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.

Logical security

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

Access privileges can be assigned separately to each second administrator ... user.

Process owners/ system owners can be given access rights to functiona... 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... can be set.

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

Second Administrator

◄ User I... Input... (GX/G...

User ID and Password ► Input Screen (GM web application)

Login

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.

The SMARTDAC... settings are cha... setting change... change from th... the data checki... the GX/GP scre... SMARTDAC+ Sta...

Reason for...

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 GM's web server.

Sign Record

Security data file transfer

SMARTDAC+ can automatically transfer data to an FTP server. FTPS, which encrypts data transferred via FTP using SSL, is also supported, allowing data files to be transferred safely.
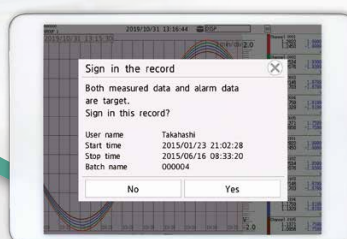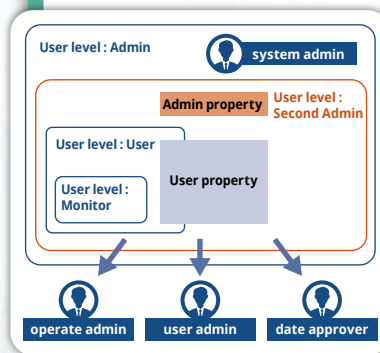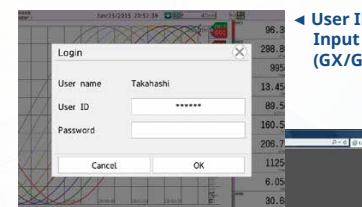
SSL-based encryption

tical & medical standards
(/AS)

user
and
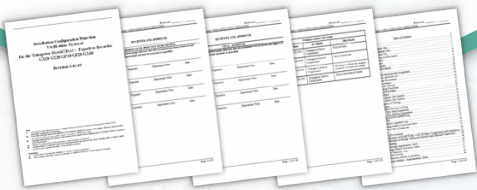lity
and
riod
xity
the

**D and Password
Screen
P main unit)**

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.

Validation documentation

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.
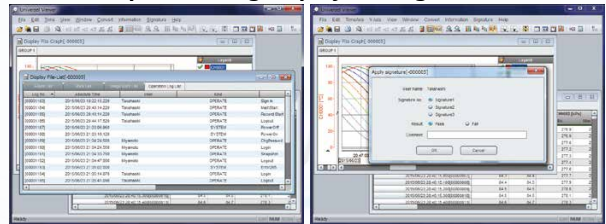
Universal Viewer software

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
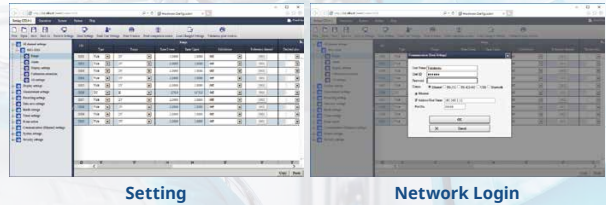
Operation Log   **Electronic Signature**

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

Setting   **Network Login**

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.

r changing settings   **Setting difference display**

Select to event

Detailed information

Comparison of settings

Easy to find !
Change point is
Strikethroughs + change color

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	Analog Input Module	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 Ω ± 0.1 %	415940
	100 Ω ± 0.1 %	415941
	10 Ω ± 0.1 %	415942
Shunt Resistor for Clamp Terminal	250 Ω ± 0.1 %	438920
	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 /CG option) *2		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/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/

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

AZ-S-1E
Printed in Japan, 103(AZ) [Ed:04/d]

YOKOGAWA ◆ Co-innovating tomorrow™