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HAAKE RheoWin

User guide

Installation and 21 CFR part 11 configuration

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Introduction

This manual describes both the standard installation of the ThermoScientific HAAKE RheoWin software (hereinafter referred to as RheoWin) and the installation of RheoWin in conjunction with the 21 CFR Part 11 tools.

The reason for this is that, on the one hand, certain parts of RheoWin (such as the User Management System) can also be used with a standard installation of RheoWin (i.e. without the 21 CFR Part 11 tools), while, on the other hand, the 21 CFR Part 11 tools (User Management System, Audit Trail and Signature functionality) must already be considered and configured during the installation of RheoWin.

Those parts of the installation that are only required and/or available when the 21 CFR Part 11 tools are installed are marked accordingly in the text. This concerns certain passages of [Chapter 2](#) (Installation) and [Chapter 3](#) (User management) as well as the entire [Chapter 4](#) (Audit Trail) and [Chapter 5](#) (Signatures and Security Settings).

This manual is based on RheoWin version 4.85.00xx and applies to all RheoWin versions starting from version 4.85.0000 with the possible exception of some points that are mentioned separately in the text.

Installation

This chapter describes both the standard installation of HAAKE RheoWin (that is without the 21 CFR part 11 tools) as well as the installation of HAAKE RheoWin in combination with the 21 CFR part 11 tools.

Computer system (PC) requirements

Certain requirements regarding the PC hardware and the PC operating system must be fulfilled in order for the HAAKE RheoWin installation to be successful and in order for RheoWin to be able to communicate with the various HAAKE rheometers, viscometers and temperature control systems.

Operating systems requirements

The HAAKE RheoWin software only runs on a PC with a Microsoft Windows operating system.

RheoWin 4.85.00xx has been tested to run under the following Windows operating systems:

- Microsoft Windows 7, 32-bit or 64-bit, with or without Service pack 1.
- Microsoft Windows 8, 32-bit or 64-bit.
- Microsoft Windows 8.1, 32-bit or 64-bit.
- Microsoft Windows 10, 32-bit or 64-bit.

RheoWin 4.85.00xx has *not* been tested and is consequently *not* supported for use under the following Windows operating systems (It is strongly recommend to use Windows 7 or newer instead):

- Microsoft Windows Vista, 32-bit or 64-bit, with or without Service pack 1 or 2.

RheoWin 4 does *not* run and/or is *not* supported under the following Windows operating systems:

- Windows 3.x and Windows NT 3.x.
- Windows 95, Windows 98 and Windows 98 SE, Windows ME.
- Windows NT 4.0 and Windows 2000.
- Microsoft Windows XP, 32-bit, with or without Service pack 1, 2 or 3.

PC hardware requirements

No special PC is required for the convenient use of RheoWin. A PC meeting the requirements of the respective operating system for an office PC is fully suitable for the purpose.

As of June 2019, the following configuration is recommended:

- At least 8 GB RAM of main memory.
- A hard disk with a minimum of 2 GB available free space (or 10 GB if the RheoScope 1 or the RheoScope Module or another camera is used).
- A DVD drive.
- A 24" (or larger) monitor with a resolution of 1920x1080 pixel (a minimum resolution of 1152x864 pixels is mandatory).
- A keyboard and a mouse.

For the communication with a viscometer or a rheometer and with temperature control systems (circulators), cameras, etc., the following ports are required:

- For all HAAKE MARS rheometer:
 - Ethernet TCP/IP interface ¹.
 - Serial (RS232) interface (or a USB interface in combination with an USB to RS232 adapter), for older temperature control systems (circulators),
 - USB interface for newer temperature control systems (circulators).
 - 6-pin IEEE 1394a interface for the RheoScope module IEEE 1394 Firewire camera.
We recommend the use of a PC with an IEEE 1394 interface which is integrated on the PC mainboard or the use of the IEEE 1394 interface card that Thermo Fisher Scientific supplies as an optional accessory.
 - USB 3.0 interface for the RheoScope module USB camera.
 - USB interface for a WDM compatible camera (WebCam).
- For the HAAKE Viscotester iQ rheometer:
 - Ethernet TCP/IP interface ².
- For all other rheometers and viscometers:
 - A serial (RS232) port or a USB port with an USB to RS232 adapter for the rheometer or viscometer.
 - A serial (RS232) port or a USB port with an USB to RS232 adapter for older temperature control systems (circulators).

¹ Two Ethernet TCP/IP ports are required if it is intended to also connect the PC on which RheoWin is installed to a network (corporate network or Internet)

Windows access privileges requirements

IMPORTANT Both during the *installation* of RheoWin and during *normal operation* of the RheoWin software *read and write privileges* must be available for the following directories and subdirectories as well as for a certain Windows registry key:

- Directories under Windows 7, Windows 8(.1) and Windows 10 (German version)
 - C: \Benutzer\Öffentl i ch\Öffentl i che Dokumente\Thermo\RheoWi n
 - C: \ProgramData\Thermo\RheoWi n
- Directories under Windows 7, Windows 8(.1) and Windows 10 (English and other language versions)
 - C: \Users\Publ i c\Publ i c Documents\Thermo\RheoWi n
(or C: \Users\Publ i c\Documents\Thermo\RheoWi n depending on the representation in Windows Explorer.)
 - C: \ProgramData\Thermo\RheoWi n
- Windows registry key (all Windows versions)
 - HKEY_USERS\ . DEFAULT\Software\Thermo\RheoWi n

IMPORTANT During the *installation* of RheoWin unrestricted *write privileges* must be available for the following directory and all of its sub-directories. This means that Windows administrator privileges are needed for the installation of RheoWin.

- For english and other language 32-bit Windows versions:
 - C: \Program Fi l es\Thermo\RheoWi n
- For english and other language 64-bit Windows versions:
 - C: \Program Fi l es(x86)\Thermo\RheoWi n
- For german 32-bit Windows versions:
 - C: \Programme\Thermo\RheoWi n
- For german 64-bit Windows versions
 - C: \Programme(x86)\Thermo\RheoWi n

After a successful installation, Windows users of the default **Administrator Group** and **Power User Group** should directly be able to use the RheoWin software. Windows users of the default **User Group** must be granted read and write access to the RheoWin folders and Windows registry key mentioned above by an administrator.

Note In case RheoWin does not run as intended after setting up RheoWin and Windows as described above, consult [Appendix C, “Configuration of Windows permissions”](#) of this manual for more detailed instructions on how to configure RheoWin specific Windows permissions

For more information on the directories and the files in those directories which RheoWin uses see [“Installation directories”](#) on [page 49](#).

Compatibility with older RheoWin versions

RheoWin can be installed parallel to existing installations of older versions of RheoWin, *but only when* the major version numbers of the individual versions are different. This means, for example, that RheoWin 4.xx.xxxx can be installed parallel to RheoWin 3.xx.xxxx and/or RheoWin 2.xx, but not parallel to RheoWin 4.10.xxxx or RheoWin 4.20.xxxx, etc.

RheoWin 4.xx.xxxx, RheoWin 3.xx.xxxx and RheoWin 2.xx must always be installed in different directories.

Only one version of RheoWin can run on one PC at the same time.

A newer RheoWin version can always read all data (*.rwd), job (*.rwj) and page (*.rwp) files as well as all template files of older versions (backward compatibility). An older version will not be able to read a file after it has been saved once by a newer version.

An older version of RheoWin can *not* import any data (*.rwd), job (*.rwj) and page (*.rwp) files or template files from newer versions (no forward compatibility).

Supported devices (rheometers, viscometers, circulators, etc.)

Table 1 lists the rheometers, viscometers, temperature control systems and circulators that can be controlled by RheoWin.

Table 1. Devices that are supported by RheoWin 4.85.00xx

Rheometer	Viscometer	Circulators	Temperature control devices
MARS 60	Viscotester iQ	SC150, AC200	MTMC (MARS)
MARS 40	Viscotester iQ Air	PC300	UTMC
MARS iQ			UTC
MARS iQ Air	VT D, VT E	ACCEL	CTC
MARS III			
MARS II	RotoVisco 1	Dynamax	Rheonaut
MARS I			RheoScope
RheoStress 6000	VT550	DC5, DC30, DC50	
RheoStress 3000		Phoenix	TC501 ^a
RheoStress 600		F6, N6, F8, N8	
RheoStress 300			
RheoStress 1			

^a Drivers for these older devices are available on special request only.

It should be noted that a RheoWin registration key is always device-specific, i.e. only the software driver (the link between RheoWin and the device, so to say) for a certain rheometer or a viscometer is installed. The drivers for all temperature control systems, circulators and other ancillary equipment that are compatible with the installed rheometer or viscometer can be selected and, if required, installed during installation.

Older HAAKE devices that are not shown in the list above may be supported by earlier versions of RheoWin, see www.rheowin.com.

Starting the installation

The Rheowin software cannot be run from the data-carrier (DVD) and must be installed before it can be used. It is recommended to reboot the computer prior to starting the installation.

The RheoWin setup should always be executed locally, i.e. directly from the DVD in the (local) DVD drive or from a local directory on the PC on which RheoWin is to be installed. The installation files should *not* be copied to a network drive first and the installation started from there.

RheoWin versions 4.40.0000 and newer

Starting from RheoWin 4.40.000 a newer version can be installed without deinstalling the previously installed older version, as long as the older version was RheoWin 4.20.0000 or newer. In this case the settings of the previously installed version are automatically transferred to the new version.

An existing installation of RheoWin version 4.00.0000 to 4.10.00xx however *must* be deinstalled before RheoWin version 4.40.0000 or newer version can be installed. In this case it is *not* possible to transfer the settings from the previous version to the new version.

Installing from the RheoWin DVD

In order to start the installation process, the RheoWin DVD is inserted into the DVD drive. Normally, the default web browser (such as, e.g., Internet Explorer) will then automatically be launched and the screen as shown in [Figure 1](#) on [page 8](#) will be displayed.

The RheoWin installation is started by clicking on the text (link) **Install HAAKE RheoWin 4.**

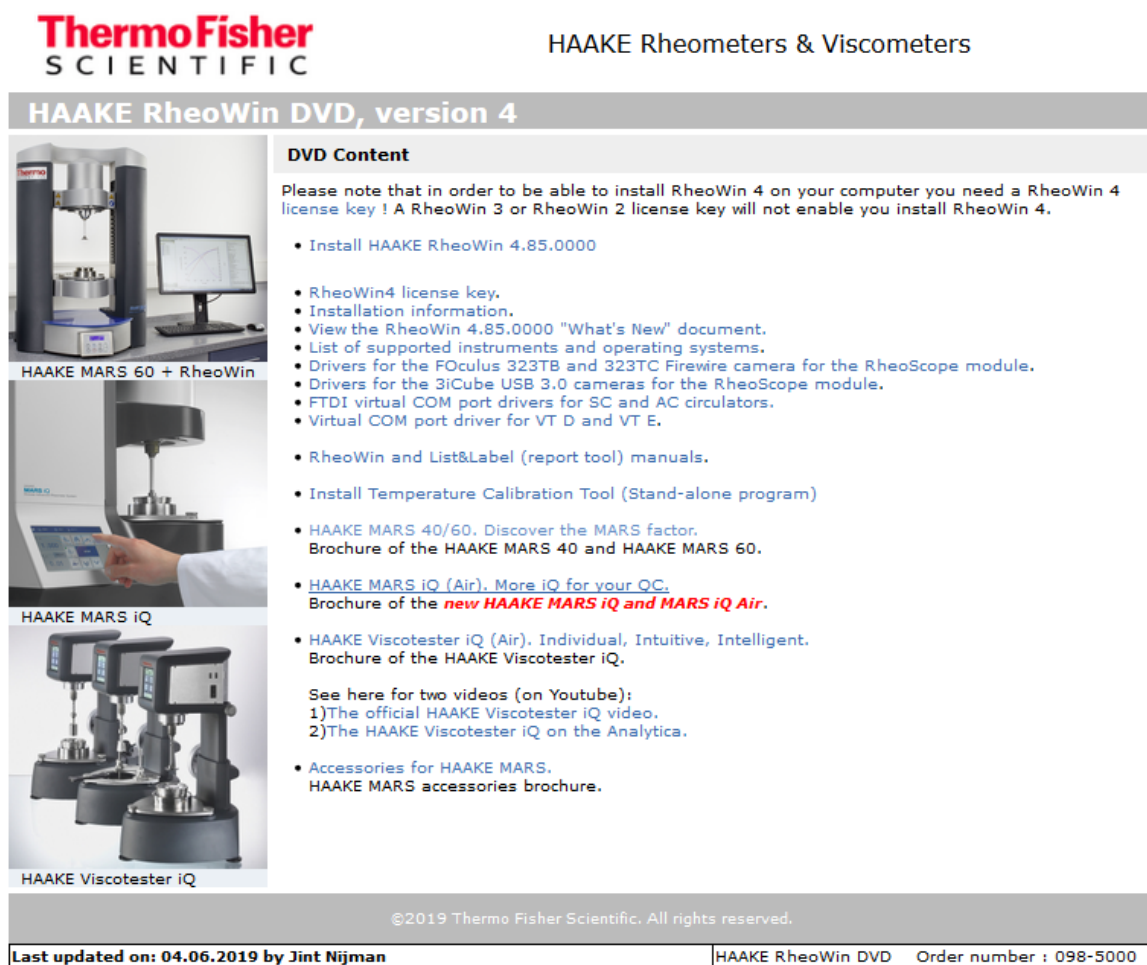
In case the default web browser does not start automatically, run the `Start.bat` program from the main directory of the DVD or load the `Index.htm` file in the HTML directory on the DVD in a browser to open the page (the RheoWin DVD start screen) shown above. Another option to start the installation process is to directly launch the `Setup.exe` program from the RheoWin directory on the DVD.

Installing from a local directory on a harddisk

The latest RheoWin version can always be downloaded from the www.rheowin.com web-page.

In case the RheoWin installation files were downloaded from the Internet to a local directory on the PC's harddisk drive (or USB drive) or were already stored (locally) on the PC due to other circumstances, then the installation can also be started by launching the `Setup.exe` program from that local directory.

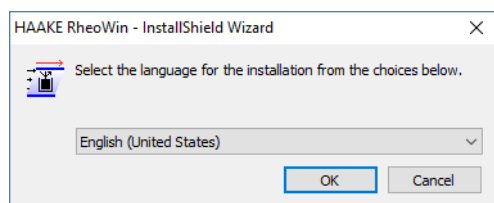
Figure 1. RheoWin DVD start screen



The installation process

After starting the installation, the dialogue language for the installation process must be selected first. This language is also automatically preset for RheoWin. The RheoWin dialogue language can be changed at any time in the RheoWin software.

Figure 2. Choose setup language

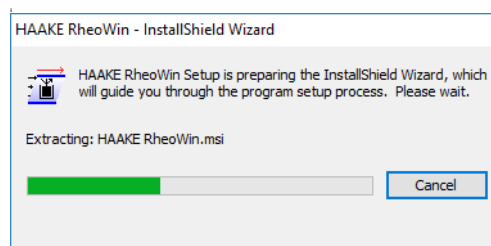


As soon as this step is completed, the InstallShield Wizard is launched.

The InstallShield Wizard will first extract and install Microsoft Visual C++ 2015 Redistributable Package and then extract and install Microsoft Access Database Engine 2007 Redistributable Package (which are both needed for certain parts of RheoWin to work).

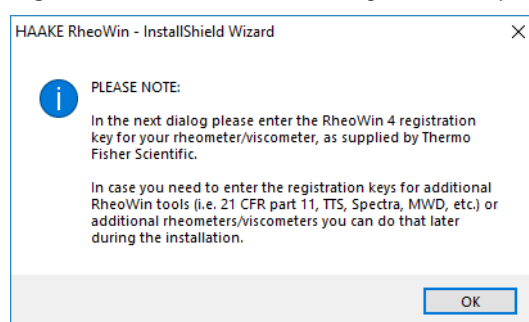
The InstallShield Wizard will then extract the RheoWin program files and install them. This can take a relatively long time, depending on the computer configuration and the operating system.

Figure 3. Installation preparation



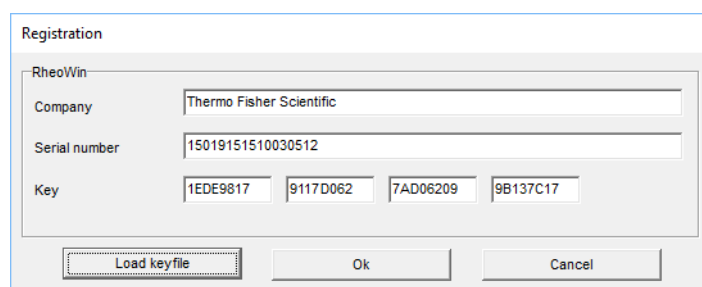
During the installation of RheoWin, it is first necessary to enter a valid registration key (license key) for a measurement device or the Data Manager. When this action is completed, up to 19 additional registration keys for other measurement devices and/or RheoWin modules (such as 21 CFR Part 11 tools, TTS, Spectra, MWD, etc.) can be entered.

Figure 4. Please note, enter registration key



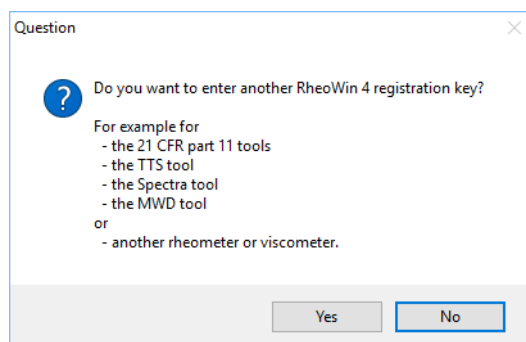
A RheoWin registration key consists of the **Company name**, **Serial number** and **Key**. This information must be entered in the appropriate fields in the **Registration** dialog (Figure 5). When entering the company name and serial number, please note that these are both case sensitive. Case sensitivity does not apply to the key itself. The complete key can be entered by cut & paste in the first key edit-field. By clicking on the **Load keyfile** button the complete registration key information can be read from an appropriate key-file.

Figure 5. Enter registration key



Other registration keys can then be entered for other rheometers/viscometers or RheoWin modules, such as the 21 CFR Part 11 tools, in any sequence desired. The company name, serial number and key must always be entered completely for each registration key.

Figure 6. Enter another registration key



Use settings from previous installation

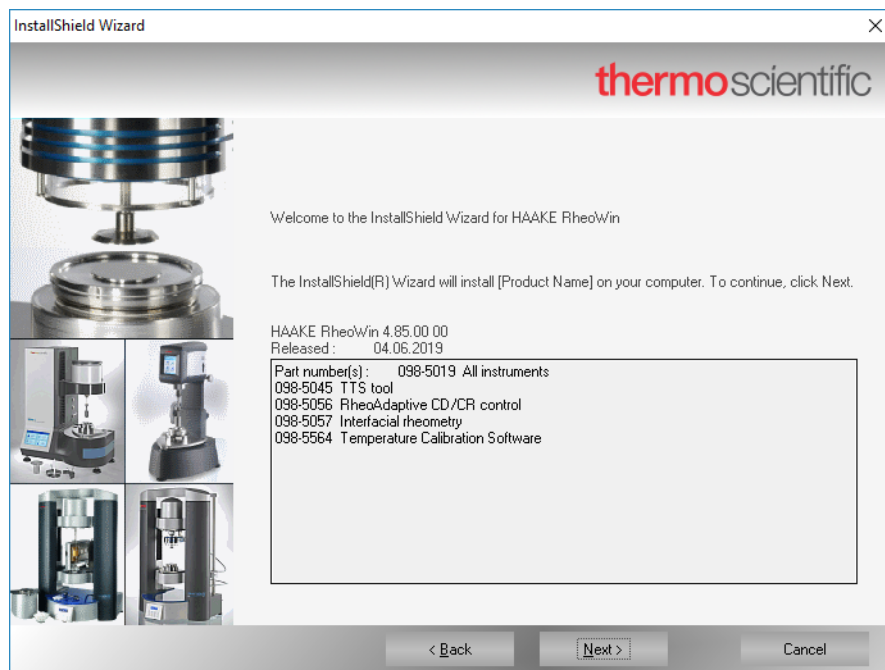
Starting from RheoWin 4.40.000 a newer version can be installed without deinstalling the previously installed older version, as long as the older version was RheoWin 4.20.0000 or newer. In this case the settings of the previously installed version are automatically transferred to the new version.

An existing installation of RheoWin version 4.00.0000 to 4.10.00xx however *must* be deinstalled before RheoWin version 4.40.0000 or newer version can be installed. In this case it is *not* possible to transfer the settings from the previous version to the new version.

Welcome dialog

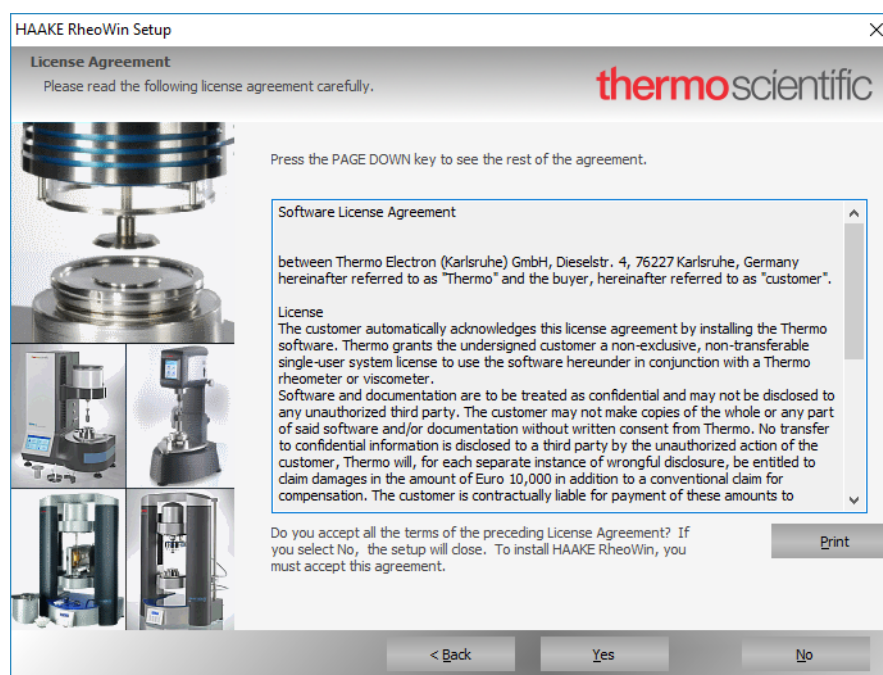
Once all registration keys are entered, the Welcome dialog will appear.

Figure 7. Welcome dialog



This window displays the following information: The RheoWin version number, serial number (of the first registration key that was entered), measurement devices to be installed, optional modules to be installed and the software expiration date (the latter only applies to demo versions).

Figure 8. License agreement

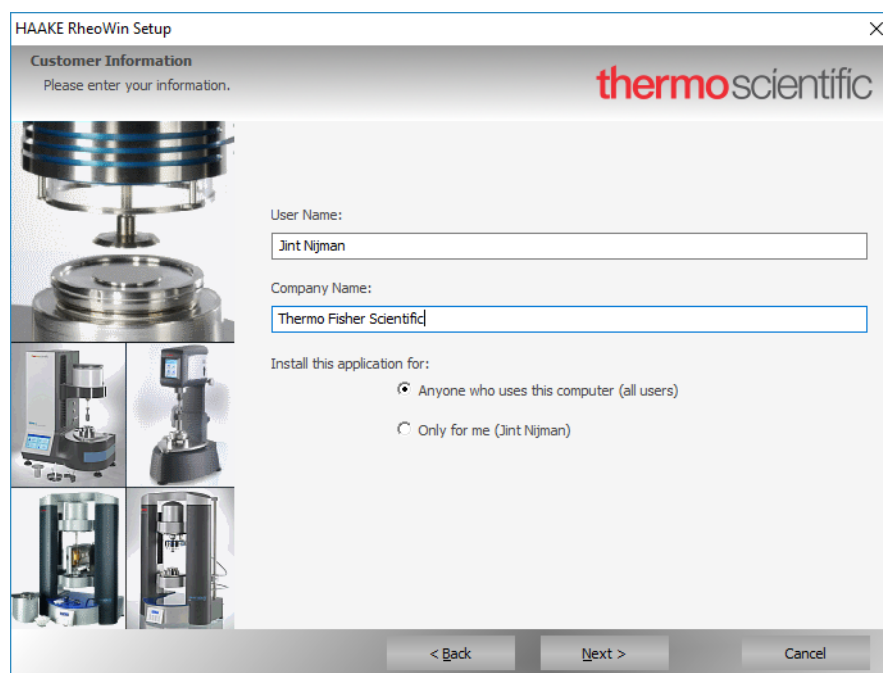


In the following dialogs, the various installation options must be configured.

Dialog customer information

This dialog allows to select whether the RheoWin software is to be installed only for the user currently logged-on to the operating system or for all users who logon to the computer (operating system).

Figure 9. Customer information

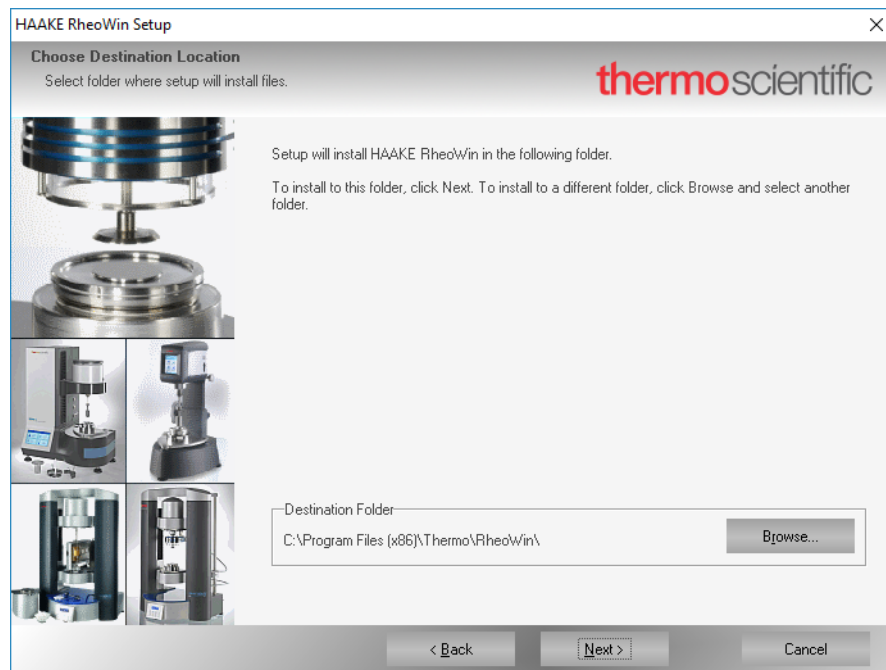


It is recommended to use the default setting **Anyone who uses this computer (all users)**.

Dialog choose destination location

This dialog provides the option to select the **Destination Folder** (directory) where RheoWin is to be installed. The dialog for the directory selection can be accessed by clicking on the **Browse...** button.

Figure 10. Choose destination location (folder)

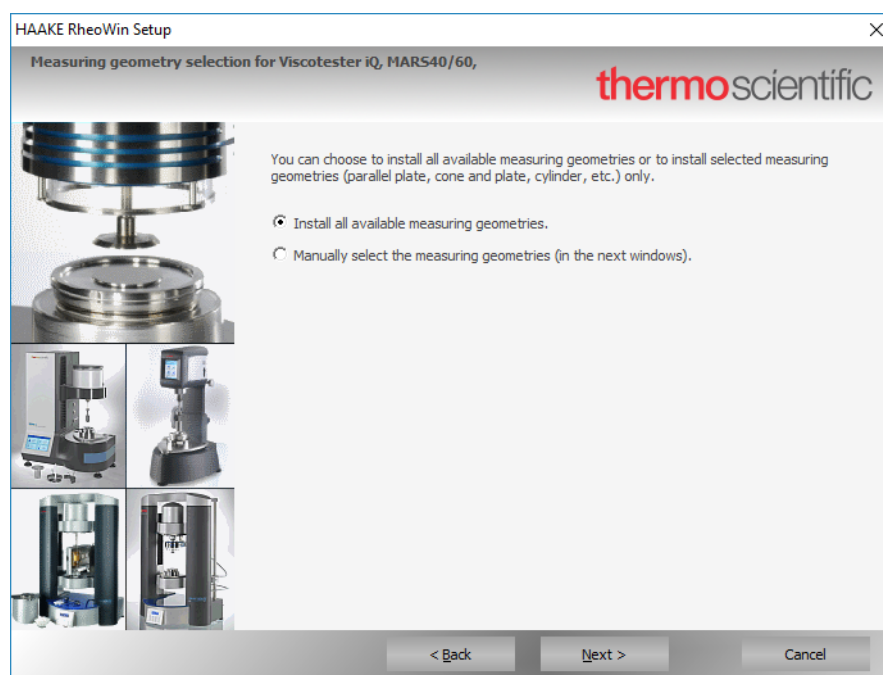


It is recommended to use the default setting **C:\Program Files\Thermo\RheoWin**. Please note that the actual default directory depends on the operating system version, see the appendix.

Dialog measuring geometry selection

This dialog provides the option to **Install all available measuring geometries** or to **Manually select the measuring geometries** that will be installed (in the next four windows). It is recommended to use the **Manual select...** option, that is to only install the measuring geometries that are actually used in conjunction with the rheometer. It is always possible to remove measuring geometries from the list (in the RheoWin DeviceManager) at a later point of time.

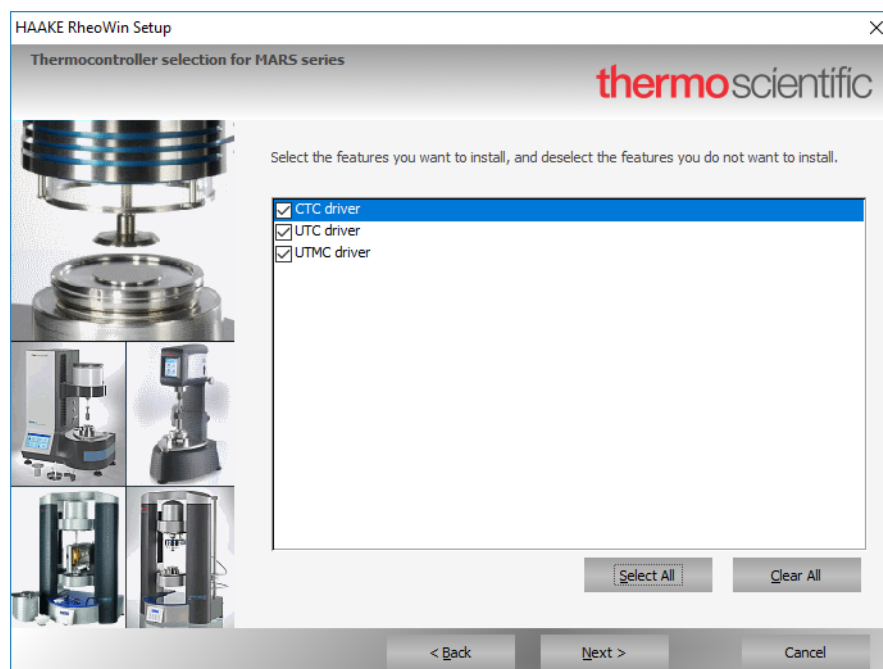
Figure 11. Measuring geometry selection



Dialog thermocontroller selection

In this dialog the thermocontrollers that are to be used with the rheometer or viscometer can be selected.

Figure 12. Thermocontroller selection

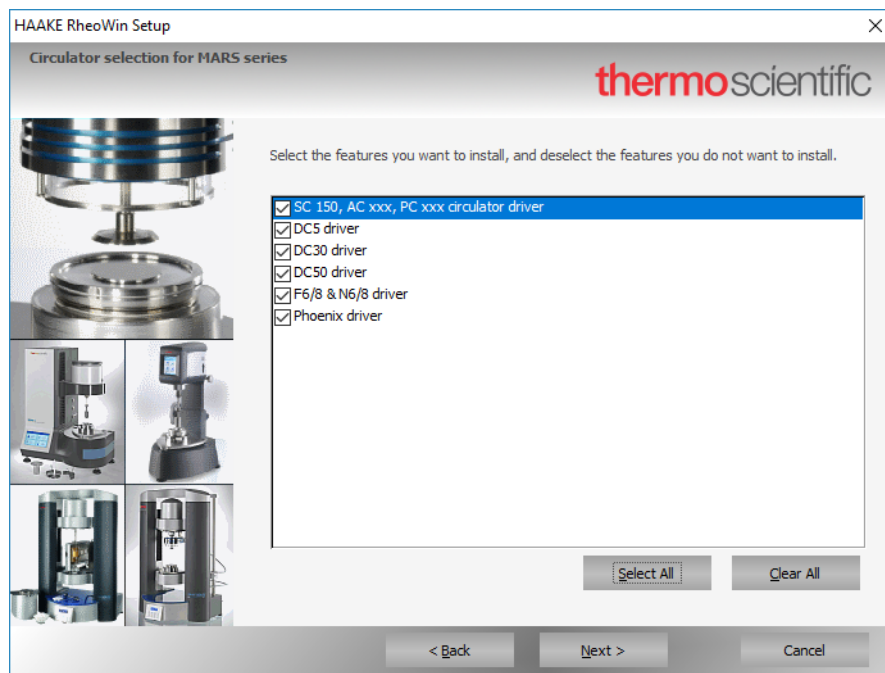


The **Select all** button can be used to select all the thermocontrollers for the installation.

Dialog circulator selection

In this dialog the circulators that are to be used with the rheometer or viscometer can be selected.

Figure 13. Circulator selection

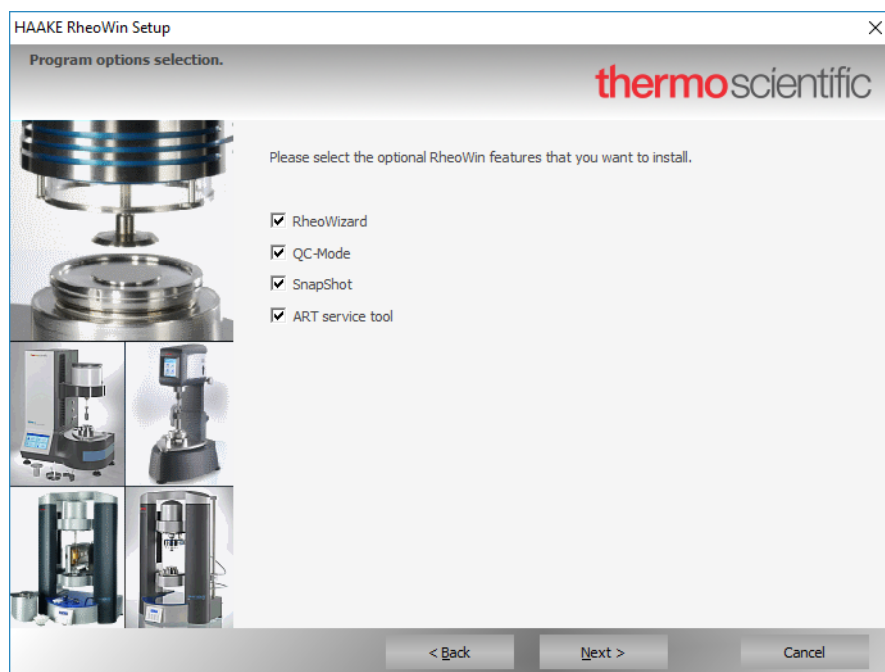


The **Select all** button can be used to select all the circulators for the installation.

Dialog program options selection

Various different program options can be selected in this dialog.

Figure 14. Program options selection

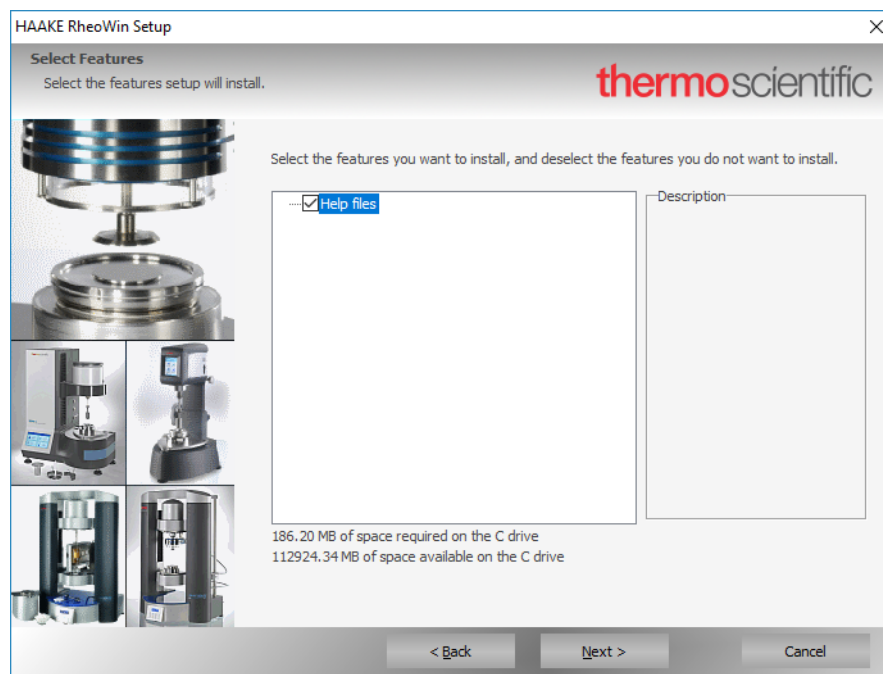


RheoWizard	Intelligent user guidance for creating a job sequence.
QC-Mode	Validation of analysis results.
SnapShot	Quick information on an unknown substance.

Dialog select features

In this dialog it can be selected which templates, sample files and help files will be installed. Starting from RheoWin version 4.60.0000 this dialog only contains the Help files entry, all example and template and media files are always installed automatically.

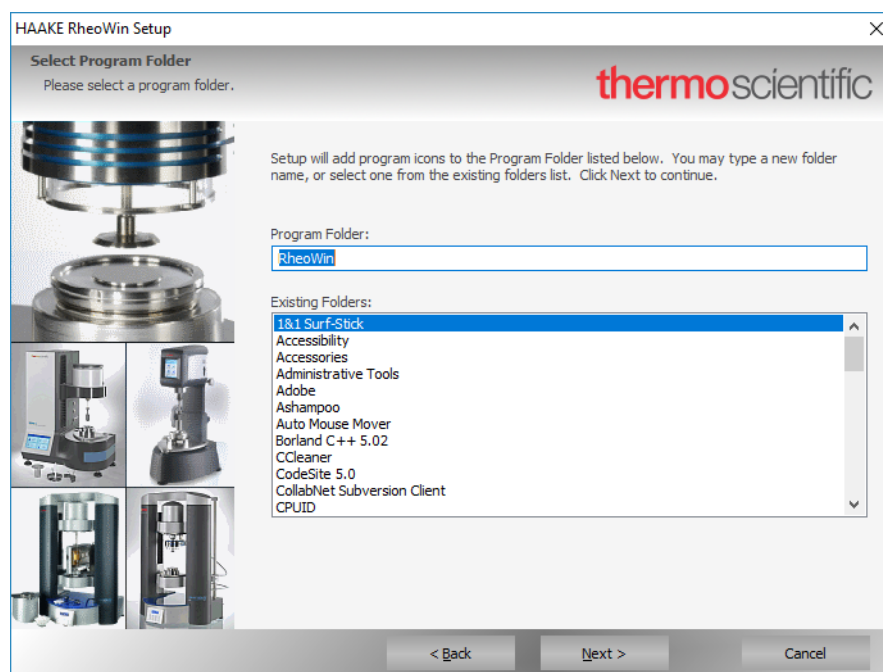
Figure 15. Select features



Dialog select program folder

In this dialog the program folder (in the Windows Start menu) can be selected in which short-cuts to the HAAKE RheoWin programs are to be created.

Figure 16. Select program folder

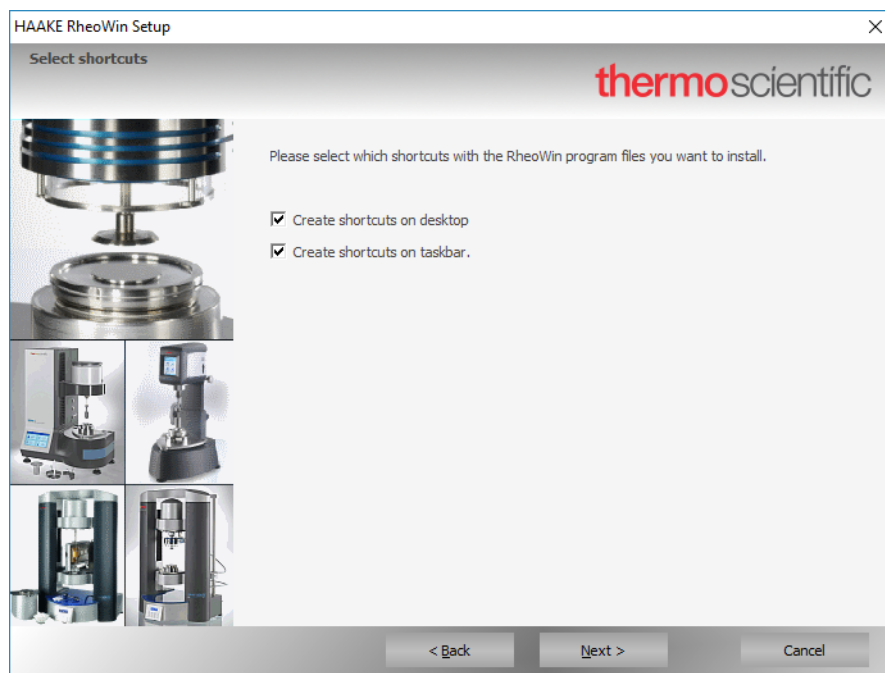


It is recommended to use the default setting RheoWin.

Dialog select shortcuts

In this dialog it can be selected whether program shortcuts to the RheoWin programs should be created on the desktop and/or on the taskbar of the PC.

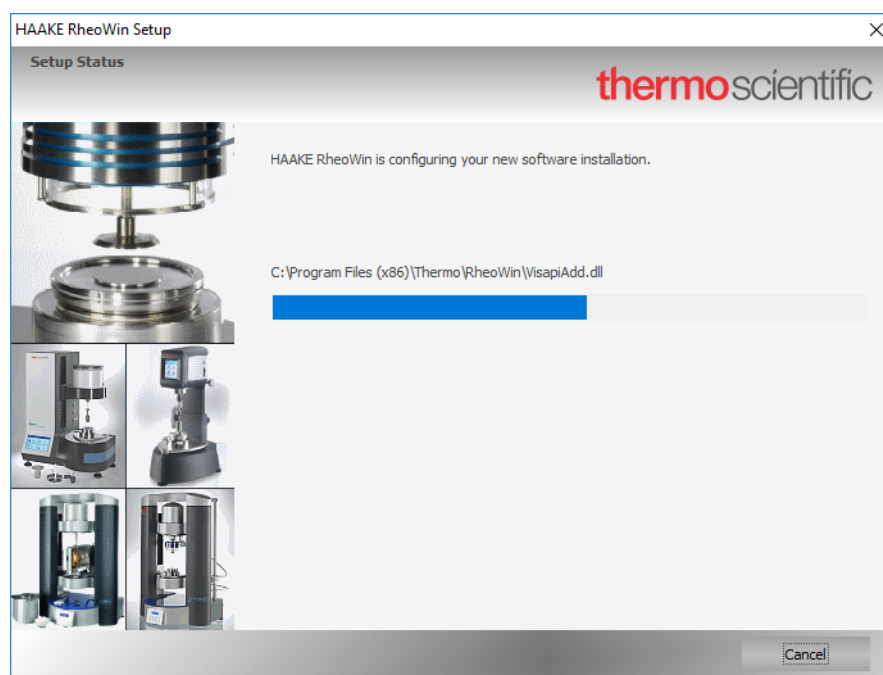
Figure 17. Select shortcuts



Dialog setup status

The actual installation will now be started. Relatively long waiting times can arise, depending on the computer configuration and the operating system.

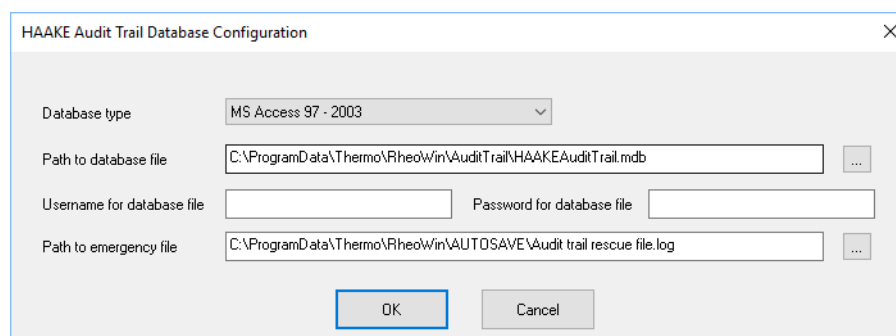
Figure 18. Setup status



Dialog HAAKE Audit Trail Database Configuration

This dialog is only displayed when the 21 CFR Part 11 tools are being installed. In the dialog certain settings for the Audit Trail Database can be defined.

Figure 19. HAAKE Audit Trail Database Configuration



IMPORTANT These settings can also be performed after the installation, but it *essential* that these *must* be made prior to the first launch of RheoWin. This in order to meet the requirements regarding of 21 CFR Part 11. For more information on the configuration of the Audit Trail, see [Chapter 4, “Audit Trail.”](#)

Dialog installation complete

This dialog provides the option to read the ReadMe file and launch the application after the RheoWin installation is complete. It is strongly recommended to read the ReadMe file.

2 Installation

Adding devices or software modules to an existing installation

Figure 20. Installation complete



Adding devices or software modules to an existing installation

Additional rheometers/viscometers and/or RheoWin modules can conveniently be added to an existing installation at any later point in time.

❖ To modify the RheoWin installation (under Windows 10)

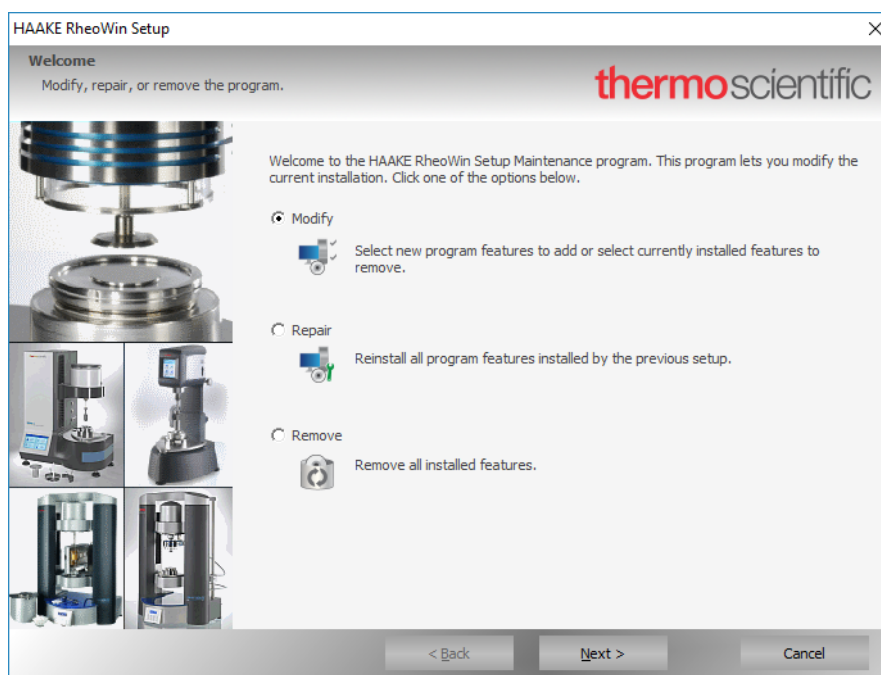
1. Click the Windows **Start** button on the Windows taskbar.
2. From the Start menu choose **Settings**.
3. In the Settings dialog select **Apps**.
4. In the **Apps & features** dialog scroll down the list of application until HAAKE RheoWin becomes visible, see [Figure 26](#) on [page 23](#).
5. Click on the list entry **HAAKE RheoWin**.
6. Click the **Uninstall** button to launch the HAAKE RheoWin Setup program.
7. In the HAAKE RheoWin Setup program select **Modify** and then click **Next >**, see [Figure 21](#).

The RheoWin installation modification uses the same dialogs as the installation, see “[The installation process](#)” on [page 8](#), starting with the Enter registration key dialog, see [Figure 5](#) on [page 9](#).

8. By entering one or more keys, one or more RheoWin modules or one or more rheometers / viscometers or a combination of both can be added to the installation.

IMPORTANT When the 21 CFR Part 11 tools are being added to an existing installation where the HAAKE User Management System was not been enabled yet, the User Management System must be activated manually. See “[Administration](#)” on [page 34](#) in the chapter User management.

Figure 21. Installation modification



First program launch after new installation

The RheoWin Job Manager, Data Manager or User Manager can be started via the shortcuts in the start menu of the operating system, on the desktop or on the taskbar.

Standard installation (without 21 CFR Part 11 tools)

If the program has been installed without the optional 21 CFR part 11 tools, the programs will start without the user having to log in to RheoWin. All program parts and menu entries are accessible. The default account is enabled on the **Administration** page of the RheoWin User Management System, so no log-in is necessary.

If a user access control system is required for RheoWin, this option can be selected in the main menu under **Configuration** by using the **User Manager** command, followed by the User Administration link.

For this purpose, the **Default** Account must be disabled on the **Administration** page of the **User management** dialog. The RheoWin User Management System is described in detail in [Chapter 3](#).

Installation with 21 CFR Part 11 tools

IMPORTANT Before RheoWin is launched for the first time, the Audit Trail **MUST** be configured to meet the 21 CFR Part 11 requirements see [Chapter 4, “Audit Trail.”](#) In case the Audit Trail has not already been configured during the installation, this step *must* be performed at this stage.

In case RheoWin was installed with the optional 21 CFR Part 11 module, a dialog is displayed once upon the first launch of the Job, Data, or User Manager in which the administrator *must* enter (define) the password for administrator access.

Figure 22. Enter administrator password

To meet the requirements of 21 CFR Part 11, a secure password *must* be set and entered here by the administrator. The entry must be repeated in order to confirm the password.

When this step is completed, the RheoWin login dialog is displayed. Here the administrator password that was previously defined must be entered.

Figure 23. Login for RheoWin

When the administrator password has been entered, the account information is shown regarding the current access.

Figure 24. Account information for Administrator

The RheoWin JobManager, DataManager or UserManager program is now launched with the *restricted* privileges of a RheoWin administrator.

Note Many of the menu and dialog items in the JobManager and DataManager are *not* accessible, since by default, a RheoWin administrator is only granted the privileges necessary to configure RheoWin and the 21 CFR Part 11 tools. See [“Users”](#) on [page 27](#) for more information.

Settings for 21 CFR Part 11

The following list shows the settings that either have to be performed prior to the first launch of RheoWin or otherwise immediately after the first start of the RheoWin software.

Audit Trail

IMPORTANT Before RheoWin is launched for the first time, the Audit Trail must be configured to meet the 21 CFR Part 11 requirements.

The configuration of the Audit Trail is described in detail in [Chapter 4, “Audit Trail.”](#)

User management

The administrator has to assign access rights to those users who are to be granted access to the RheoWin software by using the User Management System.

The User Management System can be launched as a separate application directly from the Windows desktop or the Windows **Start Menu** or via the **Configuration** menu of the RheoWin Job or Data Manager, respectively.

Each user can be allocated group rights or individual rights for access to and the operation of the RheoWin software. New groups with specific rights can be created at any time.

When the "21 CFR Part 11" tools are being added to an existing installation where the RheoWin User Management System has not been enabled, the User Management System must be activated manually. In case the "21 CFR Part 11" tools are installed in the course of the RheoWin installation, the User Management System will be enabled automatically.

The configuration of the User Management System is described in detail in [Chapter 3, “User management system.”](#)

Signatures and storage settings

The RheoWin administrator must make the desired settings regarding signatures and special options for saving in order to ensure that the installation meets the 21 CFR Part 11 requirements.

The configuration of signatures and storage settings is described in detail in [Chapter 5, “Signatures and security settings.”](#)

User settings for Job and Data Manager

All settings (that can be) made in the **Configuration** menu by using the **Language**, **Units** and **Settings** commands are stored individually for each RheoWin user.

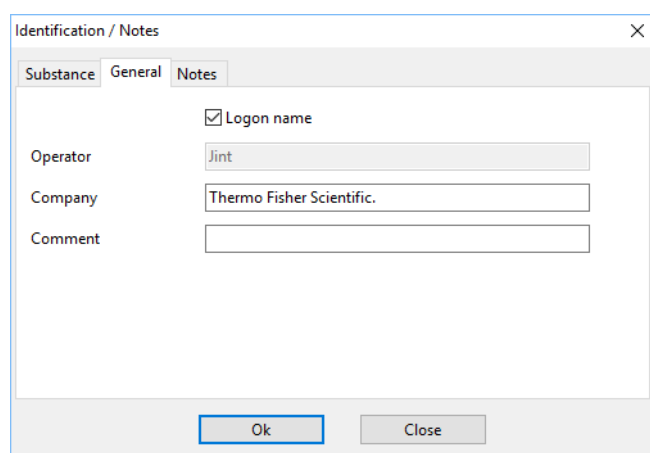
If a user is not to be given the ability to change any of these settings, this can be specified via the assignment of appropriate privileges in the User Administration (siehe [Chapter 3](#)). The settings for a user must, however, be defined in the RheoWin software prior to disabling these privileges for this user.

To this end, the RheoWin software is launched using the access of the respective user to make the appropriate settings. After completion of this step, the software application has to be closed again. The RheoWin administrator then has to disable the relevant privileges for the settings regarding this user in the User Management System.

Job settings

If the user logged into the RheoWin software is to be entered automatically as the operator whenever a job is started, the **Logon name** check box must be enabled on the **General** page of the **Identification / Notes** dialog. Thus, when a job is started, the currently logged-in user will be entered as the operator, even if another user is displayed in the definition of the job.

Figure 25. Identification automatic operator name



Installation of new RheoWin version

Starting from RheoWin 4.40.000 a newer version can be installed without deinstalling the previously installed older version, as long as the older version was RheoWin 4.20.0000 or newer. In this case the settings of the previously installed version are automatically transferred to the new version.

An existing installation of RheoWin version 4.00.0000 to 4.10.00xx however *must* be deinstalled before RheoWin version 4.40.0000 or newer version can be installed. In this case it is *not* possible to transfer the settings from the previous version to the new version.

Deinstallation of RheoWin

The RheoWin (de-)installation program can be started from the Windows Settings dialog.

❖ To deinstall RheoWin (under Windows 10)

1. Click the Windows **Start** button on the Windows taskbar.
2. From the Start menu choose **Settings**.
3. In the Settings dialog select **Apps**.
4. In the **Apps & features** dialog scroll down the list of application until HAAKE RheoWin becomes visible, see [Figure 26](#).

5. Click on the list entry **HAAKE RheoWin**.
6. Click the **Uninstall** button to launch the HAAKE RheoWin Setup program.
7. In the HAAKE RheoWin Setup program select **Remove** and then click **Next >**, see [Figure 27](#).
8. In the following dialog confirm that HAAKE RheoWin should really be deinstalled.

Figure 26. Windows Apps & features dialog

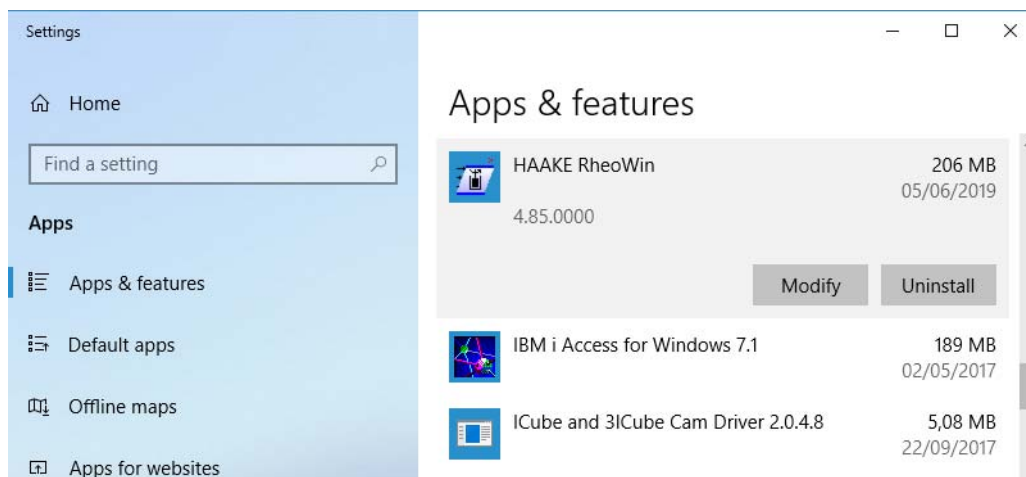
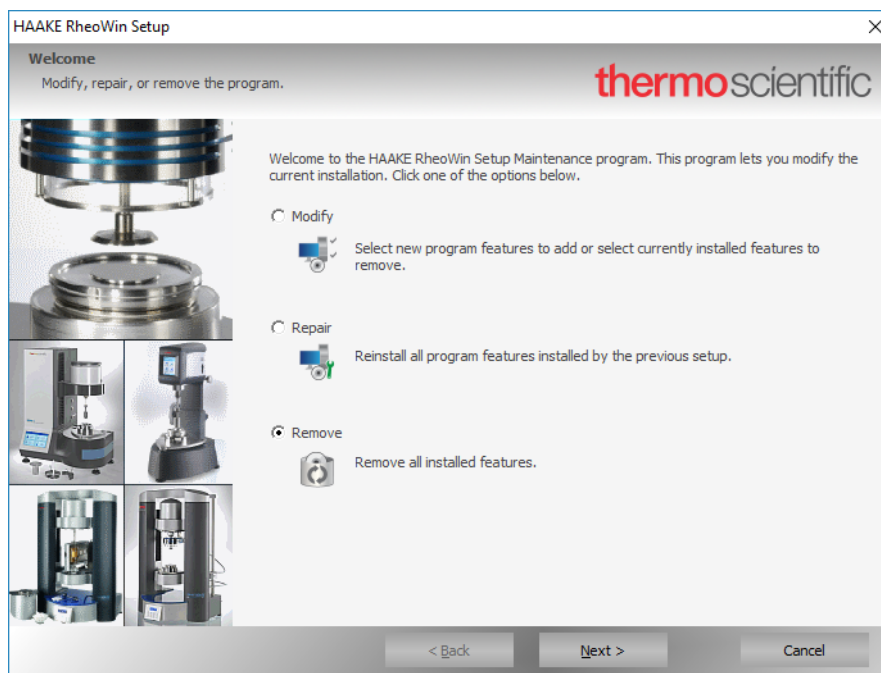


Figure 27. Remove program



All RheoWin registry key entries and all (RheoWin) files that were installed by the RheoWin installer are removed (deleted) during the deinstallation process.

Only those files that were created (by users) *after* the installation of RheoWin are not removed. This, amongst others, concerns templates, measurement data files, etc. The latter must be deleted manually, if required. In this respect it should, by all means, be ensured that no jobs, data, etc. are deleted that are still required.

User management system

The HAAKE User Management System allows for the implementation of an user access control mechanism for RheoWin.

The entire management of users, user privileges, passwords, password rules, etc. is handled by a separate program (UserManCfg.exe) which is integral part of every RheoWin installation.

The User Management System can either be launched as a separate application directly from the Windows desktop or the Windows Start Menu or from the Configuration menu of the RheoWin JobManager and the RheoWin DataManager.

All settings that are made in the User Management System are stored in a MS Access database file. This database file is password protected and therefore not accessible for Windows users. This means that only the RheoWin program has access to this database file. The ADO driver, etc., that RheoWin needs in order to access this database are installed automatically. The Microsoft Access application is not required.

When the 21 CFR Part 11 tools were installed as part of the RheoWin installation, the user access control is activated automatically, this because 21 CFR Part 11 strictly requires the use of an user access control mechanism.

Note For a standard RheoWin installation (i.e. without the 21 CFR part 11 tools), the user access control can be activated at any time when needed.

Enabling user access control

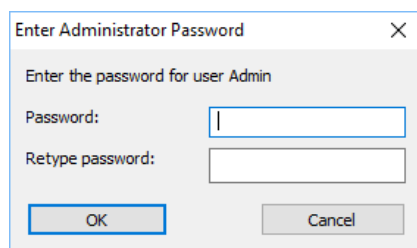
The user access control is automatically activated in case of a RheoWin installation with the 21 CFR part tools. For a standard RheoWin installation the user access control is not activated.

Standard installation (without 21 CFR Part 11 tools)

For a standard RheoWin installation the user access control can be activated at any time as required. To this end, the User Account Management System is either launched directly or from the JobManager or DataManager.

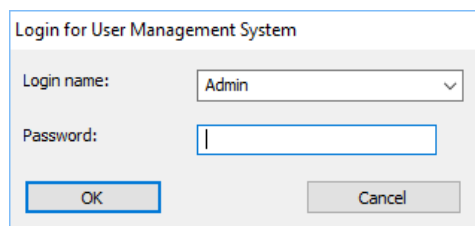
Upon the initial launch of the User Administration System a password must be defined for the build-in Admin (Administrator) user account. The password must be entered twice to confirm it.

Figure 28. Defining the Admin user account password



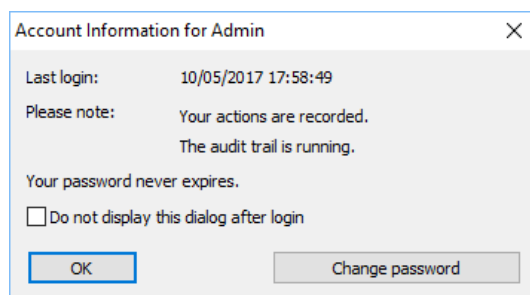
When this step is completed, the RheoWin login dialog will be displayed for the first time. In this dialog the password that was previously defined for the Admin user account must be entered in order to gain access to the User Management System.

Figure 29. RheoWin login



After entering the password for the (Admin) user, the Account information for [user] dialog will display some basic information on this user account.

Figure 30. Account information for the (Admin) user



After clicking the OK button the User Account Management System is launched and can be configured as described in „[User account management system settings](#)“.

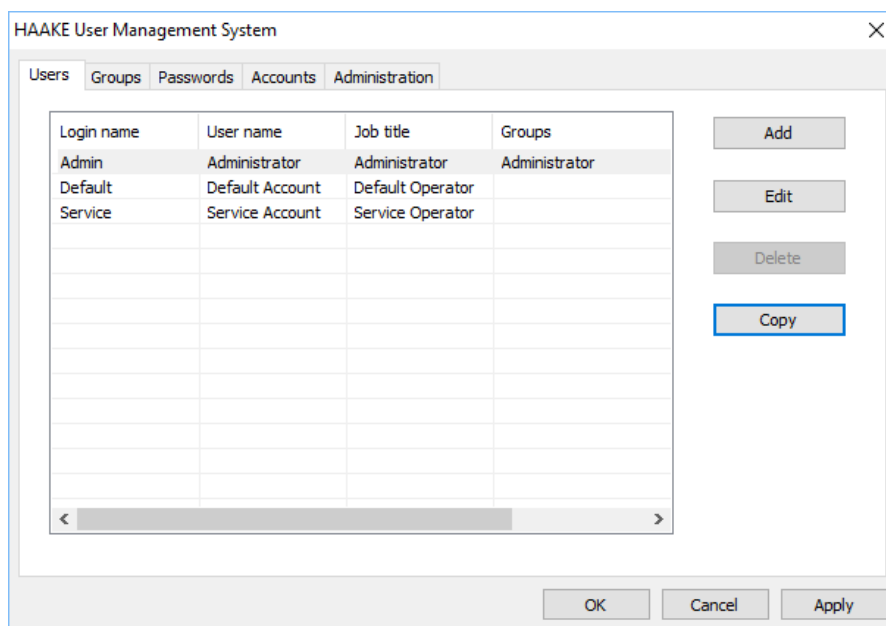
Installation with 21 CFR Part 11 tools

In case the 21 CFR Part 11 tools are installed as part of the RheoWin installation, the user account control is activated automatically and opened upon the initial launch of RheoWin (see 2.6.2.), this because 21 CFR Part 11 strictly requires the use of user access control mechanism.

User account management system settings

After launching the User Management System the dialog in Fig. xx is displayed.

Figure 31. User Management System; Users



The functionality of the five pages of this dialog is described in the following chapters.

Users

On the **Users** page a list of the currently defined users is displayed. The users **Admin**, **Default** and **Service** are predefined and can not be deleted.

The user **Admin** is a predefined (except for its password) user, with administrator privileges, who

- can create, copy, modify and delete user accounts,
- can grant privileges to and withdraw privileges from users,
- can activate and deactivate user accounts,
- by default only has those (very restricted) privileges in RheoWin that are required to manage the application and user accounts. By default the **Admin** user can not, for example, create, modify or execute jobs or load data files. This in contrast to a Windows administrator user who normally has all privileges.

The **Admin** user account can neither be locked nor deactivated or deleted. However, the **Admin** user can, of course, change its own privileges as required.

The **Default** user is a "dummy" user whose account can be activated on the Administration page of the User Account Management System dialog. When the **Default** user account is active, the RheoWin login dialog is not displayed at program start-up. This means that an user login is not possible and that each person who has access to the PC on which RheoWin is installed can use RheoWin with the privileges that have been set for the **Default** user account. These privileges can be restricted by the RheoWin **Admin** user or any other user with the proper administrative privileges. By default, as part of a standard installation the **Default** user is granted all privileges.

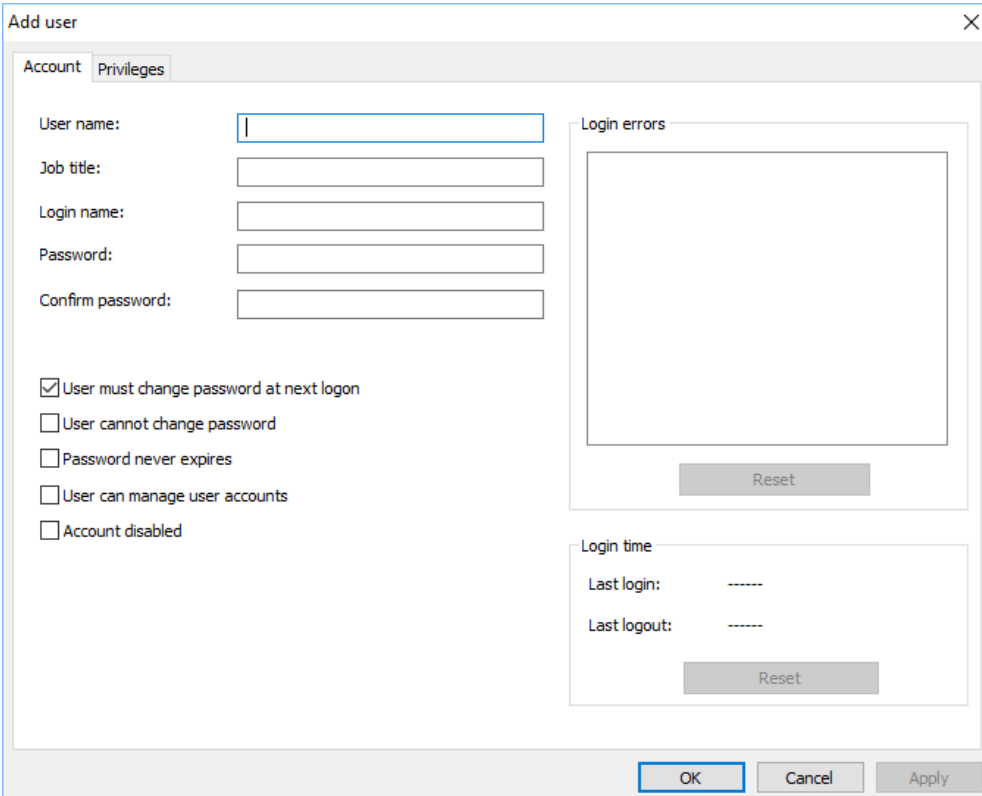
The Service user currently does not have any function and *can not* be used (this includes the use by any ThermoScientific personnel).

The number of user accounts that can be setup is only limited by the maximum size of the database file in which all the User Account Management System settings are stored. For the maximum database file size of 2 Gb, thousand user accounts are not a problem.

Adding, editing, deleting and copying users

After clicking on the Edit, Add or Copy button, a dialog is displayed where the properties, status, privileges, etc., of a (new) user can be entered and edited.

Figure 32. Adding a user



On the **Account** page of the **Add user**, **Edit user** and **Copy user** dialog the following edit fields, options and status indicators are provided:

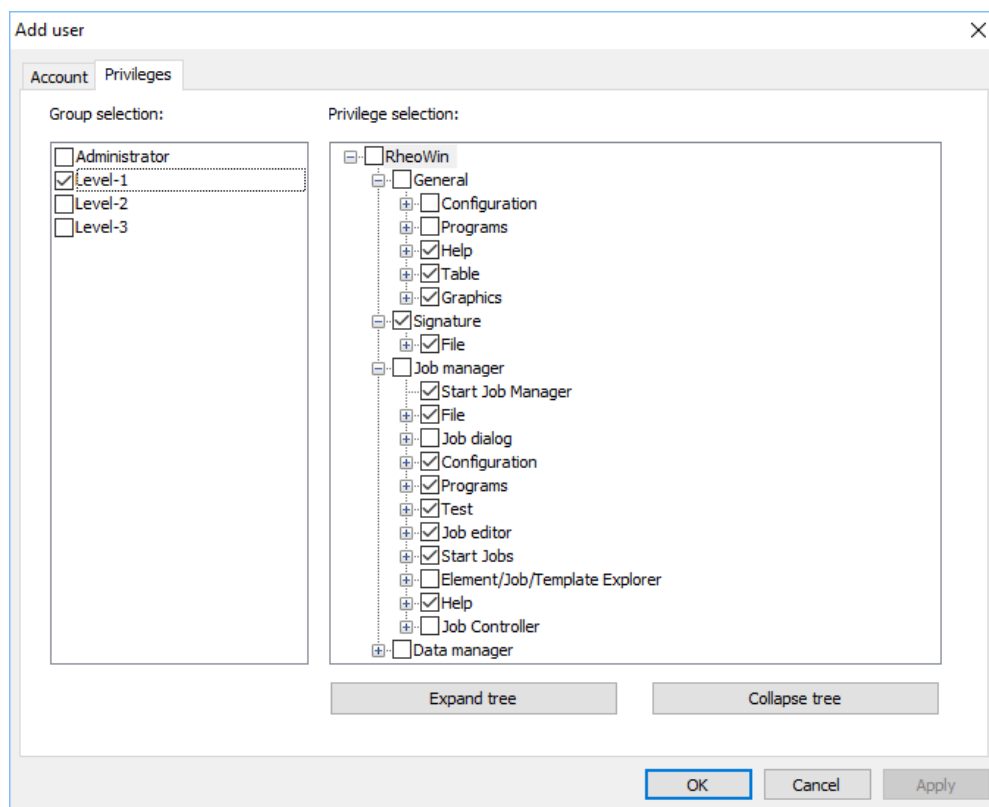
- Edit fields
 - **User name**
When the 21 CFR Part 11 tools are installed, a user ID, normally consisting of the first and last name of the user, *must* be entered for each user.
In case of a standard RheoWin installation, the user ID can be left blank, if required.
 - **Job title**
A job description can be entered in this field. This field can be left blank.
 - **Loginname**
A login name *must* be defined for each user. Without a login name, a user cannot log in to RheoWin. The login name is not case-sensitive: “Smith” is the same as “SMITH” or “smith”.

- **Password**
A password *must* be set for each user in case the 21 CFR Part 11 tools are installed. The password is case-sensitive: For example, "Password" is *not* the same as "password". The password must conform to the rules defined on the **Passwords** page of the **HAAKE User Management System** dialog.
In case of standard RheoWin installation the password can be left blank, if required.
- **Confirm password**
The password must be entered a second time in this field in order to confirm it.
- Options
 - **User must change password at next log-in**
This option *must* be enabled when the 21 CFR Part 11 tools are installed. In a standard RheoWin installation, this option should be enabled. The reason for this is that the password (for the initial login) is normally assigned by and communicated to the user by the RheoWin administrator. As the administrator, however, must not know the password of an user, the user must change her/his password at the next login into the application.
 - **User cannot change password**
This option *must* be *disabled* when the 21 CFR Part 11 tools are installed. Every user must be able to regularly change her/his password. This is required by the password rules.
In case of a standard RheoWin installation this option can be set as required.
 - **Password never expires**
This option *must* be *disabled* if the 21 CFR Part 11 tools are installed. Every user must regularly change her/his password. This is required by the password rules.
In case of a standard RheoWin installation this option can be set as required.
 - **User can manage user accounts**
This option *must* be *disabled* for all users except for the RheoWin administrators when the 21 CFR Part 11 tools are installed.
In case of a standard RheoWin installation it is recommended to set this options to *disabled*.
 - **Account locked**
With this option the account of a user can be locked or unlocked (by a RheoWin administrator).
- Status display
 - **Login errors**
All errors recorded during login attempts are shown in this status display. A login error will result, for example, when a user does not enter his/her password correctly.
The list of display errors can be deleted by clicking the **Reset** button.
 - **Login time**
In this status display the users last login and logout date/time are shown.
These values can be deleted by clicking the **Reset** button.

Defining user privileges

On the **Privileges** page of the **Add user**, **Edit user** and **Copy user** dialog, specific privileges (or rights) can be granted to each RheoWin user individually.

Figure 33. User privileges



The privileges are displayed in the form of a hierarchical "tree" structure, in the **Privilege selection** box, on the right hand side of the dialog.

The individual privileges that are assigned to a user are marked by the ☒ symbol, those that were not assigned are indicated by the ☐ symbol.

By clicking on a ☒ or ☐ symbol in front of a privilege the assignment of single privilege or all the privileges contained in a branch of the tree can be changed.

By clicking on the **Expand tree** or **Collapse tree** button, all branches of the tree that are hierarchically below the marked position are expanded or collapsed, respectively.

To simplify the allocation of an identical set of privileges to multiple users, privileges groups may be used, see "[Groups](#)."

All available groups are displayed in the **Group selection** list on the left hand side of the dialog.

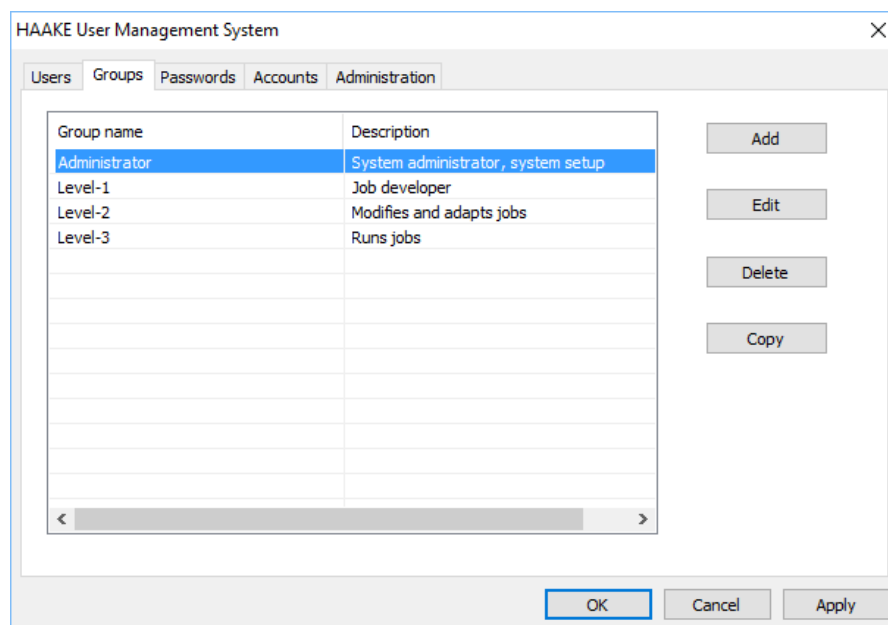
When an individual privilege (right) is withdrawn from a user that had been granted to that user through membership of a group, that user ceases to be a member of the group. However, all other privileges (rights) - including those of the now restricted group - are retained.

Groups

To simplify the creation of (many similar) user accounts, the RheoWin administrator can define **Groups** with a certain set of privileges (rights) and then assign a certain group to an user.

The four groups **Administrator**, **Level-1**, **Level-2** und **Level-3** are predefined and part of the RheoWin installation. It is recommended to rename the cryptic (but neutral) group names **Level 1**, etc., as required.

Figure 34. User Management System; Groups



The four predefined groups have been designed as follows:

- **Administrator**
A user of this group only has the typical administrator privileges that are needed to administer RheoWin. An administrator can setup users, default directories and other basic program settings. An administrator can *not* create, modify, delete and execute jobs, *nor* create, modify and delete templates *nor* evaluate data, etc. That means, an administrator is not supposed to actually use RheoWin in combination with the rheometer/viscometer for which the software is installed.
- **Level-1**
A user of this group has almost all privileges available except for the typical administrator privileges. He can make device settings, create, modify, delete and execute jobs, create, modify and delete templates and evaluate data, etc.
- **Level-2**
A user of this group has the necessary privileges to modify and execute existing jobs, to evaluate data, etc., but he can not create new jobs.
- **Level-3**
A user of this group can (only) execute predefined jobs and evaluate data, etc.

Depending on the specific requirements in a company the properties of the predefined groups can and should be modified.

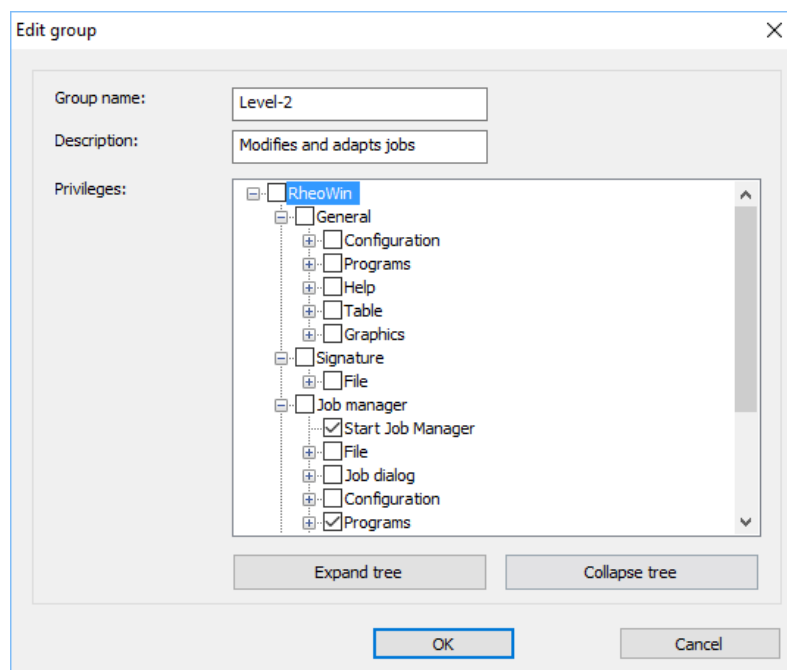
The effective privileges of a user result from the combination of the privileges of all groups to which she belongs and her individual privileges.

In case a single privilege is withdrawn from a user that had previously been granted to him through membership of a group, this user ceases to be a member of this group. However, all his other privileges - including those of the now restricted group - are retained.

The number of groups that can be setup is only limited by the maximum size of the database file in which all the User Account Management System settings are stored. For the maximum database file size of 2 Gb, thousand groups are not a problem.

By clicking on the **Edit**, **Add** or **Copy** button, a dialog is displayed in which the properties of a group can be viewed and edited.

Figure 35. Editing a group



The functionality and the content of the privileges tree is identical to that of the **Edit users** dialog, see „[Defining user privileges](#)“. In addition to the **Group name**, which must be defined, a **Description** of the group can be entered.

Passwords

When the 21 CFR Part 11 tools are installed, each user *must* have a login password. These passwords *must* conform to certain rules according to 11 CFR Part 21. These rules *must* be defined on the **Password** page of the **HAAKE User Management System** dialog (once).

In case of a standard RheoWin installation (i.e. without 21 CFR Part 11 tools), passwords and the rules for passwords can be used. However, this is not mandatory in this case.

Figure 36. User Management System; Passwords

On the **Passwords** page the following password rules can be defined:

- Maximum password age**
 When the 21 CFR Part 11 tools are installed the option **Expires in** *must* be enabled . This means that the option **Password never expires** must not be enabled. The specified number of days may vary depending on the company, **90 days** is a commonly used value.
- Minimum password age**
 This option determines how often the password can be changed. This setting can be adjusted as required.
- Password uniqueness**
 When the 21 CFR Part 11 tools are installed the option **Save n passwords** *must* be enabled . This means that the option **Do not save passwords** must not be enabled. When the option **Save n passwords** is enabled, the first password can be used again after n other passwords. The value of n = 10 is a commonly used value.
- Password characters**
 When the 21 CFR Part 11 tools are installed the option **Minimum password length** *must* be enabled . This means that the option **Blank password allowed** must not be enabled. A value of 6 is commonly used for the minimum **Character count**. In order to ensure that passwords have a certain level of complexity, it is also possible to require that a password contains **At least one alphabetic character** and/or **At least one numeric character** by activating the corresponding option.

Accounts

When the 21 CFR Part 11 tools are installed certain logon rules must be defined . These rules *must* be defined on the **Accounts** page of the **HAAKE User Management System** dialog (once).

In case of a standard RheoWin installation (i.e. without 21 CFR Part 11 tools), the logon rules can be used, but this is not mandatory in this case.

Figure 37. User Management System; Accounts

HAAKE User Management System

Users Groups Passwords Accounts Administration

Bad logon attempts

☐ No lockout

☒ Lockout after 3 attempts

Lockout duration

☒ Forever (until administrator unlocks)

☐ Duration 1 minutes

Account not used

☐ No lockout if account not used

☒ Lockout if not used for 30 days

OK Cancel Apply

On the **Accounts** page, the following logon rules can be defined:

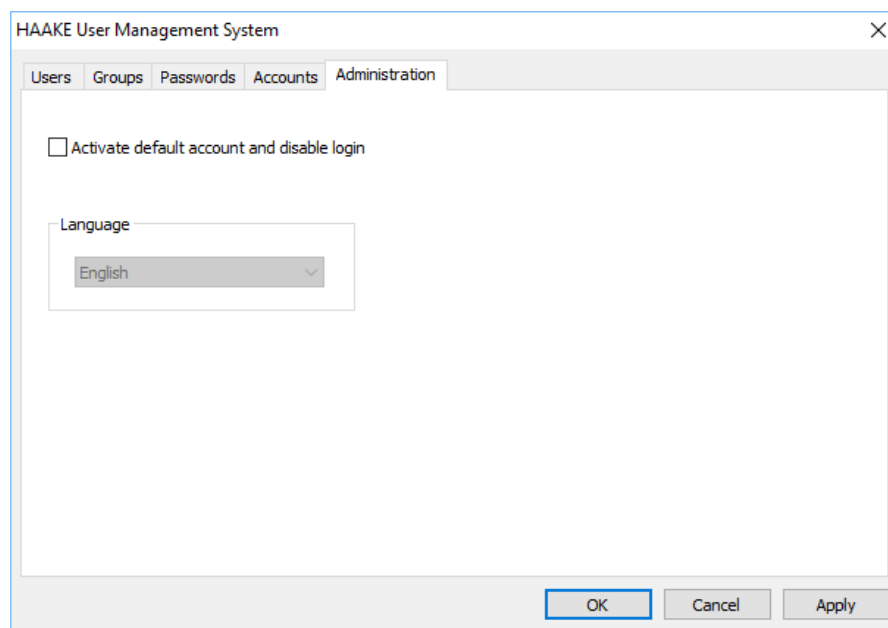
- **Bad logon attempts**
When the 21 CFR Part 11 tools are installed the option **Lock after n attempts** *must* be enabled. The option **No lockout** must not be enabled. A common value for the maximum allowed number of invalid logon attempts is $n = 3$.
- **Lockout duration**
This option can be used to define whether a lockout due to failed logon attempts remains in effect until a RheoWin administrator unlocks the account or whether the lockout will only be active for a certain period of time. This time can be specified in the **Duration** input field.
- **Account not used**
This setting determines whether a user account is automatically locked after not being used for n days. The account can only be unlocked by a RheoWin administrator.

Administration

When the 21 CFR Part 11 tool are installed the option **Activate default account and disable logon** *must* stay deactivated.

In a standard RheoWin installation (i.e. without 21 CFR Part 11 tools), the option **Activate default account and disable logon** is always enabled. This means that the logon dialog will not be displayed when launching the RheoWin Job Manager or Data Manager. Any person who has access to the PC on which RheoWin is installed can use RheoWin with the privileges that have been set for the Default user account. If no changes have been made to the Default user account privileges, there are no restrictions.

Figure 38. User Management System; Administration



In the **Language** box, the dialog language can be set for the **HAAKE User Management System** dialog in the event that the User Administration was started as a separate program either directly from the Windows desktop or via the Windows Start menu.

When the **HAAKE User Management System** was launched via the **Configuration** menu of the RheoWin JobManager or DataManager, the language selection option will be locked and the same language as in the JobManager and DataManager will be used automatically.

Audit Trail

The Audit Trail is part of the 21 CFR Part 11 tools and will *only* be installed if the 21 CFR Part 11 tools are installed. In this case, the Audit Trail will automatically be activated immediately upon initial launch of RheoWin via the Job Manager, Data Manager or User Manager. The installation of RheoWin is also logged in the Audit Trail. The Audit Trail *cannot be disabled*.

Note In a standard RheoWin installation (i.e. without 21 CFR Part 11 tools), the Audit Trail tool is not installed and can, therefore, never be activated.

General information

The Audit Trail records all actions that a user performs on a measurement definition (i.e. a *.rwj job file), a (*.rwd) data file, etc. or any another parameter which is relevant for the data acquisition.

Logged actions are, for example, the opening, editing and saving of a measurement definition as well as each log-in and log-out of a user to or from the RheoWin Job Manager, Data Manager and User Manager (but not the operating system!) as well as the start of a measurement (job). When modifications are made to a measurement definition (job file), the changes regarding all relevant parameters are only logged when the measurement definition (*.rwj job file) is subsequently saved. Temporary changes are not saved, because jobs that are not saved cannot be executed.

The events to be logged are (strictly) defined in RheoWin itself. The Audit Trail tool only provides the functionality necessary to record all changes in a database.

In the event that the Audit Trail database can not be accessed (for example due to the interruption of a network connection to the Audit Trail database file), the logged data is stored in a temporary log file on the local PC. When the contact to the Audit Trail database is re-established, the information contained in temporarily stored log file is transferred to the Audit Trail database and then deleted. Every single set in the temporary log file contains a separate checksum, so that potential manipulations can be detected and marked as such in the database.

An empty Audit Trail database file in Microsoft Access format is part of the installation and can be used immediately afterwards without any further action required.

To use a SQL database, the user must have installed the appropriate client on her/his computer. For this purpose, the SQL server must be of version 6.5 or higher.

The Audit Trail module only checks and uses the installed ADO driver (MS Jet 4.0 or MS SQL client), i.e. it does not work with ODBC drivers.

Configuration

The configuration dialog for the Audit Trail database is automatically displayed at the end of the RheoWin installation (see Section 2.4), which makes the configuration process fast and easy. The configuration must be performed by a Windows system administrator.

In case the configuration is not possible as an integral part of the installation or when changes to the configuration are necessary at a later point in time, an authorized user can start the configuration program **AuditTrailCfg.exe** separately. The program is stored in the main RheoWin program directory (default directory **C:\Program Files\Thermo\RheoWin**).

The initial configuration of the Audit Trail database *must* be performed prior to the initial launch of RheoWin (Job Manager, Data Manager or User Manager).

The configuration program does not have its own built-in access control. This means that, theoretically, any user who has access to the PC on which RheoWin was installed can start the configuration program and may make undesired modifications. Therefore, it is *mandatory* to restrict access to the configuration program.

It is the responsibility of the customer or the system administrator to restrict the access rights for the Audit Trail configuration program using the tools of the operating system, i.e. to only allow the system administrator, for example, to execute this program.

An easy way to restrict access is to completely remove the configuration program from the RheoWin program folder and store it in a safe place (i.e. a place with restricted access).

The dialog automatically detects which drivers are installed on the PC and provides the option to choose between an Access or a SQL database file.

Access database

The Access database file HAAKEAuditTrail.mdb, which is installed in the RheoWin application data directory, see [Installation directories](#), is stored in the MS Access 97 format. It can be converted to the MS Access 2000 or MAS Access 2003 format, if required. The Audit Trail module is compatible with all of these formats. The Audit Trail module is *not* compatible with the MS Access 2007, Access 2011 and Access 2013 formats

Figure 39. HAAKE Audit Trail Database Configuration; MS Access

The following parameters must be set in order to be able to use an Access database:

- **Database type**

In case the supplied Access database is to be used the entry **Microsoft Access (Microsoft.Jet OLEDB.4.0)** must be selected.

- **Path to database file**

The path to the Audit Trail database file must be entered here. By default, the file **HAAKEAuditTrail.mdb** in the **AuditTrail** subdirectory of the RheoWin application data directory (see [Installation directories](#)) is set as the standard path.

The database file does not necessarily need to have the file name **HAAKEAuditTrail.mdb**, it can be renamed as required.

IMPORTANT For data protection reasons, it is strongly recommended to copy the **HAAKEAuditTrail.mdb** file to a network directory and set the path accordingly by clicking on the [...] button.

- **Username for database file**

This field must be left blank in the case of an Access database. This function is currently not implemented (and also not required).

- **Password for database file**

In order to prevent unauthorized access to the Audit Trail database, for example via Microsoft Access, the database should be protected with a password. The password must be entered in this dialog to ensure that the password is known to RheoWin and that RheoWin is able to access the database file.

The (empty) **HAAKEAuditTrail.mdb** Access database file that is part of the installation contains no password.

IMPORTANT The password entered is *not* automatically written to the Access database; this needs to be done manually by the system administrator using Microsoft Access (Microsoft Access is not included with RheoWin).

- **Path to Emergency file**

This file is used as a temporary log file in the event of loss of contact to the database file. Once access to the database file is restored, the file is automatically transferred to the database and then deleted.

It is recommended not to change the path to this file or at least to use a local path, i.e. no network path.

SQL database

An SQL database can be used as an alternative to an Access database. If this database already contains a table named "AuditTrail", the latter will be used without any preliminary check. This means that it must comply with the definitions as described in [Database format](#). In case such a table does not yet exist, it will be created automatically.

Figure 40. HAAKE Audit Trail Database Configuration, SQL

The following parameters must be set in case an SQL database is used:

- Database type**
 In case an SQL database is to be used, the corresponding entry must be selected here.
- Path to database file**
 This entry has to consist of a server (IP address or host name) and a database file located at that point, separated by '\'. The [...] button has no function here.
 In case the database already contains a table called “AuditTrail”, this will be used without any preliminary check, this means that it has to meet the definition as described in [Database format](#). If such a table does not exist, it will be created automatically.
- Username for database file**
 In case a user name is needed in order to access the SQL database it can be entered in this field.

IMPORTANT The entered user name is *not* automatically written into the SQL database file. This needs to be done manually by the Windows system administrator.
- Password for database file**
 In case a password is needed in order to access the SQL database it can be entered in this field.

IMPORTANT The entered password is *not* automatically written into the SQL database file. This needs to be done manually by the Windows system administrator.
- Path to Emergency file**
 This file is used as a temporary log file in the event of loss of contact to the database file. Once access to the database file is restored, the file is automatically transferred to the database and then deleted.
 It is recommended not to change the path to this file or at least to use a local path, i.e. no network path.

Database format

The RheoWin Audit Trail tool supports two database formats: Microsoft Access (the Jet 4.0 engine is installed automatically) and Microsoft SQL (starting from SQL Server 6.5). An empty Access database file with an Audit Trail table as shown in table 2 is supplied and automatically installed. In case an SQL database is used, we recommend to provide the database without an Audit Trail table entry so that the Audit Trail tool can automatically create the correct matching table.

Table 2 shows the AuditTrail table format.

Table 2. Audit Trail table format

Column name	Meaning	Type (Access)	Type (SQL)
_HostID	Name of the logged-in user plus the network name of the computer		char[255]
_TimeOfDay	Date and time of the entry in IEEE-Format (jjjjmmmtt hh:mm:ss)		char[255]
_Application	Name of the program (e.g. „RheoWin JobManager“)		char[255]
_Username	User logged into the application (possibly not the same as _HostID)		char[80]
_Theme	Higher level subject of the action („User Management“, „Job“, ...“)		char[255]
_Activity	Action carried out („Login“, „Logout“, Load“, „Save“, ...)		char[255]
_Filename	Name of the affected file (Job file name, data file name, ...)		text
_P1	Additional parameter 1		text
_P2	Additional parameter 2		text
_Manipulated	*** (in case the data set in the temporary file was manipulated)		char[5]

The following gives a more detailed description of the meaning of the individual columns in the audit trail table:

- **_HostID**
is generated on the basis of the name of the PC on which RheoWin is installed and the respective Windows user currently logged into the system and has the format "User@Computer", such as, for example, "Smith@PC-LABORATORY". Here "Smith" is the name of the user who is logged into Windows (and is not necessarily identical with the user of the application), and "PC-LABORATORY" is the name of the computer in the network.
- **_TimeOfDay**
contains the date of the entry in the IEEE date/time format ("20031103" for November 3rd, 2003) and the time in 24-hour format.
- **_Application**
is the name of the Windows application that generated the entry, i.e. RheoWin Job Manager, RheoWin Data Manager or RheoWin User Administration System.
- **_Username**
is the name of the user logged into RheoWin.
- **_Theme**
is the subject to which the entry belongs ("Job Manager", "Job Run", etc.).
- **_Activity**
is the action carried out („User login“, „Load Job“, „Job Start“, etc.)
- **_Filename**
If a file is involved, its name is specified here. This is the case, for instance, if a job is being loaded or saved, but not when a user is logging in.
- **_P1/_P2**
Depending on the activity, several different parameters can be mentioned. For example the old and the new value of a certain measurement parameter.

- **Manipulated**

This column ought to be always empty because it indicates manipulated data sets. These can occur when the temporary log file is illegally altered by means of an external editor.

Audit Trail viewer

The Audit Trail database can be displayed at any time in the **HAAKE Audit Trail Viewer**. The Audit Trail Viewer can either be started from the RheoWin Job Manager and RheoWin Data Manager by using the **Audittrail Viewer** command in the **Programs** menu or directly as a separate program named **TrailView.exe**. The **TrailView.exe** is stored in the RheoWin program directory (default directory: **C:\Program Files\Thermo\RheoWin**).

Figure 41. HAAKE Audit Trail Viewer

Time	User	Theme	Activity	File name	Parameter 1	Parameter 2
22.02.2017 17:47:47		Program	Start			
22.02.2017 17:48:00		User man...	User login		User : Sasman4 Successful	
22.02.2017 17:48:18	Sasman4	Job	Open	C:\Users\Public\Documents\Thermo\Rh...		
22.02.2017 17:50:13	Sasman4	Job	Save as	D:\Jobs\Sample xyz, LVR determination.rwj	D:\Jobs\Sample xyz, LVR determination.rwj	First design.Copied from example Job
22.02.2017 17:50:13	Sasman4	Job	Changes	D:\Jobs\Sample xyz, LVR determination.rwj	Element: 5 ID: 10 New element: 10 - Linear viscoelastic range	
22.02.2017 17:50:13	Sasman4	Job	Changes	D:\Jobs\Sample xyz, LVR determination.rwj	Element: 1 ID: 3 removed - Message	
22.02.2017 17:55:09	Sasman4	Job	Close	D:\Jobs\Sample xyz, LVR determination.rwj		
22.02.2017 17:56:10	Sasman4	Job	Open	D:\Jobs\Sample xyz, LVR determination.rwj		
22.02.2017 18:10:22	Sasman4	Job	Changes	D:\Jobs\Sample xyz, LVR determination.rwj	Element: 1 ID: 4 set temp in °C: 20,00 -> 25,00	
22.02.2017 18:10:22	Sasman4	Job	Changes	D:\Jobs\Sample xyz, LVR determination.rwj	Element: 3 ID: 6 set temp in °C: 20,00 -> 25,00	
22.02.2017 18:10:22	Sasman4	Job	Changes	D:\Jobs\Sample xyz, LVR determination.rwj	Element: 4 ID: 7 step parameters:end value: 1,000 - -> 5,000 -s...	
22.02.2017 18:10:34	Sasman4	Job	Save	D:\Jobs\Sample xyz, LVR determination.rwj		Temperature changed.End Strain changed
22.02.2017 18:10:34	Sasman4	Job	Close	D:\Jobs\Sample xyz, LVR determination.rwj		
22.02.2017 18:10:35	Sasman4	Program	End			
22.02.2017 18:10:41		Program	Start			
22.02.2017 18:10:53		User man...	User login		User : JNewman Successful	
22.02.2017 18:11:07	JNewman	Job	Open	D:\Jobs\Sample xyz, LVR determination.rwj		
22.02.2017 18:11:40	JNewman	Job	Save as	D:\Jobs\Sample xyz, LVR determination.rwj	D:\Jobs\Sample xyz, LVR determination.rwj	Start Strain changed
22.02.2017 18:11:40	JNewman	Job	Changes	D:\Jobs\Sample xyz, LVR determination.rwj	Element: 4 ID: 7 step parameters:start value: 0,001000 - -> 0,005...	
22.02.2017 18:16:20	Sasman4	User man...	Login error...			
22.02.2017 18:16:29	JNewman	Job	Sign job	D:\Jobs\Sample xyz, LVR determination.rwj	Sasman4, Saskia Neumann, 22.02.2017, 18:16:29, Authorship	
22.02.2017 18:16:46	JNewman	Job	Sign job	D:\Jobs\Sample xyz, LVR determination.rwj	JNewman, Judith Newman, 22.02.2017, 18:16:46, Review	
22.02.2017 18:17:02	JNewman	Job	Sign job	D:\Jobs\Sample xyz, LVR determination.rwj	JMiller2017, Jim Miller, 22.02.2017, 18:17:02, Approval	
22.02.2017 18:18:25	JNewman	Job	Close	D:\Jobs\Sample xyz, LVR determination.rwj		
22.02.2017 18:18:27	JNewman	Program	End			

Because the Audit Trail Viewer program does not offer any editing and storage functions, it is impossible to make changes to the Audit Trail database using this application.

Signatures and security settings

The tool for the electronic signing of job and data files as well as some special security tools are described in this chapter are part of the 21 CFR Part 11 tools and will *only* be installed if an installation of the 21 CFR Part 11 tools is performed.

Note In a standard RheoWin installation (i.e. without 21 CFR Part 11 tools), the tools described in this section are not installed and can, therefore, not be used.

Settings for signatures

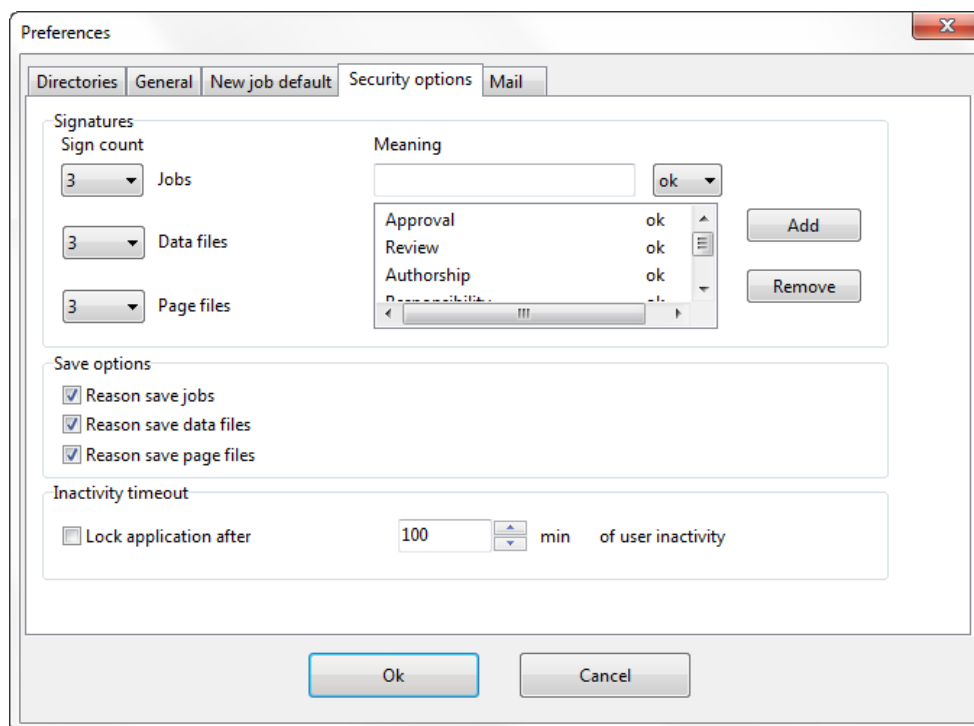
In RheoWin it is possible to electronically sign job, data, and page files (*.rwj, *.rwd, *.rwp). The use of electronic signatures is not mandatory according to the 21 CFR Part 11.

In RheoWin an electronic signature consists of the following attributes:

- The login name of the logged-in RheoWin user.
- The user name of the logged-in RheoWin user.
- The system date and time.
- The meaning of the signature with the criterion **OK** or **Not OK**.

The settings for the electronic signatures must be made (once) on the **Security options** page of the **Settings** dialog. This dialog can be accessed using the **Settings** command in the **Configuration** menu of the RheoWin **JobManager** or RheoWin **DataManager**.

Figure 42. Security options



- **Sign count**

Here the number of signatures that is required for each file type (job, data or page file) in order to complete the signing process for a file (and thus finalize it) can be defined. The default value for all file types is "1". The maximum number of signatures per file type is 5.

A file can (must) be signed as often as required until the preset number of signatures has been reached. The file is then locked, which means that it can no longer be changed (see [Signatures in JobManager](#) and [Signatures in DataManager](#)).

- **Meaning**

A signature must always have a **Meaning**. A user can, for example, sign a file as the **Author**, another user can inspect the file (**Review**) and mark it as **Ok**, and a third user can approve the file (**Approval**) or reject it (**Rejection**). Because the process may differ depending on the company, the meanings of signatures can be modified (added or removed) and thus also be adapted to different languages.

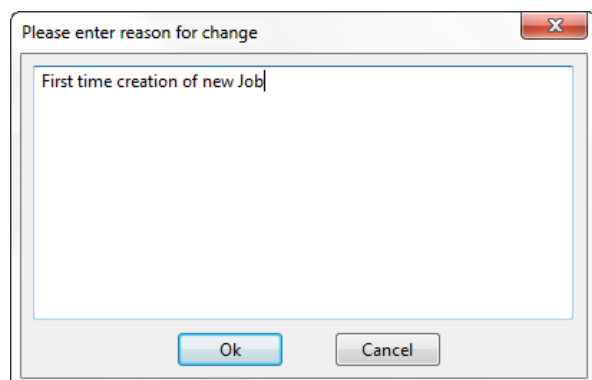
To add a **Meaning** text, the text is first entered in the input field, it must be then be selected (from the **Ok / Not Ok** drop down list) whether the **Meaning** is a confirmation (**Ok**) or a rejection (**Not Ok**). After clicking the **Add** button the new **Meaning** is added to the list and is available for the signatures.

By selecting a **Meaning** in the list and clicking the **Remove** button, the meaning is removed from the list.

Save options

In the **Save options** box it can be selected whether or not the user has to enter a reason for the changes made in a (job or data or page) file whenever the file is saved. If this option is enabled, the user is forced to enter a text justifying the changes made in a data entry dialog box every time he saves a job, data or page file. This reason is stored in the Audit Trail with the relevant file entry.

Figure 43. Enter reason for change



When the 21 CFR Part 11 tools are installed these three options *must* be enabled .

Deactivation in case of inactivity


In the box **Deactivation in case of inactivity**, the option **Deactivation of program after n min without user activity** can be enabled. When this option is enabled RheoWin will be locked after n minutes of user inactivity (i.e. without mouse click activity or keyboard input). Once the mouse is clicked again or a keyboard input is attempted, the RheoWin login dialog will be displayed and the user must login using his login name and password. A job (measurement) that is already inmidst of execution will continue to run even when the RheoWin user interface is locked.

This function is only available in RheoWin versions starting from 4.10.0000, that means that it is not implemented in older versions.

Signatures in JobManager

In the RheoWin JobManager *.rwj job files can be electronically signed when the job is opened for editing in the Job Editor.

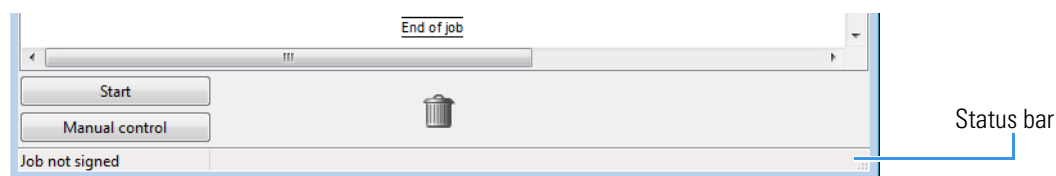
Signing jobs

A job (that has not yet been completely signed yet) can be signed by selecting the command **Sign job** from the **File** menu of the **JobManager** or by clicking the  Button in the toolbar of the JobManager or by selecting the command **Sign job** from the (right mouse-key) context menu in the **Job Editor**.

These menu items and buttons are only active when the currently logged-in user has been granted the privileges to sign jobs *and* the job is not yet completely signed yet.

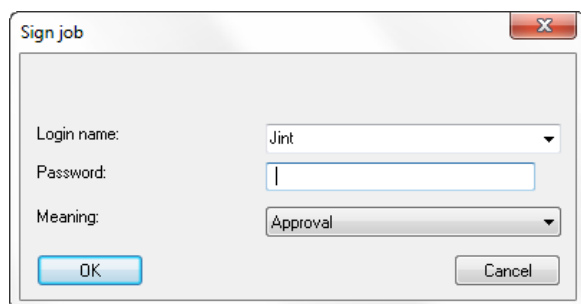
As long as a Job is not signed the text **Job not signed** is displayed in the Job Editor status bar (see [Figure 44](#)).

Figure 44. Job Editor status bar, no signature applied



In the **Sign job** dialog, a user (the currently logged-in user is pre-selected) must select his login name, enter his **Password** and choose the **Meaning** for the signature in order to sign a job.

Figure 45. Signing a job



After clicking the Ok button, the signature is added to the job file and the job file is saved. In case the job file was not yet saved before attempting to sign the job, for example because the job was just created, the **File save** dialog will be opened, before the **Sign job** dialog was opened, and a file name must be selected first.

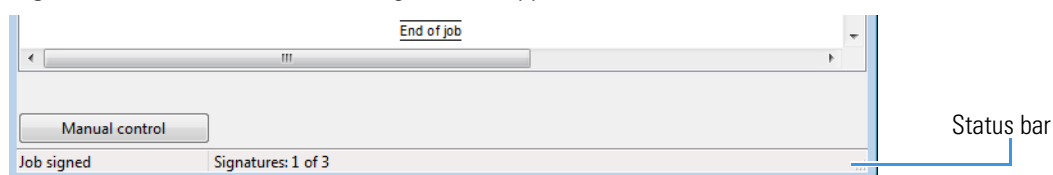
The signing of a job file is recorded in the Audit Trail.

It is not possible to remove a signature from a job file.

As soon as a job file contains at least one signature, it can not be modified anymore, only additional signatures can be entered.

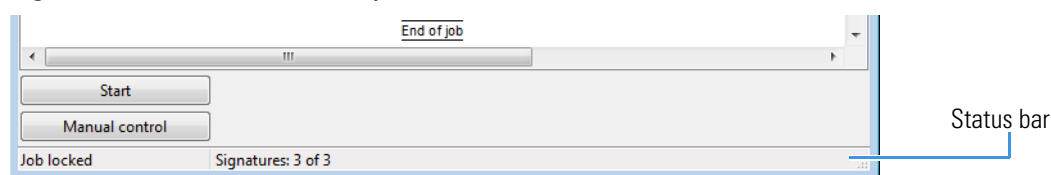
If one or multiple signatures have been entered, but not yet the defined maximum number of signatures, the texts **Job signed** and **Signatures x of y** are displayed in the Job Editor status bar (see [Figure 46](#)).

Figure 46. Job Editor status bar, signature(s) applied



When the define maximum number of signatures has been entered, the texts **Job locked** and **Signatures y of y** are displayed, indicating that the job file is now locked and approved or rejected (see [Figure 47](#)).

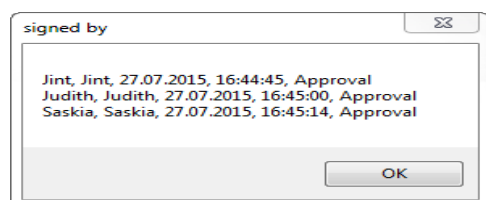
Figure 47. Job Editor status bar, job locked



Displaying the signatures

The signatures entered in a job file can be displayed in a separate window by clicking on the **Signature x of y text** in the Job-Editor status bar or by selecting the **Display signature** command from the (right mouse button) context menu of the Job Editor.

Figure 48. Signatures



Modifying a signed job

A completely signed (locked) job files *cannot be modified anymore*.

In case a completely signed (locked) job file needs to be modified it must be saved under a different name, by using the **Save as** command, first. The thus created new job file will not contain any signatures and can be modified.

Copying a job file will result in an entry in the AuditTrail.

Signatures in DataManager

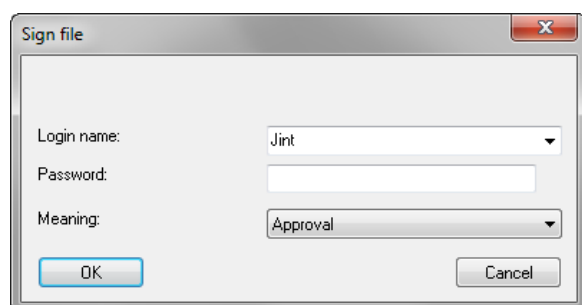
In the RheoWin DataManager *.rwd data files and *.rwp page files can be electronically signed from the **File** menu.

Signing data files and page files

A data or page file (that has not yet been completely signed yet) can be signed by selecting the command **Sign file** from the **File** menu of the **DataManager**

These menu item (command) is only active when the currently logged-in user has been granted the privilege to sign data and page file *and* the data or page file is not yet completely signed.

Figure 49. Signing a (data or page) file



In the **Sign file** dialog, a user (the currently logged-in user is pre-selected) must select his login name, enter his **Password** and choose the **Meaning** for the signature in order to sign a data or page file.

After clicking the **Ok** button, the signature is added to the file and the file is saved.

The signing of a data or page file is recorded in the Audit Trail.

It is not possible to remove a signature from a data or page file.

As soon as a data or page file contains at least one signature, it can not be modified anymore, only additional signatures can be entered.

Displaying the signatures

The signatures entered in a data or page file are directly displayed in the information window under the corresponding file name. The signatures are also shown in a report print-out.

Editing signed data files and page files

Once a job or page file has been signed at least once, it is not possible anymore to make any further changes to that file in the DataManager, evaluation data can not be added or deleted anymore.

In case a completely signed (locked) data or page file needs to be modified it must be saved under a different name, by using the **Save as** command, first. The thus created new data or page file will not contain any signatures and can be modified.

Copying a data or page file will result in an entry in the AuditTrail.

Directories, files, registry

Windows registry key

RheoWin stores all settings, parameters, paths, etc. under the following Windows registry key only (this applies to all versions of Windows):

HKEY_USERS\.\DEFAULT\Software\Thermo\RheoWin

All Windows users that want to use the RheoWin software must have read and write permissions for this registry key.

Installation directories

RheoWin consists of many files which are stored various different directories. Information on which files are stored in which directories can be found below.

Directories for program *.exe, *.dll, etc. files

The default main RheoWin program directory is,

for english and other language 32-bit Windows versions:

C:\Program Files\Thermo\RheoWin

for english and other language 64-bit Windows versions:

C:\Program Files(x86)\Thermo\RheoWin

for german language 32-bit vWindows versions:

C:\Programme\Thermo\RheoWin

for german language 64-bit Windows versions:

C:\Programme(x86)\Thermo\RheoWin

All *.exe, *.dll files belonging to RheoWin are stored in this directory and the corresponding subdirectories. Although it is possible to select another directory for the main RheoWin program directory during the installation, it is not recommended to do so.

Directories for program data files

All RheoWin program data files are stored in the following directory and its subdirectories (this directory can *not* be changed).

Directory for english and other language Windows XP versions:

C:\Documents and Settings\All Users\Application Data\Thermo\RheoWin

Directory for german Windows XP versions:

C:\Dokumente und Einstellungen\All Users\Anwendungsdaten\Thermo\RheoWin

Directory for all Windows 7, Windows 8(1) and Windows 10 versions (language independent):

C:\ProgramData\Thermo\RheoWin

Program data files are files that are automatically created and changed by RheoWin, i.e. without direct intervention of the user. Normally it is not necessary that users have direct access to these files.

Table 3. Directories for RheoWin program data files

Directory	File(s)	Usage
\RheoWin	Rheowin.log	RheoWin program log file, for debugging only
\RheoWin\EI\mdll	elmdll.ini	ini file for the RheoWin job-elements, for setting special options only
\RheoWin\Drivers	drivers.flp	in this file are almost all device settings that can be made in the RheoWin DeviceManager are stored
	drivers.ini	ini file for devices, for setting special options only
	*.log	communication log files, for debugging only
	*.err	communication error files, for debugging only
	*.msc	exported MSC table files
	*.mtc	exported MTC table files
	*.tot	exported TOT table files
\RheoWin\Autosave	autosave.rwd	automatically saved copy of the last measured data file
	Drivers_Autosave_x.xx.xx.flp	automatically saved copy of the last Drivers.flp file
	Drivers_Setup_x.xx.xx.flp	automatically saved copy of the setup Drivers.flp file
\RheoWin\UMS	UMS.mdb	The User Management System data base file
\RheoWin\Audittrail	HAAKEAudittrail.mdb	The MS Access Audit Trail data base file

Note In order to be able to view the directories listed above in the Windows Explorer, they must first be made visible. This requires that the **Show hidden files, folders or drives option** is enabled on the **View** page of the **Folder options** dialog in the Windows **Explorer**.
Under Windows XP: The **Folder options** dialog can be opened via the **Folder options** command in the **Tools** menu.
Under Windows 7, Windows 8(1) and Windows 10: The **Folder options** dialog is opened via the **Folders and search options** command in the **Organize** menu.

Directories for user files

By default, RheoWin user files are stored in the following directory and its subdirectories (these directory can be changed by the user at any time).

Directory for english and other language Windows XP versions:

C:\Documents and Settings\All Users\Documents\Thermo\RheoWin.

Directory for german language Windows XP versions:

C:\Dokumente und Einstellungen\All Users\Gemeinsame Dokumente\Thermo\RheoWin

Directory for english and other language Windows 7, Windows 8(1) and Windows 10 versions:

C:\Users\Public\Public Documents\Thermo\RheoWin

(or C:\Users\Public\Documents\Thermo\RheoWin depending on the representation in the Windows Explorer)

Directory for german Windows 7, Windows 8(1) and Windows 10 versions:

C:\Benutzer\Öffentlich\Öffentliche Dokumente\Thermo\RheoWin

User files are files that are created and modified by RheoWin through direct intervention of the user. The following file types fall under this category:

Table 4. Directories for user files

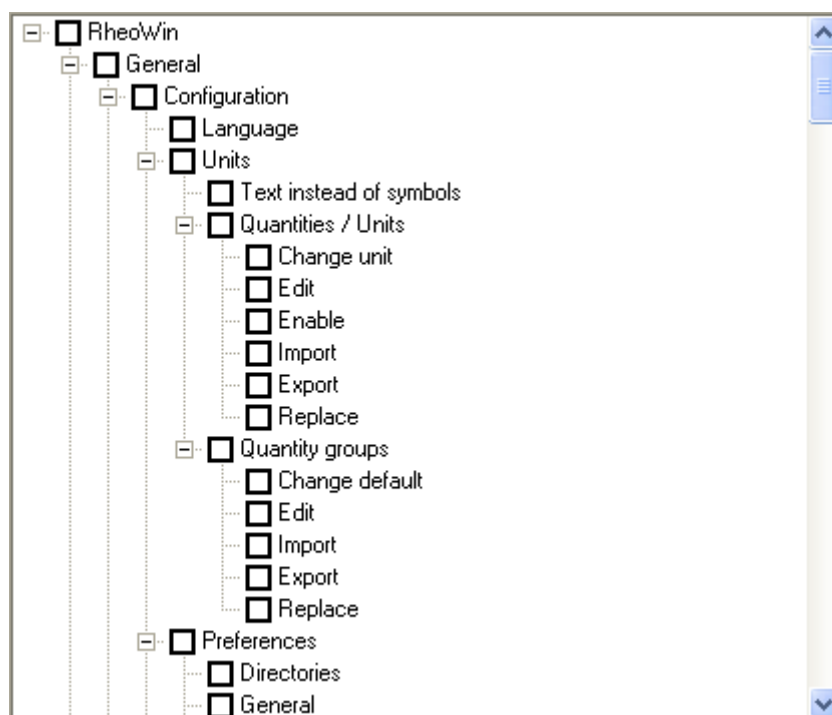
Directory	File(s)	Usage
\RheoWin\Job	*.rwj	Job files
\RheoWin\Data	*.rwd	Data files
\RheoWin\Page	*.rwp	Page files
\RheoWin\Report	*.lst	Report template files
\RheoWin\Template	*.rwt	Job template files
	*.gds	Graph template files
	*.tds	Table template files
	*.rwl	Page template files
\RheoWin\Media	various	Image, video and document files

User privileges

In total, more than 150 single privileges can be assigned to every user. All privileges can be divided into three categories as shown in the following screenshots.

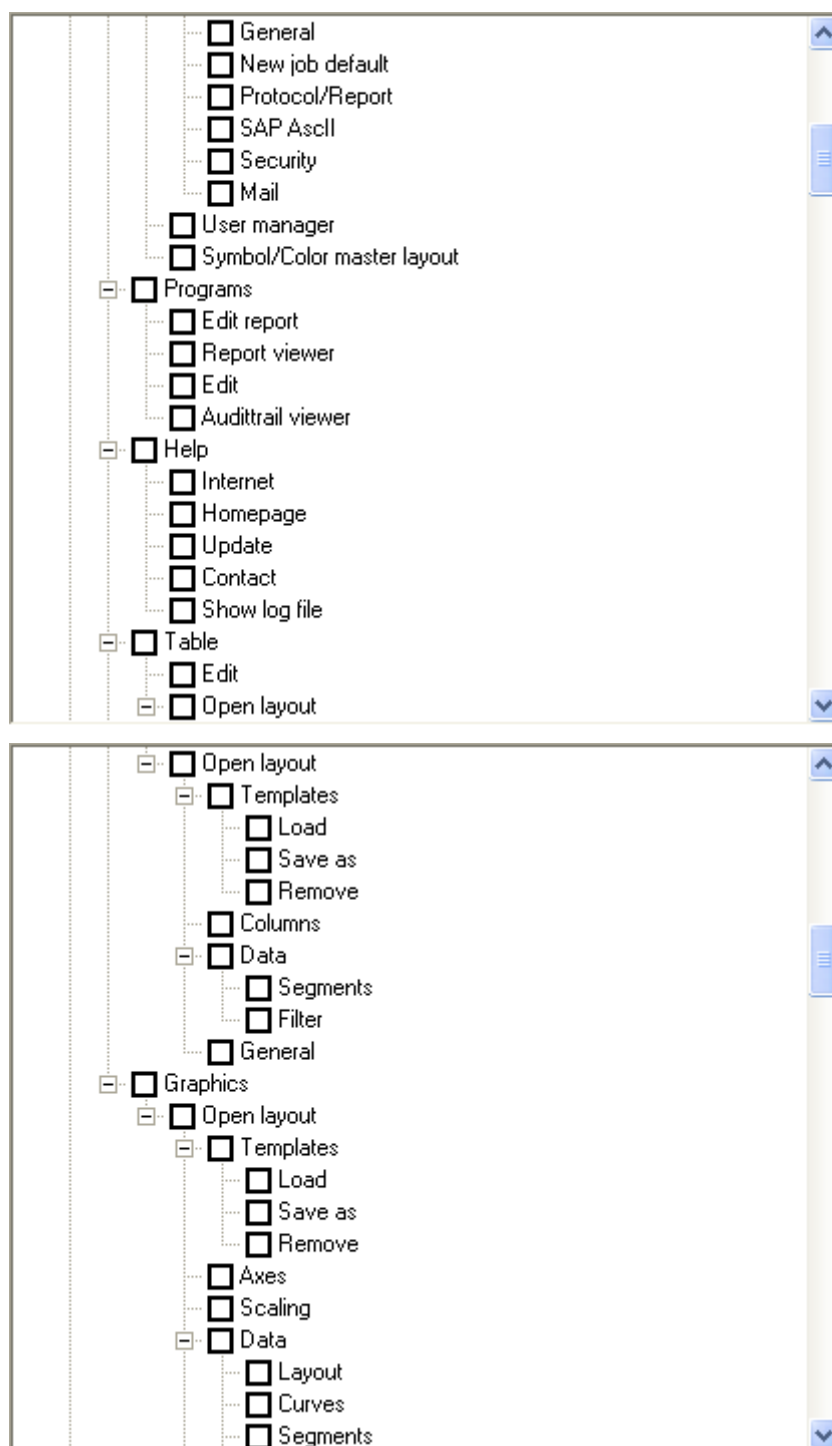
General privileges (in Job- and DataManager)

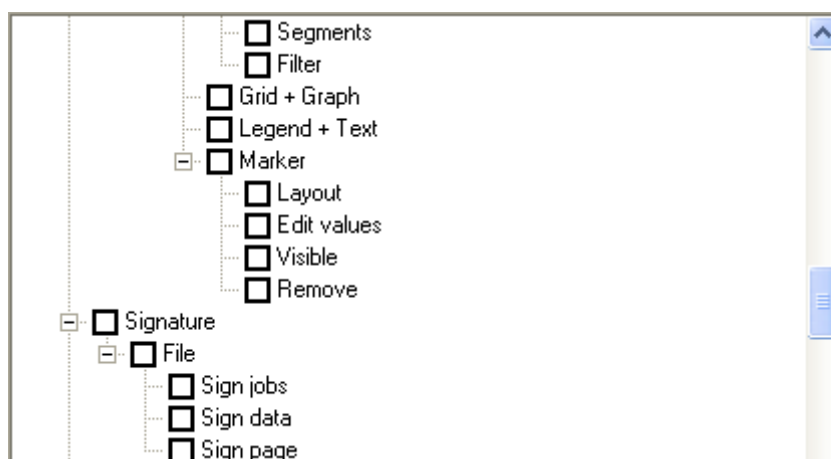
The following privileges relate to functions that are accessible both from the JobManager and the DataManager.



B User privileges

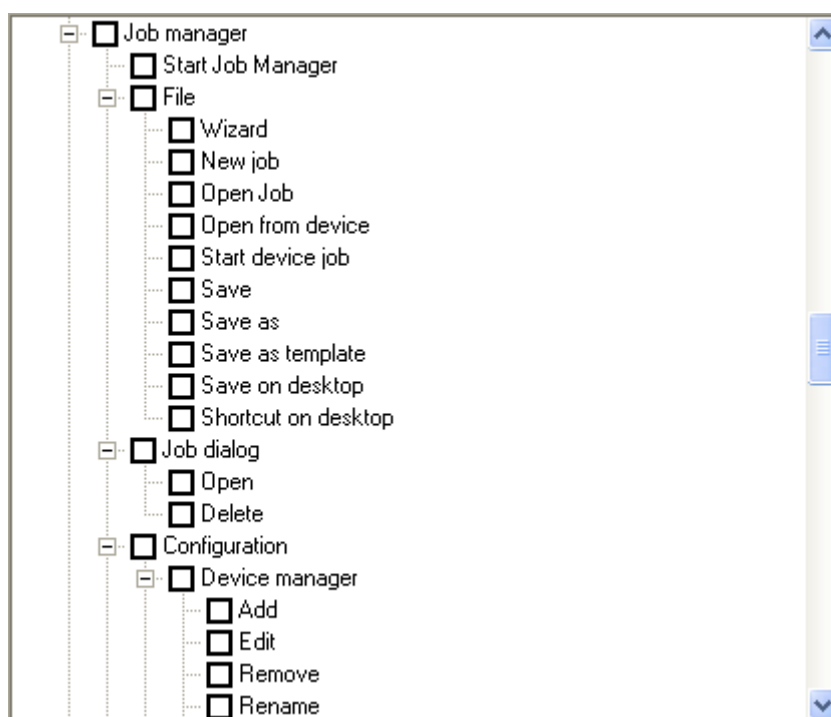
General privileges (in Job- and DataManager)

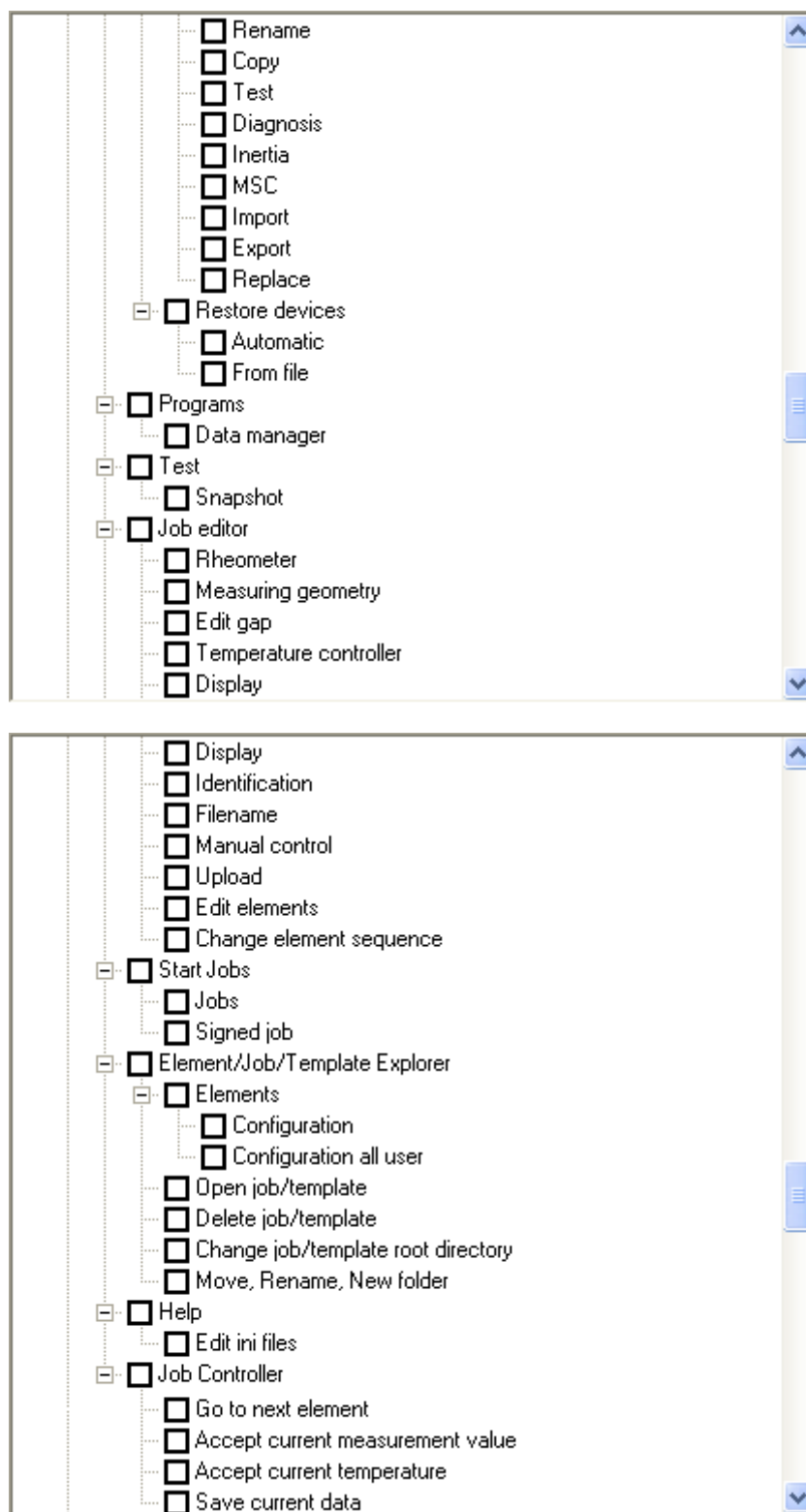




Privileges in JobManager

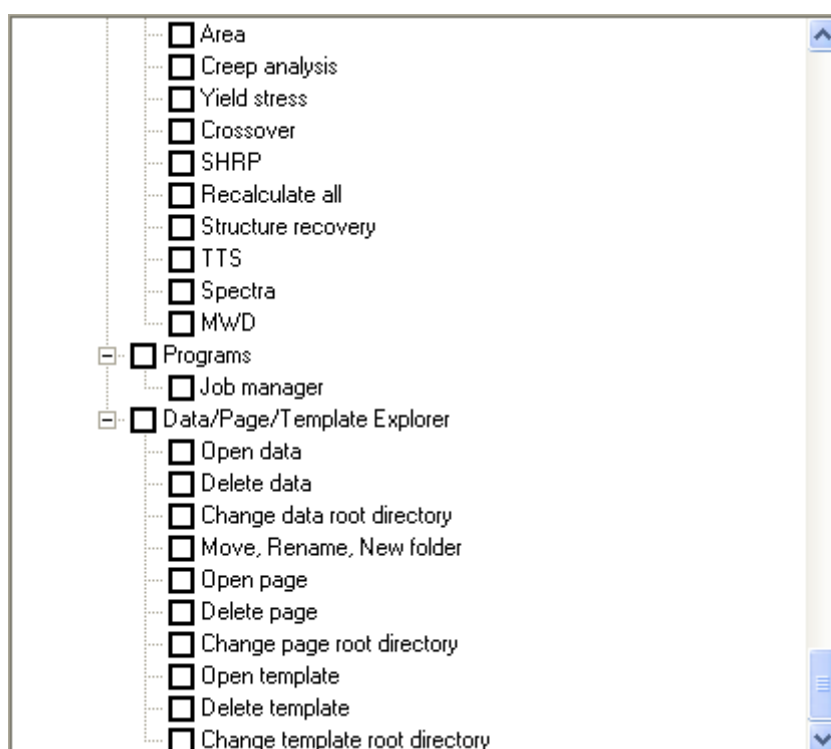
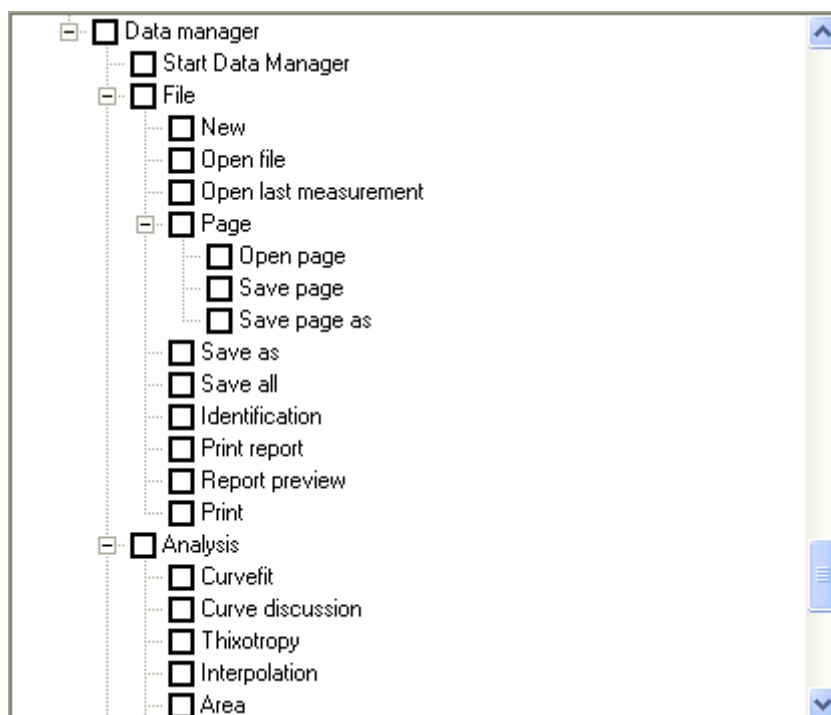
The following privileges refer to functions that are only accessible from the Job Manager.





Privileges in DataManager

The following privileges refer to functions that are only accessible from the DataManager.



Configuration of Windows permissions

Windows and RheoWin versions

The configuration described in this appendix *may* be needed for the installation of RheoWin under Windows 7, Windows 8(.1) and Windows 10. Whether this configuration is needed depends on things like Windows group policies and other Windows security setting, which differ from company to company.

The configuration described in this document is *not* needed for the installation of RheoWin version 4.00.0000 and all newer versions under Windows XP.

The RheoWin ProgramData directory

RheoWin stores many program specific settings and parameters in so-called programdata files in the following directory and its subdirectories (as recommended by Microsoft).

Directory for RheoWin programdata files: c: \ProgramData\Thermo\RheoWin

Programdata files are files which are automatically (i.e. without direct action of the user) created and modified by RheoWin. Examples for programdata files are the file **drivers.flp**, in which all settings of the RheoWin DeviceManager are saved and the file **UMS.mdb**, the UserManagement database file.

Note Under normal circumstances RheoWin users do not need direct access to these files.

RheoWin must have unrestricted read- and write-access to the above mentioned directory and all of its subdirectories for all Windows users. When this is not the case it is possible that, depending on the Windows security settings, certain Windows users can not start RheoWin at all or that RheoWin does not access the correct directory (with the consequence that certain RheoWin settings and parameters do not have the correct values).

When the Windows **User Account Control Settings** are not set to lowest level (see the screenshot below) and at the same time the permissions for the RheoWin programdata directory are not set correctly, Windows may create a copy of the RheoWin programdata directory in the so-called **Virtual Store** directory (for each Windows user separately).

In this case all RheoWin access to the files in the RheoWin programdata directory is automatically redirected to the files in the copy of the programdata directory in the **Virtual Store** without RheoWin or the Windows user being informed.

The result of this is, amongst other issues, that RheoWin does not access the same UserManagement database file and RheoWin DeviceManager settings anymore, which is definitively not the desired behavior.

In order to prevent this from happening the Windows permissions for the RheoWin programdata directory must be configured correctly.

The configuration described below is valid for all possible settings in the Windows **User Account Control Settings** dialog.

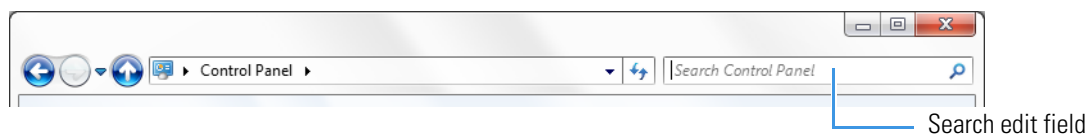
The Windows User Account Control and Virtual Store

Although the actual settings in the Windows **User Account Control Settings** dialog do not influence the RheoWin functionality, as long as the permissions for the RheoWin programdata directory are correctly configured, is it useful to be informed about these settings.

❖ To open the User Account Control Settings dialog

9. In the **Windows Start menu** click on **Control Panel**.
10. In the **Search Control Panel** edit field, see [Figure 50](#), enter the text **UAC**.

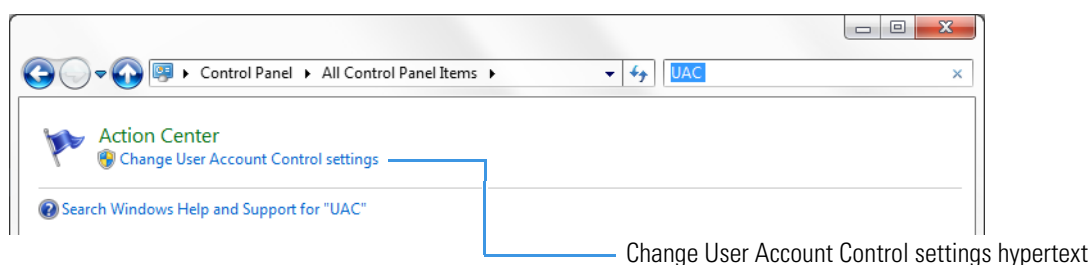
Figure 50. Search edit field in Control panel



The contents of the dialog will then change automatically while the text is entered, see [Figure 51](#).

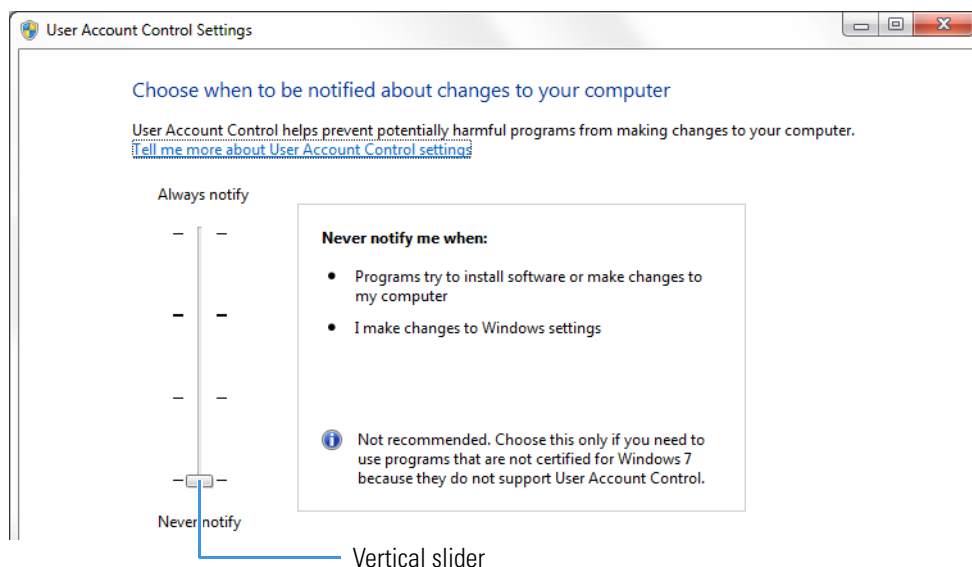
11. Click the **Change User Account Control** settings hypertext, see [Figure 51](#), to open the User Account Control Settings dialog (see [Figure 51](#)).

Figure 51. Change User Account settings



When the vertical slider in the **User Account Control Settings** dialog is not in the lowest position and the Windows permissions for the RheoWin programdata directory are not configured correctly, Windows may use copies of the RheoWin programdata directory (for each Windows user individually) in the Windows **Virtual Store**, which will result in undesired behavior of RheoWin.

Figure 52. User Account Control Settings



Note For a Windows user with the name [Windows-User], the RheoWin programdata subdirectory in the **Virtual Store**, is located (when it exists) in the following directory:
C: \Benutzer\[Windows-User]\AppData\Local \Virtual Store

IMPORTANT In order for RheoWin to work correctly there must no subdirectory
\ProgramData\Thermo\RheoWin\ in the above mentioned **Virtual Store** directory.

Making the C:\ProgramData folder visible

By default the folder C: \ProgramData is not visible in the Windows explorer.

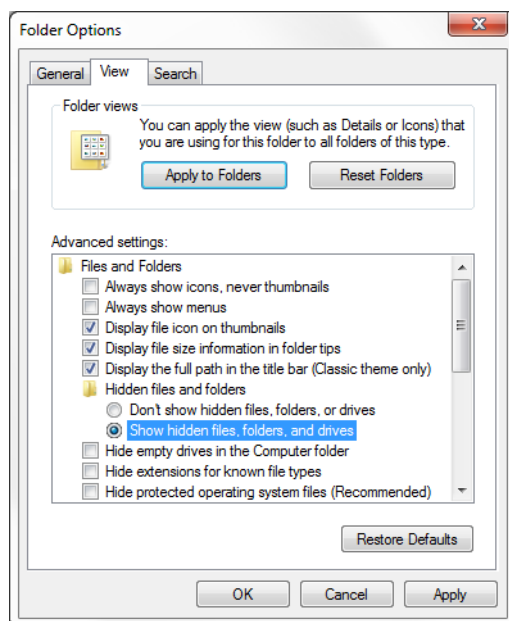
❖ To make the C:\ProgramData folder visible

1. In the Windows Explorer select **Organize** in the main menu.
2. In the **Organize** menu select the **Folder and search options** command, to open the **Folder Options** dialog, see [Figure 53](#)
3. In the **Folder Options** dialog select the **View** page, see [Figure 53](#).

C Configuration of Windows permissions

Configure the permissions for the C:\ProgramData\Thermo\RheoWin directory

Figure 53. Folder options



4. In the **Advanced settings** list scroll down until the entry **Show hidden files, folders and drives** becomes visible, see [Figure 53](#).
5. Activate the **Show hidden files, folders and drives** option.
6. Click the **OK** button to close the dialog.
7. In case the **C:\ProgramData** folder is not visible in the Windows Explorer after closing the **Folder Options** dialog, close and open the Window Explorer again.

Configure the permissions for the C:\ProgramData\Thermo\RheoWin directory

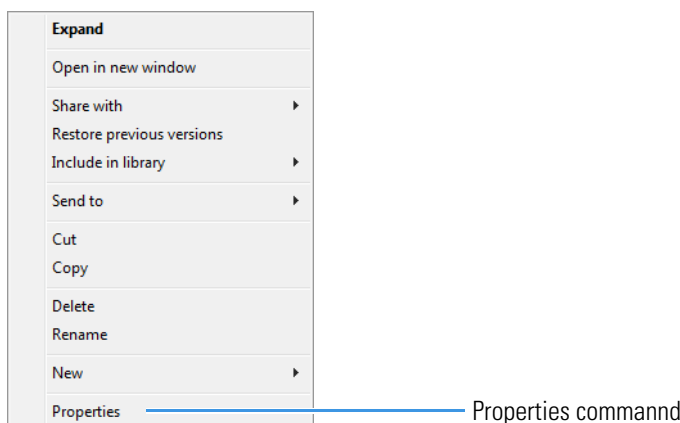
The directory C: \ProgramData\Thermo\RheoWi n must now be configured such that RheoWin has unrestricted read- and write-access to this directory for all Windows users.

IMPORTANT This configuration should be performed before the first start of RheoWin.

❖ To configure the C:\ProgramData\Thermo\RheoWin directory

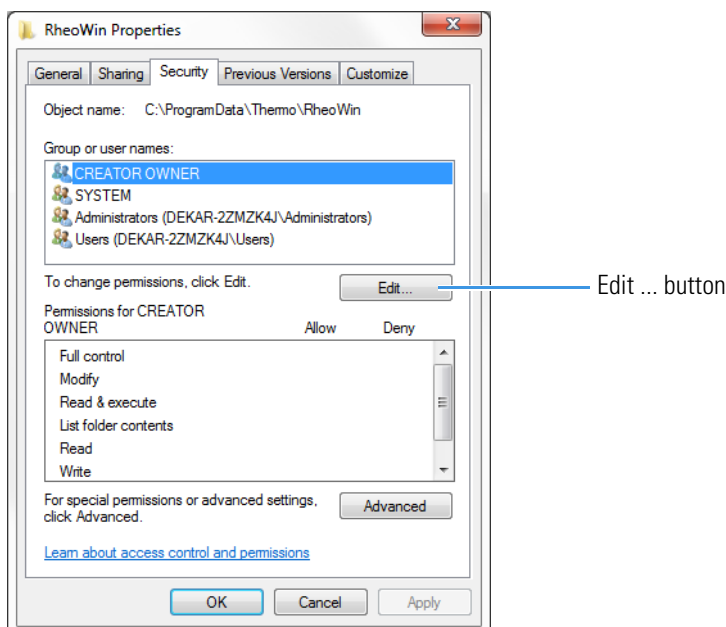
1. In the Windows Explorer select the directory C: \ProgramData\Thermo\RheoWi n with the right mouse key to open the directory context menu, see [Figure 54](#).

Figure 54. Directory context menu



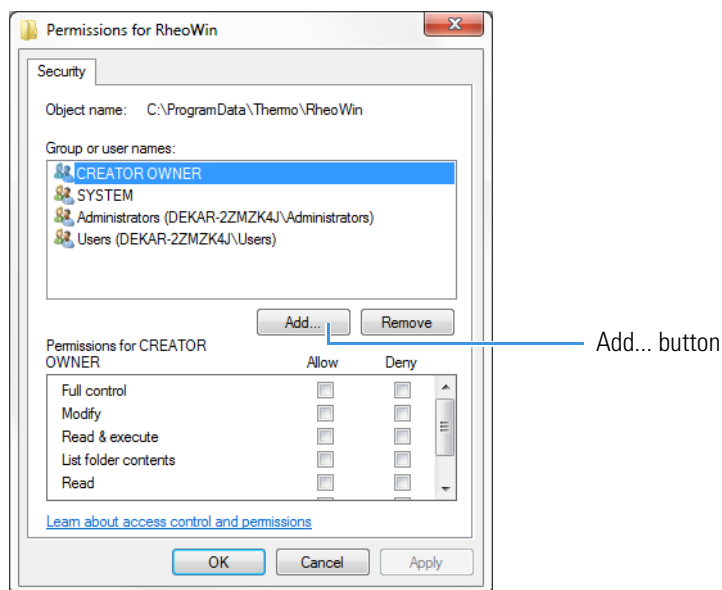
2. In the context-menu select the **Properties** command at the bottom of the menu (see [Figure 54](#)) to open the **RheoWin Properties** dialog (see [Figure 55](#)).

Figure 55. RheoWin Properties



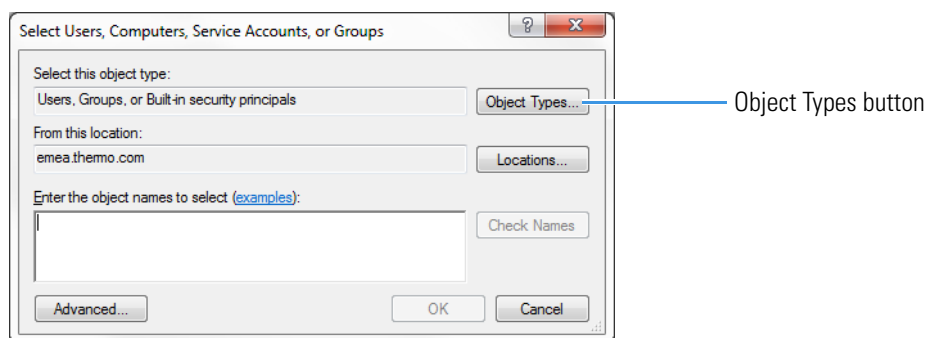
3. In the **RheoWin Properties** dialog click the **Edit...** button (see [Figure 55](#)), to open the **Permissions for RheoWin** dialog (see [Figure 56](#)).

Figure 56. Permissions for RheoWin



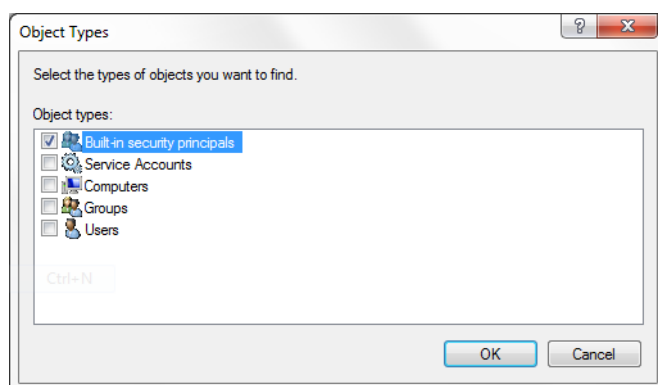
4. In the **Permissions for RheoWin** dialog click the **Add...** button (see Figure 56), to open the **Select Users, Computers, Service Accounts or Groups** dialog (see Figure 57).

Figure 57. Select Users, Computers, Service Accounts or Groups



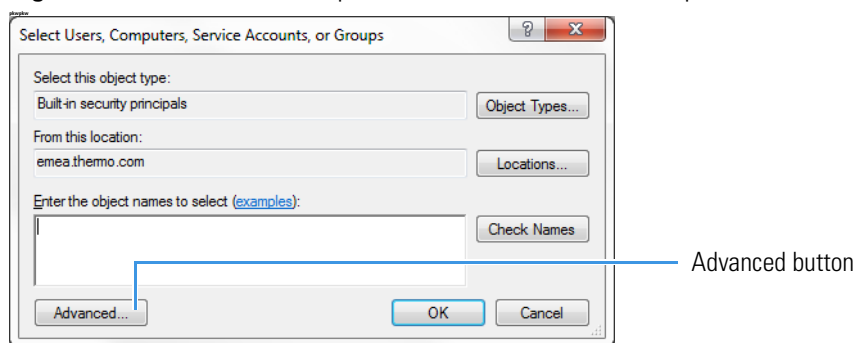
5. In the **Select Users, Computers, Service Accounts or Groups** dialog (see Figure 57) click the **Object Types...** button to open the **Object Types** dialog (see Figure 58).

Figure 58. Object types



6. In the **Object Types** dialog, in the **Object types** list, deactivate all object types apart from the type **Built-in security principals** (see Figure 58).
7. Click the **OK** button to close the **Object Types** dialog to put the **Select Users, Computers, Service Accounts or Groups** dialog in focus again (see Figure 59).

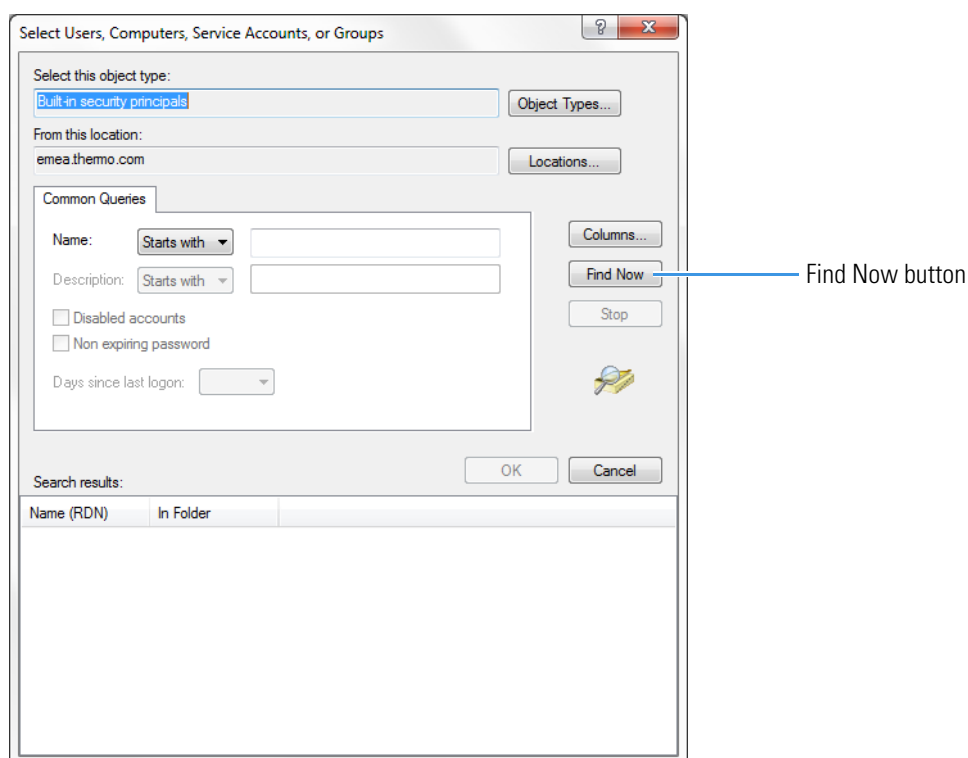
Figure 59. Select Users, Computers, Service Accounts or Groups



8. In the **Select Users, Computers, Service Accounts or Groups** dialog click the **Advanced...** button.

The dialog will then be displayed in a modified version, see [Figure 60](#).

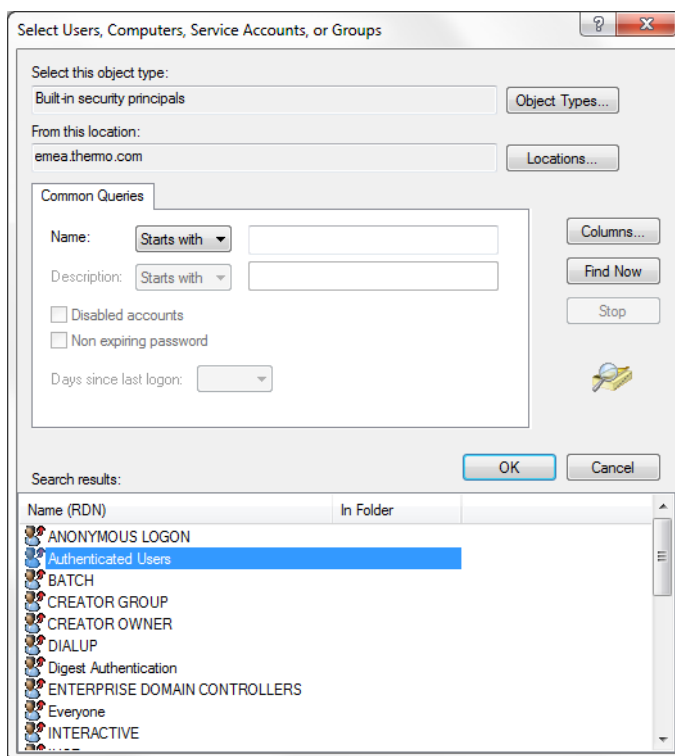
Figure 60. Select Users, Computers, Service Accounts or Groups (modified)



9. In the (modified) **Select Users, Computers, Service Accounts or Groups** dialog click the **Find Now** button.

The search result will then be displayed in the **Search results** list, see [Figure 61](#).

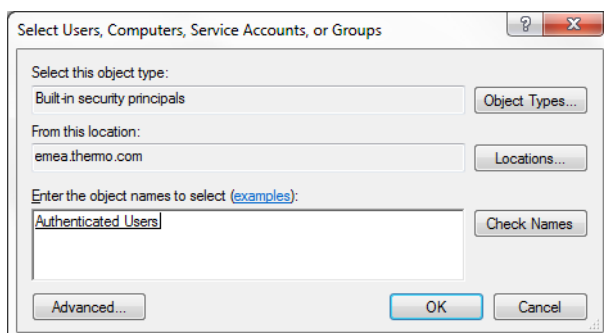
Figure 61. Select Users, Computers, Service Accounts or Groups (modified)



10. In the **Search result** list in the (modified) **Select Users, Computers, Service Accounts or Groups** dialog select the entry **Authenticated Users** and click the **OK** button.

The dialog will then be displayed in the original version again (see [Figure 62](#)).

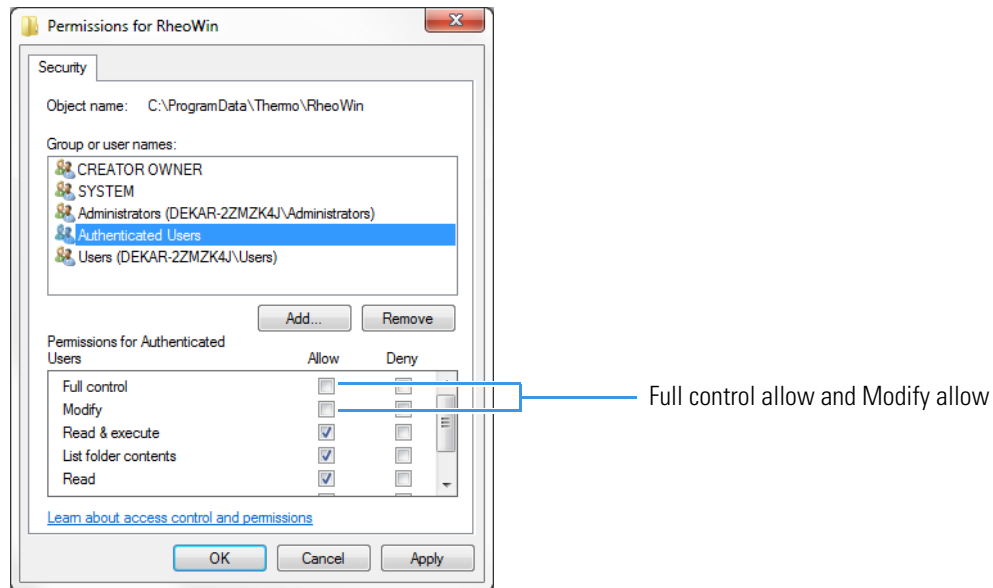
Figure 62. Select Users, Computers, Service Accounts or Groups



11. In the **Select Users, Computers, Service Accounts or Groups** dialog (see [Figure 62](#)) click the **OK** button to close the dialog.

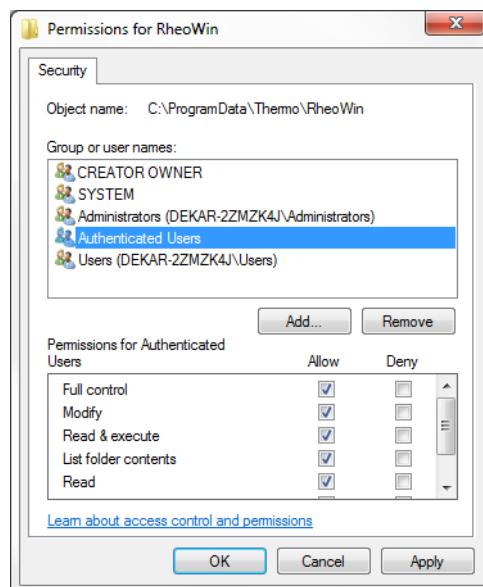
In the **Permissions for RheoWin** dialog the group name **Authenticated Users** is now added to the **Group or user names** list, see [Figure 63](#).

Figure 63. Permissions for RheoWin



- In the **Permissions for RheoWin** dialog in the **Permissions for Authenticated Users** list activate the options **Full control Allow** and **Modify Allow** (see [Figure 63](#) and [Figure 64](#)).

Figure 64. Permissions for RheoWin



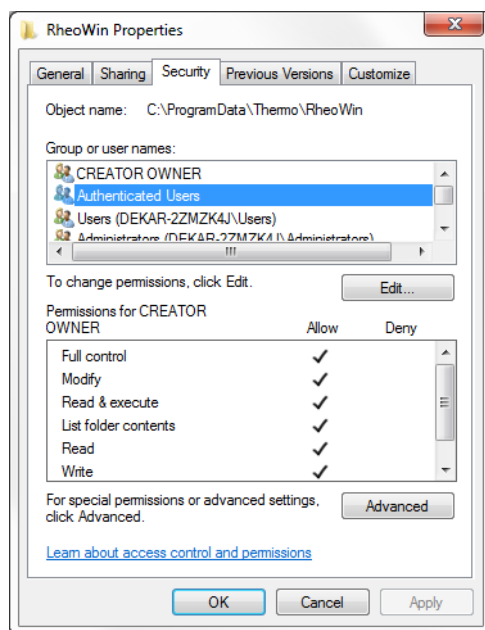
- Click the **OK** button to close the dialog.

In the **RheoWin Properites** dialog (see [Figure 65](#)) the group name **Authenticated Users** is now added to the **Group or user names** list with the permission set above.

C Configuration of Windows permissions

Configure the permissions for the C:\ProgramData\Thermo\RheoWin directory

Figure 65. RheoWin Properties



14. In the **RheoWin Properties** dialog (see [Figure 65](#)) click the **OK** button to close the dialog.

The Windows permissions for the directory C: \ProgramData\Thermo\RheoWi n are now configured such that RheoWin can be used correctly by all Windows user.

IMPORTANT When the configuration described above is performed *after* RheoWin was started at least once, the \ProgramData\Thermo\RheoWi n subdirectories in the Virtual Store *must* be deleted for all Windows users. This because, despite all configuration efforts, Windows will continue to use these directories for RheoWin as long as they exist.

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