



Software Update Notification



PSS0024-07: Spraytec v3.02 software

Abstract

This document details the release of software PSS0024-07 – v3.02 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	1 Gbyte
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

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 tested using Windows 2000 Professional, Windows XP professional is the preferred operating system.

Note: This software version is not compatible with the Windows Vista operating system.

Note: The updates associated with Windows XP Professional Service Pack 3 can cause problems with file storage within the Spraytec software. Please read the 'Known Issues' section below if you are planning to install or have installed Service Pack 3 on your 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.

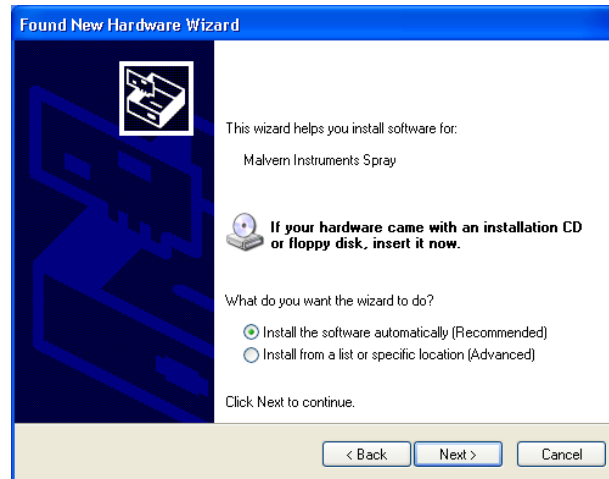
USB Driver Installation

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 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 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.

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 new features which are present in v3.02 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

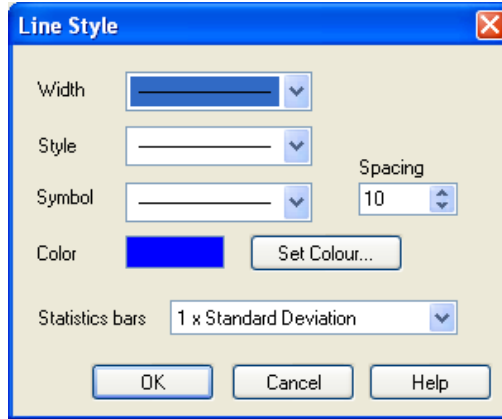
Ensemble averaging is for use on samples either where several repeat measurements are made – such as with nasal sprays – or where the sample has a natural repetitive nature – such as fuel injection in an internal combustion engine. The purpose of the ensemble average is to provide a particle size history (*.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

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

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

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.



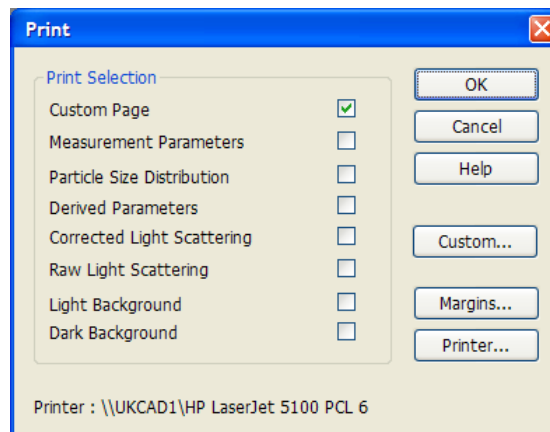
Auto-Increment of Lot Value

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.

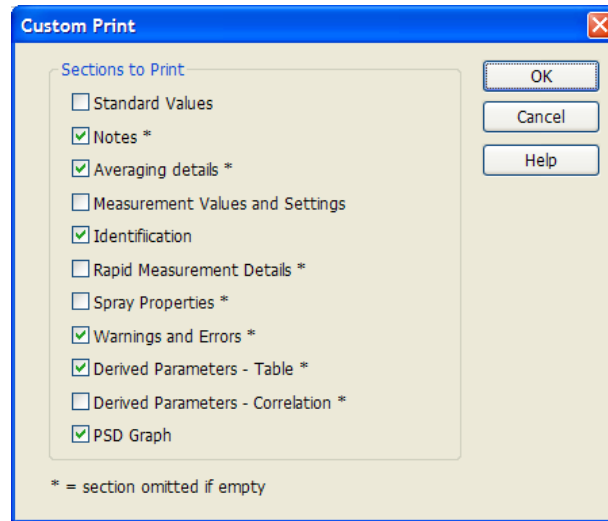
Auto-increment setting	Action
No	No auto-increment. If the lot value is not locked the operator may enter anything into the lot value edit box.
On Triggers	During a rapid-mode measurement the lot value field is incremented at each trigger. The starting number is entered by the operator (if the lot value 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

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.



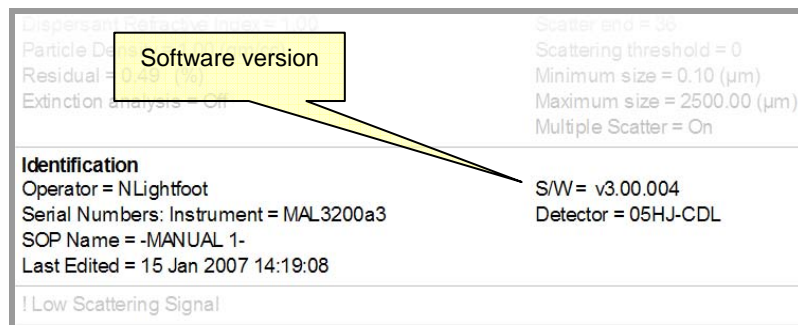
Clicking the 'Custom...' button shows a dialog where the contents of the custom page may be configured:



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.

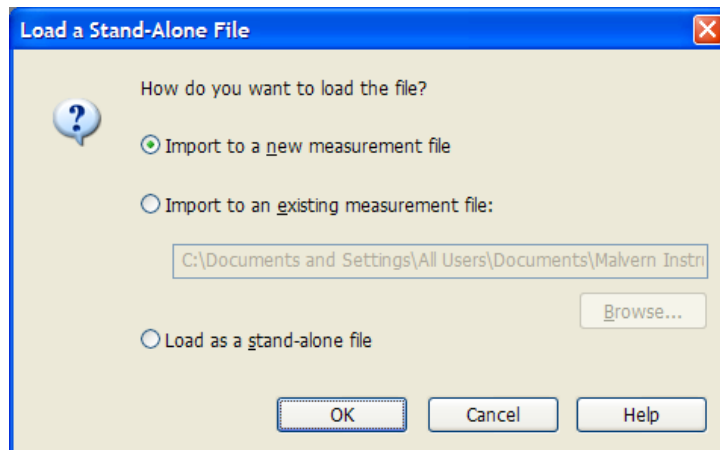
Software version number

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

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.

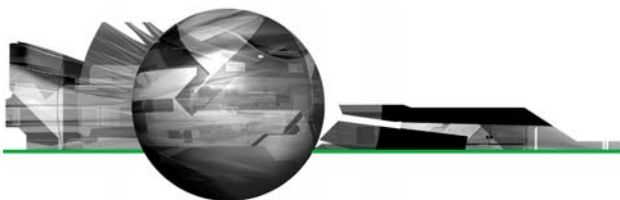
Fixed Issues

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

SCR	Description	Comment	Status
7002	Manual alignment misses steps, making alignment difficult.	Bug	Fixed
7246	Software does not check the amount of free disk space available correctly	Bug	Fixed

This version also includes the following changes which were first implemented in Spraytec v3.01 software:

SCR	Description	Comment	Status
6668	Validation of Spraytec NSS accessory position does not work at 0 degrees	Bug	Fixed
6703	Averaging of extinction channel incorrect for data-based averaging	Bug	Fixed
6707	Problems with manual measurements when using the Spraytec NSS accessory	Bug	Fixed



This version also includes the following changes which were first implemented in Spraytec v3.00 software:

SCR	Description	Comment	Status
4922	An option to export data should be provided as part of an SSOP.	Improvement	Implemented
4988	Metatables exported to Microsoft Word appeared clipped.	Bug	Fixed
5296	Group index would be useful for grouped triggered measurements.	Improvement	Implemented
5335	Provide large font for status text in the measurement manager.	Improvement	Implemented
5413	The software version should be recorded in the measurement parameters.	New Function	Implemented
5575	Enable loading if stand-alone files into a new SMEA file.	Improvement	Implemented
5663	Spraytec NSS accessory settings not validated when measurement is started.	Improvement	Implemented
5705	Provide number distribution calculations.	New Function	Implemented
5719	No units are displayed on the user sizes dialogues.	Bug	Fixed
5739	No range checking is provided within the user sizes editor.	Bug	Fixed
5745	Verification of delay on a rapid measurement SSOP is incorrect.	Bug	Fixed
5764	Make the function of the "Install Feature Key" menu option more obvious.	Improvement	Implemented
5824	Template SSOPs missing from the v2.00 install file set.	Improvement	Implemented
5940	Allow recall of previous display settings for Overlay reports.	Bug	Fixed
5988	Allow the PSD and Derived Parameters to be printed in a single report.	Improvement	Implemented
5989	Allow the Spray Shot Number to be logged in the software.	Improvement	Implemented
5991	Auto-increment does not operate within the sample details dialogue.	Improvement	Implemented
5992	Do not allow "OK" to be accessed until the Spraytec NSS is in the correct position.	Bug	Fixed
5995	Allow more than 8 results to be over plotted in an Overlay report.	Bug	Fixed
6018	The data exported for invalid results is incorrect.	Bug	Fixed
6029	Data import does not work when using "," as a decimal separator.	Bug	Fixed
6222	Laser needs to be turned off for aborted Spraytec NSS SSOP.	Bug	Fixed
6267	Cannot set up a phase average calculation for all 3 spray phases.	Bug	Fixed
6271	Averaging of scatter data takes the threshold detector setting from the first record.	Bug	Fixed
6321	User defined 21 CFR settings not retained for subsequent installs.	Bug	Fixed
6372	Backup files may have missing file extension and therefore cannot be opened.	Bug	Fixed
6375	Batch No. Label and Value printed incorrectly on reports.	Bug	Fixed
6376	Limit SSOP file name length to 32 characters.	Improvement	Implemented
6377	Setup mode required for extraction systems.	New Function	Implemented
6378	Creation of multiple files with same name during SSOP running.	Bug	Fixed
6379	Creation of multiple files with the same name during software boot up.	Bug	Fixed
6423	New lines do not appear properly on German printouts.	Bug	Fixed



6424	Invalid characters appear in German SSOP error message.	Bug	Fixed
6472	Serial number does not appear as a measurement parameter for new measurements	Bug	Fixed
6484	Provide data kill to detector 25.	Improvement	Implemented
6499	Change dialogue text for wet measurement cell in SSOP editor.	Improvement	Implemented
6549	File types not registered by the application.	Improvement	Implemented
6551	Continuous measurement SSOP template has the wrong particle type selected.	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

Operation with Windows XP Professional Service Pack 3

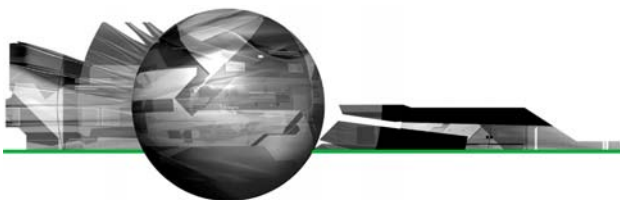
Service pack 3 for Windows XP Professional has introduced a series of security fixes which affect the operation of the Spraytec software. The updates made within this service pack cause all Spraytec measurement files to appear as if they are read-only from within the Spraytec program, preventing users from editing results. At the moment the only work-around for this issue is for users to uninstall Service Pack 3 from their computers. This will restore the correct operation of the Spraytec software.

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 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).

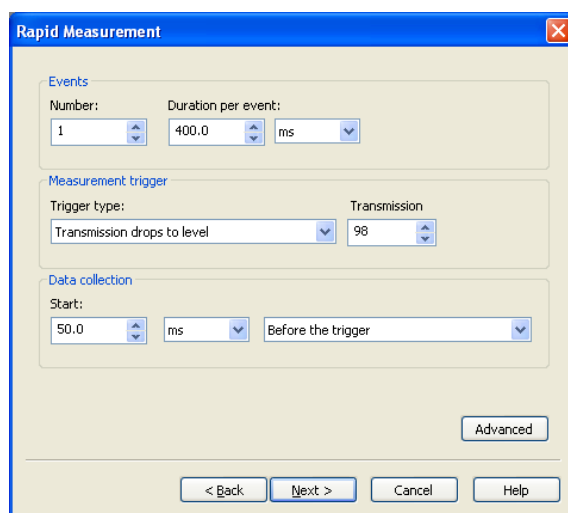
File Sizes

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.

Configure ER/ES options

Acrobat Settings
Adobe® Acrobat PDF file output directory:

 Allow the PDF filename to be changed (not recommended)

Security Settings
 Prohibit record Deletion Prohibit record Editing
 Enable Continuous Use Check
Timeout: Minutes
 Show last user at logon (not recommended)

Audit Trail Settings
Audit Trail file output directory:

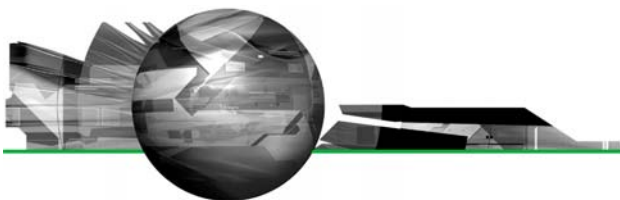
Begin new Audit Trail file:

Record Back Up Settings
Edit records back up directory:

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 (Windows XP and 2000) 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. If the sample name contains invalid characters then the software may fail to create the measurement file and any average data files at the end of the measurement process.