



ENABLING COMPLIANCE

WITH FDA 21 CFR PART 11

MOCON® software option allows compliance with popular security requirement.



What is 21 CFR Part 11?

Title 21 Code of Federal Regulations (CFR) governs food and drugs. Part 11 is a set of guidelines from the Food and Drug Administration (FDA) that sets forth the criteria under which the Agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. This regulation applies to all FDA program areas such as drug makers, medical device manufacturers, biotech companies, biologics developers and other FDA-regulated industries.

It was intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect the public health. It requires that these companies implement controls, including audits, system validations, audit trails, electronic signatures and documentation for software and systems involved in processing the electronic data that the FDA requires them to maintain.

Every MOCON® Permeation Instrument is a standalone unit equipped with its own operating software, WinPerm™2. To comply with 21 CFR Part 11, instruments must provide Users and Groups Management. This can be managed on an instrument's operating software.



Easy compliance with FDA 21 CFR Part 11

The software in MOCON permeation analyzers allows simple compliance with FDA 21 CFR Part 11, including:

- Multi-Level User Management
- Audit Trail
- Data Security
- Data Output
- Record Retention

Standalone instrument management

Each MOCON Permeation Instrument is a standalone unit equipped with its own operating software, WinPerm2.

This software features enhanced multi-level user controls, allowing the existing MOCON software option for 21 CFR Part 11 to be implemented and managed locally on each instrument.



Fig. 1 WinPerm2 Software user management and password control



Fig. 2 WinPerm2 Software 21 CFR Part 11 instrument configuration

Key features & benefits

1. User security controls with password protection
2. Configurable security privileges
3. Lock out after failed logins
4. Password aging
5. Electronic signatures
6. Audit trail (all user modification and interactions on a test will be recorded and audit logged)
7. System security (the system databases are encrypted and protected with security codes)
8. Automatic data output (pdf, csv and txt)
9. Data integrity checking
10. Record retention (the data cannot be edited or modified)



Fig. 3 WinPerm2 Software 21 CFR Part 11 test setup

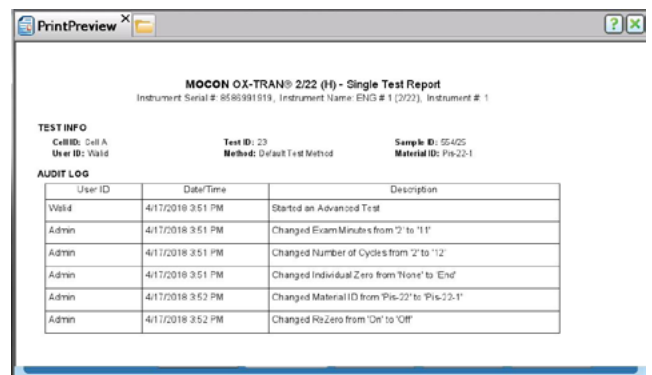


Fig. 4 21 CFR Part 11 Audit Log for test run on a MOCON OX-TRAN 2/22 instrument

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PRODUCT BROCHURE

With this built-in user control and data security, MOCON Permeation Instruments allow customers to meet 21 CFR Part 11 requirements like data management, audit trails and user management without a network or PC connection.

In addition to offering permeation instrument products and software to help you comply with 21 CFR Part 11, MOCON also offers software validation documentation, IQ/OQ documentation and on-site validation services for new instrument installations or post-installations.

Want to learn more?

Contact your local MOCON Account Manager for more information.



Specifications

Required Operating System	Instrument Compatibility
WinPerm2	OX-TRAN 2/12 OX-TRAN 2/22 OX-TRAN 2/28 OX-TRAN 2/40 OX-TRAN 2/48 AQUATRAN 3 AQUATRAN 3/38 AQUATRAN 3/40 PERMATRAN-W 3/34 PERMATRAN-C4/30



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