# ECM ECO Monitoring

**Clean room monitoring and disinfection**

## 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.
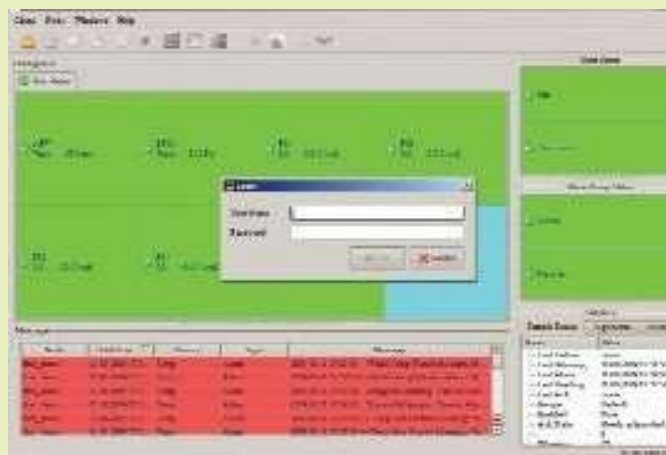


21 CFR Part 11: Unique user name and password

## 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)

## 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.
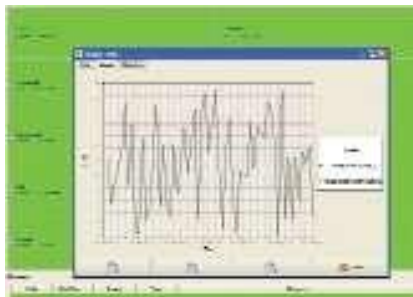
## Mapping

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.
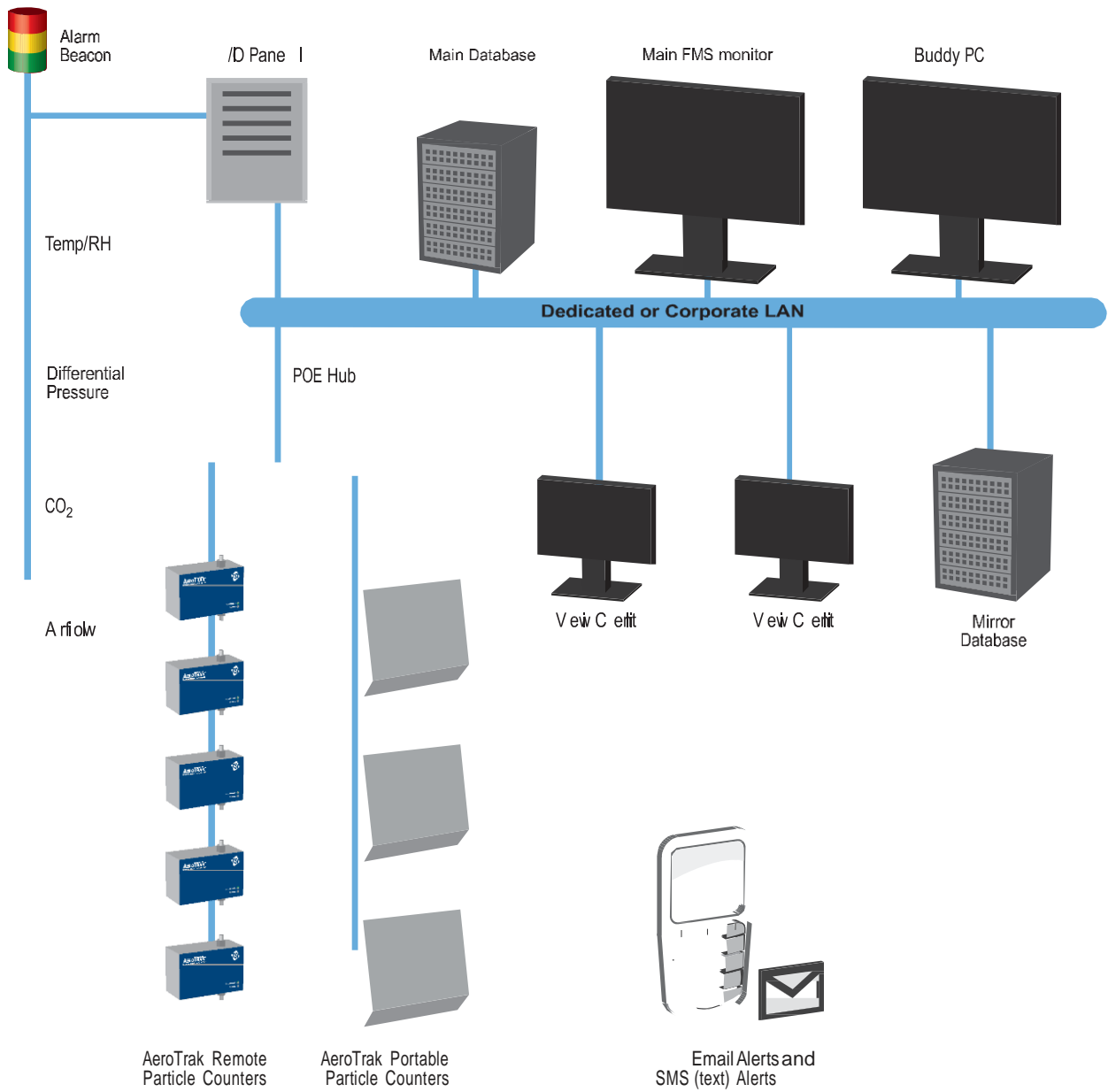
## Need a Buddy?

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:



Alarm Beacon

/D Pane l

Main Database

Main FMS monitor

Buddy PC

Temp/RH

Differential Pressure

$CO_2$

A rfiolw

**Dedicated or Corporate LAN**

POE Hub

View C eilt

View C eilt

Mirror Database

AeroTrak Remote Particle Counters

AeroTrak Portable Particle Counters

Email Alerts and SMS (text) Alerts

**BioReset**®Smart is a compact vaporized hydrogen peroxide generator, suitable to do bio-decontamination* of volume from 1 to 500 m$^3$.

Due to its small dimensions could be easily insert also in BioHazard safety cabinet, isolators or RABS.

The system should be insert inside the environment under treatment. It does not require any connection to the room. It works on stand alone mode or can be managed through a remote PLC/SCADA connection.

### Operations

- Set-up the BioReset Smart inside the area or the equipments that should be treated
- Turn off the air conditioning systems HVAC
- Secure area with warning signs for personal safety
- Set up gas distribution system inside application (fans, blowers)
- Start Bioreset Smart and leave it on inside the application for all the cycle time
- Aerate the room/application via external fresh air rinse through HVAC
- Check manually for gas residue after cycle for personnel safety before to admit anybody to enter the room

From remote control it is possible to start and stop the instrument and it is possible to receive alarm signals for different failure in the instrument.

### Optional

- Catalyser for exhaust or return air
- Special pipe dimensions on request
- Safety devices for personnel safety available
- Timer
- Mobile data logging device for process parameters
- Cable for remote connection

### Technical data

| | |
|---|---|
| Max treatable volume | max 500 m$^3$ |
| Max pump rate | 10 g/min |
| Airflow | 90 m$^3$/h |
| Remote control | through PLC o SCADA |
| Ø exit connection | 60 mm |
| Materials | stainless steel AISI 304 |
| Power supply | 230 V, 50/60 Hz, 1.7 kW |
| Dimensions (L x P x H) | 350 x 450 x 240 mm |
| Weight | 10 kg |

Activation and circle managing with "touch screen" PLC

**BioReset**®Plus is a mobile vaporized hydrogen peroxide generator equipped with wheels suitable for the bio-decontamination* of volume form 1 a 500 m³. Full automatic instrument with printer and "touch screen" display for a comfortable and user friendly memorisation of recepies and data. It is possible to generate different account with username and password.
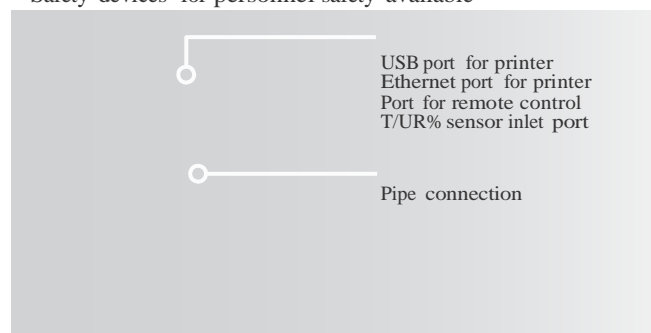
This generator must be used only outside the environment that should be treated. It is necessary to have feed-through for inlet and outlet. BioReset Plus is also able to run cycles in full automatic mode through its Siemens S7-300 PLC. The T/UR% probe (optional) drives the cycle through the presented parameters. The printer, USB or Etehernet connected, gives parameters report printout.

### Operations

- Move gas generator outside the application and connect to the inlet ports (tri-clamp)
- Turn off air condition system (HVAC) of the application
- Secure area with warning signs for personnel safety
- Set up gas distribution system inside application (fans, blowers)
- Choose the recipe and start BioReset Plus system cycle The PLC controls and storages all relevant cycle parameters of bio-decontamination circle
- Aeration of room/application via external fresh air rinse or through BioReset Plus
- Check manually for gas residue after cycle for personnel safety before to admit anybody to enter the room

### Optional

- T/UR% probe
- Catalyzer for exhaust or return air with internal blower on request
- Special pipe dimensions on request
- Safety devices for personnel safety available

USB port for printer
Ethernet port for printer
Port for remote control
T/UR% sensor inlet port

Pipe connection

### Technical data

| Max treatable volume | max 500 m³ |
|---|---|
| Max pump rate | 10 g/min |
| Airflow | up to 200 m³/h adjustable |
| Ø exit connection | 80 mm |
| Materials | stainless steel AISI 304 |
| Power supply | 230/240 V, 50/60 Hz, 3.7 kW, 24V DC |
| Dimensions (L x P x H) | 800 x 400 x 620 mm |
| Weight | 85 kg |

**BioReset**®Pro is the "buit in" model of this vaporized hydrogen peroxide vaporizer, designed and built for customers who needs a bio-decontamination* system on board for isolators, pass-boxes, RABS, filling line machines or washing machines.

Bioreset Pro is fully controlled from the PLC of the host instrument. The generator is equipped with HEPA filter to clean the inlet air.
Bioreset Pro is designed to be integrated in isolators, filling lines, biohazard safety cabinet, pass-boxes.
Amira helps the development and integration of the instrument inside the application, the control of signals and alarms of the generator.

### Operations
BioReset Pro sucks air through the HEPA filter and generates a vapor of hydrogen peroxide that exit form the instrument pushed from the 200 m3/h blower.
The final aeration, the distribution inside the environment, the control of the cycle is demanded to the customer equipment.

### Optional
- Catalyser for exhaust or return air
- Special pipe dimensions on request
- Safety devices for personnel safety available

HEPA filter

Pipe connection

Port for remote control
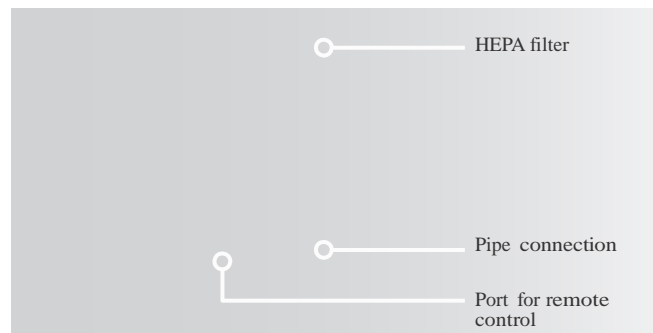
### Technical data

| Max treatable volume | max 500 m³ |
|---|---|
| Max pump rate | 10 g/min |
| Airflow | up to 200 m³/h adjustable |
| Materials | stainless steel AISI 304 |
| Power supply | 230/240 V, 50/60 Hz, 3.7 kW, 24V DC |
| Dimensions (L x P x H) | 315 x 603 x 300 mm |
| Weight | 25 kg |