

SOFTWARE UPDATE NOTIFICATION



PSS0024-04: Spraytec v3.00 software

Abstract

This document details the release of software PSS0024-04 – v3.00 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:

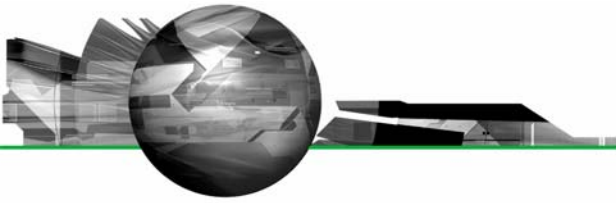
| Feature | Specification |
|--------------------------|---|
| Processor Type | Pentium P4 2.8GHz |
| Memory | 512Mbyte |
| Hard Disk Storage | 80Gbyte |
| Additional Storage Media | CD-ROM drive |
| Display Resolution | 1024 x 768 |
| Connectivity | 1 USB port |
| Operating System | Windows XP Professional™ 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.

Note: This software version is not compatible with the Windows Vista operating system. An update is planned for the second half of 2007 which will enable the use of the Spraytec software using this 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.

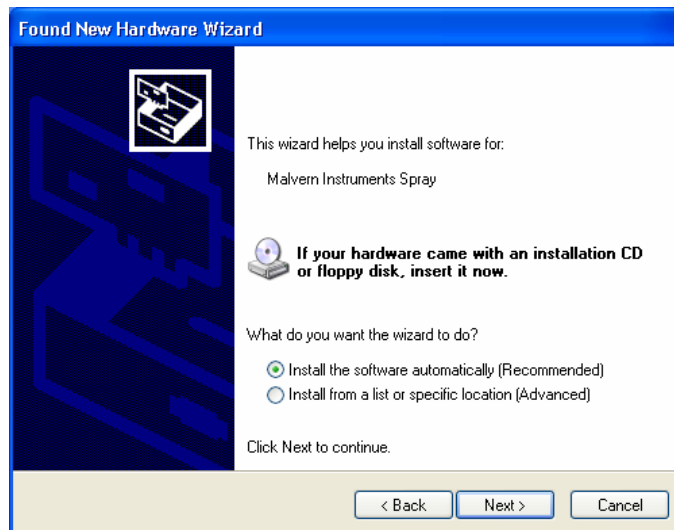
USB Driver Installation

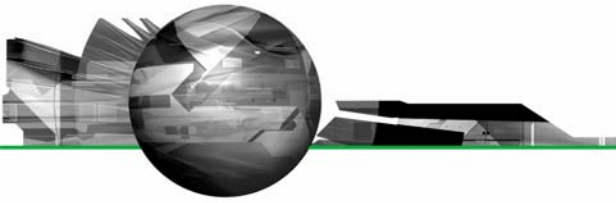
The Spraytec system uses a USB connection to allow the software to control the measurement hardware. This requires a specific USB driver to be installed when the software is first run after installation. Installation of this driver requires the instrument to be connected when the software is started.

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 **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


The following sections describe the new features which have been developed for v3.00 of the Spraytec software. 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. These can be downloaded from Malvern Instruments' web site.

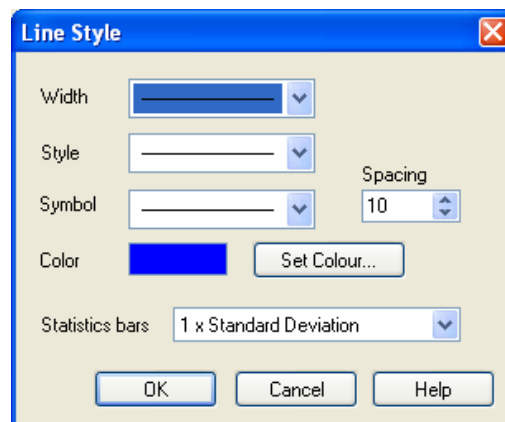
Ensemble Averaging

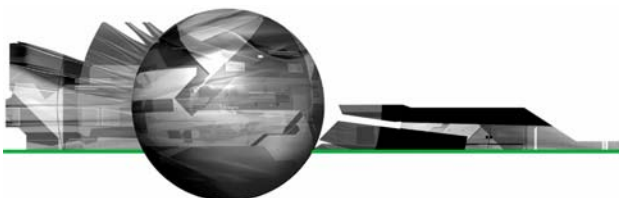
Ensemble averaging is for use on samples either where several repeat measurements are made – such as with nasal sprays – or where the sample has a natural repetitive nature – such as fuel injection in an internal combustion engine. The purpose of the ensemble average is to provide a particle size history (*.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 v3.00 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 SOP allows you to choose to have the result reported as a number distribution.

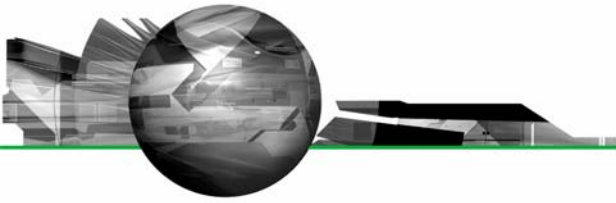
In earlier versions of the software the volume-based nature of the result was inherent; for example, the percentile values were denoted as **Dv** – a volume diameter. On the result views these are now shown as **Dn** for a number distribution. In some cases the result type is not yet known and in this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

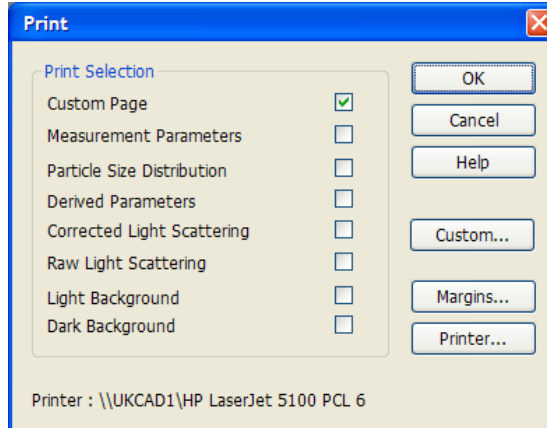
The lot-value is one of the documentation labels that may be entered by the SSOP designer and optionally edited when an SSOP is run or when a measurement is edited. This version of the Spraytec software includes an option to automatically increment the lot value at certain points during the measurement 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 SOP 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 SOP Repeats | This behaves in the same way as auto-increment on SOP runs but also increments when the option taken to repeat a SOP measurement. |

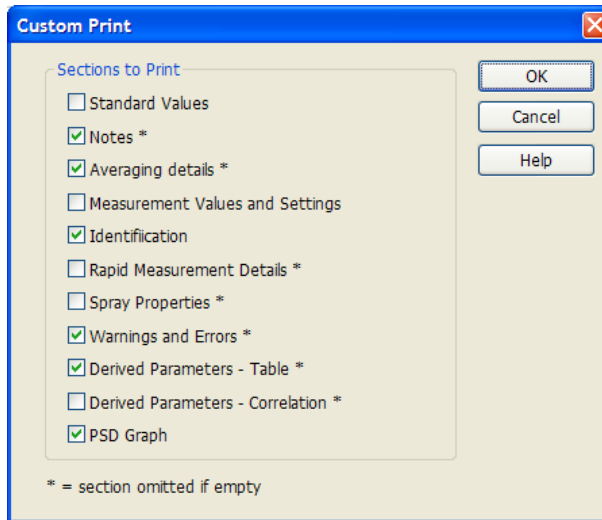


Custom Print Report

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.



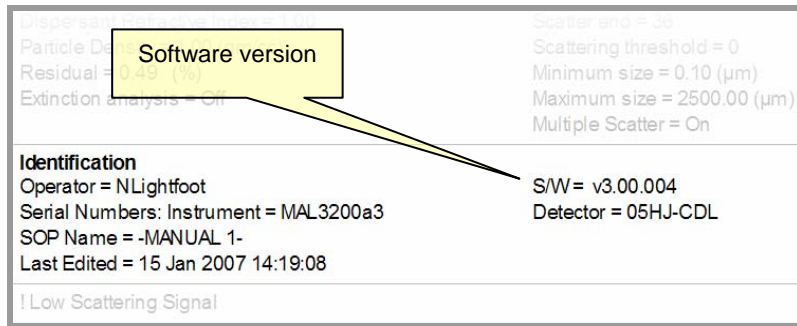
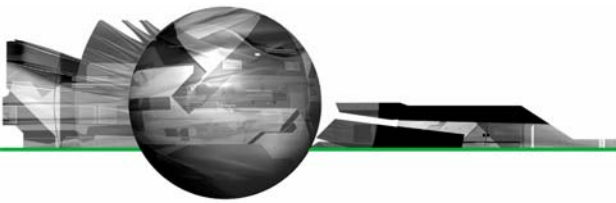
Clicking the ‘Custom...’ button shows a dialog where the contents of the custom page may be configured:



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.

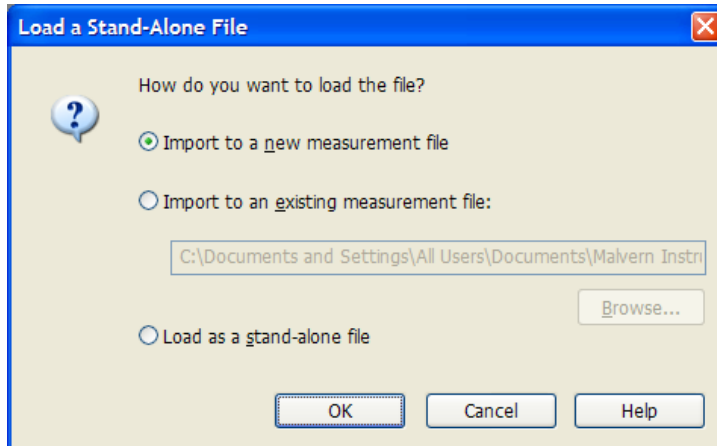
Software version number

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

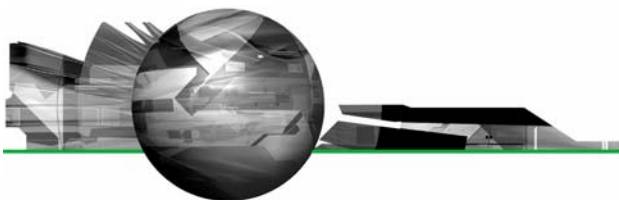
It is sometimes convenient to save a size-history (PSH) or size-distribution (PSD) as a stand-alone file. These files are smaller than Spraytec measurement files (SMEA) so are more convenient for e-mailing to other users, for example. Previously these could be opened in Spraytec as read-only stand-alone 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. |

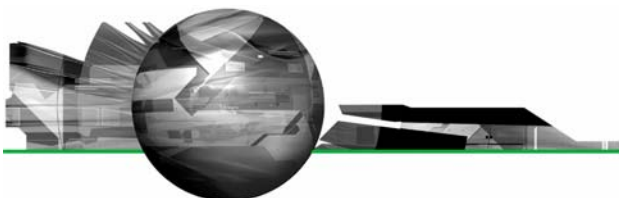
The advantage of importing the file is it may then be edited and the data it contains may be averaged. In 21 CFR Part 11 mode the import process is audited.



Fixed Issues

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

| SCR | Description | Comment | Status |
|------|---|--------------|-------------|
| 4922 | An option to export data should be provided as part of an SSOP. | Improvement | Implemented |
| 4988 | Metafiles 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 SOPs 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 SOP 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 appears 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 SOP editor. | Improvement | Implemented |
| 6549 | File types not registered by the application. | Improvement | Implemented |
| 6551 | Continuous measurement SOP template has the wrong particle type selected. | Bug | Fixed |
| 6552 | Overlay files do not display dark backgrounds. | 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

Windows Logo Testing for Windows XP

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

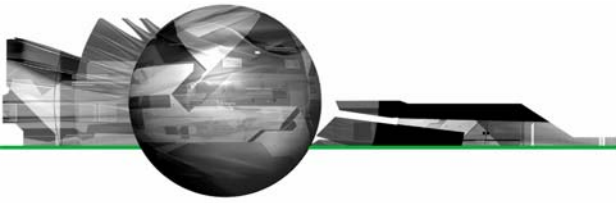


This warning can safely be ignored during the installation process as the software has been thoroughly tested using Windows XP. You should click “**Continue Anyway**” to proceed with the installation process.

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 third 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 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

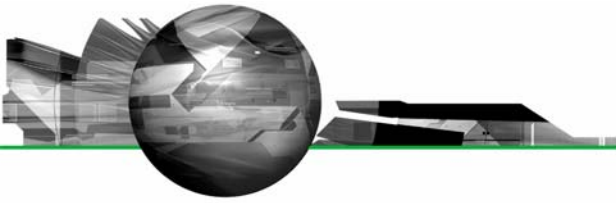
Trigger type: Transmission drops to level Transmission: 98

Data collection

Start: 50.0 ms Before the trigger

Advanced

< Back Next > Cancel Help



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.

