FACILITY MONITORING SYSTEM (FMS) SOLUTIONS

PARTICLE MONITORING FOR GMP COMPLIANT PHARMACEUTICAL MANUFACTURING

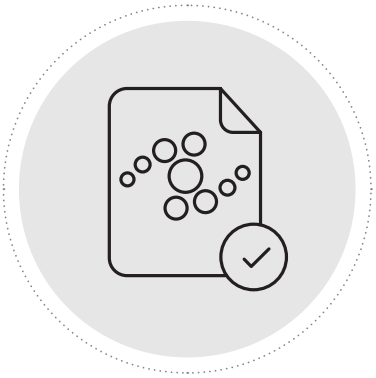
CHARACTERIZED
by ingenuity.

BECKMAN COULTER
Life Sciences

MET ONE Facility Monitoring System Solutions

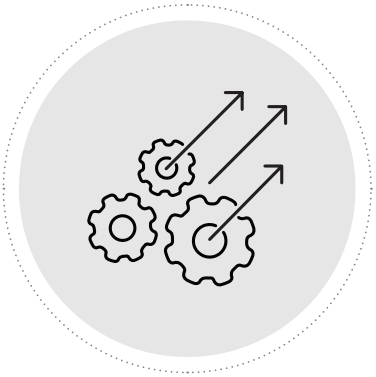
Continuous and routine environmental monitoring has never been easier or more powerful. Beckman Coulter Life Sciences offers a full suite of cleanroom Facility Monitoring System (FMS) products to enable EU GMP Annex 1, FDA, and your internal quality system compliance. Utilizing high quality MET ONE air particle counters, Beckman Coulter FMS integration software packages are easy to install, set up, validate, and operate. Utilizing years of experience in setting up complete FMS solutions around the world, our team will work with you to deliver a fully operational system on schedule and within your budget.

PARTICLE MONITORING COMPLIANCE



- Nonviable and viable particle monitoring compliant with EU GMP Annex 1 and FDA 21 CFR Part 11
- Built in Audit Logging
- Custom reports to record results
- IQ/OQ documentation for simple validation

SCALABLE SOLUTIONS



- Small scale, rapidly deployed pre-packaged software and hardware for isolators and small production line
- Batch workflow system for one or more production lines with several monitoring points
- Custom workflow optimized solutions for monitoring complex production methods across several production lines

Product Offerings

1. EnVigil PNP
2. UVO+ Standard
3. UVO+ Custom

EASE OF USE

- Graphical user interfaces available on the system or via remote access terminals
- Color coded indication of system status
- Alarms clearly identified for acknowledgement
- Single click reports to generate auditable records for compliance

On-line and Portable Particle Counters

With innovative designs specifically tailored to address the requirements of the pharmaceutical industry, MET ONE particle counters feature full ISO 21501 compliance in accordance with ISO 14644 standard adoption for all calibration parameters. Based on open-architecture communications, they integrate easily with your preferred systems. To make manual monitoring more efficient, MET ONE portable counters feature testing wizards and automatic, paperless data transfer compliant with 21 CFR Part 11. All our counters support 0.5 µm and 5.0 µm size channels per regulatory requirements and can support 4 to 6 channels to meet industrial cleanroom monitoring requirements.

MET ONE 3400 SERIES

- Available in 28.3, 50, and 100 LPM flow rates that can sample a full cubic meter of air in as little as 10 minutes.
- High performance: 0.3/0.5 µm sensitivity counter designed for ISO 21501 compliance for data accuracy and repeatability
- Flexible communications: ethernet, USB, WiFi and Serial
- Ease of use: Intuitive wizards reduce workload for classification and compliance
- 21 CFR Part 11 Compliance: allows secure USB memory stick data transfer
- Configurable for: portable, on-line or batch use

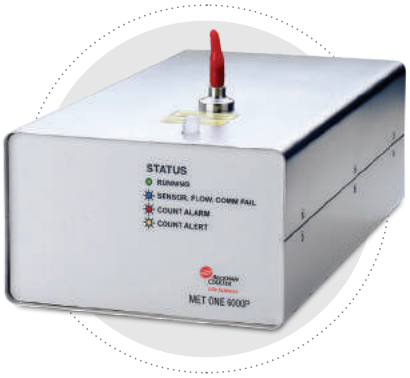
MET ONE 6000 SERIES

- High performance: 0.3/0.5 µm sensitivity counter designed for ISO 21501 compliance for data accuracy and repeatability
- Easy to integrate: multiple communication options allow easy integration into existing FMS systems
- Long life laser diode: reduced downtime and reduced cost of ownership
- Built-in flow meter: ensure data is valid during validation and monitoring
- Enhanced end user notification via built in LED: added assurance of correct sensor operation, invaluable fault finding tool

On-line and Portable Air Particle Counters

MET ONE 6000P SERIES

- All the enhanced features on the 6000 series counters and an integrated pump system
- Microprocessor controlled flow
- Reduced installation cost - no expensive distributed vacuum system required
- Flexible installation options - remote areas where vacuum isn't available



MET ONE 7000 SERIES

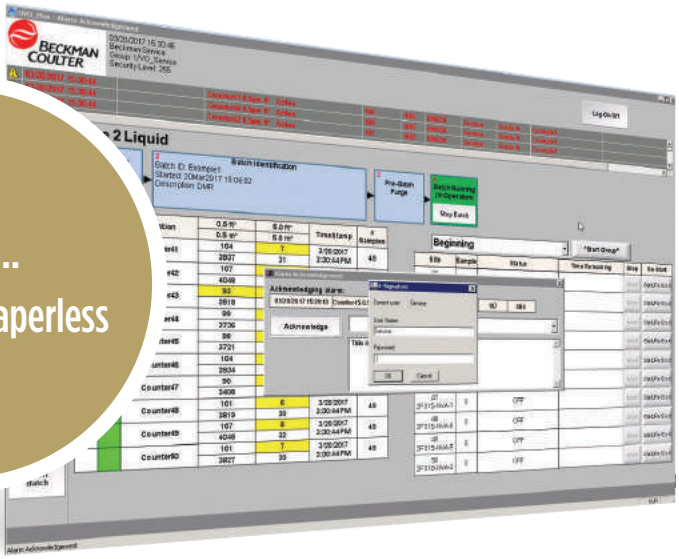
- High performance: 0.3/0.5 µm sensitivity counter designed for ISO 21501 compliance for data accuracy and repeatability
- Protected sensor: NEMA enclosure with sealed connectors and flow shut-off valve protects counter internals from accidental exposure to harmful disinfecting chemicals
- Enhanced end user notification via built in LED: added assurance of correct sensor operation, invaluable fault finding tool
- Easy to integrate: multiple communication options allow easy integration into existing FMS systems
- Long life laser diode: reduced downtime and reduced cost of ownership
- Built-in flow meter: ensure data is valid during validation and monitoring

MET ONE MANIFOLD PARTICLE COUNTING SYSTEM

- Sampling locations: allows a single 3400 series particle counter to monitor as many as 32 locations
- Continuous flow: uses a high-volume pump for continuous flow of air through all ports so particles are not lost due to fallout or surface adhesion

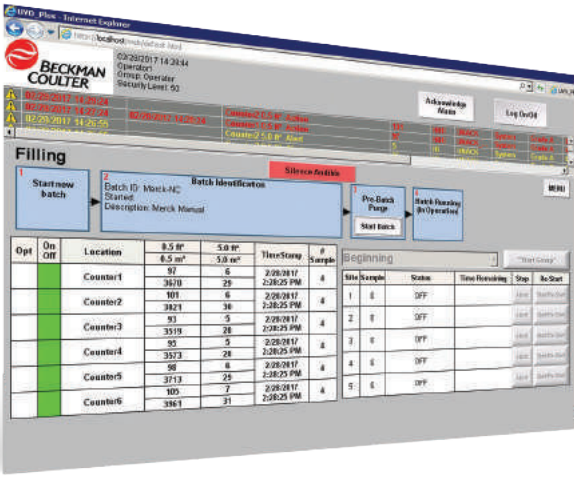
MET ONE Facility Monitoring System: Paperless – Compliance

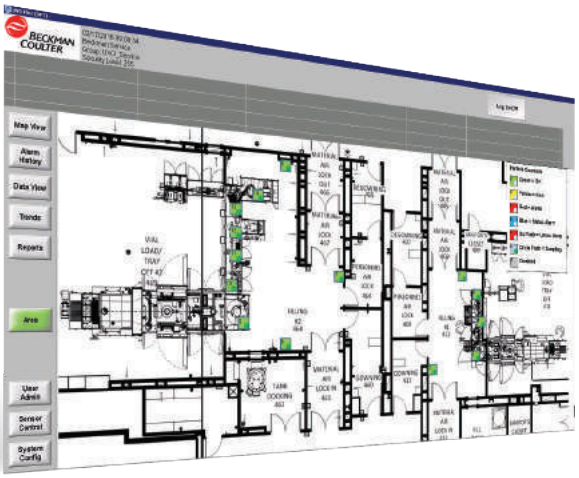
Go from here...
to here...Paperless



MET ONE UVO+ solutions set the standard of scalable on-line particle monitoring systems. Whether you run limited, short term aseptic manufacturing or multiple production lines of high-volume filling suites our MET ONE UVO+ platform adjusts to your specific requirements. Use wireless portables or dedicated on-line sensors, add environmental sensors or mix them all in a batch-driven style of operation. MET ONE UVO+ manages all data for Grade A sterile areas, including cleanroom classification, pre-production environmental qualification and aseptic on-line manufacturing.

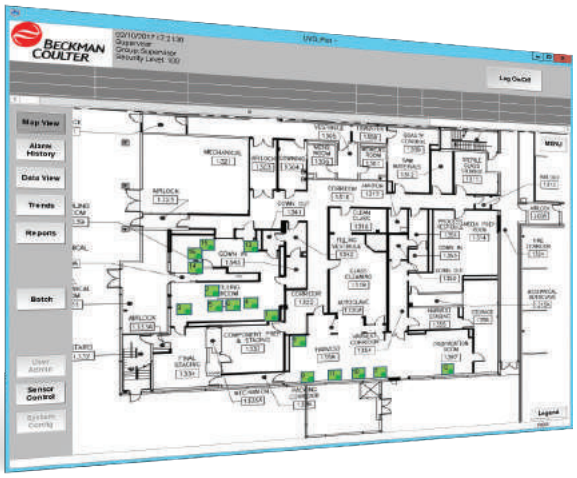
Scalable Software Solutions





MET ONE UVO+

- Windows-based SCADA (Supervisory Control and Data Acquisition) software based on the use of a real-time database
- Completely customizable user interface (map of your facility, area or tool)
- Monitor up to hundreds of locations simultaneously
- Supports 21 CFR Part 11 compliance, enabling secure data management
- Integrated secure audit trail
- Single user or client-server system
- Advanced alarming (with acknowledgment), reporting, data display (value tables, trend charts)
- Batch-driven data capture, display and reporting
- Industry standard communications protocols (analog, digital, serial, modbus RTU/TCP, OPC)



enVigil PnP

- Configure a compliant monitoring system in minutes utilizing an easy-to-use wizard
- Monitors up to 20 locations on a single screen
- Provide secure operations using Windows user names and passwords
- Includes system validation documents
- Reporting and data export
- Supports alarm panels
- Supports digital IO and analog environmental sensors (RH/Temp, Delta P)

MET ONE DATA MANAGEMENT SERVER

- Compatible with all MET ONE air particle counters
- Enables capture of enhanced features beyond just particle counts (flow, calibration dates, location, batch IDs etc.)
- Compatible with most OPC clients
- Enable secure data integration to your ERP, BMS, LIMS or other enterprise network solution
- SQL database enables simple integration and report building (simple reporting available directly from the system)

MET ONE Hardware

MET ONE 3400 PORTABLE AIR PARTICLE COUNTERS

ISO 21501 compliant portable battery-powered air particle counters offered with 0.3 or 0.5 micron sensitivity at air flow rates up to 100 liters per minute provide you with the confidence that your cleanroom is fully ISO 14644 compliant.

MET ONE 6000 SERIES REMOTE PARTICLE COUNTERS

ISO 21501 compliant fixed mount air particle counters offered with 0.3 or 0.5 micron sensitivity at air flow rates up to 28.3 liters per minute provide you with continuous monitoring capabilities that easily integrate with external software for workflow automation. These units can be integrated into a central vacuum system or provided with an internal pump for ease of installation.

MET ONE 7000 SERIES REMOTE PARTICLE COUNTERS

All the benefits of the MET ONE 6000 Series remote particle counters available in a NEMA enclosure with sealed connectors and internal flow shut off valve to prevent unintended contamination when the system is not sampling.

VIABLE AIR SAMPLING HEADS

Active microbial air sampling can be added to MET ONE FMS solutions using fixed location sampling heads that accept 90 mm petri dishes and sample on a schedule set by the user. Flow rate control guarantees a cubic meter is sampled.

MET ONE Software

MET ONE 3400 WITH SIMPLY PAPERLESS

Get 21 CFR Part 11 compliant secure records directly from your portable air particle as an easily parsed CVS or XML format or via a secure PDF. Available as a field upgrade to your 3400 series air particle counter. Offers direct upload of files via secure FTP protocol or via USB thumb drive download.

MET ONE DATA MANAGEMENT SYSTEM

Connects to remote and portable MET ONE air particle counters to automatically gather records, store them in a secure SQL database, and provide access to them via SQL or OPC connections to outside software. Also offers automatically generated custom reports to facilitate 24/7 monitoring output.

enVigil PnP

Monitors up to 10 non-viable air particle counters and 10 viable air sampling heads for rapid set up and configuration of a small FMS for use in biosafety containment hoods and on aseptic fill lines. Provides 21 CFR Part 11 compliant security and audit trail with one click reporting.

UVO+ STANDARD

Monitors up to 28 non-viable air particle counters and 28 viable air sampling heads for work flow optimized operation of batch production filling lines and processes. Allows for electronic signature on customized reports. Enables 21 CFR Part 11 compliant security and audit trail.

UVO+ CUSTOM

Work with MET ONE FMS engineers to customize UVO+ to your specific workflow needs. Define custom reports, user interfaces, alarm conditions, reports, emails, and external machine interfaces to automate your workflow and eliminate the possibility of human error. Implement electronic signatures with LDAP / Active Directory integration to simplify user management. Enables 21 CFR Part 11 compliant security and audit trail.

MET ONE Solution	Pharmaceutical Application	Industrial Application	Recommended Maximum Nonviable Sampling Locations	Recommended Maximum Viable Sampling Locations	IQ/OQ Available
MET ONE 3400 Simply Paperless	• Secure PDF straight from the counter • Automatic transfer via S/FTP to your server • Enables 21 CFR Part 11 Compliance	• Easy to parse text file straight from the counter • Automatic transfer via S/FTP to your server • Easy access to quality data	Portable to 999 locations	N/A	Yes
MET ONE Data Management System	• Gathers data from multiple portable and remote air particle counters • Stores data in a SQL database for simple retrieval or report generation • Provides OPC tags for industrial automation integration • Secure System for data storage and access		250	N/A	Yes
enVigil PnP	• Easy to operate User Interface for small scale systems • Single click reports • Automatic audit logging • Ideal for biosafety containment hoods • Enables 21 CFR Part 11 compliance	• Simple 24/7 monitoring, logging, and reporting • Provide user alarms on screen or via email or text message • Export raw data to Excel for further analysis	10	10	Yes
UVO+ Standard	• Batch optimized User Interface for running up to several lines from a single display • Custom reports and alarms • Integrated electronic signatures for starting, stopping, alarms • Integrated audit trail • Enables 21 CFR Part 11 compliance	• Batch optimized User Interface for running up to several lines from a single display • Custom reports and alarms	28	28	Yes
UVO+ Custom	• Workflow optimized user interface customized to your specific needs • Custom reports, alarms, emails, or other external interfaces (i.e. machine controls) • Electronic signatures with LDAP integration available for any point in the workflow process • Integrated audit trail with user defined audit points • Enables 21 CFR Part 11 compliance		250	250	Defined with your input based on the User Requirement Specification

Full Range of Accessories & Service Solutions

COMPLIANCE SERVICES

From assistance with SOP development for manual monitoring, to full validation documentation packages for automated systems, Beckman Coulter Life Sciences ensures that your particle monitoring program is fully compliant. We assist with URS planning, provide validation documents (IQ/OQ), and guide you through the validation testing process to final sign-off.

SYSTEM DEVELOPMENT SERVICES

When your requirements include automated monitoring, our dedicated Systems Team ensures smooth implementation.

Our service covers each phase of system deployment:

- Project management
- System requirement definition and design
- Software configuration
- Validation documentation
- System installation and commissioning

SYSTEM INTEGRATION SERVICES

Our Systems Team are also experts at integrating our instruments with your existing Enterprise Information Systems, LIMS, or Building Management System.

Let us eliminate:

- Data silos and validation for multiple systems
- Multiple reports by including non-viable and viable particle data with all other production data
- Maintenance and upgrades for multiple monitoring systems

ENVIRONMENTAL SENSORS & SYSTEM ACCESSORIES

Beckman Coulter offers a wide spectrum of accessory items to complete and perfect your facility monitoring system

- Relative humidity and temperature sensors
- Air velocity sensors
- Differential pressure sensors
- IO modules for connecting to existing sensors, door switches, tool interrupts, etc.
- Ethernet switches, touch-screen NEMA computers etc.
- Distributed vacuum systems
- Distributed DC power systems
- Variety of isokinetic sample probe options
- Multi-function alarm and stacklight modules

Compliance Experts

The MET ONE brand has years of experience meeting regulatory requirements and assisting our customers with particle monitoring systems solutions. Before published regulatory guidance, we were helping companies meet the recommendations of individual regulators. As new standards and regulations emerged, we have guided the industry and regulatory community toward practical implementations.

When your requirements include automated monitoring, our dedicated Systems Team ensures smooth implementation.

Beckman Coulter Life Sciences provides many services to help you stay abreast of current regulations:

- Regional Life Science User Group seminars
- Compliance Webinars
- On-site consulting and seminars for your particular needs

We can help you design the right particle monitoring program for improved compliance accuracy and productivity.

On-site Service

With our large global network of local service offices, we are the only company that can deliver fully compliant on-site service for your instruments, including full ISO 21501-4 calibrations. Each of our automated monitoring solutions can report the calibration status of each instrument and proactively notify you of upcoming calibrations to ensure full service compliance of all batch production and environmental monitoring measurements.

Our service agreements program provides proactive pre-scheduled on-site calibration and maintenance services, including discounts for any repairs.

Visit **beckman.com/metone** to learn more.

Why work with Beckman Coulter Life Sciences?

Our application experts have surveyed the market, looked at existing workflows and integrated our solutions at customer sites around the world. Let us help you ensure your environmental monitoring is fully compliant by leveraging our experience and our workflow solutions.

- Our products are designed to support GMP compliance.*
- We offer PROService, an internet-based application that uses a proprietary data pipeline to remotely connect to our systems in your labs to help maximize instrument uptime and service efficiency.
- We're a Danaher company, with the Danaher Business System (DBS) at its core. DBS is a proven model for achieving success. It drives every aspect of our culture and performance. We use DBS to guide what we do, measure how well we execute, and create options for doing even better. Let us help you apply DBS to your cleanroom.

Interested in talking to someone? Visit **www.beckman.com/contact-us**
Learn more about MET ONE FMS solutions at **beckman.com/metone**

Beckman Coulter Life Sciences designs, manufactures, sells, services, and markets instrument systems, reagents and services that enable new discoveries in biology-based research and development. Our products are used in the forefront of drug discovery, development and manufacturing. We offer an extensive range of products including: centrifugation, flow cytometry, particle characterization and counting, cell counting, and laboratory automation.

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The MET ONE 3400 series, MET ONE 6000 series, MET ONE 6000P series, and MET ONE 7000 Series are designed to support GMP compliance.

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