

OMNISEC SOFTWARE: v11.33 (PSS0051-17) SOFTWARE UPDATE NOTIFICATION

Introduction

This document details the release of software PSS0051-17: v11.33 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.

Users of 21 CFR functionality

If you are using the 21 CFR functionality in OMNISEC it is recommended that you read the previous SUN documents between the OMNISEC software version you have installed and this SUN.

No new OMNISEC permissions are introduced in this release, but if you are updating through multiple versions these could have changed and a new access control file may be required.

- 1. Using the OMNISEC software make a note of the location of the access control file (Administrator access required).
- 2. Close OMNISEC software.
- 3. Using the MAC software import the new permissions file. (See MAC user manual)
- 4. Check new permissions and add/remove as required to the user groups.
- 5. Export the new access control file with the <u>same name</u> as previously used to the folder location noted in step 1.
- 6. Update OMNISEC and open the software.
- 7. Access control should still be enabled with the new permissions active.

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

Table 1: Recommended system requirements for the OMNISEC software.



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,
Display Resolution	1920×1080 full HD screen resolution running in 16 bit color mode,
Connectivity	1 free USB port,
Operating System	Windows 10 64-bit Professional operating system.

Supported operating systems

OMNISEC software v11 is compatible with Windows 10 Professional/Enterprise (Tested on Windows 10 1909 version). Only 64-bit versions are supported.

Windows XP, Windows Vista, Windows 7 and Windows 8 are not supported.

Supported Languages

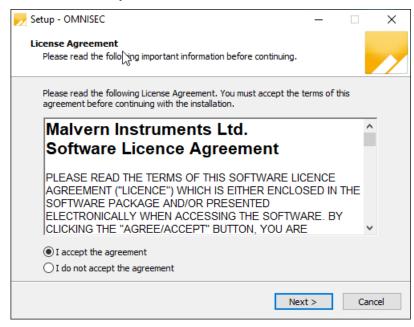
English

Installation Instructions

Windows 10 64 bit Professional

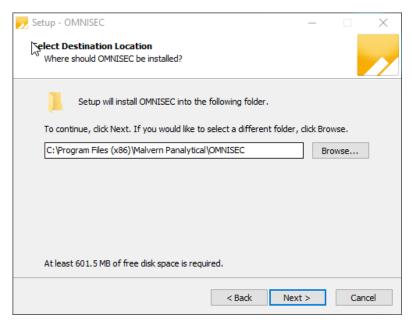
The software suite is available as a web download. The downloaded extractor contains OMNISEC1133.exe application installer and the SUN and CoC.

Run the installer by double-click on the installer file, OMNISEC1133.exe, to begin the installation.

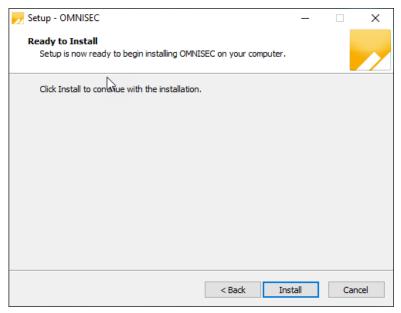




When the license agreement window appears, if you accept the agreement, select I accept the agreement and press next. You can select cancel if you would like to stop the setup and continue another time.

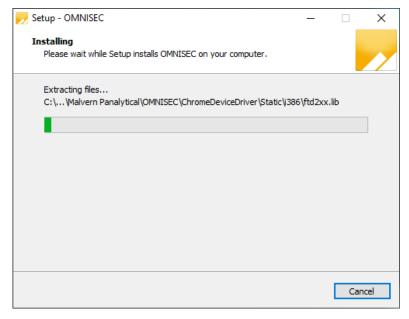


Select the destination location for OMNISEC to install. It is recommended that this remains the default path. Select Next to process.



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 v11 is being installed, it will install a 2019 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 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.



Unrestricted Document



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:

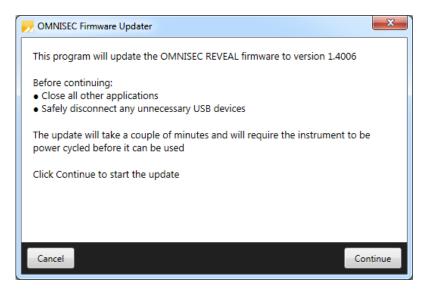


If the OMNISEC Firmware Updater fails to open, or if the updater says it could not detect the instrument, disconnect the instrument, relaunch OMNISEC V11 and reconnect the instrument. You should receive the update prompt to try again.



Note:

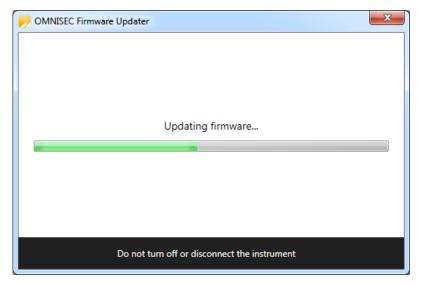
If SEC-MALS 9 or 20 is present, please turn-off and disconnect this detectors communication cable from the PC or REVEAL. Then update the firmware with just the RESOLVE-REVEAL. Once the update process has taken place the SEC-MALS can be reconnected and the settings configured.



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

Click Continue to start the update process.





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.



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 'Apps' section of Windows 10 'Settings' which can be accessed from the start menu.

New Features

No new features are introduced in this release of OMNISEC.

Fixed issues

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

Table 2: Fixed issues in OMNISEC 11.33

Reference	Issue	Comment
148734	Update Auditing component	No comment



149669	Administrator cannot unlock software during audit breach	If this problem has been encountered in earlier versions of OMNISEC, update to v11.33 to resolve.
152811	Start application with missing folders gives wrong error message	No comment
152927	Application blocks if second generation audit trail file missing/corrupt	No comment
153391	Startup integrity breach dialog can hide behind other application windows	No comment
153483	Data integrity breach dialog still active when Windows Security admin credentials dialog displayed	No comment
153848	User credentials dialog not modal when displayed from Options	No comment
153927	Exporting data files as different archive versions does not work	No comment
154153	When signing records, user credentials handle not explicitly disposed	No comment
154281	Invalid Character if user credentials contains @	No comment
154391	Chromatogram and Channel Dispose give exceptions in RFA log files	No comment
154606	Windows printing error caused application crash	No comment
156544	Attempting to process data when 21 CFR enabled can cause crash	No comment

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 3: Known issues in OMNISEC v11.33 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



Injection Volume Tooltip "Default" Validation Shown Instead of Mode-Specific-Validation	76528	Fraction collector triggers on baseline monitor activation	When a baseline monitor is run, turn off the fraction collector.
circumstances Windows 10 Style Fixes Baselines may not appear on the Raw Data chart even though the points are set Software. Copy Graph function produces 'fuzzy' graphs Limit/baseline changes after license expires causes crash No work around Axis numbers extend past chromatogram window when highlighting SQL Server 2014 Express installation fails Cycle the PC power and restart the installation 3028 A failed migration can break audit trails No workaround Deleting a recent sequence does not remove it from the Analyze Data list on the Start Page 3038 Performing a Full Zoom Out after turning off Auto-Scaling in acquisition does not refresh the axes properly 30497 Error when last MALS point deselected in Model/Fit View Deselecting all MALS point in Model/Fit View doesn't work Deselecting all MALS point in Model/Fit View doesn't work Database editor dialogs Migration from V30 to V31 discards vital validation error information No workaround APC-REVEAL calibration shifts viscometer signal when using BSA Minimum pressure alarm triggers during pump prime Set minimum pressure at 0 during prime.	77659		No workaround
Baselines may not appear on the Raw Data chart even though the points are set 87304 Copy Graph function produces 'fuzzy' graphs 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 Axis numbers extend past chromatogram window when highlighting 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 Deleting a recent sequence does not remove it from the Analyze Data list on the Start Page 93281 Performing a Full Zoom Out after turning off Auto-Scaling in acquisition does not refresh the axes properly 93283 Default Method does not work on MALS 9 No workaround Perror 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 Cannot change solvent in run conditions No Workaround User can add unbounded length description in Tools > Database editor dialogs 96589 Migration from V30 to V31 discards vital validation error information No Workaround Use a monodisperse sample for calibration. P8601 Instrument setup browser does not support MPA values No Workaround No Workaround Set minimum pressure at 0 during prime.	80765	·	No workaround
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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 93281 Performing a Full Zoom Out after turning off Auto-Scaling in acquisition does not refresh the axes properly 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 96589 Migration from V30 to V31 discards vital validation error information 97099 APC-REVEAL calibration shifts viscometer signal when using BSA 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.	91107	·	No Workaround
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User can add unbounded length description in Tools > Limit the length of the database item. 96589 Migration from V30 to V31 discards vital validation error information 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 No Workaround No Workaround Set minimum pressure at 0 during prime.	93498	Deselecting all MALS point in Model/Fit View doesn't work	Have at least 1 data point selected
Database editor dialogs Migration from V30 to V31 discards vital validation error information No workaround APC-REVEAL calibration shifts viscometer signal when using BSA Use a monodisperse sample for calibration. Instrument setup browser does not support MPA values No Workaround Minimum pressure alarm triggers during pump prime Set minimum pressure at 0 during prime.	94546	Cannot change solvent in run conditions	No Workaround
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98433 Minimum pressure alarm triggers during pump prime Set minimum pressure at 0 during prime.	97099		·
	98011	Instrument setup browser does not support MPA values	No Workaround
98614 Right-click baseline point counts as baseline change 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
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.
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.
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
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
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
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
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
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
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
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
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
141549	Log file - one or more errors have occurred when opening data	No Workaround
142246	Record View "Save changes" prompt should have Cancel option	No Workaround
142247	Record View should have an "Abandon changes?" prompt	No Workaround
142533	in distribution plot Weight fraction B does not scale well when no fraction B	No Workaround
142574	Limits should show in Raw Data when a different calibration standard is selected	No Workaround
143092	Invalid dn/dc and dA/dc values error causes limits to disappear.	No Workaround



4.42222	Fi And distribution of Conflor	
143233	Fix Analysis tick interval for flat curves	No Workaround
143642	Investigate auditing problems with MALS Model/Fit View changes	No Workaround
144421	Fix zeroes at the start of dn/dc and RI/UV Ratio curves	No Workaround
144654	Cannot delete data	No Workaround
144656	Concentration A/B should use Peak Measured Conc with multiple peaks	No Workaround
145234	Software Crash when trying to copy from Distribution plot	Copy data using the reports widget rather than the Analysis distribution plot.
145317	Reports cut off results if list too long	Create multiple shorter reports.
145373	Investigate MALS vapour sensor not triggering	No Workaround
145694	issue when copy data of distribution plot	Use reports widgets for copying data.
146092	MALS environmental tolerance controls not functioning as expected.	No Workaround
146474	% above below results issues	No Workaround
146475	method details not in the report	No Workaround
146618	Tool tips appear blank in method calculation editor	No Workaround
146648	Viewing different calculation methods can crash the application when using the next buttons in the method creator.	Don't use the next buttons when working with the Mark-Houwink Calibration.
147904	Importing data with sample type B set during processing - values can be lost - Compositional	No Workaround
148866	Overlay Reports causing crash	Overlaying 2 or more samples can infrequently cause issues. If problem occurs restart system.
148975	First RI zero failing in set up process and leaving pump running	No Workaround
149272	Audit trail does not include measurement deletions	Use the MAC to view audit trail and deletion data is reported.
149912	Sequence finished audit event appears in wrong position in audit trail	Note the expected order in the Audit trail.
152439	Extrapolation may fail on good data	No Workaround
153018	Compositional analysis does not work for conventional calibration	No Workaround
153283	Installer problem - Visual C++ 2015 to 2019 redistributable - Exit code 1638	1. Open Add or remove programs. You may find 2 versions of Microsoft Visual C++ 2015 Redistributable installed. One is listed as 22.1 MB and the other 19.8 MB.



		2. Uninstall the 19.8 MB version.
		3.Restart the installation process.
154989	Windows clipboard error caused application crash	No Workaround
155015	MALS set at runtime in instrument methods	If no MALS is present, do not adjust this parameter to prevent the problem occurring.
155758	Instrument Setup Method Editor uses invalid defaults and doesn't save state	No Workaround
156096	Copying from IV Distribution does not copy all data	No Workaround
156542	Instrument Setup Method Editor validation error	No Workaround
156588	Cancelling options does not revert/notify MPA/PSI option	No Workaround
156609	Set at runtime values are not subject to validation.	No Workaround
156650	Application crash on startup if report config file not accessible	No Workaround

Unrestricted	Document
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