SOFTWARE UPDATE NOTIFICATION MORPHOLOGI SOFTWARE v8.21: PSS0025-30

PARTICLE SIZE

PARTICLE SHAPE

CHEMICAL IDENTIFICATION

Introduction

This document details the release of software PSS0025-30: the Morphologi Software Suite including version 8.21 software for the Morphologi G3 instrument family. It covers software issues that have been 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 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: If you are upgrading from a version of software than precedes version 8.20, additional information about the intermediary versions can be found in the relevant Software Update Notifications which can also be found on this installation CD. Appendix B summarizes the version numbers of all Morphologi software releases for your reference.

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 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 C and D 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 sy	vstem requirements f	for the Morphologi software.

Feature	Specification
Processor Type	Intel Core i7 4770 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
	<i>Not</i> e: 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)
	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.

The software may also be installed from the web. To use this option, Run the web installer Malvern Morphologi v8.21 PSS0025-30 EN.exe.

In both cases the installer will prompt for the user to select Morphologi G3-ID mode or standard G3.

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 of the Morphologi software 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 use 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.

Fixed issues

The issues fixed in this version of the software are detailed below.

Reference(s)	Issue	Comment
54731	The Estimate Threshold button works as intended in the Optic section of the SOP.	Previously a very low estimate was given.
56492	Print previewing a report no longer changes the selected report	The selected report is shown when closing the print preview
56664	Automatically printing a report at the end of an SOP prints the correct report.	Previously the next report in the list was printed.
57120	Closing dialog after doing "Disperse Sample" no longer crashes the software.	
57279	21CFR registry values are no longer removed during uninstall.	If upgrading from software versions between 8.00 and 8.20 refer to known issues.
57856	Performance Check report and SOP included in the install.	To be used with the PVS5113 reference slide to check the performance of the system.
58362	The laser power is now set high at software start up and shutdown. It is recommended that the laser left for at least 15 minutes at high power to stabilize before running an ID measurement.	Previously, leaving the laser on low power sometimes caused issues with laser stability.



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
ISSUE		Comment
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.	lssue has been logged as bug #58363
If uninstalling software versions between 8.00 and 8.20 and the 21CFR registry values will be removed unless software version 7.xx was present previously.	If registry values are removed reinstall them using the 21CFR installer CD supplied with the system or contact the Malvern Helpdesk.	This bug was logged as #57279 and has been fixed so will not occur if uninstalling software version 8.21.
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.	lssue has been logged as bug #58138
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.	lssue has been logged as bug #58361
Camera drivers may not properly install/update	Install/update driver in device manager and when it asks for driver location navigate to C:\Program Files	lssue has been logged as bug #59682
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.	lssue 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.	lssue 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.	lssue 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.	lssue has been logged as bugs #31966 #52918 & #52921 #52546



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.	Issue has been logged as bug #46662
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.	lssue 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.	lssue 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.	lssue 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.	lssue 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 and #35255
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.	lssue has been logged as bug #25263
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
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 acquisition finish for long acquisition times do not press abort until laser spot is seen on the sample 	lssue 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.	lssue 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.	lssue has been logged as bug #23756
The manual targeting dialog can generate a high memory load on some PCs and may result in a crash.	Do not leaving the manual targeting dialog open when not in use	lssue has been logged as bug #52004
When re-running measurement without closing the Live Display, fixed focus, single slide measurements using a different slide index from the first measurement results in an unspecified error.	Always close the live display between sop runs.	lssue has been logged as bug #52546
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.	lssue has been logged as bug #53225
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. Image: Comparison of the instrument will not move the turret. Image: Comparison of the instrument will not move th	Ensure instrument is switched on BEFORE starting the software	lssue 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.	-
If .Net 4.5 is not present before installation of Morphologi, the Morphologi installer may display a warning about files being in use by a running application.	Install .Net 4.5 before installing the Morphologi software. Alternatively, press the Ignore button – the installer will then ask you to reboot when it has finished.	-

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. 8.21; 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		Magnification						
Consider particle size range of interest.			2.5x	5x	10x	20x	50x	
Is analysis Morphological only or is Chemical Identification required?		Morphological size range (µm)	1000-13	420-6.5	210-3.5	100-1.8	40-0.5	
Table provides guidance.		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.							



SOFTWARE UPDATE NOTIFICATION

File Management and memory load management Insufficient memory may lead to aborted measurement.	 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 		
If the memory load goes above 1,200,000 K during a measurement it can fail.	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).		
Minimize RAM usage by	j Windows Task Manager		
closing any measurement files not	File Options View Help		
in use and minimizing	Applications Processes Services Performance Networking Users		
number of records in each measurement file.	Image Name User Name CPU Memory (USER GDI Ob I/O Reads De		
	Morphologi.exe dhuck-j 00 603,412 K 1,021 1,058 31,107,623 Mc notes2.exe dhuck-j 00 76,976 K 505 872 19,151 Lo		
	POWERPNT.EXE dhuck.j 02 67,952 K 210 311 23,439 Mi		
	explorer.exe dhuck-j 00 42,140 K 639 933 19,065 Wi		
	To check the number of measurement files open go to View>Cascade		
	Morphologi ID - Lactose shapes.vmes		
	File Edit View Measure Tools Security Window Help Image:		
	D Mahamir ref naral sprawumer (Record 2: Mah		
	IIIe NGI dispersed DPI demo.vmes (Record 2: Arrange Icons		
	F Image: Sample Data Nasal Spray.vmes 1 Malvern's ref nasal spray.vmes (Record 3: Malverns ref [Chem]classed corr 0.7 - Unclassified) F Image: Sample Data Nasal Spray.vmes 2 NGI dispersed DPI demo.vmes (Record 2: DPI) 3 8206 Nasal Spray.vmes (Record 22: Innovator raw) 4 active_excipient july 2012.vmes (Record 22: commercial nasal active/excipient under QCS fil[Chem] Active) 5 G3ID Sample Data Nasal Spray.vmes (Record 22: Innovator raw) 4 active_excipient july 2012.vmes (Record 22: commercial nasal active/excipient under QCS fil[Chem] Active) 5 G3ID Sample Data Nasal Spray.vmes (Record 4: Granulac 70 2.5x r5 7mm3) 0 commercial nasal active/excipient under QCS fil[Chem] Active)		
	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	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.		
is running.	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: 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.

Software release reference	Release month
PSS0025-29 Morphologi v8.20	November 2015
PSS0025-28 Morphologi v8.13	April 2015
PSS0025-26 Morphologi v8.12	June 2014
PSS0025-25 Morphologi v8.11	September 2013
PSS0025-24 Morphologi v8.10	May 2013
PSS0226-01 Morphologi v8.00	September 2012
PSS0025-23 Morphologi v7.43	August 2012
PSS0025-22 Morphologi v7.42	June 2012
PSS0025-21 Morphologi v7.41	August 2011
PSS0025-20 Morphologi v7.40	July 2011
PSS0025-019 Morphologi v7.21	June 2011
PSS0025-018 Morphologi v7.21	August 2010
PSS0025-016 Morphologi v7.20	April 2010
PSS0025-015 Morphologi v7.12	August 2009
PSS0025-013 Morphologi v7.11	November 2008
PSS0025-12 Morphologi v7.10	September 2008



SOFTWARE UPDATE NOTIFICATION

PSS0025-08 Morphologi v7.00	February 2008
PSS0025-06 Morphologi v6.02	March 2007
PSS0025-05 Morphologi v6.01	August 2006
PSS0025-04 Morphologi v6.00	July 2006
PSS0025-03 Morphologi v5.02	January 2006
PSS0025-02 Morphologi v5.01	December 2005
PSS0025-01 Morphologi v5.00	November 2005

Appendix C: Disabling power saving

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

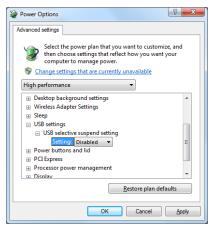
Modify the default settings to those highlighted below for your OS.

😋 🔵 🗢 😵 🕨 Control Panel 🕨	Hardware and Sound > Power Options - 49 See	arch Control Panel	
Control Panel Home	Select a power plan		
Require a password on wakeup Choose what the power button does Create a power plan	Power plans can help you maximize your computer's performance or conserve e selecting it, or choose a plan and customize it by changing its power settings. <u>Is</u> plans Preferred plans		
Choose when to turn off the display	 Balanced (recommended) Automatically balances performance with energy consumption on capabl 	Change plan settings e hardware.	
Change when the computer sleeps	Wigh performance Favors performance, but may use more energy.	Change plan settings)
	Hide additional plans		
	Power saver	Change plan settings	
See also	Saves energy by reducing your computer's performance where possible.		
Personalization			
User Accounts			



Appendix D: 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

© Malvern Instruments Ltd 2016

more information at www.malvern.com

