SOFTWARE UPDATE NOTIFICATION
MASTERSIZER **3000** SOFTWARE v3.10: PSS0223-15

PARTICLE SIZE

Introduction

This document details the release of software PSS0223-15: version 3.10 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 run using Windows 8 Enterprise, it has been fully tested under Windows 7. Windows 7 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.

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 USB port
Operating System	Windows 7 (32 bit and 64 bit) Windows 8 Enterprise (64bit)

Table 1: Minimum system requirements for the Mastersizer 3000 software.

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.

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.

If you are installing the MAC software on a Windows XP system then you must make sure that the Microsoft .NET framework 3.5 is installed first. To install this, navigate to the ***\Malvern Access Configurator*** folder and run the **dotNetFx35setup.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.

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.

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.

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.**

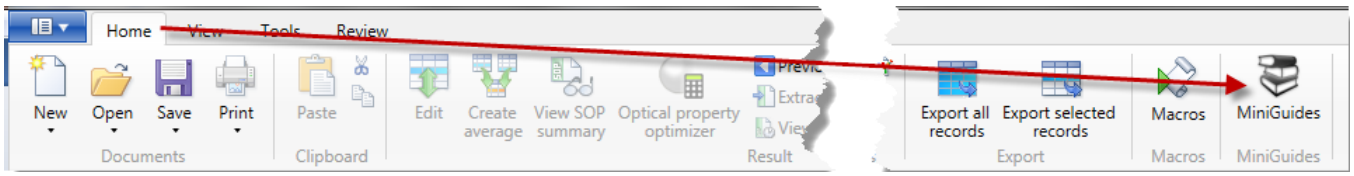
Sharing a License for Mastersizer 3000E users

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

Version 3.10 of the Mastersizer 3000 and 3000E has been developed to support the new Hydro SV small volume sample dispersion unit. In addition, the software includes the following new features:

Reference(s)	Feature	Comment
10509 **34886**	Provide the ability to select the dispersant source used for Hydro MV and Hydro LV measurements.	Implemented
27394	Provide option to switch off access to private workspaces from the program options, in order to make the software operate more like the Mastersizer 2000 software.	Implemented
28044	Show the last two SOP versions and current version only in SOP history tool, and provide an option to enable other versions to be displayed if required.	Implemented
29014	Provide a delay prior to aligning the system during an SOP measurement in order to ensure that the dispersant is thermally equilibrated before the measurement process starts.	Implemented
29355	Allow a software licence to be updated or replaced from within the software.	Implemented
29536 **36505**	Change the stirrer speed to an "idle" speed after a long period of inactivity within the measurement manager.	Implemented
29606	Allow system administrators to change the storage location for audit trails when 21CFR Part 11 mode is enabled.	Implemented
30669	Include the measurement file path and instrument serial number in footer of reports.	Implemented
30925	Wrap legend labels rather than clipping them when printing report graphs.	Implemented
32374	Provide the ability to print to PDF as single document.	Implemented

32805	Improve the robustness of the vacuum detection procedure used during Aero S measurements.	Implemented
32974	Show an exclamation mark next to the advanced button on the analysis settings SOP page when the advanced settings have been changed.	Implemented
33367 **36469**	Provide the ability to set a background alarm within an SOP, so that the user is warned if the measurement cell needs to be cleaned.	Implemented
34035	Show the name of the dispersion unit in the SOP editor window title bar.	Implemented
34037	Provide access to batch printing from the records view.	Implemented
34060	Provide auditing for SOP creation in 21CFR Part 11 mode, such that it is possible to identify who created or edited an SOP, the reason for the change and when the change occurred.	Implemented
34818	Improve the clarity of the permission names referenced within the Malvern Access Configurator application for the Mastersizer 3000 software.	Implemented
35558	Report particle size distribution mode positions as a record parameter.	Implemented

More details on the use of these new features are provided in the New Features Description section towards the end of this document. 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

The main issues fixed in this release of the Mastersizer 3000 and 3000E software are listed below.

Reference(s)	Issue	Comment
31345	Automatic upgrade of the optical bench and accessory firmware sometimes does not occur successfully following a software upgrade.	Fixed
32198	Adding text to a report causes the text entry to be duplicated.	Fixed
32575	Custom calculation parameters are not printed on reports when printing is requested as part of an SOP.	Fixed
33483	Software may crash if printing doesn't complete with approximately 30 seconds.	Fixed
33548	The stirrer speed is sometimes not changed to match the SOP demand speed.	Fixed
33973	The ability to add new parameters to a trend chart in the measurement manager is no longer available.	Fixed
34039	In the result emulation spreadsheet, the 're-calculate' button is not working.	Fixed
34073	The sample name specified at the start of an SOP Player sequence is not always applied to all records created during the sequence.	Fixed
34095	Imported Mastersizer S results are displayed using an incorrect graph interpolation method, causing the reported results to differ from those reported in the Mastersizer	Fixed

	S software.	
34584	The Mastersizer 3000 analysis periodically fails, causing a record which does not contain any particle size distribution information to be stored.	Fixed
34805	The ability to enable and disable electronic signatures should not be able to be controlled via the Malvern Access Configurator application.	Fixed
34810	A 'failed to acquire snap data' error is reported during measurements, especially during clean sequences.	Fixed
34922	Empty measurement files can be created when accessing the data quality tab when measurements are being made.	Fixed
35153	Spelling errors exist on the PV certificates produced by the software.	Fixed
35586	Selecting manual fill for the Hydro LV clean sequence can crash the software.	Fixed
35603	When the advanced analysis settings are edited to use enhanced sensitivity mode, the analysis sensitivity is incorrectly reported as 'NormalPlus'.	Fixed
35604	Copying raw data from a histogram graph causes the software to crash.	Fixed
35612	The SOP editor crashes when saving SOPs where ASD, GSD, Kurtosis or Skew have been selected for data export.	Fixed
35613	The Hydro dispersion unit stirrer start/stop controls are disabled after the sample tank is emptied.	Fixed
35660 **36117**	Decimal values are displayed incorrectly in some graphs, particularly within the Optical Property Optimizer tool. This can cause the software to crash.	Fixed
35756	The save button in the SOP editor acts the same as close and does not automatically save the SOP file.	Fixed
35761	Users are prompted to save an SOP file twice when using the SOP save option.	Fixed
35811 **36965**	The analysis sensitivity reported for imported Mastersizer 2000 records is incorrect.	Fixed
35876	Result Emulation and Extend Result should not be available for emulated MS2000 results, as these options can cause the software to crash.	Fixed
36069	The measurement cell will sometimes not load correctly.	Fixed
36414	It is not possible to extract the SOP settings from the SOP Version History window.	Fixed
36664	The force saving option can be circumvented in 21CFR Part 11 mode.	Fixed
36863	The stirrer speed for Hydro dispersion units is sometimes reset to 500rpm during an SOP.	Fixed
36963	Some unsupported features are listed in the SOP summary view.	Fixed

37197	The level sensor can sometimes be too sensitive, causing the Hydro MV and Hydro LV clean sequences to fail.	Fixed
37325	Using the Optical Property Optimizer for data in a read only file can cause the software to crash.	Fixed

Known Issues

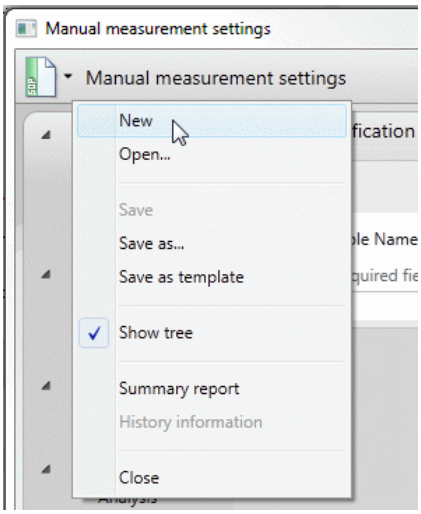
The following software bugs have been discovered within the software, and will be investigated as part of a future release. Please follow the suggested work-around for each issue when operating the software.

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.	Software Bug
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.	Software Bug
Reports occasionally appear blank or empty even when the record selection in the Records View changes.	Adjust the report zoom slider in the bottom right-hand corner of the report window to refresh the display.	Intermittent Software Bug
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.	Software Bug
The System Audit 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.	Software Bug
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.	Software Bug
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.	Software Bug
The manual measurement settings do not match the connected/active dispersion unit.	See know issue description below.	Intermittent Software Bug
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 Software Bug

Wet accessories can go into standby mode unexpectedly when switched on for a long period of time.	When this happens, stop all measurements and then select the Manual Measurement, SOP Measurement, or Accessory Control options to reactivate the accessory.	Intermittent Software Bug
A firmware update failure is occasionally reported when the software is started for the first time.	If the upgrade process fails then simply restart both the software and the instrument bench. The firmware should then update successfully.	Intermittent Software Bug
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 Software Bug
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.	Software Bug
Reports don't print correctly when many records are selected	You may find that some reports do not print correctly when more than 40 records selected are selected. This will be fixed in a future software release.	Software Bug
Some parameters 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.	Software Bug

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	**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	Prevent deletion of the files in this directory. However, read, write and modify access must

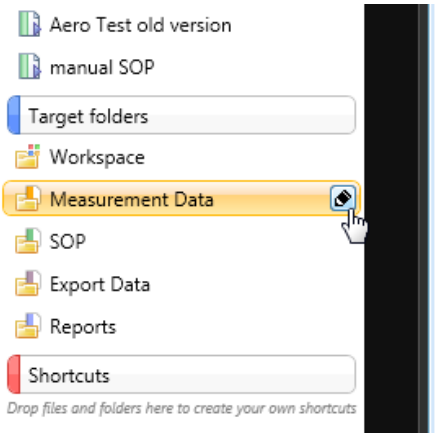
		3000\ Workspace\Reports **Private workspace:** C:\Users*{user_name}*\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Reports	be maintained. Note: it is important that users are prevented from deleting reports via the software interface as well. This can be done using the MAC application.
SOP 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.
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:

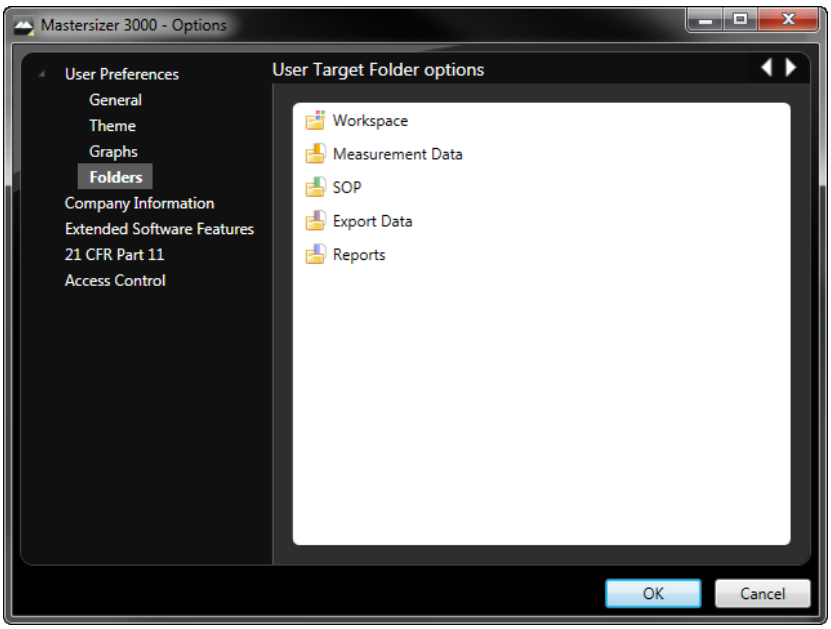
- SOP
- Measurement Data
- Reports
- Export Data

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.

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.

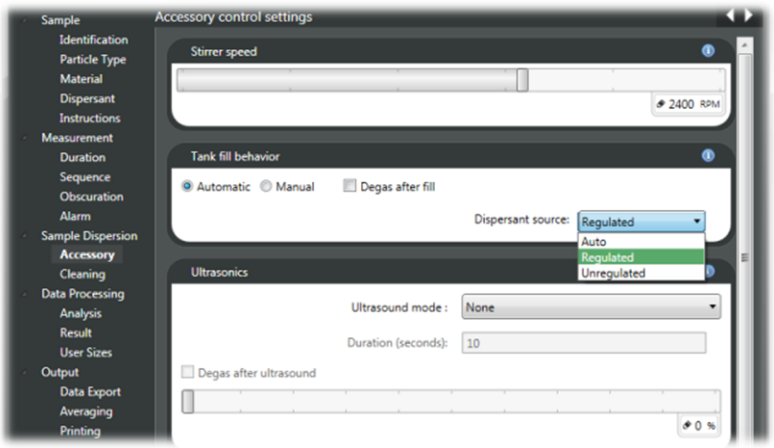
Note: The documents provided on the software CD are those which were current at the date the software was released. Please contact your local Malvern representative if you need to verify if any updated documents are available.

New Features Description

Dispersant Source Selection

The Hydro MV and Hydro LV dispersion units are provided with two dispersant inlets: a regulated dispersant inlet which is designed to be used with pressurized dispersant sources such as mains water and an unregulated dispersant inlet which is designed to work with unpressurised dispersant sources such as organic dispersants. In addition to this, the units can be used with an external switching box to enable a pump to be controlled to supply dispersant via the unregulated dispersant inlet.

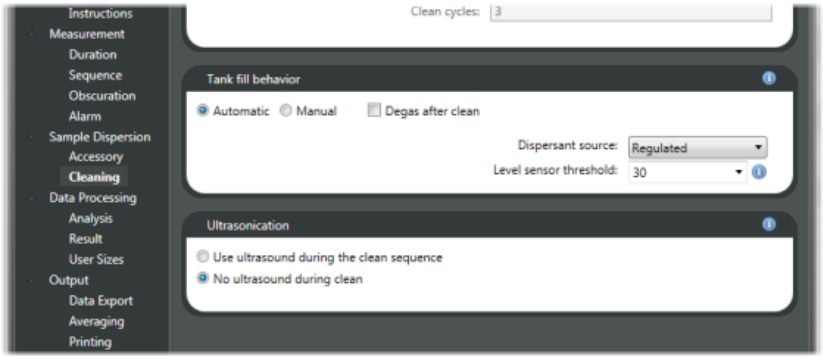
In previous versions of the software there was not possible to control which dispersant inlet was used for measurements. In v3.10 this capability has been added, enabling the dispersant inlet used for tank filling (measurement) and cleaning to be configured. The tank filling options are configured via the **Tank fill behavior** section within **Sample Dispersion->Accessory** SOP settings:



Three options are available:

- **Auto**: selecting this will cause the software to operate as in previous software versions. Select this if you do not want to specifically control which dispersant inlet is used.
- **Regulated**: selecting this will cause the software to demand dispersant via the regulated inlet. The software will not trigger an external pump to supply dispersant via the unregulated dispersant inlet in this mode.
- **Unregulated**: selecting this will cause the software to send a signal to an external pump (if installed) in order to supply dispersant via the unregulated inlet. The software will not open the regulated dispersant inlet in this mode.

In addition to the above options, the dispersant used for cleaning operations can also be configured via the **Tank fill behavior** within the **Sample Dispersion->Cleaning** options:



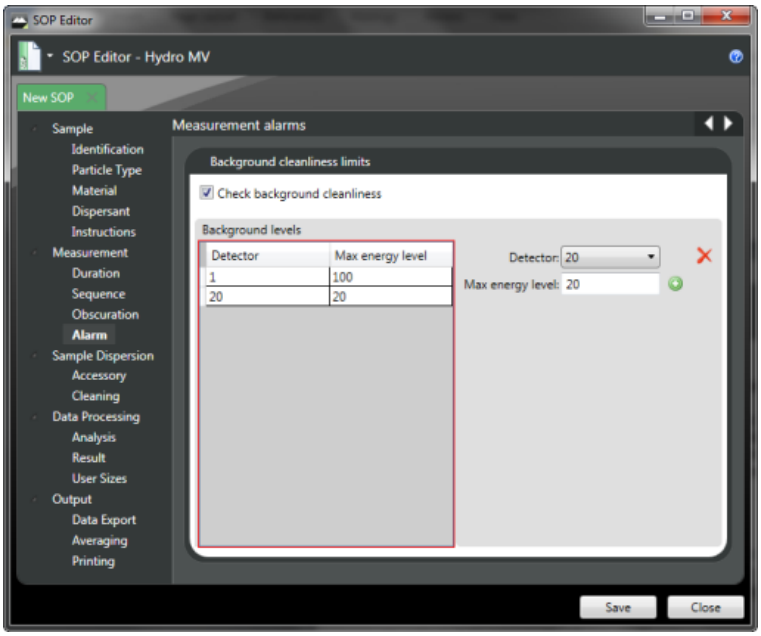
The same options are available for cleaning as for the tank fill options.

Together, the tank fill and cleaning options enable users to select one dispersant for measurements and one for cleaning. The dispersant selected for measurements is used for the final tank flush and fill during the clean sequence. This could, for example, be set-up to supply a dispersant which contains surfactants or other additives required to ensure sample stability during measurements. All other flash and fill operations carried out during the accessory clean sequence will use the dispersant selected within the cleaning options. This could, for example, be set to be mains water.

Background Alarm Settings

The light energy level observed for each detector during a background measurement is indicative of the cleanliness of the Mastersizer 3000 measurement cell. If the cell is clean then the background energy level will be low, with the maximum value observed for all detectors being no more than 100 light energy units. If the background is higher than this it may indicate that the measurement cell needs to be cleaned.

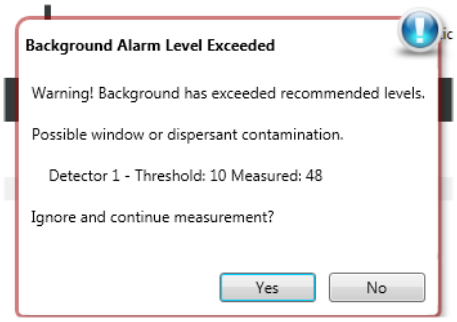
In order to help users identify whether the measurement cell needs to be cleaned, it is now possible to set acceptance levels for the background as part of the SOP settings. These are configured within the **Measurement->Alarm** section of the SOP settings:



The background alarm is enabled by checking the '**Check background cleanliness**' option. Doing this enables users add maximum allowable light energy levels for any detector to the **Background levels** table. To enter a new alarm level, first select a detector and then add the maximum energy level within the edit box. Then, click the **+** button to add the alarm level to the table.

Cleanliness is best monitored by setting alarm levels for the lower number (low angle) detectors. The acceptance levels applied will be applications dependent.

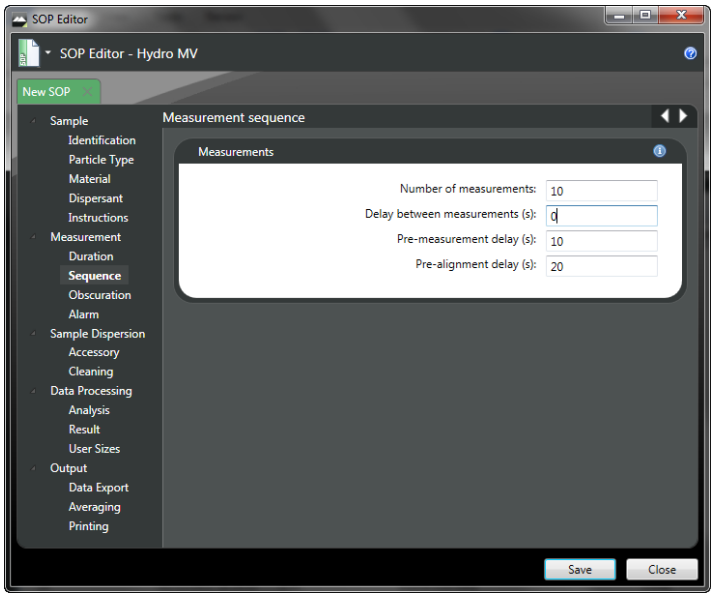
If the background cleanliness alarm is enabled, the software will check the measured background against the values in the background level table during the measurement process. If the specified level is exceeded for any detector then the following warning will be given to the user:



Users have the option to continue the measurement and accept the high background or to stop the measurement process and clean the system.

Pre-Alignment Delay

It is now possible to pause an SOP measurement before the system is aligned. The length of this pause is set using the **Pre-alignment delay** option which is included within the **Measurement->Sequence** section of the SOP settings:



Adding a pre-alignment delay may be helpful to users measuring samples in volatile liquid dispersants, as it provides time for the dispersant to thermally equilibrate prior to the measurement process starting.

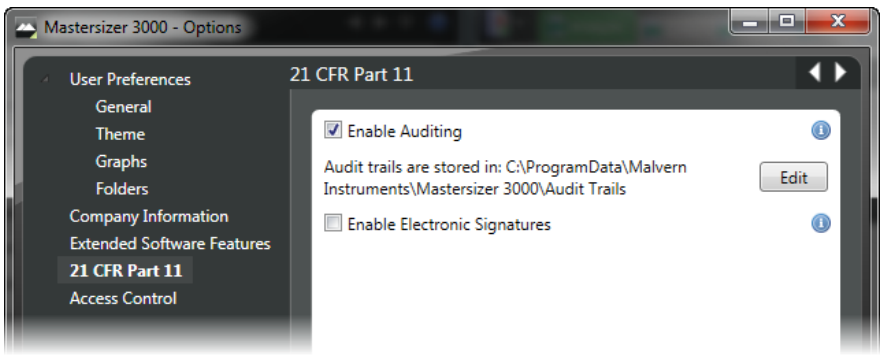
SOP Auditing

Improved auditing of SOP changes is now provided when the software is operated in 21CFR Part 11 mode. Any changes applied to an SOP will require a reason for change to be provided when auditing is enabled. The reason for the change, the identity of the user who applied the change and the date and time of the change is then stored within the SOP. This information can then be viewed within the SOP History view:

Audit Trail				
Date Modified		19/08/2014 19:47:48	19/08/2014 19:48:27	19/08/2014 19:58:21
Username		MIL\PKippax	MIL\PKippax	MIL\PKippax
User SID		S-1-5-21-623434881-1009198268-2996851928-1296	S-1-5-21-623434881-1009198268-2996851928-1296	S-1-5-21-623434881-1009198268-2996851928-1296
Computer Identifier		mil.local.UKREMPKIPPAX2	mil.local.UKREMPKIPPAX2	mil.local.UKREMPKIPPAX2
Reason for Change		Sop created.	Increased background measurement time to improve measurement stability.	Modified measurement time and triggering options to improve measurement robustness.

Audit trail Location

If auditing is enabled within 21CFR Part 11 mode, all system activities (e.g. software start-up) are logged in an audit trail file. By default, this is stored on the computer running the Mastersizer 3000 software. However, it may be useful to change the storage location for this audit to a server location in order to facilitate automatic data backup. An option to change the audit trail location has therefore been included in v3.10 of the Mastersizer 3000 software. This is configured from the 21CFR Part 11 section of the program options:



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