



Software Update Notification



PSS0024-10: Spraytec v3.20 software

Abstract

This document details the release of software PSS0024-10 – v3.20 of software 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.

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.

Minimum System Requirements

The minimum requirements for running this software are highlighted in the table below:

Feature	Specification
Processor Type	Intel 3GHz Core 2 Duo processor (or equivalent)
Memory	4 GB
Hard Disk Storage	250Gbyte
Additional Storage Media	CD-ROM drive
Display Resolution	1024 x 768
Connectivity	1 USB port
Operating System	Windows XP Professional™ with Service Pack 2 or later installed Windows 7 Professional (32 and 64 bit)

These minimum system requirements relate to the Spraytec software alone. As such, they may not account for the memory required to efficiently run the operating system on the computer, especially when operating system updates are installed. Although the software has been install tested using Windows XP Professional and Windows 7 (64 bit), Windows 7 Professional (32 bit) is preferred, as this operating system was used for software alpha testing.



Installation Instructions

The Spraytec software is provided on one auto-loading CD-ROM. Inserting the drive 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 **lsetup.exe** program from the root directory of your CD drive.

Note: During installation of the software a warning message may appear suggesting that installation of this software may destabilize the operating system or harm your computer. This warning can be safely ignored. Please refer to the advice within the 'Known Issues' section below.

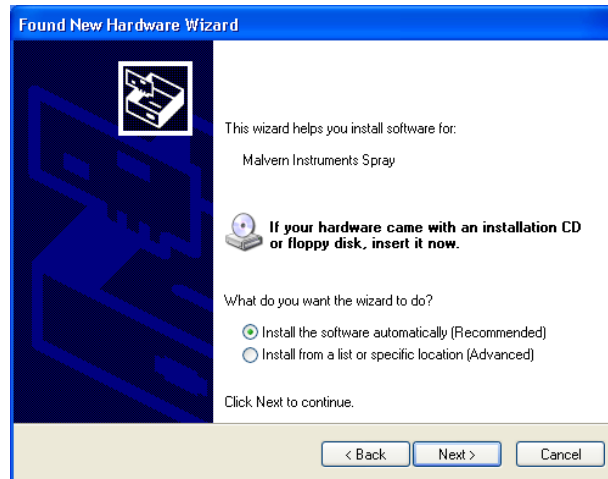
USB Driver Installation under Windows XP

The Spraytec system uses a USB connection to allow the software to control the measurement hardware. This requires a specific USB driver to be installed when the software is first run after installation. Installation of this driver requires the instrument to be connected when the software is started.

The USB driver installation process should start automatically, causing the following dialogue to appear:



From this dialogue select '**No, not this time**' and then click the '**Next**' causing the following dialogue to appear:



Select the default selection of '**Install the software automatically**' from this dialogue and the 'Next' button to proceed with installation. Once file transfer has been completed the '**Finish**' button should be pressed to complete the installation.

Note: During installation of the USB driver under Windows XP a warning message may appear suggesting that installation of the driver may destabilize the operating system. This warning can be safely ignored. Please refer to the advice within the **Known Issues** section below.

USB Driver Installation under Windows 7

With the software installed, the instrument should be connected via the USB port. The drivers should then be installed automatically without any user input.

Uninstall Procedure

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

New Features

The following sections describe the main new features which are present in v3.20 of the Spraytec software and were first provided in v3.00. For a history of all of the new features added to the software since the launch of the Spraytec, please refer to the software update notification documents associated with v1.00 and v2.00 as well. These can be downloaded from Malvern Instruments' web site.


Ensemble Averaging (v3.00)

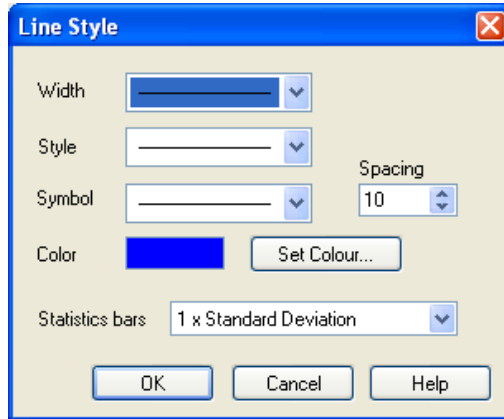
Ensemble averaging is for use on samples either where several repeat measurements are made – such as with nasal sprays – or where the sample has a natural repetitive nature – such as fuel injection in an internal combustion engine. The purpose of the ensemble average is to provide a particle size history (*.psh file) which is an average of several event cycles. The data recorded at each time point in the averaged particle size history is an average of the corresponding time points in each event cycle. The operation of this new feature is described in full in the latest version of the Spraytec manual (MAN0368-3.0) which is included on the Spraytec v3.02 software CD-ROM.



Derived Parameter Statistics Bars (v3.00)

In order to show more statistical information on an average size-history graph (as produced by the advanced averaging options) it is now possible to show statistics ('error') bars on the derived parameter curves. The statistic bars are enabled from the line style dialog.

To see the line style dialog open the Size-History Display Setup dialog and double-click on one of the line-colour styles under the  column of the 'Plotted Curves' list. The style of statistics bar may be selected between none, 1 x standard deviation, 2 x standard deviation, 3 x standard deviation and maximum-to-minimum (see below). Note that standard deviation, maximum and minimum are also shown numerically on the derived parameter view.



New Derived Parameters (v3.00)

Two new derived parameters have been added to the Spraytec software. These are detailed in the table below.

Symbol	Description
R	Residual %. This provides a measure of the residual error between the measured scattering data and the calculated data. This parameter is also shown on the measurement parameters page
Rms	Multiple scatter residual %. This provides a measure of the residual error between the measured scattering data and the predictions generated using the Spraytec's multiple scattering algorithm. The value will be zero if multiple-scattering correction not used.

Number-Based Size Distributions (v3.00)

The Spraytec – like other Malvern diffraction particle sizers – produces a volume-based particle size distribution as its fundamental result type. Other particle sizing techniques produce a number-based distribution – the obvious example being particle counters. A new option in the Analysis part of the Spraytec Standard Operating Procedure (SSOP) wizard allows you to choose to have the result reported as a number distribution.

In earlier versions of the software the volume-based nature of the result was inherent; for example, the percentile values were denoted as **Dv** – a volume diameter. On the result views these are now shown as **Dn** for a number distribution. In some cases the result type is not yet known and in this case the value is denoted as **Dx**. This is observed, for instance, when selecting derived parameters.

Note: Converting volume distribution results to number distributions increases the errors observed, particularly at the fine



end of the particle size distribution. For this reason, Malvern Instruments recommends that the number distributions produced from laser diffraction measurements should be used as indicators only and should not be relied upon to set product specifications.

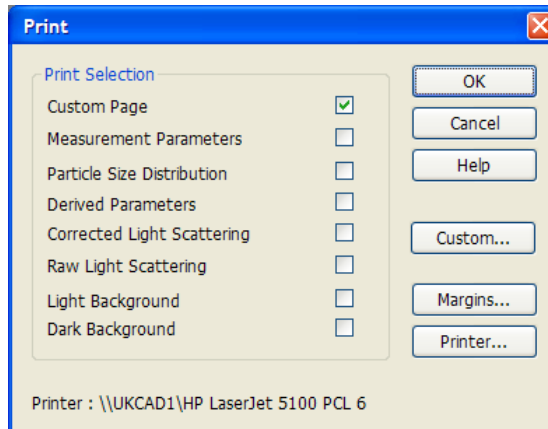
Auto-Increment of Lot Value (v3.00)

The lot-value is one of the documentation labels that may be entered by the SSOP designer and optionally edited when an SSOP is run or when a measurement is edited. This version of the Spraytec software includes an option to automatically increment the lot value at certain points during the measurement sequence. The options available are detailed in the table below.

Auto-increment setting	Action
No	No auto-increment. If the lot value is not locked the operator may enter anything into the lot value edit box.
On Triggers	During a rapid-mode measurement the lot value field is incremented at each trigger. The starting number is entered by the operator (if the lot value field is not locked) when the SSOP runs, otherwise the number stored in the SSOP is used. The user is forced to enter a number between 1 and 2000000000.
On SSOP Runs	Each time the SSOP is run the lot value number is incremented. The number may be changed by the operator if the lot value field is not locked. The user is forced to enter a number between 1 and 2000000000. The number is persistent and is stored in a file in the same location as the SSOP. Manual measurements also allow the lot value to be incremented at each run but the operator always has the ability to override the number by entering a new value in the lot value edit box.
On SSOP Repeats	This behaves in the same way as auto-increment on SSOP runs but also increments when the option taken to repeat a SSOP measurement.

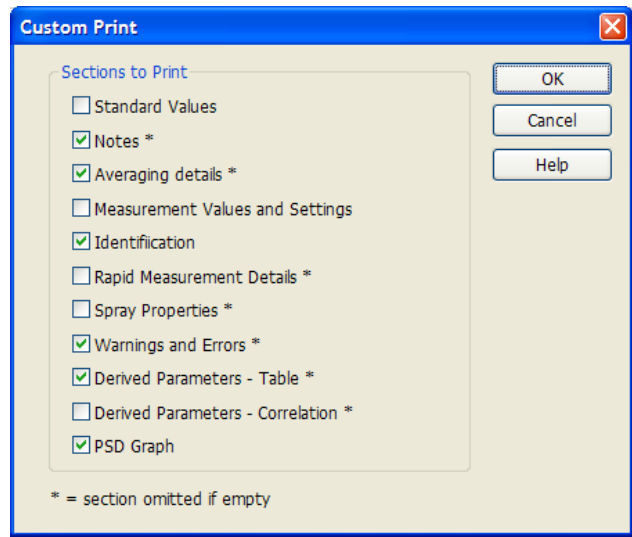
Custom Print Report (v3.00)

With a PSD window active, selecting the File->Print command shows a dialog that allows one or more report pages to be printed. In earlier software versions the contents of each page was fixed. This software version allows the user to control which elements are printed on a report using a new "Custom Page" report option, as shown below.





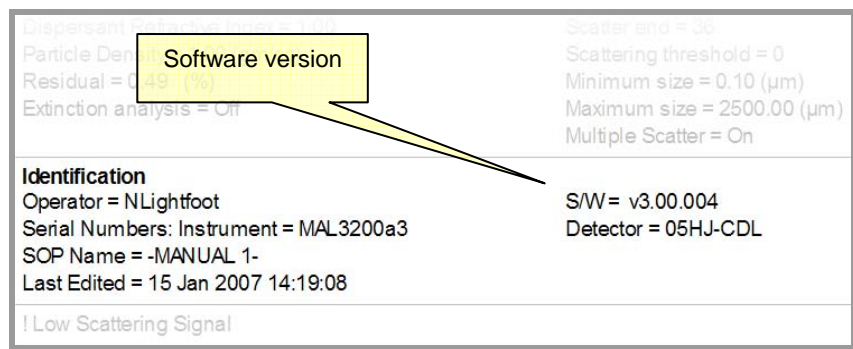
Clicking the 'Custom...' button shows a dialog where the contents of the custom page may be configured:



The options in the custom print dialog are sections from the measurement parameters page plus the derived parameters table and the size-distribution graph. Only a single page is printed so if all sections are used and fully populated some information will get cut-off. Fortunately some sections – for example, parameter correlations – are rarely used. Also the 'standard values' and 'derived parameters' often contain repeated information. If a section is not used or is empty then no space is taken up on the print. The PSD graph is sized so that it takes up all the remaining space on the page. The settings of the custom print are remembered when the Spraytec software is closed.

Software version number (v3.00)

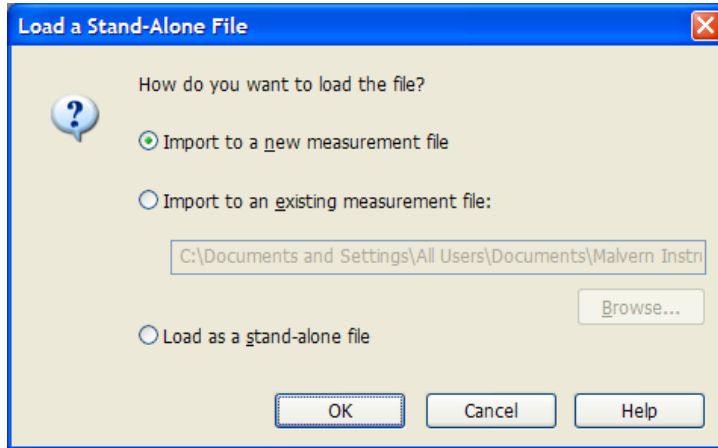
The measurement parameters view identification section now shows the version of software used to make the measurement, as shown below. For measurements made using Spraytec v2.00 and earlier this part is omitted.





Load a stand alone size-history or size-distribution file (v3.00)

It is sometimes convenient to save a size-history (PSH) or size-distribution (PSD) as a stand-alone file. These files are smaller than Spraytec measurement files (SMEA) so are more convenient for e-mailing to other users, for example. Previously these could be opened in Spraytec as read-only stand-alone files, or PSH files could be imported into existing SMEA files. In this software version the following dialog is shown when a user opens a stand-alone PSH or PSD file:



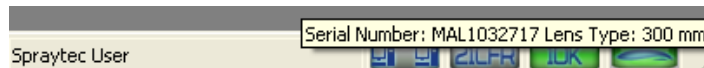
The three options available operate as follows:

Option	Action
Import to a new measurement file	A save dialog appears to allow a new SMEA measurement file to be named. The PSH or PSD file is copied to an 'Import' folder in the file. This option is disabled if a user does not have permission to import files within the Spraytec software's security system.
Import to an existing measurement file	Choose the existing file using the 'Browse' button. The name is saved and is shown when this dialog is next used. This option is disabled if a user does not have permission to import files within the Spraytec software's security system.
Load as a stand-alone file	Loads the file as a read-only file for viewing and printing.

The advantage of importing the file is it may then be edited and the data it contains may be averaged. In 21 CFR Part 11 mode the import process is audited.

Lens type verification (v3.10)

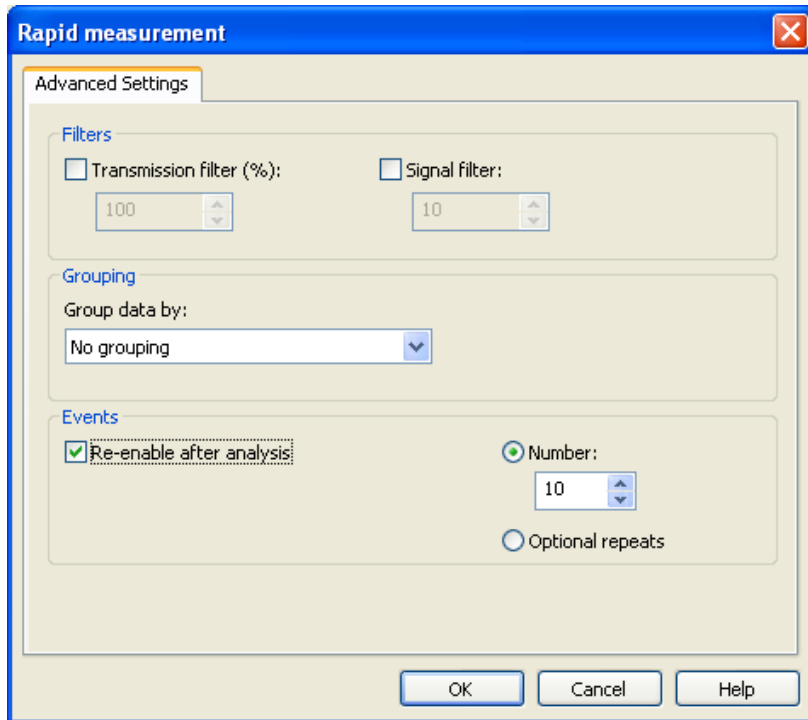
It is now possible to verify which lens is connected to the Spraytec system from within the software, by hovering the mouse over the Spraytec icon on the task bar. Doing so causes the following tool-tip to appear:





Repeating rapid mode measurements (v3.10)

Several customers have requested the ability to repeat the rapid mode measurements defined with an SOP without the need to align the Spraytec system and measure the background light scattering each time. An option has now been added to the Advanced Settings within the Rapid Mode section of the Spraytec SOP to enable this to be done:



To enable repeat measurements, the 'Re-enable after analysis' option with the Events section of the Advanced Settings needs to be enabled. Two options are then available. Users can either specify a specific number of repeat measurement sets which should be carried out. Alternatively, the 'Optional repeats' option can be enabled, allowing users to repeat the measurement set as many times as required when the SOP is run.



Fixed Issues

The following Software Change Requests (SCRs) have been implemented in this version of the Spraytec software:

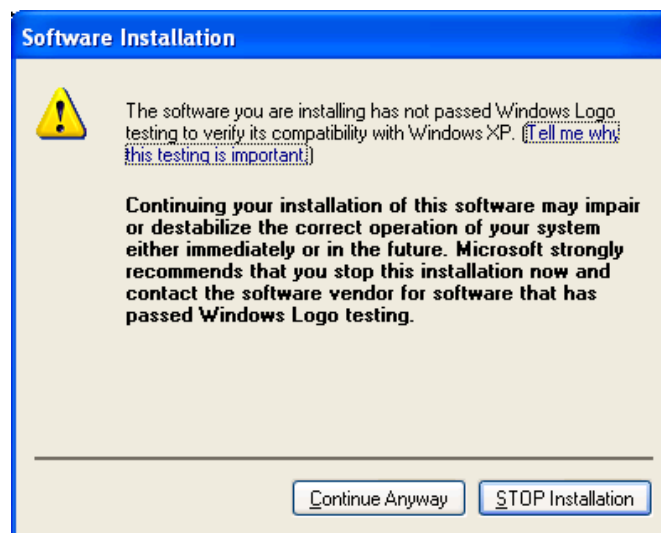
SCR	Description	Comment	Status
5937	Provide 'use last reference' option when setting up the Spraytec NSS accessory	Improvement	Implemented
6189	German language entries appear within the 21CFR11 Audit Trail	Bug	Fixed
8836	Make Spraytec software compatible with Windows 7 operating system	Improvement	Implemented
9402	Software reports only 1KB of free disk space remaining when there is actually a large amount of space on the hard drive, thus causing the measurement to fail.	Bug	Fixed

Please refer to the software update notification for previous releases for a list of SCRs which have been addressed since the release of Spraytec v1.00 software.

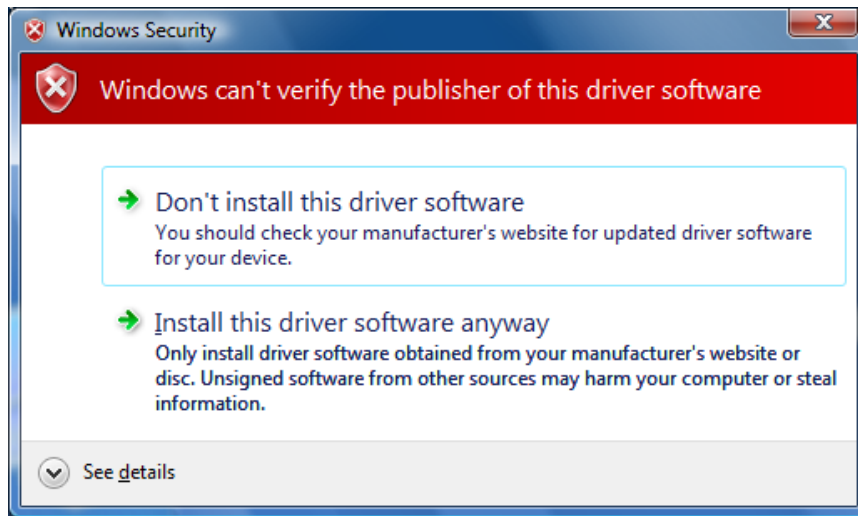
Known Issues

Software and USB Driver Installation Warning

During installation of this software and the USB driver on Windows XP Professional the following message may appear:



A similar message may be displayed under Windows 7 when the software is installed:



These warnings can safely be ignored during the installation process as the software has been thoroughly tested using both Windows XP and Windows 7. You should select to continue the install process.

USB Detection

As described above, USB detection occurs automatically on new computers. On older 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 when the software is run:



The fix for this problem is to 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:



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).

File Sizes

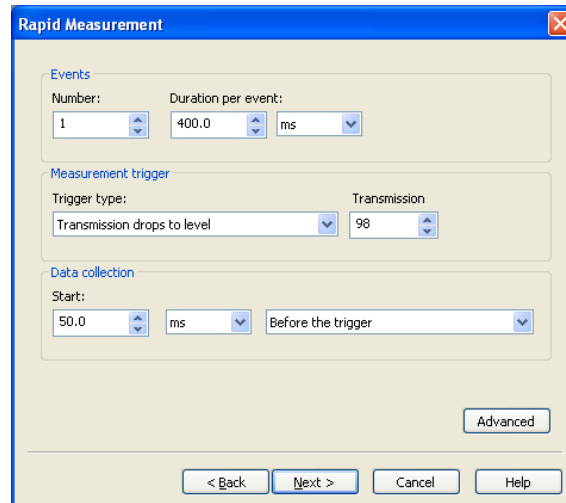
Due to the nature of the measurement which are made using the Spraytec system, the size of the measurement files (*.SMEA) may become large. Although this may not affect instrument operation, it may impact data transfer and archiving. Users should therefore monitor file sizes and change the SMEA file used for data storage according to the experimental program they are involved in.

For support purposes, the Malvern Instruments Helpdesk 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 to disk.



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 SSOP settings are show below – here data is collected for 50 msec 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.



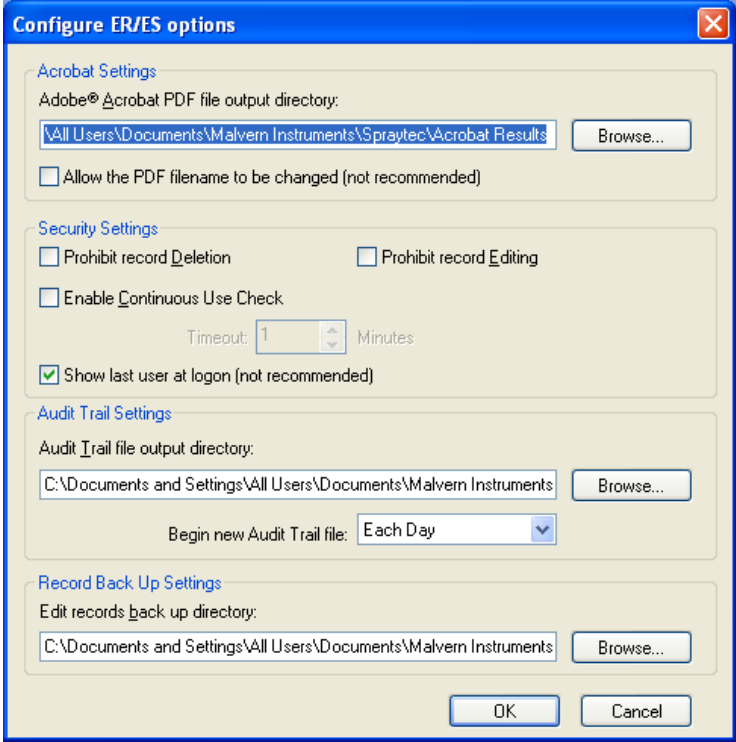
Averaging Time Window Specification

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.

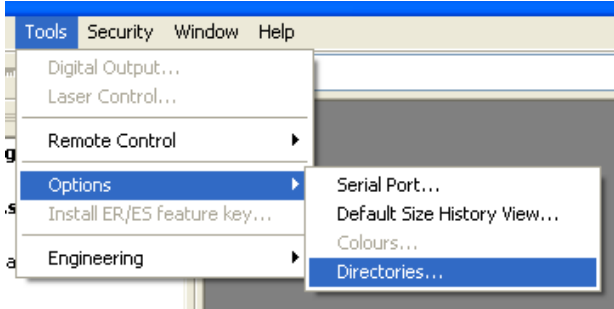
ER/ES Settings Lost by Uninstalling Version 2 Software

On a system where 21CFR Part 11 functionality is enabled, when the version 2 software is uninstalled then the settings for ER/ES are also uninstalled from the system registry. The 21 CFR Part 11 functionality will remain enabled and the security settings will be retained. However, the ER/ES settings will revert to the application defaults shown below when next installed. Users are therefore advised to copy to ER/ES settings they are using prior to uninstalling Spraytec version 2.

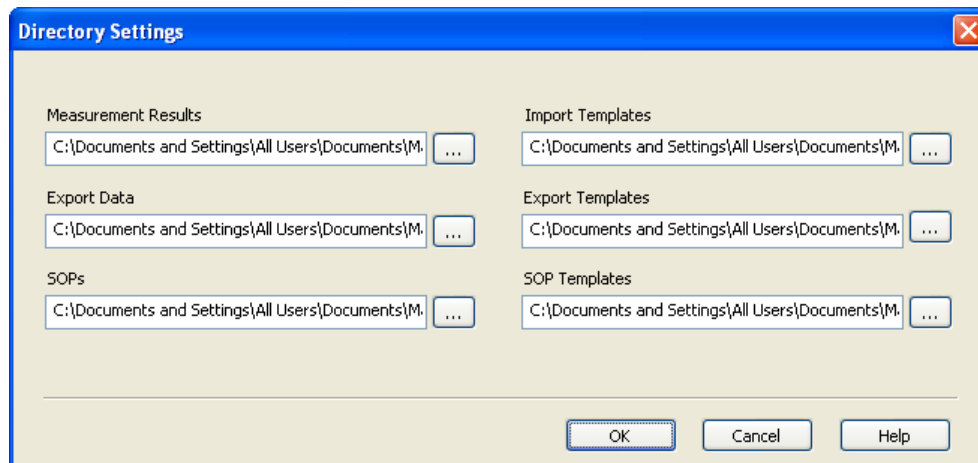


Update of Directory Settings

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 dialogue that allows the default directory locations to be reconfigured:



After the OK button has been pressed to close the dialogue, it should be noted that in order for the settings to take affect the application needs to be restarted.

Incorrect measurement times 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.

Update of the instrument lens

If the lens for the instrument is changed from the 300 mm to the 750 mm or vice versa then the software should be restarted in order 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 will be used when running SOP-based measurements.

Measurement progress bar does not behave correctly for multiple events

If you set up an SOP measurement of 5 triggered events, each of which are 3 seconds in length, the progress bar will correctly complete in 3 seconds for the first event. For the subsequent 4 events the progress bar will go to a completed state straight away (although the measurement still has some time before it completes). This can be misleading as it looks like the instrument has completed a measurement event before it has.

Enabling remote control functionality on Windows 7

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

Restrictions on the naming of files

Filename length

The length of the filenames that can be used within the Spraytec software has been limited to 63 characters. This applies to all the file types created by the software (*.smea, *.psh, *.psd, *.ssop). However, it is currently possible for users to specify filenames which exceed this limit. If this is done, the Spraytec software will not be able to access the file again once it has been closed. The only way for users to regain access is to rename the file using a name which contains a maximum of 63 characters.

Internal filenames used in Spraytec measurement files

The Spraytec measurement files (*.smea) are compound files that contain a set of folders within which both measurement files (*.psh, *.psd) and SOP files (*.ssop) can be stored in a logical fashion. These compound files may also contain folders used to store average result (*.psd) or overlays (*.ovr). The application uses a measurement view to display these files in a layout which is similar to the folders tree-view used in Windows Explorer. The files and folders displayed within this tree view are limited to a maximum length of 31 characters. Users are therefore advised to only use a maximum of 31 characters when naming standard operating procedures (SSOPs) or defining sample names.

Invalid characters

A limitation of the currently supported operating systems is that they only support certain characters for filenames. Characters such as \ / : * ? " < > | are invalid and should not be used when defining measurement file (*.smea) or standard operating procedure (*.ssop) names.

Sample naming

The issues described above relating to the naming of Spraytec data files also apply to the sample name defined by users when making a measurement. If a sample name is specified, it is used to name any measurement files (*.psh) or average data files (*.psd) created during a measurement. This means that the sample name must not be greater than 29 characters in length (2 characters are used by the file numbering system) and must not contain any invalid characters. If the sample name is too long it will be truncated when it is used to name the measurement file. The use of illegal characters such as \ / : * ? " < > | is prevented for sample names.