

MASTERSIZER 3000 SOFTWARE: v3.72 (PSS0223-26) SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0223-26: version 3.72 of the software for the Mastersizer 3000 laser diffraction system and the Mastersizer 3000E system. It covers software issues fixed and new features introduced. This information is required to perform a risk analysis to determine if the software should be installed. In this risk analysis the benefits of the new features provided and resolved software issues must be weighed against the risk of new issues that may be introduced to vital areas of the software or possible changes to the results of future analysis. Installation instructions are provided.

Installation

It is assumed that you have authority to install or update software within your facility. It is also assumed that you have Administrator rights for the system upon which the software is installed, as this is a requirement of the installation process. If you do not have this authority, please consult with your I.T. support department before proceeding.

Recommended System Requirements

The recommended computer system requirements for running this software are highlighted in table 1 below. The software can be operated using Windows 10 (Pro and Enterprise), Windows 7 32 bit (Pro, Enterprise and Ultimate) and Windows 7 64 bit (Pro, Enterprise and Ultimate). However, it has been fully tested using Windows 10 Pro (64 bit) (v1709). Windows 10 Pro (64 bit) is therefore the preferred operating system.

Supported Languages

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

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

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

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

Feature	Specification
Processor Type	Intel Core i7 Processor (Quad Core, 4 th generation or higher)
Memory	8GB
Hard Disk Storage	250GB
Additional Storage Media	CD-ROM or DVD +/-RW drive
Display Resolution	1920 x 1080 (Minimum 1440 x 900)
Connectivity	1 USB2.0 or USB3.0 port
Operating System	Windows 7 (32 bit - Pro, Enterprise and Ultimate) Windows 7 (64 bit - Pro, Enterprise and Ultimate) Windows 10 Enterprise (64 bit - Pro and Enterprise) * <small>* Preferred Operating System</small>

Note:



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

Installation Instructions

The software suite comes on an auto-loading CD-ROM. Inserting the drive into a system configured to auto-run a CD will run the installation program automatically. If your system does not support this feature, run the `\\Mastersizer 3000\setup.exe` program from your CD drive. If you are installing the software from a web download then browse to the folder where the files have been extracted to and then launch the `\\Mastersizer 3000\setup.exe` program.

Note:



It is important that the software is installed before the Mastersizer 3000 / 3000E instrument is connected to the computer and switched on. This will ensure that the instrument drivers are enabled, and that the firmware updates associated with this release are correctly downloaded to the instrument.

Note:



Any firmware updates required for your system will be installed at the same time as the software. It is important to keep the firmware and software 'in sync', since this is the configuration that will have been tested by Malvern Panalytical prior to release of the software.

Note:



If you are upgrading from a previous version of the software and have auditing enabled, you may see a message referring to an audit trail upgrade on the first initialization of the software. Please see fixed issues section for more information.

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 computer used to control the instrument or a separate networked computer. Installing on a separate computer allows you to manage the security centrally.



Note:

The MAC software does not auto-install. To install this software, navigate to the [Malvern Access Configurator](#) folder on the software CD-ROM and run the setup.exe file.

As with all Windows applications, the MAC software must be installed by a user who is an administrator on the host computer. In addition, the MAC software uses the existing Microsoft Windows users and groups configured on the host computer to control access to the Mastersizer 3000 application. As such, prior to installing the MAC, it is important to ensure that the computer running the Malvern software is installed on its host network. If the computer is a stand-alone system, the required users and groups must be configured on the computer prior to the use of the MAC.

Given the above requirements, it is advised that a user's local IT department should review the requirements for use of the MAC application. An IT representation should also be present during the software installation process.



Note:

Please read [MAN0602-XX – Malvern Access Configurator \(MAC\) User Guide](#) and [MRK1747-xx – Mastersizer 3000 - 21 CFR Part 11 Guide](#) for more information as to how to use the MAC application, particularly when operation is required in a 21CFR Part 11 compliant environment. Note that operation in 21CFR Part 11 mode is not available for Mastersizer 3000E users.

Uninstall Procedure

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

We recommend the MAC software is uninstalled in this way before updating to later versions (or even downgrading to earlier versions).

Software Categorization

GAMP 5

The GAMP 5 guide provides guidance to pharmaceutical companies wishing to understand whether the computerized systems and software they used are fit for purpose and meet current regulatory requirements. As part of this, the GAMP committee has defined a series of software categories which are designed to help users in assessing the risk and validation requirements associated with using a specific software package.

In its standard mode of operation, the Mastersizer 3000 software provides users with a series of standard interfaces and functions that enable the software to be configured to meet specific user business requirements. These interfaces include the ability to define Standard Operating Procedures (SOPs) for sample measurement, create report definitions using pre-defined functions and develop data export templates using pre-defined parameters. If users apply these functions, then the software can be considered to be a [Category 4](#) product.

In addition to the standard functions, the Mastersizer 3000 software provides users with the ability to modify the results reported by the system to fit their application requirements. This is achieved using the custom calculation reporting functions. These functions are not widely applied within regulated environments. However, if they are used to meet

business requirements then the macros included within the custom calculations should be validated according to GAMP Category 5 requirements. Users are therefore encouraged to specifically validate any custom calculations applied within their reports and ensure these are documented. Where possible, we would encourage the use of the standard result reporting features, as this minimizes the risk of errors in the reported size distribution statistics.

USP<1058>

USP<1058> provides pharmaceutical users with guidance as to how the qualification of analytical systems should be carried out. As part of this guidance, the USP define a series of instrument categories. These instrument categories different from those described in GAMP 5, although the principles applied as part of the classification of a system are similar.

The Mastersizer 3000 is a computerized analytical system where the software provides users with the functions required to meet specific analytical application requirements. As such, it is a Group C instrument. Users are therefore recommended to define their requirements for the operation of the system and then compare these requirements to the claimed capabilities of the software and hardware. This should include an assessment of whether the new features and bug fixes included in a specific version of the Mastersizer 3000 software are necessary to meet business requirements.

Validation Support Documents

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

- **21CFR Part 11 and Security System guides:**
Provide guidance on how to set up the features of the software in order to aid technical compliance to 21CFR Part 11.
- **21CFR Part 11 and Annex 11 Gap analysis documents:**
These detail the capabilities of the software and how these align with the requirements of 21CFR Part 11 and the equivalent rule set in Europe (Annex 11).
- **Malvern Instrument's ISO Certificates:**
Copies of the current ISO9001:2008, ISO14001 and OHSAS 18001:2007 certificates, issued as part of the independent audit of Malvern's business management systems. This includes certification of the development of the Mastersizer 3000 software to TickIT Plus requirements.
- **Software Certificates of Conformance:**
Copies of the software certificates of conformance for all Mastersizer 3000 software versions, providing a summary of Malvern's business management systems which are used for the development of the Mastersizer 3000 software and hardware.
- **Software Update Notifications:**
Copies of the software update notifications for all Mastersizer 3000 software versions, confirming the new features and bug fixes introduced for each version.
- **Software Update Verification Procedure:**
A procedure users can follow for verifying the success of a software upgrade.



Note:

The documents provided on the software CD are those which were current at the date the software was released. Please contact your local Malvern Panalytical 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 computer 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 computer, 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 Panalytical.**

Sharing a License for Mastersizer 3000E users

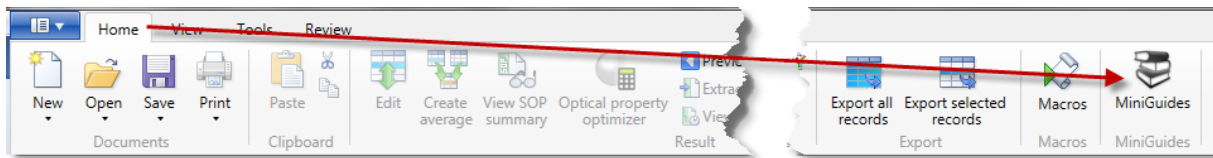
The Mastersizer 3000E system is provided with a simplified, basic version of the Mastersizer 3000 software. This basic software version is restricted to use on a single computer workstation attached to the Mastersizer 3000E system. As such, the license sharing facility offered for Mastersizer 3000 users 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:

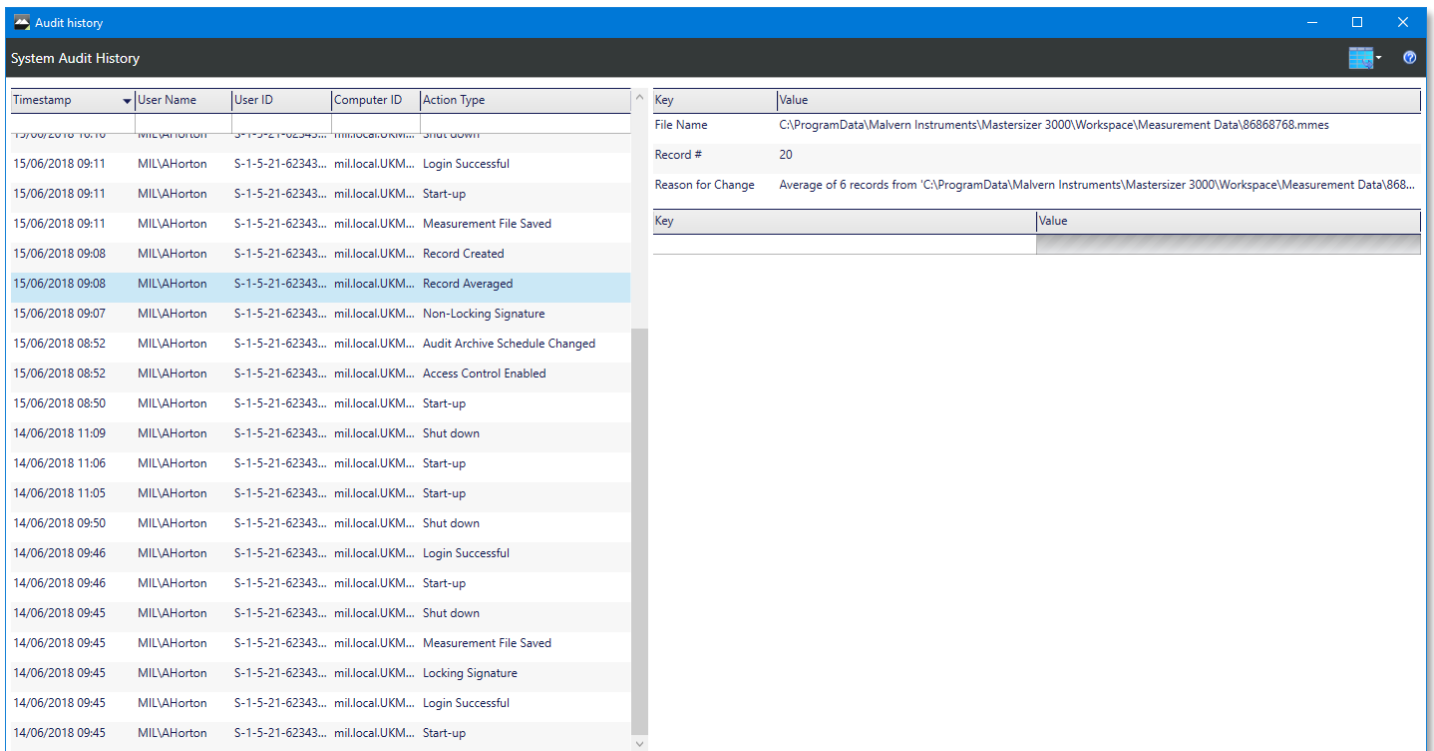


Main New Features Description

Audit history view and export

Showing the details/extension data section

The system audit history viewer within the application has been updated to enable easier review of audit entries. When an Audit Trail is opened, the detail for each entry can be seen on the righthand side of the screen, enabling easier review of audit information:



The screenshot shows the 'Audit history' window. The main area displays a table of system audit history entries. The right-hand side of the window shows a details pane for the selected entry, which is highlighted in blue in the main table.

Timestamp	User Name	User ID	Computer ID	Action Type
15/06/2018 09:11	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Login Successful
15/06/2018 09:11	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Start-up
15/06/2018 09:11	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Measurement File Saved
15/06/2018 09:08	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Record Created
15/06/2018 09:08	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Record Averaged
15/06/2018 09:07	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Non-Locking Signature
15/06/2018 08:52	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Audit Archive Schedule Changed
15/06/2018 08:52	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Access Control Enabled
15/06/2018 08:50	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Start-up
14/06/2018 11:09	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Shut down
14/06/2018 11:06	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Start-up
14/06/2018 11:05	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Start-up
14/06/2018 09:50	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Shut down
14/06/2018 09:46	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Login Successful
14/06/2018 09:46	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Start-up
14/06/2018 09:45	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Shut down
14/06/2018 09:45	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Measurement File Saved
14/06/2018 09:45	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Locking Signature
14/06/2018 09:45	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Login Successful
14/06/2018 09:45	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Start-up

Key	Value
File Name	C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data\86868768.mmes
Record #	20
Reason for Change	Average of 6 records from 'C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data\868...
Key	Value

Once an Audit Trail has opened, it is also possible to filter the audit entries based on:

- Date/Time
- user name
- action type
- User ID:

Filtering by date

System Audit History																																																					
Timestamp	User Name	User ID	Computer ID	Action Type																																																	
15/06/2018																																																					
To		S-1-5-21-62343...	mil.local.UKM...	Login Successful																																																	
<div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"> June 2018 </div> <table border="1" style="font-size: 8px;"> <tr><td>Mo</td><td>Tu</td><td>We</td><td>Th</td><td>Fr</td><td>Sa</td><td>Su</td></tr> <tr><td>28</td><td>29</td><td>30</td><td>31</td><td>1</td><td>2</td><td>3</td></tr> <tr><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td><td>10</td></tr> <tr><td>11</td><td>12</td><td>13</td><td>14</td><td>15</td><td>16</td><td>17</td></tr> <tr><td>18</td><td>19</td><td>20</td><td>21</td><td>22</td><td>23</td><td>24</td></tr> <tr><td>25</td><td>26</td><td>27</td><td>28</td><td>29</td><td>30</td><td>1</td></tr> <tr><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td></tr> </table> </div>					Mo	Tu	We	Th	Fr	Sa	Su	28	29	30	31	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	1	2	3	4	5	6	7	8
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	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Shut down																																																	
	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Login Successful																																																	
	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Start-up																																																	
	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Shut down																																																	
18/06/2018 18:59	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Login Successful																																																	

Filtering by available Action Types

System Audit History				
Timestamp	User Name	User ID	Computer ID	Action Type
				(Clear Filter)
				(Select All)
21/06/2018 10:04	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input type="checkbox"/> Access Control Enabled
18/06/2018 17:01	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input checked="" type="checkbox"/> Audit Archive Schedule Changed
18/06/2018 16:59	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input checked="" type="checkbox"/> Locking Signature
18/06/2018 16:55	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input checked="" type="checkbox"/> Login Successful
15/06/2018 09:11	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input checked="" type="checkbox"/> Measurement File Saved
15/06/2018 09:11	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input type="checkbox"/> Non-Locking Signature
15/06/2018 08:52	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input type="checkbox"/> Record Averaged
15/06/2018 08:52	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input type="checkbox"/> Record Created
15/06/2018 08:52	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input type="checkbox"/> Shut down
15/06/2018 08:52	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	<input type="checkbox"/> Start-up
14/06/2018 09:46	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Login Successful

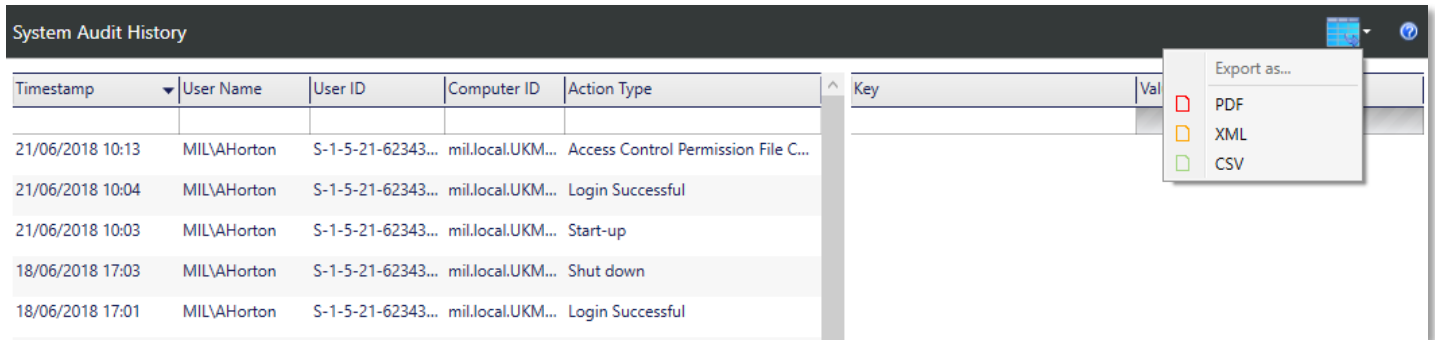
Filtering by column searching

System Audit History				
Timestamp	User Name	User ID	Computer ID	Action Type
				measurement
15/06/2018 09:11	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Measurement File Saved
14/06/2018 09:45	MILVAHorton	S-1-5-21-62343...	mil.local.UKM...	Measurement File Saved

Export button and Export button dropdown



To Export the entire audit trail, or the list of entries obtained with filters applied, click on the export button dropdown in the top-right corner of the **System Audit History Trail** viewer. The audit trail can be exported in PDF, XML or CSV formats. By default, the file will be saved into the *...ProgramData\Malvern Instruments\Mastersizer 3000\Audit Exports\ folder.*



Examples of the exported files are shown below.

PDF export



Audit Trail Export - Mastersizer 3000

Date range
22/03/2018 14:04:20 to 28/03/2018 11:57:35

Filtered Audit Trail

Timestamp	User Name	User ID	Computer ID	Action Type
28/03/2018 11:56:33	MIL\malinstall	S-1-5-21-623434881-1009198268-2996851928-21636	mil.local.UKMAL1T3399	Measurement File Saved
28/03/2018 11:56:32	MIL\malinstall	S-1-5-21-623434881-1009198268-2996851928-21636	mil.local.UKMAL1T3399	Sample Measurement Completed
28/03/2018 11:56:32	MIL\malinstall	S-1-5-21-623434881-1009198268-2996851928-21636	mil.local.UKMAL1T3399	Record Created
28/03/2018 11:56:03	MIL\malinstall	S-1-5-21-623434881-1009198268-2996851928-21636	mil.local.UKMAL1T3399	Record Created

CSV export

	A	B	C	D	E	F	G	H	I
1	Audit Trail -	Timestamp	User Name	User ID	Computer ID	Action Type		Filters -	Action Type
2		13/06/2018 11:11	MIL\AHorton	S-1-5-21-623434	mil.local.UKM	Login Successful			Auditing Breached
3		13/06/2018 10:36	MIL\AHorton	S-1-5-21-623434	mil.local.UKM	Login Successful			Insufficient Records Created
4		12/06/2018 15:02	MIL\AHorton	S-1-5-21-623434	mil.local.UKM	Login Successful			Measurement Started
5		12/06/2018 11:39	MIL\AHorton	S-1-5-21-623434	mil.local.UKM	Login Successful			Record Averaged
6		12/06/2018 11:38	MIL\AHorton	S-1-5-21-623434	mil.local.UKM	Login Successful			Login Successful

XML export

Audit Trail Export				
Audit Trail export details				
Time of export	2018-04-30 11:14:00			
Exported by User	MIL\AHorton			
Application Version	Mastersizer Software v3.70.1803.270 Alpha (non-validated)			
Date-Range				
From:	11/04/2018 10:24:57			
To:	30/04/2018 11:13:58			
Filtered Audit Trail				
The filtered Audit Trail. If no table is displayed then the filters applied returned no results.				
Timestamp	User Name	User ID	Computer ID	Action Type
30/04/2018 11:13:49	MIL\AHorton	S-1-5-21-623434881-1009198268-2996851928-29753	mil.local.UKMAL1T3399	Start-up
30/04/2018 11:04:55	MIL\AHorton	S-1-5-21-623434881-1009198268-2996851928-29753	mil.local.UKMAL1T3399	Start-up
+ 30/04/2018 10:22:27	MIL\AHorton	S-1-5-21-623434881-1009198268-2996851928-29753	mil.local.UKMAL1T3399	Record Created
+ 30/04/2018 10:22:26	MIL\AHorton	S-1-5-21-623434881-1009198268-2996851928-29753	mil.local.UKMAL1T3399	Record Averaged

New Features List

The features implemented in v3.70, v3.71 & v3.72 release(s) are confirmed in the table below:

Reference(s)	Feature
66214	Re-authenticate users on application start
82050	Change audit XML files to an encrypted format
82209	Audit Trail export function
69872	Improve viewability of audit trail details
69873	Add an entry to record audit trail confirming the record creation date when record is first created
82822	Allow users to type in direct network paths for folder selection
83526	Include security permissions to control access to Audit trail export options
65754	Add the SOP name and SOP file path to the SOP summary report
62167	Prevent users applying a locking signature if they are the creator of a record

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 **v3.72** maintenance release of the Mastersizer 3000 software are confirmed in the table below:

Reference(s)	Issue
98415	Instrument drivers do not install correctly
99568	Sample measurement fails to run when Mastersizer 2000 emulation mode is enabled

The main issues fixed in **v3.71** maintenance release of the Mastersizer 3000 software are confirmed in the table below:

Reference(s)	Issue
91576	Audit trail padding issue found in v3.70
98079	Better error reporting needed for Audit trail location change
98341	Audit trail 'Options' changes are not cleared when cancelled
98056	Errors on audit initialization should provide a useful error message
98244	Do not allow location of Audit trail folder to be set to inaccessible location
98246	Changing audit trail location by valid user should not be detected as a breach in auditing
96681	Convert of XML to Binary audit trail should not lock up UI
98234	Running SOP as PV SOP gives original file name in reports and column
96593	ASD and GSD Japanese translations should be swapped

The main issues fixed in **v3.70** release of the Mastersizer 3000 software are confirmed in the table below:

Reference(s)	Issue
48517	SOP filenames are not reported or exported correctly
55934	SOP summary reports non-spherical particle mode when the Fraunhofer particle type is used
56675	The modified date for a measurement file is not updated when it is edited
74300	The list of records used in creating an average is lost when the software is restarted.
77598	Audit trail can lose information when two users are logged in at the same time
77699	Software may crash when using Windows 10
80006	The message which appears confirming that an Audit trail may have been tampered with is misleading
80007	Users are not informed of Audit Trail tampering if the Audit Trail file is deleted
81673	It is possible on some systems to turn off 21CFR Part 11 mode by replacing the software license
81674	Spelling inconsistency on Licence info window
84638	User able to see sample size distribution without entering required sample identifiers (SOP)
48517	SOP filenames aren't reported or exported correctly



Note:

This release also contains a Firmware update for Hydro MV & Hydro LV accessories related to drain valve actuation and stirrer speed readback.

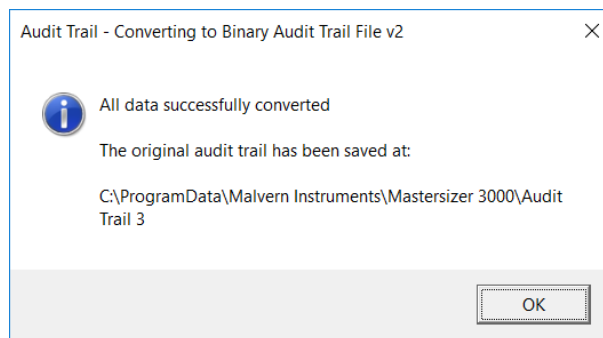
Audit trail upgrade

Versions 3.70, 3.71 and 3.72 use a different auditing file format designed to improve the security of the audit trail.

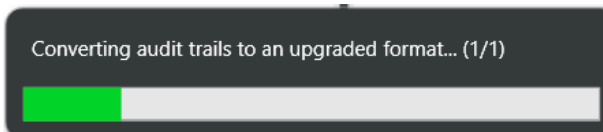
Upgrading to v3.72 from v3.63 or earlier will cause an audit trail conversion and checking process to occur when the software is first initiated. A series of messages will be displayed like the example below:



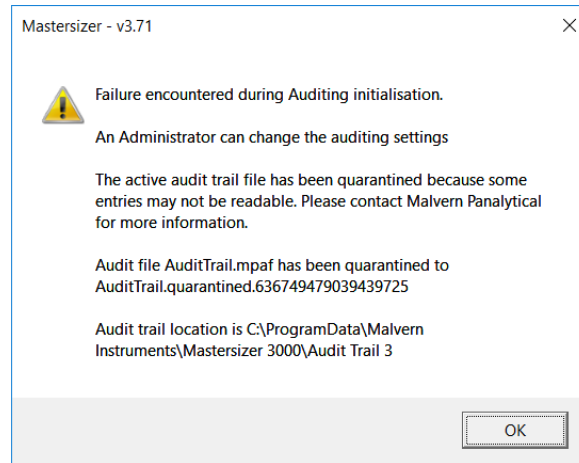
Once complete the following message will displayed:



If you are upgrading from Mastersizer 3000 software v3.70 to v3.72 the message below will be displayed, indicating that an audit trail format update is being applied to fix bug issue #91576:



However, if you are using v3.72 and have experienced the bug issue #91576, a different message will be displayed and the audit trail will be labelled 'quarantined':



Please contact for local Malvern Panalytical representative if this message appears.

File Types and Locations

The Mastersizer 3000 software uses a series of different file types in order to store data and measurement settings. These are described below, in order to help users who wish to secure the Mastersizer 3000/3000E system using the Microsoft Windows security and access settings. Guidance regarding how to set up the security settings is provided in the Windows Security Settings section of this document.

File Type	Extension	Default Path	Advised security setting for 21CFR Part 11 Mode
21CFR11 mode: Audit trails (Mastersizer 3000 only)	.mpaf	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Audit Trails</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
User sizes	.siz	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\User Sizes</i>	No control required as these settings are stored in SOPs.
User defined materials	.mmat	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Materials</i>	No control required as these settings are stored in SOPs.
User defined dispersants	.mdis	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Dispersants</i>	No control required as these settings are stored in SOPs.
Data quality addins (Mastersizer 3000 only)	.mdaq	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Quality Addins</i>	No control required as the data quality tool only provides advice.
Export data	.txt.csv.rtf	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Workspace\Export Data</i>	If data export is a critical part of the SOP used for your samples then you should prevent deletion of the files in

		Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Export Data</i>	this directory. However, read, write and modify access must be maintained.
Measurement data	.mmes	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Measurement Data</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Measurement Data</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Reports	.mrep	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Reports</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Reports</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained. Note: it is important that users are prevented from deleting reports via the software interface as well. This can be done using the MAC application.
SOP templates	.msot	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\SOP Template</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP Template</i>	No control required.
SOP	.msop	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\SOP</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\SOP</i>	Prevent deletion of the files in this directory. However, read, write and modify access must be maintained.
Data export templates	.mext	Shared workspace: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\ Workspace\Data Template</i> Private workspace: <i>C:\Users\{user_name}\Documents\Malvern Instruments\Mastersizer 3000\Workspace\Data Template</i>	No control required.
Licence file	.licence	Mastersizer3000.licence file stored in: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files</i>	Once the system has been set up and 21 CFR Part 11 mode engaged then access to this file must be set to prevent deletion. However, read, write and modify access must be maintained.

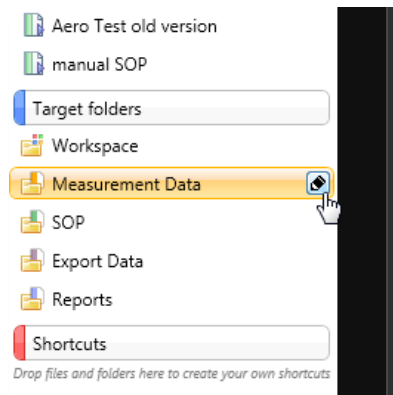
Security configuration file	.xml	Exported from the Malvern Access Configurator (MAC) application. The directory is user-specified. Malvern advise that the file should be stored in: <i>C:\ProgramData\Malvern Instruments\Mastersizer 3000\Configuration Files</i>	Prevent deletion this file once it is created. However, read, write and modify access must be maintained.
Various system wide configuration files	Various	<i>C:\ProgramData\Malvern Instruments\Mastersizer 3000</i>	Full access must be maintained to this directory for the program to function correctly.

Changing the destination path for a file

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

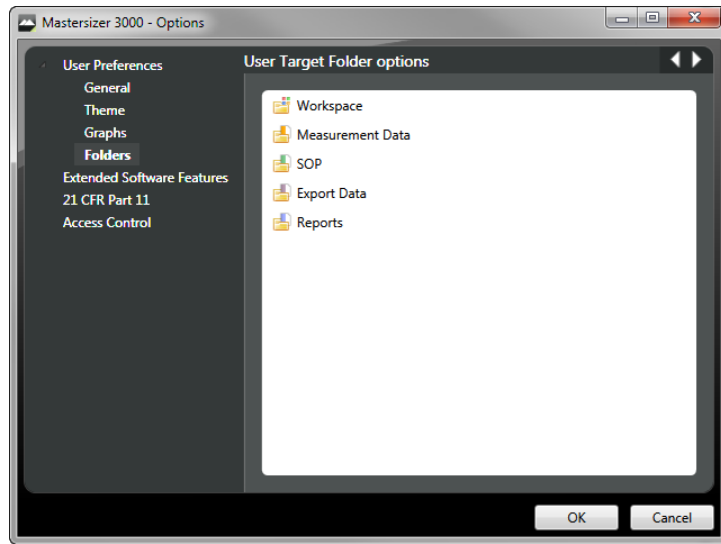
- SOP
- Measurement Data
- Reports
- Export Data

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



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

Configuration of the target directories can also be configured from the **User Preferences-Folders** section of the **Options** menu:



Again, hover over the shortcut and click on the pencil icon in order to change the target directory. Note that this is the only place in the software where the target directories can be configured when using the Basic software for the Mastersizer 3000E.

Making a backup of the files

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

Windows Security Settings

With a 21CFR11 compliant computer system, one of first concerns to address is the potential for the loss of data; either accidentally, or by intention. Utilizing the built-in security tools of Microsoft Windows®, an IT professional can effortlessly change user access to specific files and/or folders by simply removing certain file/folder permissions.

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

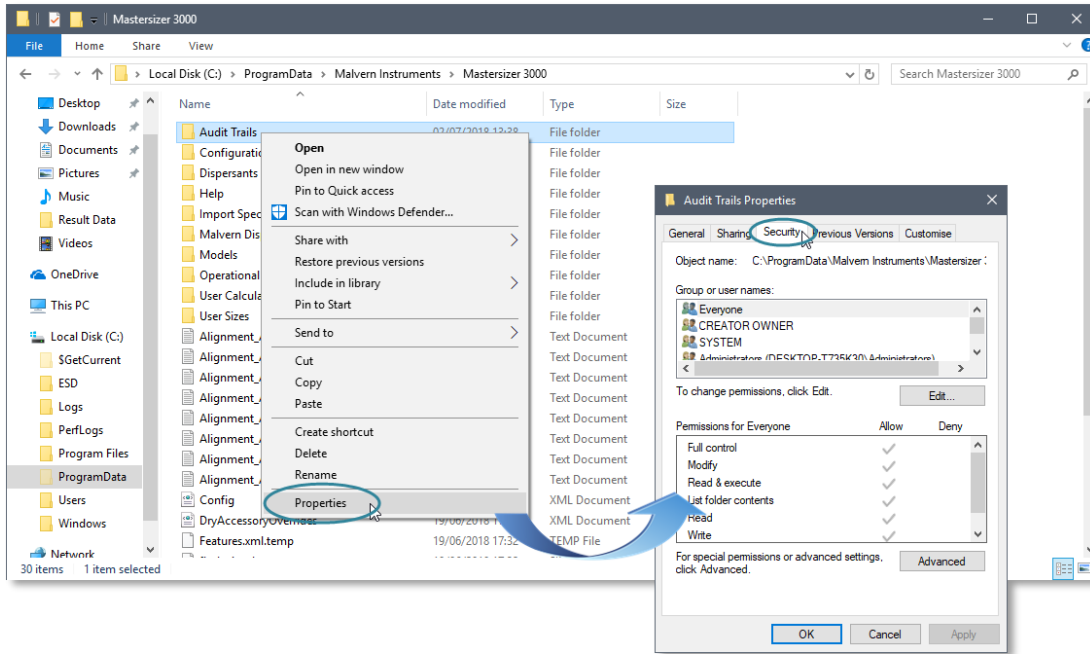
Note:



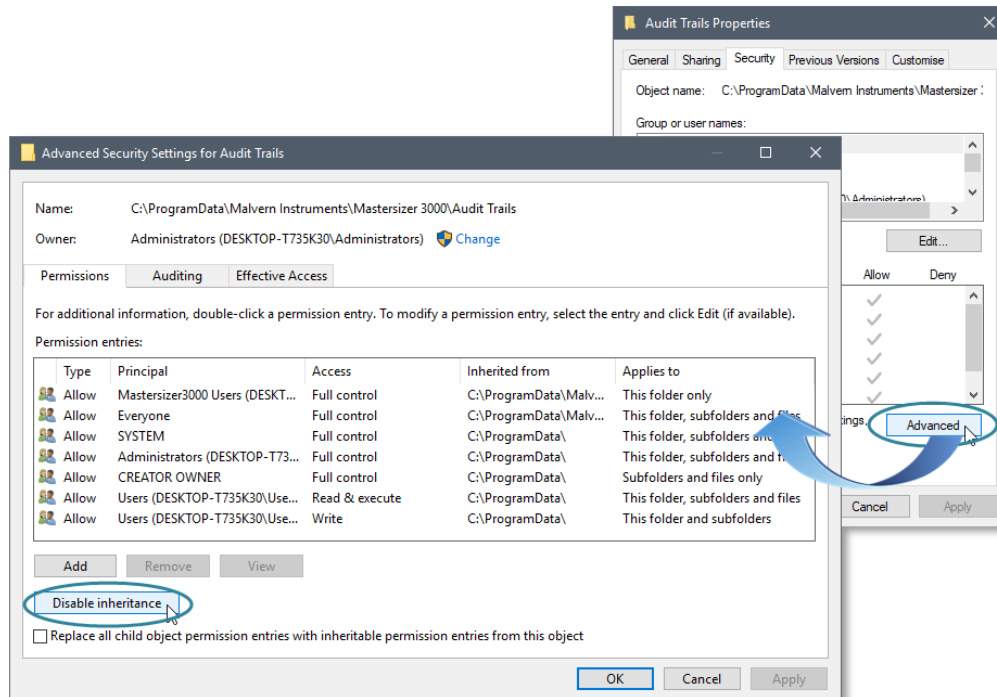
For the following demonstration we have previously created a user group, through the Computer Management console, called 'Mastersizer3000 Users'. This user group will later be added into the folder permissions of the Audit Trails folder to prevent users from deleting records. This process can be applied to any other output folder requiring limited user access. In the following illustrations, we have not removed default groups such as 'Everyone' or 'Users' - these can be deleted or used as an alternative to dedicated user group/s. However, when using these groups, we strongly advise that explicit 'Denies' are not used, unless you fully understand the Microsoft® file/folder security permissions.

Changing the folder security permissions in Windows 10

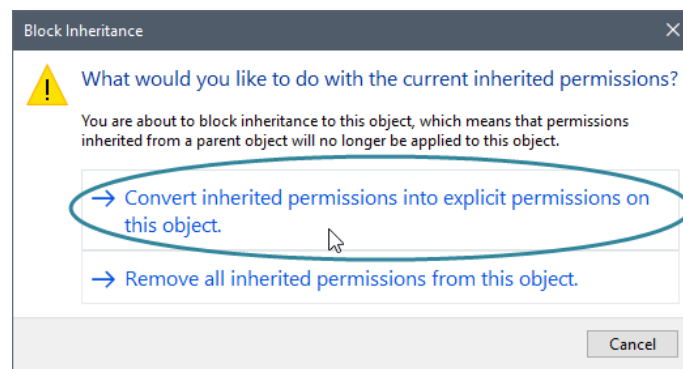
1. Navigate to one of the folders that needs to be secured - in this case we have selected the folder where the Mastersizer audit trail files are stored. Right-click on the folder and through the context menu open the folder Properties.



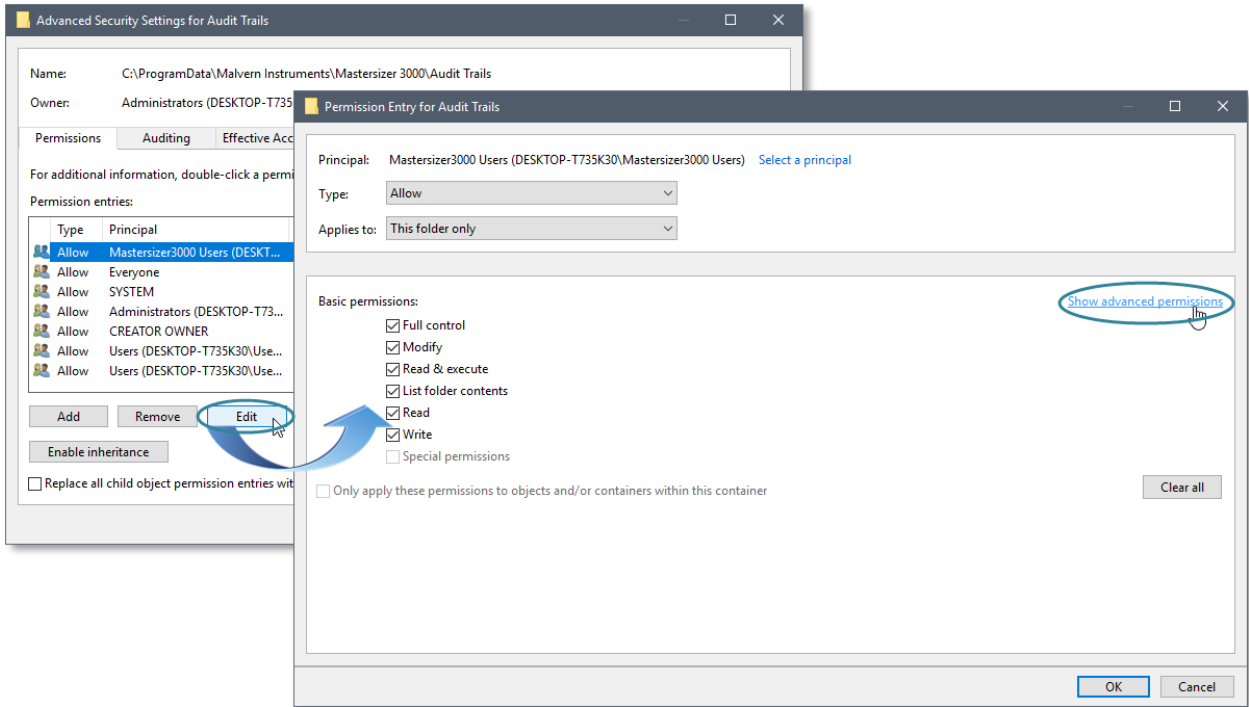
2. Within the **Audit Trails Properties** dialogue, left-click on the **Security** tab and left-click the **Advanced** button to open the **Advanced Security Settings**.
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button:



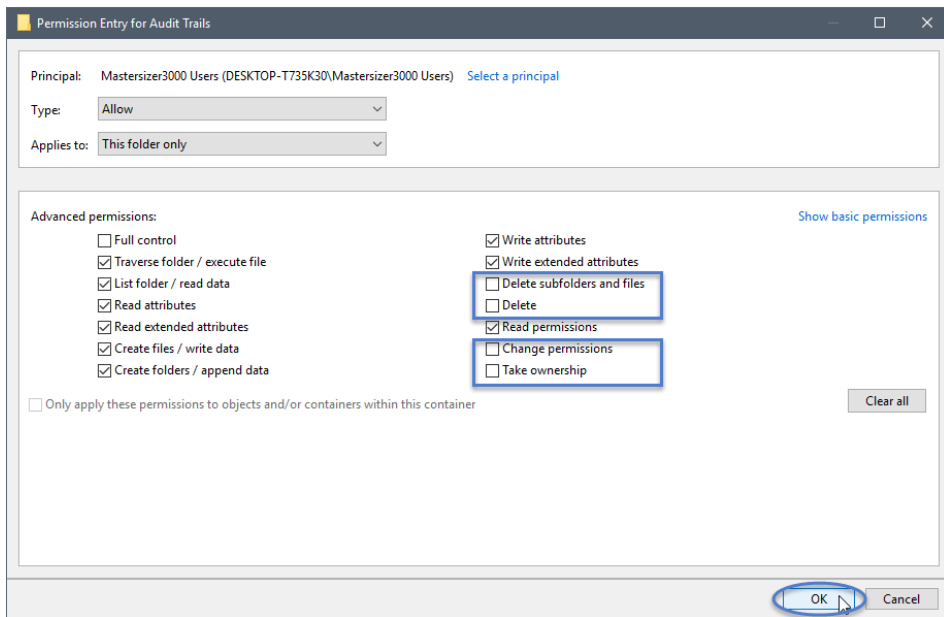
4. Within **Block Inheritance**, left-click on **Convert inherited permissions into explicit permissions on this object** – this removes the permission inheritance from the parent folder, whilst keeping the any current users and groups settings.



5. After returning to the **Advanced Security Settings** window, left-click to select the **Mastersizer3000 Users** group and then left-click the **Edit** button.
6. In the **Permissions Entry** window, left-click the **Show advanced permissions** to reveal the full permissions list.

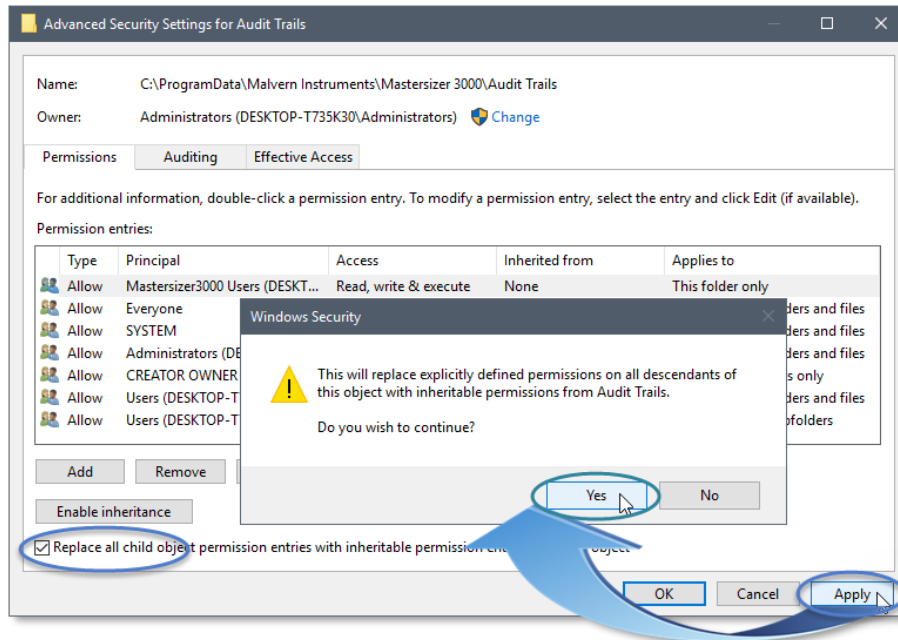


7. Left-click to de-select the check-boxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.

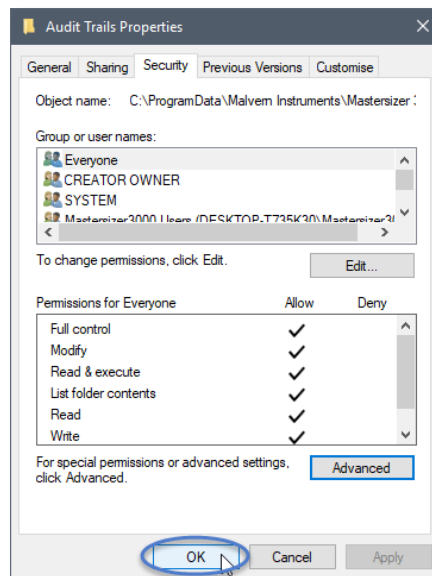


8. Left-click **Replace all child permission entries with inheritable permission entries from the object** and left-click the **Apply** button.

- Left-click the **Yes** button when prompted to replace the permissions and the **OK** button when you return to the previous window.

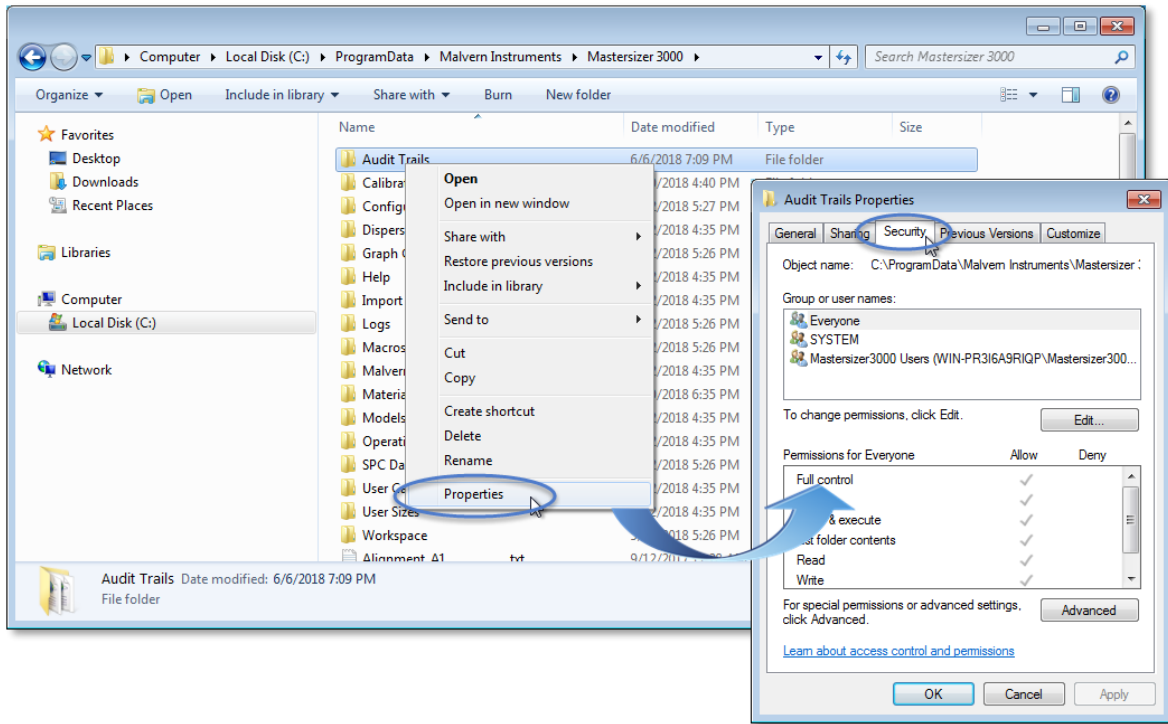


- Left-click the **OK** button when you return to original folder properties window.

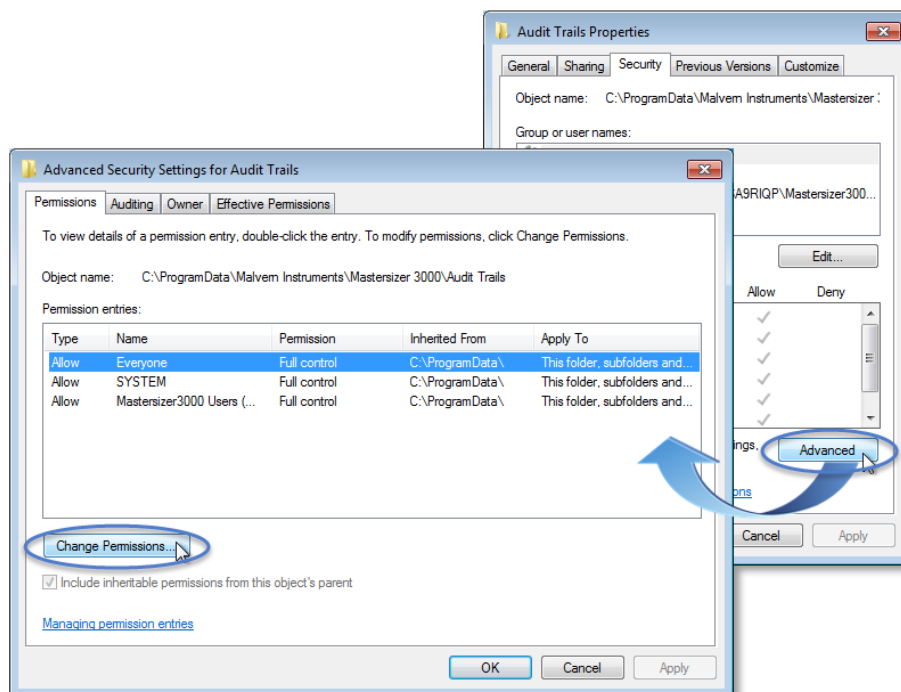


Changing the folder security permissions in Windows 7

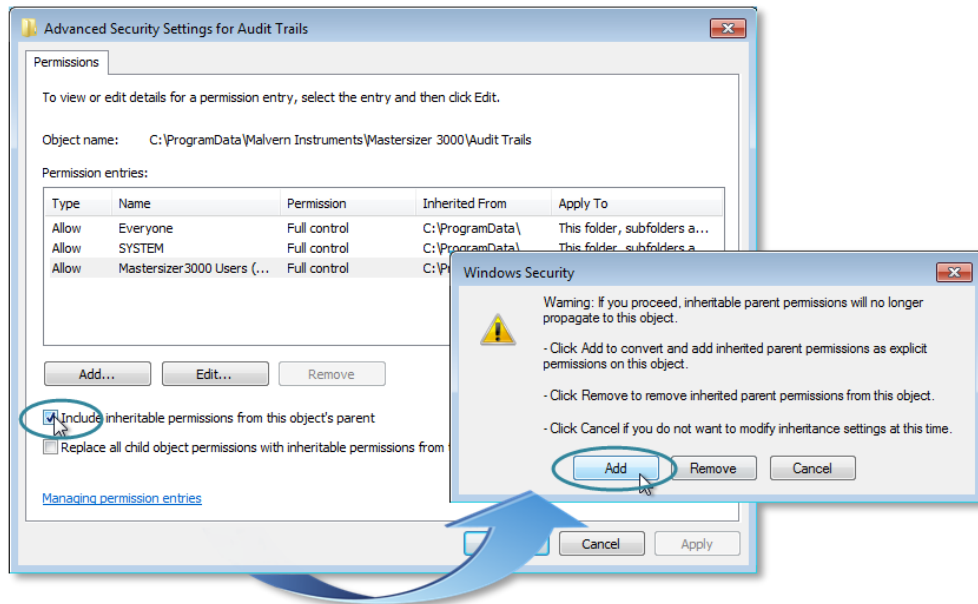
- Navigate to one of the folders that needs to be secured - in this case we have selected the folder where the Mastersizer audit trail files are stored. Right-click on the folder and through the context menu open the folder Properties.



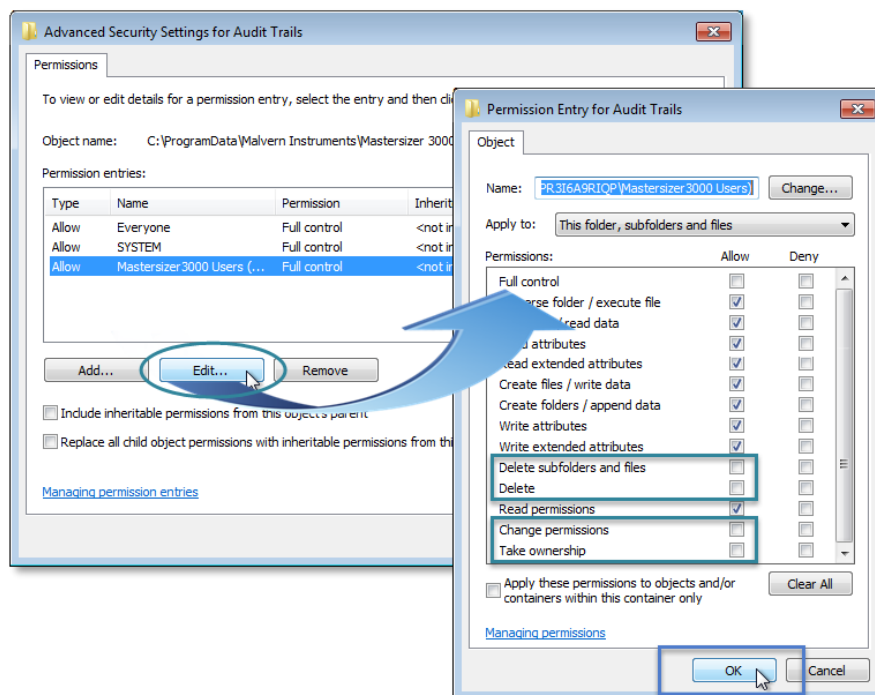
2. Within **Audit Trails Properties**, left-click on the **Security** tab and left-click the **Advanced** button to open the **Advanced Security Settings**.
3. Within the **Advanced Security Settings** left-click the **Change Permissions** button. This will open an identical with the options to change the inheritable permissions.



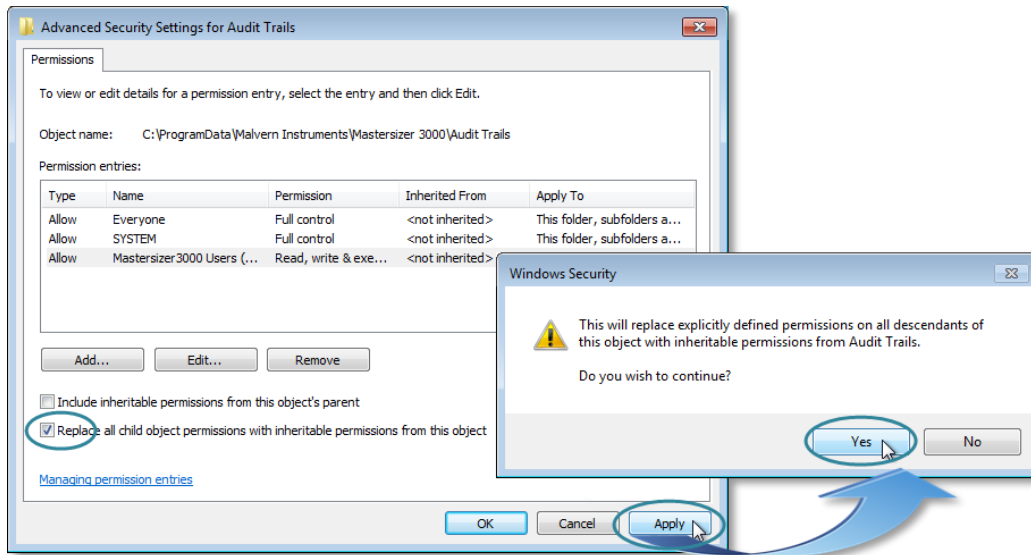
- In the second the **Advanced Security Settings** window, left-click to deselect the **Include inheritable permissions from this object's parent** check-box and when prompted left-click the **Add** button to convert and add the inherited permissions from parent.



- Left-click to select the **Mastersizer3000 Users** group and left-click the **Edit** button to open the **Permissions Entry** window.



- Left-click to deselect the **Delete subfolders and files**, **Delete**, **Change permissions** and **Take ownership** check-boxes and finish by left-clicking the **OK** button. Warning, do not select the check-box **Apply these permissions to objects and/or containers within this container only**.
- Returning to the previous window, left-click the **Replace all child object permissions with inheritable permissions from this object** check-box and when prompted to confirm left-click the **OK** button.



- Left-click **OK** on the remaining windows to close them.

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
Accessory status bar is green but SOP and Manual measurement options greyed out.	From time to time the SOP and manual measurement options are still greyed out even when the accessory status bar is green. To re-enable these options, right-click on the accessory status bar and reselect the accessory.	Intermittent Observation
Reporting of zero measurements.	In rare cases a zero measurement can occur in both wet and dry measurements. A zero distribution is recorded in the measurement file. The previous background is displayed for this zero measurement. No work around available	Medium risk issue
When either viewing or extracting some SOP's an error becomes flagged when either trying to save or even close	It is due to the ! flag against any ultrasound setting less than 8 secs, even if the ultrasound settings are greyed out. This is the software checking the validity of settings even on inactive settings.	Low risk issue

	Work round is to make the inactive setting active and change the setting to a valid number.	
Software can crash when batch printing	When selecting too many reports and/or too many records for batch printing, an error can occur causing a crash exception. No work around available	Low risk issue
User appears able to sign-off read-only measurement files	When a measurement file is read only (ie padlocked) users appear to be able to sign records. However, this sign-off will not save, but an entry will be recorded in the system Audit history. Work round is to remove the read only property on the file before signing. Or to save the file under a new file name.	Medium risk issue
Loss in connection to a Network storage location can cause a crash exception	If a file being used is stored in a Network location, and the connection to that location is lost for some reason. The software can crash when the save is attempted. No work around available	Medium risk issue
Aero S and Aero M sample feed control	When carrying out manual measurements it is possible to enable the sample feed for the Aero dispersion unit with the vacuum and dispersion air switched off by clicking the Feed button twice within the accessory controls. After approximately ten seconds the system will switch back into standby mode and an 'insufficient exhaust vacuum / air achieved' error message will be displayed. However, some sample may be lost.	Error can be avoided procedurally (avoid double-clicking the feed button).
Corrupt report settings file causes software crash on start-up	It has been observed that the global report settings file may become corrupt. This file holds the company name and logo used across all reports in the software. A symptom of this issue is the software crashing on start-up with an exception "hexadecimal value 0x00, is an invalid character". The workaround is to delete the contents of folder at <i>C:\ProgramData\Malvern Instruments \Malvern.Reporting</i> . This will trigger a new fresh settings file to be created – you will have to reconfigure your company name and logo in reports.	Medium risk issue
Warnings are displayed about corrupt measurement files	The software has built in detection of when measurement files are at risk of being corrupted. If you see one of these messages, you are probably creating too large a measurement file.	Intermittent Observation

Instrument disconnects after firmware upgrade	An issue has been seen for some installations whereby the instrument will become disconnected from the computer following a firmware upgrade. Turning the instrument off and on again will cause it to successfully reconnect to the software.	Intermittent Observation
The manual measurement settings do not match the connected/active dispersion unit.	See know issue description below.	Intermittent Observation
Some text still appears in English when running with a different language selected.	The translation of all software text will continue in future releases.	Low risk issue
Software does not open all files selected when they are opened using Windows Explorer.	Use the Open menu option in the Mastersizer 3000 software to open multiple files.	Low risk issue
The system audit trail displays duplicated columns for each language under which the system has been run when auditing has been enabled.	No work-around available.	Low risk issue
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
Trend table print out is limited by paper size.	Report widgets are designed to fit on one page, and will not wrap over pages. If you select lots of measurement records, the trend table widget will expand to fill the page. However, if you select more measurement records than can fit in a trend table on a single page then the displayed records will be truncated at the page boundary. The only work around for this issue is to print the report on a larger paper size. Paper size A4 has a limit of 56 records in a trend table, whereas paper size A3 has a limit of 86 records.	Low risk issue
Some parameters are not imported from Mastersizer 2000 measurement records	When importing Mastersizer 2000 measurement records into the Mastersizer 3000 software, some SOP parameters from the Mastersizer 2000 records do not get imported. However, all of the parameters required for result review or recalculation are present.	Low risk issue
Manual measurement errors are reported if the Aero dispersion	The manual measurement feature in the software stores the last used settings. This includes configuration of the Aero dry powder disperser. If	Low risk issue

<p>unit configuration has changed between measurements.</p>	<p>you change the configuration between measurements and then open a manual measurement, the software will report an error stating that configuration is wrong. If this happens, close and re-open the manual measurement window and change the manual measurement settings to match your new Aero configuration.</p>	
<p>Software exception is reported if the software is closed when a macro is running.</p>	<p>All currently running macros must be closed before closing the software.</p>	<p>Low risk issue</p>
<p>Some report widgets are truncated in the print preview view.</p>	<p>Some report widgets may not be displayed correctly within the print preview screen. However, if the report is printed all of the information within the widget will be shown.</p>	<p>Low risk issue</p>
<p>Software may crash when exporting data with custom sample identifiers which start with a number</p>	<p>Exporting measurement data with custom sample identifiers beginning with a number will cause the software to crash when you select an export template that contains sample identifiers. The only work-around is to prefix sample identifiers with letters.</p>	<p>Low risk issue</p>
<p>Ultrasound SOP option 'Continuous (From Measurement Start)' does not turn off in SOP playlist</p>	<p>If you use an SOP with the ultrasound option 'Continuous (From Measurement Start)' in an SOP playlist, when running a subsequent SOP with no ultrasound turned on, the ultrasound will not turn off as expected. The work around is to use the 'Continuous (From Sample Addition)' option in the SOP rather than 'Continuous (From Measurement Start)'. When this playlist is run, then the ultrasound will turn off when executing a subsequent SOP which does not require ultrasound.</p>	<p>Low risk issue</p>
<p>Cannot load old custom calculations from file</p>	<p>When trying to load a custom calculation created in v3.30 software or earlier, the software may report error and the calculation will not load. The workaround is to re-export the custom calculation from the original report in a recent version of the software.</p>	<p>Low risk issue</p>
<p>Data quality tab is not displayed immediately when selected from the extended features list</p>	<p>Given that the software has just been installed and the option to enable the extended software features is selected. Then when the application is restarted the data quality tab will not be displayed if the default view is selected. The work-around is to select the 2-pane vertical view which will display the data quality tab. Then reverting to the default view will display the data quality tab.</p>	<p>Low risk issue</p>

Ultrasound level applied during clean reported as 0%

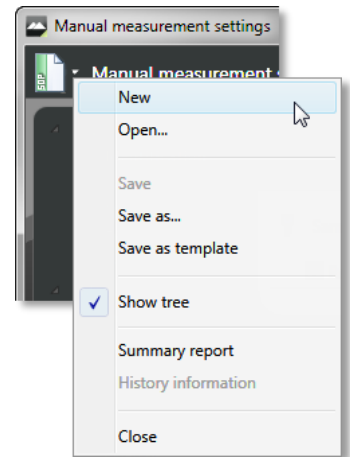
You may find that the measurement manager reports that 0% ultrasound is being applied during cleaning when you have set an ultrasound demand of greater than 0%. Evidence suggests that ultrasound is applied correctly as per the configured ultrasound demand, but the value shown in the measurement window is incorrect.

Low risk issue

Manual measurement settings do not match the connected / active dispersion unit

Occasionally, users may see the wet accessory related manual measurement settings when a dry unit is attached, or visa-versa. If this occurs, open the manual measurement settings window and click the **New** menu item from the **Window Features** menu:

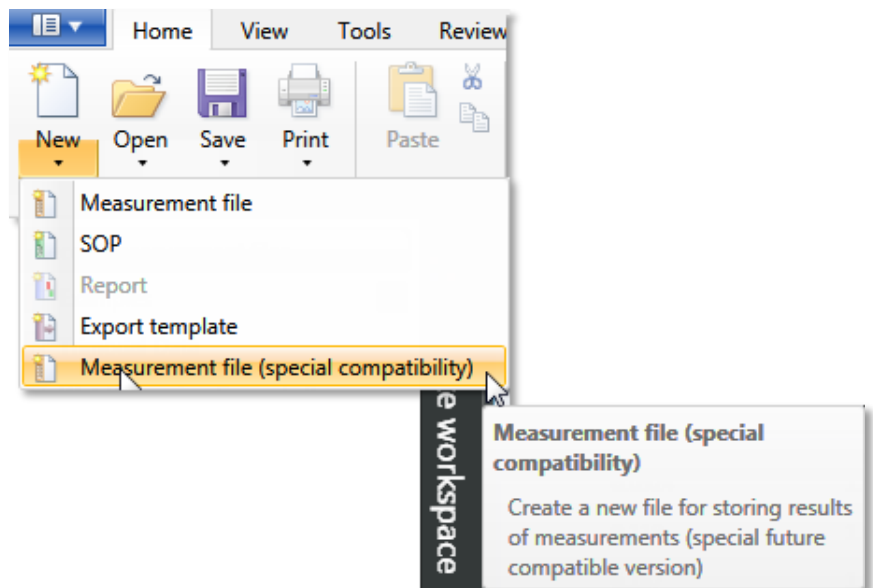
This will reset all measurement settings to their defaults for the active accessory type. This issue has been reported after upgrading from early versions of the software, but does not occur on all systems.



Measurement File Format

In v3.40 of the Mastersizer 3000 software we have re-introduced the file format used in older versions of the software (v3.10 and earlier) due to an incompatibility issue we discovered when the software's 21 CFR Part 11 features are enabled. This format is now selected by default and offers the advantage that it is compatible with all earlier versions of the software.

Note that files created using v3.20 and v3.30 of the Mastersizer 3000 software can still be opened, edited and saved using v3.40. The software will automatically switch to the correct file format if you select a file created in these versions. If you want to specifically create a file in the same format used by v3.20 and v3.30, select the **Measurement file (special compatibility)** option when creating a new measurement file:



Measurement File Size and Corruption Warnings

Version 3.20 and higher of the Mastersizer software includes the ability to detect when measurement files are at risk of becoming corrupted. If you see one of these messages, you are probably creating too large a measurement file. We recommend that you keep measurement files to a maximum size of 100 records, and advise that you try to remember to regularly create and use new files to store measurement records.

Note that Malvern are currently investigating possible alternative measurement file formats for use in future software releases, with the goal of increasing the maximum number of records which can be robustly stored within a single file.

Backward Compatibility

This software is only compatible with the Mastersizer 3000 (MAZ3000) and Mastersizer 3000E (MAZ3010) systems, and cannot be used with the Mastersizer 2000 (APA2000) or Mastersizer 2000E systems. It is possible, however, to review Mastersizer 2000 / 2000E results within the Mastersizer 3000 / 3000E software. Please refer to the user manuals and software help for guidance as to how this is achieved.

Analysis Error codes

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

Error Code	Description
1 4 5 44	Error detected with the selected material or dispersant optical properties.
3 6 7	Unable to load or generate a scattering matrix.
8	Unable to initialize the result calculation routine.
9	There is no raw data to analyze.
10	Unable to apply the selected analysis settings.
11 12	Error occurred during generation of the scattering matrix.
13	Error occurred during raw data handling.
14 15	Unable to configure the result calculation routine.
16 17	Unable to generate a result based on the input raw data.
18 20 22	Could not find any particle size distribution modes in the result.
19	The analysis residual is greater than 99.9%.

23 24	Error occurred when using the Fraunhofer analysis model.
25	Corrupt analysis settings detected.
40 41 42	Scattering matrix calculation settings errors detected.
43	Error occurred while generating the scattering matrix.
45	Matrix generation is currently busy.

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