

OpreX[™]Data Acquisition

SMARTDAC+ Advanced Security Function

Data Integrity Support for pharmaceutical & medical standards



Data Integrity Support for pharmaceu with advanced security function option

SMARTDAC+ GX/GP/GM advanced security function option (/AS) provides safe and traceable data management in applications such as pharmaceutical manufacturing, biotechnology, health management and medical institutions.

The advanced security function supports the strict requirements of US FDA 21 CFR Part 11, **EU-GMP Annex 11 and other associated guidelines** for data management.

It also supports data integrity in accordance with ALCOA+ (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available) mentioned in PIC/S, WHO, MHRA and FDA guidance documents.

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.

Security data

file transfer

SMARTDAC+ can automatically transfer

data to an FTP server. FTPS, which

Logical security

SMARTDAC+ has four main security levels (two separate administrator roles, a and monitor user). Up to 200 persons can be registered.

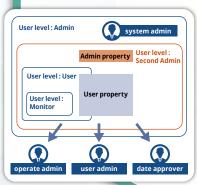
Access privileges can be assigned separately to each second administrator

Process owners/ system owners can be given access rights to functional appropriate to their role. Administrators with appropriate privileges can set register other users' login information and access privileges.

For each user, the user name, user ID, password and password expiration pe can be set.

For the password, a minimum string length and a minimum policy comple

Centralized management of user names and passwords using servers on network is possible through ActiveDirectory.





Second Administrator

Login

Electronic signature (data record signing) function

Measurement data can be displayed and confirmed on the GX/GP (only the data in the internal memory) or the SMARTDAC+ Standard Universal Viewer software, and an electronic signature can be applied to that data. 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 for review and audit.

* Electronic signature to the GM is possible only from the SMARTDAC+ Standard Software. Electronic signature cannot be applied through

Sign Record





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the data check

tical & medical standards n(/AS)

Validation documentation

Validation documentation (sold separately) is a validation protocol template that simplifies GX/GP/GM and SMARTDAC+ Standard system

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.



Validation documentation

Audit trail function

C+ operation log is saved to a file along with measurement data. When anged, it is possible to record the reason for the change along with the operation. In addition, it is possible to confirm the details of the setting e Show difference of the setting difference, and this can greatly reduce ng work during review and audit. You can view the operation log using en and Web server. It is also possible to view the operation log using the andard Universal Viewer software.

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SMARTDAC+ Standard Software

SMARTDAC+ Standard Software is possible to display measurement data, display the operation log, and configure the GX/GP/GM. It is also possible to sign in data using the SMARTDAC+ Standard Universal Viewer.

Universal Viewer software

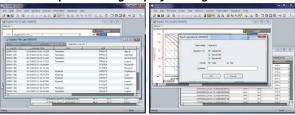
The Universal Viewer software can display data files in various forms such as waveforms and numeric values.

It can display and print not only measurement data but also alarm and message lists and operation logs.

With the operation log, a comparison of the settings before the change and those after the change can be displayed, allowing you to check the changes in detail.

It is also possible to sign the data by entering the user name, user ID and password after confirming the measurement data. If the data has already been signed, you can sign at a different level after confirming the signature state on the screen.

Operation log display and signature



Hardware Configurator software

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/OP/PQ).

In addition, a pair of selected setup data files can be compared, and their differences can be displayed and printed in table format.

Settings screen with access control



Comparison of settings

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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

Product Brochure: Bulletin 04L51B01-01EN

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

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 (noitgo)
- 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		Channels	
GX90XA-10-U2		DCV/TC/RTD/DI, Solid State Relay Scanner Type	10
GX90XA-10-L1	Analog	DCV/TC/DI, Solid State Relay Scanner Type	10
GX90XA-10-T1	Input Module	DCV/TC/DI, Electromagnetic Relay Scanner Type	10
GX90XA-10-C1	Module	DC Current (mA), Solid State Relay Scanner Type	10
GX90XD	Digital Ir	Digital Input Module	
GX90YD	Digital O	igital Output Module	
GX90WD	Digital Ir	tal Input/Output Module	
GX90XP	Pulse Inp	10	

General Specifications: GS 04L53B01-01EN

Optional Accessories and Application Software (Sold Separately)

Accessories, Software	Model & Suffix	
SD Memory Card (1GB)	773001	
	250 Ω ± 0.1 %	415940
Shunt Resistor for Screw Terminal (M3)	100 Ω ± 0.1 %	415941
	10 Ω ± 0.1 %	415942
	250 Ω ± 0.1 %	438920
Shunt Resistor for Clamp Terminal	100 Ω ± 0.1 %	438921
	10 Ω ± 0.1 %	438922
Dummy Cover	B8740CZ	
Validation Documents (for /AS option) *1	773230	
DAQStudio (Custom Screen Building Software for GX/GP with	DXA170	

- *1 Provision of Validation Documents
 - A license sheet containing the license key required for installation is provided. Download the validation document from the following URL. 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/GP20with 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/

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

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