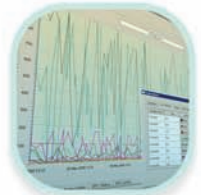


The Leading Facility Monitoring Software FMS 5.0



CONTAMINATION CONTROL

Facility Monitoring Systems



TRUST. SCIENCE. INNOVATION.

FMS 5.0, the Leading Facility Monitoring Software

TSI FMS system is an advanced, reliable, and user-friendly monitoring software suite that features a truly open architecture, supporting multiple instrument inputs from any manufacturer. Typical inputs include:

- Airborne particle counters
- Temperature and humidity sensors
- Differential pressure gauges
- Liquid particle counters
- ESD
- Airborne molecular contamination and more

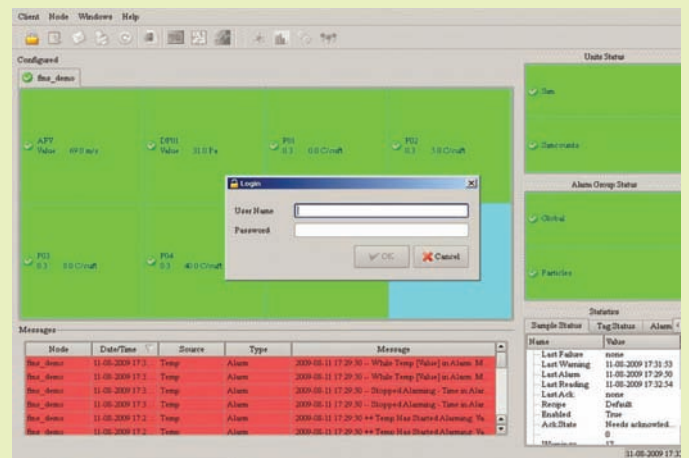
Features and Benefits

- Open architecture
- Meets all regulatory guidelines for GMP pharmaceutical production
- Fully GAMP® compliant
- Enables 21 CFR Part 11 compliance
- Built-in system redundancy
- Unique Buddy automatic hot standby option
- Back up via mirror database
- Intuitive operation
- Multi-level maps
- Notifications via email, SMS and telephone
- Display and auto reporting
- User defined reporting
- Easy data export
- Group, acknowledgement, and auto alarms
- SPC control charts

Regulatory Compliance

FMS 5.0 is compliant environmental monitoring system software for the Pharmaceutical, Medical Device and Life Science industries. All software development activities at TSI follow the ISPE GAMP® lifecycle model. FMS 5.0 is assigned current GAMP® as a configurable software. It is specifically intended for use where compliance to EU GMP Annex 1 and the aseptic processing FDA cGMP is required.

FMS 5.0 enables compliance to the FDA 21 CFR Part 11 ruling. Full audit trail, password aging and lockout after failed logins, ensures secure, tamper proof data archiving and reporting. System security is easily configurable. User groups allow users and managers appropriate levels of system access.



21 CFR Part 11: Unique user name and password

Validation

Full project based validation lifecycle documentation based on the latest ISPE GAMP® guidelines is available and tailored to meet your requirements.

- User Requirement Specification (URS)
- Functional Specification (FS)
- Configuration Statement (CS)
- Factory Acceptance Test (FAT)
- Installation Qualification (IQ)
- Operational Qualification (OQ)

Compliance with FMS 5.0



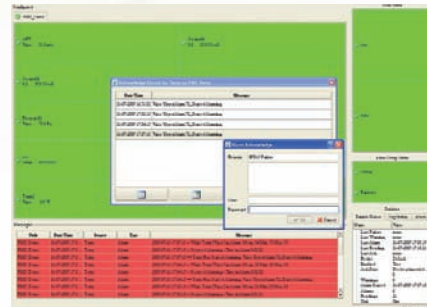
Ease of Use

An intuitive, user configurable interface means immediate visibility of real-time data. Single mouse click access to historical data and report generation leads to reduced operator training, immediate data access and improved process control.



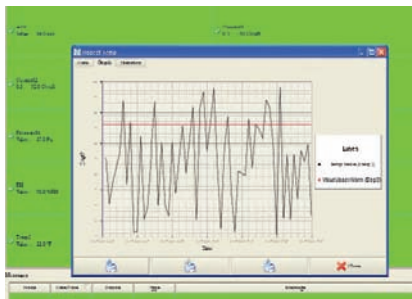
Communication

FMS 5.0 supports multiple system outputs like beacons, sounders, SMS text, email, auto-dialers and reporting are supported. Operators and managers are immediately informed of an event. This information aids in root cause investigations, process validation and improved product quality.



Graphing & Reporting

FMS comes with its own report generation tool. This allows users to create customized reports to meet your needs. Where more advanced reporting is required, third party tools can be easily deployed to use with FMS 5.0 databases. All



collected data can be turned into useful process information via powerful FMS 5.0 reporting and graphing tools. Critical reports can be generated each day, and auto reports can be created based on recorded events.

Mapping

Multi-level maps display the last recorded value for each instrument and show real-time icons in Red for Alarm, Yellow for Warning, Green for Ok and Blue for instrument failure. Simply click on the instrument icon for instant, detailed information.

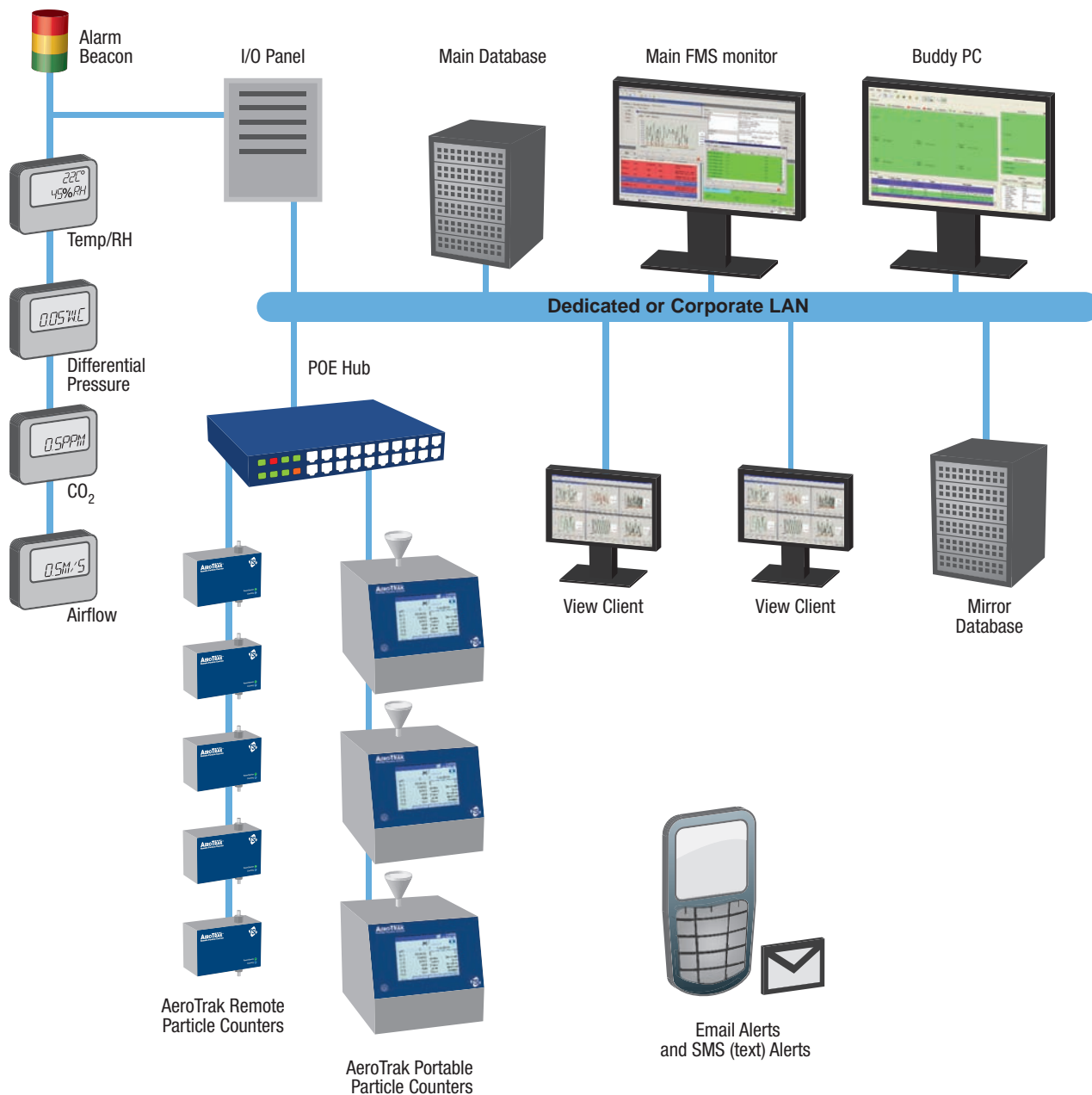


Need a Buddy?

FMS offers a unique Buddy (Automatic Hot Standby) system option for built-in system redundancy. This completely integrated back-up system resides on an alternate computer. If anything happens to the primary FMS 5.0 system, the Buddy automatically takes over, continuing to collect secure data. No manual intervention is required in the event of a computer failure, meaning no system down time, no lost validated data, and peace of mind.



Facility Monitoring System Overview:



TSI Incorporated serves a global market by investigating, identifying and solving measurement problems. As an industry leader in the design and production of precision instruments, TSI partners with research institutions and customers around the world to set the standard for measurements relating to aerosol science, air flow, health and safety, indoor air quality, fluid dynamics and biohazard detection. With headquarters based in the U.S. and field offices throughout Europe and Asia, TSI has established a worldwide presence in the markets we serve. Every day, our dedicated employees turn research into reality.

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Contact your local TSI Distributor or visit our website www.tsi.com for more detailed specifications.