

MASTERSIZER 3000 SOFTWARE: v3.85 (PSS0223-32) SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0223-32: version 3.85 of the software for the Mastersizer 3000 laser diffraction system and the Mastersizer 3000E system. It covers software issues that have been fixed.

The information within this document is required to perform a risk analysis to determine if the software should be installed. In this risk analysis the benefits of the resolved software issues must be weighed against the risk of new issues that may be introduced to vital areas of the software or possible changes to the results of future analysis. Installation instructions are provided. Data collection and analysis are unlikely to be affected following software upgrade.

This software release contains important security and compliance updates. As such, we strongly recommend that you upgrade to this 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

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.

Recommended System Requirements

The recommended system requirements for running this software are highlighted in Table 1 below. Nevertheless, we fully expect the new software version to work on PCs with lesser or more advanced specifications. Software version 3.85 was fully tested using the recommended PC specification running Windows 10 version 20H2.

The software has not been fully tested on Windows 11 and although we do not anticipate problems, **we recommend postponing the update to Windows 11 until we have completed our validation performance testing and informed you accordingly.**

Supported Languages

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

- English
- French
- German

- Japanese
- Chinese (simplified)
- Russian
- Polish
- Spanish

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

Table 1: Recommended system requirements for the Mastersizer 3000 v3.84 software.

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

Installation Instructions

If you are installing the software from a web download / USB drive, then browse to the folder where the files have been extracted to and then launch the `\\Mastersizer 3000\\setup.exe` program. Software version 3.85 contains no firmware changes over software version 3.84.

Note:



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



Note:

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

Installing the Malvern Access Configurator (MAC) Application

The software suite includes a copy of the Malvern Access Configurator tool that allows you to manage the security aspects of the Mastersizer 3000 / 3000E. The MAC software may be installed either on the computer used to control the instrument or a separate networked computer. Installing on a separate computer allows you to manage the security centrally.



Note:

The MAC software does not auto-install. To install this software, navigate to the `\Malvern Access Configurator` folder and run the `setup.exe` file.

As with all Windows applications, the MAC software must be installed by a user who is an administrator on the host computer. In addition, the MAC software uses the existing Microsoft Windows users and groups configured on the host computer to control access to the Mastersizer 3000 application. As such, prior to installing the MAC, it is important to ensure that the computer running the Malvern software is installed on its host network. If the computer is a stand-alone system, the required users and groups must be configured on the computer prior to the use of the MAC.

Given the above requirements, it is advised that a user's local IT department should review the requirements for use of the MAC application. An IT representation should also be present during the software installation process.



Note:

Please read the [Mastersizer 3000 software 21 CFR Part 11 user guide technical note \(TN130801Ms300021CFRuserGuide\)](#) for more information as to how to use the MAC application, particularly when operation is required in a 21CFR Part 11 compliant environment. Note that operation in 21CFR Part 11 mode is not available for Mastersizer 3000E users.

Uninstall Procedure

Version 3.82 (or higher) 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.



Note:

Downgrading v3.84 with 21CFR11 mode enabled to earlier versions of the software will cause this functionality to be switched off. 21CFR11 functionality can then be re-enabled once the downgrade is complete by re-enabling the Features File (navigate to the Options pages and select "Enable Auditing" and "Enable Electronic Signatures" from the 21 CFR Part 11 tab and "Enable Access Control" from the Access Control tab).

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

Software Categorization

GAMP 5

The GAMP 5 guide provides guidance to pharmaceutical companies wishing to understand whether the computerized systems and software they used are fit for purpose and meet current regulatory requirements. As part of this, the GAMP committee has defined a series of software categories which are designed to help users in assessing the risk and validation requirements associated with using a specific software package.

In its standard mode of operation, the Mastersizer 3000 software provides users with a series of standard interfaces and functions that enable the software to be configured to meet specific user business requirements. These interfaces include the ability to define Standard Operating Procedures (SOPs) for sample measurement, create report definitions using pre-defined functions and develop data export templates using pre-defined parameters. If users apply these functions, then the software can be considered to be a Category 4 product.

In addition to the standard functions, the Mastersizer 3000 software provides users with the ability to modify the results reported by the system to fit their application requirements. This is achieved using the custom calculation reporting functions. These functions are not widely applied within regulated environments. However, if they are used to meet business requirements then the macros included within the custom calculations should be validated according to GAMP Category 5 requirements. Users are therefore encouraged to specifically validate any custom calculations applied within their reports and ensure these are documented. Where possible, we would encourage the use of the standard result reporting features, as this minimizes the risk of errors in the reported size distribution statistics.

USP<1058>

USP<1058> provides pharmaceutical users with guidance as to how the qualification of analytical systems should be carried out. As part of this guidance, the USP define a series of instrument categories. These instrument categories different from those described in GAMP 5, although the principles applied as part of the classification of a system are similar.

The Mastersizer 3000 is a computerized analytical system where the software provides users with the functions required to meet specific analytical application requirements. As such, it is a Group C instrument. Users are therefore recommended to define their requirements for the operation of the system and then compare these requirements to the claimed capabilities of the software and hardware. This should include an assessment of whether the new features and bug fixes included in a specific version of the Mastersizer 3000 software are necessary to meet business requirements.

Validation Support Documents

For Validation Support Documents, please refer to the Mastersizer 3000 Product Support section on the Malvern Panalytical website (<https://www.malvernpanalytical.com/en/support/product-support/mastersizer-range/mastersizer-3000>).

Software License Files

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




Note:

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

Sharing a License for Mastersizer 3000 users

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

To share a license, follow the steps below:

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

Note:



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

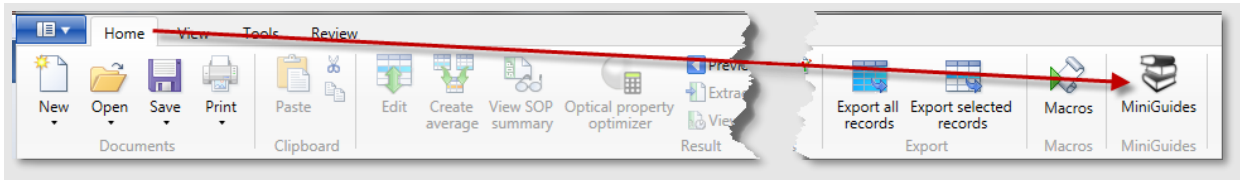
Sharing a License for Mastersizer 3000E users

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

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

Software Guides

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



New Features and Fixed Issues

New Features

There are no new features implemented in this release.

Fixed Issues

Reference(s)	Issue
154340	General software communication improvements made have reduced CPU demand and enhanced the end user software experience.
159888	Connectivity issues with software version 3.84 previously seen on Mastersizer 3000 instruments with kernel versions below 11 due to handling differences in engineering functionality of the original firmware have now been fixed.

Security Advisories

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



Note:

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



Note:

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

File Types and Locations

The Mastersizer 3000 software uses a series of different file types in order to store data and measurement settings. These are described below, in order to help users who wish to secure the Mastersizer 3000/3000E system using the Microsoft Windows security and access settings. Guidance regarding how to set up the security settings is provided in the Windows Security Settings section of this document.

File Type	Extension	Default Path	Advised security setting for 21CFR Part 11 Mode
21CFR11 mode: Audit trails (Mastersizer 3000 only)	.mpaf	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Audit Trails</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
User sizes	.siz	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\User Sizes</i>	No control required as these settings are stored in SOPs.
User defined materials	.mmat	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Materials</i>	No control required as these settings are stored in SOPs.
User defined dispersants	.mdis	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Dispersants</i>	No control required as these settings are stored in SOPs.
Data quality add-ins (Mastersizer 3000 only)	.mdaq	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins</i>	No control required as the data quality tool only provides advice.
Export data	.txt.csv.rtf	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Export Data</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Export Data</i>	If data export is a critical part of the SOP used for your samples then you should prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Measurement data	.mmes	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Reports	.mrep	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Reports</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Reports</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained. Note: it is important that users are prevented from deleting reports via the software interface as well. This can be done using the MAC application.

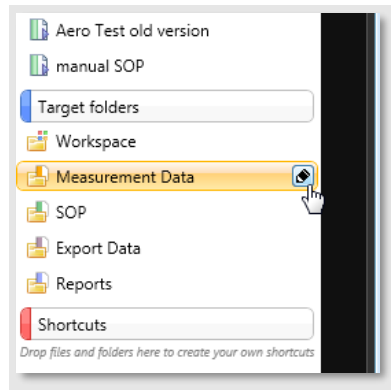
SOP templates	.msot	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template</i>	No control required.
SOP	.msop	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\SOP</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Data export templates	.mext	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Template</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Template</i>	No control required.
Licence file	.licence	Mastersizer3000.licence file stored in: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files</i>	Once the system has been set up and 21 CFR Part 11 mode engaged then access to this file must be set to prevent deletion. However, read, write and modify access must be maintained.
Security configuration file	.xml	Exported from the Malvern Access Configurator (MAC) application. The directory is user-specified. Malvern advise that the file should be stored in: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files</i>	Prevent deletion this file once it is created. However, read, write and modify access must be maintained.
Various system wide configuration files	Various	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000</i>	Full access must be maintained to this directory for the program to function correctly.

Changing the destination path for a file

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

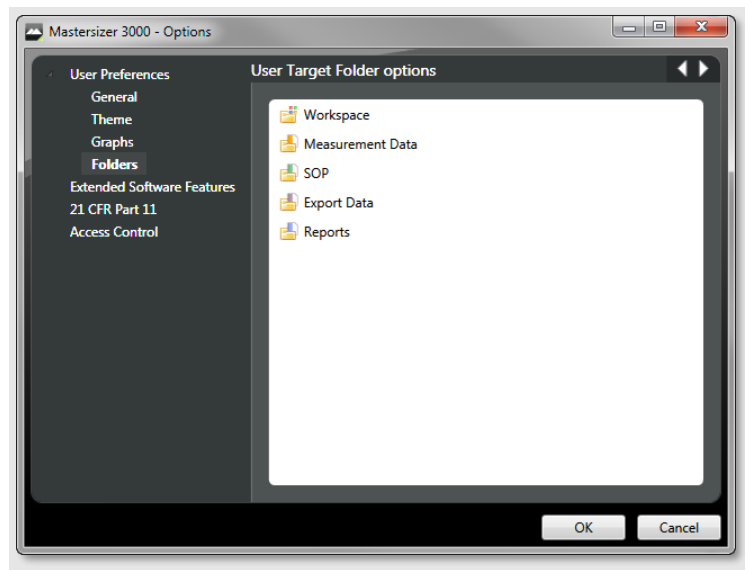
- SOP
- Measurement Data
- Reports
- Export Data

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



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

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



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

Making a backup of the files

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

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

Restoring your files to the original PC hardware

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



Note:

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

Restoring your files to a new PC

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

For pharmaceutical customers using the 21CFR features, enter your 21CFR key and re-enable the desired 21CFR features.



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 licencing of the application, if you do not delete this file before starting the application.

Windows 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. Utilizing the built-in security tools of Microsoft Windows®, an IT professional can effortlessly change user access to specific files and/or folders by simply removing certain file/folder permissions.

For the next part of this document, it is assumed that you have the required administrator rights for the system upon which the Malvern software is being installed; allowing you to install, or update software and configure windows security permissions.

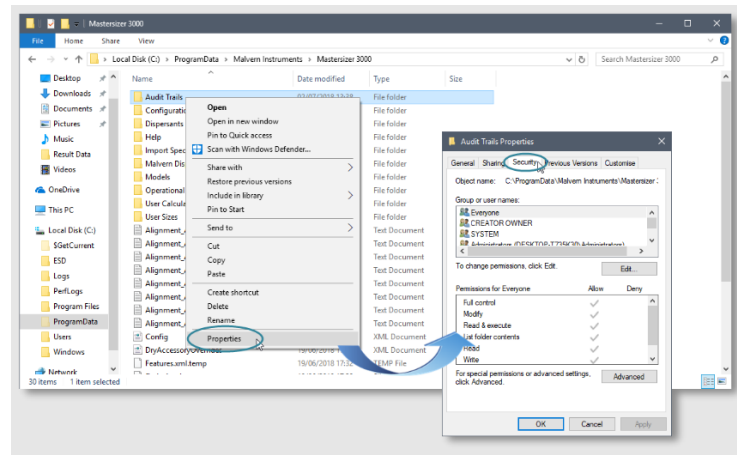


Note:

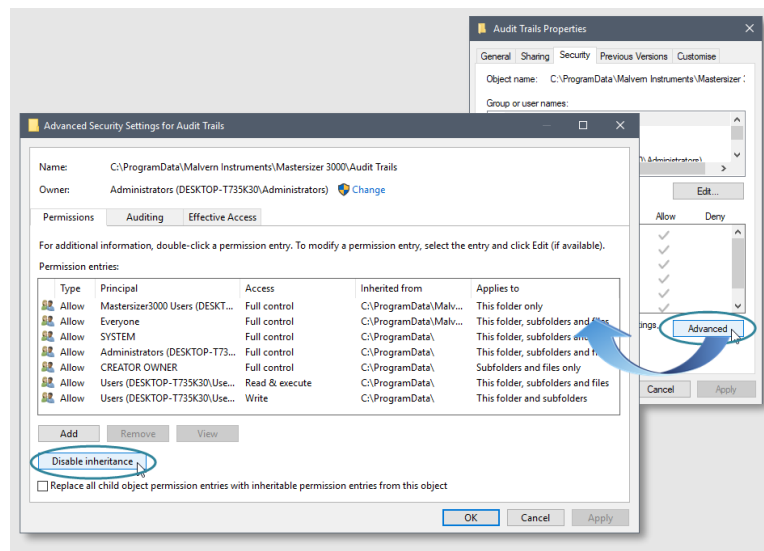
For the following demonstration we have previously created a user group, through the Computer Management console, called 'Mastersizer3000 Users'. This user group will later be added into the folder permissions of the Audit Trails folder to prevent users from deleting records. This process can be applied to any other output folder requiring limited user access. In the following illustrations, we have not removed default groups such as 'Everyone' or 'Users' - these can be deleted or used as an alternative to dedicated user group/s. However, when using these groups, we strongly advise that explicit 'Denies' are not used, unless you fully understand the Microsoft® file/folder security permissions.

Changing the folder security permissions in Windows 10

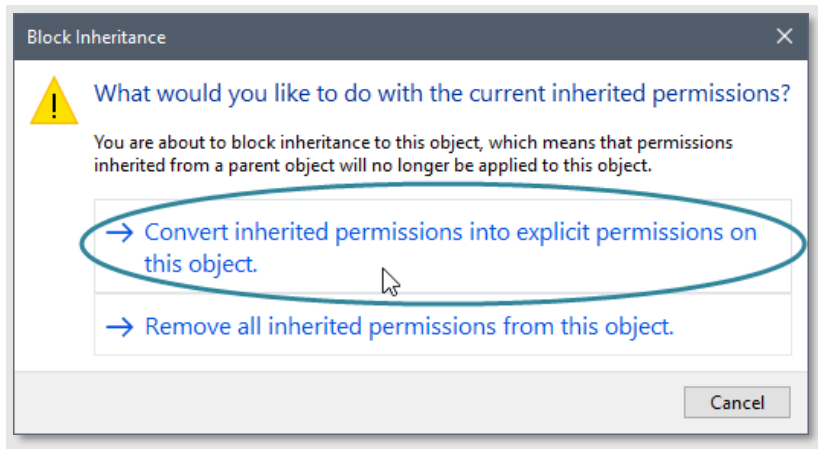
1. Navigate to one of the folders that needs to be secured - in this case we have selected the folder where the Mastersizer audit trail files are stored. Right-click on the folder and through the context menu open the folder Properties.



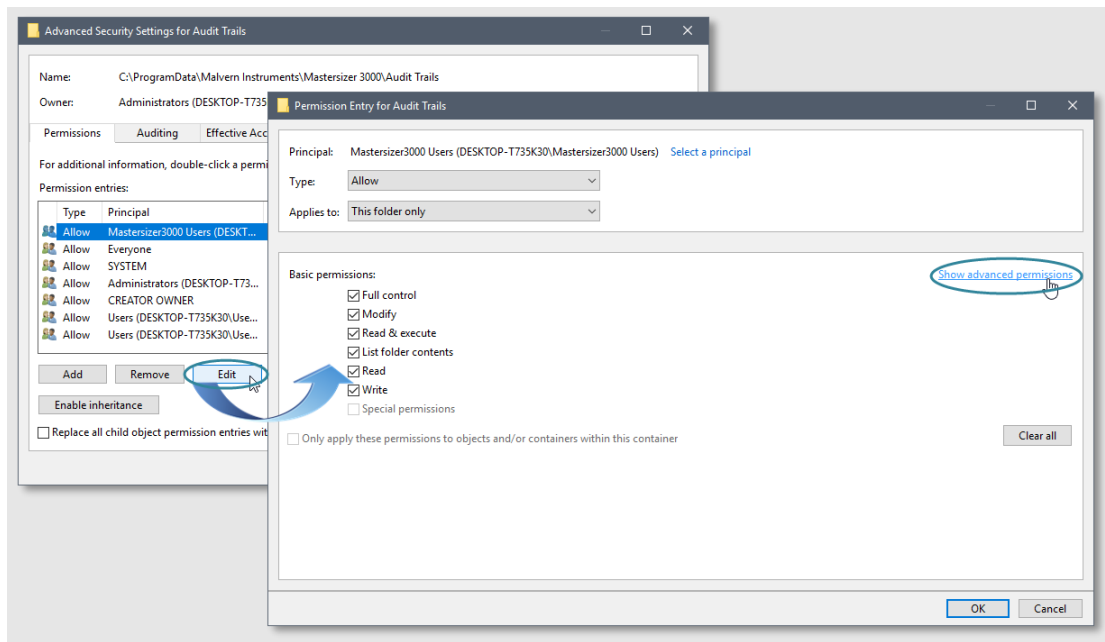
2. Within the **Audit Trails Properties** dialogue, left-click on the **Security** tab and left-click the **Advanced** button to open the **Advanced Security Settings**.
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button:



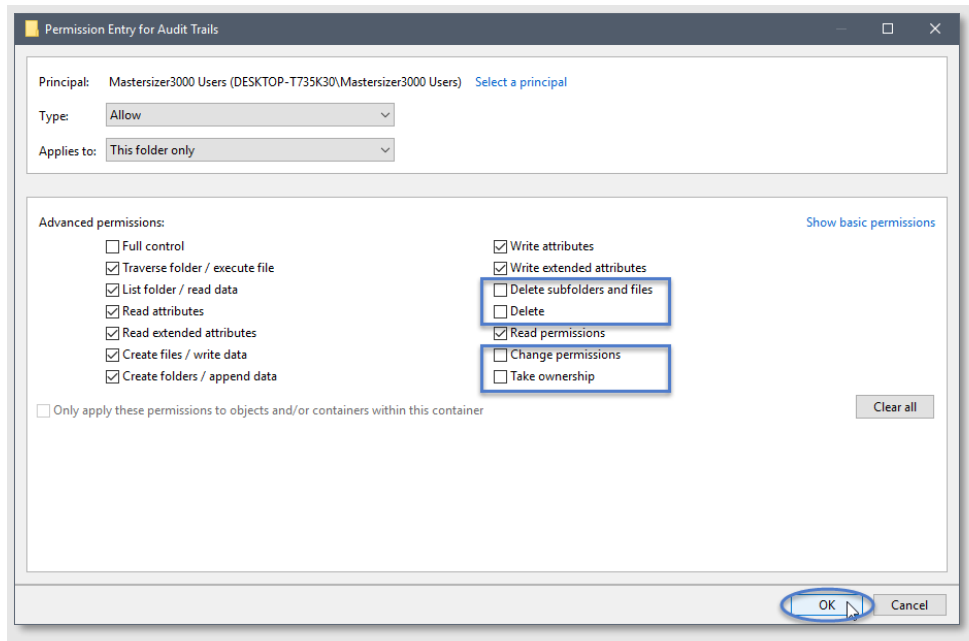
4. Within **Block Inheritance**, left-click on **Convert inherited permissions into explicit permissions on this object** – this removes the permission inheritance from the parent folder, whilst keeping the any current users and groups settings.



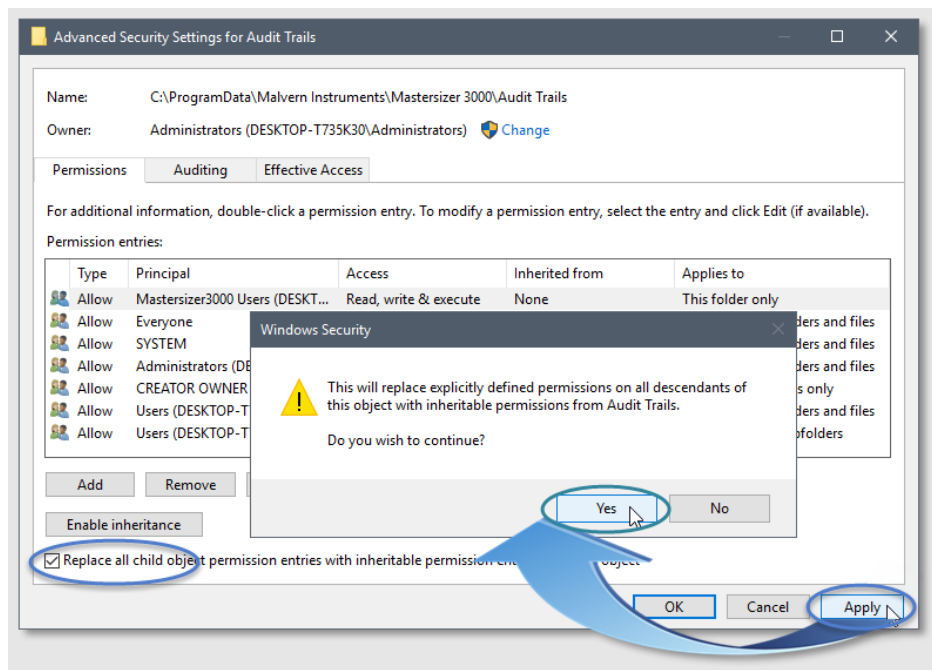
5. After returning to the **Advanced Security Settings** window, left-click to select the **Mastersizer3000 Users** group and then left-click the **Edit** button.
6. In the **Permissions Entry** window, left-click the **Show advanced permissions** to reveal the full permissions list.



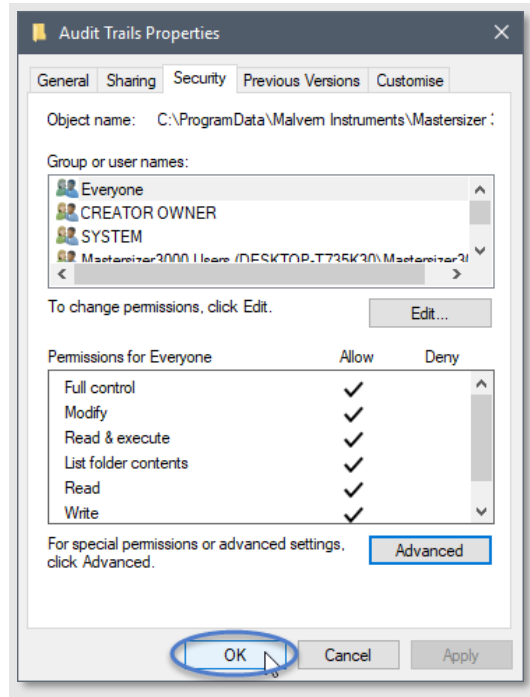
7. Left-click to de-select the check-boxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.



8. Left-click **Replace** all child permission entries with inheritable permission entries from the object and left-click the **Apply** button.
9. Left-click the **Yes** button when prompted to replace the permissions and the **OK** button when you return to the previous window.



10. Left-click the **OK** button when you return to original folder properties window.



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.

Issue	Work Around / Details	Comment
PV certificate may not be generated when clock time format in Windows was set to Short time (HH:MM).	Set the clock time format in Windows to Long time (HH:MM:SS).	Intermittent Observation
During SOP measurements there have been occasions where records have been skipped, e.g., 3 runs requested and records 1, 4, 5 generated in measurement file.	Intermittent observation no current workaround available.	Intermittent Observation
Accessory status bar is green but SOP and Manual measurement options greyed out.	From time to time the SOP and manual measurement options are still greyed out even when the accessory status bar is green. To re-enable these options, right-click on the accessory status bar and reselect the accessory.	Intermittent Observation

<p>Accessory status bar is green but SOP and Manual measurement options greyed out.</p>	<p>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.</p>	<p>Intermittent Observation</p>
<p>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.</p>	<p>We advise contacting your Malvern Panalytical representative for support to ensure the correct procedure is followed.</p>	<p>High risk issue.</p>
<p>Accessory status bar is green but SOP and Manual measurement options greyed out.</p>	<p>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.</p>	<p>Intermittent Observation</p>
<p>“% sample integration actually completed” message intermittently observed in place of “The lid must be closed” Aero message when the Aero lid is opened between analysis of multiple dry samples in SOP mode.</p>	<p>No work around available. Press Initialise Instrument button and continue with analysis.</p>	<p>Intermittent Observation</p>
<p>Reporting of zero measurements.</p>	<p>In rare cases a zero measurement can occur in both wet and dry measurements. The measurement record contains background and data but no signal information. A zero distribution is recorded in the measurement file. No work-around available.</p>	<p>Medium risk issue</p>
<p>Software can crash when batch printing</p>	<p>When selecting too many reports and/or too many records for batch printing, an error can occur causing a crash exception. Restricting the total number of pages printed to 220 or less (equivalent to 13 results batch printed with 10 reports) will mitigate this issue occurring</p>	<p>Low risk issue</p>

<p>Aero S and Aero M sample feed control</p>	<p>When carrying out manual measurements it is possible to enable the sample feed for the Aero dispersion unit with the vacuum and dispersion air switched off by clicking the Feed button twice within the accessory controls. After approximately ten seconds the system will switch back into standby mode and an 'insufficient exhaust vacuum / air achieved' error message will be displayed. However, some sample may be lost.</p>	<p>Error can be avoided procedurally (avoid double-clicking the feed button).</p>
<p>Corrupt report settings file causes software crash on start-up</p>	<p>It has been observed that the global report settings file may become corrupt. This file holds the company name and logo used across all reports in the software. A symptom of this issue is the software crashing on start-up with an exception "hexadecimal value 0x00, is an invalid character". The workaround is to delete the contents of folder at <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.</p>	<p>Medium risk issue</p>
<p>Warnings are displayed about corrupt measurement files</p>	<p>The software has built in detection of when measurement files are at risk of being corrupted. If you see one of these messages, you are probably creating too large a measurement file.</p>	<p>Intermittent Observation</p>
<p>Instrument disconnects after firmware upgrade</p>	<p>An issue has been seen for some installations whereby the instrument will become disconnected from the computer following a firmware upgrade. Turning the instrument off and on again will cause it to successfully reconnect to the software.</p>	<p>Intermittent Observation</p>
<p>Some bespoke custom macros / calculations may not run.</p>	<p>Please contact your local Malvern Panalytical representative.</p>	<p>Low risk issue</p>
<p>Some text still appears in English when running with a different language selected.</p>	<p>The translation of all software text will continue in future releases.</p>	<p>Low risk issue</p>
<p>Software does not open all files selected when they are opened using Windows Explorer.</p>	<p>Use the Open menu option in the Mastersizer 3000 software to open multiple files.</p>	<p>Low risk issue</p>
<p>The system audit trail displays duplicated columns for each language under which the system has been run when auditing has been enabled.</p>	<p>No work-around available.</p>	<p>Low risk issue</p>

<p>Various fields in the Edit result window lose their 'edited' blue background appearance when a different page in the editor is selected.</p>	<p>No work-around available. This is a display issue only, as the software correctly applies the edit values when the OK button is pressed.</p>	<p>Low risk issue</p>
<p>Trend table print out is limited by paper size</p>	<p>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.</p>	<p>Low risk issue</p>
<p>Some parameters are not imported from Mastersizer 2000 measurement records</p>	<p>When importing Mastersizer 2000 measurement records into the Mastersizer 3000 software, some SOP parameters from the Mastersizer 2000 records do not get imported. However, all of the parameters required for result review or recalculation are present.</p>	<p>Low risk issue</p>
<p>Manual measurement errors are reported if the Aero dispersion unit configuration has changed between measurements</p>	<p>The manual measurement feature in the software stores the last used settings. This includes configuration of the Aero dry powder disperser. If you change the configuration between measurements and then open a manual measurement, the software will report an error stating that configuration is wrong. If this happens, close and re-open the manual measurement window and change the manual measurement settings to match your new Aero configuration.</p>	<p>Low risk issue</p>
<p>Software exception is reported if the software is closed when a macro is running</p>	<p>All currently running macros must be closed before closing the software.</p>	<p>Low risk issue</p>
<p>Some report widgets are truncated in the print preview view</p>	<p>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.</p>	<p>Low risk issue</p>

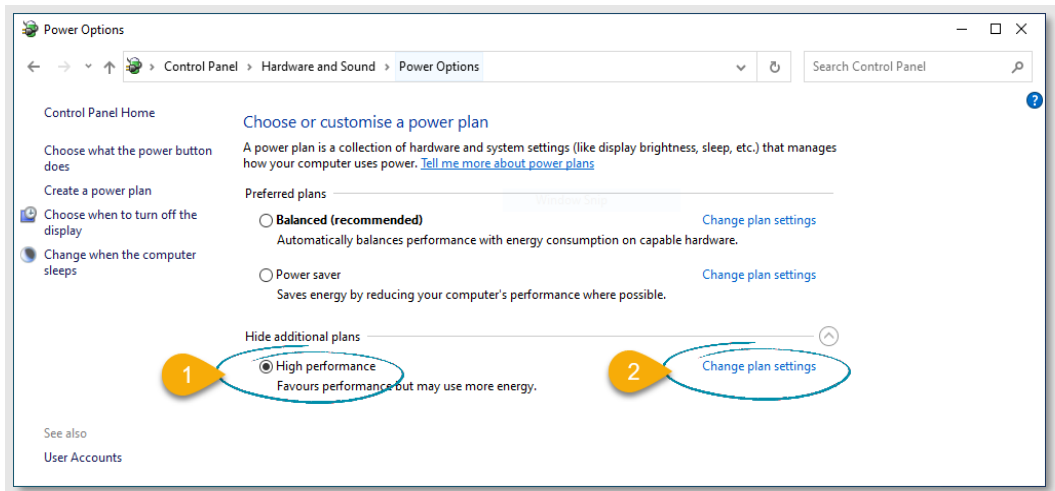
<p>Software may crash when exporting data with custom sample identifiers which start with a number</p>	<p>Exporting measurement data with custom sample identifiers beginning with a number will cause the software to crash when you select an export template that contains sample identifiers. The only work-around is to prefix sample identifiers with letters.</p>	<p>Low risk issue</p>
<p>Ultrasound SOP option 'Continuous (From Measurement Start)' does not turn off in SOP playlist</p>	<p>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.</p>	<p>Low risk issue</p>
<p>Cannot load old custom calculations from file</p>	<p>When trying to load a custom calculation created in v3.30 software or earlier, the software may report error and the calculation will not load. The workaround is to re-export the custom calculation from the original report in a recent version of the software.</p>	<p>Low risk issue</p>
<p>Data quality tab is not displayed immediately when selected from the extended features list</p>	<p>Given that the software has just been installed and the option to enable the extended software features is selected. Then when the application is restarted the data quality tab will not be displayed if the default view is selected. The work-around is to select the 2-pane vertical view which will display the data quality tab. Then reverting to the default view will display the data quality tab.</p>	<p>Low risk issue</p>
<p>Ultrasound level applied during clean reported as 0%</p>	<p>You may find that the measurement manager reports that 0% ultrasound is being applied during cleaning when you have set an ultrasound demand of greater than 0%. Evidence suggests that ultrasound is applied correctly as per the configured ultrasound demand, but the value shown in the measurement window is incorrect.</p>	<p>Low risk issue</p>

<p>“Some data may be missing” error message on attempting to resign records created in v3.30 or earlier</p>	<p>This is a false-positive error message, a consequence of a design issue fix implemented in v3.40 onwards.</p> <p>In earlier versions of the software (v3.30 and earlier), duplicate parameters were written to the measurement record. From v3.40 onwards, a fix was applied which enabled the duplicate parameters to be disregarded. However, this means that when a measurement is created in v3.30 or earlier, and then signed in a later version of the software, the signature information is written over the top of the duplicate data, causing the false-positive error message to be generated.</p>	<p>Low risk issue.</p> <p>The error message is a false-positive (data is not missing) and locking signatures are not lost on v3.81, so it is unlikely a user will need to resign a record.</p>
<p>Downgrading with 21CFR11 mode enabled to earlier version of the software can cause this functionality to be switched off.</p>	<p>Re-enable 21CFR11 functionality once downgrade is complete.</p>	<p>Intermittent observation</p>
<p>On repeated running of a dry SOP incorrect warning messages can be displayed if the lid is left open when adding more sample</p>	<p>Close the SOP at the end of each sample measurement and restart the SOP</p>	<p>Low risk issue</p>
<p>After switching to an alternative wet accessory, the ultrasound settings may not be applied correctly</p>	<p>Change accessory and then re-launch the application software</p>	<p>Low risk issue</p>
<p>The SOP history report only contains audit trail information for the last modification. The audit trail information is blank for previous versions</p>	<p>No work-around available</p>	<p>Changes made to the SOP settings can be highlighted in the SOP history view</p>
<p>The parameter ‘Ultrasound Achieved’ is always report as zero for pre-measurement ultrasound</p>	<p>The parameter ‘Ultrasound Demand’ is reported correctly</p>	<p>Low risk issue</p>
<p>Opening the Optical Property Optimizer can cause the software to crash</p>	<p>This generally occurs with a fresh software installation, restart the software, and retry the Optical Property Optimizer</p>	<p>Intermittent observation</p>
<p>After switching between a manual wet dispersion unit and an automated wet dispersion unit then running an SOP the stirrer does not start</p>	<p>Switch to the automated dispersion unit and then restart the application software.</p>	<p>Reported only to occur on the first instance of switching between the dispersion units</p>
<p>In a wet measurement an SOP can continue if the upper obscuration limit is exceeded</p>	<p>No work-around available</p>	<p>For each record the obscuration can be compared to the obscuration limits post measurement</p>

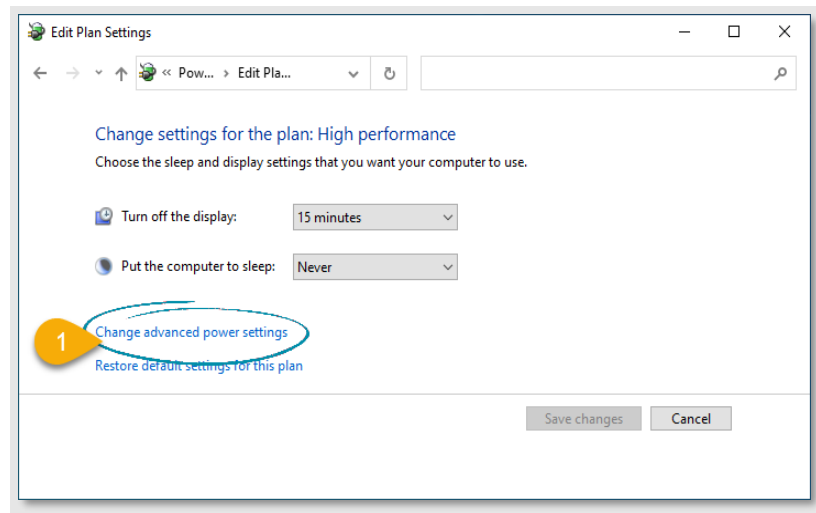
The trend table does not clear completely when records are de-selected, the results from the last record to be de-selected remain displayed in the table	No work-around available	Low risk issue
The Optical Property Optimizer view can be blank when accessed for the first time	Restart the Optical Property Optimizer	Low risk issue
On repeating an SOP, it does not ask for a new sample details and the subsequent sample is analyzed using the same sample details	Close and restart the SOP at the end of the measurement, new sample details can then be entered	Low risk issue
Incorrect warnings (in hover over tool tips) can be displayed when invalid values are entered in SOP settings	No work-around available	Low risk issue
Intermittent failure of pre-measurement ultrasound during SOPs	Intermittently the ultrasound does not turn on during the pre-measurement ultrasound phase. The timer counts down, but the ultrasound does not turn on.	If this error is observed, please contact your local Malvern Panalytical representative
<p>Communication errors can cause, slow alignment and SOPs to stop and report an error, such as the following:</p> <ul style="list-style-type: none"> • Failed to get cell code • Failed to acquire snap data • Acquired partial snap data • Failed to stop measurement • Failed to reset pipes of USB endpoints • Failed to read the level sensor type • Failed to get ultrasound percentage • Failed to acquire measurement status • Failed to get accessory status • Failed to get accessory type codes 	This error is seen more often when the PC is not routinely restarted and when certain third-party software packages are in use (such as back-up and anti-virus)	If this error is observed, please check your computers power management settings (detailed below). If errors persist, please contact your local Malvern Panalytical representative

Recommended PC power settings

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



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



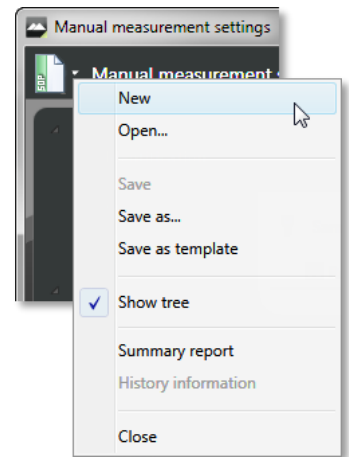
5. From the *Power Options* window, set the following.
 - *Hard Disk > Turn off hard disk after* = *Never*
 - *Sleep > Sleep after* = *Never*
 - *USB Settings > USB selective suspend setting* = *Disabled*
 - *PCI Express > Link State Power Management* = *Off*
 - *Processor power management > Minimum processor state* = *100%*
6. Click the *Apply* button followed by the *OK* button.
7. From the *Edit Plan Settings* window, click the *Save Changes* button (some versions of Windows don't make this button available, just close the window).

8. Return to the *Control Panel* home page and click the *Device Manger*.
9. From the *Device Manager* window, scroll down and click the twister adjacent to *Universal Serial Bus controllers* to expand the view.
10. Double click each listed device and look for a tab named *Power Management*.
11. Uncheck the Allow the computer to turn off this device to save power and click the OK button.
12. Repeat for all USB devices (some versions of Windows may not have the *Power Management* option).

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:

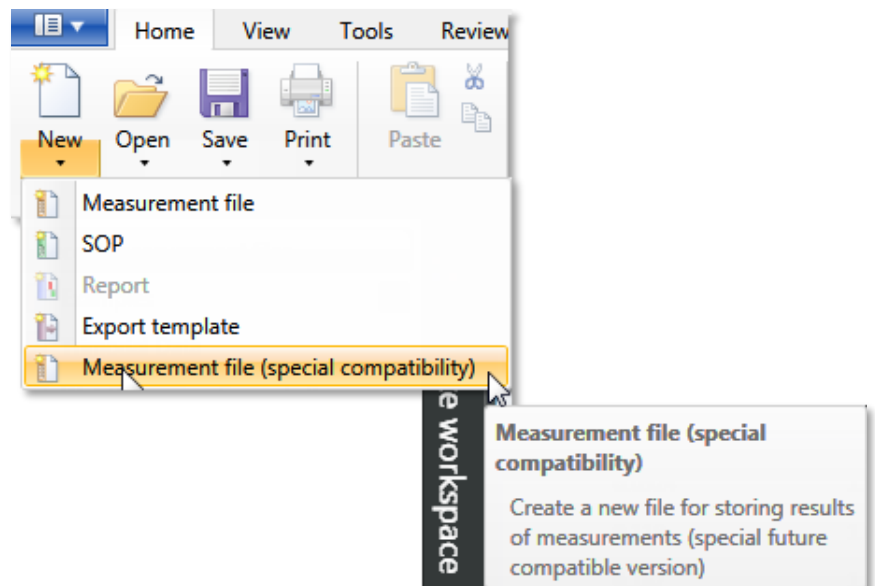
This will reset all measurement settings to their defaults for the active accessory type. This issue has been reported after upgrading from early versions of the software, but does not occur on all systems.



Measurement File Format

In v3.40 of the Mastersizer 3000 software we have re-introduced the file format used in older versions of the software (v3.10 and earlier) due to an incompatibility issue we discovered when the software's 21 CFR Part 11 features are enabled. This format is now selected by default and offers the advantage that it is compatible with all earlier versions of the software.

Note that files created using v3.20 and v3.30 of the Mastersizer 3000 software can still be opened, edited and saved using v3.40. The software will automatically switch to the correct file format if you select a file created in these versions. If you want to specifically create a file in the same format used by v3.20 and v3.30, select the **Measurement file (special compatibility)** option when creating a new measurement file:



Measurement File Size and Corruption Warnings

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

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

Backward Compatibility

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

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