RTSizer v5.60
Application Software for use with (English) Microsoft
Windows 2000 and Windows XP

Spraytec

(Part Number PSS0007-06)

1   Contents

2   Introduction

This is version 5.60 of the RTSizer application software. The software is tested and supported on the following Microsoft Operating Systems: Windows Windows 2000™ Pro (service pack 4 and higher) and Windows XP™ Pro (service pack 2 or higher). Windows XP™ Pro is the recommended platform. The software is provided on one auto-loading compact disc (CD).

3   Instrument Compatibility

The RTSizer v5.60 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 (MRK535-03)**). The document "**21CFR Part 11 Compliance Guide for Spraytec (MRK536-03)**" 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 v5.60:

Malvern Software Change Request Number	Description	Comments
1600	Report data channels used when data channels are killed.	Implemented
4702	Apparently valid records are not included in averages	Fixed
4703	Concentration average is weighted unnecessarily causing rounding errors	Fixed
4742	Access violation occurs when software closes	Fixed
5730	Temporary files are left in a delete-protected data directory	Fixed
5827	Printing errors occur when using certain printers	Fixed
5828	No security control is provided for starting a flash mode measurement	Fixed

In addition, RTSizer v5.60 contains the following software additions and changes were implemented in RTSizer v5.51:

Malvern Software Change Request Number	Description	Comments
4211	The Exported Settings option did not save the Reduction control-Files and PCV definitions.	Fixed
4212	The Flash mode settings should be stored separately as part of the measurement record.	Improvement
4213	The selected settings file name should be displayed separately on reports.	Improvement
4216	Data should be saved to a persistent location within a given session.	Improvement
4217	The text export setting should default to the most flexible format.	Fixed
4218	Instrument driver fails to work on fast WinXP computers.	Fixed
4385	21CFR11 audit trail records "unknown" users logging in.	Fixed
4393	Some distribution types cause the reporting of negative percentile values.	Fixed
4394	Averaging and deletion of records does not behave properly when viewing records in "Relative Timing" mode.	Fixed
4395	Error in the reported start time of continuous mode measurements.	Fixed
4416	Flash mode measurements cause the software to crash when a PIU file is present.	Fixed
4431	Alternate path length not recalled correctly in reduction control – files page.	Fixed

RTSizer v5.51 contained the following software additions and changes were 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.	Improvment
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
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	Fixed

Malvern Software Change Request Number	Description	Comments
	different hard drive to the RTSizer software.	
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 contained 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 v5.41 contained 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

4.3 Deletions

Software modules relating to the use of the RTSizer software for process measurements have been deleted from RTSizer v5.4x and above. 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 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.

6.2 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 v5.60.

6.3 Re-installation of 21 CFR part 11 support

Removing an earlier version of RTSizer v5.4x or v5.50 with 21 CFR part 11 support will remove the enabling key information. After RTSizer v5.60 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 or v5.50. Please contact your Malvern Representative if you no longer have the required code.

6.4 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.

7   Distribution Media

RTSizer v5.60 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 2000™ Pro (service pack 4 and higher) and Windows XP Pro (service park 2 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 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 v5.60 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 v5.60 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.

During the installation you will be asked which Spraytec instrument driver to install (figure 1).
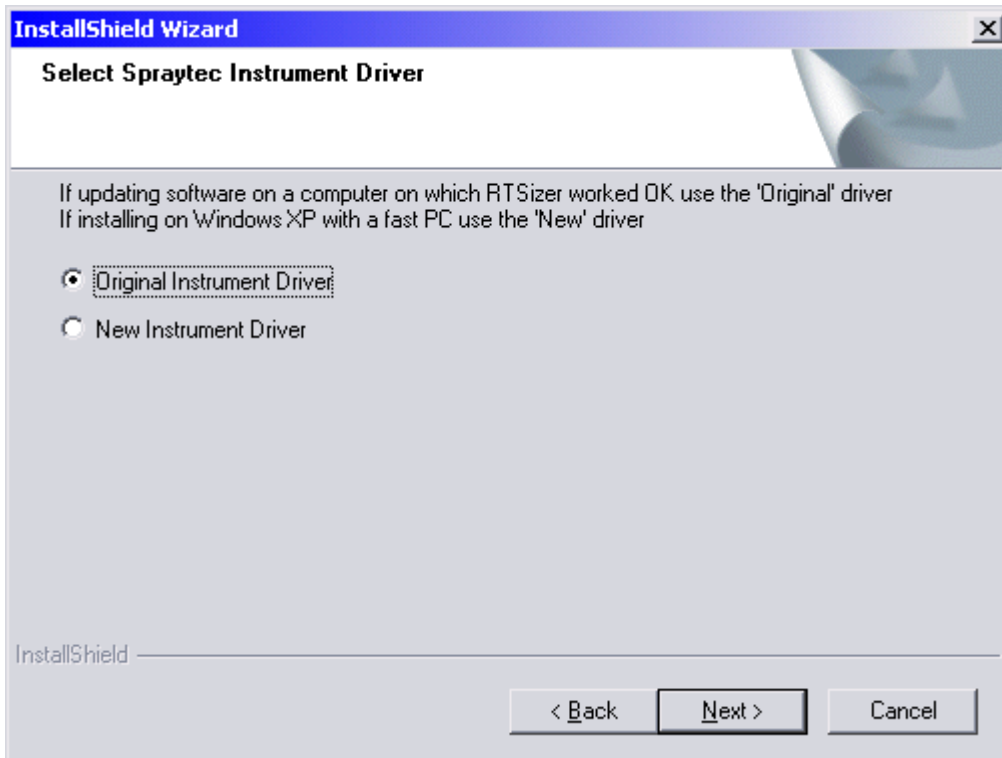

Figure 1 - Instrument Driver Selection during Installation

If the PC and Windows operating system has hosted earlier versions of RTSizer successfully then select the 'Original instrument driver' option. If you are installing on Windows XP with a fast PC (clock speed > 2 GHz) then use the 'New instrument driver' option.

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.

9   New Software Features

A number of new features have been added to the RTSizer software (v5.40 and higher) in order to provide pharmaceutical users with a route to achieve technical compliance to 21CFR Part 11. 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 were first implemented RTSizer v5.50 and have been further improved in v5.51 and v5.60.

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 shown in figure 2.
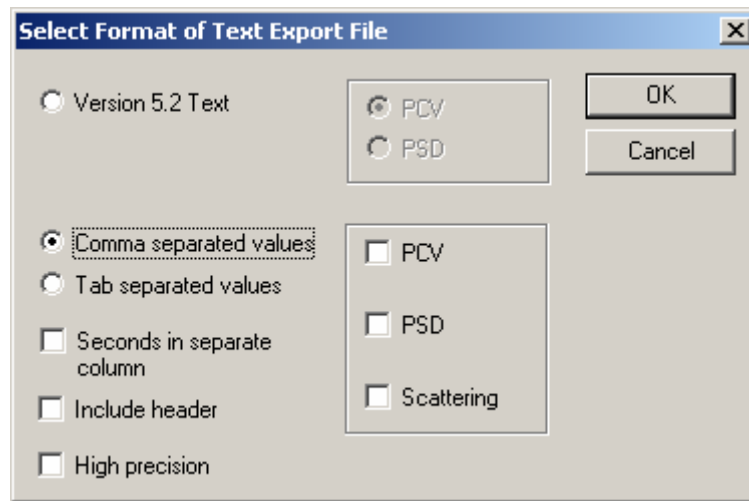
Figure 2. Data export format dialogue box.

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 of the data export 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 Data Export Settings Recall

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 current data (*.pcl) file rather than being empty.

- The default export format is a text file rather than a PCL file.

In addition, RTSizer v5.51 or higher now stores the text file export data settings selected by the user (see section 9.1 above). In previous versions of RTSizer users had to specify the text export format every time the time history data was exported.

9.3 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 (figure 3). The command is disabled when old measurement files created using earlier software versions are loaded.
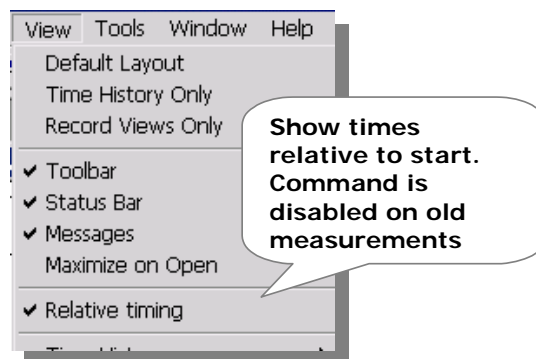

Figure 3 - View Relative Timing menu command

In the flash measurement mode the times reported using the "**Relative Timing**" option are shown with reference the to measurement trigger (figure 4).

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 event. Times before this point 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.
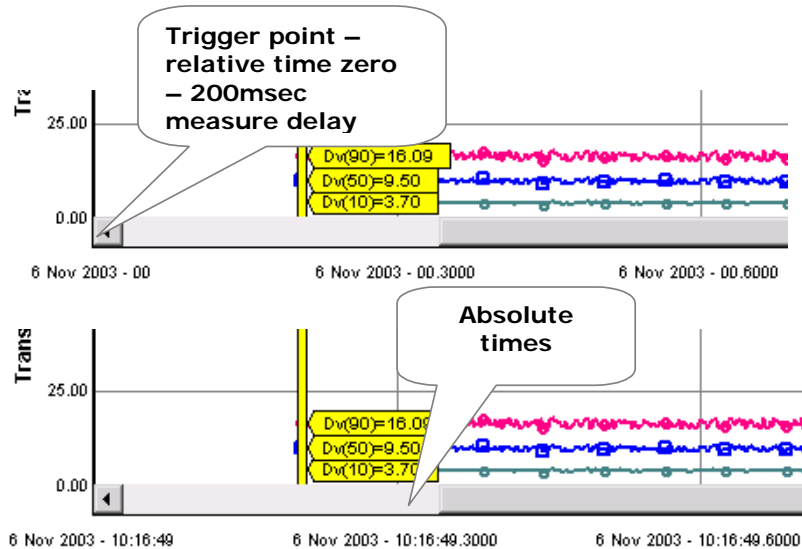
Figure 4 - Size history chart - relative times (top) and absolute times

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 5.
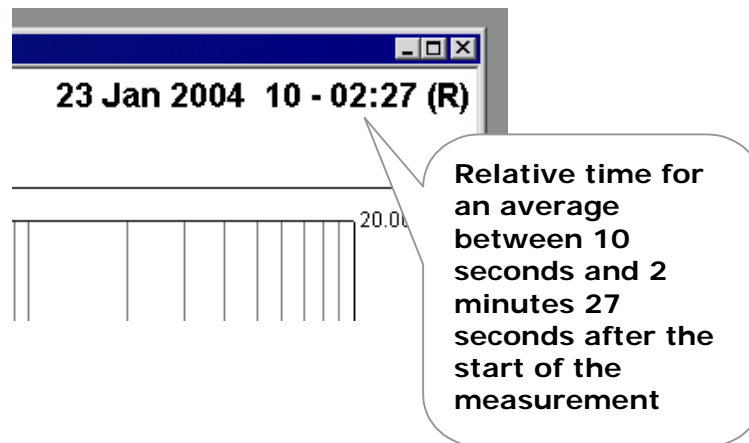

Figure 5 - Part of a PSD window showing relative times for an average

9.4   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 v5.51 and higher adds the ability for the user to enter the time interval over which the average should be calculated (figure 6). This functionally has been specifically added to aid users in defining the "fully developed" phase when making nasal spray measurements, although it has wider application.
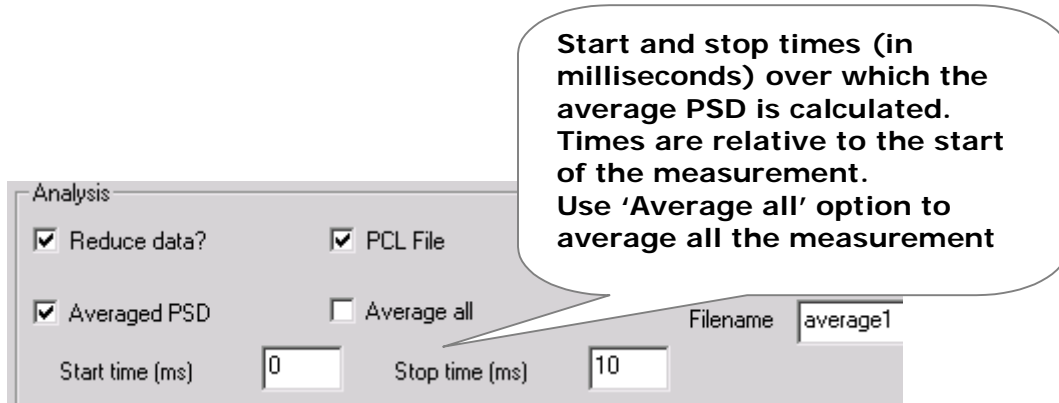
Figure 6 - Part of the flash measurement dialog box showing the averaging options

After the measurement has been done an average over a selected interval may be calculated by using the **Calculate->Average** menu command. If the 'relative timing' option is enabled (figure 3) then it possible to set the times in the record selection dialog relative to the measurement start (figure 7).
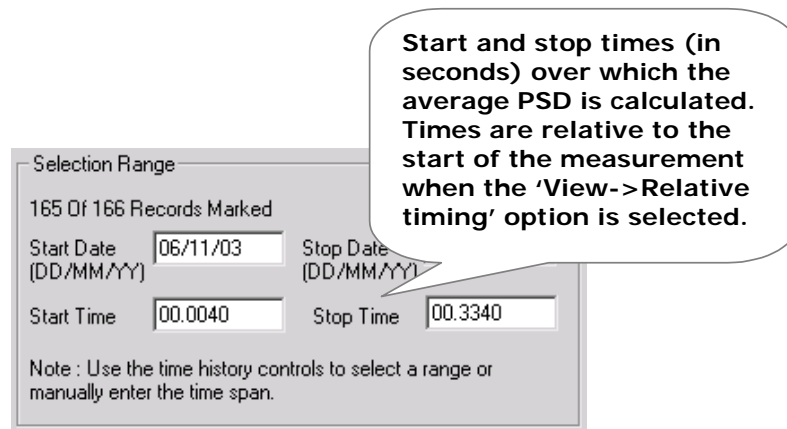

Figure 7 - Part of the record selection dialog showing the relative start and stop time fields

9.5   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 v5.51 or higher 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.
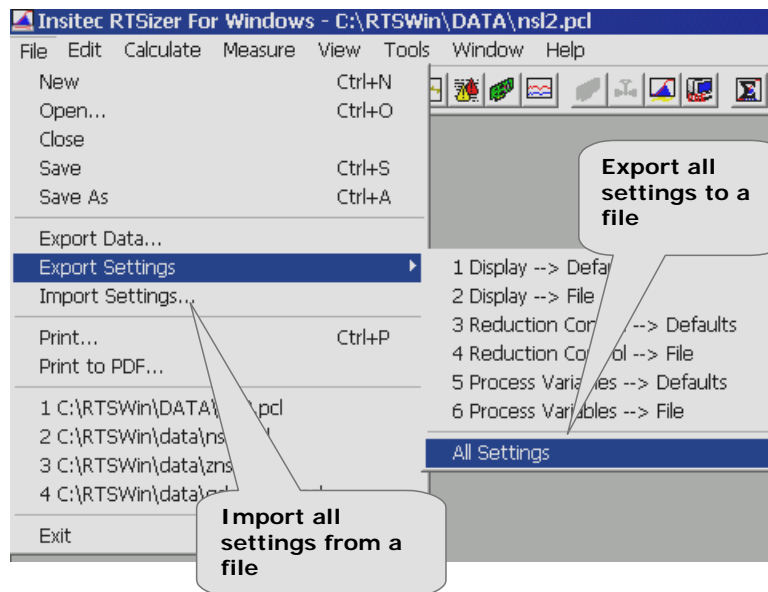
Figure 8 - Import and Export Measurement Settings with Time-History window active
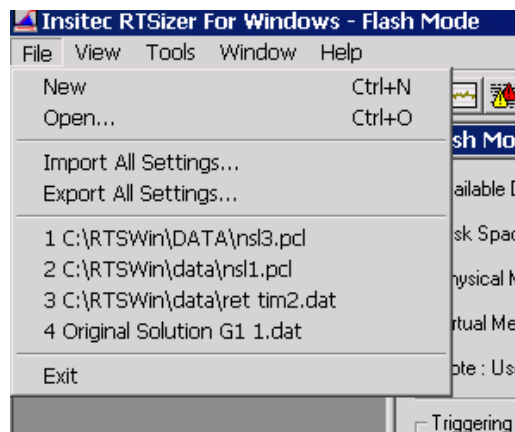
Figure 9 – Import and Export Measurement Settings with Flash Mode window active

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

Setting	Imported / Exported with Time-history active	Imported / Exported with Flash mode active	Security Permission required to export setting
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 reported on the cover page report (figure 10).

Measurement Parameters   7 Jun 2004 12:26:27.9910 - 12:26:27.9920
Valid Data Record
Material : water   Lot : 1   Experiment : 0

Standard Values:
Transmission = 76.40%   Dv(10) = 3.74 (µm)   Span =
Cv = 42.3 (PPM)   Dv(50) = 9.50 (µm)   D[3][2] =   Settings file name
SSA = 0.982 (m^2/cc)   Dv(90) = 16.03 (µm)   D[4][3] =

Notes:
notes on the measurement now limited to 100 characters

Settings File:
flash1.rtss

Flash settings:
Flash Acq : 1 Scans : 1000.0 Hz : DC = 50.0% : Dur = 1.0 (ms)   Flash measurement settings

Measurement Values and Settings
Path Length = 11.99 (mm)   Particulate Density = 1.00 (gm/

Figure 10 - Cover page format showing the settings file name and flash mode measurement settings fields.

Note that to allow the settings file name to be stored within the measurement file, the notes field has been configured to only allow 100 characters to be used. The name of the settings file can be a maximum of 26 characters long (this includes the file extension).

9.6 Display of Flash Mode Settings

In earlier versions of RTSizer the flash mode settings were stored as an entry at the end of the Tag-Notes field and could be overwritten by the user. In v5.50 and higher the amount of text that the user could enter into the Tag-Notes field was limited in order to prevent the flash settings from being overwritten. However this left little room for the user to enter details on the measurement.

In v5.51 and higher the flash settings are stored in a separate location, releasing more space for the user notes. The settings are also reported in a separate section of the cover page (figure 10), rather than as part of the notes field.

9.7   Requirement for consistent averaging

When a set of results is averaged in previous version of RTSizer, 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 methods of calculation the "Standard Values" averages may not agree with the equivalent averaged Process Variables.

In RTSizer v5.51 and higher a checkbox on the record selection dialog displayed by the **Calculate->Average** menu command (figure 11) controls the visibility of the standard values on the Cover Page and other reports and how the PCV values are averaged.
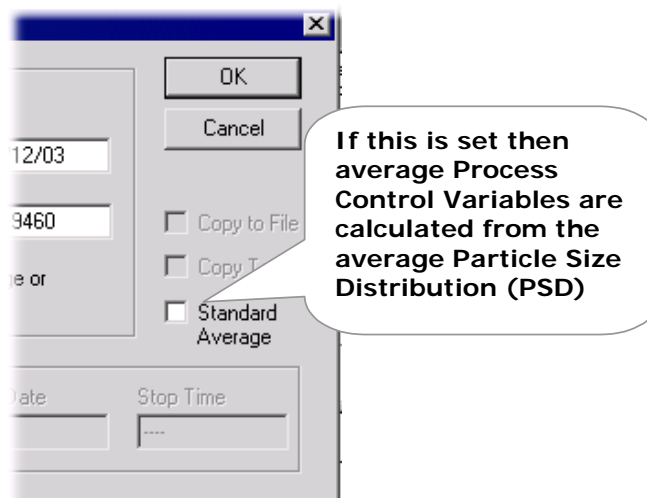

Figure 11 - Record Selection dialog showing the standard averaging control

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 versions 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 12).

Figure 12 - Part of the PCV statistics table showing additional note

The "Standard Average" option may also be selected within the flash mode measurement dialog when creating an average PSD after a flash mode measurement (figure 13).
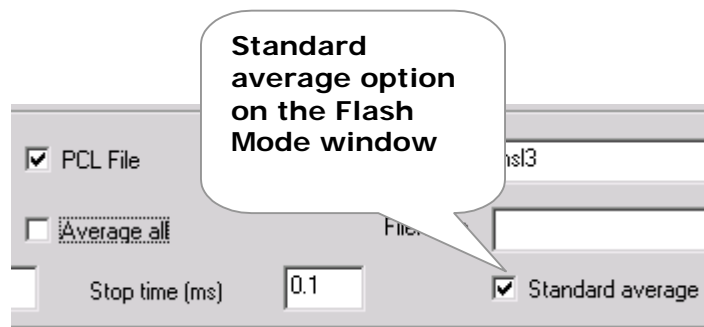

Figure 13 - Part of the Flash Mode window showing the 'Standard Average' checkbox

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.

9.8   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 the PCV report. RTSizer v5.51 and higher 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.

9.9 The PCV printed report table format

In RTSizer v5.51 and higher the printout of the PCV table 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.

9.10 Error reporting

In the rare event that the RTSizer program has a fatal error and crashes, a dialog is displayed (figure 14) 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. This helps with support of the RTSizer program, allowing Malvern Instruments to respond more quickly to any fatal errors that have been discovered.
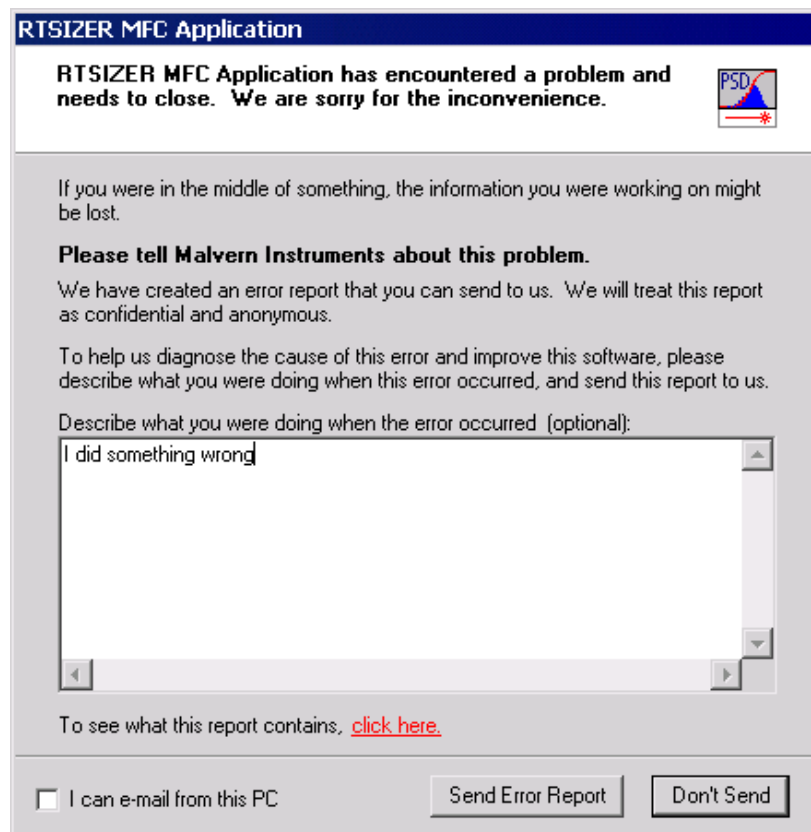

Figure 14 – Error report dialog

9.11 Persistent Location for Data Saving

When the RTSizer v 5.51 or higher software is first opened the data directory is automatically set to C:\RTSWIN\DATA. However, when any RTSizer file is loaded and saved during the current software session, the folder that the file is loaded from, or saved to, is stored. The next time a file is loaded or saved the file dialog opens pointing at the stored folder. The software will continue to track the current directory until it is closed down.

9.12 Reporting of killed data channels

In RTSizer v5.60, the cover page view includes reporting of the range of detectors used in calculating the result. Also included are the range of size bins, the scattering threshold value and the status of the multiple scattering correction. The values of Qe (the integrated extinction efficiency), Psf (the proportion of light scattered forward) and the laser wavelength are no longer reported.

The new layout of the cover page is shown below in figure 15. If the old style of cover page is required please contact your Malvern representative.

Figure 15: New cover page layout.

9.13 Valid records not included in averages

There are three reasons why a record may not be included in an average:

a) The result is invalid – usually because of a failure in a verification test.
b) The transmission is out of range. Averaging of many values is weighted by a function of laser transmission and if the calculation fails because the transmission is below 0.5% or is 100% then the record will not be added to the average.
c) The storage size range is incompatible. Averaging of the particle size distribution must be done using the same size range for all results.

To make it clear how many records are included in an average – and how many were excluded, and why – the cover page view of averaged PSD windows in RTSizer v5.60 has been revised to include details of the number of records excluded.

The cover page of an example averaged result is shown in figure 16 below:

Figure 16 - Example cover page layout for an average result.

In previous versions of RTSizer all measurement records were exported to a text file, including records that were invalid. In v5.60 you can choose not to export records that are invalid. Figure 17 below shows the new checkbox in the 'Select Format of Text Export File' dialog. Set this checkbox to exclude invalid records. Any measurements that are out-or-range for an average are still exported. Use the Reduction Control page when editing records to modify measurement results so that they are included in the average.
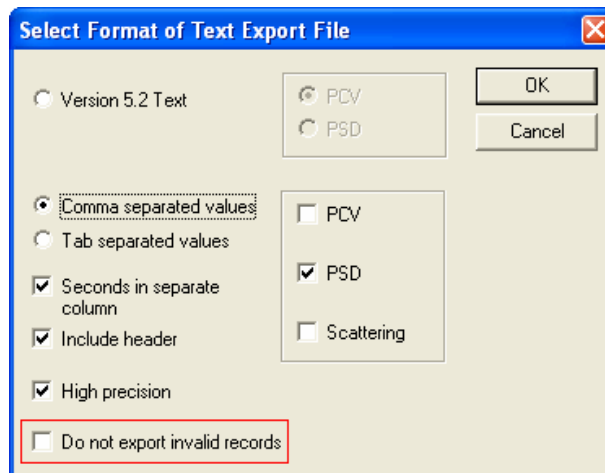

Figure 17 – New Data Export option.

9.14 Weighting of concentration during averaging

In previous versions of RTSizer, if during an average the volume concentration was chosen as a PCV value then it was weighted, like other size-related parameters, by concentration. While there is valid justification to weight the relative volume result by concentration before averaging there is none to do the same for volume concentration. Also the averaged volume concentration value calculated as part of the standard values is not weighted.

In RTSizer v5.60 volume concentration is arithmetically averaged if it chosen as a PCV value.

9.15 21CFR11 Functions

9.15.1 21CFR11 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 or v5.50 to v5.60 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.

9.15.2 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 with v5.51and higher and can therefore be disabled (figure 18).
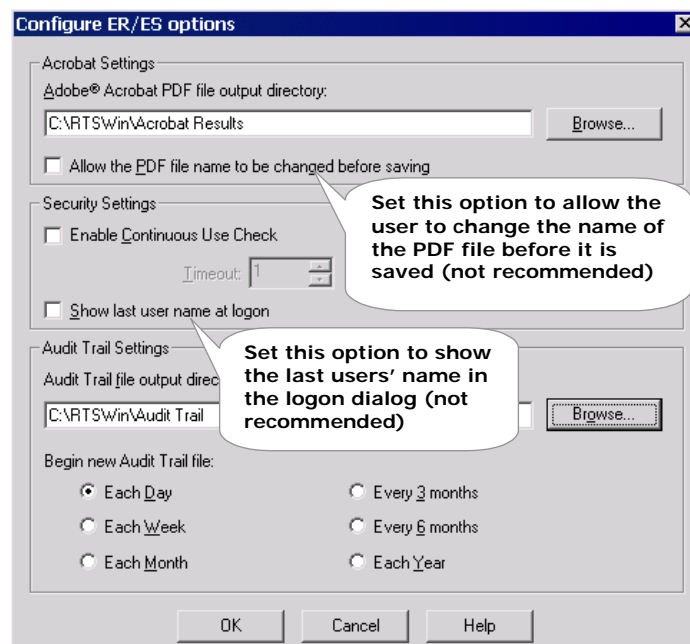

Figure 18 - ER/ES options dialog box showing new features.

9.15.3 Updated Security Display

In previous versions 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 v5.51 and higher such that locked-out accounts are identified with a padlock icon whereas disabled accounts are shown with a red cross (figure 19).
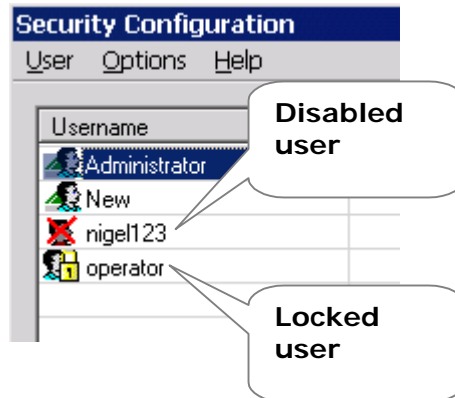

Figure 19 - Part of security configuration dialog showing disabled and locked users

9.15.4 Option to disallow changing the name of PDF files

RTSizer v5.51 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, in versions v5.51 and higher, the generated PDF filename is always used. A new option is provided in the **Tools->ER/ES Settings** dialog box (figure 18) to enable the display of the file save dialog box if users wish to be able to change the PDF output file name.

9.15.5 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 v5.51 or higher 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 20).

Format and order of expected date entry now shown

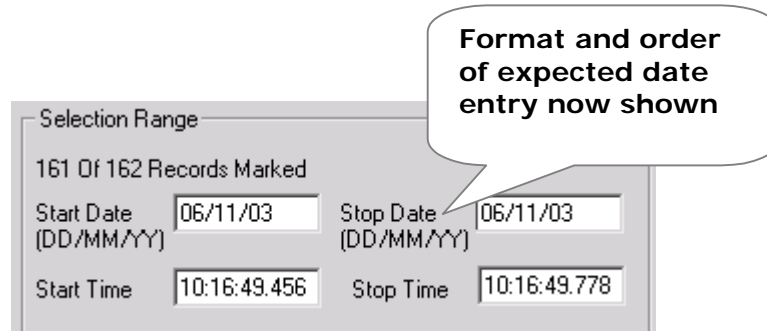**Figure 20 - Part of the record selection dialog showing date entry fields**

9.15.6 No security permission for Flash Measurements

In v5.60, a new security permission has been added to control if a user is allowed to make flash mode measurements. The entry in the security system's group properties dialog box is shown in figure 21 below.
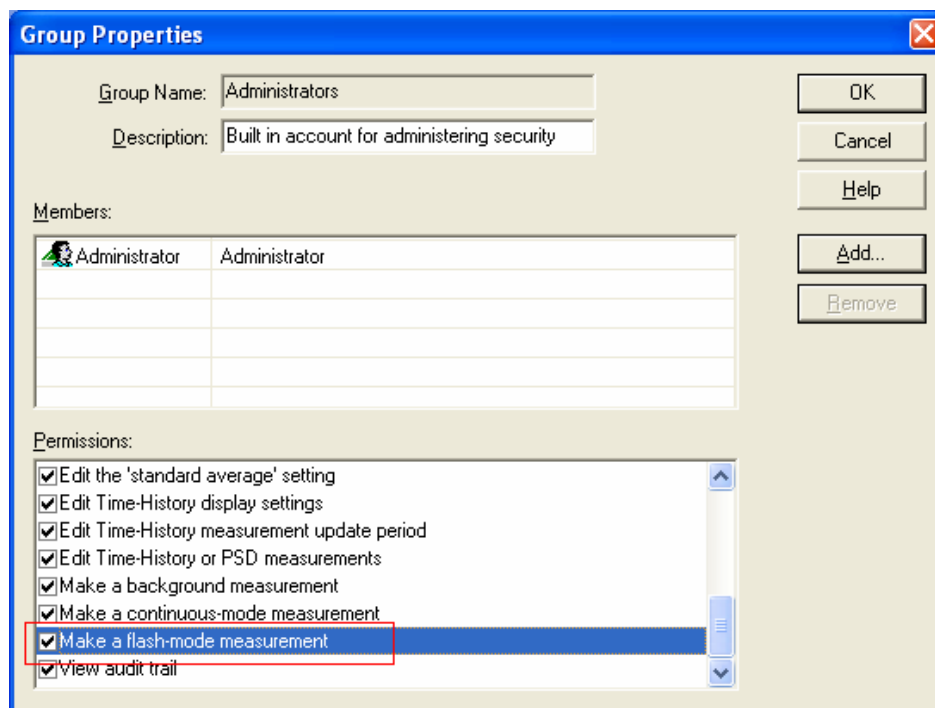

Figure 21: New flash-mode security permission.

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 v5.51 and higher will open read-only data 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 v5.51 and higher.

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 v5.51 and higher, the 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 v5.51 or higher 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.

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 RTSizer software v5.51 or higher corrects this problem, although it is still possible for the last group in a measurement to have a shorter duration than the preceding group in the case where 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 v5.51 or higher 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 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 RTSizer v5.51 or higher 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.

10.8 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. RTSizer v5.51 or higher now senses that an overlap would occur and in these cases reduces the size of the font used.

10.9 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 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 v5.51 or higher the CAL files are now always searched for in C:\RTSWIN\DATA.

10.10 Exported Settings

In RTSizer version 5.50 the settings of the flash mode measurement could be saved to a global settings file using the **File->Export All Settings** command. However, changes to the settings displayed on the Reduction Control – Files page were not saved correctly to the global settings file. Also changes to the definition of process control variables were not saved. This behaviour has been corrected in v5.51 or higher.

10.11 Software Operation on Fast Personal Computers

It has been found that RTSizer sometimes measures incorrectly when operating on fast computers running the Windows XP operating system. Symptoms include missing data channels in the scattering display. A new software driver has therefore been developed for use on Windows XP computers with a clock speed of 2 GHz or higher. Users must select this driver during the installation process if they are using a fast WinXP system.

The new driver is identified by a version number of 3.0 in the module list in the Help->About dialog box. The old driver has a version number of 2.1.

10.12 Negative Values Reported for some Percentiles

In circumstances where measurements are made at very low particle concentrations, the particle size distribution may break-up into several narrow modes (in effect the system is trying to analyse noise). If one of these modes appears in the lowest size-band then the percentile calculation may fail, giving rise to negative percentile values. RTSizer v5.51 or higher fixes this by ensuring the percentile values are restricted to the displayed size range of the measurement.

10.13 Relative Time Mode and Multiple Measurements in a File

Flash and continuous mode measurements may be displayed on the time history chart with times shown relative to the start of the measurement (see section 9.3). When multiple measurements are saved to the same file only the last measurement actually shows relative times on the time axis. Earlier measurements only show the date on the time axis, although the panes showing the details of the selected records do show the records' start and stop times relative to the start of that particular measurement.

It was found that if a range of records was selected in a measurement that is not the latest in the file then the record selection dialog would show the incorrect relative times leading to problems in averaging, exporting, printing and deleting records. In RTSizer v5.51 or higher this error has been corrected.

10.14 Problem Saving Flash Measurements

RTSizer v5.50 would fail with an access violation when a flash measurement was made to a named data file (*.PCL file) if a *.PIU file of the same name existed. PIU files are temporary files created when a PCL file is created and are used as an indicator that a file is in use by RTSizer. Versions of RTSizer earlier than v5.50 would sometimes not delete these files. They may also be left in the current data directory if RTSizer or the operating system crashes.

In v5.51 or higher a message box is displayed prior to the start of a flash mode measurement if a PIU file is found with the same root name as the file that is going to be saved. If you see the message close RTSizer and delete all the *.PIU files in the RTSizer data folder or any other folder used to save RTSizer data.

10.15 Alternate Path Length and Reduction Control

In previous versions of RTSizer the alternate path length controls on the 'Data Reduction & Control Settings' dialog were initially enabled. These controls are now disabled in software v5.51 or higher until the 'Use Alternate Path Length' control is checked. In addition, the user-specified alternate path length now appears correctly in the cover page view and report.

10.16 Access violation on software close

In the previous version of RTSizer there were some reports of an access violation error occurring when RTSizer was closed down. This was traced to an error in the security module which has been fixed in v5.60.

10.17 Printer problems

The RTSizer program now always includes a document description string when it sends pages for printing. It was found that some printers refused to print if this string was not initialised correctly. This bug has been fixed in v5.60.

10.18 21CFR11 functions

10.18.1   Noise and Background update period under control of security policy

In the previous versions 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.

10.18.2   Disable overwriting of settings files in 21CFR11 mode.

If 21CFR11 mode is active it is no longer possible to overwrite existing settings files. The operator is then given the opportunity of choosing a new filename if an attempt to overwrite an existing file occurs.

10.18.3   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 v.51 or higher 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.

10.18.4   Security password expiry

In previous versions of RTSizer, if the security system was configured so that 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. The system also warned of password expiry much earlier than designed. These bugs have been fixed in v5.51 or higher.

10.18.5   User 'unknown' in the Audit Trail

In earlier versions of RTSizer it was found that users could be logged on as 'Unknown' if the user was configured to change their password at first logon. In v5.51 or higher users are always logged on with their correct ID.

10.18.6   Wrong Time Recorded in the Audit Trail

When starting a continuous mode measurements a reminder message is displayed for the operator to confirm that the system is ready for a measurement. In previous versions of RTSizer the start time of the measurement was recorded when the 'Start' button was clicked, not when the reminder message was accepted. This lead to an apparently long first measurement and the recording of an incorrect measurement start point in the audit trail. RTSizer v5.51 or higher corrects this issue, with the start time being defined as the point when confirmation dialog is accepted.

10.18.7   Support for delete-protected data folders

In a 21 CFR part 11 environment it may be desirable to save measurements and exported PDF and text files in a folder which is protected by Windows security from deletions. In earlier versions of RTSizer use of a delete-protected folder resulted in temporary files being left in the folder. In v5.60 the software will create all temporary files in the user's 'temp' folder which must have full access enabled for the currently logged-in Windows user.

Earlier versions of RTSizer used files with the extension PIU to synchronise access to a size-history file from two instances of RTSizer running on different computers on a network. This functionality was meant primarily for process versions of RTSizer and although still present is not supported for Spraytec. This means PIU files will still be created for non-delete-protected folders and deleted when the associated PCL file is closed in v5.60. PIU files are never created in a delete-protected data folder.

In order to check that a folder is delete-protected RTSizer will occasionally attempt to create and delete a file in the folder. This file is called 'checkfordelete' and is marked as hidden so is normally not shown in Windows Explorer. There is one other circumstance where a temporary file will be created in the delete-protected

folder. If you attempt to save a file in the delete-protected folder and a file with the same name exists then the Windows common file save dialog will create a file named 'TMPxx.TMP' where xx is hexadecimal number. RTSizer shows a warning that the file may be created when an existing file is selected. An example of the warning message box is shown below. At this point click 'OK' to close the message box and type in a new name for the file in the save file dialog.
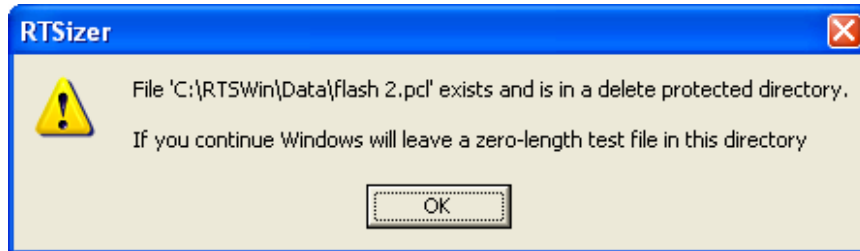

Figure 22: Error message when saving to delete-protected directories.