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Data Integrity Support for pharmaceutical & medical standards with SMARTDAC+ advanced security function

What is Data Integrity?

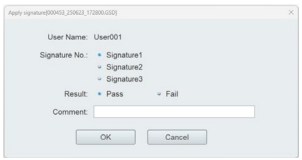
Due to the increasing number of findings related to data falsification and misconduct in inspections, regulatory authorities such as the FDA (U.S. Food and Drug Administration) and MHRA (UK Medicines and Healthcare products Regulatory Agency) are strengthening their oversight of data integrity. As a result, various regulatory authorities have been issuing a series of guidelines on data integrity. The basic principles of data integrity, known as ALCOA+ (A: Attributable, L: Legible, C: Contemporaneous, O: Original, A: Accurate, C: Complete, C: Consistent, E: Enduring, A: Available), have been adopted in these guidelines. The SMARTDAC+ GX/GP/GM with advanced security functionality is compliant with data integrity requirements.

SMARTDAC+ Paperless recorder and data logger supports Data Integrity

Electronic signature

Measurement data can be displayed and confirmed on the recorder itself or the 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.

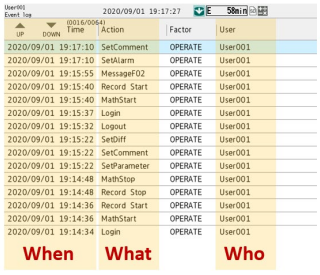
Recorder Unit



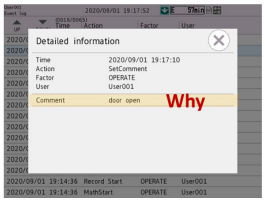
Viewer

Audit trail function

The operation log is saved to a file along with measurement data. When settings are changed, it is possible to record the reason for the change along with the setting change operation.
This feature allows you to confirm **who**, **when**, **what**, and **why** changes were made as required for data integrity. The operation log can be viewed on the recorder screen, in the web application, or in the Universal Viewer.



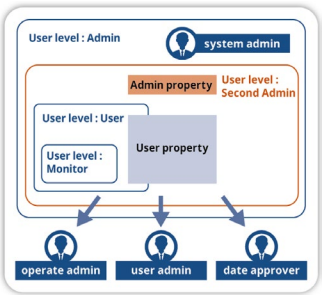
Event log



Detailed information

Logical security

There are four user levels (two separate administrator roles, user and monitor user), and up to 200 users can be registered. Access privileges can be assigned separately to each second administrator and user.
Data integrity requires that the appropriate users have access to the appropriate information. SMARTDAC+ allows you to create users with various access privileges.



User level

Login screen

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Guidance and data integrity support

Guidance issued by each regulation authority are listed below.

Guidance

Publication Date	Institution	Guidance Name
October 2021	WHO	Guidance on data integrity
March 2018	MHRA	'GXP' Data Integrity Guidance and Definitions
July 2021	PIC/S	GOOD PRACTICES FOR DATA MANAGEMENT AND INTEGRITY IN REGULATION GMP/GDP ENVIRONMENTS
December 2018	FDA	Data Integrity and Compliance With Drug CGMP Question and Answers Guidance for Industry

*As of May 2025

SMARTDAC+ compliance with ALCOA+ principles is outlined below.

ALCOA+ Principle of Data Integrity

ALCOA+	Content	SMARTDAC+ correspondence
Attributable	It must be clear who created the data	Capable of recording the user, timestamp, and operation history with an audit trail function.
Legible	Data must be legible to anyone	Data can be displayed and saved in a format that is readable by humans.
Contemporaneous	Data must be recorded at the time of measurement	Measurement data is automatically and promptly recorded together with a timestamp.
Original	Copied data must be identical to the original data	A recorded data file is saved in a unique format that cannot be tampered with. Therefore, any copied data is identical to the original.
Accurate	Data and results must be accurate without any errors	Data acquired from calibrated sensors is accurately saved in a unique format that cannot be tampered with.
Complete	All necessary information must be available to reconstruct the situation	All information regarding data acquisition and operation such as measurement values, setting information, operation history, alarm history, and so on is saved in the data file.
Consistent	Data must be consistent and contain no contradiction	SMARTDAC+ equipped with an SNTP function, records data continuously at the set interval. Channel info, units, and timestamps are automatically added to measurement data, and all user actions are securely tracked in an audit trail.
Enduring	Data must be available during the retention period	Data can be backed up on long-retention media. By saving the viewer software together with the data, it is possible to ensure future accessibility in a readable format.
Available	Data must be accessible at any time during the retention period	Recorded data can be searched and viewed by dedicated viewer software. This ensures reliable access to the data when needed.

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