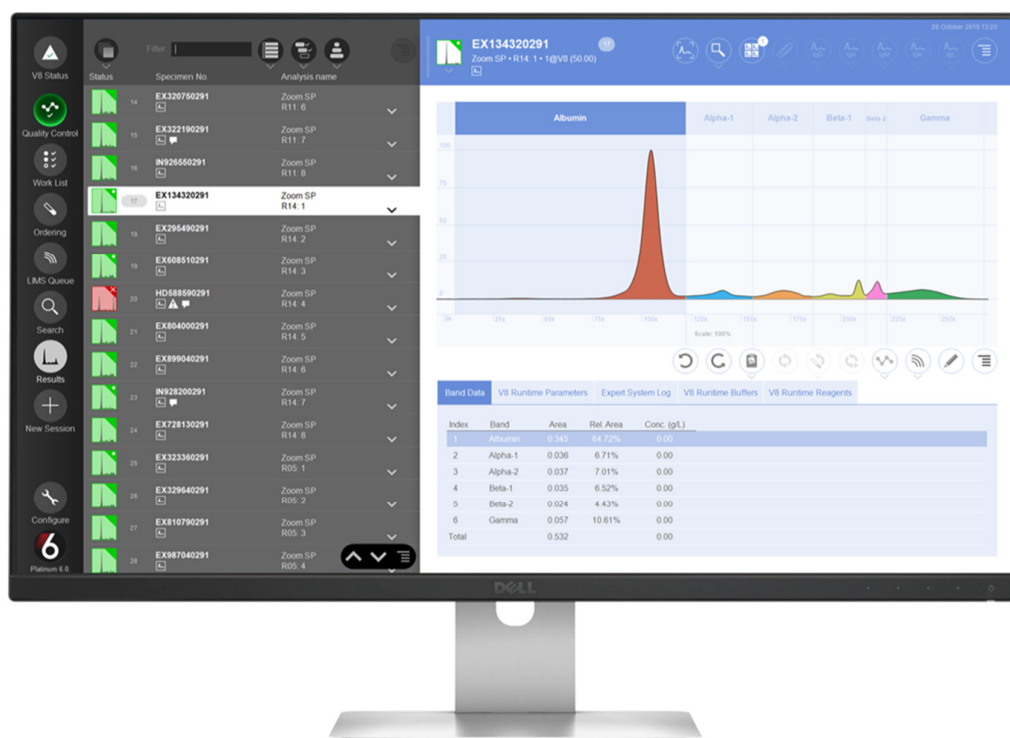


Platinum

Touchscreen Operator Manual

helena
Biosciences Europe



Touchscreen Operator Manual

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Revision History

Amended section:	Date:	Comments:
First Issue	26/01/2017	Initial Publication
Second Issue	22/12/2017	Updated to include new functionality that has been added to the software in recent patch updates. Some icons have also been changed to match updated versions.
Third Issue	03/04/2019	Operator manual updated to include a back page with mandatory manufacturer details (name and address). Document coding has been amended to conform with the new Q-Pulse standard format in preparation of its move into the electronic system. The DOI has been removed and replaced with the revision number only due to its pending move into Q-Pulse also.
Fourth Issue	06/11/2019	Images have been changed to reflect the new appearance of Platinum 6.
Fifth Issue	09/05/2022	Modification in line with the requirements of the In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746, resulting in updates in some sections.



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Acronyms

CCE	Clinical Capillary Electrophoresis
CE	Capillary Electrophoresis
IFE	Immunofixation Electrophoresis
MIU	Method in Use
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
QC	Quality Control
NWL	Navigation Work List
ES	Expert System

Intended Purpose

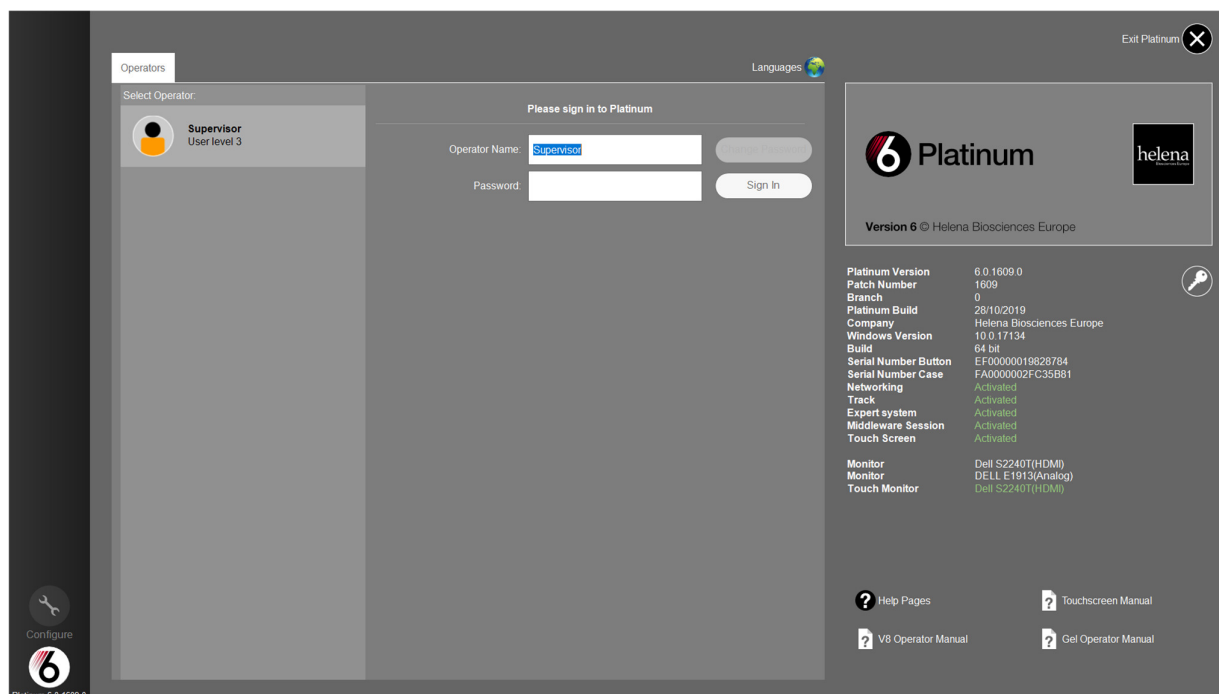
Platinum Software is an analytical software package that is used to display, edit and store the result output of numerous clinical kits. Platinum can be used as a standalone program or it can be connected to a V8 Clinical Capillary Electrophoresis system and/or a laboratory information management system (LIMS). Data imported into Platinum can be displayed, peak morphologies assessed and relative area under the curve calculated and thus, provide an operator with qualitative and quantitative information. Results can be stored with patient demographic information in a searchable database. Intended for use by a trained laboratory professional in a clinical laboratory.

1. Log in to Platinum

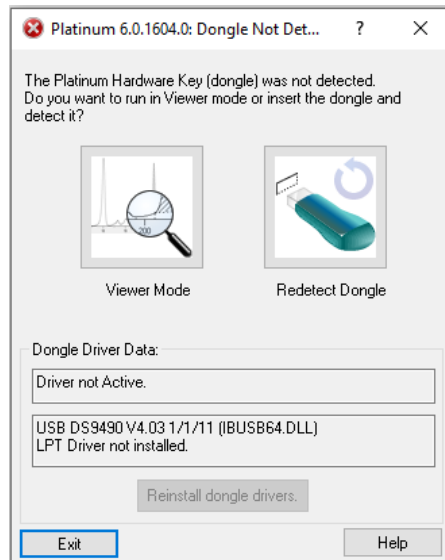
1.1 Initial Log-in Screen

When Platinum is opened, the initial log-in screen will appear. A user name and associated password must be entered in order to proceed using the software.

Please note: Platinum is for use with Windows 10.



On a Platinum system that does not have a Platinum dongle attached, or if there is an issue with dongle detection, the software will display the window “Dongle Not Detected” (see image below). In this circumstance the user can plug in the dongle and select redetect dongle or can reinstall the dongle drivers. If the user does not have a Platinum dongle they can still continue to use the system in “Viewer Mode”. This will allow the user to access archive data to interpret and to report this data but not to acquire new data or start new sessions. When in viewer mode, users must login to the system in the usual manner.



1.1.1 Operator Log

The operator log stores a full history of operator data and decision-making. This function allows all viewing/editing functions carried out by a specific user for a defined time period to be identified.

1.1.2 Additional Operator Log Options


Print – the table can be printed by selecting the Print button.

Export – The data can be saved as a tabbed .txt file by selecting the Export button and entering a file name and location in the appropriate boxes of the Save As window.

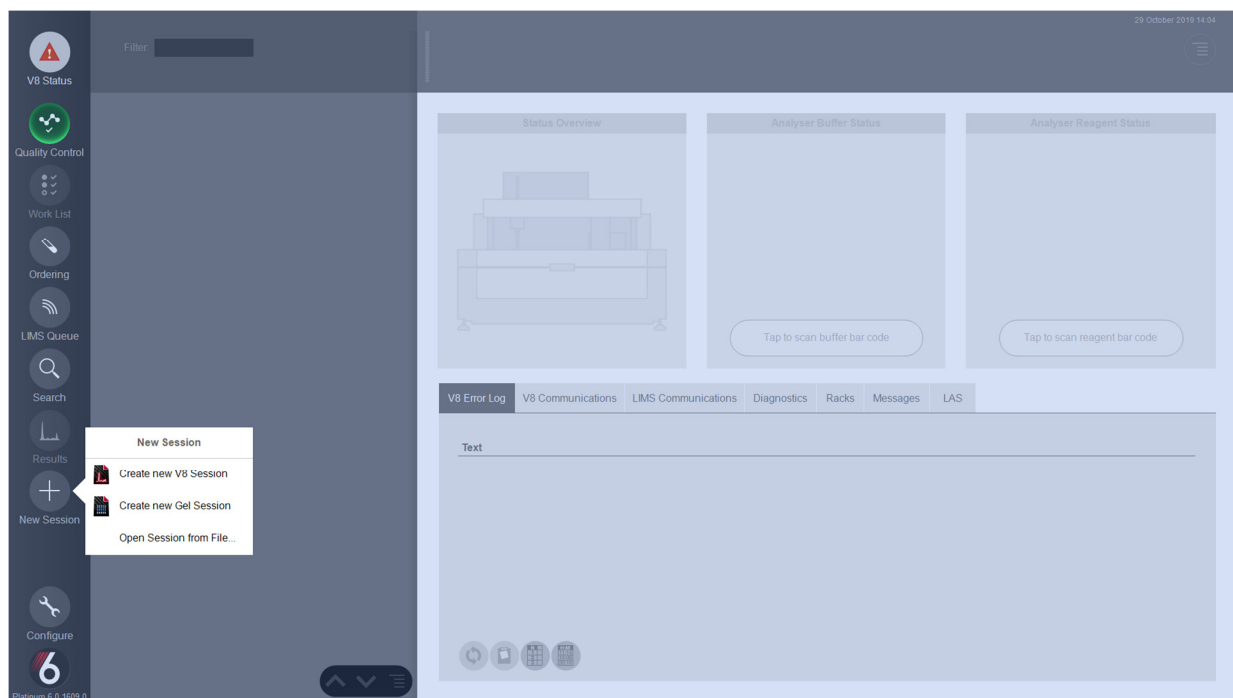
1.1.3 Product Activation

Purchasing Platinum Plus will allow the activation of extra features, including Networking, Track, Expert System and Touchscreen. Select the Product Activation icon and enter the Activation Code to enable the purchased features.

2. V8 Status Window

Once logged in, Platinum will switch to the V8 Status window, and icons will appear on the left hand side of the screen. From here, select the  icon from which you are given options that will determine the main action of the session:

- Create new V8 Session
- Create new Gel Session
- Open Session from File



The V8 Status icon will change according to its current connection status with the V8:



Not connected



V8 requires attention



Successfully connected



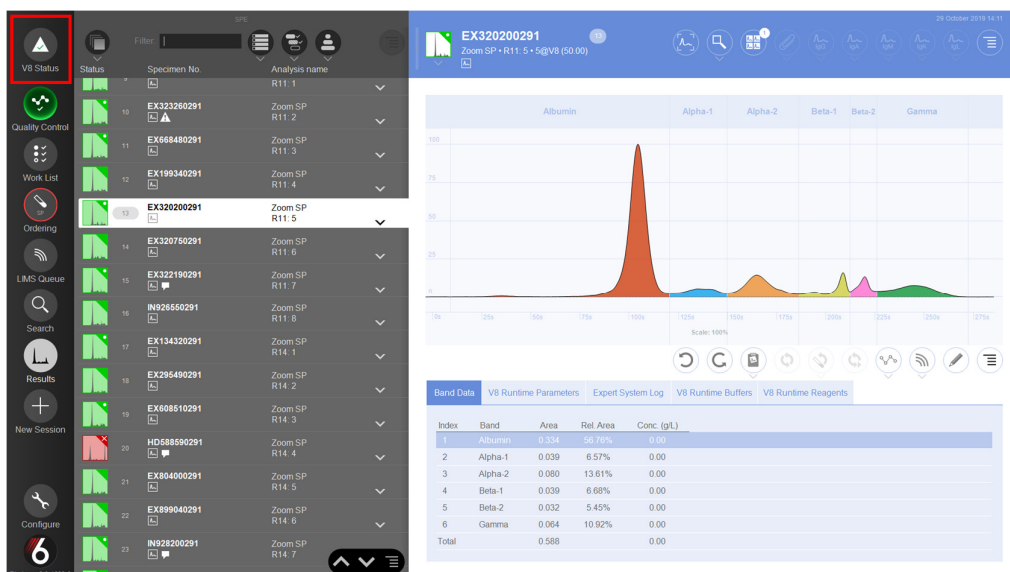
Preconditioning




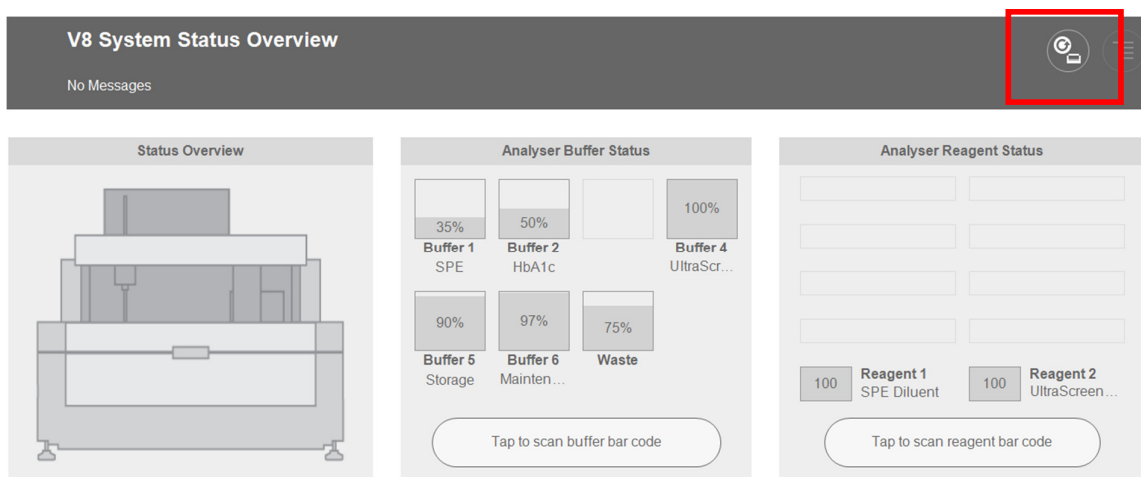
Postconditioning

When the V8 Status window initially appears, there will be no communication with the V8 until a new session has been started. This is indicated by the red V8 Status icon and no buffer or reagent information.

Once a connection is successful, the icon will turn green and buffer and reagent information will become available.



Following a breakdown in communication between Platinum and the V8 instrument, this function resets the communication loop with the last connected V8 System. To reset the communication, go to the V8 Status window and select the  icon in the top right hand corner:



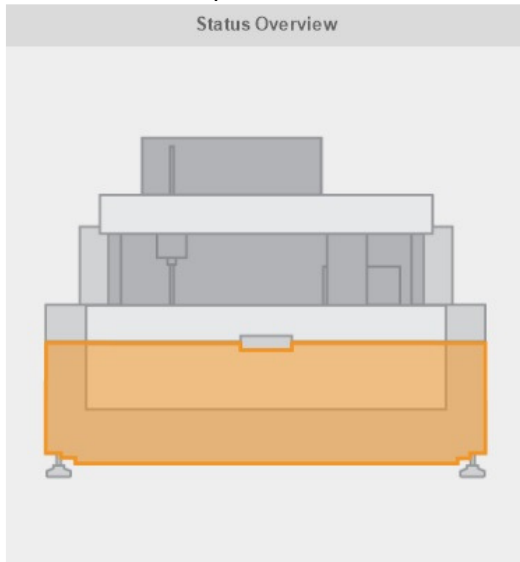
2.1 V8 System Warnings and Status

The V8 Status window continually informs the user of the instrument status, or action, and of any warning or error messages. All information regarding the status of the instrument can be found here.

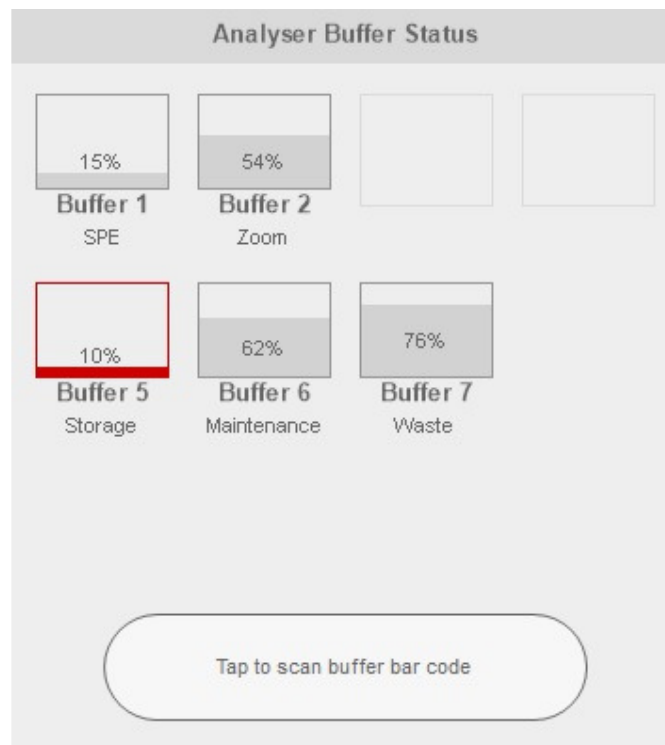
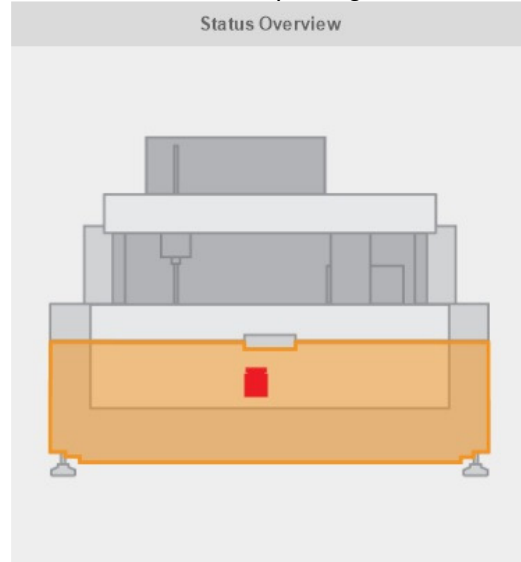
Any V8 System status that requires the user's attention will appear in the Status Overview in orange. Any status that requires immediate attention will appear in red. When a buffer drops below 10% liquid remaining, or when a reagent has no more tests remaining, they will appear red in their respective Status windows.

Front cover open and waste

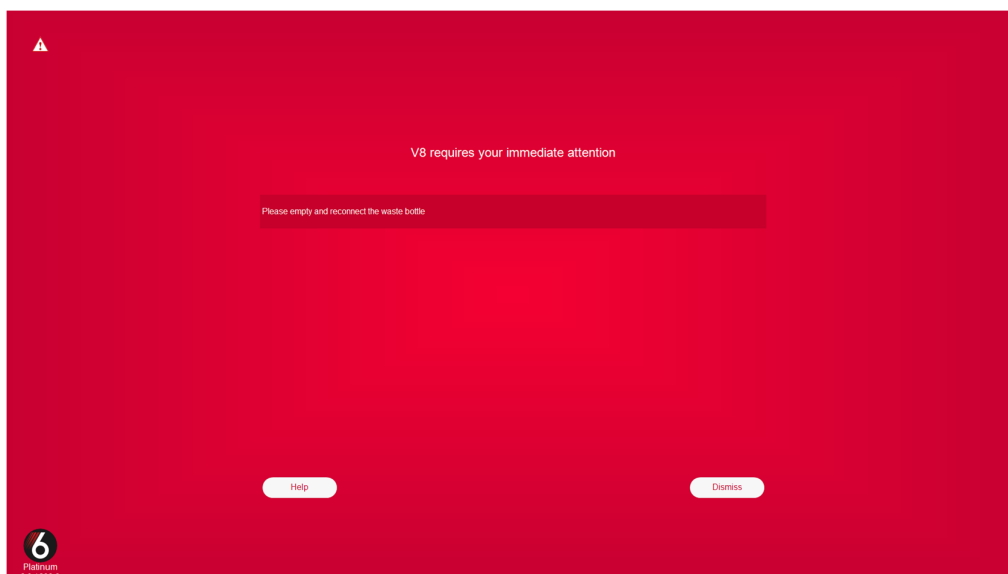
Front cover open:



bottle needs replacing:



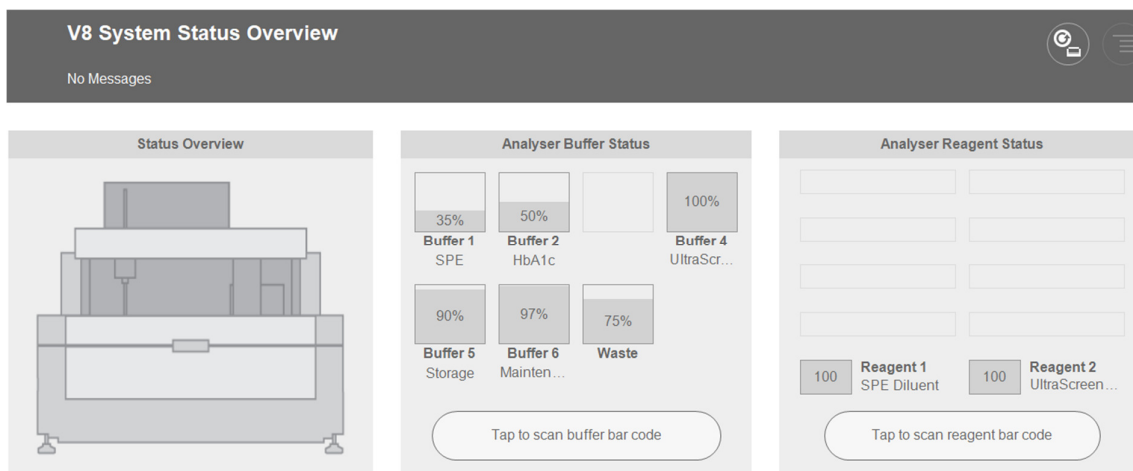
If an item requires immediate attention from the user before the V8 can continue, a larger warning message will appear on the screen. This will clearly state the issue encountered and what needs to be done to resolve the issue.



Once the operator has resolved the identified issue, the warning indication will disappear from the screen.

If the user is busy and wants to temporarily hide the window, the 'Dismiss' option can be selected and the window will disappear, however, there will still be an area of the V8 highlighted in the Status Overview until the issue has been resolved.

2.2 Defining Reagents and Buffers

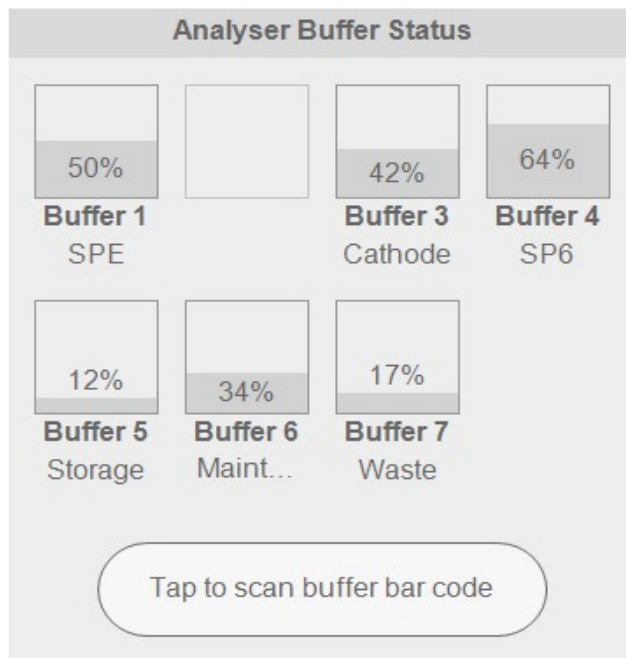


All reagents and buffers used on the V8 are individually barcoded. Using the Analyser Buffer Status and Analyser Reagent Status function allows the user to view what is in use, and the position of the buffers and reagents. It also permits the user to change buffer bottles or reagents via a prompt from the V8 or upon change of assay.

2.3 Checking Buffer Levels

It is possible to check the levels of remaining buffer onboard to ensure sufficient buffer is installed for complete analysis.

To check the buffer fluid levels go to the V8 Status window. Select the V8 Status icon again to update the values.



2.4 Loading Reagents

2.4.1 Installing Reagents using the Reagent window

To install reagents:

- Go to **V8 Status > Analyser Reagent Status > Tap to scan reagent bar code**.
- Scan or enter barcode information on the side of the reagent bottle, ensuring that the positions in Platinum correspond with those on-board the V8.
- Multiple reagents can be entered at once.
- Once entered, add the reagent to the reagent bay.

Analyser Reagent Status

50

Reagent 1
 SPE Diluent

100

Reagent 2
 UltraScreen...

Tap to scan reagent bar code

Status Overview

Analyser Buffer Status

V8 Reagents
?
×

	Reagent 1	Reagent 2	Reagent 3	Reagent 4	Reagent 5
Barcode :	0VCB69FTNC	410134LGD0	0000000000	0000000000	0000000000
Product reference :	SPE Diluent	UltraScreen Dilue			
Expiry :	1019	0421			
Lot :	20	16			
Batch index :	123	1			
Tests Left :	66	100			
Max tests :	167	100			
Cap Opened on :	28/10/2019	15/10/2019			
Open Stability (days left) :	24	12			

	Reagent 6	Reagent 7	Reagent 8	Reagent 9	Reagent 10
Barcode :	0000000000	0000000000	0000000000	0000000000	0000000000
Product reference :					
Expiry :					
Lot :					
Batch index :					
Tests Left :					
Max tests :					
Cap Opened on :					
Open Stability (days left) :					

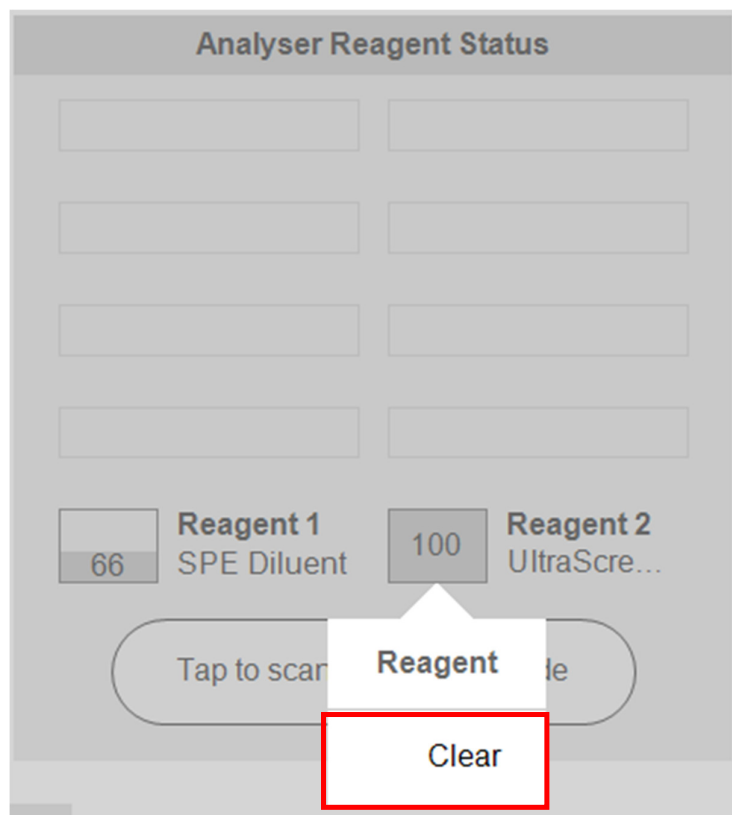
OK

Cancel


Help

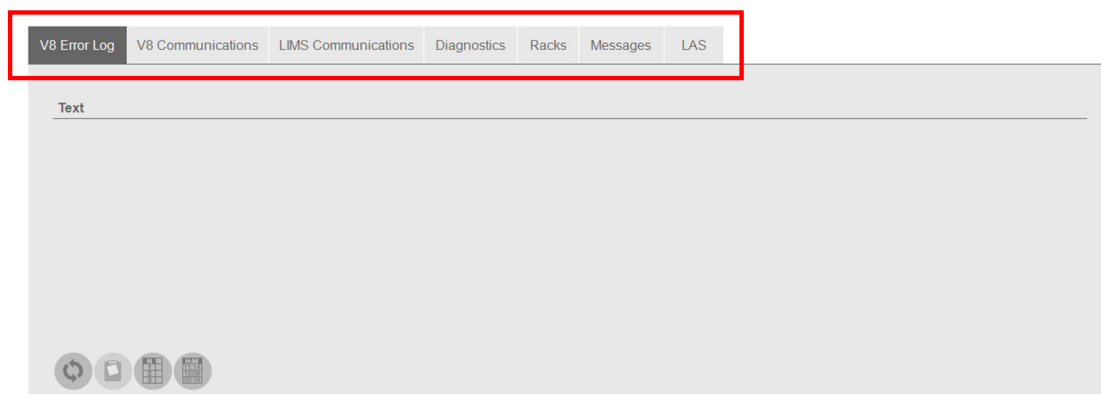
2.4.2 Clearing a reagent from the Reagent window

To clear a reagent from the Reagent window, tap on the square (displaying the number of tests remaining) next to the reagent to be removed. When the menu appears, tap 'Clear'.



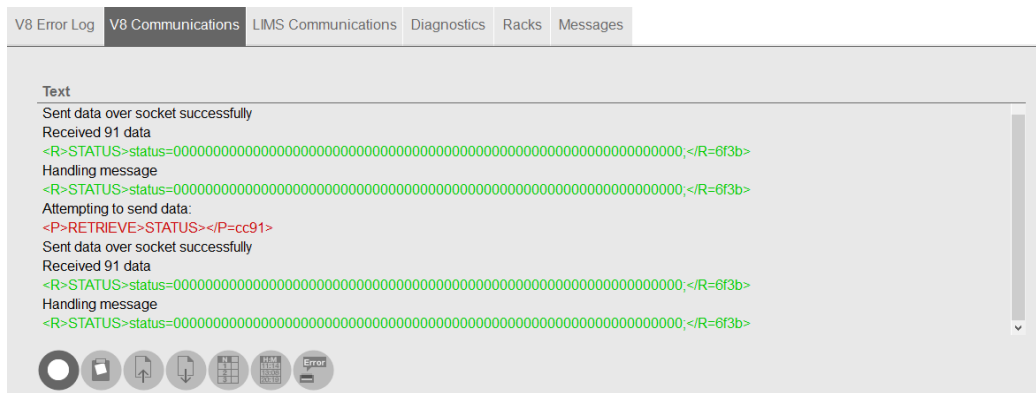
2.5 V8 Error Log

The error log will display all errors detected by the V8. Select the "Update" icon  to view the log, or to update it after it has already been viewed. The user can copy and save the error log outside of the Platinum software for easier viewing or to send to technical support.




2.6 V8 Communications

The V8 Communications log enables the user to view communications between the V8 and Platinum. Press the “Record” button to start logging these messages. The log can then be, copied, saved, or an old log opened and viewed.



2.7 LIMS Communications

This tab will only show communications between the Platinum and LIMS software.

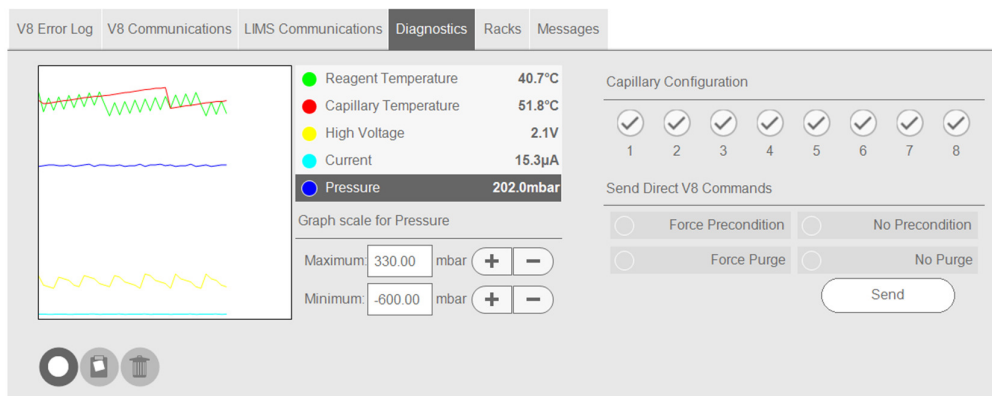
Select the “Record” icon  to start logging these messages. The user can copied and saved outside of the Platinum software.

2.8 Diagnostics

V8 System Diagnostics show the user the capillary temperature, reagent block temperature, pressure, voltage and current. It also enables the user to control the capillary configurations and direct commands to the V8 on start up.

Here the user can also record graphs of the run time parameters to track the systems performance.

To update these values, select the V8 Status window icon.



2.9 Managing Capillaries

In the event that a capillary is damaged or deemed unusable, the sample handling for that capillary can be disabled and the capillary isolated from use. The order of work will adjust so that samples will be automatically processed between several V8 runs with no further instruction required from the user. The results will be displayed showing only the available capillaries.

- Go to **V8 Status > Diagnostics > Capillary Configuration**
- Capillaries are displayed and numbered from 1-8, corresponding with positions left to right on the instrument. To isolate a capillary and switch it off, un-tick the checkbox above the capillary of interest.
- To switch the capillary on, ensure the checkbox is ticked.

2.10 Racks

This will display all racks that contain any non-barcoded or misread tubes.

2.10.1 Sample Tube Barcodes

Tubes can be loaded on to the V8 with or without individual bar codes. However, this does affect the manner in which Platinum processes samples and reflex tests.

- If barcodes are present the V8 will process each sample individually.
- If barcodes are not present the V8 will process each sample individually and recognise each one only by rack number and position. As such, racks **MUST NOT** be removed from the system or Platinum if reflex testing is needed.

The V8 will enter the barcode into the navigation work list under the first demographic usually marked as LIS identifier. If the V8 has not been able to read the barcode on the sample tube, or there is not a sample tube in every position of a sample rack this field will be left blank.

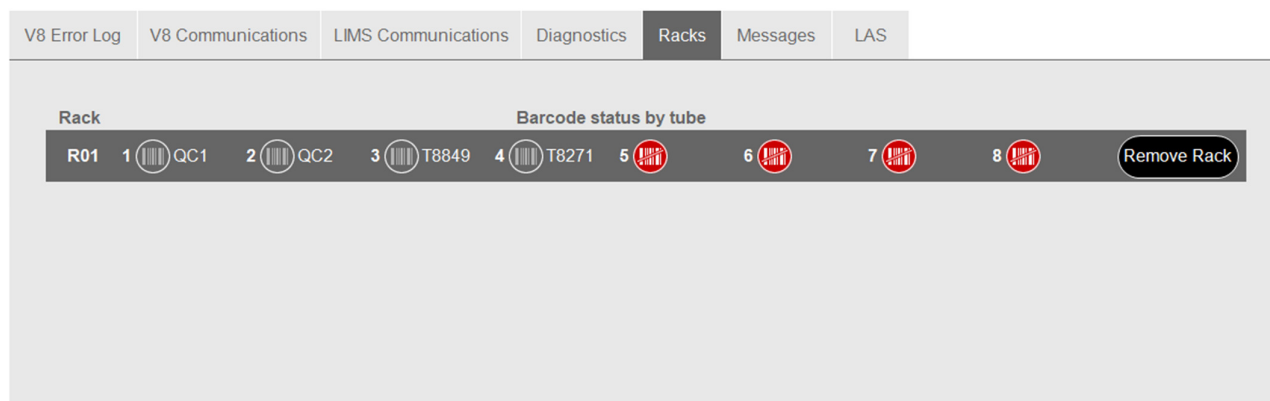
To avoid disruption of the workflow, the V8 will process all the samples, performing the default assay for all tubes, unless another test is ordered. When an unknown tube (missing or misread barcode) is detected, the tube will appear in the missing bar code work list.



Missing barcode



Barcode present

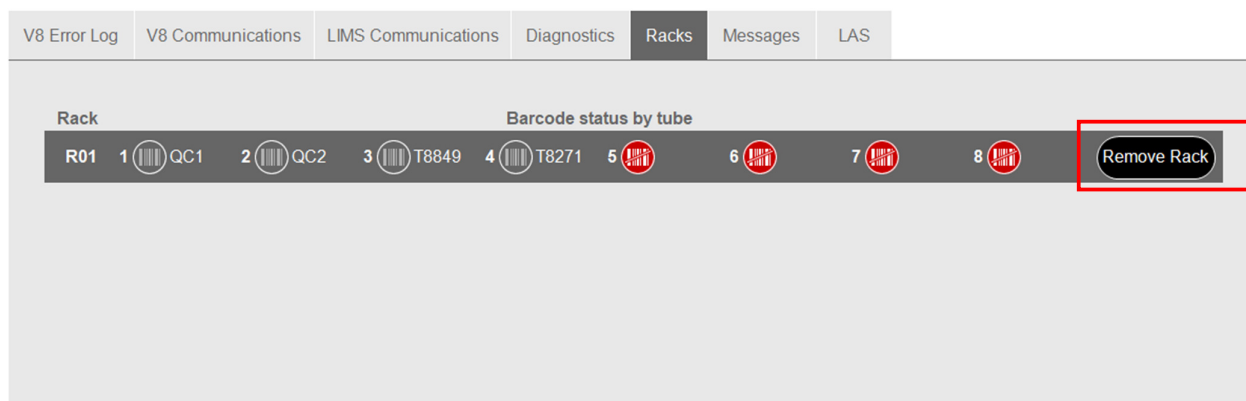


2.10.2 To Remove a “Sample Missing Barcode” flag from Platinum

Sample tubes with missing barcodes or misread barcodes will be listed in the ‘No Barcode Worklist’ list. Before this rack can be used again on the V8, this list must be manually emptied by the user. The purpose of this list is to ensure the same rack is not incorrectly run again.

N.B. Removing a rack from the system also removes the sample tubes contained within it. As such automated reflex testing cannot be performed.

To remove the rack, select the ‘Remove Rack’ button.



2.11 Messages

This tab continually informs the user of the instrument status and actions.

2.12 LAS

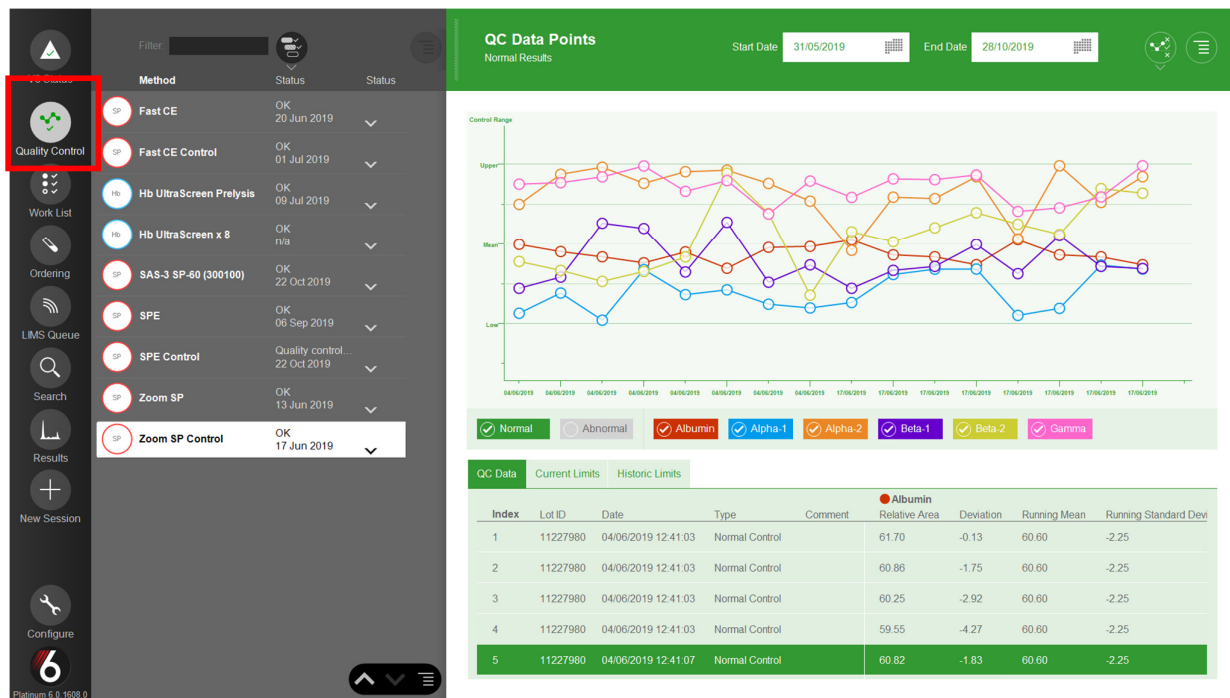
This tab will only show communications between Platinum and Inpeco for customers with a track system.

3. Quality Control Window

3.1 Key Features

- Monitor controls using the Levey Jennings plot
- Analyse data using Westgard rules
- Real time QC status of the analyser displayed
- Audit traceable comments against QC samples

3.2 Quality Control Menu Navigation



3.3 Toolbar Buttons



Quality Control Window



Mark as sample



Mark as normal control



Mark as abnormal control



Calibrator

3.4 QC Status Icons



Passed QC and within date



QC out of date



QC failure

3.5 Input lot IDs

1. Lot ID page located in **Configure > Methods**
2. Select the appropriate method from the methods list
3. Click on the **Lot ID** tab
4. Use the assay sheet provided with the control material to fill in the appropriate ranges below, including lot ID and expiry date. Values will automatically be entered as a percentage but users can select between % and g/L units using the toggle switch in the Lot ID tab

Configure Standard Methods	Method type	Chemistry Value	Geometry	Lanes	Bands	Smoothing/Filtering	Gain Settings	Lot IDs	Barcode	Controls	Carbamylated Albumin	Calibration	Regions/Zones
Barcode entry: <input type="text"/>													
Normal lot ID: <input type="text" value="11547513"/>		Expiry Date (MM/YYYY): <input type="text" value="12/2021"/>											
Abnormal lot ID: <input type="text" value="11521146"/>		Expiry Date (MM/YYYY): <input type="text" value="7/2021"/>											
<div> <input type="button" value="Band statistics"/> <input type="button" value="Unit"/> </div>													
Band	Component	Low normal	Upper normal	Low abnormal	Upper abnormal	Mean normal	SD normal	Mean abnormal	SD abnormal				
1	Albumin	54.36%	73.55%	48.20%	65.21%	63.95	0.87	56.70	0.41				
2	A1AG	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	0.00				
3	Alpha-1	3.92%	5.30%	4.05%	5.89%	4.61	0.28	4.97	0.46				
4	Alpha-2	7.01%	9.49%	6.81%	9.22%	8.25	0.48	8.02	0.56				
5	HPX	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	0.00				
6	Beta-1	6.06%	8.20%	5.32%	7.20%	7.13	0.52	6.26	0.37				
7	Beta-2	3.06%	4.15%	3.05%	4.12%	3.61	0.18	3.58	0.09				
8	Gamma	10.58%	14.32%	17.39%	23.53%	12.45	7.94	20.46	0.30				

3.6 QC Settings

Optional QC settings are defined in the Quality Control preferences located in **Configure > Quality Control**.

Tick the 'Display Levey-Jennings Status' function and select the 'Active control method' to activate real time tracking of the QC status. The Quality Control icon on the left hand side of the screen will change according to the QC status of the method highlighted in the active control method box. The countdown timer will indicate how long this result is valid.

Activating the 'Display Levey-Jennings Warning' feature will prompt a warning box if the user runs the machine when the QC is timed out or out of range.

Activation of the 'Force QC failure comment' will initiate a popup comments box when you open the Quality Control window if any of your QC results are out of range. This comment is audit traceable and can be used to document corrective action and/or justification for accreditation purposes.

Selecting this option will make it a requirement that a comment is entered before you can close the QC failure comments box. A default comment can be set up and applied.

You can activate Westgard rules by highlighting them in the 'Rules selection Defaults' box.

☒ Display Levey-Jennings Status
Active control method :
SPE

☒ Display Levey-Jennings Warning

☐ Force QC failure comment
☐ Use default comment
QC Failure :

Count down timer
☒ Use Countdown Timer.
12 Hours
Time Left:
has expired Hours

V8 Auto Control Barcodes
Configure

Rules selection Defaults
Result exceeds 3 SD
2 results exceed 2 SD on same side
2 results exceed 2 SD on different sides
3 results exceed 1 SD on same side
4 results exceed 1 SD on same side
9 results lie on same side of Mean
10 results lie on same side of Mean

Cancel Help

3.6.1 V8 Automatic QC Test Ordering

Automatic QC Test Ordering can be activated by selecting Configure and ticking 'Enable Automated V8 Control Barcode'. This will automatically order a control method and set the Normal/Abnormal control or Calibrator status in the worklist when a rack containing that barcode is scanned on the V8. Users can configure up to 8 automated barcodes through the Quality Control menu. Also included is an alert function to warn the user if Lot IDs haven't been entered for the control method being ordered.

The screenshot shows a dialog box titled "V8 Auto Control Barcode Setup". It has a checkbox "Enable Automated V8 Control Barcode" which is checked. Below this, there is a table with three columns: "Barcode From V8:", "is marked as:", and "runs with the method:". The table contains eight rows of configuration. The first seven rows are for barcodes QC1 through QC4, CAL1, CAL2, and CAL3. The eighth row is for an empty barcode field. The "is marked as:" column has dropdown menus with values: Normal Control, Abnormal Control, Calibrator Level 1, Calibrator Level 2, Calibrator Level 3, and None. The "runs with the method:" column has dropdown menus with values: SPE Control, HbA1c Control Sample, and HbA1c Calibration Sample. At the bottom, there is a checkbox "Show warning for missing Lot ID" which is checked. There are three buttons at the bottom: "OK", "Help", and "Cancel".

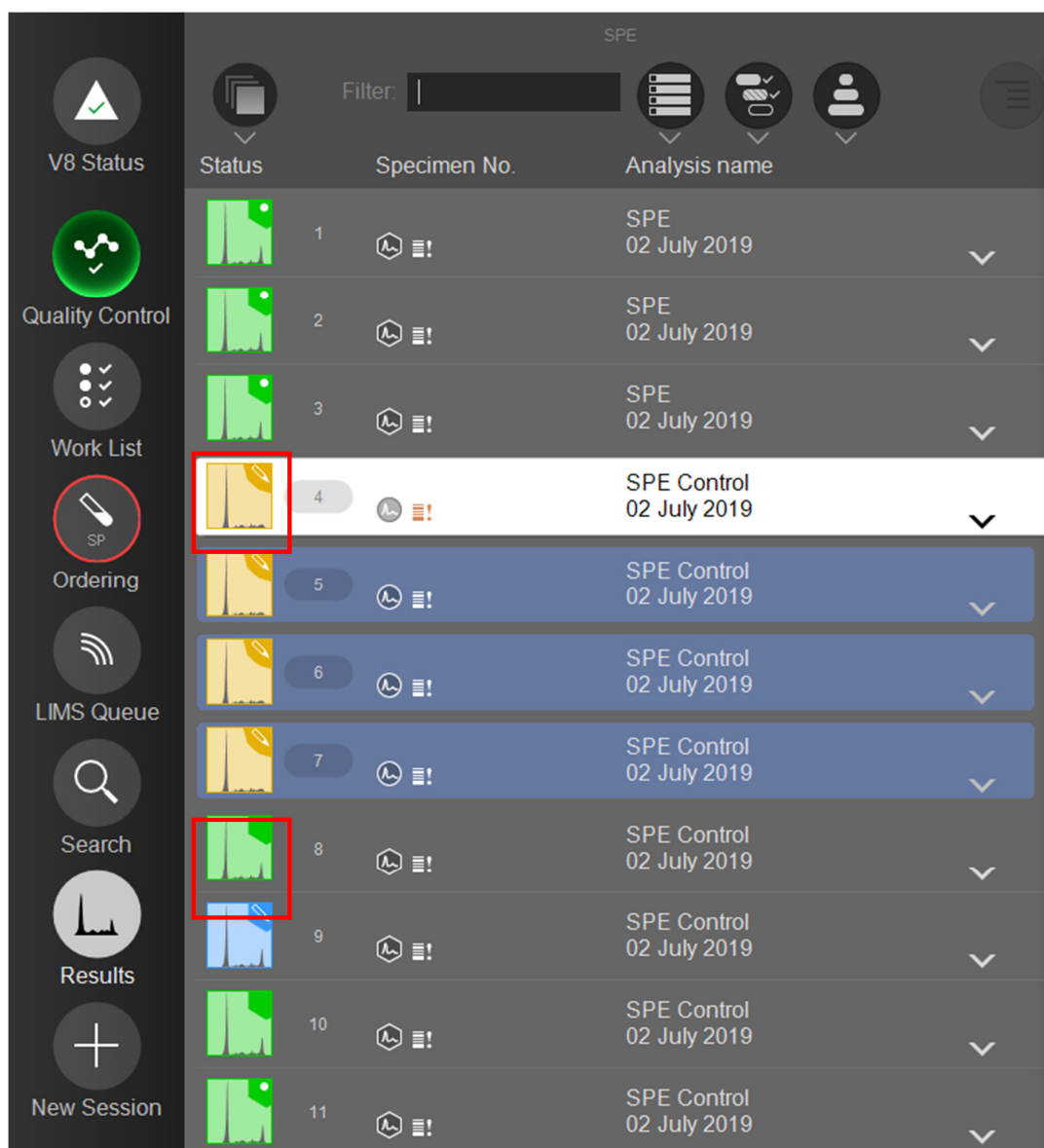
Barcode From V8:	is marked as:	runs with the method:
QC1	Normal Control	SPE Control
QC2	Abnormal Control	SPE Control
QC3	Normal Control	HbA1c Control Sample
QC4	Abnormal Control	HbA1c Control Sample
CAL1	Calibrator Level 1	HbA1c Calibration Sample
CAL2	Calibrator Level 2	HbA1c Calibration Sample
CAL3	Calibrator Level 3	HbA1c Calibration Sample
	None	None

☒ Show warning for missing Lot ID

OK Help Cancel

3.7 How to Populate the Levey-Jennings Chart

1. Run the QC using the appropriate control method ensuring the control lot information is populated
 - Multiple control types can be used by populating the Levey-Jennings chart using data derived from different base methods, i.e. all controls tested using the SPE control method will be populated into a separate chart to controls ran using the SPE method.
2. Interpret trace ensuring all bands are gated correctly
3. Mark as either a normal or abnormal control using the QC icon to populate results into the chart
4. This will result in the trace icon being displayed either normal control or abnormal control in the navigation work list




The top red square shows a control marked as normal (a quarter circle in the top right hand corner of the trace icon), and the bottom red square shows a control marked as abnormal (a pentagon in the top right hand corner of the trace icon). For further information on trace icon colour coding and markings see section 8.2.

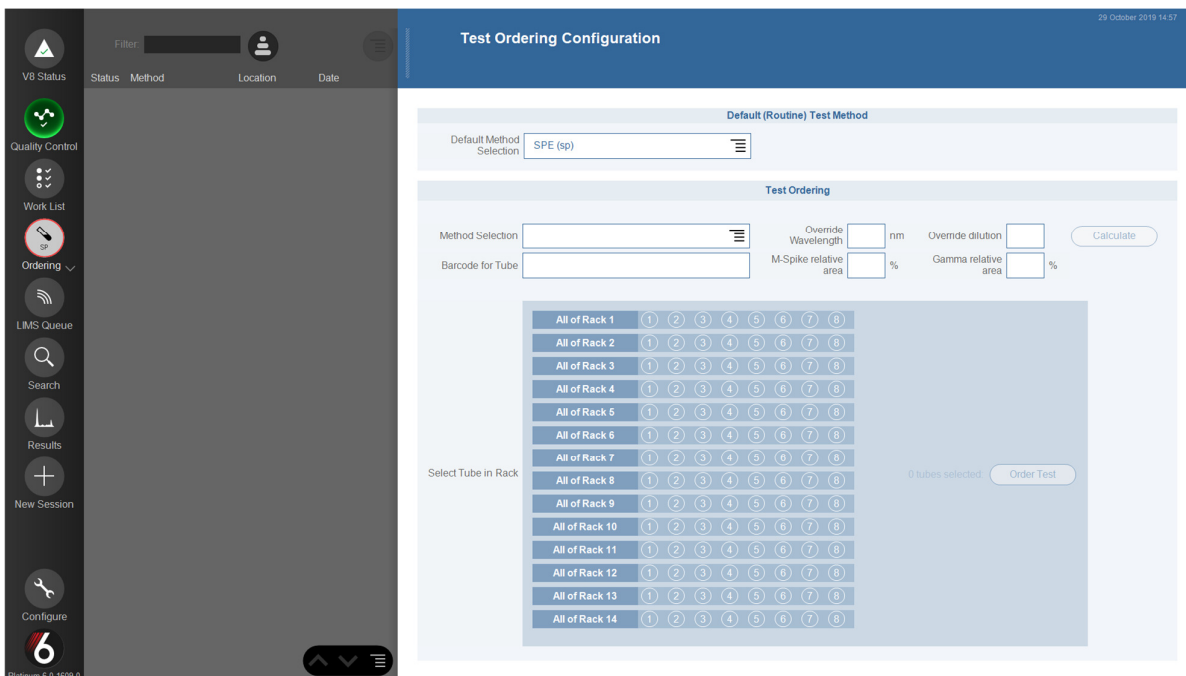
3.8 Levey-Jennings Chart Features

1. QC method selection, Lot ID and data can all be viewed alongside the QC chart
2. Changing control lot will insert a blue vertical line into the chart
3. Any result outside of the defined parameter will bring up a comments box
4. Selecting a result on the graph will jump to the data point's values in the results box and highlight them green.

Any data that is entered here should appear in the trace demographics in the results window. Please note there is a character limit of 38 for the demographics fields.

This window can also be used to create a gel worklist by using the  icon to add new samples.

5. Ordering Window

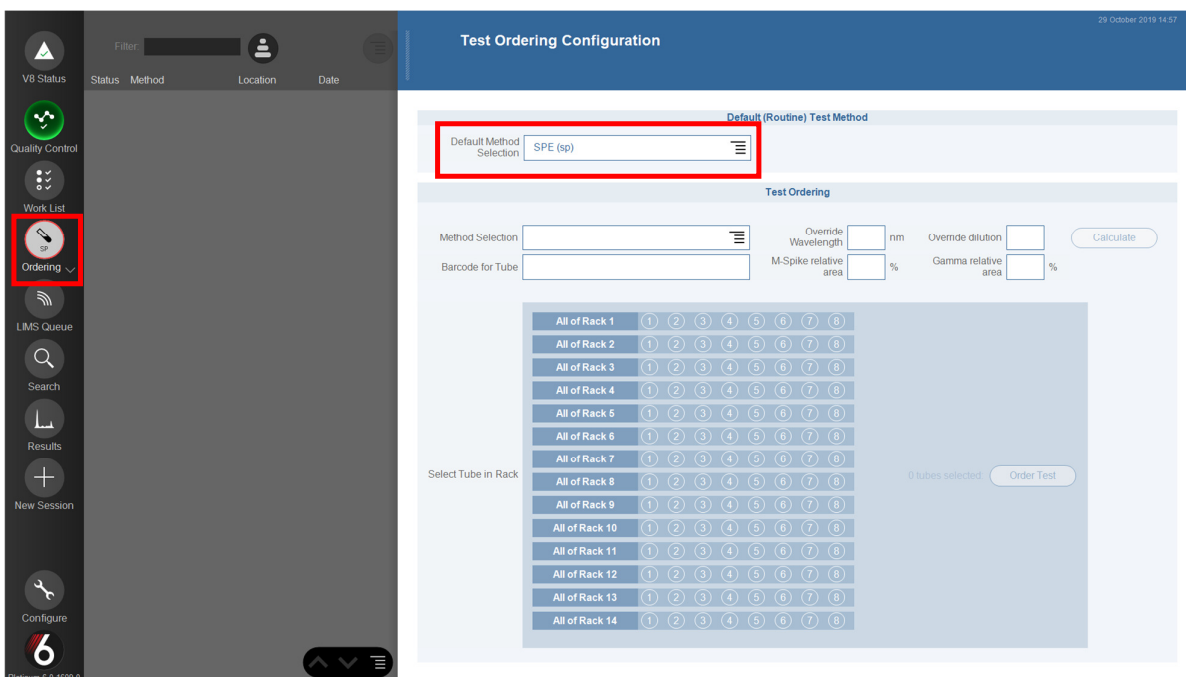


The screenshot shows the 'Test Ordering Configuration' window. On the left is a sidebar with icons for VB Status, Quality Control, Work List, Ordering (selected), LIMS Queue, Search, Results, New Session, and Configure. The main window has a top bar with 'Filter', 'Status', 'Method', 'Location', and 'Date'. Below this, the 'Default (Routine) Test Method' section shows 'SPE (sp)' selected. The 'Test Ordering' section includes fields for 'Method Selection', 'Barcode for Tube', 'Override Wavelength' (nm), 'Override dilution', 'M-Spike relative area' (%), and 'Gamma relative area' (%). A 'Calculate' button is present. Below these fields is a grid of 14 racks, each with 8 tubes (labeled 1-8). The text 'Select Tube in Rack' is on the left of the grid. At the bottom right of the grid, it says '0 tubes selected' and 'Order Test'.

5.1 Selecting the Default Method

The default method can be set in the following ways:

- Long pressing on the ordering icon to bring up the “Select Method” window.
- Selecting it from the drop down menu in the ordering window.



5.2 Test Ordering

Test ordering refers to the assignment of an assay to a sample. A test can be ordered when assays other than the default assay are required.

To order a test:

- Go to the Ordering window
- Select the method you require by clicking on the “Method Selection” dropdown box
- Enter the barcode of the sample being ordered (if applicable)
- Input any Override Wavelength or Override Dilution if they are not the same as the default.
- Select the tube position and/or barcode for which the tests will be run (the same method can be ordered for multiple samples/racks at the same time)
- Select ‘Order Test’
- The tests should appear on the left hand side of the screen in the ordered tests list
- Load the sample(s) in the sample rack, ensuring the sample rack and ID correspond with those set in Platinum.
- Place the sample rack(s) into the sample rack transport area and close the rack cover
- The V8 will automatically process the ordered assay
- Once complete, the sample will no longer appear in the Ordering window

5.2.1 How to Cancel an Ordered Test

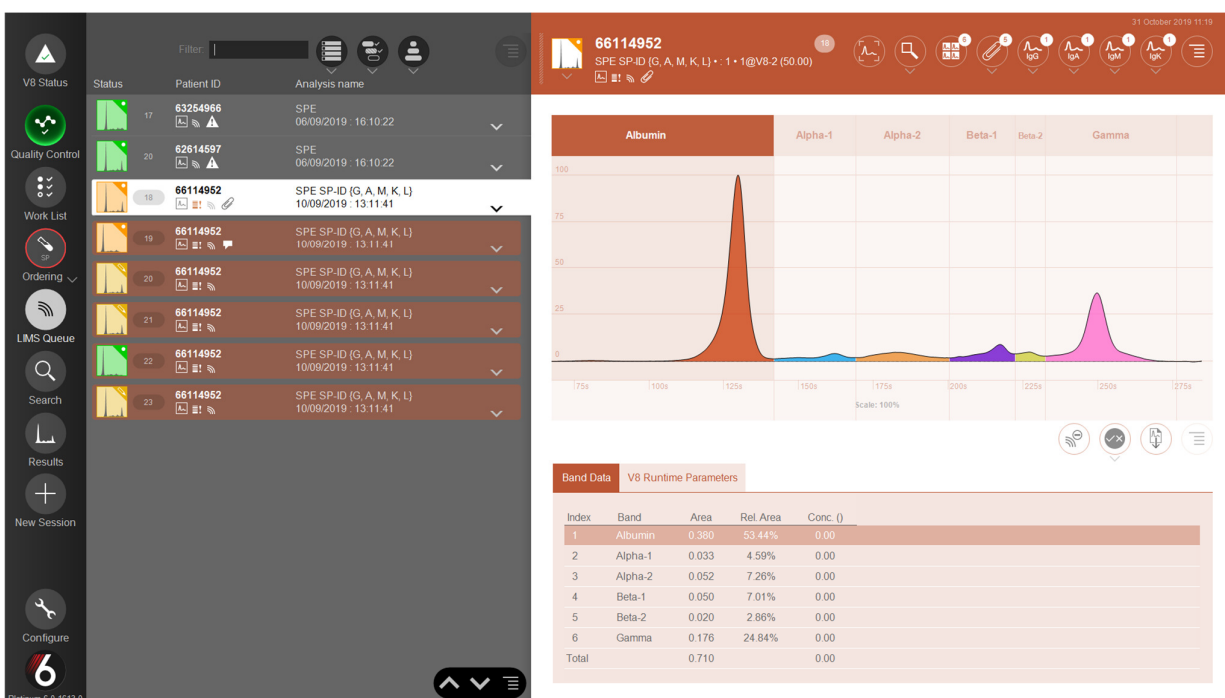
Tests that have been ordered or are awaiting Reflex testing will remain on the system as outstanding, regardless of whether the samples have been taken off-board the V8. If samples are removed from the V8 then placed back on-board, then the ordered tests will be performed unless cancelled from the system. If a tube with a missing/misread

barcode has an outstanding test, then this test will be removed automatically from the system when the rack is removed from the 'No Barcode Worklist'.

- Open the Ordering window
- Select the ordered test which you wish to remove
- Select the "Remove ordered test" icon at the bottom of the screen



6. LIMS Queue





6.1 Controlling Data to the LIMS/LIS


There are two ways to send data to the LIMS/LIS. It can either be to the LIMS queue, where the data can be validated before sending to the LIMS/LIS, or it can be sent directly without validation to the LIMS/LIS.

6.2 Sending Data to the LIMS Queue

Samples are sent to the Laboratory Information Management System (LIMS/LIS) holding queue so that once a user of a suitable seniority has validated the data as acceptable it can be sent to the LIMS database.



To send an individual lane or several lanes to the LIMS queue, select the sample which you would like to send from the Results window and then select the LIMS icon and then Add to LIMS Queue .


To send the whole session or gel scan to LIMS, select the  icon and Select All, then Select the Add to LIMS queue option .


Those samples sent to the LIMS queue will be marked with a work list icon .


6.3 Viewing and Releasing Data in the LIMS Queue



To view those samples in the LIMS queue, go to the LIMS Queue window.


To approve an individual sample to be released from the LIMS queue, select the Send Selected to LIMS icon . A blue tick will appear next to the LIMS icon .

To approve multiple selected samples to be released from the LIMS queue, highlight the samples you wish to approve by touching the small trace icon in the NWL and then select Set Approval for Sending to LIMS . Blue ticks should appear next to the LIMS icon for all selected samples.

To prevent a previous approved individual sample from being released from the LIMS queue, highlight the sample and select “Clear Approval for Sending to LIMS” . The blue tick should then be removed from the NWL. To do this for multiple samples, highlight all the samples you wish to remove the approval from by touching the small trace icon in the NWL before selecting “Clear Approval for Sending to LIMS”.

To remove an individual sample from the LIMS queue, select the “Remove from LIMS queue” icon . To remove multiple samples, highlight all of the samples you wish to remove by touching the small trace icon in the MWL before selecting “Remove from the LIMS queue”.




Once the appropriate samples have been authorised to be sent to the LIMS database, select either “Send All to LIMS” , “Send Selected to LIMS”  or “Send Selected

Approved to LIMS”  depending on the requirement to send the results to the LIMS database.

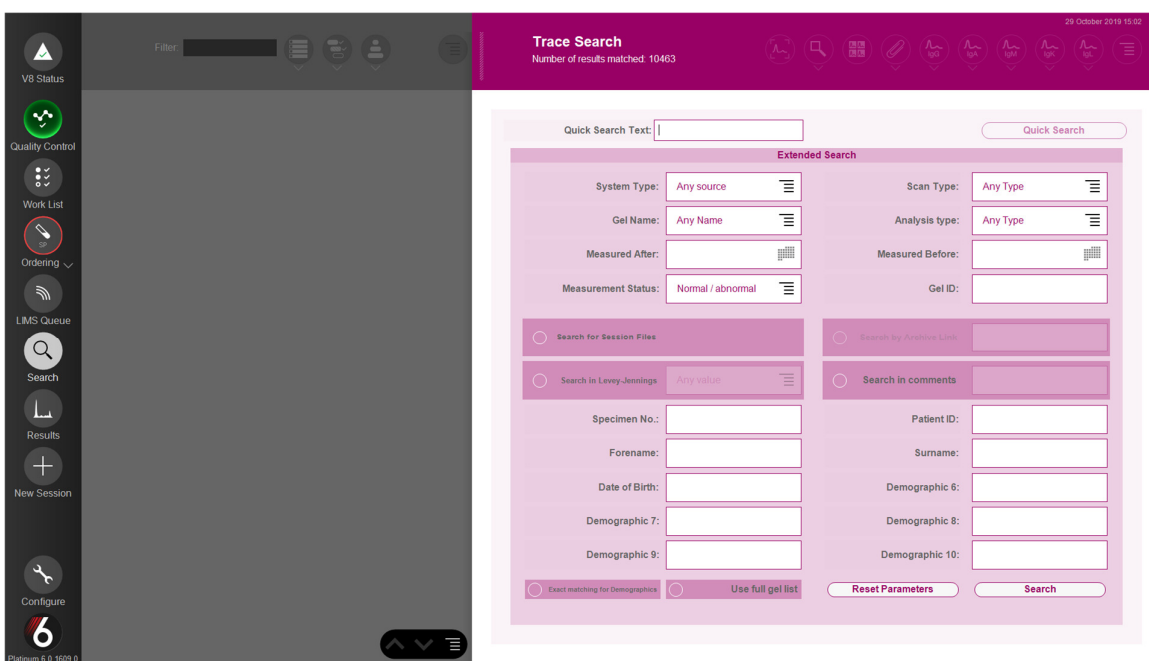
To display the progress of the LIMS transfer, go to **Configure > Customise > Sending to LIMS** and make sure the “Display inspector window” option is ticked.

6.4 Sending Sample Data Directly to LIMS

Sample can be sent directly to LIMS/LIS bypassing the use of the queuing system.

To send the whole session to LIMS, go to the Select icon  and “Select All”. Then go to the LIMS icon  and select Send to LIMS .

7. Search Window



7.1. Searching for Data

To locate previous sample results, whole gels or V8 sessions in the database, the Search window can be used. The search window will automatically search for individual samples, unless one of the following is selected:

- Search for Session Files

- Search in Levey-Jennings
- Search by Archive Link
- Search in Comments

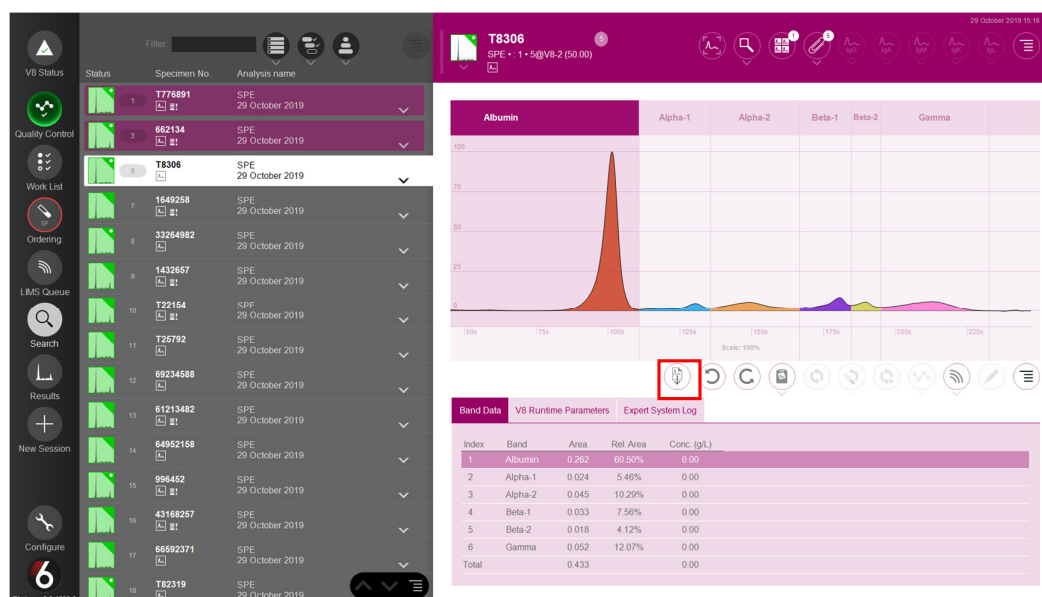
When searching for individual sample results, any of the 10 demographic fields can be used to identify the sample and filter the results.

Additionally, 7 generic filters are available:

- System Type
- Scan Type
- Gel Name
- Analysis Type
- Measurement Time
- Gel ID
- Measurement Status


When searching for a session, only the above 7 generic filters are available. By inputting any required demographic filters i.e. patient ID and clicking the Search button, a list of the search results will appear.


7.2 Search Results



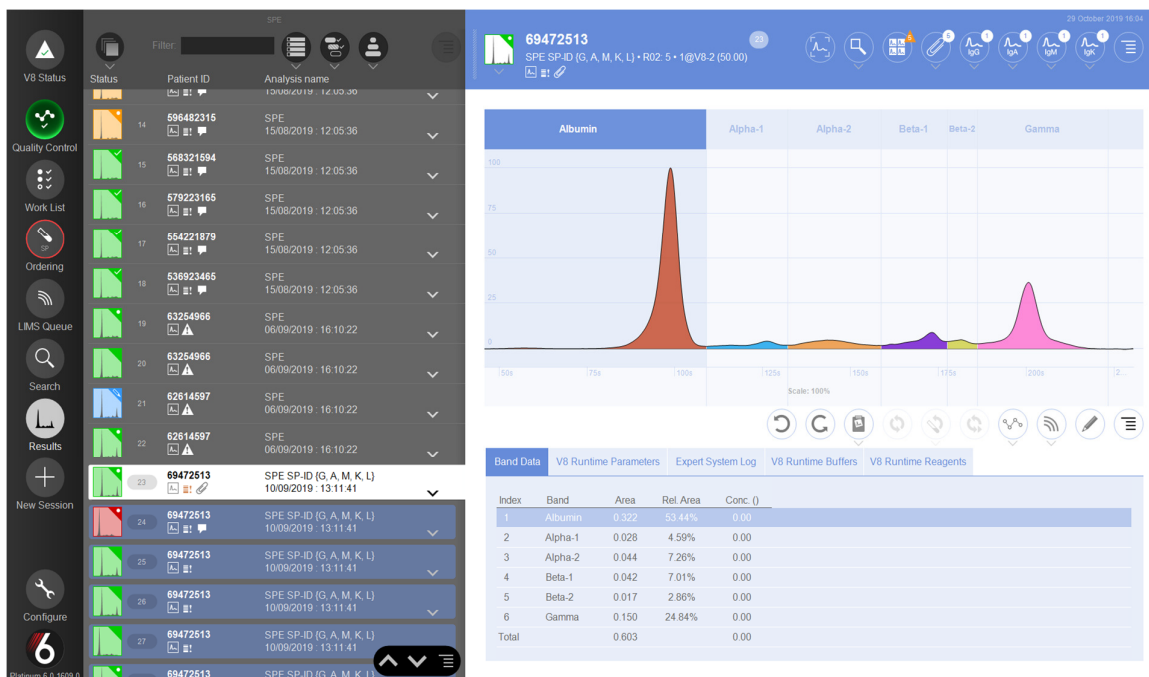
A maximum of 1000 traces can be shown at one time – if more than this is found a dialogue box will appear.

Search results can be filtered in the top left hand corner of the screen.


Once the search results are displayed, basic viewing functions can be carried out. The original V8 session can be loaded by selecting the  icon to enable more detailed sample editing.

Once viewing is complete, a new search can be started by selecting the  icon from the Options menu.

8. Results Window











8.1 Active Session Window

It is possible to have multiple session windows open in Platinum at one time. To avoid confusion as to which window is the current active session, the session is listed as the 'Active V8 System Session' when the user selects the  icon.


8.2 Editing

When a trace or gel image is first displayed, it may require some form of adjustment so that the correct interpretation of the result can be reported. Every sample trace can therefore be edited to user preferences. Samples are displayed in the navigation work list and are colour coordinated to visually show the editing status. The colours correspond as follows:

Icon	Status
	The lane has the correct number of bands with all values in range, suggesting a normal sample.
	The lane has the correct number of bands with all values in range, suggesting a normal sample. The lane has also been viewed.
	The lane has the correct number of bands with all values in range, suggesting a normal sample, but the sample has had some editing.
	Lane is unedited and may have an incorrect number of peaks/bands or values are out of range indicating the sample may be abnormal.
	Lane has been viewed and remains unedited. The sample has an incorrect number of peaks, or peaks/bands or values are out of range. Sample may be abnormal.
	Lane has been viewed and edited. The sample has an incorrect number or peaks/bands or values are out of range. Marked monoclonal bands will result in a yellow colour. Sample may be abnormal.
	The lane is a normal control with the correct number of bands and all values in range. The dot shows that the lane has been viewed.
	The lane is an abnormal control with the correct number of bands and all values in range. The dot shows that the lane has been viewed.

To manually edit the trace, use the  icon to display all of the editing options.


8.2.1 Editing Baseline

Should it be required to edit the baseline, clicking the icon  will allow manual movement of the baseline.

Selecting this icon will display large blue circles which can be moved to adjust the baseline. Long pressing on one of these circles will bring up a menu which will allow you to add and delete baseline markers.



8.2.2 Editing Peaks

Once a sample is selected, the peaks may be edited by clicking the Edit peaks icon . Long pressing on a peak marker on the sample trace provides specific options that are possible for the selected peak.

8.2.3 Add Trough Marker

To add an additional trough marker to a trace, long press on the desired location for the marker. Choose “Add Trough” from the drop down menu and the marker will be placed on the trace. Any further movement can be made by dragging the marker to the correct location within the band.


8.2.4 Delete Trough Marker

To delete a surplus trough marker, long press on the marker you wish to remove. Now choose “Remove Trough” from the drop down menu; the marker will then be removed from the trace.

8.2.5 Split Peak

To split a peak by the addition of a trough marker, long press on the desired location for the marker. Choose “Split Peak” from the drop down menu, and the marker will be placed on the trace. Any further movement can be made by dragging the marker to the correct location within the band.

8.2.6 Smoothing

To smooth a trace, select the “Filtering/Smoothing” icon and use the Smoothing slider to select your preferred setting .

8.2.7 Filtering

To filter a trace, select the “Filtering/Smoothing” icon (see Smoothing section above) and use the Filtering sliders to select your preferred setting.

8.2.8 Overlay Functionality

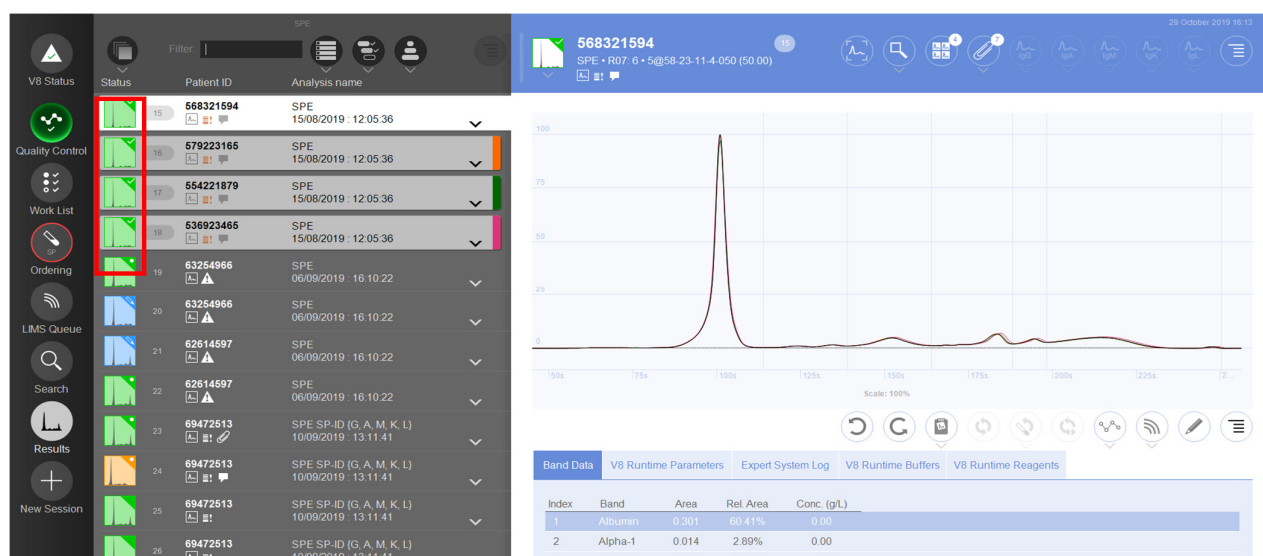
The Overlay functionality enables the comparison of a sample against a previously specified trace or against another sample.

8.2.9 Normal Overlay

The normal trace is defined by the user, depending on specified laboratory boundary reference ranges. A specific trace can be set as the default normal overlay by long pressing anywhere on the trace to bring up the drop down menu and selecting “Use as Normal Overlay”. The defined trace will then be shown in grey on the screen as shown below. To switch the normal overlay on/off, long press on the trace and select “Show Normal Overlay”.


8.2.10 Overlaying of Samples on the Screen

By clicking on the small trace icon in the NWL you can select as many samples as you like to overlay. Clicking on the icon again will deselect it.




It is also possible to select all of the samples by going to the  icon and selecting “Select All”.

8.2.11 Match Shapes

When Overlaying sample trace in Platinum it is often necessary to match the overlay from one sample to another, this is especially so with immunodisplacement samples. Platinum automates this to make it as quick and simple as possible. To do this, simply highlight two or more traces that you would like to be matched and select the  icon.

8.2.12 Stretching Samples to Overlay Bands

When overlaying samples from different time periods, it may be necessary to stretch a trace to overlay each peak over its corresponding peak in the second trace.

Overlay the required samples by clicking on their trace icons in the NWL, and then select the  icon.

This will auto align the traces over each other. Should the samples require further manipulation; the trace can be manually stretched by dragging the three vertical markers which appear on the screen.



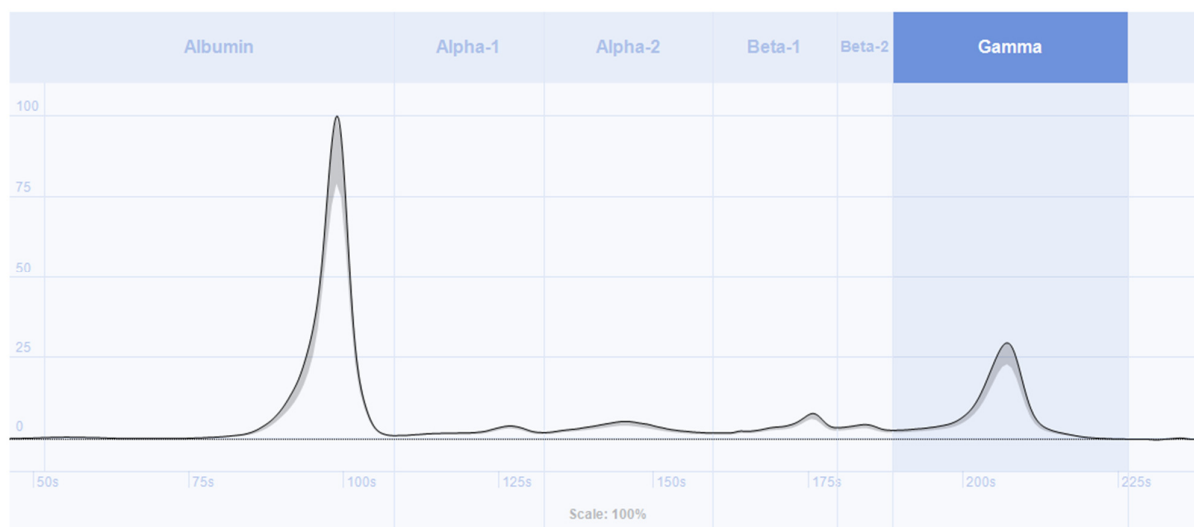
8.3. Mean Traces

Allows a visual range of normal samples to be viewed on screen relative to the currently selected trace.

To add traces to the mean overlay, select the overspill menu on the right of the screen next to the 'Edit' icon and then select 'Comparisons'. Choose "Add to Mean Traces" from the drop down menu.

To view the traces used to compose the mean overlay, go to the same overspill menu, select 'Comparisons' and then select "Load Mean Traces" from the drop down menu.

The 'Comparisons' dropdown menu also gives you the option to remove a specific sample from the mean overlay.



8.4 Quantitating a Monoclonal Protein


To quantitate a monoclonal protein, it is necessary to isolate the monoclonal band on the trace. There are two possible methods to do this which give slightly different values of the monoclonal protein; slicing and skimming. If the total protein value of the sample is known, then Platinum will automatically calculate the protein contribution of any marked M-spike.

N.B. It is recommended that users choose one method or the other, as switching between them could lead to changes in patient monoclonal quantitation over time, due to the different methods of measurement used.

8.4.1 Skimmed M-spike

This methodology takes into account the polyclonal background of a sample by allowing the user to estimate the amount of polyclonal background and remove this from the quantitation.

8.4.2 Adding a Skimmed M-spike


Select the Edit peaks icon , then long press on the monoclonal spike and select “Add Skimmed M-spike”.

Platinum will then estimate the extent of the monoclonal peak and highlight this area by filling in the trace with ‘hashed lines’. To edit the location of the start and end points of the area quantitated, drag the trough marker to a suitable location. The band list will now contain an extra band called M-spike with additional prefixes and suffixes depending on its location in the trace, and the number of M-spikes added e.g. 5 M Gamma M-spike 1 13.39%, where ‘5’ is the peak number, ‘M’ shows it as an M-spike rather than a normal peak, ‘Gamma’ is the region in which the M-spike is located, ‘M-spike 1’ shows it is the first marked M-spike (as more than one can be added), and 13.39% shows the relative area of the M-spike.

8.4.3 Sliced M-spike

This methodology assumes the monoclonal protein band is the only protein in the gel at this position, and therefore quantitates the band down to the baseline of the trace.

8.4.4 Adding a Sliced M-spike

Select the Edit peaks icon , then long press on the monoclonal peak and select “Add Sliced M-spike”. Platinum will then estimate the size of the monoclonal peak and highlight this area by filling it with ‘hashed lines’. To edit the location of the start and end points of the area quantitated, drag the trough marker to a suitable location.


8.4.5 Removing an M-spike

To remove an unnecessary M-spike, long press on the M-spike and choose “Remove M-spike”. The hashed area will then be removed.


8.5 Removing Artefacts from Traces

Artefacts are not common, but are sometimes a problem; this function enables the removal of an artefact from a trace without disturbing the data.

8.5.1 Slice Data

To edit a trace to remove an unwanted artefact (to the baseline), click the  icon and drag across the area to be removed.

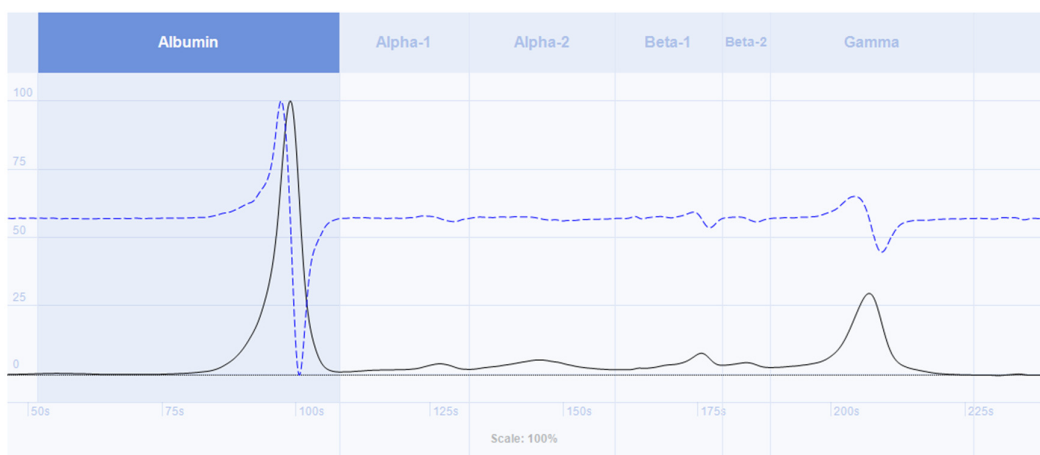
8.5.2 Skim Data

To edit a trace to remove an unwanted artefact whilst maintaining the general progression of the curve (peak to peak), select the skim icon  then drag over the area to be removed. This will be highlighted by a series of vertical bands.

8.6 First Derivative


Shows the first derivative of the selected trace. It is useful for identifying small monoclonal bands as it highlights the rate of change in the curve.

Long press on the trace and select “Show derivative” and the first derivative will appear as a dotted line. To remove the first derivative from the trace, long press on the trace and deselect “Show Derivative” in the drop down menu.



8.7 Adding Comments to a Sample Result

8.7.1 Adding a Comment to a Single Sample Result




Comments for a trace can be found by selecting the 'down' arrow in the navigation worklist, which will reveal the inspector window. Comments can then be typed manually in the 'Patient Comments' section. It is also possible to add pre-defined comments to the comments box via two different routes by selecting the  icon:

- Configure Standard Comments (see section 9.2)
- Comments Tree


Please note there is a character limit of 2000 for comments.

8.7.2 Adding Comments to Multiple Sample Results

To add the same comment to multiple traces highlight all traces that require the same comment adding to the result and tap the small trace icon in the Navigation Worklist.

Select the 'Options' menu  beneath the worklist and select Data > 'Add Comment to Selected Traces'. From there manually type the comment or select the  icon to add comments from 'Standard Comments' or the 'Comment Tree'. Select 'Add' to add them to the selected traces. A comment icon  will appear on all traces in which the comment has been added.

8.7.3 Comments Tree


To add a pre-set comment from the Comments Tree to a result, select the  icon and then select the comment(s) which you would like to add using the check boxes. Use the 'Add Selected' option to add them to the trace and then select 'Close'. The comment(s) should now appear in the 'Patient Comments' section below the trace.


New comments can be added to the tree by using the 'New Comment' or 'New to Root' options, depending on whether the comment is linked to a certain assay or not. Comments Trees that have already been configured can be loaded using the 'Load Tree' option, or the current tree can be saved to a file using the 'Save Tree' option.

N.B. IFE comments can only be added/edited in the original IFE scan.

8.8 Statistics – moved from configure window

Within Platinum, it is possible to perform basic statistical analysis on the data and to print or display this information.


To compare data from multiple samples, it is necessary to have all of the results in the same analysis window, either on a single gel image, or as the result of a database search. To select all samples for analysis, select the  icon and then “Select All”.

To display the statistics window after all of the required samples have been highlighted, select the ‘Options’ menu  beneath the worklist and select **Data > Statistics**.

The index of each band is displayed in the Index column with the number of samples in brackets. The name of each band is indicated in the band column, whilst the remaining columns can be determined in the band tab of **Configure > Preferences > Bands**. These columns are used to display the mean, the standard deviation, and the CV for the area, relative area, or concentration.


8.9 Searching for and Attaching an Immunotyping Result

It is possible within a single Platinum window to link and display Immunodisplacement traces/IFE gels relating to a specific patient next to the corresponding serum protein trace for use as a reference.

Select the serum protein sample that the Immunodisplacement/IFE is to be linked to, and select the Data icon  from the ‘Options’ menu, followed by ‘Search and Attach Immunotyping’.

A search window will appear. Select the search button, and once the results have appeared, select any immunotypes to be attached to the serum protein. Select OK. The attaching will take place and the window will close.

8.9.1 Attaching a sample from Patient History

To attach a sample directly from Patient History, select the ‘down’ arrow next to the sample to display the inspector window. At the bottom of the inspector window, next to Patient History, select the  icon. Tap the paperclip icon next to each result in order to attach it to the currently selected trace

28
6615492
SPE
06 September 2019

Specimen No.
T12445

Patient ID
6615492

Forename
George

Surname
Hopkins

Date of Birth (dd/mm/yyyy) (63)
05/11/1955

Demographic 6

Demographic 7

Demographic 8

Demographic 9

Demographic 10

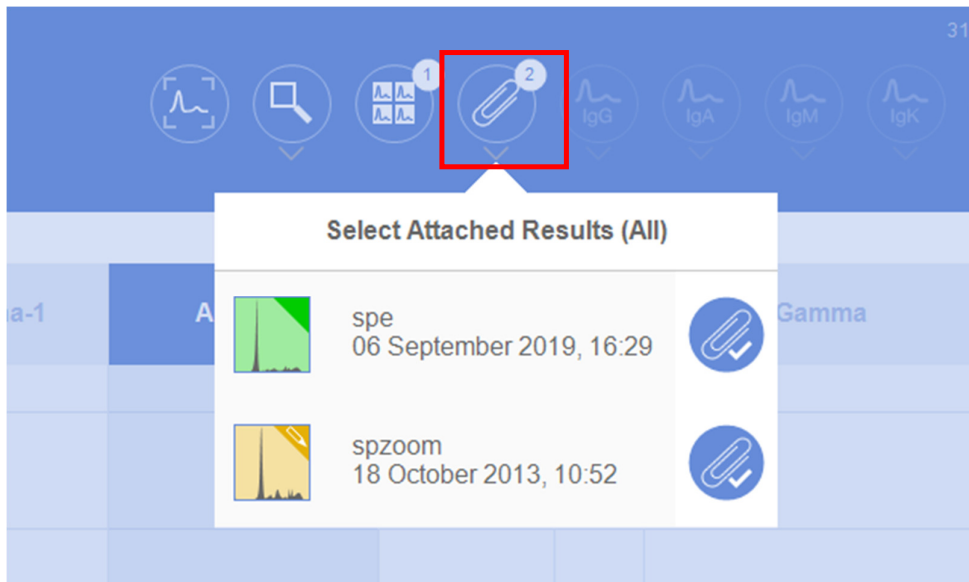
Total Protein (g/L)
0.00
Albumin (g/L)
0.00

14
6615492
Zoom SP
18 October 2013

27
6615492
SPE
06 September 2019

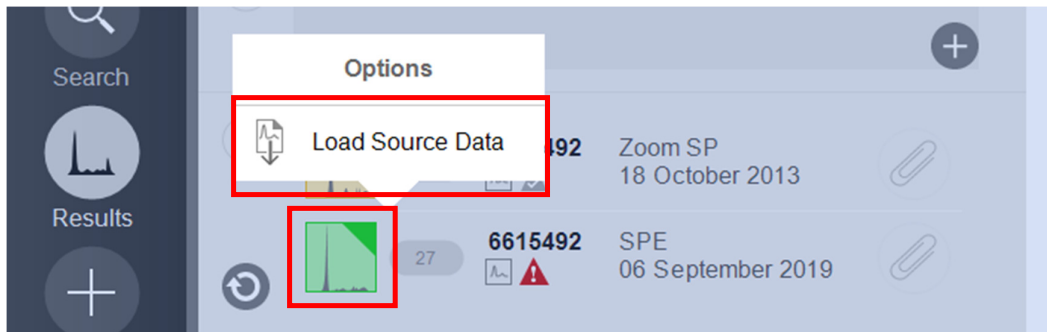
29
6821149
SPE
06 September 2019

If successfully attached, the paperclip will have a small tick, and in the top right hand corner of the screen, a '1' should appear (or the number should increase by 1 if other samples are already linked/attached) over the icon.




8.9.2 Loading Source Data for Patient History

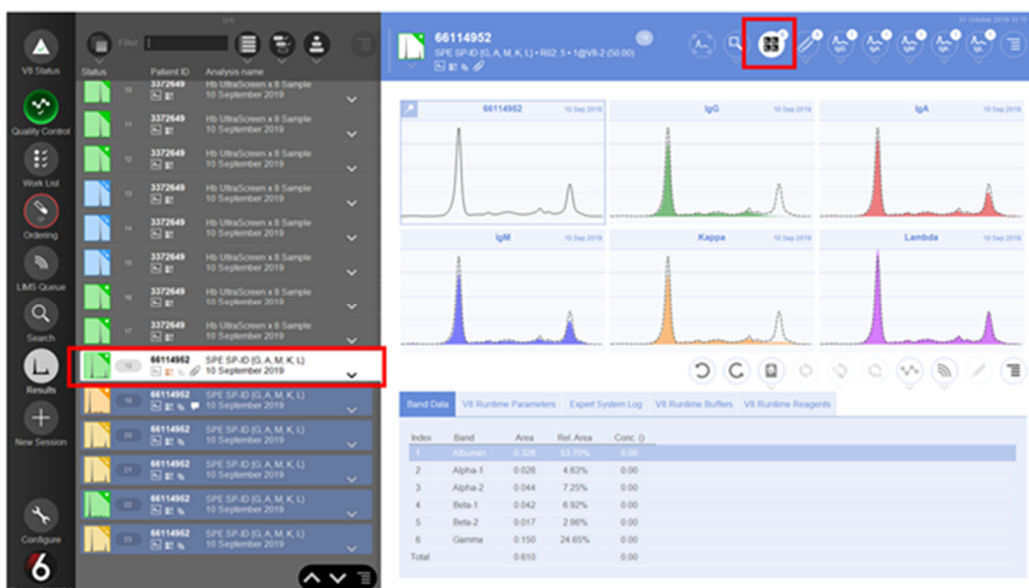
To load the source data for any of the samples found in Patient History, long press on the small trace icon for the sample and then select 'Load Source Data'.



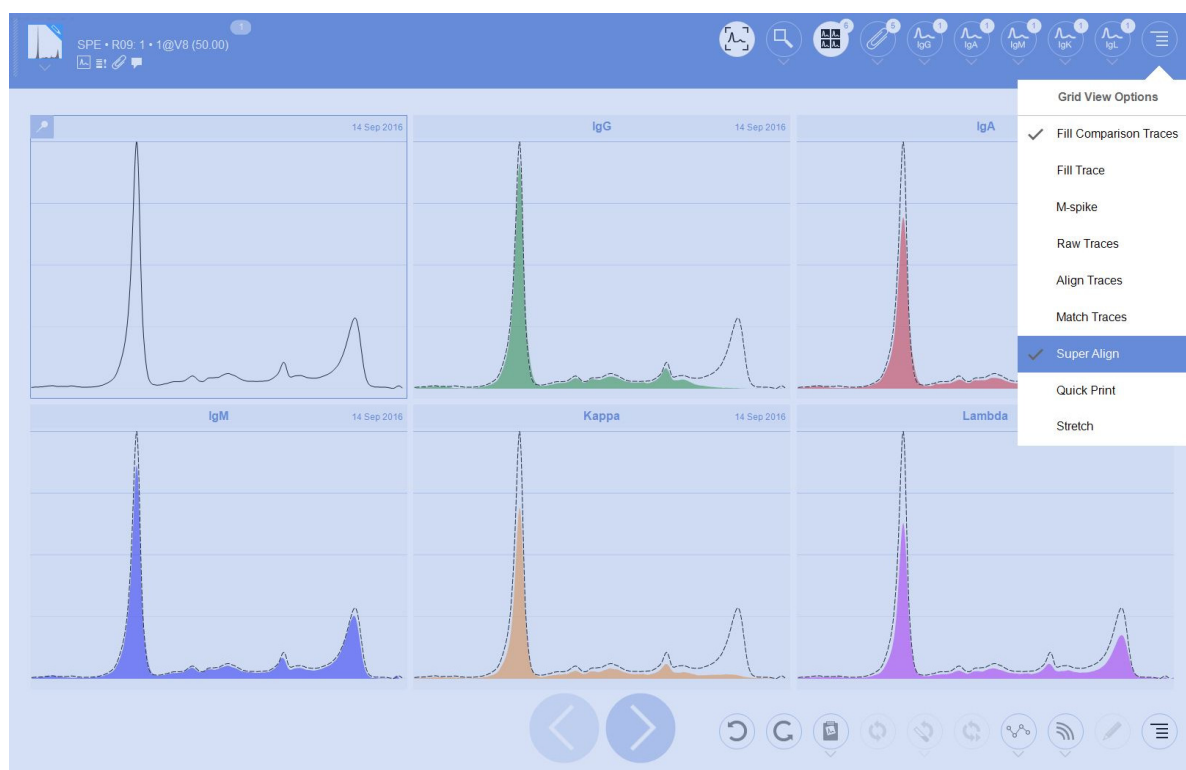
8.10 Grid Mode


Grid Mode now provides two features for viewing multiple samples – Immunowindow and Grid View.

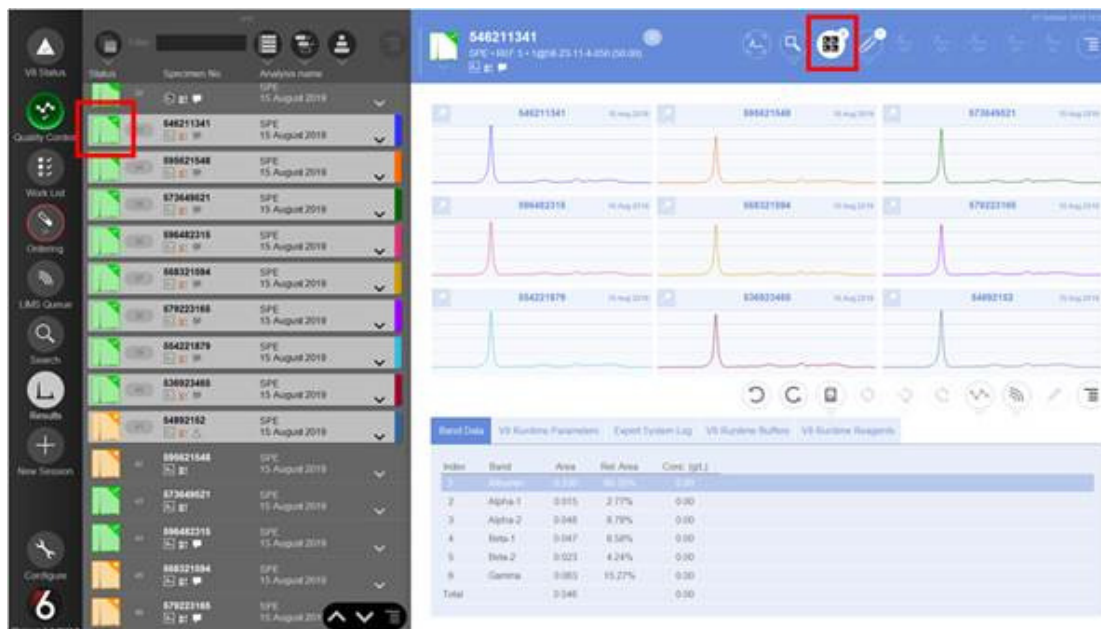
To view an Immunodisplacement using Grid Mode, select one of the Immunodisplacement samples and select the  icon.




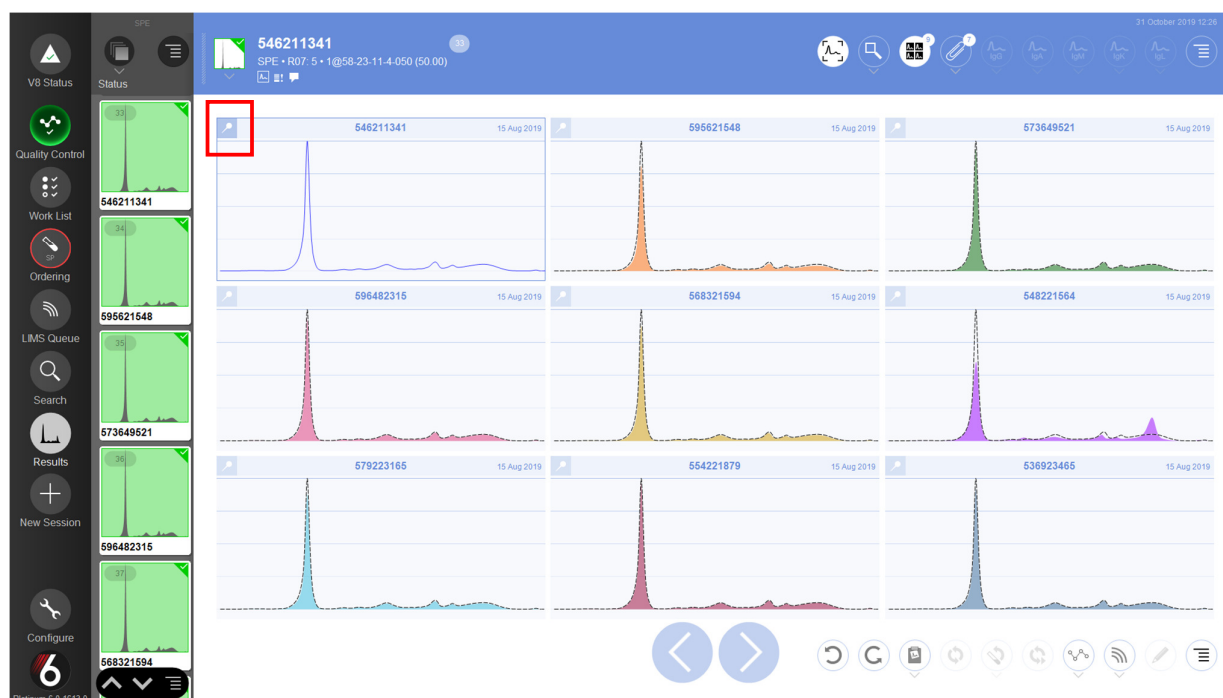
Grid Mode offers a number of viewing options to aid interpretation of immunodisplacement results. They can be found in the 'Options' menu in the top right corner, then 'Grid View Options'. This is only accessible whilst in Grid Mode. The Super Align tool is the recommended option and uses a peak matching algorithm to compare and overlay main SP and ID traces. This is especially useful when a large amount of protein has been removed during the immunodisplacement.



To view multiple traces of any type in Grid Mode, tap on the small trace icon of the sample to highlight it, and then select the  icon. A maximum of 9 samples can be shown in Grid Mode at any one time. This includes samples displayed in 'Patient History', IFE samples and gel samples.



Whilst in Grid Mode, any of the samples can be 'nominated' as the main trace. This allows the sample to be overlaid on top of all other traces in Grid Mode as a serum protein trace would in the Immunowindow. To nominate a trace select the  icon in the top left corner of the trace you wish to nominate.



8.11 Focus Mode

Focus Mode provides a basic view of the results. The currently selected trace is shown on a much larger portion of the screen making it easier to see and edit the trace. Navigation between samples can be done using the large arrows at the bottom of the screen, or by scrolling through the trace icons on the left side. Multiple samples can be overlaid by tapping with two fingers on the trace icon. All trace options, such as editing and reflex testing, are still available in the bottom left hand corner.




Grid Mode can still be used whilst in Focus Mode with samples remaining selected even when switching between views.



8.12 Adding a Tube ID to Processed Samples

Sample tubes with no barcodes or ones that have been misread are identifiable in the navigation work list as the tube ID is blank. The user can enter this information only AFTER the V8 has processed the sample and all the data has been obtained.

- To do this, select the Tube ID column of the unlabelled sample in the Work list window.
- This will enable the user to scan the tube with the barcode scanner, or manually enter a tube ID.
- It is also possible to enter the sample barcode information in the results window. Select the drop down arrow for the inspector window .
- Select the Tube ID demographic and type the barcode in manually.


8.13 How to Perform a Reflex Test

Reflex tests can be performed manually or automatically (using the Expert System). It is essential that the required reflex test is assigned as a response to the associated assay, such as Immunodisplacement, being the reflex test for a Serum Protein assay. This differs from test ordering as reflex assays are only ordered after a sample has already been run, it has been detected as abnormal, or a confirmation run is required.

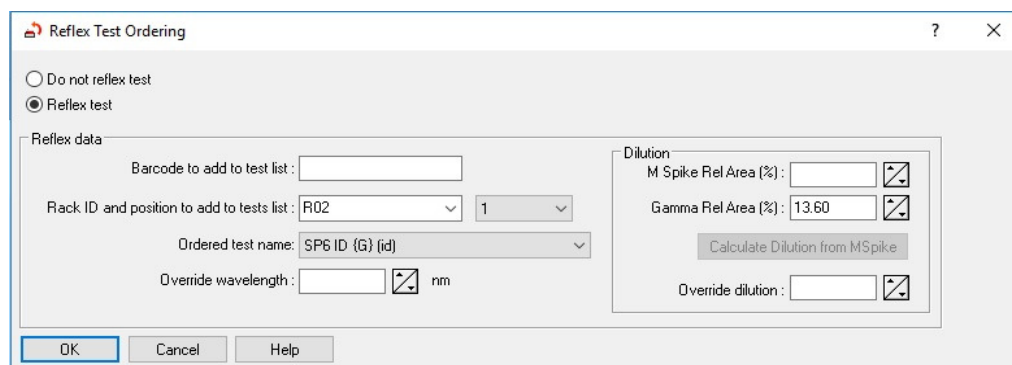
Please refer to section 9.1.3 for information regarding reflex test priority.

8.13.1 Manual Ordering for Reflex Testing

Manual reflex tests can be ordered whether or not the Expert System is switched on. To order a reflex test manually, data acquisition must have been completed. It is possible to analyse, manipulate and order reflex tests on a completed sample rack whilst another is being prepared or analysed by CE.

In the Results window, highlight the result of the sample that requires further analysis and select the  icon.

The following test ordering dialogue box will appear:




The image shows a software dialog box titled "Reflex Test Ordering". It has a close button (X) and a help button (?). Inside, there are two radio buttons: "Do not reflex test" (unselected) and "Reflex test" (selected). Below these is a section labeled "Reflex data" containing several input fields: "Barcode to add to test list:" (empty), "Rack ID and position to add to tests list:" (with dropdowns for "R02" and "1"), "Ordered test name:" (dropdown menu showing "SP6 ID (G) (id)"), and "Override wavelength:" (input field with a unit "nm" and a checkmark icon). To the right of the "Reflex data" section is a "Dilution" section with "M Spike Rel Area (%):" (input field with a checkmark icon) and "Gamma Rel Area (%):" (input field showing "13.60" with a checkmark icon). Below these is a button labeled "Calculate Dilution from MSpike" and an "Override dilution:" (input field with a checkmark icon). At the bottom of the dialog are three buttons: "OK", "Cancel", and "Help".

Select the Reflex Test option. From the drop down menu choose “Ordered test name” and then select the appropriate reflex assay.

If there is no barcode present, the rack number and position are the only factors that can be used to identify the sample. As such, it is ESSENTIAL that the tubes are not changed before the reflex test has been performed.

If a barcode is present, this will be used preferentially to perform the reflex test.

Once selected, click OK. Depending upon the preferences of the reflex test selected, the V8 will either automatically perform the reflex analysis immediately, performing each reflex test one by one, OR, the operator is required to choose the “Allow Reflex Test Batches” icon , where the V8 will store all reflex tests until required by the user to perform analyses.

8.13.2 Auto IFE for Touch

8.13.2.1 Using the IFE Auto-dilution Function

The V8 Immunofixation IFE Auto-dilution function has been designed to speed up and automate the dilution of serum protein samples for immunofixation. Using the V8’s unique onboard sample preparation, the V8 sample handler and the Platinum software the system combines to automate the preparation of the optimum IFE dilution.


To create the optimum dilution, the software uses pre-existing data to calculate the best dilution ratio. This dilution is used to automatically pipette from the sample tube into a sample cup which is then ready to be loaded into a Helena gel electrophoresis system. The dilution formula uses the monoclonal band relative % in conjunction with the relative % of other bands and from this data generates a dilution that will provide sensitivity as well as clarity.

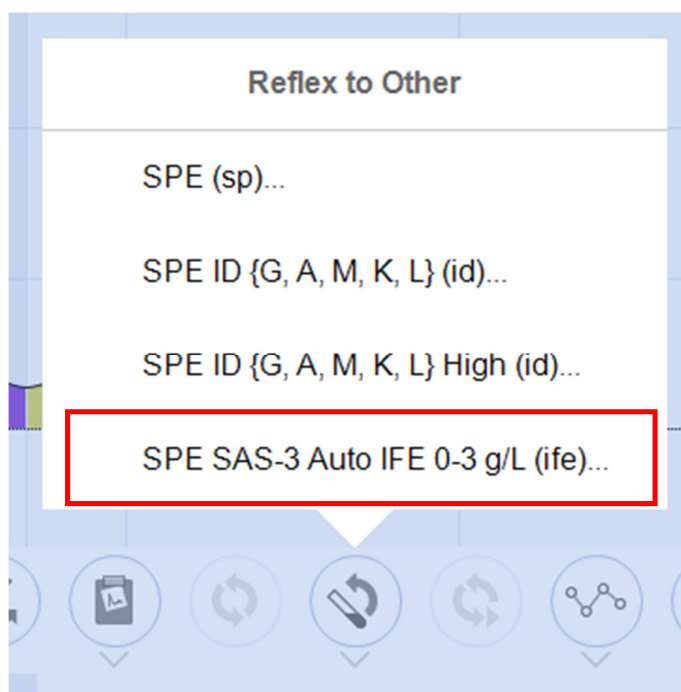
Immunofixation dilutions are traditionally provided as fixed recommendations for IFE dilutions, dependant on the protein concentration of the monoclonal band within a range of concentrations. This requires the total protein or albumin concentration of the sample to be available and then applied to a concentration range, which may not

always be ideal. It also does not take into account the polyclonal immunoglobulin expression which may make visualisation challenging.

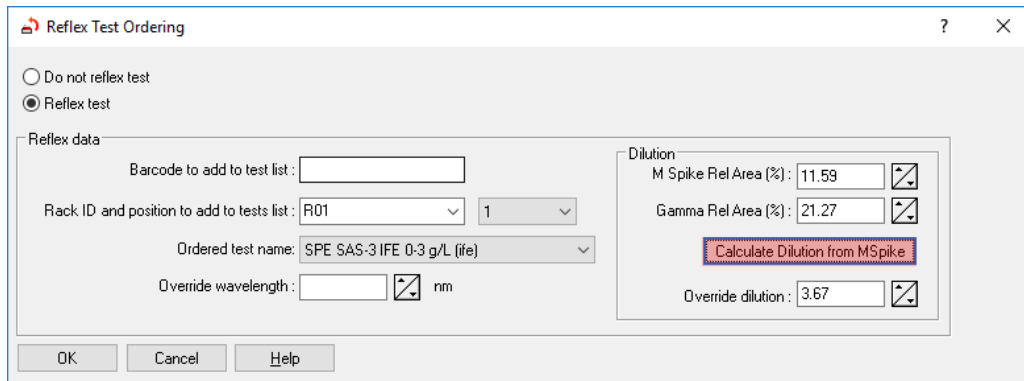
The V8 IFE Auto-dilution uses pre-existing information found within the capillary electrophoresis trace to automatically tailor the dilution for each individual sample to provide the optimal result, this feature removes the potential for errors in dilution calculations and streamlines the decision process.

8.13.2.2 Using IFE Auto-dilution with the Reflex Test Function

1. Select a sample with a monoclonal band and gate the monoclonal band using the skim/slice function see section 8.4.
2. Order a reflex test by selecting the “Reflex to Other icon  under the sample trace image.
3. Select the [MIU] SAS-1 Auto IFE or [MIU] SAS-3 Auto IFE (MIU = Method in use) if it is available in the pop up menu. If not select “More Options”.



4. In the “Reflex Test Ordering” window select “Calculate Dilution from MSpike”



Reflex Test Ordering

☐ Do not reflex test
☒ Reflex test

Reflex data

Barcode to add to test list:

Rack ID and position to add to tests list: R01 1

Ordered test name: SPE SAS-3 IFE 0-3 g/L (ife)

Override wavelength: nm

Dilution

M Spike Rel Area (%): 11.59

Gamma Rel Area (%): 21.27

Calculate Dilution from MSpike

Override dilution: 3.67

OK Cancel Help

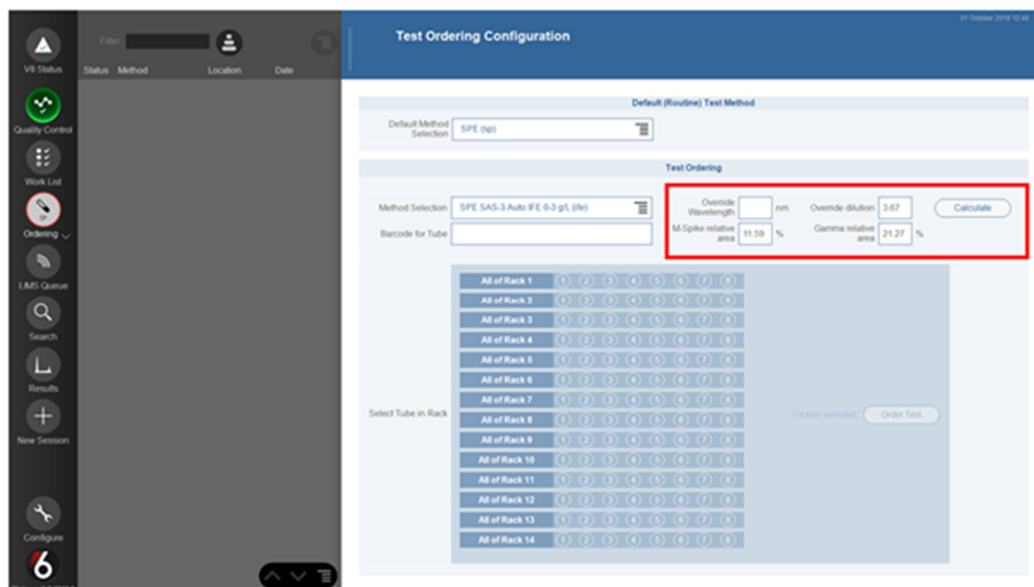
Reflex Test Ordering window with the dilution calculated.

5. Select **OK** and the V8 will prepare the dilution (in Batch Priority Mode the user must select “**Allow Reflex Test Batches**” for the reflex test to begin).

8.13.2.3 Using IFE Auto-dilution with the Manage Test Function

For users that will order immunofixation tests on samples which have been tested in a separate Platinum session:

1. Select the **Ordering** menu.
2. Select the barcode or the rack number and position of the sample to be tested.
3. Select the Ordered test name [MIU] SAS-3 IFE 0-3g/L (IFE).
4. In the Dilution section of the window input the relative % of the monoclonal band and gamma for the required sample and select “Calculate”.



Test Ordering Configuration

Default (Routine) Test Method

Default Method Selection: SPE (Ig)

Test Ordering

Method Selection: SPE SAS-3 Auto IFE 0-3 g/L (IFE)

Barcode for Tube:

Override Wavelength: nm

M Spike relative area: 11.59 %

Gamma relative area: 21.27 %

Override dilution: 3.67

Calculate

Select Tube in Rack

Ad of Rack 1 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 2 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 3 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 4 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 5 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 6 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 7 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 8 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 9 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 10 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 11 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 12 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 13 (1) (2) (3) (4) (5) (6) (7) (8)

Ad of Rack 14 (1) (2) (3) (4) (5) (6) (7) (8)

0 Tubes selected

Order Test

Image showing the M-Spike and Gamma relative area entered.

5. Select "Order Test".
6. When all tests are ordered the racks will be pulled in and the specified samples will be diluted with the appropriate override dilutions.

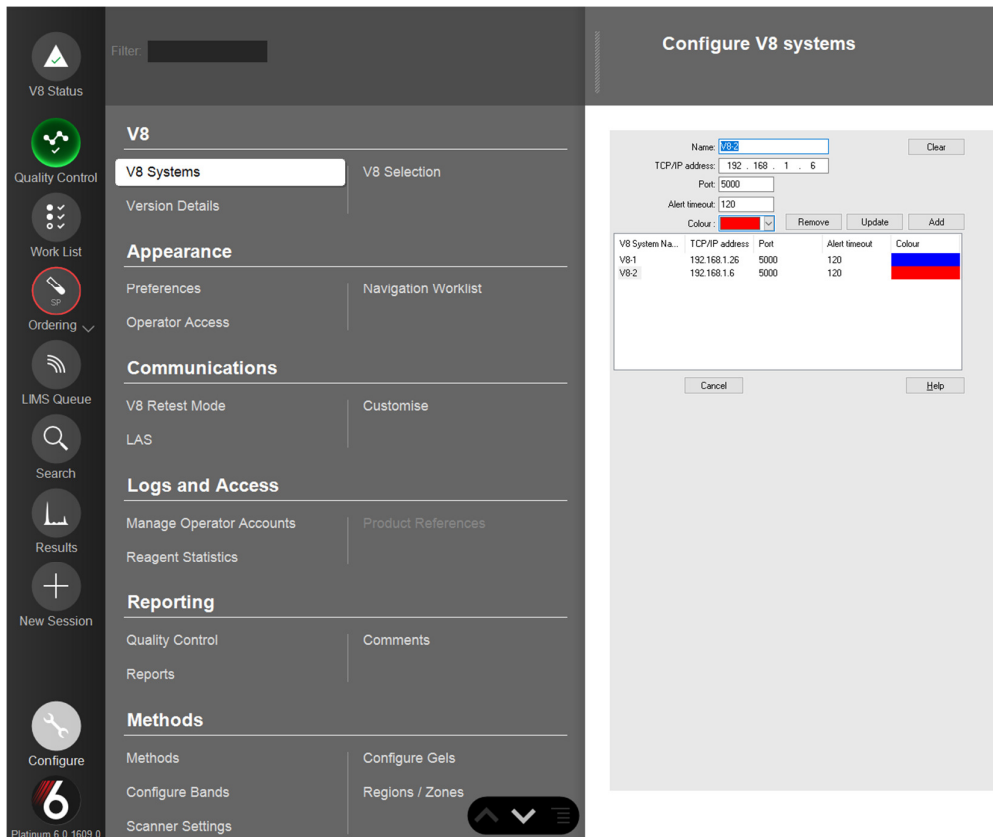
9. Configure Window

9.1 V8 Systems

Platinum must be linked to the V8 instrument that is to be used.

Go to **Configure > V8 > V8 Systems**. This will allow for new V8 systems to be linked to Platinum, and list the current/past systems that have been used. To calibrate the V8 to Platinum, enter the following:

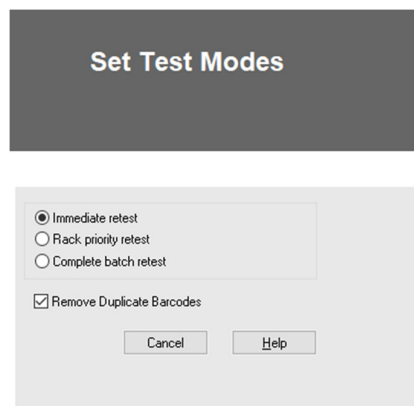
Section	Description	Example
Name	To describe the V8 system. This is user definable.	Biomedical Lab CCE
TCP/IP address:	Unique IP address of the V8. Contact your local Helena Biosciences representative for further information	192.168.1.2
Port:	Unique port number for the V8. Contact your local Helena Biosciences representative for further information.	5000
Alert time out:	This is the time gap before window reappears (s).	120
Colour	Colour that will appear in the title bar of the active session.	Red



9.1.1 Select V8 System

This allows the user to view a list of all V8 systems that have been linked to the PC, and to initiate a connection between Platinum and the V8 System. The user can manually select from the list should the default system be changed for a different instrument. To select a V8 system, go to **Configure > V8 > V8 Selection**.

9.1.2 Setting the V8 Test Mode



The V8 has two main modes of operation; (1) sampling of new samples, and; (2) reflex testing of recalled samples.

Sampling of new samples

In this mode, the V8 will process all samples on-board the instrument, scanning the rack ID and primary sample tubes, and sending the barcodes to Platinum for instruction regarding the assay to be performed.

Reflex Testing

In this mode, the V8 will only process and analyse those samples that have been flagged for reflex testing (and appear in the test list within Platinum), or those that have been individually ordered. Other samples within the sample rack will be ignored.

N.B. Test mode cannot be changed during a session. If it is required to change test mode or reflex priority then a new session must be started.

To select test mode:

To select the test mode of reflex priority, a new V8 session window must be opened. Go to **Configure > Communications > V8 Retest Mode**.

9.1.3 Reflex Test Priority

The reflex test priority determines when the V8 performs reflex tests, whether these have been ordered manually or automatically. There are three reflex Test Priority modes; Immediate, Rack Priority and Batch.

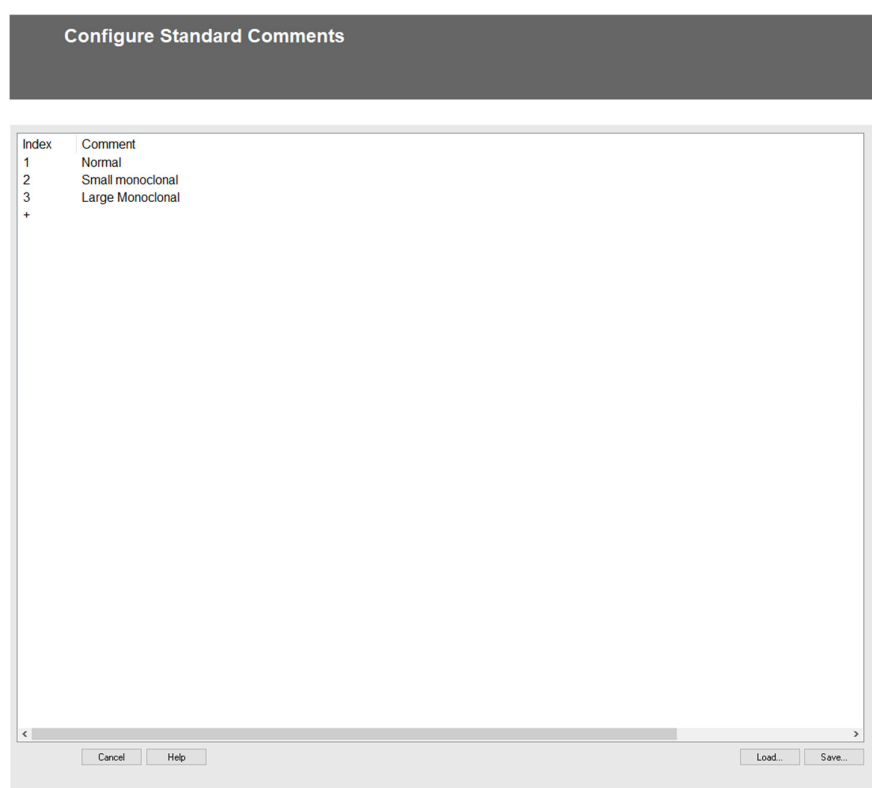
- 'Immediate retest' mode will perform each ordered test immediately, thus moving racks back into the sample handling area and switching assay if required.
- 'Rack priority retest' mode will delay retesting until there are no further racks available for processing using the default assay. If further racks are loaded during rack priority re-test, then the V8 will prioritise the new racks.
- 'Complete batch retest' mode will hold all ordered tests until prompted to perform analysis by the user.

9.2 Comments

It is possible within Platinum to store predefined comments which can be added to the individual sample records.

9.2.1 To Compose the Standard Comments

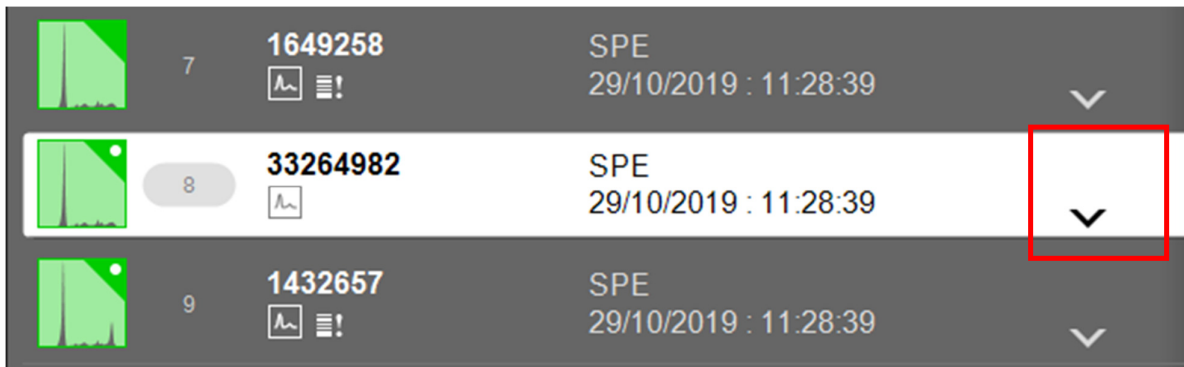
Go to **Configure > Reporting > Comments**.



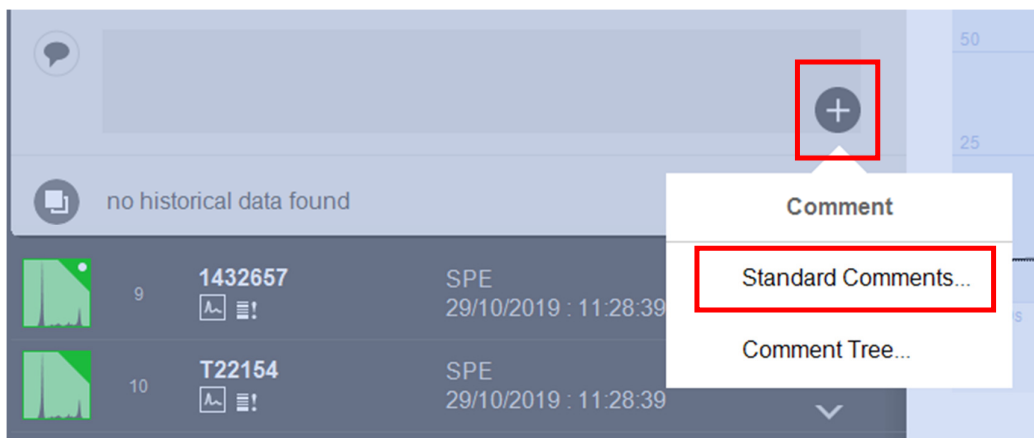
Index	Comment
1	Normal
2	Small monoclonal
3	Large Monoclonal
+	

Appropriate text can be entered into the column marked comment. Once complete the comments will save automatically. There is a 'Load' option to import previously configured Standard Comments, and also a 'Save' option so that comments can be saved externally.

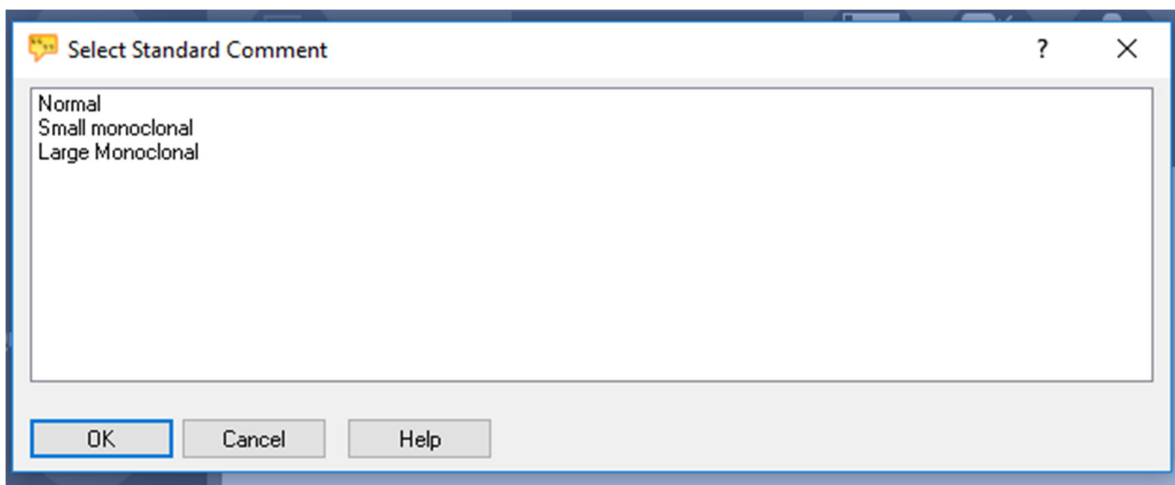
To add these comments to a sample, first select the trace and then display the inspector window by selecting the arrow to the right of the worklist:



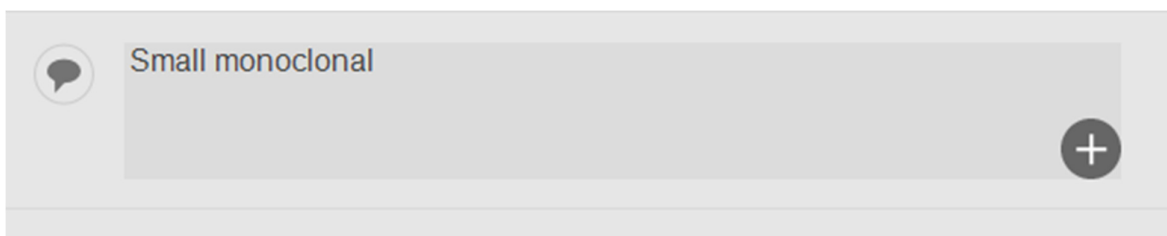
Under the 'Patient Comments' section, select the small '+' icon and select 'Add Comment':



A window will open displaying all of the configured comments:



Select the comment that is to be added to the Comments section and then 'OK'. The comment will then appear in the 'Patient Comments' box:



9.3 Database

The Platinum database stores all data that is processed and imported.

9.3.1 Database Maintenance

To validate all sessions, fix corrupted samples or validate the database, go to **Configure > Database > Database Maintenance**

9.3.2 Archive selected data

To archive selected data in Platinum, go to **Configure > Database > Archive**.

Note – archiving is not required, or recommended, for MS SQL users

9.3.3 Merge Demographics

To merge previous demographics sets into the current Platinum demographics setup, go to **Configure > Database > Demographics Merge**

9.3.4 Backup Selected Data

To back up selected data in Platinum, go to **Configure > Database > Backup**

9.3.5 Database Backup and Recovery

To backup the current databases, recover previous databases, import sessions from another directory or create a new data directory, go to **Configure > Database > Backup and Recovery**

9.3.6 Compact the Database


To compact the database, go to **Configure > Database > Compact Database**.

Note – Compacting the database is not required for MS SQL users

9.4 Report

Patient sample results can be viewed as a report and printed for use by the clinician. Templates can be altered according to preference and type of assay run.

9.4.1 Create New Report


In order to create a new report, go to **Configure > Reporting > Reports** and select the  icon. This will open a new report template with all of the functions that are required to create new template designs.

9.4.2 How to Create a Template Layout


When a template layout is created, a blank page will be displayed with tool buttons on the left hand side. Users can choose what type of results is to be shown, where it is to

be situated, and what demographic data is displayed. Data such as peak values and Immunodisplacement data can also be attached.

9.4.3 Edit Report

To edit the current method dependent default report, choose the  icon and open the report which you wish to edit.

9.4.4 Preview Report

To preview a report before printing, go to the Print icon  and select “Preview Report for Selected Results...”.

In Platinum it is possible to use user definable reports, but Helena Biosciences also provides an array of report templates that the user can customise to suit their own needs.

9.4.5 Setting a Report as the Default

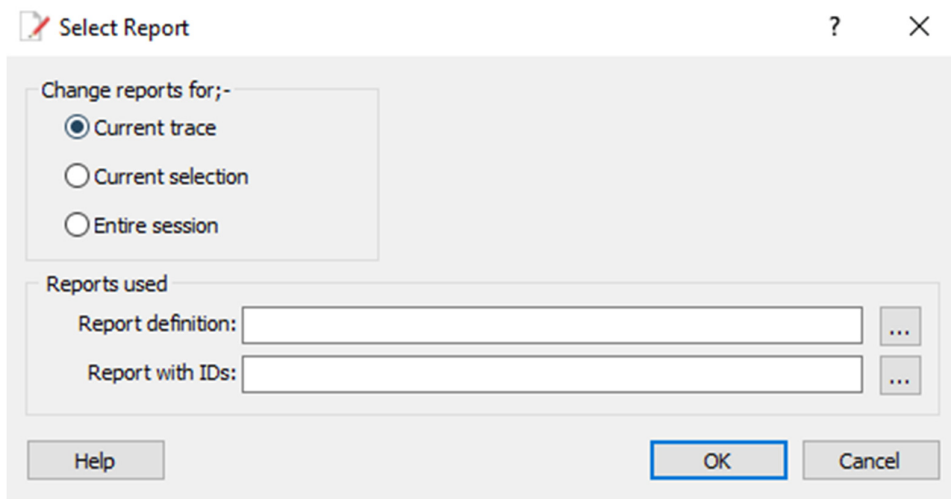
It is important to define a report type for all results; separate reports can be configured for Serum proteins and Immunodisplacement results. When an operator selects a report to be printed Platinum will automatically default to the Serum Protein report unless there are Immunodisplacement results attached to that sample, in which case Platinum will default to the Immunodisplacement report.

To select a default report for future data:

- Go to **Configure > Methods > Method Type** and in the Report Generation section make sure the “Do not report” option is unticked.
- Select the ‘...’ button next to Report Definition - this is the report to be selected for the serum protein without IDs. The default location for the report files is in the following location: C:\Program Files\Platinum.
- Repeat the selection for the Reports with IDs.
- This report definition will be applied only to the method selected. Repeat this process for each method as required.

To apply a report template to data already acquired:

- Go to Configure > Configure Bands > Report Selection
- Select which traces to apply the report template to
- Select the ‘...’ button next to Report Definition - this is the report to be selected for the serum protein without IDs. The default location for the report files is in the following location: C:\Program Files\Platinum.
- Repeat the selection for the Reports with IDs.

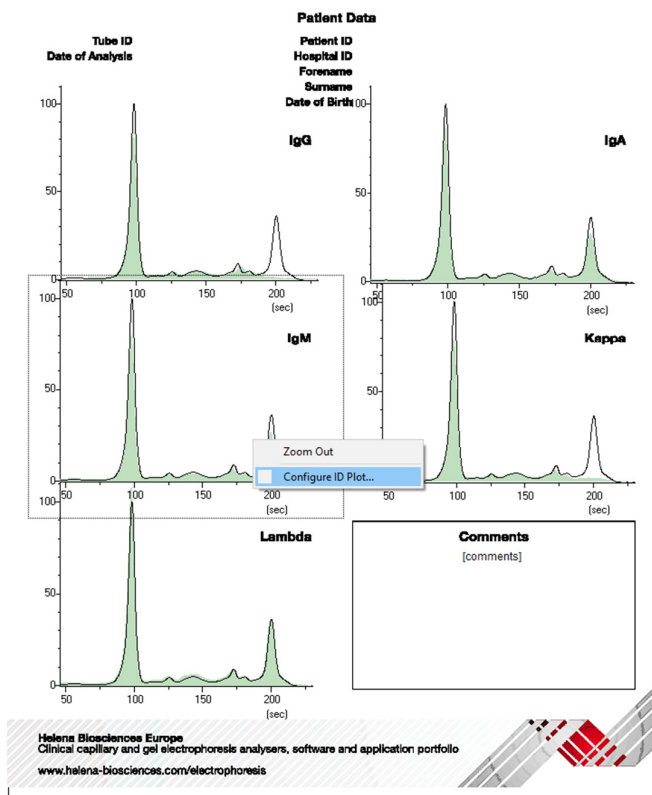


Select OK on this window after selecting report locations. In order to change the report template without reinterpreting the data select 'Cancel' in the Configure Bands window before returning to the Results window.

9.4.6 Configuring ID Reports

ID reports are configured to provide an easy to interpret document.

This can be further customised by the user providing a unique and tailored report, by long pressing on the individual trace and select "Configure ID Plot".



Each individual trace on the report can be uniquely edited to the user's preference and requirements.

ID plot configuration

☒ Plot main trace

ID plot items:

1	IgM	1
+		

☒ Match shapes before plotting

☒ Fill second trace

☐ Show method name

☒ Copy settings to report definition

9.5 Configure V8 Methods

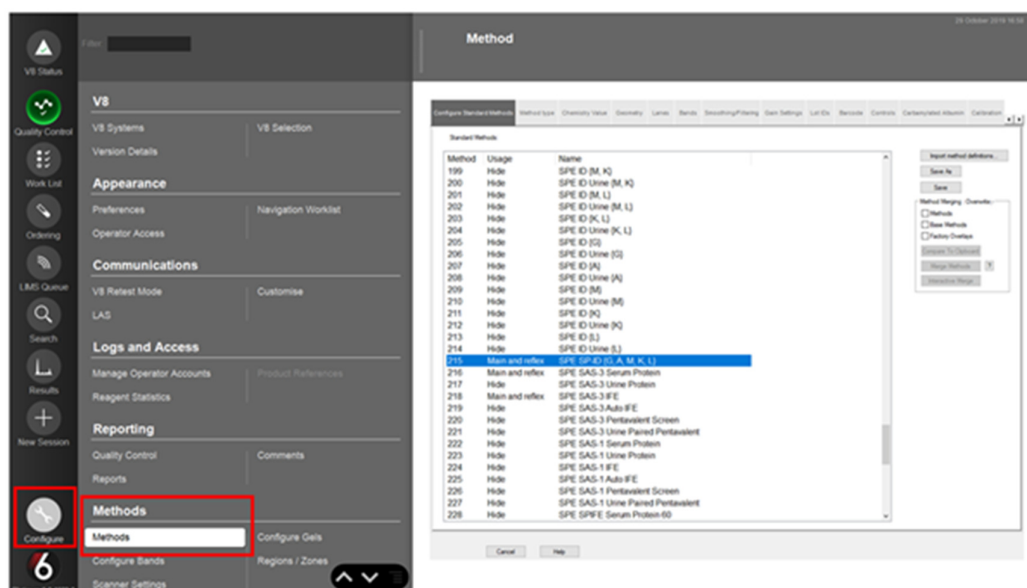
In Platinum, it is possible to configure some elements of each method used in processing samples. These elements are used to specify the limits for each band, default smoothing and filtering levels, and other factors that are interchangeable.

9.6 Methods

Go to **Configure > Methods > Configure Standard Methods**.

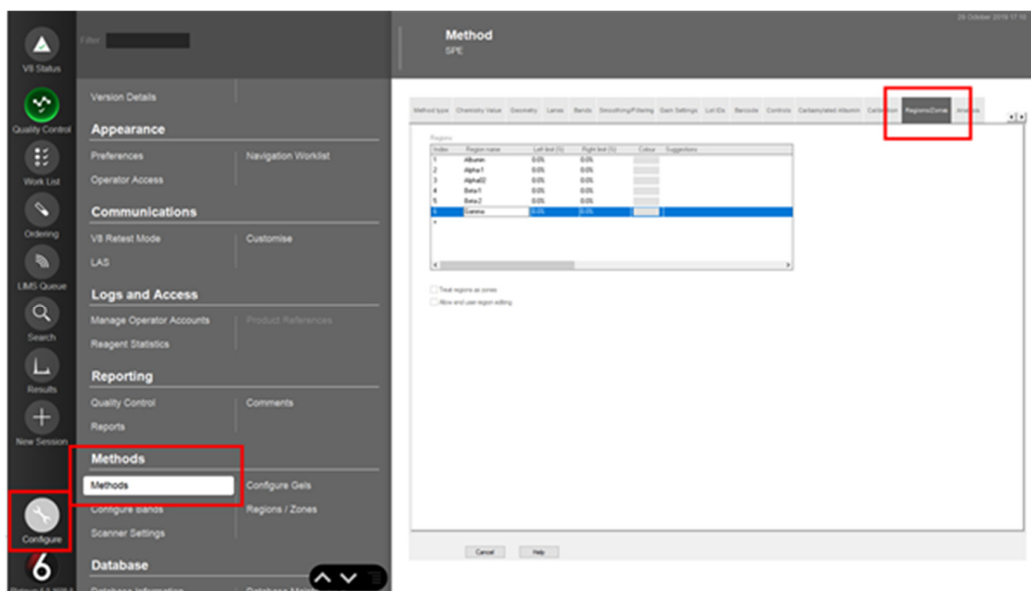
From this window, select the method you wish to configure. There is also the option here to “Show” or “Hide” methods by selecting on the “Usage” column.

Once the desired method is selected there are 14 tabular options available. It is recommended that most of these remain at their default settings.



9.6.1 Trace Regions

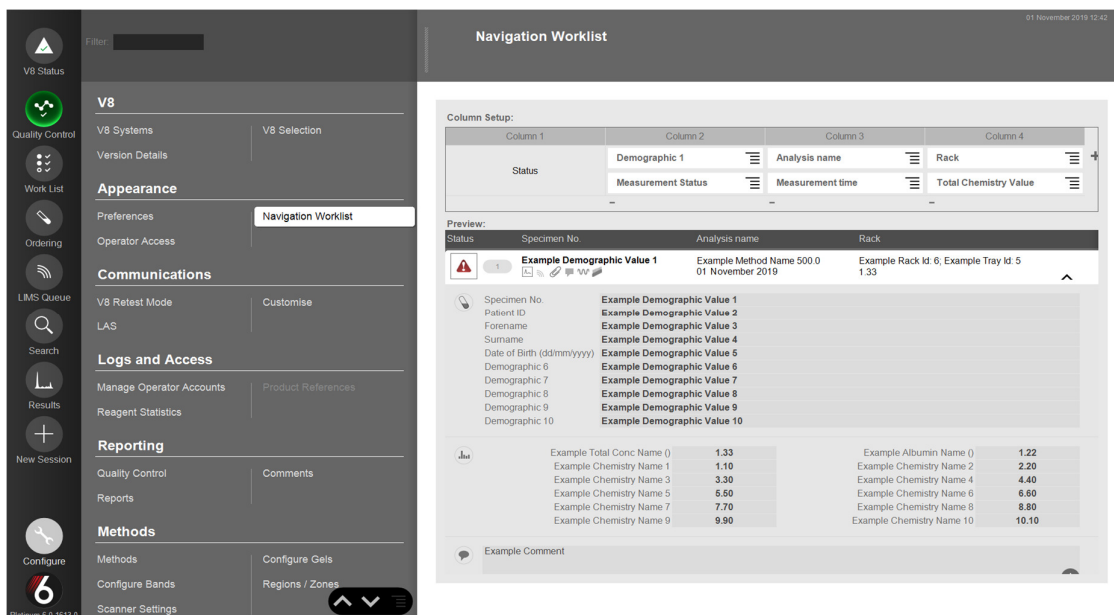
Go to **Configure > Methods > Regions/Zones** and enter the region names and limits. Suggestions of band(s) that would appear in this region can also be added in the appropriate column.



To select regions based on the trace displayed, then go to **Configure > Regions/Zones**.

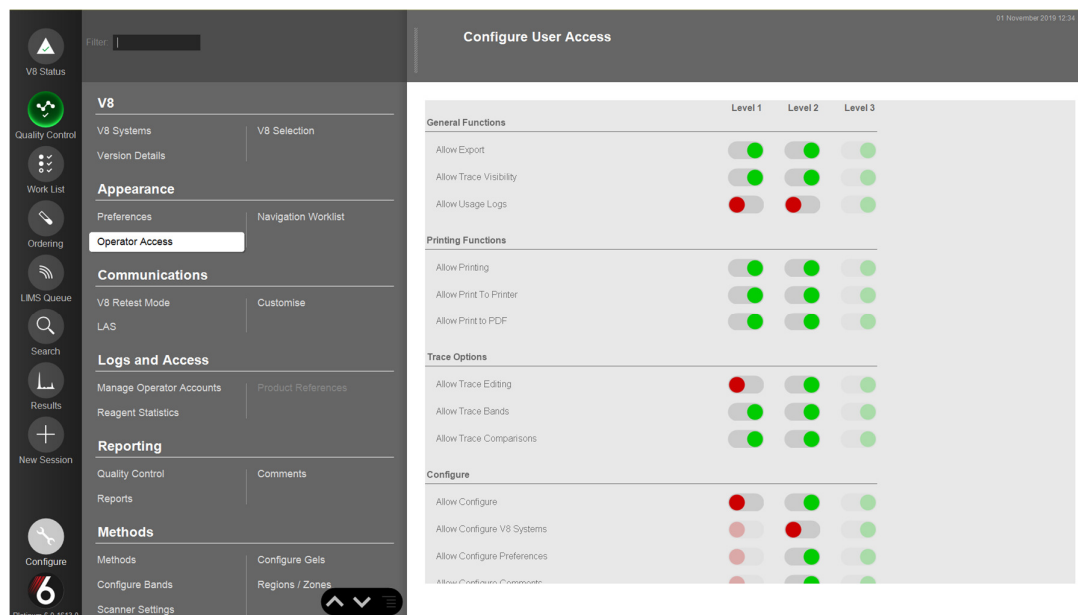
9.7 Navigation Worklist

The navigation worklist can be configured to show different runtime parameters and demographics as required. Add or remove columns using the +/- icons then select the content of each field using the options drop down menu. To configure the NWL, go to **Configure > Navigation Worklist**.



9.8 Operator Access

The Platinum permissions for each user level can be configured through the Operator Access tab. Setting a check slider to off disables that functionality for a user of that level. To configure the user access, go to **Configure > Operator Access**.



10. Gel sessions

10.1 Gel Mode

If a V8 system has not been configured in Platinum, Platinum will automatically open in 'Gel Mode'. In Gel Mode the unused V8 Status and Ordering tabs will not be visible.

10.2 Select Gel


To select a gel method, open a new gel session by going to **+** and selecting 'Create new Gel session'. Use the dropdown menu to select the gel type.

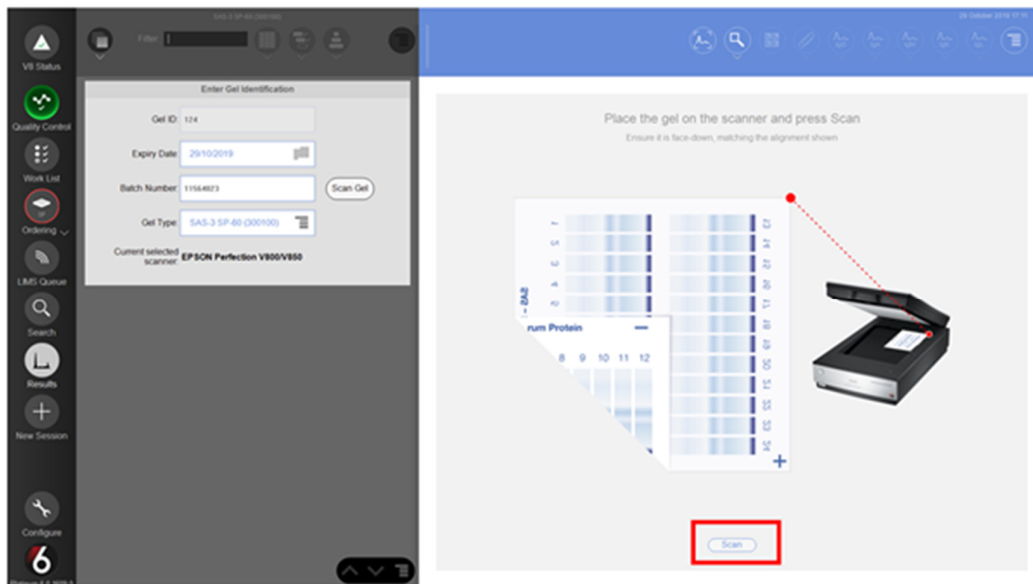
10.3 Scanning Configurations

10.3.1 Select a Scanner

The user can choose which scanner is to be used to import gel images to Platinum. All possible scan sources that are connected to the instrument will be listed in **Configure > Scanner Settings > Select Scanner**.

10.3.2 Prompting Platinum to Scan

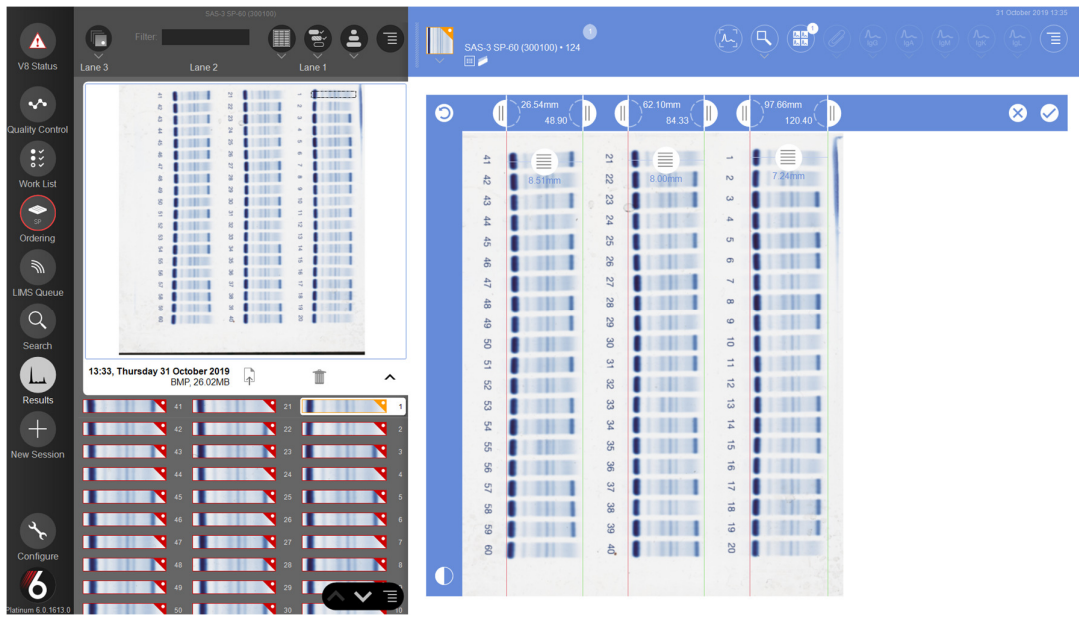
By opening a new gel session via the  icon, you will see a “Scan Gel” button which will prompt Platinum to scan the gel that is placed in the default scanner. In order to ensure data traceability, the ID of the gel must be entered (typed or scanned) in the window first before scanning commences.



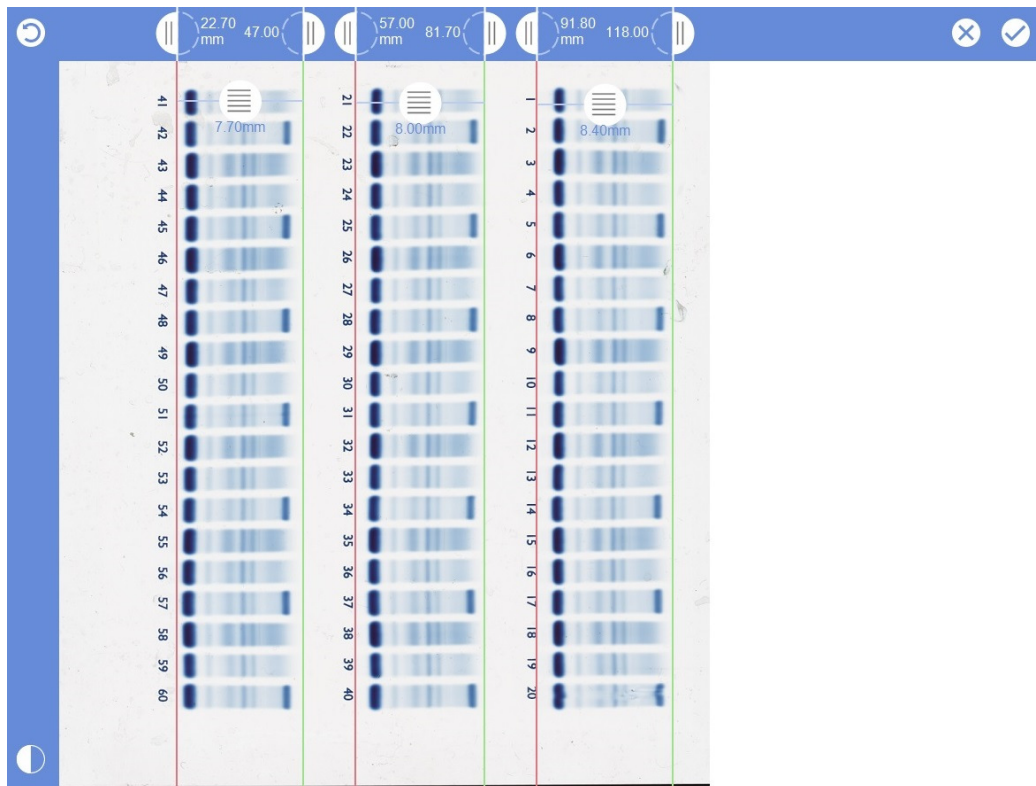
10.3.3 Aligning a Gel Template

Platinum automatically applies a gel template to gel images. It represents the areas of the gel from which the scan data will be analysed. There are several pre-set templates in the gel-type menu that correspond to particular configurations of gel size and sample number. These templates may, however, require slight adjustments to account for individual variation.


If the gel alignment needs adjusting, select the gel in the navigation worklist on the left hand side to display the ‘Align Gel’ markers:



Two vertical markers represent the left (red) and right (green) limits of each row and a single horizontal marker indicates the centre position of the first samples in each row. Each marker can be positioned by manually moving them. The displayed values are in millimetres (mm), and indicate the distance of the marker from the appropriate axis.



10.3.4 Marking a Gel

To see that a template fits correctly on a scanned image, use the  icon to overlay a template mask to the gel image. This allows the alignment of samples to be checked, which if out of line, can be corrected using the align gel function.

10.3.5 Configure Gels

In Platinum, it is possible to configure the methods that are used in processing the samples. These methods are used to specify the limits for each band, default smoothing and filtering levels, and other factors that are configurable.

11. Notice to Users

If any serious incident has occurred in relation to the device this should be reported to the manufacturer and the competent authority of the member state in which the user is established.

12. Definition of Symbols



Authorized representative in the European Community/European Union

12.1 Main Window Icons



Home Page



Warning



Connected to V8



Not Connected to V8



Quality Control Window



Quality Control Failed



Quality Control Timed Out



Quality Control Accepted



Quality Control Undefined



Work List



Search Window



Ordering Window



LIMS Queue Window



Results Window



New session



Configuration Window

12.2 General Icons (Icons that appear in more than one window)



Delete



Undo



Redo



Save



Print



Open



Select



View as Gels



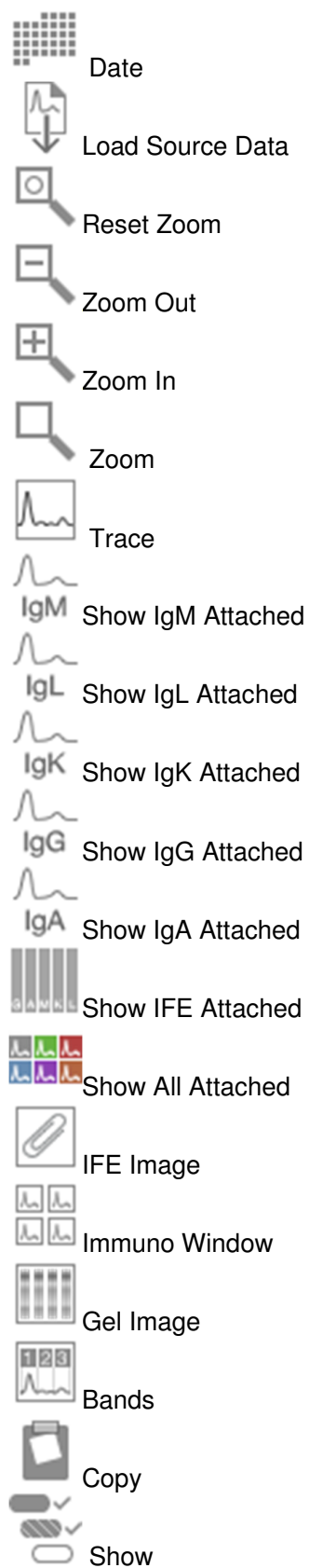
View as List



View as Traces





Sort





 Inspector window


12.3 Home Page Icons

 Language


 Help Page


 Platinum User Manual/Operator Manual


 Exit


 Product Activation


12.4 V8 Status Icons


 Reset Connection


 Start/Stop Logging


 Error


 Translate Status


 Show Timestamp


 Show System Data


 Show Performance Data

 Show Index

 Show End of Line Characters

 Update

 Capillary Disabled

 Capillary Enabled

12.5 Quality Control Icons



Rules



Scale to limits



Set Scale



Zoom Out

12.6 Work List Icons



Get Work List Data



Show Pending Trays



Show Conflicts



Add New Item



Show Chemistry Values

12.7 Ordering Icons



Order New Test



Remove Ordered Test

12.8 LIMS Queue Icons



Send Selected Approved to LIMS



Send Selected to LIMS



Send All to LIMS



Remove from LIMS Queue



Approval



Set Approval for Sending to LIMS



Clear Approval for Sending to LIMS

12.9 Search Icons



New Search

12.10 Results/Search Results Icons



Data



Reinterpret Trace



Copy



Reflex Using Method's Default Reflex Test



Reflex to Other



Allow Batch Reflex Tests



QC



LIMS



Add to LIMS Queue



Remove from LIMS Queue



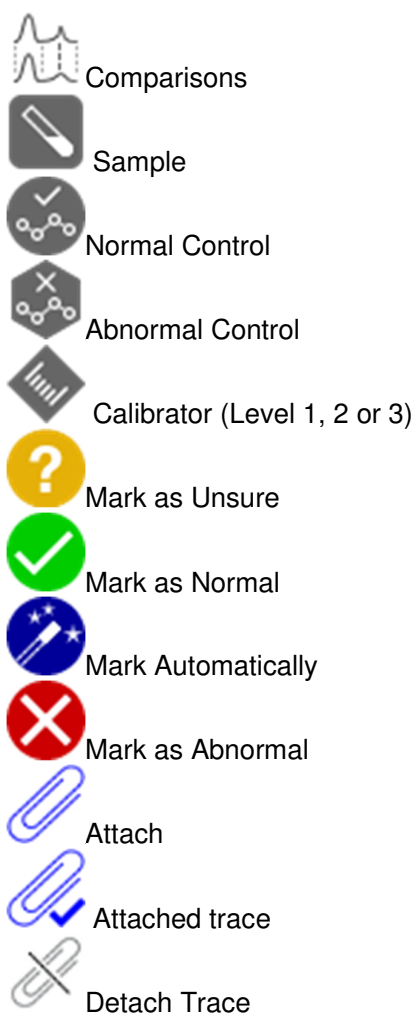
Send to LIMS



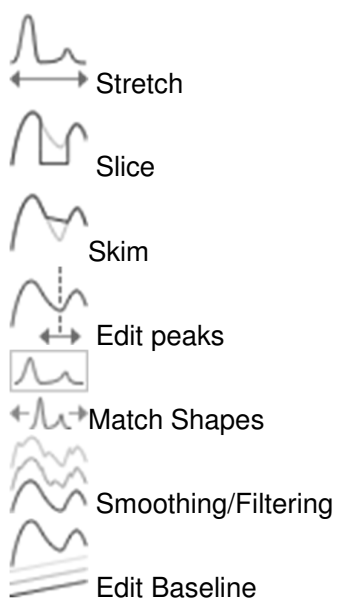
Edit

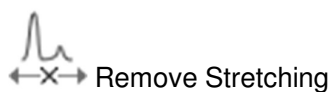


Order Other



12.11 Other Results Icons





Remove Stretching



Modified Session



Sessions



Exit Session

12.12 Gel Icons



Export image



Apply



Cancel



Mark Gel



Revert

12.13 Navigation Worklist Icons



Reflex Completed



Queued Reflex Test



Reflex Test Ordered



Comment added



CE Sample



CE Normal Control



CE Abnormal Control



Gel Sample



Gel Normal Control



























Gel Abnormal Control






Suspect QC



Accept QC

-  Sent to LIMS
-  Approved Sent to LIMS
-  Pending Send to LIMS
-  LIMS Approved
-  Expert System Warning
-  Expert System Normal
-  Expert System No Result
-  Expert System Too Few Bands
-  Expert System Too Many Bands
-  Expert System Bad Results
-  Expert System Reflex Test
-  No Result in the Database
-  Previous Monoclonal Result in Database
-  Previous Normal Result in Database
-  Previous Abnormal Result in Database
-  Traces Attached
-  Default Method
-  By Tube ID
-  By Location
-  Host Query
-  No Barcode
-  Archived
-  Run Locked
-  Comments Tree

12.14 Progress Pies

-  Sample Preparation
-  Start of Electrophoresis
-  Analysis

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Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

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