Software Update Notification

**Mastersizer 2000 version 5.00
Application Software for use with (English) Microsoft
Windows NT and Windows 2000**

Mastersizer 2000

(Part Number PSS0002/8)

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1   Introduction

This is Version 5.00 of the Mastersizer 2000 instrument 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™ (service pack 2 and higher) and comes on one auto loading compact disc (CD).

2   Instrument compatibility

The Mastersizer 2000 v5.00 software is back compatible with Mastersizer 2000 version 4.00 and below.

Note: In common with a large number of applications which undergo significant updating, Data files produced by earlier versions will be compatible with this release but data files produced by this release will not be legible by earlier versions. Where there is regular correspondence between systems, users are advised to ensure that all instruments are updated to the same level.

3   Functional Features

3.1   Planned Additions and Headline Utilities.

3.1.1   New Security System.

The security requirements of 21 CFR Part 11 are more stringent than previously required. In order to comply with these, the 'Secured Layered Access System' has been replaced with a new security system.

Features of the new security system.

- Fully compliant with 21 CFR Part 11 requirements
  '11.200 Electronic signature components and controls' and
  '11.300 Controls for identification codes/passwords'

- Independent from the Windows NT™ security allowing multiple users of a single system without the need to log in and out of Windows NT™.

- Log in and out of the application without shutting it down.

- Fully configurable users and groups.

- Each user can be a member of multiple groups.

- Encrypted passwords.

- Encrypted security settings file.

- Continuous use check can be set to log users out after predetermined periods of inactivity.

- Versioning of SOP files.

A feature that is made available when the 21 CFR Part 11 feature key is installed is the versioning of SOP files. Each time that a SOP is edited, details of the new settings are appended in the file and tagged as a new version. Details of all earlier original versions are retained.

Features of SOP versioning.

- Version history showing all versions of a SOP.

- Ability to display the difference between versions of a SOP.

- Automatic logging of persons making changes, what the changes entailed, and why they have been made.

- SOP details, including version numbers, are automatically stored in the measurement record.

3.1.2 Audit Trail.

A feature that is made available when the 21 CFR Part 11 feature key is installed is the independent audit trail facility.

Features of the audit trail.

- Auditing of security events such as logging in and out of the system.

- Auditing of deletion of user accounts

- Auditing of measurement record creation, editing, and deletion.

- Auditing of SOP record creation, editing, and deletion.

- Auditing of creation of Acrobat PDF files from within a SOP

- Display of audit trail contents.

- File encrypted and therefore uneditable.

- Decryption and export of audit trail file in ASCII format for review.

3.2 Requested Additions and changes.

SCR[1]	Description	Comments
622	The clean sequence leaves the pump and stirrer speed high	Fixed
1140	Add an inactivity log-out feature	Implemented
1168	Add security control to the report designer and the calculation editor.	Implemented
1255	Add an audit trail for 21 CFR systems	Implemented
1531	Display the current user name on the main window	Implemented
1625	Add a 21 CFR icon to the status bar	Implemented
1777	Add ability to password-protect report files	Implemented
1835	If the QC calculation returns an unexpected value, the system crashes	Fixed
1885	Batch number does not auto increment	Fixed
1961	Wet accessories manual control screen displayed faults using a green LED rather than a RED led.	Fixed

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[1] Malvern Software Change Request Number

Software Update Notification

3.3 Deletions

None.

4   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.

5   Known Issues

5.1 Minimum memory requirements increased.

On some NT systems with 32MB of RAM beta testers have reported 'out of virtual memory' errors. Upgrading the computer to 64 MB of RAM and re-configuring the virtual memory has resolved the problem.

In order to increase program performance, measurement records are kept in memory. For customers with a large number of measurements in a single file, this will affect the system performance by consuming large amounts of available memory. The best practice is to keep the number of measurement records in a single file to less than 1000. It is recommended that new files should be created on a regular basis in order to keep the record count per file to less than 1000.

5.2 Installing an earlier version after un-installing v3.x. or above

To replace the Mastersizer 2000 application with another version, it is necessary to first uninstall the software using the command provided. When moving from version 3.x to version 2.00 or below, you must replace the Mastersizer 2000.ini file for the operation to succeed. Once the later software has been uninstalled, rename the ***Mastersizer 2000.ini*** file ***Mastersizer 2000.in3***. Then install the earlier version. If this is not done, the old application will not run correctly.

5.3 Can not install version 4.0 or greater on Windows 95/98/Me

Version 4.00 of the Mastersizer 2000 application is only compatible with Windows NT™ - based systems (including Windows 2000™).

For Windows 95™, 98™ and Millennium™, version 3.2 (which contains no Autosampler support) can be installed by running the setup.exe program found on the CD-ROM in the **\ms2000\Eng98** directory.

5.4 Autosampler - flashing accessory icons.

The new version of FIDACS (v1.03 or greater) must be downloaded to any instrument where an Autosampler is to be used.

5.5 New security system.

The new security system introduced in Version 5.0 is incompatible with the pre-existing 'Secure Layered Access' system. If version 5.0 is installed, the security settings will have to be reconfigured to add users and groups.

6   Distribution Media

Version 5.00 software 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 will be notified.

The installation process has been tested on all the supported configurations of operating system.

7   Installing the Software

7.1   Before Installing Mastersizer 2000.

If you are upgrading an existing installation ensure that all data is backed up before continuing.

Uninstall the existing copy of Mastersizer 2000. To do this, follow the steps below.

1.   Reboot your computer. This ensures that no element of Mastersizer 2000 is left running.

2.   Select "Start" – "Malvern Instruments" – "Mastersizer 2000" – "Uninstall Mastersizer 2000" . This application will remove the program components of Mastersizer 2000 while preserving any data files you may have created. Answer Yes to any prompts.

3.   Once the uninstall process has completed empty the "recycle bin" to ensure all program files are removed.

Install MDAC (Microsoft Data Access Components) Version 2.7 or greater. Instructions can be found in section 7.2.

7.2   Installing MDAC.

MDAC (Microsoft Data Access Components) is required for correct operation of the Mastersizer 2000 software. MDAC forms part of the operating system and as such must be localised to suit the language of the operating system.

The CD-ROM contains a copy of MDAC for each of the languages supported by Mastersizer 2000. If your operating system language is not on the CD-ROM is can be downloaded from the Microsoft Web site at www.microsoft.com/data.

Example: If your Windows operating system is in French you must install the MDAC contained in the MDAC\French directory of the CD-ROM. This is done by closing all running applications on the computer and using Windows Explorer to locate the correct mdac_typ.exe on the CD-ROM. Double click on the \MDAC\French\mdac_typ.exe file and follow the prompts displayed on the screen.

7.3 Installing Mastersizer 2000 application software

Note: Prior to starting Windows NT installations, MDAC (Microsoft Data Access Components) Version 2.7 or greater must be present. Installation instructions can be found in section 0.2.

The software suite comes on an auto-loading CD-ROM. Inserting the disc into a system configured to Auto-run a CD will run the installation program automatically. If your system does not support this feature, run the *setup.exe* program from the root directory of your CD drive.

Note: **For Windows NT, the software 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.**

Note: **To make use of the new wash cycle, the firmware of the Hydro 2000G needs to be updated to the latest issue. The firmware of the Hydro 2000µP needs to be updated to the latest issue for additional diagnostics and some improvements to the Ultrasound control to be available.**

8   Directory Structure

The default directory structure is installed under %WINDISK%\Program Files as follows;

Malvern Instruments
  Mastersizer 2000
     Acrobat Results
     Audit Trails
     Custom Calculations
     Export Templates
     Firmware Hex Files
     Measurement Data
     Models
     Pages
     Programs
     Security Directory
     Sop
   Shared

9   What new features are present and how do I use them?

9.1 Overview

A quick scan of section 3 above will show that a number of new features have been introduced in this version of the software for your Mastersizer 2000.

These are described in detail below with instructions on their implementation.

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 all necessary details to hand before telephoning.

9.2   21 CFR Part 11 Support Features.

Support for 21 CFR Part 11 was first introduced in version 3.2. Version 5.00 adds support for more advanced security control and independent audit trails.

9.2.1   Printing Results to PDF files for Electronic Signature

If the Electronic Records/Electronic Signatures (ER/ES) feature has been enabled (by purchase of a decryption key) and Acrobat® is installed on the system, it is possible to create a PDF file automatically at the end of a SOP measurement.

This solution of using Adobe Acrobat to digitally sign electronic documents is available for any application that currently produces printed reports to manually sign. 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 on the CD-ROM in the Malvern Technical Note **TN 21 CFR – Using Acrobat V 5 for the creation of Electronic Signatures.pdf**

9.2.2   Editing Results

When a result is amended (assuming that the operator has the necessary authorisation), the following dialogue appears on saving the new result. The new result is appended to the file. The original record is retained on the file and is not modified.
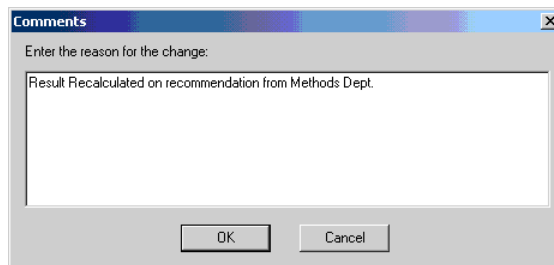
Figure 1: Reason for change dialogue

9.2.3 SOP Versioning

The SOP dialogue now has a "Versions" tab on it:
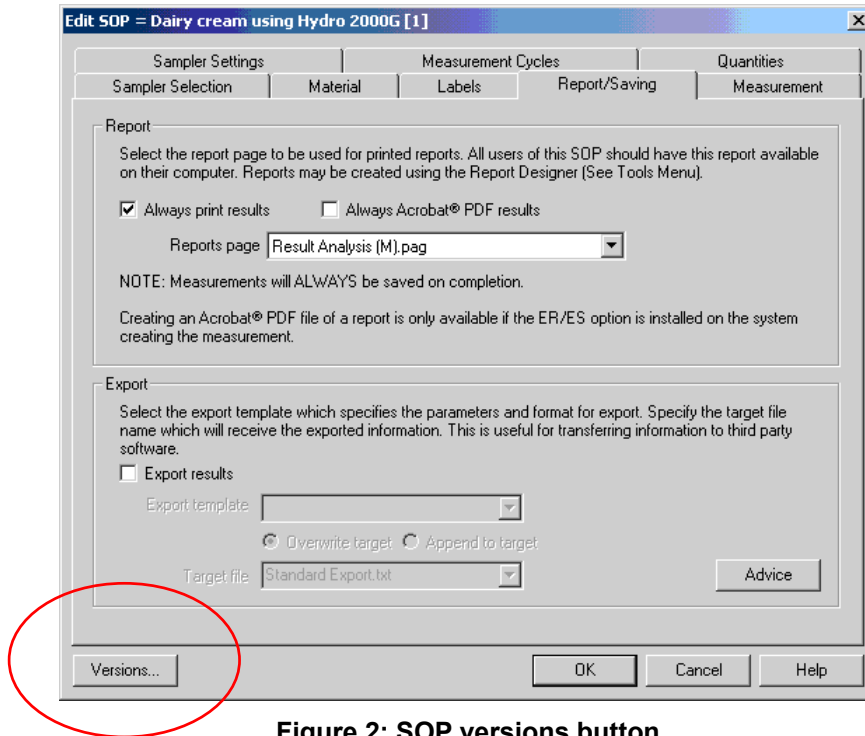
Figure 2: SOP versions button

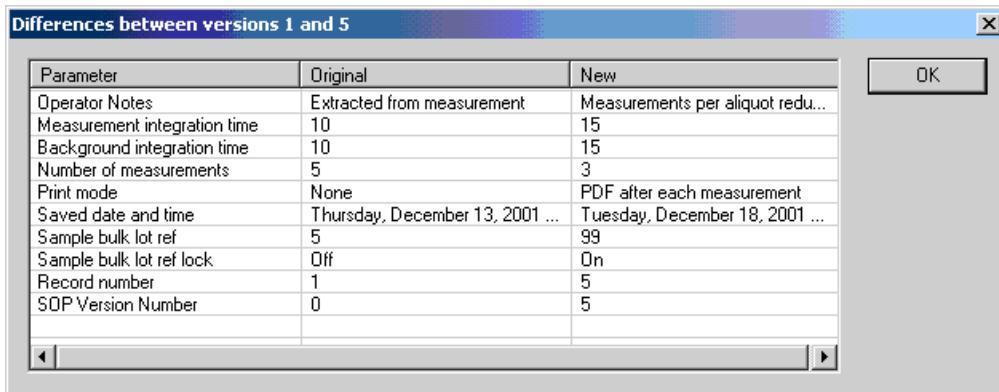Clicking on the Versions tab brings up an Audit trail for the SOP:
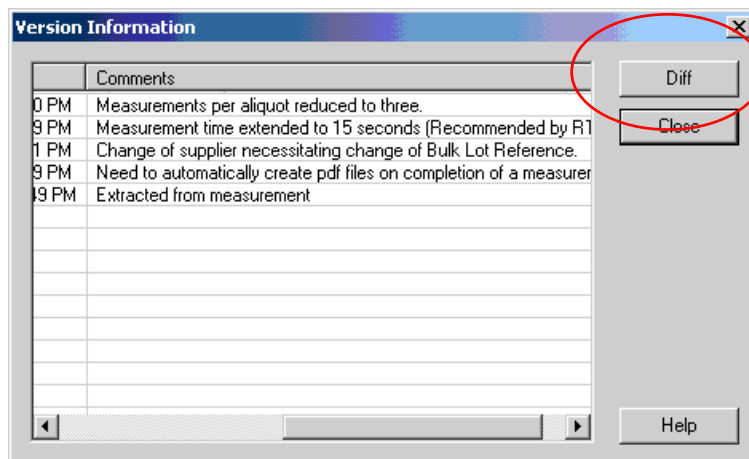
Figure 3: Version history

Clicking on the Diff button and selecting two records displays the differences between SOPs:

9.2.4 Security features.

Clicking on "Security" on the Menu Bar displays this menu:
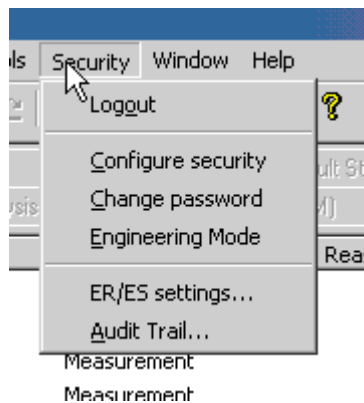
Figure 4: New security menu.

Users can log out without the need to close the application.

When fully empowered operators log-out, all the features which they were authorised to use become unavailable:
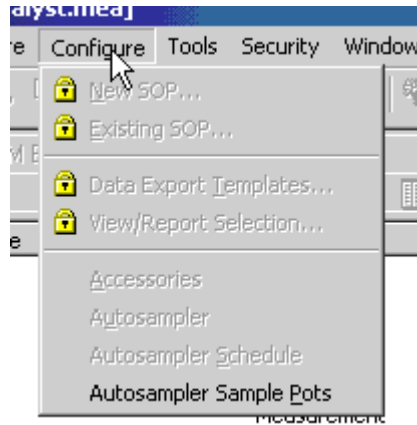
Figure 5: Secured menu options

Users are assigned to Groups having different capabilities. These can be precisely tailored using the Group Properties Dialogue:
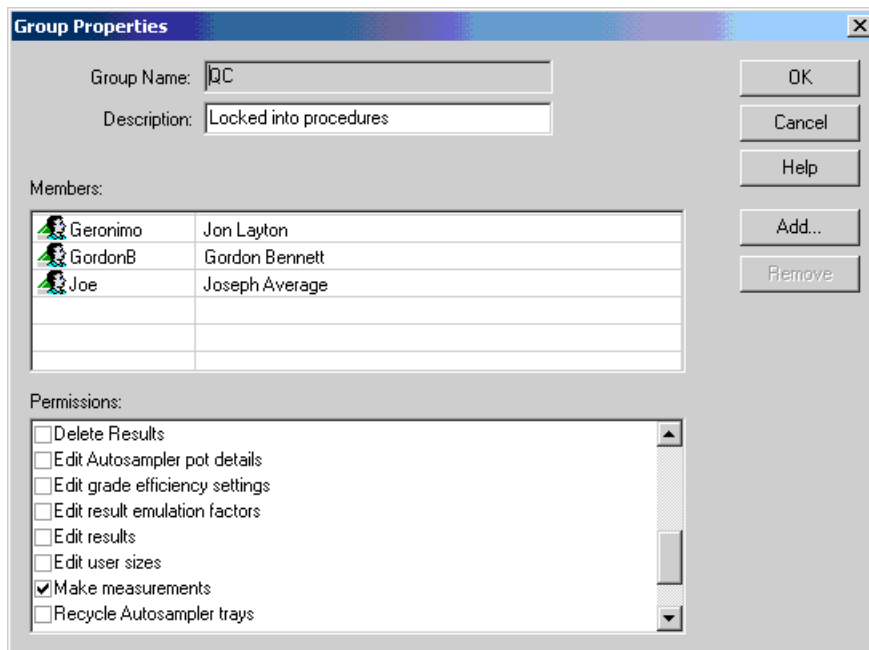
Figure 6: Group Settings

This particular group is severely constrained. R&D personnel and Administrators can have a wider scope to roam.

Selecting "Configure Security" allows the Administrator to view the individuals and their groups. (The passwords remain secret at all times.):
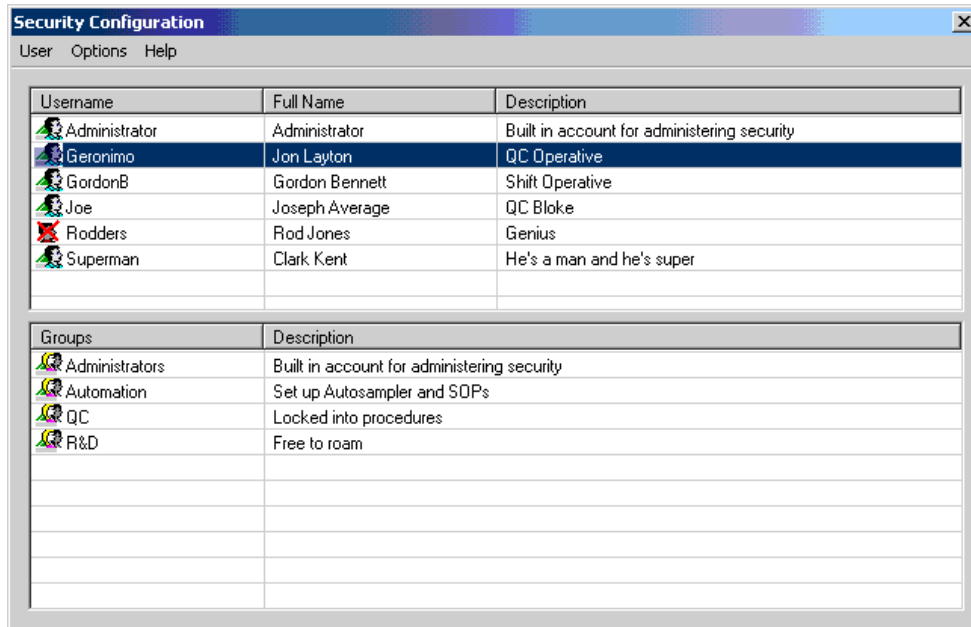
Figure 7: Security configuration

Note that it is possible to disable user access to the system without removing the user details. A disabled account is shown with a Red Cross.

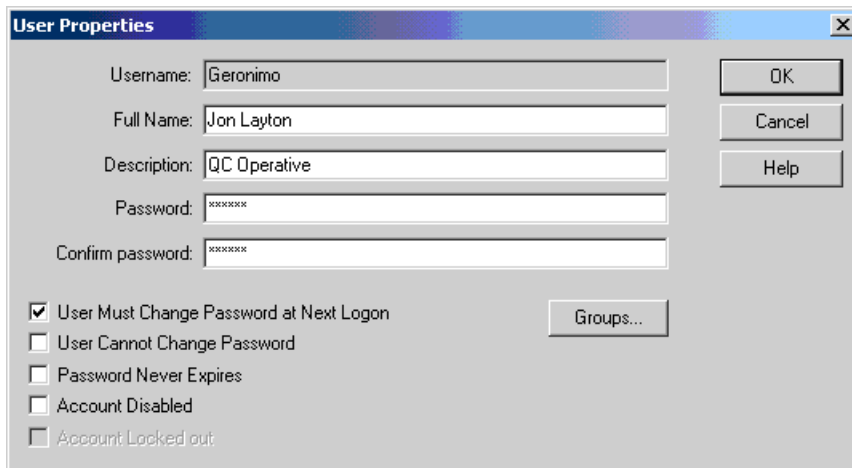The Administrator can review different users' authorisations by double clicking on one of the names on the user list:
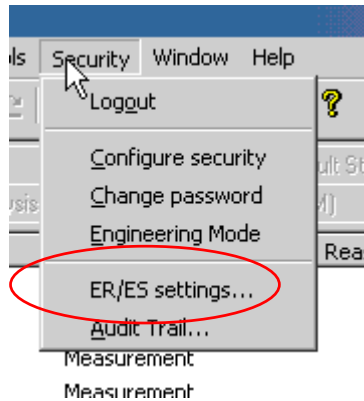

Figure 8: User properties

9.2.5 ER/ES Settings

Figure 9: Configure menu

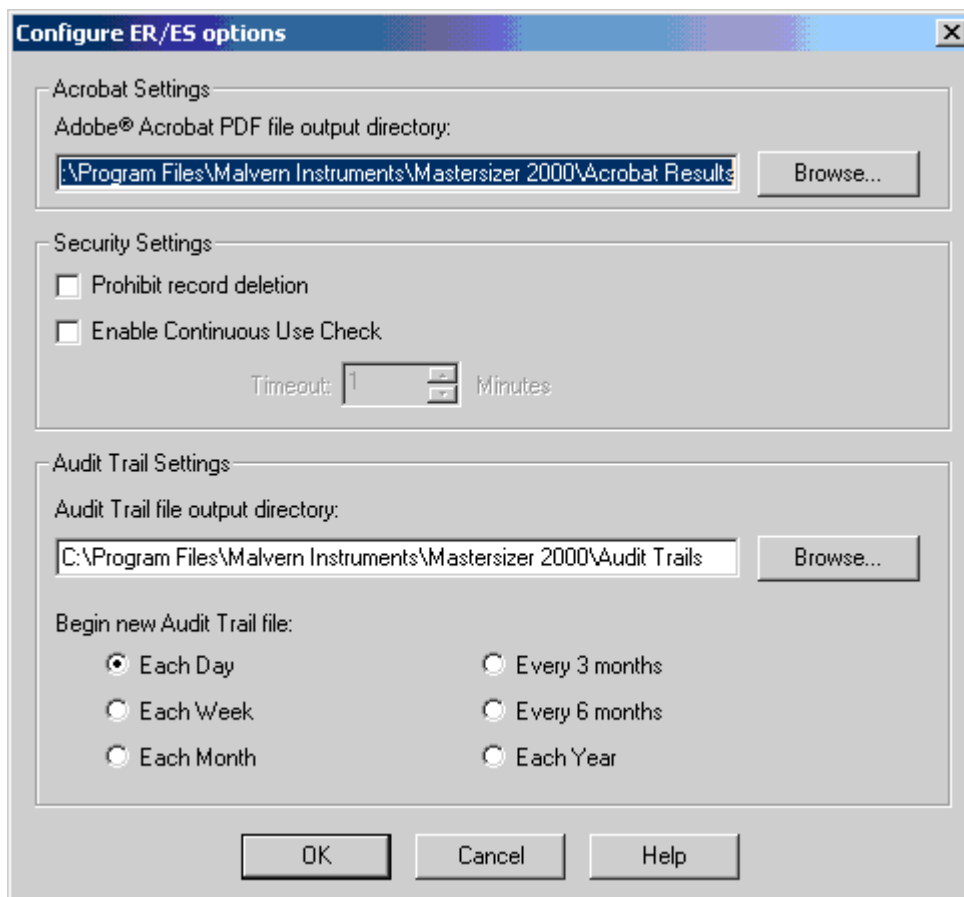Selecting Security>ER/ES Settings brings up the following dialogue:

Figure 10: ER/ES configuration dialogue

As can be seen, this dialogue enables Administrators to set 21 CFR Part 11-compliant features to suit the individual requirements of their laboratories.

Features that can be set are:

- **Prohibition of record deletion.**

  Some laboratories may have a need to delete records. When this occurs, the fact is recorded by greying the record out on the records view of the software.

- **Enable continuous use check.**

  This check will log the user out if no keyboard or mouse interaction has occurred within a certain period.

Note: This will not cause a measurement in progress to be aborted. The user can log back in to view the results and perform the next measurement.

- **Audit trail settings.**

  It is generally regarded as good practice to break files up into manageable lengths in order to facilitate the retrieval of data. This feature allows the Administrator to opt for daily, weekly or monthly record files.

9.3 Importing results from older instruments.

It is now possible to import records created on Mastersizer S, Mastersizer X, Mastersizer Micro and Mastersizer Microplus version 2.15 software and later. This provides an ongoing means of viewing records without the need to retain the original instrument:

Figure 11: Import results