

MORPHOLOGI SOFTWARE: v8.30 (PSS0025-33) SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of Morphologi G3 software version 8.30 (*Software suite: PSS0025-33*) for the Morphologi G3 family.

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.



Note:

Please check for any updates to this Software Update Notification at www.malvernpanalytical.com/en/support/product-support/morphologi-range/morphologi-g3

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 minimum 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 1909 running Windows Defender.

Table 1: Recommended minimum system requirements for the Morphologi software.

Feature	Specification	Feature	Specification
Processor Type	Intel (R) Core (TM) i7-4770S CPU @ 3.10GHz 3.10 GHz 2013	Connectivity	1 high speed USB port (not USB 3.0/Superspeed)
Memory	8 GB RAM		1 Firewire (IEEE1394) port
Hard Disk Storage	1 TB hard disk drive		Note: computers using a Morphologi G3-ID instrument will require an extra USB port (not USB 3.0/Superspeed), and an extra RS232 port
Additional Storage Media	DVD +/-R/RW drive		
Display Resolution	2 x 22" Widescreen Flat Panel Monitor for software and live video feed	Operating System	Windows 10™ operating system - Version 1909 or higher 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 B*.



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 v8.30 PSS0025-33 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 v8.30 PSS0025-33 EN.exe** to start the installation – Administrator 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.

Installation on a new Windows 10 computer

For all new Windows 10 installations please refer to additional guidance in document '*Morphologi G3 8.30 upgrade instructions*' (**CCM0074**).

Upgrading from previous versions with a regulated environment license activated

Morphologi v8.30 software has major updates to 21 CFR Part 11 features and as such a new license key is required. Previous license keys for the 21 CFR Part 11 features will not activate those features in version v8.30.

For users operating in a 21 CFR Part 11 regulated environment who want to upgrade to the latest software, please contact your Malvern Panalytical representative to purchase a new activation key. The part number for the new license key is CPS0136.

Please read the *21 CFR Part 11 compliance guide* and *21 CFR Part 11 User guide for Morphologi G3* included in the software installation disk in the Documents folder.

Upgrading an Existing Installation

Always uninstall any existing version of the Morphologi software before installing any other.

Upgrading an existing installation to this version of the Morphologi software may require the camera driver to be upgraded for older Morphologi G3 systems. To upgrade the camera driver once the Morphologi software has been upgraded, ensure that the camera is attached to the computer then open the windows device manager and uninstall the Baumer camera driver. Then, scan for hardware changes and direct windows to the Tools\camera folder inside the Morphologi installation folder when prompted for a driver.

For details see Malvern Panalytical technical note "*Updating the camera driver on a Morphologi instrument*" (MRK1516) available from Malvern Panalytical Technical Support (helpdesk@malvernpanalytical.com) or your local Malvern Panalytical representative.

Uninstall Procedure

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

Uninstalling previous versions of the software will remove all the standard Malvern reports, even if they have been edited. Best practice is to avoid overwriting standard Malvern reports but instead create new reports.

Backward Compatibility

Morphologi G3, G3SE, G3-ID and G3SE-ID instruments are fully supported.

Version 8.30 is back compatible with previous versions, existing results, SOPs and audit trails can be read. Older versions of the software will not be able to read results, SOPs or audit trails created by this version. This is standard for all Malvern Panalytical software.

New Features

Morphologi software v8.30 has been introduced to implement 21 CFR Part 11 and data integrity improvements.



Note:
We always recommend upgrading to the latest software version to take advantage of new features, bugfixes and security updates.



Note:
The Morphologi G3 audit trail viewer is a component shared with the Morphologi 4 which has more audit events than the Morphologi G3. Therefore the Morphologi G3 does not use every event type the viewer supports (Export result started and Export result finished are not used).

Reference	Description	Comment
136290	Audit the addition of new users to the security system.	New function
134915	Audit deletion of existing users from the security system.	New function
134915	Audit disabling of user accounts within the security system.	New function
134915	Audit enabling of user accounts within the security system (after account disabling).	New function
134915	Audit the unlocking of user accounts within the security system.	New function
134915	Audit the editing of user property to the security system.	New function
134915	Audit the copying of users to the security system.	New function
134937	Audit the addition of existing users to groups within the security system.	New function
134937	Audit the removal of existing users from groups within the security system.	New function
134937	Audit the addition of new groups to the security system.	New function
134937	Audit the removal of existing groups from the security system.	New function
134937	Audit the editing of group properties in the security system.	New function
134937	Audit the copying of a group to the security system.	New function
134937	Audit the addition of new members to groups in the security system.	New function
134937	Audit removal of existing members from groups within the security system.	New function
134937	Audit changes to permissions associated with a group (addition or removal).	New function
134939	Auditing of security settings.	New function
134938	Auditing of the enabling of security settings.	New function
134938	Auditing of ERES option setting.	New function
134980	Auditing of updating of user password [In Security-Change Password]	New function
134943	Audit the start of a measurement	New function
134943	Audit the abort of a measurement	New function
134944	Auditing the access of maintenance mode	New function
134944	Auditing the access of engineering mode	New function
134941	Search an open audit trail (including the current audit trail) to find events relating to the creation of specific records or the actions of specific users.	New function

Reference	Description	Comment
134941	Search the audit trail archives within the default directory as set in "ER/ES settings" to find events relating to the creation of specific records or the actions of specific users.	New function
136468	Improved memory usage to allow more measurements to be opened at once and to enable measurements to run successfully with these records visible.	New function
134948	Installer: Migrate installer tool from using InstallShield to Inno Setup.	Improved function
134948	New implementation to ensure audit trails files cannot be overwritten	Improved function
134948	Updated software branding from Malvern Instruments to Malvern Panalytical.	Improved function
134969	New license key to activate ERES features	Improved function

Fixed Issues

The main issues addressed in this release of the software are listed in the following table.

Reference	Description	Comment
139296	Intermittent composite failure where not all the scan area is represented in the composite image. The scan area composite displays many black frames.	Fixed.
134940	User actions can be logged as "User Unknown" in certain circumstances	Fixed
109455	Wiley's send to 'Knowitall' feature does not automatically search spectra.	Fixed
134966	PDF exports from file menu are not audited	Fixed
134966	PDF export can overwrite each other in certain circumstances.	Fixed
134966	PDF export do not default to the PDF exports folder selected in the ERES settings dialog.	Fixed
134970	In security setting, changing the password length setting in security can cause problems when updating existing user settings.	Fixed
134979	A user could login even if password has expired.	Fixed

Security Advisories

The following section details any security updates that have been addressed in this release, including fixes for identified vulnerabilities.



Note:
We always recommend updating to the latest software version which will provide you with new features, bugfixes and most importantly, security updates.



Note:
Other products may also be affected by any issue described here. We recommend you regularly check the Software Updates Notifications (SUNs) for all of your Malvern Panalytical products, and register on our website to receive updates.

Reference	Description	Recommendation
138735	Security improvements to the reporting feature to prevent the execution of code that might be embedded in a custom calculation from making unwanted changes to the underlying system.	Upgrade to version 8.30 of the software. Never open files from an untrusted source, even if they appear to be non-executable.
139975	Audit trails are now protected from accidental deletion or modification.	Upgrade to version 8.30 of the software.

Known Issues

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

Reference	Issue	Workaround
58363	The filter analysis check box is not displayed as ticked if running an SOP originally created in software version 7.xx. The top light settings and light calibration over sample still operate as intended.	SOP will still run as intended with correct settings. DO NOT tick the check box as this will reset the SOP to default settings.
58138	Refine Scan area before measurement does not function for multiple areas. The scan area refinement dialog is only shown once.	DO NOT use refine scan area with multiple areas.
58361	Legacy Z-Stacking does not work. During a measurement with legacy Z-Stack in the SOP no particles are detected, and a crash will occur at the end.	Use differential Z-Stack instead.
59682	Camera drivers may not properly install/update	Install/update driver in device manager and when it asks for driver location search subfolders of <i>C:\Program Files (x86)\Malvern Instruments</i>
31151	If an SOP is extracted from a measurement, and the “Grab New Image.” button is pressed on the threshold page, the manual microscope is opened but no connection occurs to the instrument. Since the SOP has been extracted it should not be possible to change the Threshold so the “Grab New Image” should not be available.	To change the threshold save the extracted SOP first and then open for editing from the main software window.

30871	Stop on particle limit does not work with multiple optics. The measurement does not stop on particle limit, whether the limit is reached on the first or subsequent optics scans.	We do not recommend applying particle count limit when using multiple optics, as this can cause sample biasing.
30307	If a measurement is stopped and a new measurement is started from the open live measurement manager display window, the 2nd measurement will not complete if it is set up to use a different slot in the slide holder.	Close the live measurement manager display window and start a new measurement.
31966, 52918, & 52921, 52546	If the user runs an SOP requiring multiple slides but does not select them all at the beginning of the measurement but instead selects them one by one via the live measurement manager display, the measurement only succeeds in measuring the first slide.	Select all the intended slides at the beginning of the measurement.
46662	It is not possible to abort a measurement during the plate level operation	Wait till the plate level operation is complete. Note: if the coverslip option is selected in the SOP the plate level operation takes several minutes.
29158	The Bright Field (BF) or Dark Field (DF) setting is not automatically controlled during SOP threshold image acquisition	Ensure that instrument is in the right BF/DF condition prior to editing the SOP.
28786	1-Click measurements with merged slide results will not do a Chemical ID measurement.	We do not recommend merging slides on ID measurements. Instead, it is better to measure separately then combine the measurements afterwards.
31285	If a wet cell is fitted in the instrument, and a SDU dispersion is attempted, the software will not recognize that an unsuitable plate type is fitted and will continue with the dispersion process. This may damage the wet cell windows.	Users are advised to ensure that a wet cell is not fitted before carrying out a dry powder dispersion.
31286	When reanalyzing a record with many spectra, the software can crash if the reanalyzed record is viewed immediately after it is created.	None. However, the measurement data is saved correctly. If users experience poor software performance following a reanalysis, we recommend restarting the software.
35255	When the file permissions for the Morphologi documents library are set up to deny deletion of files or folders, it is not possible to save new spectra or signed reports from Adobe Acrobat directly.	Save into a different folder and then copy into the controlled folder
25263	Slow stage on start-up after unexpected power down of the instrument	Wait for the stage to initialize. This may take 10 minutes or more depending on the stage position when it was powered down.
-	Some Morphologi G2 instruments can lose the position of the optical turret when switching optics.	Restart the measurement. <u>Note</u> that this does not affect Morphologi G3 or Morphologi G3-ID instruments.

SCR5901	Stopping a merge measurement while measuring with the first optic only aborts the measurement with the current optic. The system then goes on to measure with the next optic	Stop the measurement for each optic in the merge measurement process.
31442	In manual microscope, aborting Raman acquisition can lead to a software crash if abort is clicked during spectrometer bench set up. Bench set up happens after the acquisition settings have been changed.	For short acquisition times avoid aborting, allow the acquisition to finish. For long acquisition times do not press abort until the laser spot is seen on the sample
31397	Reanalysis of records whilst acquiring a Raman spectrum in manual microscope may cause a software crash	Do not reanalyze records whilst capturing a Raman spectrum.
23756	Manual chemical measurement with shroud removed doesn't stop properly can lead to a software crash	Do not attempt to measure chemistry while the shroud is removed.
52004	The manual targeting dialog can generate a high memory load on some computers and may result in a crash.	Do not leave the manual targeting dialog open when not in use
52546	Re-running an SOP which uses fixed focus and a single slide in a four-slide holder, without closing the Live Display but using a different slide from the first measurement, results in an unspecified error.	Always close the live display between sop runs.
53225	If plate tilt compensation is disabled and the selected magnification is greater than 5x, the recorded focus in SOPs is not portable between instruments	Use plate tilt compensation for magnifications greater than 5x.
3340	Turret error in the manual microscope or when running an SOP, The user may: - Experience difficulty when swapping objectives using the manual microscope where no objectives are highlighted, and the instrument will not move the turret.  - Observe an error when running an SOP 	Ensure instrument is switched on <u>before</u> starting the software.
52892	If the user clicks Close on the live display during a measurement, the measurement stops but the live display does not close.	If the user clicks on Close for a second time, once the measurement process has terminated, the live display will close as intended.
53239	When a particle from a measurement that used the Thin-Path Wet Cell is viewed in its original image the manual microscope is shown and in the navigation panel on the right the Thin-Path Wet Cell is displayed. However, the toolbar at the top shows the SDU glass.	

57124	The 'G3/G3-ID' icon in the bottom-right-hand corner can disappear off the right edge of the software if the application window is made too narrow.	
58039	Report pages can render badly when the user provides long text inputs.	
58132	An exception is thrown in the Multi-Statistic reports if a record contains no particles or if it is a Point Spectra record.	
-	If the computer goes into standby mode after a period of inactivity the measurement can hang. Since measurements of large areas can take some time this is a likely event.	<i>See Appendix B: Disabling power saving, hard disk sleep and USB selective suspend</i>
-	Installation of software for remote computer support and desktop sharing can interfere with the live display on the second monitor and cause the software to crash during measurement.	None.
-	Backup of data to external devices like external hard drives or network servers during measurement can slow down the measurement or cause the software to crash.	Automatic backups should be scheduled at times when the instrument is not in use.

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 accidentally, or by intention. Utilizing the built-in security tools of Microsoft Windows®, an I.T. 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 Panalytical software is being installed; allowing you to install, or update software and configure windows security permissions.

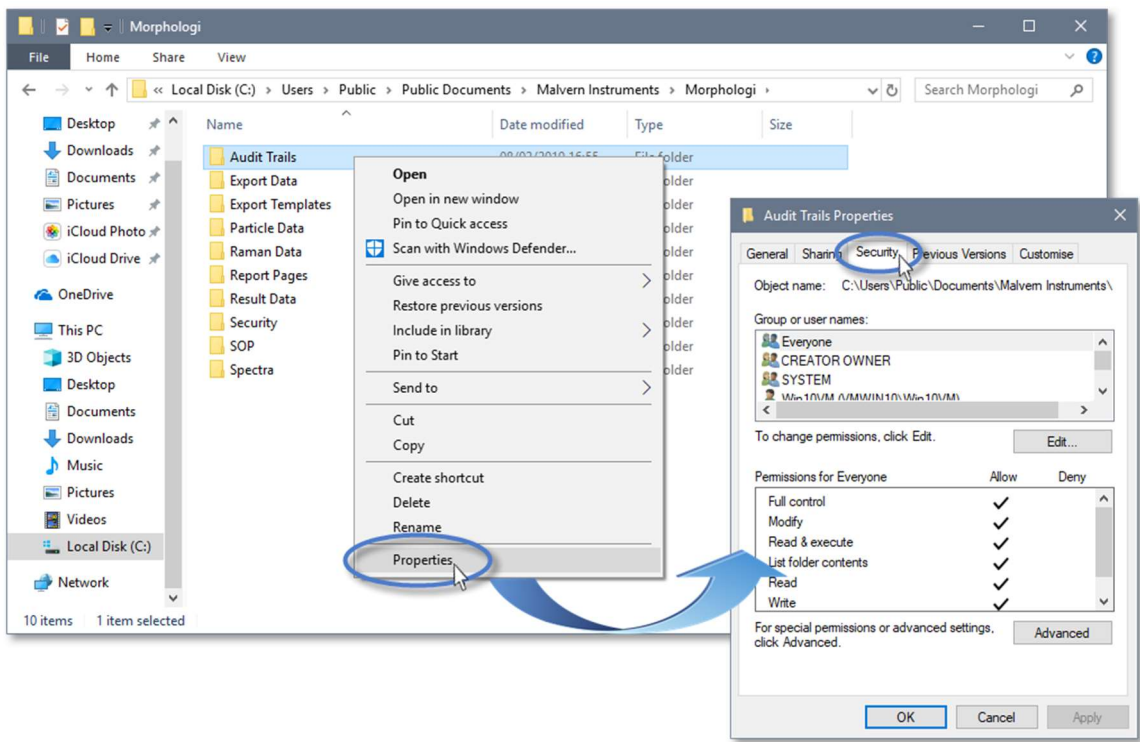
Note:

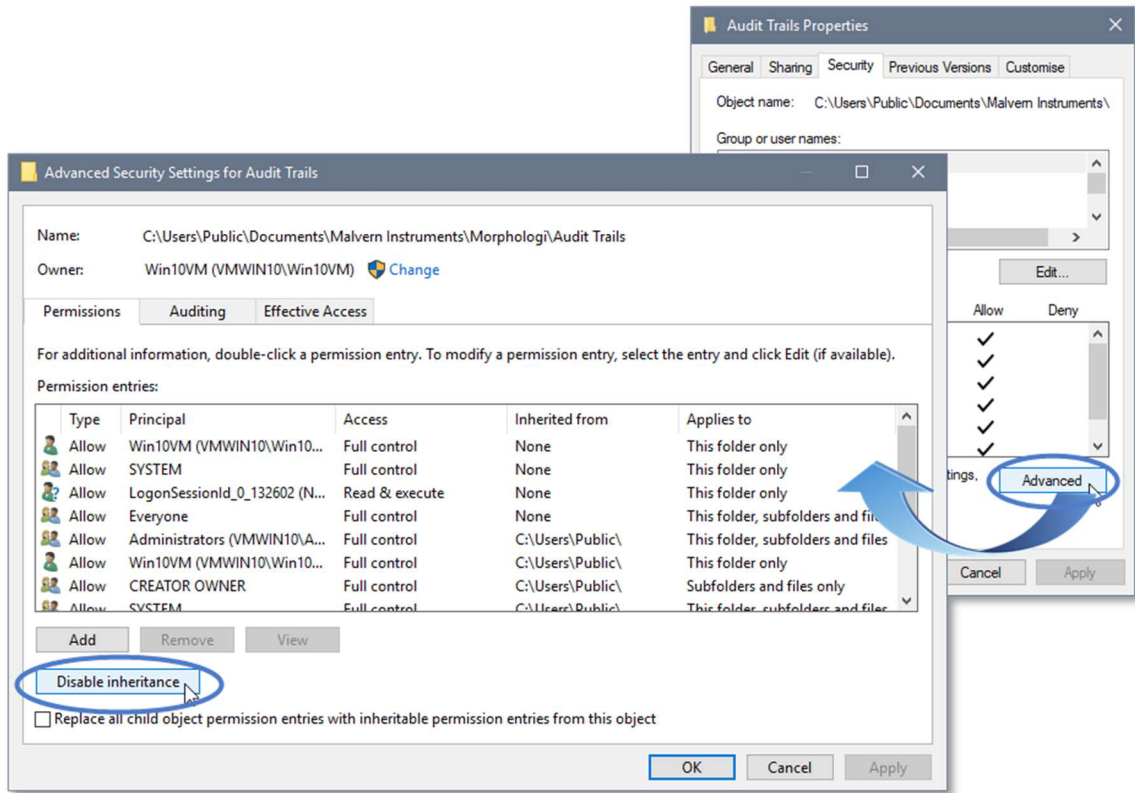


For the following demonstration we have previously created a user group, through the Computer Management console, called 'Morphologi Users'. This user group will later be added into the folder permissions of the Audit Trails folder to prevent users from deleting records. This process can be applied to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

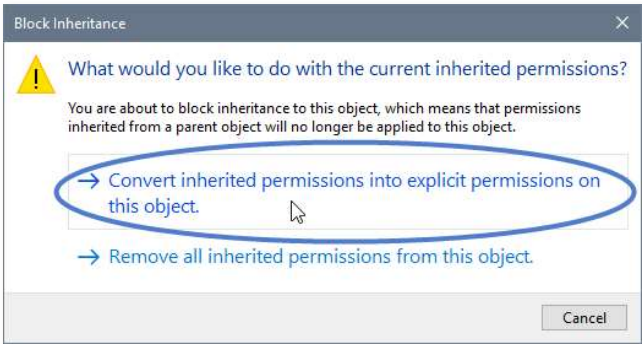
Changing the folder security permissions in Windows 10

- 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.

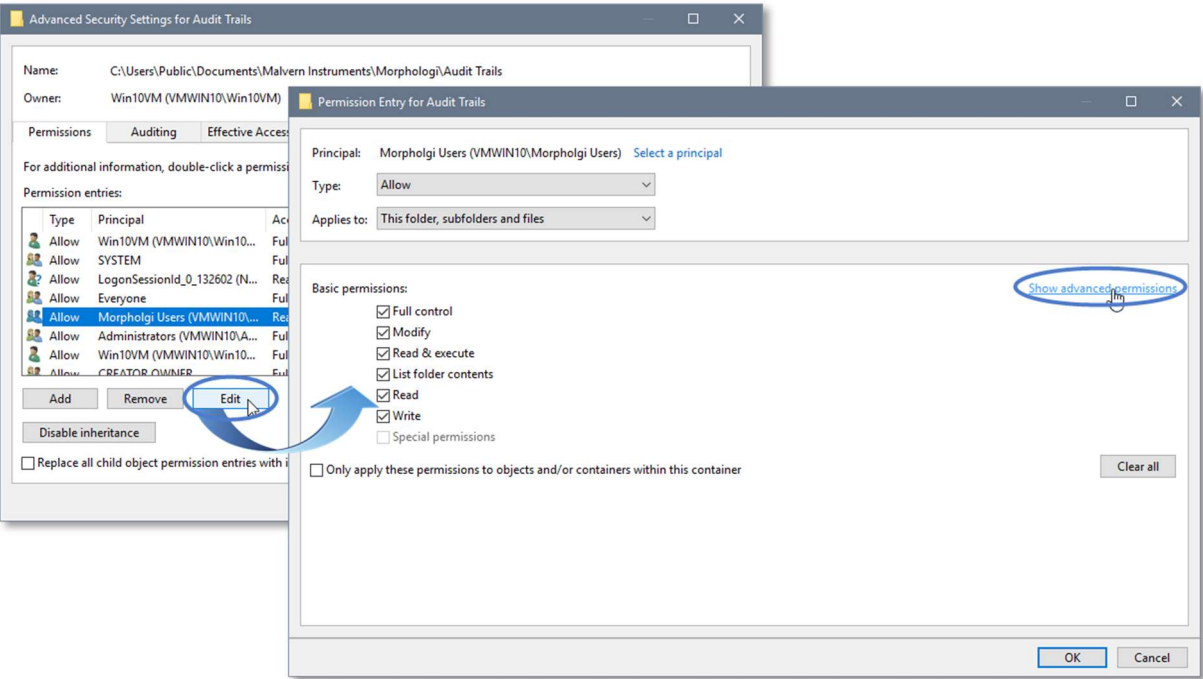




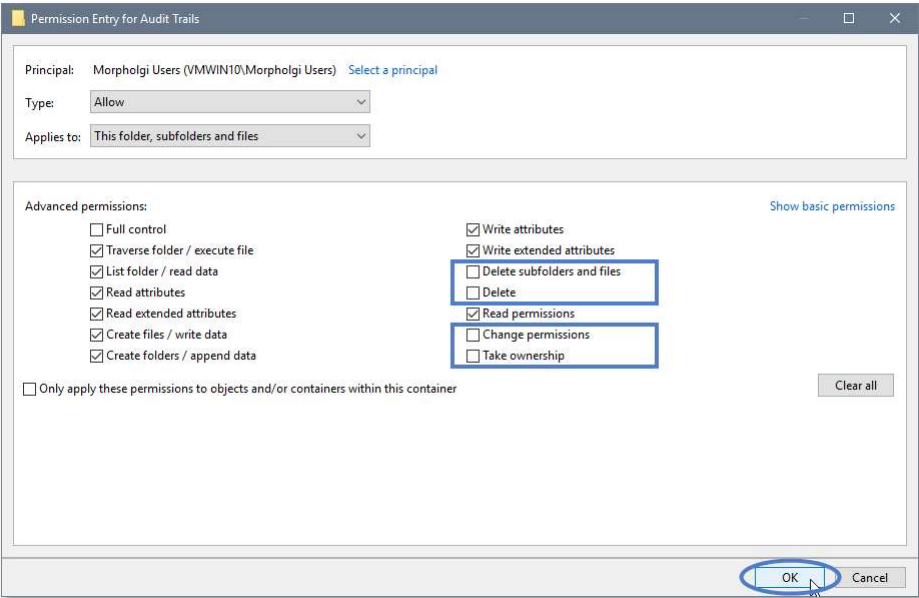
- 3. Within the **Advanced Security Settings** left-click the **Disable inheritance** button.
- 4. Within **Block Inheritance**, left-click on **Convert inherited permissions into explicit permissions on this object** – this removes the permission inheritance from the parent folder, whilst keeping the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



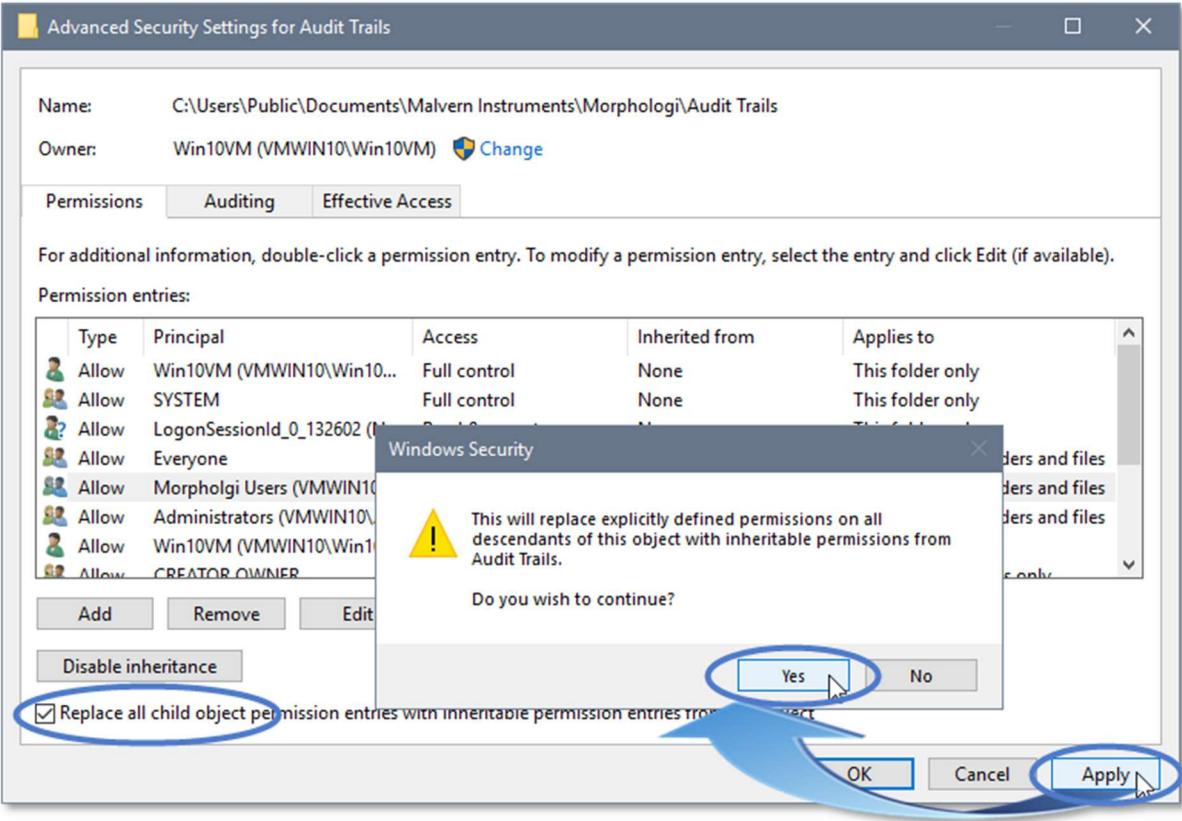
- 5. After returning to the **Advanced Security Settings** window, left-click to select the **Morphologi Users** group and then left-click the **Edit** button.
- 6. In the **Permissions Entry** window, left-click the **Show advanced permissions** to reveal the full permissions list.



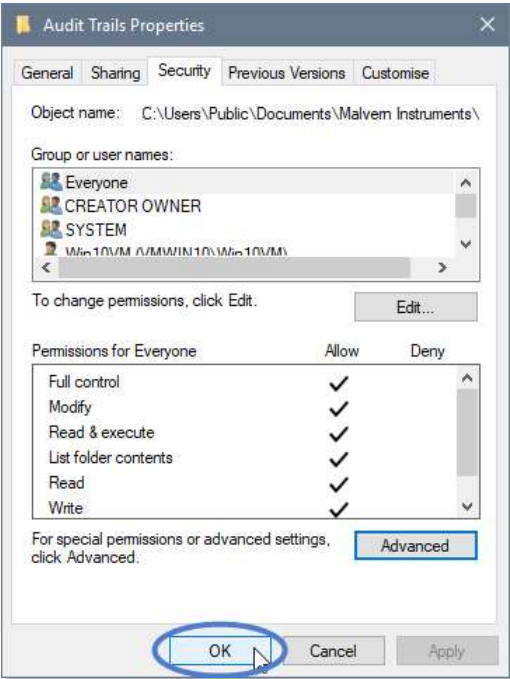
7. Left-click to de-select the check-boxes of **Delete subfolder and files**, **Delete**, **Change permissions**, **Take ownership** and finish by left-clicking the **OK** button to return you to the previous window.



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. 8.30; all digits are important)
- System information – double click on the G3 or G3ID 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** and save the text file to include on error report.

Appendix A:
Good Practice Guidance

Comment	Description																		
Size range Consider particle size range of interest. Is analysis Morphological only or is Chemical Identification required? Table provides guidance.	Morphological: Maximum size is when using default frame overlap, Minimum size related to adequate number of pixels for shape. <table><tr><th>Magnification</th><th>2.5x</th><th>5x</th><th>10x</th><th>20x</th><th>50x</th></tr><tr><th>Morphological size range (µm)</th><td>1000-13</td><td>420-6.5</td><td>210-3.5</td><td>100-1.8</td><td>40-0.5</td></tr><tr><th>Potential range for chemical ID (µm)</th><td>1000-100</td><td>420-25</td><td>210-20</td><td>100-20</td><td>40-1</td></tr></table> Chemical ID: Minimum size (2.5x – 20x) related to ability to return to particle when measurement made with objective other than 50x, Minimum size for 50x is dependent on sample type.	Magnification	2.5x	5x	10x	20x	50x	Morphological size range (µm)	1000-13	420-6.5	210-3.5	100-1.8	40-0.5	Potential range for chemical ID (µm)	1000-100	420-25	210-20	100-20	40-1
Magnification	2.5x	5x	10x	20x	50x														
Morphological size range (µm)	1000-13	420-6.5	210-3.5	100-1.8	40-0.5														
Potential range for chemical ID (µm)	1000-100	420-25	210-20	100-20	40-1														
Multiple measurement for ID analyses	If performing an ID analysis, in the SOP do not select any of the following: - multiple slides - multiple objectives - multiple scan areas																		
Maximum number of particles to target for an ID analysis	The maximum number of particles analyzed using an ID measurement during instrument development was 10,000 with a 1 second acquisition time. Analysis time was >1.5 days. If targeting a larger number of particles and/or using a longer acquisition time it is recommended to perform separate morphological scans followed by Raman analysis on each independently and then combine the data later. Note when combining data sets, any particle tags will be lost.																		
Chemical classes in full Morphologi and Chemical 1-click SOPs	If running a chemical measurement, either as part of a 1-click SOP or from a base morphological measurement, you must ensure any classes in the SOP or result do not contain both chemical correlation parameters and have the ‘exclude unclassified’ particles option selected. This is because at the end of the morphological analysis no particles are classed (as no chemical data yet exists) thus all particles will be excluded and therefore will not be available for chemical measurement.																		
Avoid viewing previous results whilst measurement is running.	Viewing results may increase memory load on computer and affect the measurement, see above. As such it is especially important to avoid viewing results if several hours through a long ID measurement to avoid loss of data. Additionally, editing results during a measurement is not recommended, including applying filters/classes and saving as new record. If editing the results is required, it is recommended to copy the data to another computer. In particular do <u>not</u> do the following: - Switch between measurement files – the active file at the end of the measurement run must always be the one open when the measurement was started to ensure the result data is saved into the correct measurement - Create a mean spectrum - Edit chemical correlation based classes or filters																		
Save data locally and back up to network, storage drive or shared computer.	Morphologi data set can be very large. Many network drives may not support such files. Direct saving to a network may affect the system performance, resulting reduced analysis speed and cause the system to be affected by other network traffic. It is recommended to back up data to a network, shared access drive or computer when the instrument is not in use, e.g. overnight. Software can be installed on alternative computers for data review.																		

Avoid virus scans, windows updates etc. occurring during a measurement.

If any other computer activity causes the Software to crash or causes the computer to shut down measurements in progress will be lost.

USB Ports

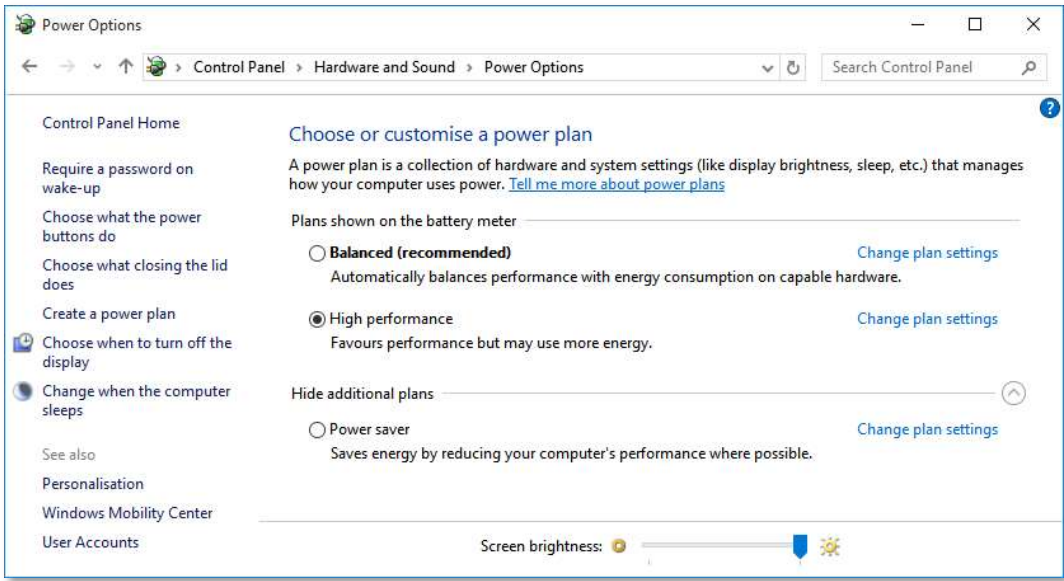
Use USB SS (USB 3.0) ports for Keyboard and mouse only and not for any system connection. Morphologi G3 instruments must be connected to a different bank of USB ports to the mouse and keyboard.

For Morphologi G3-ID instruments the Raman bench connection must be in a different bank of USB ports to any other connection.

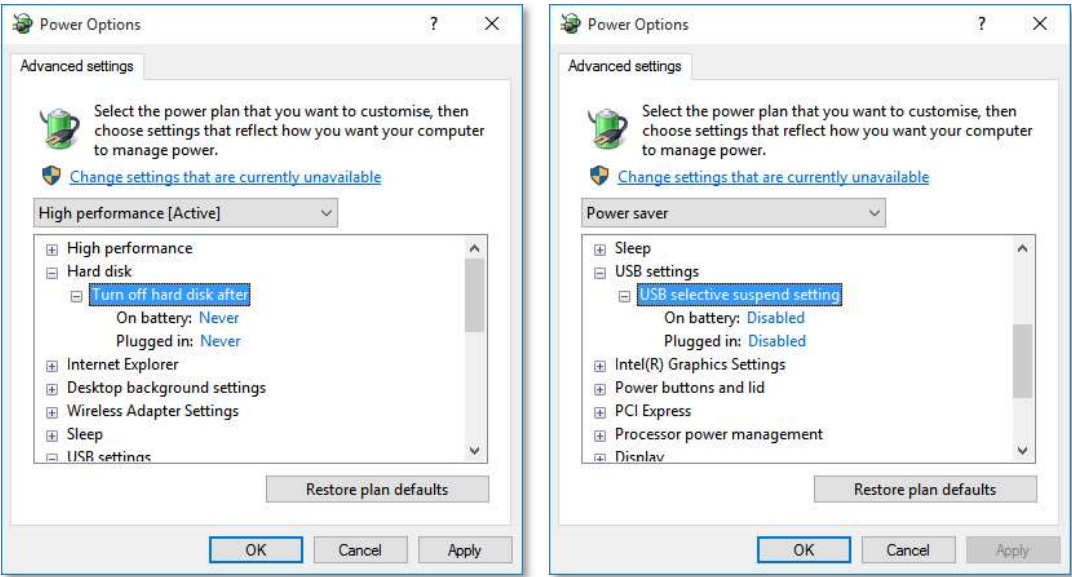
Appendix B:
Disabling power saving, hard disk sleep and USB selective suspend

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 C:

Table of previous Morphologi Software versions.

The Software Update Notifications (SUNs) for all of the previous versions of Morphologi software can be found on the software installation disk in the \Documents\Release History folder and on the Malvern Panalytical website at www.malvernpanalytical.com/en/support/product-support/morphologi-range/morphologi-G3.

Software release reference	Release month	Software release reference	Release month
PSS0025-01 Morphologi v5.00	November 2005	PSS0025-21 Morphologi v7.41	August 2011
PSS0025-02 Morphologi v5.01	December 2005	PSS0025-22 Morphologi v7.42	June 2012
PSS0025-03 Morphologi v5.02	January 2006	PSS0025-23 Morphologi v7.43	August 2012
PSS0025-04 Morphologi v6.00	July 2006	PSS0226-01 Morphologi v8.00	September 2012
PSS0025-05 Morphologi v6.01	August 2006	PSS0025-24 Morphologi v8.10	May 2013
PSS0025-06 Morphologi v6.02	March 2007	PSS0025-25 Morphologi v8.11	September 2013
PSS0025-08 Morphologi v7.00	February 2008	PSS0025-26 Morphologi v8.12	June 2014
PSS0025-12 Morphologi v7.10	September 2008	PSS0025-28 Morphologi v8.13	April 2015
PSS0025-13 Morphologi v7.11	November 2008	PSS0025-29 Morphologi v8.20	November 2015
PSS0025-15 Morphologi v7.12	August 2009	PSS0025-30 Morphologi v8.21	June 2016
PSS0025-16 Morphologi v7.20	April 2010	PSS0025-31 Morphologi v8.22	July 2017
PSS0025-18 Morphologi v7.21	August 2010	PSS0025-32 Morphologi v8.23	September 2017
PSS0025-19 Morphologi v7.21	June 2011		
PSS0025-20 Morphologi v7.40	July 2011		

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