SOFTWARE UPDATE NOTIFICATION (SUN) – OMNISEC SOFTWARE v10.30: PSS0051-04

MOLECULAR WEIGHT

MOLECULAR SIZE

MOLECULAR STRUCTURE

Introduction

This document details the installation and known issues with OMNISEC v10.30. This release is a major release to fix a number of critical issues and introduce a number of new features, including 21CFR part 11 compliance.

Installation

It is assumed that you have authority to install or update software within your company's SOPs. If you do not have this authority, please consult with your I.T. support department before proceeding.

It is assumed that you have Administrator rights for the computer. This is required by the installation process.

Minimum System Requirements

Intel Core i7 processor, 4 GB RAM, 500 GB free hard disk space, 1600 x 900 screen resolution running in 16 bit color mode, CD-ROM drive, 1 free USB port, Windows 7 64bit Professional operating system.

Recommended System Requirements

Intel Core i7 processor (Quad Core HT, 3.1 GHz Turbo, with HD Graphics), 8 GB RAM, 500 GB free hard disk space, 1920 x 1080 full HD screen resolution running in 16 bit color mode, CD-ROM drive, 1 free USB port, Windows 7 64 bit Professional operating system.

Supported operating systems

OMNISEC software v10.30 is compatible with Windows 7. Only 64 bit Professional versions are supported.

Windows XP, Windows Vista, and Windows 8 and Windows 10 are not supported.

Supported Languages

English

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Installation Instructions

Windows 7 64 bit Professional

In most cases, OMNISEC should install automatically when the CD is inserted in the drive. If it doesn't, the user can double-click on the installer file, OMNISEC1030.exe, to begin the installation.

When the Setup window appears, select Next to process. You can select cancel if you would like to stop the setup and continue another time.
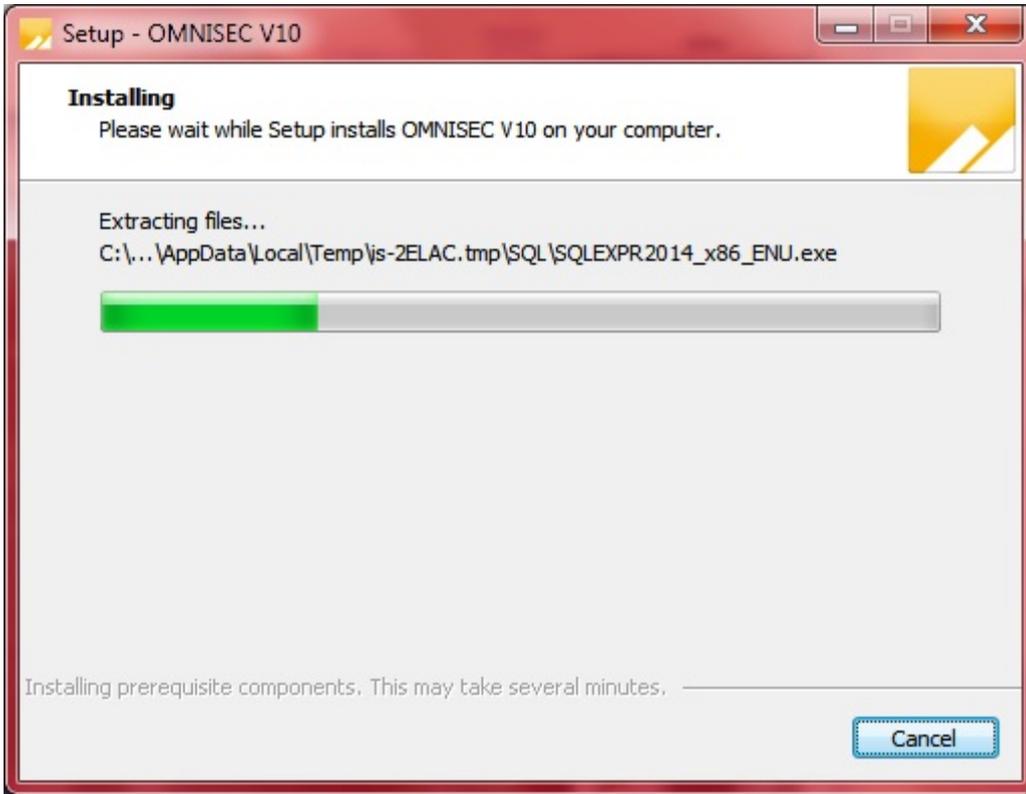
Once you have followed all of the instructions and clicked "Install", the software will begin the installation process.
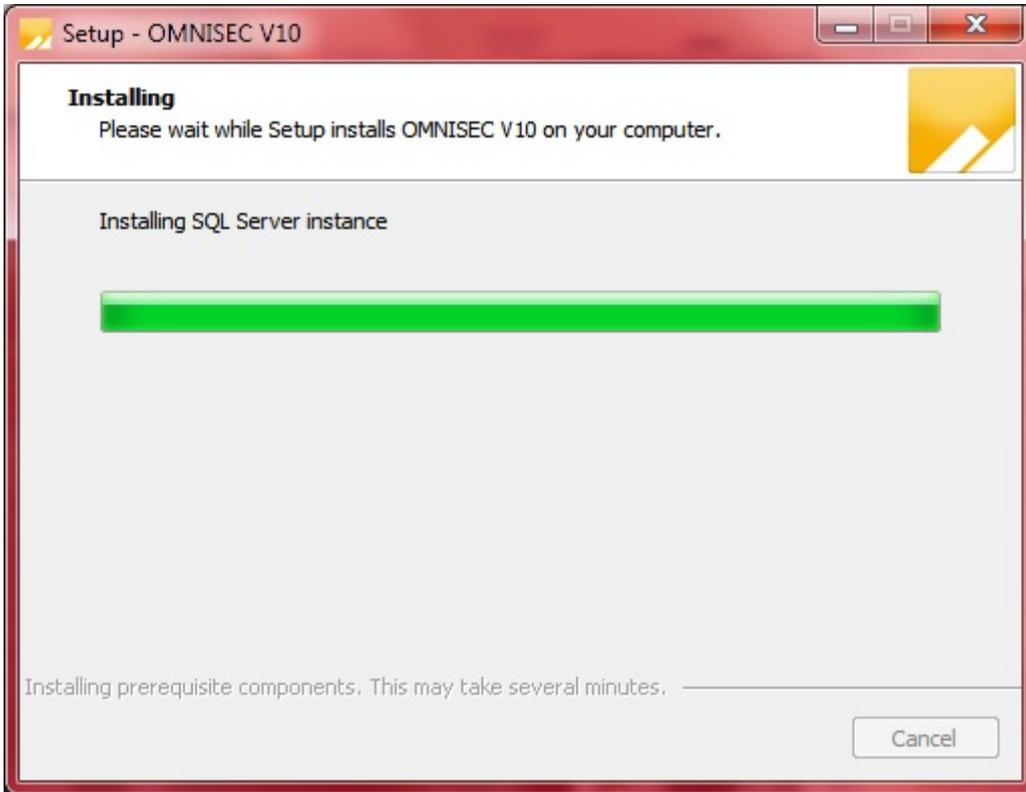
If this is the first time OMNISEC v10 is being installed, it will install a 2014 SQL Server instance. This process may take 10 to 20 minutes to complete.

During the installation, a Windows Security window may appear asking if you would like to install a device.

Select "Install" to install the device.
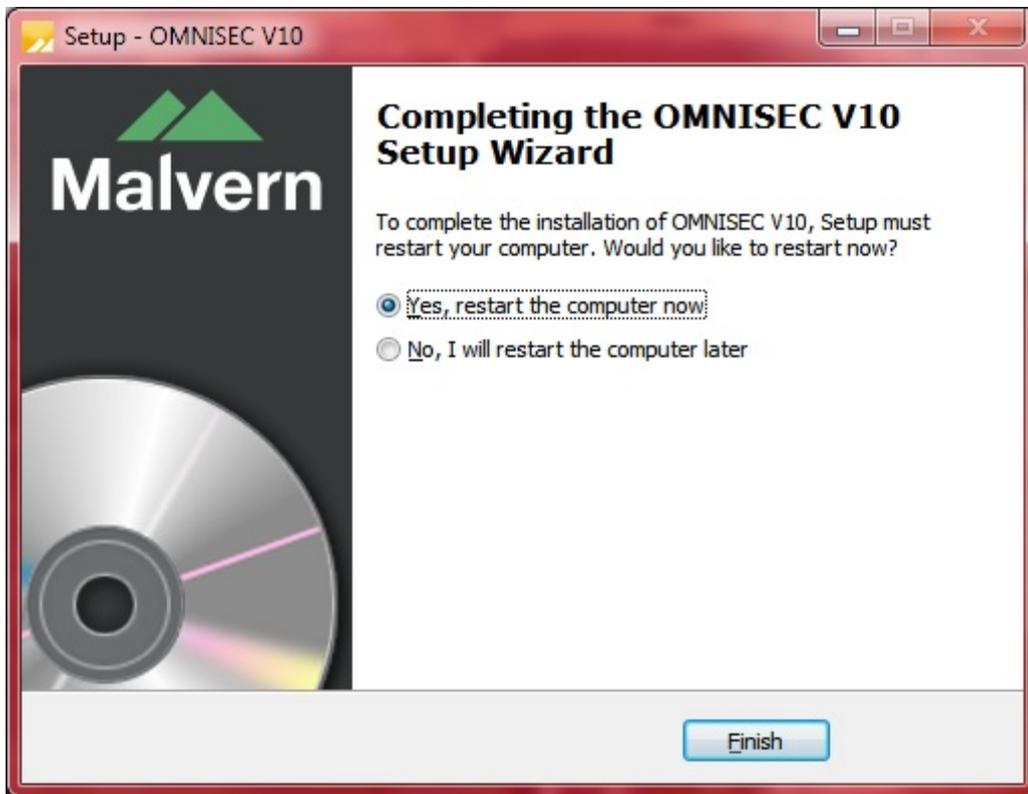
The last section in the Setup window will inform you that the computer needs to be restarted to complete the setup. Once the computer has been fully restarted, OMNISEC v10 will be ready to use.

Connecting the OMNISEC to a PC

With the software installed, the instrument should be connected via the USB port, and the system switched on. If present, turn on OMNISEC RESOLVE first and wait 30 seconds for it to complete its startup. Next, turn on OMINSEC REVEAL and wait 1 minute to allow it to complete its startup and connect to OMNISEC RESOLVE. When the two instruments are connected, the light bars on both instruments should be green.

If this is the first time connecting the instrument to the PC, there will be a message that appears saying "Installing device driver software". The names used to identify the drivers will be "CMULx25", "CHROME TAU A" and "CHROME TAU B". Allow the installation to proceed and do not disconnect the instrument from the PC during this process. Once the drivers have been installed, Windows will indicate that they are ready to use.

## Updating the OMNISEC REVEAL firmware

The first time you launch OMNISEC 10.30 with an OMNISEC REVEAL connected, you may be prompted to install a new version of the instrument firmware.
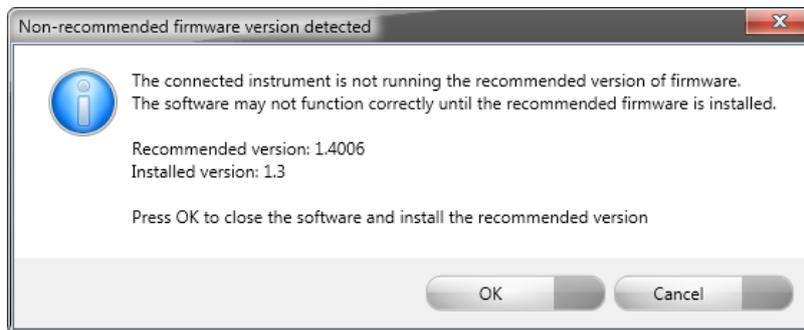

Updating the firmware improves system reliability and compatibility with the version of OMNISEC V10 you have installed on your computer. The update process takes up to 10 minutes and the instrument will need to be power cycled after the update is complete.

Click **OK** to close the OMNISEC application. After a few seconds the OMNISEC Firmware Updater program should automatically launch.

Note: If the OMNISEC Firmware Updater fails to open, or if the updater says it could not detect the instrument, disconnect the instrument, relaunch OMNISEC V10 and reconnect the instrument. You should receive the update prompt to try again.
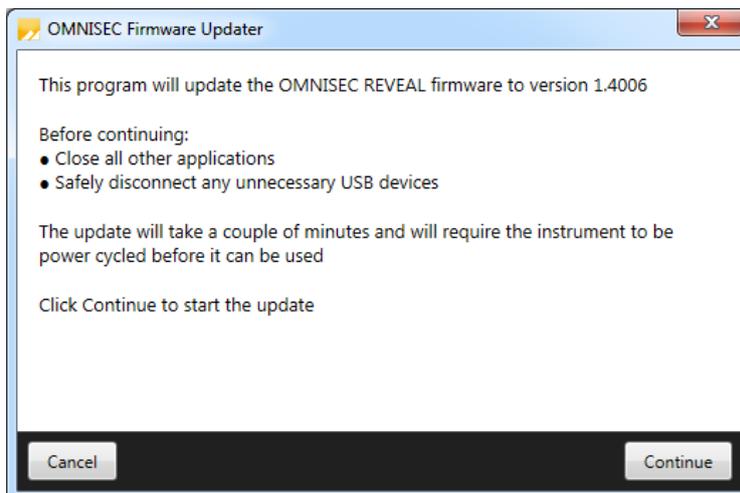
When the OMNISEC Firmware Updater launches, you should carefully read the information presented to you before continuing.

Click **Continue** to start the update process.
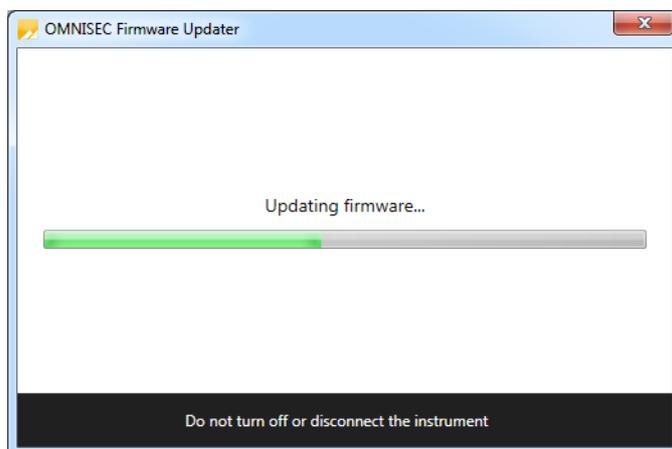
The update process takes several minutes. It is recommended that you do not do anything else on your computer during the update.

After the firmware update has completed, you will be prompted to power cycle the instrument. Once the power up cycle has completed and you see the green lights on the front of RESOLVE and REVEAL click **Exit** and relaunch OMNISEC V10.

Note: If the update process fails, you don't see two green lights on the instrument or you are still being prompted to update the firmware, try power cycling the instrument and restarting OMNISEC V10 again.

Uninstall Procedure

The software can be uninstalled using the 'Programs and Features' section of the Windows 7 'Control Panel'.

New Features

The new features added to the software are shown in table 1:

Table 1: New features added to OMNISEC 10.30

Reference	Feature
64851	Protein Method
64857 64960	21 CFR: Restricted acquisition mode with licensing
64858 66092 66121 67436 67437	21 CFR: Auditing
64859 64860 64891	21 CFR: Digital signatures
64861	21 CFR: Access control

64862 **68779**	21 CFR: Access control (MAC permissions)
66087 **68844**	21 CFR: Measurement Log
67976	21 CFR: Authenticate at launch
65538	Firmware updating in software
70307	Improved Sequence Editor
70320	More robust sequence running system
66791	Added option for instrument controls to sit to the side, rather than overlay
76558	Added support for fraction collectors via external trigger (see known issues)

Fixed issues

The main issues fixed in this release of the software are listed in table 2.

Table 2: bug fixes implemented in OMNISEC 10.30.

Reference	Issue	Comment
65313	Flow rate ramp rate minimum limit too high	Minimum ramp rate limit is now 0.001 mL/min
65454	Extrapolation limits incorrectly calculated on noisy UV signal	The extrapolation no longer includes values which are below the baseline after band broadening correction
66878	Incorrect error message when RI zeroing fails	Error message corrected
67512	Unable to delete calibration standards	Fixed
67756	Minimum pump pressure alarm might not trigger when returning to standby flow rate after a sequence completes	Fixed
70288	Setting baselines is not deterministic	Fixed
72637	Calculate button may become incorrectly enabled on unanalyzed injections	Fixed
72722	Pump pressure displays not updated after changing unit preference	Fixed
74070	Certain MALS data might cause the Method Report to crash	Fixed
74260	Overlay chart legend can be incorrect if viewing multiple records with similar sample names	Fixed
74566	The installer may refuse to start again after a reboot was required for a prerequisite to install	Fixed
75378	Overlay axes may scroll multiple plots when multiple samples with similar names are selected	Fixed
66732	Sequences may end randomly before they have completed	Fixed
67101	The injection volume you can specify is limited to OMNISEC RESOLVE's capabilities when using a 3rd party fluid system	Limits are now less restrictive
75879	In the PDA view, the UV Chromatogram chart may become blank when switching between certain datasets. Rolling the mouse over the chart causes the application to crash.	Fixed

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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.

Table 1: Known issues in OMNISEC v10.30 software.

Reference	Issue	Workaround
40278	Autoscaling does not work as intended	Manually scale the axes and save them using the "Save my axes" command
39602	After extended periods of working with large datasets, the software may run out of memory	Save analyses regularly and restart the software if the problem occurs
39314	The search feature in the columns database only works for column sets, not columns.	Manually search the columns list.
39315	Internet Explorer may block the help file from appearing depending on security settings	Allow Internet Explorer to display blocked content.
39617	After some crashes, the software may not restart	Disconnect the OMNISEC system from the PC and reconnect it. Alternatively, re-install the software. No data will be lost by doing this.
39364	The Help button in the Report Selector does not function	Open the help file from the Start Page or another area.
39446	The Copy button does not work in the Print Preview window	Copy the image directly from the report pages or the charts.
39480	It is possible for the Zoom buttons in the ribbon bar to be inappropriately greyed out.	Use the right click menu in the chart you wish to zoom out of.
64698	Copy data from Derived chart without IP & DP data causes application to crash	No workaround
	When sample type, dn/dc or concentration are updated, it updates this value for all injections in that sample, however, only the currently selected injection is recalculated.	Select other injections for that sample and recalculate and save them to bring all the results up to date. This requirement is noted in the 'Edit Run Conditions' dialog
	Importing an archive might get stuck and never complete	After waiting a reasonable amount of time where the progress bar has not changed, forcefully close the OMNISEC application using Windows Task Manager, then restart the software and try again.
	Running baseline monitors with the UV detector enabled may cause Out of Memory crashes	Restart the software before and after running a baseline monitor with the UV detector enabled
	Opening baseline monitors with UV data in the PDA view may cause an Out of Memory crash	Do not open baseline monitors with UV data in the PDA view
65981	The channel buttons in the Ribbon do not enable/disable appropriately for the selected view	No workaround
66441	The legend in the distribution and overlay charts may not be in the same order as in the Record View	No workaround
66452	Sequence & Sample name can be set to empty in the Edit Run Conditions window, causing errors in analyses	Do not set a blank sequence or sample name
66520 67510 67578	Creating and editing Column Sets does not work as expected	Delete and recreate column sets from scratch instead of trying to edit them
66731	Sequences with a large number of samples are very slow to open	Try to create and run sequences with no more than about 10 samples each. Do not keep adding new samples to already run sequences.
69856	Application crashes when trying to print or print preview a report where a table is longer than the page	Break long report tables into separate smaller tables

69862	Report printing exhibits incorrect page setup behavior	No workaround
72239	The Delete button may be disabled for a user created Sample Type / Calibration Standard / Solvent	Rename the record, save and try again
72240	When deleting a Sample Type / Calibration Standard / Solvent, clicking the X button on the message box asking for confirmation will delete the record anyway	Do not click the X button on message boxes, always choose from the available buttons below the message
72242	The Malvern icon is missing next to pre-defined Sample Types	No workaround
72938	The Cancel button does not work as expected in the Calculation Method editor window	Close the window from the title bar to discard any changes to a calculation method
75976	The Concentration field in the Edit Run Conditions window does not allow enough precision	No workaround
75977	The top of the MALS Fit Order view can be cut off	Resize the view
75978	The MALS fit order slider remains on the Raw data view after switching from a MALS method to a non-MALS method	No workaround
75980	When copying a Results by Peak report table, the Sample Name is not included	No workaround
76127	When exiting the application after the instrument has been disconnected, the user is still asked whether they want to return the pump to standby flow rate	No workaround
76528	Fraction collector triggers on using Baseline monitor	Disconnect fraction collector trigger lead from fraction collector or switch fraction collector off prior to using Baseline monitor function.

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