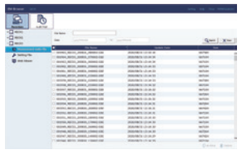
Packages

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

Audit Trails

All file operations by an authorized user are recorded in the audit trail.

- File operations (Archive, Delete)
- Backup and Restore

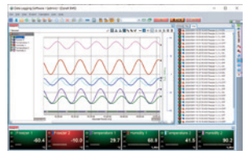
Configuration Tool

Adminstrator configures the Data Management Package using this tool.

- Register new recorders
- Register new users
- License management

GA10 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 7 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

OpreX™ Yokogawa achieves operational excellence by providing products, services, and solutions based on the OpreX comprehensive brand that cover everything from business management to operations.

YOKOGAWA ELECTRIC CORPORATION
Life Innovation Business Headquarter
http://www.yokogawa.com/
E-mail: Inquiry_LI_DMP_GLsales@cs.jp.yokogawa.com

YOKOGAWA CORPORATION OF AMERICA
http://www.yokogawa.com/us/

YOKOGAWA EUROPE B.V.
http://www.yokogawa.com/eu/

YOKOGAWA ENGINEERING ASIA PTE. LTD.
http://www.yokogawa.com/sg/

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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.

Data Integrity

Meets ALCOA+ requirements

Attributable
Legible
Contemporaneous
Original
Accurate
Complete
Consistent
Enduring
Available

Recorder setting

Data file display

Recorded data file management

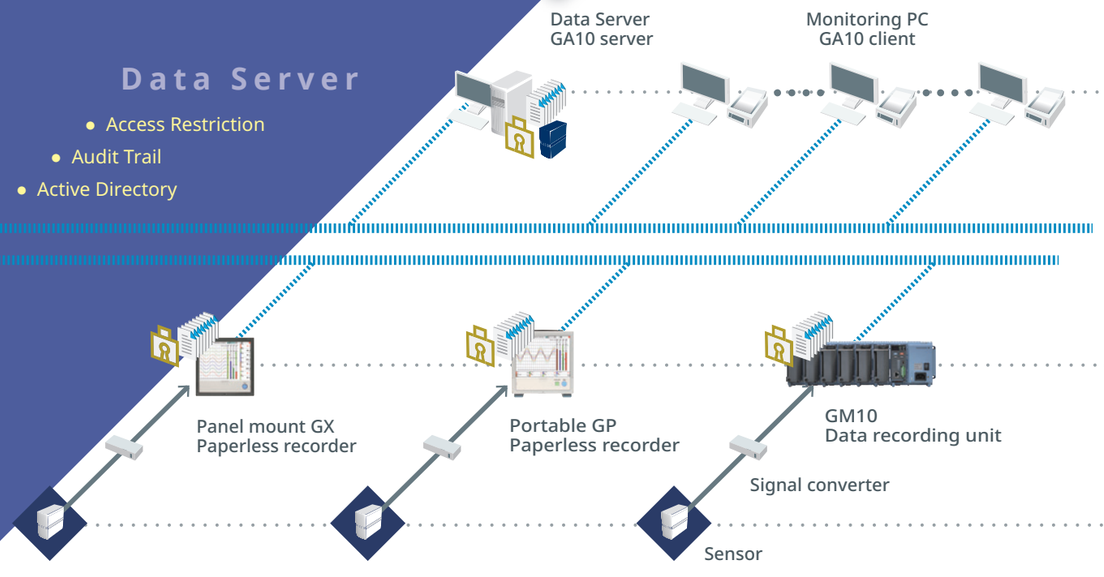
Real-time monitoring

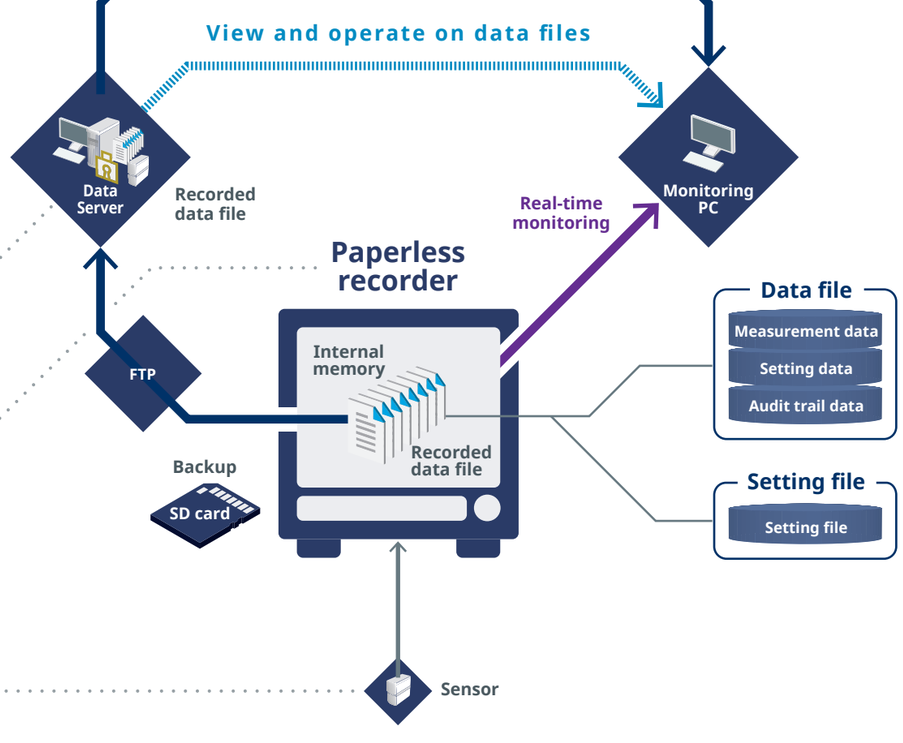
Support for GAMP5, CSV of PIC/S GMP Annex11

- 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

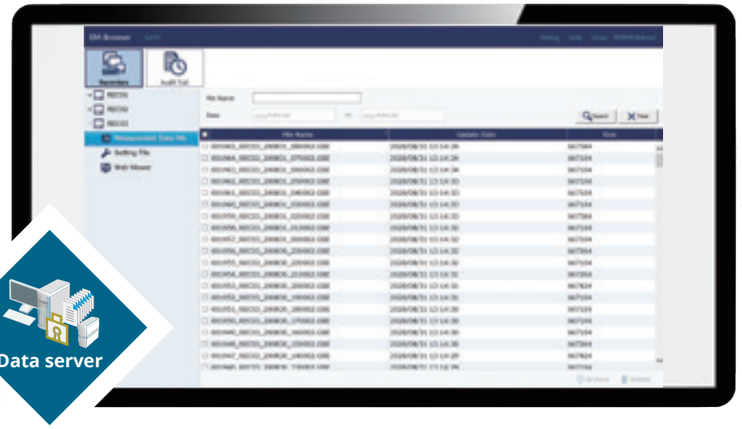
- Access Restriction
- Audit Trail
- Active Directory





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, pressure differential, etc.)

Administrator operations

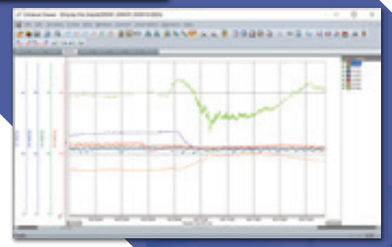
- File operation (Archive, Delete)

Monitoring PC

Operator operations

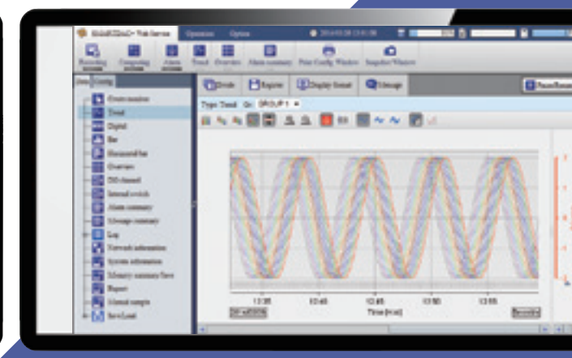
- View the recorded data

Universal Viewer



Real-Time Data Monitoring

Monitor measured data and alarms using the monitoring software



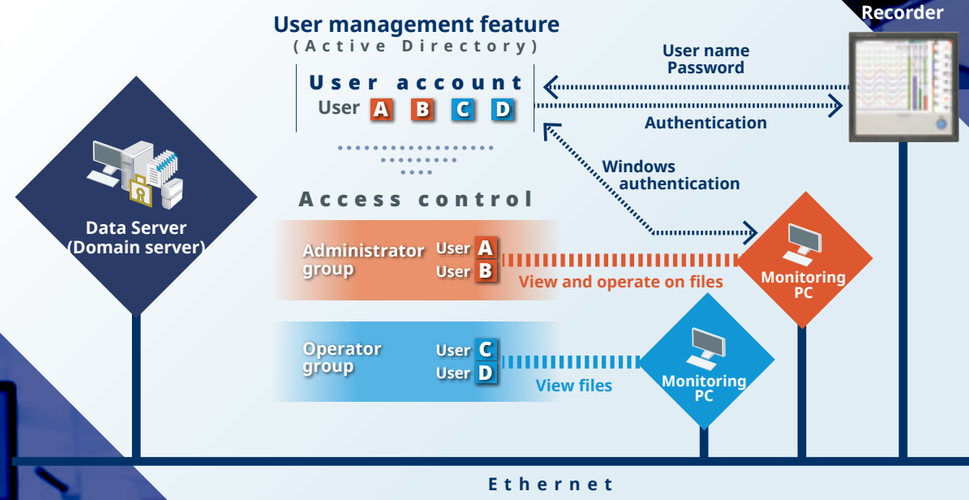
GA10
Real-time monitoring software

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