

OpreX™ Data Acquisition

Environmental Monitoring System

Bulletin 80P01A03-01EN



OpreX™ Environmental Monitoring System

Environmental Monitoring Compliant with Pharmaceutical Regulations

OpreX Environmental Monitoring System collects, measures, and stores data such as temperature and humidity as well as other management data to monitor the environment in pharmaceutical manufacturing area, quality control area, and storage area.

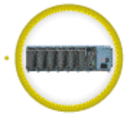
Click here for more information about OpreX EMS!
(Duration：2 and half minutes)

Ensure and Improve your Data Integrity!

OpreX™ Environmental Monitoring System


Panel mount GX Paperless recorder


Portable GP Paperless recorder


GM10 Data recording unit

Manufacturing area

Temperature | Humidity | Differential Pressure | Particulate

Clean Room

Production Equipment

Reactor, Sterilizer
Granulator, Blender

Quality Control area

Temperature | Humidity

Stability Testing Equipment

Temperature and Humidity Test Chamber

Cold Storage

Freezer
Refrigerator

Storage area

Temperature | Humidity

Raw Material

Receiving

Shipping

Distribution

Hospital
Wholesale
Logistics Center

Product

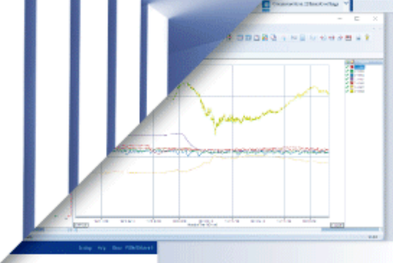
Data Integrity

Meets ALCOA+ requirements

Attributable
Legible
Contemporaneous
Original
Accurate
Complete
Consistent
Enduring
Available



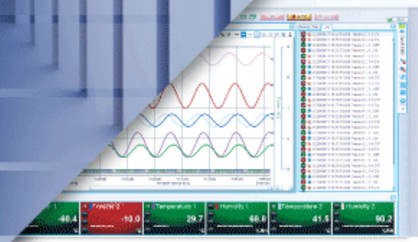
Recorder setting



Data file display



Recorded data file management



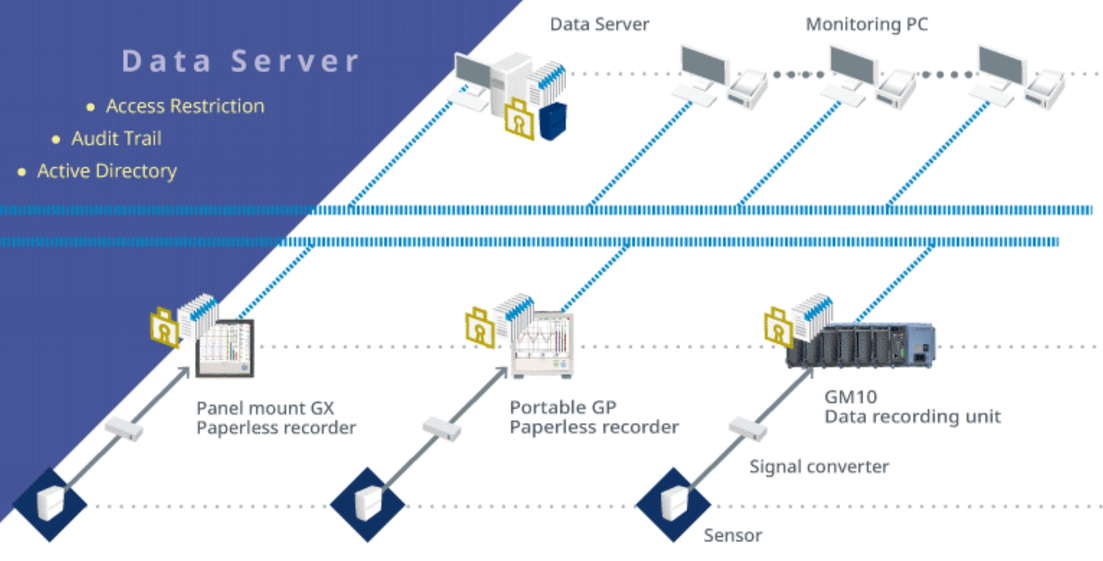
Real-time monitoring

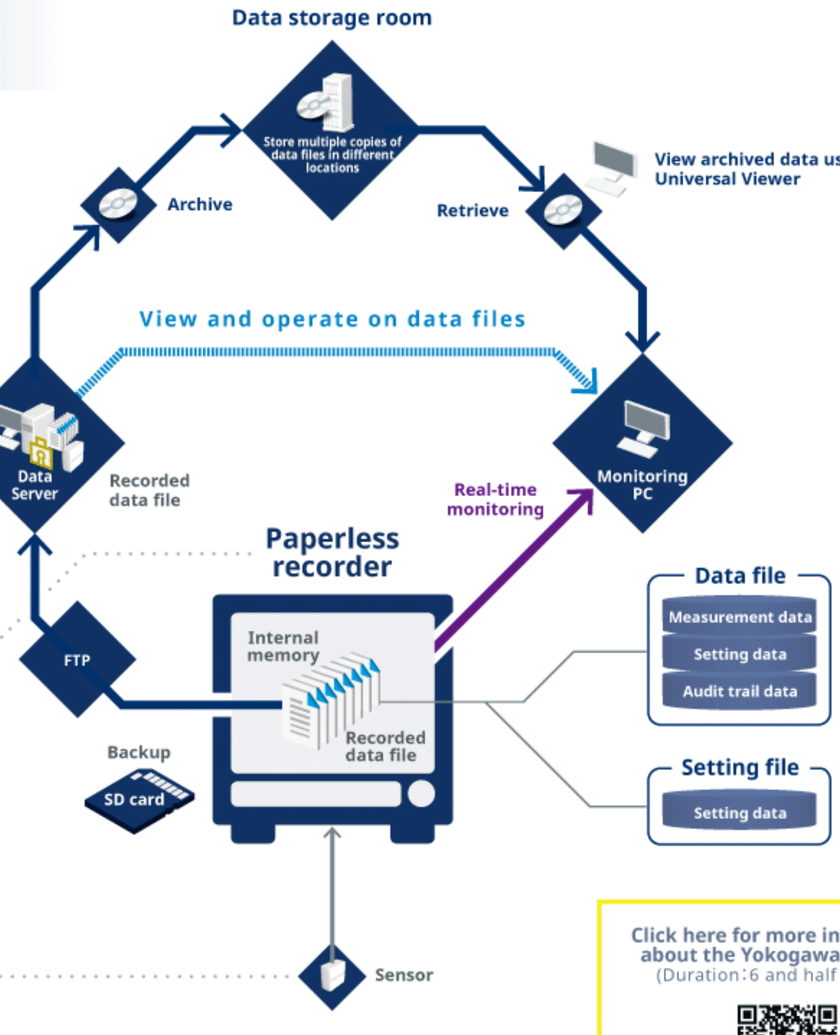
Support for PIC/S GMP·Part11·Annex11

- Validation Plan (QPP)
- Functional Specification (FS)
- Hardware/Software Specification (HSS)
- FAT Plan/Report (FTP/FTR)
- SAT Plan/Report (STP/STR)
- Test Report, Calibration Certificate
- Instruction Manual

Data Server

- Access Restriction
- Audit Trail
- Active Directory

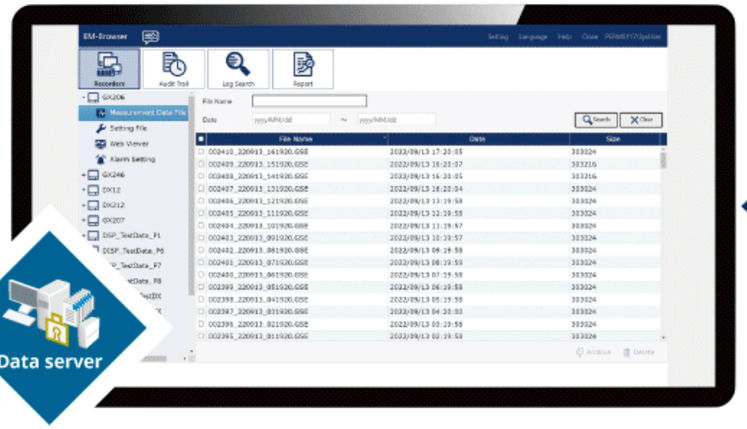




Click here for more information about the Yokogawa recorder!
(Duration：6 and half minutes)

Data Collection and Long-Term Storage

Long-term storage of collected data in recorders that are FDA 21 CFR Part 11 compliant

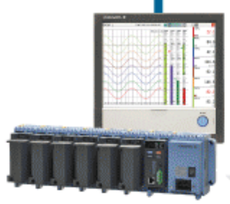


Data server

Data Management Package controls access to the Data Server.
File operations performed by any user logged into the Monitoring PC are recorded in the audit trail.

Login

Transfer



Our recorders are compliant with FDA 21 CFR Part 11, and the recorded data can be saved in a file format that prevents tampering of the data. Data files are stored long-term in the data servers that allow access only to authorized users.

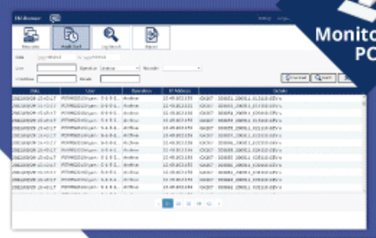


Each sensor
(Temperature, humidity, differential pressure, etc.)

Administrator operations

- File operation (Archive, Delete)

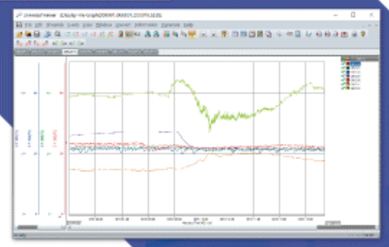
Monitoring PC



Operator operations

- View the recorded data

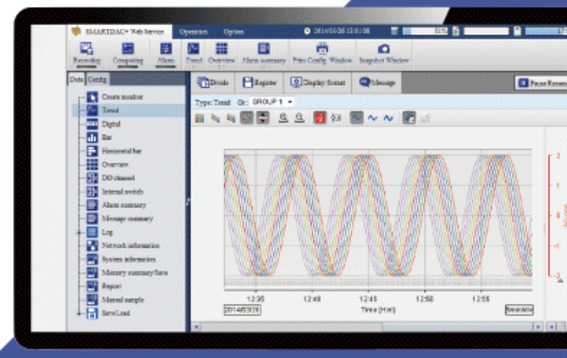
Universal Viewer



Real-Time Data Monitoring

Monitor measured data and alarms using the monitoring software





Real-time monitoring software

Display measured data in real time.
Measured data abnormality is reported with a visual alarm (red blinking) as well as a buzzer sound.

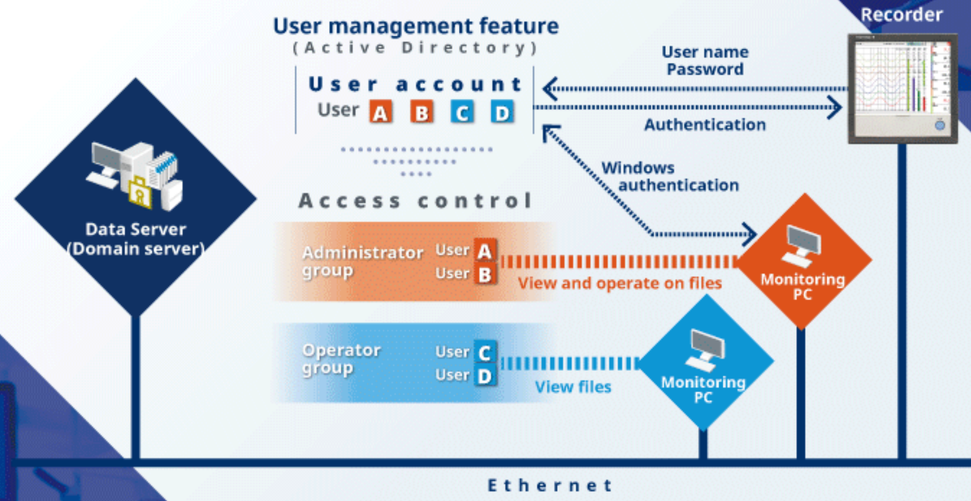
Web application

Users can monitor the operation status and measured data on recorders through a web browser in real time.

Centralized Management for Login User

Centralized management of user names and passwords using servers on the network is possible through Active Directory

- Centralized management of user name/password in Data Server and recorders
- User login access control



Exceptional Usability and Functionality for Data Management

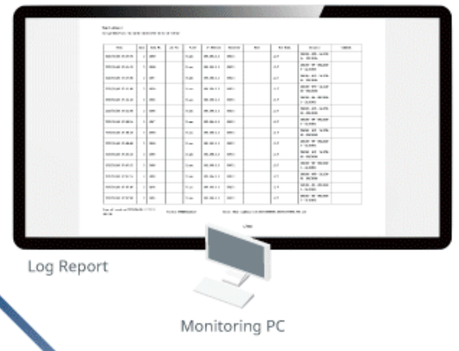
Audit Trail Function

- All operations on records by an authorized and logged-in user are automatically recorded and saved in the audit trails.
- Data server and recorder audit trails are listed.
- The recorded audit trail can be downloaded as a PDF file.



Log Search Function

- Displays a list of "Alarms," "Marks," "Image Marks," and "Operation History" logs saved for each recorder.
- You can search logs using keywords and download log reports.



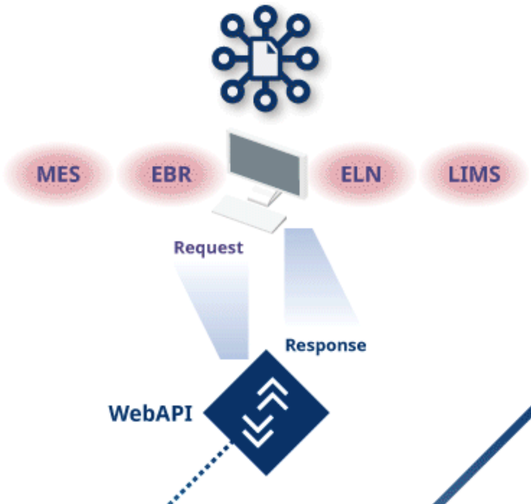
Report Function*

- A Report is generated based on the data Recorded from multiple recorders.
  Daily Report/Monthly Report/
  Alarm Report/Periodic Report/Trend Report



External Interface Function*

- Provides trend data and periodic statistical data to other systems.



Integrated management of data collected by multiple recorders



*These functions are optional.

Packages and service

Data Management Package

Centralized management of the recorded data file

Access Control

Users are assigned to groups and are given access privileges based on the group they belong to. Only authorized users can login to the system and search and browse through data.



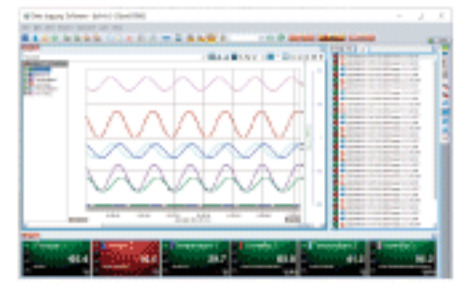
Validation Documents

Prepare validation documents based on the risk-based approach (GAMP5)

Real-time Monitoring Software

Monitor measured data in real time

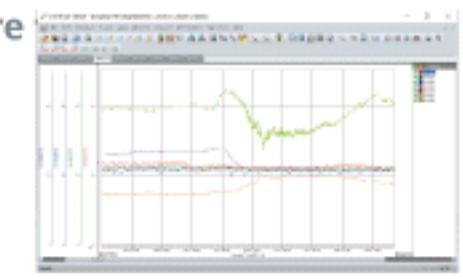
- Measured value display (Trend display / Digital display)
- Alarm notification on the screen
- Monitor data for each measurement group



Universal Viewer

Dedicated viewer software browsing recorded data

- Display recorded data
- Supports latest OS and offers best viewing quality
- Supports 8 languages



Paperless Recorder SMARTDAC+Series

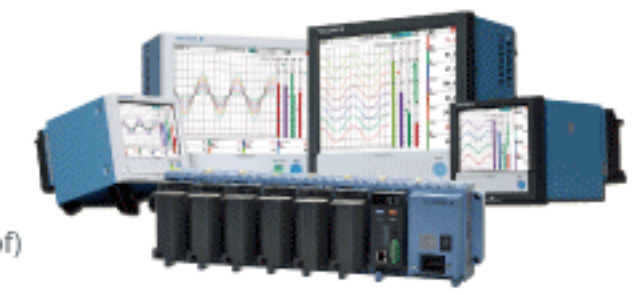
Measure and record a variety of data

- Add I/O modules as needed
- Wide variety of powerful display functions
- A full range of network functions

Advanced Security Function

Electronic recording of data is compliant with pharmaceutical regulations

- Logical security
- Audit trail function
- Secure data storage in binary format (fraud proof)
- Dedicated viewer software





Through the comprehensive OpreX portfolio of products, services, and solutions, Yokogawa enables operational excellence across the enterprise.

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