

# Mastersizer Xplorer Software: v5.50 (PSS0223-48)

## Software Update Notification



## Introduction

This document details the release of software Mastersizer Xplorer version 5.50 of the software for the Mastersizer 3000+ Ultra, Mastersizer 3000+ Pro, Mastersizer 3000+ Lab, Mastersizer 3000 and Mastersizer 3000E laser diffraction systems. Known issues and lots of other helpful information to help you install and administer the application software are also covered.

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 a software upgrade.

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

**Note:** Please check for any updates to this Software Update Notification at  
[www.malvernpanalytical.com/en/support/product-support/mastersizer-range/mastersizer-3000](http://www.malvernpanalytical.com/en/support/product-support/mastersizer-range/mastersizer-3000)  
[www.malvernpanalytical.com/en/support/product-support/mastersizer-range/mastersizer-3000+](http://www.malvernpanalytical.com/en/support/product-support/mastersizer-range/mastersizer-3000+)

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# New Features and fixed issues

## New Features

Table 1: A reminder of new features introduced in 5.50

New features
To improve performance and ensure long-term functionality, version 5.50 introduces new file formats for measurements (.m3m) and SOPs (.m3s). Measurements and SOPs created in previous versions can be opened in read-only mode and converted to the new format for continued use. Further details are available in the Mastersizer User Guide.
<b>OmniTrust Updates</b> OmniTrust version 1.8 is now supported with support for Entra ID. Microsoft Entra ID (formerly Azure Active Directory) is designed to provide cloud-based identity and access management without relying on traditional domain-based Active Directory
<b>License Manager upgraded to version 2.1.1</b> – allows activation of entitlements per product line item, which is required for situations where different license products need to be activated on different PC's
Support for 64-bit operating systems
In SOP Architect, progress can now be saved at intermediate stages during the workflow
During installation Smart Manager opt-in is no longer ticked by default, to benefit from Smart Manager please tick this option to send telemetry

## Fixed issues

A recap of fixed issues in version 5.50 is included in Table 2.

Table 2: Recap of fixed issues in version 5.50

Reference(s)	Fixed Issue
348522	Resolved incorrect marking of record data integrity as Invalid. This occurred when measurement files are opened in a different time zone to which they were created. Plus, where average records are pasted into a new file and the parameter 'average result records' information is lost.
348070	Updated the parameter selection list
196842	RSS Feed fixed
353962	Updated the name of the OmniTrail default authorization configuration file for Mastersizer Xplorer to Xplorer_OmniTrail-Authorization.config. Only for use with OmniTrust and when completing the regulated compliance test document.

For existing bugs, please refer to the Known Issues table

## Recommended System Requirements

Testing of this software was conducted primarily on Windows 11 23H2 and functionality testing on Windows 10 Professional 22H2 operating system.

For optimal performance and compatibility, it is advised to use Mastersizer Xplorer on either Windows 10 or Windows 11 operating systems.

**Table 3 : Recommended system requirements for the Mastersizer software**

Feature	Specification	Feature	Specification
Processor Type	Intel Core i7 Processor (8 <sup>th</sup> generation or higher) *(See Appendix 2 for details about 12 <sup>th</sup> generation and higher PCs)	Power Settings	Best performance (see details of advanced settings in Appendix 1)
Memory	16GB	Connectivity	1 USB 2.0 or USB3.0 port
Solid State Storage	250 GB SSD	Operating System	Windows 11 Pro 23H2 OR Windows 10 21H2 IOT (64 bit)
PC power settings	High or Best Performance (Detailed configuration in Appendix 1). Ensure display lock outs allow enough time for measurements to complete	Software rendering	May be enabled to improve stability (See Appendix 2 for details)

## Supported Languages

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

- English
- French
- German
- Japanese
- Chinese (simplified)
- 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 (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.

**Note:** It is important to initially install the software onto the PC without the Mastersizer 3000+/Mastersizer 3000 being connected. Following download the PC should be powered down and the Mastersizer 3000+/ Mastersizer 3000 optical bench connected to the PC before powering up. Finally, the Mastersizer wet and/or dry dispersion accessories should be connected to the optical bench which is already attached to the PC and the PC then be 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 before the release of the software.

## Uninstall procedure

Downgrading from v5.50 to a previous software version requires workspace and configuration files to be deleted. Please contact your local Malvern Panalytical representative for guidance.

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!



Due to the change in measurement and SOP file formats introduced in v5.50, backward compatibility to previous versions is not possible. SOP and measurement files created in v5.50 will not work in any previous version. SOP and measurement files created in earlier versions can be converted to the new format for continued use.

### Caution!



Due to the .NET upgrade, backward compatibility of SOPs and data prior to the release of v4.0 will not be possible. SOP and measurement file saved from this version will not work in any previous version. Forward compatibility will remain.

### Caution!



Downgrading v3.82, or higher, with 21CFR Part 11 mode enabled to earlier versions of the software will cause this functionality to be switched off. 21CFR Part 11 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 21CFR Part 11 tab and "Enable Access Control" from the Access Control tab).

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 Xplorer 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 Xplorer software on additional computers, you will need to follow the procedure below for sharing a software license.

**Note:** Software feature entitlements are specific to the computer on which they are installed and therefore cannot be shared. Some feature entitlements may have multiple activations.

## Sharing a license for Mastersizer Xplorer users

To enable the use of the Mastersizer Xplorer software on a computer which is not connected to an instrument, users must 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 Xplorer software and click on the **File Menu** 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. On a separate computer, install the Mastersizer Xplorer software and start the program. At the license screen, click the **Install** button.

- 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+ / 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+ / 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 and Mastersizer 3000+ Lab users

The Mastersizer 3000E and Mastersizer 3000+ Lab systems are provided with a simplified, basic version of the Mastersizer Xplorer software. This basic software version is restricted to use on a single computer workstation attached to the Mastersizer 3000E / Mastersizer 3000+ Lab system. As such, the license-sharing facility offered for Mastersizer 3000 / Mastersizer 3000+ Ultra and Pro 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 an upgrade. This upgrade will enable the premium features associated with the Mastersizer Xplorer software, including the ability to create shared licenses. Please contact your local Malvern Panalytical representative if you would like to purchase this upgrade.

## Software feature entitlements

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

The following feature entitlements are compatible with Mastersizer Xplorer.

**Table 4: Feature entitlements compatible with Mastersizer Xplorer**

Feature	Description	Compatibility	Version first introduced
OmniTrust OMT0200 / OMT0210	<a href="#">OmniTrust</a> is Malvern Panalytical's instrument-agnostic solution for regulatory compliance and data integrity.	Mastersizer 3000+ Ultra Mastersizer 3000  Mastersizer 3000+ Pro	4.0  Available on Mastersizer 3000+ Pro from Mastersizer Xplorer 5.10.
OmniAccess for Mastersizer OMT0250	Standalone version of OmniAccess for user authentication and authorization.	Mastersizer 3000+ Ultra, Mastersizer 3000+ Pro, Mastersizer 3000, Mastersizer 3000E with extended software	Mastersizer Xplorer 5.40
Workflow Guidance	Contains access to Data Quality guidance. Flags possible data quality issues and provides a list of causes and solutions at all stages of your measurement.  Data from all Workflow packages are viewable.	Mastersizer 3000+ Ultra, Mastersizer 3000+ Pro, Mastersizer 3000 and Mastersizer 3000E with extended software	4.10
Workflow Developer	Contains access to all the features of Workflow Guidance plus SOP Architect. SOP Architect guides you through a standardized workflow that supports novice users and validates the experts' decision-making. Its specialized tests and smart algorithms give you the best possible starting point for your research method or SOP.	Mastersizer 3000+ Ultra and Mastersizer 3000+ Pro, Mastersizer 3000	Mastersizer Xplorer 5.0
Workflow Expert	Contains access to all the features of Workflow Developer plus Size Sure. By using Size Sure in your analyses, you can	Mastersizer 3000+ Ultra, Mastersizer 3000	Mastersizer Xplorer 5.0

characterize your samples quickly and reliably. You get a clear view of steady state sample results vs transient events, and this will reduce the time you spend on troubleshooting misleading results. The Size Sure measurement mode helps to mitigate environmental factors during measurement such as contamination and the effects of unstable conditions, making analysis easier for expert users and non-experts alike.

## Activating a software feature entitlement

License Manager is installed automatically as part of Mastersizer software installs from version 4.0 and above. 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 entitlement. This is provided by email to a nominated email address. A product activation entitlement 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 an internet connection is required to download a file, this does not need to be attached to the instrument.

### Activating a software feature entitlement – Online

For online activation. Open the License Manager and follow the onscreen prompts. You will need the product activation entitlement, Company name and address where the 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 entitlement to become inactive.

### Activating a software feature entitlement – Offline

For offline activation. Open the License Manager and follow the onscreen prompts. You will need the product activation entitlement, Company name and address where the 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 an internet connection.

From the computer connected to the internet. Visit [www.malvernpanalytical.com/softwareactivation](http://www.malvernpanalytical.com/softwareactivation) and log in with your product activation entitlement.

Select Offline Activation and then upload the C2V fingerprint file.

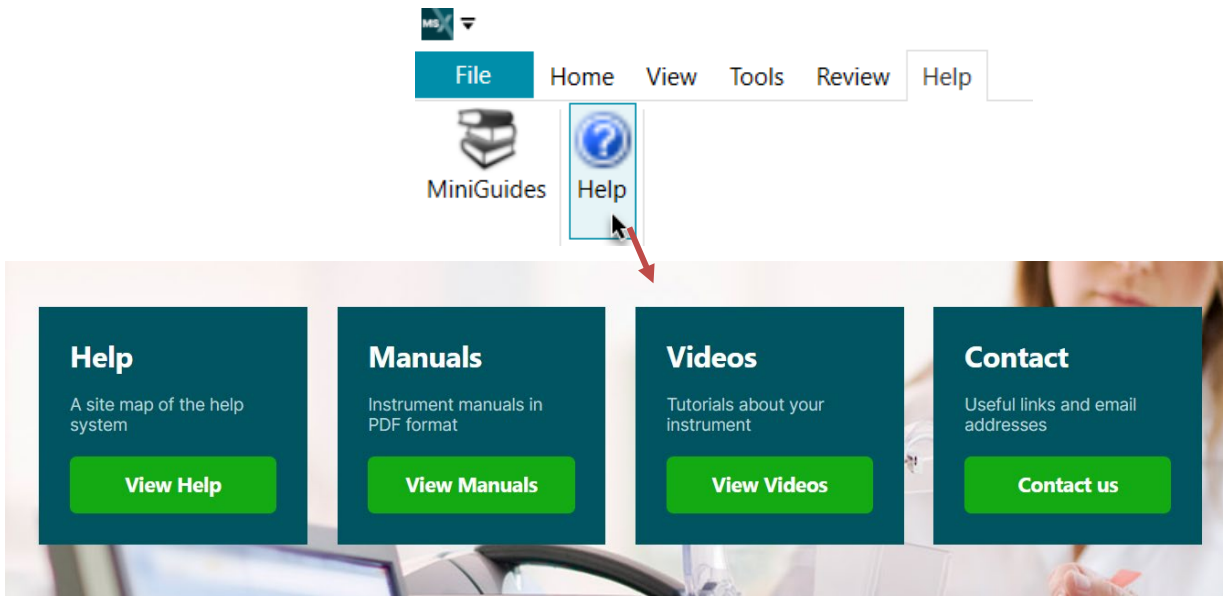
Select 'Generate' button to generate the V2CP license file. Download the V2CP license file and save it.

Copy the V2CP license file back to the computer connected to the instrument.

From the computer connected to the instrument. Follow the onscreen prompts through the license manager and enter the file location of the V2CP file where required.

## Software guides

The Mastersizer Xplorer software includes a comprehensive help system which contains access to a site map of the system, Manual as well as useful tutorial videos about your instrument



## Security advisories

The USB driver has been updated to apply a security fix to an escalated privileges vulnerability.

**Note:** We always recommend updating to the latest software version which will provide you with new features, bug fixes 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

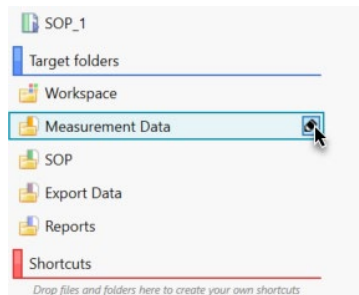
The default folder path is `C:\Program Data\Malvern Instruments\Mastersizer 3000\Workspace`. If upgrading from an existing installation and/or if you wish to apply additional settings or to other folders, this may need to be done manually.

### Changing the destination path for a file

The following folders can be configured from within the Mastersizer Xplorer software:

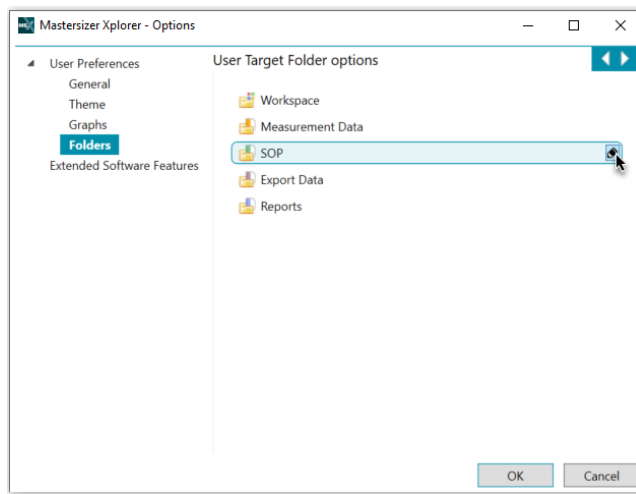
- SOP
- Measurement Data
- Reports
- Export Data

For users of Mastersizer 3000+ Ultra, Mastersizer 3000, Mastersizer 3000+ Pro and Mastersizer 3000E with extended 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 Xplorer 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. To access this, select File- Options from the Menu Bar



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 3000+ Lab and Mastersizer 3000E.

## Backup and restore files

### What to backup

By installation default, Mastersizer Xplorer 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 Part 11 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 or reinstallation of windows

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 Xplorer software.

#### Caution!




If restoring the 21CFR Part 11 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.**

**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 Xplorer 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 Xplorer software installation, you can simply right-click the same application, and 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 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. Our information security management system also complies with the strictest international security standards (ISO/IEC 27001:2013).

## Upgrading from an earlier version of the software

Version 5.50 introduces a new file format for measurements (.m3m) and SOPs (.m3s). Any measurement files or SOPs created in previous versions can be opened as read only and converted to the new format for continued use. More details can be found in the Mastersizer User Guide.

Table 2 contains major changes to compatibility between versions of software, please consult this if upgrading from an earlier version of the software. Contact your Malvern Panalytical representative for previous Software Update Notifications with more detailed information.

**Table 5: Major changes to compatibility between software versions**

Software version	Regulated environment	Measurement file	SOP	Malvern Link	Firmware	.NET	License Manager
5.5	OmniTrust (v1.6 or higher)	.m3m	.m3s	Not compatible	No change	v8	2.1.1
5.4	OmniTrust (v1.6 or higher)	.mmes	.msop	Not compatible	New optical bench firmware	v8 (no impact on file or SOP compatibility)	2.0.0
5.2	OmniTrust (v1.6 or higher)	.mmes	.msop	Not compatible	New optical bench and accessory firmware	v6	1.3.2
5	OmniTrust (v1.6 or higher)	.mmes	.msop	Not compatible	New optical bench firmware	v6	1.3.2
4	OmniTrust (v1.6 or higher)	.mmes	.msop	Not compatible	No change	v6 Files and SOPs created in v4 cannot be opened in previous versions	1.3.1
3.88	21 CFR part 11 / Malvern Access Configurator	.mmes	.msop	Compatible	No change	.NET framework v4.6.1	N/A

**Note:** Custom calculations (.mcal) created in version 3.30 and earlier require an update to be used in later versions.

## 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.

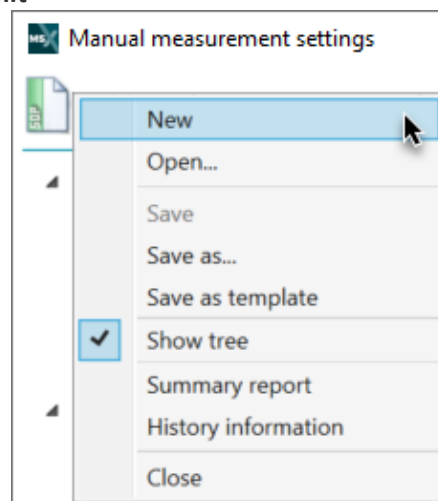
### Switching between dry and wet accessories

When switching to or from a dry accessory (Aero M or S), a 'failed to achieve dry status' error or 'system rail voltage' error can be observed which prevents measurements being started. Closing down the Mastersizer Xplorer software and re-opening will clear this issue.

### 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.



### Signatures table

The 'Signatures' table is no longer automatically appended to any reports when 21CFR is enabled. This was removed in v5.40 and is still not available in v5.50. Customers are advised to refer to the Approval Report

Issue	Work Around / Details	Comment
The accessory status bar is green but SOP and Manual measurement options are 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 is available.
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 is available.	Medium risk issue.
The 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 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 the folder at <i>C:\ProgramData\Malvern Instruments\Malvern.Reporting</i> . 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.
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.
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.
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 the 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 the 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 is 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 is 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 is available.
Opening the Optical Property Optimizer can be blank or 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 and then running an SOP the stirrer stops at the "Add sample stage" and does not re-start. After switching to an alternative wet accessory, the ultrasound settings may not be applied correctly	Switch to the automated dispersion unit and then restart the application software.	Low risk issue. Work around procedure is 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 is rejected if the upper obscuration limit has been exceeded.	Intermittent observation. Work around procedure is 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.
Locking the PC screen can cause the accessory to become disconnected	Restart software.	Intermittent Accessory. The status button remains Green even though it is inactive.
PV certificate may not be generated when the clock time format in Windows is set to short time (HH:MM).	To resolve ensure that the Windows OS clock time format is set to a long time (HH:MM:SS).	Intermittent Observation. Resolution is available – see details.

## 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 application 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 to 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 entitlement.

Users of the existing 21CFR Part 11 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 legacy 21CFR Part 11 solution must remain on Mastersizer software 3.88.

## Caution!



This version of the software does not support Malvern Access Control (MAC) or 21CFR Part 11 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

For users that wish to upgrade from the legacy 21CFR Part 11 solution to the OmniTrust platform. The legacy audit trail information will **not** be converted into OmniTrust files, but it is still accessible.

- Legacy Record Audit trail can be viewed; in software version 5.0 onwards or in MAC application or exported Mastersizer Legacy Audit Trail Exporter tool
- Legacy System Audit trail can be viewed in the MAC application or exported using Mastersizer Legacy Audit Trail Exporter tool

Since software version 5.0 the Mastersizer 3000 Legacy Audit Trail Exporter. has been included in the installer. This is a standalone tool and must be manually run to export Legacy audit trails to .XML. No data will be deleted by this application.

If you wish to run this executable navigate to Program Files (x86)\Malvern Instruments\Mastersizer 3000 which contains the Mastersizer 3000 Legacy Audit Trail Exporter tool and a supporting document "**CCM0139-01-EN - Mastersizer 3000 - Audit Trail Export Tool.pdf**"



Mastersizer 3000 Legacy Audit Trail Exporter

## Software categorization

### GAMP 5

The GAMP 5 guide guides 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 assess the risk and validation requirements associated with using a specific software package.

In its standard mode of operation, the Mastersizer Xplorer 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 Xplorer 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 are 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.

## ISO certificates and policy documents

For Malvern Panalytical's ISO certificates and policy documents please refer to the following link:

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

## 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 Part 11 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.

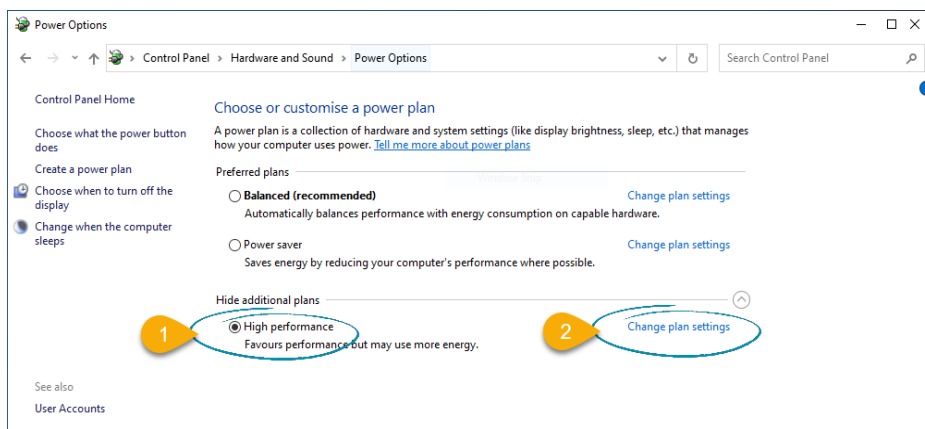
## Installing the OmniTrust application

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 entitlement.

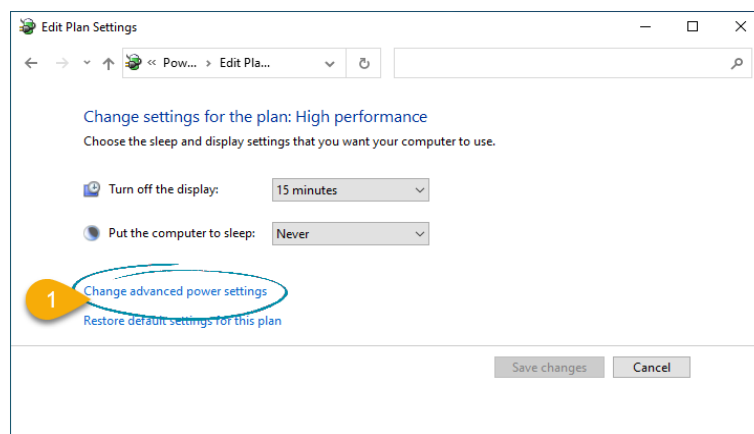
## Appendix 1 - Recommended PC power settings

- The Mastersizer 3000 and 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.
- From the list of Preferred Plans, choose High or Best Performance.

1. Click on Change Plan Settings.



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



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

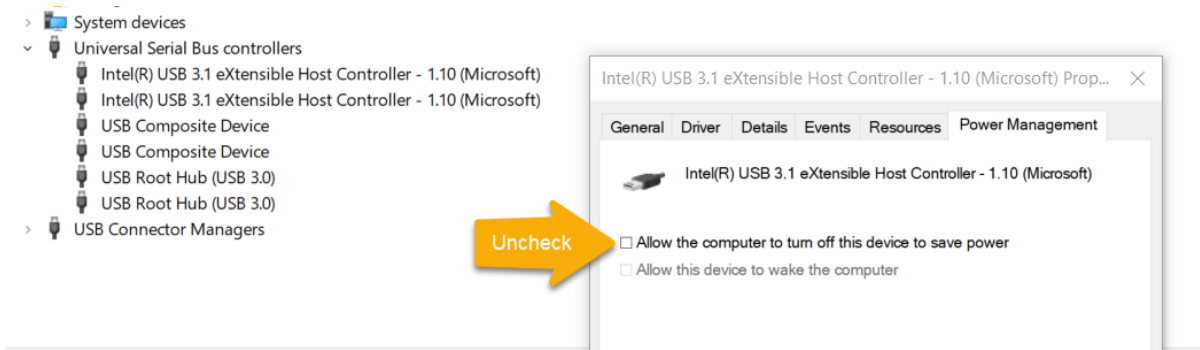
- *Hard Disk > Turn off hard disk after = Never*
- *Sleep > Sleep after = Never*
- *USB Settings > USB selective suspend setting = Disabled*
- *PCI Express > Link State Power Management = Off*
- *Processor power management > Minimum processor state = 100%*

4. Click the **Apply** button followed by the **OK** button.

5. 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).

6. Return to the **Control Panel** home page and click the **Device Manager**. Scroll down and click the twister adjacent to **Universal Serial Bus controllers** to expand the view.

7. Double-click each listed device and look for a tab named **Power Management**.



8. Uncheck the 'Allow the computer to turn off this device to save power' and click the OK button.
9. Repeat for all USB devices.

Note: Some versions of Windows may not have the 'Power Management Option' visible. In these cases, please refer to the PC manufacturer's support webpage for details on how to make the option visible.

## Appendix 2 – Software rendering

### “System Out of Memory” and/or “UCEERR\_RENDERTHREAD” messages

Occasionally the application will close intermittently, sometimes with a “UCEERR\_RENDERTHREAD” message.

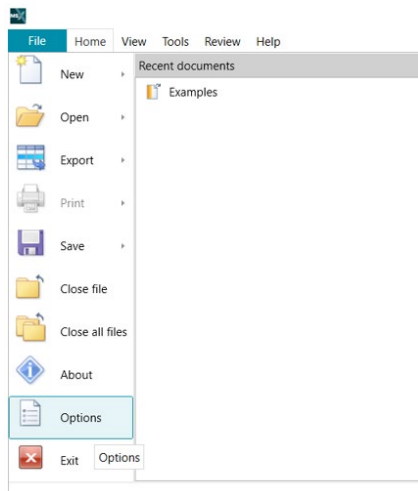
It is suspected that this issue is being observed mainly on PCs with 12th-generation or higher processors.

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.

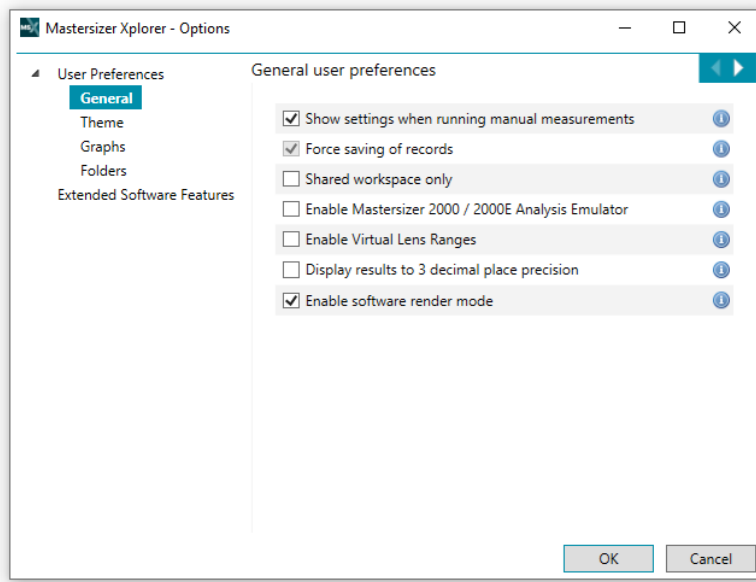
Version 5.01 also introduced a new software render mode, which is intended to improve performance if this issue persists even after following the above guidance. This changes the rendering from the default hardware rendering to software rendering.

To enable this option, perform the following:

1. Navigate to File – Options



2. Under User Preferences – General, ensure 'Enable software render mode' is selected.



3. Click OK to apply the change.

If you continue to experience this error, please contact your local Malvern Panalytical representative, for up-to-date guidance.



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