Software Update Notification

PSS0017-05: Mastersizer 2000 E v5.60 software

Abstract

This document details the release of software PSS0017-05. This is version 5.60 of software for the Mastersizer 2000 E 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.

Note: This software update only relates to the English and Japanese language versions of the Mastersizer 2000 software. French, German and Chinese language options are only available for v5.12 of the Mastersizer 2000 software. The installation files for these versions are included on this software CD-ROM.
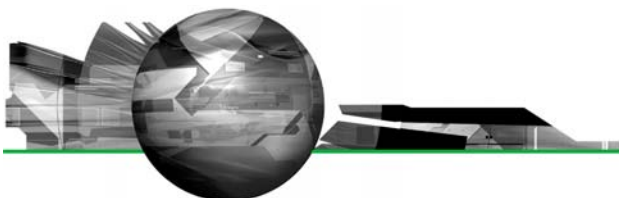
Installation

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.

Minimum System Requirements

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

Feature	Specification
Memory	512MB, although it is recommended that at least 1024MB is available when using Windows XP and 2GB when using Windows Vista.
Hard Disk Storage	80Gbyte
Additional Storage Media	CD-ROM drive
Display Resolution	1024 x 768
Connectivity	1 RS232 COM port
Operating System	Windows Vista Business Edition ^{TM} Windows XP Professional ^{TM} with SP2 or higher installed Windows 2000 Professional ^{TM} with SP4 or higher installed

Although the software has been tested using Windows 2000^{TM} and Windows Vista Business Edition ^{TM}, Windows XP Professional ^{TM} is the preferred operating system.

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Instrument compatibility

The Mastersizer 2000 v5.60 software is backwardly compatible with all prior versions of Mastersizer 2000.

> **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 may 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.

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 ^{TM} operating systems, the directory structure used by the Mastersizer 2000 software has been changed. 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 dispersion accessories require the accessory firmware to be updated when upgrading previous versions of the Mastersizer 2000 software.
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> **Please contact Malvern Instruments for information regarding how to upgrade the accessory firmware.**
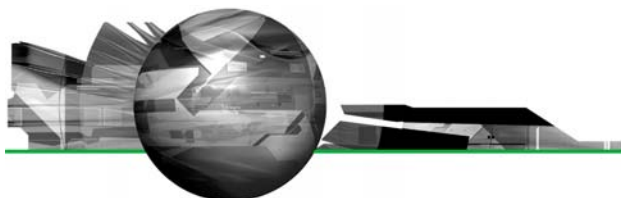
Operating System Component Updates

Mastersizer 2000 v5.12 for French, German and Chinese language systems can be installed on systems running Windows NT 4.0 ^{TM}. However, some of the Microsoft components required for the operation of the Mastersizer 2000 system may not be present within Windows NT ^{TM} operating system. This includes the Microsoft MDAC 2.5 components as well as Internet Explorer v4.1.

The Mastersizer 2000 software installer will automatically detect if any operating system updates are required for these software versions. The required updates are included on a separate installation CD (PSS0018-01: Operating System Component Update Suite) for all the supported languages and are also available from the Microsoft Internet site for download.

Uninstall Procedure

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

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New Features

Windows Vista™ Support

Mastersizer 2000 v5.53 or higher has been modified to run on Windows Vista™ and has been fully tested using Windows Vista Business Edition. While it has not been tested on the other available Windows Vista variants, we are not aware of any potential compatibility issues.

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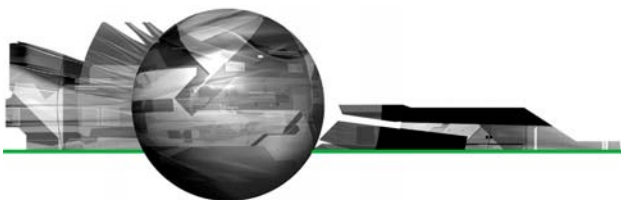
Full details of the 21 CFR Part 11 features available within the Mastersizer 2000 software can be found in the following documents included on the Mastersizer 2000 software CD-ROM:

- **21 CFR Part 11 User Guide (MRK1065-01)** – 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 (MRK537-03)** – 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

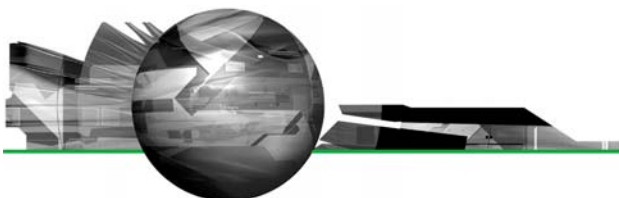The following Software Change Requests (SCRs) have been implemented in version 5.60 of the Mastersizer 2000 software:

SCR Number	Description	Type	Comments
6398	When the 'ignore first measurement' option is enabled in a dry measurement SOP, it is not applied consistently.	Bug	Fixed
6769	If the application is launched by double clicking on a measurement file in Windows Explorer, the application crashes on exit.	Bug	Fixed
7187	Russian characters do not display correctly.	Bug	Fixed
7190	The instrument intermittently reports a CRC failure for the characterisation data.	Bug	Fixed
7191	A "kernel FLASH CRC error" message is reported intermittently.	Bug	Fixed
7266	The Audit Trail occasionally shows measurements created by an 'unknown' user.	Bug	Fixed
7267	The system occasionally locks-up when the live display is active.	Bug	Fixed

SCR Number	Description	Type	Comments
7326	In remote mode, the background alarm should stop the SOP.	Improvement	Implemented
7424	Problems within instrument control when using the Variflow options for the Hydro 2000G accessory.	Bug	Fixed
7487	The advice links for the SOP pages do not seem to work.	Bug	Fixed
7609	[CFB 00748] The code for ignoring the first result for dry powder measurements causes strange SOP values to be recorded.	Bug	Fixed
7713	Some of the help buttons do not function correctly.	Bug	Fixed
8085	Dry accessory measurements do not terminate correctly.	Bug	Fixed
8087	Negative values displayed in some particle size distribution report tables.	Bug	Fixed
8088	The Mastersizer 2000 application does not start when a user double-clicks on a measurement file.	Bug	Fixed
8118	The dates displayed in report footer are not localised for foreign language systems.	Bug	Fixed
8232	Instrument status can become corrupted, causing the ER/ES settings to be reset within the system registry.	Bug	Fixed
8446	Edit->Copy parameter causes the application to crash.	Bug	Fixed
8495	Parameters with names longer than the boxes in which they are displayed can't be selected because of tool tips getting in the way. This applies when setting the Export or View select fields.	Bug	Fixed

In addition, the following changes were made between v5.53 and v5.54:

SCR Number	Description	Type	Comments
6772	New lot and batch labels are not added to the label list correctly.	Bug	Fixed
6785	Displaying the manual configuration screen for the Autosampler 2000 accessory causes the software to crash.	Bug	Fixed

SCR Number	Description	Type	Comments
6787	Files are exported in UNICODE rather than ASCII format.	Bug	Fixed
6788	Batch printing a report which includes a custom calculation causes the software to crash.	Bug	Fixed
6794	The default value for background quality alarm should be 300 units rather than 200.	Improvement	Implemented
6820	Yellow is one of the default line colours for graphs in v5.53 software. This colour should be removed.	Improvement	Implemented
7031	When an SOP is edited some parameters are set to zero that should not be. This impacts result emulation most noticeably.	Bug	Fixed

The software update notification documents relating to previous versions of the Mastersizer 2000 software are available from the support section of the Malvern Instruments website (www.malvern.com). Please refer to these documents for details of the new features released within each version of the Mastersizer 2000 software.

Deletions

No program features have been removed in this version of the Mastersizer 2000 software.

Known Issues

New Directory Structure

Since the launch of Windows 2000^{TM}, the Windows^{TM} 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:
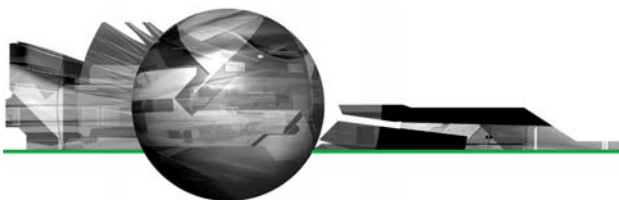
- **For Windows Vista**^{TM}: C:\ Users\ Public\ Public Documents\ Malvern Instruments \ Mastersizer 2000
- **For Windows XP**^{TM}: C:\ Documents and Settings\ All Users\ Shared Documents\ Malvern Instruments\ Mastersizer 2000
- **For Windows 2000**^{TM}: C:\ Documents and Settings\ All Users\ Documents\ 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 behaviour 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.
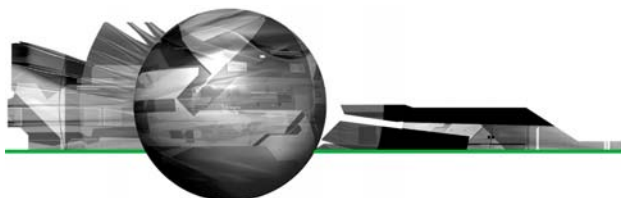
File sizes

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. 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.

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.

Autosampler – engineering screen is not painted under XP themes

When showing the tabbed engineering screen (only available to Malvern service representatives) under windows XP the tab contents are not correctly displayed. Clicking on another tab and then returning repaints the screen correctly.

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.

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.