SOFTWARE UPDATE NOTIFICATION
MASTERSIZER **3000** SOFTWARE v3.00: PSS0223-14

PARTICLE SIZE

Introduction

This document details the release of software PSS0223-14: version 3.00 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 XP Professional and 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

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- 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 USB 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.

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

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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.

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> **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:
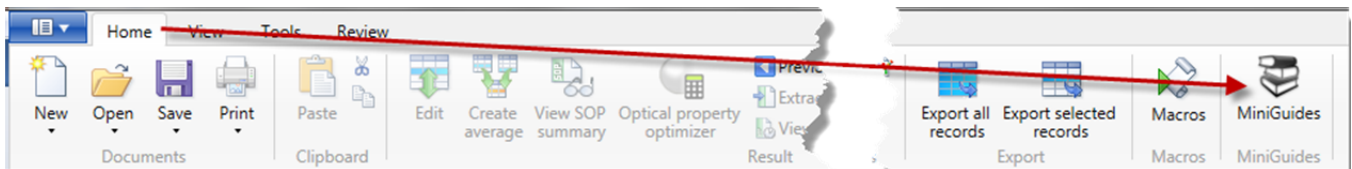
New mini-guides are available in v3.00 of the software, which provide videos covering the following topics:

- Data quality:
    - o How to use the data quality tool to check your measurement data or assess the variability of your results.
    - o Understanding what negative data is, and how it can be avoided.
    - o Recognizing if your system needs cleaning by looking at the background light scattering data recorded during a measurement.
- Software Hints:
    - o How to use the new Optical Property Optimizer tool. This is also described in the New Features section of this document.
    - o How to add a custom parameter to the records view parameters list.
    - o How to add a measurement pass/fail QC check to a report.
- Support:
    - o How to carry out a Starter Sample measurement - useful if you are new to the Mastersizer 3000 system.

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New Features

Version 3.00 of the Mastersizer 3000 and 3000E software includes the following new features:

Reference(s)	Feature	Comment
33378	Ensure the averaging dialog box pops up on the correct monitor when creating average records.	Fixed
32813 **31047** **31046** **31041** **30955** **31646** **31629** **31502** **17723** **32085** **31859** **31847** **32200** **32426** **32333** **32481** **32775** **31196** **32792** **32966** **9421** **32815**	Develop a tool for optimizing the optical properties used for particle size calculations.	Implemented Extended software only
29772	Provide emulation factors as part of the analysis settings.	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 all other previous software releases can be found on the software CD-ROM.

Fixed issues

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

Reference(s)	Issue	Comment
30273 **30255**	Software crashes when saving measurements imported from older Mastersizer systems.	Fixed
30281	Crash occurs when attempting to edit some older measurement files.	Fixed
30323	Errors occur when creating a report with a backslash character in the title	Fixed
30329	Aero S fails to reach the specified pressure when the target pressure is changed	Fixed
30413	Software focus does not move to the report tab when a new report is created.	Fixed
30433	Adding 'Run SOP' to quick access toolbar crashes the software	Fixed
30471	Software reports an error during the final fill in a Hydro unit clean sequence.	Fixed
30678	Time entry text boxes do not work well when setting ultrasound times.	Fixed

30852	Opening a dry and a wet dispersion SOP at the same time causes conflicts with the blue light property selections.	Fixed
30864	Records are deselected during measurements, causing the reports to be blank at the end of the measurement sequence.	Fixed
30920	Wet dispersion parameters are not blank for dry dispersion records	Fixed
30942	All reports are added to the active list when creating a new workspace view	Fixed
24058	Line style selection does not apply correctly to trend charts	Fixed
31205	Incorrect analysis sensitivity is reported for dry measurements	Fixed
31256	Attempting to export parameters which are not included in older measurement files causes no data to be exported.	Fixed
31306	Averages are sometimes not stored to the correct file during SOP measurements.	Fixed
11071	Symbols to not appear in graph keys.	Fixed
30198	Measurement continues after cell removal for manual accessory measurements.	Fixed
31745	Data quality report is not shown for records stored in a new measurement file	Fixed
32097	Cannot close software after opening a locked (Read Only) file	Fixed
32187	Blue light error reported in the maintenance window for Mastersizer 3000E systems.	Fixed
32237	Mastersizer 2000 emulation analysis fails if the sum of the Mastersizer 3000 data is negative	Fixed
32269	Software crashes when printing from an sop	Fixed
32457	Software can freeze at the end of a manual fill clean sequence	Fixed
32488	Reports can be deleted even when the access control permissions are set to prevent this from occurring	Fixed
32490	Trend table displays incorrect record number after the All files tab has been viewed	Fixed
32503	Software exception reported when copying raw data from frequency and oversize size distribution graphs.	Fixed
32506	Dispersant details not saved into measurement records created by manual accessory	Fixed
32507	Malvern Link 2 automation interface fails if print or export actions are included in an SOP	Fixed
32510	Copy raw data can export the wrong data from data and size distribution graphs.	Fixed
32711	Software exception reported if selected records are changed during batch printing	Fixed
31106	It is possible to 'Close all Files' via file menu whilst running a measurement therefore losing data	Fixed
32779	Due to changes in the structure of the help content, all help buttons fail to display a help page.	Fixed
32818	Add custom size button is hidden for user size entry for some foreign languages when using a small computer screen.	Fixed
32828	Extend Result should not be available if a MS2000 result is edited	Fixed
33126	Clean routine types are not populated correctly when using the Chinese software translation.	Fixed
33158	Software exception reported if a linear x-axis is selected for result graphs after limiting result range.	Fixed
33196	System health check fails for MS3000E	Fixed

| 33225	Confusing message is displayed when a software license expires within the Mastersizer 3000E basic software.	Fixed
33273	Wrong result graph lower limit is displayed when result range is limited.	Fixed
33029	Unable to save extracted measurement settings as an SOP.	Fixed
33321	Software crashes when anything is typed into the filter row in the records view.	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.	Always use a USB 2.0 port.	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 open the Manual Measurement, SOP Measurement, or Accessory Control to reactivate the accessory.	Intermittent Software Bug

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Downgrading to version 2.01 causes exception.	After installing version 2.10 then downgrading to 2.01, an exception may be seen when the software is first started. To work around this, you need to delete the **Features.xml** file from **C:\ProgramData\Malvern Instruments\Mastersizer 3000\.** This will remove 21CFR settings, which you will then need to reconfigure.	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

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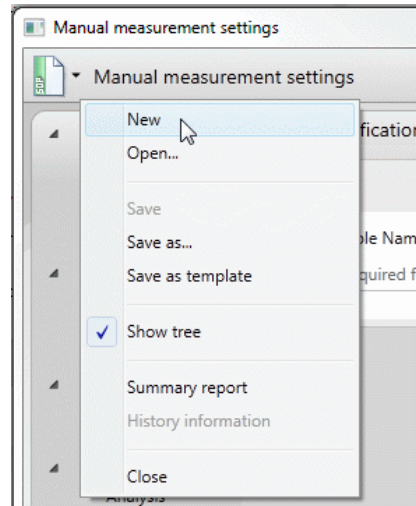
This will reset all measurement settings to their defaults for the active accessory type. This issue has been reported after upgrading from early versions of the software, but does not occur on all systems.

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
21CFR11 mode: Audit trails **(Mastersizer 3000 only)**	.xml	C:\ProgramData\Malvern Instruments\Mastersizer 3000\Audit Trails
User sizes	.siz	C:\ProgramData\Malvern Instruments\Mastersizer 3000\User Sizes
User defined materials	.mmat	C:\ProgramData\Malvern Instruments\Mastersizer 3000\Materials
User defined dispersants	.mdis	C:\ProgramData\Malvern Instruments\Mastersizer 3000\Dispersants
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
Export data	.txt, .csv, .rtf	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Export Data **Private workspace:** C:\Users\KBaines\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Export Data
Measurement data	.mmes	**Shared workspace:** C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Measurement Data **Private workspace:** C:\Users\KBaines\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data
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
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

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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
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
Various system wide configuration files	Various	C:\ProgramData\Malvern Instruments\Mastersizer 3000

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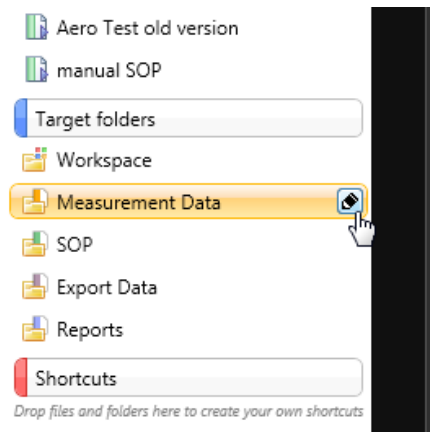
Changing the directory associated with this shortcut will change the default directory accessed by the Mastersizer 3000 software for the selected file type.

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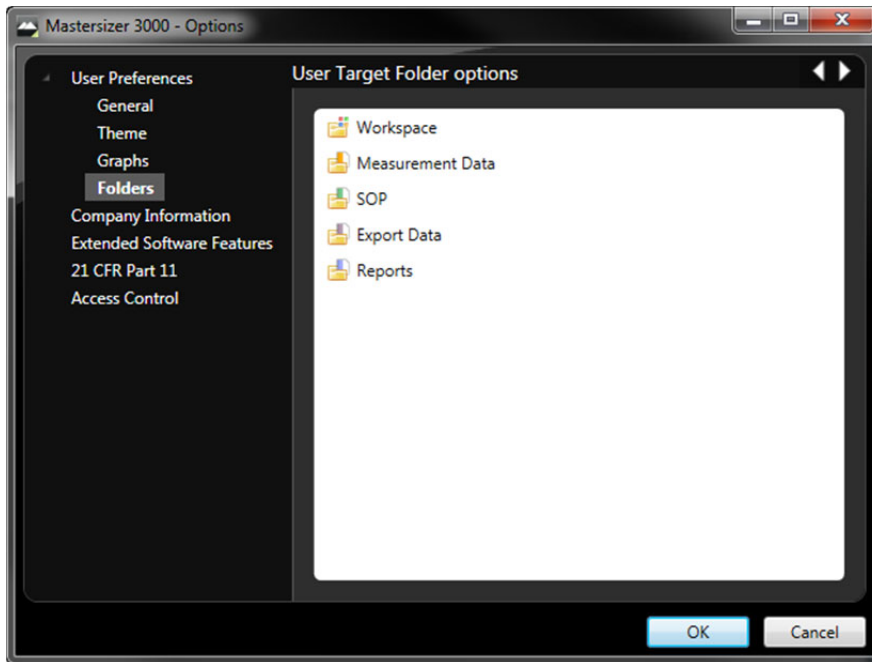
Again, hover over the shortcut and click on the pencil icon in order to change the target directory. Note that this is the only place in the software where the target directories can be configured when using the Basic software for the Mastersizer 3000E.

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.

Why do you no longer use the Program Files folder?

With the introduction of Windows Vista and Windows 7, Microsoft changed the default permissions for the Program Files folder to prohibit software maliciously changing files associated with installed software. All software runs with standard user permissions on Windows Vista/7, even when a user is logged in as an Administrator. By adhering to these default permissions, Malvern's software platforms can execute without additional configuration changes by the end user.

New Features Description

Optical Property Optimizer

Version 3.00 of the Mastersizer 3000 software contains a new Optical Property Optimizer tool which is designed to aid users in understanding the robust of results to changes in the refractive index and absorption values used within the analysis.

The optimizer tool is accessed by first selecting a set of records for optimization from the records view. Clicking on the Optical Property Optimizer icon on the ribbon bar then launches the tool:
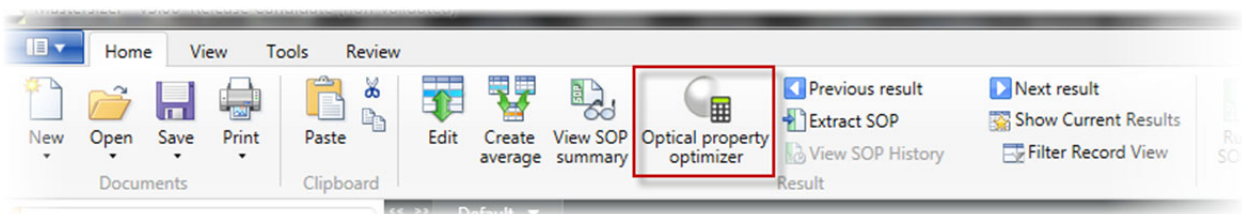
Within the optimizer tool, the optical properties used in the calculation of the selected results can be changed without causing new records to be created. It helps to speed up the process of setting up the analysis settings during method development.

The optimizer interface is split into the following sections:

1. A list of the records selected for optimization. Within this section of the tool, you can also select which records are displayed within the particle size and data fit graphs on the right hand side of the optimizer interface.

2. A grid tool for selecting the optical properties used for calculating the selected results. You can adjust the selected refractive index and absorption values by moving the red and blue indicators on the grid tool. This causes the results to be updated in real time.

3. During the optimization process, you may want to store optical property sets which look realistic. These are stored in the Optical Property Sets list. This list also includes the original optical property values applied to the selected records when they were imported into the tool.

4. A graph showing the current results relating to the properties selected on the optical properties grid.

5. A graph showing the data and data fit relating to the properties selected on the optical properties grid.

6. A trend table showing the distribution statistics calculated for the selected records using the properties selected on the optical properties grid.

A full description of the operation of the Optical Property Optimizer is provided in the software help. In addition, a video showing the tool in use is included as part of the software MiniGuides.

Result Emulation Factors

Version 3.00 of the Mastersizer 3000 software contains a new result emulation function which can be used to modify results in order to make them similar to those reported using other particle sizing techniques. This capability is particularly useful when transferring methods from sieving to laser diffraction.

The result emulation factor tool is accessed as part of the **Data Processing->Result** section of the measurement and SOP settings:
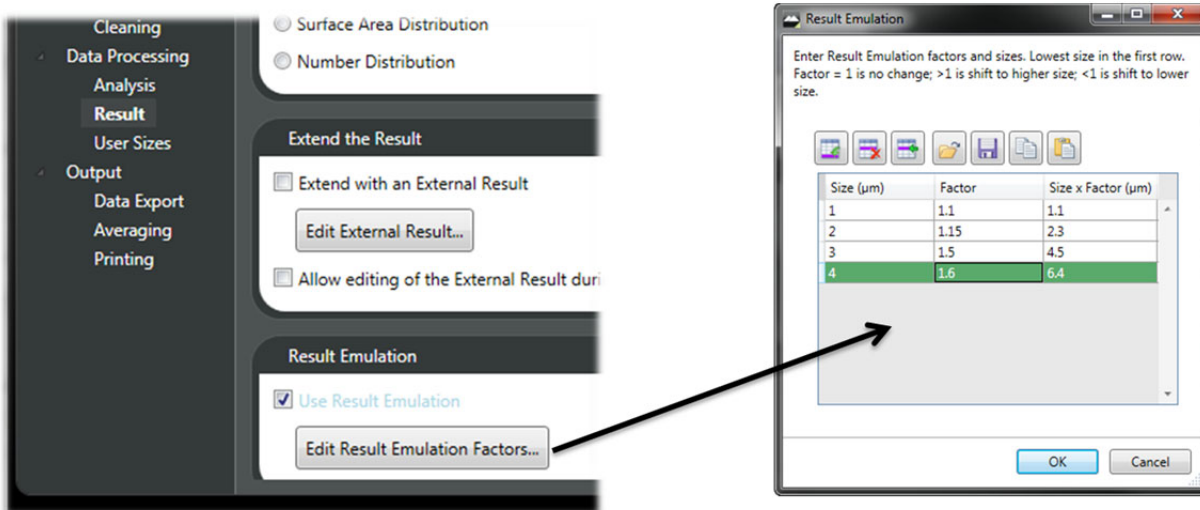
Emulation factors are set up by first specifying a particle size and then a factor by which that size must be multiplied to bring it into agreement with the result which needs to be emulated. Emulation factors can be specified for single size points, causing the entire size distribution to be shifted along the size axis, as in this case:
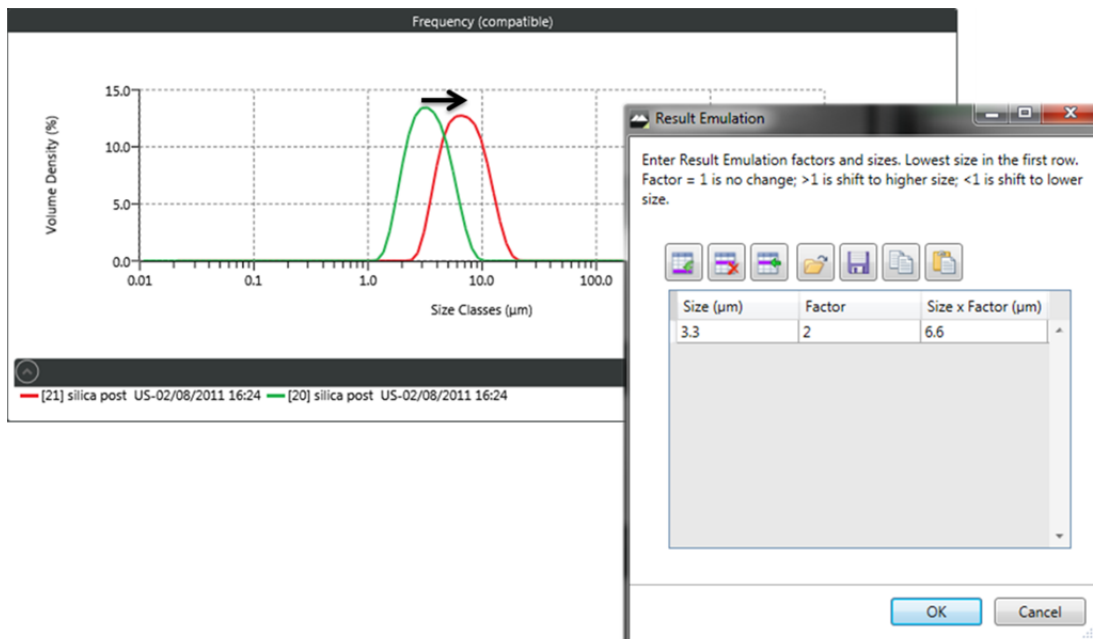
Alternatively, multiple emulation points can be specified, enabling both the position of the size distribution on the x-axis and the shape of the distribution to be modified, as in this case:

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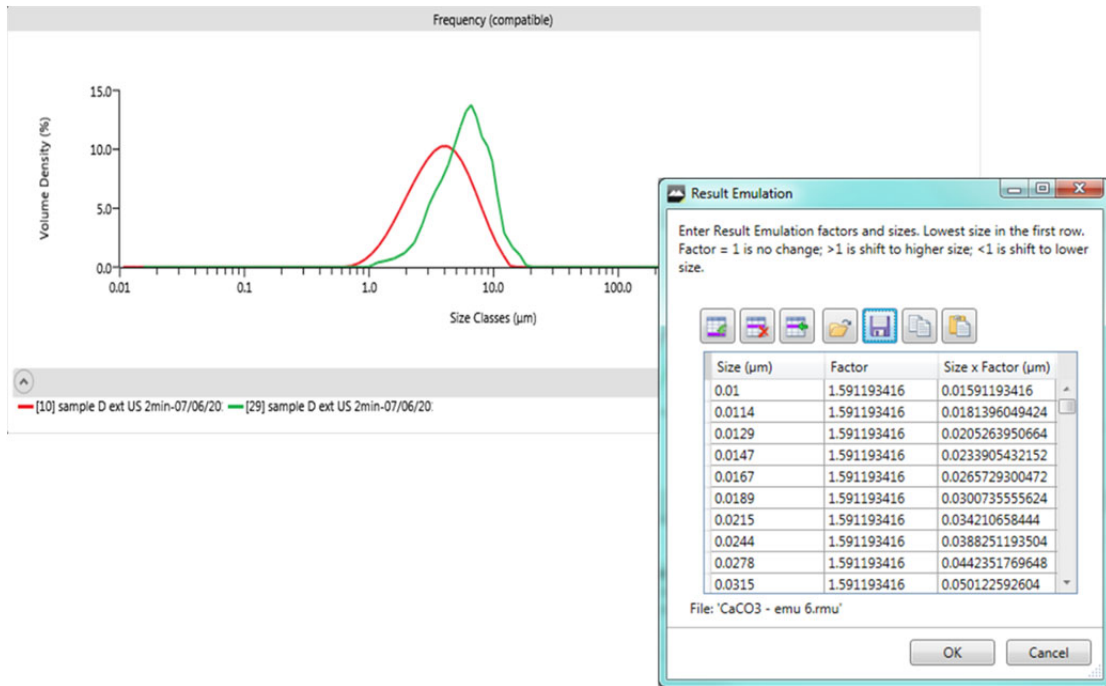
An excel spreadsheet to help with the calculation of complex sets of emulation factors is provided on the software CD-ROM. In addition to this, the emulation tool can read in emulation files (*.rmu) created using the Mastersizer 2000 software.

more information at www.malvern.com

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