SPRAYTEC SOFTWARE v4.10

Software Update Notification

Introduction

This document details the release of Spraytec software version 4.10 (Software suite PSS0024-13) for the Spraytec laser diffraction system.

It covers software issues fixed and new features introduced. This information is required to perform a risk analysis to determine if the software should be installed. In this risk analysis the benefits of the new features provided and resolved software issues must be weighed against the risk of new issues that may be introduced to vital areas of the software or possible changes to the results of future analysis. Installation instructions are provided.

> **Note:**
> Please check for any updates to this Software Update Notification at
> *www.malvernpanalytical.com/en/support/product-support/spraytec*

Installation

It is assumed that you have authority to install or update software within your facility. It is also assumed that you have Administrator rights for the system upon which the software is installed, as this is a requirement of the installation process. If you do not have this authority, please consult with your I.T. support department before proceeding.

Recommended system requirements

The requirements for running this software are highlighted in *Table 1* below. The software has been partially tested on Windows 10 (Version 22H2) and Windows 11 (Version 21H2) primarily with English locale settings. Partial testing was considered appropriate due to the minimal changes made in this release.

Table 1: Recommended system requirements for the Spraytec v4.10 software.

Feature	Specification
Processor Type	Intel (R) Core (TM) i7-4770S CPU @ 3.10GHz 3.10 GHz 2013
Memory	8 GB RAM
Hard Disk Storage	250 GB free hard disk space
Display Resolution	1920 x 1080 full HD screen resolution
Connectivity	1 free USB port
Operating System	Windows 10 Version 22H2 (Build 19045) or later Windows 11 Version 21H2 (Build 22000) or later

Supported languages

- English

Installation Instructions

The Spraytec software is available via the web download. Disconnect the Instrument from the PC. If the instrument was connected during installation, disconnect and re-connect to force windows to reload the correct driver or restart the PC.

Run the installer Spraytec v4.10 Installer.exe. Admin rights are required.

The installer will prompt for confirmation to install the USB drivers.

Press Install to continue with installation of the USB drivers.

Windows 7 & 8 are no longer supported by Microsoft. It is not recommended to use Windows 7 or 8 with the Spraytec software.

USB driver installation

During the installation of the USB drivers you may be prompted several times with the following message:
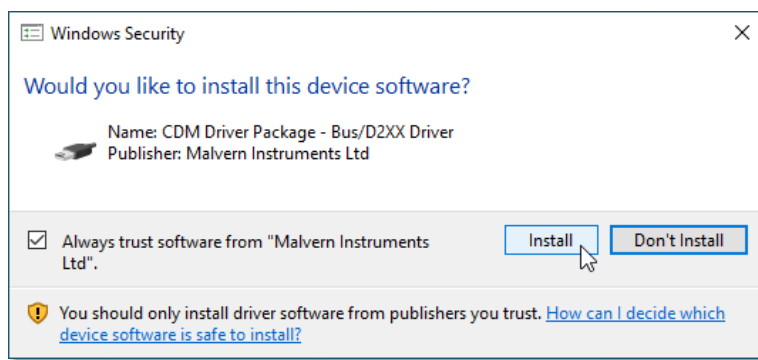
Press **Install** to continue with installation of the USB drivers.

- Refer to <u>all</u> the Notes below:

IMPORTANT!
Backward compatibility

This is the latest release of the software which supports the new Spraytec system (Serial number series *STPxxxx*). This software is only compatible with the new Spraytec system. It cannot be used with the Spraytec '97 system (Serial number series *RTSxxxx*).

IMPORTANT!
Upgrading from Version 2 software: 21 CFR Part 11 settings lost by uninstalling Version 2 software

When the Spraytec v2.00 software is uninstalled on a system where 21 CFR Part 11 functionality is enabled, the ER/ES settings are also uninstalled from the system registry. The 21 CFR Part 11 functions will remain enabled when a new software version is then installed and the security settings will be retained. However, the ER/ES settings will revert to the application defaults.

Users are therefore advised to copy the ER/ES settings they are using prior to uninstalling Spraytec v2.0 so these can be re-entered within the new software version.

> **Note:**
> **Enabling remote control functionality on Windows 7 and above**
>
> Microsoft has tightened the operating system security within Windows 7 and above. As a result, the Windows firewall settings need to be reconfigured in order to use the Spraytec remote control functionality. A Technical Note documenting the firewall configuration changes required (Windows 7 Remote Functionality Configuration) is included on the Spraytec software CD-ROM.

> **Note:**
> **Windows security settings**
>
> With a 21 CFR Part 11 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 I.T. professional can effortlessly change user access to specific files and/or folders by simply removing certain file/folder permissions.
>
> Please refer to the Windows Security Settings section later in this document and for further information please refer to the technical note Spraytec 2000 Securing files from deletion (*CCM0035*) which can be found with the installation documents, and check for any updates at
> *https://www.malvernpanalytical.com/en/support/product-support/spraytec*

Uninstall procedure

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

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 has 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.

In its standard mode of operation, the Spraytec software provides users with a series of standard interfaces and functions that enable the software to be configured to meet specific user business requirements. These interfaces include the ability to define Standard Operating Procedures (SOPs) for sample measurement. The software should therefore be considered to be a Category 4 software package. Users should therefore consider the settings used for measurements with reference to the product they are testing and validate these in line with compendial and regulatory guidance for methods validation.

USP <1058>

USP <1058> provides pharmaceutical users with guidance as to how the qualification of analytical systems should be carried out. As part of this guidance, the USP define a series of instrument categories. These instrument categories are

different from those described in GAMP 5, although the principles applied as part of the classification of a system are similar.

The Spraytec is a computerized analytical system where the software provides users with the functions required to meet specific analytical application requirements. As such, it is a Group C instrument. Users are therefore recommended to define their requirements for the operation of the system and then compare these requirements to the claimed capabilities of the software and hardware. This should include an assessment of whether the new features and bug fixes included in a specific version of the Spraytec software are necessary to meet business requirements.

Updates
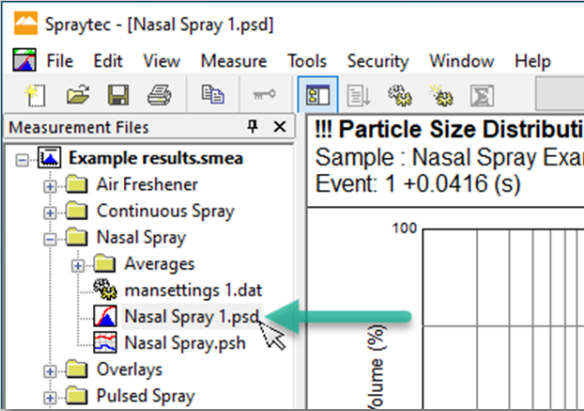
Spraytec software v4.10 has been introduced primarily to support Windows 11.

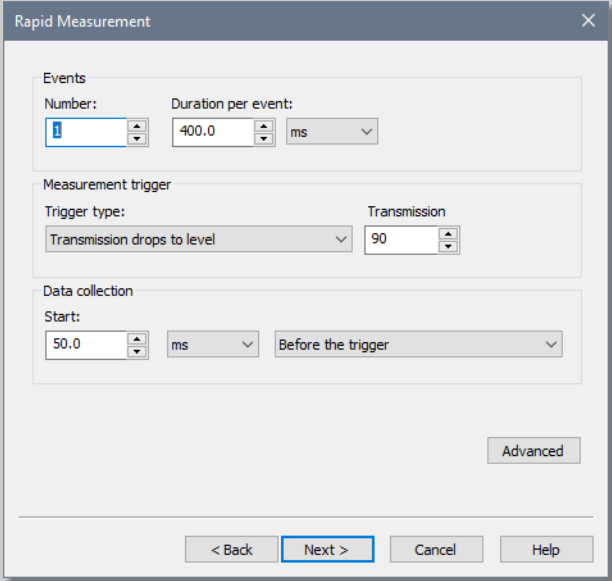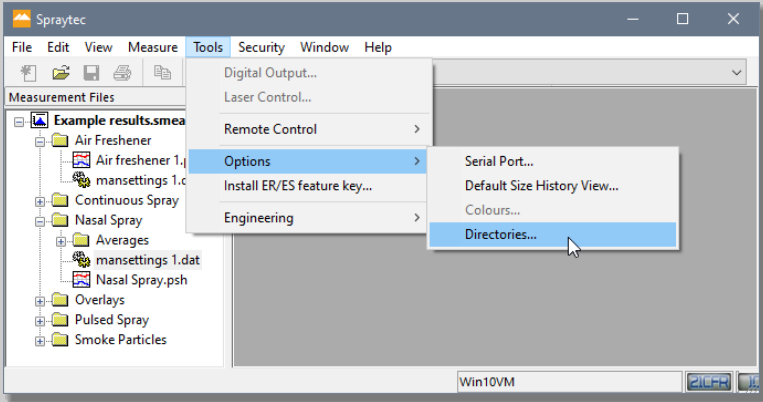| Reference	Description
306680	Remove CoC and SUN from the installer
322928	[Win 10 & 11] Spraytec USB driver supports HVCI core isolation feature
123040	[Known Issue in v4.00] Yellow exclamation icon shown at Device Manager
336411	RFA-2492 Actuator information missing on the report for v4.00

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 where applicable.
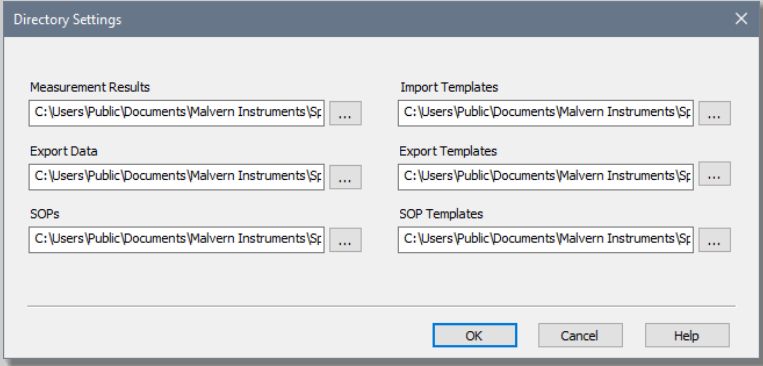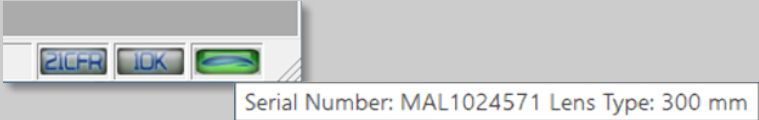
Reference	Description	Workaround (where available)
181886	The audit trail search function can return events outside of the range applied in the date filter. The audit trail remains intact and navigating to a specific audit trail will display the information correctly. The current audit trail will display all information correctly.	This behavior can be avoided by limiting the number of individual audit trail files created in a single folder to less than 100, for example by scheduling new audit trails to be generated weekly or monthly. If you have observed this behavior in your audit trail, please contact your Malvern Panalytical representative for assistance.
125454	The permission "**Delete PSD records from Size History**" does not enable or disable deletion of PSD record files.	To prevent PSD record deletion, ensure the permission "**Delete files in**

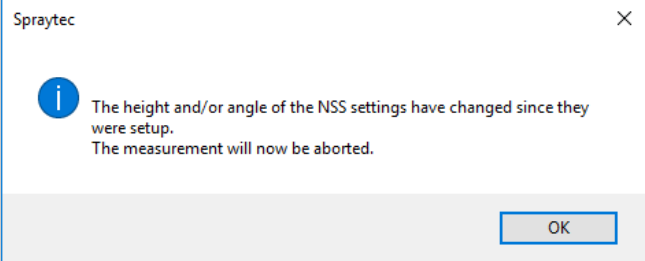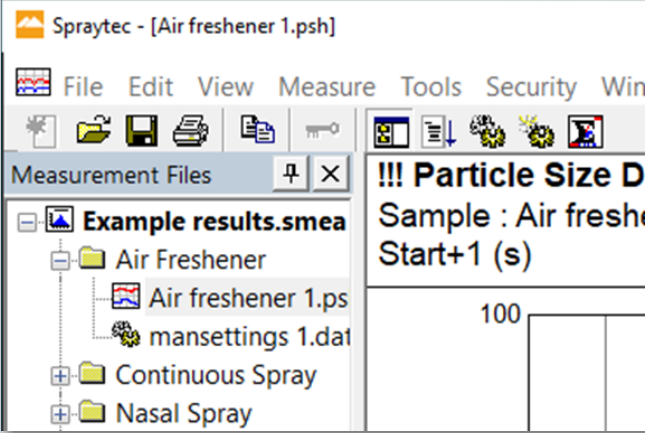| Reference	Description	Workaround (where available)
		the measurement file window" is not checked and if ER/ES features are enabled check the setting "Prohibit record Deletion"
123131	**Restrictions on naming files** The Spraytec software uses a compound file format to store data with the *.smea measurement file. As a result, there are restrictions on the length of sample and file names, and Illegal characters that are not to be used. • File path length restrictions The file path for the Spraytec measurement and data files (*.smea, *.psh) must not exceed 255 characters, as this is the maximum acceptable within the Microsoft Windows operating system. This is inclusive of the internal Spraytec filename and the whole *.smea filename (including path). For example, consider the examples measurement file. This is stored, by default, in the following location: *C:\Users\Public\Documents\Malvern Instruments\Spraytec\Measurement Data\Example results.smea* Within this file, there is an Experiment folder called 'Nasal Spray'. There is a data file stored in this folder called '*Nasal Spray.psh*': The combined file path for this data file is as follows: *C:\Users\Public\Documents\Malvern Instruments\Spraytec\Measurement Data\Example results.smea\Nasal Spray\Nasal Spray.psh* This is 120 characters long, so is acceptable. • Measurement file name restrictions The name of a measurement file (*.smea) is limited to a maximum of 63 characters. This includes the file extension, leaving 59 characters for the user-defined name.	Ensure file path, measurement and sample names used are within the guidelines given in the Issue description.

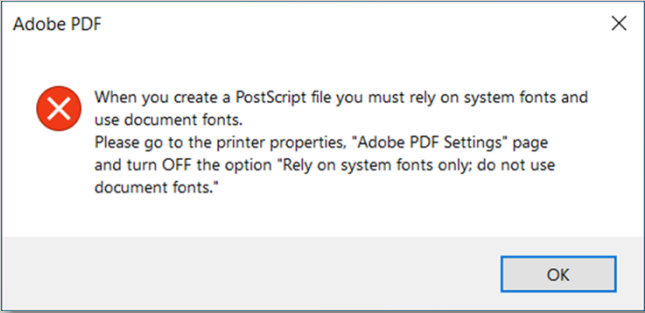| Reference	Description	Workaround (where available)
	These restrictions must be considered alongside the file path restriction mentioned above. So, if the file name is the maximum of 63 characters then the maximum path name for any file must not exceed 192 characters • Sample name size restrictions Within the measurement file (*.smea) there is a 31 character restriction on the name of any data file (*.psh, *.psd, *.pso). This restriction includes the file extension, leaving 27 characters for the name. In addition, the file numbering system used for experiments and averages uses 2 characters. This leaves 25 characters for the user-defined name. Within the Spraytec software, the sample name is used to define the file name for data file. As a result, sample names are restricted to 25 characters. • Sample name character restrictions As mentioned above, the sample name is used to define the name of any data file (*.psh, *.psd, *.pso) stored within the Spraytec measurement file (*.smea). As a result, illegal characters (for example ~|\:*?"<>/) must not be used in sample names.	
124664	**USB detection** Detection of the Spraytec USB connection during software start-up should occur automatically. However, on older computer systems the instrument is not always detected automatically and the instrument icon in the right-hand corner of the status bar will remain greyed-out in the software.	Close the application, restart the computer and restart the software. Once this is done connection to the instrument should be possible, as shown by a green instrument icon:
123132	**Averaging Time Window Specification** When a user selects a time window for averaging, the software must calculate which measurement records from the size history are included within the specified range. This is done by examining the stop time for each record. All records which have a stop time within the time limits specified for averaging are included in the average calculation. It has been found that, when the start time for averaging matches precisely with the stop time for one of the records in the size history, the software sometimes includes one too many records within the average by including the record collected just before the specified time range. A similar effect can also be observed when the end time for averaging matches the start time for one of the records. In each case the calculated average size distribution is correct for the range of records selected by the software.	

Reference	Description	Workaround (where available)
123133	**Confusing time period may be reported for phase averages** The phase average option selects records for averaging based on the stop time of each measurement. However, when an average is displayed, the PSD report screens quote the averaging range based on the start time of the records included in the average. This can cause confusion with users as the reported time period for averaging can be outside of the range specified. For example, consider a measurement which has been acquired using an acquisition rate of 1 kHz with a stable phase average time window selected from 25 ms to 75 ms. When the phase average is reported, the software will report that it is obtained for a time period from 24 ms and 74 ms.	
112897	Closing a measurement file without making any changes updates the last modified date	None: the software calculates the PSD/PSH graph from the stored data and is therefore registered as a modification in Windows
123134	**Measurement triggering at low transmission levels** It has been found that, for some Spraytec systems, it is possible to observe false trigger events for Rapid Mode measurements when using a transmission trigger of 99%. To avoid this, users are advised to use a transmission trigger of 98% and then use the Data Collection options to store data from before the trigger value was reached. An example set of Spraytec SOPs (*SSOP) settings are shown below – here data is collected for 50 ms prior to a transmission level of 98% being detected. This ensures that the measurement triggers robustly whilst allowing data from the low-concentration part of the spray plume to be captured.	Use guidance in Issue description if false trigger events occur when using a transmission trigger of 99%.

Reference	Description	Workaround (where available)
123135	**Updating the user directory settings** In the main menu, the software provides an option to set the data directories which are used to store the files that are accessible by the user: This option displays a window that allows the default directory locations to be reconfigured:	Ensure software is restarted to apply any changes made to user directory settings.

Reference	Description	Workaround (where available)
	 Clicking OK will store the directory settings. You will need to restart the software for the settings to be applied.	
123043	**Instrument lens reporting** If the lens for the instrument is changed from the 300 mm to the 750 mm lens or vice versa then the software may need to be restarted for the change to be registered within the status bar. To confirm that the lens change has been detected the mouse should be hovered over the instrument icon so that the lens type is displayed: Note that lens detection occurs correctly when running measurements, even when the software is not restarted following a lens change. As such, there is no risk that the incorrect lens within the analysis when running SOP-based measurements.	Restarting the software may be required to update lens type in the status bar. Note this is a reporting issue only and SOP-based measurements are not affected.
123136	**Incorrect measurement times reported for manually-triggered rapid mode measurements** It has been found that the relative start times for each of the measurements making up a manually-triggered rapid mode measurement are offset by one measurement duration. As an example, consider a manually-triggered rapid mode measurement with an acquisition rate of 2.5 kHz and a duration of 400 ms. The above error will cause the first measurement record to have a relative stop time of 0.8 ms instead of 0.4 ms. The second measurement will have a relative stop time of 1.2 ms instead of 0.8 ms; and so on until the last measurement, which will have a relative stop time of 400.4 ms instead of 400.0 ms. It should be noted that there is no loss of data, as the correct number of records is always produced. For instance, a measurement with an	

Reference	Description	Workaround (where available)
	acquisition rate of 2.5 kHz and a duration of 400 ms will generate 1000 measurement records regardless of which triggering mode is used.	
124665	**File size limitations** Due to the nature of the measurements which are made using the Spraytec system, the size of the measurement files (*.smea) may become large. Although this will not affect instrument operation, it may impact data transfer and archiving. Users should therefore monitor file sizes and change the .smea file used for data storage according to the experimental program they are involved in. For support purposes, the Malvern Panalytical Support team may request that you send data for analysis. To enable this, it is possible to export individual Particle Size History files (*.psh) from within a *.smea file. To do this, open the .psh file and then use the **File-Save As**... menu option to save the file.	Monitor file sizes and change the SMEA file used for data storage if necessary.
124667	**Sequential rapid mode measurements of long duration (e.g. over 10 seconds) may result in computer running out of memory** Rapid mode measurements generate a large volume of data during a measurement. This can cause a significant increase in the amount of memory used by the application when carrying out rapid mode measurements over long time scales (e.g. greater than 10 seconds). As a result, we advise that no more than 15 measurements of 30 seconds each are run sequentially before restarting the computer. Obviously, this number will vary depending on the length of the measurement so that if the measurement is only 10 seconds long then the number of measurements before the computer needs to be started will treble to 45. The above advice will help avoid the situation where the computer runs out of memory during a series of long rapid mode measurements. Please note that these are only rough guidelines and it will vary depending on the specification of the computer being used (i.e. processor, RAM etc.).	Follow advice in Issue description on limiting the number of rapid mode measurements taken sequentially before restarting the computer.
123137	**Intermittent problems with timed measurements** It has been noticed that there are problems with timed measurements on Windows 7 and above. When releasing Windows 7 Microsoft updated some of the Operating System functions relating to timing. As a result, the reported measurement time for timed measurements may sometimes be one second out (e.g. a one-minute measurement maybe 61 seconds instead). This may be observed in up to half of the measurements made in timed mode. Note that the Spraytec data integrity and reported size distributions are not affected by this error.	

Reference	Description	Workaround (where available)
123138	**Spraytec Nasal Spray Support (NSS) accessory error notification appears twice** During repeat measurements with the Spraytec Nasal Spray Support (NSS) accessory the values for height and the angle of the NSS are verified against the values stored in the measurement SOP at the very start of the measurement (before the light background). If the values differ then the following window is correctly displayed: If you press the **OK** button, then the same window will appear a second time. It is necessary to press **OK** on this window too continue using the software.	Press **OK** on both (duplicate) window that appear to continue using the software.
123044	**Issue with Spraytec application if PDF settings not correctly configured in Adobe Acrobat** The Spraytec application may go into a Not Responding state when printing to PDF if the settings within Adobe Acrobat are not correctly configured: The following Adobe PDF message window appears when the program enters this state:	If printing to PDF is required ensure that Adobe Acrobat settings are configured as described in the Issue description.

Reference	Description	Workaround (where available)
	However, this message is hidden behind the Spraytec software screen, making it appear that the Spraytec software has crashed. To recover this situation, use the Alt-Tab function to bring the Adobe PDF message to the foreground and click **OK**. This will cause the Spraytec software to recover from the error. However, you will then need to shut down the Spraytec software and restart the computer to close any PDF creation processes. Then, go to the settings in Adobe Acrobat Writer and turn off the option to "Rely on system fonts only; do not use document fonts", as suggested within the message window.	

Windows Security Settings

With a 21 CFR Part 11 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 I.T. professional can effortlessly change user access to specific files and/or folders by simply removing certain file/folder permissions.

> **Note**:
> For further information please refer to the technical note Spraytec 2000 Securing files from deletion (*CCM0035*) which can be found with the installation documents, and check for any updates at *https://www.malvernpanalytical.com/en/support/product-support/spraytec*

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

In the following example, we're going to change the folder permissions on the Audit Trail folder on a none-networked computer. We strongly advise that customers seek the help of I.T. professionals when implementing security changes on the computer used for operating the Spraytec.

> **Note**:
> For the following demonstration, we have previously created a user group, through the Computer Management console, called 'Spraytec Operators'. This user group will later be added into the folder permissions of the Audit Trails folder to prevent users from deleting records. This process can be applied to any output folder requiring limited user access. In the following illustrations, we have not removed default groups such as 'Everyone' or 'Users' - these can be deleted or used as an alternative to dedicated user group/s. However, when using these groups, we strongly advise that explicit 'Denies' are not used, unless you fully understand the Microsoft file/folder security permissions.

Table 1 below identifies the important folders that should be secured for most typical installations, where protection is a 'Must' - Other less frequently utilized folders are marked as 'If Used'.

*Table 1. Folders where security should be applied.*

Folder	Protection Required
C:\ProgramData\Malvern Instruments\Spraytec\Security	Must
C:\Users\Public\Documents\Malvern Instruments\Spraytec\Acrobat Results	Must
C:\Users\Public\Documents\Malvern Instruments\Spraytec\Audit Trails	Must
C:\Users\Public\Documents\Malvern Instruments\Spraytec\Measurement Data	Must
C:\Users\Public\Documents\Malvern Instruments\Spraytec\SOP	Must
C:\Users\Public\Documents\Malvern Instruments\Spraytec\Backup	If used
C:\Users\Public\Documents\Malvern Instruments\Spraytec\Export Data	If used
C:\Users\Public\Documents\Malvern Instruments\Spraytec\Export Templates	If Used
C:\Users\Public\Documents\Malvern Instruments\Spraytec\Import Templates	If 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 Spraytec 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**.
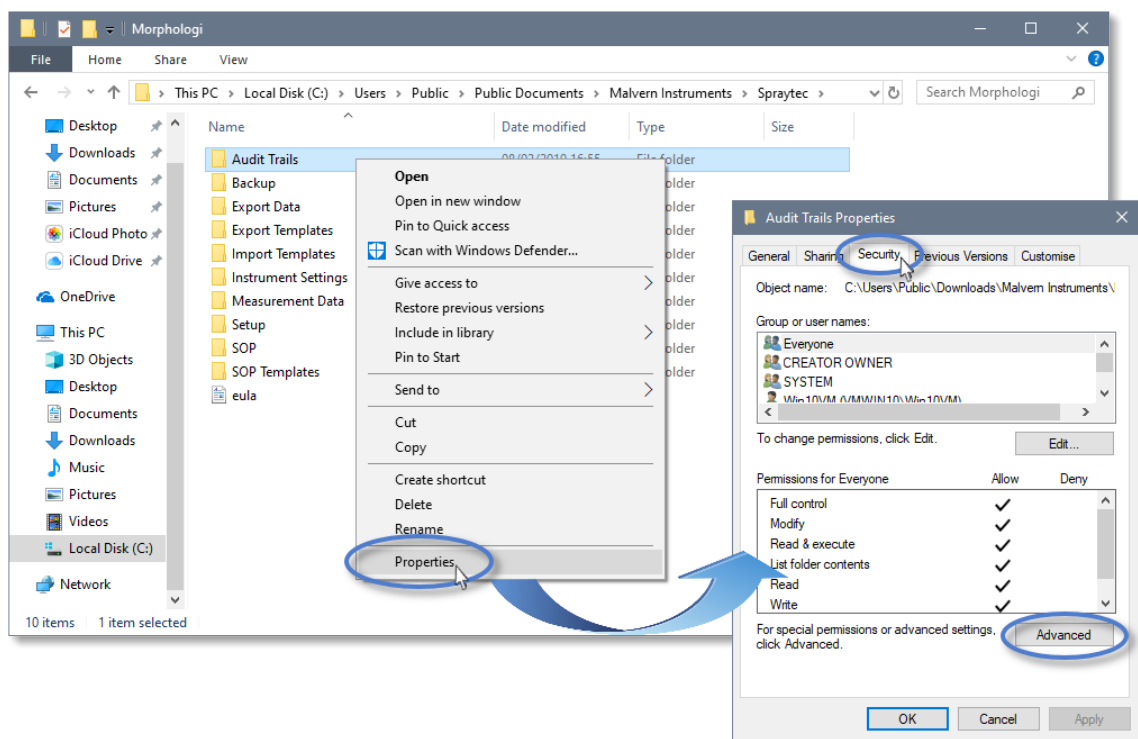
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button (if this button is not available, you will need to left-click the **Change permissions** button first).
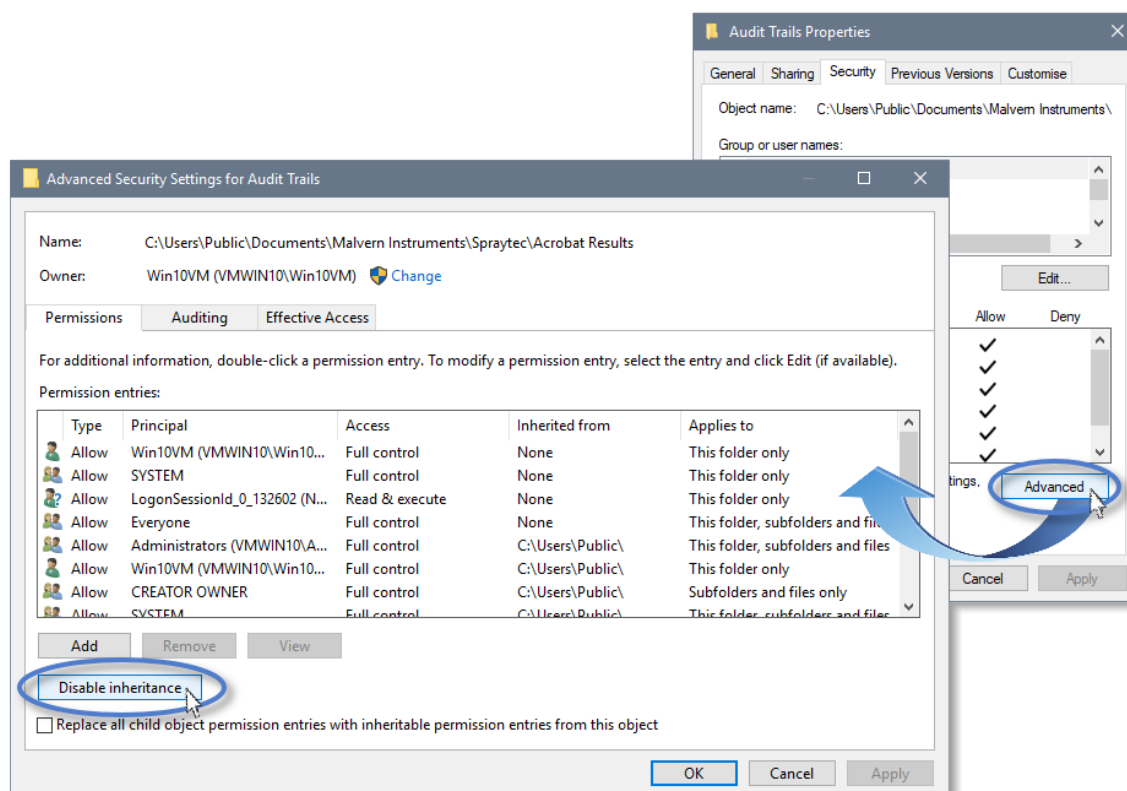

4. Within **Block Inheritance**, left-click on **Convert inherited permissions into explicit permissions on this object** – this removes the permission inheritance from the parent folder, whilst keeping the any current users and groups settings.
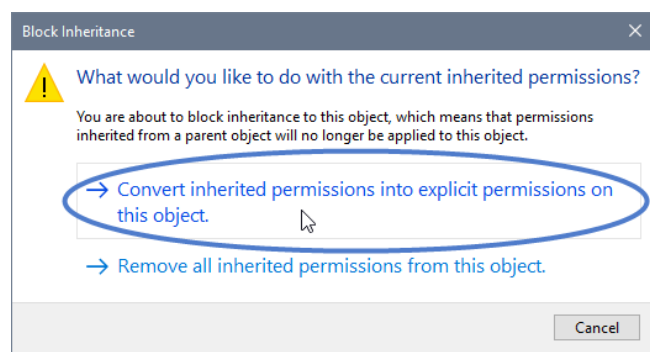

5. After returning to the **Advanced Security Settings** window, left-click to select the **Spraytec Operators** group and then left-click the **Edit** button.

6. In the **Permissions Entry** window, left-click the **Show advanced permissions** to reveal the full permissions list.
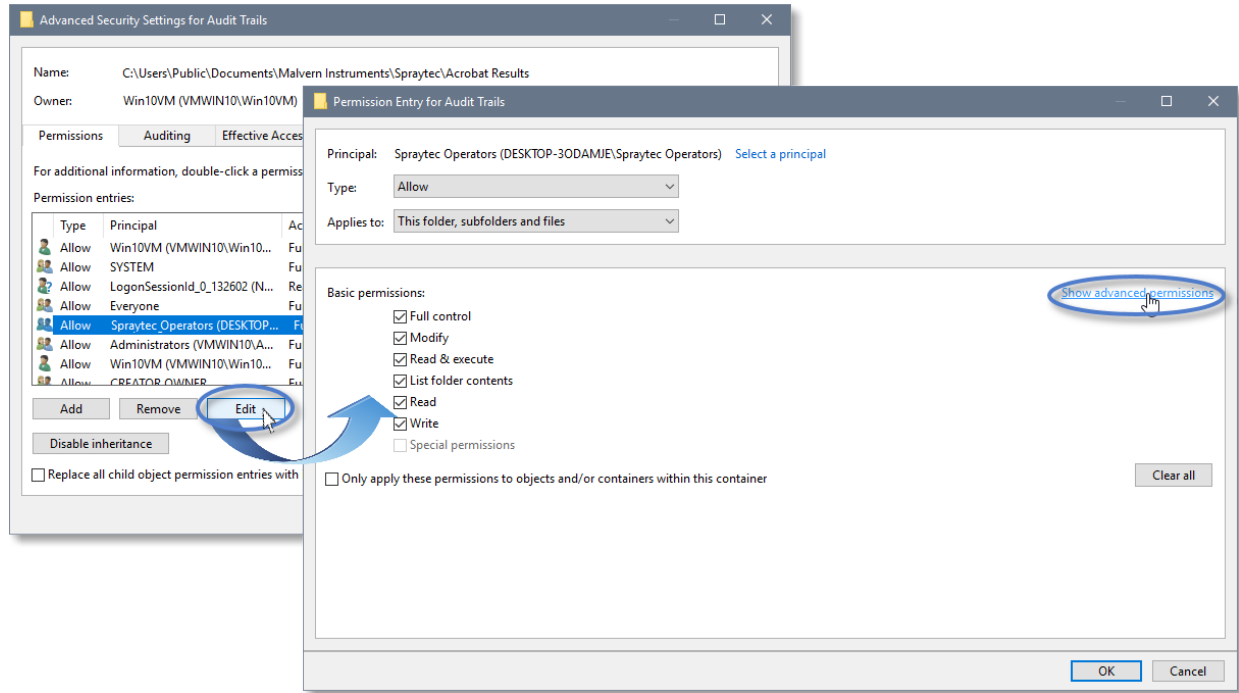
7. Left-click to deselect the checkboxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.
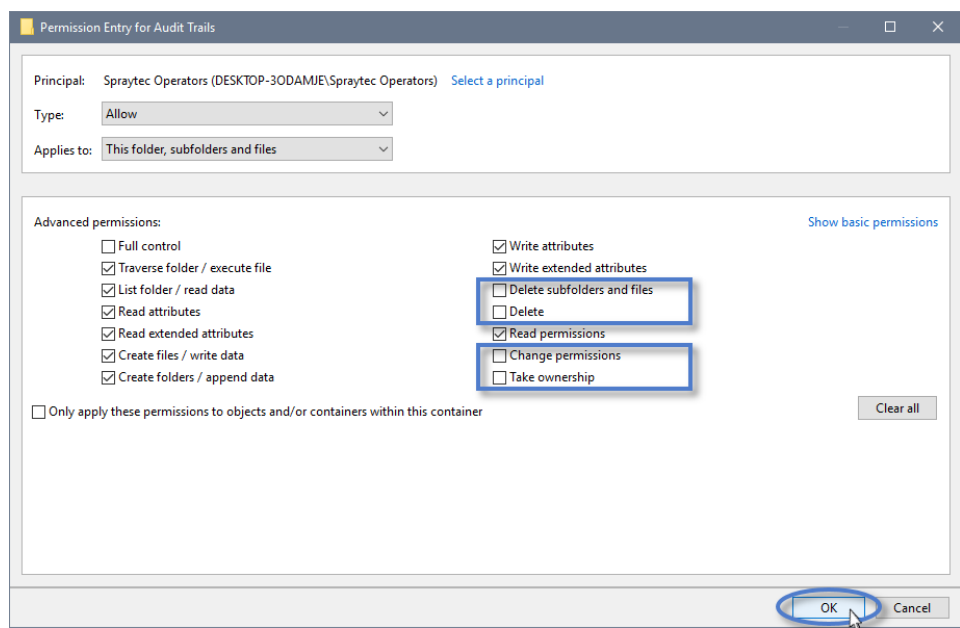
File Types and Locations

File Type	Extension	Default Path	Advised security setting for 21 CFR Part 11 Mode
Audit trails	.adt	*C:\Users\Public\Documents\Malvern Instruments\Spraytec\Audit Trails*	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Data export Templates	.exp	*C:\Users\Public\Documents\Malvern Instruments\Spraytec\Export Templates*	No control required as these settings are stored in SOPs.
Export data	.txt .csv	*C:\Users\Public\Documents\Malvern Instruments\Spraytec\Export Data*	If data export is a critical part of the SOP used for your samples then you should prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Measurement data	.smea	*C:\Users/\Public\Documents\Malvern Instruments\Spraytec\Measurement Data*	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
SOP templates	.ssop	*C:\Users\Public\Documents\Malvern Instruments\Spraytec\SOP Templates*	No control required as these settings are stored in SOPs.
SOP	.ssop	*C:\Users\Public\Documents\Malvern Instruments\Spraytec\SOP*	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Various system configuration files	Various	*C:\ProgramData\Malvern Instruments\Spraytec*	Full access must be maintained to this directory for the program to function correctly.

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