Rheology Solutions

Rheology Solutions is the sole Australian distributor of this product range and we welcome the opportunity of discussing your application requirements.

We hope the information you are seeking is contained within this file. If you have any questions, or require further information please contact us. We look forward to being of further service.

Regards from the Team at Rheology Solutions.

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Product Specifications

HAAKE RheoWin 3 with 21 CFR part 11 tools helps users in both research and quality control to comply with the stringent requirements of the regulated industry. It provides an user management system, file integrity, an audit trail and electronic signatures to ensure that the integrity of electronic records is always maintained.

HAAKE RheoWin 3 Software 21 CFR Part 11 tools

Key features

- **Adaptable and comprehensive user management system for access control**
- **Audit trail automatically records all significant events and actions**
- **User-definable electronic signatures to meet diverse laboratory requirements**
- **Build-in file integrity and security for method and result files**

HAAKE RheoWin Software

HAAKE RheoWin is the universal rheometer software from Thermo Electron Corporation for rheological measurements ranging from routine quality control measurements to sophisticated R&D work. Since its introduction in 1997 HAAKE RheoWin has set standards regarding ease-of-use with its unique JobEditor user interface. The JobEditor, which is part of the HAAKE RheoWin JobManager program allows the definition of highly flexible and fully automated methods (called Jobs in HAAKE RheoWin) using simple drag & drop functionality, for increased laboratory productivity. In HAAKE RheoWin Jobs can consist of a sequence of measurements and/or evaluations routines. Different kind of measurements, like flow-curves, oscillation, creep-recovery, etc. can be combined and mixed with automatic data evaluation, user-defined messages, report generation, etc., in any needed sequence. Jobs can also be defined and controlled externally from data systems like SAP and LIMS using a script-language that is build into HAAKE RheoWin.

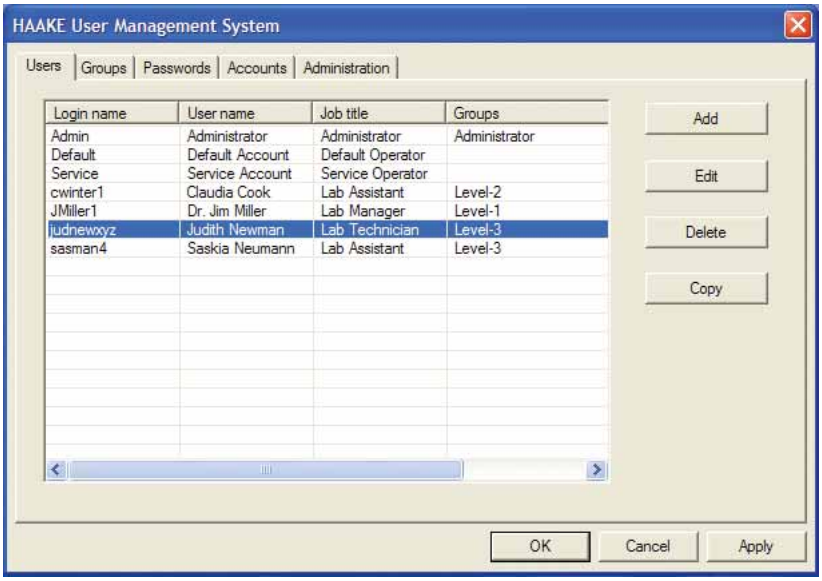
The HAAKE RheoWin DataManager program offers extended functionality for interactive evaluation of measured data as well as sophisticated tools for the creation of reports which can be be printed and exported in the following formats: PDF, XLS, HTM, TIFF, JPG, etc.

HAAKE RheoWin is equipped with a comprehensive user management system for access control. The user management system includes password controls like minimum password length, password uniqueness, password age limits, etc. More then 80 specific privileges, based on pre-defined or user-defined user groups, can be assigned to each user, exactly defining the scope of activity of that user.

HAAKE RheoWin 3 Software
21 CFR Part 11 tools

The optionally available 21 CFR Part 11 tools add audit trail and electronic signature functionality to HAAKE RheoWin 3. By maintaining a secure, computer generated, time stamped audit trail, HAAKE RheoWin automatically tracks all operator entries and actions that create, modify or delete electronic records. The audit trail records the time and date of each event, along with the name of the operator involved. The system administrator can grant specific user groups or individual users the privilege of applying electronic signatures to both HAAKE RheoWin Job and Data files.

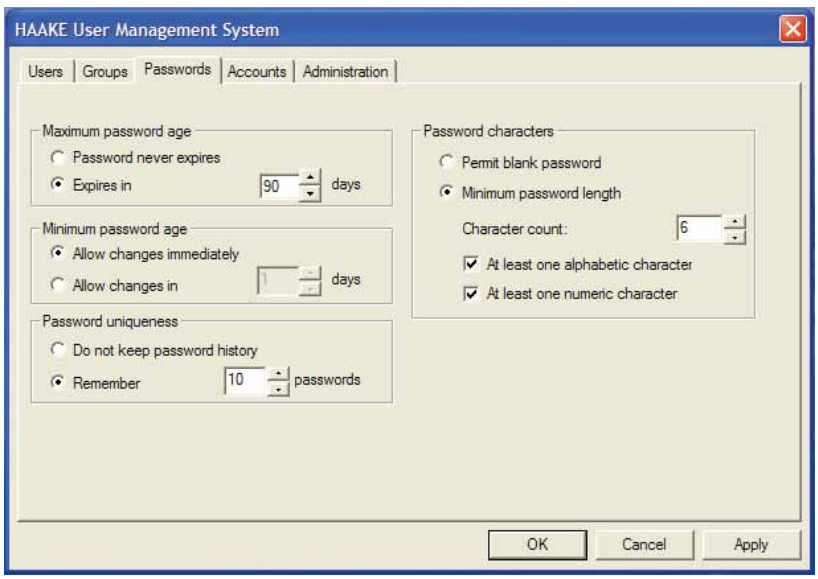
HAAKE RheoWin combines the power of the Windows operating system with your laboratory's network to provide improved performance essential for the productive operation of all of your rheological techniques.



The FDA and 21 CFR Part 11

The Electronic Records and Signatures Rule, known as 21 CFR Part 11, was established by the U.S. Food and Drug Administration (FDA) in order to define requirements for the use of electronic documents in lieu of paper records. The law, published in the Federal Register on March 20, 1997 and in effect since August 20, 1997, specifies the system elements, controls, and procedures that are necessary to ensure the trustworthiness, authenticity, integrity and confidentiality of electronically-stored records and electronic signatures. Because compliance requires the combination of electronic systems and Standard Operating Procedures, no product alone can ensure compliance. However, products with integrated functionality that meets the 21 CFR Part 11 requirements can significantly ease the task of achieving and maintaining full compliance with the law. In response to 21 CFR Part 11 and the increasing data security requirements in other industries, Thermo developed the HAAKE RheoWin 21 CFR part 11 tools to offer the "technical compliance" needed to meet these mandatory regulations. With the HAAKE RheoWin 21 CFR part 11 tools, the regulated industries will be confident in their ability to provide the complete story about the generation and handling of the data.

Thermo makes its security functionality available to both existing and new customers. The HAAKE RheoWin 21 CFR Part 11 tools are fully compatible with the following range of instruments that use the HAAKE RheoWin software platform including HAAKE Viscotester 6 und 7 (plus), HAAKE Viscotester 550, HAAKE RotoVisco 1, HAAKE RheoScope 1, HAAKE RheoStress 1, HAAKE RheoStress 150, HAAKE RheoStress 300 and HAAKE RheoStress 600. Users may be required to upgrade to version 3 of the HAAKE RheoWin applications software to be able to use the HAAKE RheoWin 21 CFR Part 11 tools.



File Integrity

HAAKE RheoWin 3 and the 21 CFR Part 11 tools provide several layers of protection to ensure that accurate records can be readily retrieved. The foundation for record protection is a secure operating system (Microsoft® Windows NT® 4.0, Windows® 2000 or Windows® XP with the NTFS file system) that provides positive user tracking and prevents unauthorized access to computers and files.

The next layer of protection is formed by the binary file format of the HAAKE RheoWin method and result files (Job, Data and Page files), which ensures that even those users who have access to files at the operating system level cannot read or modify records through means outside the secured application. HAAKE RheoWin method and result files are protected against external file tampering by a build-in checksum (hash-code). HAAKE RheoWin will not load an external modified file, an attempt to load such a file is registered in the Audit Trail.

Beyond the protections realized by the operating system and the special file format, HAAKE RheoWin is equipped with an user management system, a comprehensive security system that controls access to data. This ensures that only authorized users are able to access records and make changes; any such changes are tracked by the computer-generated audit trail.

HAAKE RheoWin 3 Software
21 CFR Part 11 tools

User Management System and security

The HAAKE RheoWin 21 CRF Part 11 tools offer a secure login process that is based on user groups and different privilege levels, reflecting the laboratory workflow. For example, the laboratory manager might be the only person allowed to release a new method, while a laboratory technician may only be permitted to use existing methods and run certain analysis routines.

HAAKE RheoWin initially provides one administrator user with a set of privileges that is limited to configuring the system and four predefined user groups. These groups can be used as is or modified as needed. In addition, new groups can be created and privileges assigned to meet your laboratory's specific requirements. Over 80 different privileges can be granted to each user.

To ensure that only authorized individuals can use the system, electronically sign records, access system functions, modify electronic records, etc., the HAAKE RheoWin's security system provides the user management capabilities most often requested by system administrators:

- Users are identified by a unique combination of UserID, User Name, and Job Title throughout the software.
- Password requirements – such as minimum password length, password uniqueness, and password age limits – can be enforced.
- User logins are automatically logged in the audit trail.
- Users can be automatically locked out after a pre-set number of login failures.

Audit Trail

HAAKE RheoWin with 21 CFR Part 11 tools maintains a secure, computer-generated, time-stamped audit trail, which records all changes that are made to method and result files (Job, Data and Page files), all changes in the program settings (JobManager, DataManager and UserManager) and user logon/off actions. For ease of use, audit trail items are created fully automatically with minimal user interaction. The audit trail records the what, how, who, when, where, and why of every change.

- What was changed (indicates the parameter that was changed)
- How the change was made (displays the previous and the new value of the altered field)
- Who made the change (displays user name from login)
- When the change occurred (shows the date and time of the change)
- Where the change was made (specifies the file or record that was modified)
- Why the change was made (reason for the change)

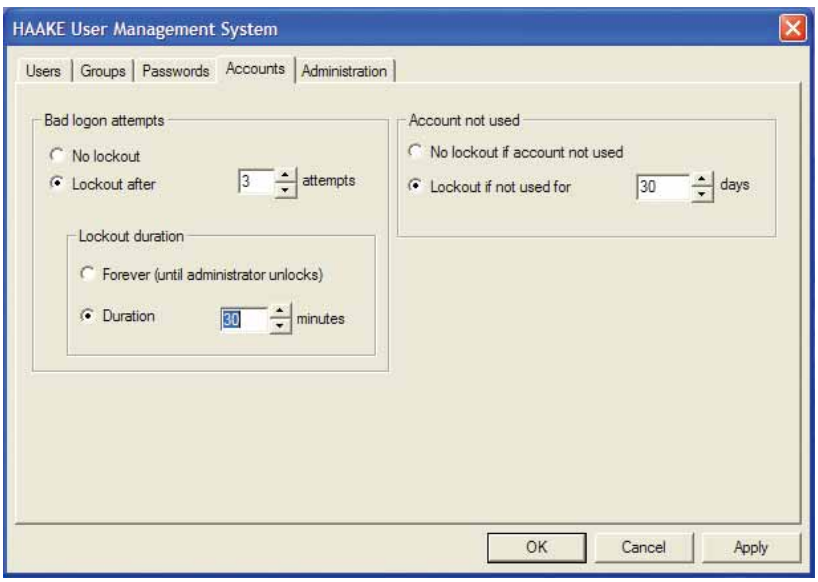
The Audit Trail is saved in a MS Access or SQL Server compatible database file which can reside on a secure network drive.

The Audit Trail can be a viewed using MS Access or any other compatible database program. For ease of use, the Audit Trail database file (in MS Access format) contains an appropriate query form.

Electronic Signatures

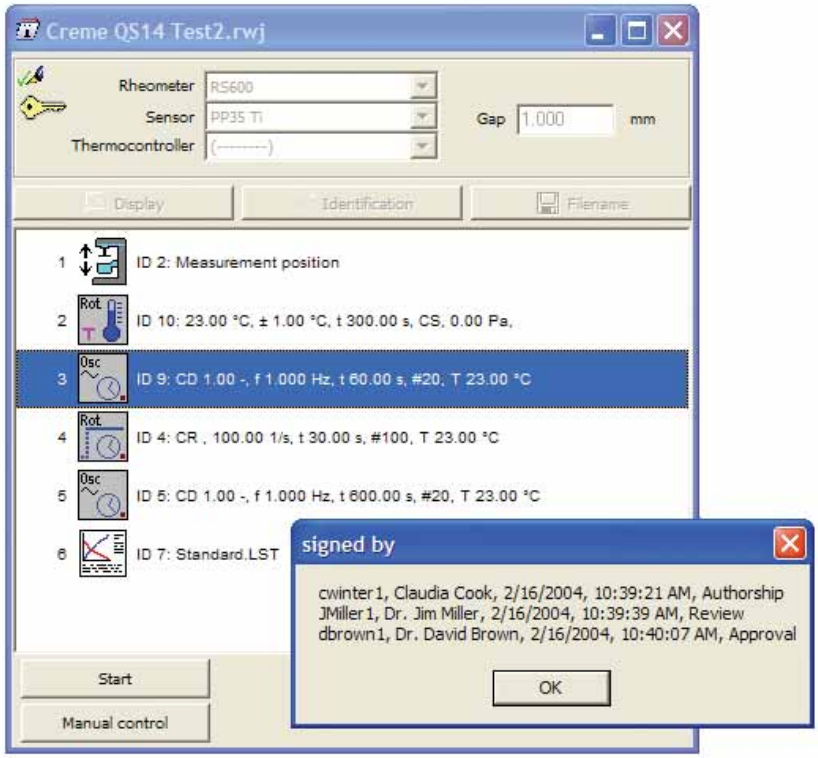
According to the 21 CFR Part 11 regulations, an electronic signature is defined as "a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature" and each electronic signature "shall be unique to one individual and shall not be reused by, or reassigned to anyone else".

In HAAKE RheoWin an electronic signature can be applied to any method or result file (Job, Data and Pages files). An electronic signature in HAAKE RheoWin consists of the User Name and Password, as two distinct identification components unique to an individual, the reason for the signature and the date/time the signature was applied. The electronic signatures are an integral part of the files they are applied to, they can not be removed or copied from that file. Because laboratory requirements vary, the HAAKE RheoWin 21 CFR Part 11 tools provide an electronic signature feature that is userdefinable, as well as a customizable reasons list.



HAAKE RheoWin 3 Software
21 CFR Part 11 tools

HAAKE RheoWin can be configured so that the application of a certain number of signatures will automatically lock the file for any future changes.



Validation Services

The regulation requires "validation of systems to ensure accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records" and the user must validate the system to ensure that it is suitable for use within its particular regulatory environment. Thermo uses a professional software development process to ensure reliability. HAAKE RheoWin and the 21 CFR Part 11 tools are developed following a Certified Quality System which conforms to the ISO 9001 guidelines. Our software development life cycle follows the ISO-9000 guidelines. Thermo offers Installation Qualification (IQ) and Operational Qualification (OQ) services and can assist you with Performance Qualification (PQ), if required.

A complete solution from a market leader

Viscometers and rheometers from Thermo are installed and validated in laboratories around the world. Thermo's broad range of experience includes providing instrumentation to laboratories following GLP/GMP regulations and the HAAKE RheoWin 21 CFR Part 11 tools are yet another example of Thermo's commitment to quality and to customer satisfaction.

It provides technical compliance by offering the additional capabilities needed by highly regulated laboratories such as those operating under the FDA's 21 CFR Part 11 rules. The HAAKE RheoWin 21 CFR Part 11 tools can be used on many existing Thermo viscometers and rheometers and give the security required by the regulated industries about the generation of the data. Thermo provides a complete solution, giving you the confidence needed for your success.

Important

The installation and proper configuration of HAAKE RheoWin 3 with the 21 CFR Part 11 tools will ensure technical compliance to 21 CFR Part 11. In addition, the user's organization must establish a range of policies and standard operating procedures that complement the capabilities provided by the software in order to ensure complete compliance to the rule.

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