Mastersizer Xplorer Software: v5.40 (PSS0223-47)

Software Update Notification

Introduction

This document details the release of software Mastersizer Xplorer version 5.40 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.

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. This application replaces the previous 21CFR Part 11 feature entitlement and will need to be activated by a new feature entitlement.

Note: This software update is not compatible with users of the Malvern Access Configurator (MAC) and/or 21CFR Part 11 Feature entitlement. If you upgrade the software to version 4.0 onwards, you must have a valid OmniTrust feature entitlement.

Note: Due to the .NET 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
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 feature(s) introduced in 5.40

New features
OmniTrust Updates OmniTrust version 1.7a is now supported, which introduces security updates for the OmniAccess, OmniTrial and Regulated Environment Service applications. Additionally, Mastersizer Xplorer is now compatible with a purchasable standalone version of OmniAccess, called OmniAccess for Mastersizer. This can be used for user authentication and authorization without the need for OmniTrail to be installed.
Feedback Form Users of Mastersizer Xplorer can now provide optional feedback on their Mastersizer Xplorer experience by completing a feedback form. This is accessible through the feedback icon at the top right hand corner of the main Mastersizer Xplorer window.
Adaptive Diffraction Several improvements to the Size Sure measurement mode have been made: -   The graphs for undersize and oversize results can be normalized to 100% for the steady state and transient state -   Results for relevant parameters can also be normalized for the steady state and transient state, namely: Result Below (size), Result Above (size), Result In Range (lower size, upper size), Result In Sizes, Result Over Sizes -   In record view, the 'Extract Classic Result' can now be used with multiple records at the same time

Fixed issues

A recap of fixed issues in version 5.40 is included in Table 2.

Table 2: Recap of fixed issues in version 5.40

Reference(s)	Fixed Issue
346362	If a new-type microprocessor is used with the Mastersizer optical bench, users can experience time-outs on measurements with total durations (i.e. for red and blue light) exceeding approximately 60 seconds. If this time-out occurs, no particle size data will be reported. Background stability checks are also observed to time-out.
212635	Measurement files becoming corrupt due to averaged record ID duplication
331484	Reported error 'The process is unable to auto-save changes to the measurement file. Changes to the file will be left un-saved, you can attempt to re-save manually through the record view'
337490	SOP Architect workflow incorrectly continues from ultrasound titration to next stage when clicking 'Next' despite titration failure being reported to user
341446	In the SOP selector window, there is a long delay before SOPs are visible and selectable
343024	The column configuration option is missing from the record edit view
343308	Signatures widget for reporting shows different times to the Record Audit Trail for signing and approving of records. Note: Signatures widget has now been removed in version 5.40 and users are encouraged to look at the Approvals report for specific records.
344272	With OmniTrust installed and active, measurements do not record data after the first SOP whilst using SOP Player

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 (8th generation or higher) *see known issue section about 12th generation and higher	Power Settings	Best 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 11 Pro 23H2 OR Windows 10 21H2 IOT (64 bit)

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.

Caution!

This version of the software does not support Malvern Access Control (MAC) or 21CFR Part 11 via MAC. This functionality will now be provided via the OmniTrust feature entitlement.
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 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).

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

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.

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.

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	OmniTrust 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 WRK0100	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 WRK0200	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 WRK0300	Contains access to all the features of Workflow Developer plus Size Sure. By using Size Sure in your analyses, you can 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	Mastersizer 3000+ Ultra, Mastersizer 3000	Mastersizer Xplorer 5.0

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	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.		

Note: This software is not compatible with users of the Malvern Access Configurator (MAC) and/or 21CFR Part 11 Feature entitlement. If you upgrade the software to version 4.0 onwards, you must have a valid OmniTrust feature entitlement to remain in a regulated environment

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 entitlementhas 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 and log in with your product activation entitlement.

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 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 V2C 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
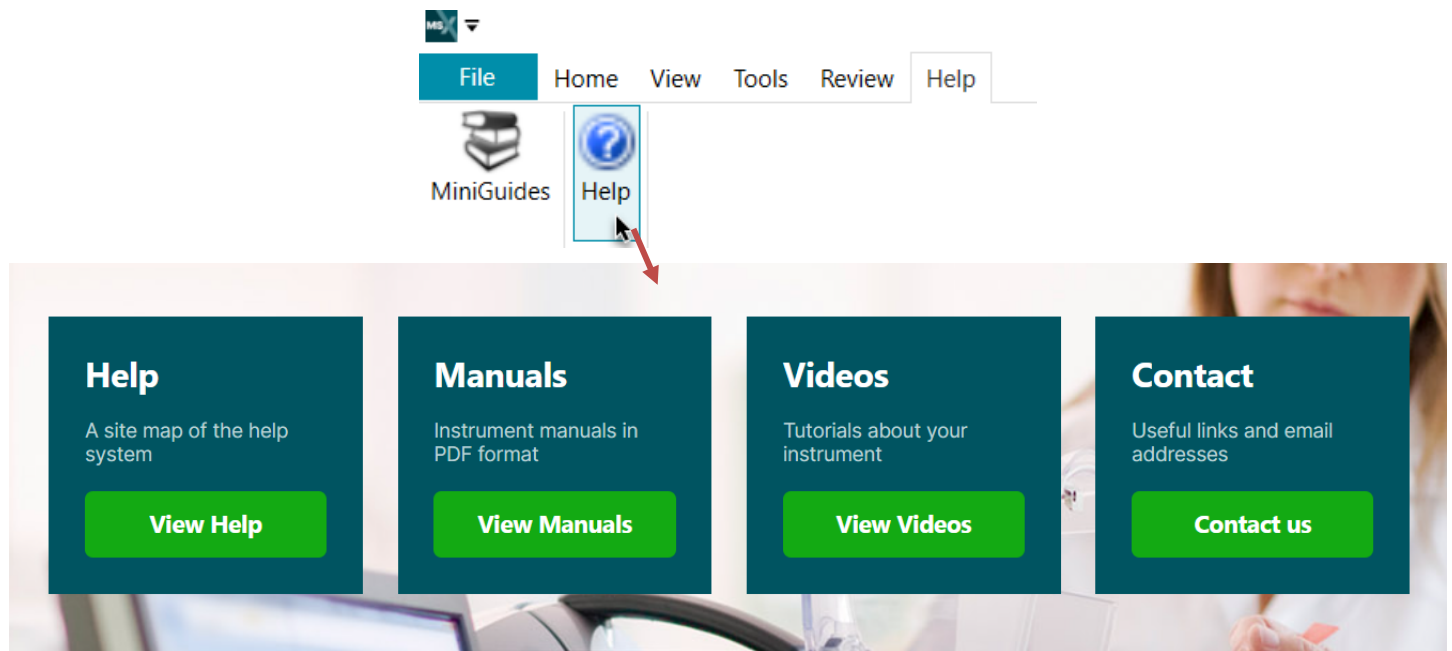
Security advisories

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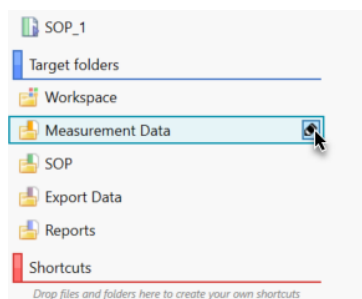
Changing the directory associated with this shortcut will change the default directory accessed by the Mastersizer Xplorer software for the selected file type.

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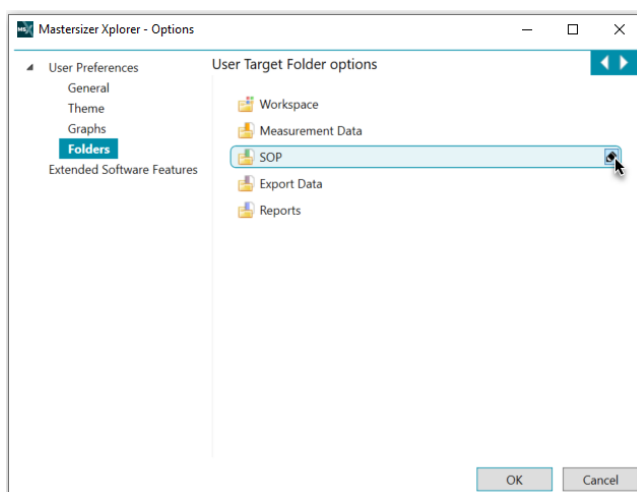
Again, hover over the shortcut and click on the pencil icon to change the target directory. Note that this is the only place in the software where the target directories can be configured when using the Basic software for the Mastersizer 3000+ Lab and Mastersizer 3000E.

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!

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*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.***

For customers using the previous 21CFR Part 11 features license entitlement (on software version 3.88 or previous), this will no longer be valid with versions 4.0 and above. To continue working in the regulated environment, upgrading to OmniTrust is required. If you are interested in the OmniTrust application, please contact your Malvern Panalytical representative for more information.

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).

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.
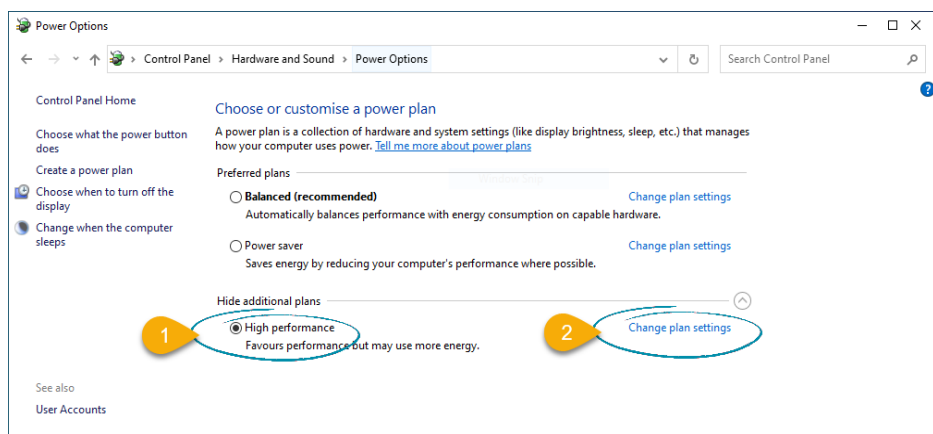
2. From the Edit Plan Settings window, click on Change advanced power settings.
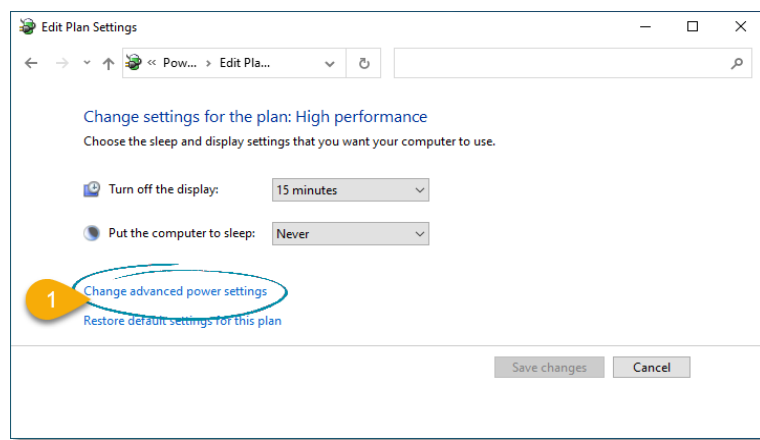
3. From the Power Options window, set the following.

   - *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.

• From the Device Manager window, 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.

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

• 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.

Upgrading from an earlier version of the software

Backward compatibility with Mastersizer 3000 v3.88 or previous versions

Due to the .Net6 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 Part 11 / Malvern Access Configurator (MAC)

The feature entitlement that provides 21CFR Part 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 Part 11 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.

MAC and the 21CFR Part 11 feature entitlement is available up to and including software version 3.88

For users who wish to upgrade to the OmniTrust platform

The existing audit trail information will **not** be converted into OmniTrust files, but it is still accessible

   • Record Audit trail can be viewed in the new software, in the MAC application or exported Mastersizer 3000 Legacy Audit Trail Exporter tool

• System Audit trail can be viewed in the MAC application or exported using Mastersizer 3000 Legacy Audit Trail Exporter tool

Since software version 5.0 the Mastersizer 3000 Legacy Audit Trail tool has been included in the installer. This is a standalone tool and must be manually run to export Legacy audit trails.

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 is 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+ Ultra (MAP3000), Mastersizer 3000+ Pro (MAP3010), Mastersizer 3000+ Lab (MAP3020), 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.

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.
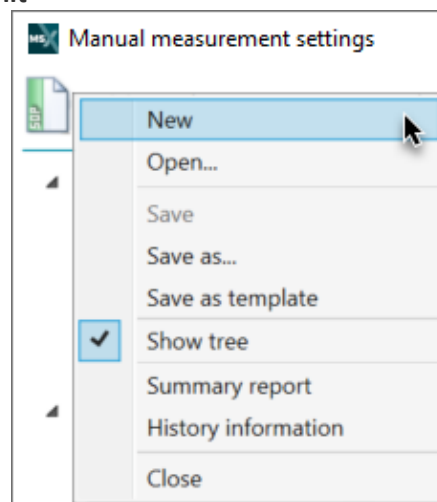
"System Out of Memory" and/or "UCEERR_RENDERTHREAD" messages

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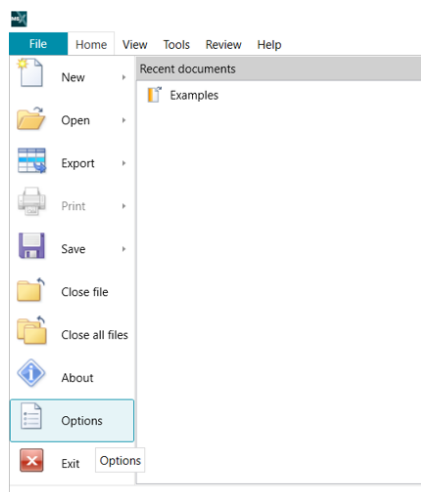
2. Under User Preferences – General, ensure 'Enable software render mode' is selected.

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.

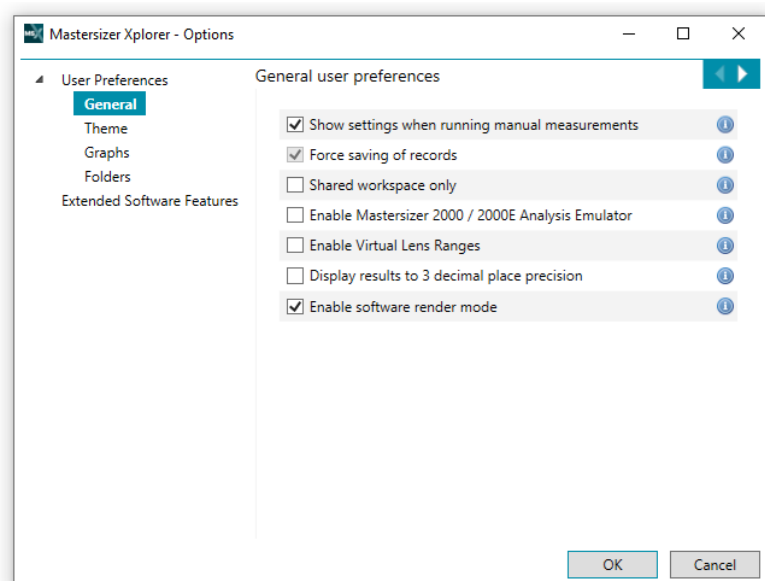| Issue	Work Around / Details	Comment
PV certificate may not be generated when the clock time format in Windows is set to short time (HH:MM).	To resolve ensure that the Windows OS clock time format is set to a long time (HH:MM:SS).	Intermittent Observation. Resolution is available – see details.
The accessory status bar is green but SOP and Manual measurement options are greyed out. 203508	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.

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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.	
Reporting of zero measurements. 171313	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 153660 / 170370	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 *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.
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.
Some parameters are not imported from Mastersizer 2000 measurement records	When importing Mastersizer 2000 measurement records into the Mastersizer Xplorer software, some SOP parameters from the Mastersizer 2000 records do not get imported. However, all 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 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 183976	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 153706	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.
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 an 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 is available.
Installing software with 21CFR Part 11 mode enabled to a different version of the software can cause this functionality to be switched off.	Re-enable 21CFR Part 11 functionality once installation is complete. Note: a valid 21CFR Part 11 feature entitlement is required for software version 3.88 or below or a valid OmniTrust feature entitlement is required for software version 4.0 or above	Work around procedure is available.
Opening the Optical Property Optimizer can be blank or cause the software to crash. 153608 153698	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 153632	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 212504	No work-around available	Low risk issue.
Occasionally the application will close intermittently, sometimes with "UCEERR_RENDERTHREAD" and/or "System Out of Memory" messages.	It is suspected that this issue is being observed mainly on PCs with 12th generation or higher processors. Enable 'software render mode' within the software as described above.	If you continue to experience this error, please contact your local Malvern Panalytical representative, for up-to-date guidance. Low risk issue.
Users of Malvern Access Configurator (MAC) and/or 21CFR Part 11 license entitlement that upgrade will not be able to view the, system audit trail from within software version 4.0 or later The MAC viewer is not affected.	For 21CFR Part 11 feature entitlement users only: Only upgrade to this software if you now wish to use the OmniTrust solution. Software version 5.0 onwards contains the Mastersizer 3000 Legacy Audit Trail Exporter tool. This tool can be used to export Record and System Audit trail data created in software version 3.88 and previous.	No data is deleted in the upgrade process. 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

Software Update Notification for Instrument software v5.40 (PSS0223-47)

Users of Malvern Access Configurator (MAC) that upgrade to software version 4.0 or later will no longer have access control.	OmniTrust can provide this functionality. If an upgrade has taken place but wish to continue using access control, revert to the previous software version that was installed on your PC.	Users wanting to continue using MAC should not upgrade to this version. MAC is available up to and including software version 3.88 For more information, please contact your Malvern Panalytical representative. If this error is observed, please contact your local Malvern Panalytical representative.
This version of the software is not compatible with Malvern Link II	Users of Malvern Link II v.3.48 should install v3.88 Mastersizer software	
Upgrading from software version 3.88 or previous to 4.0 or later takes a while to begin	Due to the .Net6 upgrades and added features the installer takes a longer time than would normally be expected. Wait for the installer to commence this can take around 5 minutes.	Minimal effect on memory when installed will be seen. For more information, please contact your Malvern Panalytical representative.
Locking the PC screen can cause the accessory to become disconnected 214784	Restart software.	Intermittent Accessory. The status button remains Green even though it is inactive.

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.

Validation support documents

For Validation Support Documents, please refer to the Mastersizer 3000 and Mastersizer 3000+ Product Support section on the Malvern Panalytical website. Ensure the documents are relevant to 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 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.

Malvern Access Configurator (MAC) application

> ⚠️ **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

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 software 3.88.
Existing users who are not actively using the MAC and/or 21CFR Part 11 feature entitlement can continue to upgrade their usual.

Audit Trail data will not be deleted and can be found in *C:\Program Data\Malvern Instruments\Mastersizer 3000\Audit Trails*

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 MAC application or exported Mastersizer 3000 Legacy Audit Trail Exporter tool

•Legacy System Audit trail can be viewed in the MAC application or exported using the Mastersizer 3000 Legacy Audit Trail Exporter tool

Since software version 5.0 the Mastersizer 3000 Legacy Audit Trail tool has been included in the installer.   This is a standalone tool and has to 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**"

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 of all files and folders.

- Basic user permissions must be applied to the Everyone group.
- Advanced user 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 accounts.
- 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 accounts.
- 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.

ised 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 the 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: • **Mastersizer Xplorer- Authorization.config** contains the deployed authorization settings (roles, members and permissions) for Mastersizer Xplorer, **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.