

# Software Update Notification



PSS00002-22: Mastersizer 2000 v5.40 software

## Abstract

This document details the release of software PSS0002-22. This is version 5.40 of 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.

**Note:** This software update only relates to the English language version of the Mastersizer 2000 software. French, German, Japanese 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

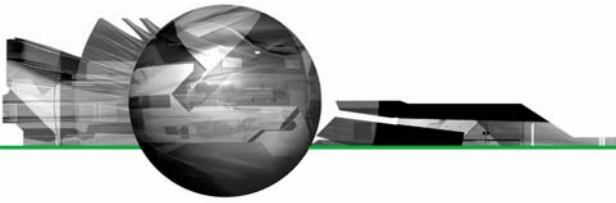
It is assumed that you have authority to install or update software within your facility. It is also assumed that you have Administrator rights for the system upon which the software is installed, as this is a requirement of the installation process. If you do not have this authority please consult with 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	64MB, although it is recommended that at least 256MB is available when using Windows XP.
Hard Disk Storage	80Gbyte
Additional Storage Media	CD-ROM drive
Display Resolution	1024 x 768
Connectivity	1 RS232 COM port
Operating System	Windows XP Professional™ with SP2 or higher installed Windows 2000 Professional™ with SP4 or higher installed

Although the software has been tested using Windows 2000 Professional™, Windows XP Professional™ is the preferred operating system.



### Instrument compatibility

The Mastersizer 2000 v5.40 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 will 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 **lsetup.exe** program from the root directory of your CD drive.

**Note:** In order to comply with the security requirements for the Windows 2000™ and Windows XP™ 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. This is true for the changes made under Software Change Requests 4715 and 4728. In addition, when upgrading from software versions earlier than v5.00, accessory firmware updates are required to access (i) improvements to the clean cycle used with the Hydro 2000G accessory and (ii) diagnostics and ultrasound control used with the Hydro 2000uP dispersion accessory. **Please contact Malvern Instruments for information regarding how to upgrade the accessory firmware if the above updates are required for your installation.**

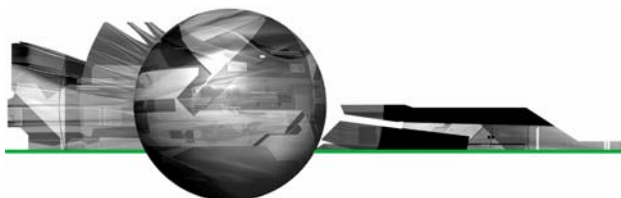
### Operating System Component Updates

Mastersizer 2000 v5.12 for French, German, Japanese and Chinese language systems can be installed on systems running Windows NT 4.0™. However, some of the Microsoft components required for the operation of the Mastersizer 2000 system may not be present within Windows NT™ 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 (PSS0019-01: 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'.



## New Features

### 21 CFR Part 11 Support

Mastersizer 2000 v5.xx software includes full support for customers who require the software to run within a 21CFR 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 21CFR11 features on your system.

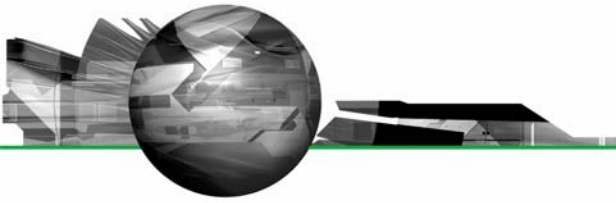
Full details of the 21CFR11 features available within the Mastersizer 2000 software can be found in the following documents included on the Mastersizer 2000 software CD-ROM:

- **21CFR Part 11 User Guide (MRK531-02)** – provides a full description of the software features associated with 21CFR11, including the software's security system.
- **21 CFR Part 11 Compliance Guide for the Mastersizer version 5.12 or later (MRK537-02)** – background information for users relating the functionality provided within the Mastersizer 2000 software to each of the requirements mentioned with 21CFR11

### Fixed Issues

The following Software Change Requests (SCRs) have been implemented in version 5.30 and 5.40 of the Mastersizer 2000 software:

SCR Number	Description	Comments
5604	Application can crash when viewing very long audit trail entries	(Fixed issue 22)
5738	The Malvern supplied report pages were not installed read-only	(Fixed issue 22)
5834	Since an SOP requires an open result file to work correctly the menu and toolbars should be disabled if no file is open.	(Implemented issue 22)
5983	Mastersizer 2000 v5.22 incorrectly set the security permissions of the application INI file.	(Fixed issue 22)
6097	The accessory indicator did not change to amber when the cell was removed from the instrument	(Fixed issue 22)
6172	Upgrading SOP files created pre version 5.30 should correctly set the export separator character to TAB not COMMA	(Implemented issue 22)
6181	The desktop short cut to the data files does not work on German or French operating systems.	(Fixed issue 22)
6182	The bulk lot and source fields in the SOP are not updated correctly	(Fixed issue 22)
6192	The autosampler additives file is not installed to the correct location	(Fixed issue 22)
6213	The 5.3x installers remove the 21 CFR feature key settings	(Fixed issue 22)
6214	The Hydro S+ beam length is incorrect leading to errors in the concentration calculation.	(Fixed in issue 22)
6215	When replying Yes to the question "Run this SOP again?" the user entered documentation values should be preserved for update rather than replaced with the SOP default.	(Implemented issue 22)



SCR Number	Description	Comments
6216	The documentation page should be displayed before the optical background is taken to prevent large delays between the background an measurement.	(Implemented issue 22)
6240	When entering a new source or bulk lot label in a manual measurement; new values should be added to the list.	(Implemented issue 22)
6299	The firmware update was not robust against changes to the kernel flash programming algorithm. This could lead to corrupt firmware on the accessories.	(Fixed issue 22)

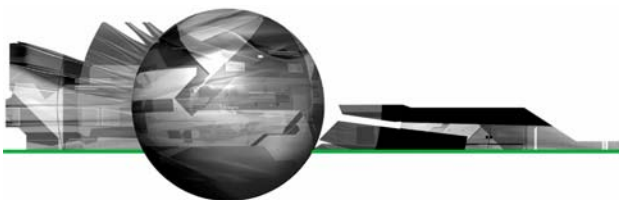
In addition, issues associated with security access to some of the program files have been addressed in the release of version 5.40.

### Deletions

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

### Known Bugs

There are no known bugs in this version of the Mastersizer 2000 software. If you suspect that you have found a bug then please contact Malvern Instruments detailing all aspects of the symptoms observed.



## Known Issues

### 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 *C:\Documents and Settings\All Users* set of folders. The root Mastersizer 2000 program directory will therefore be set to:

- **For Windows XP™:** C:\Documents and Settings\ All Users\ Shared Documents\ Malvern Instruments \Mastersizer 2000
- **For Windows 2000™:** C:\Documents and Settings\ All Users\ Documents\ Malvern Instruments \Mastersizer 2000

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. **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 v5.30 and v5.40 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

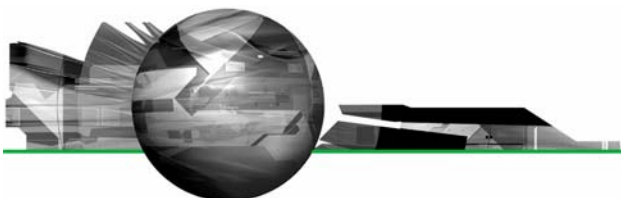
In v5.30 and v5.40, the ability to detect the type of venturi fitted to the Scirocco dry powder feeder has been provided. This requires the setting of one of the accessory identification switches (the A/B switch). As such, this feature will only work correctly for new Scirocco dry powder feeder units 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 v5.30 or higher 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 v5.40 is installed on a system with v4.00 or below, 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.

### 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 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.

## Software Update History

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.co.uk](http://www.malvern.co.uk)). Please refer to these documents for details of the new features released within each version of the Mastersizer 2000 software.