



PHARMABILITIES

COMPREHENSIVE
CONTAMINATION
MONITORING

PRODUCTS & SERVICES



Without measurement, there is no control.



**PARTICLE
MEASURING
SYSTEMS**
www.pmeasuring.com

AIR PARTICLE MONITORING

PORTABLE MONITORING

LASAIR® III Particle Counter

The Lasair III Particle Counter sets the new standard for aerosol particle counters. The on-board Pulse Height Analyzer (PHA) ensures ISO 21501-4 compliance. The large IR touch screen controls and intuitive user interface make the system very easy to use. The Lasair III is capable of operating at several flow rates up to 100 L/min. This allows sampling 1m³ in just 10 minutes making it suitable for cleanroom certification and EU GMP compliance. Accessory environmental probes are available, along with complete validation support documentation.

SEQUENTIAL MONITORING

Aerosol Manifold AMII

Particle Measuring Systems® manifolds provide a cost-effective approach by sequentially monitoring aerosol contamination at multiple sample points using a single particle counter. The AMII is ideal for trend analysis and cleanroom verification where accuracy is critical and continuous sampling is not needed.

CONTINUOUS MONITORING

IsoAir® and IsoAir® PLUS

IsoAir Particle Sensors make it easy and cost-effective to continuously monitor your most critical locations. Protected in 316L stainless steel enclosures, these sensors offer a small footprint, superior performance, unsurpassed longevity and superior data capabilities. The XR option uses special coatings to protect the internal optics against potentially corrosive or oxidizing environments, such as VHP sterilization, that would incapacitate standard counters.

IsoAir PLUS Particle Sensors have an incorporated vacuum pump making simplified installation. The IsoAir PLUS also has 4-20 mA inputs, a 3000 sample point memory and is Wi-Fi compatible allowing for mobile cart monitoring, required for transferring between filling and lyophilization activities.

BENEFITS ▶

- Real time monitoring against contaminating particles
- 0.5 and 5.0 microns channel selection for easy to read screen information
- High 100 L/min flow rate capable of sampling 1m³ in just 10 minutes for EU GMP compliance
- Proven long life laser technology
- Low cost solutions for multi-location facility monitoring
- Interface with software packages for comprehensive cleanroom control management



IsoAir® and IsoAir® PLUS



Lasair® III 5100 L/min



Aerosol Manifold II

MICROBIAL SAMPLING

SLIT-TO-AGAR

AirTrace®

The AirTrace Environmental Air Sampler is a state of the art slit-to-agar microbial air sampler. The sampler rotates a 150 mm agar plate 360° while maintaining the agar plate at a fixed distance from a precision cut slit. The built-in software automatically stores user ID and unique location information for each run, and an RS232 serial printer can be used to download data. A specially designed version is available for the monitoring of compressed gases.

PORTABLE SAMPLING

MiniCapt®

The MiniCapt Portable Microbial Sampler enables an operator to collect biocontamination samples throughout cleanrooms and clean air devices. Sampling intervals are completely customizable by the user with automated start and stop times per run so the entire process can be monitored. The fully autoclavable BioCapt® Impactor Head, highly sanitizable sampler case, and HEPA filtered outlet air ensure that the MiniCapt Portable Microbial Sampler does not contaminate the cleanroom environment. Monitoring of compressed gases or remote sampling of aseptic environments is possible with optional accessories.

CONTINUOUS

BioCapt®

The BioCapt Impactor Active Microbial Air Sampling Atrium enables the capture of microbiologically viable particulates on a suitable media surface. The slits in the BioCapt Impactor are precision cut to ensure laminar flow, thus maximizing collection efficiencies for viable particles in accordance with ISO 14698-1. BioCapt heads are installed into the facility at locations based upon a risk analysis.

BENEFITS ▶

- *Slit-to-agar technology using standard agar plates, 4 hour exposure times available*
- *ISO 8573 approved technology for certification of compressed gases*
- *Portable sampling at 50 L/min and 20+ hour battery life*
- *Compressed gas and remote sampling accessories, reduces the number of devices required*
- *Point of use sample heads for continuous process sampling*
- *Software controlled monitoring solutions for all microbial requirements*
- *Validated high physical and biological efficiency per ISO 14698-1*



MiniCapt®



MiniCapt® Monitoring Kit



AirTrace®



BioCapt®

LIQUID PARTICLE TESTING

LIQUID INJECTABLES

APSS

The APSS Syringe Sampling System is designed to size and count suspended particulate matter in a wide range of liquids. This system meets and exceeds all current USP <788>, EP <2.9.19>, and JP<6.07> requirements and the accompanying data collection and reporting software is 21 CFR Part 11 compliant. Contained within the APSS Syringe Sampling System is the LiQuilaz® Volumetric Spectrometer. The LiQuilaz is designed to accurately measure particles in liquids for a wide range of applications. This spectrometer monitors fluids with various refractive indexes, colors, viscosities, and operating temperatures. The LiQuilaz can be purchased separately from the APSS system.

PARTS CLEANLINESS

SURFEX®

SURFEX from Particle Measuring Systems is a completely integrated testing station designed to measure particle levels on almost any type of complex shaped part. The SURFEX combines ultrasonic extraction, particle measurement, high-purity fluidics, and automated software control to reduce testing time and therefore reduce the cost of parts testing. High throughput provides the ability to increase the number of tests performed, and therefore increases the confidence that out-of-spec parts are identified before they adversely affect final product quality.

ON-LINE

LiQuilaz®

The LiQuilaz Optical Particle Counters are volumetric instruments with a variety of sizing sensitivities as low as 0.2 microns. Volumetric particle counters offer the highest precision possible by measuring 100% sample volumes (up to 80 mL/min) so that short sampling intervals can be utilized without sacrificing statistical significance. They provide high precision analysis for most processes including WFI loop monitoring and filter performance in real-time.

BENEFITS ▶

- 100% sample volume means greater accuracy for tighter process control
- APSS System comes with the Validation Manual, providing IQ/OQ/PQ protocols
- APSS System complies with the USP; EP and JP regulations
- Complex parts can be verified for contaminating particles proving quality assurance
- Removes sample variance in testing through logical recipes
- Monitor water systems for contamination issues in advance of failure



LiQuilaz®



APSS-200 Syringe Sampling System



SURFEX®

SOFTWARE

FACILITY MONITORING SYSTEMS

Particle Measuring Systems facility monitoring software is a Windows®-based data acquisition package, providing collection, storage, and analysis of data reported by any particle counting or environmental facility monitoring devices. Our facility monitoring software solutions have been proven and validated by major pharmaceutical companies as meeting the data integrity and security rulings, including 21 CFR part 11.

The software is installed onto a central server and data is distributed to remote access terminals. Integration of other software application via an OPC Client/Server is also available.

- 21 CFR Part 11 Compliance with electronic signatures, audit trail, security authentication and data storage
- Batch Management including start and stop functionality, batch labeling and Crystal® reporting
- NEW-Windows Security authentication with Active Directory® for the Server and Network Station

PORTABLE DATA

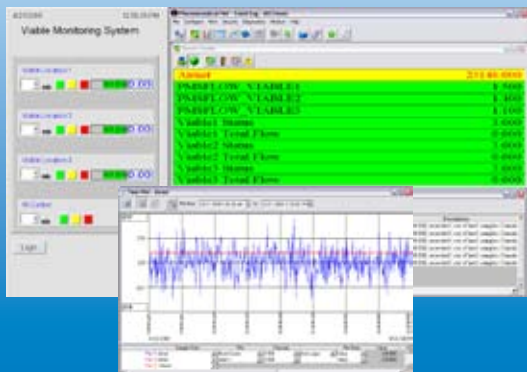
DataAnalyst

DataAnalyst is Particle Measuring Systems supporting software package for the Lasair III and Lasair II Particle Counters. DataAnalyst allows for downloading, archiving and reporting that is fully compliant with all secure data transfer requirements. The comprehensive reporting structure works with specific inputs from the particle counter and filters sampling data based upon location, date/time or product batch information. Reports can be generated to meet industry requirements. The reporting tool also gives various report formats, including certification to ISO14644, FDA/EU GMP, or FS 209 standards.

- Create cleanroom certification reports to meet ISO14644, FDA EU GMP and FS209E standards
- Long term data archiving for Lasair II/ III Particle Counters
- Centralized SQL Server® database for access to all Lasair II III particle counter data and reports across a site wide LAN

BENEFITS ▶

- *Compatible with Windows® Operating Systems*
- *Secure database format supporting 21 CFR Part 11 Compliance*
- *Real time displays for tabular, graphical and statistical data from environmental sensors*
- *Validation manual available supporting design, test and release of applications*
- *Full system reporting capabilities for batch product release*



DataAnalyst with Lasair® III

SERVICES

PROJECT MANAGEMENT

Particle Measuring Systems offers complete project management support to design, install, commission, and validate a facility monitoring system. With hundreds of projects world-wide in the pharmaceutical-biotechnology; medical device and cleanroom-related industries, we can manage your contractor or provide all services for a true turn-key solution.

SYSTEM INSTALLATION

Particle Measuring Systems have a dedicated team of system installation engineers who ensure that installation is performed on time and within budget. The ability to integrate the facility monitoring system into your timetable is important to guarantee project completion.

SITE ACCEPTANCE TESTING

Site Acceptance Testing is the final stage in ensuring the system meets design and requirement specifications. Tests are performed on site to assure installation complies with the standards and the system operates as expected. Documentation is written to GAMP® and IQ/OQ requirements. A final report of all system testing is issued to close the validation requirements.

BENEFITS ▶

- *Industry proven systems designed to meet current GMP requirements*
- *Single source for total turn-key project*
- *PMP® Certified Project Managers*
- *Dedicated team of system installation, integration and validation engineers*
- *Full training capabilities for system operation, management and understanding*
- *FAT prior to installation available in controlled conditions at our factory*
- *GAMP validation and risk assessments support system approval*

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