SOFTWARE UPDATE NOTIFICATION
MORPHOLOGI SOFTWARE v8.12: PSS0025-27


PARTICLE SIZE


PARTICLE SHAPE


CHEMICAL IDENTIFICATION

Introduction

This document details the release of software PSS0025-27: the Morphologi software Suite including version 8.12 software for the Morphologi G3 instrument family. It covers software issues fixed. 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.

In addition, Appendix A provides good practice guidance to help users get the best performance from the instrument based on our experience using it.

Note: This release supports the introduction of a new Sample Entrainment Spool disperser which is included with the Morphologi G3SE and G3SE-ID instruments, and as such is not backward compatible with the Sample Cartridge disperser originally supplied with Morphologi G3S and G3S-ID instruments. Please read the New Features section of this document for more details.

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. Although the software can run using Windows XP™ Professional and Windows 7™ (64-bit), it has been fully tested under Windows 7™ (32-bit). Windows 7 (32-bit) is therefore the preferred operating system. *Note:* The Morphologi G3-ID family is only compatible with Windows 7 (32-bit) and English language.

Note: Power saving and USB selective suspend should be disabled, see Appendices B and C to ensure that the software can operate correctly during long measurements

Note: Some 3rd party software or OS 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.

Table 1: Recommended system requirements for the Morphologi software.

Feature	Specification
Processor Type	Intel Core i7 3770 Processor,
Memory	4GB
Hard Disk Storage	1Tb HDD,
Additional Storage Media	DVD +/-R/RW drive
Display	1 x 22" Widescreen Flat Panel Monitor for software 1 x 22" Widescreen Flat Panel Monitor for live video feed
Connectivity	1 high speed USB port (not USB 3.0/Superspeed) 1 Firewire (IEEE1394) port *Note:* PCs using a Morphologi G3-ID instrument will require an extra USB port (not USB 3.0/Superspeed), and an extra RS232 port.
Operating System	Morphologi G3: Windows 7 (32 bit and 64 bit), Windows XP™ (32-bit) Morphologi G3-ID: Windows 7 32 bit, English language

Installation Instructions

The software is supplied on a CD-ROM that will automatically start the installation process when inserted into the drive. If your system does not support this feature run the \Morphologi\setup.exe program from the root directory of your CD drive.

Upgrading an Existing Installation

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

Note: 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 PC then open the windows device manager and uninstall the Baumer camera driver. Then, scan for hardware changes and direct windows to the drivers\camera folder inside the Morphologi installation folder when prompted for a driver. For details see Malvern technical note "Updating the camera driver on a Morphologi instrument" (MRK1516) available from Malvern helpdesk or your local Malvern representative.

Note: Upgrading an existing installation to use a 64-bit operating system may require a firmware upgrade for the camera on the instrument. Please contact your local Malvern representative for more information.

Note: Please read *MRK1059- xx CFR Part 11 compliance guide* and *MRK1058 - xx CFR Part 11 – User guide* (where –xx refers to the latest versions of these documents).

Uninstall Procedure

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

Note: 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

This version is back compatible with all prior versions of the Morphologi software.

Morphologi G3, G3SE, G3-ID and G3SE-ID instruments are fully supported. This release supports the introduction of the Sample Entrainment Spool disperser which is included with the Morphologi G3SE and G3SE-ID instruments, and as such is not backward compatible with the Sample Cartridge disperser supplied with Morphologi G3S and G3S-ID instruments. To upgrade to the latest hardware specification please contact your local Malvern representative.

There is no support for the predecessor PVS 830 instrument with this release.

Note: existing systems must not be upgraded from version 5.xx until a Malvern representative has visited to perform an 'instrument characterization' process.

New Features

The previous version (v8.11) of the Morphologi software suite was developed to support the introduction of the Sample Entrainment Spool disperser, which is included with the Morphologi G3SE and G3SE-ID instruments. No other new features have been introduced. These features are included in v8.12.

Fixed issues

The issues fixed in this version of the software are primarily related to improving the reliability/robustness of the 21 CFR Part 11 features of the software:

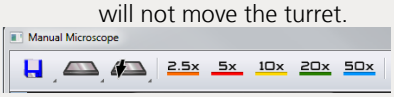
Reference(s)	Issue	Comment
31287	File permissions can cause problems with file creations	Fixed
35142	Can't run chemical SOPs or 1-click with security enabled	Fixed
34858	Serial response limited to 5 characters	Fixed
34989	Error message on security login	Fixed
35471	With ER/ES enabled, 'save as' deletes target file on attempted overwrite	Fixed

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 where one is available.

Issue	Work around	Comment
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.	Issue has been logged as bug #31151
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.	Issue has been logged as bug #30871

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.	Issue has been logged as bug #30307
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.	Issue has been logged as bug #31966
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.	Issue has been logged as bug #29158
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.	Issue has been logged as bug #28786
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.	Issue has been logged as bug #31285
When reanalyzing a record with a large amount of 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 would recommend restarting the software.	Issue has been logged as bug #31286
When the file permissions for the Morphologi documents library are set up to deny deletion of files or folders, it is not possible to create new files.	None	Issue has been logged as bug #31287
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.	Issue has been logged as bug #25263
Automated ID measurements do not work with manual illumination settings	Use automatic illumination settings in ID measurements.	Issue has been logged as bug #29999
Some Morphologi G2 instruments can lose the position of the optical turret when switching optics.	Restart the measurement. Note that this does not affect Morphologi G3 or Morphologi G3-ID instruments.	-
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.	Issue has been logged as SCR5901
If an SOP requires manual focus system moves by default to the position used when setting threshold in SOP and not the center of the scan area.	See detailed guidance in Appendix A.	Issue has been logged as bug #33409

In manual microscope, aborting Raman acquisition can lead to a software crash if abort is activated during spectrometer bench set up	1) For short acquisition times avoid aborting, allow acquisition finish 2) for long acquisition times do not press abort until laser spot is seen on the sample	Issue has been logged as bug #31442
Reanalysis of records whilst acquiring a Raman spectrum in manual microscope may cause a software crash	Do not reanalyze records whist capturing a Raman spectrum.	Issue has been logged as bug #31397
Stopping or aborting automated Raman measurement during spectrometer bench set up can lead to a software crash	Do not stop or abort an automated Raman analysis until the laser spot is seen on sample particles.	Issue has been logged as bug #23756
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 **BEFORE** starting the software	Issue has been logged as bug #33408
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.	Disable the power saving options of the computer using the instructions in Appendix B: Disabling power saving. USB suspend must also be disabled on the PC. See Appendix C: Disabling USB selective suspend.	-
Installation of software for remote PC 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.	-

Error Reporting

Should persistent problems occur contact the local Malvern Helpdesk. To speed up response time include all of the following.

- A **fullscreen** 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 - found under the triangular cover right side of instrument (e.g. MAL1060289)
- Software version - go to Help>About Morphologi (e.g. 8.11; 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.

Size range

Consider particle size range of interest.

Is analysis Morphological only or is Chemical Identification required?

Table provides guidance.

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

Morphological: Maximum size is when using default frame overlap, Minimum size related to adequate number of pixels for shape.

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.

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

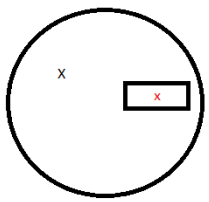
Full Morphologi and Chemical 1-click SOPs

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.

Using manual focus

When manual focus is selected in an SOP, at run time, ideally the system moves to the center of the scan area (as indicated by x) and the focus should be set as close as possible to that point. As described by bug #33409 the system takes you to the coordinates where the threshold was originally set in the SOP, which could be away from the scan area as indicated by the X and thus is not at the optimal position with respect to the plate tilt correct positions.



The possible work-arounds are:

a) Where possible use fixed focus (not for measurement using coverslips)

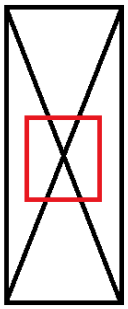
b) Set the SOP slightly out of order - i.e. set the scan area first, note the coordinates of its center then drive the stage to those coordinates to grab the image on which to set the threshold. At run time, the system will then go to that place when it asks you to set the focus. See extra note if measuring a suspension sandwiched between slide and cover slip.

c) Note the coordinates of the center of the scan area and at run time drive the stage to that position. IF using refine scan area, drive the stage to the center of the refined area at run

time.

d) If using z-stack set the fixed focus to 0.00 and have the stacks move up from it.

If measuring a suspension sandwiched between slide and cover slip and using a high objective such as the 50x (e.g. for nasal spray analysis) manual focus should always be used in this case since the plate tilt correction will use the top surface and the focus position will be dependent on the thickness of liquid in between the two layers of glass.
In this case, it may be useful to make a positioning template for the sample preparation as follows:
On a normal glass slide draw diagonal lines joining opposite corners. Then draw a square or circle (depending on the type of coverslips used) cantered over where the diagonal lines cross.



To prepare the sample:
Place a clean sample slide on top of the template
Pace the drop of sample at the cross
Place the cover slip at the position of the square or circle.

When first setting the SOP ensure the scan area is set around the center of the coverslip position and make sure the image for the Threshold is grabbed from the center of that scan area. When running the SOP the position the system moves to for the user to set the focus will then be the center of the area it is going to scan.

File Management and memory load management

Insufficient memory may lead to aborted measurement.

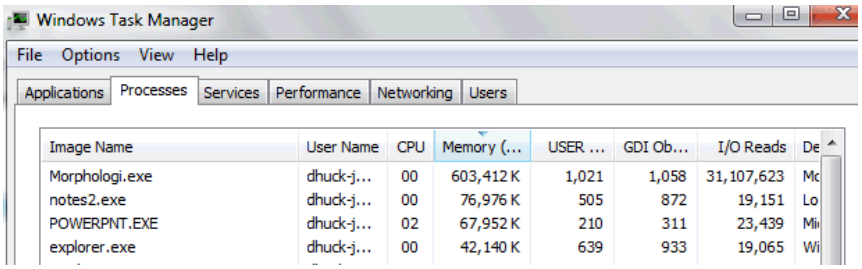
If the memory load goes above 1,200,000 K during a measurement it can fail.

Minimize RAM usage by closing any measurement files not in use and minimizing number of records in each measurement file.

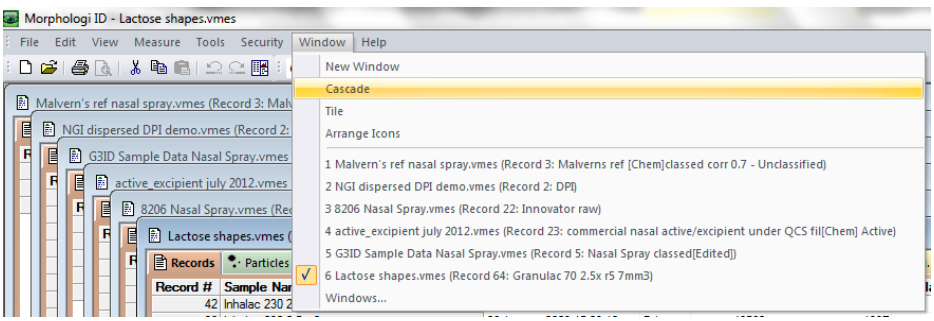
The amount of PC RAM available for an analysis is reduced and may not be sufficient to run the measurement if:

- several measurement files are open,
- measurement files contain a large number of records and/or large numbers of particles,
- if they contain large amounts of Raman data

To check the memory load go to the Windows task Manager. If the Morphologi.exe process load is more than 400,000 K BEFORE you start the measurement it is recommended that you close open measurement files and/or open a new measurement file if the number of records in the open measurement is high(>10).



To check the number of measurement files open go to View>Cascade

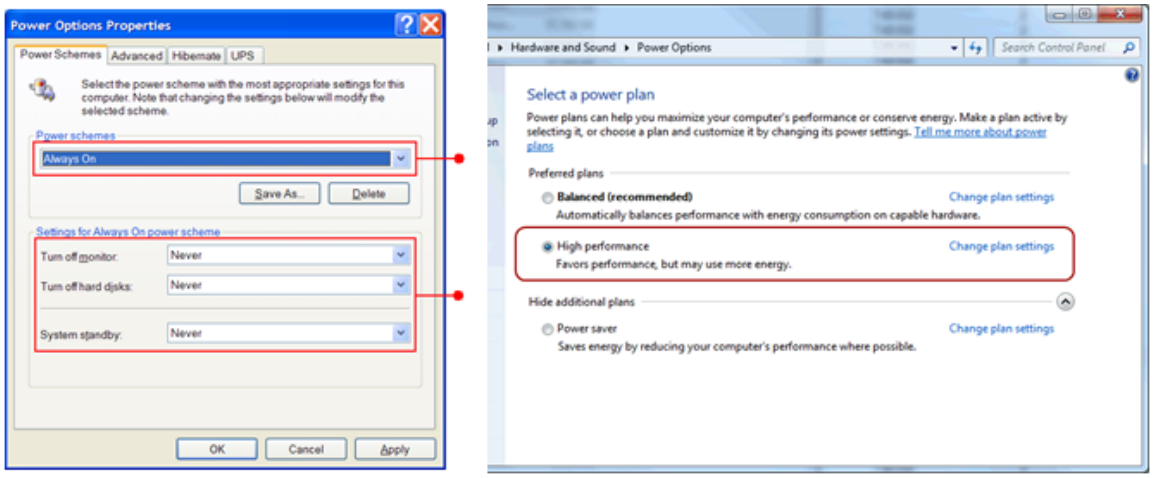


	If several measurement files can be seen, close all those that are not in use. Look at number of records and number of particles in results including any filtered particles that may not be included in the particle number count in the workspace. In the example shown there were over 60 results and some contain more than 150000 particle images before considering filtered/excluded particles. 54 Spherolac 100 2.5x r5 — 29 January 2009 17:08:24 — False — 13471 **55 Granulac 70 5x r1 — 29 January 2009 19:11:4 — False — 158346** 56 Granulac 70 2.5x r1 — 30 January 2009 11:14:49 — False — 50660 57 Granulac 70 5x r2 — 30 January 2009 13:58:34 — False — 154010 58 Granulac 70 2.5x r2 — 30 January 2009 14:52:40 — False — 56442 59 Granulac 70 5x r3 7mm3 — 30 January 2009 17:01:12 — False — 123322 If the memory load rises above 1,200,000Kb during a measurement the software can cease to operate leading to a failed measurement.
Avoid viewing previous results whilst measurement is running.	Viewing results may increase memory load on PC 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 recommend to copy the data to another PC. In particular **do not** 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 PC.	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 PC when the instrument in not in use, e.g. overnight. Software can be installed on alternative PCs for data review.
Avoid virus scans, windows updates etc. occurring during a measurement.	If any other PC activity causes the Software to crash or causes the PC 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

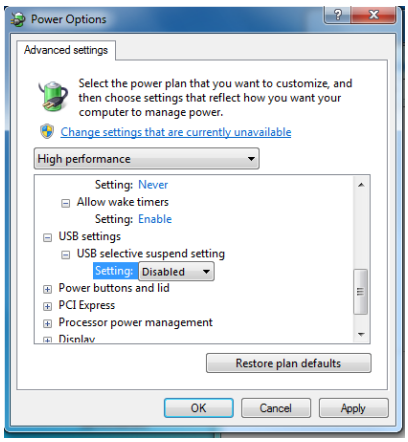
To disable the power saving options of the computer use the Power Options available in Control Panel.

Modify the default settings to those highlighted below for your OS: Windows XP (left), Windows 7 (right).



Appendix C: Disabling USB selective suspend

From the power options dialog shown in Appendix B, select Change plan settings and set USB selective suspend setting to Disabled.



Malvern Instruments Ltd

Enigma Business Park • Grovewood Road
Malvern • Worcestershire • UK • WR14 1XZ

Tel: +44 (0)1684 892456
Fax: +44 (0)1684 892789

Malvern Instruments Worldwide

Sales and service centers in over 50 countries
for details visit www.malvern.com/contact

more information at www.malvern.com