



# FDA - 21 CFR part 11 Compliance Guide

## Using Vision controllers to create FDA - 21 CFR part 11 compliant application: Electronic Records & Signatures

Unitronics' Vision all-in-one PLC+HMI controller series are an excellent choice for Life Science manufacturers requiring a cost effective solution for systems that require compliance with the FDA 21 CFR part 11.

Supported by VisiLogic, the comprehensive Application Programming Environment, Vision series controllers allow the system to be validated to the 21 CFR Part 11 regulations by featuring widgets, functions and tools that enable:

- User-access control and administration
- Program version control and revision history tracking
- Generating records showing changes in configuration, operator actions, and alarms
- Storing & exporting data records for audit trail purposes

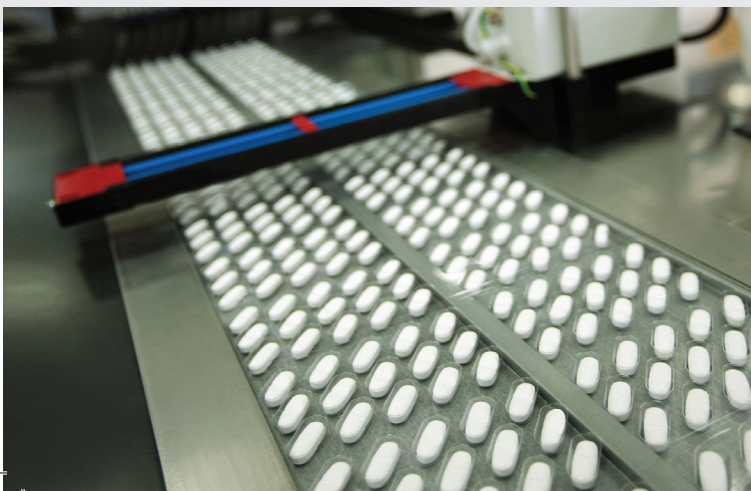
This document discusses the Unitronics Vision PLC+HMI control tools for creating applications that are compliant with the 21 CFR Part 11 regulations.

### Version control of Electronic Data Records and Audit Trail in VisiLogic software

The VisiLogic programming environment provides comprehensive tools for complying with version control of electronic data records regulations as specified by 21 CFR part 11.

The programmed project can be protected by restricting access to functions and procedures to authorized users only. VisiLogic logs all project changes each time a new program is downloaded to a Vision controller. The amended object, type of change, time stamp, and the user identification (electronic signature) are recorded. The logged data is encrypted and saved in the project database. The data can then be displayed in a clear list, enabling full traceability regarding the changes in the project program.

The VisiLogic Verify utility enables the identification of changes in a Vision controller program (in hardware configuration, ladder, HMI etc.). Downloading a new program to a controller can be restricted to only authorized users, and can be controlled by assigning a user name and a password. The programmer also has the option of downloading the code only, rather than a complete project. This enhances the application security. Access to the computer on which the VisiLogic application is installed must be controlled by utilizing the operating system's built-in passwords and encryption mechanisms.





## HMI user administration and signing

In accordance with FDA 21 CFR Part 11, no unauthorized access should be possible to the controller HMI. In order to comply with this regulation, the program of the Vision controller should include the usage of multilevel access control. The combination of the user name and password is the electronic signature of a user or a system operator. The data table functionality is recommended to be used in order to pre-define user name and passwords that allow different access rights, thus limiting system actions to individuals with specified user names. The use of data tables allows the administrator to perform periodic password updates to enhance the access control protection.

As the controller program is a binary code, it is not possible to access the HMI/PLC program and alter it.

Furthermore, it is possible to control the access to the HMI/Controller by either disabling certain communication ports, or restricting the use of them to only certain users. Physical barriers should be used (e.g. rooms or cabinets with locked doors) in order to control the access to the HMI/PLC and the computer on which the VisiLogic software is installed.

## Audit trails of operator entries and actions recordings

The Vision controller provides tools for security and logs operator actions, track alarms, and logs other operational data enabling audit trail. Using the data table functionality enables the Vision controller program to record any action that is performed by the system user/operator. The recording can include the identification of the user, the action that was performed and a time stamp. The data is stored in a log file in a proprietary file format or a CSV file. Using the Vision Alarms widget, an alarm log can be recorded by the controller. Acknowledgments of alarms by authorized users only can be recorded by utilizing the Alarms widget and by requiring the users to enter their user name and password for acknowledging the alarm. Alarms, their time stamp and user acknowledgment are logged in a proprietary file format or a CSV file.

In a similar fashion, the Trends functionality can be used to log data about the controlled process/application and can be uploaded by authorized users only to other database systems for data acquisition purposes. Changes to the values logged into these database files do not overwrite previous values. Furthermore, these log files cannot be edited as long as they are stored in the Vision controller.

It is important to emphasize that once application-related electronic records have been exported from the Unitronics Vision and VisiLogic environment they should be protected using the data base application, operating system, or other security application access control mechanism.

Detailed instructions and consulting on programming a 21 CFR Part 11-compliant application as well as VisiLogic programming examples can be provided free of charge by Unitronics technical support specialists.

Note:

We reserve the right to make changes or modify the contents of this document without prior notice. Unitronics does not accept any responsibility whatsoever for potential errors or possible lack of information in this document as well as for noncompliance of end user application or system with FDA regulations.



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