

Software Update Notification

PSS0024-03: Spraytec v2.00 software



Abstract

This document details the release of software PSS0024-03. This is the second version of software for the new 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:

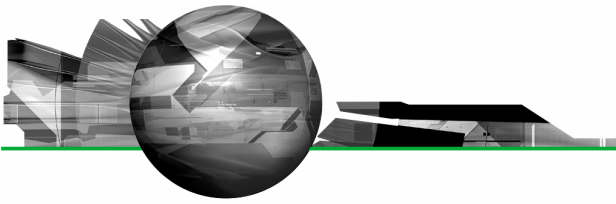
Feature	Specification
Processor Type	Pentium P4 2.8GHz
Memory	512Mbyte
Hard Disk Storage	80Gbyte
Additional Storage Media	CD-ROM drive
Display Resolution	1024 x 768
Connectivity	1 USB port
Operating System	Windows XP Professional™ with Service Pack 2 installed Windows 2000 Professional™ with Service Pack 4a installed

Although the software has been tested using Windows 2000 Professional, Windows XP professional is the preferred operating system.

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



Note: There are some additional instructions for those users who have previously installed alpha versions of this software. If you are updating an alpha software version please refer to the advice within the **Known Issues** section below.

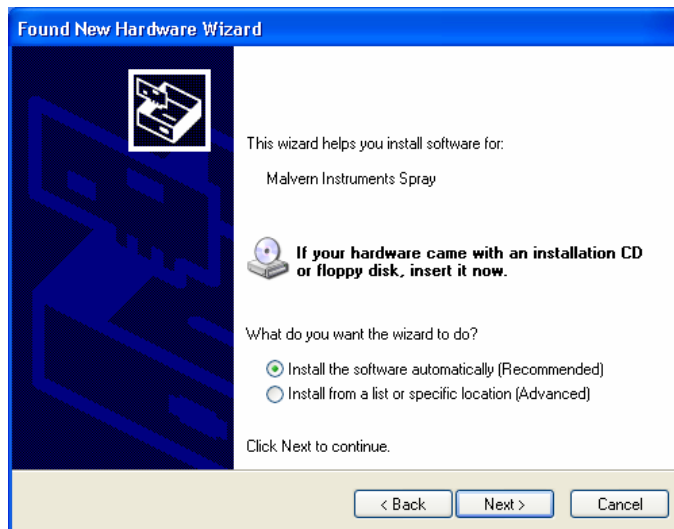
USB Driver Installation

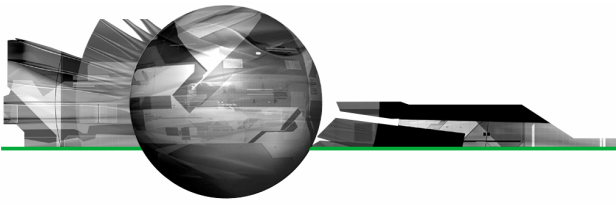
The new Spraytec system uses a USB connection to allow the software to control the measurement hardware. This requires a specific USB driver to be installed when the software is first run after installation. Installation of this driver requires the instrument to be connected when the software is started.

The USB driver installation process should occur automatically. On Windows 2000 Pro systems this will occur without the need for user intervention. For Windows XP Pro systems the following dialogue will appear:



From this dialogue select '**No, not this time**' and the click the '**Next**' causing 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 **Know Issues** section below.

Uninstall Procedure

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

New Features

21CFR11 Support

This version of the Spraytec software is the first version to contain features specifically designed to provide technical compliance to 21 CFR Part 11, the FDA's ruling on the use of electronic records and signatures. This includes the introduction of a software security system, an system audit trail, new file management systems and the ability to track changes to standard operating procedures (SOPs). In addition, the software can be used along with Adobe Acrobat to provide a solution for the electronic signing of results.

Full details of the 21CFR Part 11 features included in the software can be found in the 21CFR11 user guide included on the software CD-ROM (**21CFR11 User Guide for Spraytec Software (MRK723-xx)**). The document "**21 CFR Part 11 Compliance Guide for Spraytec Series STPxxxx (MRK724-xx)**" provides some background information regarding 21CFR Part 11 and the Spraytec software.

The main 21CFR Part 11 features are detailed below.

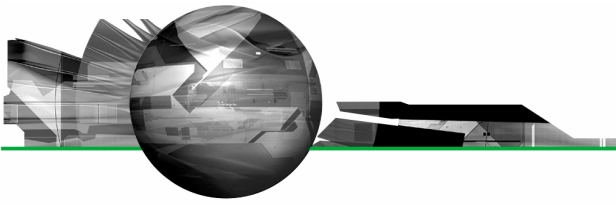
Security System

A security system has been introduced with this version of the software. This provides:

- Independent from Windows 2000™ Pro and Windows XP™ Pro security, allowing multiple users of a single system without the need to log in and out of Windows 2000™ or Windows XP™.
- Fully configurable users and groups.
- Each user can be a member of multiple groups.
- Encrypted passwords.
- Encrypted security settings file.
- Log in and out of the application without shutting it down.

In addition, the following features that are made available when the 21 CFR Part 11 feature key is installed:

- Continuous use check.
- Password ageing
- Password size
- Password uniqueness



- Account lockouts following failed access attempts.

Versioning of SOP files

When the 21 CFR Part 11 features of the software are enabled, it is possible to track changes in different versions of an SOP. This provides:

- A version history showing all versions of an SOP that have been saved.
- The ability to display the difference between versions of an SOP.
- Automatic logging of who edited a given SOP and the reason for any edits.

Audit Trail

In 21CFR11 mode, an audit trail is made available. This provides:

- Auditing of security events such as logging in and out of the system.
- Auditing of measurement record creation, editing, and deletion.
- Auditing of SOP file creation, editing, and deletion.

Users having the required security privileges can view the contents of the audit trail. In addition, the audit trail can be exported to an ASCII file for review.

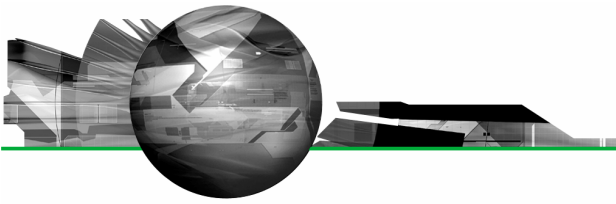
File Management

The file management features within the Spraytec software are modified when 21 CFR Part 11 mode is enabled. This ensures that:

- When using the 'Save As' dialogue box it is not possible to overwrite existing measurement files.
- A backup copy is made when editing measurement files.
- A backup copy is made when deleting measurement files.

File Locations

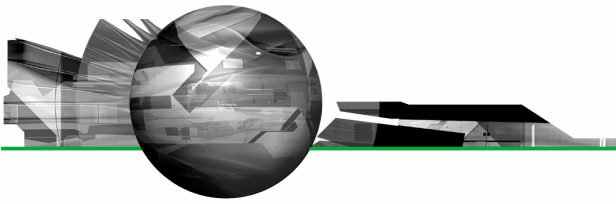
The file locations for all of the files used by the Spraytec software can now be specified using the **Tools-Options-Directories...** menu options. This allows all files to be saved on network locations, enabling record retention and back-up.



Fixed Issues

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

SCR	Description	Comments	Status
4976	Security.cfg is currently being stored in the measurement data folder. This needs to be stored in a separate security folder.	Software Bug	Fixed
5030	The 750mm lens auto-alignment can sometimes fail, causing the alignment process to enter a continuous loop.	Software Bug	Fixed
5457	Allow the Spraytec data directories to be set as network locations.	Improvement	Implemented
5517	The Result Editor does not allow the running average period to be edited.	Software Bug	Fixed
5531	The log-normal width (N) parameter is currently estimated from the arithmetic standard deviation. The software should use the geometric standard deviation.	Software Bug	Fixed
5534	Allow the slope of the output TTL trigger to be defined.	Improvement	Implemented
5536	Numerical validation failure for unweighted size distribution averages.	Software Bug	Fixed
5543	Improvements to SSOP numbering in the measurement file tree view	Improvement	Implemented
5549	If the records in the size history have already been averaged, prevent averaging when printing.	Improvement	Implemented
5550	PSH files imported to a SMEA file should be stored in a folder called 'Import' rather than a new experiment folder.	Improvement	Implemented
5551	Folders and files in the measurement file tree should be displayed in chronological order.	Improvement	Implemented
5570	Enable the editing of imported PSD records.	Improvement	Implemented
5579	If an SMEA file is read-only then 'read-only' should be shown in the caption and all editing or file deletion functions should be disabled.	Improvement	Implemented
5580	Spray profile settings are not recalled when PSH or PSD files are edited.	Software Bug	Fixed
5583	It is not possible to change the spray plume settings from the Spray Profile dialogue accessible within the Spraytec Nasal Spray Support settings.	Software Bug	Fixed
5586	Digital output trigger does not work in continuous mode.	Software Bug	Fixed
5590	No filename verification means that import wizard does not work properly.	Software Bug	Fixed
5596	It is not possible to enable a single phase within the Phase Average options.	Software Bug	Fixed
5597	When editing records in a PSH, the running average period is reset to zero rather than being set by the parameters stored in first record to be edited.	Software Bug	Fixed
5598	Cannot create SOPs as a standard Windows XP user.	Software Bug	Fixed
5601	The triggering of rapid-mode measurements by scattering level is not working.	Software Bug	Fixed
5618	An import configuration can be created without having any import parameters set, causing the software to crash when the configuration is saved.	Software Bug	Fixed
5631	If the running average period is set as a multiple of the measurement period then rounding errors can occur.	Software Bug	Fixed

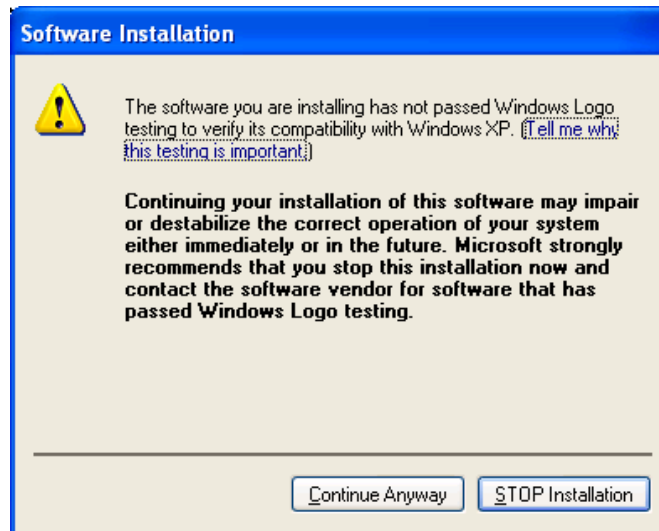


SCR	Description	Comments	Status
5634	The analysis fails when the lower limit of the analysis is set to a value greater than 4 microns using the analysis range option.	Software Bug	Fixed
5637	The event counter within the measurement manager window fails to advance when carrying out measurements which are less than 30msec long.	Software Bug	Fixed
5644	If user sizes are active the PSD result exported to text is normalised to 100%, but if user sizes are off the result is normalised to 1.0.	Software Bug	Fixed

Known Issues

Windows Logo Testing for Windows XP

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



This warning can safely be ignored during the installation process as the software has been thoroughly tested using Windows XP. You should click “**Continue Anyway**” to proceed with the installation process.

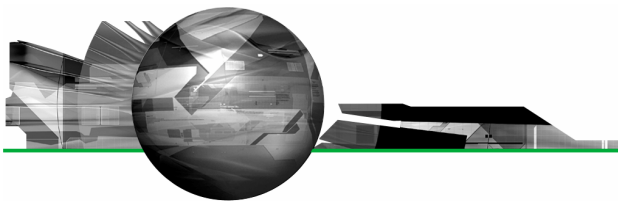
USB Detection

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 second 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).

Menu Structures

The Spraytec software uses a new menu structure which is different to that used on the Mastersizer 2000 and Zetasizer Nano products. This has been designed to allow new users to more easily find typical software options for creating and editing files. The most noticeable difference is the removal of the “**Configure**” menu, which previously provided access to SOP management options. SOP management is now carried out using the following options:

Previous Menu Location	New Location
Configure-New SOP...	File-New SOP...
Configure-Existing SOP...	File-Open SOP...

Please refer to the software’s on-line help to obtain details as to how each of the menu commands operates.

Log-Normal 2-Parameter Model Calculations

The changes made under SCR5531 will cause log-normal calculations made under this version of the software to be different from those calculated using version 1 of the Spraytec software. The changes made should provide a more realistic estimate of the best-fit log-normal curve for a given result.

Average Calculations

Numerical validation of the un-weighted size distribution averaging process used in the Spraytec software revealed a bug in the averaging process. This has been corrected in this version of the software under SCR5536. However, the changes made will cause a shift in the average parameters calculated. Users will need to recalculate results produced using version 1.0 in order to obtain comparability.

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.

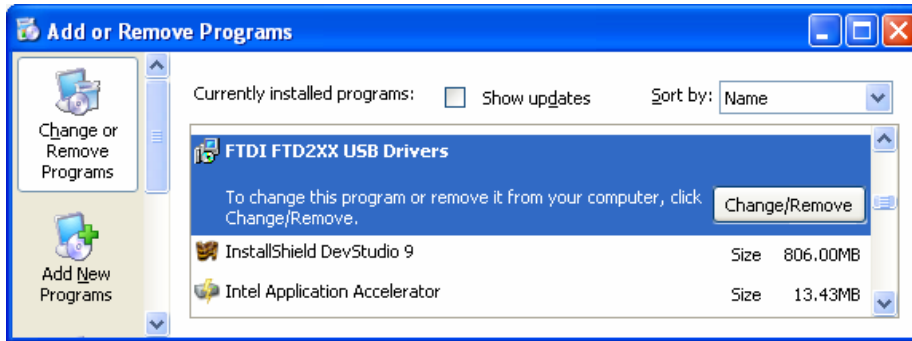
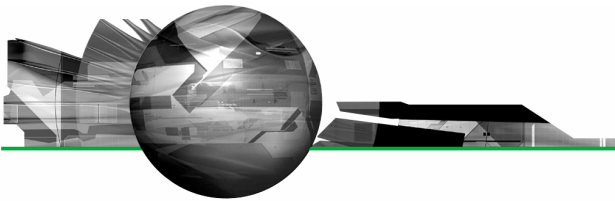
For support purposes, the Malvern Instruments Helpdesk may request that you send data for analysis. To enable this, it is possible to export individual Particle Size History files (*.PSH) from within a SMEA file. To do this, open the PSH file and then use the **File-Save As...** menu option to save the file to disk.

Update of USB drivers for Alpha Software

Note: This must be complete **before** the old software is uninstalled.

To avoid problems when installing the USB driver it is necessary to manually uninstall the old USB drivers if an alpha version of software has previously been used.

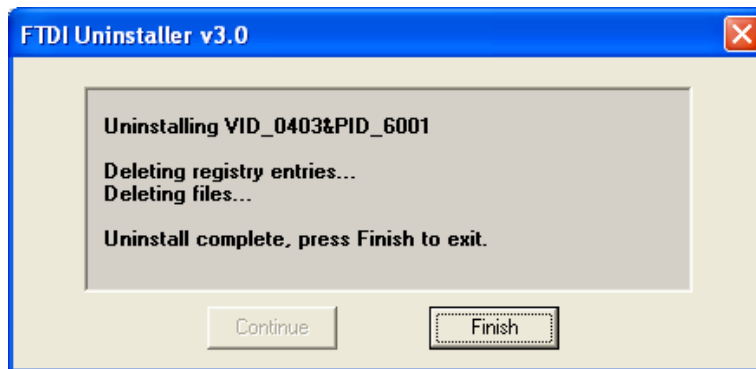
From the control panel select Add/Remove Programs, select FTDI FTD2XX USB Drivers and press the ‘**Change/Remove**’ button:



This will result in the following dialog appearing:



Disconnect the instrument if it is connected and press the 'Continue' button. The dialogue should now display text similar to the following:

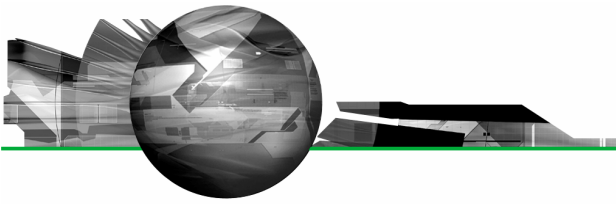


Press the 'Finish' button and proceed with the software installation process as described above.

Update of Manual Measurement for Alpha Software

In order to ensure that problems are not encountered when running manual measurements the following steps should be taken during the installation if an alpha version of software has previously been used.

1. Uninstall the existing software as normal using the standard Add/Remove feature in the Windows 'Control panel'.



2. Delete the 'mansettings.dat' file from within the Spraytec SOP directories. This can be found at the following location:
'C:\Documents and Settings\All Users\Documents\Malvern Instruments\Spraytec\SOP'
3. Install the software referring to the instructions given above.

SOP problem for Alpha Software

In moving from the last alpha version of this software to the release version the format of the laser intensity value displayed within the measurement manager has changed from being a value in counts to being expressed as a percentage of the maximum possible laser output. This has required the format of the SOP dialogues relating to the minimum transmission signal warning and error levels to change to support percentage-based laser intensity values. These settings are found in the background alarms section of the SOP and are applied if "Use default values" is deselected. This means that for any SOPs created with the alpha software these values need to be updated to appropriate values expressed as a percentage of the maximum laser intensity unless the default values are used.

Data format change for Alpha Software Users

The units for the laser power measurement have been changed in moving from the alpha versions of the Spraytec software to this release version. The laser power, shown on the transmission signal detector within the background view (channel 0), was previously stored as a raw "counts" value. It is now expressed as a percentage of the theoretical maximum output of the laser system. This change will cause a zero value to be shown for the transmission signal detector within the background view (channel 0) when measurements carried out using alpha software are reviewed using this 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 SOP 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.

Rapid Measurement

Events

Number: 1 Duration per event: 400.0 ms

Measurement trigger

Trigger type: Transmission drops to level Transmission: 98

Data collection

Start: 50.0 ms Before the trigger

Advanced

< Back Next > Cancel Help