

Mastersizer 3000 Software: v4.10 (PSS0223-40)

Software Update Notification

Introduction

This document details the release of software PSS0223-40: version 4.10 of the software for the Mastersizer 3000 and Mastersizer 3000E laser diffraction systems. It covers new features, bug fixes, known issues and lots of other helpful information to help you install and administer the application software.

The information within this document may also be required to perform a risk analysis to determine if the software should be installed. In this risk analysis the benefits of the 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. Data collection and analysis are unlikely to be affected following software upgrade.

Software release version upgrades often contain important security and compliance fixes. As such, we strongly recommend that you upgrade to the most version of the software at your earliest convenience.

Software version 4.0 of software introduced OmniTrust to the Mastersizer platform. OmniTrust is Malvern Panalytical's solution for regulatory compliance and data integrity across different product ranges.

Note: This software update is not compatible with users of the Malvern Access Configurator (MAC) and/or 21CFR Feature key. We recommend remaining on your existing software version until an upgrade path is available.

Note: Due to the .Net6 framework change in v4.0 onwards, backwards compatibility of SOPs and data prior to release 4.0 will not be possible.

Note: Please check for any updates to this Software Update Notification at www.malvernpanalytical.com/en/support/product-support/mastersizer-range/mastersizer-3000

New Features and fixed issues

Table 1: New feature(s) and fixed issues introduced in 4.10.

Reference(s)	Feature
<p>Workflow Guidance</p> <p>This is a new feature that provides data quality guidance during the measurement. This feature is visible in the measurement manager window when running a manual measurement or standard operating procedure (SOP). This feature requires a license, see details below on how to install the license.</p> <p>Please contact your Malvern Panalytical representative for details on how to get a license.</p>	165244

Recommended System Requirements

The recommended system requirements for running this software are highlighted in Table 1 below. Nevertheless, we fully expect the new software version to work on PCs with lesser or more advanced specifications. Software version 4.10 was fully tested using the recommended PC specification running Windows 10 version 22H2.

Table 2: Recommended system requirements for the Mastersizer software

Feature	Specification	Feature	Specification
Processor Type	Intel Core i7 Processor (8 th generation or higher) *see known issue section, pg14 about 12 th generation	Power Settings	High performance (see details of advanced settings in the Known Issues section)
Memory	16GB	Connectivity	1 USB 2.0 or USB3.0 port
Solid State Storage	250 GB SSD	Operating System	Windows 10 Enterprise (64 bit - Pro and Enterprise) * * Preferred Operating System

Supported Languages

The Mastersizer 3000 software currently supports operation in the following languages:

- English
- French
- German
- Japanese
- Chinese (simplified)
- Russian
- Polish
- Spanish

The language used by the application is automatically configured based on the operating system settings. If you want to force the application to use English instead of the operating system language, you need to start the application using the **Mastersizer 3000 (English)** start menu shortcut.

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.

Installation instructions

If you are installing the software from a web download / USB drive, then browse to the folder where the files have been extracted to and then launch the `\\Mastersizer 3000\\setup.exe` program. Software version 4.10 contains no firmware changes over software version 3.84.

Note: It is important to initially install the software onto the PC without the Mastersizer 3000 being connected. Following download the PC should be powered down and the Mastersizer 3000 optical bench connected to the PC prior to powering up. Finally, the Mastersizer 3000 wet and / or dry dispersion accessories should be connected to the optical bench which is already attached to the PC and the PC then powered up. This will ensure that the instrument drivers are enabled, and that any firmware updates associated with this release are correctly downloaded to the instrument.

Note: Any firmware updates required for your system will be installed at the same time as the software. It is important to keep the firmware and software 'in sync', since this is the configuration that will have been tested by Malvern Panalytical prior to release of the software.

Caution!



This version of the software does not support Malvern Access Control (MAC) or 21CFR via MAC. This functionality will now be provided via OmniTrust.

Users wanting to continue using MAC should not upgrade to this version.

MAC is available up to and including software version 3.88

Uninstall procedure

Version 3.82 (or lower) of the software can be uninstalled using the standard Add/Remove Programs feature in the *Windows Control Panel*.

For v3.82 (or higher) of the software a new set of Windows® Drivers were created. These drivers are not compatible with earlier versions of the Mastersizer 3000 software (v3.81 and earlier). If for any reason a customer wishes to downgrade to a software version earlier than v3.82, they should contact their local service support team for assistance.

Caution!



Downgrading v3.82, or higher, with 21CFR11 mode enabled to earlier versions of the software will cause this functionality to be switched off. 21CFR11 functionality can then be re-enabled once the downgrade is complete by re-enabling the Features File (navigate to the Options pages and select "Enable Auditing" and "Enable Electronic Signatures" from the 21 CFR Part 11 tab and "Enable Access Control" from the Access Control tab).

Caution!



Due to the .NET6 upgrade, backward compatibility of SOPs and data prior to this release will not be possible. SOP and measurement file saved from this version will not work in any previous version. Forward compatibility will remain

We recommend the MAC software is uninstalled in this way before updating to later versions (or even downgrading to earlier versions).

Software license files


The Mastersizer 3000 software requires a valid license file to run. When connected to an instrument, the system automatically generates this file, and the user will be asked to accept the license.

Note: If you wish to install the Mastersizer 3000 software on additional computers, you will need to follow the procedure below for sharing a software license.

Sharing a license for Mastersizer 3000 users

In order to enable the use of the Mastersizer 3000 on a computer which is not connected to an instrument, it is necessary for users to create a license. This can then be shared with other users, allowing them to gain access to the software.

To share a license, follow the steps below:

1. At the computer that is connected to the instrument, run the Mastersizer 3000 software and click on the **Application Menu** icon  at the top left of the screen.
2. Select **About** and click on the **View License...** button.
3. Click on the **Share this License...** button. The system tells you what information the license file contains.
4. To accept that information click **Yes** and choose a location to copy the file to (e.g. a memory stick).
5. At the separate computer, install the Mastersizer 3000 software and start the program. At the license screen, click the **Install** button.
6. Browse to the folder that contains the license file from step 4 above and select the license file. The licensee details will be shown, and you can now accept or decline the license.

Note: The software license is specific to a given Mastersizer 3000 system. When a license is shared, detailed user and computer information is stored in the license file, ensuring it can be traced back to its source Mastersizer 3000 system. Users should only share the license with users within their organizations who need to analyze data off-line. The software license must not be shared with other organizations without the consent of Malvern Panalytical.

Sharing a license for Mastersizer 3000E users

The Mastersizer 3000E system is provided with a simplified, basic version of the Mastersizer 3000 software. This basic software version is restricted to use on a single computer workstation attached to the Mastersizer 3000E system. As such, the license sharing facility offered for Mastersizer 3000 users is not available.

Users of the Mastersizer 3000E system who want to be able to use the software on multiple workstations will need to purchase a software upgrade. This upgrade will enable the premium features associated with the Mastersizer 3000 software, including the ability to create shared licenses. Please contact your local Malvern representative if you would like to purchase this upgrade.

Software feature keys

Software feature keys unlock functionality from within the software. Feature keys are restricted to use on a single computer workstation. They are PC specific and can not be shared to other PCs.

The following feature keys are compatible with v4.10 and above.

Table 3: Feature keys compatible with v4.10 and above

Feature	Description	Compatibility	Version first introduced
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OmniTrust OMT0200	OmniTrust is Malvern Panalytical's instrument-agnostic solution for regulatory compliance and data integrity.	Mastersizer 3000	4.0
Workflow Guidance WRK0100	Workflow Guidance flags possible data quality issues and provides a list of causes and solutions at all stages of your measurement.	Mastersizer 3000 and Mastersizer 3000E with extended software	4.10

Note: This software not compatible with users of the Malvern Access Configurator (MAC) and/or 21CFR Feature key. We recommend remaining on your existing software version until an upgrade path is available.

Activating a software feature key

Since software version 4.0 license manager is installed automatically. This will be either placed on your desktop or can be accessed through the start menu.

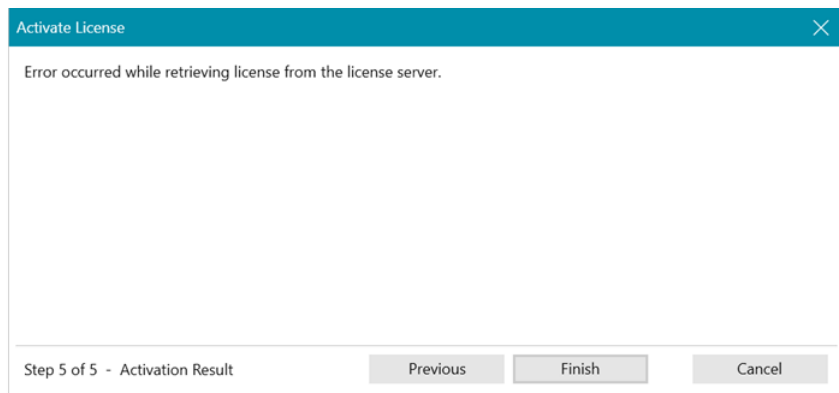


To activate a license, you will need a product activation key. This will be delivered by post following purchase. A product activation key has the following format XXXXXXXX-XXXX-XXXX-XXXXXXXXXXXX.

Licenses can be activated on-line or off-line. For off-line activation, access to a computer with internet connection is required in order to download a file, this does not need to be attached to the instrument.

Activating a software feature key - Online

For online activation. Open the License manager and follow the onscreen prompts. You will need the product activation key, Company name and address where instrument is located. If an error with the server occurs, click on the '**previous**' button to return to Step 4 of 5 and then click on '**Next**'. Do not return to the start as this may cause your activation key to become inactive.



Activating a software feature key - Offline

For offline activation. Open the License manager and follow the onscreen prompts. You will need the product activation key, Company name and address where instrument is located.

From the computer connected to the instrument you will be prompted to save a C2V fingerprint file. Copy this file to a computer with internet connection.

From the computer connected to the internet. Visit www.Malvernpanalytical.com/softwareactivation and login with your product activation key. Select Offline Activation and then upload the C2V fingerprint file.

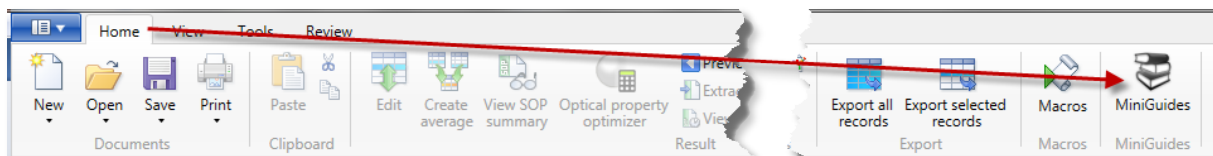
Select 'Generate' button to generate the V2C license file. Download the V2C license file and save it.

Copy the V2C license file back to the Instrument connected to the instrument.

From the computer connected to the instrument. Follow the onscreen prompts through license manager and enter the file location of the V2C file where required.

Software guides

The Mastersizer 3000 software includes a comprehensive help system, which provides a functional description of each of the software elements. In addition to this, the software includes a series of 'MiniGuides', which provide an introduction to useful software tools and new features. These are accessed via the MiniGuides option on the Home ribbon bar:



Security advisories

This software version does not contain any specific security updates since version 3.83. For 3.83 security updates please refer to SUN v3.83.

Note: We always recommend updating to the latest software version which will provide you with new features, bugfixes and most importantly, security updates.

Note: Other products may also be affected by any issue described here. We recommend you regularly check the Software Updates Notifications (SUNs) for all your Malvern Panalytical products and register on our website to receive updates.

File types and locations

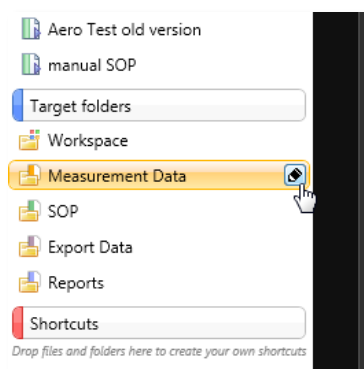
The default folder path is *C:/Program Data/Malvern Instruments/Mastersizer 3000/Workspace*. If upgrading from an existing installation and/or if you wish to apply additional settings or to other folders, this may need to be done manually.

Changing the destination path for a file

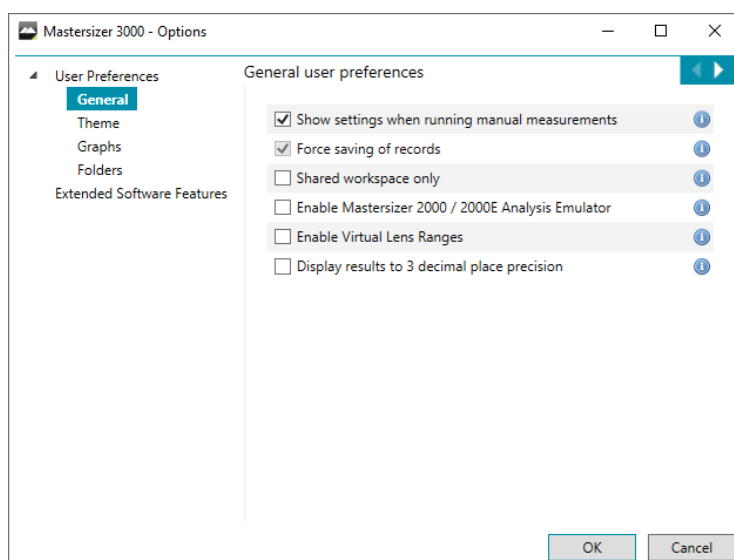
The following folders can be configured from within the Mastersizer 3000/3000E software:

- SOP
- Measurement Data
- Reports
- Export Data

For Mastersizer 3000 users and those who have upgraded the Mastersizer 3000E software, the default file location for these files can be configured via the Target Folders section of the Workspace viewer. To do this, click on the pencil icon which appears when you hover over the directory shortcut:



Changing the directory associated with this shortcut will change the default directory accessed by the Mastersizer 3000 software for the selected file type.



Configuration of the target directories can also be configured from the **User Preferences-Folders** section of the **Options** menu:

Again, hover over the shortcut and click on the pencil icon to change the target directory. Note that this is the only place in the software where the target directories can be configured when using the Basic software for the Mastersizer 3000E.

Backup and restore files

What to backup

By installation default, the Mastersizer 3000 application uses the **C:\ProgramData\Malvern Instruments\Mastersizer 3000** and its subfolders for configuration and user created output files. For ease, we would suggest this is the simplest folder to backup and restore.

For customers with the additional 21CFR OmniTrust applications, we recommend that the **C:\ProgramData\Malvern Panalytical** folder should also be backed up.

To create a backup, we recommend that you consult your IT department to select the best method to achieve this. For pharmaceutical regulated environments, you should also consult your validation department, as they may have specific compliance requirements, and/or recommendations.

Restoring your files to the original PC hardware

If you have recovered your PC by having to re-install Windows®, you can simply restore your backup files to their original folder/s, then reinstall the Malvern Mastersizer application software.

Note: You must only install your original, or later version, as some files will not be backwards compatible.

Restoring your files to a new PC

Restore your backup files to their original folder/s, then delete the **C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files\Mastersizer3000.licence file**, before installing the Mastersizer 3000 application software.

Caution!



If restoring the 21CFR OmniTrust System Audit Trails and other files within the **C:\ProgramData\Malvern Panalytical** folder to a replacement PC, the replacement PC name must remain the same.


For customers using the previous 21CFR features, the licence key will no longer be valid. To continue working in the regulated environment, upgrading to OmniTrust is required. We recommend remaining on your existing software version until an upgrade path is available. If you are interested in the OmniTrust application, please contact your Malvern representative for more information. Users of Mastersizer v4.0 or later with the existing Mastersizer solution for regulated environment can continue to view the historic system audit trail within the MAC (providing the MAC has been installed on the PC).

Users will also be able to continue to view these in Mastersizer software if transferred to a separate PC which has Mastersizer v3.88 or earlier.

Note: The **C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files\Mastersizer3000.licence file**, contains information taken from your old PC and may cause issues with the licensing of the application, if you do not delete this file before starting the application.

Smart Instrument

If you have an internet connection and have chosen to make your instrument a Smart Instrument during the Mastersizer 3000 software installation, your instrument will automatically start uploading key parameters to Malvern Panalytical.

You can check the status of your connection by locating the Malvern Panalytical Cloud Service application on the Windows taskbar - right-click the icon then click Status. 

If you did not allow the service to send data to Malvern Panalytical during the Mastersizer 3000 software installation, you can simply right-click the same application, then click Register.

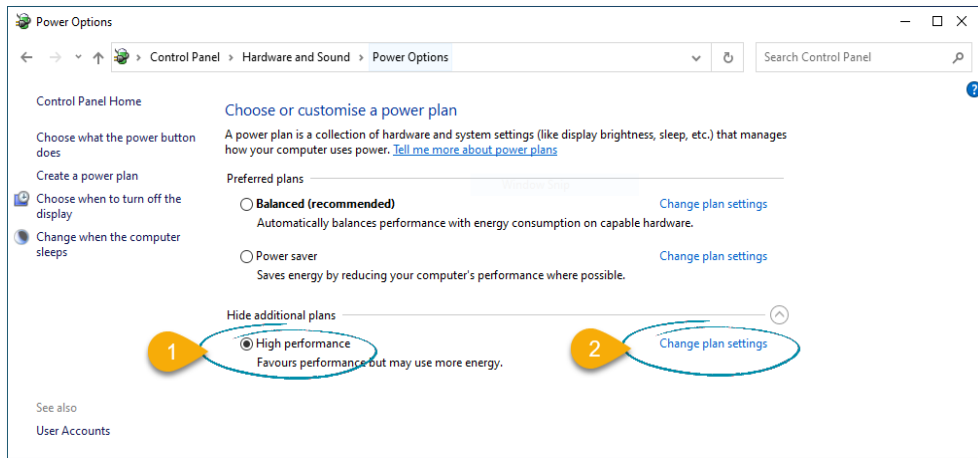
Note: We only collect low-level telemetry data and the results of Malvern Panalytical calibration tests from your instrument. We don't collect any of your actual test data, and we can't control your instrument remotely.

The data that we do collect is safe with Smart Manager – it is stored and processed securely on the Microsoft cloud. With more certifications than any other cloud provider, Microsoft is committed to security, transparency, and regulatory compliance. And our own information security management system also complies with the strictest international security standards (ISO/IEC 27001:2013).

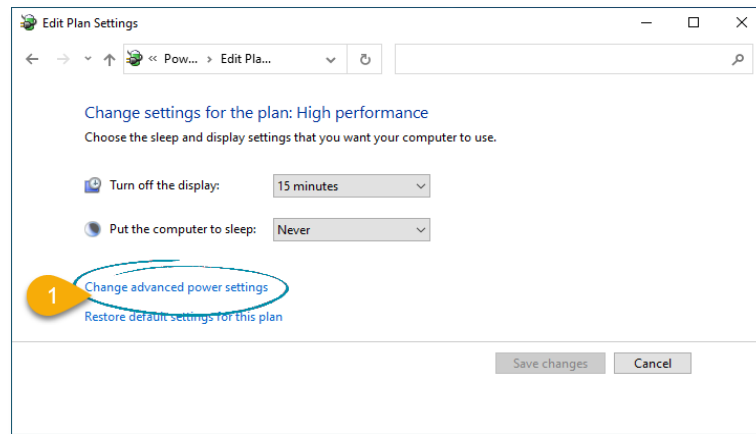
Recommended PC power settings

1. The Mastersizer 3000 works best with High Performance power settings. The following information shows how to configure the power options for optimum performance. Launch the Control Panel app, then Hardware and Sound then Power Options.
2. From the list of Preferred Plans, choose High Performance.

3. Click on Change Plan Settings.



4. From the Edit Plan Settings window, click on Change advanced power settings.



5. From the Power Options window, set the following.

- *Hard Disk > Turn off hard disk after = Never*
- *Sleep > Sleep after = Never*
- *USB Settings > USB selective suspend setting = Disabled*
- *PCI Express > Link State Power Management = Off*
- *Processor power management > Minimum processor state = 100%*

6. Click the Apply button followed by the OK button.

7. From the Edit Plan Settings window, click the Save Changes button (some versions of Windows do not make this button available, just close the window).

8. Return to the Control Panel home page and click the Device Manger.

9. From the Device Manager window, scroll down and click the twister adjacent to Universal Serial Bus controllers to expand the view.

10. Double click each listed device and look for a tab named Power Management.

11. Uncheck the Allow the computer to turn off this device to save power and click the OK button.

12. Repeat for all USB devices (some versions of Windows may not have the Power Management option).

Upgrading from an earlier version of software

Backward compatibility with Mastersizer 3000 v3.88 or previous versions

Due to the .Net6 framework change from v4.0 backward compatibility of SOPs and data prior to v4.0 release will not be possible. Measurement data and SOPs generated in (v4.0 or later) and future releases, will not be able to be displayed in releases prior to and including v3.88. Data and SOPs will remain forward compatible.

21CFR pt.11 / Malvern Access Configurator (MAC)

The feature key that provides 21CFR pt.11 features has changed from MAC supported to the OmniTrust platform. This version of the software does not support Malvern Access Control (MAC) or 21CFR via MAC. From software version 4.0 this functionality has been provided via OmniTrust. Users wanting to continue using MAC should not upgrade to this version. For users that wish to upgrade to the OmniTrust platform we recommend remaining on your existing software version until an Audit trail exporter tool is released.

MAC is available up to and including software version 3.88

Measurement file size and corruption warnings

Version 3.20 and higher of the Mastersizer software includes the ability to detect when measurement files are at risk of becoming corrupted. If you see one of these messages, you are probably creating too large a measurement file. We recommend that you keep measurement files to a maximum size of 100 records and advise that you try to remember to regularly create and use new files to store measurement records.

Note that Malvern Panalytical are currently investigating possible alternative measurement file formats for use in future software releases, with the goal of increasing the maximum number of records which can be robustly stored within a single file.

Backward compatibility with Mastersizer 2000

This software is only compatible with the Mastersizer 3000 (MAZ3000) and Mastersizer 3000E (MAZ3010) systems and cannot be used with the Mastersizer 2000 (APA2000) or Mastersizer 2000E systems. It is possible, however, to review Mastersizer 2000 / 2000E results within the Mastersizer 3000 / 3000E software. Please refer to the user manuals and software help for guidance as to how this is achieved.

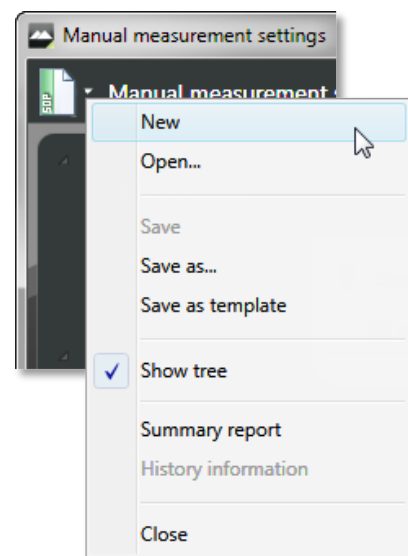
Known issues

The following software bugs have been discovered within the software and will be investigated as part of a future release. Please follow the suggested work-around for each issue when operating the software.

Manual measurement settings do not match the connected / active dispersion unit

Occasionally, users may see the wet accessory related manual measurement settings when a dry unit is attached, or visa-versa. If this occurs, open the manual measurement settings window and click the New menu item from the window Features menu:

This will reset all measurement settings to their defaults for the active accessory type. This issue has been reported after upgrading from early versions of the software but does not occur on all systems.



Issue	Work Around / Details	Comment
PV certificate may not be generated when clock time format in Windows was set to Short time (HH:MM).	To resolve ensure that Windows OS clock time format is set to Long time (HH:MM:SS).	Intermittent Observation. Resolution available – see details.
During SOP measurements there have been occasions where records have been skipped, e.g., 3 runs requested and records 1, 4, 5 generated in measurement file.	Intermittent observation no current workaround available.	Intermittent Observation.
Accessory status bar is green but SOP and Manual measurement options greyed out.	From time to time the SOP and manual measurement options are still greyed out even when the accessory status bar is green. To re-enable these options, right-click on the accessory status bar and reselect the accessory.	Intermittent Observation. Work around procedure available.
Downgrading this version of the software to v3.81 or below will mean that the software will not function, as v3.82 introduced updated Windows Drivers. These drivers are not compatible with versions of the Mastersizer 3000 software prior to v3.82.	We advise contacting your Malvern Panalytical representative for support to ensure the correct procedure is followed.	High risk issue. Work around procedure available.
Measurement data and SOPs generated in (v4.0 or later) and future releases, will not be able to be displayed in releases prior to and including v3.88. SOPs and Data will remain forward compatible.	Due to the .Net6 framework change from v4.0 backward compatibility of SOPs and data prior to v4.0 release will not be possible.	
“% sample integration actually completed” message intermittently observed in place of “The lid must be closed” Aero message when the Aero lid is opened between analysis of multiple dry samples in SOP mode.	No work around available. Press Initialise Instrument button and continue with analysis.	Intermittent Observation.
Reporting of zero measurements.	In rare cases a zero measurement can occur in both wet and dry measurements. The measurement record contains background and data but no signal information. A zero distribution is recorded in the measurement file. No work-around available.	Medium risk issue.

Software can crash when batch printing	When selecting too many reports and/or too many records for batch printing, an error can occur causing a crash exception. Restricting the total number of pages printed to 220 or less (equivalent to 13 results batch printed with 10 reports) will mitigate this issue occurring	Low risk issue.
Corrupt report settings file causes software crash on start-up	It has been observed that the global report settings file may become corrupt. This file holds the company name and logo used across all reports in the software. A symptom of this issue is the software crashing on start-up with an exception "hexadecimal value 0x00, is an invalid character". The workaround is to delete the contents of folder at C:\ProgramData\Malvern Instruments\Malvern.Reporting. This will trigger a new fresh settings file to be created – you will have to reconfigure your company name and logo in reports.	Medium risk issue.
Warnings are displayed about corrupt measurement files	The software has built in detection of when measurement files are at risk of being corrupted. If you see one of these messages, you are probably creating too large a measurement file.	Intermittent Observation.
Instrument disconnects after firmware upgrade	An issue has been seen for some installations whereby the instrument will become disconnected from the computer following a firmware upgrade. Turning the instrument off and on again will cause it to successfully reconnect to the software.	Intermittent Observation.
Some text still appears in English when running with a different language selected.	The translation of all software text will continue in future releases.	Low risk issue.
Software does not open all files selected when they are opened using Windows Explorer.	Use the Open menu option in the Mastersizer 3000 software to open multiple files.	Low risk issue. Work around procedure available.
Various fields in the Edit result window lose their 'edited' blue background appearance when a different page in the editor is selected.	No work-around available. This is a display issue only, as the software correctly applies the edit values when the OK button is pressed.	Low risk issue.
Trend table print out is limited by paper size	Report widgets are designed to fit on one page and will not wrap over pages. If you select lots of measurement records, the trend table widget will expand to fill the page. However, if you select more measurement records than can fit in a trend table on a single page then the displayed records will be truncated at the page boundary. The only work around for this issue is to print the report on a larger paper size. Paper size A4 has a limit of 56 records in a trend table, whereas paper size A3 has a limit of 86 records.	Low risk issue.
Some parameters are not imported from Mastersizer 2000 measurement records	When importing Mastersizer 2000 measurement records into the Mastersizer 3000 software, some SOP parameters from the Mastersizer 2000 records do not get imported. However, all of the parameters required for result review or recalculation are present.	Low risk issue.
Manual measurement errors are reported if the Aero dispersion unit configuration has changed between measurements	The manual measurement feature in the software stores the last used settings. This includes configuration of the Aero dry powder disperser. If you change the configuration between measurements and then open a manual measurement, the software will report an error stating that configuration is wrong. If this happens, close and re-open the manual measurement window and change the manual measurement settings to match your new Aero configuration.	Low risk issue.
Software exception is reported if the software is closed when a macro is running	All currently running macros must be closed before closing the software.	Low risk issue. Work around procedure available.
Some report widgets are truncated in the print preview view	Some report widgets may not be displayed correctly within the print preview screen. However, if the report is printed all of the information within the widget will be shown.	Low risk issue.

Software may crash when exporting data with custom sample identifiers which start with a number	Exporting measurement data with custom sample identifiers beginning with a number will cause the software to crash when you select an export template that contains sample identifiers. The only work-around is to prefix sample identifiers with letters.	Low risk issue. Work around procedure available.
Ultrasound SOP option 'Continuous (From Measurement Start)' does not turn off in SOP playlist	If you use an SOP with the ultrasound option 'Continuous (From Measurement Start)' in an SOP playlist, when running a subsequent SOP with no ultrasound turned on, the ultrasound will not turn off as expected. The work around is to use the 'Continuous (From Sample Addition)' option in the SOP rather than 'Continuous (From Measurement Start)'. When this playlist is run, then the ultrasound will turn off when executing a subsequent SOP which does not require ultrasound.	Low risk issue. Work around procedure available.
Cannot load old custom calculations from file	When trying to load a custom calculation created in v3.30 software or earlier, the software may report error and the calculation will not load. The workaround is to re-export the custom calculation from the original report in a recent version of the software.	Low risk issue. Work around procedure available.
Data quality tab is not displayed immediately when selected from the extended features list	Given that the software has just been installed and the option to enable the extended software features is selected. Then when the application is restarted the data quality tab will not be displayed if the default view is selected. The work-around is to select the 2-pane vertical view which will display the data quality tab. Then reverting to the default view will display the data quality tab.	Low risk issue. Work around procedure available.
Ultrasound level applied during clean reported as 0%	You may find that the measurement manager reports that 0% ultrasound is being applied during cleaning when you have set an ultrasound demand of greater than 0%. Evidence suggests that ultrasound is applied correctly as per the configured ultrasound demand, but the value shown in the measurement window is incorrect.	Low risk issue.
"Some data may be missing" error message on attempting to resign records created in v3.30 or earlier	This is a false-positive error message, a consequence of a design issue fix implemented in v3.40 onwards. In earlier versions of the software (v3.30 and earlier), duplicate parameters were written to the measurement record. From v3.40 onwards, a fix was applied which enabled the duplicate parameters to be disregarded. However, this means that when a measurement is created in v3.30 or earlier, and then signed in a later version of the software, the signature information is written over the top of the duplicate data, causing the false-positive error message to be generated.	Low risk issue. The error message is a false-positive (data is not missing) and locking signatures are not lost on v3.81, so it is unlikely a user will need to resign a record.
Downgrading with 21CFR11 mode enabled to earlier version of the software can cause this functionality to be switched off.	Re-enable 21CFR11 functionality once downgrade is complete.	Intermittent observation. Work around procedure available.
On repeated running of a dry SOP incorrect warning messages can be displayed if the lid is left open when adding more sample	Close the SOP at the end of each sample measurement and restart the SOP	Low risk issue. Work around procedure available.
After switching to an alternative wet accessory, the ultrasound settings may not be applied correctly	Change accessory and then re-launch the application software	Low risk issue. Work around procedure available.
The parameter 'Ultrasound Achieved' is always report as zero for pre-measurement ultrasound	The parameter 'Ultrasound Demand' is reported correctly	Low risk issue.
Opening the Optical Property Optimizer can cause the software to crash	This generally occurs with a fresh software installation, restart the software, and retry the Optical Property Optimizer	Intermittent observation.
After switching between a manual wet dispersion unit and an automated wet dispersion unit then running an SOP the stirrer stops at the "Add sample stage" and does not re-start.	Switch to the automated dispersion unit and then restart the application software.	Low risk issue. Work around procedure available.

In a wet measurement an SOP can continue if the upper obscuration limit is exceeded	For each record, the obscuration can be compared to the obscuration limits post measurement and the record data rejected if the upper obscuration limit has been exceeded.	Intermittent observation. Work around procedure available.
The trend table does not clear completely when records are de-selected, the results from the last record to be de-selected remain displayed in the table	No work-around available	Low risk issue.
The Optical Property Optimizer view can be blank when accessed for the first time	Restart the Optical Property Optimizer	Low risk issue.
On repeating an SOP, it does not ask for new sample details and the subsequent sample is analyzed using the same sample details	Close and restart the SOP at the end of the measurement, new sample details can then be entered	Low risk issue.
Incorrect warnings (in hover over tool tips) can be displayed when invalid values are entered in SOP settings	No work-around available	Low risk issue.
Intermittent failure of pre-measurement ultrasound during SOPs	Intermittently the ultrasound does not turn on during the pre-measurement ultrasound phase. The timer counts down, but the ultrasound does not turn on.	If this error is observed, please contact your local Malvern Panalytical representative.
Occasionally the application will close intermittently, sometimes with a "System Out of Memory" and/or "UCEERR_RENDERTHREAD" messages.	It is suspected that this issue is being observed mainly on PCs with 12 th generation or higher processors. Please ensure all hardware drivers and PC power settings are up-to-date and correct. Ensure autosave is enabled. Restart the PC daily/during each shift. If this error is observed, restart the PC and continue as normal.	If you continue to experience this error, please contact your local Malvern Panalytical representative, for up to date guidance.
Users of Malvern Access Configurator (MAC) and/or 21CFR pt.11 license key that upgrade will not be able to view the record audit trail, system audit trail or locked record status from within software version 4.0 or later The MAC viewer is not affected.	For 21CFR pt.11 feature key users only: we recommend remaining on your existing software version until an upgrade path is available. If upgrade has taken place, we recommend reverting to the previous software version that was installed on your PC. This may require you to re-enable 21CFR11 functionality once downgrade is complete by re-enabling the Features File	No data is deleted in the upgrade process. For more information, please contact your Malvern Panalytical representative.
Users of Malvern Access Configurator (MAC) that upgrade to software version 4.0 or later will no longer have access control.	We recommend remaining on your existing software version until an upgrade path is available. If upgrade has taken place, we recommend reverting to the previous software version that was installed on your PC to restore Access Control.	
Optical Property Optimizer sliders do not have lock or relative lock options	Values in the optical property optimizer can also be set by typing the value into the sliders, use this option to set an exact value more quickly	Low risk issue
Loading the Toner Dispersion Simulator causes the software to crash	No-work around available	Low risk issue
When viewing the Mastersizer 3000 license OmniTrust is shown as licensed even when a license has not been applied	If OmniTrust is activated the 21CFR icon in the Status bar will turn green	Low risk issue
Exporting the SOP from the SOP history view causes the software to crash	The SOP for a record can be exported by right clicking from the record view	Low risk issue
Using CTRL V to paste records into an empty measurement file does not work	From the empty measurement file use the right click context menu to paste the records	Low risk issue
'Failed to get dry status' error in the measurement manager window on changing from dry to wet accessories.	Restarting the application enables the software to connect to the correct accessory	Intermittent observation when switching from Aero to Hydro accessories
'Failed to set the accessory mode' error observed in dry measurements after the clean sequence following multiple accessory changes between wet and dry	The error can be reset to continue the measurement and restarting the application will stop the error from appearing	This is a low risk error observed after multiple accessory changes

Service & Support

Malvern Panalytical provides the global training, service and support you need to continuously drive your analytical processes at the highest level. We help you increase the return on your investment with us and ensure that as your laboratory and analytical needs grow, we are there to support you. Our worldwide team of specialists adds value to your business processes by ensuring applications expertise, rapid response, and maximum instrument uptime.

- Local and remote support.
- Full and flexible range of support agreements.
- Compliance and validation support.
- Onsite or classroom-based training courses.
- e-Learning training courses and web seminars.
- Sample and application consultancy.

Remote support

Malvern Panalytical offers remote support over a secure internet connection. This is typically the most convenient way for our customers to get help with their applications and technical support needs. For remote support over the Internet, we recommend TeamViewer®, WebEx®, or Microsoft® Teams® - but we are also happy to accommodate other technologies our customers may prefer.

Installation questions & support

For contact information for your local office, please visit:

<https://www.malvernpanalytical.com/en/about-us/contact-us/>

<https://www.malvernpanalytical.com/en/support/contact-support/support.html>

Regulated Environment

This section details specific information relating to the regulated environment.

Software version 4.0 introduced OmniTrust to the Mastersizer platform. OmniTrust is Malvern Panalytical's solution for regulatory compliance and data integrity across different product ranges. Please contact your local Malvern Panalytical representative if you would like to purchase this feature key.



Caution!

This version of the software does not support Malvern Access Control (MAC) or 21CFR via MAC. This functionality is now provided via OmniTrust.

Users wanting to continue using MAC should not upgrade to this version.

MAC is available up to and including software version 3.88

Users of the existing 21CFR solution on 3.88 and earlier will no longer be able to use this feature within software version 4.0 or later. Users wanting to continue using MAC and the existing 21CFR solution are encouraged not to upgrade to a version above 3.88.

Users who upgrade to software version 4.0 or later will no longer be able to view audit trail information generated in v3.88 or previous. For those users we recommend remaining on your existing software version until an audit trail exporter tool is made available.

Software categorization

GAMP 5

The GAMP 5 guide provides guidance to pharmaceutical companies wishing to understand whether the computerized systems and software they use 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 3000 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 3000 software provides users with the ability to modify the results reported by the system to fit their application requirements. This is achieved using 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 3000 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 3000 software are necessary to meet business requirements.

Validation support documents

For Validation Support Documents, please refer to the Mastersizer 3000 Product Support section on the Malvern Panalytical website. Ensure the documents are relevant for the version of software that you are using,

<https://www.malvernpanalytical.com/en/support/product-support/mastersizer-range/mastersizer-3000>

Windows file security settings

With a 21 CFR Part 11 compliant computer system, one of first concerns to address is the potential for the loss of data, either accidentally, or by intention. During the initial installation of the Mastersizer application software, we automatically set the security permissions of the user output folders to prevent deletion. However, we strongly recommend that you consult your internal validation and IT departments for advice, should you wish to change from the default folder structure.



CAUTION!

We strongly advise customers not to disable the Windows UAC feature, as this may allow users to delete files and/or folders, compromising audit history and/or measurement data critical to 21CFR compliance.

Changing the folder security permissions in Windows 10 & 11

On new installs, folder permissions are now automatically applied to the Measurement Data and SOP folders in *C:/Program Data/Malvern Instruments/Mastersizer 3000/Workspace* to prevent deletion. If upgrading from an existing installation, previously set folder permissions will be carried over.

For OmniTrust software users, the additional recommended file permissions are shown in the [Appendix](#) of this document.

Installing the OmniTrust application

Users with software version 4.0 and above, who require a regulated environment, will need to purchase OmniTrust software. Please contact your local Malvern Panalytical representative if you would like to purchase this application.

Malvern Access Configurator (MAC) application

Users of the existing 21CFR solution on 3.88 and earlier will no longer be able to use this feature within software version 4.0 or later. Users wanting to continue using MAC and the existing 21CFR solution are encouraged not to upgrade to a version above 3.88.

An upgrade path for existing users of the 21CFR feature key will be made available in a later release of software. For existing users of the MAC and/or 21CFR pt.11 feature key it is not recommended to upgrade to software version 4.1 at this time. Existing users who are not actively using the MAC and/or 21CFR pt.11 feature key can continue to upgrade their software to 4.10 as usual.

Audit Trail data will not be deleted and can be found in *C:\Program Data\Malvern Instruments\Mastersizer 3000\Audit Trails* but users of 4.0 and above will no longer be able to view the data view, or view Audit or Archive audit trails that were generated in v3.88 or earlier, from within the Mastersizer software.

Users with System Audit trail information from software version 3.88 or earlier can continue to view the historic system Audit trail within the MAC (providing the MAC has been installed on the PC). Users will also be able to continue to view these in Mastersizer software if transferred to a separate PC that has v3.88 or earlier.

Caution!



This version of the software does not support Malvern Access Control (MAC) or 21CFR via MAC. This functionality is now provided via OmniTrust.

Users wanting to continue using MAC should not upgrade to this version.

MAC is available up to and including software version 3.88

Appendix – OmniTrust File System Permissions

OmniTrust configuration

This section describes the files and directories used by OmniTrust:

- The minimum file system permissions required for the software to operate correctly.
- The optional file permissions which may need to be set depending on a user's role.
- Change folder security permissions manually. Refer to Section 5.1.

The Administrator has full control to all file and folders.

- Basic user permissions must be applied to the Everyone group.
- Advanced users permissions must be applied to a group created for this file type and to Advanced users if applicable.
- Inherited permissions must be disabled, and all other permissions must be removed.

Folder permission settings:

- The folders under **%ProgramData%\Malvern Panalytical\Regulated Environment** must be readable by regular users but only writable by administrators / system account.
- The folders under **%ProgramData%\Malvern Panalytical\OmniAccess** must be both readable and writable by regular users.
- The folders under **%ProgramData%\Malvern Panalytical\OmniTrail** must be both readable by regular users but only writable by administrators / system account.
- The folders under **%Public%** must be both readable and writable by regular users.

File extensions:

- Files with extension **.config** are text (XML) files that can be read in any text editor. They have a digital signature to prevent changes.
- Files with extension **.db3** are database files in binary format.
- Files with extension **.log** are regular text files (logs).
- Files with extension **.json** are regular json files.

Advised OmniTrust file security settings

#	File type	Extension	Default path %ProgramData%\Malvern Panalytical	Creation	Scope	Minimum required permissions (basic users) Applicable to Folder and File	Notes
1	OmniTrail-Application information.config	.config	\Regulated Environment\Application Information	First run	User	ReadAndExecute, Write	Application information file with permissions descriptions and application version (this file is not editable in OmniAccess)
2	Authentication.config	.config	\Regulated Environment\Authentication	On Software Install	System	ReadAndExecute, Write	It contains the list of authentication sources that will be used by Regulated Environment to validate user names and passwords during login and signature.
3	MalvernPanalyticalUserStore.db3	.db3	\Regulated Environment\Authentication	On Software Install	User	ReadAndExecute, Write	The Malvern Panalytical User Store database file.
4	Authorization files	.config	\Regulated Environment\Authorization	On Software Install	System	ReadAndExecute, Write	Examples: <ul style="list-style-type: none"> • ZSXplorer- Authorization.config contains the deployed authorization settings (roles, members and permissions) for ZSXplorer, OmniAccess- Authorization.config for OmniAccess only. • OmniTrail- Authorization.config for OmniTrail only.

5	SigningAndReason.config	.config	\Regulated Environment\Signing	On Software Install	System	ReadAndExecute, Write	File contains the list of possible System Audit trail events and, for each one, settings about whether signing and reason are mandatory or optional.
6	Synchronization.config	.config	\Regulated Environment\System Audit Trail	On Software Install	System	ReadAndExecute, Write	File contains the settings for synchronization of data among Regulated Environment instances on different machines in the network.
7	System_audit_trail.db3	.db3	\Regulated Environment\System Audit Trail	On Software Install	System	ReadAndExecute, Write	The system audit trail database
8	OmniAccessStore.db3	.db3	\OmniAccess\Configurations	On Software Install	System	ReadAndExecute, Write	File contains authorization data such as roles, role members, permissions, etc.
9	Log files for OmniAccess	.log	\OmniAccess\Logs	On Software Install	System	ReadAndExecute, Write	Log files can be used for diagnostic and troubleshooting purposes.
10	Log files for OmniTrust	.log	\OmniTrail\Logs	On Software Install	System	ReadAndExecute, Write	Log files can be used for diagnostic and troubleshooting purposes.
11	OmniTrailSettings.json	.json	%USERPROFILE%\AppData\Roaming\Malvern Panalytical\OmniTrail	By user	User	ReadAndExecute, Write	File contains user settings for the OmniTrail application. Preferences such as the number of entries per page visible.
12	Filter files	.json	%Public%\Documents\Malvern Panalytical\OmniTrail	By user	User	ReadAndExecute, Write	This is the default folder where filter files are saved and loaded from.



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