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Mastersizer S, X, Micro and Microplus Version 3.10 Application software for operation on Microsoft Windows NT, Windows 2000 and Windows XP only

(Not compatible with Windows 95™, 98™ or Millenium™.)

Note: For convenience, Mastersizer S, X, Micro and Microplus will simply be referred to as "Legacy Systems" throughout this document.

(PSS0008/05 Legacy Diffraction Software Suite)

Important Note: Licensing.

Before making measurements, you will be required to enter a licence code obtained from Malvern Instruments. If you do not have a licence code, you should contact Malvern Instruments to purchase one. You will need to know the serial number of the specific Mastersizer instrument that you propose to use with the version 3.10 software.

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1 Introduction

This is Version 3.10 of the application software for the Mastersizer S, Mastersizer X, Micro and Microplus which, for simplicity, will be referred to throughout this document as "Legacy Systems". (Systems which were in production at the time that FDA 21CFR Part 11 was passed into Law in August 1997).

Version 3.00 of this software used Adobe Acrobat PDF Writer to create PDF files for Digital Signature. PDFWriter is no longer available in Version 6 of Adobe Acrobat and so it was necessary to introduce this version of the application software to be able to use Distiller.

This current version of software provides the necessary compatibility with Adobe Acrobat Versions 4 and 5 as well as version 6.

It has been fully Alpha Tested on Windows 2000 SP2 and has been functionally tested on Windows XP and Windows NT 4.0 SP 6a. Note that this software will require Windows NT, XP or 2000 to ensure the fullest possible compliance with the requirements of 21 CFR Part 11.

2 Instrument compatibility

This software is back compatible with Legacy Systems having software versions 3.00 and earlier back to version 2.15. Owing to the fact that the record structure has not been changed, Version 3.10 records will also be readable by earlier versions of software back to version 2.15

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It should also be noted that, with the issue of Version 5.00 software for the Mastersizer 2000, all records created on Legacy Systems software from Version 2.15 onwards can be imported into the Mastersizer 2000 application software.

3 Functional Features

3.1 Planned Additions and Headline Utilities.

Apart from addressing the Adobe Acrobat compatibility issue described in the Introduction, no further functional changes have been introduced with this update from Version 3.00 to 3.10. The following features of the software were introduced with Version 3.00 and are listed here for the benefit of users migrating from Version 2.19 or earlier.

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.

- Independent from the Windows operating system security allowing multiple users of a single system without the need to log in and out of the operating system.
- Encrypted passwords.
- Encrypted security settings file.
- Ability to log in and out of the application without shutting it down.

Tighter control over changes to measurement records and sample files

The operation of the Mastersizer software is modified when the 21 CFR Part 11 feature key is installed such that it is no longer possible to overwrite or delete measurement records.

New or modified software behaviour

- Records saved to alternate files are always saved to the end of the file.
- All processed records are added to the end of a file instead of replacing the source records.
- It is no longer possible to delete files or records from within the application.

Modified user status settings – level 3 no longer assigned.

Instead of having four levels of security as in the previous version of the software, there are now only three (0 to 2). The constraints on a level 2 user are now much more stringent than before in order to prevent changes to the configuration or result. Because of the changes to security level 2, level 3 has been removed from this version of the software. Therefore any level 3 users from the previous version of the software should be upgraded to level 2 by the security administrator when the system is first setup.

Increasing the flexibility of permissions assigned to Level 2 users.

To make the system more flexible, the controller can use a combination of assigned Basic macros and Easy Buttons to give users access to normally disabled commands. These macros are assigned to users' config files so that they can be unique to individual users if required.

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Requested Additions and changes.

SCR	Description	Comments
134	Printer port string not long enough	Fixed
166	Printer name string not long enough	Fixed
910	Provision for non-deletion of records and introduction of increased restrictions for user access level 2.	Implemented
744	Monomodal analysis can pick a mode of 0.05µm rather than the main mode of 5µm.	Fixed
2147,2148	Setup Analysis box no longer causes mouse cursor to disappear	Fixed
2051	Individual users' configuration settings not loaded on startup.	Fixed
2155	Whenever 'µm' appears, Windows interprets it as a single Chinese character. (English version on Chinese Windows)	Fixed
2180	Unique user i/d required to provide 21 CFR compliance.	Fixed
2181	Need to remove drop-down box from user name field showing history.	Fixed
2230	Not possible to have multiple administrators.	Fixed
3475	The Basic command "Document" now allows the "Save" and "Analysis" verbs to be used but ignores them	Fixed
3488	Adobe Acrobat Versions 5 and 6 are supported using the "Distiller" control.	Implemented
3670	Automatically generate .pdf filename if a filename is not set in Basic.	Fixed

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

Requirement for a printer to be connected for correct functioning of the system

The default printer settings are used by the application in order to format reports, graphs and tables for display in a view. This means that in order for the software to function correctly, a printer must be installed and connected whilst running the application. If Adobe Acrobat is being used as the printer the software will pick up the settings and will function correctly.

New security system – compatibility with previous system – level 3 no longer assigned.

The new security system introduced with version 3.00 of this software is broadly compatible with the pre-existing 'Secure Layered Access' system.

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However, instead of having four levels of security as in the pre-version 3.00 versions of the software, there are now only three (0 to 2 with level 2 being the least enabled). The constraints on a level 2 user are now much more stringent than before in order to prevent changes to the configuration or result. Because of these changes to security level 2, level 3 was removed when version 3.00 was introduced. Therefore any level 3 users set up in pre-Version 3.00 versions of the software should be upgraded to level 2 by the security administrator when the system is first set up. This means that Version 3.10 software will then recognise any existing users and their passwords

5.1 PrintPDFFilename Basic command

The **PrintPDFFilename** Basic command sets the root name for saved PDF files. If a file with the same name already exists, a sequence number in parentheses is added to the name. It is recommended that this command is not used because the automatically generated name contains unique information about the source measurement. If the Basic command is used then, after the PDF save, use the command:

```
PrintPDFFilename ""
```

to set the PDF filename back to being automatically generated.

5.2 Problem with the File->Open dialog box in Adobe Acrobat versions 6.0.0 and 6.0.1

The Mastersizer software generates PDF filenames by adding a sequence number in parentheses if the file already exists. Adobe Acrobat v6.0 has a problem opening these files through the File->Open dialog box if a file exists with the same name without the number in parentheses; in this case, the file without the parentheses is opened. However, the correct file is opened if the PDF file is double-clicked in Windows Explorer or dragged to the Acrobat window.

5.3 Other issues.

There are no other known issues at the time of this release. If you have any problems with installing or running this software please contact Malvern Instruments with full details of the problem encountered.

6 Distribution Media

Version 3.10 software is contained on a single self-installing CD-ROM, part no. PSS0008/05.

The full suite of software contained on this disc is detailed in the table overleaf:

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	New Issue	Previous Issue
PSS0008/05 Legacy Diffraction Software Suite	5	4
Suite Contents:		
Software		
PSW0002 Mastersizer S (English)	3.10	3.0
PSW0003 Mastersizer X (English)	3.10	3.0
PSW0004 Mastersizer μ (English)	3.10	3.0
PSW0005 Mastersizer $\mu+$ (English)	3.10	3.0
PSW0006 DIF2021 (QSpec Small Volume) Macros	No change	1.01
PSW0013 Macros for MSX+MAM2461 (Qspec DPF)	No change	2.0
PSW0056 Macros for MSS+MAM2461 (Qspec DPF)	No change	2.0
PSW0014 Chocosizer Macros for MS μ	No change	1.2
PSW0018 Chocosizer Macros for MS $\mu+$	No change	1.2
Documentation		
QSpec:		
QSpec Software Update Notification for MAM2461 QSpec DPF	No change	1 (14 Sept 1999)
Qspec Software Update Notification for Version 2.17	No change	1 (17 Dec 1997)
Qspec Software Update Notification for Version 2.18	No change	2 (14 Jun 1999)
Qspec Software Update Notification for Version 2.19	No change	1 (14 Jun 1999)
QSpec Software Update Notification for Mastersizer Legacy Systems Software Version 3	No change	1 (17 Jan 2003)
QSpec Software Update Notification for Mastersizer Legacy Systems Software Version 3.10	8 March 2004	None
21 CFR:		
Legacy systems ER&ES Advice	1	1 (8 Oct 2002)
Manuals:		
MAN0079 Sample Dispersion and RI Guide	No change	3.1
MAN0100 MSS MSX Installation Guide	No change	1.1
MAN0101 MSS MSX Getting Started Guide	No change	1.3
MAN0102 Software Reference Manual	No change	1.1
MAN0103 Basic Reference Manual	No change	1.1
MAN0104 Health and Safety Manual	No change	1.3
MAN0105 MS μ MS $\mu+$ Installation Guide	No change	1.1
MAN0106 MS μ MS $\mu+$ Getting Started Guide	No change	1.1
MAN0107 MS μ MS $\mu+$ Health and Safety	No change	1.1
MAN0161 Qspec Small Volume Unit Manual	No change	1.1
MAN0204 Qspec DPF Manual	No change	1.0
MAN0232 Chocosizer Manual	No change	1.0

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Installing the Software.

7.1 Before Installing.

NB If you are updating from an earlier version of the Mastersizer series software, you **MUST** do the following:

Installing over version 3.0.

1. Copy the following files to a safe location – these may be removed when version 3.0 is uninstalled

SIZER.INI	
HCPA.INI	Chocosizer only
USR_RI.INI	
Programs/SAM_DET.S.INF	Small volume unit support only
Programs/SOP.INF	Small volume unit support only
@&\$~\$&.\$@	This is the security file in the same directory as SIZER.EXE and is marked as a hidden and system file so you may have to modify your Windows explorer settings to see it listed

2. Remove 'Malvern Mastersizer S, X, M, MP version 3.0' using the Windows Control Panel Add/Remove programs.
3. Install Mastersizer version 3.10

IMPORTANT - Use the default install directories as recommended by the installer. This is particularly important if you install the Qspec dry powder feeder or Chocosizer macros as these contain hard-coded directories.

4. Copy the files in the safe location over the files just installed.

Installing over version 2.1x

1. In Windows Explorer, re-name the directory where the sizer program is installed (e.g. rename C:\SIZERS (for the Mastersizer S) to C:\MSS219). After the directory is re-named, the sizer programme will no longer work as the paths to the sizer support files in the SIZER.INI file will no longer point to the correct locations.
2. Install Mastersizer version 3.10

IMPORTANT - Use the default install directories as recommended by the installer. This is particularly important if you install the Qspec dry powder feeder or Chocosizer macros as these contain hard-coded directories.

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- To keep all the settings from version 2.1x copy the following files from the re-named directory. Using the example back-up directory above, copy from C:\MSS219 to C:\SIZERS.

SIZER.INI	
HCPA.INI	Chocosizer only
USR_RI.INI	
Programs/SAM_DET.S.INF	Small volume unit support only
Programs/SOP.INF	Small volume unit support only
@&\$~\$&.\$@	This is the security file in the same directory as SIZER.EXE and is marked as a hidden and system file so you may have to modify your Windows explorer settings to see it listed

- Copy any data, programs or page files from the re-named old location (e.g. C:\MSS219) to the corresponding place in the version 3.10 installation.

7.2 Installing on Windows NT* / Windows 2000 / Windows XP

Mastersizer Series version 3.10 software requires Windows NT 4.0 SP 6a, Windows 2000 SP2 or Windows XP. The NTFS file system must be supported.

To run on Windows NT 4.0, 64 MB of RAM is recommended. On Windows 2000/XP 128 MB is recommended. The software suite comes on an auto-loading CD-ROM. Inserting the disk 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. Use the installation software to specify the appropriate instrument model and the relevant macros.

Note: For Mastersizer series software, Windows NT™, Windows 2000™ and Windows XP™ 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.

***Please note that this installation will require Service Pack 6a or later for Windows NT operation and Service Pack 2 or later for operation on Windows 2000.**

Please also note that this software has been fully Alpha tested on Windows 2000 with Service Pack 2. It has been partially tested (Installed, measurement made and printed) on Windows XP and Windows NT4.0 with Service Pack 6a.

7.3 Additional instructions for Small Volume Unit Macros (DIF2021) (PSW0006)

Follow the instructions above to run the installation program for the Small Volume Unit macro files, and see Appendix D of the User Manual for further installation instructions. This procedure refers to copying files to the Mastersizer Program directory, but this is only relevant for a floppy disk installation and these files should already be present.

In the event of any differences occurring between the instructions in this document and the User Manual, the information given here is more current and will take priority.

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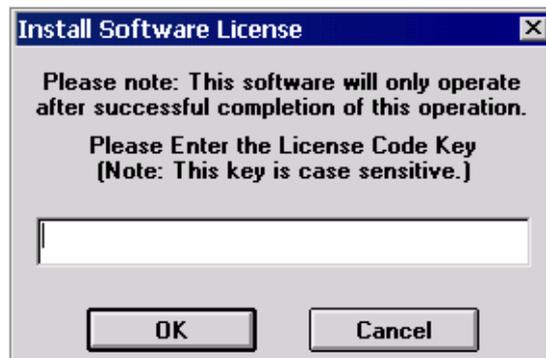
7.4 Installation from Floppy Disk

This version of software does not support installation from floppy disks.

7.5 Inputting the Product Licensing Code.

Before making measurements, you will be required to enter a licence code obtained from Malvern Instruments. You will need to know the serial number of the Mastersizer instrument you are using with the version 3.10 software.

This dialog is shown the first time that you connect to the Mastersizer instrument:



Type in the licence number given to you by Malvern Instruments. This number is unique to your Mastersizer and will not enable the software for any other instrument.

If you do not have a licence code number, you should contact Malvern Instruments to purchase one.

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 in this version of the software for your Legacy Mastersizer System.

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

Any feedback should be reported to Malvern Instruments via email to helpdesk@malvern.co.uk or by telephoning the Helpdesk directly on +44 (0)1684-891800. Please have all necessary details to hand before telephoning.

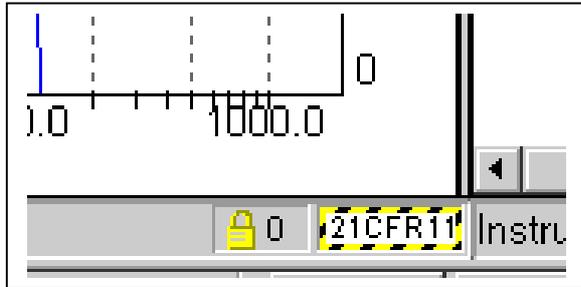
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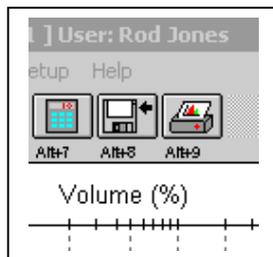
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New status line indicators show the security access level and 21 CFR part 11 mode at a glance:



The main window caption shows the name of the current user:

*With full privileges:
Saving and calculation available*

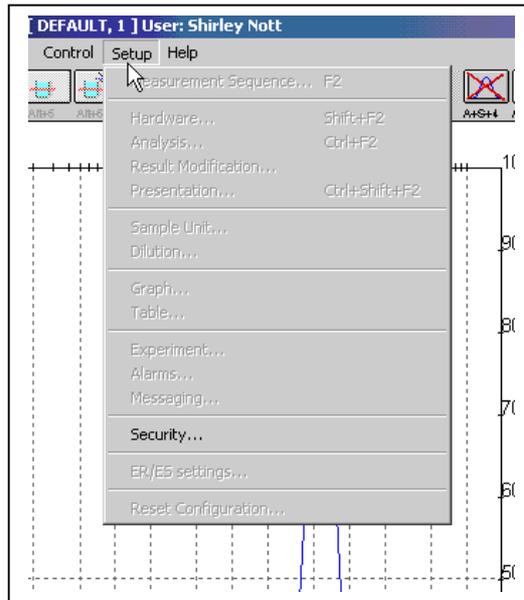


*Security Level 2:
Saving and calculation icons greyed out.*



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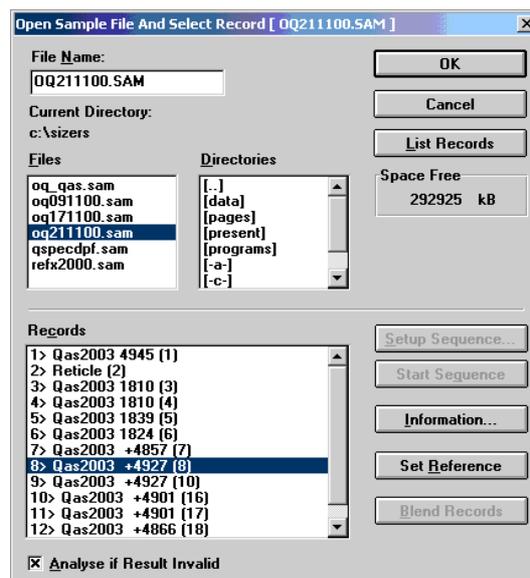
All functions which would modify or delete a record are greyed out and clearly unavailable to Level 2 users:



8.2 Measurement Sample Files

Open Sample File - The *Delete File* and *File Manager* buttons have been removed.

The *Delete Records* button has been removed.



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In *File-Process* and the '*Process*' command on the Open Sample File dialogues, all processed records are *appended* to the sample file instead of replacing the source records as before.

File-SaveAs - the '*Record Number*' edit control appearing in previous software versions in the dialogue is now hidden. Records saved to alternate files are always saved to the end of the file.

8.3 System Security

The Security command has been moved from the System menu to the Set-up menu. A new dialog allows users to logon, logoff and change their passwords.

Logging on now requires a password *and* a user name to be entered. Passwords must have six or more characters and are case-sensitive

At security access level 2, all commands that can affect how a measurement is made or how a result is presented are disabled.

If the administrator wishes to allow operators access to some of these commands, then they may be enabled by assigning a Basic macro to a toolbar button and saving the configuration in the operator's configuration file.

8.4 Electronic Records / Electronic Signatures

Support for electronic records and electronic signatures (ER/ES) is provided by Adobe Acrobat technology.

(Note - this requires Adobe Acrobat version 4.0, or later, to be installed) New command **Set-up - ER/ES Settings** allows a path to be selected where Portable Document Format (PDF) files may be saved.)

Note that this version of software is compatible with Acrobat V6 as well as versions 4.0 and 5.0. Version 3.00 of this software was only compatible with Acrobat versions 4.0 and 5.0.

New command *File - Print to PDF* allows the current measurement report to be saved as a PDF file. Options in the measure or process sequence also support saving as PDF files.

A new dialog box, *Set Report*, accessible from the Print and Print-to-PDF dialogs allows a named report to be assigned. This report can have one or two pages and, if assigned, is used in preference to the report associated with the current table view.

Measurements printed to paper or PDF have footers which show who printed the document, their access levels and the source record if the result has already been saved in a different location.