



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

Mastersizer 2000 version 5.12 English French German Chinese Japanese

Application Software for use with Microsoft Windows NT, Windows 2000 Professional and Windows XP Professional

Mastersizer 2000

(Part Number PSS0002-12)

QSpec Software Update Notification



QSpec Update Notification (PSS0002-12) v5.12.doc File Name :

0 **Contents**

0 Co	ntents	. 2
1 Ins	tallation	. 3
1.1	Microsoft Internet Explorer	
1.2	Microsoft Data Access Components (MDAC)	3
2 Ins	trument compatibility	3
3 Fu	nctional Features Released in v5.xx	
3.1	Planned Additions and Headline Utilities.	. 4
3.1.1	·····	
3.1.2		
3.1.3		
3.2	Requested Additions and changes.	
3.3	Deletions	
4 Kn	own Bugs	. 8
5 Kn	own Issues	. 8
5.1	File sizes	-
5.2	Installing an earlier version after un-installing v3.x. or above	
5.3	Can not install version 4.00 or greater on Windows 95/98/Me	
5.4	New security system.	
5.5	Autosampler - flashing accessory icons	
5.6	Localised number formats	9
6 Dis	tribution Media	. 9
7 Ins	talling the Software	. 9
7 Ins 7.1	talling the Software Installing Mastersizer 2000 application software	
7.1	Installing Mastersizer 2000 application software	. 9
7.1 8 Wh	Installing Mastersizer 2000 application software at new features are present and how do I use them?	. 9 10
7.1	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview	. 9 10 10
7.1 8 Wh 8.1	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview	. 9 10 10 10
7.1 8 Wh 8.1 8.2	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview	. 9 10 10 10 10
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview	. 9 10 10 10 10 10 10
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3 8.2.4	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview	. 9 10 10 10 10 10 11 12
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview	. 9 10 10 10 10 10 11 12 15
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3 8.2.4	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview	. 9 10 10 10 10 10 11 12 15
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3	Installing Mastersizer 2000 application software at new features are present and how do I use them?	9 10 10 10 10 10 11 12 15 16 17
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3	Installing Mastersizer 2000 application software	9 10 10 10 10 10 11 12 15 16 17
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3 9 Sot 9.1 9.2	Installing Mastersizer 2000 application software	9 10 10 10 10 10 10 11 12 15 16 17 17
7.1 8 Wh 8.1 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3 9 Sof 9.1 9.2 9.3	Installing Mastersizer 2000 application software	9 10 10 10 10 10 11 12 15 16 17 17 17
7.1 8 Wh 8.1 8.2 8.2.3 8.2.4 8.2.5 8.3 9 Sot 9.1 9.2 9.3 9.4	Installing Mastersizer 2000 application software	9 10 10 10 10 10 11 12 15 16 17 17 17 17
7.1 8 Wh 8.1 8.2 8.2.3 8.2.4 8.2.5 8.3 9 Sof 9.1 9.2 9.3 9.4 9.5	Installing Mastersizer 2000 application software	9 10 10 10 10 10 10 10 11 12 15 16 17 17 17 18 18
7.1 8 Wh 8.1 8.2 8.2.3 8.2.4 8.2.5 8.3 9 Sot 9.1 9.2 9.3 9.4 9.5 9.6	Installing Mastersizer 2000 application software	9 10 10 10 10 10 10 10 11 12 15 16 17 17 17 18 18 19
7.1 8 Wh 8.1 8.2 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3 9 Sof 9.1 9.2 9.3 9.4 9.5 9.6 9.7	Installing Mastersizer 2000 application software	. 9 10 10 10 10 11 12 15 16 17 17 17 18 18 19 20
7.1 8 Wh 8.1 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3 9 Sol 9.1 9.2 9.3 9.4 9.5 9.6 9.7 9.8	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview 21 CFR Part 11 Support Features. Printing Results to PDF files for Electronic Signature Editing Results SOP Versioning Security features	. 9 10 10 10 10 11 12 15 16 17 17 17 18 18 19 20 20
7.1 8 Wh 8.1 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3 9 Sol 9.1 9.2 9.3 9.4 9.5 9.6 9.7 9.8 9.9	Installing Mastersizer 2000 application software	. 9 10 10 10 10 11 12 15 16 17 17 17 18 18 19 20 21
7.1 8 Wh 8.1 8.2.1 8.2.2 8.2.3 8.2.4 8.2.5 8.3 9 Sol 9.1 9.2 9.3 9.4 9.5 9.6 9.7 9.8	Installing Mastersizer 2000 application software at new features are present and how do I use them? Overview 21 CFR Part 11 Support Features. Printing Results to PDF files for Electronic Signature Editing Results SOP Versioning Security features	. 9 10 10 10 11 12 15 16 17 17 17 18 18 19 20 21 21

QSpec Software Update Notification

Page 2 of 22 pages



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

1 Installation

This is Version 5.12 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 4 and higher) and Windows XP[™] Pro (service pack 1a and higher) and comes on one auto loading compact disc (CD).

1.1 Microsoft Internet Explorer

Mastersizer 2000 v5.12 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.

1.2 Microsoft Data Access Components (MDAC)

Mastersizer 2000 v5.12 software requires MDAC 2.5 or greater to be present in order for it to install.

This software is included in Windows 2000 Pro and Windows XP Pro but may need to be installed on Windows NT 4.0. The installer will detect if it is required.

This software is included on the installation CD for all the supported languages and is available from the Microsoft Internet site for download.

2 Instrument compatibility

The Mastersizer 2000 v5.12 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.



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

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.

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.



File Name :QSpec Update Notification (PSS0002-12) v5.12.doc

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 ¹	Description	Comments
2941,	German text appears in French SOP	Fixed (Issue 12)
2968		
2963	French translation of open incorrect	Fixed (Issue 12)
2964	Dry tray is incorrect type in French SOP	Fixed (Issue 12)
2965	Air pressure units are incorrect in French	Fixed (Issue 12)
2967	Autosampler editor has text too large to fit screen in	Fixed (Issue 12)
	French	
3065	The tray code can mismatch on localized software	Fixed (Issue 12)
3328	Non-Automation variable used in remote interface	Fixed (Issue 12)
3207	Make the autosampler script less sensitive to intermittent	Implemented (Issue 12)
	error signals from accessory	
3277	Acrobat 6.0 support for 21 CFR Enabled Systems	Implemented (Issue 12)
CFB	Obscuration should be a real number not an integer. 0.5 is	Implemented (Issue 12)
0086	a valid value	

¹ Malvern Software Change Request Number

QSpec Software Update Notification



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

Version 5.12 also includes the following changes that were included in the release of Version 5.11 (English):

SCR	Description	Comments
2210	Start menu icon is in the wrong place	Fixed (PSW 0037-5.11)
2212	The Mastersizer S/X record fails to import within 8 hours of creating the S record	Fixed (PSW 0037-5.11)
2191	The Mastersizer S/X record import can fail if the comments field is too long	Fixed (PSW 0037-5.11)
2279	The Mastersizer S/X record import can fail if the date format is not understood by the Mastersizer 2000	Fixed (PSW 0037-5.11)
2188	If security is not enabled the user name can be reset to Unknown instead of the NT user name	Fixed (PSW 0037-5.11)
2233	If the additive name is not entered the SOP editor does not warn the user that the other additive settings will not be retained	Fixed (PSW 0037-5.11)
2529	The obscuration SOP values are now validated between 0-100	Implemented (PSW 0037-5.11)
2532	Enabling password expiration disables the force change password function	Fixed (PSW 0037-5.11)
2595	The default autosampler obscuration in the SOP editor was 0 which is outside the allowable range	Fixed (PSW 0037-5.11)
2622	In 21 CFR mode password expiration warns too soon	Fixed (PSW 0037-5.11)
2645	The edit SOP in the Quick Start was not controlled by the security system	Fixed (PSW 0037-5.11)
2950	The Hydro 2000µP incorrectly applied pre-measurement ultrasound before each measurement. It now only applies ultrasound before the first measurement in a series of measurements.	Fixed (PSW 0037-5.11)
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 (PSW 0037-5.11)
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 (PSW 0037-5.11)
3032	The locked out accounts in the security system now have a different icon to indicate their status.	Implemented (PSW 0037-5.11)

Version 5.12 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)



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

Version 5.12 also includes the following changes that were included in the release of Version 5.10:

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	Fixed (issue 10)
	Scirocco had transposed pressure settings	
2207	The installer fails to install Measurement.dat if upgrading	Fixed (issue 10)
	a previous installation of 5.00	

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 recorded in the average data file notes.	Implemented (issue 9)
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 5.12 also includes the following changes that were included in the release of Version 5.00:

SCR ¹	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	Implemented (issue 8)
	calculation editor.	
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)

QSpec Software Update Notification

Page 7 of 22 pages





8 of 22

SCR ¹	Description	Comments
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.

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.

Known Issues 5

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. Mastersizer 2000 v3.20 is available from the Malvern Instruments web site www.malverninstruments.com

5.4 New security system.

The new security system introduced in Version 5.00 is incompatible with the pre-existing 'Secure Layered Access' system. If version 5.12 is installed on a system with v4.00 or below, the security settings will have to be reconfigured to add users and groups.

QSpec Software Update Notification





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 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 of 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 5.12 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 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.



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

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 v5.12 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 <u>helpdesk@malvern.co.uk</u> 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.

Comments			×
Enter the reason for the chang	ge:		
Result Recalculated on recor	mmendation from Metho	ds Dept.	
Г	ок	Cancel	
L		Sancer	

Figure 1: Reason for change dialogue





8.2.3 SOP Versioning

The SOP dialogue now has a "Versions" tab on it:

Sampler Settings		Measurement Cy	cles	Qua	antities
Sampler Selection	Material	Labels	Report/Savir	ng M	leasureme
Report					
Select the report page to on their computer. Report					ort availabl
Always print results	🗖 Always /	Acrobat® PDF resul	ts		
Reports page	esult Analysis (M).	.pag	-		
NOTE: Measurements w	ill ALWAYS be sa	ved on completion.			
Creating an Acrobat® P[)E filo of a report i	o oplu pupilablo if the	ED/EC option is	installed on th	o ouotom
		s only available if the	e Em/Ep option is	installed on th	ie system
	ot				
creating the measuremer	nt.				, in the second s
	nt.				
creating the measuremen Export	nt.				
Export Select the export templa	te which specifies				rget file
Export Select the export templat name which will receive	te which specifies				rget file
Export Select the export templat name which will receive software.	te which specifies				rget file
Export Select the export templat name which will receive	te which specifies				rget file
Export Select the export templat name which will receive software.	te which specifies				rget file
Export Select the export templat name which will receive software.	te which specifies				rget file
Export Select the export templat name which will receive software. Export results Export template	te which specifies the exported inforr		l for transferring ir		rget file
Export Select the export templat name which will receive software. Export results Export template	te which specifies the exported infor Overwrite target	mation. This is usefu	l for transferring ir		rget file ird party
Export Select the export templat name which will receive software. Export results Export template	te which specifies the exported inforr	mation. This is usefu	l for transferring ir		rget file
Export Select the export templat name which will receive software. Export results Export template	te which specifies the exported infor Overwrite target	mation. This is usefu	l for transferring ir		rget file ird party
Export Select the export templat name which will receive software. Export results Export template	te which specifies the exported infor Overwrite target	mation. This is usefu	l for transferring ir		rget file ird party
Export Select the export templat name which will receive software. Export results Export template	te which specifies the exported infor Overwrite target	mation. This is usefu	l for transferring ir		rget file ird party
Export Select the export templat name which will receive software. Export results Export template	te which specifies the exported infor Overwrite target	mation. This is usefu	l for transferring ir		rget file ird party

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

	Comments Diff	
D PM	Measurements per aliquot reduced to three.	
9 PM -	Measurement time extended to 15 seconds (Recommended by R1 Close	
1 PM	Change of supplier necessitating change of Bulk Lot Reference.	
9 PM -	Need to automatically create pdf files on completion of a measurer	
9 PM	Extracted from measurement	
	I ▶I Help	

Figure 3: Version history



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

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

Parameter	Original	New	OK
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.



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

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

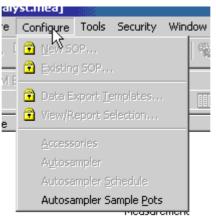


Figure 5: Secured menu options

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

Group Properties			×
Group Name:	jac		ОК
Description:	Locked into procedures		Cancel
Members:			Help
A Geronimo	Jon Layton		Add
A GordonB	Gordon Bennett		Remove
∕ ∰Joe	Joseph Average		Thomp is
I			
Permissions:			
Delete Results	at dataila	<u> </u>	
Edit grade efficient			
Edit result emulatio			
Edit results			
Edit user sizes			
Make measuremer	its		
Recycle Autosamp	ler traus		

Figure 6: Group Settings

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



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

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

Username	Full Name	Description		
🕵 Administrator	Administrator	Built in account for administering security		
🥵 Geronimo	Jon Layton	QC Operative		
🥵 GordonB	Gordon Bennett	Shift Operative		
🕵 Joe	Joseph Average	QC Bloke		
📕 Rodders	Rod Jones	Genius		
🧟 Superman	Clark Kent	He's a man and he's super		
Administrators		nisterina security		
Groups	Description			
Automation	Built in account for administering security			
QC Automation	Locked into procedures	Set up Autosampler and SOPs		
	Free to roam			
MAR BYD	Fiee to toan			
🧟 R&D				
₩ K&D				
*** H&D				

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:

User Properties				×
Username:	Geronimo		[OK
Full Name:	Jon Layton			Cancel
Description:	QC Operative			Help
Password:	xxxxxx			
Confirm password:	******			
User Must Change User Cannot Chan Password Never E Account Disabled	zpires	Groups		





File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

8.2.5 ER/ES Settings



Figure 9: Configure menu

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

directory:		
•	t Results	Browse
k		
× Minutes		
nents\Mastersizer 2000\Audit 1	Trails	Browse
	·	
C Every 3 months		
C Every 6 months		
C Each Year		
	k Minutes nents\Mastersizer 2000\Audit © Every 3 months © Every 6 months	Minutes Minutes Minutes Nents\Mastersizer 2000\Audit Trails Every 3 months Every 6 months

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.

QSpec Software Update Notification



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

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:

Amastersizer 2000 - [#Mastersizer5Results.mea]							
	Ctrl+N	ire Tools Security Window Help	?		→ II = 1 ④ 6	v • • • []	 ⊑ ç≣ 曾 Current User: Admir
☐ ☐ Open Close ☐ Save	Ctrl+O	() Fe Re ult Analysis (M) Data	sult Statistics (M (M))	Farame	ter report (M) ence (M)	Trend (M)
Sa Save <u>A</u> s		Result source	Software ver	rsion d (0.1)	d (0.5)	d (0.9)	Measured on
Export Data Import S/X Brint Print Preyjew Print Setup Batch Print	Ctrl+P	Old Mastersizer result Old Mastersizer result	2.15 2.15 2.15 2.15 2.15 2.15 2.15 2.15	1.350 1.359 1.350 1.360 1.350 1.330 1.338 1.338 1.336	4.125 4.156 4.123 4.151 4.131 4.028 4.045 4.045 4.052 4.042	10.168 10.199 10.119 10.200 10.160 9.803 9.808 9.850 9.813	Monday, December 08, 1997 9:53:17 AM Monday, December 08, 1997 9:53:25 AM Monday, December 08, 1997 9:53:25 AM Monday, December 08, 1997 9:53:40 AM Monday, December 08, 1997 9:53:47 AM Monday, December 08, 1997 9:56:42 AM Monday, December 08, 1997 9:56:57 AM Monday, December 08, 1997 9:56:57 AM
Print PDF Send MastersizerSR 2 catalyst.mea 3 Examples.mea	esults.mea	Old Mastersizer result Old Mastersizer result	2.15	1.336	4.049	9.820	Monday, December 08, 1997 9:57:12 AM

Figure 11: Import results



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

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 PSS0002/12 Mastersizer 2000 v5.12

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.
- The French, German, Japanese, and Chinese versions require MDAC 2.5 to be installed.

New Features

- Support for Adobe Acrobat version 6.0 in 21 CFR Enabled Systems.
- Localized versions of Mastersizer 2000 v5.12

Bug Fixes

- Obscuration limits below 1.0 were not supported.
- Translation errors on French version.

9.2 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.

9.3 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.



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

• 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 issue.
- 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.

9.4 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.

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.

9.5 PSS0002/08 Mastersizer 2000 v5.00

General

General Release.

QSpec Software Update Notification



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

- 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/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.

9.6 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 2000µP accessory firmware caused the install to crash on Japanese and Chinese systems. The file was renamed to not use the µ character.



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

9.7 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.

9.8 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 2000µP 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 2000µP 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.



QSpec Update Notification (PSS0002-12) v5.12.doc File Name :

9.9 PSS0002/04 Mastersizer 2000 v3.01

General

General Release. •

New Features

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

Bua Fixes

None. •

9.10 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.

9.11 PSS0002/02 Mastersizer 2000 v3.01

General

General Release. ٠

New Features

- Hydro 2000µP 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. .



File Name : QSpec Update Notification (PSS0002-12) v5.12.doc

9.12 PSS0002/01 Mastersizer 2000 v3.00

General

• Only released to customers with the Hydro 2000 μ P accessory.

New Features

- Added support for the Hydro 2000 µP.
- 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.