SOFTWARE UPDATE NOTIFICATION
MASTERSIZER **3000** SOFTWARE v3.50: PSS0223-19

PARTICLE SIZE

Introduction

This document details the release of software PSS0223-19: version 3.50 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 minimum requirements for running this software are highlighted in table 1 below. Although the software can be operated using Windows 10 Enterprise (64 bit), Windows 8.1 Enterprise (64 bit), Windows 8 Enterprise (64 bit), Windows 7 Professional (32 bit) and Windows 7 Ultimate (64 bit), it has been fully tested under 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

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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: Minimum system requirements for the Mastersizer 3000 software.

Feature	Specification
Processor Type	Intel Core i5 Processor
Memory	4GB
Hard Disk Storage	250GB
Additional Storage Media	CD-ROM or DVD +/-RW drive
Display Resolution	1024 x 768
Connectivity	1 high speed USB2 or USB3 port
Operating System	Windows 7 Professional (32 bit)
	Windows 7 Ultimate (64 bit)
	Windows 8 Enterprise (64bit)
	Windows 8.1 Enterprise (64 bit)
	Windows 10 Enterprise (64 bit)

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 **MRK1828-xx - Guide to setting up access permissions in the Malvern Access Configurator Application** 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.

New Features Description

Sample Detail Recall

The Mastersizer 3000 system is often used for routine quality control measurements. For these, the sample details may be similar for each sample measured using a given SOP. In previous software versions, users had to re-enter all of the sample details each time an SOP was run, increasing the time required to prepare for a measurement.

In version 3.50 an option to recall the sample details has been added to aid sample through-put. To enable this new option, you need to edit your SOP(s) and open the **Sample-> Identification** section of the SOP settings:
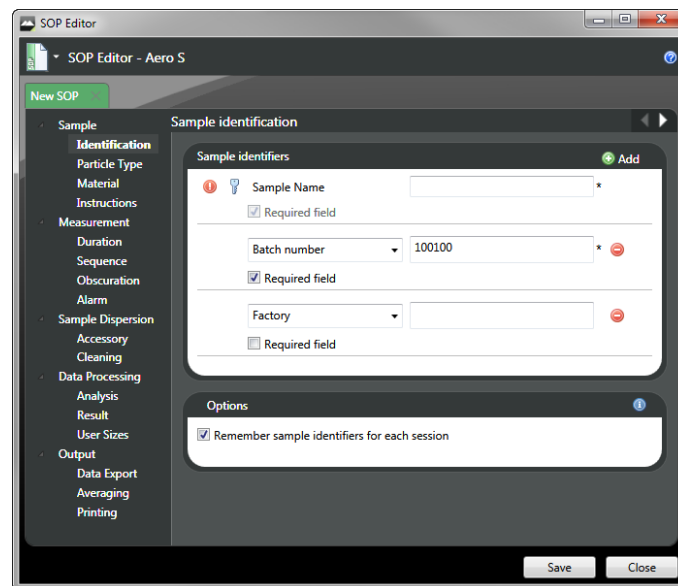

Within this section there is new option to **Remember sample identifiers for each session**. Select this if you would like the sample details to be recalled.

Note that the sample details are only recalled within the current software session. If the software is closed down and reopened the SOP sample identifiers will be re-set to their default values.

Close measurement manager option

Often users like to be able to walk away from the Mastersizer 3000 system at the end of a measurement, leaving the software to clean the dispersion unit and prepare the system for the next measurement. However, one issue with doing this is that the measurement manager window remains open. This can lead to a situation where the dispersion unit is left switched on for a long period of time.

To manage the above situation, version 3.50 includes a new option SOP to automatically close the measurement manager window at the end of the measurement. This is configured within the **Measurement-> Sequence** section of the SOP settings:
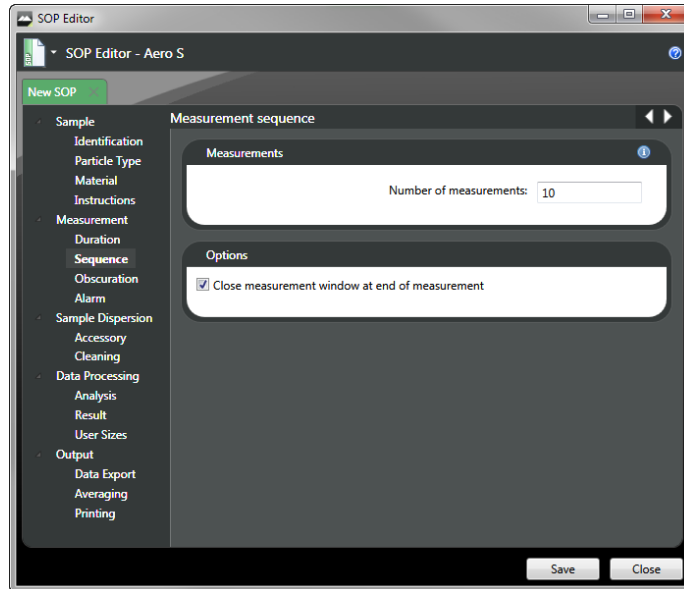

Enable the **Close measurement window at end of measurement** option if you would like the measurement manager to automatically close at the end of the SOP. This will ensure the dispersion unit is switched to low power mode once the measurement sequence has completed.

Edit Graphs without edit mode

Malvern introduced a new report designer in v3.30 of the Mastersizer 3000 software which made it easier to define the report layout. However, when this was introduced the ability to change the format of graphs without entering edit mode was lost. This function has now been added back into the application, making it easier to make graph changes when reviewing results.

To access the new edit mode, click on the cog item which appears on the window boarder for the graph object you want to edit:
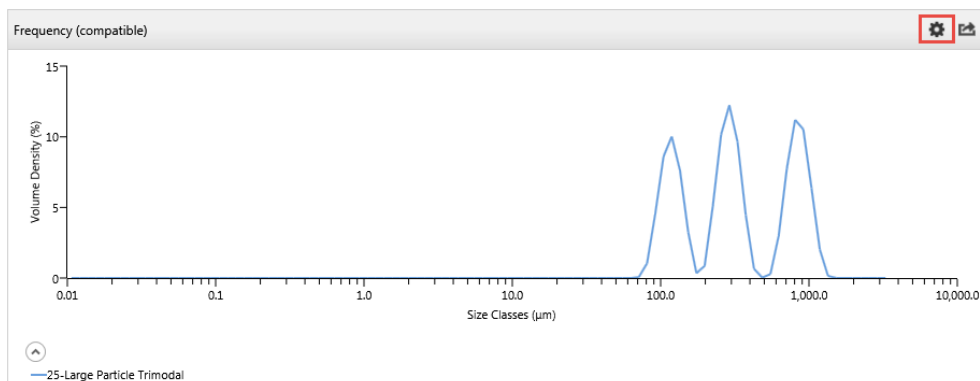
Doing this will cause the graph properties dialogue to appear, allowing you to change the format of the graph. Changes to the graph format are remembered within the current software session. If the software is closed and reopened the graph will revert to the format specified in the report definition. Also, the graph format changes are only applied to the software screen view and to the format of the graph when it is exported. The format of the print out always follows the report definition.
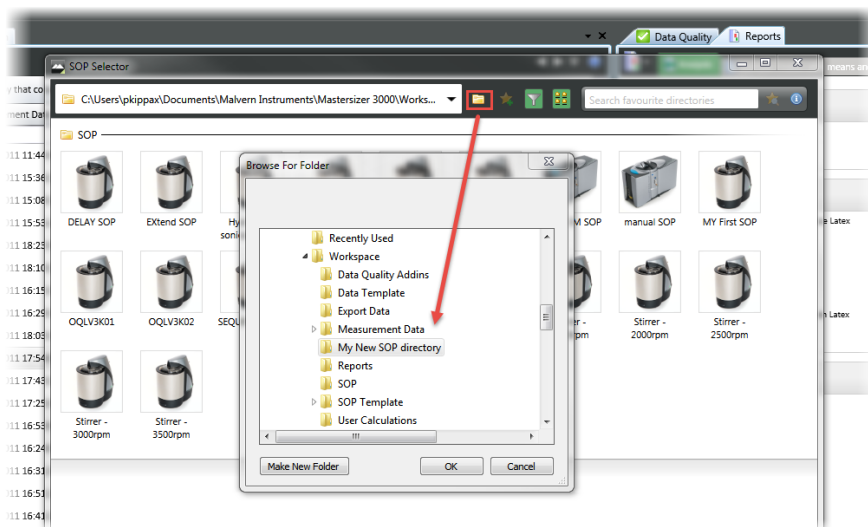
Search for SOPs

It is common for users to have a range of samples which they measure using the Mastersizer 3000 system, for which they will need to define separate SOPs. This can cause the SOP selector window to look crowded when it opens at the beginning of an SOP measurement sequence, making it difficult for users to find the correct SOP.

To help users with finding the correct SOP, a new SOP search box has been added to the SOP Selector window:
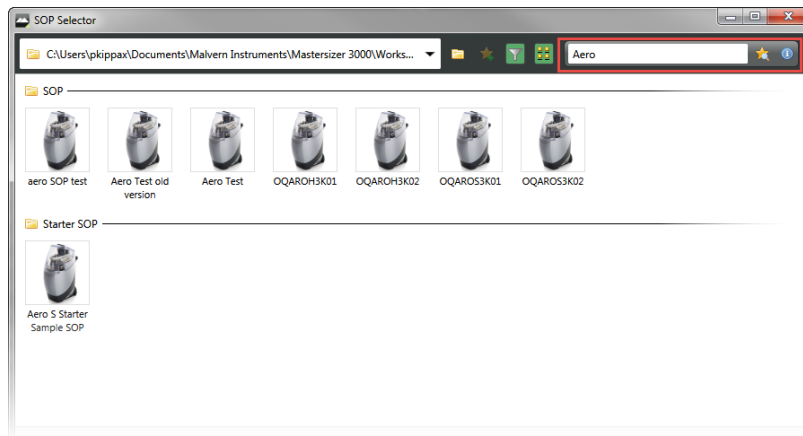

The search box works in the same way as standard Windows OS searches and can accept wildcards as well as letters and numbers. The search occurs within the current directory, including any child directories. In addition, any directory selected as a favorite for SOP storage is included in the search path, along with any child directories for the favorite directories.

Directories can be added to the favorites list by first navigating to them within the SOP Selector dialogue. First, click on the folder icon in the menu bar and select the directory you want to add:


Once the directory is selected, it can be added to the favorites list by clicking on the star icon:
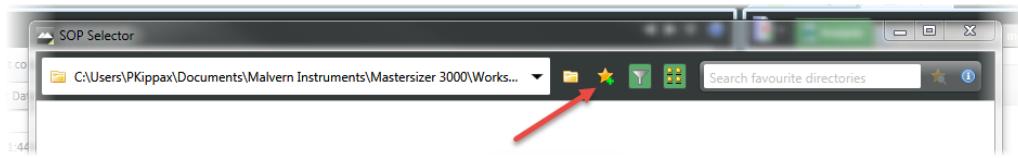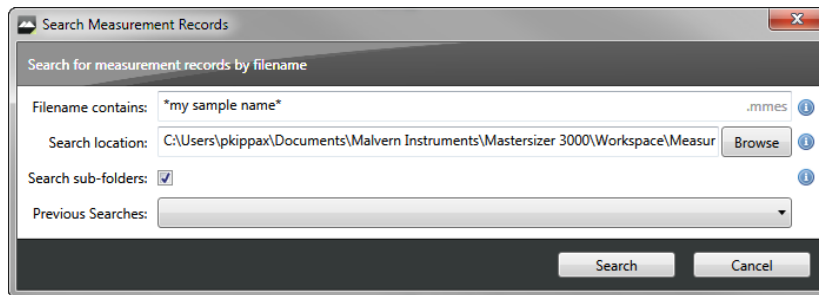
This will ensure that the directory, and its child directories, are included in the SOP search.

Search for measurement records

Version 3.50 contains a new function to help users find measurement files (*.mmes). To access this new search function, click on the **Search** option in the **Home** ribbon bar:
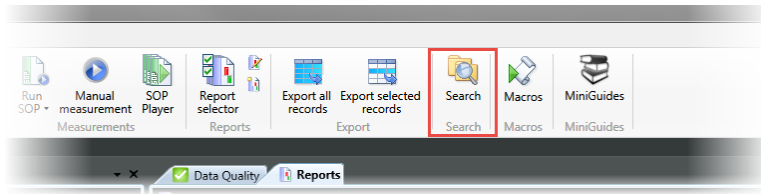
This causes the **Search Measurement Records** dialogue to appear:

With this you can specify the following fields:

- **Filename contains**: Provide a search string for finding measurement files of interest. This can accept wildcards as well as letters and numbers.

- **Search location**: sets the directory within which the search is performed. Use the **Browse** button to select the directory and enable the **Search sub-folders** option to include child directories within the search.

- **Previous Searches**: provides a drop-down list of searches which have been applied previously so you can quickly recall and apply these.

The search process will locate all of the measurement files which match the search criteria. The records from within these files are then loaded into a new result file tab within the software. In this example, the search was set to find all measurements in files which included the word 'example' in the file name:

Once all of the records are loaded, the record view sorting and filtering options can be used to locate records relating to specific samples.

Note that this is the first stage in a series of planned search functions to help users find result data. For example, the ability to search for specific records within files will be provided in a future software version.

Row alignment setting for parameter grids

The feedback from users relating to the new report designer function provided in v3.30 of the Mastersizer 3000 software has been positive. However, a common request has been for Malvern to provide improved control of the formatting of Parameter Grid report widgets in order to make better use of the space within a report.

To help with efficient report space use, a new function has been added to v3.50 to allow the position of the columns used within Parameter Grids to be adjusted. To configure this, first add a Parameter Grid to the report and select to edit its properties. The column position is then set using the slider bar control within the Properties dialogue:
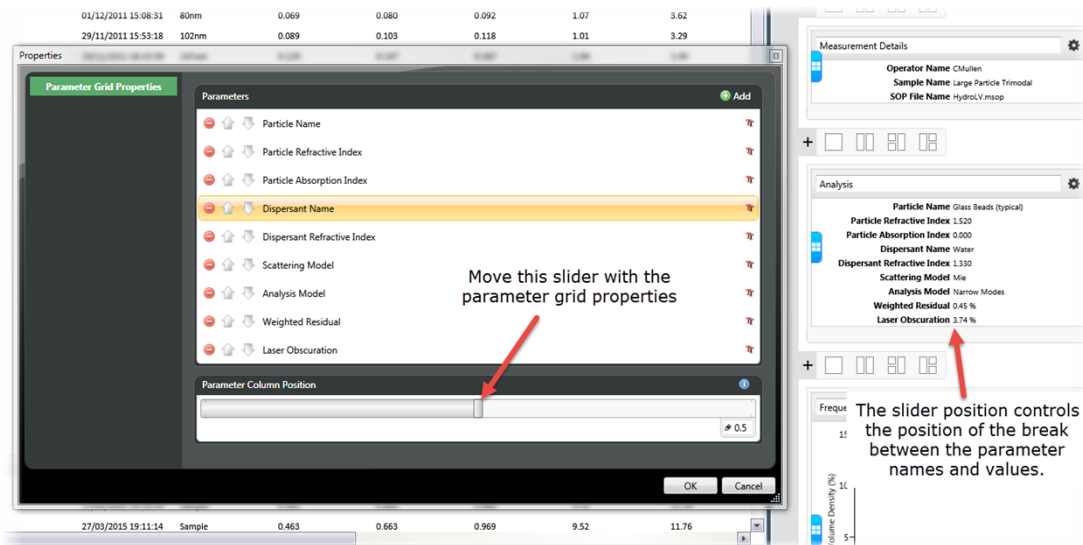
Software Categorization

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-define 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 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

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).

5. At the separate PC, install the Mastersizer 3000 software from the CD 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 licensee 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 Instruments.**

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:
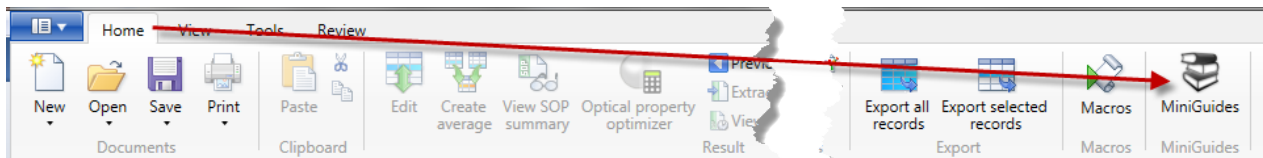
New Features List

Version 3.50 of the Mastersizer 3000 and 3000E software includes the following new features:

Reference(s)	Feature
9949	Allow sample information to be recalled on repeat runs of an SOP.*
10180	Provide the ability to normalise data plots in order to remove the effect of obscuration differences.
28040	Add an option to turn off negative data in all data graphs.
45896 **48076** **54645**	Provide a search function to locate records within multiple measurement files.*
46427	Improve USB communications resilience.
46527	Add an SOP option to close the measurement manager window at the end of an SOP measurement.*
47043	Add a permission to restrict editing the result emulation factors.
48371	Enable graph widgets to be configured within reports without entering edit mode.*
49380	Provide a 'Save As New' option for reports.
50473	Add search function for SOPs when selecting an SOP to run.*
51987	Provide the ability to set the default dispersion settings for Aero M SOPs.
52339	Allow remote access to data files which are open on the Mastersizer 3000 system.
52741	Adjust alignment of rows in parameter grid widget.*
53132	Signature table needs to show all of the signatures applied to a record.
53763	Hide background stability option for dry measurements.
54115	Implement Japanese language mini-guides.
54579	Update the materials and dispersants databases to ensure these only include optical properties which have been verified or obtained from recognised sources.
54828	Add applications-specific reports to the default report selection.

*See the New Features section above for more information.

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 and 3000E software are listed below.

Reference(s)	Issue
27212	Accessories can time out when left running overnight.
33938	SOPs load slowly from the SOP selection dialog (CFB-02459 / CFB-02503).
44795	Ultrasound 'continuous from start' does not always work correctly when using the Hydro EV.
44848	Firmware randomly upgrades when the software starts up.
48412	Using the pencil icon for the report edit option is confusing (needs to change to a cog icon)
48846	Optical Property Optimizer scan crashes or never completes on some computers.

36413	Saving an SOP with the same name as an open SOP is possible and corrupts the SOP.
49433	Ultrasound elapsed timer doesn't reset when the measurement manager window is closed and then re-opened.
51040	Range limits for the Optical Property Optimizer can do not accept localised (comma) decimal separators.
51372	Changes to the manual measurement settings are not always applied correctly when the settings window is closed.
51411	The reference and notes fields for material and dispersant properties appear as single line at bottom of the dialogue box.
51523	Opening and then closing the Optical Property Optimizer window quickly can cause the software to crash.
51664	The system health check can report incorrect results for the laser power test.
52006	Software crashes when a user tries to save an SOP to an unauthorised location.
52010	Aero S/M dispersion air and sample feed do not turn off when the measurement cell is removed.
52074	Japanese translations are not accurate in some cases.
52075	Spontaneous crash occurs when opening the optical property optimizer.
52252	Editing number of columns or rows in a table output custom calculation causes an error to be reported which cannot be corrected.
52288	In 21 CFR Part 11 mode a reason for change is not requested for SOPs when responding to the 'Do you want to save changes?' prompt following an edit.
52716	The dispersant name and refractive index parameters should be displayed in reports for dry measurements.
53034	Software crashes when a user tries to save a measurement file to an unauthorised location.
52836	A corrupt data file is not flagged as being corrupted by the software.
52843	Opening a corrupted file causes the software to crash.
53466	The company name and logo settings in software options have no effect and should be removed (they are replaced by new report designer options).
54556	Result Emulation/Extension can cause an empty result to be reported if the emulation/extension factors are not set.
55983	Hydro dispersion unit SOPs continuously loop when run through automation interface if the SOP does not request cleaning.

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).

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. A fix will be implemented in a future software release.	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. A fix will be implemented in a future software release.	Low risk issue
When graph symbols are displayed in reports, they do not show on printouts.	No work-around available. A fix will be implemented in a future software release.	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
The manual measurement settings do not match the connected/active dispersion unit.	See know issue description below.	Intermittent Observation
Mastersizer 3000 driver errors appear when using the instrument with a USB 3.0 port.	We believe this is was an issue with 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
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
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
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
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

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 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
Invalid durations for pulsed ultrasound reported for manual measurements	A validation error for the pulsed ultrasound settings may be reported when closing the measurement settings for a manual wet measurements. Unfortunately, it is not possible to clear this error from within the settings dialogue. Instead, click Cancel to close the dialogue and switch to the Accessory Controls tab in the measurement manager window. Correct the ultrasound settings there and then re-open the settings dialog to configure your measurements. This should remove the validation error.	Intermittent Observation
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. This will be fixed in a future software release.	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. This will be fixed in a future software release.	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:
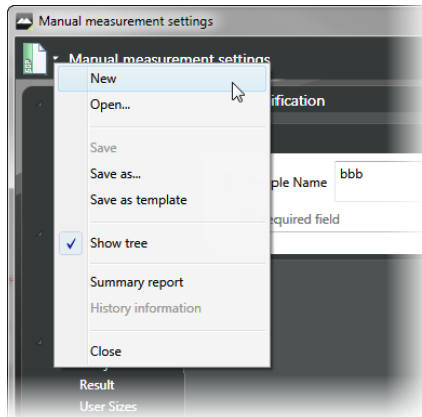
This will reset all measurement settings to their defaults for the active accessory type. This issue has been reported after upgrading from early versions of the software, but does not occur on all systems.

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:
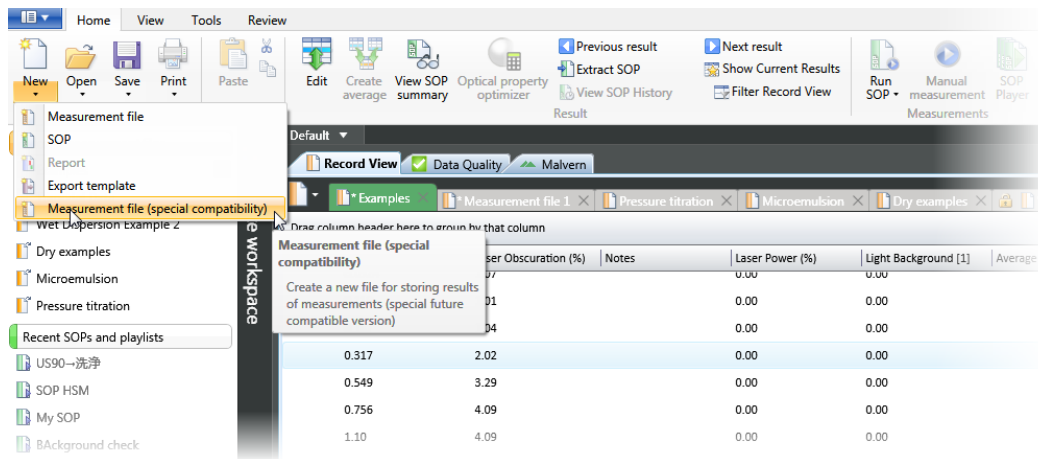
Measurement File Size and Corruption Warnings

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.

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	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins **Private workspace:** 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	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Export Data **Private workspace:** 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	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data **Private workspace:** 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	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Reports **Private workspace:** 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	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template **Private workspace:** C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template	No control required.
SOP	.msop	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\SOP **Private workspace**: C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Data export templates	.mext	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Template **Private workspace:** C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Template	No control required.
Licence file	.licence	Mastersizer3000.licence file stored in C:\ProgramData\Malvern Instruments\Mastersizer 3000	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\ directory.	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:
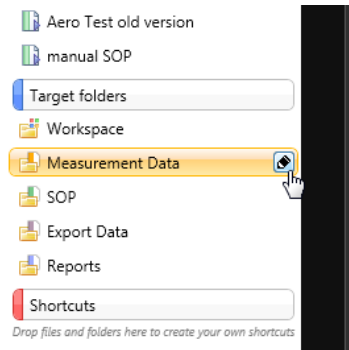
Changing the directory associated with this shortcut will change the default directory accessed by the Mastersizer 3000 software for the selected file type.

Configuration of the target directories can also be configured from the User Preferences-Folders section of the Options menu:
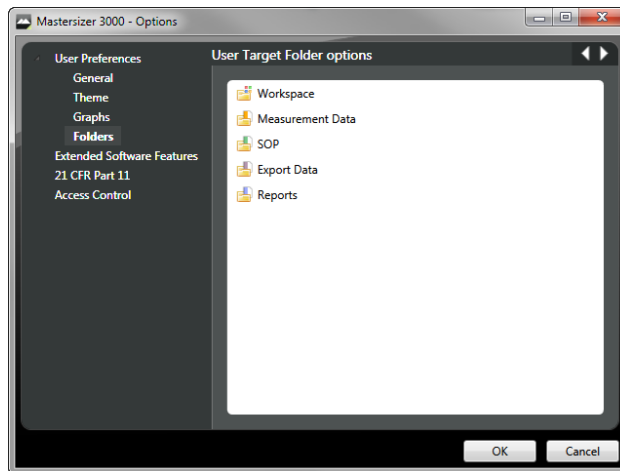
Again, hover over the shortcut and click on the pencil icon in order to change the target directory. Note that this is the only place in the software where the target directories can be configured when using the Basic software for the Mastersizer 3000E.

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.
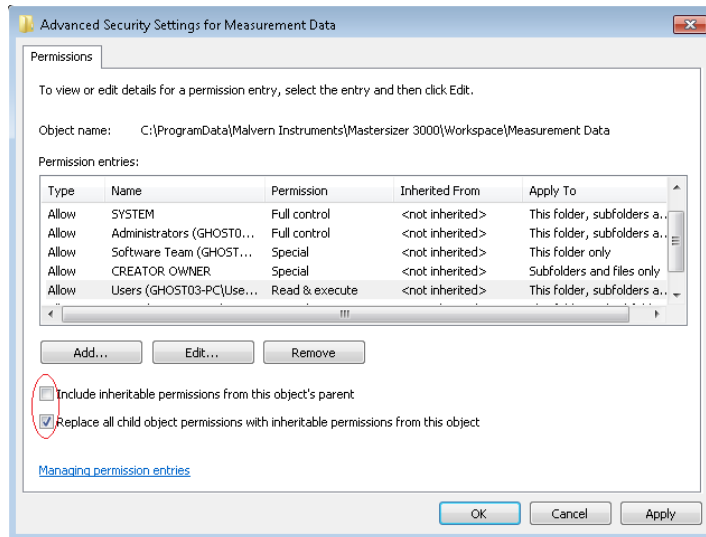
Windows Security Settings

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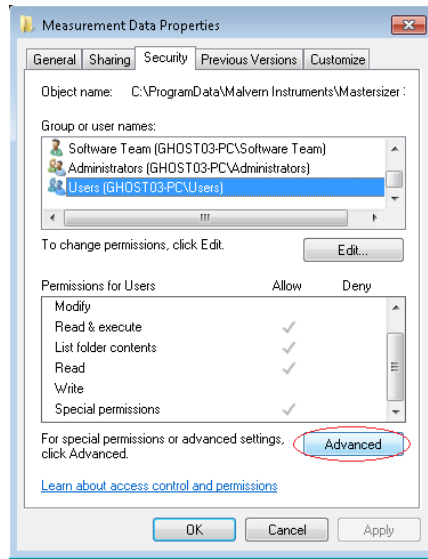
Within the Security tab, click on the **Advanced** button. This will cause the Advanced Security Settings to be displayed. Within this dialogue click on the 'Change Permissions…' button. This will bring up the permissions tab:

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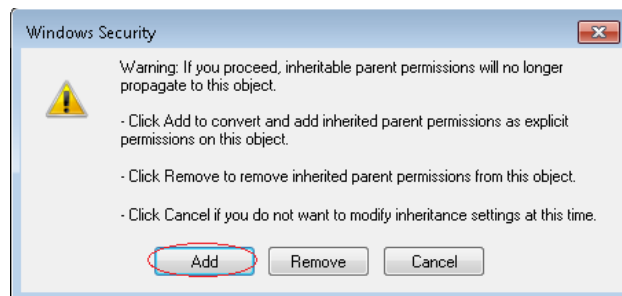
Next, **Check** the 'Replace all child object permissions…', as shown above. This will apply the changes we make to permissions for all files in this directory. Select the **Users** group and **Edit** the group's permissions. This causes the **Permission Entry** dialogue to appear:
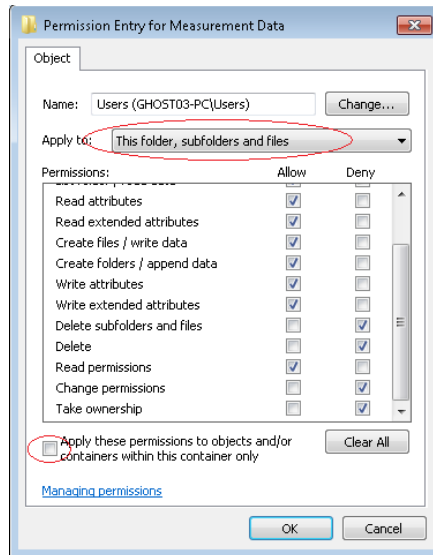
Allow access to all permissions with the exception of:

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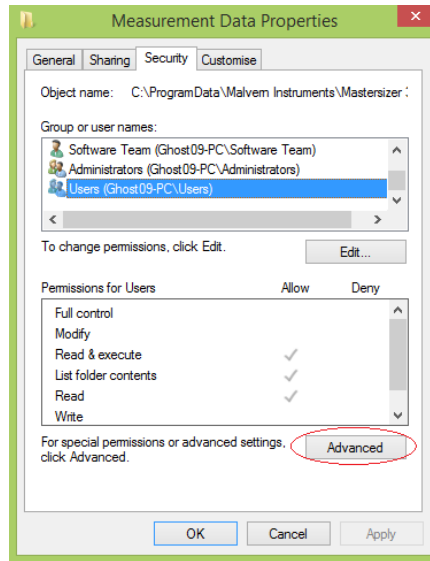
Within the Security tab, click on the **Advanced** button. This will cause the Advanced Security Settings to be displayed. Within this dialogue click on the 'Change Permissions…' button. This will bring up the permissions tab:
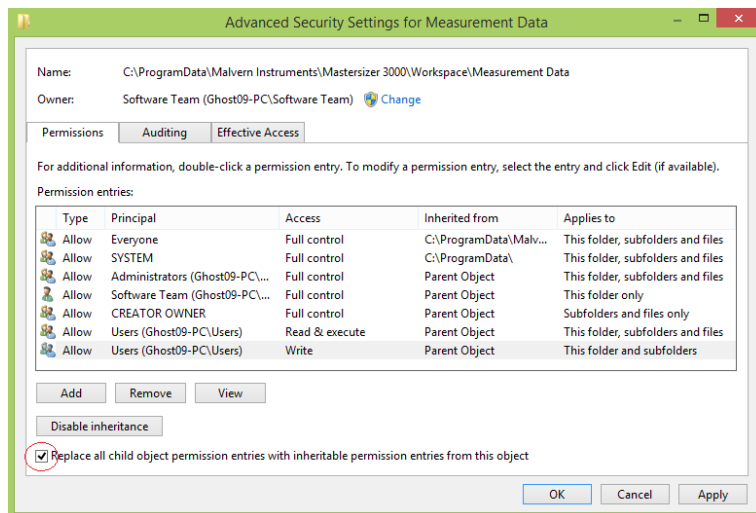

Disable the inheritance by selecting the **Disable inheritance** shown in the figure above. If a warning is displayed **Convert** the inherited permissions into explicit permissions:
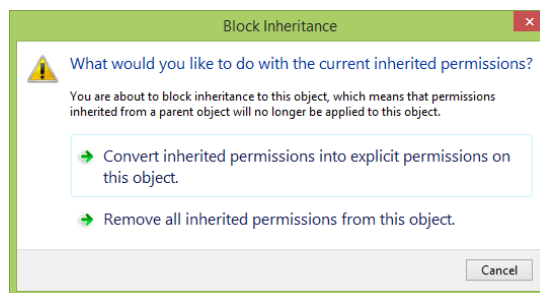
This will prevent modifications to parent directories overriding the changes we are implementing. Next, **Check** the 'Replace all child object permissions…' option shown above. This will apply the changes we make to permissions for all files in this directory.
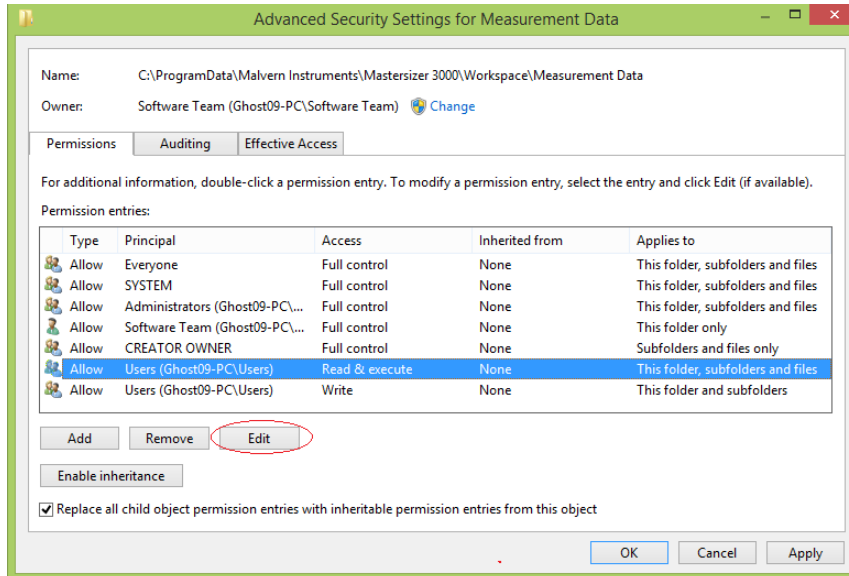
Select the **Users** group specifically for **Read & execute** that applies to **This folder, subfolders and files** and select to **Edit** the permissions. This will cause the Permission Entry dialogue to appear:
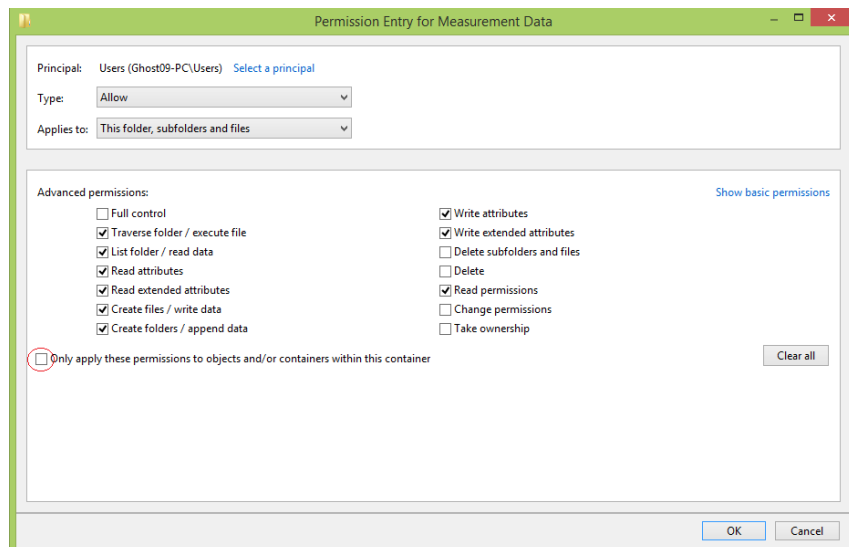
In the Permission entry dialogue, toggle the view to show **Advanced** permissions. Then, allow access to all permissions with the exception of:

- 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.

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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