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# Software Update Notification



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**Mastersizer 2000 version 5.11**

**Application Software for use with (English) Microsoft  
Windows NT, Windows 2000 Professional and  
Windows XP Professional**

**Mastersizer 2000**

**(Part Number PSW0037-5.11)**

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## 1 Introduction

This is Version 5.11 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™ Pro (service pack 3 and higher) and Windows XP™ Pro (service pack 1a and higher) and comes on one auto loading compact disc (CD).

## 2 Instrument compatibility

The Mastersizer 2000 v5.11 software is back compatible with Mastersizer 2000 version 4.00 and below.

**Note:** In common with a large number of applications that 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 Released in v5.xx

### 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.

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## 3.1.2 SOP Version Control

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.

## 3.1.3 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 have been included in issue 12 of this software:

SCR <sup>1</sup>	Description	Comments
2210	Start menu icon is in the wrong place	Fixed (Issue 12)
2212	The Mastersizer S/X record fails to import within 8 hours of creating the S record	Fixed (Issue 12)
2191	The Mastersizer S/X record import can fail if the comments field is too long	Fixed (Issue 12)
2279	The Mastersizer S/X record import can fail if the date format is not understood by the Mastersizer 2000	Fixed (Issue 12)
2188	If security is not enabled the user name can be reset to Unknown instead of the NT user name	Fixed (Issue 12)
2233	If the additive name is not entered the SOP editor does	Fixed (Issue 12)

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

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SCR <sup>1</sup>	Description	Comments
	not warn the user that the other additive settings will not be retained	
2529	The obscuration SOP values are now validated between 0-100	Implemented (Issue 12)
2532	Enabling password expiration disables the force change password function	Fixed (Issue 12)
2595	The default autosampler obscuration in the SOP editor was 0 which is outside the allowable range	Fixed (Issue 12)
2622	In 21 CFR mode password expiration warns too soon	Fixed (Issue 12)
2645	The edit SOP in the Quick Start was not controlled by the security system	Fixed (Issue 12)
2950	The Hydro 2000 $\mu$ P incorrectly applied pre-measurement ultrasound before each measurement. It now only applies ultrasound before the first measurement in a series of measurements.	Fixed (Issue 12)
3029	It is possible to specify in the registry that the security system should not show the name of the last user in the login window.	Implemented (Issue 12)
3031	The time stamp format for the audit trail files was confusing for international systems. It has been modified to dd-MMM-yyyy TZ e.g. 11-Jun-2002 GMT	Implemented (Issue 12)
3032	The locked out accounts in the security system now have a different icon to indicate their status.	Implemented (Issue 12)

Version 5.11 also includes the following changes that were included in the release of Version 5.10:

SCR	Description	Comments
2229	The installer fails on Japanese systems	Fixed (issue 11)

SCR	Description	Comments
2205	Version 3.2 of Mastersizer is missing from the	Fixed (issue 10)
2206	The QAS standard SOP for the ceramic and stainless Scirocco had transposed pressure settings	Fixed (issue 10)
2207	The installer fails to install Measurement.dat if upgrading a previous installation of 5.00	Fixed (issue 10)

SCR	Description	Comments
2044	The creation of a new audit trail file should be logged in the current audit trail file.	Implemented (issue 9)
2055	The records used to create an average result should be	Implemented (issue 9)

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SCR	Description	Comments
	recorded in the average data file notes.	
2070	The autosampler stirrer can still be left spinning when the head returns to the wash pot.	Fixed (issue 9)
2071	The prompt for a reason for record deletion should only occur when 21CFR11 mode has been enabled	Fixed (issue 9)
2095	The data fit table is blank for measurements taken using the red light source alone.	Fixed (issue 9)
2109	Editing a result clears the accessory details from the new result	Fixed (issue 9)
2112	User settings are not preserved with software version 5.0	Fixed (issue 9)
2126	The data in the audit trail files is not encrypted and can be viewed using an external text editor.	Fixed (issue 9)
2127	The security permissions on edit and delete results are confused.	Fixed (issue 9)
2151	It is possible for the size range to be set to zero, causing an error when running SOP-driven or manual measurements	Fixed (issue 9)

In addition to these changes, a new software installer program was used to simplify the installation process. Version 5.11 also includes the following changes that 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 (issue 8)
1140	Add an inactivity log-out feature	Implemented (issue 8)
1168	Add security control to the report designer and the calculation editor.	Implemented (issue 8)
1255	Add an audit trail for 21 CFR systems	Implemented (issue 8)
1531	Display the current user name on the main window	Implemented (issue 8)
1625	Add a 21 CFR icon to the status bar	Implemented (issue 8)
1777	Add ability to password-protect report files	Implemented (issue 8)
1835	If the QC calculation returns an unexpected value, the system crashes	Fixed (issue 8)
1885	Batch number does not auto increment	Fixed (issue 8)
1961	Wet accessories manual control screen displayed faults using a green LED rather than a RED led.	Fixed (issue 8)
2002	The auto-start stabilisation delay period is not validated in the SOP editor.	Fixed (issue 8)

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

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## 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 File sizes

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™ Pro and Windows XP Pro).

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 5.11 is incompatible with the pre-existing 'Secure Layered Access' system. If version 5.11 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 2000 v5.11 software requires Microsoft Internet Explorer 4.1 or greater to be present in order for it to install. This software is included on the installation CD for all the supported languages and is available from the Microsoft internet site for download.

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## 5.7 Localised number formats.

The software does not function correctly if the number format set in the localisation settings of the system has the comma character either as the decimal marker or as the separator for thousands. The remedy is to modify the number format to exclude this character. This can be done in the Regional Options of Control Panel.

## 6 Distribution Media

Version 5.11 software is contained on a single self-installing CD-ROM. The installation process has been fully automated by the industry standard software installer InstallShield Developer™. 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 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 **lsetup.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 v5.11 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.

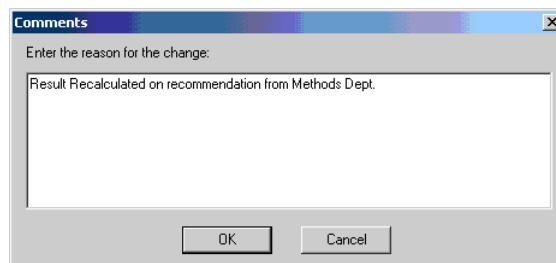


Figure 1: Reason for change dialogue

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## 8.2.3 SOP Versioning

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

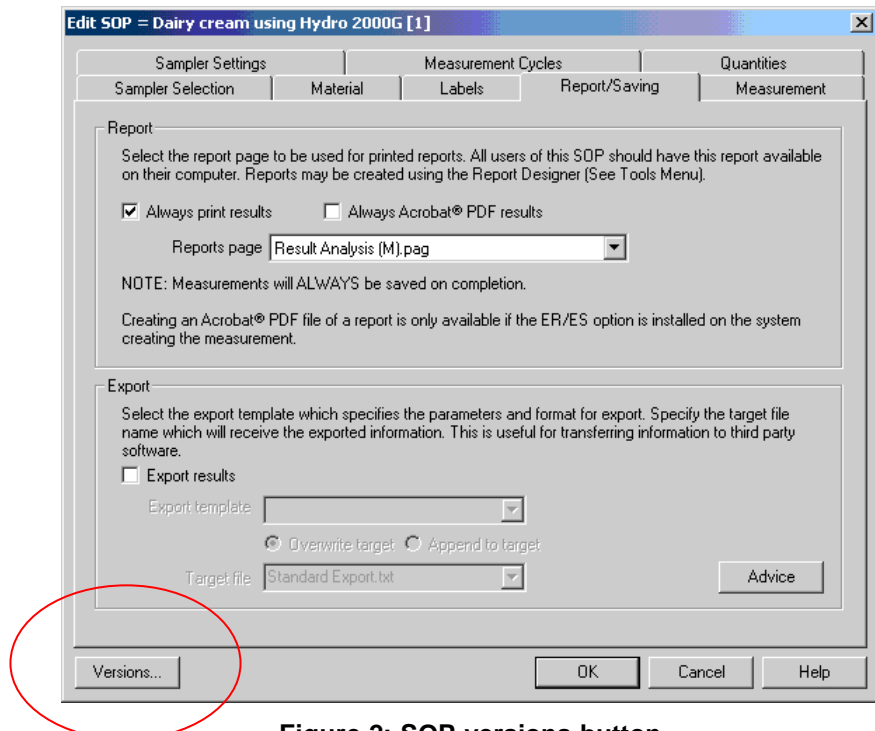


Figure 2: SOP versions button

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

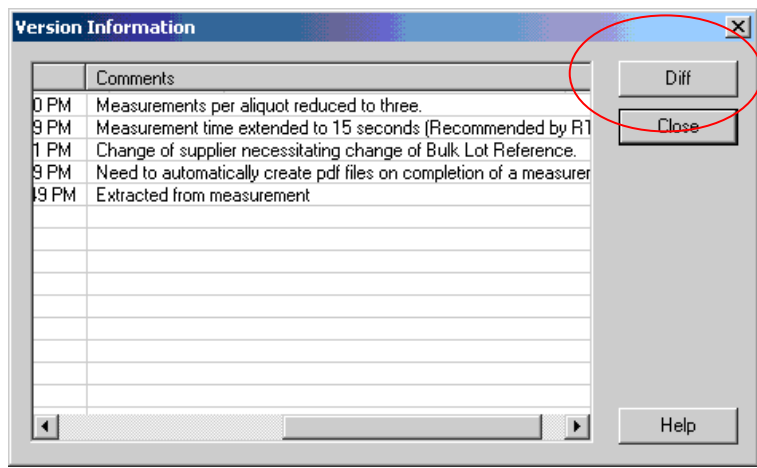
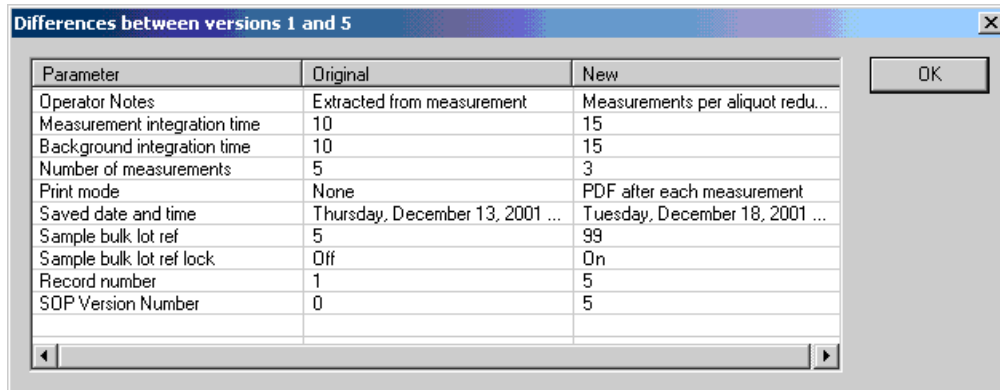


Figure 3: Version history

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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:

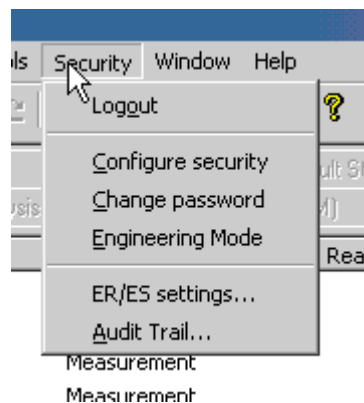
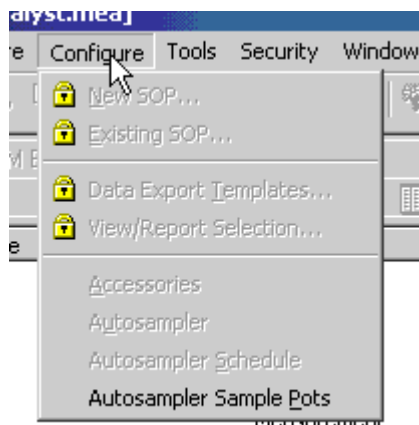


Figure 4: New security menu.

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

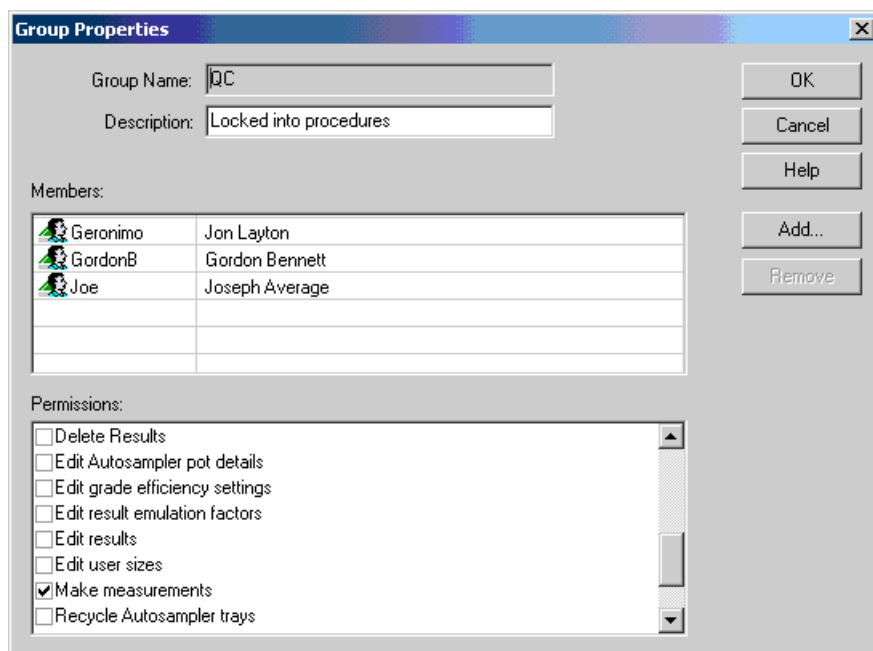
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When fully empowered operators log-out, all the features which they were authorised to use become unavailable:



**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.):

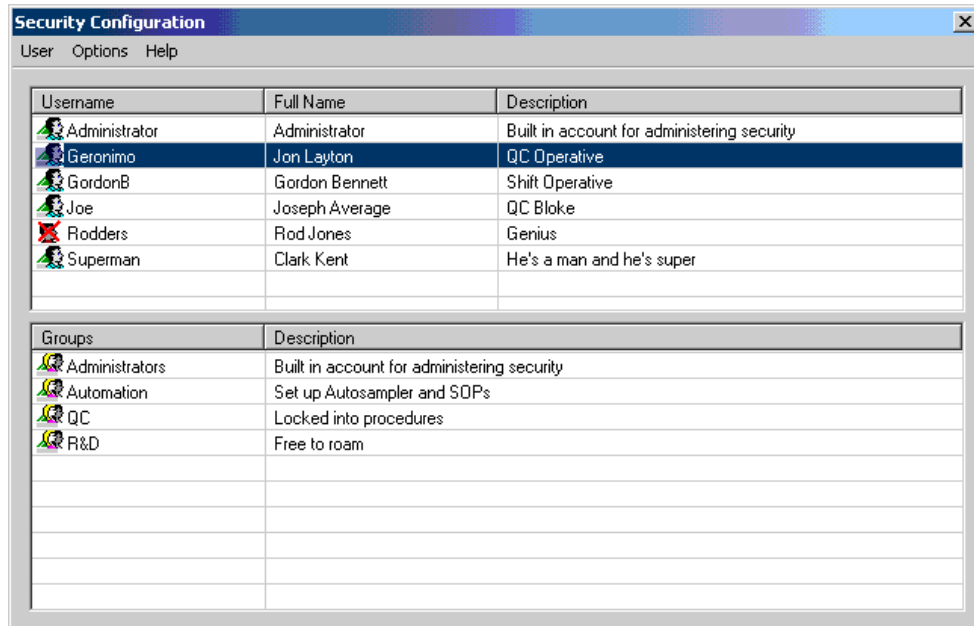


Figure 7: Security configuration

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. Accounts that have been locked-out due to incorrect password use are shown with a padlock.

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

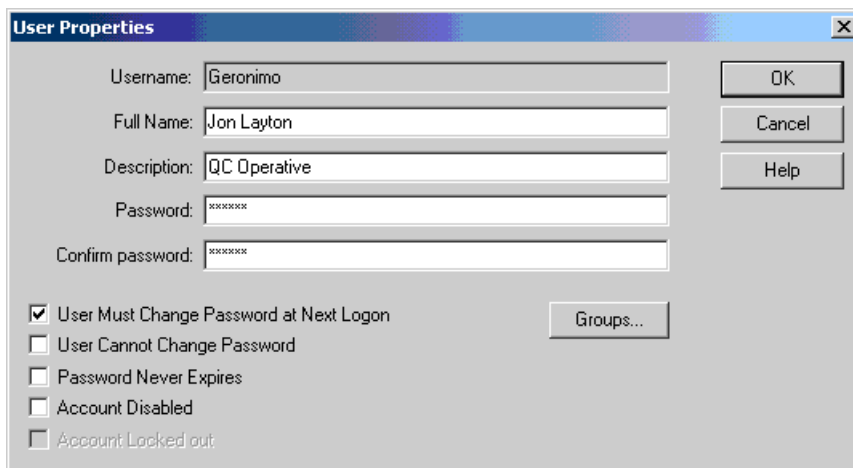


Figure 8: User properties

## 8.2.5 ER/ES Settings

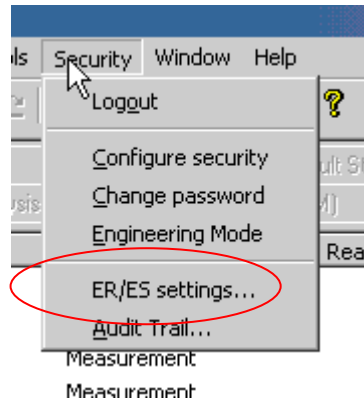


Figure 9: Configure menu

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

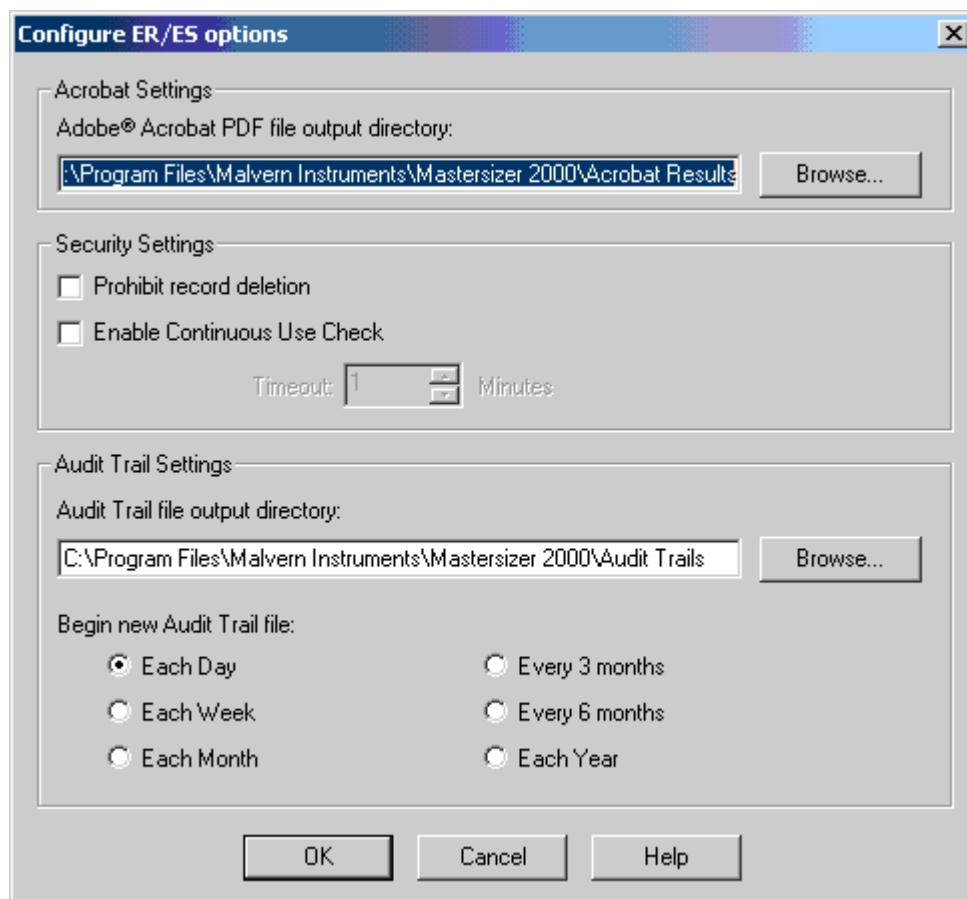


Figure 10: ER/ES configuration dialogue

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. Details for the current release are given in sections 1 to 3 of this document.

### 9.1 PSS0002/11 Mastersizer 2000 v5.10

#### General

- General Release.
- This software will only run on Windows NT 4.0, Windows 2000 Pro, and Windows XP Pro.
- This software requires Microsoft Internet Explorer 4.1 or later to be installed before it will install.

#### New Features

- None.

#### Bug Fixes

- The software installation failed on Japanese and Chinese systems.

### 9.2 PSS0002/10 Mastersizer 2000 v5.10

#### General

- General Release.
- This software will only run on Windows NT 4.0, Windows 2000 Pro, and Windows XP Pro.
- This software requires Microsoft Internet Explorer 4.1 or later to be installed before it will install.

#### New Features

- none.

#### Bug Fixes

- The Windows 95/98/Me compatible version of Mastersizer 2000 was missing off the previous.
- The QAS SOP settings for the Ceramic and Stainless Scirocco were transposed.
- The installer did not correctly upgrade 5.00 installations resulting in report designer not working correctly. All other areas of the system operated without error.

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

#### General

- General Release.
- This software will only run on Windows NT 4.0, Windows 2000 Pro, and Windows XP Pro.
- This software requires Microsoft Internet Explorer 4.1 or later to be installed before it will install.



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## 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.

## 9.4 PSS0002/08 Mastersizer 2000 v5.00

### General

- General Release.
- This software will only run on Windows NT 4.0, Windows 2000 Pro, and Windows XP Pro.
- 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.

### 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/ $\mu$ / $\mu$ + 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.

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- Batch number auto increment did not work correctly.

## 9.5 PSS0002/07 Mastersizer 2000 v4.00

### General

- International Release.
- This software will only run on Windows NT 4.0, Windows 2000 Pro, and Windows XP Pro.
- 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 2000 $\mu$ P accessory firmware caused the install to crash on Japanese and Chinese systems. The file was renamed to not use the  $\mu$  character.

## 9.6 PSS0002/06 Mastersizer 2000 v4.00

### General

- General Release.
- This software will only run on Windows NT 4.0, Windows 2000 Pro, and Windows XP Pro.
- 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

- 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.

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## 9.7 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.

## 9.8 PSS0002/04 Mastersizer 2000 v3.01

### General

- General Release.

### New Features

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

### Bug Fixes

- None.

## 9.9 PSS0002/03 Mastersizer 2000 v3.01

### General

- General Release.

### New Features

- None.

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# Software Update Notification



File Name : QSpec Update Notification for Mastersizer 2000 v5.11.pdf

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## Bug Fixes

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

## 9.10 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.

## 9.11 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.
- 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.