

OMNISEC SOFTWARE: v11.30 (PSS0051-14) SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0051-14: v11.30 of the software for the OMNISEC system. 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.

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.

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 or 10 64bit Professional operating system.

Recommended System Requirements

The recommended computer system requirements for running this software are highlighted in table 1 below.

| Feature | Specification |
|--------------------------|--|
| Processor Type | Intel Core i7 processor (Quad Core HT, 3.1 GHz Turbo, with HD Graphics), |
| Memory | 8 GB RAM |
| Hard Disk Storage | 500 GB free hard disk space, |
| Additional Storage Media | CD-ROM drive, |
| Display Resolution | 1920 x 1080 full HD screen resolution running in 16 bit color mode, |
| Connectivity | 1 free USB port, |
| Operating System | Windows 7 or 10 64 bit Professional operating system. |

Table 1: Recommended system requirements for the OMNISEC software.





Supported operating systems

OMNISEC software v11 is compatible with Windows 7 or 10. Only 64 bit Professional versions are supported.

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

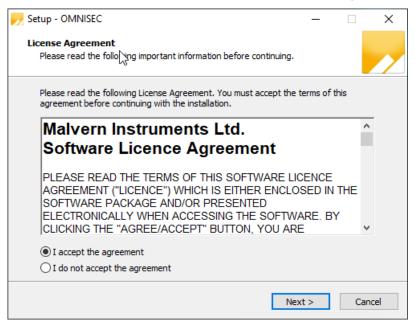
Supported Languages

English

Installation Instructions

Windows 7 or 10 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, OMNISEC1130.exe, to begin the installation.



When the license agreement window appears, if you accept the agreement, select **I accept the agreement** and press next. You can select cancel if you would like to stop the setup and continue another time.



| Netup - OMNISEC | _ | | \times |
|--|-----------|------|----------|
| Select Destination Location Where should OMNISEC be installed? | | | |
| Setup will install OMNISEC into the following folder. | | | |
| To continue, click Next. If you would like to select a different folder, | click Bro | wse. | |
| C:\Program Files (x86)\Malvern Panalytical\OMNISEC | Br | owse | |
| At least 601.5 MB of free disk space is required. | | | |
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Select the destination location for OMNISEC to install. It is recommended that this remains the default path. Select Next to process.

| 规 Setup - OMNISEC | _ | | × |
|--|------|-----|-----|
| Ready to Install Setup is now ready to begin installing OMNISEC on your computer. | | | |
| Click Install to convigue with the installation. | | | _ |
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Once you have followed all of the instructions and clicked "Install", the software will begin the installation process.



| Netup - OMNISEC — | | × |
|--|----|-------|
| Installing Please wait while Setup installs OMNISEC on your computer. | | |
| Extracting files C:\ \Malvern Panalytical\OMNISEC\ChromeDeviceDriver\Static\i386\ftd2xx.lib | , | |
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If this is the first time OMNISEC v11 is being installed, it will install a 2014 SQL Server instance on Windows 7 and 2019 SQL server on Windows 10. This process may take 10 to 20 minutes to complete.

| Windows Security |
|---|
| Would you like to install this device software? Name: CDM Driver Package Publisher: Malvern Instruments Ltd |
| Image: Always trust software from "Malvern Instruments Install Image: Install Don't Install Ltd". Image: I |
| You should only install driver software from publishers you trust. How can I decide which device software is safe to install? |

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 v11 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 v11 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 v11 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.

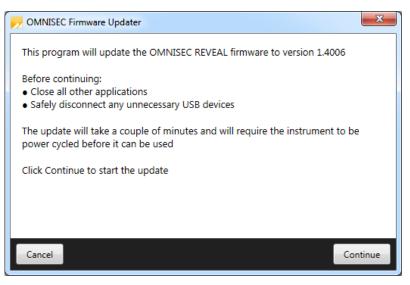
Note:

If the OMNISEC Firmware Updater fails to open, or if the updater says it could not detect the instrument, disconnect the instrument, relaunch OMNISEC V11 and reconnect the instrument. You should receive the update prompt to try again.

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Note:

If SEC-MALS 9 or 20 is present, please turn-off and disconnect this detectors communication cable from the PC or REVEAL. Then update the firmware with just the RESOLVE-REVEAL. Once the update process has taken place the SEC-MALS can be reconnected and the settings configured.



When the OMNISEC Firmware Updater launches, you should carefully read the information presented to you before continuing.

Click Continue to start the update process.



| P OMNISEC Firmware Updater |
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| Updating firmware |
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| Do not turn off or disconnect the instrument |

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 v11.

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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 V11 again.

Uninstall Procedure

The software can be uninstalled using the 'Programs and Features' section of the Windows 7 'Control Panel' or the 'Apps' section of Windows 10 'Settings'.

New Features

The new features in this release of the software are listed in Table 2.

Table 2: New features implemented in OMNISEC 11.30

| Reference | lssue | Comment |
|-----------------|--|--|
| 121767 - 121769 | % above/below | Report % above/below user defined molecular weight values |
| 121770 | Molecular weight @ % | Report the Molecular weight at a specific % cumulative molecular weight |
| 132592 - 139674 | Compositional Analysis: Requires feature key license | Calculate macromolecule composition |
| 132578, 132584 | AAV and DAR | Automatically calculate critical attributes for AAV and DAR applications – enabled though compositional analysis feature key. |



| 132750 | Copy from tabular report widgets harmonized | Improved data copying from the reports widgets. |
|--------|---|---|
| 132606 | Rename TripleDetection -> Multi-Detectors | More accurately reflect the use of the analysis method |
| 139673 | Updated sample database viewer | Improve the database viewer to allow more data rows to be visible |

Fixed issues

The fixed issues in this release of the software are listed in Table 3.

Table 3: Fixed issues in OMNISEC 11.30

| Reference | Issue | Comment |
|-----------|--|--|
| 126090 | Firmware update lowering transducer overpressure limits | IP limit 90mV DP limit 4900mV |
| 133353 | [Installer] The SQL Server instance did not install successfully on Windows 10 | Improved messaging |
| 135016 | [21CFR11] Fix an integrity issue upgrading from 10.41 | Fixed |
| 134057 | [21CFR11] Permissions renamed "OMNISEC Access Control", version changed | Customers should import to MAC/export/import to OMNISEC |

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 4: Known issues in OMNISEC v11.30 software.

| Reference | Issue | Workaround |
|-----------|--|--|
| 73366 | Calculation method not refreshed when save permission is denied through access control file | 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 if MALS Model/Fit View window is active | Do not have the MALS Model/Fit View as an active window |
| 76199 | UV causing out of memory crashes | No workaround |
| 76528 | Fraction collector triggers on baseline monitor activation | When a baseline monitor is run, turn off the fraction collector. |



| 77659 | Injection Volume Tooltip "Default" Validation Shown Instead of Mode-Specific-Validation | No workaround |
|-------|---|--|
| 80765 | Derived data plot shows kick in logMw trace in some circumstances | No workaround |
| 80874 | Windows 10 Style Fixes | No workaround |
| 82353 | Baselines may not appear on the Raw Data chart even though the points are set | Switch to a different record then switch back. If the problem remains, restart the software. |
| 87304 | Copy Graph function produces 'fuzzy' graphs | No workaround. Copy from report designer rather than the analysis screen. |
| 90230 | Limit/baseline changes after license expires causes crash | No work around |
| 91107 | Axis numbers extend past chromatogram window when highlighting | No Workaround |
| 92608 | SQL Server 2014 Express installation fails | Cycle the PC power and restart the installation |
| 93028 | A failed migration can break audit trails | No workaround |
| 93246 | Deleting a recent sequence does not remove it from the Analyze Data list on the Start Page | No workaround |
| 93281 | Performing a Full Zoom Out after turning off Auto-Scaling in acquisition does not refresh the axes properly | No workaround |
| 93283 | Default Method does not work on MALS 9 | No workaround |
| 93497 | Error when last MALS point deselected in Model/Fit View | Have at least 1 data point selected |
| 93498 | Deselecting all MALS point in Model/Fit View doesn't work | Have at least 1 data point selected |
| 94546 | Cannot change solvent in run conditions | No Workaround |
| 96064 | User can add unbounded length description in Tools > Database editor dialogs | Limit the length of the database item. |
| 96589 | Migration from V30 to V31 discards vital validation error information | No workaround |
| 97099 | APC-REVEAL calibration shifts viscometer signal when using BSA | Use a monodisperse sample for calibration. |
| 98011 | Instrument setup browser does not support MPA values | No Workaround |
| 98433 | Minimum pressure alarm triggers during pump prime | Set minimum pressure at 0 during prime. |
| 98614 | Right-click baseline point counts as baseline change | No Workaround |
| 98939 | Safety event display is delayed until after a purge | No Workaround |
| | | |



| 99104 | User must select set on instrument controls to get the temperatures value | No Workaround |
|--------|--|--|
| 99144 | Detector oven set point at 0 | No Workaround |
| 99195 | Finding Limits and Baseline Dialog locking Audit Validation | No Workaround |
| 99232 | Autosampler loop volume setting does not take effect without restarting the software | Restart the software when volume changes are made. |
| 99380 | Modifying the angles used in a MALS method does not update the Method name. | No Workaround |
| 99381 | Method in record view drop down menu and in calculation method do not match | No Workaround |
| 99383 | Changing the MALS model fit does not update the MALS data report automatically | No Workaround |
| 99385 | Load Axis not functioning | No Workaround |
| 99670 | Light scattering laser turns off when sequence paused for over 1 hour | Don't pause sequences for longer than 1 hour. |
| 99677 | Software fatal error when standard parameters adjusted | No Workaround |
| 99730 | Distribution plot - multiple axis appear | No Workaround |
| 99766 | Software crashes if grid column settings file(s) missing | No Workaround |
| 99980 | RALS/LALS channels not used correctly in an analysis | No Workaround |
| 100533 | When instrument method is applied update Target temperatures | No Workaround |
| 100564 | Portion of OMNISEC name cut off | No Workaround |
| 100566 | Name of pump flow rate incorrect in sequence information table report designer | No Workaround |
| 100746 | Data from baseline monitor acquisition not saved | No Workaround |
| 101098 | Not all experiment settings method properties are reportable | No Workaround |
| 101552 | Cant adjust sample concentration lower that 0.0xxxxx | No Workaround |
| 101648 | Calculation Method - detectors 'active' checkbox gets muddled when sorting | Don't re-sort the method detectors |
| 102002 | Baseline point markers don't show the correct x and y values | No Workaround |
| 102318 | Injection Volume set to 100 when stopping Acquisition | No Workaround |
| 102324 | Missing audit trails created on database migration | No Workaround |
| 102636 | Alarms are not being caught/handled | No Workaround |
| 102999 | Non-fatal exception when aborting sequence | No Workaround |
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| 103113 | Fatal error while processing - out of memory errors. | No Workaround |
|--------|--|---|
| 103398 | Failure to save when analyzing an injection stopped by safety event | No Workaround |
| 103508 | derived data view axis changes cause a crash | No Workaround |
| 103588 | Signature context menu items do not always respect permissions | No Workaround |
| 104085 | Can add sample to a completed sequence without restarting | No Workaround |
| 104258 | search in report item selector does not work | Manually select the items that you want in a report. |
| 104285 | Print preview does not update when analysis changes | No Workaround |
| 104387 | Gridlines re-appear after being disabled. | No Workaround |
| 106118 | Under pressure alarm not reached in instrument setup template | No Workaround |
| 106891 | User.config file can be corrupted during software shutdown | No Workaround |
| 106893 | Corrupted user.config file prevents startup, bypasses global error handler | No Workaround |
| 107573 | Data Selector - 'From - to' Date is not fetching data correctly | No Workaround |
| 107907 | Access Denied Error when upgrading existing installation | Rename the Audit Trails folder so it is recreated. Audit trails can then be moved back into the new folder post-installation before starting the software. |
| 108236 | Instrument method - default temperatures | No Workaround |
| 108237 | Instrument methods - flow rate changes should be to 0.1 | No Workaround |
| 108239 | Report designer - MALS channels collapse into a sub heading | No Workaround |
| 108252 | Experiment Templates - Not displaying the correct template on close and reopen of client | No Workaround |
| 108289 | y-axis in raw data report widget - display with no dp | No Workaround |
| 108290 | top of the peaks cut off in raw data report widget | No Workaround |
| 108291 | Raw data view - show processed data - offset and BB taken into account | No Workaround |
| 108619 | Import errors can effectively hang the software | No Workaround |
| 108620 | axes flashing and non-responsive | No Workaround |
| 109600 | Setup Methods: Purge time limit value not being set | No Workaround |
| 109689 | dA/dc units in the methods are incorrect | No Workaround |
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| 109774 | Flow rate setup method action doesn't stop on simulated pressure safety event | No Workaround |
|--------|--|--|
| 110709 | User prompted to install into the correct folder on upgrade | No Workaround |
| 110910 | Investigate - Error when moving limits with multiple analysis selected | No Workaround |
| 111888 | Unsaved New Reports can't be Printed or Previewed via Analysis Tab Print/Preview Option | Save the report. |
| 111889 | New Reports can't be Printed or Previewed via File>Print/Preview Option | Select another tab and then return to the new report. Print/preview will work. |
| 111949 | all report charts show the wrong axis numbers | No Workaround |
| 112410 | Notes added in the Sequence have no max character | No Workaround |
| 112820 | make column labels consistent in reports | No Workaround |
| 112881 | MALS bug | No Workaround |
| 112889 | table alignment | No Workaround |
| 112912 | Strange extrapolations on the derived plots | No Workaround |
| 112913 | Flow rate decimal places | No Workaround |
| 113056 | Temperature tolerances are applied during baseline monitor | No Workaround |
| 113427 | Temperature alarms intermittent | No Workaround |
| 113451 | Abandon Changes Error and Fatal Exception | No Workaround |
| 114114 | Inconsistent capitalization in Calculation Method Editor page list | No Workaround |
| 114255 | Environment tolerance alarm text displayed for non tolerance alarms | No Workaround |
| 114410 | "Set at runtime" does not work for delays | No Workaround |
| 114545 | Overlay and export goes "Breaky" when use a certain set of data in Build 20191008.8 | No Workaround |
| 115017 | Methods generation value incorrect | No Workaround |
| 115416 | User authentication loop | No Workaround |
| 115443 | Export archives can be silently corrupted | No Workaround |
| 115499 | Signed on/by columns in Record View do not show signatures | Refer to the Signature widget |
| 115620 | Polymer reports crash | No Workaround |
| 115779 | First enabled Electronic Signatures can cause an exception | No Workaround |
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| 115808 | Exporting the currently selected file throws up an Exception Error | No Workaround |
|--------|--|--|
| 115865 | Report with same name cancelled causes the selector to incorrectly display | No Workaround |
| 116556 | Locked analysis – Column calibration analysis lost if exported to v33 then reimported to v40 | Don't export v40 column calibration analysis to pre-v40 database versions |
| 116574 | Software fails to start if Reports folder permissions are incorrect | Ensure permissions are correct |
| 117076 | Min/Max Pressure alarm changed during sequence Alarm triggers at completion | Do not change the pressure alarm during a sequence |
| 118112 | Temperature tolerance - adjust decimal places | No Workaround |
| 118428 | Creating a calculation method with limits but no baselines removes limits/adds baselines | No Workaround |
| 118966 | REVEAL needs restarting after an overpressure event | No Workaround |
| 118998 | Ctrl+right-click add baselines adds baseline(point)s incorrectly | No Workaround |
| 119316 | Introduce the "Batch number" to the advanced data selector so that it can be used as a search parameter. | No Workaround |
| 119415 | Column header not displayed in reports when duplicate names used | No Workaround |
| 124958 | Error plotting (and multiple) MALS Temperature axis | No Workaround |
| 124961 | Invalid Raw Data calibration points when switching between column cal method type | No Workaround |
| 124963 | Select sensible defaults for MALS Temperature axis | No Workaround |
| 129962 | Crash when opening injection in paused sequence | Don't open an injection from paused sequence. |
| 132390 | Overlay report widget crashes w/ >2 selected injections | Only have reports with 1 overlay plot |
| 132591 | Update to latest released Malvern.Reporting and Malvern.Charting | No Workaround |
| 133950 | pump run rate in method editor set low | No Workaround |
| 134932 | Auto update added to requirements | No Workaround |
| 134982 | Analysis view - Distribution plot extrapolations incorrect | No Workaround |
| 134983 | Data in analysis view and reports widget does not match | No Workaround |
| 135237 | Acquisition should not continue if REVEAL connection fails | No Workaround |
| 135643 | "Audit trail history" doesn't show acquisition audit events | View 1 st and 2 nd generation audit individual audit trails using MAC. |
| 135861 | Features file does not update to latest version number when upgrading | No Workaround |
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| 136396 | Percentage RSD is negative for MH K parameter | No Workaround |
|--------|--|---|
| 136525 | When multiple peaks are selected the calculated concentration per peak is not displayed | No Workaround |
| 136582 | Installation failed when Microsoft Visual C++2015 - 2019 redistributable (x86) 14.28.29334 resided on the Windows | No Workaround |
| 137629 | Difference between the angles seen active on the "MALS model fit view" and in the calculation method | No Workaround |
| 139136 | Investigate BBv2 noisy compositional channels | Use BBV1 |
| 139712 | Fix crash if viscometer balance times out | No Workaround |
| 139713 | Fix USB log missing errors | No Workaround |
| 141133 | Derived Data chart settings do not persist for Molecular Weight (A) and (B) | No Workaround |
| 141154 | Investigate crash exporting image of Raw Data report widget | No Workaround |
| 141444 | when removing Baselines and limits in compositional the analysis does not update | No Workaround |
| 141470 | Fix analysis plot "Paste scale" | Use "Scale all to this Axis" |
| 141549 | Log file - one or more errors have occurred when opening data | No Workaround |
| 141550 | Limit markers disappear when not sample B set | No Workaround |
| 141573 | Default columns in record view when no compositional license | Manually remove unused columns in the record view |
| 141635 | Object reference error issue | No Workaround |
| 141642 | Raw data chart - results shading disappears after pressing save | No Workaround |



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