
Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 1 of 23

RTSizer v5.50
Application Software for use with (English) Microsoft
Windows NT, Windows 2000 and Windows XP

Spraytec

(Part Number PSS0007-04)

Software Update Notification



1 Contents

1	Contents	2
2	Introduction	4
3	Instrument Compatibility	4
4	Functional Features	4
4.1	Planned Additions	4
4.1.1	21CFR11 Support	4
4.2	Requested Additions and Changes	5
4.3	Deletions	7
5	Known Bugs	7
6	Known Issues	7
6.1.1	English Language Only	7
6.1.2	No Support for Insitec	7
6.2	Re-installation of 21 CFR part 11 support	7
6.3	Security access rights with NTFS	7
7	Distribution Media	8
8	Installing the Software	8
8.1	System Requirements	8
8.2	Standard Installation From CD-ROM	8
8.3	Installation from Floppy Disk	9
9	New Software Features	9
9.1	Data Export Template Improvements	9
9.2	Time history display format	11
9.3	Flash measurement - averaging part of a measurement	12
9.4	Global SOP settings file	14
9.5	Requirement for consistent averaging	15
9.6	Export of time history records	17
9.7	Printed time-history chart no longer has statistics table	17
9.8	The PCV printed report table format	17
9.9	Error reporting	18
9.10	21CFR11 Functions	18
9.10.1	21 CFR11 Enabled Mode	18
9.10.2	Recall of last user at login	19
9.10.3	Updated Security Display	19
9.10.4	Option to disallow changing the name of PDF files	20
9.10.5	Date/Time stamping of measurements	20
10	Bug Fix Details	21
10.1	Loading read-only size history files	21
10.2	Removal of 'Temp' files	21
10.3	Exported size history data has repeated headers	21
10.4	Using RTSizer when not a Windows administrator	21
10.5	Errors in flash measurement group averaging	22
10.6	Saving default settings	22
10.7	Flash measurement notes should not be overwritten	22

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 3 of 23

10.8	Registry settings for instrument are not accessible by non-administrators.....	22
10.9	Printing – title header overlaps date.....	22
10.10	Problem with display of refractive index values.....	22
10.11	21CFR11 functions	23
10.11.1	Noise and Background update period under control of security policy	23
10.11.2	Disable overwriting of settings files in 21CFR11 mode.	23
10.11.3	Audit trail file location	23
10.11.4	Security password expiry	23

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 4 of 23

2 Introduction

This is version 5.50 of the RTSizer application software. The software is tested and supported on the following Microsoft Operating Systems: Windows NT 4.0™ (service pack 6a and higher), Windows 2000™ Pro (service pack 4 and higher) and Windows XP™ Pro (service pack 1a or higher). Windows 2000™ Pro is the recommended platform. The software is provided on one auto-loading compact disc (CD).

3 Instrument Compatibility

The RTSizer v5.50 software is back compatible with all previous releases of RTSizer v5.xx. The changes made to the software in this release are to support the Spraytec instrument only.

4 Functional Features

4.1 Planned Additions

4.1.1 21CFR11 Support

The security requirements of 21 CFR Part 11 are more stringent than previously required. In order to comply with these, the Access Level security system previously provided within the RTSizer software has been replaced with a new security system. This provides:

- Independent security system from the Windows NT™ security system, allowing multiple users to use the Spraytec system without the need to log in and out of Windows NT™.
- Fully configurable users and groups.
- Fully compliant with 21 CFR Part 11 requirements '11.200 Electronic signature components and controls' and '11.300 Controls for identification codes/passwords'
- Encrypted passwords.
- Encrypted security settings file.
- Log in and out of the application without shutting it down.
- Continuous use check.

Audit trail functionality is provided within the software so that an external auditor can review the measurement process. This includes:

- Auditing of security events such as logging in and out of the system.
- Auditing of main software functions.
- Auditing of measurement record creation, editing, and deletion.
- Audit trail viewing and export to ASCII for review.

Support for Electronic signatures is provided through the use of Adobe Acrobat. Details of the 21CFR11 features included in the software can be found in the 21CFR11 user guide included on the software CD-ROM (**21CFR Part 11 User Guide for Spraytec (MRK535-01)**). Full information on the use of Adobe Acrobat® can be found in the technical note "**Creation of Digital Signatures (MRK532-01).pdf**". Finally, the document

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 5 of 23

"21CFR Part 11 Compliance Guide for Spraytec (MRK536-01)" provides some background information regarding 21CFR11 and the Spraytec software.

4.2 Requested Additions and Changes.

The following software additions and changes have been implemented in RTSizer v5.50:

Malvern Software Change Request Number	Description	Comments
2146	Global settings file developed to store measurement settings.	Improvement
2179	RTSizer fails to work when data directory is set to read-only	Fixed
2625	Security problems found in RTSizer v5.41	Fixed
2668	Temp file not removed following flash-mode measurements	Fixed
2669	Export file header is repeated throughout an export file when data filtering is used	Fixed
2670	Size History display format changed to allow relative measurement times to be viewed.	Improvement
2748	Audit Trail file location does not default to the correct directory.	Fixed
2901	System settings are not recalled when logging in as a non-administrator.	Fixed
2996	Date / Time Stamping in 21CFR11 mode should use an unambiguous format.	Improvement
2998	As default the security system should not recall the username of the last user when 21CFR11 mode is enabled.	Improvement
2999	Data Reporting Interval incorrect when using data filtering / grouping options	Fixed
3020	Nasal Spray Macro required to specify the Fully Developed phase.	Improvement
3021	Add support for Numerical Validation of the software	Improvement
3022	The flash mode settings need to be stored in the record file in a more robust way.	Improvement
3025	The software does not always recall the correct default measurement and display settings.	Fixed
3027	Need to change report formats so that the averaging method used when reporting results is consistent across all reports.	Improvement
3289	Error flag in PCL record stays permanent even when the software is rebooted	Fixed
3464	Support required for Adobe Acrobat v5 and v6 in order to provide an Electronic Signatures solution.	Improvement
3535	Provide an option to not allow PDF file to be re-named when printing to PDF.	Improvement
3606	Noise and background update period editing should be controlled by the security system.	Fixed
3607	Measurement and display settings files must not be overwritten when in 21CFR11 mode.	Fixed
3609	The software registry settings are accessible to non-administrators	Fixed
3688	The software should default to text file format when exporting data	Improvement
3689	The software should use a default export file name that is the same as the current PCL file name.	Improvement
3730	Remove statistics table from particle size history chart printed report.	Improvement
3784	Add contents of the cover page to the top of the PCV table report.	Improvement

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 6 of 23

Malvern Software Change Request Number	Description	Comments
3790	Printing – header information overlaps the measurement date for average PSD reports.	Fixed
3791	PCV averages should not be reported when the PCV definition changes within the selected data range.	Fixed
3906	Custom refractive indices are not displayed on reports if the PCL file is on a different hard drive to the RTSizer software.	Fixed
3984	Security client updates – enable the display of accounts which are locked-out and disabled accounts with the Security Configuration view.	Improvement
3985	Automated reporting of fatal errors in the program direct to Malvern Instruments	Improvement

RTSizer v5.50 contains the following software additions and changes, which were implemented in RTSizer v5.41:

Malvern Software Change Request (SCR) Number	Description	Comments
2565	Allow time history printing and averaging in the case where the selected range includes measurements at greater than 100% transmission.	Implemented

RTSizer v5.50 contains the following software additions and changes, which were implemented in RTSizer v5.40:

Malvern Software Change Request (SCR) Number	Description	Comments
2043	Changes export function to export time in seconds into a separate column.	Implemented
2047	Change software messages for background and size measurements so that they are less confusing for Spraytec customers.	Implemented
2143	Add the option to include an information header in any exported files.	Implemented
2145	Add an export and import function for the flash mode measurement settings.	Implemented

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 7 of 23

4.3 Deletions

Software modules relating to the use of the RTSizer software for process measurements have been deleted from RTSizer v5.50. In addition, all references to Process Control Outputs (PCOs) have been removed.

5 Known Bugs

There are no known bugs at the time of this release. If you suspect that you have discovered a bug, you should report this to Malvern Instruments detailing all aspects of the symptoms.

6 Known Issues

6.1.1 English Language Only

The changes made to the software are only for the English-language version. If the software is run on French, German or Japanese version of Windows then the text that is inherited from previous versions of the software will appear in the correct language but new text will appear in English.

6.1.2 No Support for Insitec

The changes made to the software are to support the Spraytec instrument only. The modules used for process application such as the valve and process controllers and RTSizerX have not been modified or tested for use with RTSizer v5.50.

6.2 Re-installation of 21 CFR part 11 support

Removing an earlier version of RTSizer 5.x with 21 CFR part 11 support will remove the enabling key information. After RTSizer v5.50 is installed you will have to re-enable 21 CFR part 11 support by using the **Tools->Install Feature Key** command and typing in the same feature key code you used for RTSizer v5.4x. Please contact your Malvern Representative if you no longer have the required code.

6.3 Security access rights with NTFS

With the Windows NT file system (NTFS) it is possible to secure folders and files so that non-administrators have limited access. The file 'c:\rtswin\settings\security.cfg' contains the RTSizer security data and should be protected from change by all users other than the administrator. It is recommended that only the RTSizer administrator logs in as Windows administrator; all other RTSizer users should be logged in as normal Windows users. Note that the other files in the 'settings' directory **must** be given full access to all users.

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 8 of 23

7 Distribution Media

RTSizer v5.50 is contained on a single self-installing CD-ROM. The installation process has been fully automated by the industry standard software installer InstallShield™. Any fault during the installation process will be detected and the user is notified. The installation process has been tested on all the supported configurations of operating system.

8 Installing the Software

8.1 System Requirements

The software requires an IBM compatible computer with a Pentium Class Processor (300MHz or faster), 3 Gigabytes of free hard disk space, 128Mbyte Memory, CD-ROM and 1024x768 display in order to operate correctly. 1 free serial port and **1 free full-length ISA slot** is required when running the software on the computer system which is to be connected to the Spraytec instrument. As mentioned above, the software is tested and supported on the following Microsoft Operating Systems: Windows NT 4.0™ (service pack 6a and higher) and Windows 2000™ Pro (service pack 4 and higher) and Windows XP Pro (service park 1a or higher).

8.2 Standard Installation From CD-ROM

All data is the user's responsibility. It is good practice to backup all data files on a daily basis. It is also good practice to backup all data before installing new application software.

Note: Windows NT / 2000 / XP will not allow an installation if the user does not have Administrator access. This is in line with Microsoft's Logo policy and is standard practice.

This is v5.50 of the RTSizer software suite and is for Spraytec instruments only. In earlier versions of this software some of the component modules had separate installation programs. In this version the flash measurement module and multiple scattering module are automatically installed.

Before starting the install you should remove any earlier v5.xx version of RTSizer. In Windows Control Panel select the Add/Remove Programs icon. In the Add/Remove Programs window select the 'RTSizer' option and click 'Add/Remove'. The RTSizer software will be removed. Answer 'Yes' to any questions about removing DLLs from the system directory. Repeat the remove operations for the 'RTSizer Flash Mode' and 'RTSizer Multiple Scattering Module' if these are present in the program list.

Put the RTSizer v5.50 CD in the drive. The CD should auto-start but if it does not use Explorer to start the application SETUP.EXE in the root directory of the CD. In common with the earlier versions of RTSizer this software will be installed in the folder C:\RTSWIN.

The install program may need to re-boot your PC up to two times. If the setup program does not automatically re-start after re-booting use Explorer to run the SETUP.EXE program in the root directory of the CD to continue the install process.

The install program puts a shortcut on the desktop and two shortcuts in **Start->Programs->Malvern Instruments->RTSizer** menu - one for normal use and the other for starting the software in simulation mode. There is also a shortcut for showing the RTSizer help.

Note: The Uninstall Shield has a list of programs and files which it originally installed and it can therefore correctly delete them. This means that it cannot delete your data files as they will not be on the list of files to be uninstalled.

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 9 of 23

8.3 Installation from Floppy Disk

For installation on a PC that does not have a CD-ROM drive, you should follow the steps listed below:

1. Copy the contents of each named disk directory (i.e. disk 1, disk 2, etc) from the '144MB' directory on the installation CD-ROM onto some similarly labelled floppy disks.
2. Put disk 1 into the floppy drive of the target computer. Using Windows Explorer, select the floppy drive and double-click on 'Extract.exe'.
3. When requested change to the next disk.
4. When the setup program has been extracted it will start automatically. Follow the on-screen instructions in order to install the RTSizer software

9 New Software Features

A number of new features have been added to the RTSizer software (v5.40 and higher) in order to allow it to be operated in a 21CFR Part 11 compliant environment. The features associated with 21CFR11 and the new RTSizer security system are described in separate reference documents included on the software installation CD-ROM. In addition, improvements have been made to the data reporting, data export, measurement parameter recall and averaging functionality within the RTSizer software. These are described in detail below with instructions on their implementation. These features are new to RTSizer v5.50.

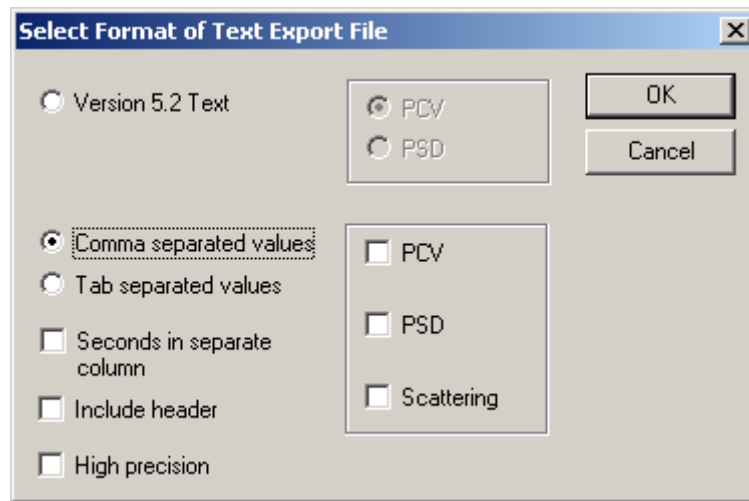
Any feedback should be reported to Malvern Instruments via email to helpdesk@malvern.co.uk or by telephoning the Helpdesk directly on +44 (0)1684-891800. Please have the serial number of your Spraytec system and the software version to hand when contacting the helpdesk.

9.1 Data Export Template Improvements

The data export process used to export time history data into a spreadsheet program has been improved to allow more flexibility and easier spreadsheet formatting.

To use the export feature you first need to select the range of results you wish to export from the time history using the yellow cursor. The export process is started using the **File->Export Data** menu command. You must choose the data to be exported in the next dialogue box (either chose the **Range** you selected from the time history; **All** the data currently in the active data file; all the data currently viewed on the **Screen** or just the **Current** result). Then, at the next dialogue box select to export the data to a text file by changing the file type. This will then bring up with following dialogue box:

Software Update Notification



From this dialogue you can select the following output formats:

- **Version 5.2 Text** – This outputs the data in the same format as RTSizer v5.20. This is provided to offer compatibility with any external macros you may have written to process v5.20 export data. Output of the Process Control Variables (PCVs) or Particle Size Distributions (PSDs) at each time point is available.
- **Comma Separated Values** – Produces a text file following the standard CSV format. This allows for easier formatting in external software packages. Using this format you can select to export the PCVs, PSDs or the Scattering Data associated with each time point. It is possible to include a file header containing all the important instrument and analysis parameters in order to improve data traceability. Finally, the time for each point is exported in hrs:min:sec format as standard. However, for flash mode measurements it is possible to separate the seconds into a separate column. This makes it easier to process time-points where the time in seconds is expressed to an accuracy of 4 decimal places.
- **Tab Separated Values** – Produces a text file following the standard Tab-Delimited format. Again, this allows easy formatting in external software packages. The same output options are available in this format as for the CSV format.
- **Seconds in separate column** – Produces a text file with the time-stamp separated into one column containing the Hour and Minute reference and a separate column containing the Seconds reference. This allows for easier plotting of data produced using Flash mode.
- **Include Header** – This option includes the measurement header information at the top to the data file when enabled.
- **High Precision** – This option has been included to support software numerical validation. Enabling this option increases the precision of the exported values to avoid rounding errors. The format of the export file is also changed when exporting PSD data. **As default this option should be disabled.**
- **PCV** – Enabling this option outputs the PCV values specified for each point in the selected measurement range into the export file.
- **PSD** - Enabling this option outputs the particle size distribution information for each point in the selected measurement range into the export file.

- **Scattering** - Enabling this option outputs the scattering data recorded for each point in the selected measurement range into the export file.

9.2 Time history display format

Flash and continuous mode measurements may now be displayed on the time-history display with times relative to the start of the measurement or trigger point, rather than with an absolute time stamp. Use the **View->Relative Timing** command with a time-history window selected to toggle the display between absolute and relative times. The command is disabled when old measurement files created using earlier software versions are loaded.

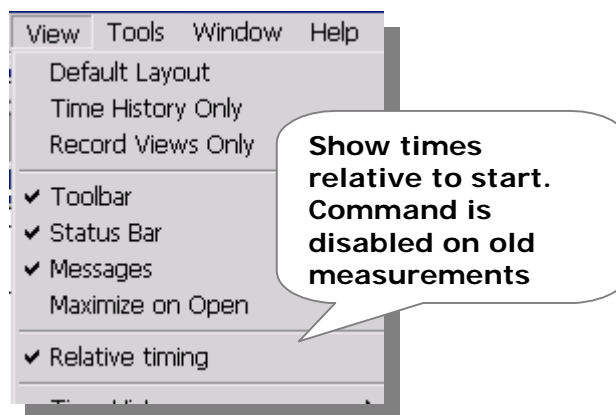


Figure 1 - View Relative Timing menu command

In the flash measurement mode the times reported using the “**Relative Timing**” option are shown with reference the to measurement trigger.

In continuous measurement mode the relative times are set relative to the last “measurement start” event. The time axis cannot show multiple zero times therefore the zero time is only shown for the most recent measure start. Times before this point show only show the date part of the absolute time stamp. Times show in the cover page, PSD and scattering data windows (displayed in the top two display windowpanes when a time history file is loaded) show the times relative to when the currently selected measure sequence was started.

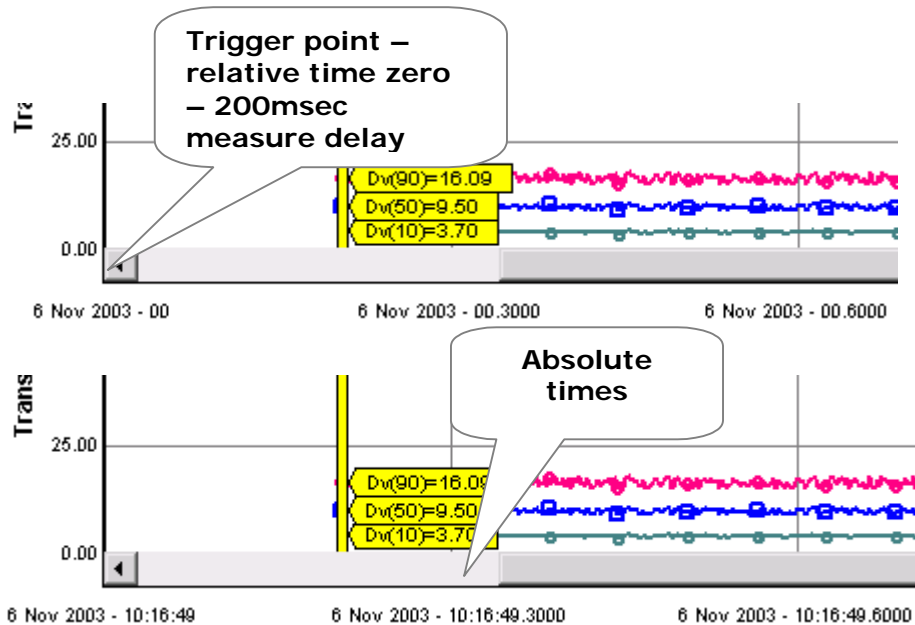


Figure 2 - Size history chart - relative times (top) and absolute times

PSD windows created from a time history either through double-clicking a PSD view, or through calculating an average, may also be switched between showing relative or absolute times (select the **View->Relative timing** command when the PSD view is active). Relative times are identified by showing them with a trailing '(R)' as shown in Figure 3.

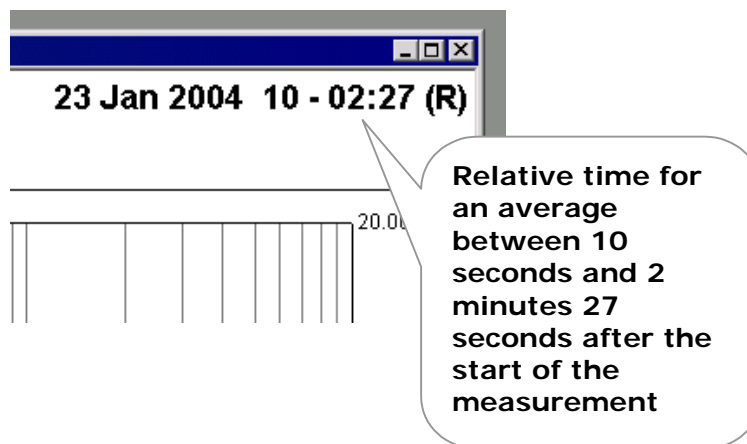


Figure 3 - Part of a PSD window showing relative times for an average

9.3 Flash measurement - averaging part of a measurement

After a flash measurement it is possible to create an average of the time-history data over a user-specified interval. In previous versions of RTSizer this could be done automatically after the flash measurement, but only over the whole of the measurement. RTSizer v.50 adds the ability for the user to enter the time interval over which the average should be calculated (Figure 4). This functionality has been specifically added to aid

users in defining the “full developed” phase when making nasal spray measurements, although it has wider application.

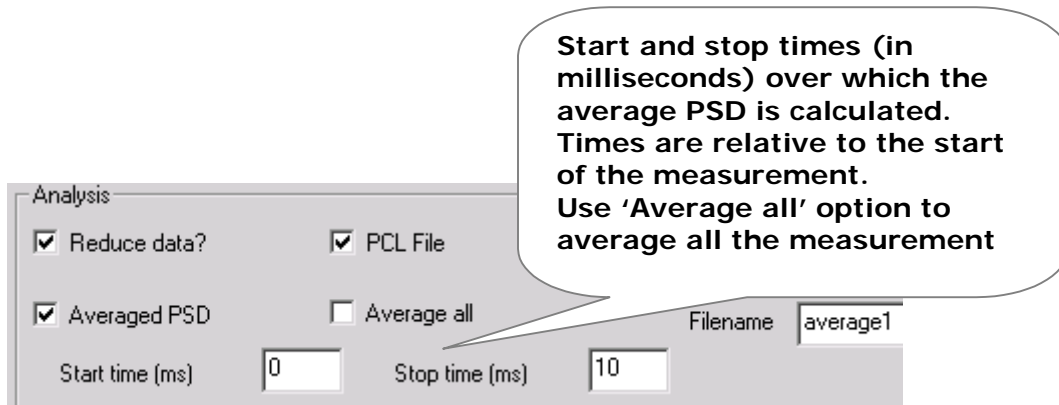


Figure 4 - Part of the flash measurement dialog box showing the averaging options

After the measurement has been done an average over a selected interval may be calculated by using the **Calculate->Average** menu command. In RTSizer v5.50 if the ‘relative timing’ option is enabled (Figure 1) then it possible to set the times in the record selection dialog relative to the measurement start (Figure 5).

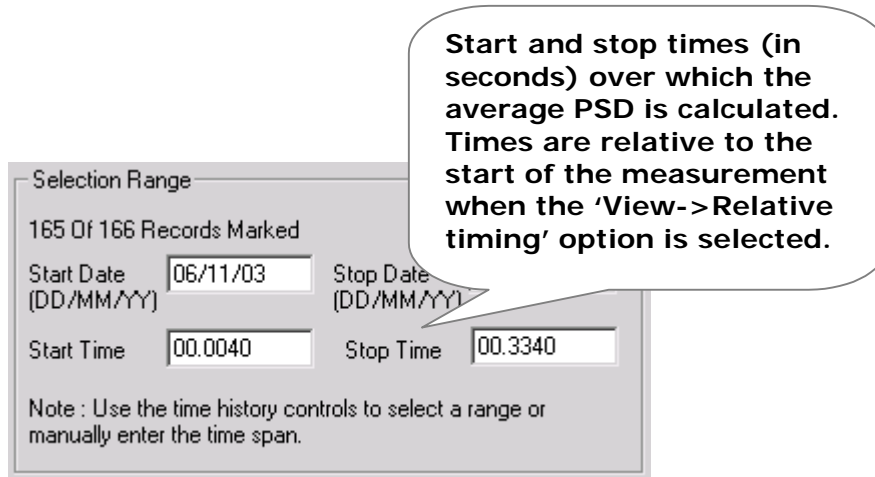


Figure 5 - Part of the record selection dialog showing the relative start and stop time fields

Software Update Notification



9.4 Global SOP settings file

In previous versions of RTSizer the settings that configured the measurement and how the result was processed could be saved to and recalled from a series of settings files; where each configuration section had its own file type (display settings, flash mode settings, reduction control settings, etc..).

RTSizer v5.50 still allows each part of the configuration to be stored separately, including the ability to save default settings. However, a new global settings file format is now provided, allowing users to save a single SOP file that can then be recalled in order to set up an entire measurement procedure. Access to importing and exporting global settings files (file extension '*.rtss') is enabled when the time history or flash mode measurement windows are selected. Settings are exported using the **File->Export Settings->All Settings** menu option (figure 8) when a time history view is active or the **File->Export All Settings** option (figure 9) when the flash mode measurement window is active. Settings are recalled using the **File->Import Settings** or **File->Import All Settings** menu options. The table below shows which configuration items can be saved and recalled for each window type and the security permissions which need to be enabled to allow users to export settings.

Setting	Imported / Exported with Time-history active	Imported / Exported with Flash mode active	Security Permission required to export setting
Reduction control settings	Yes	Yes	Edit reduction control settings
Flash measurement settings	No	Yes	Edit flash-mode measurement settings
PCV definitions	Yes	Yes	Edit process variable definitions
Background duration	Yes	Yes	Edit background and noise measurement duration
Measurement update period	Yes	No	Edit Time-History measurement update period
Display settings for the Time-history chart	Yes	No	Edit Time-History display settings
Setting of 'standard average' (see Section 9.3.2 of this document)	Yes	Yes	Edit 'standard average' setting

If security permissions are set so that the current user may not export one or more of the settings types then these settings are not included in the 'all settings' file. If the user has no permission to export any settings the 'All Settings' menu command is disabled. Global settings files exported with one window type active may be imported with the other window type – settings that are not relevant to the active window type are left unchanged when this occurs.

The name of the current imported global settings file is saved in the notes tag field in the same way as the flash mode settings. To protect the settings file entry in the notes tag there is a new security permission '**Edit Tag Notes**' with the RTSizer security system - if this is not set then the Notes field in the **Edit->Tag** dialog box is disabled.

Software Update Notification

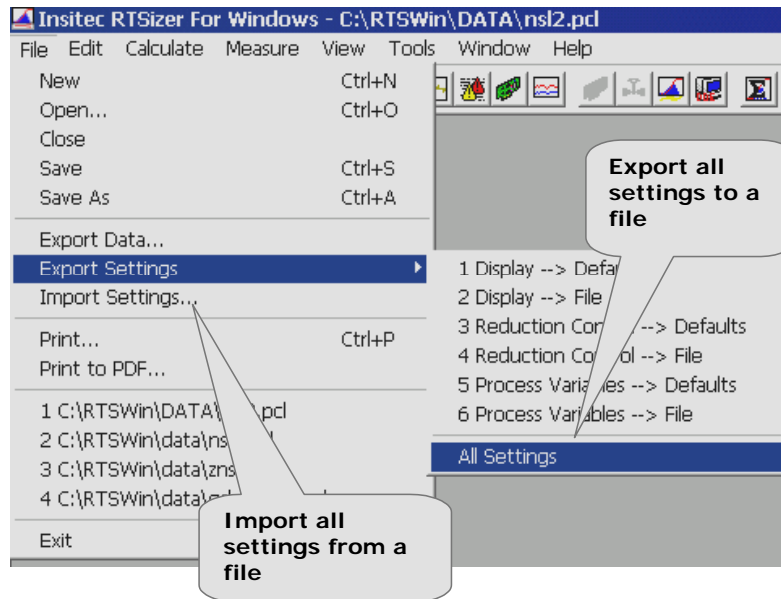


Figure 6 - Import and Export Measurement Settings with Time-History window active

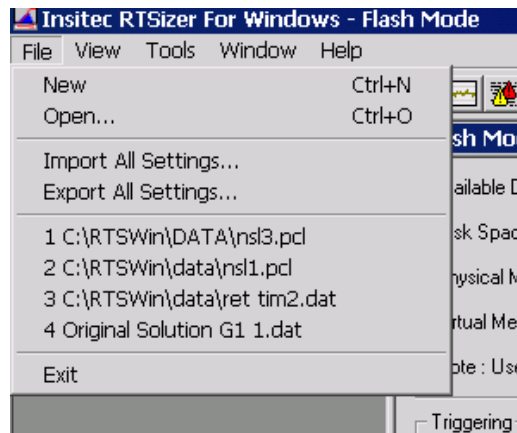


Figure 7 – Import and Export Measurement Settings with Flash Mode window active

9.5 Requirement for consistent averaging

When a set of results is averaged the statistics of the selected PCV values are calculated and the concentration-weighted average, standard deviation and maximum and minimum values are reported on the Process Variables page. The Cover Page report view also reports a set of “Standard Values”, calculated from the averaged particle size distribution, which includes some parameters that may be selected within the Process Variables table. Because of the different method of calculation the “Standard Values” averages may not agree with the equivalent averaged Process Variables.

In the new version of RTSizer a checkbox on the record selection dialog (see Figure 8 displayed by the **Calculate->Average** menu command) controls the visibility of the standard values on the Cover Page and other reports and how the PCV values are averaged.

Software Update Notification

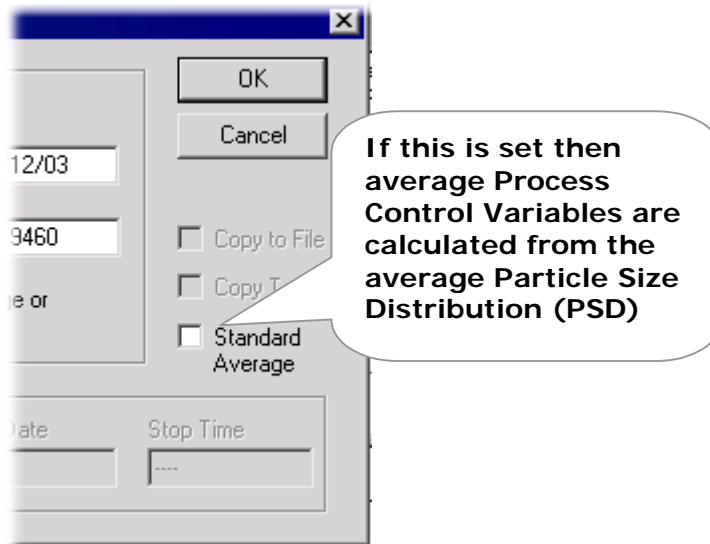


Figure 8 - Record Selection dialog showing the standard averaging control

The table below describes how a particle size distribution (PSD) average is calculated

'Standard Average' control	Standard Values on reports and Cover Page view	Calculation of average PCVs
Clear	No	Concentration-weighted average of the PCV values reported at each point in the time history.
Checked	Yes	Calculated from the average PSD

The equivalent of the previous version of RTSizer is for the 'standard average' checkbox to be clear (the default) except that now the 'standard values' are not shown because they may be different to the equivalents in the PCV table. If the average is calculated with the 'standard average' checkbox set then the PCV statistics table has a comment added specifying that the calculations are based on the averaged PSD (Figure 9).

Transmission (%)	9.67	ε User notified that average PCVs are derived from the average PSD
D[4][3] (µm)	40.70	
D[3][0] (µm)	1.74	

171 Records Averaged (from average PSD)

Figure 9 - Part of the PCV statistics table showing additional note

Standard Average may also be selected within the flash mode measurement dialog as an option when creating an average PSD after a flash mode measurement (Figure 10).

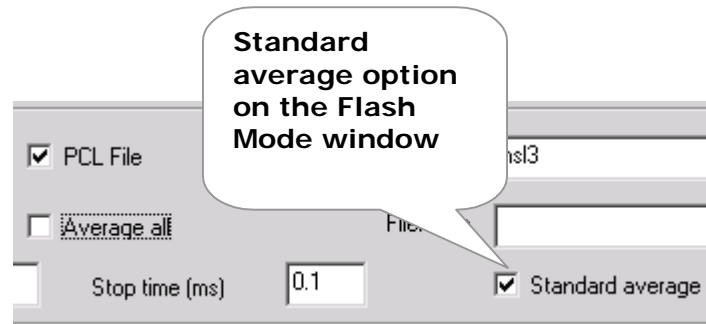


Figure 10 - Part of the Flash Mode window showing the 'Standard Average' checkbox

The 'Standard Average' setting is saved in the global settings file and users may be prevented from changing the setting by using a new security policy – the **Edit 'Standard Average'** security setting.

9.6 Export of time history records

When exporting time-history records using the **File->Export Data** menu command the state of the file save dialog box is changed:

- The file name defaults to showing the root name of the PCL file rather than being empty.
- The directory to which the file will be saved defaults to the standard data directory (usually C:\RTSwin\Data).
- The default export format is a text file rather than a PCL file.

9.7 Printed time-history chart no longer has statistics table

In previous versions of RTSizer if you selected a range of records in the time-history chart and selected **File->Print** or **Edit->Copy** menu option, the time-history chart was printed (or copied as a metafile) with a legend table which included the statistics of the selected records. This was often viewed as confusing, especially when producing data reports which included in PCV report. RTSizer v5.50 no longer prints a table of average record statistics with the time-history chart as default. To print a table of record statistics use the **Calculate->Average** command and print the PCV report separately.

Note that in this case the old behaviour of the software can be restored in order for the averages to be reported as part of the time history printout. If this is required please contact your local Malvern representative.

9.8 The PCV printed report table format

In RTSizer v5.50 the print of the PCV table now also includes the contents of the cover page (i.e. standard values, tag documentation notes, measurement values and settings and calibration settings are added). The PCV table as selected as a view on the time-history or PSD windows is unchanged.

9.9 Error reporting

In the rare event that the RTSizer program has a fatal error and crashes the dialog, shown in Figure 11, is displayed which allows technical information about the crash to be either e-mailed directly to the helpdesk at Malvern Instruments or saved to be e-mailed later.

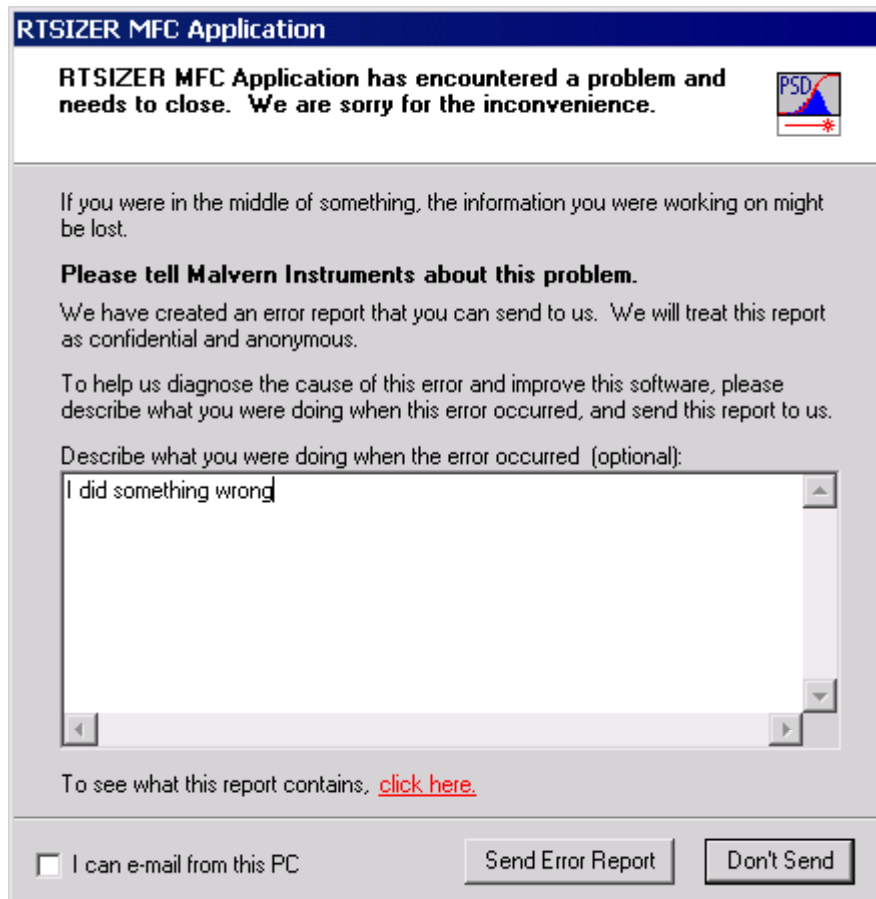


Figure 11 – Error report dialog

9.10 21CFR11 Functions

9.10.1 21 CFR11 Enabled Mode

The 21 CFR Part 11 options within the software have to be enabled using an encrypted "feature key". Entry of the key is achieved using the **Tools-Install Feature Key** menu option. Entry of a valid key will enable 21 CFR Part 11 mode once the software has been restarted. The key is unique to each system and can be obtained on request from Malvern Instruments. Basic security options are available without entry of the 21 CFR11 feature key. **Note that when upgrading the software from v5.4x to v5.50 users will need to re-enter the feature key in order to enable 21CFR11 mode.** This is due to changes in the way the security settings are stored.

9.10.2 Recall of last user at login

Earlier versions of RTSizer remembered the user that last logged in and showed that user's login name in the login dialog the next time RTSizer started. This contravenes 21CFR Part 11 as this provides possible fraudulent users with one of the two pieces of information required to identify a user. Recall of the last user's login name is now controlled from the **Tools->ER/ES Settings** dialog box and can therefore be disabled (Figure 12).

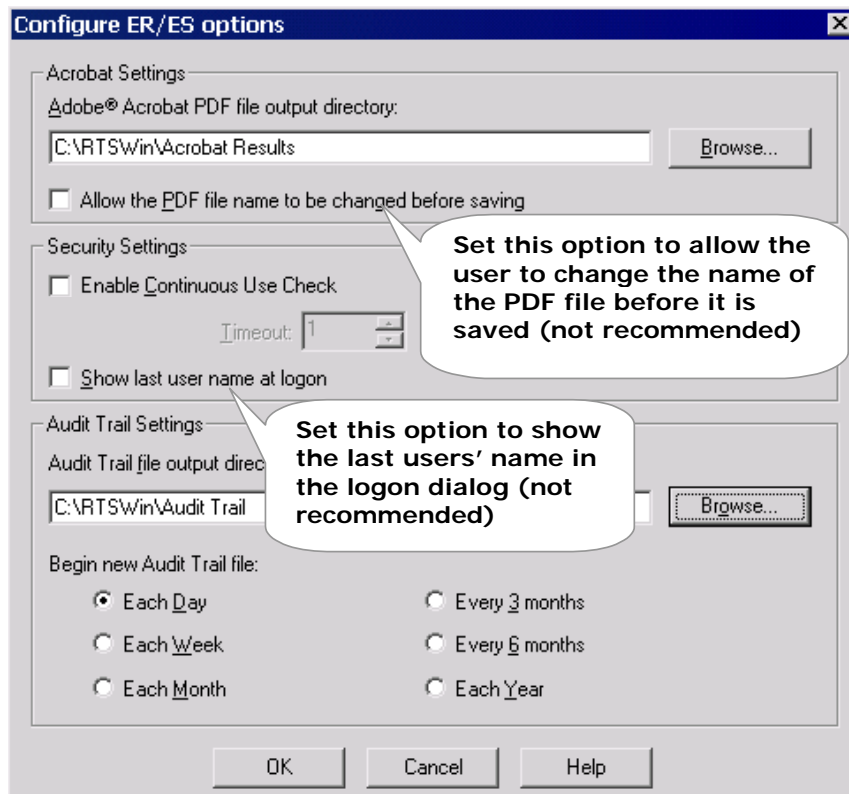


Figure 12 - ER/ES options dialog box showing new features.

9.10.3 Updated Security Display

In previous version of RTSizer it was not possible for administrators to easily identify when user accounts had been disabled or locked out due to possible fraudulent activity. The Security Configuration display has therefore been updated in RTSizer v5.50 such that locked-out users are identified with a padlock icon whereas disabled users are shown with a red cross.

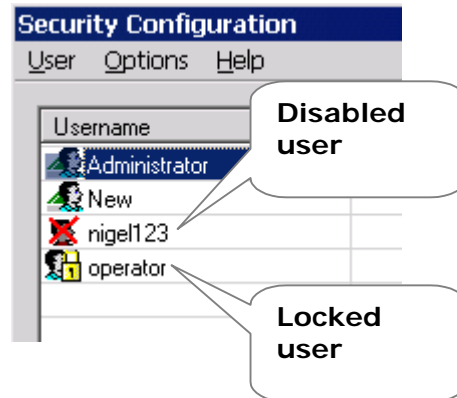


Figure 13 - Part of security configuration dialog showing disabled and locked users

9.10.4 Option to disallow changing the name of PDF files

RTSizer v.5.50 can be integrated with Adobe Acrobat in order to provide a method of electronically signing electronic records within a 21CFR11 compliant environment. The name of the PDF file created by Acrobat is automatically generated from the name of the measurement file being printed. In previous versions of RTSizer a file save dialog box was displayed just before the PDF file was saved to allow the user to change the name of the output file. This is no longer recommended and by default the generated PDF filename is always used. A new option is provided in the **Tools->ER/ES Settings** dialog box (Figure 12) to enable the display of the file save dialog box if users wish to be able to change the PDF output file name.

9.10.5 Date/Time stamping of measurements

To prevent confusion about day/month/year order and 12/24 hour clock, most places which show a date and time within the RTSizer v5.50 software now use a format where the abbreviated month name and full 4-character year is used with the time in 24-hour format. Note that these times often have decimal seconds (4 decimal place accuracy for flash mode measurements).

Date and time stamps are used by the software when saving various files (e.g. audit trail files, PDF files and backup PCL and DAT). In these cases the order of day, month and year comes from the Windows regional settings and the time is in 12-hour format with AM/PM indicator. Note that the separator characters between date and time elements are fixed to be compatible with file-naming conventions.

Note that the only place where a fixed numerical date format is used in the software is when selecting a record range in the dialogue boxes associated with the **File->Print**, **Edit->Records** and **Calculate->Average** menu options. In these places the dialog boxes emphasise the expected order and format of date entry (Figure 14).

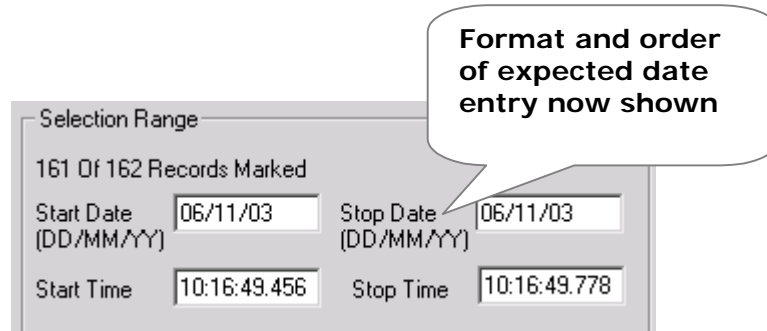


Figure 14 - Part of the record selection dialog showing date entry fields

10 Bug Fix Details

10.1 Loading read-only size history files

In earlier versions of RTSizer, the opening of size history files required users to have write access. If the files were security protected or marked read-only then they could not be opened. RTSizer v5.50 will open read-only PCL files for viewing. The file may be saved to a new name but the original file will not be changed.

10.2 Removal of 'Temp' files

If a flash measurement is made to a named PCL file then a temporary file named 'Tempx.pcl' (where x is a number) is created. In previous versions of RTSizer this temporary file was not deleted after the measurement was completed. This bug has been fixed in v5.50.

10.3 Exported size history data has repeated headers

When a flash measurement was exported as a text file using RTSizer v5.4x repeated headers could appear even though the measurement details had not changed. In RTSizer v5.50 header blocks are not repeated in the exported text files unless the 'Index Group Tag' option is enabled in Flash Mode.

10.4 Using RTSizer when not a Windows administrator

The user who installs the RTSizer software must be logged in to Windows as an administrator. The windows administrator should also configure the security in RTSizer if required. In the previous versions of RTSizer if a normal Windows user was logged in then the RTSizer settings were not saved when RTSizer was closed. This is because the settings were saved in files in the WINNT directory; a directory that is normally protected from change by non-administrators. When RTSizer v5.50 is installed the settings files are moved from the 'C:\WINNT' directory to 'C:\RTSWIN\SETTINGS'. All users **must** have write access to this directory. This allows all of the software and hardware settings to be recalled for all users.

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 22 of 23

10.5 Errors in flash measurement group averaging

The flash mode measurement options allow the flash measurement to be split into equal interval groups, with the average of each group being reported in the time history. In earlier versions of RTSizer it was possible that consecutive groups would be merged leading to inconsistent averaging. The latest RTSizer corrects this problem, although it is still possible to get the last group in a measurement with a shorter duration than the preceding group in the case of the measurement duration not being a multiple of the group interval.

10.6 Saving default settings

In previous versions of RTSizer the default settings (those set by the 'Save Default' buttons in the configure dialogs) were saved in the WINNT directory. This directory is protected from change by Windows users who are not administrators (NTFS file system only). This meant that the default settings were not properly recalled for non-administrators. RTSizer v5.50 saves configuration and default settings in the 'C:\RTSWIN\SETTINGS' directory. The Windows administrator **must** make sure all users have write access to this directory so that any default settings can be recalled correctly.

10.7 Flash measurement notes should not be overwritten

The flash measurement uses part of the tag notes field to store the important flash mode settings for display in the report pages. In previous versions of RTSizer if the user-entered notes were too long some or all of the flash settings were lost. In RTSizer v5.50 the user is limited to entering 40 characters of tag notes – leaving room for the flash settings to be appended. There is no such restriction when a continuous (i.e. non-flash) measurement is made.

To further protect the flash mode settings there is a new security permission (**Edit Tag Notes**) within the RTSizer security system. If this is not set then the Notes field in the **Edit-Tag** dialog box is disabled.

10.8 Registry settings for instrument are not accessible by non-administrators

The Spraytec instrument controller card settings are stored as part of the Windows system registry. The registry is normally write-protected to users who are not Windows administrators. In the new version of RTSizer the installer creates this registry section and changes the security permission so that all users have write access. This means that all users of RTSizer who have permission to "**Access the system controller window**" within the software security system may change the system controller address and interrupt number. It also ensures that the default configuration is correctly recalled for all users.

10.9 Printing – title header overlaps date

In some circumstances the header title of an averaged PSD window would overlap the range of date-times over which the average was made. The software now senses that an overlap would occur and in these cases reduces the size of the font used.

10.10 Problem with display of refractive index values

In earlier versions of RTSizer if a custom calibration (CAL) file was generated then it was possible that the refractive index values were not displayed in the cover page view. This was because the refractive index

Software Update Notification



File Name : Software Update Notification for RTSizer v5.50.doc

Page: 23 of 23

values for custom CAL files are extracted from the files (the refractive index values of standard CAL files are derived from the name of the file). The system searched for the CAL files in the RTSWIN\CAL folder on whatever was the current drive; if data was loaded from a network drive then that would be the current drive, not drive C:. In version 5.50 the CAL files are now always searched for in C:\RTSWIN\DATA.

10.11 21CFR11 functions

10.11.1 Noise and Background update period under control of security policy

In the previous version of RTSizer the update period dialog box for the noise and background measurement windows was permanently disabled when security control was active. Changing the update period is now under control of the "**Edit background and noise measurement duration**" security policy.

10.11.2 Disable overwriting of settings files in 21CFR11 mode.

If 21 CFR part 11 mode is active it is no longer possible to overwrite existing settings files. A message box is displayed advising the operator that 21 CFR part 11 policy does not permit the overwriting of files. The operator is then given the opportunity of choosing a new filename.

10.11.3 Audit trail file location

In the previous version of RTSizer the audit trail files (with an ADT file extension) were saved in the root directory. In this version the files are created in the 'C:\RTSWIN\AUDIT TRAIL' directory. If an old version of RTSizer is upgraded the old audit trail files are not moved or deleted from the root directory.

10.11.4 Security password expiry

In previous versions of RTSizer if the security system was configured so that if a user's password expired after a set time then it was not possible to force the user to change the password at the next logon. Also the system warned of password expiry much earlier than designed. These bugs have been fixed in v5.50.