
Software Update Notification



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**RTSizer v5.41
Application Software for use with (English) Microsoft
Windows NT and Windows 2000**

Spraytec

(Part Number PSS0007/03)

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2 Introduction

This is version 5.41 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) and Windows 2000™ (service pack 2 and higher). Windows 2000™ is the recommended platform. The software is provided on one auto-loading compact disc (CD).

3 Instrument Compatibility

The RTSizer v5.41 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 New Security System.

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

4.1.1.1 Features of the new security system.

- Independent from the Windows NT™ security allowing multiple users of a single system without the need to log in and out of Windows NT™.
- Fully configurable users and groups.
- Each user can be a member of multiple 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.

4.1.2 Audit Trail.

An independent audit trail facility is made available when the 21 CFR Part 11 software "feature key" is installed.

4.1.2.1 Features of the audit trail.

- 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.
- Display of audit trail contents.

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- Export of audit trail file to ASCII for review.

4.2 Requested Additions and Changes.

The following software additions and changes were implemented in RTSizer v5.40:

Malvern Software Change Request (SCR) Number	Description	Comments
2043	Change 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

In addition, the following changes have been 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

4.3 Deletions

Software modules relating to the use of the RTSizer software for process measurements have been deleted from RTSizer v5.41. 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 21 CFR part 11 Support Only

The changes in this version are for 21 CFR part 11 support only, although some changes have been made to the data export functionality. Issues or bugs that were found in earlier versions of RTSizer are not addressed in this version of the software.

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6.1.2 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.

6.1.3 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 v5.41.

7 Distribution Media

RTSizer v5.41 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™ (service pack 2 and 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: that Windows NT 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.

If this is the first-ever installation of the software, then it can be installed either by putting the disc in the CD drawer and relying on the auto-load sequence or by selecting the CD drive within Explorer and, in the root directory, running the setup.exe program and following the instructions.

If this version of software supersedes the software already installed on your computer, it will be wise for you to uninstall the previous version of software first. 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 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.

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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 they will not be on the list of files to be uninstalled.

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 is extracted it will start automatically. Follow the on-screen instructions in order to install the RTSizer software

9 What New Features are Present?

9.1 Overview

A number of new features have been added to the RTSizer software in order to allow it to be operated in a 21CFR Part 11 operating environment. In addition, improvements have been made to the data export functionality. These are described in detail below with instructions on their implementation. These features have been available since the release of RTSizer v5.40. Version 5.41 contains the additional minor features described in section 4.2 above.

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.

9.2 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.

9.3 Security Features

Previous versions of RTSizer used a simple access level security that had two passwords, common to all users, which controlled advanced measurement functions. This has been replaced by a security system modelled on that of Windows NT.

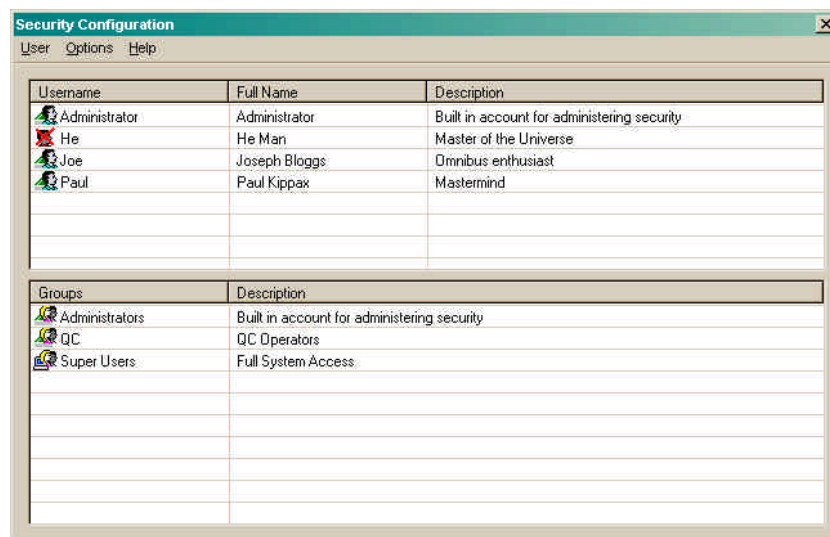
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The security system requires one user to be designated as the system administrator. The duty of the administrator is to set up different operator groups for which certain instrument features can be enabled or disabled. One group - the administrators group - is allowed to configure the security system. All other groups should not be allowed to change the security settings. The administrator sets each group to have permissions to do certain actions, such as make background measurements or edit existing measurement records. The administrator then creates user accounts and assigns each user to a group.

The new security options can be enabled and set-up by the system administrator using the **Tools-Security-Configure Security** menu option:



This gives access to the following dialogue where the current users and the operator groups are displayed:



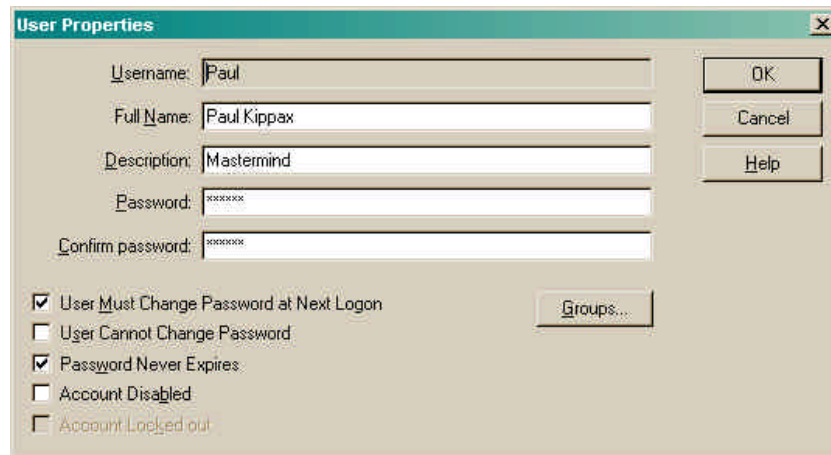
All of the users configured on the system are shown in the top half of the window, with inactive users shown by a red cross through the username icon. The current operator groups are shown in the bottom half of this window. The security system can be configured by double clicking on the users and groups or by using the **User** and **Options** menu items. The security settings can be saved (**User-Save** menu option) following changes. Exiting without saving any changes will cause the system to prompt the user as to whether a save should be carried out.

9.3.1 Configuring User Accounts

Double clicking on an existing user within the security configuration window allows the user's password and group affiliations to be configured (also accessible by selecting the user and using the **User-Properties**

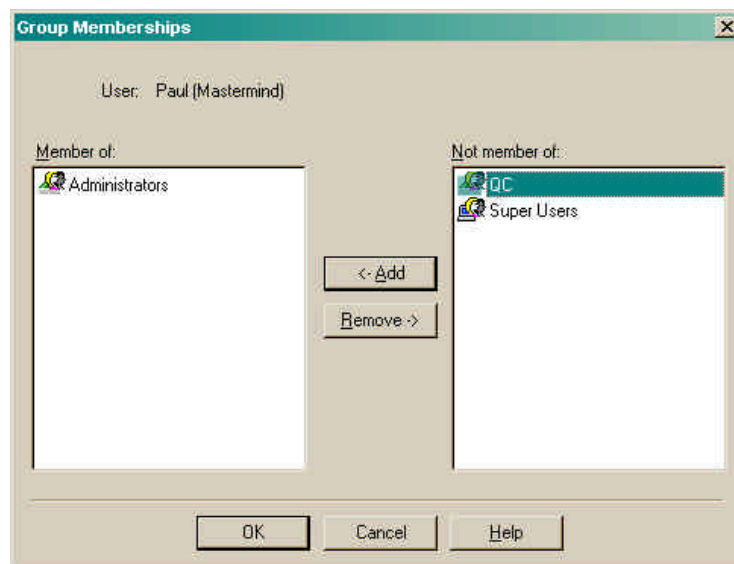
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menu option). The **User-New User....** menu option allows for the creation of new user accounts. Each option opens the following dialogue box:



User descriptions and password settings are available from this dialogue box. It is also possible to disable user accounts without deleting the user from the security settings database (deletion of user accounts is not allowed on 21 CFR 11 controlled systems). Finally, the administrator can re-enable an account if the user has been locked out due to the use of an incorrect password.

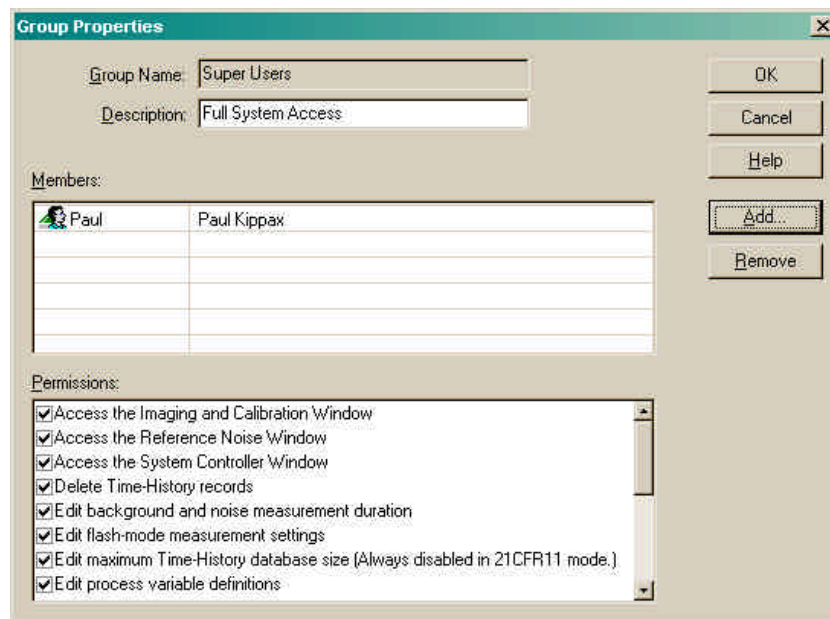
The groups to which a user belongs can be changed using the “Groups” button within the User Properties Dialogue box, causing the following dialogue to appear:



The user’s current groups are listed in the left-hand column and all other groups are listed in the right-hand column. The user’s membership can be changed by selecting the appropriate groups and using the Add/Remove buttons.

9.3.2 Configuring Operator Groups

New operator groups can be configured using the **User-New Group....** Menu option. Existing groups can be configured by double clicking on the appropriate group within the security configuration window. Both operations cause the following dialogue to appear:

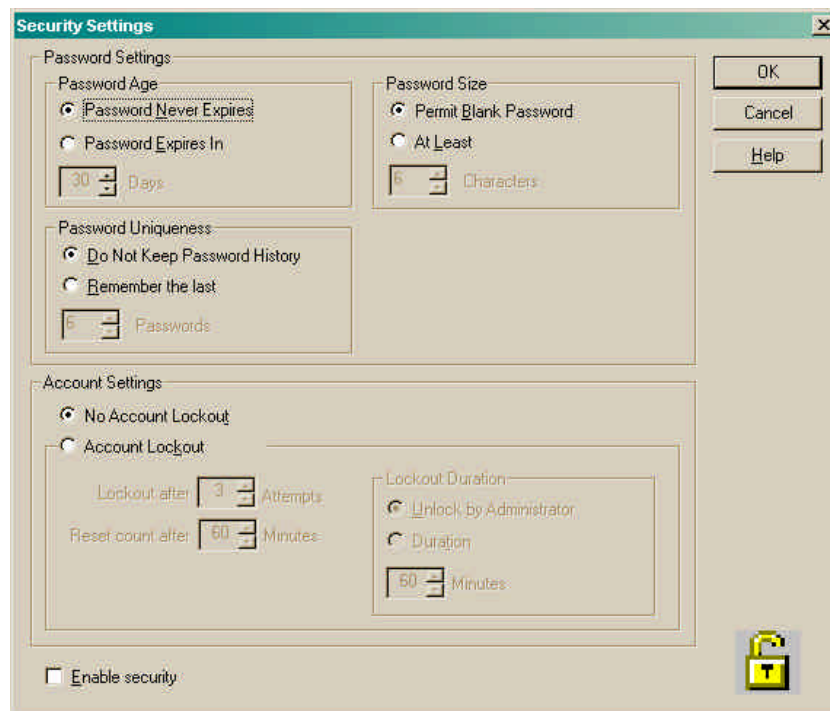


Within this dialogue the group name and description can be specified. The current members of the selected group are also shown – the group membership can be changed using the Add and Remove buttons to the right of the member’s list.

The permissions assigned to each group are shown in the bottom half of the dialogue box. These control what users in the specified group are allowed to do. For example, users in a QC group may be allowed to make measurements but not edit or delete measurements once they have been saved. Users in a “super user” group may be allowed to edit and delete records but not change security settings; and so on. The ability to configure the security settings should only be assigned to the Administrators group.

9.3.3 Security Options

The security system behaviour can be configured using the **Options-Security Settings** menu option within the Security Configuration window. When 21 CFR 11 mode has not been enabled this option will simply allow the security system to be enabled or disabled. In 21CFR 11 mode the following dialogue appears:



Within this dialogue Administrators can:

- Set expiry times for user passwords (**Password Age**).
- Set the size of password which is accepted for all users (**Password Size**).
- Set up the tracking of passwords so users cannot use the same password when they are forced to change (**Password Uniqueness**).
- Configure the locking-out of accounts following the entry of an incorrect password (**Account Lockout**).
- Enable the security system within the RTSizer software (**Enable Security**).

Note that once the security system has been enabled within 21CFR 11 mode it cannot be disabled. This is in line with the requirements of 21 CFR Part 11.

9.3.4 Changing Passwords

Users can be allowed to change their own passwords without having access to the security settings. This is achieved using the **Tools-Security-Change Password** menu option. Access to this option can be controlled by the system Administrator using the security settings.

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9.3.5 Login / Logout

Users are automatically asked to supply a username and password during software start-up when security is enabled. The software will select the current WinNT user name as the default username. Beyond this, it is possible for users to log in and out without closing the software down. This is achieved using the **Tools-Login / Tools-Logout** menu option.

9.4 Audit Trails

The security features described above are available even with 21 CFR part 11 support disabled. Audit trails require the 21 CFR part 11 or ER/ES (Electronic Records/Electronic Signatures) features to be enabled.

The audit trail records events during system use that create, modify or delete measurement data - these are:

- PCL file *PCL-filename* saved as *PCL-filename*
- DAT file *DAT-filename* created from *PCL-filename*; *date-time*
- DAT file *DAT-filename* saved as *DAT-filename*
- Measurement started (*PCL-filename*)
- Measurement stopped (*PCL-filename*)
- Flash measurement carried out (*PCL-filename*)
- DAT file *DAT-filename* created as average of *PCL-filename*; *date-time-range*
- Record edited (Time range: *date-time-range*) (*PCL-filename*) *operator-comment*
- Record deleted (Time range: *date-time-range*) (*PCL-filename*) *operator-comment*
- Record edited (*DAT-filename*) *operator-comment*
- Background measurement file saved (*BKG-filename*)
- Noise measurement file saved (*RFN-filename*)

In addition, the following system events are also logged:

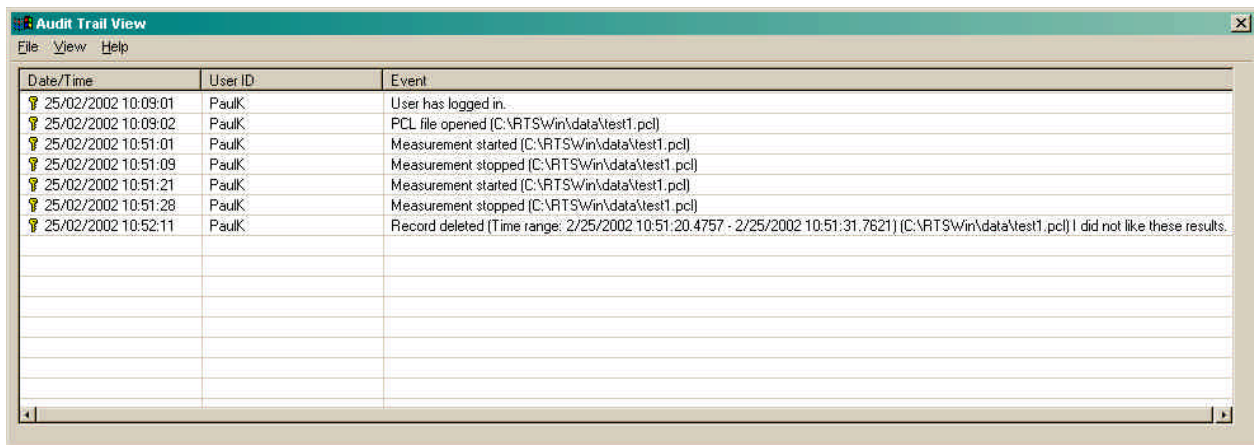
- RTSizer started/stopped
- User has logged in/out
- Engineering mode enabled/disabled
- User account *name* locked after successive login failures.
- User *name* deleted

When a measurement record, whether within a time-history (PCL) file or a separate (DAT) file, is edited or deleted a new file is created which is a backup of the file before the edit or deletion. This file is given a name based on the original file name appended with a tag "before edit of *date-time*" or "before deletions of *date-time*". In this way it is always possible for an auditor to see what the operator did to a measurement and be able to recover the measurement before the modification was carried out.

9.4.1 Viewing Audit Trails

The audit trail can be view using the **Tools-Security-Audit trail** menu option. This causes the following dialogue to appear, listing the events recorded in the current audit trail file:

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Date/Time	User ID	Event
25/02/2002 10:09:01	PaulK	User has logged in.
25/02/2002 10:09:02	PaulK	PCL file opened (C:\RTSwin\data\test1.pcl)
25/02/2002 10:51:01	PaulK	Measurement started (C:\RTSwin\data\test1.pcl)
25/02/2002 10:51:09	PaulK	Measurement stopped (C:\RTSwin\data\test1.pcl)
25/02/2002 10:51:21	PaulK	Measurement started (C:\RTSwin\data\test1.pcl)
25/02/2002 10:51:28	PaulK	Measurement stopped (C:\RTSwin\data\test1.pcl)
25/02/2002 10:52:11	PaulK	Record deleted (Time range: 2/25/2002 10:51:20.4757 - 2/25/2002 10:51:31.7621) (C:\RTSwin\data\test1.pcl) I did not like these results.

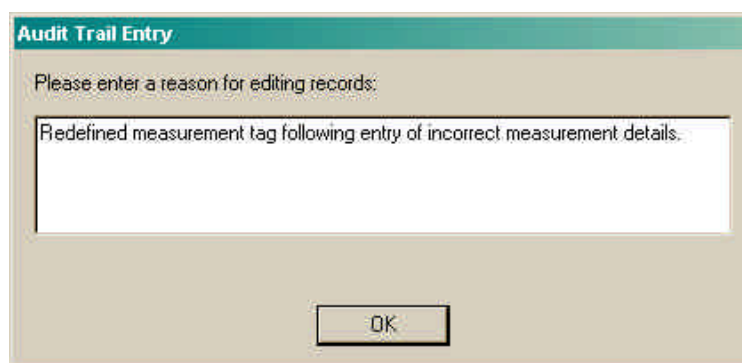
The time of each event is displayed along with the username of the operator and a description of the event itself. The auditor can export the audit trail to a text file using the **File-Export...** menu option within the Audit Trail View. It is also possible to view and then export old Audit files using the **File-Open...** menu option.

9.4.2 Automatic Audit Trail Comments

The RTSizer software will require users to provide a reason for the following software functions when 21CFR 11 mode is enabled:

- Result Editing (using the **Edit-Records...** menu option)
- Result Deletion (using the **Edit-Delete Records...** menu option)

Using these options causes the following Audit Trail Entry dialogue box to appear:



Audit Trail Entry

Please enter a reason for editing records:

Redefined measurement tag following entry of incorrect measurement details.

OK

A comment **MUST** be supplied before the desired action is completed (it is not possible to cancel the process once the Audit Trail Entry box appears). As mentioned above, a back up of the measurement (*.pcl) or data (*.dat) file affected by the selected action is made. This allows the previous state of the measurement or data file to be viewed.

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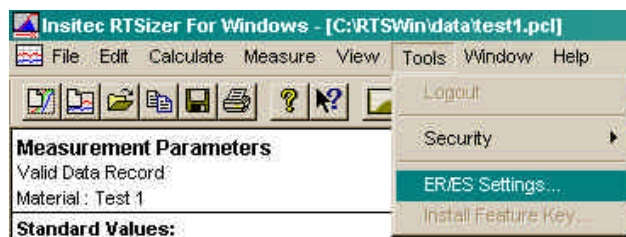
9.4.3 Manual Audit Trail Comments

It is possible for users to add a manual entry to the audit trail. This is carried out using the **Tools-Security-Add Audit trail Entry...** menu option.

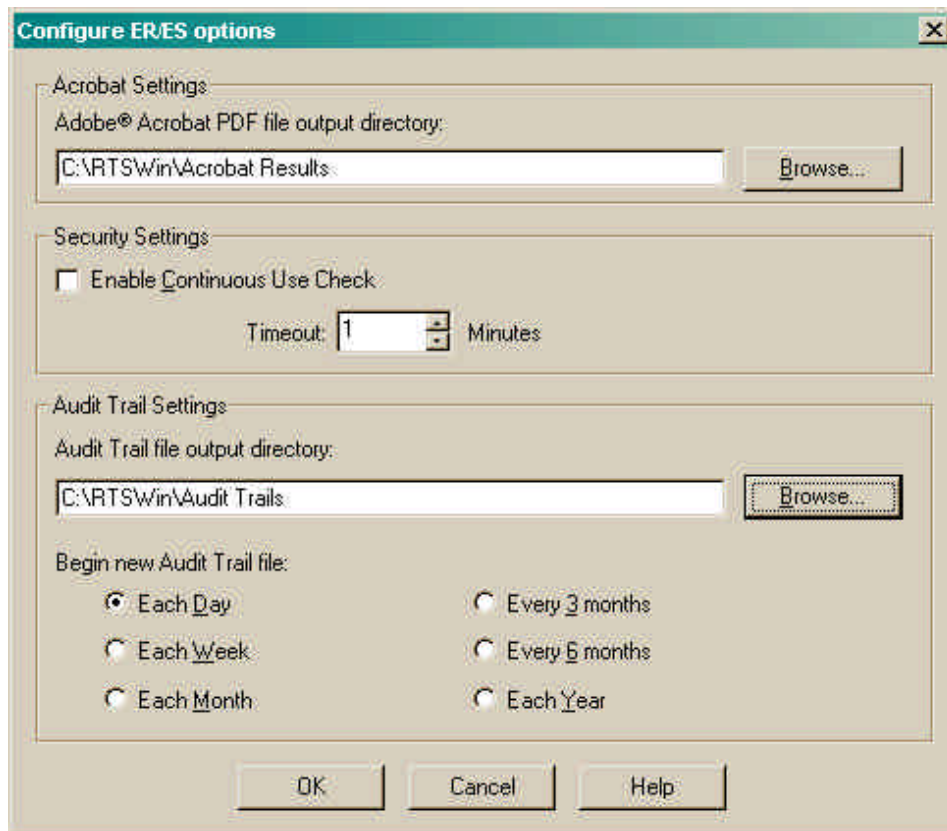
9.5 Electronic Records and Signatures (ER/ES Settings)

RTSizer v5.41 has been configured at use Adobe Acrobat® for electronic records and signatures. 21 CFR 11 mode must be enabled for this option to become available.

The ER/ES settings can be configured using the **Tools-ER/ES Settings...** menu option:



Selecting this menu option reveals the following dialogue box:



As can be seen, this dialogue allows Administrators to set the following 21 CFR 11-compliant features:

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- **Electronic record settings:** The directory in which electronic records are stored can be changed.
- **Enable continuous use check:** This feature will log the current user if no keyboard or mouse activity has occurred within a certain period.
- **Audit trail settings.** It is generally regarded as good practice to limit to size of the audit trail files in order to facilitate the retrieval of data. This feature allows the Administrator to opt different length record files.

9.6 Printing Results to PDF Files for Electronic Signing

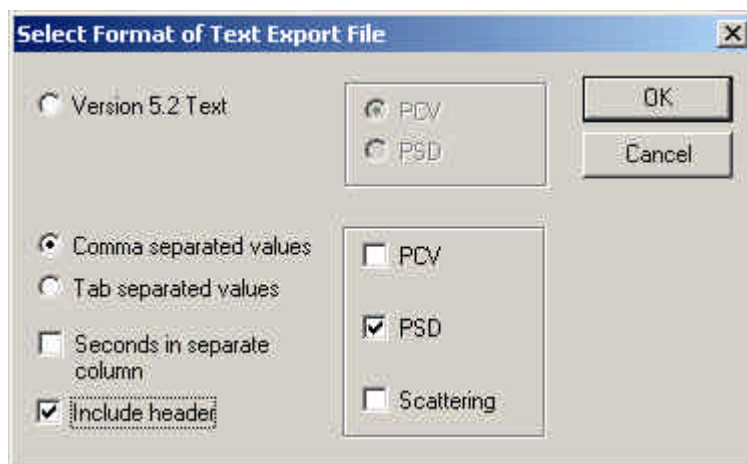
It is possible to save results in PDF format if the Electronic Records/Electronic Signatures (ER/ES) feature has been enabled (by purchase of a feature key) and Adobe Acrobat® is installed on the system. This is achieved using the **File-Print to PDF...** menu option. This solution of using Adobe Acrobat® to digitally sign electronic documents is available for any application that currently produces printed reports. This solution is especially effective in a GxP environment because it is very similar in usage to existing paper based systems but provides the technology benefits of electronic storage and transfer of information.

Full information on the use of Adobe Acrobat® can be found in the technical Note “**ER&ES Advice for Spraytec_RTSizer v5.41.pdf**” which is included on the installation CD for RTSizer v5.41.

9.7 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:



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.

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- **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.