savic-net™ for FDA Title 21 CFR Part 11 Compliance

General

The savic-net™ for FDA Title 21 CFR Part 11 Compliance (hereinafter referred to as savic-net for Part 11) is a building management system applicable to "Federal Register / Vol. 62, No. 54 - DEPARTMENT OF HEALTH AND HUMAN SERVICES, Food and Drug Administration, 21 CFR Part 11, Electronic Records; Electronic Signatures, Final rule".

[Stored data protection]
The savic-net for Part 11 meets the requirements of data accuracy and protection for falsification in 21 CFR Part 11.
With respcet to Audit Trails, all the history of operation is recorded automatically. Also, in the savic-net for Part 11, all of the measured data are secured from the sensing device via system network, and stored in a durable way. No one is able to alter the contents of data.

[Electronic signature]
The savic-net for Part 11 meets the following requirements of electronic signature in 21 CFR Part 11.

- Signature unencrypted electronic records
- Handwritten and electronic signature correlated
- Electronic signature unique and not re-assignable
- Safety not bio-metric

[User Control]
The savic-net for Part 11 meets the following requirements of system security in 21 CFR Part 11.

- User authentification for any operation
- Restricted operation rights by each user

Note:

* FDA stands for Food and Drug Administration.

* CFR stands for the Code of Federal Regulations.

Trademark Information
savic-net is a trademark of Azbil Corporation in Japan or in other countries.
BACnet is a registered trademark of American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE).
Internet Explorer, Microsoft, Windows are registered trademarks of Microsoft Corporation in the United States and other countries.

Safety Instructions

Please read instructions carefully and use the product as specified in this manual.   Be sure to keep this manual nearby for ready reference.
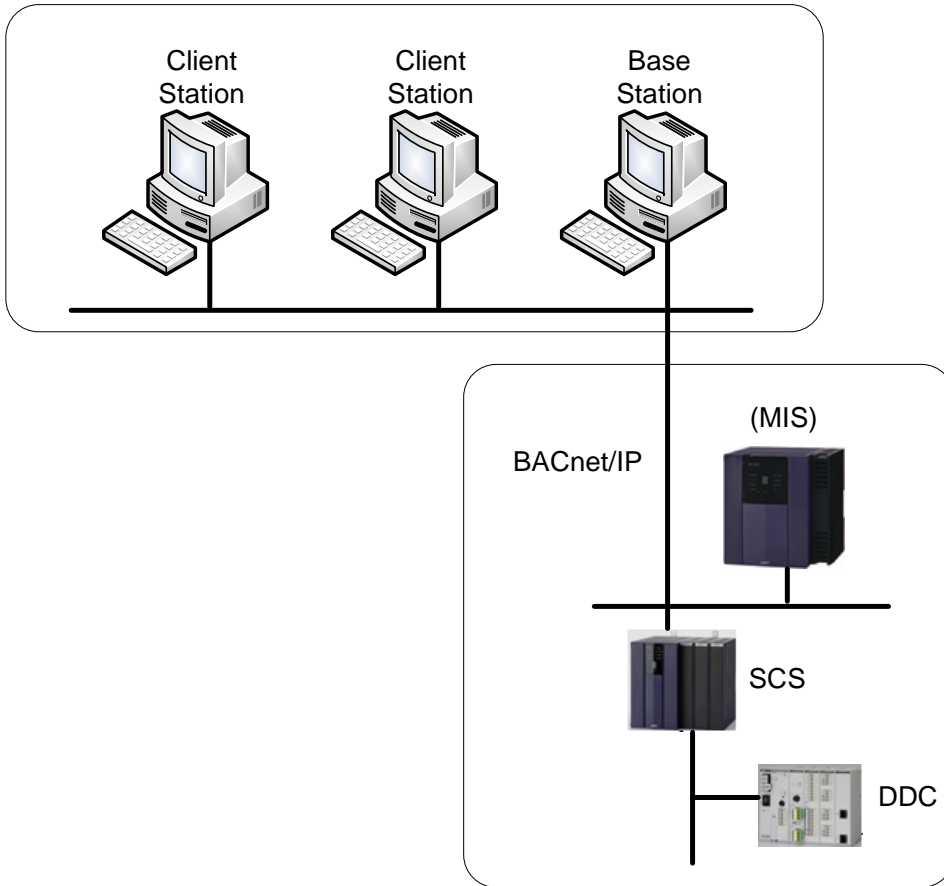
Usage Restrictions

This product is targeted for general air conditioning.   Do not use this product in a situation where human life may be affected. If this product is used in a clean room or a place where reliability or control accuracy is particularly required, please contact Azbil Corporation's sales representative.   Azbil Corporation will not bear any responsibility for the results produced by the operators.

⚠ CAUTION

- ❗ • Installation must be performed by qualified personnel in accordance with all applicable safety standards.
- ❗ • Use the product under the operating conditions (temperature, humidity, power, vibration, shock, mounting direction, atmospheric condition, etc.) as listed in the specifications.
  Failure to do so might cause fire or device failure.
- ❗ • Use the product within the rated operating ranges as listed in the specifications.
  Failure to do so might cause device failure.

System Configurations

savic-net™ for FDA Title 21 CFR Part 11 Compliance

savic-net™ FX Building Management System
(HVAC System)

Note:

* MIS stands for Management Integration Server.

* SCS stands for System Core Server.

* DDC stands for Direct Digital Controller.

Table 1   Devices configuring savic-net for Part 11

Item	Description
Base Station	The Base Station consists of all the supervisory and control functions including inter-node messaging with direct access to the industrial equipment. ・Graphic ・Alarm & Event Management ・Historical Trending & Log ・Communication Driver (BACnet / Modbus / OPC)
Client Station	The Client Station consists of all the supervisory and control functions including internode messaging but without any direct access to the industrial equipment (no communication protocols).

Conformance to FDA Title 21 CFR Part 11

- Stored data protection
  - ➢ Protection of process data
    - Keeping records on electronic format.
    - Quick review and possible extraction.
    - Closed system.
    - Possible access to authorized persons.
    - Automatic logout.
  - ➢ Audit traceability
    - Any user action must be recorded in an traceable audit.
    - Authorization control.
  - ➢ Traceability of changes in software versions
    - Version history

- Electronic signature
  - ➢ Signature unencrypted electronic records
    - Any electronic record must contain:
      Name, name of signatory.
      Meaning of signature (approval, review, responsibility)
      Date and time record.
  - ➢ Handwritten and electronic signature correlated
    - The records and the signature are linked.
    - The signature is protected to prevent his transfer to another record. It is protected against any signature modification.
    - Any change of signature must be recorded.
  - ➢ Electronic signature unique and not re-assignable
    - The electronic signature is unique to a person.
    - The electronic signature is not reassignable to a person.
  - ➢ Safety not bio-metric
    - Identification code and password for each user.
    - Signature name and password for critical action.
    - Automatic operator logout.
    - Double signature on desired action.

- User Control
  - Each combination password and identification code is unique and can not be re-used.
  - Expiration name and user password.
  - Traceability of fraudulent access attempts.

Detail comparison of 21 CFR Part 11 Requirements and savic-net for Part 11 system functions

Table 2   Article-by-article interpretation

Electronic Records

Section		21 CFR Part 11 Requirements	Compliance Statement of savic-net for Part 11
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. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	Keeping records on electronic format.
11.10 (c)		Protection of records to enable their accurate and ready retrieval throughout the records retention period.	Quick Review and possible extraction.
11.10 (d)		Limiting system access to authorized individuals.	Closed system. Possible access to authorized persons. Automatic logout.
11.10 (e)		Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	Any user action must be recorded in an traceable audit.
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.	Authorization Control.
11.10 (k)	(2)	Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	Version history.
11.50 (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; and (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.	Any electronic record must contain: Name, name of signatory. Meaning of signature (approval, review, responsibility). Date and Time Record.
11.70		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.	The records and the signature are linked. The signature is protected to prevent his transfer to another record. It is protected against any signature modification. Any change of signature must be recorded.

Electronic Signatures

Section			21 CFR Part 11 Requirements	Compliance Statement of savic-net for Part 11
11.100(a)			Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	The electronic signature is unique to a person. An electronic signature is not reassignable to a person.
11.200(a)	(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.	Signature name and password for critical action.
		(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.	Automatic operator logout.
	(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.	Double signature on desired action.
11.300(a)			Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	Each combination password and identification code is unique and can not be re-used.
11.300(b)			Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).	Expiration name and user password.
11.300(d)			Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	Traceability of fraudulent access attempts.

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Rev. 0.0   Apr. 2014   AS-983E