

SOFTWARE UPDATE NOTIFICATION

SPRAYTEC SOFTWARE v3.30: PSS0024-11



Introduction

This document details the release of software PSS0024-11: version 3.30 of the 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.

Recommended System Requirements

The minimum requirements for running this software are highlighted in table 1 below. 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.

The software has been install tested using Windows 7 (32 and 64 bit), Windows 8 (64 bit), Windows 8.1 (64 bit) and Windows 10 (64 bit). It has been fully tested using Windows 7 (64 bit) and Windows 8.1 (64 bit). Windows 7 (64 bit) and Windows 8.1 (64 bit) are therefore the preferred operating systems.

Supported Languages

The Spraytec software currently supports operation in English only.



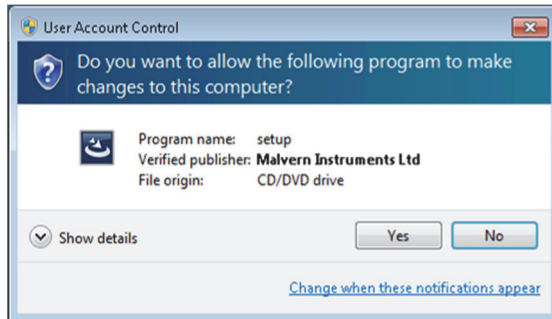
Table 1: Minimum system requirements for the Spraytec software.

Feature	Specification
Processor Type	3GHz Core 2 Duo
Memory	4GB
Hard Disk Storage	250GB
Additional Storage Media	CD-ROM or DVD +/-RW drive
Display Resolution	1024 x 768
Connectivity	1 USB port
Operating System	Windows 7 (32 bit) Windows 7 (64 bit) Windows 8 Enterprise (64bit) Windows 8.1 Enterprise (64 bit) Windows 10 (64 bit) Windows 7 (64 bit) and Windows 8.1 (64 bit) are preferred

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 **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 **\\Spraytec\\setup.exe** program.

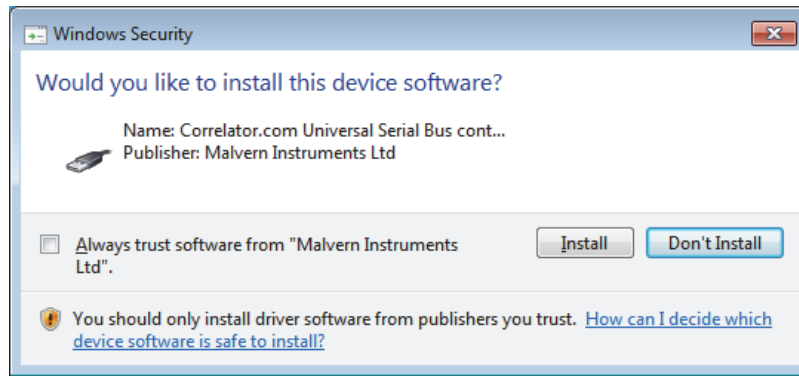
At the beginning of the installation you may be prompted by the following dialog:



Please click on the "Yes" button to continue with the installation process.

USB Driver Installation

During the installation of the USB drivers you may be prompted several times with the following message:



This warning can safely be ignored as the software installation has been tested on each of the operating systems listed in table 1. Press "Install" to continue with installation of the USB drivers.

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 differ 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 and Fixed Issues

Version 3.30 of the Spraytec software has been produced as a maintenance release in order to enable the software to be used on newer Windows operating systems. This has involved a major update to the software code base. In addition, the following improvements and bug fixes have been applied:

Reference(s)	Issue	Comment
SCR 7252	In continuous mode the sampling rate can differ from that specified, causing data gaps to appear.	Bug Fixed
SCR 7384	The Spraytec remote control interface should contain a method returning the active measurement file (*.smea and *.psh)	Improvement
SCR 8663	The measurement progress bar does not behave correctly for multiple events, making it look like the measurement is complete when it is still active	Bug Fixed
SCR 9397	Provide a method of stopping an SOP measurement using the Spraytec remote interface.	Improvement
SCR 9424	Incorrect error message displayed when print fails due to the printer not being present.	Bug Fixed
SCR 9460	When exporting data, ensure the software creates the export data file even when append mode is selected.	Improvement
SCR 9461	SOP data export fails for repeat runs of an SOP, as the data from the repeat measurements is stored with identical time stamps.	Bug Fixed
SCR 9463	Light background does not display laser signal value correctly	Bug Fixed
SCR 9541	Review file associations used within the Windows operating system to ensure that only relevant files are assigned to the Spraytec application.	Improvement
SCR 9867	If a security group is created using the same name as an existing group, the existing group settings are lost.	Bug Fixed
SCR 9868	Password history function does not operate correctly, allowing matching passwords to be used multiple times.	Bug Fixed
SCR 9964	For manual measurements, data may be exported from an inactive measurement file (*.PSH) file rather than from the selected active measurement file.	Bug Fixed
SCR 9978	Laser shutter not closed if instrument connection lost	Bug Fixed
SCR 9997	The Windows OS denies users the right to save data to a new file when the directory permissions are set to prevent file deletion.	Bug Fixed
PBI 40664	Update SOP so that the actuator force and velocity settings displayed correctly	Bug Fixed

Known Issues

The following issues have been discovered within the software, and will be investigated as part of a future release.

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. It is also important that illegal characters are not used.

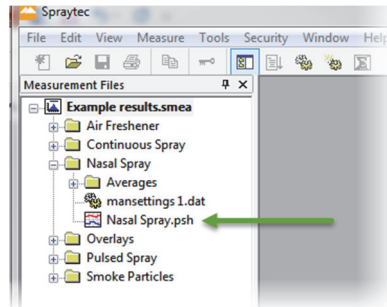
- **File Path Length Restrictions:**

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. This restriction 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.

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).

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 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:



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.

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 customers as the reported time period for averaging can be outside of the range specified.

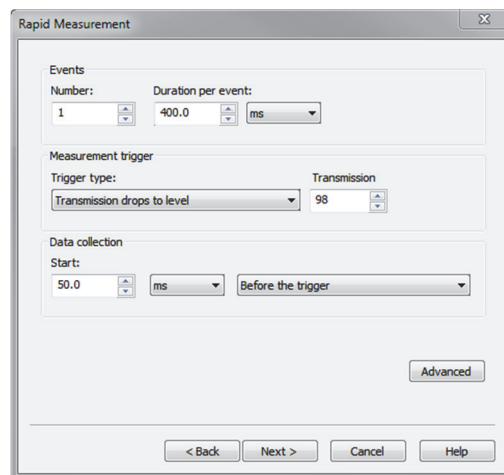
For example, consider a measurement which has been acquired using an acquisition rate of 1kHz with a stable phase average time window selected from 25msec to 75msec. When the phase average is reported, the software will report that it is obtained for a time period from 24msec and 74msec.

21CFR Part 11 settings lost by uninstalling Version 2 software

When the Spraytec v2.00 software is uninstalled on a system where 21CFR 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.

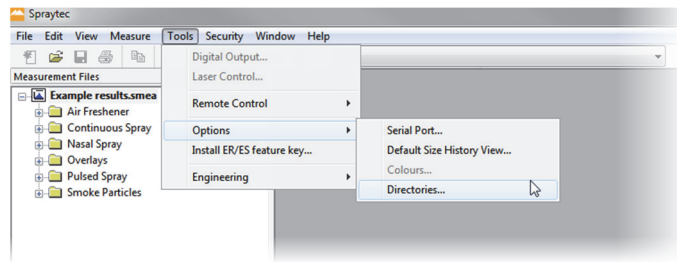
Measurement triggering at low transmission Levels

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.

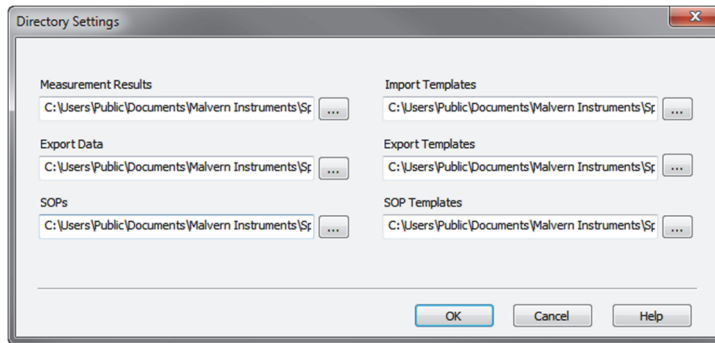


Updating the user directory settings

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 dialogue 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.

Instrument lens reporting

If the lens for the instrument is changed from the 300mm to the 750mm lens or vice versa then the software may need to 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 within the analysis when running SOP-based measurements.

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.

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 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.

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.

Rapid mode measurements of long duration (e.g. over 10 seconds)

Rapid mode measurements generate a large volume of data during the course of 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 (greater than 10 seconds). As a result we advise that no more than 15 measurements of 30 seconds 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.).

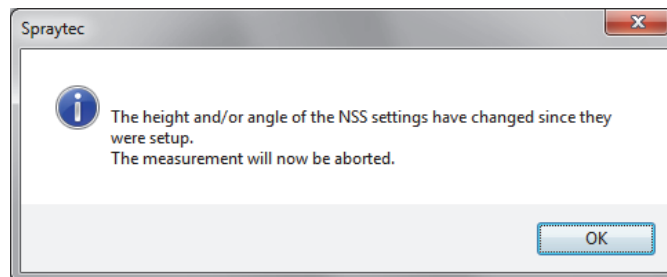
Intermittent problems with timed measurements

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.

Spraytec NSS accessory error notification appears twice

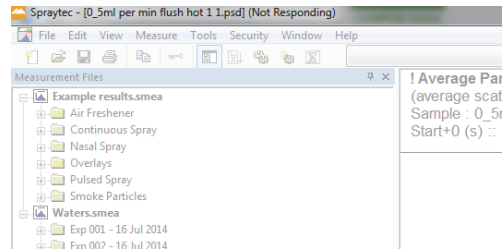
During repeat measurements with the Spraytec NSS Nasal Spray Support accessory the values for height and the angle of the NSS are verified against the values stored in the measurement SOP at the very start of the measurement (before the light background). If the values differ then the following dialogue is correctly displayed:



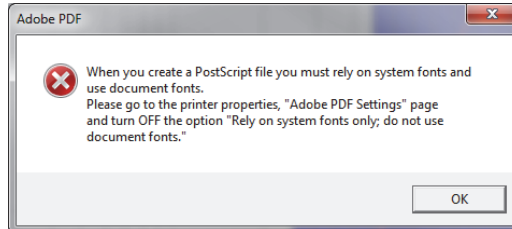
If you press the OK button then the same dialogue will appear a second time. It necessary to press OK on this dialogue too continue using the software.

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:



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.

File Types and Locations

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

File Type	Extension	Default Path	Advised security setting for 21CFR 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 wide 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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