

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.

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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.

Feature	Specification	Feature	Specification
Processor Type	Intel Core i7-8700 (minimum) Display Processor		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

Table 1: Recommended system requirements for the Morphologi software.





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 <i>Appendix C</i> .



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 <i>Appendix B</i>	
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 <u>I.T. professional</u> 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:

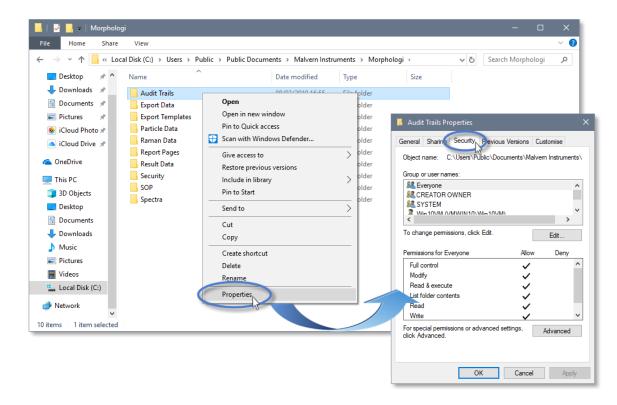


For the following demonstration we have previously created a user group, through the Computer Management console, called 'Morphologi Users'. This user group will later be added into the folder permissions of the Audit Trails folder to prevent users from deleting records. This process can be applied to 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.





				Addit Italis Properties	
				General Sharing Security Previous Versions Customise	e
				Object name: C:\Users\Public\Documents\Malvem Instr	uments
				Group or user names:	
Advance	ed Security Settings for Audit Trails			– 🗆 X	î
Name:	C:\Users\Public\Documents\	Malvern Instruments\/	1orphologi∖Audit Trails		>
Owner:	Win10VM (VMWIN10\Win10\	(M) 😫 Change		Edit.	
	•	· · · · · · · · · · · · · · · · · · ·			
Permissio	ons Auditing Effective A	ccess		Allow De	eny
					1
For additi	onal information, double-click a per	mission entry. To mod	ify a permission entry, selec	t the entry and click Edit (if available).	
		2			
Permissio	n entries:				
Туре	Principal	Access	Inherited from	Applies to	
Allov		Full control	None	This folder only	
	· · · · · ·	Full control	None	This folder only	
Allov			None	This folder only Advance	ced N
🚉 Allov		Full control	None	This folder, subfolders and fit	/
🚨 Allov	w Administrators (VMWIN10\A	Full control	C:\Users\Public\	This folder, subfolders and files	
Allov	w Win10VM (VMWIN10\Win10	Full control	C:\Users\Public\	This folder only Cancel	Apply
Se Allov		Full control	C:\Users\Public\	Subfolders and files only	. Abi
	M SVSTEM	Full control	C\Lleare\Dublic\	This folder, subfolders and files	
Add	Remove View				
	Nemove View				
Add					
	e inheritance				
Disable	and a second sec	with inheritable nermis	sion entries from this object		
Disable	e inheritance	vith inheritable permis	sion entries from this object		
Disable	and a second sec	vith inheritable permis	sion entries from this object	OK Cancel Apply	

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

Audit Trails Properties



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.

Block Inher	ritance X	<
<mark>∕</mark> w	hat would you like to do with the current inherited permissions?	
	u are about to block inheritance to this object, which means that permissions herited from a parent object will no longer be applied to this object.	
<	\rightarrow Convert inherited permissions into explicit permissions on this object.	>
-	ightarrow Remove all inherited permissions from this object.	
	Cancel	

- 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.

📙 Advanced Security Settings for Audit Trails	- D X	
	rn Instruments\Morphologi\Audit Trails	
Owner: Win10VM (VMWIN10\Win10VM)	-	×
Permissions Auditing Effective Access For additional information, double-click a permission entries: Type Principal Acc Type Principal Acc Auditional information, double-click a permission entries: Allow Type Principal Acc Allow Status Allow Win10VM (VMWIN10\Win10\ Ful Ful Ful Allow LogonSessionId_0_132602 (N Rec Ful Allow Morpholgi Users (VMWIN10\ Rec Sul Allow Administrators (VMWIN10\ Rec Administrators (VMWIN10\ Rec	Principal: Morpholgi Users (VMWIN10,Morpholgi Users) Select a principal Type: Allow ✓ Applies to: This folder, subfolders and files ✓ Basic permissions: Show advanced permissions: Show advanced permission ✓ Full control ✓ Modify ✓	issions
Allow Win10VM (VMWIN10,Win10 Fu Add Remove Edit Disable inheritance Replace all child object permission entries with i	 ☐ Read & execute ☐ List folder contents ☐ Read ☑ Write ☐ Special permissions ☐ Only apply these permissions to objects and/or containers within this container 	rall
	Uniy apply these permissions to objects and/or containers within this container	011
	OK C	ancel

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.



Permission	Entry for Audit Trails				-		×
Principal: Type: Applies to:	Morpholgi Users (VMWIN10\Morpholgi Users) Allow This folder, subfolders and files	Select a principal					
	ermissions: Full control Traverse folder / execute file List folder / read data Read attributes Read extended attributes Create files / write data Create folders / append data ly these permissions to objects and/or container	s within this contain	Write attributes Write extended attributes Celte subfolders and files Celte Read permissions Change permissions Take ownership er]	Show basic	permissi Clear all	
					ОК	Cano	cel

- 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.

Advanced Se	ecurity Settings for Audit Trails				— 🗆	>
Name: C:\Users\Public\Documents\Malvern Instruments\Morphologi\Audit Trails Owner: Win10VM (VMWIN10\Win10VM)						
Permissions Auditing Effective Access For additional information, double-click a permission entry. To modify a permission entry, select the entry and click Edit (if available).						
Type Allow Allow Allow Allow	Principal Win10VM (VMWIN10\Win10 SYSTEM LogonSessionId_0_132602 (I	Access Full control Full control ndows Security	Inherited from None None	Applies to This folder only This folder only		^
Allow Allow Allow Allow Allow Add	Everyone WII Morpholgi Users (VMWIN10 Administrators (VMWIN10\ Win10VM (VMWIN10\Win1 CREATOR OWNER Remove Edit	This will replace	ce explicitly defined permissi of this object with inheritabl o continue?		ders and files ders and files ders and files	
Disable inh	neritance child object permission entries w	ith inneritable permi	Ssion entries from		el Ap	ply



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

📕 Audit Trails Properties 🛛 🗙							
General Sharing	Security	Previous Versions	Customise				
Object name: C	Object name: C:\Users\Public\Documents\Malvem Instruments\						
Group or user nam	ies:						
Serveryone				^			
SCREATOR C	WNER						
SYSTEM 8							
2 Win10VM //	MM/INI10\)	Min 10\/M)		Ň			
-		E In					
To change permis	SIONS, CIICH	Edit.	Edit				
Permissions for Ev	000000	Alloy	w Denv				
	eryone	71101	w Deny				
Full control		~		<u> </u>			
Modify		~					
Read & execute		~					
List folder conte	ents	~					
Read		~					
Write		√		<u> </u>			
For special permissions or advanced settings, Advanced click Advanced.							
		K					
		K Cance	el Ap	ply			

Error Reporting

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

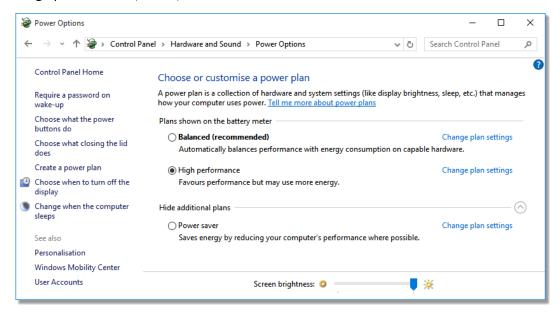
- A full-screen screen shot of any error message and everything behind it.
- Full description of what was happening at time of issue and ideally leading up to it.
- Instrument serial number (e.g. MAL1060289)
- Software version go to Help-About Morphologi (e.g. 10.31; all digits are important)
- System 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.



Power Options ? X	Power Options ? X
Advanced settings	Advanced settings
Select the power plan that you want to customise, then choose settings that reflect how you want your computer to manage power. Change settings that are currently unavailable High performance [Active]	Select the power plan that you want to customise, then choose settings that reflect how you want your computer to manage power.
 ➢ High performance ➢ Hard disk ➢ Turn off hard disk after On battery: Never Plugged in: Never ➢ Internet Explorer ➢ Desktop background settings ※ Wireless Adapter Settings ※ Sleep □ USB settinos 	 Sleep USB settings USB selective suspend setting On battery: Disabled Plugged in: Disabled Intel(R) Graphics Settings Power buttons and lid PCI Express Processor power management Disnlav
Restore plan defaults	Restore plan defaults
OK Cancel Apply	OK Cancel Apply

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.



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		rivacy	Content	connections	rrograma		
Setting	s					1	_
	Show Security Allow Allow	pictures active con active con software	ntent from o tent to run to run or in	ceholders CDs to an on I n in files on My stall even if the	Computer*	- 1	
< * Ti	Check	for publis for serve for signa	her's certif r certificate tures on do	th other mixed icate revocation e revocation* ownloaded proc ed vour compu	n grams	>	
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Ta	Check	for publis for serve for signat after you	her's certif r certificati tures on do 've restarti	icate revocation e revocation ownloaded proc ed your compu	n grams		

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.

🗲 🕘 🗐 C:\Program Files (x86)\Malvern Instruments\Morphologi\Help\Content\Content\Resources\videos.ht	Undo	
Malvern	Cut	
Malvern Panalytical	Сору	Pre
a spectris company	Paste	
Search this help system	Delete	
	Select All	
You are here: <u>Resources</u> > Videos	Right to left Reading order Show Unicode control characters Insert Unicode control character >	
Videos	Open IME Reconversion	

3. Copy browser link from Internet Explorer

\Box Videos \times	+		
\leftrightarrow) \odot	file:///C:/Program%20Files%20(x86)/Mal	vern%20Instrume	nts/Morphologi/Help/Content/Content/Resources/videos.htm
Add to the favourites bar by s	Top sites	Paste	
	MSN UK Latest news, Hotmail s	Undo	email, Skype, live scores
		Select All	nalytical
	1		a spectins company



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*

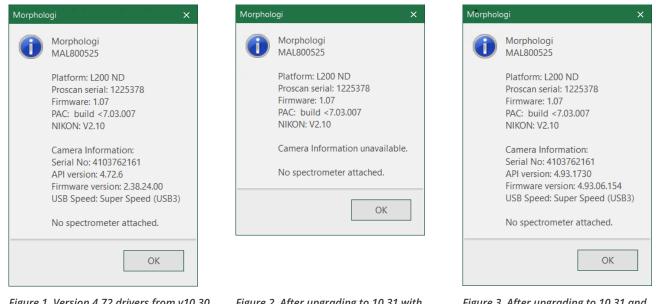


Figure 1. Version 4.72 drivers from v10.30 software

Figure 2. After upgrading to	10.31 with
camera attached	

Figure 3. After upgrading to 10.31 and restarting the computer.



🜆 Computer Management	
File Action View Help	
🗢 🄿 🖄 🖬 🛛 💭 💭	
 Computer Management (Local) System Tools Task Scheduler Event Viewer Shared Folders Local Users and Groups Performance Device Manager Storage Disk Management Services and Applications 	 Audio inputs and outputs Computer Disk drives Display adaptors Firmware Firmware Imaging devices Keyboards Monitors Network adapters Network adapters Network adapters Other devices Beagle USB 5000 SuperSpeed Protocol Analyzer Morphologi 4 Firmware Ports (COM & LPT) Ports (COM & LPT) Processors Software components Software devices Software devices Software devices Sortware devices Sortware devices Cond game controllers System devices Generic USB Hub Generic USB Hub Generic USB Hub Generic USB Hub Universal Series USB Composite Device
	USB Root Hub (USB 3.0)
	T USB Senal Converter

Figure 4. Device manager view of the Morphologi



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