



## Advanced Security Functions with 21 CFR Part 11 compliance

# 21 CFR Part 11 Compliance

## with advanced security function option (/AS)

New advanced security option for SMARTDAC+ GX/GP/GM series provides secure and traceable data management that is often used in pharmaceutical, biotech, healthcare and medical device applications. Advanced security option meets the rigorous requirements of FDA regulation 21 CFR Part 11. In addition, advanced security option can also be used for applications that require extra layer of security, data management and electronic signature.

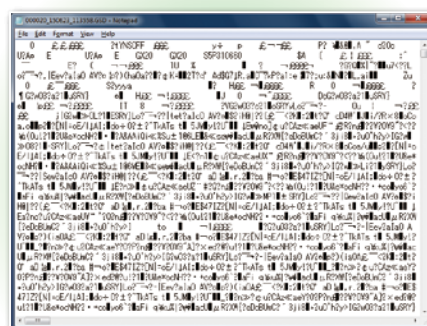


FDA 21 CFR PART 11

## 21 CFR Part 11 Electronic records regulation

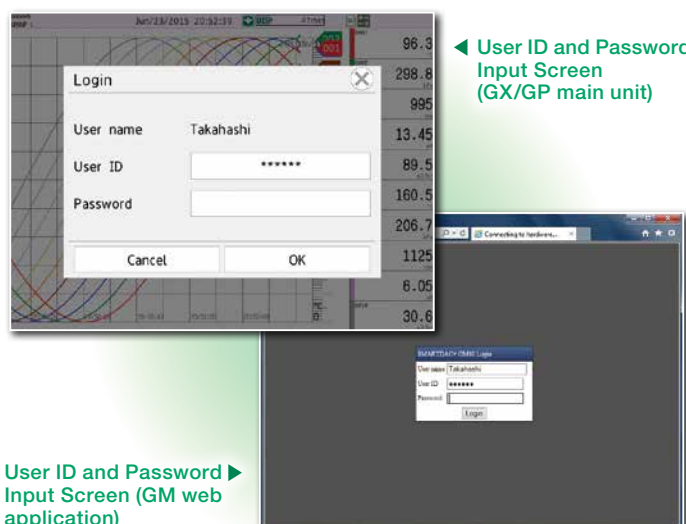
### Secure electronic records

Measured data, settings, and operation logs, are saved to a single encoded binary file. Encoded data in binary format offers a high level of security because it cannot be opened in most text editors. If the data files are damaged or tampered with, SMARTDAC+ Standard Universal Viewer software will identify the nonconformity and notify the user accordingly.



Binary Data Display

### Controlled system access

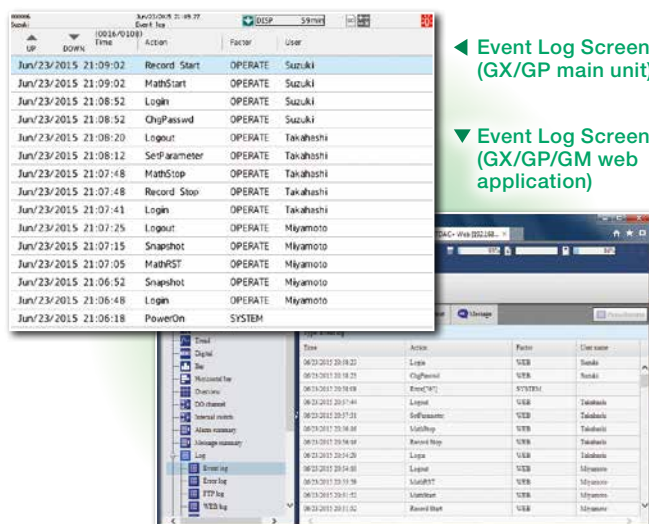


User ID and Password Input Screen (GX/GP main unit)

User ID and Password Input Screen (GM web application)

Up to 100 users can be registered into the system and each user can be assigned individual access rights. System administrator access allows for registration of other users and individual login rights which allows limited access for specific users. Username, User ID, password and password expiration can also be assigned for each user. Active directory allows for user name and password to be managed through a centralized server on the network.

### Audit trail function



Event Log Screen (GX/GP main unit)

Event Log Screen (GX/GP/GM web application)

Setting changes and operation logs are automatically recorded and saved into a file along with measured data. The logs can be viewed on the GX/GP main unit and GX/GP/GM web server (files in internal memory only). Or, the logs can be viewed on SMARTDAC+ Standard Universal Viewer software (files stored on SD memory card or external storage media).



# 21 CFR Part 11 *Electronic signature regulation*

## Electronic signature (data record signing) function

An electronic signature can be added once measured data is loaded on the GX/GP main unit (files in internal memory only), or SMARTDAC+ Standard Universal Viewer software (files stored on SD memory card or external storage media). Three levels of signature are available: operator, supervisor and quality control. The signature along with information such as pass/fail and comments can be saved to the data record for review and audit.

\* GM electronic signature can only be applied through SMARTDAC+ Standard Universal Viewer software. Electronic signature cannot be applied through GM's web server.

Sign Record ►



## SMARTDAC+ Standard Software

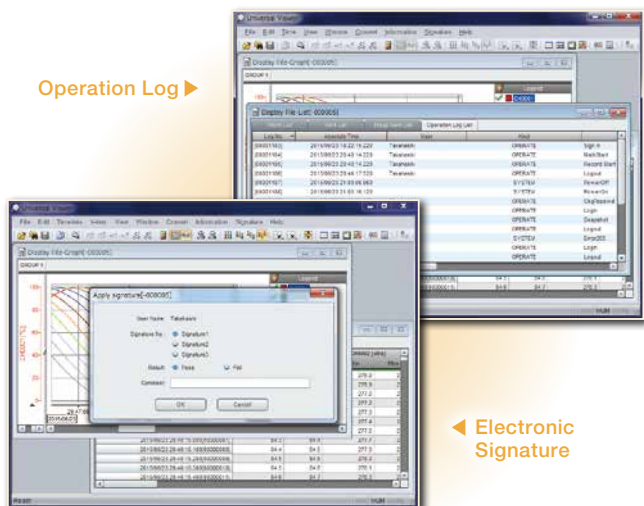
Updated with CFR Part 11 compliance, SMARTDAC+ Standard software (free download) provides configuration, record viewing, audit trail and electronic signature functions.

### Universal Viewer software

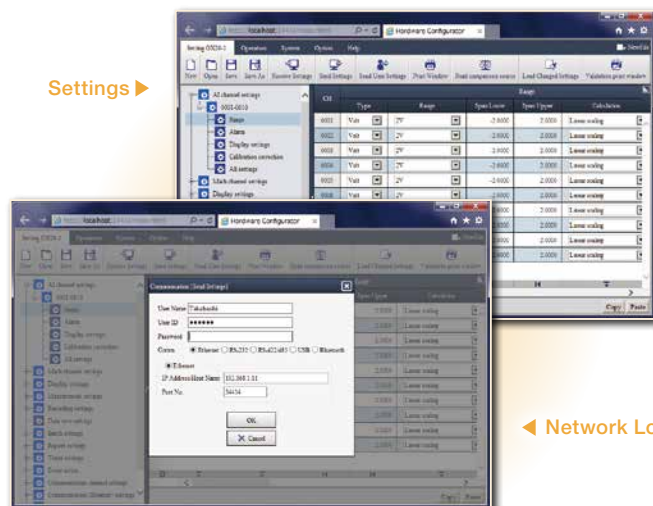
### Hardware Configurator software

Operation Log ►

Settings ►



◀ Electronic Signature



◀ Network Login

The software allows visual display of data files recorded from the GX/GP/GM in a variety of formats including waveform and digital display. In addition, the software can also display and print alarm and message lists as well as operation logs. Electronic signature can be applied once the measured data is reviewed. The software will verify if the measured data was previously signed by a different user and allow for additional signatures to be applied under a different user level (operator, supervisor, quality control).

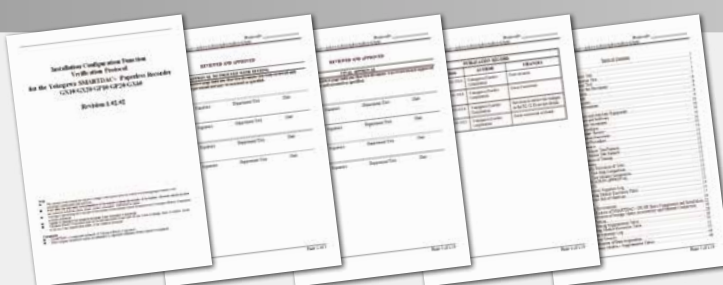
Hardware Configurator software allows for offline system configuration which can be imported via SD memory or external storage media as well as Ethernet communication\*. System settings can be printed in a table format to support GX/GP/GM system validation (IQ/OQ/PQ).

\*Requires system administrator privileges

## Validation documentation

Validation documentation (sold separately) is a validation protocol template that simplifies GX/GP/GM and SMARTDAC+ Standard system validation. The document is provided on the Yokogawa website as an MS Word file for easy editing. \*

\* The validation and document verification are the customer's responsibility.



## Paperless Recorder (Panel Mount Type) GX10/GX20



### GX10

- Vertical panel mount
- 5.7" TFT color LCD
- Up to 30 channels (built-in), 100 channels (with expansion unit)
- 500 MB internal memory
- Up to 32 GB SD/SDHC card, USB flash memory (option)
- Ethernet, RS-232 (option), RS-422/485 (option)
- 100 to 240 VAC or 24 VDC/AC powered

### GX20

- Vertical panel mount
- 12.1" TFT color LCD
- Up to 100 channels (built-in), 450 channels (with expansion unit)
- Maximum 1.2 GB internal memory
- Up to 32 GB SD/SDHC card, USB flash memory (option)
- Ethernet, RS-232 (option), RS-422/485 (option)
- 100 to 240 VAC or 24 VDC/AC powered

Product Brochure: Bulletin 04L51B01-01EN  
General Specifications: GS 04L51B01-01EN, GS 04L53B00-01EN

## Paperless Recorder (Portable Type) GP10/GP20



### GP10

- Desktop
- 5.7" TFT color LCD
- Up to 30 channels (built-in), 100 channels (with expansion unit)
- 500 MB internal memory
- Up to 32 GB SD/SDHC card, USB flash memory (option)
- Ethernet, RS-232 (option), RS-422/485 (option)
- 100 to 240 VAC or 12 VDC powered

### GP20

- Desktop
- 12.1" TFT color LCD
- Up to 100 channels (built-in), 450 channels (with expansion unit)
- Maximum 1.2 GB internal memory
- Up to 32 GB SD/SDHC card, USB flash memory (option)
- Ethernet, RS-232 (option), RS-422/485 (option)
- 100 to 240 VAC powered

Product Brochure: Bulletin 04L51B01-01EN  
General Specifications: GS 04L52B01-01EN, GS 04L53B00-01EN

## Data Acquisition System GM



- Desktop, DIN rail mount, wall (screw) mount
- Up to 100 channels (single-unit configuration), 420 channels (multi-unit configuration)
- Maximum 1.2 GB internal memory
- Up to 32 GB SD/SDHC card
- Ethernet, USB communication, RS-422/485 (option), Bluetooth (option)
- 100 to 240 VAC or 12 to 28 VDC powered

Product Brochure: Bulletin 04L55B01-01EN  
General Specifications: GS 04L55B01-01EN, GS 04L53B00-01EN

## I/O Modules



Model	Product Name, Description	Channels
GX90XA-10-U2	DCV/TC/RTD/DI, Solid State Relay Scanner Type	10
GX90XA-10-L1	DCV/TC/DI, Solid State Relay Scanner Type	10
GX90XA-10-T1	DCV/TC/DI, Electromagnetic Relay Scanner Type	10
GX90XA-10-C1	DC Current (mA), Solid State Relay Scanner Type	10
GX90XD	Digital Input Module	16
GX90YD	Digital Output Module	6
GX90WD	Digital Input/Output Module	DI: 8/DO:6
GX90XP	Pulse Input Module	10

General Specifications: GS 04L53B01-01EN

## Optional Accessories and Application Software (Sold Separately)

Accessories, Software	Model & Suffix
SD Memory Card (1GB)	773001
Shunt Resistor for Screw Terminal (M3)	250 $\Omega \pm 0.1 \%$
	100 $\Omega \pm 0.1 \%$
	10 $\Omega \pm 0.1 \%$
Shunt Resistor for Clamp Terminal	250 $\Omega \pm 0.1 \%$
	100 $\Omega \pm 0.1 \%$
	10 $\Omega \pm 0.1 \%$
Dummy Cover	B8740CZ
Validation Documents (for /AS option) *1	773230
DAQStudio (Custom Screen Building Software for GX/GP with /CG option) *2	DXA170
Data Logging Software *1	GA10

\*1 Installation license key will be shipped. Please download installation software at:  
<http://www.smartdacplus.com/software/en/>

\*2 A CD-ROM with installation license key will be shipped.

### Calibration Certificate (Sold Separately)

A calibration certificate is available for each analog input module. When ordering the GX10/GX20/GP10/GP20 with analog input options, the calibration certificate for the modules is included in and shipped with the calibration certificate of the main unit. When ordering an analog input module separately, each module gets its own calibration certificate (one certificate per module).

### Test Certificate (QIC, Sold Separately)

A QIC is available for each unit/module. When ordering the GX10/GX20/GP10/GP20 with analog input options, the QIC for the modules is included in and shipped with the QIC of the main unit.

### User's Manual

Product user's manuals can be downloaded or viewed at:  
<http://www.smartdacplus.com/manual/en/>

### Software

SMARTDAC+ Standard software and other useful tools can be downloaded at:  
<http://www.smartdacplus.com/software/en/>

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### NOTICE



Before operating the product, read the user's manual thoroughly for proper and safe operation.

### YOKOGAWA ELECTRIC CORPORATION

Control Instruments Business Division  
E-mail: [ns@cs.jp.yokogawa.com](mailto:ns@cs.jp.yokogawa.com)

<http://www.yokogawa.com/>

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