

MASTERSIZER 2000 SOFTWARE: v6.00 (PSS0002-35) SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0002-35. This is version 6.00 of software for the Mastersizer 2000 laser diffraction system and has been released specifically to support customers in the pharmaceutical industry who need improved compliance to data integrity requirements. It covers software issues fixed and new features introduced. This information is required to perform a risk analysis to determine if the software should be installed. In this risk analysis the benefits of the new features provided and resolved software issues must be weighed against the risk of new issues that may be introduced to vital areas of the software or possible changes to the results of future analysis.

Installation

It is assumed that you have authority to install or update software within your facility. It is also assumed that you have Administrator rights for the system upon which the software is installed, as this is a requirement of the installation process. If you do not have this authority please consult with your I.T. support department before proceeding.

Recommend System Requirements

The recommend requirements for running this software are highlighted in the table below:

Feature	Specification
Memory	4 GByte RAM
Hard Disk Storage	80 GByte
Storage Media	CD-ROM drive
Display Resolution	1024x768
Connectivity	1 RS232 COM Port or RS232 to USB convertor
Operating System	Windows 7, Windows 10

Supported Languages

This software update only relates to English language versions of the Mastersizer 2000 software.

Installation Instructions

The Mastersizer 2000 software is provided on one auto-loading CD-ROM. Inserting the CD-ROM 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 Mastersizer 2000 v6.00 PSS0002-35 EN.exe program from the root directory of your CD drive.

Note: The feature key required to enable the 21CFR Part 11 capabilities within Mastersizer 2000 v6.00 software is different to the feature key used for previous software versions. Please ensure you have purchase this software with a new feature key before proceeding with the install.

Note: To comply with the security requirements for the Windows™ operating systems, the directory structure used by the Mastersizer 2000 software has been changed. Please refer to the Known Issues section of this document to understand these changes prior to installing this software.

Note: Some of the changes made to the control of the Mastersizer 2000 accessories require the accessory firmware to be updated when upgrading previous versions of the Mastersizer 2000 software.

Please contact Malvern Instruments for information regarding how to upgrade the accessory firmware.

Uninstall Procedure

The Mastersizer 2000 software can be uninstalled using the standard Add/Remove Programs feature in the Windows 'Control panel'.

New Features

21 CFR Part 11 Support

Mastersizer 2000 v6.00 software includes full support for customers who require the software to run within a 21 CFR Part 11 compliant environment. This includes new features relating to software access control, measurement auditing and the setting up of SOPs. These features are enabled by use of a software feature key which is specific to each instrument. Please contact your local Malvern Representative if you wish to obtain a feature key to enable the software's 21 CFR Part 11 features on your system.

Full details of the 21 CFR Part 11 features available within the Mastersizer 2000 software can be found in the following documents included on the Mastersizer 2000 software CD-ROM:

- 21 CFR Part 11 User Guide (MRK1065-xx) – provides a full description of the software features associated with 21CFR Part 11, including the software's security system.
- 21 CFR Part 11 Compliance Guide for the Mastersizer version 5.12 or later (MRK537-xx) – background information for users relating the functionality provided within the Mastersizer 2000 software to each of the requirements mentioned with 21CFR Part 11.

The new features implemented in Mastersizer 2000 version 6.00 are as follows:

Reference(s)	Issue
77179	Audit the addition of new users to the security system
77181	Audit deletion of existing users from the security system
77182	Audit disabling of user accounts within the security system
77183	Audit the unlocking of user accounts within the security system
80248	Audit the editing of user property to the security system
80250	Audit the copying of user to the security system
84664	Audit the addition of existing users to groups within the security system
84664	Audit the removal of existing users from groups within the security system
77184	Audit the addition of new groups to the security system
77185	Audit the removal of existing groups from the security system
82069	Audit the editing of group property to the security system
82070	Audit the copying of group to the security system
77186	Audit the addition of new members to groups in the security system
77207	Audit removal of existing members from groups within the security system
77211	Audit changes either addition or removal to the permissions associated with a group
77306	Auditing of security settings
84895	Auditing of ERES (Electronic Records and Electronic Signatures) option settings
79093	Audit the start of a measurement (Manual and SOP measurements)
79094	Audit abort of a measurement (Manual and SOP measurements).
79095	Search an open audit trail (including the current audit trail) to find events relating to the creation of specific records or the actions of specific users.

79096	Search the audit trail archives to find events relating to the creation of specific records or the actions of specific users.
79099	New implementation to ensure audit trails files cannot be overwritten

Fixed Issues

The software bugs fixed in version 6.00 release of the Mastersizer 2000 software:

Reference(s)	Issue	Comment
79091	Fixed 'Unknown' user appearing in the Audit trail	Fixed
85317	Fixed 'Unknow' user appearing in user and group dialog box	Fixed
79186	Signed digitally executable file using sha256 certificate	Fixed
84411	Fixed Measurement file disappears if Save As used	Fixed
85205 & 85212	Fixed help fails to load when user clicks on the help button in various dialog boxes	Fixed
84921	Fixed closing the manual measurement window after measurement causes an abort	Fixed
84922	Fixed in an SOP the stop button can be used to pause a measurement	Fixed
84923	Fixed in a manual measurement the stop button can be used to pause the measurement	Fixed
84617	Fixed creation of blank measurement record	Fixed
79091	Fixed 'Unknown' user appearing in the Audit trail	Fixed

Known Issues

Autosampler 2000 Additive and Dispersant Syringe Operation

It is possible for the Autosampler 2000 additive and dispersant syringe pumps to stall during operation, causing the Autosampler measurement schedule to halt. In order to overcome this, the firmware for the Autosampler 2000 has been updated to ensure that the syringes slowly accelerate to the required pump rate during operation. This has improved the robustness of operation of the Autosampler 2000 system.

Note: All new Autosampler 2000 systems will be shipped with new firmware (v1.04). Customers wishing to update the firmware for existing Autosampler 2000 systems should contact their local Malvern Instruments service representative.

Loss of security settings

It has been discovered that, when upgrading to Mastersizer 2000 v6.00 software from versions earlier than v5.54, it is possible for information relating to the security system set-up to be lost, including the user names and passwords for any users set up on the system. Users who have configured the security system to control access to the Mastersizer 2000 software for different user groups are advised to read Malvern Instruments' Technical Bulletin 1296, which provides a procedure for ensuring that the software can be upgraded without loss of the security system settings. This technical bulletin is included in the Documents section of the software CD-ROM. If you are in doubt about this procedure, please contact your local Malvern Representative for advice.

New Directory Structure

Since the launch of Windows 2000™, the Windows™ operating system has been set up to discourage the storage of data files into the Program Files group of folders. In order to avoid the security access problems associated with using the Program Files folders, this version of software has been set up to store data in the shared folders. The root Mastersizer 2000 data directory will therefore be set to:

- For Windows 7: *C:\Users\Public\Documents\Malvern Instruments\Mastersizer 2000*
- For Windows 8.1: *C:\Users\Public\Documents\Malvern Instruments\Mastersizer 2000*
- For Windows 10: *C:\Users\Public\Documents\Malvern Instruments\Mastersizer 2000*

When updating an earlier software version, the software installation procedure will automatically move all of the user data from the previous root directory (C:\Program Files\ Malvern Instruments\ Mastersizer 2000) into the new directory structure.

Note: It is recommended that users back-up their data prior to carrying out the installation process and should note both the old and new locations of the Mastersizer 2000 data files.

Changes to SOP version control

In previous software versions a mismatch could be observed between the SOP version number reported from the Compare SOPs window and the version number reported on the records view. This inconsistency has been addressed in version 5.30 and above of the Mastersizer 2000 software. However, the fix applied may cause the reported version number to change on result printouts. The observed behavior will be:

- If the SOP version shown in the Compare SOPs window was the same as the SOP version number reported on the records view then no change will be observed.
- If the SOP version shown in the Compare SOPs window was lower than the SOP version number reported on the records view then the SOP version will be taken to be the higher value.

As such, it is possible that some users will notice an increase in the SOP version number reported in the software.

Scirocco Venturi Identification

In version 5.30 and above, the ability to detect the type of venturi fitted to the Scirocco dry powder feeder has been provided. This requires the setting of one of the accessory identification switches (the A/B switch). As such, this feature will only work correctly for new Scirocco dry powder feeder units where the identification switch has been set according to the venturi type. For older Scirocco systems users should select the **Original Configuration** option in the SOP settings

associated with the Scirocco in order to disable the auto-sensing feature. If users want to enable the ability to sense the venturi type for older Scirocco systems then please contact your local Malvern representative.

Upper Size Limits and Dv100 reporting

Note: The use of the Dv100 as a control parameter is not advised, as this parameter is subject to large variations based on small changes in the dispersion and sampling regime. Malvern recommends that users use percentiles such as the Dv90 or Dv95 to provide control of the upper end of the size distribution.

In previous software versions, some variability in the reported upper size limit for Mastersizer 2000 results was observed. This was caused by an incorrect tendency for the analysis to report an extremely small volume percentage of material (>0.0001%) at the limits of the analysis. This, coupled with the calculation method used for percentiles, caused the reported Dv100 to change considerably between measurements.

In version 5.30 or above the analysis error associated with the reporting of small volumes of material at the analysis limits has been fixed and a new method for calculating the Dv100 has been implemented. These changes may affect the Dv100 reported by the analysis, especially for those samples where the Dv100 value was always reported to be 2000µm. Testing has shown, however, that the shift in the reported values for percentiles below the Dv99.5 is negligible.

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, by creating new files on a regular basis. File access problems will be experienced within the Mastersizer 2000 application if the file size increases to greater than 2GB.

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.

New security system

The new security system introduced in v5.00 and higher is incompatible with the pre-existing 'Secure Layered Access' system. If v5.00 or higher is installed on a system with v4.00 or lower, the security settings will have to be reconfigured to add users and groups.

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.

Localized number formats

The software does not function correctly if the number format set in the localization 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.

Lactose Refractive Index

The Lactose refractive index listed in the Mastersizer 2000 particle property database (1.347) is incorrect. The correct value for Lactose should be between 1.52 and 1.54. The entry has not been changed, as this could affect existing methods. If users wish to use the correct value, they are requested to set up a new entry in the software's particle properties database.

Edit-Copy Parameter

In Mastersizer 2000 version 5.60, a bug fix has been applied to ensure the **Edit-Copy** function associated with report views does not cause the software to crash. Users should note that this menu option will only copy the first parameter added to the report during report creation. If the copying of multiple parameters is required, users are advised to set up an export template containing the desired parameter set. The **File-Export Data** command, available when the Records view is active, can then be used to export the parameters to the Windows clipboard. Alternately, if the export template is set as the default template, the **Edit-Copy** menu option can be used to transfer the parameters to the clipboard.

Accessing Measurement Files via Windows Explorer

In the past, it has been possible to open a Mastersizer 2000 measurement file by double-clicking on the file from within Windows Explorer. This caused the Mastersizer 2000 software to start with the selected file opened. The operating system mechanism required to enable this to occur (Dynamic data exchange) has been removed from Windows VISTA. For this reason, this mechanism for opening files has been disabled in v5.60 of the software. Double clicking on a Mastersizer 2000 measurement file will cause the software to start, but users will have to browse for the file using the **File-Open** menu option within the software.

If you are using Windows XP, a mechanism does exist for re-enabling the ability to open files from within Windows Explorer. Please contact your Malvern Representative for a technical note describing how this can be done.

Overlay cumulative color problem

The frequency and undersize/oversize plot should be the same color so you can see which plots belong to which record. The 4th undersize/oversize plot has different colors for these curves making it harder to figure out which plot belongs to which curve.

SOP Parameter Reporting

For computer systems operating in time zones which are set at half-hour increments from GMT (e.g. Mumbai, India at GMT +5:30hrs, Adelaide Australia at GMT +9:30hrs), a bug has been discovered relating to the way some time-based parameters are displayed within the SOP editor windows. For parameters such as the Pre-measurement delay and Obscuration Filter Time-out, the software appears to add 30 minutes to any user-specified time. So, if 45 seconds is entered for the premeasurement delay and the SOP is saved, the value appears to be shifted to 30min 45 sec when the SOP is opened for review.

It is only the display of some time-based parameters in SOP windows which is affected by the above bug, rather than the application of these parameters during an SOP-based measurement. For example, if 45 seconds is specified by a user for the pre-measurement delay, this will be correctly applied during an SOP measurement even though 30min 45 sec is displayed in the relevant SOP window. In addition, the correct value for the pre-measurement delay (or any other time-based parameter) is stored in the measurement record and would be correctly printed on any reports referencing this value. Users can therefore validate that the correct time has been applied post-measurement.

Firmware change for the Hydro 2000S and Hydro 2000G accessories

The electronics and firmware used in the Hydro 2000S and Hydro 2000G accessories has been updated in order to improve the supportability of these systems in the long term. This has caused an update to the accessory calibration procedures, which are typically carried out during an Operational Qualification. To support the new calibration methods, the following software macros have been developed:

- *Hydro G Pump + Stir Cal.BAS*
- *Hydro S Stirrer Cal.BAS*

These macros are compatible with v5.30 and above of the Mastersizer 2000 software. For customers using versions prior to v5.30, any change to the calibration values will need to be carried out using a computer running v5.30 or above (e.g. using a service engineer's laptop).

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