OpriX™ Data Acquisition

SMARTDAC+
Advanced Security Function

Data Integrity Support for pharmaceutical & medical standards
**Data Integrity Support for pharmaceutical and medical institutions 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 encrypts data transferred via FTP using SSL, is also supported, allowing data files to be transferred safely.

### Logical security

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

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

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

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

For the password, a minimum string length and a minimum policy complexity can be set.

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

### 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.

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User ID and Password Input Screen (GM web application)
EU-GMP Annex 11 and other associated guidelines MHRA and FDA guidance documents. Enduring, Available) mentioned in PIC/S, WHO, pharmaceutical manufacturing, biotechnology, Original, Accurate, Complete, Consistent, strict requirements of US FDA 21 CFR Part 11, data management in applications such as for data management.

With advanced security function option (AS) Data Integrity Support for pharmaceutical & medical standards ALCOA+ (Attributable, Legible, Contemporaneous, encryption using SSL, is also supported, allowing data files to be transferred safely. Data files encoded 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 software will identify the nonconformity and notify the user accordingly.

Measurement data can be displayed and confirmed on the GX/GP (only the data in the internal memory) or the SMARTDAC+ can be applied to that data. Three levels of signature are saved to the data for review and audit. Standard Universal Viewer software, and an electronic signature along with information such as pass/fail and comments can be applied to the GM is possible only from the SMARTDAC+ GM's web server. Standard Software. Electronic signature cannot be applied through network is possible through ActiveDirectory.

For the password, a minimum string length and a minimum policy complexity process owners/ system owners can be given access rights to functionality. Centralized management of user names and passwords using servers on the network is possible. SMARTDAC+ has four main security levels (two separate administrator roles, user and monitor). Up to 200 persons can be registered. Access privileges can be assigned separately to each second administrator and user. Administrators with appropriate privileges can set and change from the Show difference of the setting difference, and this can greatly reduce setting change operation. In addition, it is possible to confirm the details of the setting changes are changed, it is possible to record the reason for the change along with the data checking work during review and audit. You can view the operation log using the GX/GP screen and Web server. It is also possible to view the operation log using the SMARTDAC+ Standard Universal Viewer software. The SMARTDAC+ operation log is saved to a file along with measurement data. When changed, 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 changes are changed, it is possible to record the reason for the change along with the data checking work during review and audit. You can view the operation log using the GX/GP screen and Web server. It is also possible to view the operation log using the SMARTDAC+ Standard Universal Viewer software. The 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.

SMARTDAC+ Standard Software

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.

Audit trail function

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.

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

Settings screen with access control

Comparison of settings

Easy to find! Strikethrough = change value
Paperless Recorder (Panel Mount Type)  
GX10/GX20

- 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
General Specifications: GS 04L51B01-01EN, GS 04L53B00-01EN

Paperless Recorder (Portable Type)  
GP10/GP20

- 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

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

<table>
<thead>
<tr>
<th>Model</th>
<th>Product Name, Description Channels</th>
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</thead>
<tbody>
<tr>
<td>GX90XD</td>
<td>Digital Input Module 16</td>
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<tr>
<td>GX90YD</td>
<td>Digital Output Module 6</td>
</tr>
<tr>
<td>GX90WG</td>
<td>Digital Input/Output Module DL: 8/DIO-8</td>
</tr>
<tr>
<td>GX90XP</td>
<td>Pulse Input Module 10</td>
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</tbody>
</table>

Optional Accessories and Application Software (Sold Separately)

<table>
<thead>
<tr>
<th>Accessories, Software</th>
<th>Model &amp; Suffix</th>
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<tbody>
<tr>
<td>SD Memory Card (1GB)</td>
<td>773001</td>
</tr>
<tr>
<td>Shunt Resistor for Screw Terminal (M3) 250 O ± 0.1 % 415940</td>
<td></td>
</tr>
<tr>
<td>Shunt Resistor for Clamp Terminal 100 O ± 0.1 % 415941</td>
<td></td>
</tr>
<tr>
<td>Dummy Cover 10 O ± 0.1 % 415942</td>
<td></td>
</tr>
<tr>
<td>Validation Documents (for iAS option) *1 88740C2</td>
<td></td>
</tr>
<tr>
<td>DAQStudio Custom Screen Building Software for GX/GP with /CG option) *2 DXA170</td>
<td></td>
</tr>
</tbody>
</table>

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

Synaptic Business Automation creates sustainable value by connecting everything in our customers’ organization. To realize this, Yokogawa integrates its business and domain knowledge with digital automation technologies, and co-innovates with customers to drive their business process transformation.

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