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MORPHOLOGI SOFTWARE: v10.31 (PSS0065-06)
SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of Morphologi 4 software v10.31 (PSS0065-06) for the Morphologi 4 instrument family. It covers software issues that have been fixed and introduces new features.

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

If upgrading from a software version other than v10.30, please also refer to the Software Update Notification (SUN) for each version released since the version currently installed.

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 Pro (64-bit) version 1909 running Windows Defender which is the recommended operating system.

Table 1: Recommended system requirements for the Morphologi software.

Feature	Specification	Feature	Specification
Processor Type	Intel Core i7-8700 (minimum) Processor	**Display**	2 x 23" Widescreen Flat Panel Monitors for software and live video feed
Memory	16GB (2x8GB)	**Additional Storage Media**	DVD +/-R/RW drive
Solid State Storage	512 GB	**Connectivity**	USB3
Hard Disk Storage	2Tb HDD	**Operating System**	Windows 10 Pro (64 bit) – Version 1909 using Windows defender security

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 only 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 v10.31 PSS0065-06 EN.exe*** program from your CD drive – Administrator rights are required.

If you are installing the software from a web download, simply double-click the ***Malvern Morphologi v10.31 PSS0065-06 EN.exe*** to start the installation – Administrator rights are required.

During the installation of the Morphologi application software, the Windows User Account Control (UAC) will request permission to install the hardware drivers that are required to support the Morphologi 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 sixth 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

This release improves the Installation Qualification (IQ) process with new Performance Verification (PV) and system check reports for Morphological and ID components as detailed in *Table 2*. Stability and security have also been improved with new camera drivers and restrictions on custom calculation functionality.

Table 2: New features implemented in Morphologi 4 software version 10.31

Reference	New Feature
104246	Addition of a system check for the ID component of a Morphologi 4-ID which checks the spectrum of a serialized polystyrene slide with a pass/fail tolerance.
119031	Integration of performance verification for the Operational Qualification (OQ) and system checks into the software removing the need for engineers to have to export data externally.

Fixed issues

The main issues fixed in this release of the software are listed in *Table 3.*

Table 3: Bug fixes implemented in Morphologi 4 software version 10.31

Reference	Issue	Fix
110782 PROSOLV-2083	Reported stability issues found to be related to camera drivers	Update to the latest camera driver version has enabled the software to recover the connection to the camera in the event of a comms error. See *Appendix C.*

Unrestricted Document

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Known Issues

Software bugs that have been discovered within the software and will be investigated as part of a future release are listed in *Table 4*. Please follow the suggested work-around where one is available.

Table 4: Known issues in Morphologi 4 software version 10.31.

Reference	Issue	Workaround
146899	Export particles crash when there's no spectra in result	Manually targeting a single particle and saving a spectrum to it will generate a new record where the particles can be safely exported.
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.	

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.

Windows Security Settings

With a 21 CFR Part 11 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 I.T. professional can 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**.
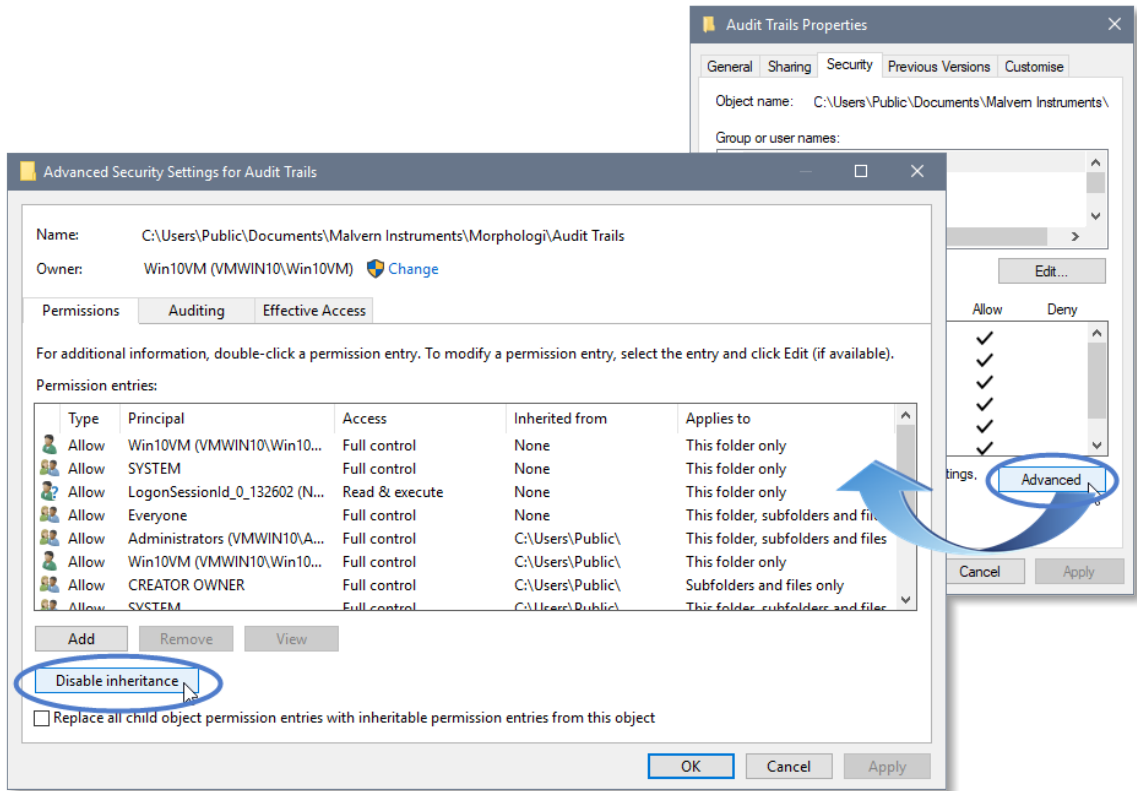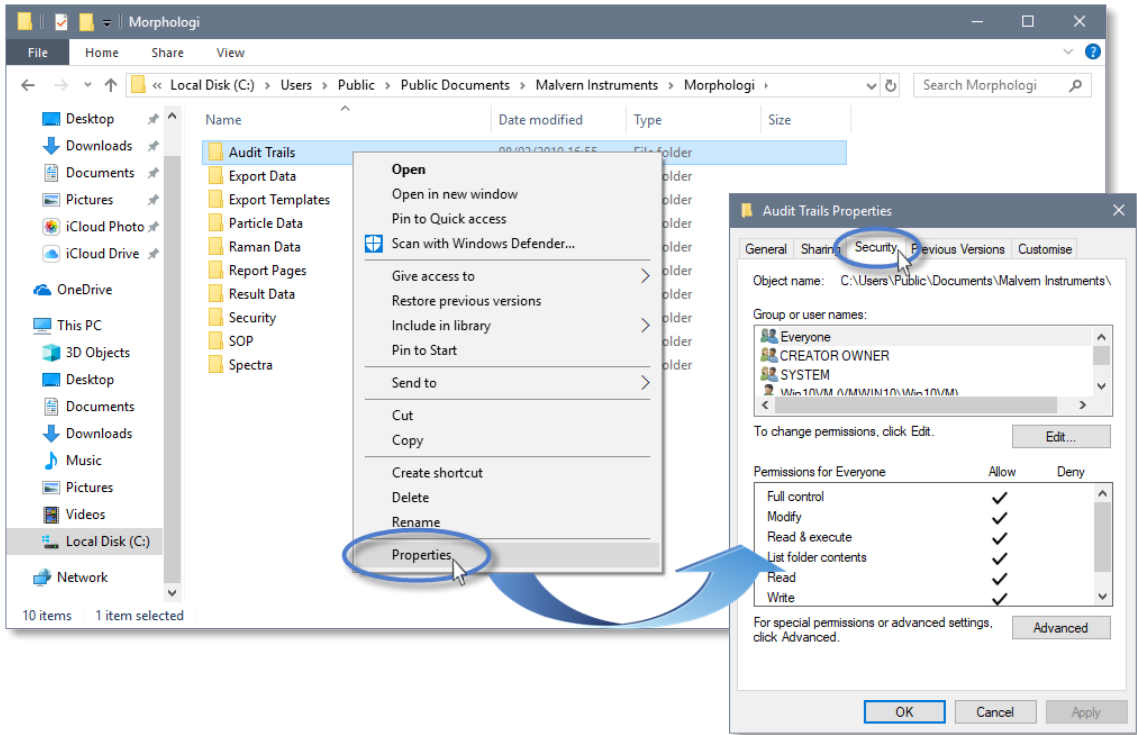
3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button.

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 current users and groups settings.
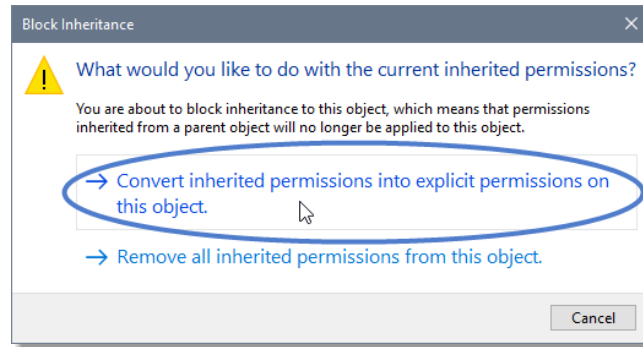

5. After returning to the **Advanced Security Settings** window, left-click to select the **Morphologi Users** group and then left-click the **Edit** button.

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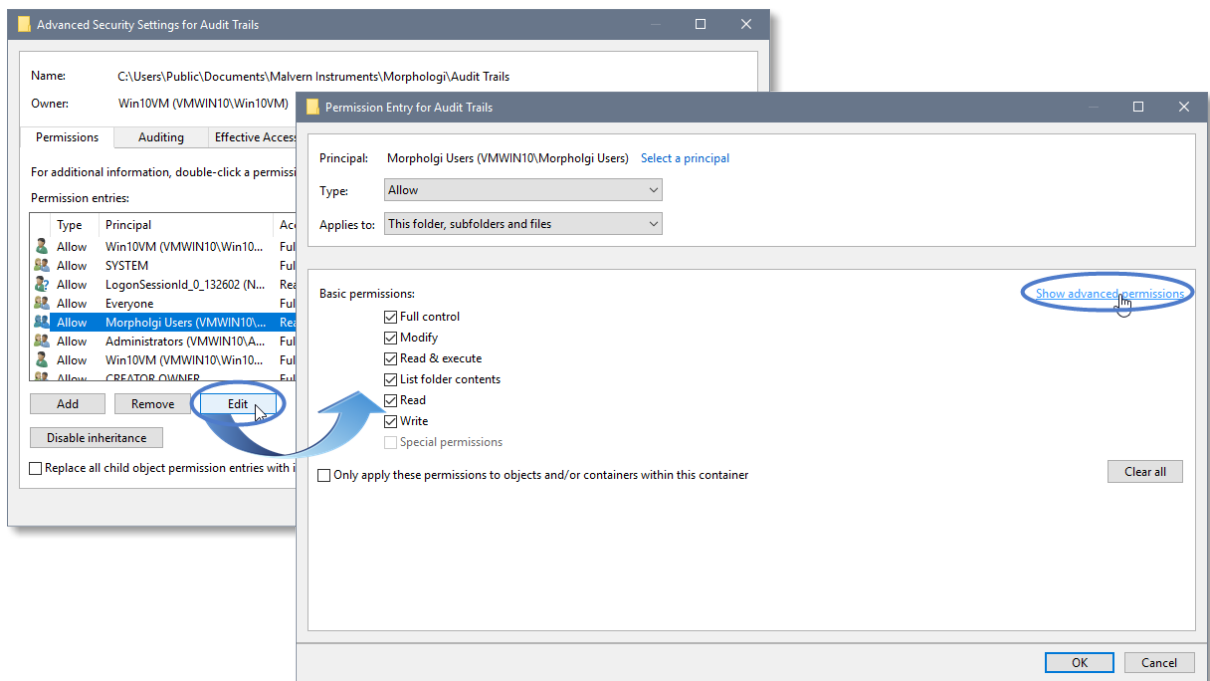
7. Left-click to de-select the check-boxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.
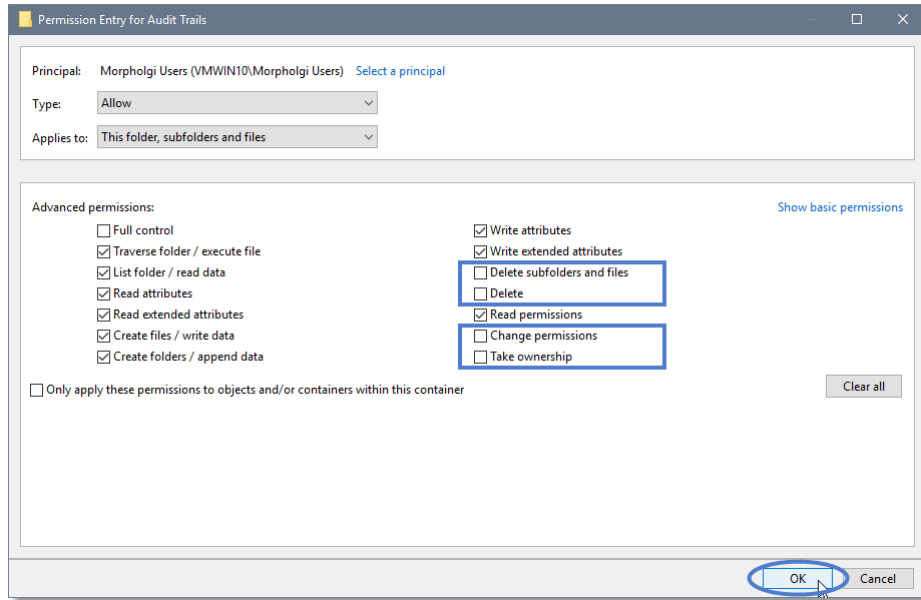
8. Left-click **Replace all child permission entries with inheritable permission entries from the object** and left-click the **Apply** button.

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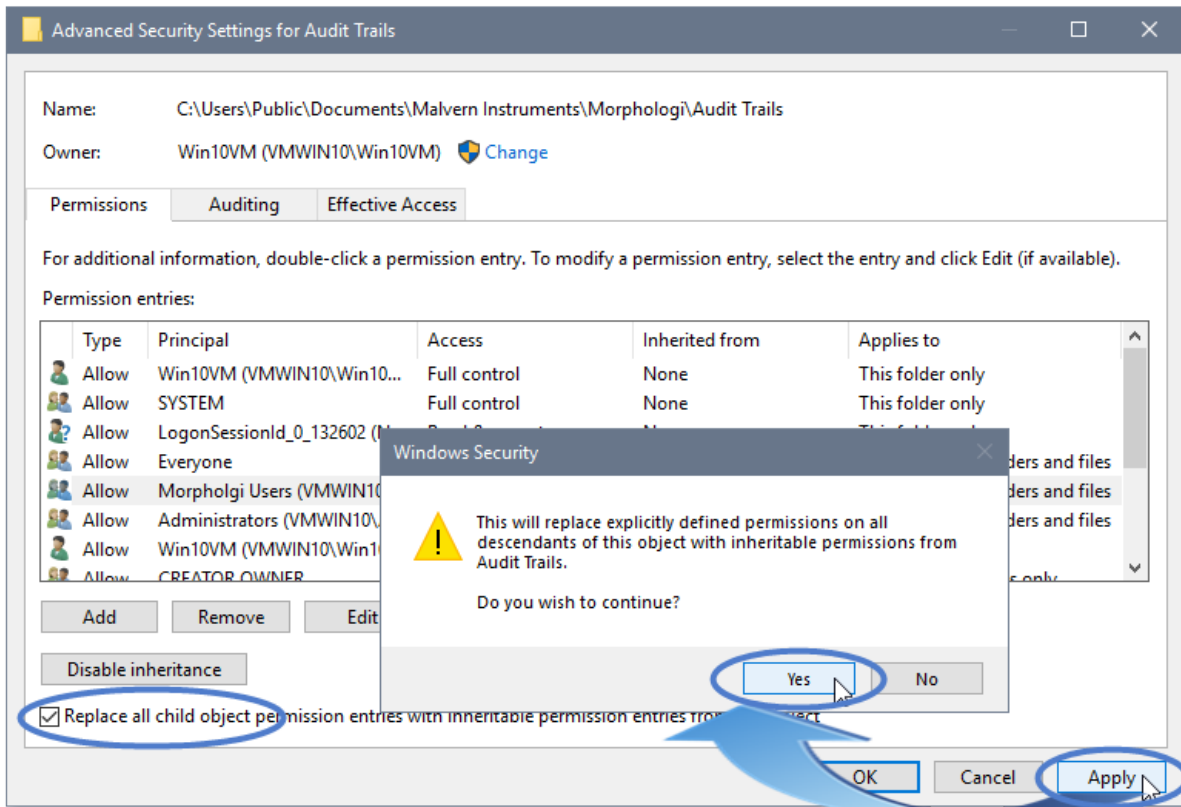
10. Left-click the **OK** button when you return to original folder properties window.
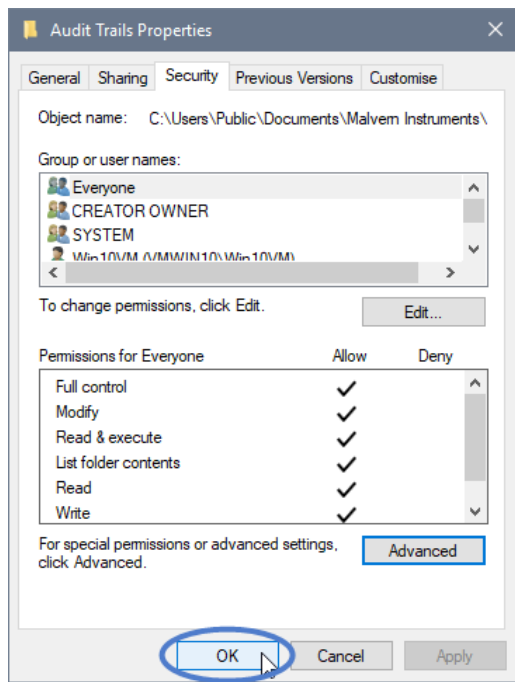

Error Reporting

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. 10.31; 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.
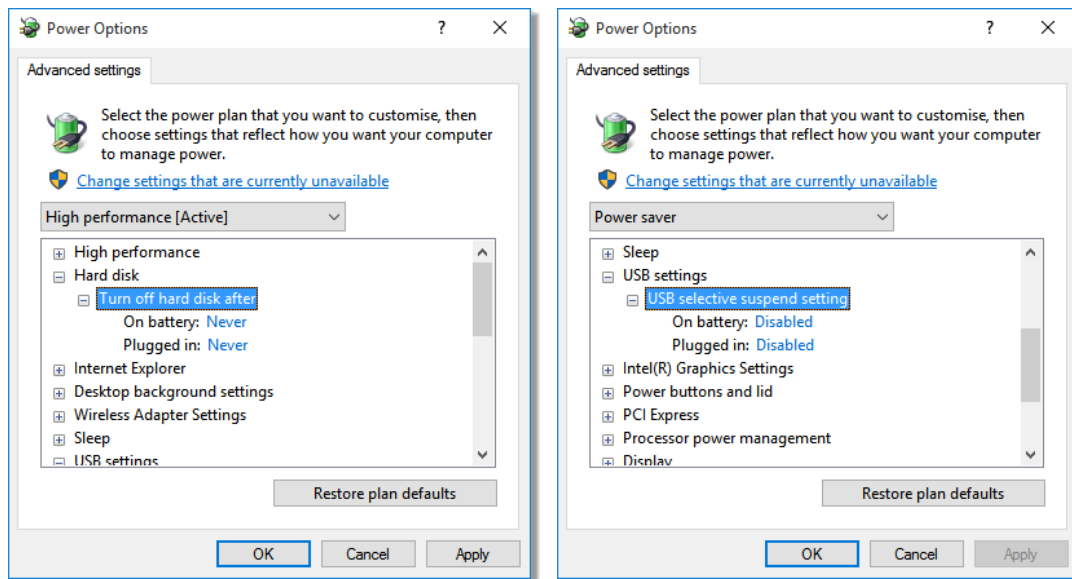
Appendix A:
Disabling power saving, hard disk sleep and USB selective suspend

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.
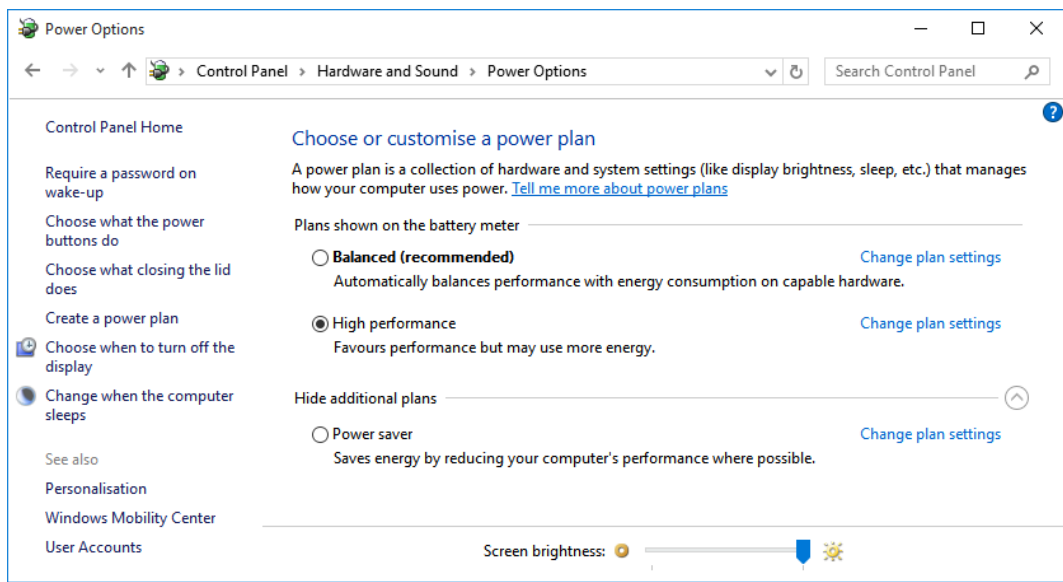
2. Change plan settings for **Turn off hard disk** to **Never**, and **USB selective** to **Disabled**.

Software Update Notification for Morphologi 4 software v10.31 (PSS0065-06)

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.

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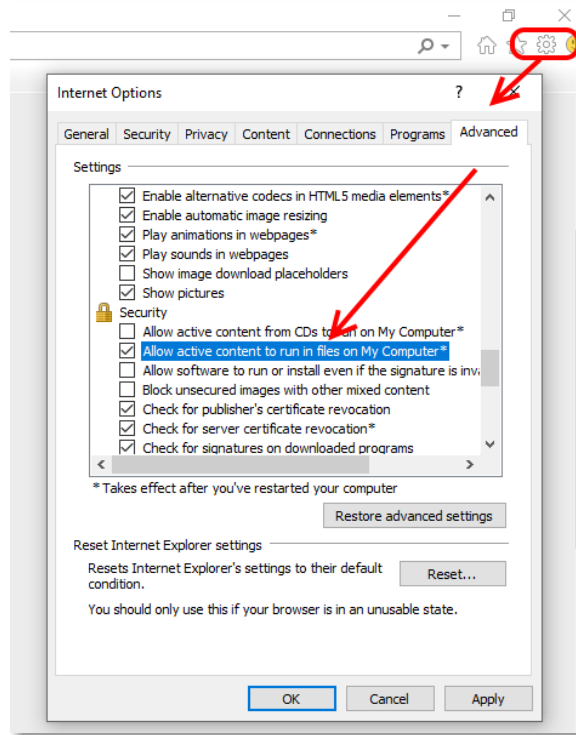
2. To open the Help in another browser that supports active content by default, copy the help link from Internet Explorer to another browser such as Microsoft Edge or Google Chrome and verify that these browsers have the rights to run local video content.
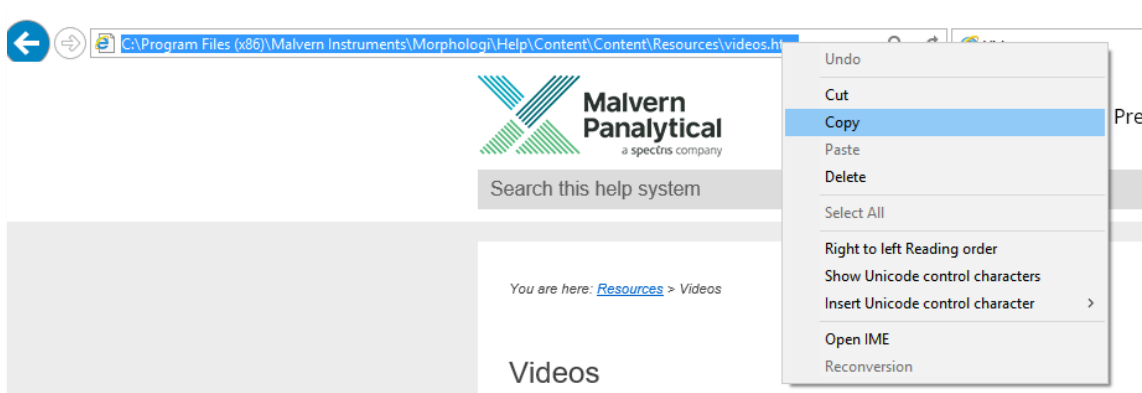
3. Copy browser link from Internet Explorer
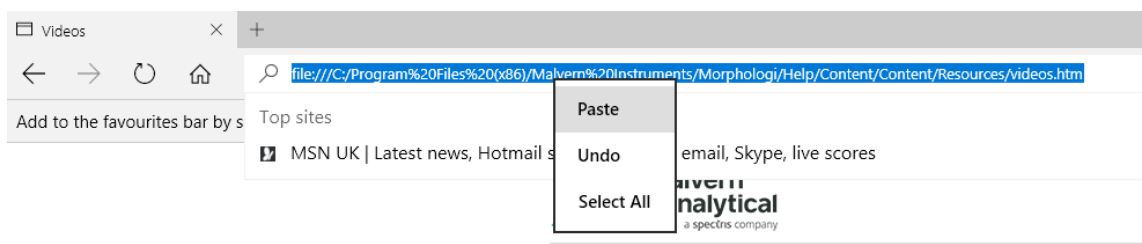
4. Paste browser link into Edge then press <enter> to load page.

Appendix C:
Upgrade behavior Morphologi 10.30 to 10.31

When the 10.31 version of software is installed and the instrument is not connected to the computer, the camera drivers are installed straight away and will connect when the instrument is plugged in again, as per the *Installation* section above.

If the instrument is connected to the computer while the 10.31 software version is installed the existing drivers are disabled and the new drivers are queued to be installed when the computer is restarted. Trying to use the camera in this state will cause the software to crash. The computer must be restarted before the instrument can be used properly.

To determine the camera driver state, double click the Morphologi 4 instrument icon **Morphologi 4** at the bottom right of the software to see the camera driver state. The camera driver version should be 4.93 (*Figure 3*).

If the driver is not loaded (*Figure 2*) restart the computer and check again.

If the connection window consistently shows the wrong camera firmware version re-install the software. If that doesn't work, open the **Device manager** and right click on "uEye UI-359x Series" and install the drivers manually (*Figure 4*). The drivers are located in *C:\Program Files (x86)\Malvern Instruments\Morphologi\Drivers\uEye*
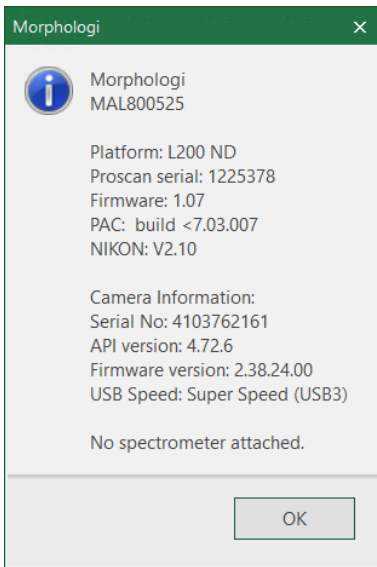
Morphologi ✕	Morphologi ✕	Morphologi ✕
Morphologi MAL800525 Platform: L200 ND Proscan serial: 1225378 Firmware: 1.07 PAC: build <7.03.007 NIKON: V2.10 Camera Information: Serial No: 4103762161 API version: 4.72.6 Firmware version: 2.38.24.00 USB Speed: Super Speed (USB3) No spectrometer attached. OK	Morphologi MAL800525 Platform: L200 ND Proscan serial: 1225378 Firmware: 1.07 PAC: build <7.03.007 NIKON: V2.10 Camera Information unavailable. No spectrometer attached. OK	Morphologi MAL800525 Platform: L200 ND Proscan serial: 1225378 Firmware: 1.07 PAC: build <7.03.007 NIKON: V2.10 Camera Information: Serial No: 4103762161 API version: 4.93.1730 Firmware version: 4.93.06.154 USB Speed: Super Speed (USB3) No spectrometer attached. OK

Figure 1. Version 4.72 drivers from v10.30 software

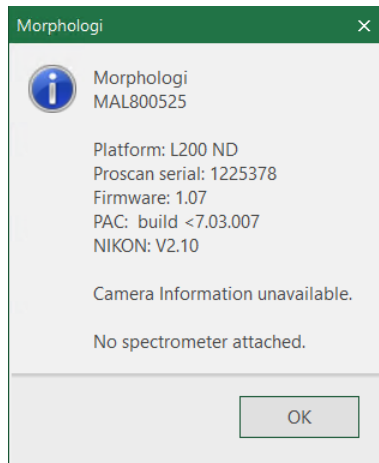*Figure 2. After upgrading to 10.31 with camera attached*
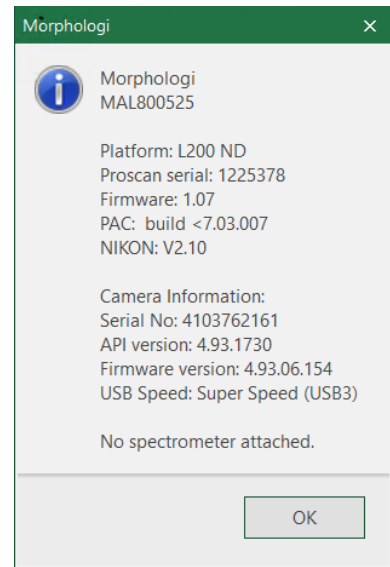
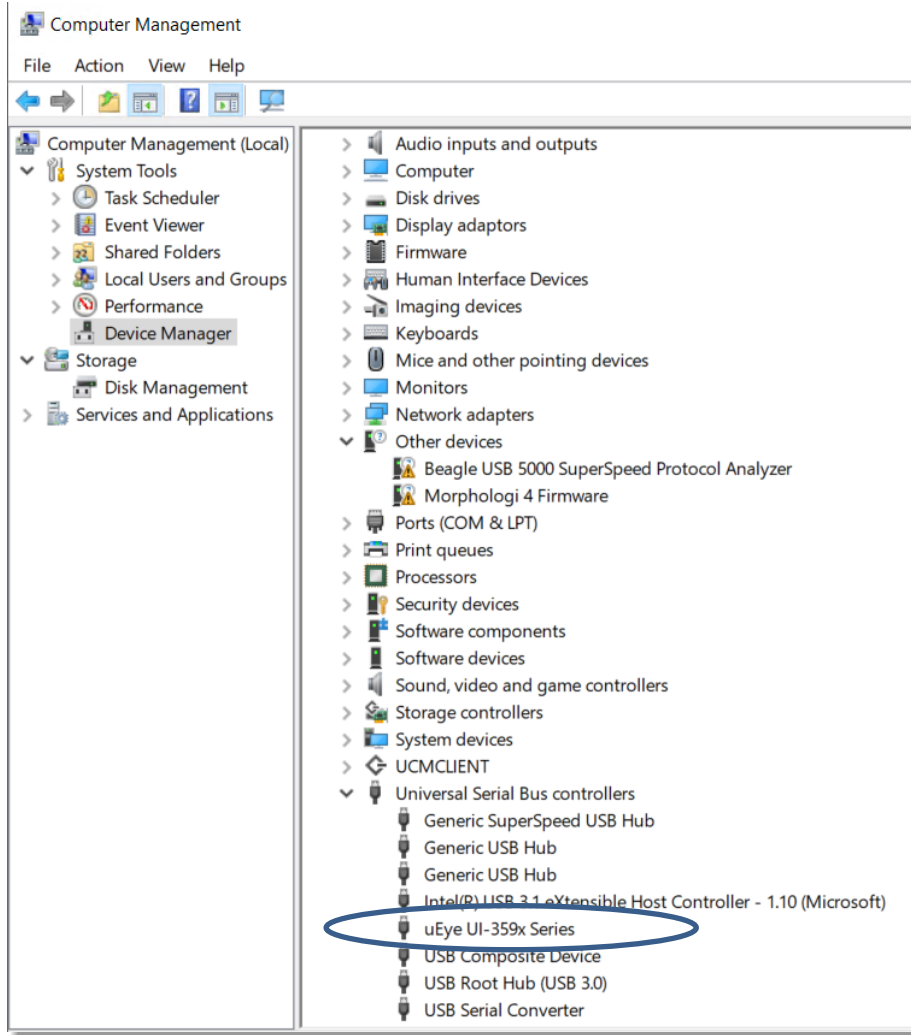*Figure 3. After upgrading to 10.31 and restarting the computer.*

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Figure 4. Device manager view of the Morphologi

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