

# SOFTWARE UPDATE NOTIFICATION

## MASTERSIZER **3000** SOFTWARE v3.63: PSS0223-23



### Introduction

This document details the release of software PSS0223-23: version 3.63 of the software for the Mastersizer 3000 laser diffraction system and the Mastersizer 3000E system. It covers software issues fixed and new features introduced. This information is required to perform a risk analysis to determine if the software should be installed. In this risk analysis the benefits of the new features provided and resolved software issues must be weighed against the risk of new issues that may be introduced to vital areas of the software or possible changes to the results of future analysis. Installation instructions are provided.

### 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 computer system requirements for running this software are highlighted in table 1 below. The software can be operated using Windows 10 (Pro and Enterprise), Windows 8.1 (Pro and Enterprise), Windows 8 (Pro and Enterprise), Windows 7 32 bit (Pro, Enterprise and Ultimate) and Windows 7 64 bit (Pro, Enterprise and Ultimate). However, it has been fully tested using Windows 7 Ultimate (64 bit). Windows 7 Ultimate (64 bit) is therefore the preferred operating system.

### Supported Languages

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

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

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

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

Feature	Specification
<b>Processor Type</b>	Intel Core i7 Processor (Quad Core, 3.40GHz)
<b>Memory</b>	4GB
<b>Hard Disk Storage</b>	250GB
<b>Additional Storage Media</b>	CD-ROM or DVD +/-RW drive
<b>Display Resolution</b>	1024 x 768
<b>Connectivity</b>	1 high speed USB2 or USB3 port
<b>Operating System</b>	Windows 7 (32 bit - Pro, Enterprise and Ultimate) Windows 7 (64 bit - Pro, Enterprise and Ultimate) * Windows 8 Enterprise (64bit - Pro and Enterprise) Windows 8.1 Enterprise (64 bit - Pro and Enterprise) Windows 10 Enterprise (64 bit - Pro and Enterprise)

\* Preferred Operating System

**Note:** In order to address Windows 7 vulnerabilities associated with driver signing, this software only uses the latest driver authentication protocol recommended by Microsoft (SHA 256 certification). As a result, a Windows OS update may be required in order for the system to work. Please refer to Microsoft Knowledgebase reference KB3033929 for details. Any computer system which has been updated with Microsoft patches since March 2015 should operate correctly.

## Installation Instructions

The software suite comes on an auto-loading CD-ROM. Inserting the drive into a system configured to auto-run a CD will run the installation program automatically. If your system does not support this feature, run the **\Mastersizer 3000\setup.exe** program from your CD drive. If you are installing the software from a web download 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 that the software is installed before the Mastersizer 3000 / 3000E instrument is connected to the computer and switched on. This will ensure that the instrument drivers are enabled, and that the 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 Instruments 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 PC used to control the instrument or a separate networked PC. Installing on a separate PC 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 on the software CD-ROM 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 **MAN0602-01 - Malvern Access Configurator (MAC) User Guide** and **MRK1747-xx - Mastersizer 3000 - 21 CFR Part 11 Guide** 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

The software can be uninstalled using the standard **Add/Remove Programs** feature in the Windows Control Panel.

## 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 through the use of 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 differ 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

The Mastersizer 3000 software CD contains the following documents, which are provided to help users who work within validated laboratories:

- **21CFR Part 11 and Security System guides:** provide guidance on how to set up the features of the software in order to aid technical compliance to 21CFR Part 11.
- **21CFR Part 11 and Annex 11 Gap analysis documents:** these detail the capabilities of the software and how these align with the requirements of 21CFR Part 11 and the equivalent rule set in Europe (Annex 11).
- **Generic Audit Questions and Answers:** provides users with answers to the common questions included within postal audit questionnaires, in line with GAMP 5 supplier audit requirements.
- **IQ and OQ Documents:** preview copies of all of the current versions of the Installation Qualification and Operation Qualification documents for the Mastersizer 3000 optical bench and accessories.
- **Malvern Instrument's ISO Certificates:** copies of the current ISO9001:2008, ISO14001 and OHSAS 18001:2007 certificates, issued as part of the independent audit of Malvern's business management systems. This includes certification of the development of the Mastersizer 3000 software to TickIT Plus requirements.
- **QAS Measurement Procedures:** copies of the Malvern Quality Audit Standard data sheets and procedures. These standards are used both as part of the system Operational Qualification procedure. However, they also provide users with a polydisperse standard which meets USP, EP and ISO13320:2009 requirements for system qualification / verification.
- **Software Certificates of Conformance:** copies of the software certificates of conformance for all Mastersizer 3000 software versions, providing a summary of Malvern's business management systems which are used for the development of the Mastersizer 3000 software and hardware.
- **Software Update Notifications:** copies of the software update notifications for all Mastersizer 3000 software versions, confirming the new features and bug fixes introduced for each version.
- **Software Update Verification Procedure:** a procedure users can follow for verifying the success of a software upgrade.

**Note:** The documents provided on the software CD are those which were current at the date the software was released. Please contact your local Malvern representative if you need to verify if any updated documents are available.

## 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 PC 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).

- At the separate PC, install the Mastersizer 3000 software from the CD and start the program. At the license screen, click the **Install** button.
- Browse to the folder that contains the license file from step 4 above, and select the licensee file. The licensee details will be

**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 Instruments.**

shown and you can now accept or decline the license.

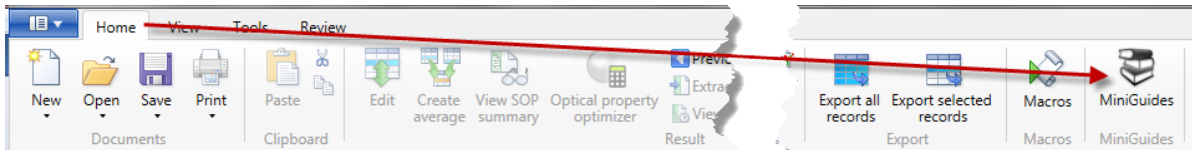
## Sharing a License for Mastersizer 3000E users

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 List

Mastersizer 3000 v3.63 is a maintenance release of the Mastersizer 3000 and 3000E software which has been produced to address issues associated with instrument driver signing. The features implemented in the release are confirmed in the table below. These were first introduced in Mastersizer 3000 v3.60

Reference(s)	Feature
62957	Update materials database to include references for the values provided by Malvern.
61173	Audit the closing of the measurement manager if this occurs before completion of the measurement sequence.
61481	Audit the process of saving measurement files so that it is clear where and when data has been saved.
60599	Ensure measurements are saved when then they are created instead of waiting until the end of an SOP measurement sequence.
59919	Only show size distribution preview in the measurement manager when obscuration is within limits
59015	Change report boarder colour to avoid use of black (required to address localisation issues).
55948	Audit the start time for SOP and manual measurements
56124	Translate the data quality tool to work in Japanese

**57544** Store the Mastersizer 3000 licence file in a specific directory which can be set for access by administrators only

In addition to the above, this software version includes improvements made to the automation interface used to control the Mastersizer 3000 software via Malvern Link 2. These improvements have been applied as part of User Story 57596.

Details of the new features developed for previous software releases can be found in the Software Update Notification documents stored on the software CD-ROM.

## Fixed issues list

The main issues fixed in this release of the Mastersizer 3000 software are confirmed in the table below:

Reference(s)	Issue
<b>71329</b>	Instrument driver is reported as not being valid, causing problems within installation of the software on new computers running the Windows 10 operating system. Driver needs to be signed using the current Microsoft driver approval process to address this.

This release also includes the bug fixes referenced in the table below, which were first implemented in Mastersizer 3000 v3.62:

Reference(s)	Issue
<b>65841</b>	Invalid Permission File exception reported when importing Malvern Access Controller (MAC) permissions into the Mastersizer 3000 application.
<b>66467</b>	Update instrument drivers to be signed by using the SHA256 certification process.

In addition, this release also includes the bug fixes referenced in the table below, which were first implemented in v3.61:

Reference(s)	Issue
<b>65996</b>	Mastersizer 3000 permissions file needs to be updated to reflect correct version number when it is imported into the Malvern Access Controller application.

In addition, this release includes the bug fixes referenced in the table below, which were first implemented in v3.60:

Reference(s)	Issue
<b>54060</b>	Pulsed ultrasound settings are not set correctly, causing the applied settings to be in error.
<b>54730</b>	Crash may occur when report printing is cancelled during a print run.
<b>58025</b>	Hydro LV stirrer speed can sometimes be set to 3000rpm at the end of a clean sequence instead of returning to the SOP-demand stirrer speed.
<b>58192</b>	Hydro LV and Hydro MV dispersant fill time-out is not applied correctly, causing the software to lock-up.
<b>58487</b>	Exception reported when reading saved Optical Property Optimiser data sets when uses non-English language settings.
<b>59013</b>	Records can be stored with zero values when using the Mastersizer 2000 analysis emulator.
<b>59916</b>	Timeout occurs when batch printing a large number of records.
<b>59918</b>	SOP comparison tool does not report the ultrasound mode correctly.
<b>60000</b>	File locking mechanism fails to prevent data overwrite when two instances of the Mastersizer 3000 software access the same measurement file at the same time.
<b>60921</b>	Electronic signature report widget does not show correct usernames or signature times.
<b>61089</b>	The audit trail may report that an average has been created when no record has been produced.
<b>62460</b>	Fill dispersant source identifier is incorrectly reported in the SOP summary report.

62747

It is sometimes possible to lose measurement records when recovering data in 21CFR Part 11 mode following a software crash.

## 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)	.xml	C:\ProgramData\Malvern Instruments\Mastersizer 3000\Audit Trails	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
User sizes	.siz	C:\ProgramData\Malvern Instruments\Mastersizer 3000\User Sizes	No control required as these settings are stored in SOPs.
User defined materials	.mmat	C:\ProgramData\Malvern Instruments\Mastersizer 3000\Materials	No control required as these settings are stored in SOPs.
User defined dispersants	.mdis	C:\ProgramData\Malvern Instruments\Mastersizer 3000\Dispersants	No control required as these settings are stored in SOPs.
Data quality addins (Mastersizer 3000 only)	.mdaq	<b>Shared workspace:</b> C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins <b>Private workspace:</b> C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins	No control required as the data quality tool only provides advice.
Export data	.txt .csv .rtf	<b>Shared workspace:</b> C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Export Data <b>Private workspace:</b> C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Export Data	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	<b>Shared workspace:</b> C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data <b>Private workspace:</b> C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Reports	.mrep	<b>Shared workspace:</b> C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Reports <b>Private workspace:</b> C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Reports	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	<p><b>Shared workspace:</b> C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\SOP Template</p> <p><b>Private workspace:</b> C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template</p>	No control required.
SOP	.msop	<p><b>Shared workspace:</b> C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\SOP</p> <p><b>Private workspace:</b> C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP</p>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Data export templates	.mext	<p><b>Shared workspace:</b> C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Data Template</p> <p><b>Private workspace:</b> C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Template</p>	No control required.
Licence file	.licence	Mastersizer3000.licence file stored in C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files	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 the C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files	Prevent deletion this file once it is created. However, read, write and modify access must be maintained.
Various system wide configuration files	Various	C:\ProgramData\Malvern Instruments\Mastersizer 3000	Full access must be maintained to this directory for the program to function correctly.

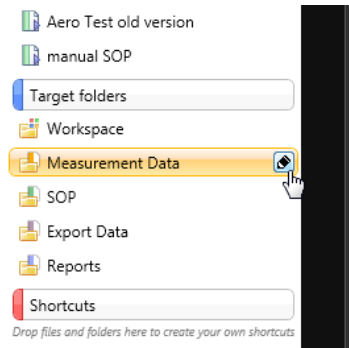
## Changing the destination path for a particular file type

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

- SOP
- Measurement Data
- Reports
- Export Data

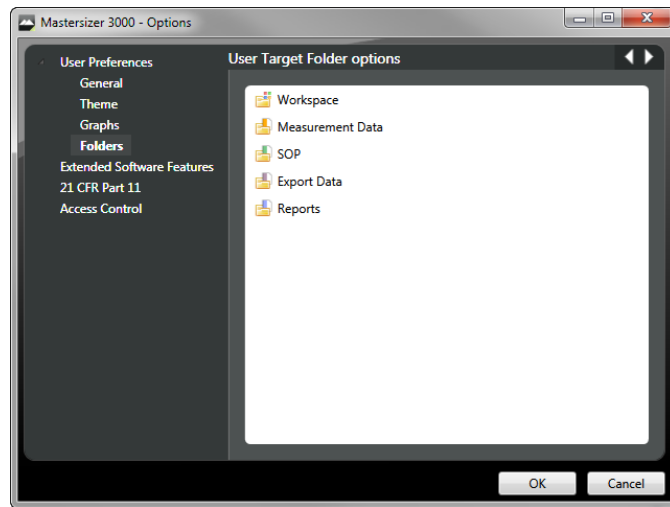
For Mastersizer 3000 users and those who have upgraded the Mastersizer 3000E software, the default file location for these files can be configured via the Target Folders section of the Workspace viewer. To do this, click on the pencil icon which appears when you hover over the directory shortcut:





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

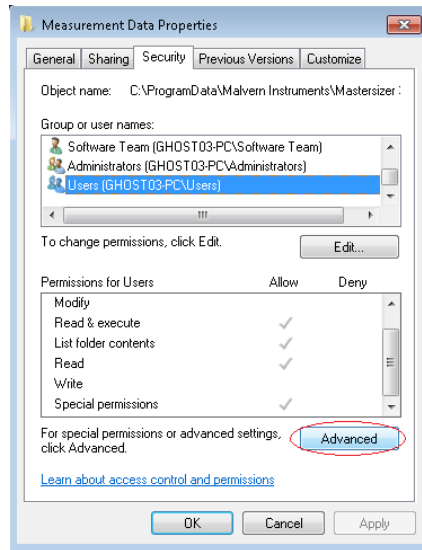
The Mastersizer 3000 software does not create backup copies of any of the file listed above. However, there are third-party software tools that will allow you to schedule regular backups, if required, for each of the file locations.

## Windows Security Settings

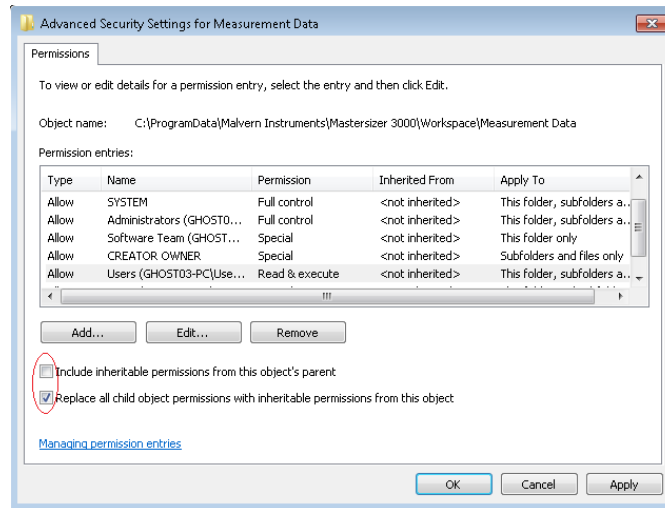
For the next part of this document, it is assumed that you have the required administrator rights for the system upon which the Malvern software is being installed; allowing you to install or update software and configure windows security permissions.

### Changing the directory security permissions in Windows 7

Navigate to one of the directory folders that need to be secured. In this case we have selected the directory where the Mastersizer 3000 measurement files are stored. Right-click on the folder and through the context menu open the folder properties. Within this, switch to the security tab:



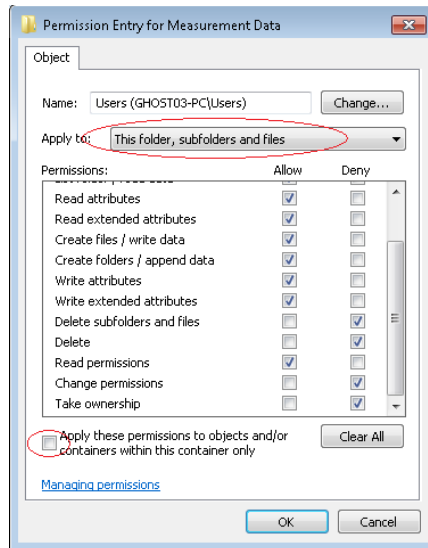
Within the Security tab, click on the **Advanced** button. This will cause the Advanced Security Settings to be displayed. Within this dialogue click on the 'Change Permissions...' button. This will bring up the permissions tab:



**Clear** the checkbox 'Include inheritable permissions from this object's parent', shown in the dialogue above. If a warning is displayed **Add** the parent settings before changing the security settings. This will prevent modifications to parent directories overriding the changes which are being implemented:



Next, **Check** the 'Replace all child object permissions...', as shown above. This will apply the changes we make to permissions for all files in this directory. Select the **Users** group and **Edit** the group's permissions. This causes the **Permission Entry** dialogue to appear:



Allow access to all permissions with the exception of:

- Full Control
- Delete subfolders and Files
- Delete
- Change Permissions
- Take Ownership

Ensure that the **Apply To** setting is changed to **This folder, subfolders and files**. Clear the 'Apply these permissions to objects...' checkbox as shown above. Then, click **OK** to apply the security settings.

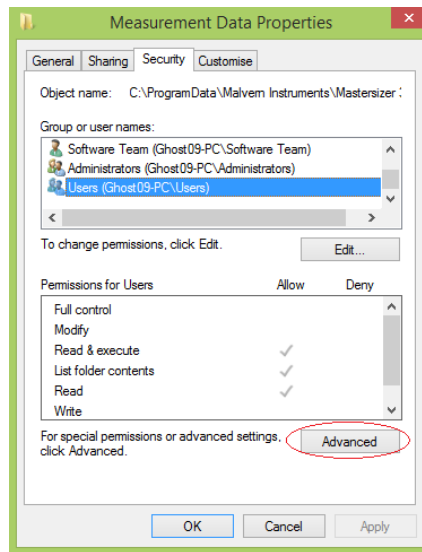
Repeat this procedure for the following directories at a minimum:

- Audit Trails
- Measurement Data
- Reports
- SOP

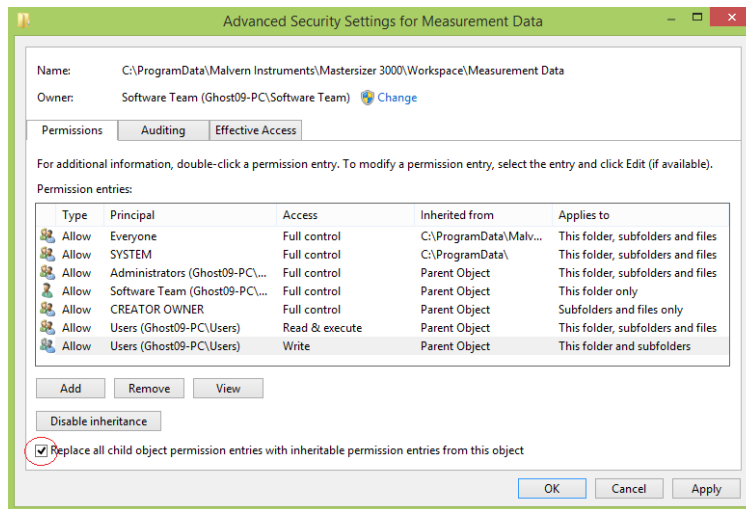
The location of these directories are provided in the File Types and Locations section of this document. This section also details individual file types which must be controlled, including the program security and license files.

## Configuring Windows 8/10 security permissions

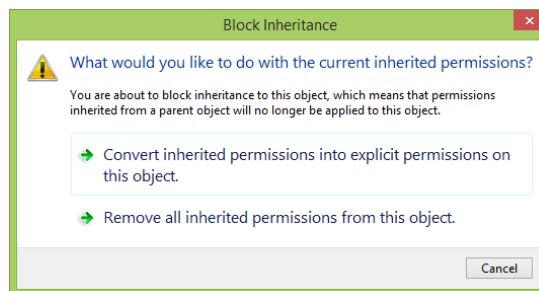
Navigate to one of the directory folders that need to be secured. In this case we have selected the directory where the Mastersizer 3000 measurement files are stored. Right-click on the folder and through the context menu open the folder properties. Within this, switch to the security tab:



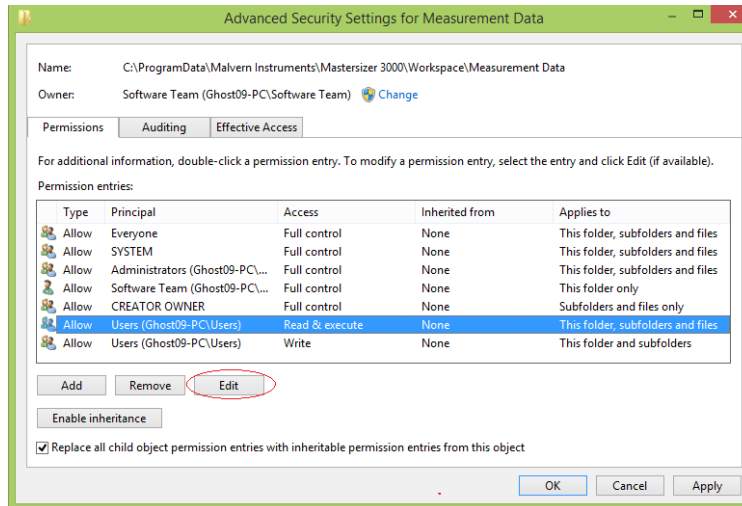
Within the Security tab, click on the **Advanced** button. This will cause the Advanced Security Settings to be displayed. Within this dialogue click on the 'Change Permissions...' button. This will bring up the permissions tab:



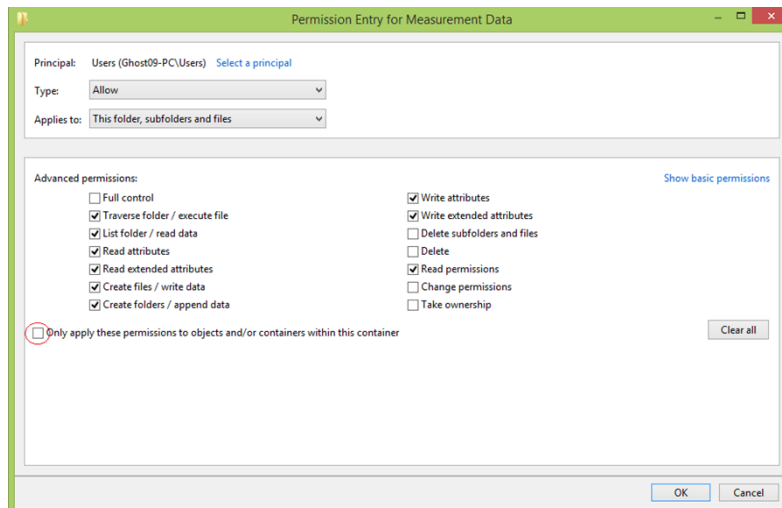
Disable the inheritance by selecting the **Disable inheritance** shown in the figure above. If a warning is displayed **Convert** the inherited permissions into explicit permissions:



This will prevent modifications to parent directories overriding the changes we are implementing. Next, **Check** the 'Replace all child object permissions...' option shown above. This will apply the changes we make to permissions for all files in this directory.



Select the **Users** group specifically for **Read & execute** that applies to **This folder, subfolders and files** and select to **Edit** the permissions. This will cause the Permission Entry dialogue to appear:



In the Permission entry dialogue, toggle the view to show **Advanced** permissions. Then, allow access to all permissions with the exception of:

- Full Control
- Delete subfolders and Files
- Delete
- Change Permissions
- Take Ownership

Ensure that the **Applies To** setting is still **This folder, subfolders and files**. Clear the 'Apply these permissions to objects...' checkbox as shown above. **Apply** the setting and select **OK** to close the dialogue. This will configure the security settings.

Repeat this procedure for the following directories at a minimum:

- Audit Trails
- Measurement Data
- Reports
- SOP

The location of these directories are provided in the File Types and Locations section of this document. This section also details individual file types which must be controlled, including the program security and license files.

## 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	Comment
Aero S and Aero M sample feed control	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.	Error can be avoided procedurally (avoid double-clicking the feed button).
Corrupt report settings file causes software crash on start-up	It has been observed that the global report settings file may become corrupt. This file holds the company name and logo used across all reports in the software. A symptom of this issue is the software crashing on start-up with an exception "hexadecimal value 0x00, is an invalid character". The workaround is to delete the contents of folder at C:\ProgramData\Malvern Instruments\Malvern.Reporting. This will trigger a new fresh settings file to be created – you will have to reconfigure your company name and logo in reports.	Medium risk issue
Warnings are displayed about corrupt measurement files	The software has built in detection of when measurement files are at risk of being corrupted. If you see one of these messages, you are probably creating too large a measurement file.	Intermittent Observation
Instrument disconnects after firmware upgrade	An issue has been seen for some installations whereby the instrument will become disconnected from the PC following a firmware upgrade. Turning the instrument off and on again will cause it to successfully reconnect to the software.	Intermittent Observation
The manual measurement settings do not match the connected/active dispersion unit.	See know issue description below.	Intermittent Observation
Some text still appears in English when running with a different language selected.	The translation of all software text will continue in future releases.	Low risk issue
Software does not open all files selected when they are opened using Windows Explorer.	Use the Open menu option in the Mastersizer 3000 software to open multiple files.	Low risk issue
Record number and detector number values are displayed to one decimal place on trend and data graphs.	No work-around available.	Low risk issue
The system audit trail displays duplicated columns for each language under which the system has been run when auditing has been enabled.	No work-around available.	Low risk issue

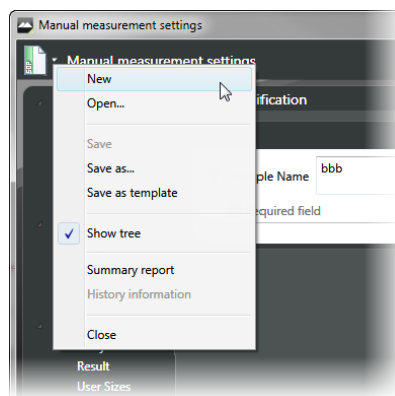
# SOFTWARE UPDATE NOTIFICATION

When graph symbols are displayed in reports, they do not show on printouts.	No work-around available.	Low risk issue
Various fields in the Edit result window lose their 'edited' blue background appearance when a different page in the editor is selected.	No work-around available. This is a display issue only, as the software correctly applies the edit values when the OK button is pressed.	Low risk issue
Mastersizer 3000 driver errors appear when using the instrument with a USB 3.0 port.	We believe this is an issue which relates to the use of early USB3 ports. Evidence suggests the software works with the current version of USB3 installed on newer computers. If you suspect there is an issue with your system, try switching the USB port used to connect to the Mastersizer or use a USB 2.0 port instead.	Intermittent Observation
Trend table print out is limited by paper size.	Report widgets are designed to fit on one page, and will not wrap over pages. If you select lots of measurement records, the trend table widget will expand to fill the page. However, if you select more measurement records than can fit in a trend table on a single page then the displayed records will be truncated at the page boundary. The only work around for this issue is to print the report on a larger paper size. Paper size A4 has a limit of 56 records in a trend table, whereas paper size A3 has a limit of 86 records.	Low risk issue
Some parameters are not imported from Mastersizer 2000 measurement records	When importing Mastersizer 2000 measurement records into the Mastersizer 3000 software, some SOP parameters from the Mastersizer 2000 records do not get imported. However, all of the parameters required for result review or recalculation are present.	Low risk issue
Manual measurement errors are reported if the Aero dispersion unit configuration has changed between measurements.	The manual measurement feature in the software stores the last used settings. This includes configuration of the Aero dry powder disperser. If you change the configuration between measurements and then open a manual measurement, the software will report an error stating that configuration is wrong. If this happens, close and re-open the manual measurement window and change the manual measurement settings to match your new Aero configuration.	Low risk issue
Software exception is reported if the software is closed when a macro is running.	All currently running macros must be closed before closing the software.	Low risk issue
Some report widgets are truncated in the print preview view.	Some report widgets may not be displayed correctly within the print preview screen. However, if the report is printed all of the information within the widget will be shown.	Low risk issue
Software may crash when exporting data with custom sample identifiers which start with a number	Exporting measurement data with custom sample identifiers beginning with a number will cause the software to crash when you select an export template that contains sample identifiers. The only work-around is to prefix sample identifiers with letters.	Low risk issue
Ultrasound SOP option 'Continuous (From Measurement Start)' does not turn off in SOP playlist	If you use an SOP with the ultrasound option 'Continuous (From Measurement Start)' in an SOP playlist, when running a subsequent SOP with no ultrasound turned on, the ultrasound will not turn off as expected. The work around is to use the 'Continuous (From Sample Addition)' option in the SOP rather than 'Continuous (From Measurement Start)'. When this playlist is run, then the ultrasound will turn off when executing a subsequent SOP which does not require ultrasound.	Low risk issue

Cannot load old custom calculations from file	When trying to load a custom calculation created in v3.30 software or earlier, the software may report error and the calculation will not load. The workaround is to re-export the custom calculation from the original report in a recent version of the software.	Low risk issue
Operating System reported as Windows 7	When running the Mastersizer 3000 software on Windows 8 or 10, the Maintenance dialogue may report the OS as Windows 7.	Low risk issue
Measurement file (*.mmes) date and time are not updated when new records are saved.	The modified date for measurement files is not updated when new records are saved. Instead, the modified date is always reported as the original file creation date. There is no workaround for this issue. However, the measurement and analysis date and time stored for records within the measurement files are reported correctly.	Low risk issue
Workspace shortcut display text does not update	You may find that if you edit the display text for a workspace shortcut then the display text doesn't appear to update in the shortcuts list. When you restart the software, you will find that the display text has indeed updated successfully.	Low risk issue
Edited Malvern reports become de-selected when the software is re-started	You will find that when you edit a Malvern report, then close and re-open the software, your edited report is no longer selected and instead the original Malvern report is selected. The work around is to open the report selection dialog and re-select your edited report. At that point, the report selection will be saved.	Low risk issue
Data quality tab is not displayed immediately when selected from the extended features list	Given that the software has just been installed and the option to enable the extended software features is selected. Then when the application is restarted the data quality tab will not be displayed if the default view is selected. The work-around is to select the 2 pane vertical view which will display the data quality tab. Then reverting to the default view will display the data quality tab.	Low risk issue
Ultrasound level applied during clean reported as 0%	You may find that the measurement manager reports that 0% ultrasound is being applied during cleaning when you have set an ultrasound demand of greater than 0%. Evidence suggests that ultrasound is applied correctly as per the configured ultrasound demand, but the value shown in the measurement window is incorrect.	Low risk issue

## 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:



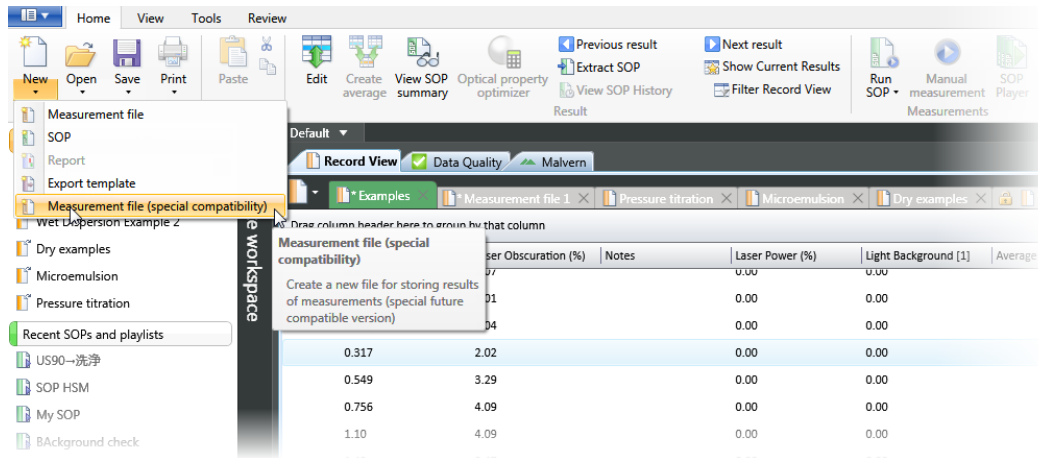


This will reset all measurement settings to their defaults for the active accessory type. This issue has been reported after upgrading from early versions of the software, but does not occur on all systems.

## 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 1000 records, and advise that you try to remember to regularly create and use new files to store measurement records.

Note that Malvern 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.

## Analysis Error codes

The following error codes may be returned by the analysis routine as a result of data collection or result calculation errors:

Error Code	Description
1 4 5 44	Error detected with the selected material or dispersant optical properties.
3 6 7	Unable to load or generate a scattering matrix.
8	Unable to initialise the result calculation routine.
9	There is no raw data to analyze.
10	Unable to apply the selected analysis settings.
11 12	Error occurred during generation of the scattering matrix.
13	Error occurred during raw data handling.
14 15	Unable to configure the result calculation routine.
16 17	Unable to generate a result based on the input raw data.
18 20 22	Could not find any particle size distribution modes in the result.
19	The analysis residual is greater than 99.9%.
23 24	Error occurred when using the Fraunhofer analysis model.
25	Corrupt analysis settings detected.
40 41 42	Scattering matrix calculation settings errors detected.
43	Error occurred while generating the scattering matrix.
45	Matrix generation is currently busy.

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