



GMP Monitoring System for Rooms and Processes

FactoryLayer Environment Monitoring System

**Electronic data recording and archiving
in compliance to FDA 21 CFR Part 11 and
EU Annex 11 guidelines**

The System



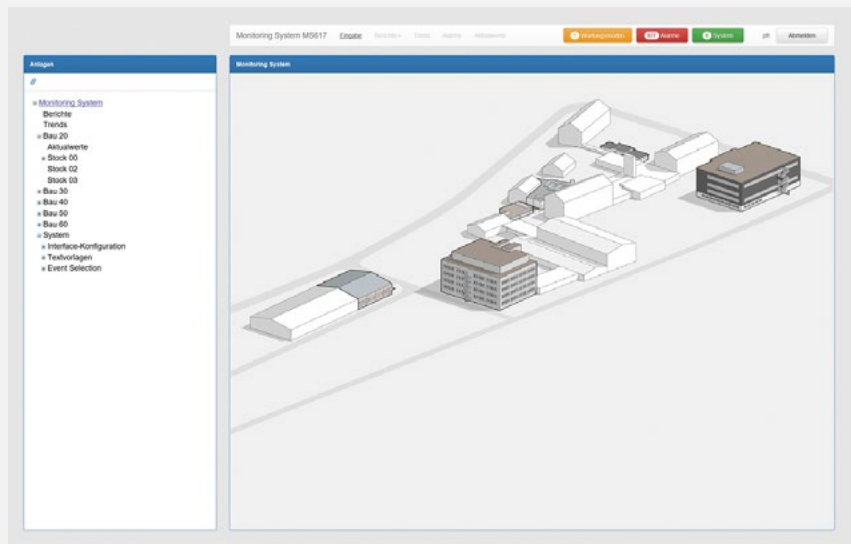
User-friendly GMP Monitoring System for monitoring, trend recording, alarming and logging GMP-critical values. It is possible to collect and record different physical measured variables such as temperature, pressure, humidity, airflow and number of particles.

The system is implemented in compliance with FDA 21 CFR Part 11 and EU Annex 11 regulations.

The scope of supply consists of the turnkey version including qualification testing in accordance with GAMP5 comprising qualification testing stages DQ, IQ and OQ. Thanks to the modular structure and extensibility of the components used, it is also possible to integrate measuring points from existing systems made by third-party manufacturers. Deploying future-oriented Web technology yields a system that meets any requirements of operation and extensibility.

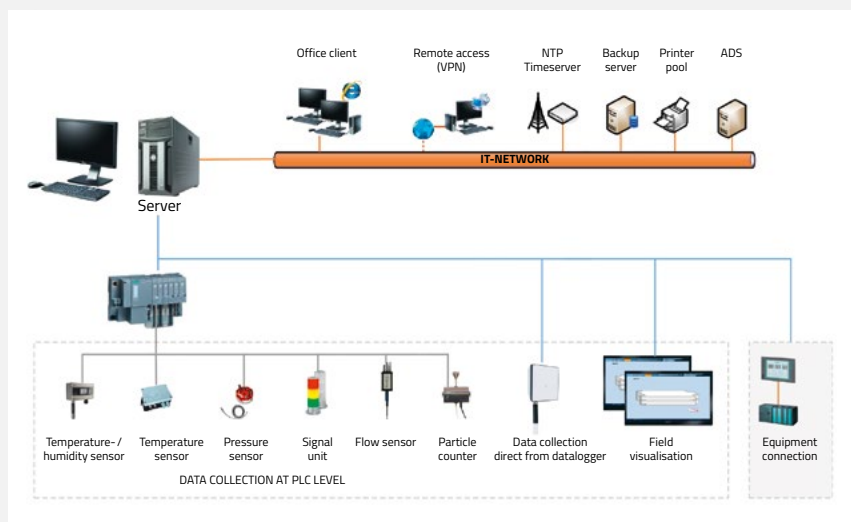
Clear operation

- Simple, intuitive system handling
- Little time and effort needed for support
- Clear signaling of limit value violations
- Easy analysis of historical measured value records



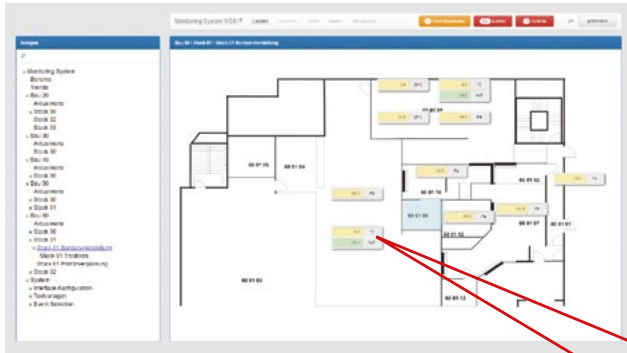
Facts

- Realtime
- Alarming
- Reports
- Trend Representation
- Audit Trail
- Remote Alarming
- Web Access
- Remote Access
- Interfaces
- Data Backup
- Link to IT network



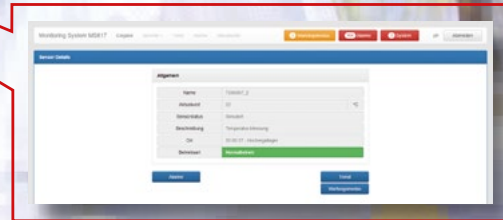
The operation of the monitoring's user interface is adapted to Windows standards.

The User Interface



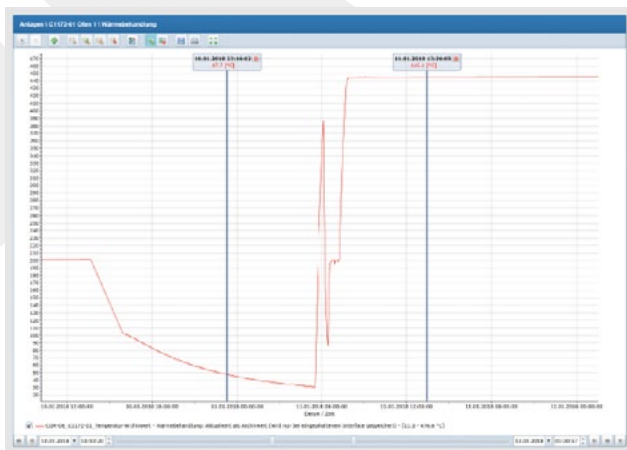
Display of the Sensor Measured Values

Depending on the size of the building to be monitored and the number of sensors, operators use the main screen to get to the story or room view. This view shows a floor plan of the room with all the measuring points and possible alarms.



Detailed Information for Each of the Sensors

With just a mouse click, you get from the floor plan with the displayed measured value to the detailed information of the corresponding sensor. The relevant settings in addition to the individual trend and the entry in the alarm list are available as information for the analysis. With appropriate authorization, it is possible to customize the settings of each individual sensor on a user-defined basis.



Recording the Data

All the measured values are recorded as trends. In this connection, it is possible to group trend diagrams in accordance with a functional grouping. Authorized users can generate their own individual user-defined trend configurations from the recorded values at any time. You can print out diagrams for a time range that can be defined in any way you like.

ID	Alarm	Warning	Alarm	Group	Comment	Handled	Group
1027	Warning	Warning High Sensor: L26154102 Bereich: 20.05.02 - Druckluftdruck	26.03.2018 11:30:50	26.03.2018 14:12:55			MSE17
1028	Warning	Warning High Sensor: L26154102 Bereich: 20.05.02 - Druckluftdruck	26.03.2018 11:30:50	26.03.2018 11:30:50			MSE17
1029	Warning	Warning Temp Sensor: T200007_2 Bereich: 20.06.07 - Hochregaltemperatur <=> 15	26.03.2018 11:30:50	26.03.2018 14:12:55			MSE17
1030	Warning	Warning Temp Sensor: T200007_3 Bereich: 20.06.07 - Hochregaltemperatur <=> 15	26.03.2018 11:30:50	26.03.2018 14:12:57			MSE17
1043	Warning	Warning Temp Sensor: T200007_4 Bereich: 20.06.07 - Hochregaltemperatur <=> 15	26.03.2018 11:30:50	26.03.2018 14:12:56			MSE17
1044	Alarm	Warning High Sensor: L26154102 Bereich: 20.05.02 - Druckluftdruck	26.03.2018 11:30:50	26.03.2018 11:30:50			MSE17
1045	Alarm	Warning High Sensor: L26154102 Bereich: 20.05.02 - Druckluftdruck	26.03.2018 11:30:50	26.03.2018 11:30:50			MSE17
1053	Warning	Warning Temp Sensor: T200007_5 Bereich: 20.06.07 - Hochregaltemperatur <=> 15	26.03.2018 11:30:50	26.03.2018 14:12:57			MSE17
1071	Alarm	Temp Alarm 1110	26.03.2018 12:04:12	26.03.2018 11:30:57			MSE17
1072	Warning	Warning Temp Sensor: T200006 Bereich: 20.06.00 - Partikelanzahl im Saugrohr	26.03.2018 11:30:50	26.03.2018 14:12:56			MSE17

Monitoring and Alarming

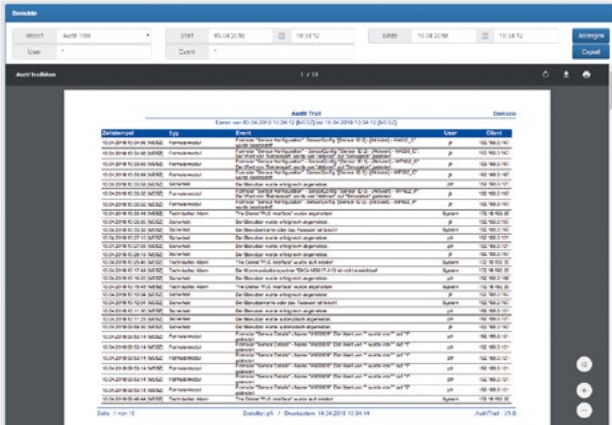
You can set any alarm limit values you like for each measured value. If an alarm limit value is exceeded for longer than a freely selectable time, the system triggers an alarm. All alarms are listed in the alarm list. Authorized users can acknowledge alarms and add comments on them. In a similar way to trends, the alarm list also includes a History function that allows you to view previous alarms.

The Output

Data Conditioning / Reporting System

The system offers a wide range of functionality for data conditioning and reporting in various representations. The GMP Monitoring System enables the following reports:

- Trend report configuration
- Alarm and audit trails
- General statistics
- Disturbance reporting statistics
- Delimited file export of GMP data for offline analysis



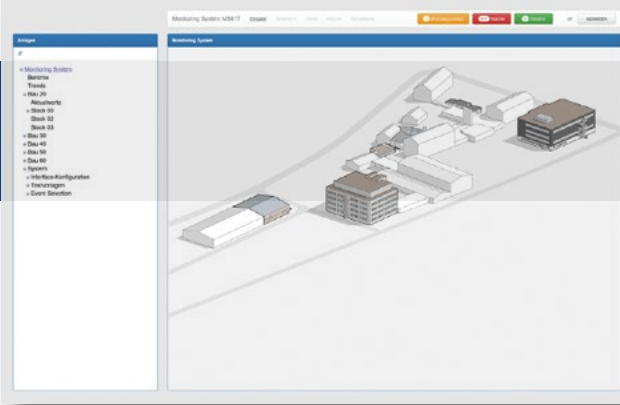
Ergebnis	Benutzer	Obj	Rev	Status	Benutzer	Komponente
08:17:2008 12:14:56	LogIn				admin	
08:17:2008 08:09:16	MESSE	LogIn			GMP-MON-20	
08:17:2008 02:02:00	MESSE	Backup auf C:\GMP-MON\gmpmon-backup			GMP-MON-20	
08:17:2008 03:00:00	MESSE	Backup auf C:\GMP-MON\gmpmon-backup			GMP-MON-20	

Ergebnis	Benutzer	Benachrichtigung	Ergebnis	Komponente	Benutzer
08:17:2008 12:14:56	MESSE	MESSE: Parameter-Veränderung (Parameter-Setpoint)	OK	in-Datenbank	admin
08:17:2008 12:14:56	MESSE	MESSE: Parameter-Veränderung (Parameter-Setpoint)	OK	in-Datenbank	admin
08:17:2008 12:14:56	MESSE	MESSE: Parameter-Veränderung (Parameter-Setpoint)	OK	in-Datenbank	admin

Objekt	Objekt	Objekt	Objekt	Objekt	Objekt	Objekt	Objekt
13.00.000	13.00.000	13.00.000	13.00.000	13.00.000	13.00.000	13.00.000	13.00.000
13.00.000	13.00.000	13.00.000	13.00.000	13.00.000	13.00.000	13.00.000	13.00.000

Web Access to GMP Monitoring

Using Internet Explorer, authorized client stations have Web access to the functionality of GMP Monitoring at any time.



Turnkey project supply as total contractor:

- User requirements analysis
- Planning and realization
- Installation & start-up
- Qualification and training



RETEL[®]
Engineering | Software | Automation

RETEL Neuhausen AG
Rundbuckstrasse 6
CH-8212 Neuhausen a. Rhf.
Phone +41 52 533 96 00
info@retel.ch
www.retel.ch