

SOFTWARE UPDATE NOTIFICATION

MASTERSIZER **2000** SOFTWARE v5.61: PSS0002-34



PARTICLE SIZE

Introduction

This document details the release of software PSS0002-34: version 5.61 of the software for the Mastersizer 2000 laser diffraction system. 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 instructions are provided.

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.

Recommended System Requirements

The recommended computer system requirements for running this software are highlighted in table 1 below. The software can be operated using Windows 10 (Pro and Enterprise), Windows 8.1 (Pro and Enterprise), Windows 8 (Pro and Enterprise), Windows 7 32 bit (Pro, Enterprise and Ultimate) and Windows 7 64 bit (Pro, Enterprise and Ultimate). However, it has been fully tested using Windows 7 Ultimate (32 bit). Windows 7 Ultimate (32 bit) is therefore the preferred operating system.

Supported Languages

Mastersizer 2000 v5.61 software currently supports operation in the following languages:

- English
- Japanese
- Chinese (simplified)

French and German language options are only available for v5.12 of the Mastersizer 2000 software.

Table 1: Recommended system requirements for the Mastersizer 3000 software.

Feature	Specification
Memory	1024 MB
Hard Disk Storage	80GB
Additional Storage Media	CD-ROM or DVD +/-RW drive
Display Resolution	1024 x 768
Connectivity	1 RS232 COM Port
Operating System	Windows XP Windows 7 (32 bit - Pro, Enterprise and Ultimate) Windows 7 (64 bit - Pro, Enterprise and Ultimate) Windows 8.1 (64 bit - Pro and Enterprise) Windows 10 (64 bit - Pro and Enterprise)

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 \setupMS2K.exe program from the root directory of your CD drive.

Note: In order to comply with the security requirements for the Windows operating systems, the directory structure used by the Mastersizer 2000 software has been changed compared to earlier versions. Please refer to the Known Issues section of this document in order 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 software can be uninstalled using the standard **Add/Remove Programs** feature in the Windows Control Panel.

Software Categorization

GAMP 5

The GAMP 5 guide provides guidance to pharmaceutical companies wishing to understand whether the computerized systems and software they used are fit for purpose and meet current regulatory requirements. As part of this, the GAMP committee has defined a series of software categories which are designed to help users in assessing the risk and validation requirements associated with using a specific software package.

In its standard mode of operation, the Mastersizer 2000 software provides users with a series of standard interfaces and functions that enable the software to be configured to meet specific user business requirements. These interfaces include the ability to define Standard Operating Procedures (SOPs) for sample measurement, create report definitions using pre-defined functions and develop data export templates using pre-defined parameters. If users apply these functions then the software can be considered to be a **Category 4** product.

In addition to the standard functions, the Mastersizer 2000 software provides users with the ability to modify the results reported by the system to fit their application requirements. This is achieved through the use of the custom calculation reporting functions. These functions are not widely applied within regulated environments. However, if they are used to meet business requirements

then the macros included within the custom calculations should be validated according to GAMP Category 5 requirements. Users are therefore encouraged to specifically validate any custom calculations applied within their reports and ensure these are documented. Where possible, we would encourage the use of the standard result reporting features, as this minimizes the risk of errors in the reported size distribution statistics.

USP<1058>

USP<1058> provides pharmaceutical users with guidance as to how the qualification of analytical systems should be carried out. As part of this guidance, the USP define a series of instrument categories. These instrument categories different from those described in GAMP 5, although the principles applied as part of the classification of a system are similar.

The Mastersizer 2000 is a computerized analytical system where the software provides users with the functions required to meet specific analytical application requirements. As such, it is a **Group C** instrument. Users are therefore recommended to define their requirements for the operation of the system and then compare these requirements to the claimed capabilities of the software and hardware. This should include an assessment of whether the new features and bug fixes included in a specific version of the Mastersizer 2000 software are necessary to meet business requirements.

New Features List

21 CFR Part 11 Support

Mastersizer 2000 v5.xx 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 in order 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.

Fixed issues list

Mastersizer 2000 v5.61 includes the bug fixes referenced in the table below.

Reference(s)	Issue
9070	Appearance of application needs to be updated to show new Malvern logo
9219	User icon does not display for locked-out user within the security system.
9307, 9308	Unknown user sometimes appears in the audit trail.
9318	21CFR11 security: Most Recently Used list is not correct
9360	Reason for change is sometimes not added to the audit trail when editing a record
9769	21 CFR 11 issue for Japanese Software: In exported audit trail, the software version and user name appear blank

9788	21 CFR Part 11 bug relating to security server.
9977	Software version reported incorrectly in the Windows Control Panel
9987	21 CFR Part II: On Windows 7, after the Windows permission is set to deny deleting files within a folder, Windows also denies permission to save a new file

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.

Loss of security settings

It has been discovered that, when upgrading to Mastersizer 2000 v5.61 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 XP: C:\Documents and Settings\All Users\Shared Documents\Malvern Instruments\Mastersizer 2000
- For Windows 7-10: C:\Users\Public\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 dialogue 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 dialogue 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 dialogue 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 determine 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 dialogues. 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 dialogues 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 dialogue. 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

SOFTWARE UPDATE NOTIFICATION

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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