ABB MEASUREMENT & ANALYTICS | INFORMATION | INF13/147-EN REV. A

ScreenMaster RVG200

Paperless recorder

FDA-approved record keeping

Measurement made easy

ScreenMaster RVG200 paperless recorder

1 Introduction

On August 20th 1997 the Food and Drug Administration made 21 CFR Part 11 effective. This regulation is summarized as follows:

'The Food and Drug Administration (FDA) is issuing regulations that provide criteria for acceptance by FDA, under certain circumstances, of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on paper. These regulations, which apply to all FDA program areas, are intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to promote and protect public health. The use of electronic records as well as their submission to FDA is voluntary.'

This guide provides details of the relevant sections of 21 CFR Part 11 and gives information on how the RVG200 Paperless Recorder can be used to meet these FDA requirements for the creation of electronic records in a closed system.

2 For more information

Further information is available from:
www.abb.com/analytical

or by scanning these codes:

Sales Service

3 FDA21 CRF

3.1 FDA 21 CFR Part 11 Subpart B – Electronic Records, Section 11.10: Controls for Closed Systems

'*Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity and, when appropriate, the confidentiality of electronic records and ensure that the signer cannot repudiate the signed record as not genuine.*'

Process data is archived in a Binary encoded format that can be viewed in a human readable format only through the use of ABB's Datamanager Pro advanced data review software. The recorded data contains in-built integrity checks for each block of data to detect corruption or attempted falsification of the record. The Datamanager Pro software checks the data against the in-built checksums to validate the integrity of the data and to warn the user of any invalid records before displaying the data.

3.2 FDA 21 CFR Part 11 Section 11.10 (a)

'*Validation of systems to ensure accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records.*'

Validation is a function that is performed either by the end-user directly or a third party acting on behalf of the end-user to ensure that the system is acceptable for its intended use as per the original system User Requirement Specification. The RVG200 has been developed and manufactured in accordance with ISO9001 standard processes.

A validation template designed in accordance with GAMP 5 guidelines is available for the RVG200 paperless recorder to assist the customer with validation of the recorder. The accuracy of the recorder measurements can be ensured by exercising the system calibration procedures described in the relevant user guide. The RVG200 has an encoded audit log feature that allows the identification of changes to the system by recording the nature of the change, the time and date at which the change was made and the name of the authorized user who made that change.

3.3 FDA 21 CFR Part 11 Section 11.10 (b)

'*The ability to generate accurate and complete copies of records in both human-readable and electronic form suitable for inspection, review and copying by the agency (FDA).*'

The RVG200 can create process data files and archive them to SD cards, USB memory sticks or internal flash memory for transfer over Ethernet. The data files are created from secure records stored in internal flash memory. Error detection algorithms are used to ensure that the actual raw measurements made by the recorder are faithfully represented by the stored data. Each write to the archive media is also verified to ensure the integrity of the data record. The archived process data can then be viewed using ABB's Datamanager Pro advanced data review software. The data can be viewed and printed in graphical and tabular formats, with the option to export to an Excel™ spread sheet if required. Data can also be packaged using DataManager Pro's data package functionality, and sent to others for evaluation and approval. This enables data to be sent and reviewed in Datamanager Pro without losing the data integrity checks.

3.4 FDA 21 CFR Part 11 Section11.10 (c)

'*Protection of records to enable their accurate and ready retrieval throughout the records retention period.*'

The RVG200 paperless recorder uses solid-state flash memory for data storage in the form of SD (Secure Digital) cards, USB (Universal Serial Bus) memory sticks and up to 2 GB Internal Flash memory. Data retention for these devices is specified as a minimum of 10 years. They provide zero power data retention, meaning the data integrity is not dependant on battery backup and the data is not affected by magnetic fields.

Once the data files have been imported into the Datamanager Pro database, the database can be backed up to a CD or a network file server for longer term data storage.

3.5 FDA 21 CFR Part 11 Section11.10 (d)

'*Limiting system access to authorized individuals.*'

The RVG200 provides the ability to limit access to the instrument's configuration and critical operator functions. Access to these areas of the recorder's functionality can be controlled by 1 of 2 different security modes that are available as standard:

1. **Password Protection**

   Up to 12 users can be configured, each with a unique Username and Password, to control access to critical operator functions (for example, access to the logging pages) and configuration parameters.

   Usernames can be alphanumeric and up to 20 characters in length.

   Passwords can also be alphanumeric, and a minimum password length (from 4 to 20 characters) can be specified.

   A password expiry time can be set to prevent password aging and also to bring the RVG200 in line with general network policy.

   A password failure limit (from 1 to 10 attempts) can be configured to prevent illegal use of a user ID. Access is denied after the preconfigured number of incorrect password entries is reached.

   Users can be de-activated after a configurable time period (7 days to 1 year) of user inactivity.

   Different levels of access privilege can be assigned to each user:

   a. No access
   b. The ability to load existing configuration files
   c. Limited access (read access plus the ability to adjust alarm trip points)
   d. Full read / write access

   To gain access to the configuration or critical operator parameters, a valid operator username and password must be entered. In keeping with 21 CFR part 11 compliance, the RVG200 does not have a secret override password.

   Any modification of the instruments' configuration is recorded in the audit log together with identification of the user who was responsible for the change.

2. **Security Switch Protection**

   With this security option enabled, access to the recorder's configuration is protected by an internal security switch. To gain access to the internal security switch, the recorder must be removed from its case. A tamper-evident seal can be fitted to the case to indicate unauthorized removal.

In addition to the security modes, access to the archive media can also be restricted. A lockable media door can prevent unauthorized access to the SD card archive media and, provided the rear of the RVG200 is located securely behind a locked panel, long-term secure USB storage can be achieved by inserting a USB memory stick in the RVG200's rear USB port.

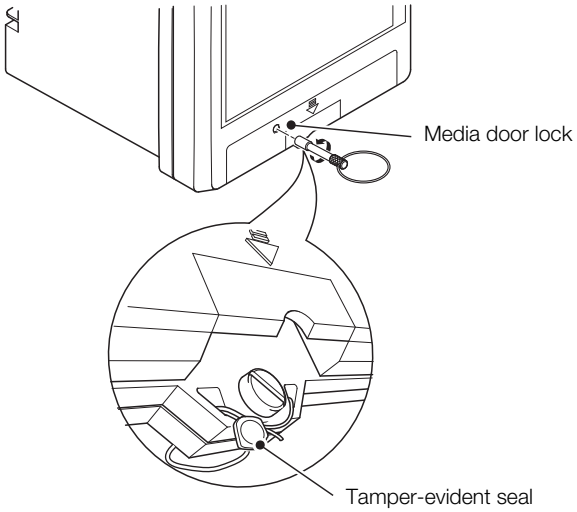


Fig. 3.1 Recorder security

3.6 FDA 21 CFR Part 11 Section11.10 (e)

'*Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator actions that create, modify or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained at least as long as that required for the subject electronic records and shall be available for agency review and copying.*'

The RVG200 produces a time-stamped audit trail automatically that includes disk insertion and removal, power failure and recovery, configuration changes, file deletions, system diagnostics and calibration changes. This information is stored in an audit log that can be archived automatically to a permanent file on an SD card, USB memory stick or internal flash memory. A separate alarm event log automatically produces a time-stamped record of all alarm state changes and operator messages and can also be archived automatically to a permanent file.

Each time the configuration is changed, a new file is created that can be stored as a permanent file to external media. Each file is time-stamped to indicate the time and date when the change occurred. This ability to store the RVG200's configuration history enables configurations before and after any changes or events to be reviewed.

The audit and alarm event logs are stored in an encoded format with checksum protection to prevent falsification of their contents.

3.7 FDA 21 CFR Part 11 Section 11.10 (g)

'*Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record or perform the operation at hand.*'

The RVG200's security system previously outlined in Section 3.5 limits access to the system to modify any configuration parameters.

3.8 FDA 21 CFR Part 11 Section 11.10 (h)

'*Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.*'

The Analog inputs provided on the RVG200 have built-in broken sensor and over- and under-range detection. Indication of these conditions is provided on the recorders display and in the recorded data files.

3.9 FDA 21 CFR Part 11 Section 11.10 (i)

'*Determination that the persons who develop, maintain or use electronic record/electronic signature systems have the education, training and experience to perform their assigned tasks.*'

As a developer, only suitably qualified personnel are employed in product design and development and their training is regularly updated to meet advances in technology. Levels of competence and training needs are externally audited by the British Standards institute (BSI) for our ISO 9001 quality management system.

As an end-user, training, education and experience for those personnel who are to use the product must be provided and documented as part of the overall system validation.

3.10 FDA 21 CFR Part 11 Section 11.10 (k)

'*Use of appropriate controls over systems documentation including:*

(1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.'

As a developer of a paperless recording system, a design control system is used that is fully documented and traceable. It is externally audited by the British Standards Institute (BSI) for our ISO 9001 quality management system. 2 documents are provided for installation, configuration and operation; Commissioning instructions and Operating instructions.

As an end-user, access and document control procedures are required to be maintained and monitored according to the system validation requirements. As a result, system and operation maintenance and changes must be reported as part of the validation requirements and these documents updated as required.

3.11 FDA 21 CFR Part 11 Subpart B – Electronic Records, Section 11.50: Signature manifestations

'*a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:*

1) The printed name of the signer

2) The date and time when the signature was executed

3) The meaning (such as review, approval, responsibility or authorship) associated with the signature.

b) The items identified in paragraphs a) 1), a) 2), and a) 3) of this section shall be included as part of any human readable form of the electronic record (such as electronic display or printout).'

The RVG200's electronic signature system records each signature complete with the Operator's username (up to 20 characters), the date and time at which the signature was activated and a 20 character message that the operator can use to indicate the purpose of the signature. ABB's Datamanager Pro advanced data review software also enables digital signatures to be enter after the data was produced; these signatures are encrypted together with the data file in Datamanager Pro's database and can be used as a post-production sign off measure.

3.12 FDA 21 CFR Part 11 Subpart B – Electronic Records, Section 11.70: Signature/record linking

'*Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred to falsify an electronic record by ordinary means.*'

Electronic signatures are stored in the RVG200's alarm event log. This log is stored on archive media in an encoded format with checksum protection to prevent falsification of its contents. The archived alarm event log and channel data files both contain the instrument tag and unique instrument serial number. This can be used to ensure the electronic signature and associated data are securely linked. ABB's Datamanager Pro advanced data review software also saves the files together as part of the same database enabling electronic signatures to be displayed on the chart next to the data it relates to.

3.13 FDA 21 CFR Part 11 Subpart C – Electronic Signatures, Section 11.100: General requirements

'*a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.*'

The RVG200 does not permit the same username to be assigned to more than 1 operator. This function together with procedural controls can be used to meet this requirement.

3.14 FDA 21 CFR Part 11 Subpart C – Electronic Signatures, Section 11.200: Electronic signature components and controls.

'*a) Electronic signatures that are not based upon biometrics shall:*

1) Employ at least two distinct identification components such as an identification code and password.

i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.

ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access each signing shall be executed using all of the electronic signature components.

2) Be used only by their genuine owners; and

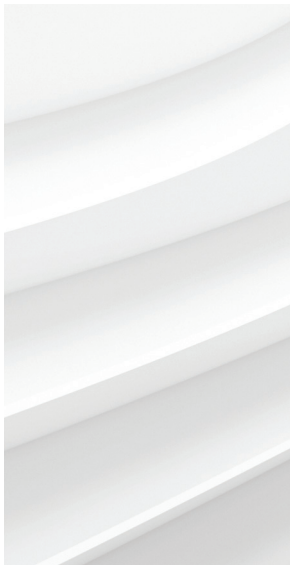
3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.

To perform any electronic signing, the RVG200 and Datamanager Pro both require the operator to provide a valid username and password. The RVG200 does not have a security override code. The security can be overridden only by the use of an internal switch, access to which can be protected by a tamper-evident seal.

ABB Limited
Measurement & Analytics
Howard Road
St. Neots
Cambridgeshire
PE19 8EU
UK
Tel: +44 (0)1480 475 321
Fax: +44 (0)1480 217 948
Email: instrumentation@gb.abb.com

ABB Inc.
Measurement & Analytics
125 E. County Line Road
Warminster
PA 18974
USA
Tel: +1 215 674 6000
Fax: +1 215 674 7183

abb.com/measurement



INF13/147-EN Rev. A 09.2018