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# Software Update Notification



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## **Mastersizer S, X, Micro and Microplus Version 3.00 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/nn 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 3.00 software.**

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## 1 Introduction

This is Version 3.00 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).

This version of software has been produced specifically for users in the pharmaceutical industry to improve compliance with the requirements of 21CFR part 11. 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 Part11.

## 2 Instrument compatibility

This software is back compatible with Legacy Systems having software versions 2.19 and earlier back to version 2.15. Owing to the fact that the record structure has not been changed, Version 3.00 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.

#### **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
2051	Individual users' configuration settings not loaded on startup.	Fixed
744	Monomodal analysis can pick a mode of 0.05µm rather than the main mode of 5µm.	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

## 3.2 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.

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

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

However, 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

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version of the software should be upgraded to level 2 by the security administrator when the system is first set up. This means that Version 3.00 software will then recognise any existing users and their passwords

## **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 3.00 software is contained on a single self-installing CD-ROM, part no. PSS0008/01.

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

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	New Issue	Previous Issue
PSS0008/01 Legacy Diffraction Software Suite	1	None
<b>Suite Contents:</b>		
<b>Software</b>		
PSW0002 Mastersizer S (English)	3.00	2.19
PSW0003 Mastersizer X (English)	3.00	2.19
PSW0004 Mastersizer $\mu$ (English)	3.00	2.19
PSW0005 Mastersizer $\mu+$ (English)	3.00	2.19
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 $\mu$	No change	1.2
PSW0018 Chocosizer Macros for MS $\mu+$	No change	1.2
<b>Documentation</b>		
<b>21 CFR 11 Compliance:</b>		
Legacy Systems ER/ES Advice.pdf	1.0	None
<b>Change History:</b>		
QSpec Software Update Notification for Version 2.17.pdf	No Change	1.0
QSpec Software Update Notification for Version 2.18 .pdf	No Change	2.0
QSpec Software Update Notification for Version 2.19.pdf	No Change	1.0
QSpec Software Update Notification for MAM2461 QSpec DPF.pdf	No Change	1.0
<b>Manuals:</b>		
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 $\mu$ MS $\mu+$ Installation Guide	No change	1.1
MAN0106 MS $\mu$ MS $\mu+$ Getting Started Guide	No change	1.1
MAN0107 MS $\mu$ 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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## 7 Installing the Software.

### 7.1 Before Installing.

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

- 1) Copy the relevant directory and its contents (e.g. for an old S installation in the default directory - C:\SizerS) to a temporary location.
- 2) Delete the directory.
- 3) Install the software to the required location.
- 4) Copy any files that are required (e.g. configuration, security, measurement) back to the installation directory from the temporary directory.

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

Mastersizer Series version 3.0 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.

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## 7.4 Installation from Floppy Disk

### Small Volume Unit Macros (DIF2021) (PSW0006)

To install this product, copy all the files from the directory on the CD to a floppy disk, and see Appendix D of the User Manual for installation instructions.

### QSpec DPF Macros (PSW0013 and PSW0056)

To create floppy disk set, copy the files from the Disk1 directory to the root of one floppy disk, and the files from the Disk2 directory to another floppy disk. Label accordingly.

Put Disk1 into the floppy drive of the target computer, double-click on 'Setup.exe' and follow the on-screen prompts.

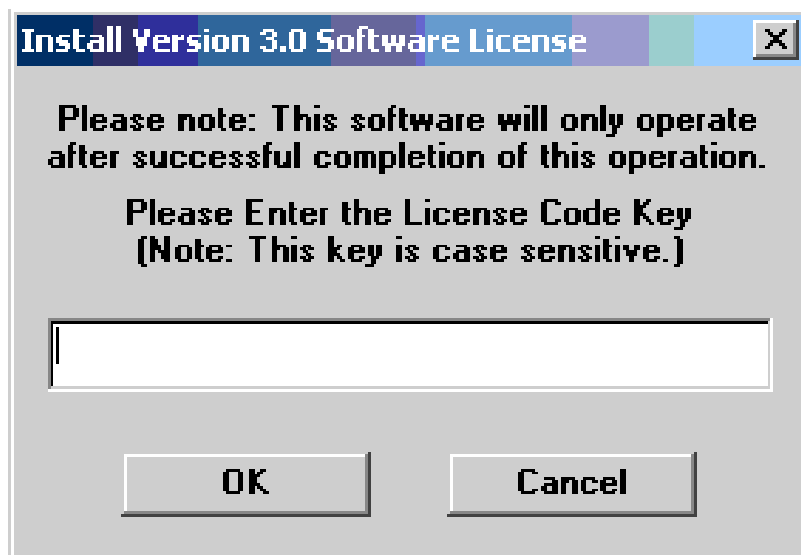
### Chocosizer Macros (PSW0014 and PSW0018)

To create a floppy disk set, copy the contents of the correct directory to a floppy disk and run install.bat on the target computer.

## 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 3.00 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.



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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?

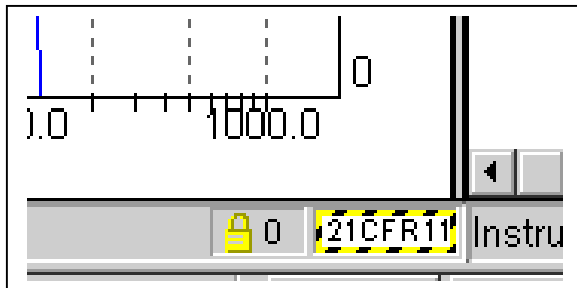
### 8.1 Overview

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.

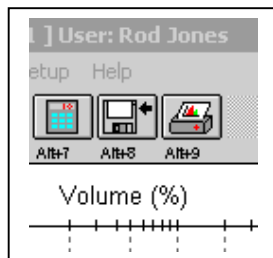
Any feedback should be reported to Malvern Instruments via email to [helpdesk@malvern.co.uk](mailto:helpdesk@malvern.co.uk) or by telephoning the Helpdesk directly on +44 (0)1684-891800. Please have all necessary details to hand before telephoning.

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

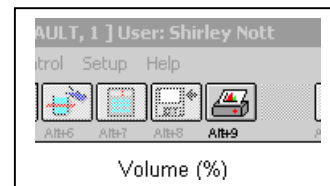


**The main window caption shows the name of the current user:**

*With full privileges:  
Saving and calculation icons available*

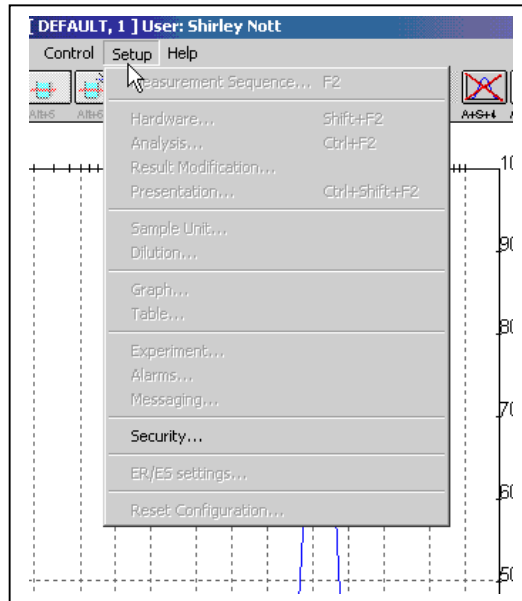


*Security Level 2:  
Saving and calculation icons greyed out.*



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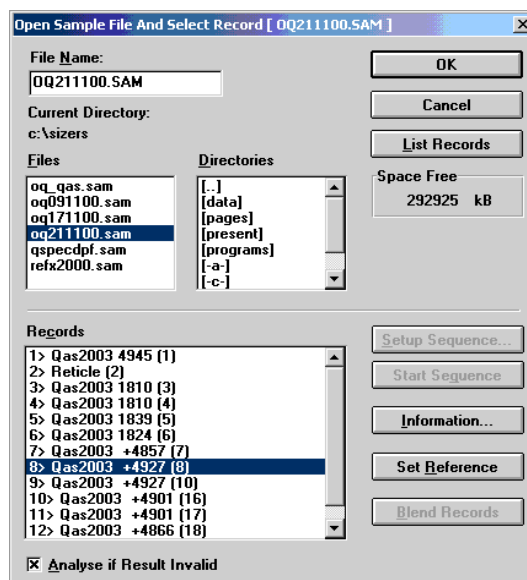
All functions which would modify or delete a record are greyed out and clearly unavailable to Level 2 users:



## 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.)

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.