ▪ Particle loss testing
Digital Integration	▪ Digital integration diagrams ▪ Technical Notes for system configuration



3 Validation

Following installation, the ***BioTrak®*** II BFPC needs to be qualified as part of the system and validated as per EP 5.1.6, USP <1223>, and PDA TR33. Per these guidelines, TSI® has performed an extensive primary validation of the ***BioTrak®*** II BFPC. This validation involved testing with controlled bioaerosols, which users are not expected to repeat. Instead, users are required to perform a secondary validation to demonstrate that the ***BioTrak®*** II BFPC meets their specific intended use. This secondary validation includes non-inferiority and interferent testing.

Key Actions	Support Resources
Calibration	▪ On-site calibration services
FAT / SAT / IQ / OQ	▪ OPC UA test scripts ▪ Error generation program
PQ	▪ PQ template tool ▪ Particle loss testing



4 Routine Use

Once accepted for use, the ***BioTrak®*** II BFPC can perform all in-process environmental monitoring in Grade A environments. Its operation is fully automated, functioning similar to a remote particle counter, with the exception of gelatin filter handling.

The ***BioTrak®*** II BFPC features a well-established calibration process backed by years of proven reliability. However, in the event of an out-of-tolerance (OOT) condition, assessing the impact can be challenging due to the use of multiple sensors for viability determination. To address this, TSI simplifies the process by reporting the bioefficiency, making it easier to understand the impact.

Key Actions	Support Resources
Routine Use	▪ User instruction manual ▪ TSI Application Note CC-134: Gelatin Filter Handling Guide
Maintenance and Calibration	▪ On-site calibration services ▪ TSI Application Note CC-135: BioTrak Algorithm Performance

BioTrak® II BFPC
Implementation Roadmap

The *BioTrak*® II BFPC is an alternative microbiological method that offers clear benefits for assuring product quality and improving efficiency. While implementing such an alternative method can often be challenging, improved regulatory guidance and the established use of the *BioTrak*® II BFPC for monitoring Grade A environments have made the process more straightforward. Built on years of experience, this document provides a clear, step-by-step roadmap—from project initiation and system design to validation and routine use following installation.

Support Resources

The supporting resources listed for each stage of implementation include reference articles, validation documents, and testing services. Many of these documents are readily available on the TSI website and can be quickly accessed using the QR code below. To take advantage of additional services and resources, please contact a TSI sales professional.



Scan to explore the *BioTrak*® II BFPC supporting resources.

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Distributed by:
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P/N 5003386 Rev B
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Printed in U.S.A.

MAR-2821