

Technical Information

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SMARTDAC+ GX/GP/GM
Advanced Security Function (IAS)
Functional Differences for Supporting Data Integrity

SMARTDAC+TM



Part 11

For FDA 21 CFR PART 11

The contents of this Technical Information are subject to change without notice.

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Introduction

This document explains the functional differences in the GX/GP/GM advanced security function (/AS option) between the older versions (R4.06 and earlier) and the latest version (version 4.07 (hereafter referred to as R4.07)), which features data integrity functions.

■ Notice

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Functional Differences for Supporting Data Integrity

This document explains the functional differences in the GX/GP/GM advanced security function (/AS option) between the older versions (R4.06 and earlier) and the latest version (R4.07), which features data integrity functions.

Note

- There are no changes to the advanced security function operation up to R4.06.
- Only the functional differences are described in this document. Functions not described in this documents aren't changed between the older versions and R4.07
- This document does not cover functional differences not related to advanced security.

Simple Check Sheet

Below is a simple check sheet listing the functional differences.

There are a check mark and comment for items whose function will be different when the R4.06 settings are migrated to R4.07.

No.	Function added in R4.07	R4.06
1	Logical security	–
1.1	Password policy	–
1.2	Advance notice of expiry date	–
1.3	Changing values from comm command	–
1.4	Number of users	–
1.5	User level	–
1.6	Admin property	–
2	Configuration changes comment input	–
2.1	Comment input when configuration are changed	The function is different when Configuration changes comment is set to On.
2.2	Changing alarm value from the monitor	The function is different when Configuration changes comment is set to On.
3	Operation when recording is stopped	–
3.1	Automatic saving of the setting file	✓
4	Alarm ACK	–
4.1	Comment input when Alarm ACK	–
5	Event log	–
5.1	Event log when configuration are changed (Recording is stopped)	✓
5.2	Event log when configuration are changed (Recording is in progress)	The function is different when Configuration changes comment is set to On.
5.3	Alarm ACK	–
5.4	Display the difference	✓
6	Setting changes during recording	–
6.1	Variable constant	✓

List of Functional Differences

The following table shows functional differences between R4.06 and R4.07.

For functions not in this table, there are no differences between R4.06 and R4.07.

No.	Function	R4.06	R4.07	Description
1	Logical security			
1.1	Password policy	Setting is not available. The password is fixed to six characters or more.	Can be set with the password policy setting. Minimum character length and password constituent characters (upper case, lower case, numeric character, symbols) can be set.	A new function added in R4.07. The same operation as R4.06 is possible with the default password policy setting (minimum character length set to 6 and all other settings set to Off).
1.2	Advance notice of expiry date	Function is not available.	Password expiration can be notified in advance at login. Can be set to Off, 5 days before, or 10 days before.	A new function added in R4.07. The function can be set to On or Off (Default is Off).
1.3	Changing values from comm. command	If the communication login function is not in use, writing to communication channels is not possible.	Writing to communication channels is possible through a setting even when the communication login function is not in use.	A new function added in R4.07. The function can be set to On or Off (Default is Off). The operation is the same as R4.06 when the function is set to Off.
1.4	Number of users	GX10/GX20-1/GM10-1: 100 GX20-2/GM10-2: 100	GX10/GX20-1/GM10-1: 100 GX20-2/GM10-2: 200	This difference does not have a problem because the number of users in R4.07 is greater than equal to that of R4.06.
1.5	User level	Can be set to Admin, User, or Monitor.	Second administrator level has been added. Can be set to Admin, SecondAdmin, User, or Monitor.	Second administrator is a new user level added in R4.07. There are no changes to the user levels that can be used in R4.06.
1.6	Admin property	Function is not available.	A portion of administrator privileges that can be assigned to the second administrator level.	Admin property is a new function that is used by the second administrator level added in R4.07.

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No.	Function	R4.06	R4.07	Description
2	Configuration changes comment input			
2.1	Comment input when configuration are changed	A comment can be entered when a setting is changed.	A comment can be entered when a setting is changed.	Configuration changes comment is the same for R4.06 and R4.07.
		The entered comment is recorded in the setting file.	The entered comment is recorded in the setting file and event log.	There is a difference in the function. There will be a difference in all cases when Configuration changes comment is set to On.
		Function is not available.	The comment to be entered can be selected from preset comments.	There is a difference in the comment input screen. The operation is the same if preset comments are not used.
		The comment to be entered can be NULL.	The comment to be entered cannot be NULL.	There is a difference in the function. There will be a difference in all cases when Configuration changes comment is set to On.
2.2	Changing alarm value from the monitor	A comment cannot be entered when a setting is changed.	A comment can be entered when a setting is changed.	The operation will be different when Configuration changes comment is set to On. R4.06: Change alarm value → Complete R4.07: Change alarm value → Enter comment → Complete
		Function is not available.	(Recording stopped) The entered comment is recorded in the setting file and event log.	The event log will be different regardless of the Configuration changes comment setting. R4.06: "SetDiff" not available. R4.07: "SetDiff" available. In addition to the above, the event log will be different if the Configuration changes comment is set to On. R4.06: "SetComment" not available. R4.07: "SetComment" available.
		Function is not available.	(Recording) The entered comment is recorded in the event log.	The event log will be different if the Configuration changes comment is set to On. R4.06: "SetComment" not available. R4.07: "SetComment" available.
3	Operation when recording is stopped			
3.1	Automatic saving of the setting file	Function is not available.	If the settings are changed during recording, the setting file is automatically saved when the recording is stopped.	A new function added in R4.07. There is a difference in all cases.
4	Alarm ACK			
4.1	Comment input when alarm ACK	Function is not available.	A comment can be entered when performing alarm ACK (individual/all).	A new function added in R4.07. The function can be set to On or Off (Default is Off).
		Function is not available.	The comment to be entered can be selected from preset comments.	
		An alarm ACK event log is recorded.	The entered comment is recorded in the alarm ACK event log.	An alarm ACK event log is recorded both in R4.06 and R4.07.

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No.	Function	R4.06	R4.07	Description
5	Event log			
5.1	Event log when setting are changed (recording is stopped)	The following is recorded in the event log when a setting is changed. "SetParameter"	The following three items are recorded in the event log when a setting is changed. "SetParameter" "SetComment" (only when Configuration changes comment input is set on) "SetDiff"	The event log will be different regardless of the Configuration changes comment setting. R4.06: "SetDiff" not available. R4.07: "SetDiff" available.
5.2	Event log when setting are changed (redording in progress)	The following is recorded in the event log when a setting is changed. "SetAlarm" (when an alarm value is changed)	The following two items are recorded in the event log when a setting is changed. "SetAlarm" (when an alarm value is changed) "SetComment" (only when Configuration changes comment input is set on)	The event log will be different if the Configuration changes comment is set to On. R4.06: "SetComment" not available. R4.07: "SetComment" available.
5.3	Alarm ACK	Alarm ACK is recorded in the event log.	Alarm ACK is recorded in the event log. The entered comment is added when alarm ACK comment input is set to On.	Alarm ACK comment input is a function added in R4.07. The function can be set to On or Off (Default is Off).
5.4	Display the difference (SetDiff)	Function is not available.	Compares the setting files before and after making changes and displays the differences.	A new function added in R4.07. There is a difference in all cases.
6	Setting changes during recording			
6.1	Variable constant	The variable constant setting cannot be changed during recording.	The variable constant setting can be changed during recording. Recording to the event log and auto message writing are possible.	A new function added in R4.07. There is a difference in all cases when a variable constant is in use.

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