

SOFTWARE UPDATE NOTIFICATION

MASTERSIZER **3000** SOFTWARE v3.30: PSS0223-17

**PARTICLE SIZE**

Introduction

This document details the release of software PSS0223-17: version 3.30 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 8 Enterprise (64 bit) and Windows 7 (32 bit), it has been fully tested under Windows 7 (64 bit). Windows 7 (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: 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 (32 bit and 64 bit) Windows 8 Enterprise (64bit)

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

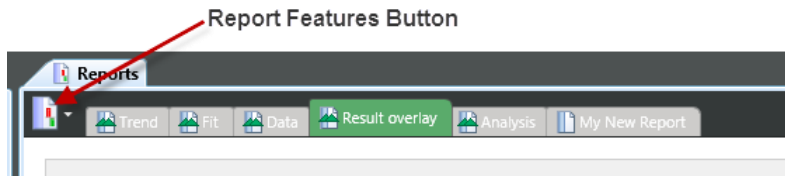
The software can be uninstalled using the standard **Add/Remove Programs** feature in the Windows Control Panel.

Main New Features Description

New Report Designer (v3.30)

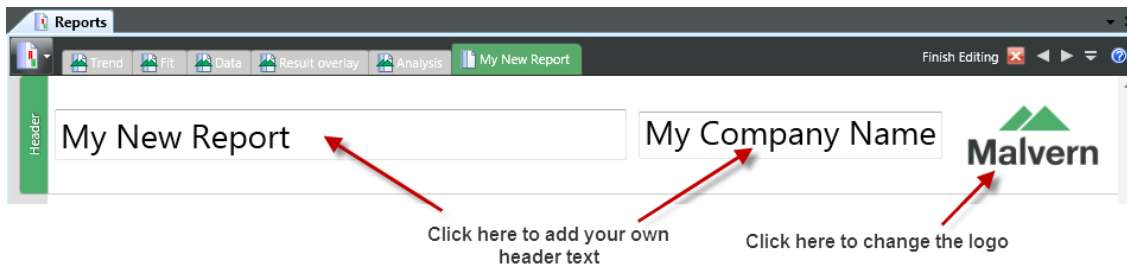
As a result of customer feedback regarding the report designer in the Mastersizer 3000 software, Malvern have developed a new report designer tool which improves the flexibility of report definition while also retaining the ease of use of the tool.

Creation of new reports is started in the same way as in previous version of the software by selecting the New Report option via the Reports features button:

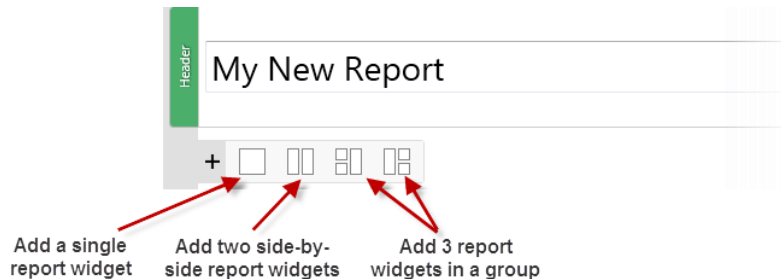


Doing this will cause a blank new report to appear. Within this you can:

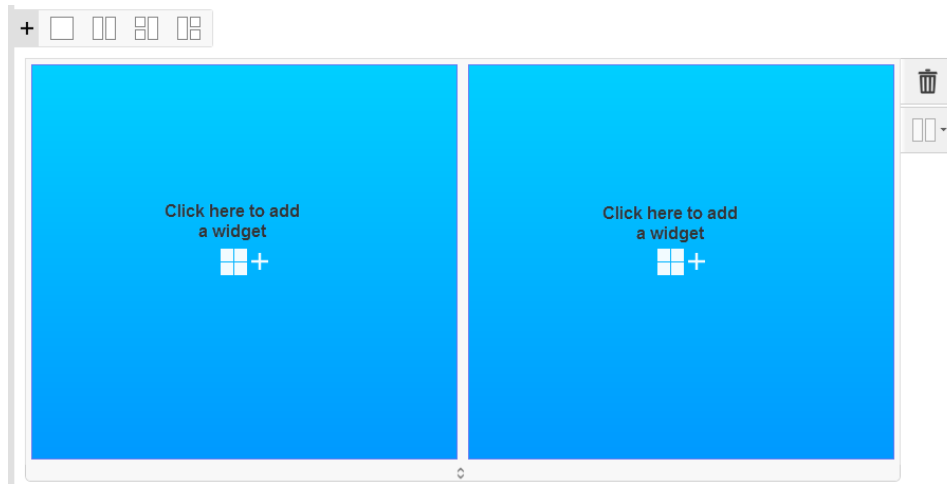
- 1) Edit the Header information within the report by adding a report name and company name. In addition, clicking on the Malvern logo will provide access to an option where you can load your own logo image for use on the report.



- 2) Add as many report containers as required for your report. The containers provide locations within the report where report widgets can be positioned side-by-side as well as one above the other:



- 3) Add report widgets to each container. This is done by clicking in the center of each widget container and then selecting the widget you want from the list available. All of the report widgets available in previous software versions are available for use within the new report designer tool.



- 4) Change the appearance of the report or edit the container layout:



- 5) Save the report by click 'Finish Editing'.



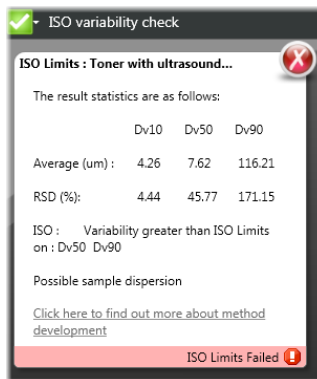
It is also possible to use a similar process to edit an existing report.

Note: The changes to the report designer framework mean that you will need to recreate any reports you used within previous software versions.

Updates Data Quality Calculations (v3.30)

The data quality calculations have been updated in v3.30 of the Mastersizer 3000 software in order to help you understand more about the results you obtain for your samples and optimize your methods.

In the past, running the ISO variability data quality calculation allowed the variability of the Dv10, Dv50 and Dv90 for your samples to be compared to the limits provided in ISO13320:2009. The software would then report a pass or fail for each parameter. The v3.30, this check is still carried out. However, if the variability for a given parameter is outside of the ISO13320:2009 limits, the software will provide advice as to why this may be the case. In the example below, all of the parameters are out-of-specification and the software correctly reports that this is due to changes in the state of dispersion of the sample:

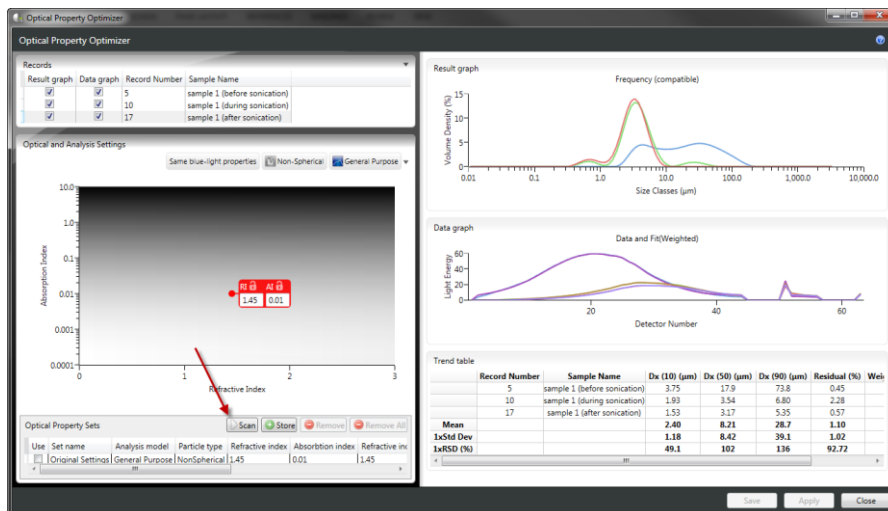


In addition to providing advice regarding the likely reason for result variability, the data quality tool now provides links to support documentation which may help you optimize your methods. In the above example a link is provided to a method development application note relating to liquid dispersion methods.

Optical Property Optimizer Scan (v3.30)

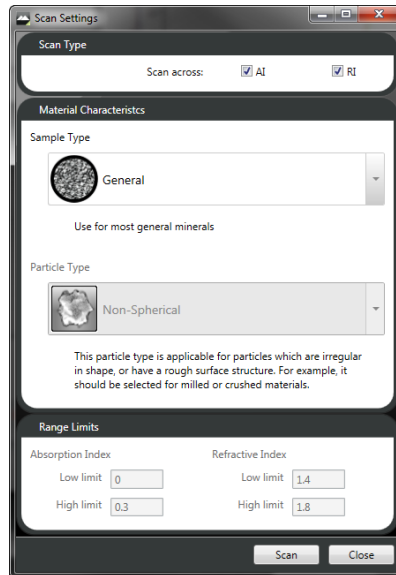
The Optical Property Optimizer (OPO) was introduced in v3.00 of the Mastersizer 3000 software, providing the ability to determine the robustness of results to changes in the optical properties. However, selection of the optical properties remained a manual task. In v3.30 we have therefore introduced a new optical property scan mode which is designed to provide guidance as to the optical properties which may be used in analyzing a sample.

To start an optical property scan, click the Scan button within the OPO interface:



Doing this will cause a Scan Settings Dialogue to appear where the following can be selected:

- Scan Type: select to scan the values for either the Absorption Index (AI) or Refractive Index (RI) or both.
- Sample Type: provides access to realistic optical properties ranges for different sample types. In addition, a 'Custom' option is available where it is possible to manually select the scan range.
- Particle Type: either spherical or non-spherical can be selected.
- Range Limits: provides the upper and lower limits for the AI or RI for the scan. These settings are automatically set if you select a specific sample type. If you select the 'Custom' option for the sample type then these values will be able to be edited.



Clicking OK causes the scan to start. During the scan process, you will see the optical property selection automatically update along with the data and result views. At the end of the process, the software will select a possible optimum set of optical properties for you to consider. This selection takes into account the fit between the optical model and the scattering data for your sample. It also considers the complexity of the particle size result.

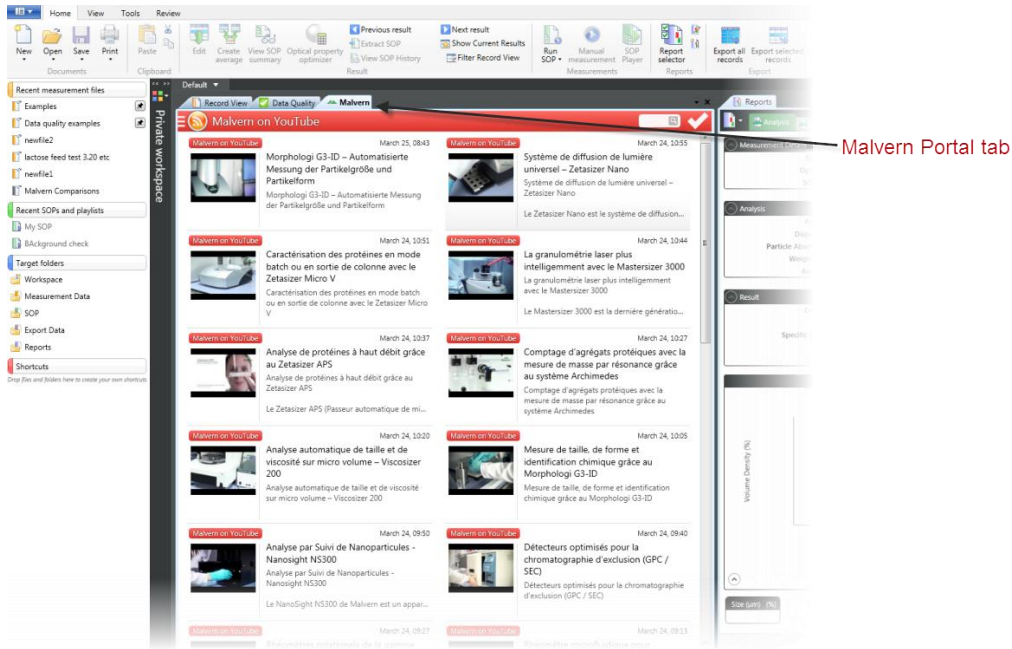
The success of the scan mode is very much dependent on the quality of the scattering data obtained for your sample. In addition, it is important to limit the scan to a range of optical properties which are realistic for the sample you are measuring. If you specify a very wide range for both the RI and AI then the analysis process is less likely to report a realistic result. Also, it is worth considering the particle size of your sample. For example, if you are working with large particles then the Fraunhofer scattering model may apply – in this situation the change in result as a function of changes in RI and AI will be small and the scan process may therefore not lock on to an optimal set of properties. The same is often true for very small particles as well.


Note: It remains important for you to consider the nature of your sample and investigate the likely optical properties you should select before using the scan mode, as this will ensure you can test whether the result returned is realistic.

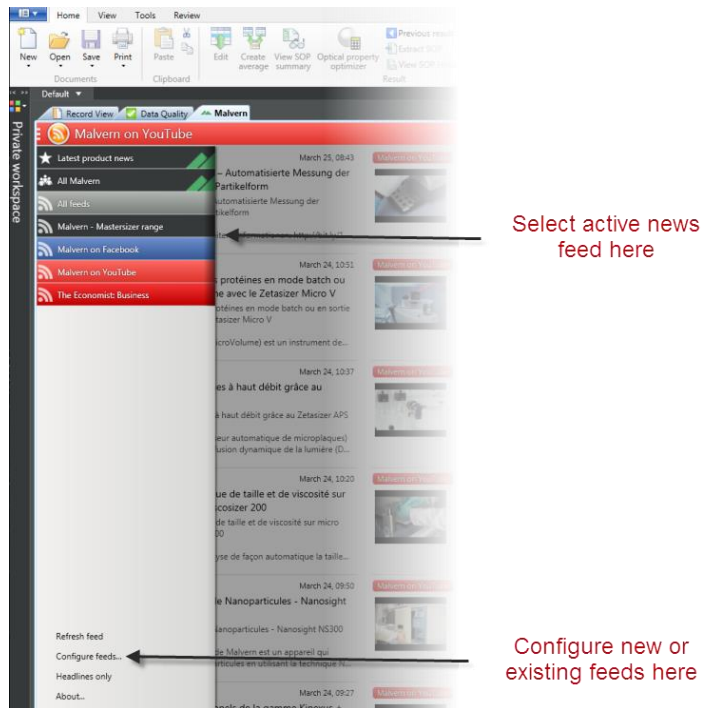
Malvern Portal (v3.20)

A new Malvern Portal tab has been developed for the Mastersizer 3000 application. This is designed to enable you to obtain direct access to information which can help you in using the Mastersizer 3000 system and software for new applications and routine measurements. The portal is accessed via a new '**Malvern**' tab within the application:

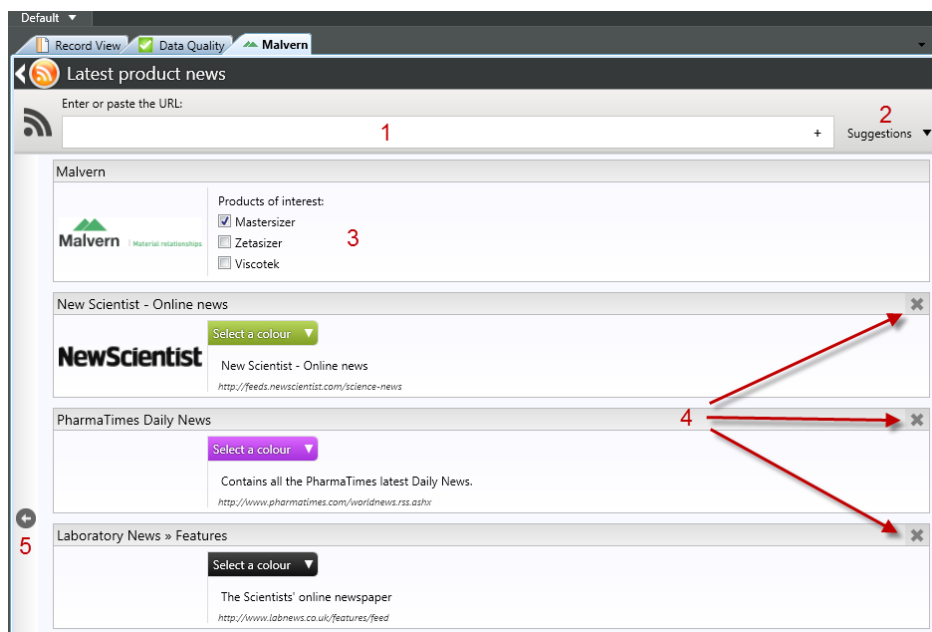
SOFTWARE UPDATE NOTIFICATION



The information presented within the portal is configured by clicking on the  icon. This will display a menu where the current news feed can be selected and new feeds added:



Clicking on the icon for any of the active news feeds will cause them to be shown in the main portal window. Clicking on **Configure Feeds...** provides access to the following options:



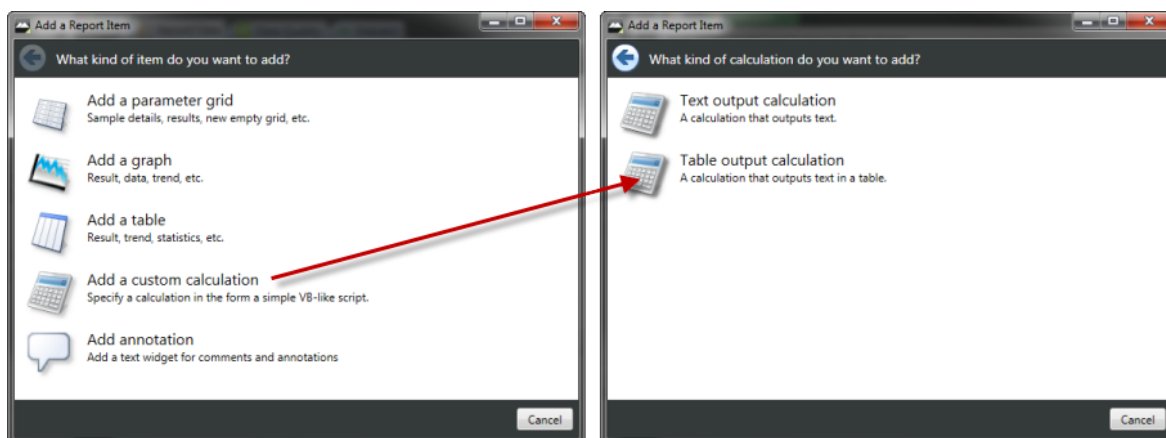
From within this window you can:

1. Enter or paste the URL for a web site RSS Feed which you would like to view within the portal application. This can be for any web site you like.
2. Access a list of suggested news feeds which we believe may be of interest to you.
3. Configure the news feeds from Malvern so that these only show information relevant to the product(s) you use.
4. Manage your existing news feeds and delete these if required.
5. Exit back to the portal application to view the news feeds you have configured.

By configuring the Malvern news feeds to only show information about your products, we hope that the portal will provide the best way for you to learn about new applications and obtain information about product and software updates. The ability to view other news feeds alongside the Malvern feeds should make the portal a useful place for learning about general scientific research and development as well.

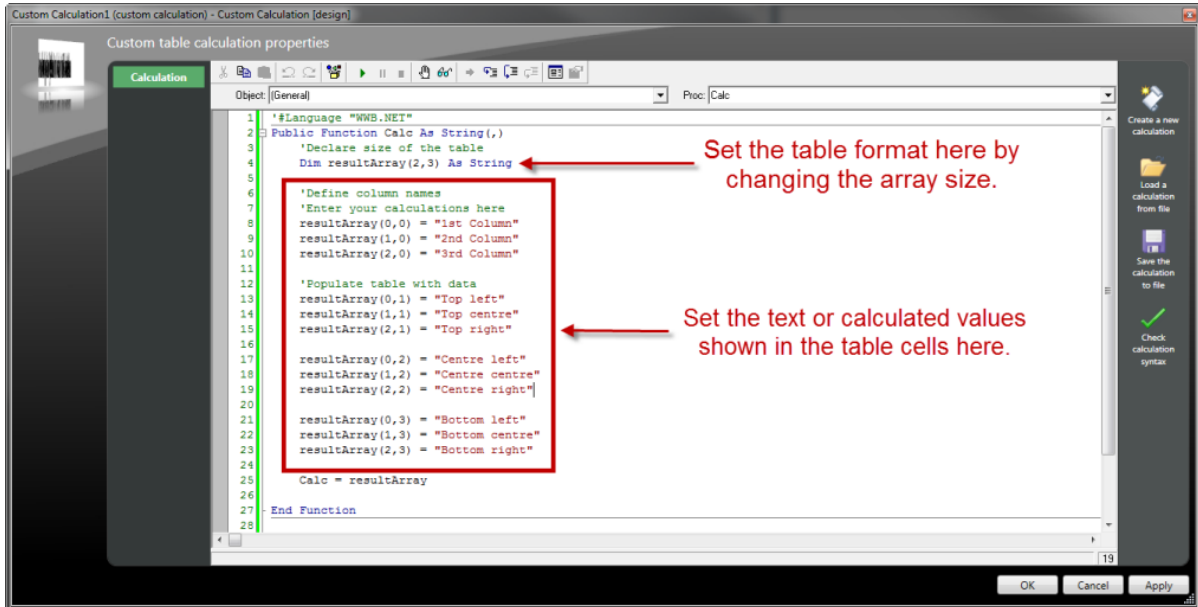
Output custom calculations to tables (v3.20)

It is now possible to output a custom calculation to a table in order to improve the formatting and legibility of the result:



SOFTWARE UPDATE NOTIFICATION

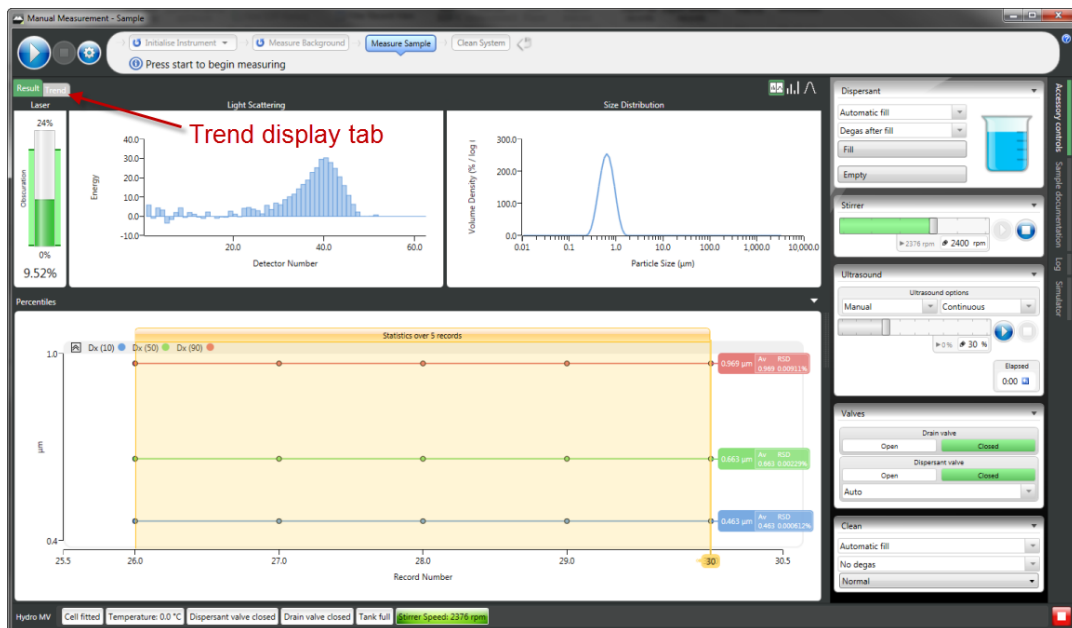
Selecting this option adds a custom calculation table widget to the report. The editor used to define the calculation is similar to that used for a text output calculation. However, instead of returning a single object, the calculation returns an array of objects which are used to fill a table:



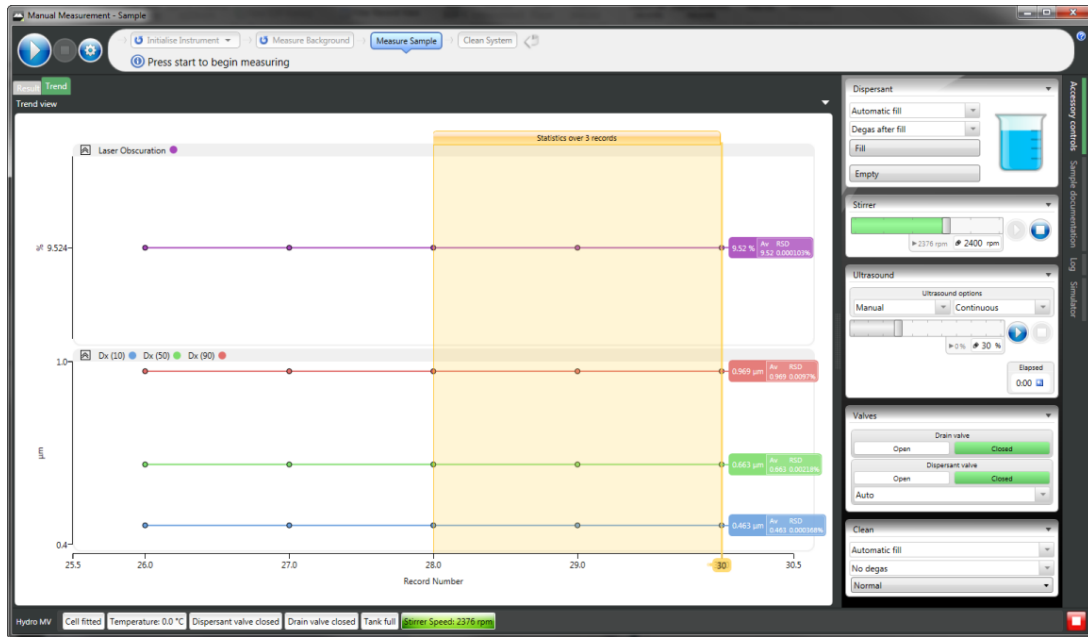
The format of the table is set by defining the size of a result array. Each element within the result array can then be assigned a text or calculated value as required.

New Trend Display View (v3.20)

Feedback from users suggested that the trend display view within the Measurement Manager can become too crowded if multiple trend plots are selected. As a result of this feedback, we have fixed the configuration of the main Measurement Manager view so that it only shows a trend for the calculated values for the Dv10, Dv50 and Dv90. Trend information for other parameters can then be viewed by clicking on a new **Trend** tab:



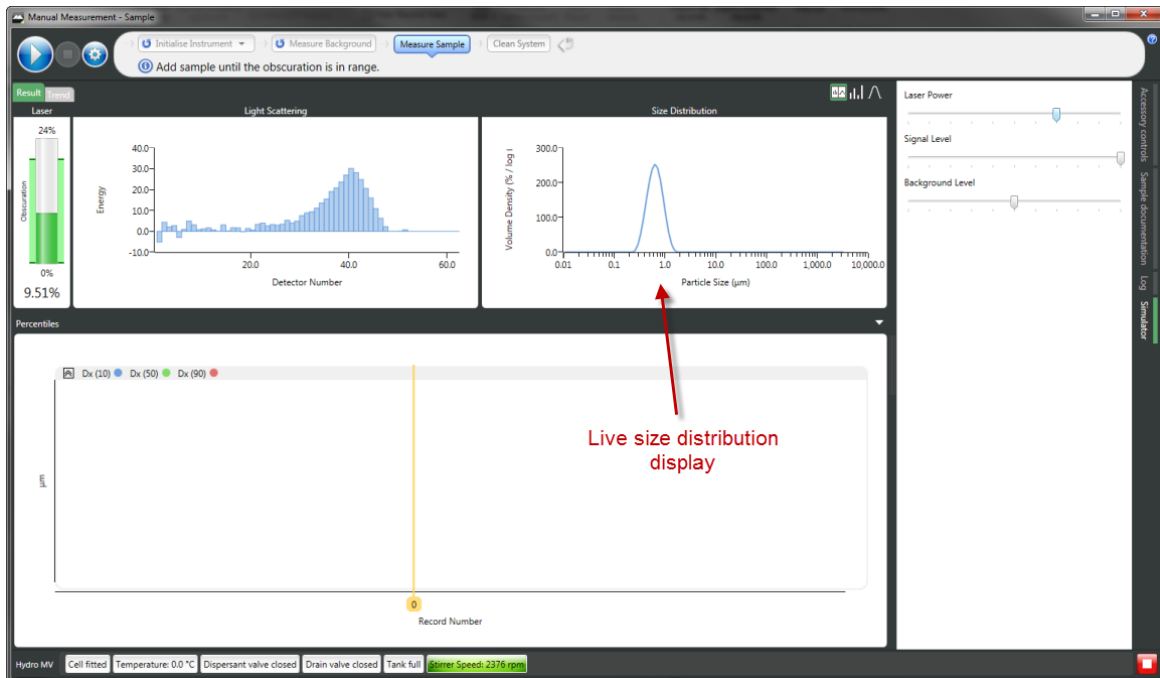
Clicking on the Trend tab causes the trend view to appear, where multiple trend plots can be configured and viewed:



Right-click on any of the trend graphs to add new parameters or create new trend plots.

Live Result Display (v3.20)

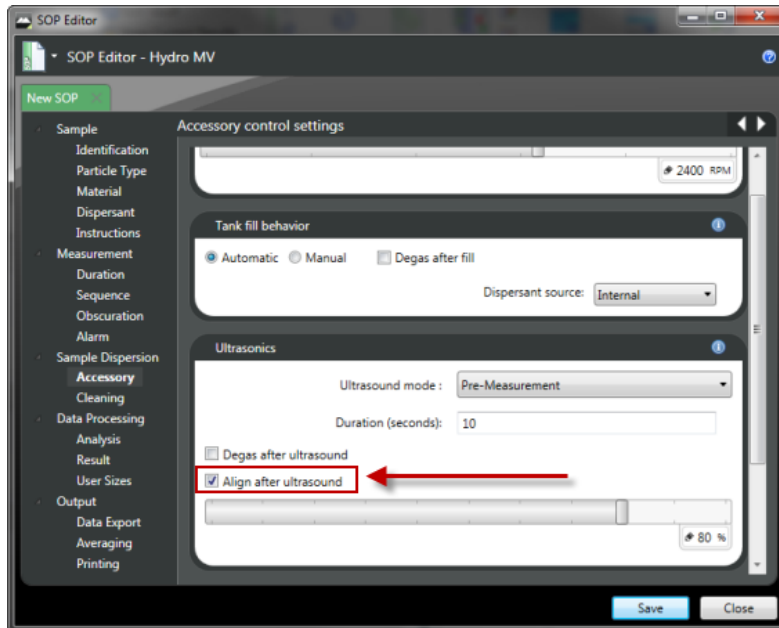
The software provided for previous Mastersizer instruments allowed users to view the size distribution of their sample during sample addition. This was updated in real-time as more sample was added to the dispersion unit. This feature has now been added to the Mastersizer 3000 software:



The current size distribution for the sample is shown during sample addition as soon as the sample obscuration is within the limits specified within the SOP / measurement settings. Note that the result displayed may be different to the final calculated result, as it is based on red-light scattering data only.

Re-align system following sonication (v3.20)

The temperature of the dispersant in the Hydro dispersion units increases in temperature during the application of ultrasound. In some cases this may cause a change in the alignment of the Mastersizer 3000 optical bench. As a result of this, a new option has been added to Hydro unit SOPs which enables the system to re-align following pre-measurement sonication:



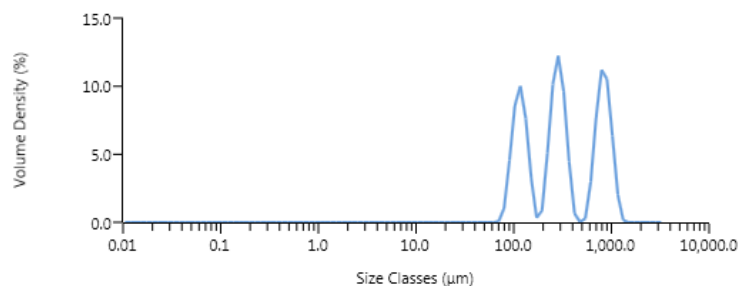
This option may be useful to you if you sometimes see a mode of large particles reported within the size distribution for your sample which is not believed to be present.

Mode reporting parameters (v3.20)

A set of parameters are now available for the records view and reports which enable the position and percentage in each mode of a size distribution to be reported. These parameters are:

- **Mode**: provides the mode of the distribution (size band containing the highest population)
- **Mode [significance]**: reports the position of each mode, where the 'significance' is in the number of the mode where Mode [0] is the mode containing the largest volume of material, followed by Mode [1], Mode [2]...up to Mode [n],
- **Mode Percent [significance]**: reports the percentage in each mode.

As an example, here is the size distribution for a sample containing three modes:



For this distribution the Mode, Mode [significance] and Mode Percent [significance] parameters report the following:

Mode Percent [0] 36.03 %	Mode [0] 288 μm
Mode Percent [1] 34.43 %	Mode [1] 841 μm
Mode Percent [2] 29.54 %	Mode [2] 117 μm
Mode 288 μm	

Note that the Mode and Mode [0] parameters report the same value as they both relate to the most significant mode.

GAMP 5 Software Categorization

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.

The Mastersizer 3000 software provides users with the ability to modify the results reported by the system to fit a user's specific application requirements. This is achieved through the use of custom calculations within reports and also through the application of emulation factors as part of the analysis settings. Given this, the software should be considered to be a Category 5 software package. Users are therefore encouraged to specifically validate the custom calculations and emulation factors applied within SOPs, 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.

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. Gap analysis documents are also provided which 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.
- **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 Malvern Instrument certificates for ISO9001:2008, ISO14001 and OHSAS 18001:2007.
- **QAS Measurement Procedures:** copies of the Malvern Quality Audit Standard data sheets and procedures.
- **Software Certificates of Conformance:** copies of the software certificates of conformance for all Mastersizer 3000 software versions.
- **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.**

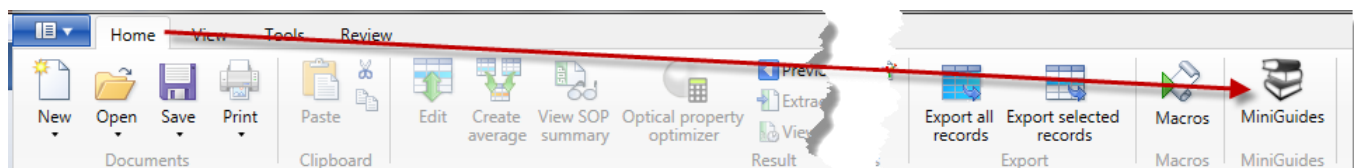
Sharing a License for Mastersizer 3000E users

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.

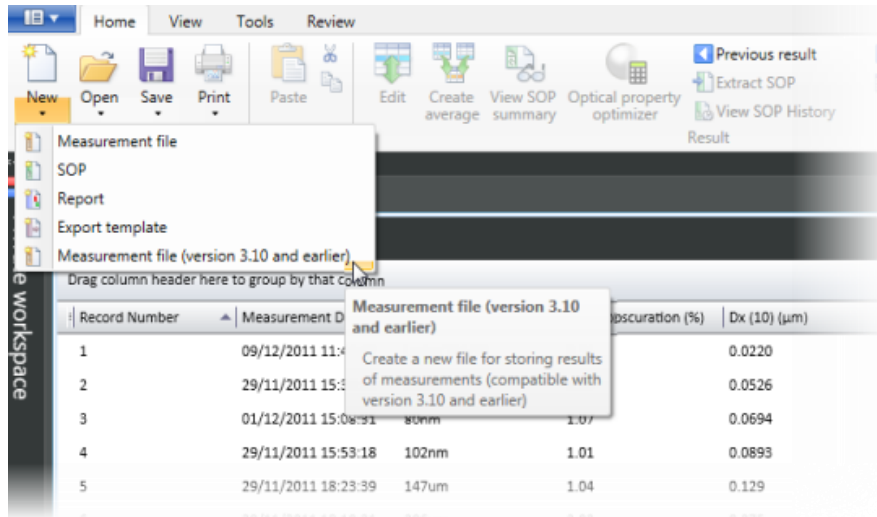
Software Guides

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:



Measurement File Format

In v3.20 of the Mastersizer 3000 software we have introduced a new measurement file format which is designed to be more resilient to possible file corruption errors. As a result of this, measurement files created within v3.20 cannot be opened using earlier software versions. If you need to share data with users of systems where an older software versions are in use then you will need to first create a new measurement file which uses the older file format (**Measurement file (version 3.10 and earlier)**):



You will then need to copy your measurement records into this new file and save it. This file will then be able to be read using earlier software versions.

Note that v3.20 is able to access all measurement files created in earlier software versions.

Measurement File Size and Corruption Warnings

As well as improving the resilience of measurement files to possible corruption, v3.20 of the Mastersizer software also 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.

New Features List

Version 3.30 of the Mastersizer 3000 and 3000E has been developed to provide users with a new report designer which is designed to improve the layout of reports. In addition, the software includes the following new features:

Reference(s)	Feature
45944	Enable SOPs to be saved to directories where the 'no delete' permissions is set
45795 45796	Implement automatic scan function for the Optical Property Optimizer *
45471	Add Hyperlinks to Data Quality Widgets, so that links can be made to support documents *
44947	Remove zoom limits on graphs in order to make the graphs easier to read
36589	Remove range edit boxes from x and y axis following a zoom action in order to make the graphs easier to read
36608	Update data quality calculations *

SOFTWARE UPDATE NOTIFICATION

38537 Provide data quality feedback on the use of fine powder mode

*See the Headline New Features section above for more information.

Version 3.30 also includes features which were released in v3.20. This version was developed to support the Aero M dry powder dispersion accessory for use with the Mastersizer 3000E. The other new features provided in v3.20 are listed here, as this version was not released via the Malvern Instruments website:

Reference(s)	Feature
42727	Improve the descriptions for the available Hydro MV and Hydro LV dispersant fill options.
42137	Improve descriptions for the Aero S sample trays.
42255	Provide the ability to show videos directly within the Miniguides tool.
41898	Improve the wording used with the analogue level sensor calibration procedure of the Hydro LV and Hydro MV.
38535 40882 41180	Implement a new file structure and file handling methods which are more resilient to possible file corruption (see the Measurement File Format section above for more details).
40609	Output custom calculation to a table. *
38528	Show null value for particle optical properties when the Fraunhofer particle type is selected.
40194 40195	Provide a new configurable trend display view within the measurement manager. *
37713	Use different symbol style for the data sets shown in over plots.
36584	Add the new Malvern Portal application into the Mastersizer 3000 software. *
35535	Add the ability to re-align the system following pre-measurement ultrasound. *
35614	Allow the percentage of sample in each mode to be reported as result parameter. *
35658	All measurement averages to be exported as part of an SOP measurement sequence.
35862	Add an advanced option to change the optical properties applied when calculating a result using the Mastersizer 2000 mimic analysis.
31204	Show a live particle size result in measurement manager during sample addition. *
31748	Change import for Mastersizer Micro (*SAM) measurement files to support Extended ASCII.

*See the Headline 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	Comment
37107	Some method parameters not included in SOP summary report.	Improved
37689	Program exception is reported when printing.	Fixed
42468	Timed and pulsed sonication times for manual wet measurements are reported incorrectly due to time input formatting problems.	Fixed
42659	'Dry Dispersion' shown as a dispersant option for wet measurements.	Fixed
42946	Result and scattering data view buttons are not always visible in the measurement manager window.	Fixed
45237	Ultrasound status read back can report incorrect values.	Fixed
46413	21CFR Part 11 workspace permission does not prevent users being able to change folder paths.	Fixed
45891	Stirrer speed does not return to the correct level following a clean cycle.	Fixed
47597	Analysis result may change on reanalysis depending upon whether a model is already generated.	Fixed

In addition, this version of software includes the following fixes which were released in v3.20. These are listed here as v3.20 was not released via the Malvern Instruments website.

Reference(s)	Issue	Comment
34144	Aero accessory controls to not respond correctly to rapid changes to the air pressure setting.	Fixed
37199	Hydro dispersion unit level sensor can be falsely triggered.	Improved
37554	The demanded speed level for the Hydro SV drops which the control knob is turned quickly.	Fixed
38080	Audit trail archive file is not easy to read.	Fixed
38256	The software crashes if it cannot obtain the MAC address of the PC when the software starts.	Fixed
38264	Cannot connect to a manual liquid dispersion unit if an automated liquid dispersion unit is connected to the Mastersizer 3000 unit.	Fixed
38503 41560	The Hydro unit stirrer speed does not return to the correct level following a clean cycle.	Fixed
38521	Firmware download occurs multiple times when the software is updated	Fixed
38716	Changing the sample identifiers during measurement may cause the software to crash.	Fixed
40133	Audit trail archive is overwritten when the software detects it has been tampered with.	Fixed
40134	Accessory connection flickers, causing the firmware download to fail.	Fixed
41143	Tank fill errors reported for the Hydro LV, especially during a clean sequence.	Fixed
41518	A background alarm is raised event when background is good.	Fixed
41564	Save button not enabled for the SOP settings dialogue.	Fixed
41608	Hydro unit stirrer speed sometimes changes during the running on an SOP.	Fixed

41703		
44783	The Hydro EV stirrer switches on at an incorrect point during a clean cycle.	Fixed
45132		
41767	Accessing the compare SOP function from the shared files tab within the records view can cause the software to crash.	Fixed
41794	The software sometimes crashes when reports are edited.	Fixed
41912	The graphs in the measurement manager do not display axis values or labels.	Fixed
41974	Measurement files fail to load when the data they contain is partially corrupted.	Fixed
42110	Analysis of Mastersizer 2000 records fails if a new analysis model is required.	Fixed
42406	The ultrasound time set in the SOP settings is incorrectly interpreted in some cases.	Fixed
44207	Aero S clean cycle fails for some SOPs.	Fixed
44420	One of the source results used to calculate an average may disappear from the records view when calculating averages with the 'show current results' option enabled.	Fixed
44523	Software crashes when importing Mastersizer Micro measurement files created using non-English character sets.	Fixed
44784	The SOP measurement sequence pauses at the background stage when this is not required.	Fixed
44841	Measurement files created using a software installation with 21 CFR Part 11 mode enabled are not shown as read-only when viewed using a software installation which is installed outside of 21 CFR Part 11 control.	Fixed
44974	It is currently possible to try and save read-only measurement files, causing the software to crash.	Fixed
45536	The ultrasound transducer sometimes fails to switch on correctly when using the Hydro MV, LV or EV dispersion units.	Fixed
45882	The software fails to ask users if they want to save their measurement file changes when the File->Close menu option is selected.	Fixed

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.

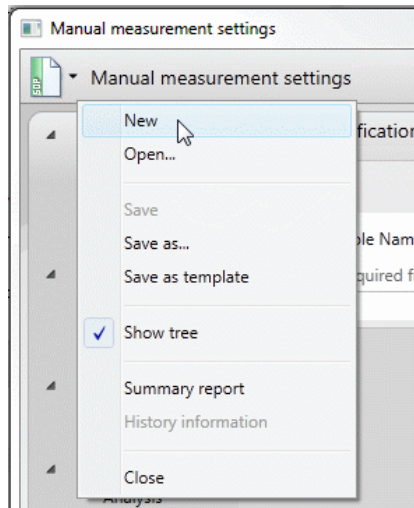
Issue	Work Around	Comment
Some text still appears in English when running with a different language selected.	The translation of all software text will continue in future releases.	Low risk issue
Software does not open all files selected when they are opened using Windows Explorer.	Use the Open menu 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

SOFTWARE UPDATE NOTIFICATION

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, use a USB 2.0 port instead.	Intermittent Observation
Wet accessories can go into standby mode unexpectedly when switched on for a long period of time (>24hrs).	When this happens, stop all measurements and then select the Manual Measurement, SOP Measurement, or Accessory Control options to reactivate the accessory.	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
SOPs load slowly from the SOP selection dialog	The SOP selection dialog may load slowly if you have stored many SOPs in the default SOP folder. A fix for this issue will be implemented in a future software release. In the meantime, if you group your SOPs into sub-folders, then the dialog will only attempt to load SOPs for the selected folder. This will speed up the operation of 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. This may be fixed in a future software release.	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	The manual measurement feature of the software stores the last used settings. This includes configuration of your Aero, .e.g. hopper. If you change the configuration of your aero, then open manual measurement, it will immediately complain that the configuration is wrong. If this happens, close and re-open the window if necessary such that you can see the settings dialog, change settings to match your new Aero configuration, then reset the measurement.	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.

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.

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	<p>Shared workspace: C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins</p> <p>Private workspace: C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins</p>	No control required as the data quality tool only provides advice.

SOFTWARE UPDATE NOTIFICATION

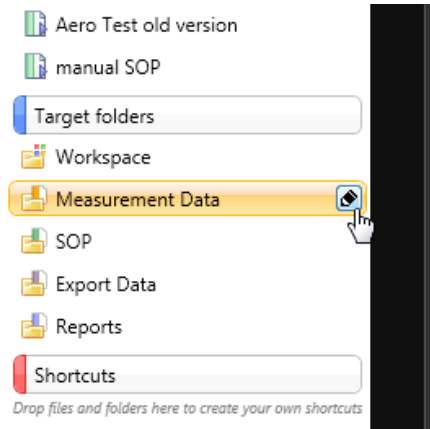
Export data	.txt .csv .rtf	<p>Shared workspace: C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Export Data</p> <p>Private workspace: C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Export Data</p>	If data export is a critical part of the SOP used for your samples then you should prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Measurement data	.mmes	<p>Shared workspace: C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data</p> <p>Private workspace: C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data</p>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Reports	.mrep	<p>Shared workspace: C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Reports</p> <p>Private workspace: C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Reports</p>	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>Shared workspace: C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template</p> <p>Private workspace: C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template</p>	No control required.
SOP	.msop	<p>Shared workspace: C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\SOP</p> <p>Private workspace: 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>Shared workspace: C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Template</p> <p>Private workspace: C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Template</p>	No control required.
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:

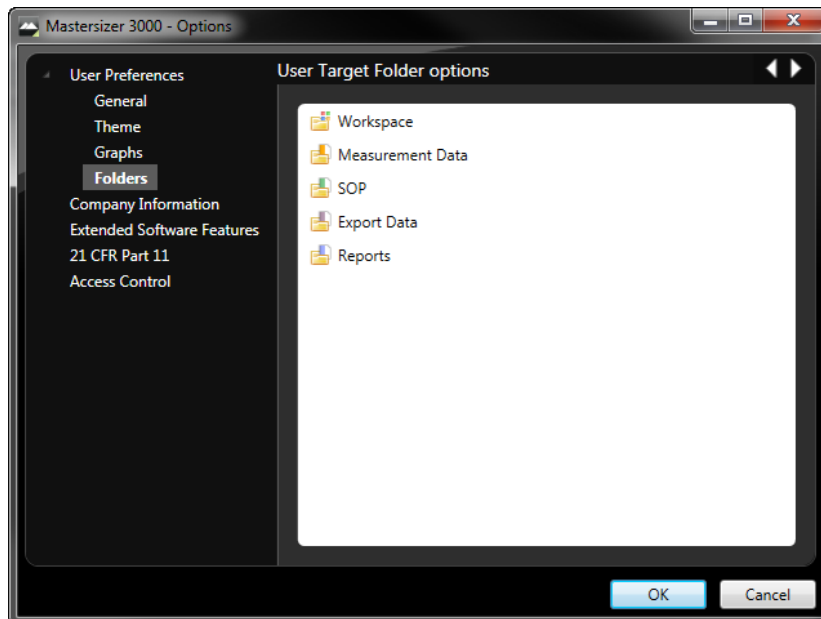
- SOP
- Measurement Data
- Reports
- Export Data

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.

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	Unable to load or generate a scattering matrix.
7	
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	Could not find any particle size distribution modes in the result.
22	
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	Scattering matrix calculation settings errors detected.
42	
43	Error occurred while generating the scattering matrix.
45	Matrix generation is currently busy.

Malvern Instruments Ltd

Enigma Business Park • Grovewood Road
Malvern • Worcestershire • UK • WR14 1XZ

Tel: +44 (0)1684 892456

Fax: +44 (0)1684 892789

Malvern Instruments Worldwide

Sales and service centers in over 50 countries
for details visit www.malvern.com/contact

© Malvern Instruments Ltd 2015

more information at www.malvern.com