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# Software Update Notification



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**Mastersizer 2000 version 5.10  
Application Software for use with (English) Microsoft  
Windows NT and Windows 2000**

**Mastersizer 2000  
(Part Number PSS0002/9)**

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## 1 Introduction

This is Version 5.10 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 Windows XP™ and comes on one auto loading compact disc (CD).

## 2 Instrument compatibility

The Mastersizer 2000 v5.10 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.

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

### 3.2 Requested Additions and changes.

The following software additions and changes are included in version 5.10:

SCR <sup>1</sup>	Description	Comments
2044	The creation of a new audit trail file should be logged in the current audit trail file.	Implemented
2055	The records used to create an average result should be recorded in the average data file notes.	Implemented
2070	The autosampler stirrer can still be left spinning when the head returns to the wash pot.	Fixed
2071	The prompt for a reason for record deletion should only occur when 21CFR11 mode has been enabled	Fixed
2095	The data fit table is blank for measurements taken using the red light source alone.	Fixed
2109	Editing a result clears the accessory details from the new result	Fixed

<sup>1</sup> Malvern Software Change Request Number

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SCR <sup>1</sup>	Description	Comments
2112	User settings are not preserved with software version 5.0	Fixed
2126	The data in the audit trail files is not encrypted and can be viewed using an external text editor.	Fixed
2127	The security permissions on edit and delete results are confused.	Fixed
2151	It is possible for the size range to be set to zero, causing an error when running SOP-driven or manual measurements	Fixed

In addition to these changes, a new software installer program has been used to simplify the installation process. Version 5.10 also includes the following changes were included in the release of Version 5.00.

SCR <sup>1</sup>	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

A full history of all the software changes included in Mastersizer 2000 software versions from v2.00 onwards is given in section 9.

## 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. It is recommended that 256MB of memory be available when running the software under Windows 2000 or Windows XP.

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 4.00 or greater on Windows 95/98/Me

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

For Windows 95™, 98™ and Millennium™, version 3.20 (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 New security system.

The new security system introduced in Version 5.10 is incompatible with the pre-existing 'Secure Layered Access' system. If version 5.10 is installed on a system with v4.00 or below, the security settings will have to be reconfigured to add users and groups.

### 5.5 Autosampler - flashing accessory icons.

The new version of the instrument firmware (FIDACS (v1.03 or greater)) must be downloaded to any instrument where an autosampler is to be used. A full description of how to do this is included in the contents.txt file, stored in the root directory of the installation CD.

### 5.6 Microsoft Internet Explorer

Mastersizer 20000 v5.10 software requires Microsoft Internet Explorer 4.1 or greater to be present in order for it to run.

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## 6 Distribution Media

Version 5.10 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 Installing Mastersizer 2000 application software

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 2000 $\mu$ P needs to be updated to the latest issue for additional diagnostics and some improvements to the Ultrasound control to be available.

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

### 8.1 Overview

A quick scan of section 3 above will show that a number of new features have been introduced to version v5.00 and v5.10 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](mailto:helpdesk@malvern.co.uk) or by telephoning the Helpdesk directly on +44 (0)1684-891800 Please have all necessary details to hand before telephoning.

### 8.2 21 CFR Part 11 Support Features.

Support for 21 CFR Part 11 was first introduced in version 3.20. Version 5.00 adds support for more advanced security control and independent audit trails.

#### 8.2.1 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**

#### 8.2.2 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.

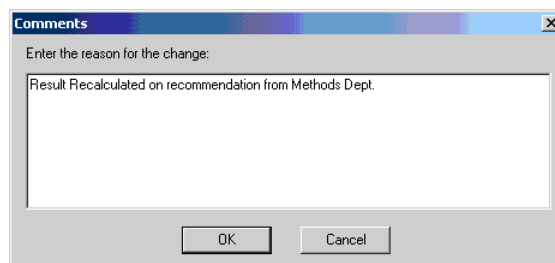


Figure 1: Reason for change dialogue



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## 8.2.3 SOP Versioning

The SOP dialogue now has a “Versions” tab on it:

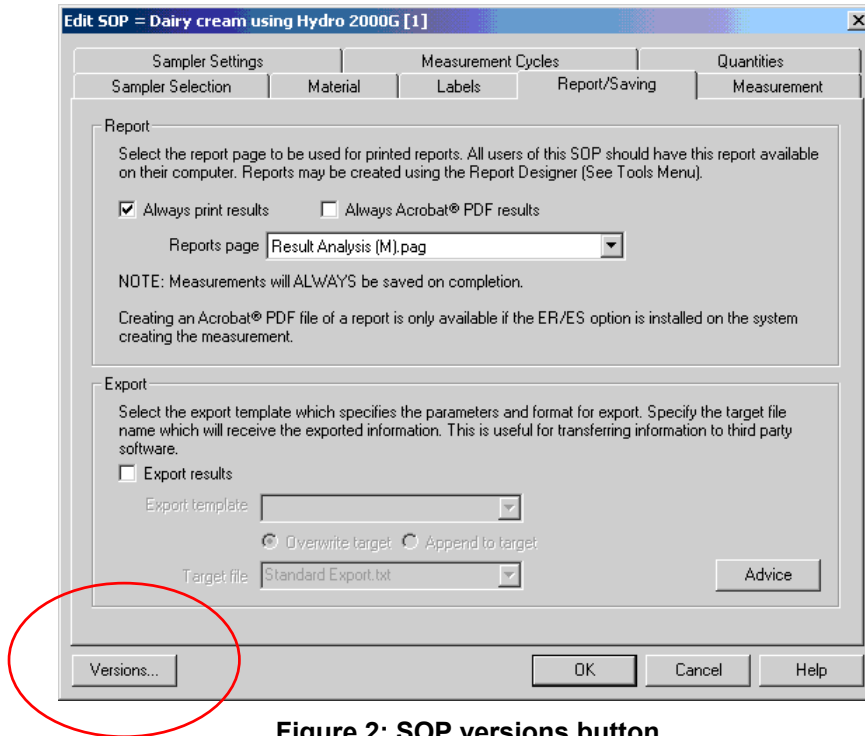


Figure 2: SOP versions button

Clicking on the Versions tab brings up an Audit trail for the SOP:

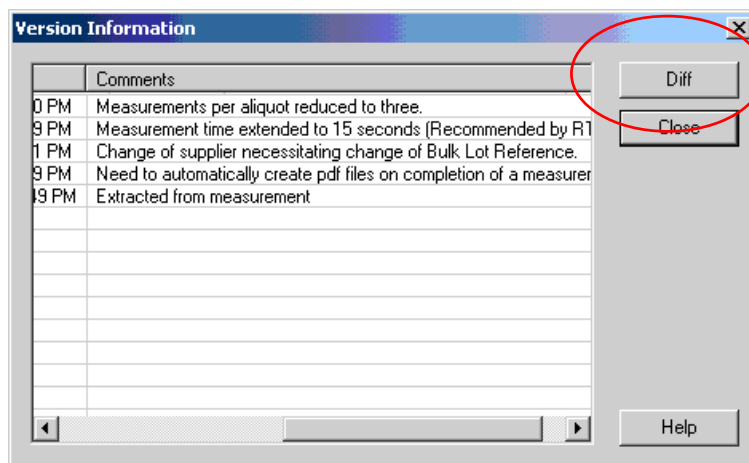
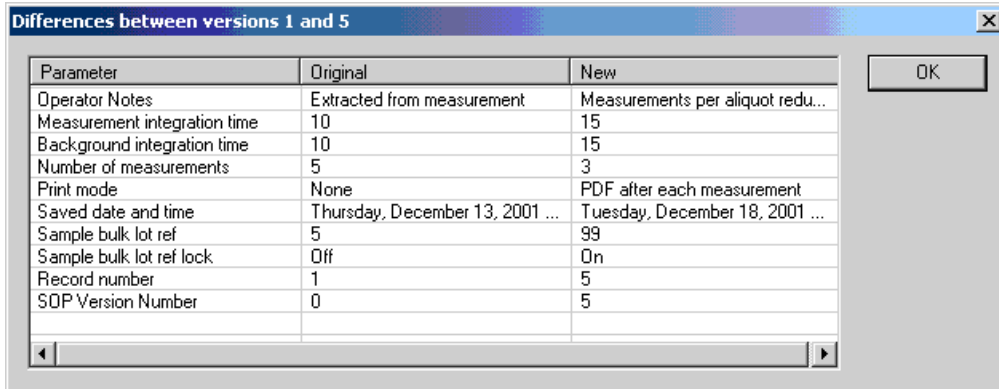


Figure 3: Version history

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



Parameter	Original	New
Operator Notes	Extracted from measurement	Measurements per aliquot redu...
Measurement integration time	10	15
Background integration time	10	15
Number of measurements	5	3
Print mode	None	PDF after each measurement
Saved date and time	Thursday, December 13, 2001 ...	Tuesday, December 18, 2001 ...
Sample bulk lot ref	5	99
Sample bulk lot ref lock	Off	On
Record number	1	5
SOP Version Number	0	5

## 8.2.4 Security features.

Clicking on “Security” on the Menu Bar displays this menu:

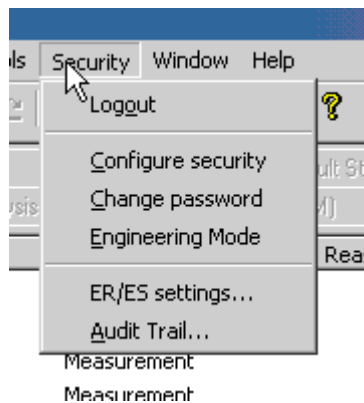
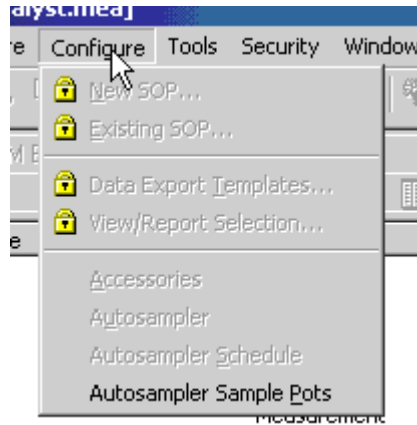


Figure 4: New security menu.

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

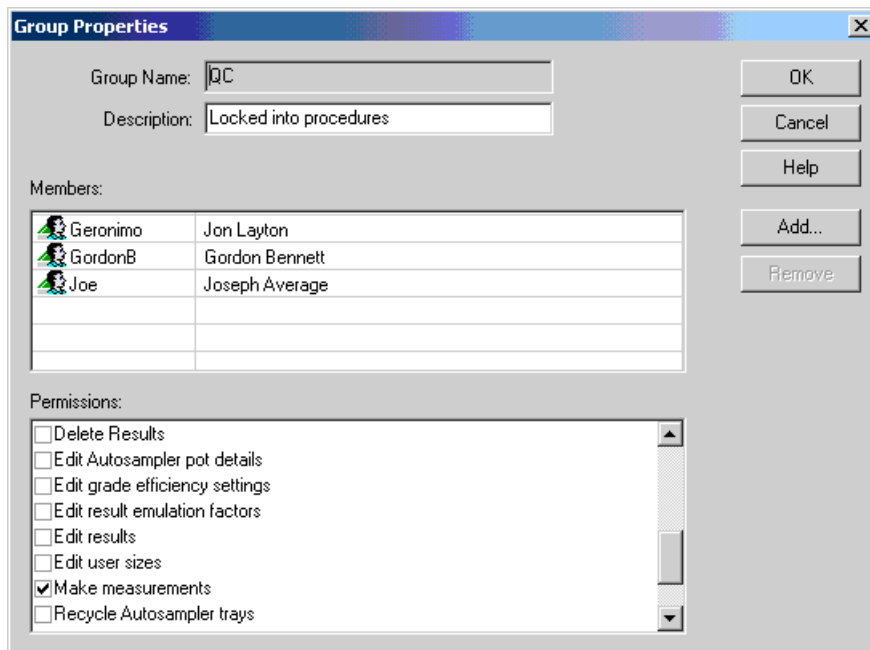
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When fully empowered operators log-out, all the features which they were authorised to use become unavailable:



**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.

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Selecting “Configure Security” allows the Administrator to view the individuals and their groups. (The passwords remain secret at all times.):

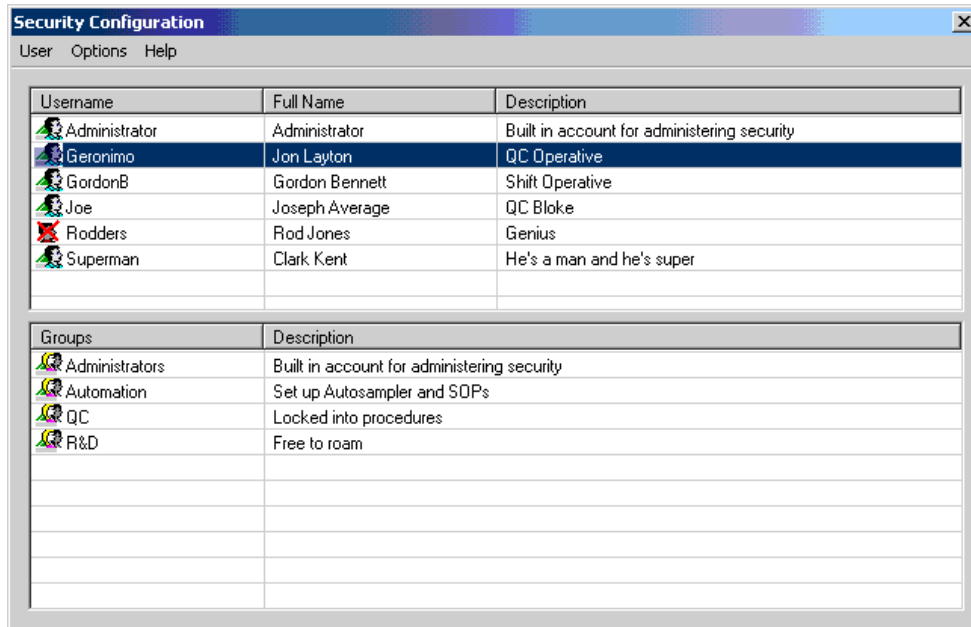


Figure 7: Security configuration

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:

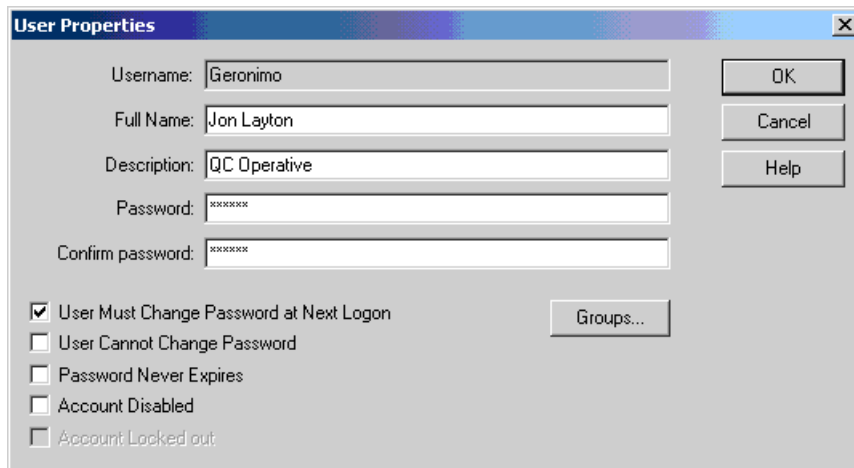
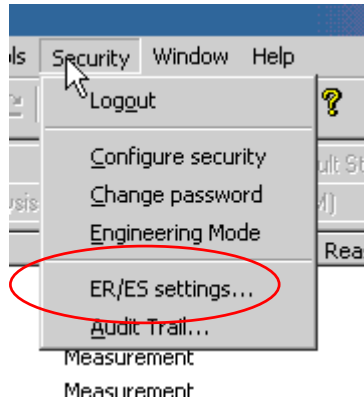


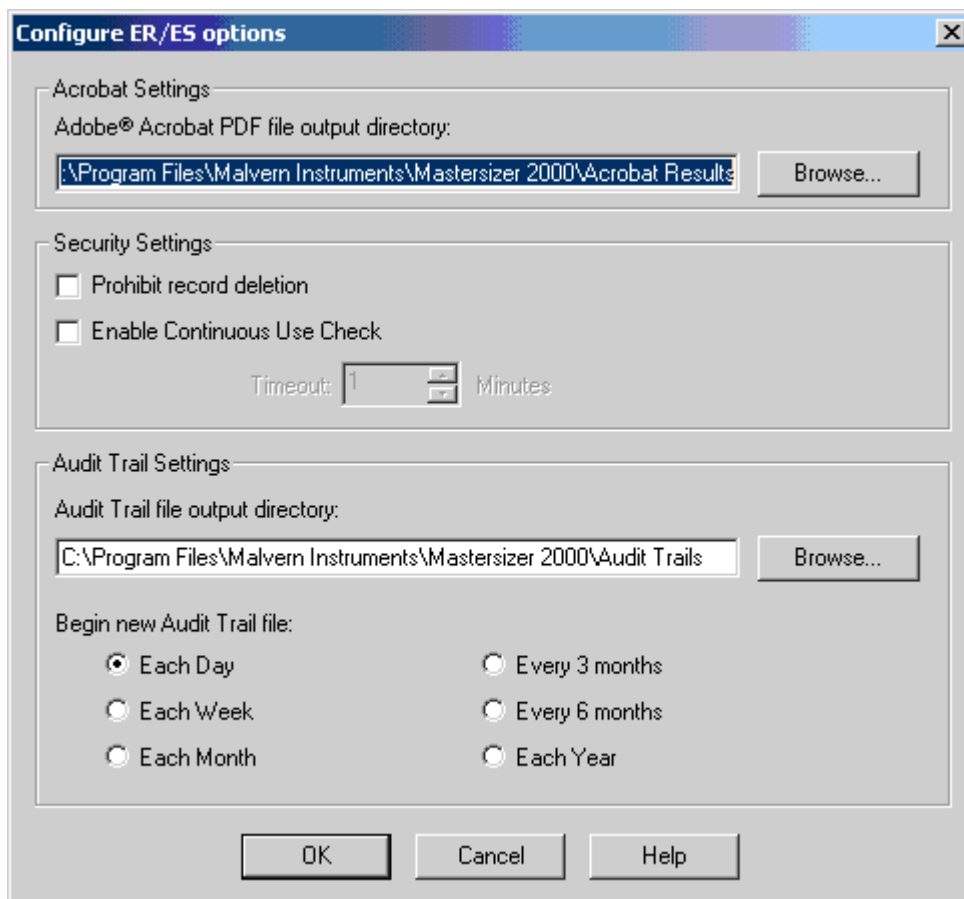
Figure 8: User properties

## 8.2.5 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.

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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.

### 8.3 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:

Result source	Software version	d (0.1)	d (0.5)	d (0.9)	Measured on
Old Mastersizer result	2.15	1.350	4.125	10.168	Monday, December 08, 1997 9:53:17 AM
Old Mastersizer result	2.15	1.359	4.156	10.199	Monday, December 08, 1997 9:53:25 AM
Old Mastersizer result	2.15	1.350	4.123	10.119	Monday, December 08, 1997 9:53:32 AM
Old Mastersizer result	2.15	1.360	4.151	10.200	Monday, December 08, 1997 9:53:40 AM
Old Mastersizer result	2.15	1.350	4.131	10.160	Monday, December 08, 1997 9:53:47 AM
Old Mastersizer result	2.15	1.330	4.028	9.803	Monday, December 08, 1997 9:56:42 AM
Old Mastersizer result	2.15	1.338	4.045	9.808	Monday, December 08, 1997 9:56:49 AM
Old Mastersizer result	2.15	1.338	4.052	9.850	Monday, December 08, 1997 9:56:57 AM
Old Mastersizer result	2.15	1.336	4.042	9.813	Monday, December 08, 1997 9:57:04 AM
Old Mastersizer result	2.15	1.336	4.049	9.820	Monday, December 08, 1997 9:57:12 AM

Figure 11: Import results

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## 9 Software Update History

The following section provides a brief description of the software changes implemented in all Mastersizer 2000 software versions starting from version 2.00.

### 9.1 PSS0002/09 Mastersizer 2000 v5.10

#### General

General Release.

This software will only run on Windows NT 4.0, Windows 2000, and Windows XP.

This software requires Microsoft Internet Explorer 4.1 or later to be installed before it will install.

#### New Features

- Improved installation program.
- An additional parameter lists the records that make up an average result.

#### Bug Fixes

- The Autosampler stirrer can be left spinning when the head moves to the clean pot.
- The prompt for reason to delete now only appears if 21 CFR Part 11 features are enabled.
- The user settings are now preserved. Logging in sets the files and record view settings to the users preferences.
- Editing a result no longer clears the accessory information from the edited record.
- The audit trail data is now encrypted.
- The fit table would appear blank if a red light only measurement was made.
- The date formatting used the system locale and not the users locale. This caused problems on systems with non-Gregorian calendars.
- If editing was allowed by the security settings then delete was also enabled even if prohibited by the security permissions.

### 9.2 PSS0002/08 Mastersizer 2000 v5.00

#### General

- General Release.
- This software will only run on Windows NT 4.0, Windows 2000, and Windows XP.
- This software requires Microsoft Data Access Components (MDAC) 2.7 to be installed before it will install. This software is included on the distribution CD-ROM.
- MDAC requires Microsoft Internet Explorer 4.1 or later to be installed before it will install.

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## New Features

- Full support for 21 CFR Part 11 when the additional 'Feature Key' software is installed.
- New comprehensive security system.
- The Hydro 2000 clean resets the pump/stirrer speed to the previous set point.
- Report pages can be password protected.
- Import of Mastersizer S/X/μ/μ+ records.

## Bug Fixes

- Failure of the Blue light during measurement crashed the software.
- Pressing STOP during the measurement in version 3.2 does not work correctly.
- The wrong accessory name and type is stored in the measurement record.
- Batch number auto increment did not work correctly.

## 9.3 PSS0002/07 Mastersizer 2000 v4.00

### General

- International Release.
- This software will only run on Windows NT 4.0, Windows 2000, and Windows XP.
- This software requires Microsoft Data Access Components (MDAC) 2.5 to be installed before it will install. This software is included on the distribution CD-ROM.
- MDAC requires Microsoft Internet Explorer 4.1 or later to be installed before it will install.

### New Features

- None.

### Bug Fixes

- The file name for the Hydro 2000μP accessory firmware caused the install to crash on Japanese and Chinese systems. The file was renamed to not use the μ character.

## 9.4 PSS0002/06 Mastersizer 2000 v4.00

### General

- General Release.
- This software will only run on Windows NT 4.0, Windows 2000, and Windows XP.
- This software requires Microsoft Data Access Components (MDAC) 2.5 to be installed before it will install. This software is included on the distribution CD-ROM.
- MDAC requires Microsoft Internet Explorer 4.1 or later to be installed before it will install.



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## New Features

- Support for the Autosampler accessory has been added.
- Support for "Remote Control" using Double Agent software has been added to the Scirocco and Hydro 2000 S/G accessories.
- QAS SOP files added to the CD-ROM.

## Bug Fixes

- The reason for change dialogue does not force the user to enter a reason.
- The quick start dialogue is not displayed when the application is run.

## 9.5 PSS0002/05 Mastersizer 2000 v3.20

### General

- General Release.
- This software is the last version to support Windows 95/98/Me.

### New Features

- Limited support for 21 CFR Part 11. Full support planned for version 5.00.
- Improvements to the Hydro 2000 $\mu$ P manual control dialogue.
- Reduced clean cycle introduced for the Hydro 2000 G.

### Bug Fixes

- The date was not correctly formatted to the localised settings.
- The ultrasound on the Hydro 2000 $\mu$ P did not time out if the manual control dialogue is displayed.
- The customer calculations always used the first result in the measurement file rather than the current result.
- Requested reports were not printed when a result is edited.
- The 21 CFR enabled software can only be run by users with Administrator rights.

## 9.6 PSS0002/04 Mastersizer 2000 v3.01

### General

- General Release.

### New Features

- Added translations of Mastersizer 2000 v2.00 to CD-ROM.

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## Bug Fixes

- None.

## 9.7 PSS0002/03 Mastersizer 2000 v3.01

### General

- General Release.

### New Features

- None.

### Bug Fixes

- Date format was fixed in American MM/DD/YY format. Corrected to pick up localised setting.

## 9.8 PSS0002/02 Mastersizer 2000 v3.01

### General

- General Release.

### New Features

- Hydro 2000 $\mu$ P ease of use features.
- Removed yellow as a first choice colour from graphs.

### Bug Fixes

- Export of calibration data adds to many commas in header record.
- Customer calculations did not use the correct measurement data when calculating the result.
- Red light only setting not preserved between manual measurements.

## 9.9 PSS0002/01 Mastersizer 2000 v3.00

### General

- Only released to customers with the Hydro 2000  $\mu$ P accessory.

### New Features

- Added support for the Hydro 2000  $\mu$ P.
- The measurement display update rate was reduced to 10 times a second. This makes the display more stable on faster computers.

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- User defined calculations in both the measurement and the report pages.
- Limited recovery tool for corrupted result files.
- A reduced sensitivity analysis mode was added.
- Support for red only measurement for blue light absorbing pigments.

## **Bug Fixes**

- The level sensor sensitivity check was removed for those accessories without a level sensor.
- The passwords were displayed in plain text in the secured layers access screen.
- Showing the data graph with no data caused an exception.