MORPHOLOGI SOFTWARE: v10.20 (PSS0065-03)
SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0065-03 v10.20 of the software for the Morphologi 4 instrument family. It covers software issues that have been fixed and introduces new features. In particular, the software release supports customers in the pharmaceutical industry who need improved compliance to data integrity requirements.

The information within this document 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.

Note:
Please check for any updates to this Software Update Notification at
www.malvernpanalytical.com/en/support/product-support/morphologi-range/morphologi-4

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. The software has been fully tested under Windows 10 (64-bit) version 1809 which is the only recommended operating system.

Table 1: Recommended system requirements for the Morphologi software.

Feature	Specification	Feature	Specification
Processor Type	Intel Core i7-7700 vPRO Processor QC/8MB/8T/3.6GHz/65W) (CPU: 5th generation i7 minimum)	**Display**	2 x 23" Widescreen Flat Panel Monitors for software and live video feed
		Additional Storage Media	DVD +/-R/RW drive
Memory	16GB (2x8GB)	**Connectivity**	USB3
Hard Disk Storage	2Tb HDD	**Operating System**	Windows 10 (64 bit) version 1809

Note:
Power saving, turn off hard disk and USB selective suspend should be disabled, to ensure that the software can operate correctly during long measurement, see *Appendix A*.

Note:
Some 3rd party software or operating system patches may prevent the Morphologi software from running correctly. It is not possible to test for compatibility with all windows programs.

Supported Languages

The Morphologi software suite is available as an English language application.

Installation Instructions

Installer

Disconnect the Instrument from the computer. This prevents Windows from loading its default driver for the camera which causes the software to crash if run straight from installation. If the instrument was connected during installation, disconnect and re-connect to force Windows to reload the correct driver.

The software suite comes on an auto-loading CD-ROM disc. Inserting the disc into a system configured to auto-run a CD will start the installation program automatically. If your system does not support this feature, run the ***Malvern Morphologi v10.20 PSS0065-03 EN.exe*** program from your CD drive - Admin rights are required.

If you are installing the software from a web download, simply double-click the ***Malvern Morphologi v10.20 PSS0065-03 EN.exe*** to start the installation - Admin rights are required.

During the installation of the Malvern Panalytical application software, the Windows UAC will request permission to install the hardware drivers that are required to support the Malvern Panalytical product. When prompted, you **must** allow the installation of these drivers.

Uninstall Procedure

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

Backward Compatibility

This is the third release of the software which supports the Morphologi 4 and 4-ID. This software is only compatible with the Morphologi 4 platform and cannot be used with Morphologi G3 systems. However, it is possible to review Morphologi G3 results within the Morphologi 4 software.

New Features

21 CFR Part 11 Support

Morphologi 4 version 10.20 software includes full support for customers who require the software to run within a 21 CFR Part 11 compliant environment. This includes new features relating to software access control, measurement auditing and the setting up of SOPs. These features are enabled by use of a software feature key which is specific to each instrument. Please contact your local Malvern Panalytical Representative if you wish to obtain a feature key to enable the software's 21 CFR Part 11 features on your system.

Full details of the 21 CFR Part 11 features available within the Morphologi 4 software can be found in the following documents included on the Morphologi 4 software CD-ROM:

- 21 CFR Part 11 User Guide (MAN0609-01EN) provides a full description of the software features associated with 21 CFR Part 11, including the software's security system.

- 21 CFR Part 11 Compliance Guide for the Morphologi 4 software version 10.20 and higher (CCM0007) provides background information for users relating the functionality provided within the Morphologi 4 software to each of the requirements mentioned with 21CFR Part 11

The new features implemented in Morphologi 4 software version 10.20 are listed in Table 1.

Table 1: New features implemented in Morphologi 4 software version 10.20

Reference	Issue

69998
98366
	Changes to users and groups are audited and a reason for the change is required.
	   a. Users: Add/Delete/Edit/Disable/Unlock users
	   b. Groups: Add/Delete/Edit/Add users/Remove users/Change permission

70001	Changes made to security settings, ER/ES configuration and changes to group permissions are audited

70004
96060
99679
	Additional auditing of measurement events: start, end and abort.
	   a. Measurement abort including during measurement setup
	   b. Start of Manual measurements
	      • Analyze from Image file
	      • Manual microscope grab and analyze
	      • Manual microscope point Raman spectrum acquisition
	      • Manual microscope SDU operation
	      • Manual Raman targeting
	   c. Merge spectrum in main Spectra Panel
	   d. Partial ID measurement saved if aborted midway
	   e. Export measurement

70006
70009
98440
99866
	Improved search functions of the audit trail viewer.
	   a. Filter by date, user and event type
	   b. Search over multiple audit trails
	   c. Warn if search end date is earlier than start date when filtering audit trails so results are not accidentally excluded
	   d. Long audit messages are truncated to 260 character limit

96091	Protect audit trail files from being overwritten.

99960
99967
99958
	Improving the SOP comparison function.
	   a. Improved handling of collection data (such as classification, spectral libraries and background spectra)
	   b. Truncate large data fields (spectra, spectral masks,) sufficiently to illustrate difference

	Updated help and manuals.

Fixed issues

The main issues fixed in this release of the software are listed in Table 2.

Table 2: Bug fixes implemented in Morphologi 4 software version 10.20

Reference	Issue
98382 102796	Mechanical stage limit switches are checked during measurement, if this limit is reached, the user will be warned, and the measurement will be aborted. This prevents possible rescanning and duplication of particles if the scan area extends beyond the mechanical stage limit.
69343 97720 98367	Fixed 'Unknown' user appearing in the user and group dialog box and in the Audit trail when 21 CFR part 11 features and security have been enabled.
97464	Fixed lines styles changes not being saved
95833	Fixed Send to 'Know It All' feature not always performing spectral search automatically with Windows 10.
94456	Fixed Export Spectra only exporting all spectra (including excluded particle spectra). User can now select to export included, excluded or spectra from within selected classes.

Known Issues

Software bugs have been discovered within the software, and will be investigated as part of a future release are listed in Table 3. Please follow the suggested work-around where one is available.

Table 3: Known issues in Morphologi 4 software version 10.20.

Reference	Issue	Workaround
98382 102796	If the mechanical stage limit is reached, the user will be warned, and the measurement will be aborted.	Adjust the scan area in the SOP moving it away from the mechanical limit (move it up in the Y-axis). Inform your local Malvern Panalytical Representative.
103355	Potential discontinuity in merged objective measurement result.	Under investigation, avoid using this feature.
93685	Renaming an SOP via Windows file system rather than from within Morphologi software results in the original SOP name being reported when running the SOP, in reports and in the audit trail.	Rename SOPs using the 'save as' function within the Morphologi Software and not via Windows file system.
101309	Problem reporting version differences if the combined length of any SOP parameters (such as sample name, comments or reason for change) is >120 characters.	Restrict SOP inputs to <120 characters.
104635	Video content may need enabling to view videos from the Morphologi Help.	Either enable active content in Internet Explorer or open the help in another browser that supports active content by default. See appendix B

84954	Exporting spectra to default file locations is not possible if security settings require no file deletion (for example with 21 CFR part 11 restrictions applied) since temporary files are initially created and then need to be removed.	Export spectra to alternative folder not restricted by no delete
N/A	Morphologi G3-ID reference spectra can be used in chemical libraries for Morphologi 4-ID but will not match the full wavenumber range of the new instrument.	Where possible acquire new reference spectra with the Morphologi 4-ID.
N/A	Measurement aborts at start of scan if memory allocation fails. An error will be reported, and the user will be instructed to restart the software.	Restart software if this issue occurs.
85435	Edge stitching memory load – Use of edge stitching on some samples will cause memory use issues which can end the measurement.	Edge stitching is designed for long thin particles to extend the upper size limit. It should not be used for particles where the 2nd dimension is close to the standard maximum size for the objective.
78601	Power cycle required to end process after Crash.	

Windows Security Settings

With a 21CFR11 compliant computer system, one of first concerns to address is the potential for the loss of data; either accidently, 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 'Morphologi 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 Morphologi 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**.

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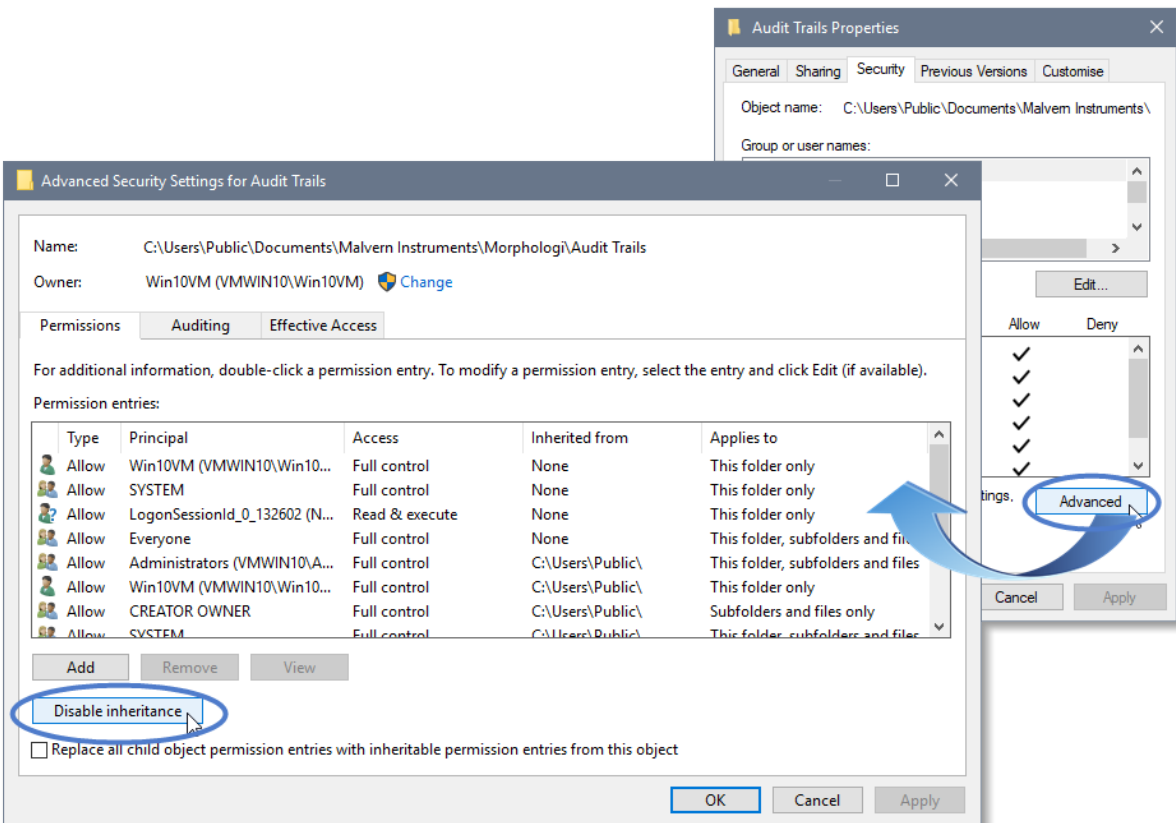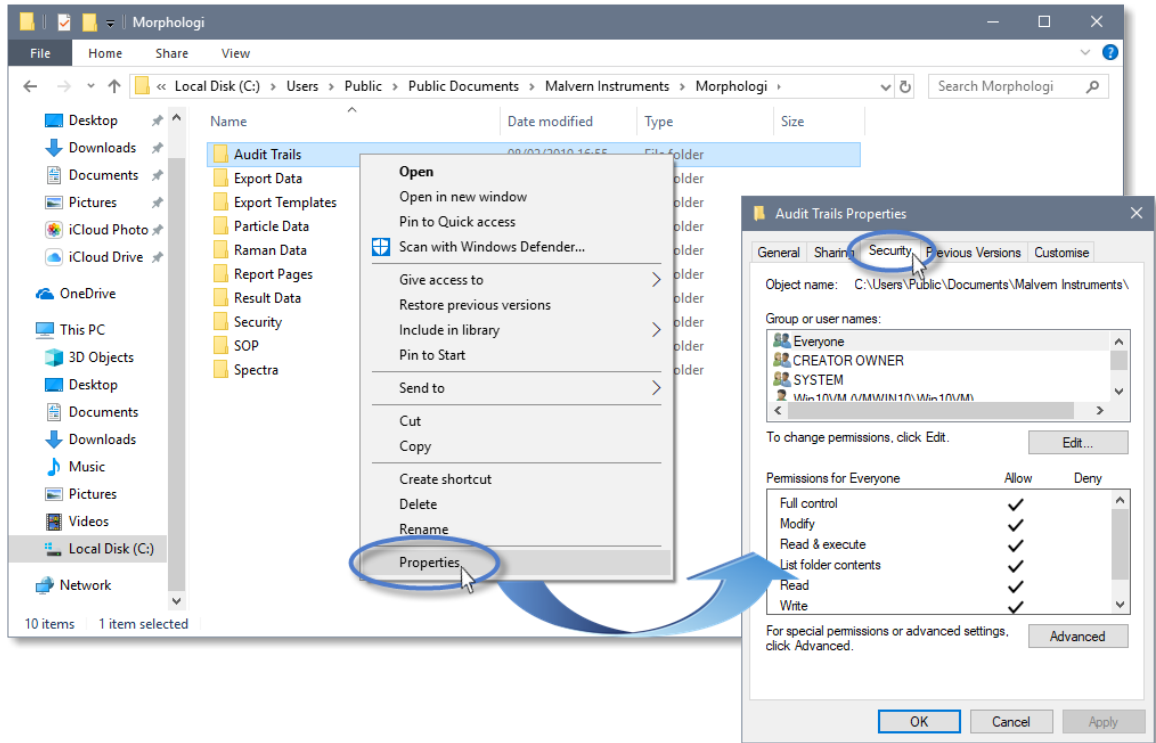
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button.

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.
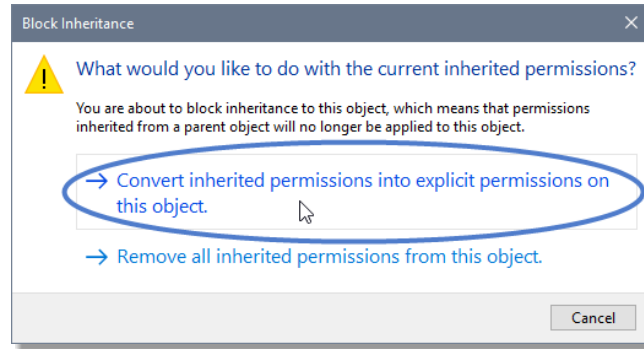

5. After returning to the **Advanced Security Settings** window, left-click to select the **Morphologi Users** group and then left-click the **Edit** button.

6. In the **Permissions Entry** window, left-click the **Show advanced permissions** to reveal the full permissions list.
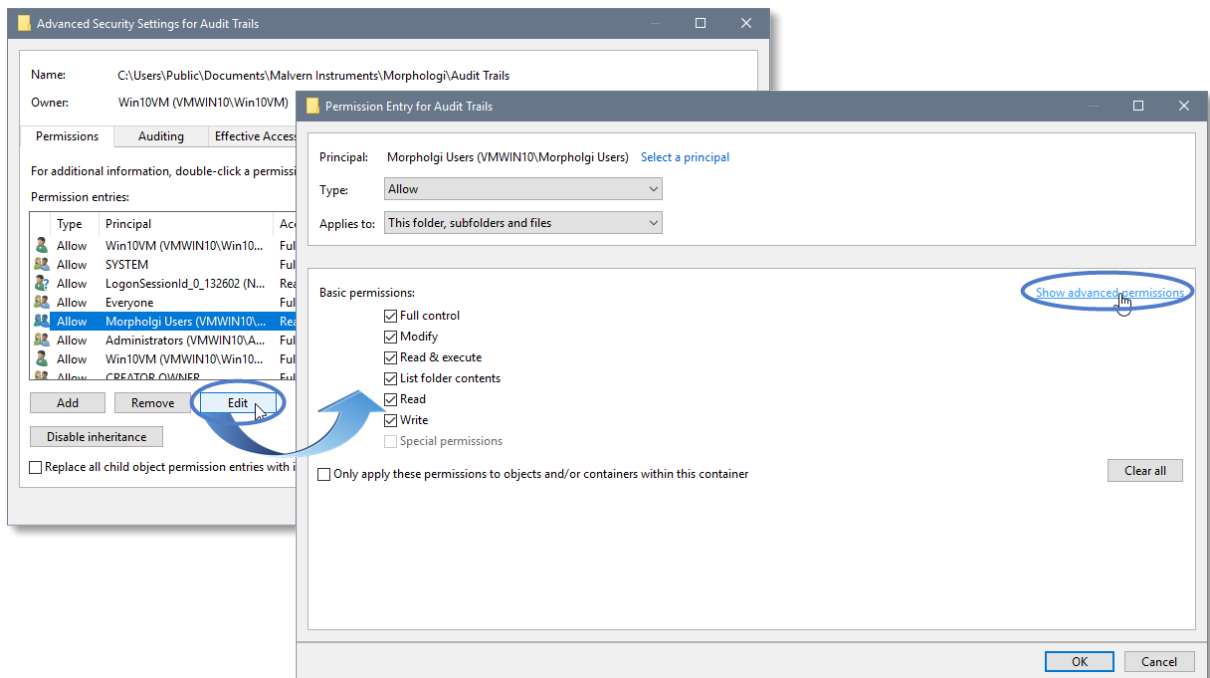
7. Left-click to de-select the check-boxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.
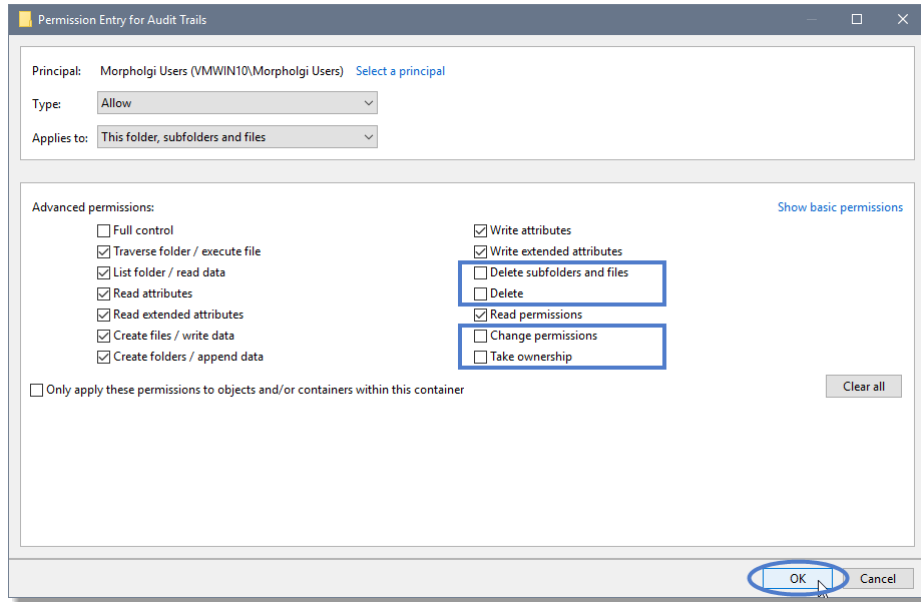
8. Left-click **Replace all child permission entries with inheritable permission entries from the object** and left-click the **Apply** button.

9. Left-click the **Yes** button when prompted to replace the permissions and the **OK** button when you return to the previous window.
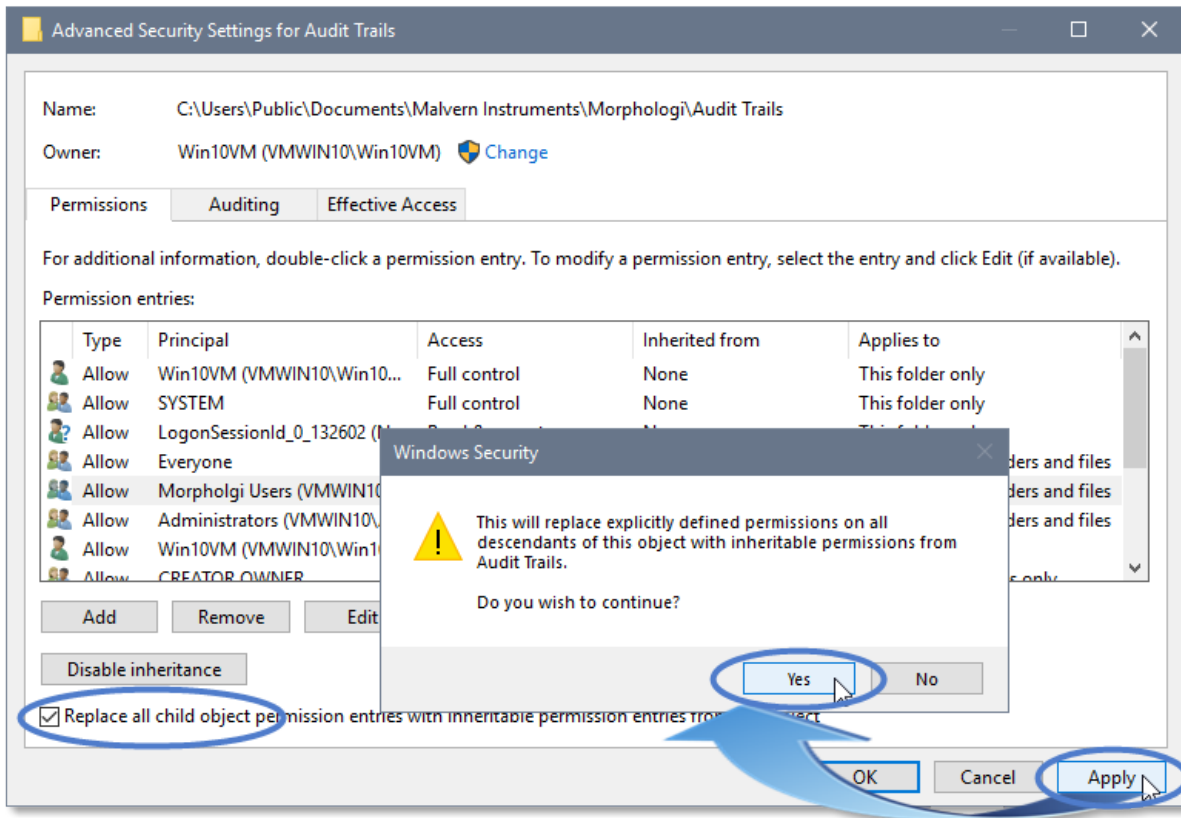
10. Left-click the **OK** button when you return to original folder properties window.
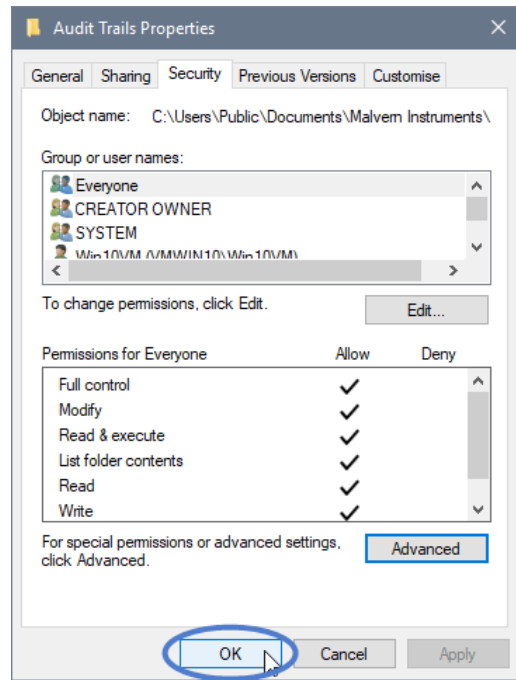
Error Reporting

Should persistent problems occur please contact your local Malvern Panalytical Helpdesk. To speed up response time include all the following:

- A **full-screen** screen shot of any error message and everything behind it.

- Full description of what was happening at time of issue and ideally leading up to it.

- Instrument serial number (e.g. MAL1060289)

- Software version – go to **Help–About Morphologi** (e.g. 10.20; all digits are important)

- System information – double click on the Morphologi 4 or 4-ID logo at bottom right corner of the Software. Take a screen shot of system information and include on error report.

- Additional system setting export – go to **tools–maintenance**. Enter the password (maintenanceon). Select **Export Site File** and save the text file to include on error report.

Appendix A:
Disabling power saving, hard disk sleep and USB selective suspend

To disable the power saving options of the computer, use the **Power Options** available in **Control Panel**.

1. Select the **High performance** power plan as shown.
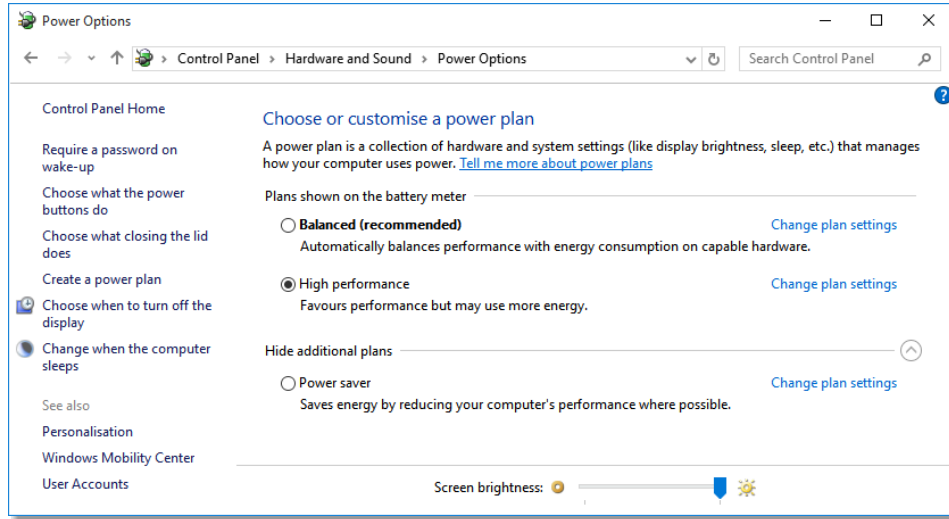
2. Change plan settings for **Turn off hard disk** to **Never**, and **USB selective** to **Disabled**.
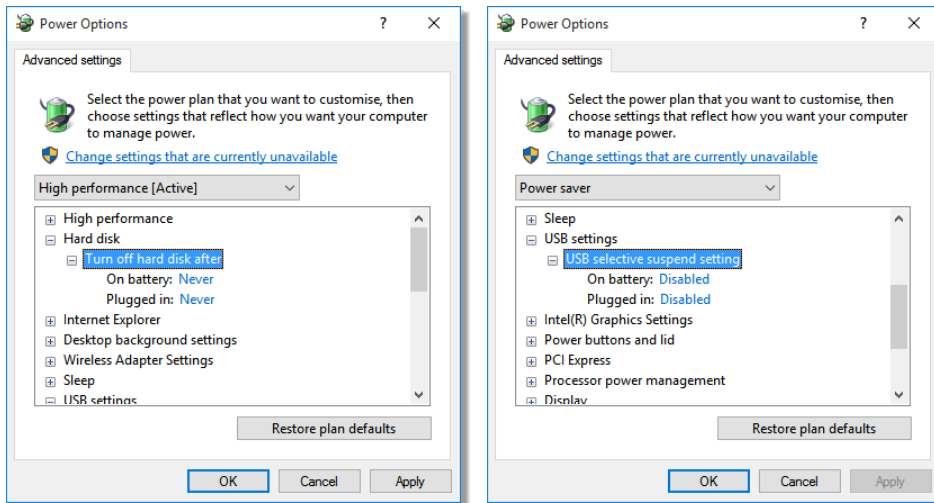
Appendix B: Enabling video content for Morphologi Help.

To view the video tutorials in the Morphologi Help either enable active content in Internet Explorer or open the Help in another browser that supports active content by default.

To enable active content in Internet Explorer, open the Internet Options and go to the advanced options then go to the advanced tab.
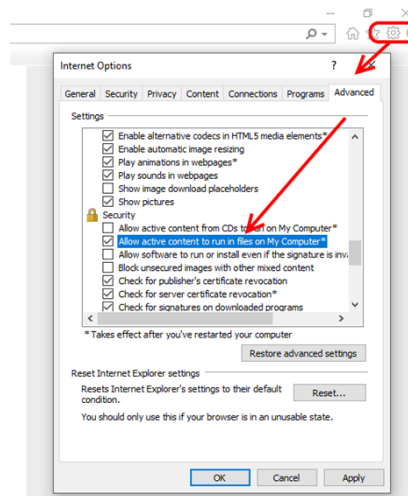
To open the Help in another browser that supports active content by default copy the help link from Internet Explorer to another browser such as Edge or Chrome and verify that these browsers have the rights to run local video content.
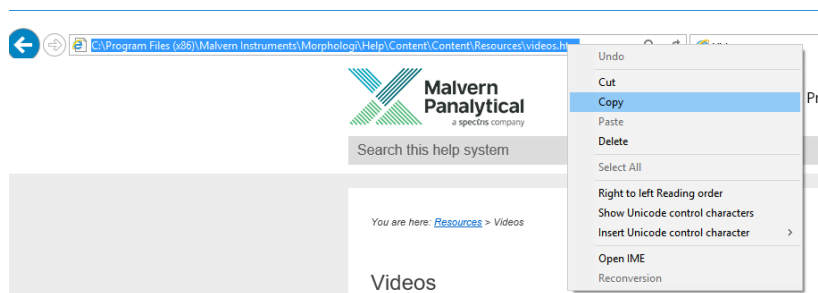
Copy browser link from Internet Explorer
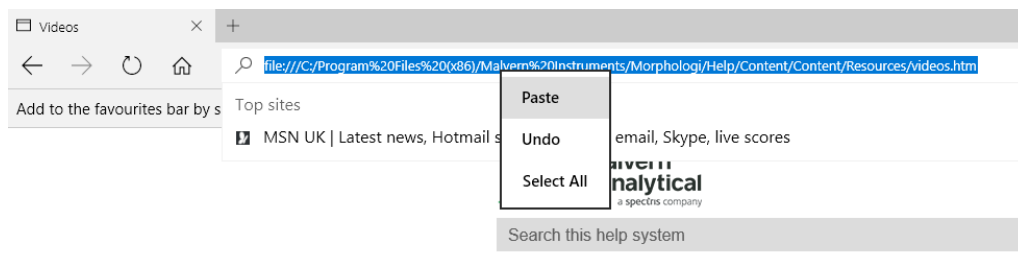
Paste browser link into Edge then press <enter> to load page.

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