ZETASIZER (NANO, µV, APS) SOFTWARE: v7.13 (PSS0012-39)
SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0012-39. This is the Zetasizer software version 7.13.

It covers the additions and improvements as well as issues fixed in this release of the software.

> **IMPORTANT**:
> Data files (.dts) recorded in previous versions of the software will be readable by V7.13. However, once opened in V7.13, these files will no longer be readable in the previous version.

> **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.

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 Core 2 Duo
Memory	4GB 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 7 Pro or Enterprise SP1 operating system.
	* Preferred Operating System

Table 1: Recommended system requirements.

Supported Languages

- English
- Japanese

Supported Operating Systems

The following operating systems are supported by the Zetasizer software v7.13:

- Windows 7 Pro or Enterprise SP1 (32bit and 64bit)
- Windows 10 Pro or Enterprise Build 1703 (64 bit)

> **Note**:
> In order to address Windows 7 vulnerabilities associated with driver signing, this software only uses the latest driver authentication protocol recommended by Microsoft (SHA 256 certification). As a result, a Windows OS update may be required in order for the system to work. Please refer to Microsoft Knowledgebase reference KB3033929 for details. Any computer system which has been updated with Microsoft patches since March 2015 should operate correctly.

Supported Software Integration

If using existing Zetasizer software with any of the following it is not recommended to upgrade to v7.13:

- Malvern Link II
- 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 7.13 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*).
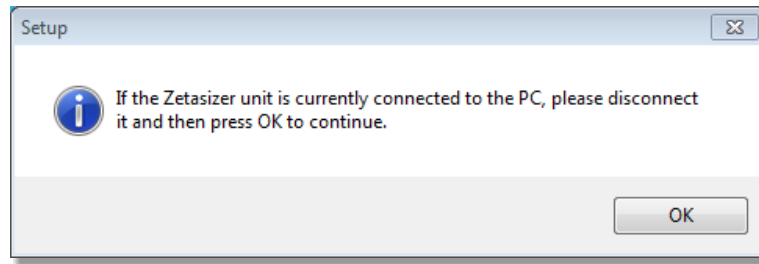
Figure 1"Disconnect Zetasizer Unit" message

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

The Microsoft .Net Framework 4 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 a few minutes, and in the case of Windows 7 64 bit can take over 10 minutes. Whilst the .Net Framework is being installed the following window will be displayed:
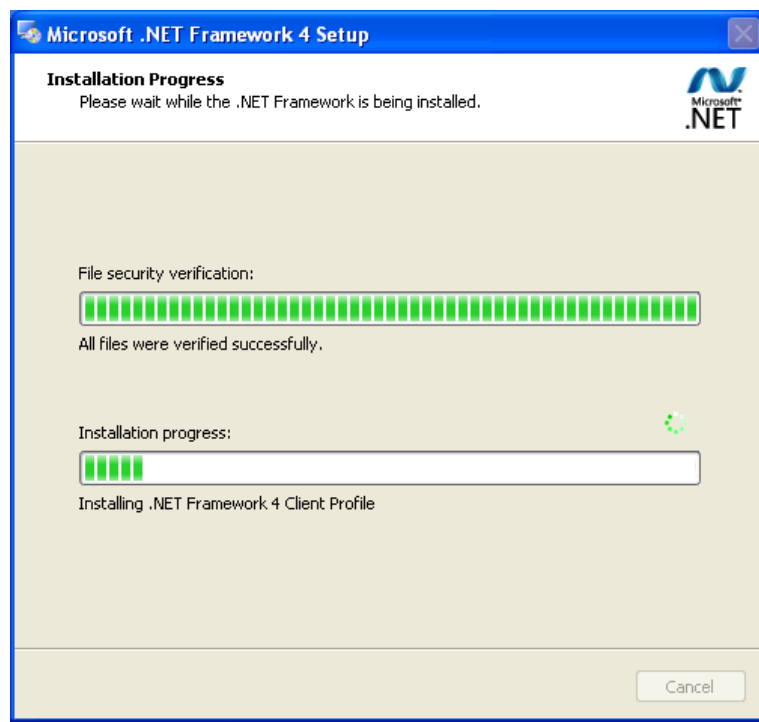

Figure 2: Microsoft .Net 4 Installation Window

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.
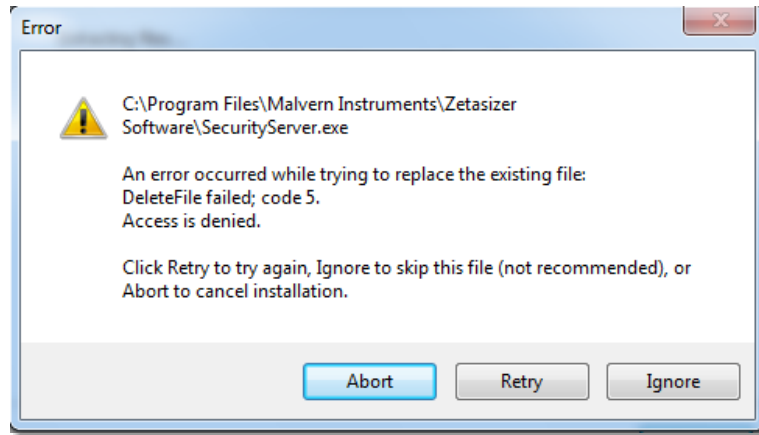
Figure 3: Warning during installation

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.

USB Driver Installation

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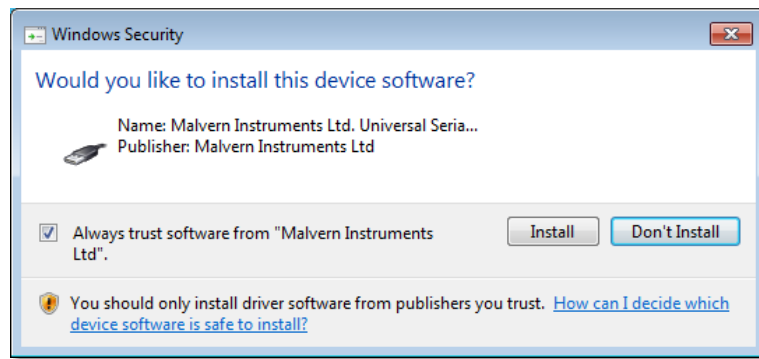

Figure 4 Install USB window

This warning can safely be ignored as the software installation has been tested on Windows 7 and Windows 10. Press **Install** to continue installation of the USB drivers.

Installation with Viscotek OmniSEC software

If the Zetasizer software is being installed on a PC that already contains the Viscotek software OmniSEC version 4.7, the following message may appear:
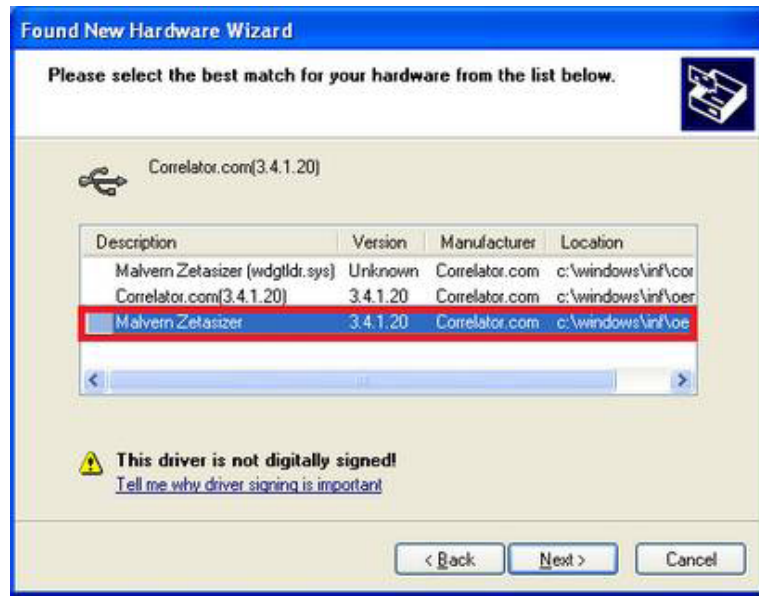
Figure 5: Select USB Drivers on Windows with OmniSEC software

Select the **Malvern Zetasizer** and click **Next**. The **Malvern Zetasizer (wdgtldr.sys)** option must <u>not</u> be selected.

Uninstall Procedure

The software can be uninstalled using the standard **Add/Remove** feature in the **Windows Control Panel**.

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.
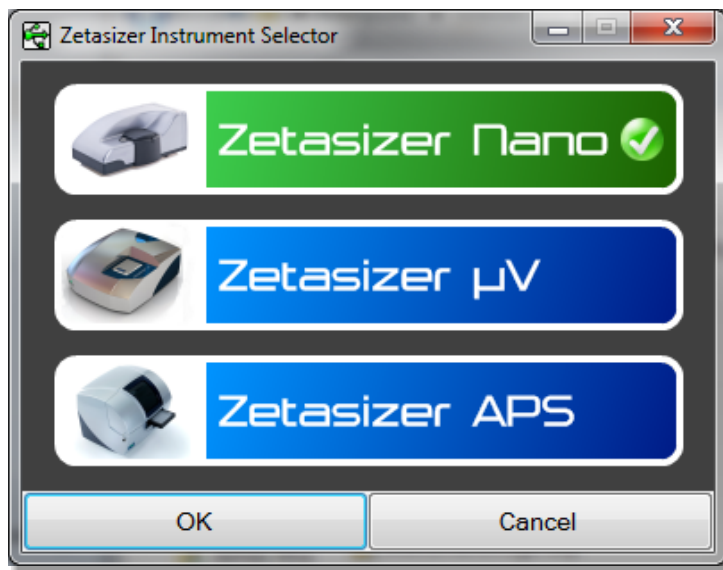

Figure 6: Zetasizer Instrument Selection

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 through the use of 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.

Fixed issues

The following software bugs have been fixed in this software release

Reference	Issue	Comment
88841	Updated Zetasizer drivers signing to support PCs with both Secure Boot enabled and a Secure Boot aware operating system such as Windows 10	Fixed
89218	Software Branding: Updated copyright information	Fixed

Known Issues

The following software bugs have been discovered within the software, and will be investigated as part of a future release. Please follow the suggested work-around for each.

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
Occasionally, it has been observed that feature keys can be disabled after detaching one instrument and then attaching a different instrument.	This problem can be resolved by restarting the Zetasizer software.	Software Bug

In certain circumstances the 21CFR audit trail does not update if the Windows user is changed from the original user that installed the 21-CFR key.	The following procedure should be followed to enable the 21CFR Part 11 ER/ES audit trail for all users: 1. Open Windows Explorer as an administrator to edit the file permissions. 2. Type "%ALLUSERSPROFILE%\Application Data" into the address bar. 3. Hit Enter and open the [Malvern Instruments] folder from the folder list. 4. Right click the [Zetasizer] folder and select [Properties] from the menu. 5. Click on the [Security] tab. 6. Under the "Group or user names" list, click on the [Add] button. The "Select Users or Groups" dialog should open. 7. In the "Enter the object names to select" box, type in "Everyone" and click on the [Check Names] button. The word "Everyone" should become underlined. 8. Click [OK] to accept and close the "Select Users or Groups" dialog. The group "Everyone" should be added to the "Group or user names" list. 9. Select the [Everyone] item in the list and tick the [Allow] box for the "Full control" option in the "Permissions for Everyone" list below. 10. Click [OK] to accept and close all properties windows. 11. The audit trail should now work correctly for all user accounts on this computer.	Software Bug
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
21 CFR Part 11 audit log does not capture changes in privileges to user accounts	Use documentation and Windows user levels to control access.	Software feature request

Under certain circumstances a workbook can start at record 2. No data is lost.	By observing usual workflows this will not occur. No data is actually lost.	Software Bug

Other Issues of Note

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:\ProgramData\Malvern Instruments\Zetasizer\Audit Trails	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
SOP	.sop .sopl	C:\ProgramData\Malvern Instruments\Zetasizer	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Export Data	.txt .csv	C:\Users\{user_name}\Documents\Malvern Instruments\Zetasizer\Macros	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Reports	.pag	C:\Users\{user_name}\Documents\Malvern Instruments\Zetasizer\Protein Calculations	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\Audit Trails	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	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Audit Trails Export	.csv .txt	C:\Users\{user_name}\Documents\Malvern Instruments\Zetasizer\Macros	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
License file	.lkd	C:\Users\{user_name}\Documents\Malvern Instruments\Zetasizer\Protein Calculations	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:\ProgramData\Malvern Instruments\Zetasizer\Audit Trails	Prevent deletion of the files in this directory.
Protein Calculations	.xml	C:\ProgramData\Malvern Instruments\Zetasizer	No control required

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

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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:

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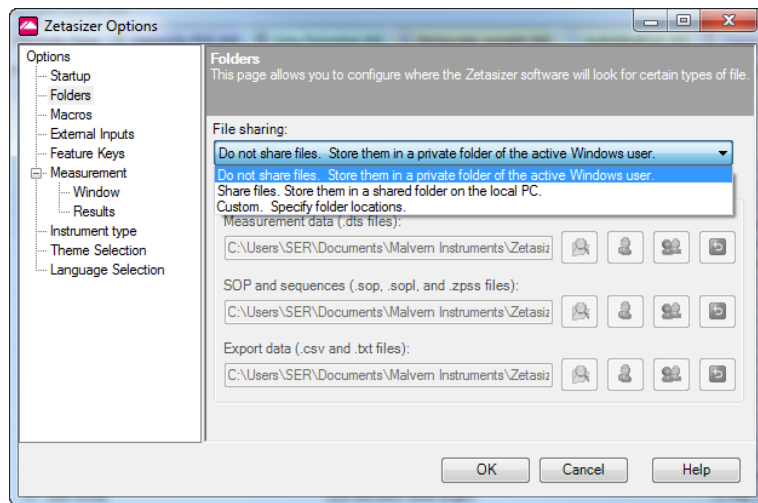- Custom. Specify folder locations.

Figure 7: 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 7

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**.
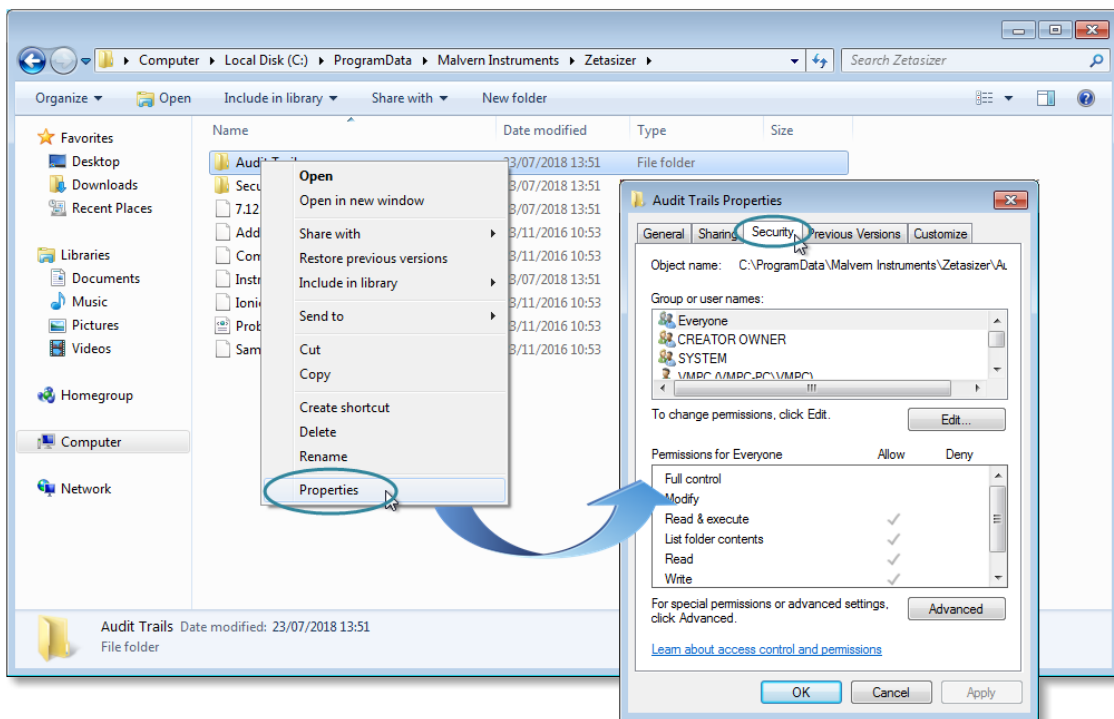

2. Within **Audit Trails Properties**, left-click on the **Security** tab and left-click the **Advanced** button to open the **Advanced Security Settings.**

3. Within the **Advanced Security Settings** left-click the **Change Permissions** button. This will open an identical Window with the options to change the inheritable permissions.
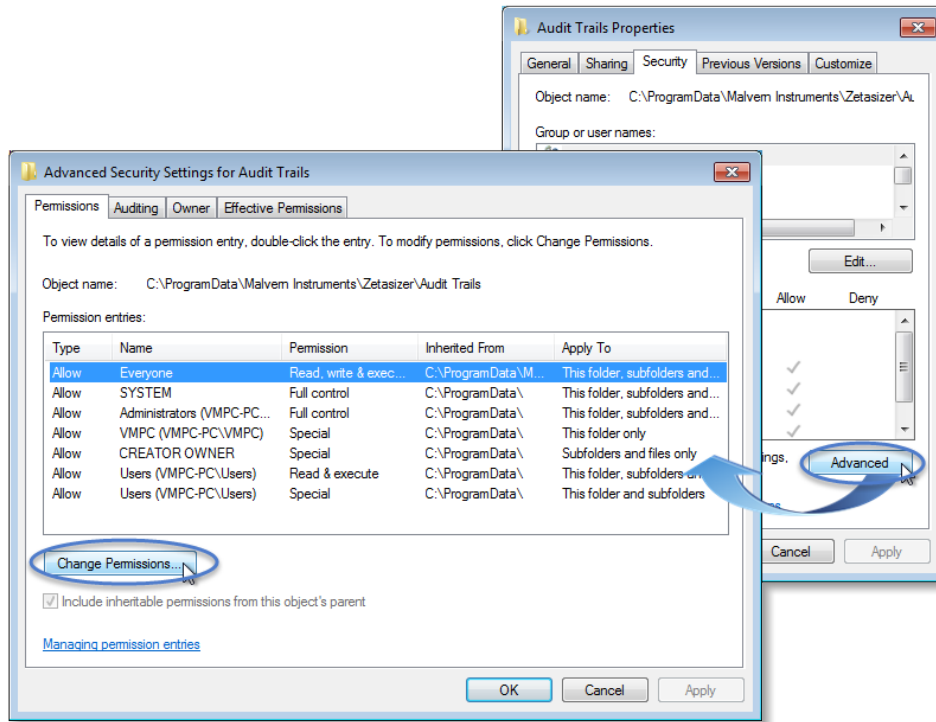
4. In the second **Advanced Security Settings** window, left-click to <u>deselect</u> the **Include inheritable permissions from this object's parent** check-box and when prompted left-click the **Add** button to convert and add the inherited permissions from parent.
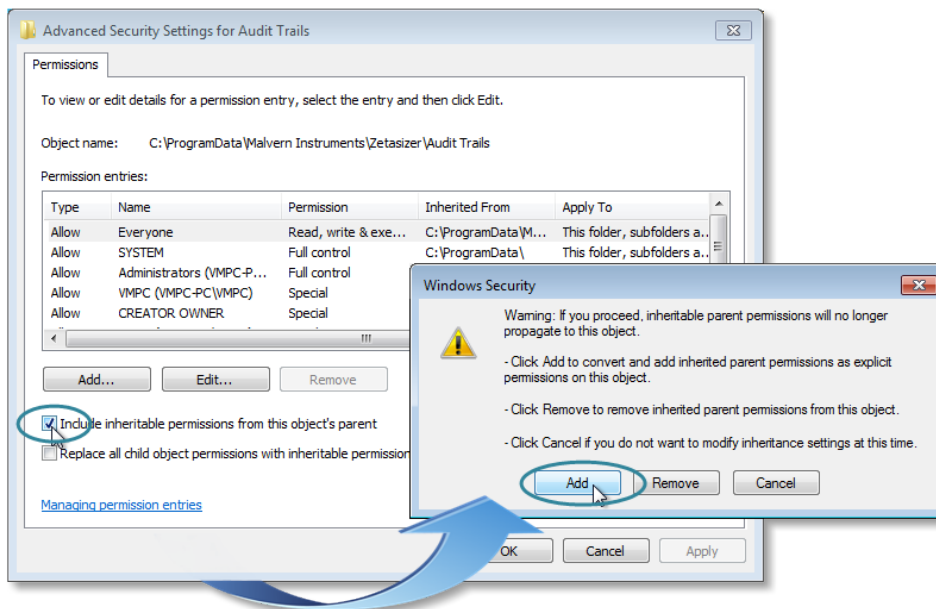
5. Left-click to select the **Zetasizer Users** group and left-click the **Edit** button to open the **Permissions Entry** window.
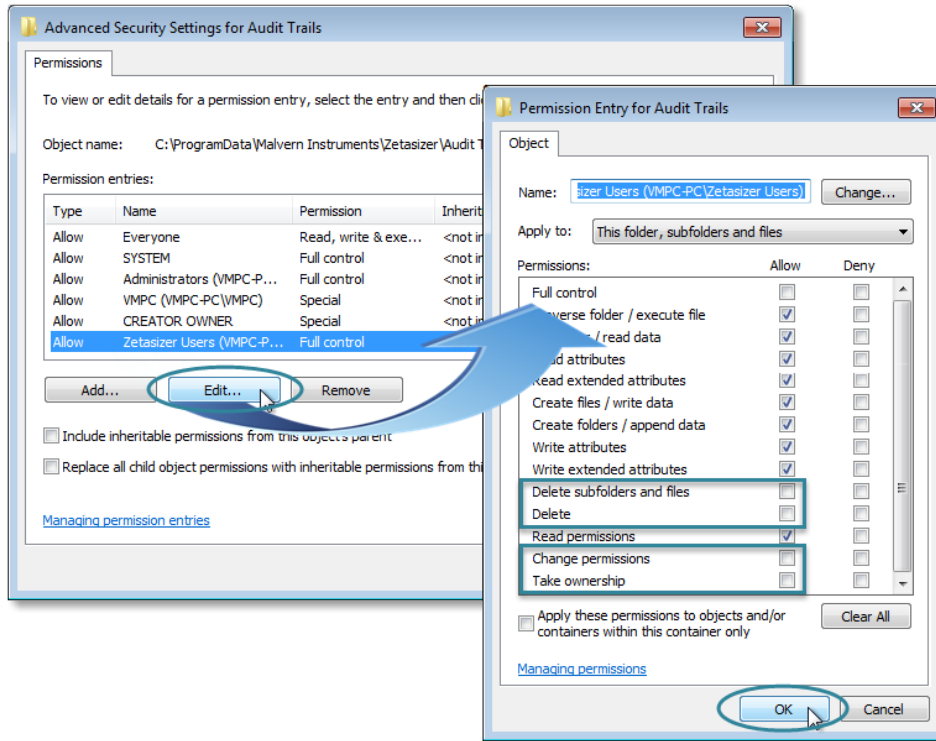
6. Left-click to deselect the **Delete subfolders and files**, **Delete**, **Change permissions** and **Take ownership** check-boxes and finish by left-clicking the **OK** button. Warning, <u>do not</u> select the check-box **Apply these permissions to objects and/or containers within this container only.**

7. Returning to the previous window, left-click the **Replace all child object permissions with inheritable permissions from this object** check-box and when prompted to confirm left-click the **OK** button.
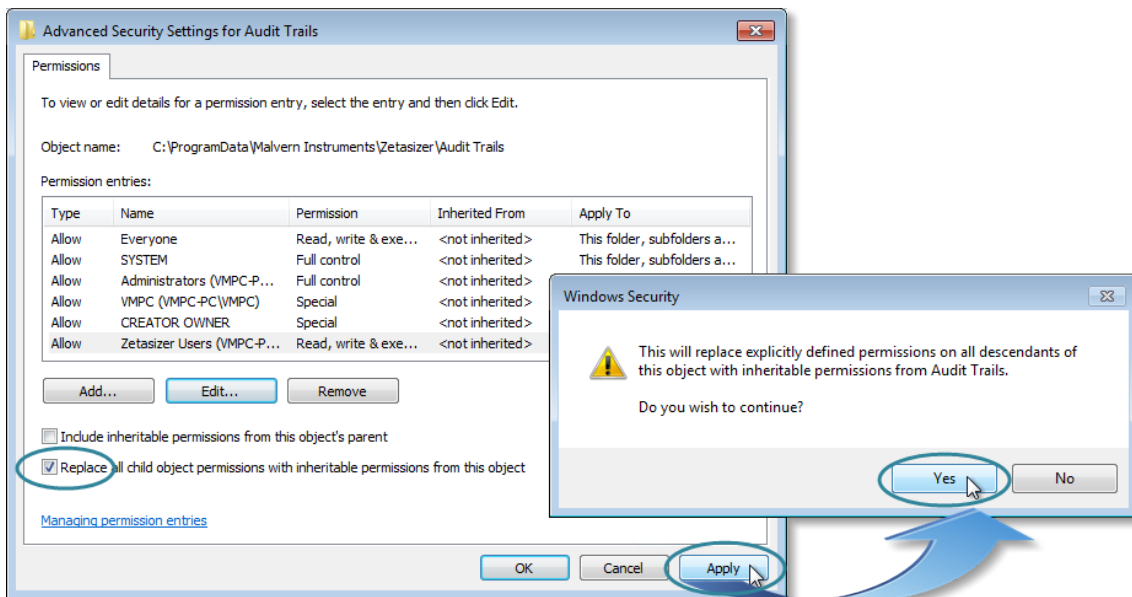
8. Left-click **OK** on the remaining windows to close them.

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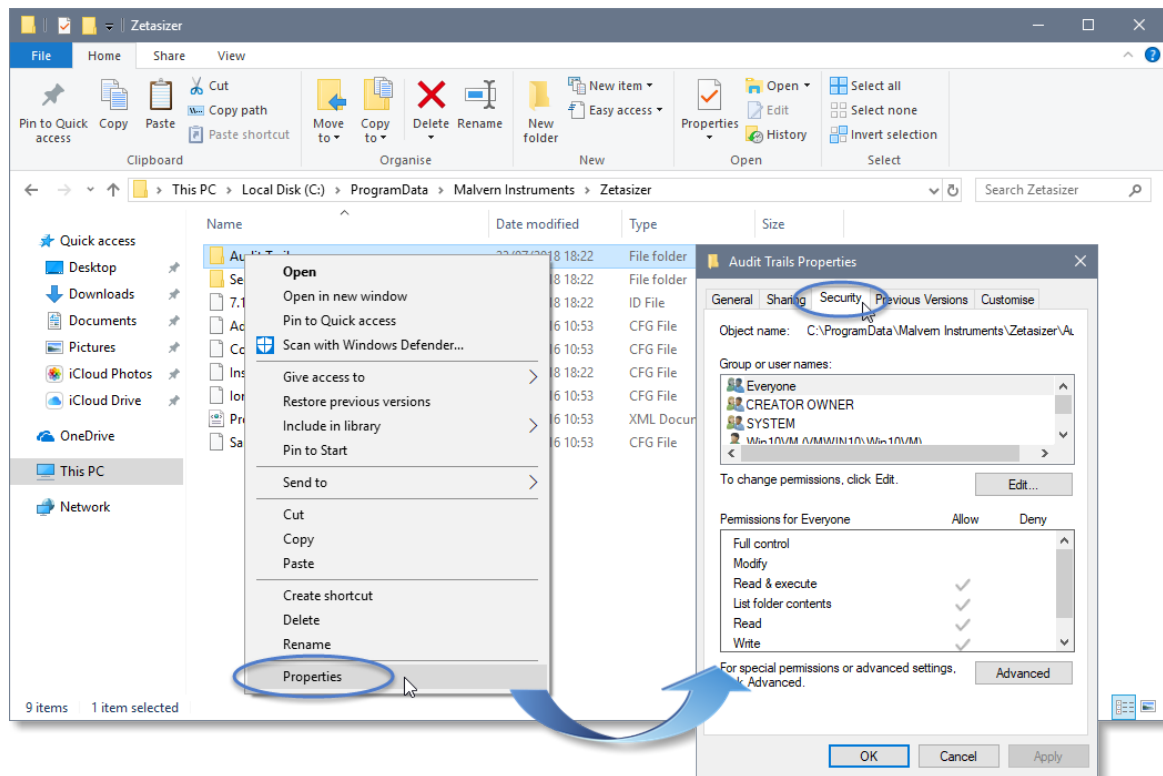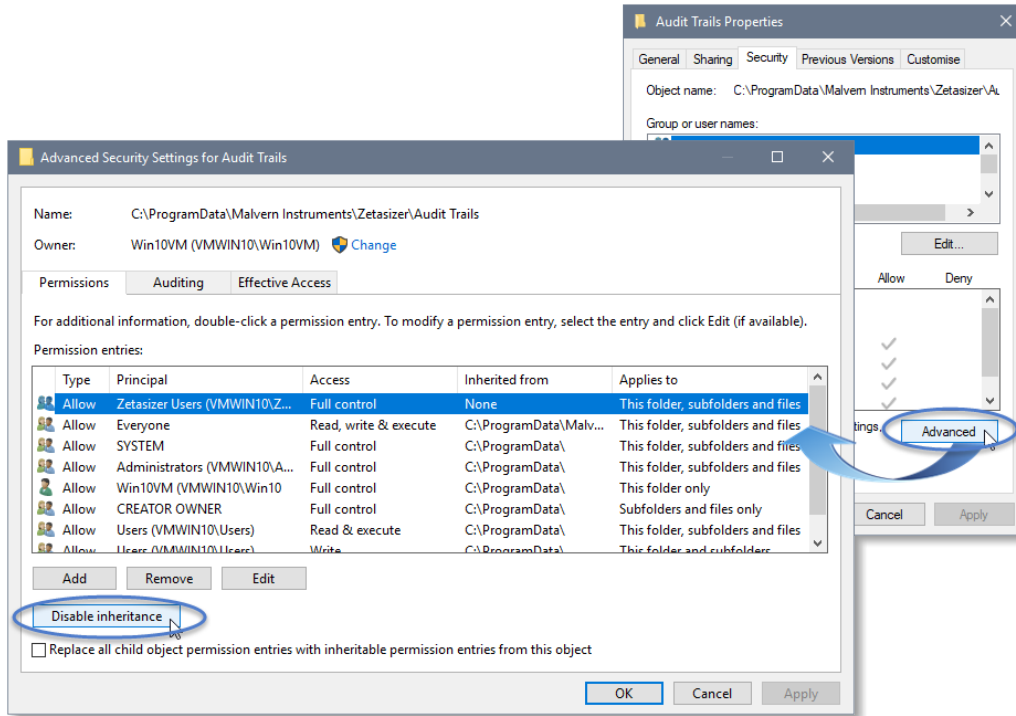
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button.

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.
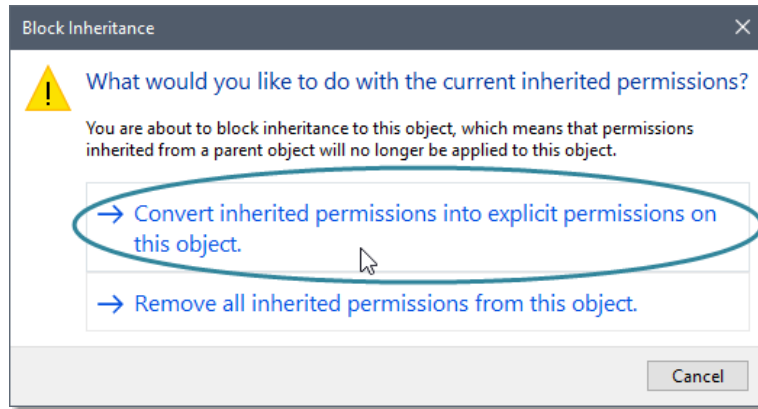

5. After returning to the **Advanced Security Settings** window, left-click to select the **Zetasizer Users** group and then left-click the **Edit** button.

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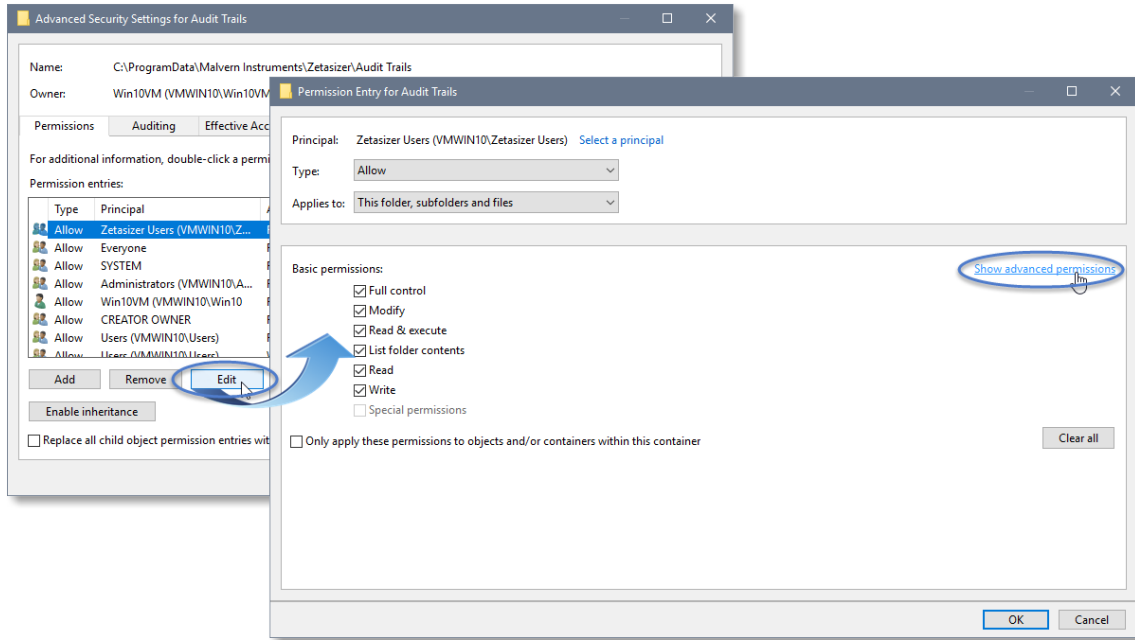
7. Left-click to de-select the check-boxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.
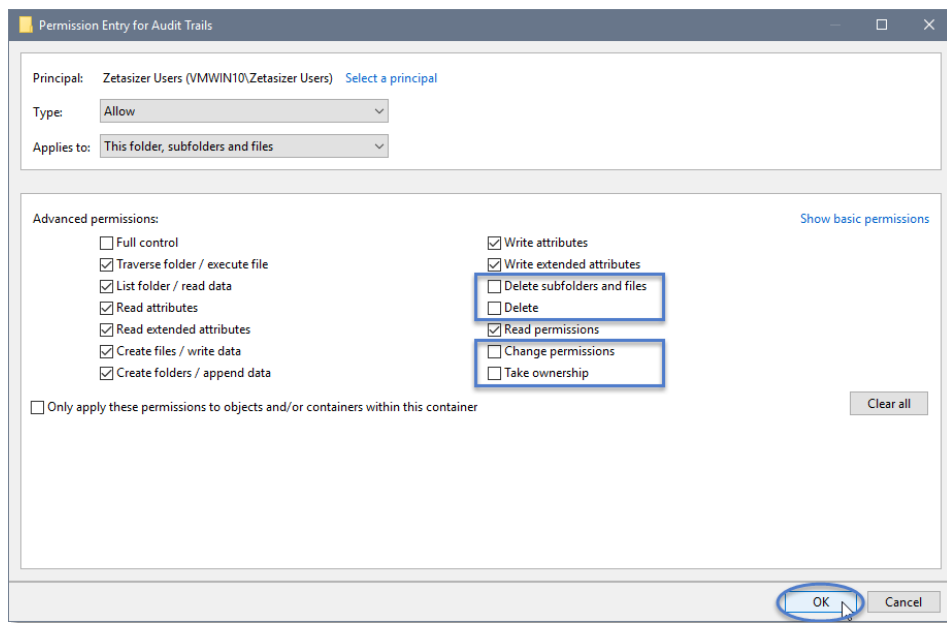
8. Left-click **Replace all child permission entries with inheritable permission entries from the object** check-box and left-click the **Apply** button.

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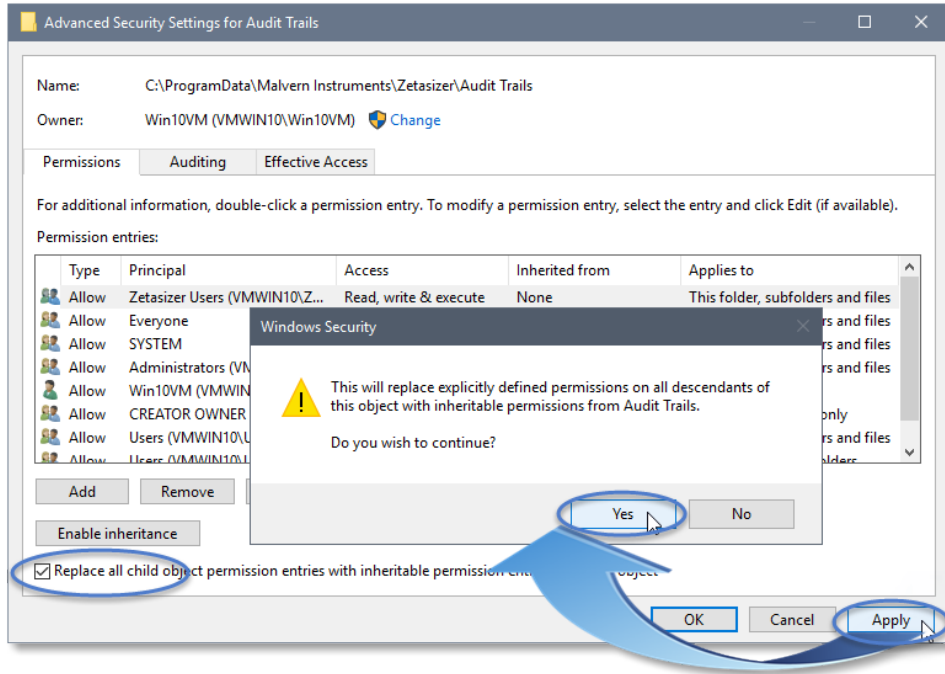
10. Left-click the **OK** button when prompted to close all the previous windows to exit the set-up.

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 *7.13.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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