



VectorPro[®] software FDA 21 CFR Part 11



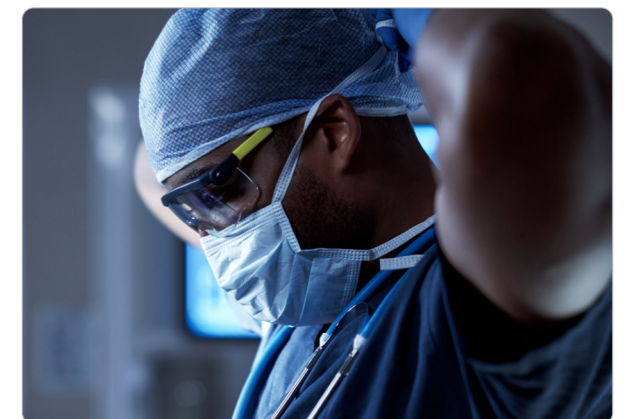
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Ensuring data integrity in FDA-regulated industries

Our guide to FDA 21 CFR part 11 compliance with VectorPro software.

Established by the United States Food and Drug Administration (FDA), 21 CFR Part 11 outlines essential regulations for electronic records and signatures. The primary goal of this regulation is to provide clear guidance on maintaining the reliability and integrity of electronic records, ensuring robust security measures, facilitating effective data retention, and enabling comprehensive audit trails.

This regulation pertains to any organisation under FDA jurisdiction, with particular emphasis on pharmaceutical companies, manufacturers of medical devices, and laboratories involved in FDA-regulated activities.



FDA 21 CFR part 11 compliance

To adhere to 21 CFR Part 11, organisations must implement policies and procedures specifically addressing electronic records and signatures. These guidelines should encompass the creation, modification, maintenance, archiving, retrieval, transmission, and security of electronic records within the system.

Data integrity, a critical aspect of compliance, involves maintaining and ensuring the accuracy and consistency of data throughout its life cycle. Adhering to the ALCOA principle, which outlines five essential qualities, is crucial:

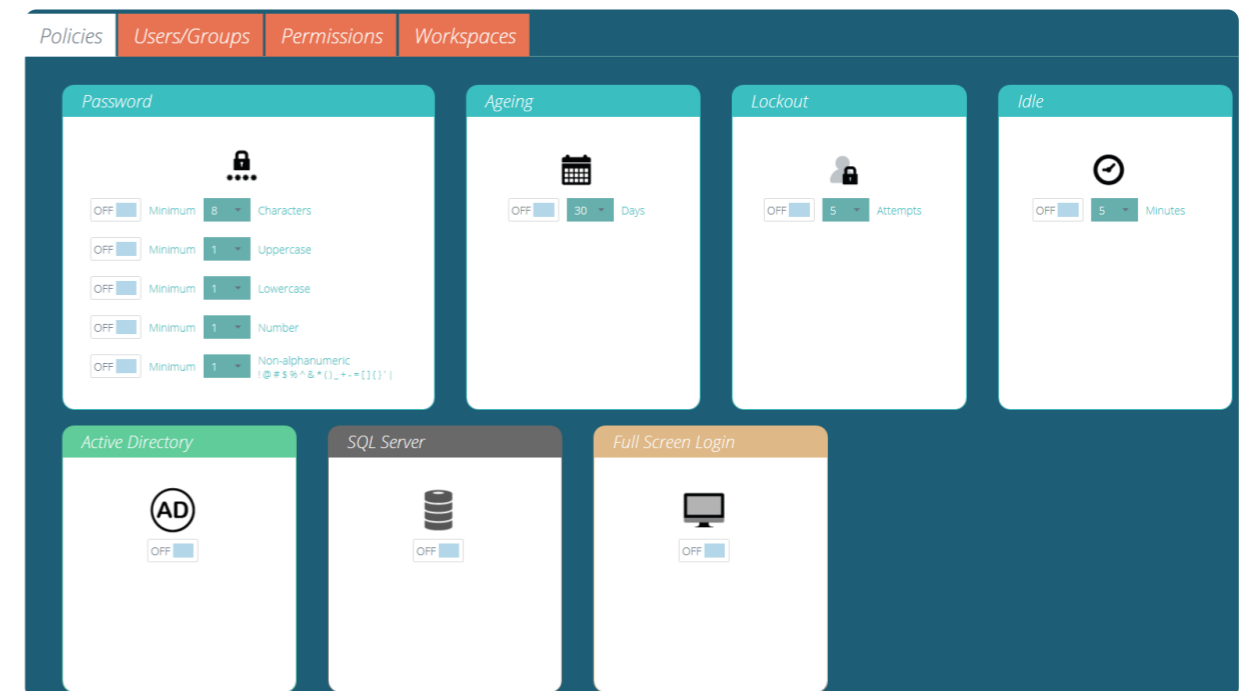
- Attributable (A) – Clearly specify who performed the action and when.
- Legible (L) – Ensure data is easy to understand, recorded permanently, and preserved in its original form.
- Contemporaneous (C) – Record data at the time the work is performed to maintain its relevance.
- Original (O) – Preserve data in its original form or as a certified true copy to safeguard authenticity.
- Accurate (A) – Guarantee data is error-free in accordance with established protocols.

VectorPro software has been designed with best practices of the ALCOA principle, which in turn helps professionals achieve compliance with 21 CFR Part 11 as part of their quality system requirements.

VectorPro[®] software's traceable and reliable results

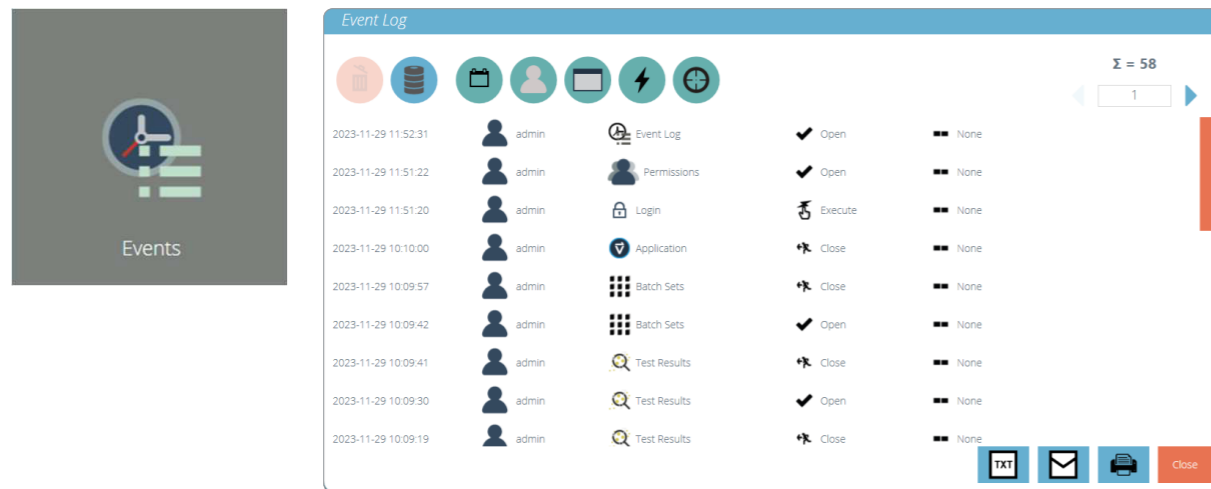
VectorPro is an intuitive force and torque testing software package, developed for our range of universal testing machines (UTMs), compression testers, torque testing systems and handheld instruments. Our test systems are used globally by medical device and pharmaceutical companies to deliver accurate, reliable and affordable testing solutions, for environments from production, quality control to R&D.

The ever-growing demands on software within the medical and pharmaceutical sectors necessitate robust mechanisms for documenting the traceability of completed actions. Essential when manufacturing safety-critical products. With its traceable and reliable test results VectorPro software is the ideal solution to help you meet FDA 21 CFR Part 11 requirements.



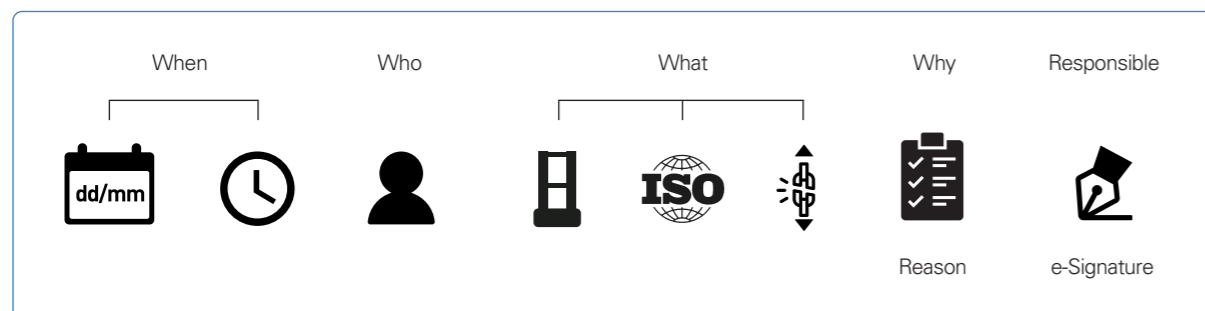
Software traceability and event logging

VectorPro, is equipped with a comprehensive Event Log, which automatically records all actions and changes throughout the entire testing process.



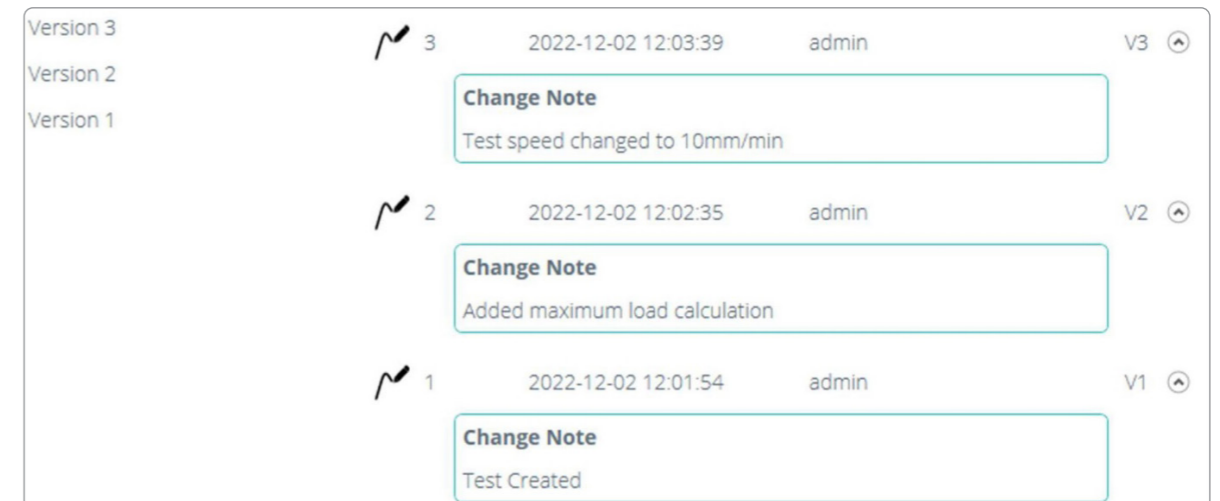
This includes the date, UTC and local time stamps, details of the user and activities before, during, and after the test, ensuring that test results and accompanying documentation remain traceable and are tamper-proof. The Event Log has indexing functionality and is easy to search by date, date range, user action etc. Only the VectorPro Administrator has access to the Event Log. The Event Log provides a comprehensive, permanent and searchable audit trail showing who did what, why and when within VectorPro. This ensures traceability, accountability and transparency in the testing process and full visibility into all system activities during an audit. It also reduces the risk of losing post test data.

Audit trail



Test versioning and modifications

Tests changes are saved each time the test is modified from its original form and a new revision or version is created. This revision history includes an optional comments section to note why a test has been changed, which is stored with the revised version as a Change Note.



Electronic signatures

VectorPro has an Electronic Signatures approvals feature, which replaces the need for manual, hard copy signatures. Electronic signatures can be configured in the Permissions Tab to ensure that data critical actions such as method revisions are reviewed, authorised and signed off by a Reviewer or Supervisor.

For example, Reviewers or Supervisors can be used within individual permissions in a test to authorise Saving Tests, Printing Reports and Deleting Samples. These are logged as actions, which forms the electronic signature, providing an additional layer of protection against tampering with test results.

Security

VectorPro's comprehensive security options allow administrators to configure user permissions in the software, granting access to trained personnel and limiting access where needed. User permissions can be configured directly within VectorPro or using an existing Microsoft Active Directory or an compatible LDAP directory service.

- **Safety:** Prevent untrained users from potentially damaging the test system or having accidents
- **Data integrity:** Prevent users from inadvertently changing test procedures or deleting test samples or data

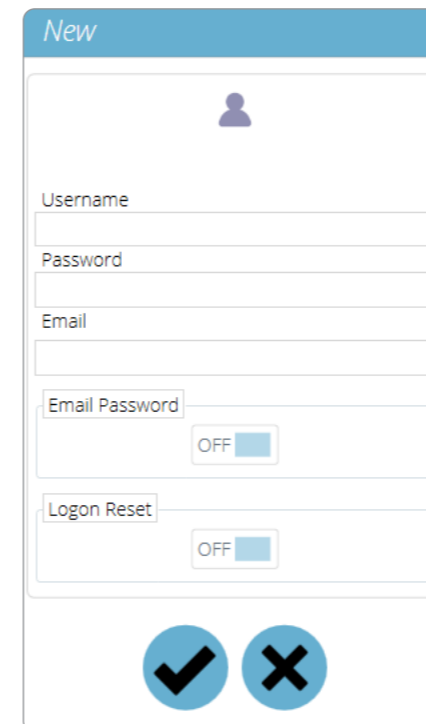
Permissions can be set for individual users or groups, where all users in the group will have the group's assigned privileges. For example, VectorPro Reviewers can be set to view particular screens, access specific hardware, test attributes and functionality and electronic reviewing and electronic signature functionality. This removes the risk of edits or changes being made without authority.

The Workspace area within VectorPro shows what functionality is available to each user.

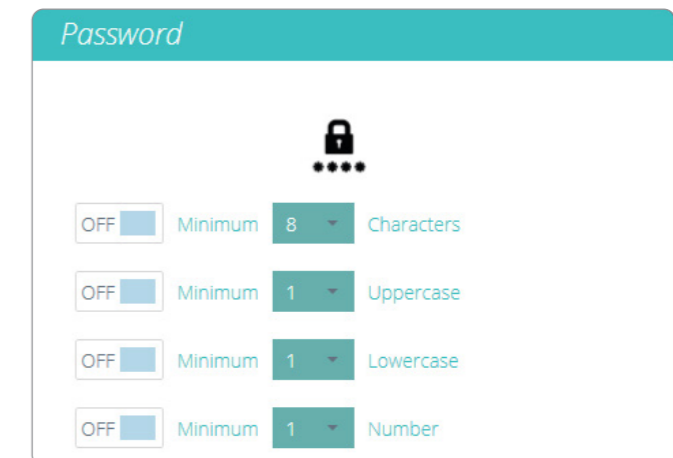


Assigning passwords

Setting up new users in the Permissions Tab in VectorPro is simple. Administrators can create new users and email them their temporary password from the software for their first-time login. They can also choose the Login Reset option to force users to change their password after logging in for the first time. VectorPro will prompt users to reset their password on next login.




VectorPro has a number of options to assist Administrators in setting strong, secure passwords. For example passwords can be defined by a minimum number of numbers; a minimum number of upper case characters; a minimum number of lower case characters; minimum number of numbers and a minimum number of non-alphanumeric characters.



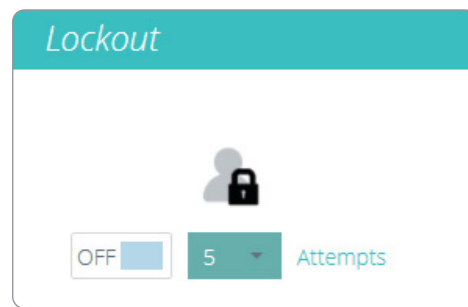
Password ageing

Administrators can set password expiration criteria in VectorPro, which require all users to change their password after a set period of time, up to 90 days.



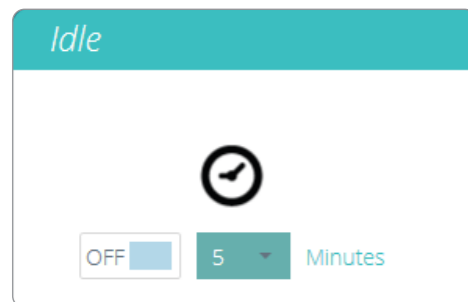
System lockout

Users can also be locked out after a set number of attempts to log in with the wrong password. They will need to contact the VectorPro Administrator, who can reinstate the user with a new password and login reset.



System idle

Administrators can set VectorPro to automatically lock due to inactivity and select the duration for system idle before locking users out.



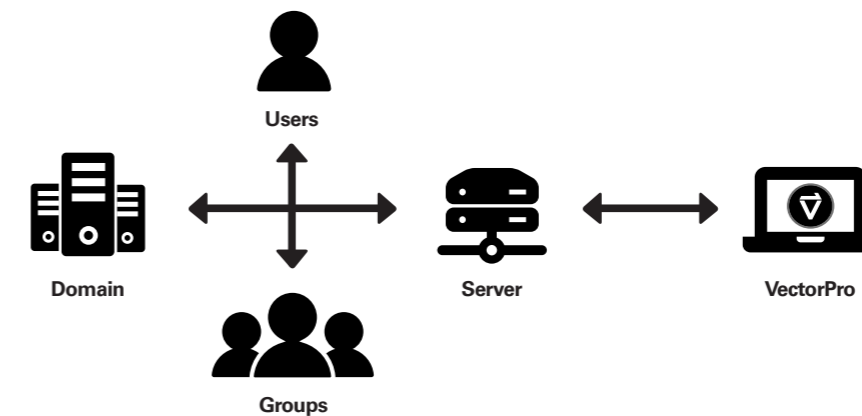
IT integration

VectorPro can be operated locally or via a company network. Software security can be integrated into a company's domain and a common IT policy set for all users.

Active Directory

For companies that want security based on user groups on the system's corporate network VectorPro has a Microsoft® Active Directory (AD) option, available to purchase as an add on module. Active Directory is a directory service that centralizes the management of users and computers. Its primary function is to authenticate and authorize users and computers in a windows domain.

Active Directory enables IT professionals to populate VectorPro users and groups with the PC user's Windows domain login rather than creating the users and groups locally on the PC using a VectorPro Admin login.



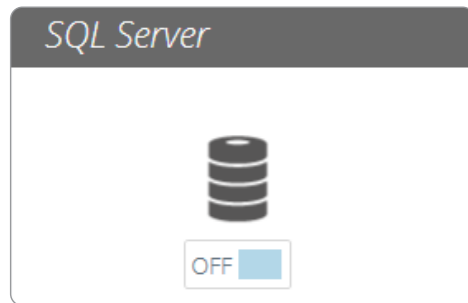
This supports user accounts on company domains for logging in and electronically signing files in VectorPro. Installation of Active Directory should be done in conjunction with an IT professional who manages the company's network.



SQL server

VectorPro stores information in a local database on a PC. For enhanced security VectorPro also offers an option to install Microsoft® SQL Server® 2019 Express. This is available to purchase as an add-on module.

SQL Server is a database management system that can be used to store and access information, with online backup, that will help to protect your data if anything goes wrong, such as a local PC crash. SQL Server Express enables IT professionals to maintain VectorPro database in a familiar and secure enterprise environment.



IQ/OQ/PQ Protocol

As part of our commitment to comprehensive validation support, we offer an optional IQ/OQ/PQ qualification pack to further enhance the reliability and compliance of VectorPro.

This is used to verify and validate instrument performance in relation to regulatory requirements in the medical device and pharmaceutical industry:

IQ: Is the software correctly installed?

OQ: Is the software operating as expected, and do users understand its limits?

PQ: Does the software reliably produce the correct result?

Each IQ/OQ/PQ documentation pack is specific to the serial number of the test instrument supplied.



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The PPT Group offers an extensive selection of universal test machines and force/torque testing systems, all driven by VectorPro software. Our comprehensive range caters to various applications and budgets, making them ideal for testing raw materials, components, assemblies, and products, ensuring the highest quality standards are met.



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