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SPRAYTEC SOFTWARE: v4.00 (PSS0024-12)
SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of Spraytec software version 4.00 (Software suite PSS0024-12) 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 Window 7 Enterprise Service Pack 1 (64-Bit) and fully tested under Windows 10 (64-bit) version 1909 which is the only recommended operating system.

Table 1: Recommended system requirements for the Spraytec v4.00 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
Additional Storage Media	CD-ROM drive
Display Resolution	1920 x 1080 full HD screen resolution
Connectivity	1 free USB port
Operating System	Windows 10™ operating system (Build 1909), 64bit with latest updates

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Supported languages

· English

Installation Instructions

The Spraytec software is provided on one auto-loading CD-ROM or is available via the web download. Inserting the CD-ROM into a system configured to Auto-run a CD will run the installation program automatically providing you have the correct access rights for the computer system. If your system does not support this feature run the **setup.exe** program from the root directory of your CD drive. If you are installing the software from a web download, then browse to the folder where the files have been extracted to and then launch the **setup.exe** program.

USB driver installation

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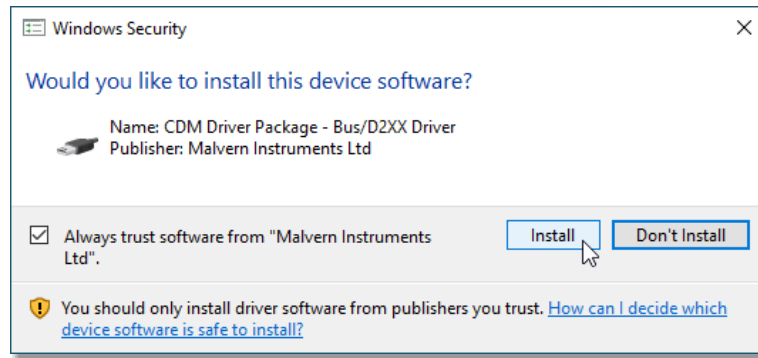
Press **Install** to continue with installation of the USB drivers.

- 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.

New Features

Spraytec software v4.00 has been introduced primarily to implement 21 CFR Part 11 and data integrity improvements.

Reference	Description	Comment
103147	Audit the addition of new users to the security system.	New function
103149	Audit deletion of existing users from the security system.	New function
103153	Audit disabling of user accounts within the security system.	New function
103169	Audit enabling of user accounts within the security system (after account disabling).	New function
103159	Audit the unlocking of user accounts within the security system.	New function
103170	Audit the editing of user property to the security system.	New function
103171	Audit the copying of users to the security system.	New function
103174	Audit the addition of existing users to groups within the security system.	New function
103174	Audit the removal of existing users from groups within the security system.	New function
103160	Audit the addition of new groups to the security system.	New function
103161	Audit the removal of existing groups from the security system.	New function
103167	Audit the editing of group properties in the security system.	New function
103168	Audit the copying of a group to the security system.	New function
103162	Audit the addition of new members to groups in the security system.	New function
103163	Audit removal of existing members from groups within the security system.	New function
103164	Audit changes to permissions associated with a group (addition or removal).	New function
103166	Auditing of security settings.	New function
103172	Auditing of the enabling of security settings.	New function
103173	Auditing of ERES option setting.	New function
103177	Audit the start of a measurement for Particle Size.	New function
103178	Audit the abort of a measurement for Particle Size.	New function
103154	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
103155	Search the audit trail archives within the default directory as set in "ER/ES settings" to find events relating to the creation of specific records or the actions of specific users.	New function
104388	Installer: Migrate installer tool from using InstallShield to Inno Setup.	Improved function

Reference	Description	Comment
113294	Given the user has been asked to unplug the connection to the Instrument prior to installing the software, the final act of the installer requests the user to plug it back in again for the installation of the drivers.	Improved function
114656	Updated software branding from Malvern Instruments to Malvern Panalytical.	Improved function
91581	Support multiple selections of Particle Size Distributions using shift click.	Improved function

Fixed Issues

The main issues addressed in this release of the software are listed in the following table.

Reference	Description	Comment
46909	Making 15 rapid mode measurements in succession causes the application to crash.	Fixed
52250	The Rapid Measurement SOP page contains 'duration' and 'delay' edit boxes that accept any arbitrary value.	Fixed: The edit boxes are limited to multiples of the data acquisition period.
66230	On larger disks, greater than 2 GB, a 10 MB disk full warning was displayed even when there was more than 10 MB of free space left which meant that the PSH file could be left empty.	Fixed: The 10 MB disk full warning message is only displayed when there is 10 MB or less of free disk space left.
103190	Nasal Spray template SOP with the velocity actuator selected does not run successfully.	Fixed
103218	Light background does not display transmission channel in all cases (raw light scattering, corrected light scattering, light background.	Fixed
103221	In example results, time scale disappears when duration is less than one second.	Fixed
103222	When an average is added to a new overlay and the measurement file is closed a prompt to save appears, opting to save causes an error to appear.	Fixed: The new overlay is saved, and no error message appears.
103224	Potential unknown user access after logged on user timeout.	Fixed: after time out no further user access is possible until a user logs in again
113197	After completion of an SOP, Measure-SOP points to the data directory not the SOP directory	Fixed: Measure-SOP points to the set SOP directory
113288	Installer doesn't place a shortcut on the desktop for Standard User.	Fixed
113539	When 21CFR Part 11 is enabled the original PSH file, before editing, should be preserved in the 'Backup' folder by default.	Fixed

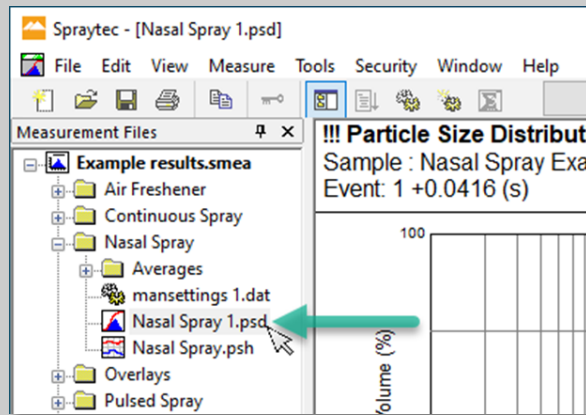| Reference	Description	Comment
114138	Software could be opened by multiple Windows users leading to communication issues.	Fixed: if the software is opened by any local Windows user, it cannot be opened by another Windows user.
114254	When switching to a standard user account, 21 CFR Part 11 may become disabled for that user	Fixed: 21 CFR Part 11 remains enabled
114256	When running a timed measurement, pressing stop the measurement resets to the start with no Reason for Change being requested	Fixed: During the Data acquisition stage the stop button is disabled and if the X is pressed a Reason for Change window appears.
115072	A user could login even if password has expired.	Fixed
115108	When 21 CFR Part 11 is enabled, changing windows profiles causes problems accessing the audit trail functionality.	Fixed
115307	When 21 CFR Part 11 is enabled, and an SOP has been edited the reason for change is not recorded	Fixed
118338	Enabling 'Continuous Use Check' in ER/ES Setting gives error when user logs in.	Fixed
118796	SOP version differencing feature does not work correctly.	Fixed
118846	Application's status bar is not updated when user logs out.	Fixed
118850	'Select Range of Records to Delete' window contains truncated user interface control.	Fixed
119199	Opening a non-existing SOP file gives incorrect error message.	Fixed:
119325	Particle diameter unit is incorrect in the PSD file.	Fixed:
119761	When 21 CFR Part 11 is enabled if a user attempts to change the audit trail directory to one where they do not have write access, access is denied, and the audit continues in the current target but with no warning.	Fixed: a warning message is displayed, and the directory is not changed to the target directory
119763	When 21 CFR Part 11 is enabled, and the audit trail frequency is changed there is no instruction to the user to restart the software which is required for the change to take effect	Fixed: a warning is given
119918	Help links in the security configuration window do not work.	Fixed
121775	In a rapid mode manual measurement, analysis can be started too early by switching tabs.	Fixed
120545	With remote functionality turned on, remote users can make a measurement without it being in the audit trail.	Fixed: When 21 CFR Part 11 is enabled then remote control is disabled.
120618	Changing **Tools-Options-Directories-Measurement Results** directory does not update the path of directory.	Fixed
121632	Edit- Find a record window has an erroneous title.	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 where applicable.

Reference	Description	Workaround (where available)
193866	Too many measurements in one experiment folder can cause the software to crash. The exact number of measurements depends on the performance of the PC.	Minimize the number of measurements in each experiment folder (chose not to repeat the SOP to create a new experiment regularly).
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 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).	Ensure file path, measurement and sample names used are within the guidelines given in the Issue description.

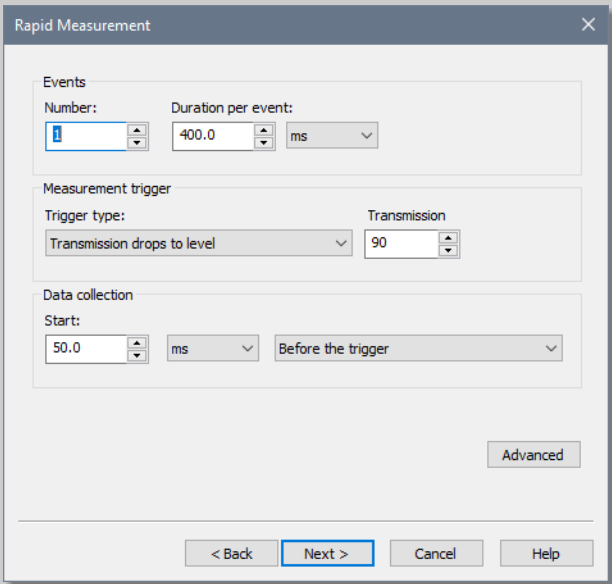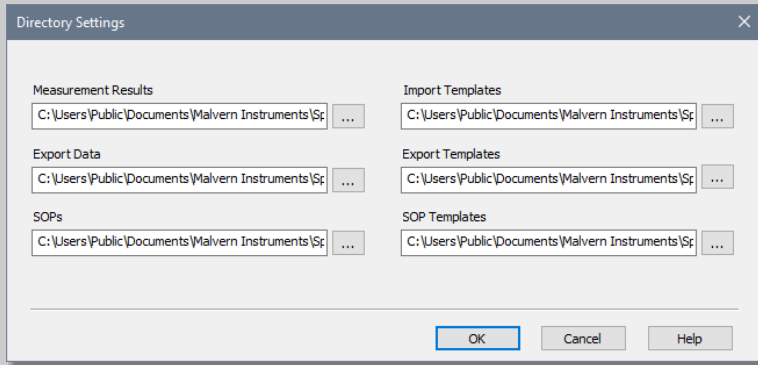| Reference	Description	Workaround (where available)
	For example, consider the examples measurement file. This is stored, by default, in the following location: *C:\Users\Public\Documents\Malvern Instruments\Spraytec\Measurement Data\Example results.smea* Within this file, there is an Experiment folder 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. 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	

Reference	Description	Workaround (where available)
	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.	
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

Reference	Description	Workaround (where available)
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%.
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:	Ensure software is restarted to apply any changes made to user directory settings.
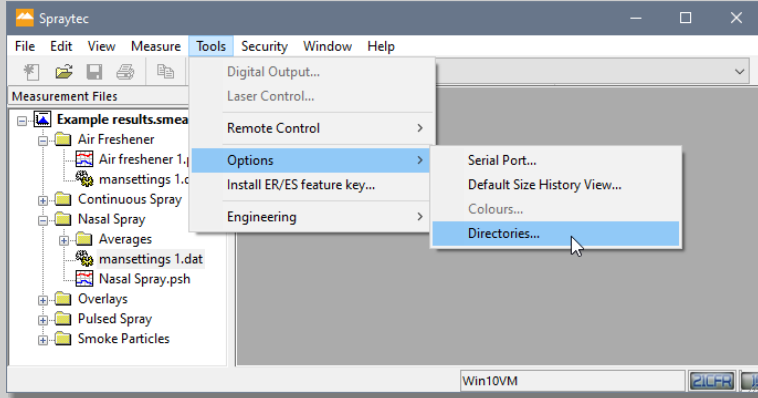
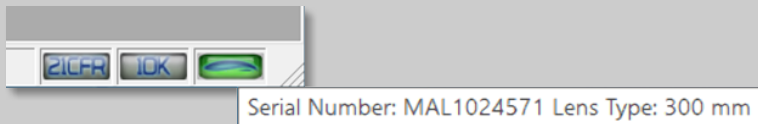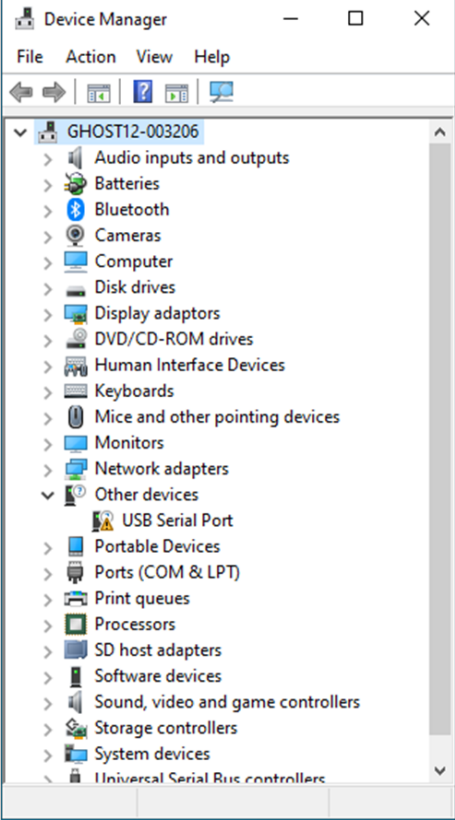| Reference	Description	Workaround (where available)
	  This option displays a window that allows the default directory locations to be reconfigured: Clicking OK will store the directory settings. You will need to restart the software for the settings to be applied.	
123043	**Instrument lens reporting** 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.
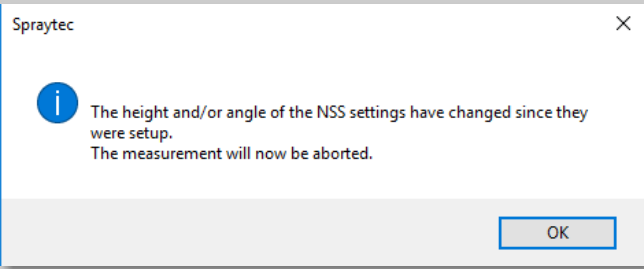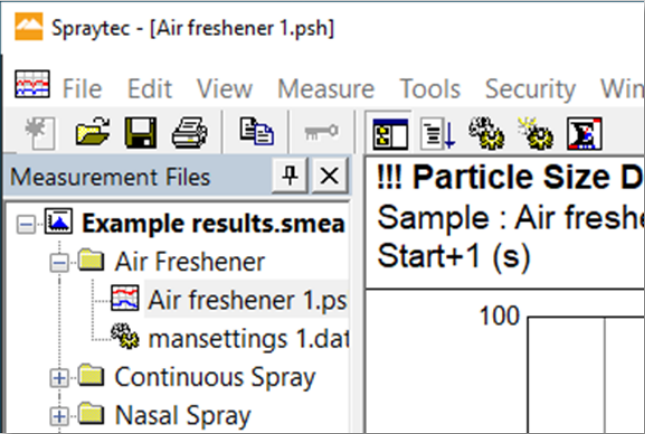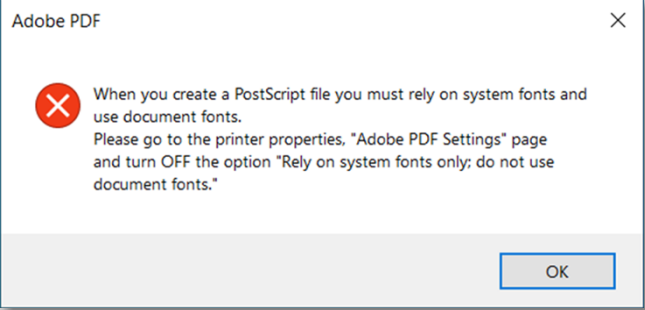
Reference	Description	Workaround (where available)
123136	**Incorrect measurement times reported for manually-triggered rapid mode measurements** It has been found that the relative start times for each of the measurements making up a manually-triggered rapid mode measurement are offset by one measurement 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 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.

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Reference	Description	Workaround (where available)
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.	
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:	If printing to PDF is required ensure that Adobe Acrobat settings are configured as described in the Issue description.

Reference	Description	Workaround (where available)
	The following Adobe PDF message window appears when the program enters this state: 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.	
123040	**Yellow Exclamation Mark in Device Manager against USB Serial Port** In Device Manager, there may be a yellow exclamation mark besides the USB Serial Port, as shown in the following diagram.	Please ignore incorrect notification of error state against USB Serial Port.

Reference	Description	Workaround (where available)
	Please note even if there is a yellow exclamation mark, the USB connection to the Instrument will work properly.	

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 Malvern 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**.
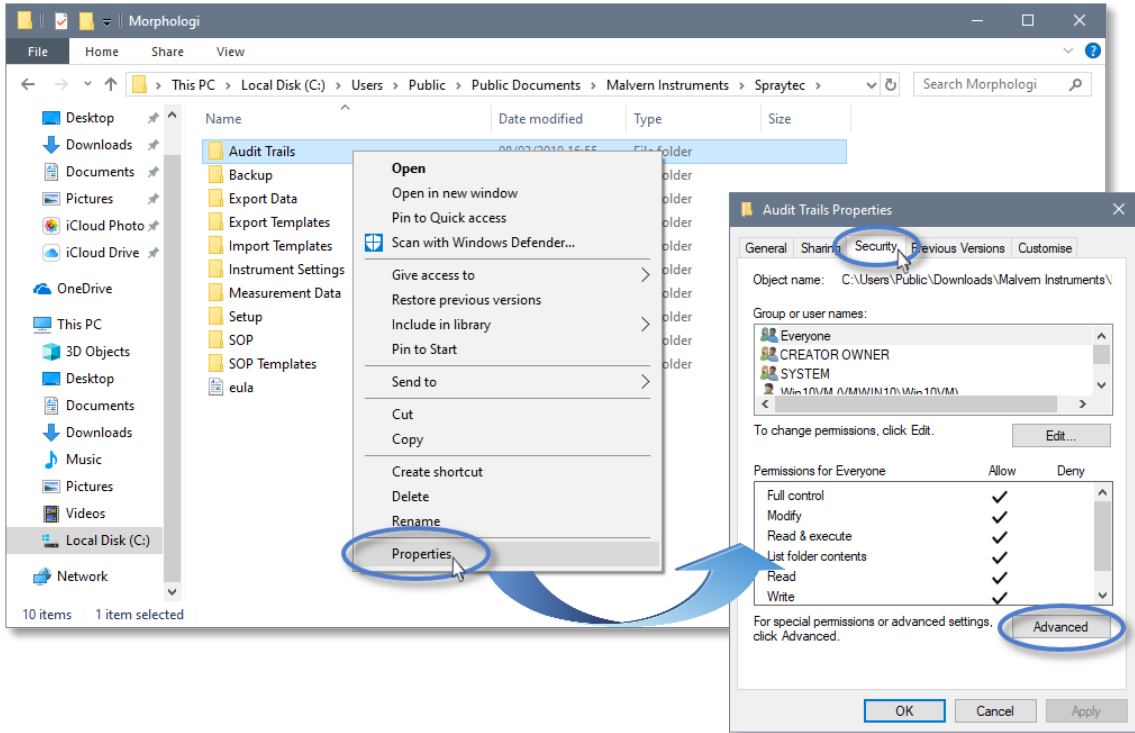
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button (if this button is not available, you will need to left-click the **Change permissions** button first).
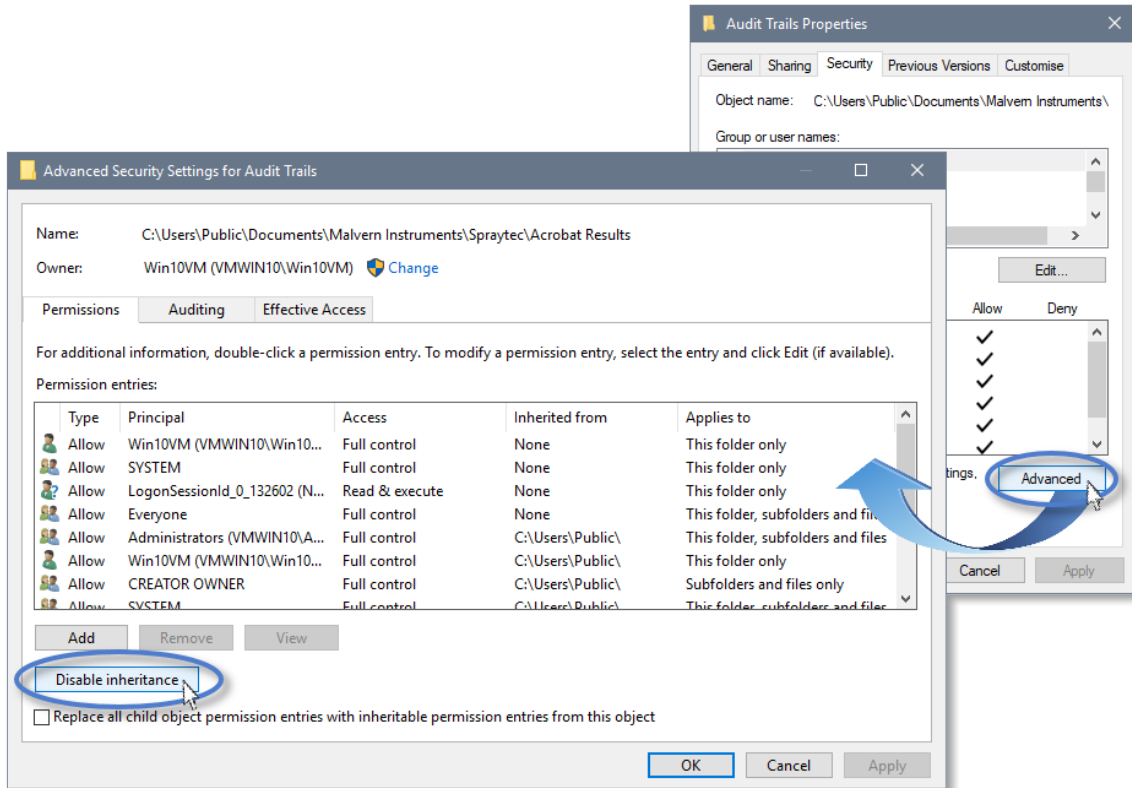
4. Within **Block Inheritance**, left-click on **Convert inherited permissions into explicit permissions on this object** – this removes the permission inheritance from the parent folder, whilst keeping the any current users and groups settings.
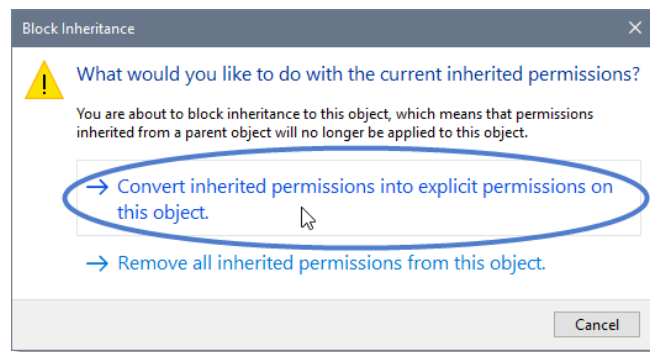

5. After returning to the **Advanced Security Settings** window, left-click to select the **Spraytec Operators** group and then left-click the **Edit** button.

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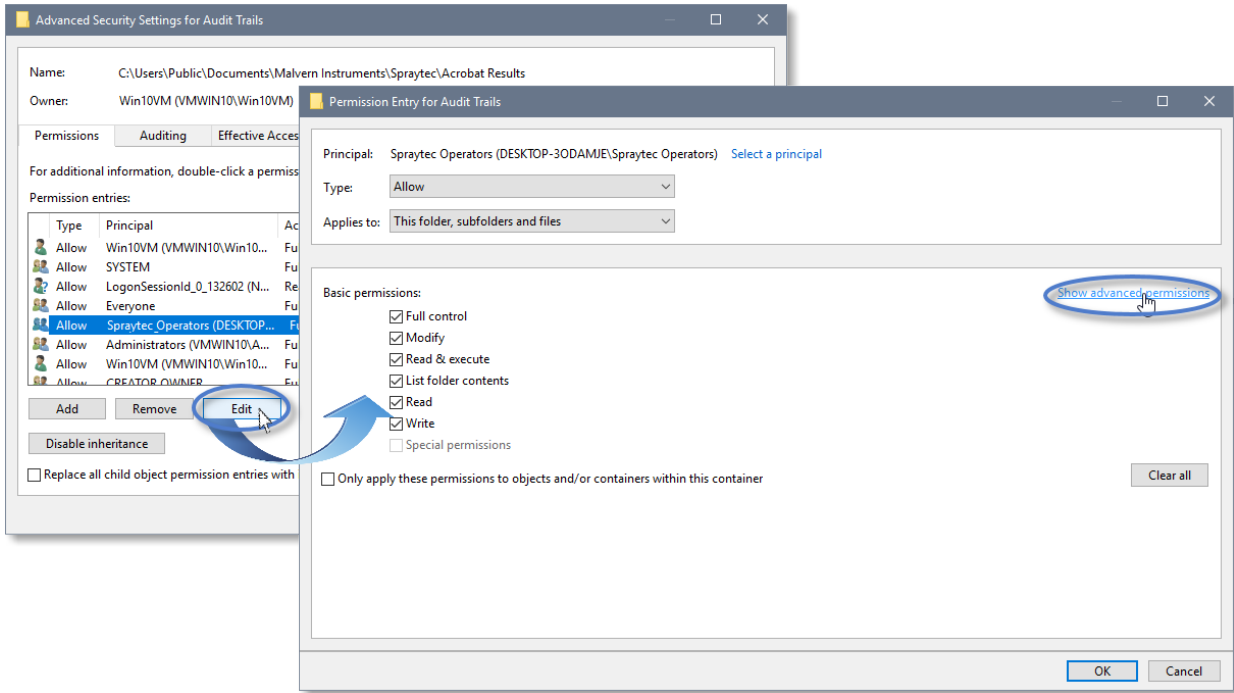
7. Left-click to deselect the checkboxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.
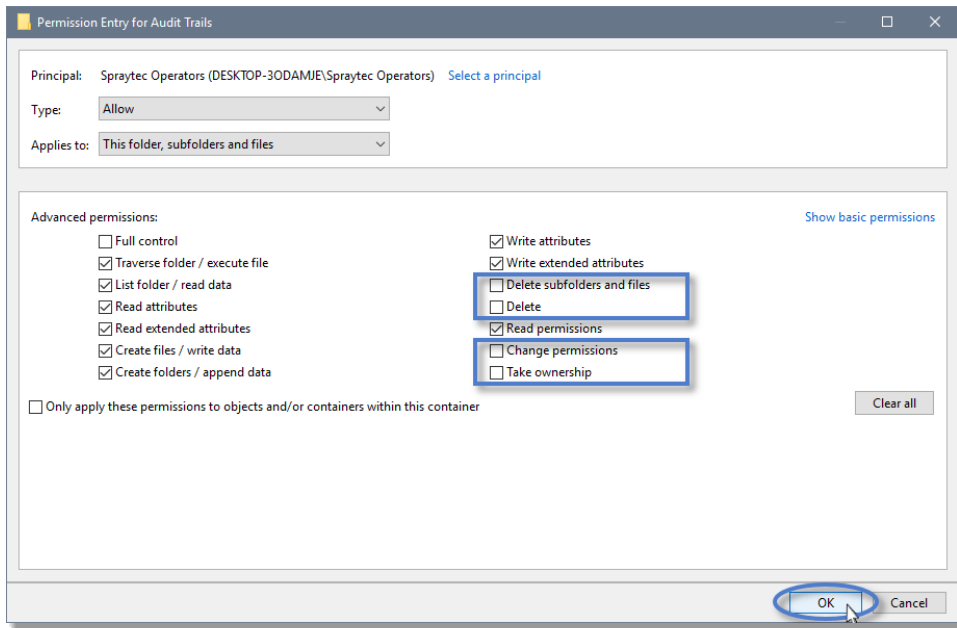
File Types and Locations

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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