ZETASIZER (NANO, µV, APS) SOFTWARE: v8.01 (PSS0012-42)
SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0012-42. This is the Zetasizer software version 8.01.

It covers the additions and improvements as well as issues fixed in this release of the software and also the previous major release, version 8.00.

IMPORTANT:
Data files (.dts) recorded in previous versions of the software will be readable by V8.01. However, once opened in V8.01, these files will no longer be readable in the previous versions earlier than version 8.00.

Note:
If you are upgrading from any version before 7.01, you should also read the SUN documents issued with version 7.01, 7.02, 7.03, 7.04, 7.10 and 7.11.

Note:
Please check that this is the latest version of the Software Upgrade Notification. The latest SUN is available from *https://www.malvernpanalytical.com/en/support/product-support/zetasizer-range*.

Choose your instrument model and the version of software you require the SUN from the documentation section.

Upgrading from previous versions with a regulated environment license activated

Zetasizer Nano software version 8.01 has major updates to 21CFR part 11 features and as such a new license key is required for users upgrading from previous versions of software where a 21CFR part 11 license key has been installed, i.e. those systems operating in a 21CFR part 11 regulated environment. Previous license keys for 21CFR part 11 feature sets **will not** activate those features in version 8.01.

The part number for the new license key is CPS0009, please contact your Malvern Panalytical representative to order the activation key. Please do not upgrade your system until you have received your activation code for the new implementation of 21CFR feature set.

Upgrading to version 8.01 software over previous installations has been tested and this has not shown any problems with retention of data. However, Malvern Panalytical would recommend backing up the relevant files as a precaution. The default path for the files is **C:\Users\Public\Documents\Malvern Instruments\Zetasizer**. It is recommended that all files in this location should be backed up. If you have chosen a different location for previous installs, then please back up the installation location.

Installation

It is assumed that you have authority to install or update software within your company's SOPs. If you do not have this authority, please consult with your I.T. support department before proceeding.

It is assumed that you have Administrator rights for the computer. This is required by the installation process. For Zetasizer Series software, Windows 7 and later will not allow an installation if the user does not have administrator access. This is in line with Microsoft's Logo policy and is standard practice.

Before installation of the software, the instrument must be switched off and disconnected from the USB connector of the PC.

Recommended System Requirements

The recommended computer system requirements for running this software are highlighted in table 1 below.

Feature	Specification
Processor Type	Intel i5-6600 or better
Memory	8GB RAM
Hard Disk Storage	160 GByte free hard disk space
Additional Storage Media	CD-ROM drive
Display Resolution	1440 x 900 32bit color screen resolution, or higher
Connectivity	1 free USB 2.0 port
Operating System	Windows 10 operating system, 64bit build 1903 with its latest updates

Table 1: Recommended system requirements.

Supported Languages

- English
- Japanese

Supported Operating Systems

The following operating systems are supported by the Zetasizer software v8.01:

- Windows 10 Pro or Enterprise Build 1903 (64 bit)

Note:

The operating system must be from a clean installation on the PC. Malvern Panalytical cannot provide support for operating systems that have been "upgraded" from Windows 7™ (or 8) operating systems.

Supported Software Integration

If using existing Zetasizer software with any of the following it is not recommended to upgrade to v8.01:

- Zetasizer Helix
- Any 3rd Party Software / Interfaces

Installation Instructions

The software suite comes on an auto-loading CD-ROM. Inserting the CD into a system configured to auto-run a CD will run the installation program automatically. If your system does not support this feature run the setup program from the root directory of your CD drive.

> **Note:**
> All DTS version 3.xx, 4.xx, 5.xx, 6.xx software must be uninstalled before version 8.01 is installed. The installer will uninstall a previous version if it detects an older version is installed (7.xx and later only).

During the installation process, if the installer detects that an instrument is connected, you will be prompted with the following message (*Figure 1*).
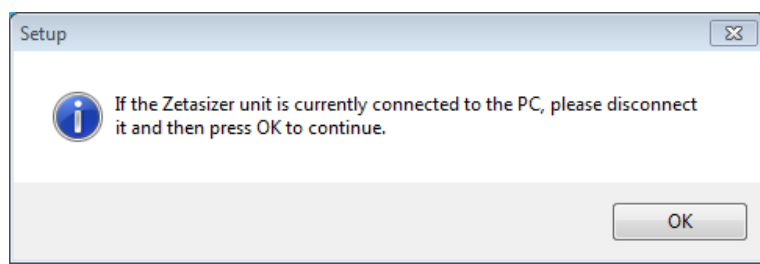

Figure 1"Disconnect Zetasizer Unit" message

You must unplug the USB cable from the PC or Zetasizer Nano and then press OK. If you press the OK button without performing these previous steps, then the installation will not continue.

Microsoft .Net Framework 4.6.2

The Microsoft .Net Framework 4.6.2 must be installed for the Zetasizer software to run. This is installed during the Zetasizer software installation progress and under certain circumstances can involve the PC needing to restart. Completion of this stage of the installation can take from a few minutes to over 10 minutes. Whilst the .Net Framework is being installed the following window will be displayed:
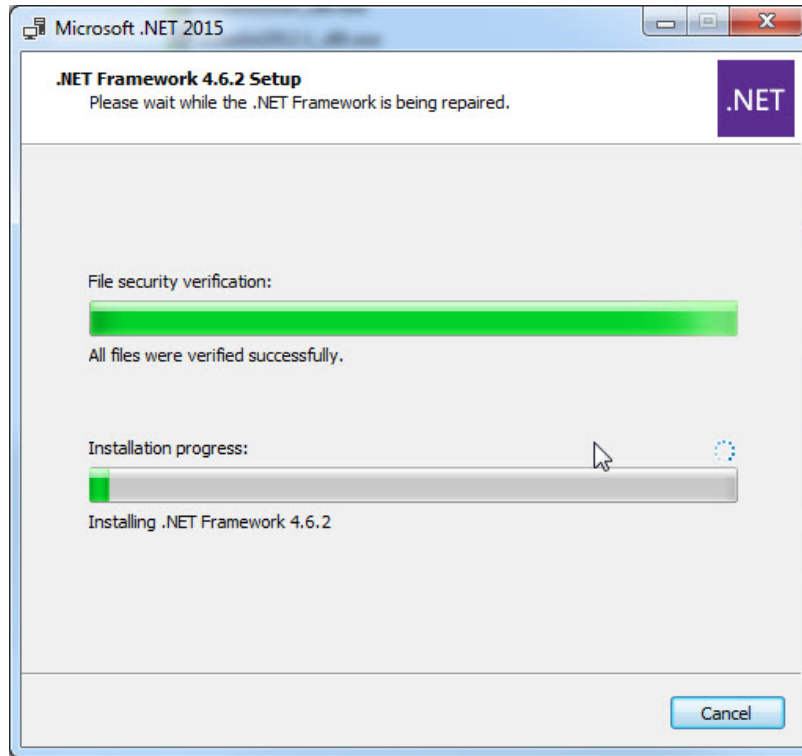
Figure 2: Microsoft .Net 4.6.2 Installation Window

Running the installer before the Zetasizer Software has closed down

If the installer is run immediately after closing down a previous installation of the Zetasizer software then the error shown in *Figure 3* may be displayed during the installation process.
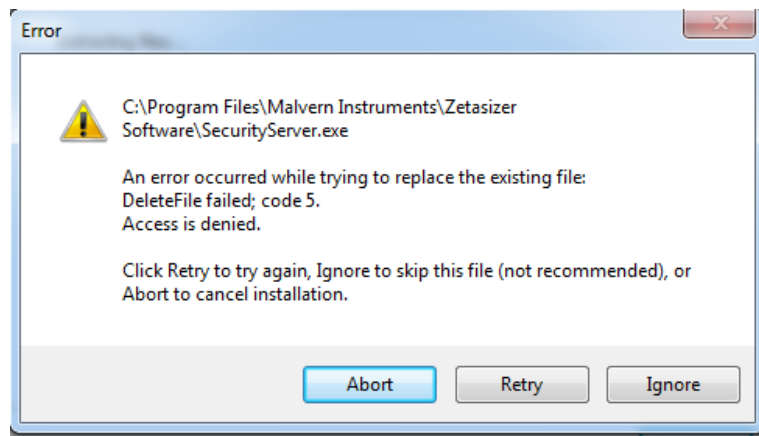

Figure 3: Warning during installation

If this error is encountered then the user must open **Windows Task Manager**, go to the **Processes** tab and select the process described in the first line of the warning (in *Figure 3* this would be *SecurityServer.exe*) and then select **End Process**. Once this is done the **Retry** button can be selected on the original error window and the installation will continue successfully.

Software Update Notification for Zetasizer (Nano, μV, APS) software v8.01 (PSS0012-42)

USB Driver Installation

During the installation of the USB drivers you may be prompted multiple times with the message shown in *Figure 4*.
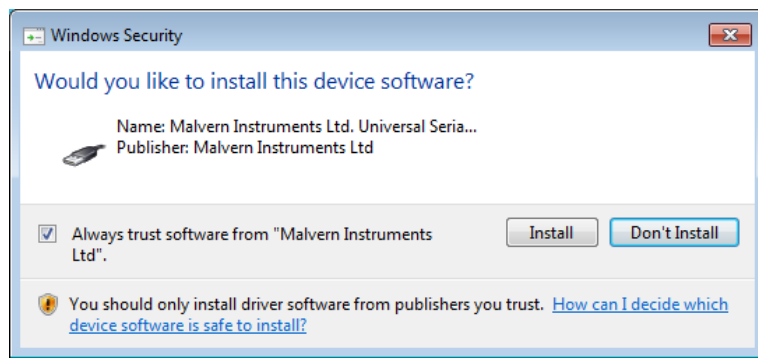

Figure 4 Install USB window

This warning can safely be ignored as the software installation has been tested on Windows 10. Press **Install** to continue installation of the USB drivers.

Application files in user or custom folder

This section applies to the following users:

- Existing users upgrading the software from a previous version, and

- Users who stored the application files in the private user folder or custom folders, and

- Users who added new or modified existing application files.

Measurement, SOP and Export files

From version 8.00 onwards, the default folder for Measurement, SOP and Export files is now in this location: **C:\Users\Public\Documents\Malvern Instruments\Zetasizer**.

If you have stored the above files in the private user folders or other custom folders, and prefer to continue as it is, you can go to **Tools – Options – Zetasizer Options – Folders** to set to your prefer folder location. Please refer to section on "Changing the destination path for a particular file type".

Other Application files

The following folders can be found in the private user or custom folder.

- Export Templates

- Macros

- Protein Calculations

- Reports

- User Calculations

For users who added new file or modified files in the above folder, and would like them to apply to version 8.00 or later of the software, please copy the files to the respective folders in **C:\Users\Public\Documents\Malvern Instruments\Zetasizer**.

Zetasizer APS and µV users

Due to a driver update in the 7.02 release of the software, you may have to follow the steps described in section **Error! Reference source not found.** to install the driver twice.

Uninstall Procedure

The software can be uninstalled using the standard **uninstall** feature in **Settings – Apps & Features** of Windows 10.

Running the software

When the software is started the first time, the following dialog box will appear. Click on the appropriate system to select it. This dialog will not appear the next time the software is started.
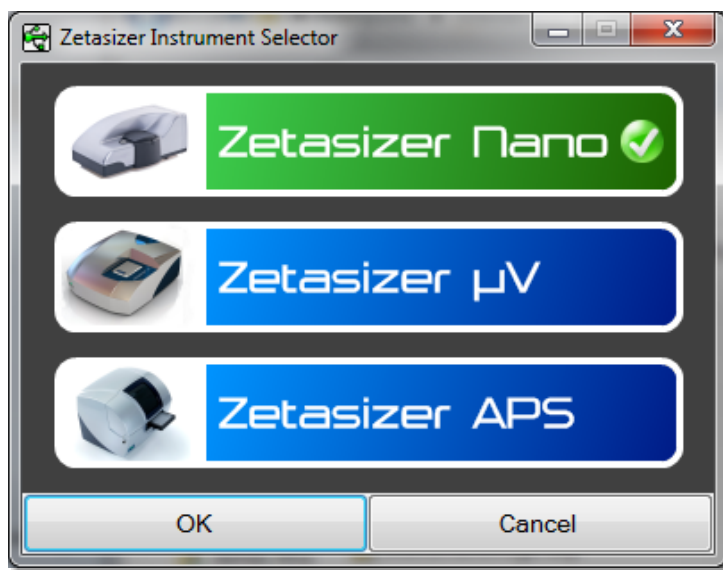

Figure 5: Zetasizer Instrument Selection

The instrument type can be changed at any point by selecting the menu item; **Tools–Options–Instrument type**. Once the instrument type has been changed the software must be restarted for the change to take effect.

Importing SOP sample settings (software upgrade only)

The SOP sample settings will be copied to a backup location during the installation process. To maintain these settings with the new installation, the relevant files need to be manually copied to the correct location to replace the installed files.

1. Ensure that you are logged onto the computer as an administrative user

2. Run the Zetasizer software once then close it down so there are no copies of it running.

3. Use Windows Explorer to copy the files:

   SampleProperties.cfg

   CompoundProperties.cfg

   IonicSpecies.cfg

   to the relevant location. The locations of the files depend on the operating system.

Copy from *C:\ProgramData\Malvern Instruments\Zetasizer<date/time of install>* to overwrite files in *C:\ProgramData\Malvern Instruments\Zetasizer*

Note that the *ProgramData* folder is a hidden folder. To view it, you need to access the **Control Panel** then select **Appearance** and **Personalization–Folder Options–Show Hidden files and folders** and then enable the option **to Show hidden files, folders and drives**.

If the installation process is terminated prematurely, the backup from the last installation is maintained in the following directory: *C:\ProgramData\Malvern Instruments\Zetasizer_BACKUP*

Software Categorization

GAMP 5

The GAMP 5 guide provides guidance to pharmaceutical companies wishing to understand whether the computerized systems and software they used are fit for purpose and meet current regulatory requirements. As part of this, the GAMP committee have defined a series of software categories which are designed to help users in assessing the risk and validation requirements associated with using a specific software package.

The Zetasizer software provides users with the ability to modify the results reported by the system to fit their specific application requirements. This is achieved using custom calculations within reports and also through the application of emulation factors as part of the analysis settings. Given this, the software should be considered to be a Category 5 software package. Users are therefore encouraged to specifically validate the custom calculations and emulation factors applied within SOPs and ensure these are documented. Where possible, we would encourage the use of the standard result reporting features, as this minimizes the risk of errors in the reported size distribution statistics.

Fixes in version 8.01 software

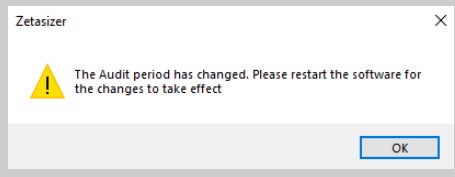| Reference	Issue	Comment
130178	21CFR part 11 error for new users. Software would not allow addition of new users when in 21CFR part 11 mode without also requesting the 21CFR Part 11 software key. Now fixed so the software only needs license activation once per installation and will allow addition of new users.	Bug Fix

21CFR part 11 ER/ES Changes in version 8.00

Zetasizer Software Version 8.00 has been introduced to implement the following 21CFR part 11 and data integrity improvements.

Reference	Issue	Comment
89341	Audit the addition of new users to the security system	New function
89343	Audit deletion of existing users from the security system	New function
89344	Audit disabling of user accounts within the security system	New function
91851	Audit enabling of user accounts within the security system (after account disabling)	New function
91837	Audit the unlocking of user accounts within the security system	New function
91852	Audit the editing of user property to the security system	New function
91853	Audit the copying of user to the security system	New function
91857	Audit the addition of existing users to groups within the security system	New function
91857	Audit the removal of existing users from groups within the security system	New function
91838	Audit the addition of new groups to the security system	New function
91839	Audit the removal of existing groups from the security system	New function
91849	Audit the editing of group property to the security system	New function
91850	Audit the copying of group to the security system	New function
91841	Audit the addition of new members to groups in the security system	New function
91842	Audit removal of existing members from groups within the security system	New function
91844	Audit changes either addition or removal to the permissions associated with a group	New function
91847	Auditing of security settings	New function
91855	Auditing of the enabling of security settings	New function
91856	Auditing of eres option setting	New function
91911	Audit the start of a measurement for particle size	New function
91912	Audit the start of a measurement for zeta potential	New function
91917	Audit the start of a measurement for molecular weight	New function
91918	Audit the start of a measurement for flow	New function
91920	Audit the start of a measurement for titration	New function
91921	Audit the start of a measurement for temperature trend	New function
91922	Audit the start of a measurement for surface zeta potential	New function
91923	Audit the start of a measurement for protein mobility	New function

Reference	Issue	Comment
91924	Audit the abort of a measurement for Particle Size	New function
91925	Audit the abort of a measurement for Zeta Potential	New function
91926	Audit the abort of a measurement for Molecular Weight	New function
91927	Audit the abort of a measurement for Flow	New function
91929	Audit the abort of a measurement for Titration	New function
91930	Audit the abort of a measurement for Temperature Trend	New function
91931	Audit the abort of a measurement for Surface Zeta Potential	New function
91932	Audit the abort of a measurement for Protein Mobility	New function
91820	Search an open audit trail (including the current audit trail) to find events relating to the creation of specific records or the actions of specific users.	New function
91821	Search the audit trail directory to find events relating to the creation of specific records or the actions of specific users.	New function
91824	New implementation to ensure audit trails files cannot be overwritten	Improved function
111895	Updated software branding from Malvern Instrument to Malvern Panalytical	Improved function
115495	Support for new zeta transfer standard ZTS1240 (DTS1235 obsolescence)	Improved function
115629	Add logging capability during software initialization	New function
119068	In Tools–Options-Folders, the default share file folder is now in C:\Users\Public\Documents\Malvern Instruments\Zetasizer	Improved function

Fixed issues in version 8.00

Reference	Issue	Comment
98210	Remove Zeta Analysis version 6.1	Zeta analysis v 6.1 was not intended for public release – it has now been removed. Existing SOPs calling for v 6.1 analysis will still use v 6.1 analysis
29699	Fixed: The Reason for Change dialog now only pops up for the parent measurement and the reason copies in as the reason for the change for any child measurements.	
31232	Fixed: Reports - Automatic report printing to PDF gets stuck in a loop if 'Acrobat Results' folder is not present	
32509	Fixed: Given 21CFR is enabled but the security is not enabled, when the software has been launched, then there is now no "User Unknown" entry made in the Audit Trail.	
35346	Fixed: [SOP Player] When run a SOP in the SOP Player with an open read-only measurement file causes a crash.	
62463	Fixed: [SOP Player] Selecting all files in file open dialog can lead to the software hanging up. SOP Playlist can only open playlists from the file open dialog.	
63639	Fixed: [21CFR] Audit trail file can lose data or append the wrong file if a duplicate instance of AuditTrailServer.exe is running	
63646	Fixed: First record in a new measurement file sometimes starts at record number 2. First record should start at record number 1.	
91864	Fixed: User 'Unknown' should not appear in the audit trail if the time out occurs	
91865	Fixed: Given 21CFR is enabled, editing a user causes unknown user.	
91867	Fixed: Given 21CFR is enabled, if a user has been deleted and later the decision has been reverted (by not saving the changes), audit trail still records user deletion	
91897	Fixed: Given 21CFR is enabled when security is enabled then the user who enabled it should be listed alongside the action in the Audit Trail. There should not be Unknown User listed for this action.	
91905	Fixed: Given 21 CFR is enabled, and continuous use check is enabled, then Unknown should not appear in the Current User box on the main screen and there should be no Unknown user entry in the Audit Trail when a timeout occurs	

Reference	Issue	Comment
91907	Fixed: In ERES Option Setting, a message to inform the user that software will require a restart when audit period is changed is now displayed.	
91969	Fixed: At the logon dialog, when user clicks on cancel button, unknown user is shown.	
91978	Fixed: Software crashes when connection has been lost with the instrument	
92083	Fixed: [SOP Player] Copied manual SOP will crash/freeze software during a measurement	
95917	Fixed: [Flow Mode] Software freezes after some runs of the SOP Player without any reason	
95919	Fixed: [Flow Mode] Software crashes when lost USB connection	
95921	Fixed: [Flow Mode] When running a sample on the playlist, user cannot stop it halfway and restart, any stoppage means the software needs restarting	
95923	Fixed: [Flow Mode] When editing a DLS data file to get individual size information on peaks, the automatically integrated regions need deleting one by one, and therefore it takes time to do	
101334	Prohibit record deletion option is now applied even when security settings are disabled – previously security had to be enabled for prohibit record deletion to be active, even though the user could check the function in the settings	
101553	Fixed: [SOP Player] After opening a playlist, opening non playlist files caused exception error	
101606	Fixed: Zetasizer Software crashes if connection is lost more than once in a session	
101688	Fixed: Given 21CFR has been enabled Then the default Acrobat Results directory should be created when the default Audit Trail directory is created. The automatic pdf results should be written to "My Documents\Malvern Instruments\Zetasizer\Acrobat Results" by default.	
101794	Fixed: Given the Audit Trail directory has been changed in ER/ES settings when the ER/ES changes are accepted then a message appears informing the user that the new directory will be used once the current audit period has expired.	
101795	Fixed: Given 21 CFR has been enabled and continuous use check is enabled, then Unknown should not appear in the Current	

Reference	Issue	Comment
	User box on the main screen and there should be no Unknown user entry in the Audit Trail	
102184	Fixed: Given 21CFR and Security are enabled, when a user is logged out by the software, then the Audit Trail should record that logout.	
102884	Fixed: Attempting to open a second instance of the software should not disable auditing.	
103423	Fixed: Temperature set and stored at SOP is not used for the measurement.	
104223	Fixed: Using Cell Type ZEN2112, during dual angle measurement, forward scatter and back scatter have measurement position set to 4.65mm. It should be 4.20mm	
104861	Fixed: Report page "Size Result Export" does not show the right option in the pop-up menu	
108193	Fixed: In Options-Measurement-Results-"Save results if measurements are aborted" should always be checked and is no accessible to a user when in 21CFR mode	
109611	Fixed: Audit trail entries disappear from viewer after sequentially opening multiple audit trail files.	
109612	Fixed: 21CFR mode not enabling for new Windows users, unless they log into the Zetasizer application for a second time.	
109613	Fixed: PDF file creation at the end of measurement does not now crash the software as it previously may have.	
109974	Fixed: Given 21CFR and Security are enabled, when the "Configure Communications Settings" permission is disabled for a particular user, then the whole Tools > Instrument menu should be disabled.	Note: MPT-2 manual controls are not included so that all users can maintain/clean the titrator.
109978	Fixed: Given 21CFR and Security are enabled, when the "Create and edit export templates" is disabled then on the Export Data menu the create and edit buttons should be disabled.	
110777	Fixed: User changing security settings does not get logged by audit trail	
112983	Fixed: Software installer takes a long time to install file	
115534	Fixed: Custom parameters do not retain values in SOPs	
116173	Fixed: Aborting the APS during measurement causes unhandled exception	
127187	Inconsistent measurement start-times between record parameters and system audit trail parameters – especially affects Zeta measurements due to processing timings	Fixed, measurement start times now synchronized between record and audit entries.

Known Issues

The following software issues are known.

Reference	Issue	Comment
Using CONTIN analysis (in Research mode) can cause the NanoSampler schedule to fail	If CONTIN analysis required, create SOP with general analysis and reanalyze data using CONTIN.	Software Bug
PC entering sleep mode can disconnect the Zetasizer	It is recommended to disable the sleep function while the Zetasizer is being used.	Software Bug
If, during a measurement, the lid is opened, all of the safety cut offs will work as expected, but the measurement will continue to completion rather than aborting.	No workaround available as instrument operation is not affected.	Software Bug
Missing parameters in user reports	Changes to the parameter dictionary may affect custom user report templates – see below	Update to template by user required
Saving data to non-local fixed drives It should be noted that the software does not support saving directly onto non-local drives unless the drive can be guaranteed to be 100% available. This is because the software is continually reading and writing to the active measurement file and if the connection to the drive is lost then the file can become corrupted and measurement data lost.	It is suggested that users interact with a local file and then save this file to a network location once the session has been completed.	Hardware
When launching the Zetasizer software from a .dts file in Windows Explorer an error message will appear with the following txt: "There was a problem sending the command to the program"	This error message does not stop the file from loading and can be safely ignored.	Software Bug

Other Issues of Note

Missing parameters in user reports

The parameter dictionary has been updated for this version of the software and some of the parameters have changed. For reports that the user may have created containing the affected parameters, the parameters will become undefined. This can be seen when a report is opened, and the parameter displays the text 'No parameter has been selected' or if nothing is shown next to the text label (i.e. the value appears blank). To fix this problem for each parameter carry out the following steps:

- Open the affected report template in the Report Designer (Tools – Report Designer)
- Double-click on the affected parameter(s) to bring up its property dialogue.
- Click the 'Select' button to display the 'Select a parameter' dialogue.

- Select the relevant parameter.

N.B. Remember to correct the affected parameters on both the screen and page layout views

Records and Analysis

The analysis algorithms for the calculation of size, zeta potential and molecular weight, including data filtering, are being continually improved. The effect of this is that if data taken from a previous version of software is edited, the result may change, even if only the sample name is edited. This is because the algorithms themselves are not stored with the record. This does not apply to parameters stored with the record such as the viscosity, and refractive index etc. as the same parameters are always used in the recalculation of the edited result.

This does not of course change the result of the stored record, as after editing a new record is created. To tell if a record is the original or has been edited, the parameter 'Is edited' can be added to a report or the record view. This can be found in the measurement audit information section of the parameters list. It will display 'False' if the record has not been edited.

File Types and Locations

The Zetasizer software uses a series of different file types in order to store data and measurement settings. These are described below, in order to help users who wish to apply security setting to the Zetasizer software using the Microsoft Windows security and access settings.

File Type	Extension	Default Path*	Advised security setting for 21CFR Part 11 Mode
Measurement Data	.dts	C:\Users\Public\Documents\Malvern Instruments\Measurement Data	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
SOP	.sop .sopl	C:\Users\Public\Documents\Malvern Instruments\SOP	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Export Data	.txt .csv	C:\Users\Public\Documents\Malvern Instruments\Export Data	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Reports	.pag	C:\Users\Public\Documents\Malvern Instruments\Reports	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Acrobat Results	.pdf	C:\ProgramData\Malvern Instruments\Zetasizer\Acrobat Results	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Audit Trails	.adt	C:\ProgramData\Malvern Instruments\Zetasizer\Audit Trails	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Audit Trails Export	.csv .txt	C:\ProgramData\Malvern Instruments\Zetasizer\Audit Trails	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
License file	.lkd	C:\ProgramData\Malvern Instruments\Zetasizer	Once the system has been set up and 21 CFR Part 11 mode engaged then access to this file must be set to prevent deletion. However, read, write and modify access must be maintained.
Macros	.bas .zmac	C:\Users\Public\Documents\Malvern Instruments\Zetasizer\Macros	Prevent deletion of the files in this directory.

File Type	Extension	Default Path*	Advised security setting for 21CFR Part 11 Mode
Protein Calculations	.xml	C:\Users\Public\Documents\Malvern Instruments\Zetasizer\Protein Calculations	No control required

*please note that paths containing …\Public\Documents\… may also be referred to as …\Public\Public Documents\…

Changing the destination path for a particular file type

The following folders can be configured from within the Zetasizer software:

- SOP
- Measurement Data
- Export Data

Configuration of the target folder can be done from the **Tools–Options** menu and select **Folders** section.
The file sharing options are shown in the following:

- Share files. Store them in a shared folder on the local PC.
- Do not share Files. Store them in a private folder of the active Windows user.
- Custom. Specify folder locations.
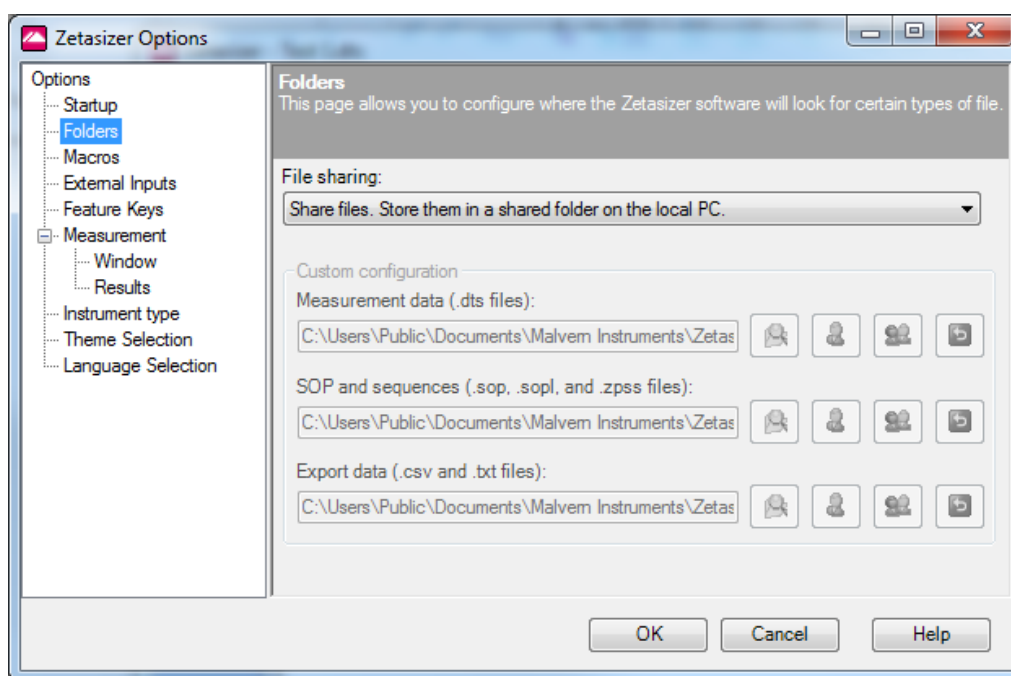
Figure 6: File Sharing Option

Windows Security Settings

With a 21CFR11 compliant computer system, one of first concerns to address is the potential for the loss of data; either accidently, or by intention. Utilizing the built-in security tools of Microsoft Windows®, an IT professional can effortlessly change user access to specific files and/or folders by simply removing certain file/folder permissions.

For the next part of this document, it is assumed that you have the required administrator rights for the system upon which the Malvern software is being installed - allowing you to install, or update software and configure windows security permissions.

> **Note**:
> In the following demonstration we have previously created a user group, through the Computer Management console, called 'Zetasizer Users'. This group will then be added into the folder permissions of the Audit Trails folder to prevent users from deleting records. This process can be applied to any other output folder requiring limited user access. In the illustrations below, we have not removed default groups such as 'Everyone' or 'Users' and we strongly advise that explicit 'Denies' are not used.

Changing folder security permissions in Windows 10

1. Navigate to one of the folders that needs to be secured - in this case we have selected the folder where the Zetasizer audit trail files are stored. Right-click on the folder and through the context menu open the folder **Properties**.

2. Within **Audit Trails Properties**, left-click on the **Security** tab and left-click the **Advanced** button to open the **Advanced Security Settings**.

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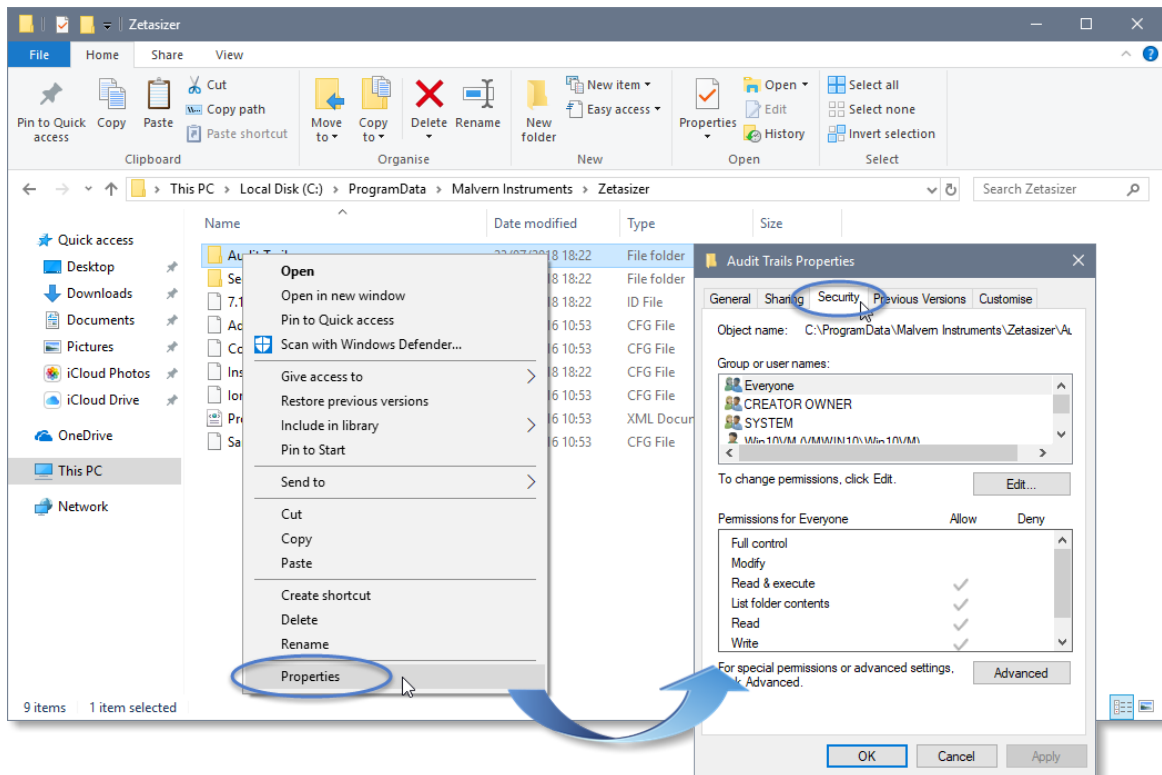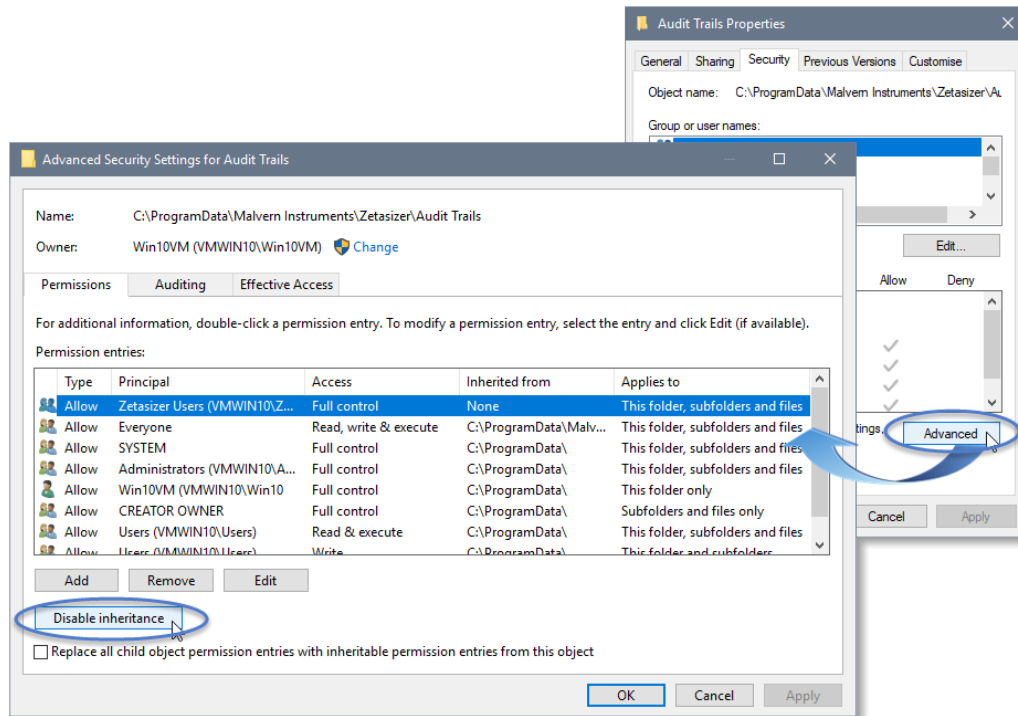
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button.

4. Within **Block Inheritance**, left-click on **Convert inherited permissions into explicit permissions on this object** – this removes the permission inheritance from the parent folder, whilst keeping the any current users and groups settings.
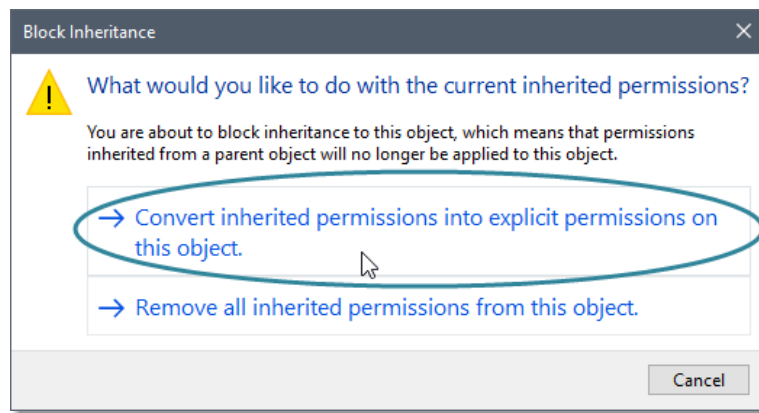

5. After returning to the **Advanced Security Settings** window, left-click to select the **Zetasizer Users** group and then left-click the **Edit** button.

6. In the **Permissions Entry** window, left click the **Show advanced permissions** to reveal the full permissions list.
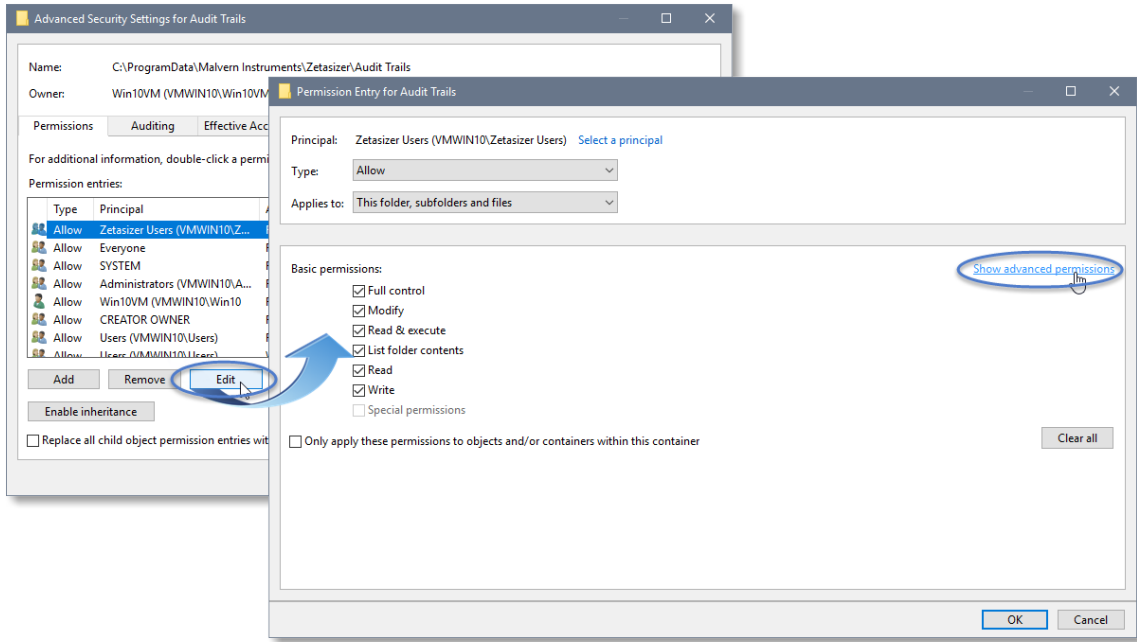
7. Left-click to de-select the checkboxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.
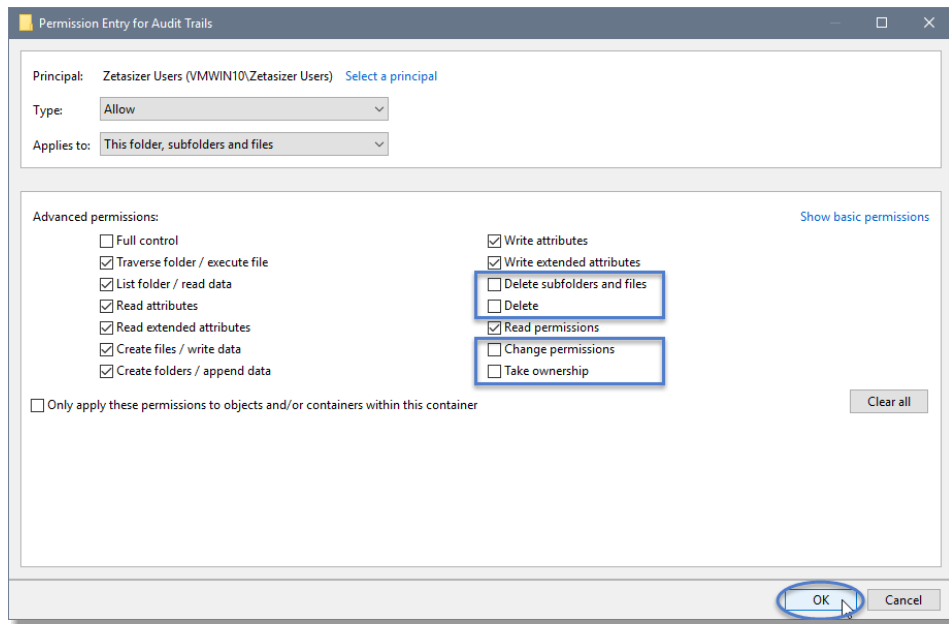
8. Left click **Replace all child permission entries with inheritable permission entries from the object** checkbox and left-click the **Apply** button.

9. Left click the **Yes** button when prompted to replace the permissions and the **OK** button when you return to the previous window.
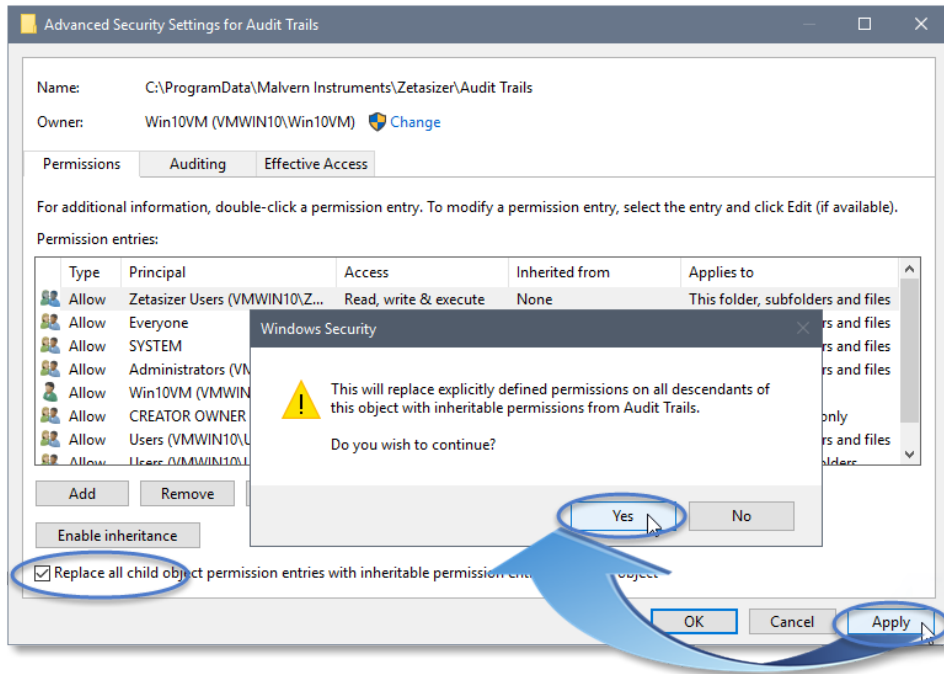
10. Left click the **OK** button when prompted to close all the previous windows to exit the set-up.

➜ Note:
Once these settings are applied, any attempt to upgrade, or downgrade, will prompt a '*File Access Denied*' dialog which necessitates administrator privileges to delete the *8.01.ID* file.

Customer deliverables

Application software suite

The software is contained on one CD-ROM.

- Operating software
- Zetasizer User manuals
- MPT-2 manual
- Accessories User manuals
- Software Update Notification (SUN) with changes from previous software version (this document)
- Adobe Acrobat Reader

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