

Platinum Gel Analysis Software

Operator Manual

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Licence Agreement Revision History

A copy of the Platinum Gel Analysis Software licence agreement can be found in the following location after installation.

C:\ProgramFiles\Platinum\PlatinumLicense.pdf

Revision History

Amended section:	Date:	Comments:
First Issue	24/05/2013	Initial Publication
Second Issue	06/03/2020	Content updated for Platinum 6.
Third Issue	03/05/2022	Modification in line with the requirements of the <i>In Vitro</i> Diagnostic Regulation (IVDR) (EU) 2017/746, resulting in updates in some sections.
Fourth Issue	18/12/2024	Update to section 2.2
Fifth Issue	16/07/2025	Updated to section 1.1 & 4.2

Acronyms

CV	Coefficient of Variation
ESH	Electrophoresis Sample Handler
IFE	Immunofixation
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
Pt	Platinum
RTF	Rich Text File
SD	Standard Deviation

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Appendix 1

Toolbar functions in Platinum
 Notice to Users
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Scanner Compatibility

Please contact Helena Biosciences for validated scanner compatibility.

Installation Of Scanner

The scanner should be installed according to the instructions provided by the manufacturer.

Ensure the reflective document mat is removed before use.

Placement of the gel alignment template on the scanner

In order to scan transparently, the included Scanner Alignment Guide (Ref: 211800) must be placed on the scanner as per the instructions for use provided with the scanner alignment guide.

The origin (0) location is generally located at right rear of the scanner, where the transparency lid joins the base unit.

Platinum Software


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.

1.0 Log in to Platinum

1.1 Initial Log-in Screen

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



Operator

6 Platinum
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Platinum 6.0.133.0 on 1/4/2020
Patch Number : 133
Helena Biosciences Europe
Serial Number Button : B20000001A7F4784

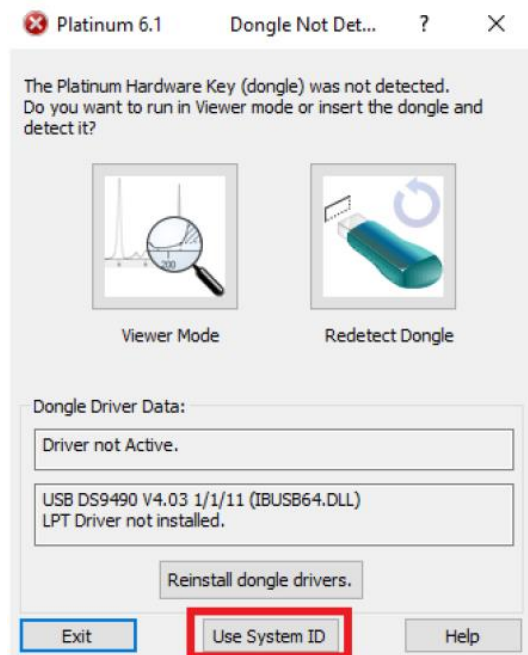
Operator: supervisor

Password: CAPS LOCK

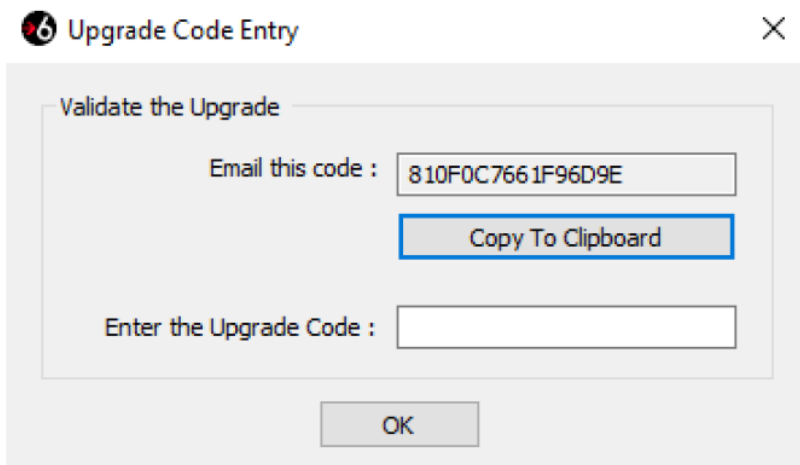
OK Exit Change Password...

On a Platinum system that does not have a Platinum dongle attached, it is possible to activate the main software and any additional features without the need for a dongle to be present (Platinum 6.1.111 onwards).

To do this, the System IF will be used for the activation, rather than the Dongle ID. When Platinum is first activated, the following window will appear. Select 'Use System ID':

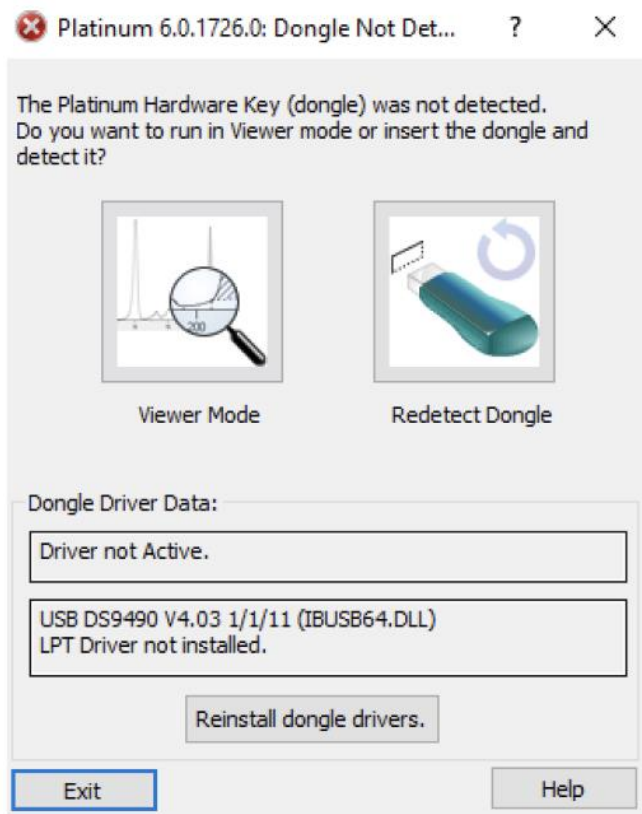


After you have selected 'Use System ID', the Upgrade Code can be sent to V8 Technical Support. V8 Support will then return an Activation Code which can be used in Product Activation.



NB. Customers who already have a dongle will not need to make any changes to their setup.

For Platinum systems that don't have a dongle and are running a patch prior to 6.1.111, the software will display a 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. However 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.



Once you have logged in, this window will appear. From here, you are given options that will determine the main action of the session:

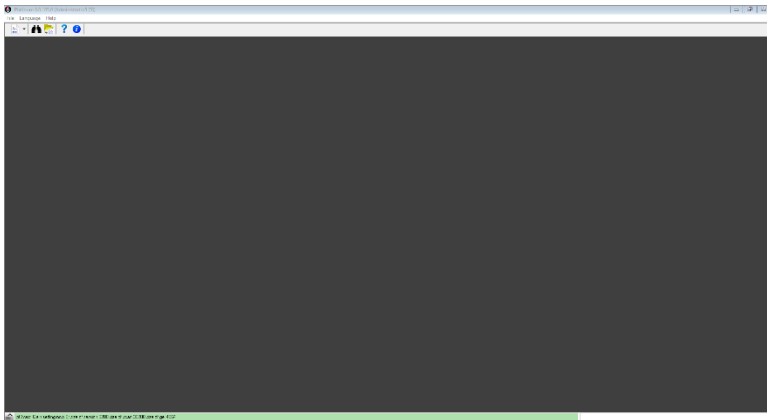
■ You can open a new Gel Session



■ Search for previously saved data



■ Or, open a saved file

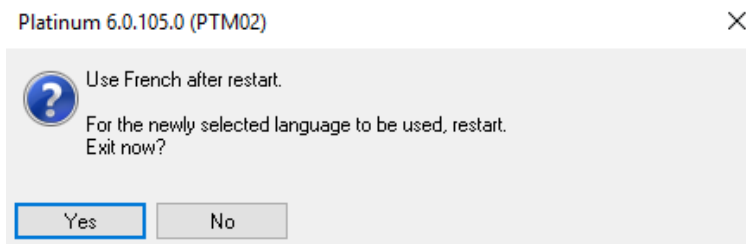


2.0 Platinum initial setup (Part 1)

The following settings must be configured before first use of the software to ensure correct operation.

2.1 Language

Selecting the Language menu heading provides a drop down list of available languages. To select an alternative language click on the language name. A window will appear informing you that the language selected will apply after the software is restarted. Clicking Yes will close the software immediately.



2.2 Configuration of demographics

The software allows up to 10 demographic fields (e.g. Tube Barcode, Patient Identification Number, Name, Date of Birth) to be set. This allows any future results to be searched / filtered by any of the fields set. The demographics apply to all methods used and should be only set once during the initial setup of the software. Open a new gel scan by choosing **File > New > Gel Scan**. Then choose **File > Customise**.

With the **Customisation** window open; click the **Configure Demographics** tab and input up to 10 demographic fields as required. (If the system is to be linked to a LIS/LIMS system either immediately or possibly in the future, then ensure wherever possible the demographic fields match identically to those used by the LIMS as this will significantly ease the LIMS linkup in the future).

The field type for each demographic can be selected from the drop-down list as appropriate for each demographic. The field marked as LIS identifier will be the location for the tube barcode. Select one demographic field to be used for searching similar data by selecting the check box. This is usually a unique patient identification number or a demographic field used as the LIS identifier. It is of paramount importance that the demographic field used as a LIS identifier, matches identically the field name being used by the LIS.

Customise [X]

Institution Data		Configure sample handler	Platinum Middleware	Configure Menu
Database	Sending to LIMS	Receiving from LIMS	Reports	Configure Demographics
Demographics:				
Index	Item	Field Type		
1	Tube ID	LIS Identifier		
2	Forename	String		
3	Surname	String		
4	DOB	Date		
5	Patient ID	String		
6	Hospital ID	String		
7	Demographic 7	String		
8	Demographic 8	String		
9	Demographic 9	String		
10	Demographic 10	String		

Demographics search mode: ▼

Archive searching: ▼

NOTE: Users shall report patient results under unique identification to ensure they are not misreporting.

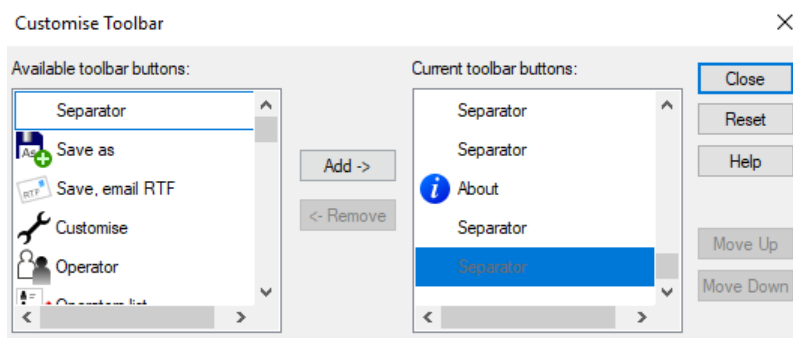
Click the **Save** button, save the file under the name **demos.dem** in the Platinum folder. Click **Load**, and find the file you have saved in the previous step. Choose the required file to open. This will activate the correct demographic fields. Click **OK** to return to the gel session.

3.0 Platinum initial setup (Part 2)

The following settings should be configured before first use of the software to ensure correct operation, although they can be changed at any time.

3.1 Toolbar Buttons

To change the toolbar icons visible on screen select: **File > Customise Toolbar**.



The left side of the window shows unused toolbar buttons, the right side those currently visible on screen.

To add or remove a toolbar button select the icon and then select **Add** or **Remove** button. To change the order of the toolbar buttons on screen use the **Move Up** / **Move Down** buttons to move each toolbar button. Once the required changes have been completed select the Close button.

3.2 Chemistry Values

Platinum allows up to 12 different chemistry values (e.g. Total Protein) to be input manually or imported from a LIMS per quantitative scan type.

To set the chemistry values for each scan type, from a gel session select **Gel > Configure Gels > Chemistry Values**.

SAS-3 SP-60 (300100)

Controls Carbamylated Albumin **Chemistry Value** Geometry Lanes Bands Calibration Smoothing/Filtering Gain Settings Regions/Zones Lot IDs Barcode

Configure Standard Methods Method type

Total Chemistry Value name : Total Protein

External compound name : Albumin

Concentration unit : g/l

LIMS Name:

Chemistry ID	Name	Unit	LIMS Name
Chemistry 1	IgG	g/L	IgG

+

OK Cancel Help

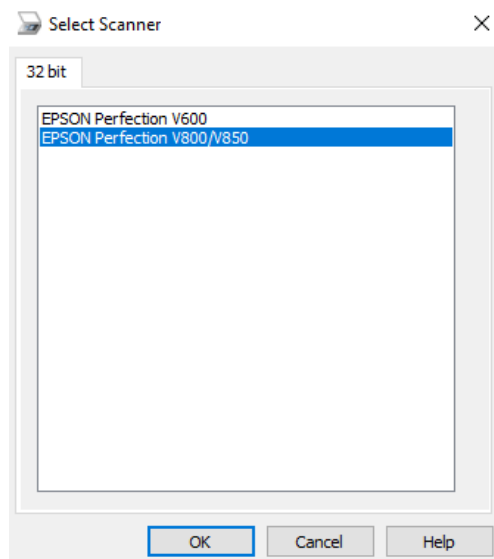
Enter the Name, Unit and the LIMS Name for each chemistry value.

Once complete click **Close** and the data will be saved.

3.3 Scanner

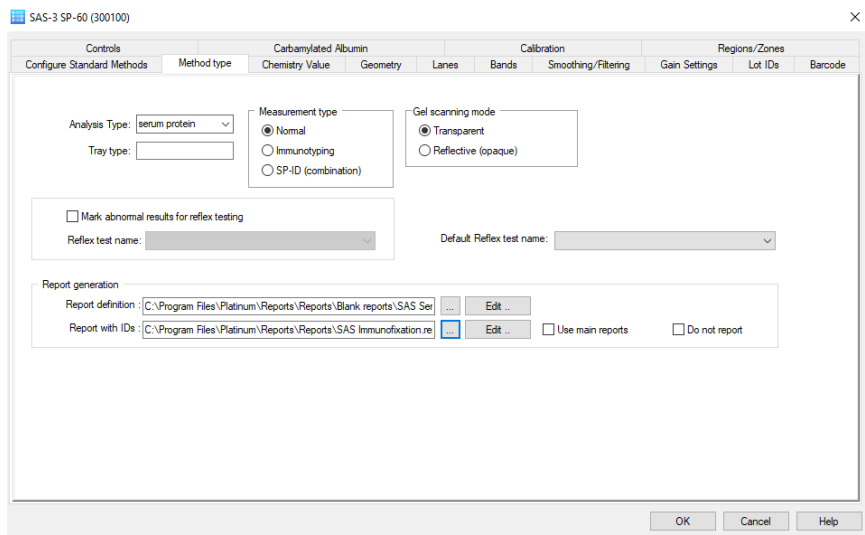
Once the scanner has been installed, you will be required to select the scanner model. From a gel session select: **Gel > Select Scanner**.

Highlight the scanner model. Note: If two options for the same scanner model are present **do not** select the option ending in WIA.



3.4 Reports

The report template used for each scan type must be set prior to scanning the gel. Once a template has been set it will apply to all future scans of that type. From a gel session Select **Gel > Configure Gels > Method Type**.



At the bottom of the window is a section titled Report Generation. Select the button marked ... at the end of the Report definition box. This will open a window allowing you to select an appropriate report template from the those supplied. Once selected the report can be edited by selecting the **Edit** button.

3.5 Normal Patient Ranges

Platinum allows entry of a normal range for patient samples. The normal range can be entered in either % or a concentration unit (as defined by the unit for total protein in the chemistry value setup).

Note: Values entered as % must be suffixed with a % symbol.

3.6 Control Ranges / Levey-Jennings

Platinum allows entry of ranges for both normal and abnormal control samples.

From a gel session select **Gel > Configure Gels > Lot IDs**.

SAS-3 SP-60 (300100) ×

Controls

Carbamylated Albumin

Calibration

Regions/Zones

Configure Standard Methods

Method type

Chemistry Value

Geometry

Lanes

Bands

Smoothing/Filtering

Gain Settings

Lot IDs

Barcode

Barcode entry:

Normal lot ID: Expiry Date (MM/YYYY):

Abnormal lot ID: Expiry Date (MM/YYYY):

Band statistics:

Band	Component	Low normal	Upper normal	Low abnormal	Upper abnormal	Mean normal	SD normal	Mean abnormal	SD abnormal
1	Albumin	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	(
2	Alpha 1	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	(
3	Alpha 2	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	(
4	Beta	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	(
5	Gamma	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	(

■ Enter the Lot numbers from the assay data sheet provided with the controls used, in the appropriate on screen box.

■ Ranges can be entered in either % or the concentration unit entered for Total Protein in the Chemistry Values tab (e.g. g/L). If the data is entered in as %, then each value must be suffixed with a % symbol e.g. 3.1% otherwise the system will assume it is a concentration unit.

Normal control ranges should be entered in the column **Low normal / Upper normal**.

Abnormal Control range should be entered in the column **Low abnormal / Upper abnormal**.

If Levey Jennings analysis is required then the Mean and Standard Deviation (SD) should be entered in to the **mean normal / abnormal and SD normal / abnormal columns**. These values can only be entered as % and **do not** require the suffix with a % symbol.

NOTE: The above data must be entered before scanning a gel. This information cannot be added retrospectively.

3.7 Barcode Position

Platinum allows a unique gel identification barcode to be scanned automatically by the scanner provided it is in a dedicated position on the gel. The location of the barcode is defined by the values shown on-screen.

To set the barcode location, from a gel session select **Gel > Configure Gels > Barcode**.

SAS-3 SP-60 (300100)

Controls Carbamylated Albumin Calibration Regions/Zones

Configure Standard Methods Method type Chemistry Value Geometry Lanes Bands Smoothing/Filtering Gain Settings Lot IDs Barcode

Barcode

☐ Scan for barcode

Left edge (mm) : 50.0

Upper edge (mm) : 128.0

Width (mm) : 33.0

Height (mm) : 10.0

Barcode scanning mode

☐ Transparent

☒ Reflective (opaque)

OK Cancel Help

Select **Scan for barcode** to activate the function.

Note: The barcode scanning mode should be set as reflective if the barcode is printed on an opaque material.

3.8 Default Control Position

Platinum allows a dedicated position on each row to be always automatically marked as a normal or abnormal control. To activate this function select the type of control and the standard lane position in which it will be run.

SAS-3 SP-60 (300100) ✕

Configure Standard Methods	Method type	Chemistry Value	Geometry	Lanes	Bands	Smoothing/Filtering	Gain Settings	Lot IDs	Barcode
Controls		Carbamylated Albumin			Calibration			Regions/Zones	

Default control positions:

<input checked="" type="radio"/> Not used	<input type="radio"/> Normal control	<input type="radio"/> Abnormal control	Position: 1	<input checked="" type="checkbox"/>
<input checked="" type="radio"/> Not used	<input type="radio"/> Normal control	<input type="radio"/> Abnormal control	Position: 2	<input checked="" type="checkbox"/>

OK

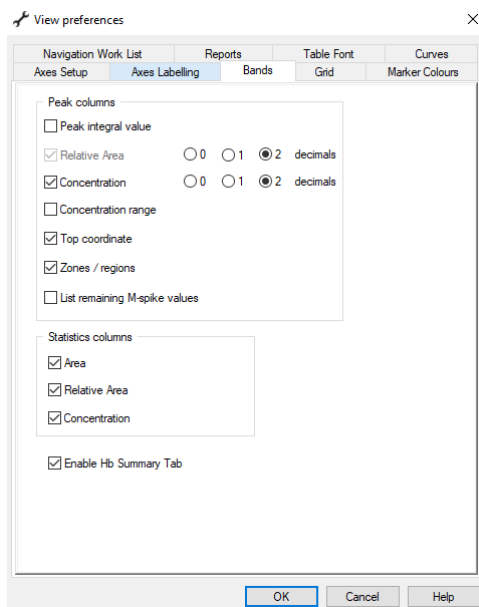
Cancel

Help

3.9 Display Preferences

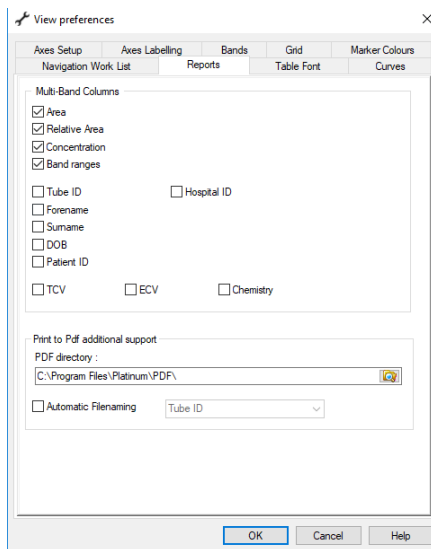
The display preferences can be set using the following option. From a gel session select **View > Preferences > Bands**.

The visible options on screen in relation to the quantitative data can be set by selecting the required option.



3.10 Reports

The columns visible on hard copy print outs such as the worklist can be selected using the tick boxes in the reports window. From a gel session select **View > Preferences > Reports**.



3.11 Operator levels

Platinum has 3 different operator levels offering user definable access from basic through to advanced access and function. The purpose of this is to control the release of data to the LIMS/LIS system by configurable access settings for audit trail purposes as well as creating user definable functionality.

Level 1

This is the lowest level of access, offering basic functions to acquire and analyse data, which is completely defined and controlled by the operator with Level 3 user status (see below). This level is useful for trainee personnel, or where restriction to configurable menus is required.

Level 2

Definable by the operator with Level 3 user status, this is the standard level of access offering functions to acquire and analyse data, and alter configurable menus.

Level 3

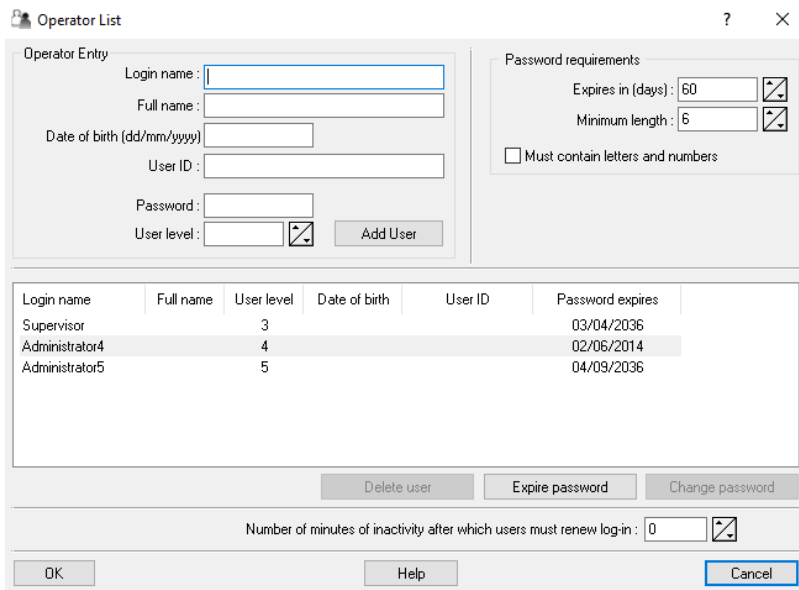
For the purpose of ensuring the validity and quality of data stored on the system, and transference to the hospital LIMS, Level 3 status is the highest level of access, granted to the laboratory supervisor or manager. Users that are designated level 3 access will have full control of all functionality and settings in Platinum .

Level 3 access controls user settings and assigns user level permissions. As each user is given a password, the Level 3 user will have access to the user control panel and will be able to expire (not view) passwords forcing a password change of users for additional security and control. The level of access for each operator is set by the Level 3 user.

When logging into Platinum for the first time, the Level 3 operator will be assigned a password set by Helena Biosciences. Please see your local distributor/sales representative for further information.

3.12 Adding a new user

Only users with level 3 (supervisor) can add a new user.



The dialog box is titled "Operator List" and contains two main sections: "Operator Entry" and "Password requirements".

Operator Entry

- Login name:
- Full name:
- Date of birth (dd/mm/yyyy):
- User ID:
- Password:
- User level: (dropdown menu)
-

Password requirements

- Expires in (days): 60 (dropdown menu)
- Minimum length: 6 (dropdown menu)
- ☐ Must contain letters and numbers

User List Table

Login name	Full name	User level	Date of birth	User ID	Password expires
Supervisor		3			03/04/2036
Administrator4		4			02/06/2014
Administrator5		5			04/09/2036

Buttons:

Inactivity: Number of minutes of inactivity after which users must renew log-in: 0 (dropdown menu)

Footer:

- Choose **File > Manage Operator Accounts**.

- In the dialogue boxes enter the required information according to the field. The criteria of the password, such as minimum length, expiry and format, can be assigned here by the Level 3 for added security. (Minimum data required: Login name: Password, User Level).

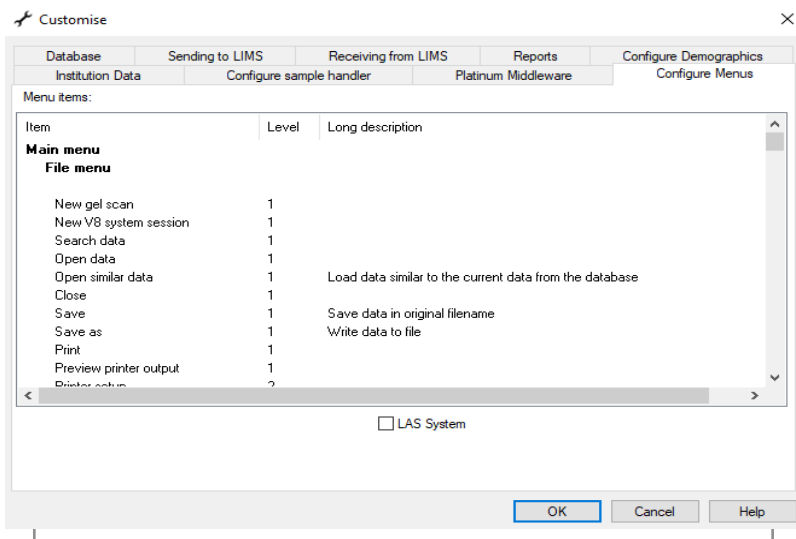
- After filling in the required fields, choose **Add User**.

3.13 Configuration of menus

The Level 3 user can configure user access by configuring the menus in the **Customisation** window. All menu items and functions are listed with a drop down menu of operator level access. The Level 3 user is able to customise each user level access by selecting **Level 1**, **Level 2**, or **Level 3** from the drop down level menu.

Choose **File > Customise** to open the customisation dialogue box.

Click the **Configure menus** tab from the customisation dialogue box.

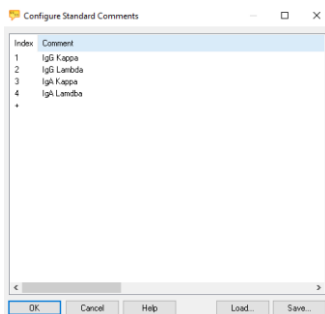


3.14 Configuration of visible scan settings

Platinum allows the user to show or hide the types of gels it is possible to scan to simplify the scanning process. To display only those gels used with the specific system, from a gel session select **Gel > Configure Gels**. In the usage column next to the gel scan name select **Hide** to remove this from view or **Main and Reflex** to enable the name to be seen.

3.15 Comments

Platinum allows user pre-configured text comments to be stored within the system. To add comments to the list, from a gel session select **Comments > Configure Comments**.

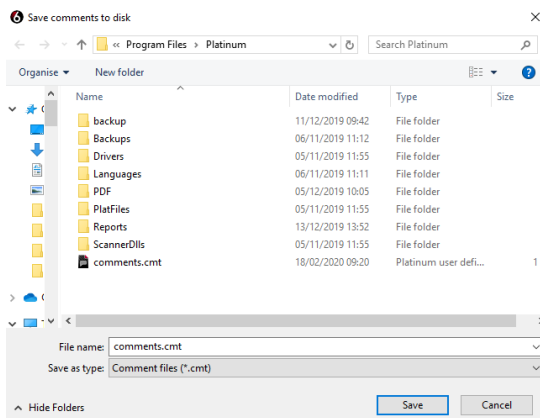


Appropriate text can then be entered into the column marked comment.

■ Once complete click Save.

Save the file as **comments.cmt** and if prompted to replace existing file choose **Yes**.

Click close to exit the configuration window.



3.16 Data Backup Location

To allow backup of the system database, a backup location must be defined. To define the location select **File > Customise > Database > Location for backups >** and select the button Identify the location for the backup and select OK.

The screenshot shows the 'Customise' dialog box with the 'Database' tab selected. The 'Location for backups' section is active, showing the path 'C:\Program Files\Platinum\Backups\'. The 'Location for new data' section shows the path 'C:\Program Files\Platinum\'. The 'MS Access' section has 'Network Database' and 'Slave' checkboxes, and a 'Network Database Location' field. The 'MS SQL Server' section has 'Activate MS SQL Server' and 'Change Server' buttons, and a 'Server' field set to 'localhost'. The 'OK' button is highlighted.

Institution Data		Configure sample handler		Platinum Middleware		Configure Menus	
Database	Sending to LIMS	Receiving from LIMS	Reports	Configure Demographics			
Data							
Location for new data :		C:\Program Files\Platinum\					
Location for backups :		C:\Program Files\Platinum\Backups\					
Use old session names :		<input type="checkbox"/>					
Use V8 name :		<input type="checkbox"/>					
MS Access							
Network Database :		<input type="checkbox"/>					
Slave :		<input type="checkbox"/>					
Activate MS Access		Network Database Location :					
		Passworded :					
MS SQL Server							
Activate MS SQL Server		Change Server		Server :			
				localhost			

4.0 Quick Start

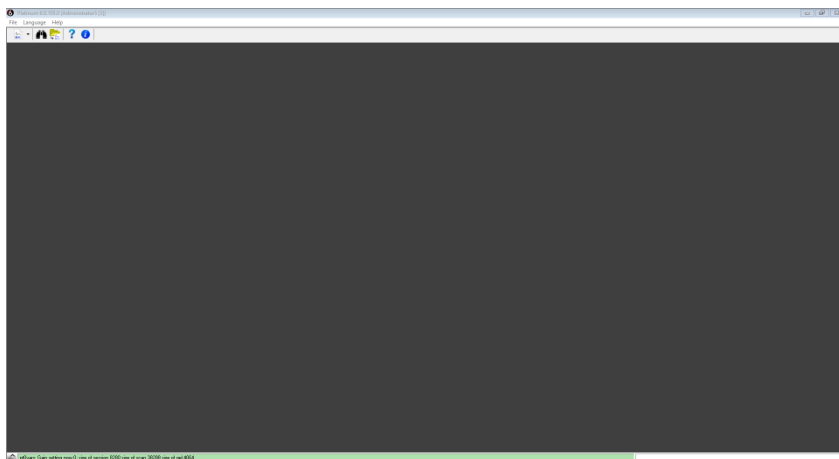
4.1 How to scan an agarose gel

This guide provides a short introduction into the basics of scanning a Helena agarose gel using Platinum software.

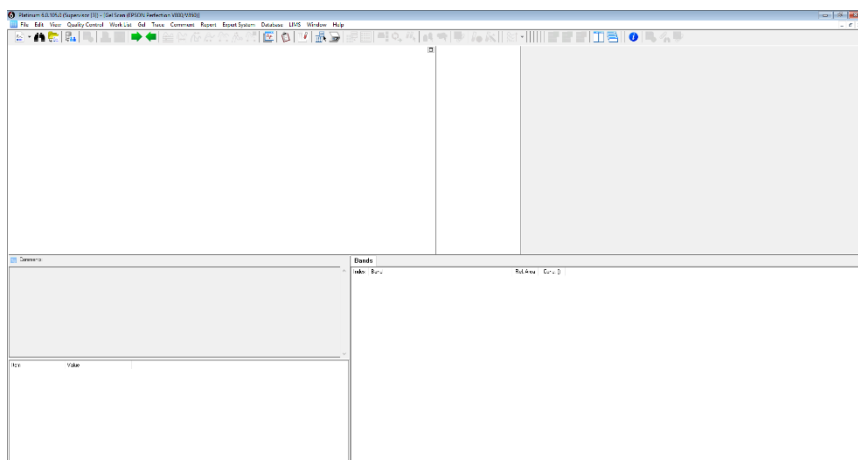
Open the Platinum software by double clicking the icon on the desktop.

Log into the software using the appropriate username and password.

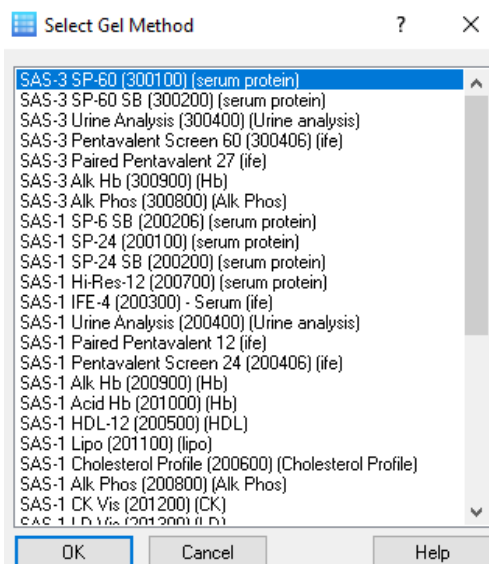
The home screen will appear.



Click the  icon or select **File > New > Gel Scan**, a new scan window will appear.



Select the gel type you wish to scan by selecting the **Gel > Select Gel**.



Select the type of gel you are running from the list, and select **OK**. If you wish to enter the patient sample barcodes and demographic information prior to scanning select **Worklist > Setup Work list**.

Set Up Work List


Work List ID: 123456 SAS-3 SP-60 (300100) ☒ Display external chemistry values

Line	Sample/Co...	Tube ID	Forename	Surname	DOB	Patient ID	Hospital ID	IgG (g/L)	IgG (g/L)	IgG (g/L)	IgG (g/L)
1	Normal Co...	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2	Abnormal Contr	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
3	Sample							0.00	0.00	0.00	0.0
4	Sample							0.00	0.00	0.00	0.0
5	Sample							0.00	0.00	0.00	0.0
6	Sample							0.00	0.00	0.00	0.0
7	Sample							0.00	0.00	0.00	0.0
8	Sample							0.00	0.00	0.00	0.0
9	Sample							0.00	0.00	0.00	0.0
10	Sample							0.00	0.00	0.00	0.0
11	Sample							0.00	0.00	0.00	0.0
12	Sample							0.00	0.00	0.00	0.0
13	Sample							0.00	0.00	0.00	0.0
14	Sample							0.00	0.00	0.00	0.0
15	Sample							0.00	0.00	0.00	0.0
16	Sample							0.00	0.00	0.00	0.0
17	Sample							0.00	0.00	0.00	0.0
18	Sample							0.00	0.00	0.00	0.0
19	Sample							0.00	0.00	0.00	0.0

Buttons: Add Blank, Clear All, << Prev, Next >>, Print..., LIMS..., Help, Close

In the worklist window select the **Add Blank** button until the required number of lines are visible for the number of sample positions used. The required data can now be added to the worklist for increased traceability as worklist ID can be entered in the worklist ID box.

NOTE: The worklist can be completed before or after scanning of the gel.

Click the  icon or select **Gel > Scan**

A window will appear, enter an identification number for the gel (if required or defined previously) and select **OK**

Enter Gel Identification

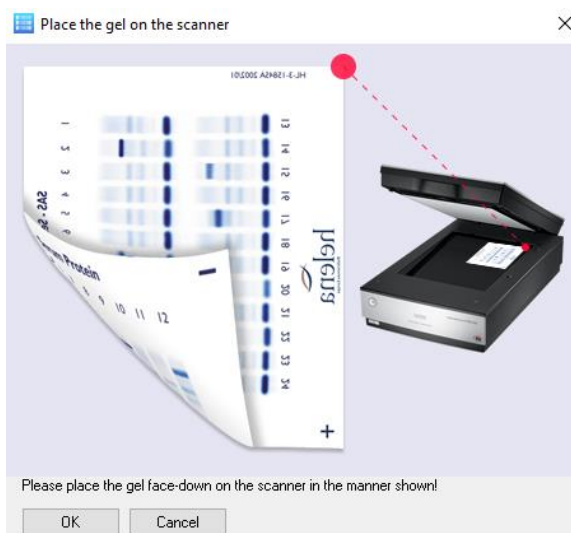
Gel ID:

Expiry Date (dd/mm/yyyy):

Batch Number:

OK **Cancel**

A window will appear displaying how to place the gel on the scanner.



Place the completed gel on the scanner agarose side down, close the scanner lid and select **OK**.

The gel scan will begin and progress will be shown on screen. Once scanning is complete the gel image will be visible on screen.

4.2 Aligning a gel template

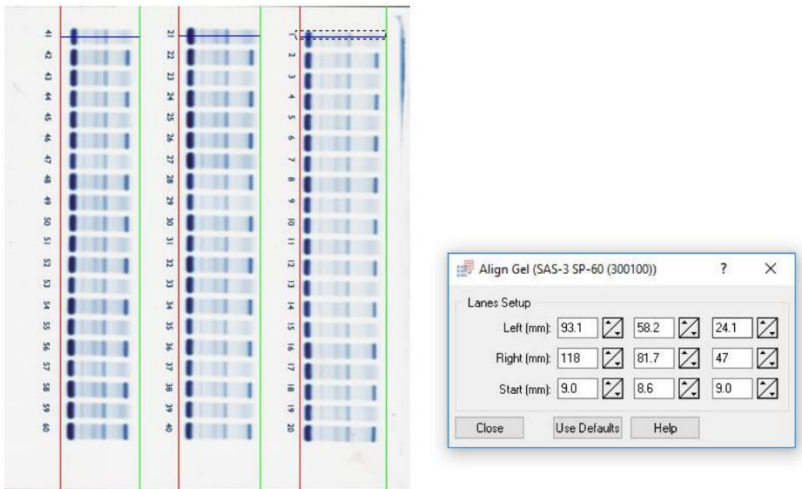
Platinum automatically applies a template to gel images. It represents the areas of the gel from which the scan data will be analysed and saved. These are pre-set in the gel-type menu and correspond to the particular gel size and sample number. These templates may, however, require slight adjustments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

Marking a gel

To ensure the correct area is analysed, selecting **Gel > Mark Gel** will overlay a template mask to the gel image. This allows the alignment of analysis area to be checked, which if out of line, can be corrected using the align gel function.

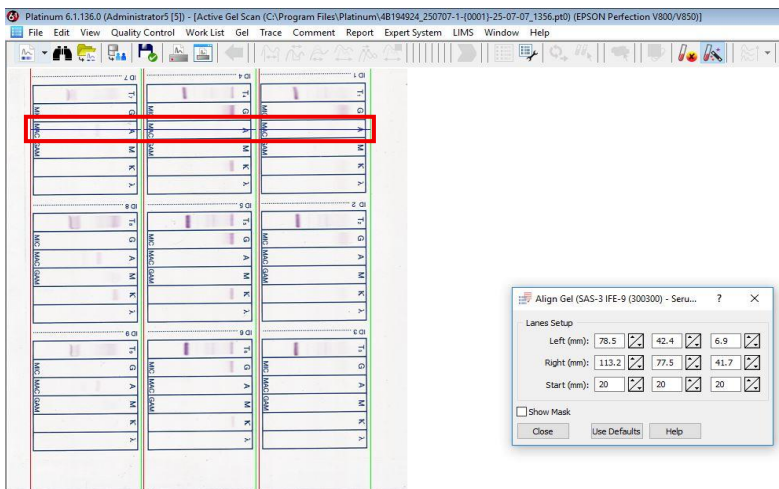
Aligning a gel

If after marking a gel it is found that the template requires adjustment then this is done by using the **Gel > Align Gel** function. When this is active, the template mask is removed and replaced by a set of three markers (red, green, blue) for each sample row.



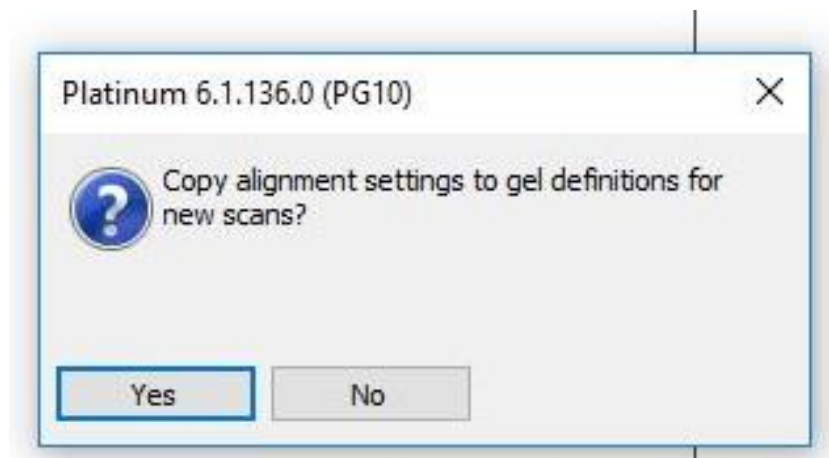
Two vertical markers represent the left (red) and right (green) hand limits of each row and a single (blue) horizontal marker indicates the centre position of the first sample in each row. Each marker can be positioned either by clicking and dragging with the cursor, or by altering the values that are displayed in the table. These values are in mm, and indicate the distance of the marker from the appropriate axis.

For an IFE gel, the horizontal markers should be positioned in the centre of the IgA lane:



NB. Do not move these markers beyond the edge of the gel.

Upon accepting a change to the alignment settings by selecting 'Close', an options box will pop up to ask if the setting should be saved for future gel scans:



Selecting 'Yes' will update the default values.


N.B. Result reporting should always be carried out directly from the original gel. The gel is scanned into Platinum only as a record of the result.

4.3 Configure gels

In Platinum, it may be necessary to configure the templates that are used in processing samples. These templates are used to specify what the limits for each protein fraction are, default smoothing and filtering levels, and other factors that are interchangeable. This function is only available at Level 3 user access.

5.0 Common User Functions

5.1 Searching for data

To locate previous sample results or whole gels in the database, the search tool can be used. Click  or choose **File > Search**.

To search for individual samples, select the **Samples** radio button, or to search for an entire gel scan select the **Session Ration** button.

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

Search
? ? X

Search Item	(Low) Value	High value		
System type	Any source ▾		<input checked="" type="radio"/> Sample <input type="radio"/> Session	
Scan type	Any type ▾			
Gel name	Any Name ▾			
Analysis type	Any type ▾			
Measurement time (dd/mm/yyyy)				
Gel ID				
Measurement status	Normal / abnormal ▾			<button>Clear</button>
Tube ID				
Patient ID				
Forename				
Surname				
DOB				
Demographic 6				<button>Search</button>
Demographic 7				<button>Archive Search</button>
Demographic 8				<button>Configure</button>
Demographic 9				<button>Help</button>
Demographic 10				<button>Close</button>

Search Results
□

Number of records found: 1478

Scandate	SystemType	Type	GelName	GelType	GelID	Measurement time	UpdateDate	Status
30	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Normal
32	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
33	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
35	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
36	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
37	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
38	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
39	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
40	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
41	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Normal
42	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
43	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
44	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
45	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
46	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
47	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
48	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
49	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
50	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
51	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
52	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
53	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
54	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal
55	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Normal
56	Gel Scan	Sample	SAS-3 SP-40 (...)	serum protein	19108-5555-(...)	07/11/2019 15:...	08/11/2019 15:...	Abnormal

<
OK
Select All
Deselect All
Cancel

Additionally, 7 generic filters are available:

System type:	Gel scans or CE sessions
Scan Type:	Sample, Normal (control), Abnormal (control), Calibration
Gel Name:	e.g. SAS-3, Serum Protein 3 band
Analysis type	Type of test e.g. serum protein
Measurement time (dd/mm/yyyy)	start and end date point can be selected.
Gel ID:	gel id input at point of scanning
Measurement status:	Normal or Abnormal

When searching for a session (entire gel), only 7 of the generic

Search

Search item	(Low) Value	High value
System type	Any source	
Scan type	Any Gel	
Gel name	Any Name	
Analysis type	Any type	
Measurement time (dd/mm/yyyy)		
Gel ID		

☐ Sample
☒ Session

Clear

Search

Archive Search

Configure

Help

Close

By inputting any required demographic filters i.e. patient ID and clicking the **Search** button, a list of search results will appear.

- To view the required search results, left click the mouse over the sample, this will highlight the sample blue. This can then be repeated for additional samples. Clicking **OK** will then display the samples selected.
- Additionally, it is possible to select or deselect all samples in the search results list using the appropriate button.

■ Sorting of results (e.g. newest to oldest) can be achieved by clicking on the results header.

Once the search results are displayed, basic viewing functions can be carried out. Right clicking the mouse over a sample provides an option to load the original gel to enable more detailed sample editing.

Once viewing is complete, the search window can be closed, and this will prompt to save any changes to a new file name. This should not usually be necessary as any editing should always be carried out on the original data file.


5.2 Editing

When a trace or gel image is first displayed, it is likely that the data will require some form of adjustment so that the correct interpretation of the result(s) 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 user the editing status. The colours correspond as follows:

Colour	Editing Status
Red	Lane is unedited and may have an incorrect number of peaks/bands or values are out of range.
Orange	Lane has been viewed and remains unedited. The sample has an incorrect number of peaks/bands or values are out of range.
Yellow	Lane has been viewed and edited. The sample has an incorrect number of peaks/bands or values are out of range. Marked monoclonal bands will result in a yellow colour.
Green	The lane has been viewed and has the correct number of bands with all values in range.
Grey	Simple Status mode can be activated in View > Preferences > Marker Colours.

Using this colour code, after editing of a session all normal samples should be green and all reportable samples should be yellow.

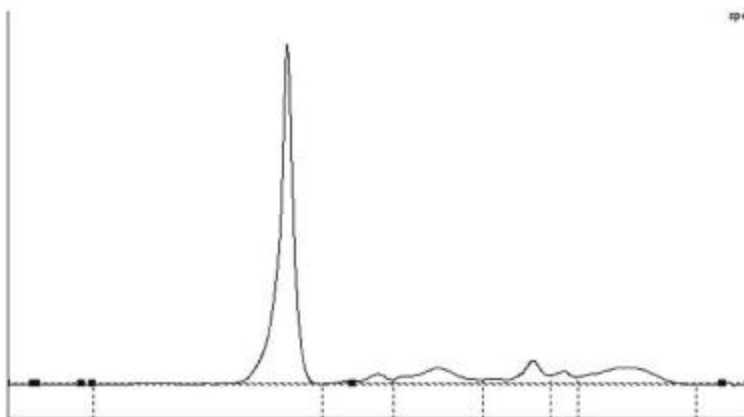
5.2.1 Editing baseline

Should it be required to edit the baseline, clicking the icon  or **Edit > Edit Baseline** will allow manual movement of the baseline.


Moving the computer mouse over the edges of the baseline will show a four point arrow over the trace, allowing movement of the baseline on an angle for each edge of the trace. **Holding down the SHIFT key** while moving the baseline allows movement in a horizontal plane up and down.

5.2.2 Spline node addition

Right clicking over the trace allows the option of adding or deleting a spline node from the baseline.



5.2.3 Editing peaks

Once a sample is selected, the peaks may be edited by clicking the **edit peaks** icon  or choosing **Edit > Edit Peaks**. Right clicking over a peak on the sample trace provides specific options that are possible for the selected peak.

5.2.4 Add trough marker

To add an additional trough marker to a trace, move the mouse to the desired location for the marker and right click. Choose **Add trough** from the drop down menu, 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. (A double arrow will appear when hovering over the trough marker).


5.2.5 Delete trough marker

To delete a surplus trough marker, move the mouse over the surplus marker (a double arrow will appear) and right click. Now choose **Delete Trough** from the drop down menu; the marker will then be removed from the trace.


5.2.6 Split peak

To split a peak by addition of a trough marker move the mouse to the desired location for the marker and right click. 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 (a double arrow will appear when hovering over the trough marker).

5.2.7 Smoothing

To smooth a trace, click the  icon, or choose **Trace > Smoothing** from the drop down menu.

5.2.8 Filtering


To filter a trace, click the  filtering icon, and choose either the option of threshold filtering or slope, or select **Trace > Threshold Filtering** or **Trace > Slope Filtering** from the drop down menu.

5.3 Overlay functionality

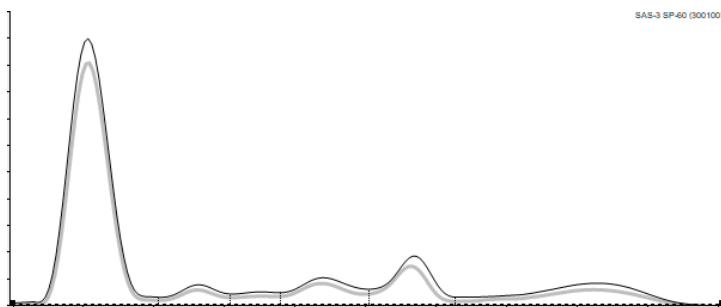
The overlay function enables comparison of a sample trace against a previously specified 'norm' or against another sample.

5.3.1 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 clicking on the icon  or choosing **Trace > Use as Normal Overlay** from the drop down menu. The defined trace will then be shown in grey on screen, as shown below.

To switch the normal overlay on/off, right click on the trace and select “**show normal overlay**”.




5.3.2 Overlaying of sample traces on screen

Holding the **SHIFT** key while selecting a second sample trace will also select all samples between the original and the newly selected sample, allowing overlay of the samples.

N.B. A maximum of two gel images can be seen in the overlay function.


Holding **CTRL** key while selecting a second sample will only select the two samples (original and the newly selected sample), allowing overlay of the two samples. Additional samples can also be selected in the same manner.

5.3.3 Match Shapes

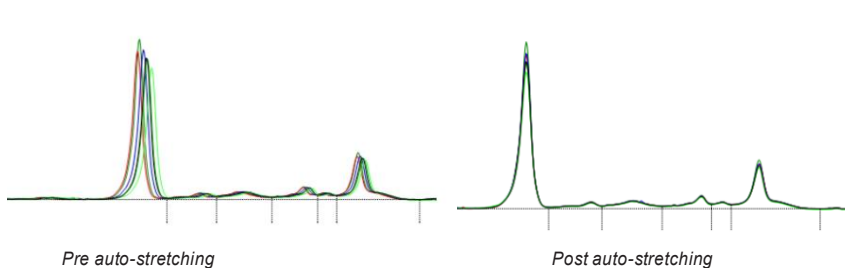
When Overlaying sample traces it may often be necessary to match the overlay from one sample to another. Platinum automates this to make it as quick and simple as possible. To do this simply highlight two or more traces that you would like to be matched and click **Edit > Match Shapes** or on the toolbar click the  icon.

5.3.4 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 holding down the **Ctrl** key whilst selecting from the sample list, and then click the **stretch** icon  or choose **Edit > Apply Stretching** from the drop down menu.


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



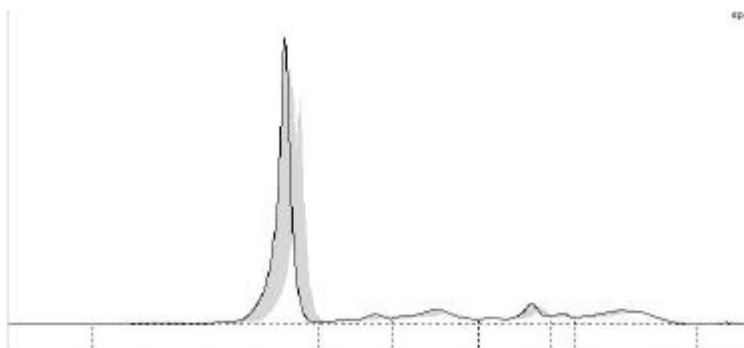
5.3.5 Mean traces

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, highlight the sample and choose **Trace > Add to Mean Traces** from the drop down menu.

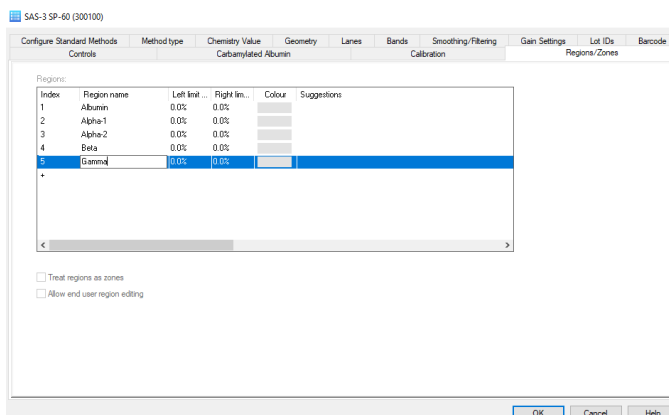
To view the traces used to compose the mean overlay, click the icon  or choose **Trace > Load Mean Traces** from the drop down menu.

Right clicking on a sample in the list provides an option to remove a specific sample from the mean overlay.

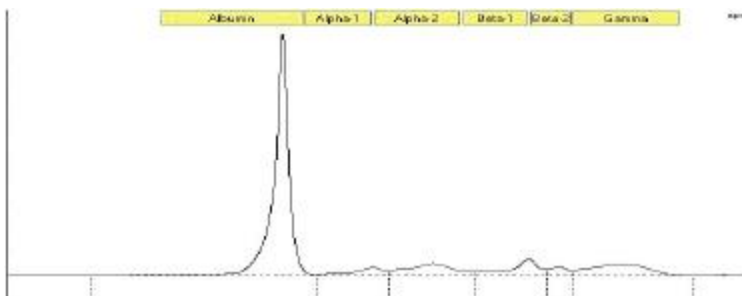


5.3.6 Trace regions

Choose **Gel > Configure Gel > Regions/Zones tab**, 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.




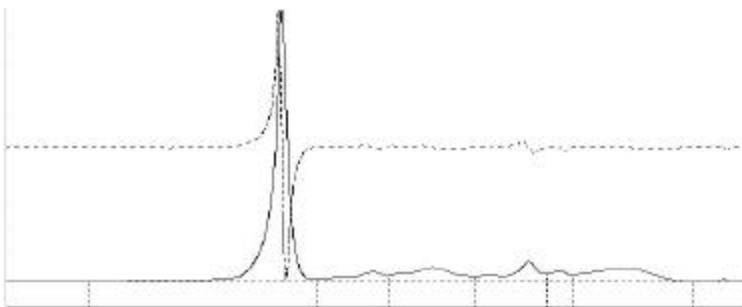
To select regions based on a trace displayed, then choose **Gel > Edit regions / zones** from the drop down menu.



5.3.7 First derivative

Shows the first derivative of the selected trace.

Choose **View > Trace Options > Show Derivative**, click the show derivative icon  or alternatively right click on the trace and select **Show Derivative**. This will show the first derivative of the trace as a dotted line. To remove this, right click on the trace and **un-tick Show Derivative** in the drop down menu.



5.4 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.

NOTE. It is recommended that users choose one method or the other, and do not under any circumstances inter-change between methods as this can lead to changes in patient monoclonal quantitation overtime, due to the different methods of measurement used.

5.4.1 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.

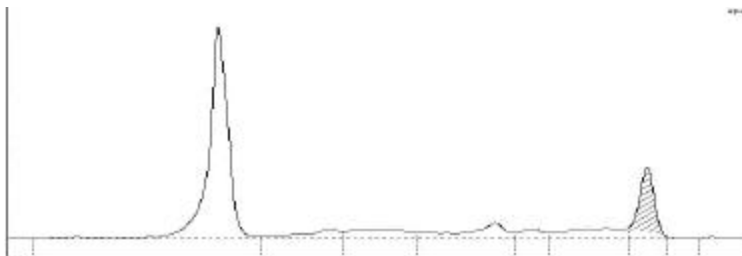
Adding a skimmed M-spike

Select the Edit Peaks icon, then right click 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,

hover the mouse pointer over the trough marker until a double headed arrow appears, then drag and drop until a suitable location is found.

The band list will now contain an extra band called M-spike with additional prefix 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%.



Example of a monoclonal spike quantitated using the skimmed M-spike function

5.4.2 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.

Adding a sliced M-spike

Select the Edit Peaks icon, then right click on the monoclonal spike and select **Add sliced M-spike**. Platinum will then estimate the extent of the monoclonal spike and highlight this area by filling in the trace to the baseline with hashed lines. To edit the location of the start and end points of the area quantitated, hover the mouse pointer over the trough marker until a double headed arrow appears, then drag and drop until a suitable location is found.



Example of a monoclonal spike quantitated using the sliced M-spike function

5.4.3 Removing an M-spike


To remove an un-necessary M-spike, right click the mouse while hovering over the M-spike and choose **Remove M-spike**. The hashed area will then be removed.

5.5 Removing artefacts from traces


Artefacts are not common, but are sometimes a problem; these functions enable the removal of an artefact from a trace without disturbing the data.

5.5.1 Slice data

To edit a trace to remove an unwanted artefact (to the baseline),


click the icon  or choose **Edit > Apply Slice** from the drop down menu and then using the mouse, left click and drag the mouse over the area to be removed.

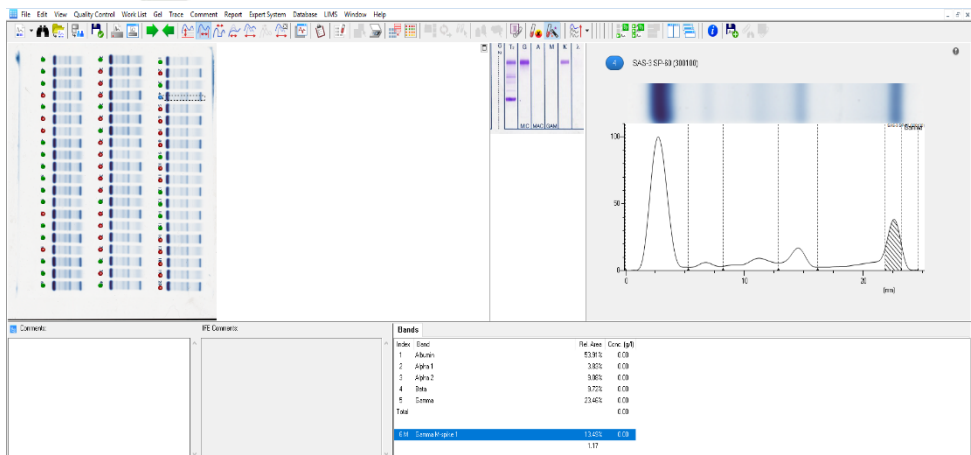
5.5.2 Skim data

To edit a trace to remove an unwanted artefact whilst maintaining the general progression of the curve (peak to peak), click the **skim data** icon  or choose **Edit > Apply Skim** from the drop down menu. Using the mouse, left click and drag the mouse over the area to be removed, this will be highlighted by a series of vertical bands (releasing the mouse button will complete the process).

5.6 Searching for & attaching an Immunotyping result

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

Select the serum protein sample to which the IFE is to be linked, and select **Gel** > **Search & Attach Immunotyping** or the 'search and attach immunotyping' icon  (demographic data must be present).



Search Results

Number of records found: 1

ScanID#	SystemType	Type	GelName	GelType	GelId	Measurement time	UpdateDate	Status
1506	Gel Scan	Sample	SAS-3 IFE-9 (3...	ife	000129-68-55...	18/02/2020 10:...	18/02/2020 10:...	Normal

OK Select All Deselect All Cancel


A search window will appear. Click the search button, and once the results have appeared, highlight any immunotypes (IFE) you wish to link to the serum protein. Click **OK**. The linking will now take place and the window will close.

N.B. To detach a linked immunotyping right click on the immunotyping result and choose **Detach**.

5.7 Result comments

It is possible within Platinum to store predefined comments which can be added to the individual sample records. (see section 3.15)

5.7.1 Adding a comment to a sample result

To add a comment to a result select **Comment > Add comment** or click the **add comment** icon  and then highlight the required comment and click **OK**. The comment will appear in the **comments** window.

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

5.8 Levey-Jennings

This function allows the user to ensure that results obtained for patient samples are correct through the use of a corresponding control. In addition, it enables the development of trends in performance before a control actually falls out of range.

5.8.1 Setting up the Levey-Jennings analysis (see section 3.6)

5.8.2 Day to day running of controls and Levey-Jennings

■ Scan the gel containing the control. (If an abnormal control is to be viewed in the Levey-Jennings plot, then a normal control must also be present on the same gel).


■ Mark the lane containing the control either using the drop down box in the worklist or by choosing **Trace > Mark as normal / abnormal control**.

Set Up Work List

Work List ID: 1112 SAS-3 SP-60 (300100) ☒ Display external chemistry values

Line	Sample/Co.	Total Pt.	Abundance	Tube ID	Forename	Surname	DOB	Patient ID	Hospital ID	lgG (g/L)	lgG (g)
1	Sample	0.00	0.00								
2	Sample	0.00	0.00								
3	Normal Control	0.00	0.00								
4	Calibrator Level 1	0.00	1111								
5	Calibrator Level 2	0.00	0.00								
6	Calibrator Level 3	0.00	0.00								
7	Sample	0.00	0.00								
8	Sample	0.00	0.00								
9	Sample	0.00	0.00								
10	Sample	0.00	0.00								
11	Sample	0.00	0.00								
12	Sample	0.00	0.00								
13	Sample	0.00	0.00								
14	Sample	0.00	0.00								
15	Sample	0.00	0.00								
16	Sample	0.00	0.00								
17	Sample	0.00	0.00								
18	Sample	0.00	0.00								
19	Sample	0.00	0.00								

Buttons: Add Blank, Clear All, Print, LIMS, Help, Close

- Click **Save** or close the gel scan window to save the updated information.
- Select the Levey-Jennings plot by clicking the icon  or choose **Validation > Show Levey-Jennings** from the drop down menu.
- Select the gel type, control type and then input the date range you wish to analyse, select any Westgard rules you wish to apply, then click **OK**.

Search for Controls

Method selection



Method type

Fast CE Control
Hb UltraScreen Prelysis
Hb UltraScreen Quantitative Control x 4
Hb UltraScreen x 8
SAS-3 SP-60 (300100)

Control type:

☒ Normal
☐ Abnormal
☐ Both

Lot ID :

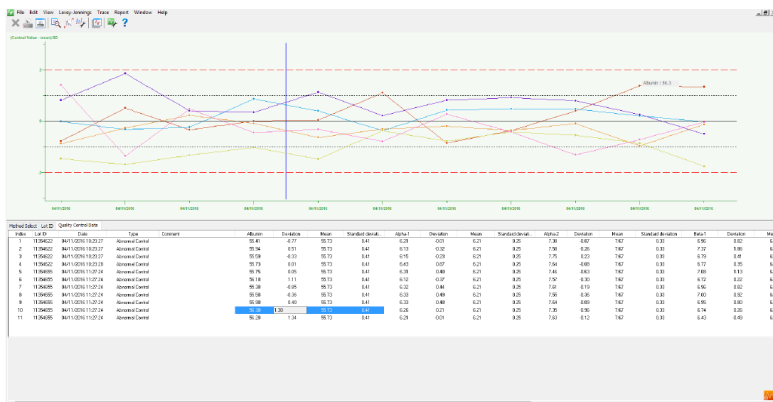
Start date: 
End date: 

Rules selection

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

Buttons: OK, Cancel, Help

- A Levey-Jennings plot will appear.



- Different bands can be viewed by right clicking over the table and choosing the appropriate band from the menu.
- Any Westgard exceptions will be highlighted with the Westgard rule number coloured red in the table. Hovering over this text will show further information.

5.9 Performing statistics in Platinum

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, choose **Edit** > **Select All** or hold down the **Ctrl** key whilst selecting the desired samples.

To display the statistics window after all of the required samples have been selected, choose **Gel > Statistics**.

The index of each band is displayed in the Index column with the number of samples n 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 [View > Preferences](#) window. These columns are used to display the mean, standard deviation, and the C.V. for the area, area %, or concentration

5.10 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.

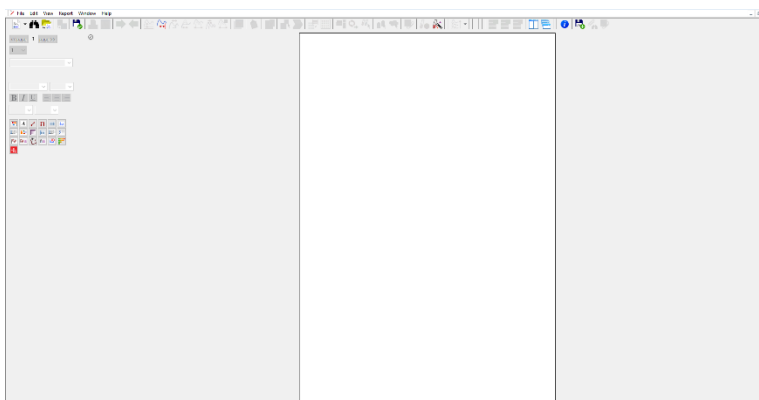
5.10.1 Create new report

In order to create a new report, choose **Report > New Report**.

This will open a new report window that will display the report template layout with all of the functions that are required to create new templates.

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 result is to be shown, where it is to be situated, and what demographic data is displayed. Data such as peak values and immunofixation images can also be included.



5.10.2 Edit report

To edit the current method dependent default report, choose **Report > Edit Current Report template**.

To edit another user selected report template, choose **Report > Edit Other Report template**.

This will enable selection from a list of saved reports, when one is selected, choose **Open**. This will open the report in a new window with all the required functions to edit the report.

5.10.3 Preview report

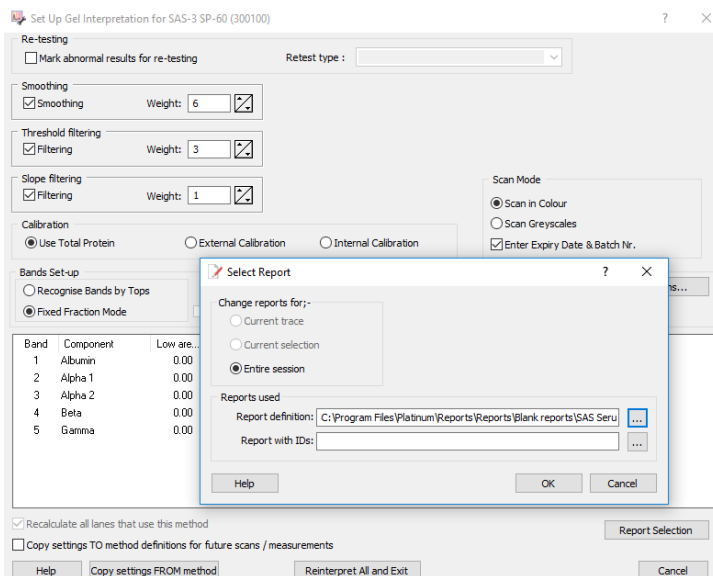
To preview a report before printing, choose **Report > Current Report**.

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.

5.10.4 Applying a report definition retrospectively to data

From time to time it may be necessary to use a different report or apply a new report to some old data retrospectively. In this circumstance the user may wish that this application be session specific. This is possible using the following method:

- From the main Platinum window, select, **Gel > Configure Bands**.
 - Select "Report Selection", followed by the ... button (see below) in the report definitions column, this is the report to be selected for the Serum protein without IDs. The default location for the reports files is in the following location: C:\Program Files\Platinum.




- Reports with IDs is not applicable to gel scanning.
- This report definition will be applied to this session only.

Select "OK" on the reports box and "Cancel" on the Configure Bands box as this will apply the report to the current session without reinterpreting the gel. Another option (using non-touch version only) is to select Report > Select Report.


5.11 Database

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

5.11.1 Back up new data

To back up new data in Platinum, choose **Database > Back-up > New and Changed** or click the  icon.

5.11.2 Back up all data

To back up all data in Platinum, choose **Database > Back-up > All** or choose the  icon.

5.11.3 Archive selected data

To archive selected data in Platinum, choose **Database > > Archive Selected Data**.

This option is available, however if Archiving is required, is it recommended to change to an SQL Database.

5.11.4 Compact the database

To compact the Platinum database, choose **Database > Compact Database**.
Note: Only Access databases can be compacted.

5.11. 5 Database Maintenance

To be used as a troubleshooting tool which includes validation of sessions.

5.11. 6 Database Backup

To backup and recover databases. Both MS Access and MS SQL database systems are supported.

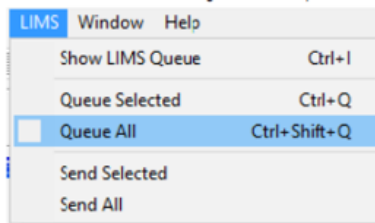
5.12 LIMS

Controlling data to the LIMS/LIS

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


5.12.1 Sending data to the LIMS queue

Samples are sent to the LIMS/LIS holding queue so that once a user of suitable seniority has validated the data as acceptable it can be sent to the LIMS database. To send an individual lane or several lanes currently selected to the LIMS queue, choose **LIMS > Queue Selected**. To send the whole CE session or gel scan to LIMS then choose **LIMS > Queue All**.



Those samples sent to the LIMS queue will be marked with an orange icon.

5.12.2 Viewing and releasing data in the LIMS queue

To view those samples in the LIMS queue click the icon  or choose **LIMS > Show LIMS queue**.

- To approve an individual sample to be released from the LIMS queue, choose **Trace > Approve** sending lane to LIMS. The red arrow marking the sample will now turn green.
- To approve multiple selected samples to be released from the LIMS queue, choose **Trace > Approve sending selected lanes** to LIMS. The red arrow marking the samples will now turn green.
- To prevent a previous approved individual sample from being released from the LIMS queue, click the Disapprove sending to LIMS icon **Trace > Disapprove sending lane to LIMS**. The green arrow will now turn red.
- To prevent multiple previously approved samples from being released from the LIMS queue, click the **Disapprove sending to LIMS**. The green arrow will now turn red.
- To remove an individual sample from the LIMS queue, choose **Trace > Do not send to LIMS**.
- To remove multiple samples from the LIMS queue, choose **Trace > Do not send selected lanes to LIMS**. Any arrow present will be removed and the

sample will not appear in any future LIMS queue searches.

- Once the appropriate samples have been authorised to be sent to the LIMS database, select either **Send selected and approved** or **Send all approved** depending on the requirement to send the results to the LIMS database.
- To display the progress of the LIMS transfer, choose **LIMS > Inspect**.

5.12.3 Sending sample data directly to LIMS

Samples can be sent directly to LIMS / LIS bypassing the use of the queuing system. This is accessed from the same menu as the queuing function.

- To send the whole CE session or gel scan to LIMS, choose **LIMS > Send All** or **Send selected**.


N.B. If the queuing system is the preferred method of sending data to LIMS, the function for sending directly to LIMS must be locked out by the user, using the method described in configuration of menus.

5.13 Usage log

The usage log stores a full history of operator data and decision-making.

5.13.1 Gel Session usage log

Shows a list of the user activity for the current active session.

To view this, click the  icon or choose **Quality Control > Show Gel Usage Log**.


Session Usage Log : C:\Program Files\Platinum\20-02-18_1102.pt0

Close Gel ID: 000129-68-(1112)-20-02-18_1102
Gel file: C:\Program Files\Platinum\20-02-18_1102.pt0

Help Print... Export...

Li...	User name	Date & time	Type	Subtype	Ind...
1	Supervisor	18/02/2020 11:...	Edit	Trace	1
2	Supervisor	18/02/2020 11:...	Edit	Trace	2
3	Supervisor	18/02/2020 11:...	Edit	Trace	3
4	Supervisor	18/02/2020 11:...	Edit	Trace	4
5	Supervisor	18/02/2020 11:...	Edit	Trace	5
6	Supervisor	18/02/2020 11:...	Edit	Trace	6
7	Supervisor	18/02/2020 11:...	Edit	Trace	7
8	Supervisor	18/02/2020 11:...	Edit	Trace	8
9	Supervisor	18/02/2020 11:...	Edit	Trace	9
10	Supervisor	18/02/2020 11:...	Edit	Trace	10
11	Supervisor	18/02/2020 11:...	Edit	Trace	11
12	Supervisor	18/02/2020 11:...	Edit	Trace	12
13	Supervisor	18/02/2020 11:...	Edit	Trace	13
14	Supervisor	18/02/2020 11:...	Edit	Trace	14
15	Supervisor	18/02/2020 11:...	Edit	Trace	15
16	Supervisor	18/02/2020 11:...	Edit	Trace	16
17	Supervisor	18/02/2020 11:...	Edit	Trace	17
18	Supervisor	18/02/2020 11:...	Edit	Trace	18
19	Supervisor	18/02/2020 11:...	Edit	Trace	19
20	Supervisor	18/02/2020 11:...	Edit	Trace	20
21	Supervisor	18/02/2020 11:...	Edit	Trace	21
22	Supervisor	18/02/2020 11:...	Edit	Trace	22
23	Supervisor	18/02/2020 11:...	Edit	Trace	23

5.13.2 Sample usage log

Shows a list of the user activity for the individual sample trace that is currently selected on screen. To view this, click the  icon, or select **Quality Control > Show sample usage log**.

Sample Usage Log : Trace = 3

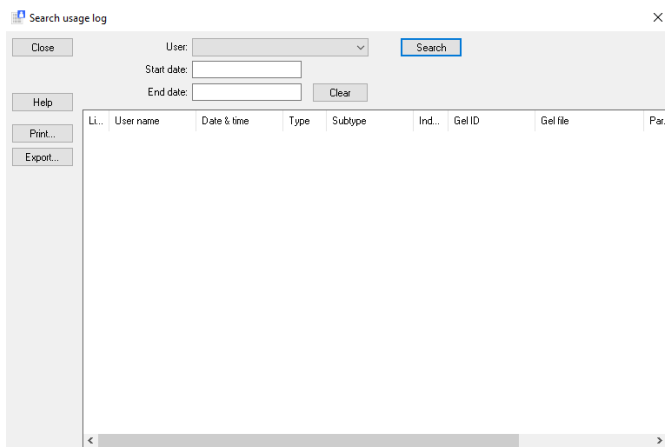
Close Gel ID: 000129-68-(1112)-20-02-18_1102
Gel file: C:\Program Files\Platinum\20-02-18_1102.pt0

Help Print... Export...

Li...	User name	Date & time	Type	Subtype	Ind...
1	Supervisor	18/02/2020 11:...	Edit	Trace	3
2	Supervisor	18/02/2020 11:...	Edit	Scan image	3
3	Supervisor	18/02/2020 14:...	View		3
4	Supervisor	18/02/2020 14:...	Edit	LIMS status	3
5	Supervisor	18/02/2020 14:...	Autho...	Cancelled	3
6	Supervisor	18/02/2020 14:...	Edit	LIMS status	3

5.13.3 Operator usage log

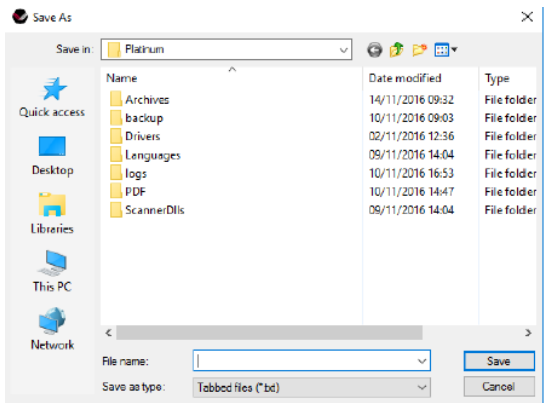
This function allows all viewing/editing functions carried out by a specific user for a defined time period to be identified. Right clicking on the selected entry allows the original file data to be opened. To view this, click the icon, or select **Quality Control > Show operator usage log**.



5.13.4 Additional usage 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.



Show all – all data can be loaded into the search window. By default, only the most recent data is shown without the user having to scroll down the window.

Appendix 1

Toolbar functions in Platinum

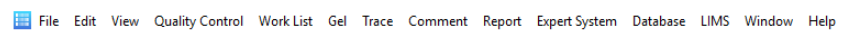
Glossary of software icons

Toolbar functions in Platinum

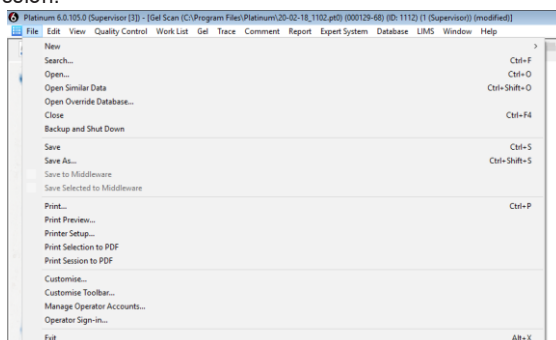
Menu bar

Gel Session

An active gel session will be displayed in the layout shown below.



Menu Bar: there are fourteen drop down menus in the menu bar of a gel session.



File menu

New: allows the opening of a new V8 or gel session.

Search: allows the operator to search for previously saved data along with demographic information.

Open: allows the operator to open files that have been saved in previous sessions or to allow files to be imported from other instruments. This can be used to open previously entered worklists that have not had a scan attached (they are displayed as *.wl0 files).

Open Similar Data: allows the operator to open any previous data relating to a specified demographic. The demographic that is used to call up previous data is set in the demographic configuration.

Close: allows the current window to be closed by the operator, with any new data being automatically saved.

Save: allows the operator to save the current data without exiting the program or closing the active window. At user level access, there is no choice as to the file name, or to the destination of the saved data. The data is saved with a unique number relating to the exact time and date the analysis was performed.

Save As: allows the user to select an alternative file name and location when using the **Save** function.

Save to Middleware/ Save Selected to Middleware: These options are only available if Middleware is activated. Please contact your Helena Representative for further details on Middleware.

Export Traces: allows the operator to export traces to a specified location.

Print: print a report of the selected sample on the preconfigured report template.

Print Preview: preview the report for the selected sample on the preconfigured report template.

Printer Setup: allows the configuration of the printer that will be used to print report.

Customise: this submenu allows the operator to configure the settings of Platinum. This can only be accessed under the operator level of 'Level 3'.

File Locations: this is used to define the default directory for saving traces, gels and worklist files. This functions allows the operator to select Access or SQL databases.

Configure Demographics: allows you to define the demographics used for database management and LIS identification.

Institution Data: with the **Customisation** window open; select the **Institution data** tab and input the information as required.

Configure Sample Handler: this enables the operator to confirm that positive patient ID's are used.

Receiving from ESH: allows configuration of Platinum to receive data from ESH.

Receiving from LIMS: configuration of Platinum to allow communication with a host system and reception of data from LIMS.

Sending to LIMS: configuration of Platinum to allow communication with a host system and to define what data is sent to LIMS.

Configure Menus: allows the operator to view all menu functions with access levels that are permitted to use each one.

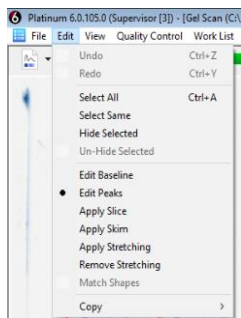
Customise Toolbar: allows the operator to choose which icons are displayed on the tool bar based on personal preferences.

Manage Operator Accounts: Allows operators with "Level 2" operator level access to add, remove or edit all operators on the list of users.

Operator Sign-In: Allows the operator to change the operator or operator level at which they are logged on during a session.

Exit: allows the operator to exit the program and will automatically save any new data or update any editing that has taken place during the session.

Edit menu



Undo: Allows the user to remove any editing on a trace or gel that has taken place.

Redo: If an editing operation has been undone, this function allows it to be redone without performing the operation again.

Select All: Platinum is defaulted to have only one sample active at any one time, with the corresponding data displayed. Using Select All allows the operator to select all data at once.

Select Similar: Selects all data taken from the same position on the rack.

Hide Selected: Hides selected samples from being displayed on the navigational worklist.

Show Hidden: Shows all hidden selected samples.

Edit Baseline: Allows the operator to edit the baseline of the current trace being displayed. For further information, see 'Editing Scan Data'.

Edit Peaks: Allows the operator to edit the peaks of the current trace being displayed. Peaks are defined at two trough markers, which are automatically placed at the lowest point between two peaks. For further details, see '**Editing Scan Data.**'

Apply Slice: Allows the operator to slice out trace data that is thought to be an anomaly. This could be an artefact in a spike on an otherwise smooth curve. When Apply Slice is checked, the cursor will show as active over the trace. The area to

be removed is highlighted by keeping the left mouse button pressed whilst dragging over the required area. The trace is drawn to the baseline rather than peak to peak as in Apply Skim.

Apply Skim: Allows the operator to stretch out trace data that is thought to be an anomaly. This could be an artefact in a spike on an otherwise smooth curve. When Apply Skim is checked, the cursor will show as active over the trace. The area to be removed is highlighted by keeping the left mouse button pressed whilst dragging over the required area.

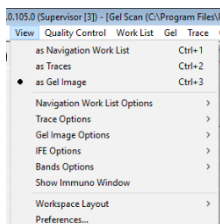
Apply Stretching: Allows the operator to stretch a selected trace to match that of another i.e a reference trace. When Apply stretch is checked, the outer edges and centre of the trace will be highlighted. Using the left mouse button, these markers can be dragged to the new position and the trace will be scaled to fit.

Remove Stretching: Removes any previous editing applied to the trace.

Match Shapes: Allows you to match two shapes for direct overlay and comparison.

Copy: Allows the operator to copy any of the displayed trace data to be pasted into other Windows applications.

View menu



As **Navigation Worklist:** Shows data as a worklist.

As **Traces:** Shows all results as traces.

As **Gel Image:** Shows all results as a gel image.

Navigation Worklist Options > Options on how the worklist is displayed.

Normal view: Default view.

Show hidden items: Samples can be hidden from the navigation work list by right clicking and selecting **Hide Selected**. When this option is selected hidden

samples can be viewed and restored to normal view.

Trace Options > this function allows the operator to specify options such as the Gain settings, scale and zoom on the scan plot.

Gain Settings: Allows the gain settings to be altered for the sample being analysed.

Set Scale: Allows the operator to set the x and y axis on the scan trace image.

Zoom Out: Allows the operator to reverse any Zoom in steps that have been taken.

Reset Scale: This will return the scale of the trace image to the default settings.

Show Regions/zones: This displays the individual regions on the trace for clarification.

Auto Align Regions: Lines up regions with where platinum has added trough markers and peaks.

Show Peaks: This adds a trough marker up the middle of each peak for clarification.

Label Peaks: This labels areas on the peak with A, A2, F, S etc, to make differentiation easier.

Colour Peaks: This separates each peak / band area by colour, to further delineate between areas on the trace.

Show Gel: This shows a computer generated image of what the trace would look like were it ran on a gel.

Second Trace as Solid: If two traces are compared within the worklist the second trace will be displayed as a solid coloured trace.

Stacked Display: If multiple traces are selected they will be displayed in the trace window stacked one on top of the other.

Show Derivative: This allows the operator to view the 1st derivative of the trace.

Show Mean Traces: This overlays the mean traces as specified in previous sessions for comparison with the selected trace.

Show Factory Overlay: This function places the normal overlay used by the operator onto the selected trace for comparison.

Show Normal Overlay: This overlays a user-specified trace on screen.

Gel Image Options > This enables the operator to edit the gel image, with respect to colour, magnification and intensity.

Full Scale View: This manipulates the gel Image to show the whole image.

Detail View: This changes the gel Image back to the last zoomed-in settings.

Negative Image: This inverts the gel Image image to a negative picture.

Enhance Contrast: This displays the gel image and scan image in a single colour, which is determined by the darkest pixel point on the scan.

Intensity: This adjusts the level of contrast that is used to display the IFE and scan image.

Full Colour Spectrum: This displays the gel image in false colour, where black is the darkest colour and blue is the lightest.

Maximise: This enlarges the gel image window to full screen size.

Restore: This returns the screen layout to the default view.

IFE Options > This enables the operator to edit the IFE image, with respect to colour, magnification and intensity.

Full Scale View: This manipulates the IFE to show the whole image.

Detail View: This changes the IFE image back to the last zoomed-in settings.

Negative Image: This inverts the IFE image to a negative picture.

Enhance Contrast: This displays the IFE image and scan image in a single colour, which is determined by the darkest pixel point on the scan.

Intensity: This adjusts the level of contrast that is used to display the IFE and scan image.

Full Colour Spectrum: This displays the IFE and scan image in false colour, where black is the darkest colour and blue is the lightest.

Helper Lines: This displays 3 lines on the IFE image to allow alignment of monoclonal bands.

Bands Options > This allows the operator to choose which data, if any, is displayed in the band list table.

Show Band Integral Value (IF): This allows the operator to select whether or not the peak integral values are displayed in the bands list table next to each band.

Show Band Concentrations: This allows the operator to select whether or not the band concentrations are displayed in the bands list table next to each band.

Show Band Ranges: This allows the operator to select whether or not the normal ranges are displayed in the bands list table next to each band.

Show Band Tops: Used in haemoglobin analysis to identify the x-axis position of the peak top.

Show Band Zones / Regions: Used in Haemoglobin analysis to define potential run positions of different haemoglobin variants.

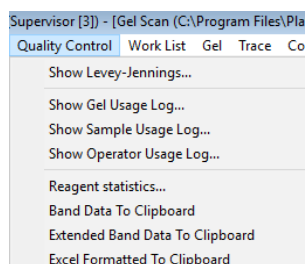
Workspace Layout > This allows the user to edit or use previously saved layouts for Platinum.

Use Layout 1-5: This allows you to use a predefined or saved layout for Platinum.

Store Layout 1-5: This allows you do save your customised layout for Platinum in space 1-5.

Preferences: Opens a window that allows alterations to the appearance of features of the analysis window, reports and tables. This is only available to operators with “level 3” user level access.

Quality Control menu



Show Levey-Jennings: this allows the operator to enter in to the Levey-Jennings window. Control data can be searched and displayed in a Levey-Jennings plot.

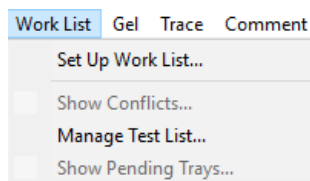
Show Gel Usage Log: this allowsthe operator to view the actions of other users during a particular session.

Show Sample Usage Log: this allows any operators to scan the usage log for a particular trace, including users and any changes that have been made.

Show Operator Usage Log: this allows any operators with ‘Level 3’ user level status to search the usage log for information on a particular user or session.

Reagent Statistics: allows the user to query the number of tests that have been carried out using a defined set of analyses or over a range of dates.

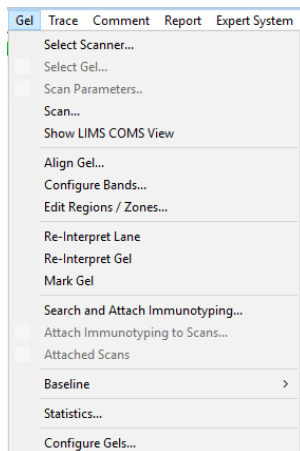
Worklist menu



Set Up Work list: allows the operator to set up a work list of patient demographic information. This can be stored for later use when samples are scanned, or it can be implemented immediately if the samples are on board the instrument. For details on how to set up a work list, please see the section ‘Setting up a Work list.’

Show Conflicts: allows the user to identify conflicts with data imported from

Gel menu



Select Scanner: this enables the user to select a gel scanner for use. Any scanning hardware connected to the computer will be listed.

Select Gel: this allows the user to select which gel tray (SAS-1, SAS-3, SAS-5) and which test type is to be used. Default smoothing, filtering and band set-up can be found in the prompt window also.

Select and Configure Gel: allows the user to make changes to the gel method settings, including Smoothing settings, and default report setting

Scan Parameters: this allows the user to specify the scan mode (8/24 bits or 12/36 bits) and to alter the resolution and gamma correction values.

Scan: this allows the user to enter the ID of the gel tray that is loaded onto the instrument. This can be typed or scanned.

Align Gel: this allows the user to align the gel.

Configure Bands: this enables the operator to configure the bands, and to apply default levels of filtering and smoothing.

Edit Regions / Zones: this allows the operator to edit the regions defined on the gel to clarify individual band regions.

Re-interpret Lane: this allows the operator to re-interpret a selected lane if the result is questionable, or the configuration parameters have been changed.

Re-interpret Gel: this allows the operator to re-interpret an entire gel if the result does not seem right, or the configuration parameters have been changed.

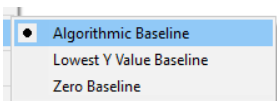
Mark Gel: this allows the user to mark the gel to pick out points of interest.

Search and Attach Immunotyping: this is used to search the database for any previously stored IFE scans for the current sample in the active window. Once found, the IFE is attached so that when the trace data is retrieved the attached IFE is displayed.

Attach Immunotyping to Scans: this is used to search the database for an IFE that will be linked and displayed relating to a specific patient next to the corresponding serum protein gel for use as a reference.

Attached Scans: when viewing an IFE sample this allows the operator to retrieve any samples that have the selected IFE attached.

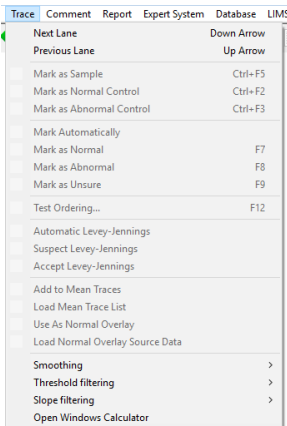
Baseline: This allows the user to select Baseline settings. They can choose between the following Baseline settings:



Statistics: this displays a table of means, standard deviations and CVs for any selected gel data. More than one sample at a time can be selected by keeping the Ctrl key pressed when selecting samples.

Configure Gels: this allows any Level 3 users to configure the set up for gel including smoothing, filtering, band region limits and default gain settings.

Trace menu



Next Lane: this allows the operator to advance to the next patient sample.

Previous Lane: this allows the operator to advance back to the previous patient sample.

Mark as Sample: the selected sample is marked as a sample.

Mark as Normal Control: the selected sample is marked for use as a normal control.

Mark as Abnormal Control: the selected sample is marked for use as an abnormal control.

Mark as Calibrator: the selected sample is marked for use as a calibrating trace.

Mark Automatically: this is the default selection and all lanes are marked as samples either normal or abnormal dependant on the configuration.

Mark as Normal: this marks the selected patient sample as abnormal by the default method relative to the configuration to be marked as normal.

For example, if a serum protein were to show seven bands rather than six it would be marked as abnormal. The actual sample may still be normal and so it could be marked as such without editing to remove one of the bands.

Mark as Abnormal: this marks the selected patient sample marked as normal by the default method relative to the configuration to be marked as abnormal. For example, if a serum protein were to show five bands with a small monoclonal band in the gamma and the whole gamma region was still in range then the sample may be marked as normal. The sample could then be marked as abnormal without having to edit the monoclonal band.

Mark as Unsure: this marks a patient sample as unsure. If the operator is unsure whether a sample is normal or abnormal, this will flag the sample so that another clinician may view it.

Test Ordering: this enables the user to manually order tests.

Automatic Levey-Jennings: this function automatically marks a sample as having a control that is in range or out of range to within 2 SDs of the assigned mean.

Suspect Levey-Jennings: if a control is in range but there appears to be a trend taking the gel or trace out of range it can be marked as suspect.

Accept Levey-Jennings: this allows the operator to accept the results on a gel or trace and mark it as such even if a control is shown to be out of range.

Add to Mean Traces: this adds a selected trace to those that are used to define the mean values.

Load Mean Traces: this overlays the mean trace for comparison with a selected sample.

Use as Normal Overlay: this allows the operator to select a trace for use as the normal overlay.

Load Normal Overlay Source Data: this loads the source data of the trace being used as the normal overlay.

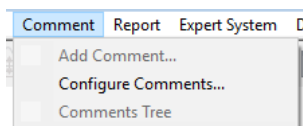
Smoothing: the smoothing function allows the operator to reduce the effect of and display of noise shown on the trace.

This is achieved by plotting the rolling average of results rather than individual points. The degree of smoothing used is on an arbitrary scale and increasing the smooth weight too much can result in an adverse effect on the quantitated values. A default smooth weight can be set in configuration; however it is applied here to selected samples.

Threshold Filtering / Slope Filtering: filtering alters the detection point at which a trough marker is automatically placed on the trace. Filtering is set in configuration, but this function allows individual filtering to be applied to each sample.

Open Windows Calculator: This provides the operator with a shortcut to the windows calculator.

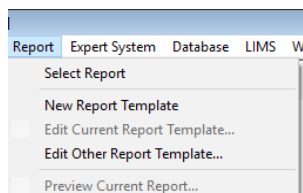
Comment menu



Add Comment: allows the operator to add a comment to the current sample from a list of predefined comments. The user can also add free hand comments in the comments tile of the active analysis window.

Configure Comments: allows the operator to configure the comments that are held in the predefined Add Comments table.

Report menu



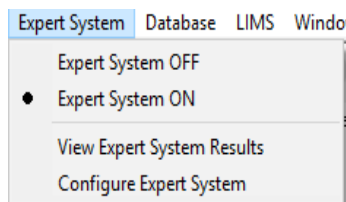
New Report Template: To select a new report template, Select "Report" > "New Report Template": This function allows the to create a new report template. user . See 'Creating a Report' for further details.

Edit Current Report Template: allows the operator to edit the current report template.

Edit Other Report Template: allows the operator to edit a previously created and saved report template.

Preview Current Report: Allows the operator to preview the current report layout associated with the method.

Expert System menu (V8 Only)



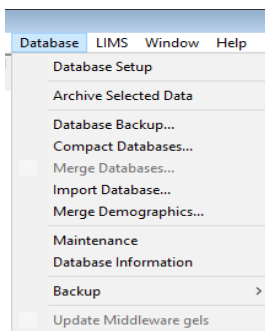
Enabled: allows the operator to switch on the Expert System, removing the manual operation of the instrument.

Disabled: allows the operator to switch off the Expert System and operate Platinum and the V8 manually.

View Expert System Results: allows the operator to view the results.

Configure: enables the operator with 'Level 3' user status to configure the Expert System to laboratory/hospital defined criteria to enable correct identification of normal and abnormal samples.

Database



Database Set Up:

Allows the user to view/configure the Location for new data and the Location for backups.

Archive Selected Data: Allows the user to make archive records by filters including, Date, Analysis Type and Result Type.

Database Backup: this function backs up all data stored in the Database. Allows for recovery of the database and is where sessions can be imported.

Compact Database: this function reduces the size of the database through the removal of duplicate entries created during the patient data retrieval.

Merge Databases: this function allows historical databases to be merged. Once the merge is complete a message will display at the bottom left of the Platinum window. This allows databases to be imported using specific Platinum demographics.

Import Databases: This allows databases to be imported into Platinum. This function correctly matches the imported trace demographics to the Platinum demographics.

Goes into Platinum demographic :	Name	Date of birth / age	Gender	Department	ID
Tube ID:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Forename:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Surname:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
DOB:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Patient ID:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hospital ID:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Not used: ☐ ☐ ☐ ☐ ☐

Import
From this Database:

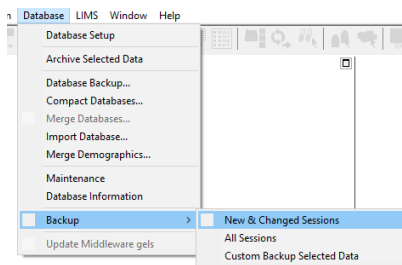
Import

Merge Demographics: The Demographic Merge allows the merging of old database demographics into the current demographic set. It is recommended that demographics are the same across all data. Imported data that has different demographics can be merged into the current demographic set using this tool.

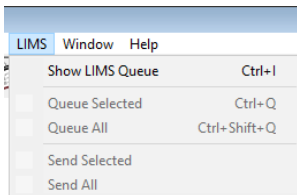
Maintenance: This allows the display of database data and additional maintenance options including Method Table, Comment Table, Session Files and Session/Database Validation.

Database Information: This provides assorted information about the state of Platinums database and networking status.

Backup: Backups can be performed on New and changed sessions, all sessions or by customising the backup selected data.



LIMS menu



Show LIMS Queue: this opens up a window that displays the LIMS queue. From here, operators with 'Level 3' user status can send and receive data from LIMS.

Queue Selected: this allows the operator to send selected processed data to the LIMS queue.

Queue All: this allows the operator to send all of the data from the session to the LIMS queue.

Send Selected: this allows the operator to send selected processed data directly to the LIMS.

Send All: this allows the operator to send all of the data from the session directly to the LIMS.

Window menu



Cascade: this allows all opened windows and sessions to be laid out as a cascade for easier viewing.

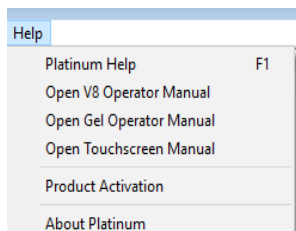
Tile Horizontal: this tiles all open windows horizontally.

Tile Vertical: this tiles all open windows vertically.

Close All: this closes all open windows, with any data and demographic data saved automatically.

Open .pt sessions. Allows quick and easy transition between open platinum sessions.

Help menu



Platinum Help: Displays help menu.

Open V8 Operator Manual: Open V8 operator manual.

Open Gel Operator Manual: Open Gel Operator Manual

Open Touchscreen Manual: Open the Touchscreen Manual

Product Activation: Allows the user to activate additional Platinum features, including Touch Screen, Networking, Track, Middleware and Expert System.

About Platinum: Displays the Platinum version, including the Patch Number and Serial Number Button.

Notice to Users

Once the Eudamed public website is available, a summary of safety and performance of these devices will be accessible from there.

Definition of Symbols



Authorized representative in the European
Community/European Union

Glossary of software icons

The following software icons have been designed to make operator use simple and efficient.

Basic functions



About



Help



Open data



Search data



Open similar data



Save



Save as



Save, Email RTF



Operator



Operator list



Customise



View preferences



Undo



Redo



Usage search



Print



Preview printer output



Cascade



Tile Horizontally



Tile Vertically



Screen layout 1



Screen layout 2



Screen layout 3



Screen layout 4



Screen layout 5



Store screen layout 1



Store screen layout 2



Store screen layout 3



Store screen layout 4



Store screen layout 5



Scan Usage



Session Usage

Database Management



Backup all



Backup changed / new



Backup / Archive



Restore

Gel icons



Configure gel



Re-interpret gel



Scan



Mark gel



Worklist



Select gel type



Align gel

Expert System



Expert system OFF



Expert system ON



Redo external chemistry values

Sample marking



Mark as abnormal control



Mark as normal control



Mark as sample



Next lane



Previous lane



Automatically mark



Mark normal



Mark abnormal

Analysing tools



Add to mean traces



Load mean traces



Display IFE as negative



IFE contrast



Display image as negative



Show normal overlay



Load normal overlay's file



Show region / zones



Statistics



Zoom out



Zoomed / Full scale



IFE Zoomed / Full scale



First derivative



Helper lines



Show mean trace



Add comment



Gain



Make normal overlay

Editing tools



Filtering



Edit regions / zones



Set scale



Edit baseline



Match shapes



No stretching



View as gel



View as navigation workload



View as traces



Gel contrast



Edit peaks



Skim



Slice



Stretch



Smoothing



Re-interpret scan



Select all lanes



Optimise scale

Levey-Jennings



Levey- Jennings



Accept Levey-Jennings



Automatic Levey-Jennings



Suspect Levey-Jennings

Report icons



Centre text



Left align text



Right align text



Bold text



Underlined text



Italic text



New bands list



New demographics item



New gel image plot



New IFE image



New Levey-Jennings plot



New Levey-Jennings table



New line



New logo



New multiple bands list



New reagents list



New rectangle



New scan trace



New statistics list



New text item



New whole gel image



New Worklist

LIMS icons



Unqueue for LIMS



Send all to LIMS



Queue pending approval



Send selected to LIMS



Approve send to LIMS



Display LIMS queue

The below functions are not applicable to gel systems



V8 system actual values



V8 system status



Allow reflex tests



Enter reflex test status



Reset Communication



Define buffers



Define reagents



Enable / Disable capillaries




Manage test list



Select V8 system



Select default method



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