

SIMPLIFYING FDA 21 CFR PART 11 COMPLIANCE

Unitronics' built-in features take the complexity out of FDA 21 CFR Part 11 compliance

INTRODUCTION

Unitronics' UniStream series controllers and UniLogic programming software (version 1.40 and above) provide comprehensive tools to meet the requirements of FDA 21 CFR Part 11. With our easy-to-use, automated solutions, achieving compliance has never been simpler. Designed to help you navigate and fulfill these regulatory standards easily, our UniStream products simplify the process while ensuring robust performance. Below are four critical aspects of compliance: access protection, audit trails, records storage, and digital electronic signatures.



REGULATION COMPLIANCE OVERVIEW

Regulation	Requirements	Unitronics' UniStream series Compliance
Access Protection	The system must limit access to authorized individuals, ensuring only those with proper credentials can view or modify electronic records.	<ul style="list-style-type: none"> The UAC (User Access Control) module is embedded in all models of the UniStream controller series. The UAC data is stored in the PLC runtime environment and is therefore secure against external access. The UAC is part of the HMI software module (whether a physically connected display or a remote display via VNC protocol) but is not applied to the Web Server module. 21 CFR part 11 regulated systems should therefore allow view-only functionality over the web (not to allow operational records changes). The UniStream controllers provide the option to disable remote display access via VNC (default). UAC users and group properties can be set in UniLogic Studio and can be modified using the UniApps runtime menu (by the system administrators only).
Audit Trails	A secure, computer-generated record that documents the sequence of events or activities to provide accountability and traceability.	<ul style="list-style-type: none"> Generate user action traces automatically—no programming required User operations and system parameters changes are automatically traced for modifications. Alarm log automatically generated and signed. Remote VNC access events are recorded to ensure authorized access.
Record Storage	Electronic records must be maintained to ensure they are accurate, readily available, and securely stored over the required retention period.	<ul style="list-style-type: none"> Audit Trail files and user logs will be stored locally on an SD card. The system developer must monitor SD card health to prevent locking and out-of-space issues. The system developer's responsibility is to manage the logs backup, this can be via FTP or email transfers. UniCloud's "Backup and Restore" feature offers secure storage for records and files. It enables machine builders to perform daily backups of machine configurations and files, preventing log loss in the event of external storage corruption.
Electronic Digital Signatures	Requires electronic signatures to be uniquely linked to their signatories to ensure authenticity and integrity of electronic records.	<ul style="list-style-type: none"> Supports digital signing for Audit Trail files, Data Table records, Alarm Logs, and Data Sampler logs. UniLogic offers digital signature verification software ensuring record integrity. Digitally signed records can be exported to human-readable formats using the UniStream Data Conversion Suite.

Unitronics' UniStream series controllers and UniLogic software offer a seamless path to FDA 21 CFR Part 11 compliance. With advanced security features, detailed audit trails, and digital signatures, UniStream ensures that your data is secure, traceable, and regulatory-compliant.