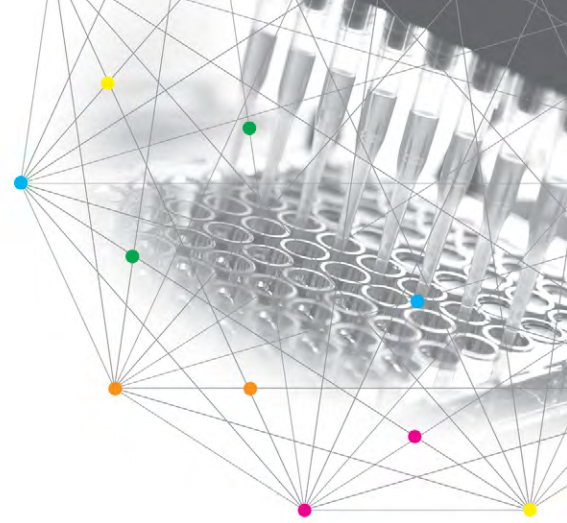


# FMS 5 FACILITY MONITORING SOFTWARE FOR LIFE SCIENCE APPLICATIONS



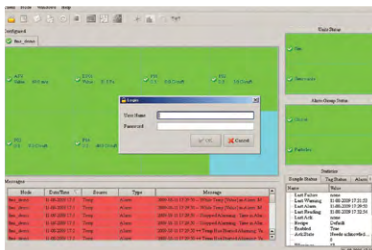
UNDERSTANDING, ACCELERATED

# COMPLIANCE AND PEACE OF MIND

## REGULATORY COMPLIANCE

FMS 5 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 is assigned current GAMP® category 4 as configurable software. It is specifically intended for use where compliance to EU GMP Annex 1 and FDA cGMP aseptic processing guidance is required.

FMS 5 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

## Robust Facility Monitoring Software

TSI FMS system is an advanced, reliable, and user-friendly monitoring software suite that features a truly distributed architecture. High availability databases and hot standby system failover functionality assures compliance and peace of mind. Multiple system inputs are supported. Typical inputs include:

- + Airborne particle counters (multiple manufacturers)
- + Analog inputs
  - + Temperature and humidity
  - + Differential pressure
  - + Air velocity
  - + 4-20mA inputs
- + Digital Inputs

## Features and Benefits

- + Built-in system and database redundancy for compliance and peace of mind:
  - + Secure, high availability, high speed SQL databases enables real-time mirror database back up
  - + Buddy option, complete system automatic failover functionality on computer failure, no manual intervention required
- + Meets all regulatory guidelines for GMP life science applications
  - + Fully GAMP® compliant
  - + Enables 21 CFR Part 11 compliance
- + Intuitive operation ensures the right information reaches the right people:
  - + Alarm acknowledgement, display, and notification (email, SMS and telephone)
  - + User configurable system views, status windows and multi-level maps
- + Demonstrate compliance using powerful user defined reporting, auto reporting and easy data export tools

## Validation

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

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

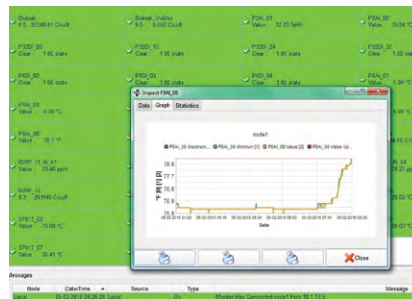
## Ease of Use

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.



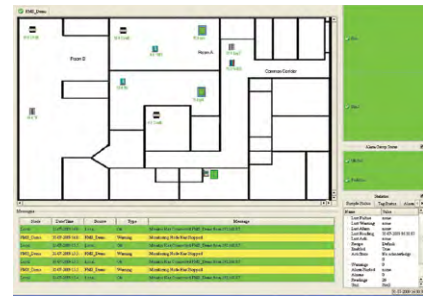
## Graphing & Reporting

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 databases. All collected data can be turned into useful process information via powerful FMS 5 reporting and graphing tools. Critical reports can be generated each day, and auto reports can be created based on recorded events.



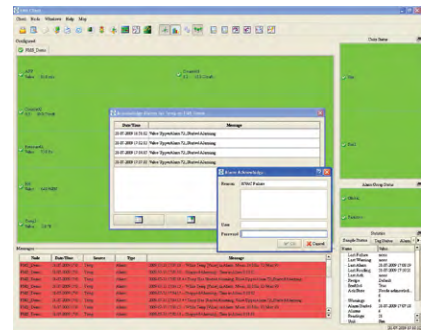
## Mapping

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 Okay and Blue for Instrument Failure. Simply click on the instrument icon for instant, detailed information.



## Communication

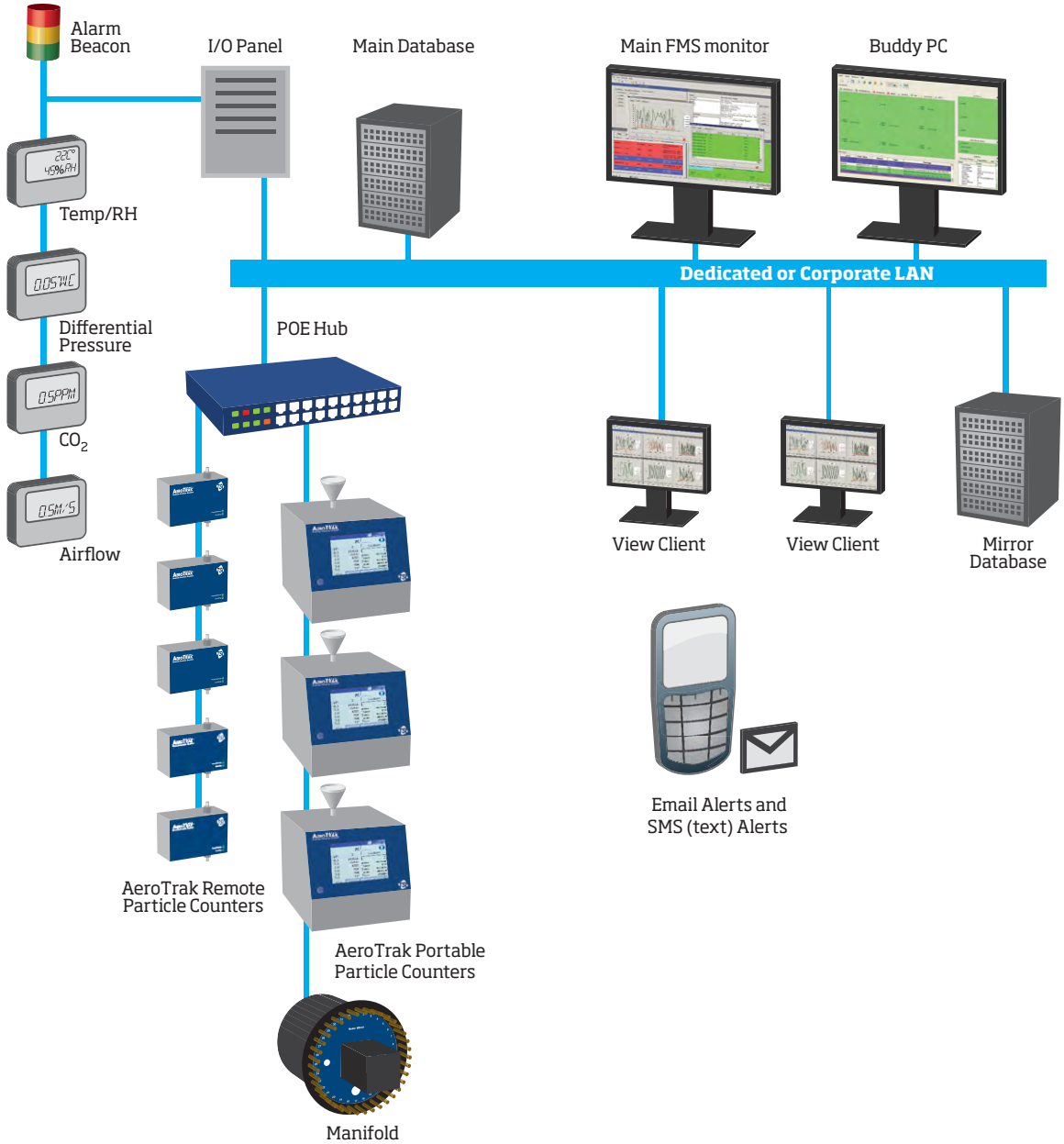
FMS 5 supports multiple system outputs like beacons, sounders, SMS text, email, auto-dialers and reporting are supported. Operators and managers are immediately informed of an event. This information aids in root cause investigations, process validation and improved product quality.



## NEED A BUDDY?

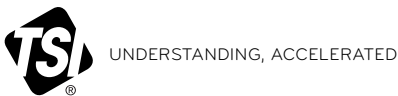
FMS offers a unique Buddy (Automatic Hot Standby) system option for built-in system redundancy. This completely integrated back-up system resides on an alternate computer. If anything happens to the primary FMS 5 system, the Buddy automatically takes over, continuing to collect secure data. No manual 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



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