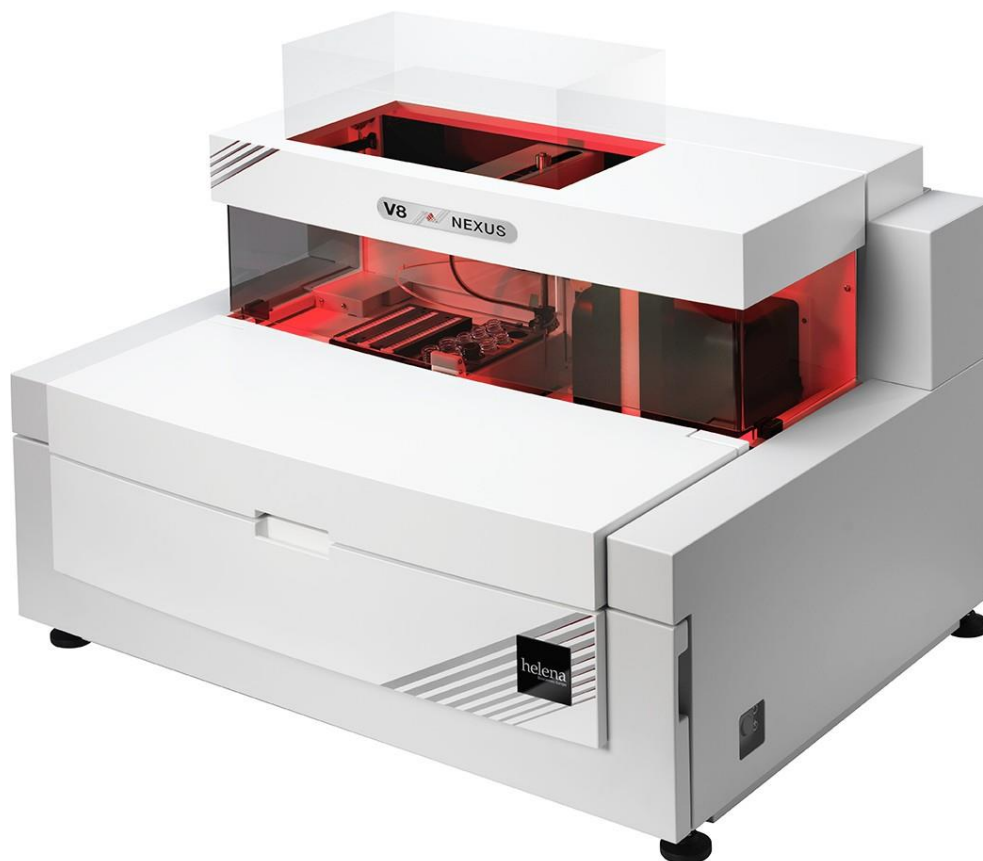


V8

High Performance Clinical Capillary Electrophoresis



Operator Manual
English

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Revisions to this operator manual

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Seventh Issue	15/03/2023	EC Representative Updated
Eighth Issue	18/07/2025	Updates to section 5.9

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Company liability

The information in this manual has been carefully compiled and verified for technical accuracy, and should be read thoroughly to ensure correct and safe usage. Helena Biosciences Europe trusts that the information contained herein is valid and accurate; and thereby accepts no liability or responsibility for system malfunctions, damage or personal injury caused by misuse or mishandling. For more information, please contact your local Helena Biosciences Europe representative.

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Health and safety

While the primary risks of using this product have been resolved through instrument design there are still residual risks to the operator and to third parties involved in the daily running, maintenance and installation of the V8.

This document details all the protective features and user instructions for ensuring health and safety. It is strongly recommended that this document is read thoroughly prior to the use of the system. Failure to comply with the stated precautions or specific warnings elsewhere in this guide violates the safety standards built relevant to the design, manufacture and intended use of this instrument. Helena Biosciences assumes no liability for the operator's failure to comply with these requirements.



WARNING

Protection impairment if the operator uses the system in a manner not as specified by Helena Biosciences.

Informational Symbols

The following information applies to operating personnel. It is the responsibility of the user to ensure that all safety information and operating instructions are read and understood before use. General warnings and cautions will be found throughout the manual where they apply.



WARNING

WARNING: Risk of danger.



CAUTION

CAUTION statements identify conditions or practices that could result in personal injury. Proceed with caution.



CORROSIVE

A substance which may destroy living tissues on contact with them. Severe burns on the skin and flesh might result from splashes of such substances on the body.



TOXIC

A substance which, if it is inhaled or ingested, or if it penetrates the skin, may involve extremely serious, acute (immediate) health risks and even death.



WARNING

WARNING, BIOLOGICAL HAZARD



HAZARD

CAUTION: High voltage hazard



CAUTION

CAUTION separate collection of electric and electronic waste at the end of life, as required by European legislation.



WARNING: Pinch point hazard

HAZARD



Laser Radiation: Laser beam hazard

LASER RADIATION

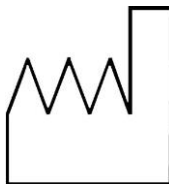


Danger: Serious health hazard. May damage fertility or the unborn child

DANGER



E.U. authorised representative



Date of manufacture



Eurasian conformity mark



European conformity mark



Federal Communication Commission conformity mark



A medical device intended for in vitro use



Manufacturer



Consult electronic instructions for use



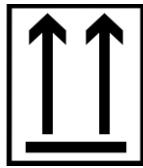
Catalogue number



Fragile



Keep Dry



This Way Up

Preface: Welcome to your V8

Helena Biosciences Europe welcomes you to your brand new V8 system; an advance in automated Clinical Capillary Electrophoresis – now at the heart of your laboratory.

Your V8 system promises to deliver you the latest automated technology and software systems for the diagnosis and monitoring of patient health across a broad spectrum of clinical investigations. It promises to provide reproducible results at optimum speeds with walkaway convenience at the touch of a button.

V8 is a sophisticated and yet simple system to run with the potential to meet varying and high workload requirements. Your V8 is a robust diagnostic system, built for flexibility, intelligence and speed, providing great savings in buffers and reagents.

V8 has been built with an extraordinary amount of features and benefits, and we want you to understand them as quickly as possible. As a result, this user-manual is designed to be accessible and simple to understand. It describes all of the V8's features and functionality, and provides simple instructions for fast user interaction.

For more detailed information and support, please visit our website at www.helena-biosciences.com. Alternatively, send your queries and questions to v8support@helena-biosciences.com.

Terminology used in this manual

In order to make this document as clear as possible, these conventions will be followed:

Text alerts and messages

Text, in the form of messages and alerts from Platinum or Windows™ software, will be shown as follows:

"It is now safe to remove the device."

whereas voice feedback from the V8 is shown like this:

"Please empty the waste drawer."

Hardware items

When referring to parts of the V8 instrument, accessories or other items used in conjunction with the V8, the following style is used:

To begin analysis, close the *Sample preparation and analysis lid*. The V8 should automatically begin processing your samples.

Platinum items

Things such as buttons, windows and menu items will be displayed as shown:

To close Platinum, choose **File > Exit**. When prompted to save or discard your current session, click **Discard**.

In dialogue boxes or when editing text fields in the Platinum session window, text which is expected to be supplied by the user is shown like this:

Enter "my_template.rep" in the Save As dialogue box.

Acronyms

CCE	Clinical Capillary Electrophoresis
CDT	Carbohydrate Deficient Transferrin
CE	Capillary Electrophoresis
CSF	Cerebrospinal Fluid
CZE	Capillary Zone Electrophoresis
CV	Coefficient of Variation
DCI	Dynamic Compression Injection
EOF	Electroosmotic Flow
ESH	Electrophoresis Sample Handler
FOB	Free on Board
Hb	Haemoglobin
IEF	Isoelectric Focussing
IFE	Immunofixation
IFU	Instructions for Use
ID	Immunodisplacement
LAS	Laboratory Automated System
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
PCB	Printed Circuit Board
pI	Isoelectric point
PPE	Personal Protection Equipment
Pt	Platinum
RTF	Rich Text File
SD	Standard Deviation
SP	Serum Protein
UP	Urine Protein
ID	Immunodisplacement (or Identity when used with Patient ID, tube ID and lot ID)

1 Intended Purpose

1.1 Intended purpose

The V8 is a fully automated in-vitro diagnostic Capillary Electrophoresis instrument which uses electrolytic buffers and high voltage to separate the constituent fractions of human serum, urine and whole blood samples. The component fractions are then visualised by use of the absorption of light within a range of 200-600nm. The V8 is to be used in conjunction with associated quantitative and qualitative Helena Biosciences V8 Assays. Intended for use by a trained laboratory professional in a clinical laboratory.

1.2 Test principle

V8 and V8 Nexus Piercing and Agitation Upgrade is an instrument and does not have an assay principle.

1.3 V8 technologies and functionality: quick reference guide

V8 has been specially designed with advanced system features to provide you with a wide variety of user functionality. To get the best out of your V8, please read the following technology driven solutions and tips, and optimise your system to its full potential. Please refer to the relevant sections.

Complete Chemistry

All reagents and buffers held on board for next-generation automation

- Correct installation of buffer bottles, see 5.7.1
- Loading reagents on-board, see 5.7.4
- Checking fluid levels, see 5.7.3

Multi Assay

Simultaneous separation capability for high throughput multi-assay testing

- Set-up the V8 for single assay testing, see 5.4.1 and 5.4.2
- Set-up the V8 for multi-assay testing, see 5.5
- How to manage capillaries, see 5.7.12

Intuitive Status

Visual effect system for visual status updates

- Responding to visual status updates, see Appendix 2 2.2
- The importance of pre and post-conditioning cycles, see 9.3 and 9.4
- What to do when it goes blue, see Appendix 2

True Identity

Total audit trail accountability and analysis security

- Setting up user names and passwords in Platinum, see 2.6
- Searching and retrieving data, see 5.9.4
- Setting up the Levey-Jennings analysis, and using controls, see 5.9.19

Auto Pilot

Define your assay, load your samples and close the lid – it's as simple as that

- How to automate your testing needs, see 5.1, 5.2, 5.8 and 5.9.3.4
- Understand automated maintenance cycles, see 9.2

Expert System

Intelligent identification and retesting of abnormal samples

- Using the Expert System, see 5.8 and 5.9.1.8
- Switching your Expert System on and off, see 5.8

Continuous Loading

Total random access for continuous high throughput analyses

- Loading samples into the sample rack 5.7.7.1
- Adjusting the sample rack for different tube sizes, see 5.7.7
- Set-up system for high-throughput batch loading without workflow interruption, see 5.4.3

Fast Track

Queue jump your urgent samples for speedy results

- Fast track an urgent or STAT sample, see 5.4.3 and 5.9.3.4
- Set the priority of STAT samples, see 5.9.3.2 and 5.9.3.6

Sample Recall

Recall tested samples for further diagnostic analysis

- System memory of on-board/off-board samples, see 5.9.3.3
- How to recall a sample for specific testing requirements, see 5.9.3.4
- Prepare a sample for gel electrophoresis, see 5.7.9

Reflex Testing

Automated marking of abnormal samples for confirmatory reflex tests

- Understand how to set up a reflex test, see 5.9.3.4
- Automate reflex testing on the V8, see 5.9.3.4 and 5.9.3.5
- Set the priority of automated reflex tests, see 5.4.3
- Auto dilution calculation, see 5.9.3.6.1
- FlexWave retesting, see 5.9.3.4

Audible Feedback

Audible system status updates for total peace of mind

- Understand all the voice commands on the V8, see Appendix 2 2.3

Smart System

Intelligent platform maximises up-time and productivity

- Perform Immunodisplacements hands free, see 5.4.3
- Set-up automated assay switching, see 5.5

Gel Integration

Integrated sample handling for gel electrophoresis preparation

- How to load a SAS gel tray, see 5.7.9.2
- How to prepare a sample for gel electrophoresis, see 5.7.9
- How to reflex to gel, see 5.9.3.4
- Auto dilution calculation, see 5.9.3.6.1

Future Proof

In-built flexibility and high-tech modular platform for product evolution

- Understand the automated maintenance procedures on the V8, see 9.1 and 9.2
- Future proof your V8, see 9.8, 9.9, 9.10 and 9.11
- Contact your local Helena Biosciences representative for the latest product information and developments; or consult www.helena-biosciences.com

Eco System

- Energy efficient technology for a green result you can rely on
- When will my V8 go to sleep mode to save power? see 5.2.1

2 Installation and special requirements

2.1 Overview

Your V8 is an automated bench-top system requiring minimal installation requirements for space, on-line power and bi-directional interfacing. Your V8 will need to be installed, set-up and configured by a Helena Biosciences trained and certified engineer. We recommend that you read this section thoroughly to understand the items supplied with your V8, the packaging of the instrument, and the essential requirements needed for an efficient installation.

2.1 Storage and Transport

No special storage or transport conditions are required.

2.2 Packaging and installation

V8 has been carefully packaged to safely secure all items and mechanical components from damage during transportation and storage. Your V8 will be unpacked and installed by a Helena Biosciences trained and certified service engineer, who will ensure that the entire system is fit for purpose.





N.B. The V8 must always be shipped in its original packaging. As a precautionary measure, please safely store all original packaging for future use.





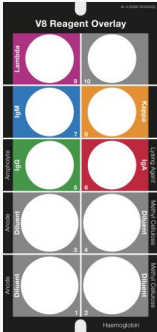

Please do not attempt to unpack the V8 or the PC and attempt installation without the presence or assistance of a qualified engineer. Failure to adhere to this could invalidate your warranty.

No special transport conditions are required.


2.3 Included in your V8 system

Helena Biosciences Europe V8 Capillary Electrophoresis System

Item	Description	Quantity Supplied
	V8 Instrument	1
	Waste Bottle	1
	Waste bottle if using the V8 Nexus Piercing and Agitation Upgrade	1
	Bottle Connectors (1x Biohazard labelled)	7 (6 supplied with a V8 Nexus fitted with the Piercing and Agitation Upgrade)

Item	Description	Quantity Supplied
	Sample racks + inserts	14
	Ethernet cable (1 x cross cable, 1x patch cable)	2
	Mains flex	1
	Fuses T6.3A	2
	Barcode Scanner	1
	Spare Capillaries	8
	ID/Hb Overlay	1
	Sample Tray Sticker Sheet	1
	Waste Drawer	1
	Skip Position Barcode Sticker Sheet	1

PC

Item	Description	Quantity Supplied
	Screen	1
	PC Tower (Windows 10)	1
	Keyboard	1
	Mouse	1
	Platinum CD	1
	Power cords (black)	2

2.4.1

Surroundings and space requirements

The setting-up location must be free of smoke, dust, or highly corrosive gases and vapours and should not be exposed to direct sunlight.

- Ambient temperature: +15°C to 30°C.
- Relative air humidity: 35% - 80%, without condensation.
- Installation height: 0m - 2000m above sea level
- Provide good access to the instrument system.
- Ensure good access to the rear power switch and power socket in the event that immediate removal of power is required.
- 895 mm × 680 mm × 703 mm (W × D × H).
- Bench-top sufficient to carry the full weight of the instrument and all accessories.
- Provide at least 10 cm between the rear of the instrument and a back surface.
- Additional space will be required for optional external equipment, e.g. printer.
- V8 will require access to at least 3 power outlets.
- Your Helena Biosciences trained service engineer will advise on the best position for the system.
- Helena Biosciences recommends the use of a suitable Uninterruptible Power Supply (UPS).
- The V8 is for indoor use.

2.4.2

Electrical information

V8 has to be connected to an approved standard socket with protective conductor. The approved wall outlet must be provided near the place of installation. The electrical supply must also be compliant with the local safety regulations and must have been approved by an authorised electrician prior to connecting the V8 system. The V8 power cable should be considered the disconnection device. The V8 must be positioned to ensure access to this disconnection device.

Mains voltage	Cat: 800008 230V ± 10%
	Cat: 800018 115V ± 10%
Input frequency	50/60Hz
Line protection (fuse)	Cat: 800008 (T6.3A)
	Cat: 800018 (T6.3A)
Maximum power consumption	500 VA
Caution	the supplied power cable is the only recommended power cable for use.
Electrical Safety	Class 1 device. This instrument must be earthed.
Overvoltage Category	Category II

2.4.3

Pollution Degree

The V8 is Pollution Degree 2.

2.5

Platinum to V8 configuration

The V8 must be configured to the PC and Platinum which are supplied as part of the system. The Helena Biosciences installation engineer will configure the V8 to the PC.

2.5.1

Platinum initial setup

The Platinum initial setup will be carried out during the installation process by a fully trained and certified engineer.

2.5.2

LIMS/LIS configuration

This will be carried out by a trained LIMS/LIS engineer during the installation process. Information required to set up the LIMS connection can be obtained by contacting technical support at Helena Biosciences: V8support@helena-biosciences.com.

2.6 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.

2.6.1 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.

2.6.2 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.

2.6.3 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.

Login name	Full name	User level	Date of birth	User ID	Password expires
Supervisor		3			11/05/2036
Administrator4		4			10/07/2011
Administrator5		5			12/05/2036
admins		5			04/02/2014
theuser		3			08/07/2014

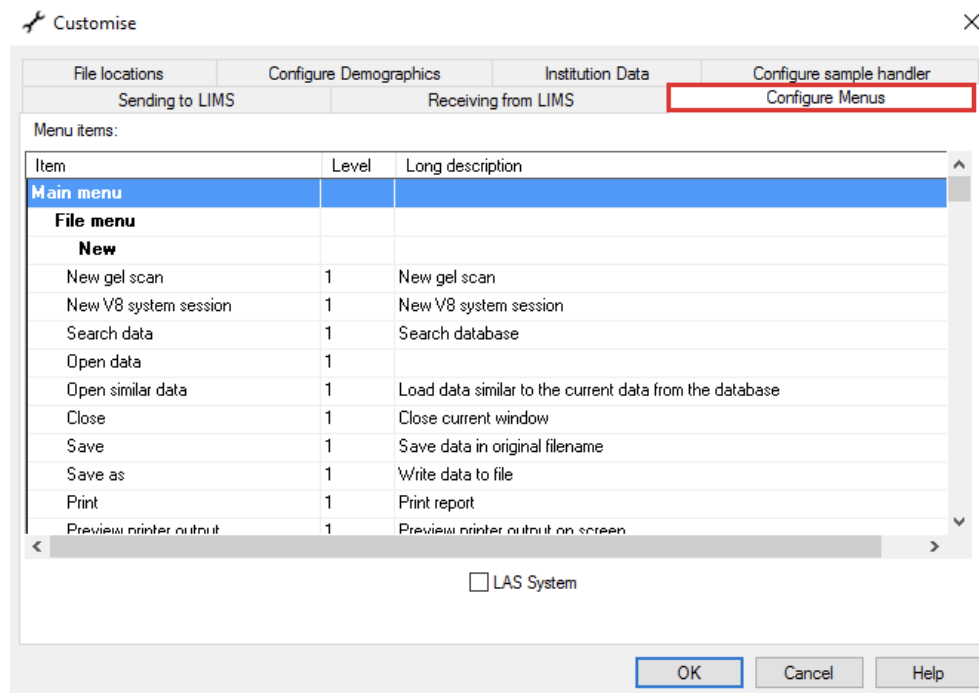
2.7 Adding a new user

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

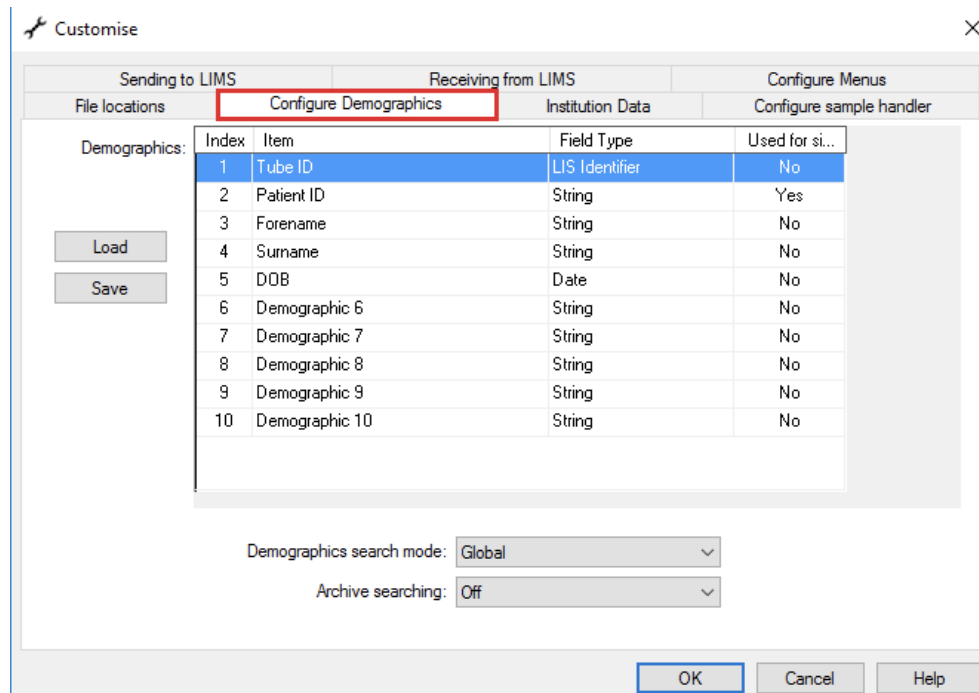
- Choose **File > Manage Operator Accounts**.
- In the dialogue boxes enter the required information according to the field. The criteria of the password, such as minimum length, expiry and format, can be assigned here by the Level 3 for added security.
- After filling in all the fields, choose **Add User**.

The Level 3 user can configure user access by configuring the menus in the **Customise** 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.



- 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 id as read by the V8
- 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.

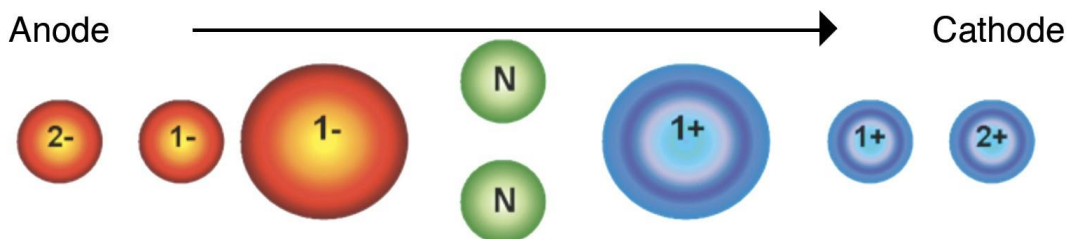


- a. Click the **Save** button, save the file under the name **demos.dem** in the Platinum folder.
 - b. Click **Load**, and find the file you have saved in the previous step. Choose the required file to open. This will activate the correct demographic fields.
- Click **OK** to return to the V8 or Gel session.

3.1

Capillary Electrophoresis

Capillary electrophoresis is a powerful analytical technique which separates sample components based on differences in mass to charge ratio. This is achieved using a microbore, fused silica capillary filled with an appropriate electrolyte medium under high voltage. Positively charged ions are drawn through the capillary toward the cathode, the smallest ions eluting first. Electroosmosis of small ions within the buffer electrolyte draws neutral molecules through the capillary and overcomes the electrostatic attraction of negatively charged ions. This electroosmotic flow means negative ions are still drawn through the capillary.



The efficient heat dissipation of small diameter capillaries make the use of very strong electric fields possible allowing high efficiency separations and rapid migration times. This powerful analytical technique can be employed to resolve closely related compounds including large proteins with only a single amino acid difference.

3.2

Capillary Electrophoresis and its clinical application

3.2.1

Capillary Zone Electrophoresis (CZE)

Capillary Electrophoresis occurs when voltage is applied to an uncoated capillary tube filled with a uniform electrolyte solution. Separation of the charged analytes is due to differential migration in the electrical field, whereby the charged particles migrate toward an electrode with an opposite charge. In order to detect the separated analytes, all species must move past a detector. Under normal electrophoretic conditions this cannot occur due to the differential motion of the charged particles.

However, if the inner wall of the capillary is also charged, the fluid in the capillary will begin to flow toward the electrode that has the opposite charge. The bulk movement of the fluid is termed electroosmotic flow or EOF. The chemical equilibrium between a solid surface and an electrolyte solution typically leads to the interface acquiring a net fixed electrical charge, a layer of mobile ions known as an electrical double layer, or the Debye layer. When an electric field is applied to the fluid, the net charge in the electrical double layer is induced to move by the resulting Coulomb force. As the EOF has a higher magnitude than electrophoresis, the analytes, positive and negative, will ultimately be carried in the same direction albeit at different rates. The application of the EOF and Coulomb force allows all charged species to be detected at one end of the capillary within zones of migration, due to mass to charge ratio separation alongside the EOF induced movement towards the detector. Separation of serum proteins, urine proteins and transferrins on the V8 is via Capillary Zone Electrophoresis.

3.2.2

Capillary Isoelectric Focusing

V8 is the only automated multichannel CE system to use Isoelectric Focusing for the separation and quantitation of haemoglobins by CE. Many analytes can be separated in single runs with minimal sample and reagent consumption. The CE separation of haemoglobins utilises the different isoelectric points of each of the haemoglobin molecules when separated in an isoelectric focusing pH gradient.

The technique takes advantage of the fact that the charge of an analyte changes with the pH of its surroundings. Thus, a species that is in a pH region below its isoelectric point (pI) will be positively charged and so will migrate towards the cathode. As it migrates through a gradient of increasing pH, however, the protein's overall charge will decrease until the protein reaches the pH region that corresponds to its pI. At this point, it has no net charge and so migration ceases. As a result, the analytes become focused into sharp stationary bands with each being positioned at a point in the pH gradient corresponding to its pI. The technique is capable of extremely high resolution and has the potential to separate analytes with only a single charge difference.

For IEF to be successful, the molecules are separated over a medium which has a pH gradient. An electric current is passed through the medium, creating a 'positive' anode and 'negative' cathode end. Negatively charged molecules migrate through the pH gradient in the medium toward the 'positive' end, while positively charged molecules move toward the 'negative' end. As a particle moves towards

the pole opposite of its charge, it moves through the changing pH gradient until it reaches a point in which the pH of that molecule's isoelectric point is reached. At this point, the molecule no longer has a net electric charge (due to the protonation or deprotonation of the associated functional groups) and as such will not proceed any further. In a separate mobilisation step, the analytes are moved past the detector for analysis.

4.1

V8 technical specifications

Identification

- Positive patient identification.
- Sample rack barcoded identification.
- Barcoded buffer and reagent containers.

Barcode

- Embedded barcode reader.
- 70° angle.
- Symbolologies: Code 39, Codabar, Code 128, Interleave 2 of 5, Code 93 and UPC/EAN.

Loading

- Up to 14 sample racks of 8 primary tubes; total 112 standard operations.

Gel sample trays

- Compatible with SAS-1 sample tray (24 samples).
- SAS-3 sample tray (60, 80, 100 samples).
- SPIFE 60 sample tray.
- IFE-3, IFE-6, IFE-9 and IFE-15 SPIFE trays.

Sampling

- Generic sample cups.
- Sampling is direct from uncapped primary tubes:
- Diameter: max. 16mm.
- Height: max. 100mm.
- Dead volume: 30µL (Sample tube dependant).
- See section 5.7.7 for the sampling specification when using the V8 Nexus Piercing and Agitation Upgrade (800020)

Pre-analytical

- Dilutions, cell lysis, reagent addition and reagent incubation.

Migration

- Eight fused-silica capillaries.
- Peltier controlled temperature capillary chamber.

Buffers

- Six on-board buffer system containers; up to four open user-defined assay buffer positions.
- Dynamic buffer level monitoring.
- 5 on-board buffer system containers; up to three open user-defined assay buffer positions when using the V8 Nexus Piercing and Agitation Upgrade (800020)

Reagents

- Ten open positions for reagents and antisera; Anti-IgG, -IgA, -IgM, Kappa and Lambda.
- Sample diluents and preparatory solutions.
- Peltier controlled reagent positions.
- Dynamic reagent level monitoring.

Maintenance

- On-board maintenance solutions.
- Automated maintenance procedures.
- Automated purging between assay changes.
- Automated startup and shutdown procedure.

Detection

- Light source: deuterium lamp. When using the V8 Nexus Piercing and Agitation Upgrade (800020) the V8 uses an LED light source with a fixed wavelength of 415nm.
- Wavelength detection: monochromator with 200-600nm wavelength range.

- Detection: eight photodiodes.
- XYZ arm.
- Up to 160 dilutions per hour; active fluid level detection.

Walk-away automation

- 112 primary sample tubes.

Assays

- Serum Protein 6-band.
- Serum Protein SPE.
- Serum Protein 6-band Zoom.
- Urine Protein 6-band.
- Urine Protein SPE.
- Urine Protein 6-band Zoom.
- Immunodisplacement (IgG, IgA, IgM, Kappa, Lambda).
- Fast CE.
- Carbohydrate Deficient Transferrin.
- Haemoglobin UltraScreen.
- Haemoglobin A1c.
- Glyco Liver Profile.

Sensitivity

- Detection of serum proteins at 208mg/L (Method dependent).
- Detection of urine proteins at 20mg/L.

Data processing

- Unlimited capacity for patient storage in single session.
- Trace capture.
- Trace editing.
- Statistical calculation and display.
- Quantitated calculation and display.
- Database flagging of patient status.
- Bi-directional communication; import and export of patient data and results.
- Immunodisplacement image capture & linkage to scan traces.
- Multiple search parameters with overlay capacity.
- Expert System.
- Automatic LIMS query.

Report printing

- Full in-built desktop publishing package.

Q.C. and validation

- Levey-Jennings and statistics reports.

User interface

- Platinum – advanced diagnostic software.

Dimensions

- 895mm (width) × 680mm (depth) × 703 mm (height)

Weight

- V8 Instrument weighs 72kg.

Connections

- Ethernet connection from V8 to PC.
- Ethernet connection to LIS / lab network.
- USB connection to peripheral utilities.
- Serial RS232 to LIS.

Power

- Typical consumption of 489 VA (normal operation).
- Internal power supplies deliver up to 650 W.

Environmental operating conditions

- Ambient temperature 15-30°C.
- Non-condensing relative humidity between 35% and 80%.
- Maximum altitude of 2000 metres.

The following schematic highlights and describes all the component parts important to the safe operation of your V8. Please refer to Part Five of this manual for correct operating instructions.

4.2.1

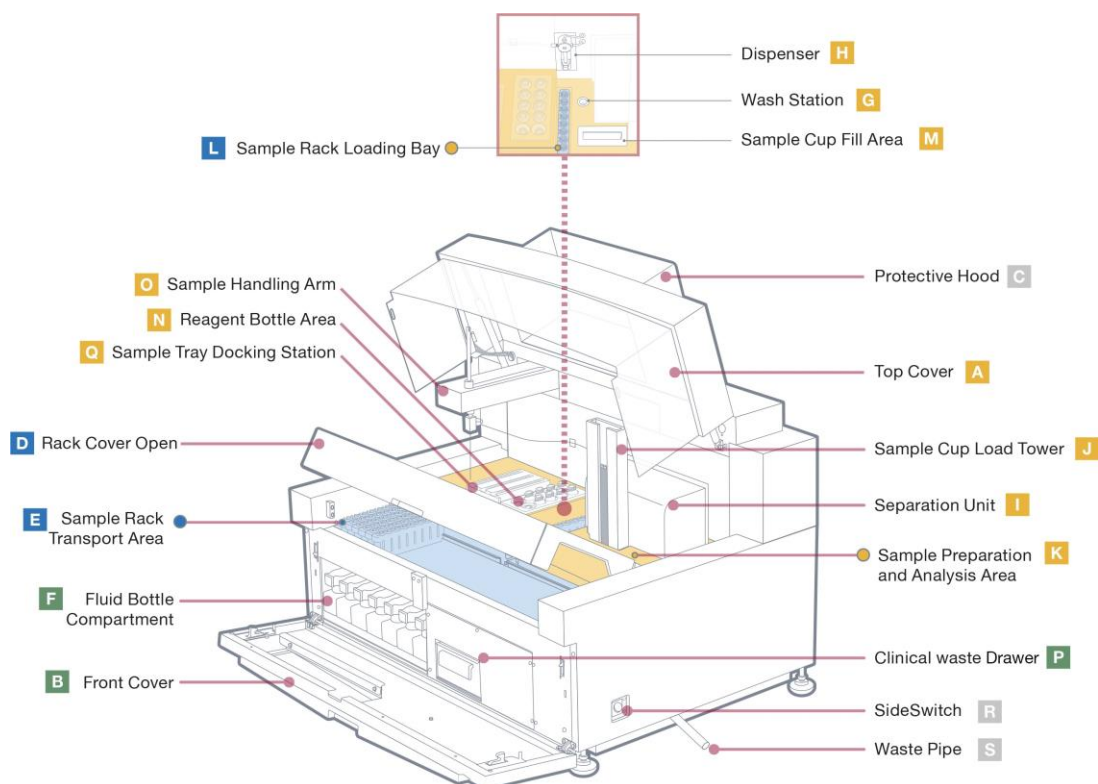
V8 system description

The V8 system combines a bench-top analyser and a free-standing PC pre-loaded with Platinum software for instrument management and results analysis. The system is self-sufficient enabling an efficient out-of-box installation requiring only electrical mains supply for system power; network ports for bi-directional host interfacing; and web access for remote service support.



The V8 clinical capillary electrophoresis system

4.2.2

V8 instrument technical overview

Instrument technical drawing

a. Top cover

The sample preparation and analysis lid contains the components which make up the sample preparation and analysis area. This part of the instrument is concealed to prevent sample and fluid contamination; and is protected from user interaction during analysis and preparation, due to the hazardous movement of the sample handling arm, and its needle.

b. Front cover

The front panel contains the buffer compartment area and the clinical waste drawer. The front panel can be opened to change buffers or empty the waste bottle or waste drawer with no interruption to the workflow. Users are notified when to empty the liquid waste bottle or clinical waste drawer.

c. Protective hood

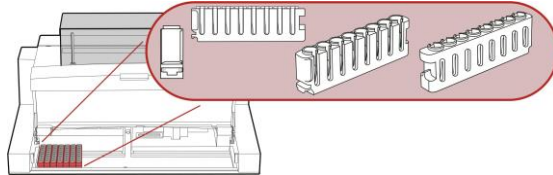
The protective hood is made of transparent plastic and is present to prevent contamination to the sample and preparation area, and to protect the user from the mechanical movements of the sample handling arm. It should not be removed from the instrument.

d. Rack cover (open)

The sample rack transport cover provides protection and access to all sample racks loaded on to the sample transport area of the V8. For continuous loading and urgent STAT samples, the user can access this area continually, although sample processing and preparation will pause, due to the potentially hazardous movement of the sample handling arm and its needle

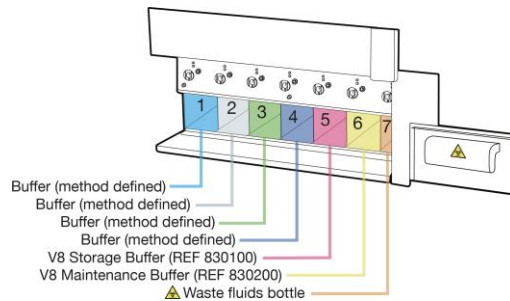
e. Sample rack transport area

The sample rack transport area handles sample racks for continuous loading, random access and urgent samples. The sample rack loading bay automates the transport and barcode reading of all sample racks and tubes placed on-board the V8 with immediate communication of data to Platinum. It is a flexible system, allowing the user to place sample racks onto the transport area for random access and rack queue jumping for urgent testing requirements.

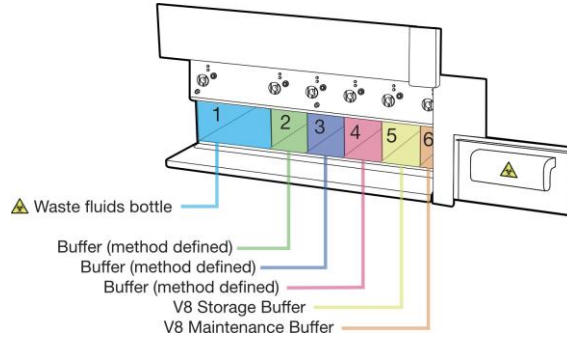


f. Fluid bottle compartment

The fluid bottle compartment is accessed through the front panel. Buffer (re)installation requires careful steps and must be managed through Platinum. The buffer module has locations for seven specially designed bottles. These are defined as:



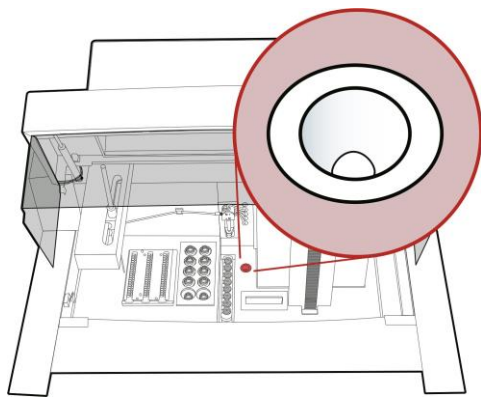
V8 Nexus



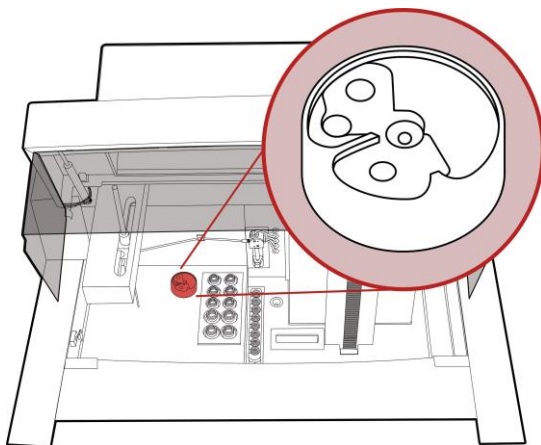
V8 Nexus fitted with the Piercing and Agitation Upgrade

g. Wash station

The wash station is designed for full and effective needle cleaning and purging of the buffer lines. The needle moves directly to the wash station following the preparation of each sample for zero cross contamination. Cleaning and buffer fluids are purged through the needle into the wash station, automating the maintenance of system components.



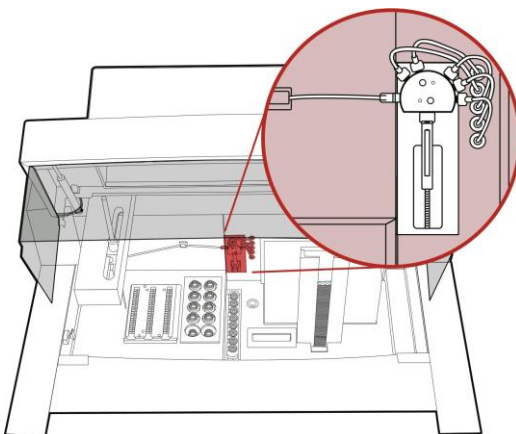
V8 Nexus



V8 Nexus fitted with the Piercing and Agitation Upgrade

h. Dispenser

The dispenser is a device that accurately aspirates and dispenses precise amounts of sample, buffer and cleaning fluid for reproducible results for each application served on the V8.

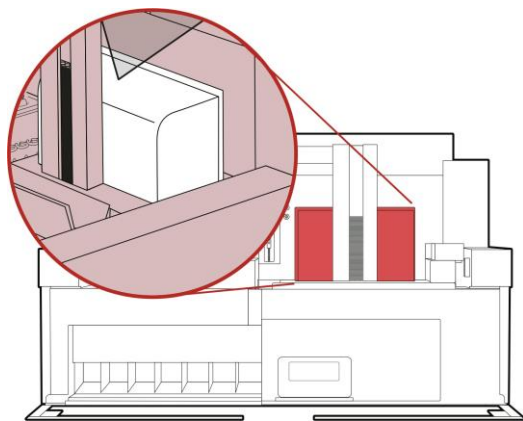


i. Separation unit



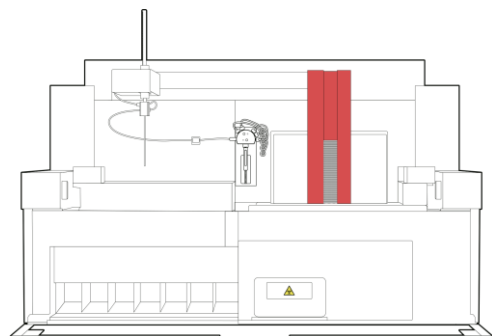
HAZARD

The V8 separation unit is a specially designed casing that contains 8 Peltier regulated capillaries ensuring optimum performance across all separation channels. The separation unit protects the end-user from a high-voltage area containing fragile components. This area is not accessible to the end-user for health and safety reasons; and should only be directly handled by a Helena Biosciences trained and certified engineer.



j. Sample cup load tower

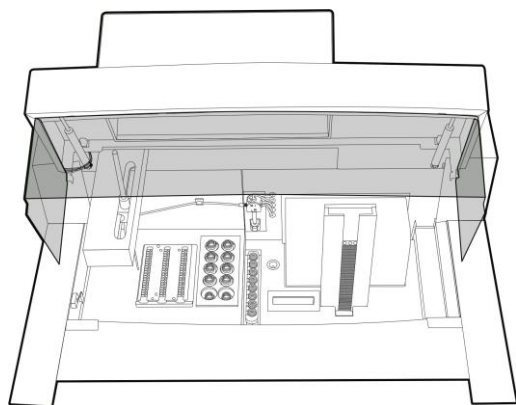
The sample cup dispenser is a holding magazine that contains and dispenses disposable sample cups into the sample cup fill area.



k. Sample preparation and analysis area

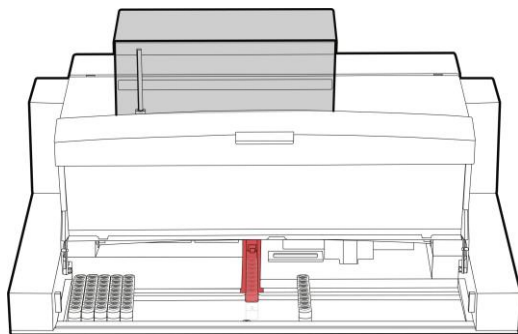
The sample preparation and analysis area contains all the primary components facilitating the automatic preparation and analysis of samples held on-board the V8. The user will be required to interface with this area only when:

- Changing reagent bottles.
- Cleaning and disinfecting area.
- Change removable sample tray.
- Replenish sample cups.



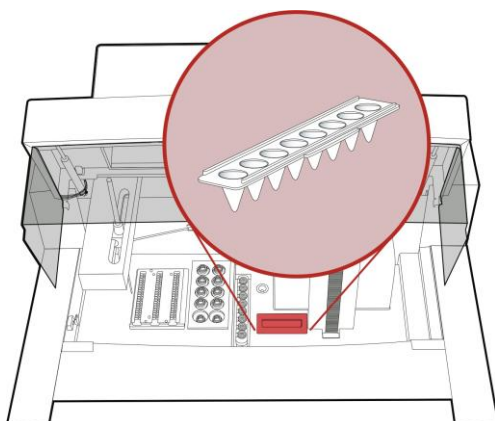
l. Sample rack loading bay

The sample rack loading bay accepts V8 sample racks for the preparation and analysis of samples by the handling arm. The loading bay will hold the sample rack until the preparation of samples for analysis has been completed. Once finished, the sample rack loading bay will eject the processed rack to the right and accept the next rack from the left for the very same process.



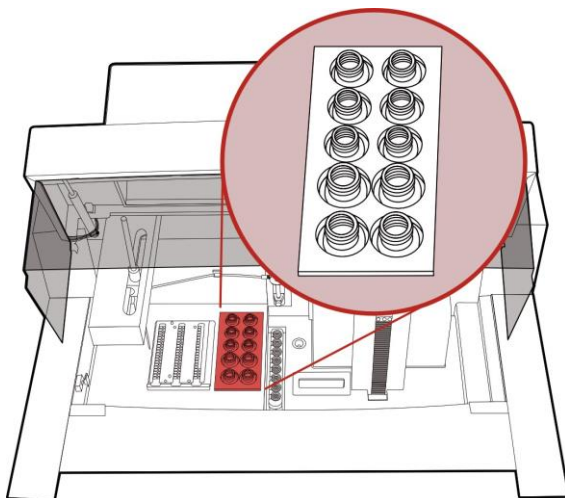
m. Sample cup fill area

The sample cup fill area accepts sample cups supplied by the dispenser for preparation of buffers and samples. Once the sample cup has been prepared for analysis, it will be transported for capillary loading under the separation unit.



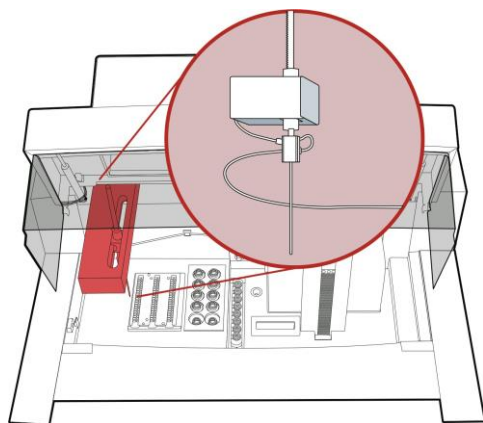
n. Reagent bottle area

The on-board reagent area has locations for ten reagent bottles e.g. antisera, lysing agent and sample diluent. The sample handling arm can access any of these locations which are defined by the method. An active Peltier device cools the bottle area to 15°C so that reagents can be left on-board throughout the day and overnight if required.



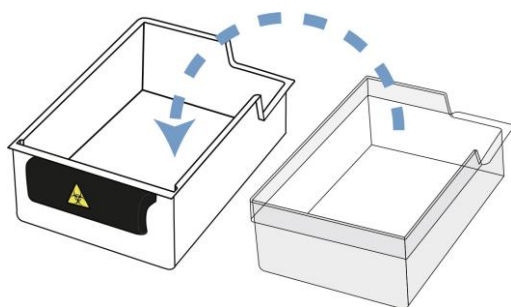
o. Sample handling arm

The sample handling arm handles all sample transfer functions including initial sampling, dilutions, reagent transfer and transfer to gel trays.



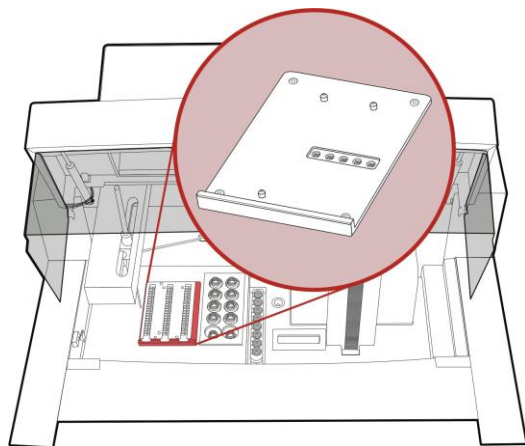
p. Clinical waste drawer

The clinical waste drawer collects and safely contains waste sample cups, residual sample, buffer, reagent and other fluids. Lined with a disposable insert, the waste drawer is designed with health and safety in mind. The clinical waste drawer is designed to hold approximately 100 sample cups and should be emptied when prompted by the V8.



q. Sample tray docking station

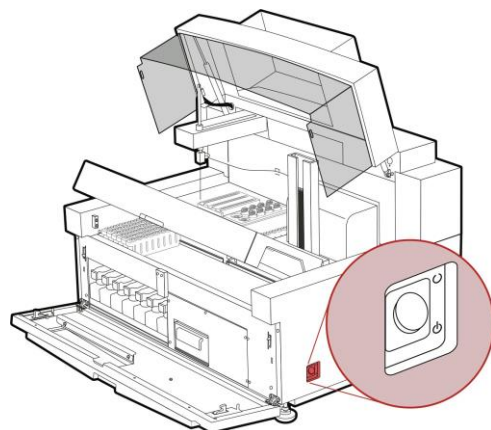
The sample tray docking area is designed to accept a range of removable sample trays for the auto-preparation of samples designated for further testing by gel electrophoresis or as additional dilution positions for further CE analysis. The docking station can accept the full range of SAS and SPIFE sample trays. The optical reader embedded in the surface automatically detects the type of tray on the system and ensures that it matches the method selected. (Sample tray must have V8 identification sticker applied to base).



r. Side switch

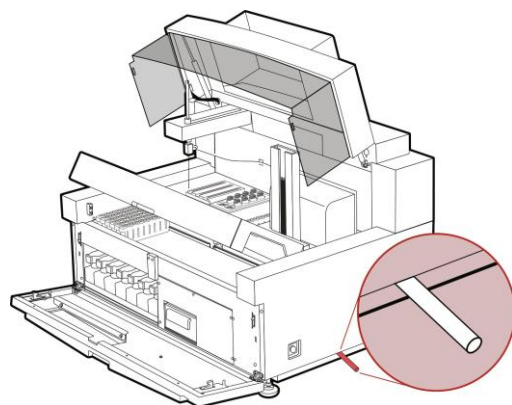
The side switch is designed to initiate hands free, essential maintenance cycles without user intervention. By side switching the V8 to Start-up mode (⏻) the V8 will begin system pre-conditioning in preparation for sample analysis. At the end of the sample analysis, the V8 can be side switched to (⏻) to initiate Shut-down Mode, during which the V8 will post condition. The main power switch situated on the rear of the instrument must be set to "I" in order for the side switch to work.

IT IS IMPORTANT THE V8 IS POSTCONDITIONED AT THE END OF THE DAY AND WHEN THE INSTRUMENT IS NOT IN USE.



s. Waste pipe

The waste pipe will be utilised in the event of overflow within the system, it allows any overflow in the system to exit via a single route. This should be connected to a suitable clinical waste outlet or alternatively to the waste overflow bottle (cat: 0031-176).



V8 Nexus Piercing and Agitation Upgrade – 800020

The V8 Nexus Piercing and Agitation Upgrade is a factory fitted sample handling upgrade that allows the piercing and agitation of capped whole blood sample tubes. The upgrade comprises –

- Cap piercing needle
- Large wash station to allow full needle washing
- Increased volume waste bottle
- 5 port buffer bay with dedicated wash station fluid position
- High intensity LED light source

The V8 Nexus Piercing and Agitation Upgrade is for use with haemoglobin methods only (V8 Haemoglobin UltraScreen, V8 Hb A1c, etc) and cannot be used with other V8 methods and kits. In order to accommodate the new modules the sample tray docking station is removed on all upgraded systems.

Mode of action

- a. Capped tubes are brought into the sampling area and scanned via the inbuilt barcode reader.
- b. The rack is positioned so that the first tube location is positioned under the tube stripper
- c. The tube stripper clamps the capped tube in place and the needle pierces the cap septum
- d. The sample is agitated by the needle using plasma picked up at the surface of the sample and expelled deep within the red blood cell layer.
- e. Further mixing is carried out within the cell layer
- f. A sample aliquot is taken to the V8 sample cup
- g. The needle is washed both inside and out
- h. The stripper rises and the next tube location is positioned beneath it

Considerations

- Buffer position 4 is dedicated to the full needle wash station. V8 Storage Buffer must be placed on this position at all times
- If samples have been stood for longer than 24 hours it is recommended that the sample is manually agitated or vortexed and analysed within the next 24 hours
- Packed cells cannot be used
- Tubes must contain at least 1 ml functional sample volume
- Agitation should not be attempted on uncapped tubes
- Only haemoglobin methods can be used on a V8 Nexus with a V8 Nexus Piercing and Agitation Upgrade.

The use of cap piercing and agitation at the external sample position when using a track connection can be accommodated upon request.

Tube Specifications

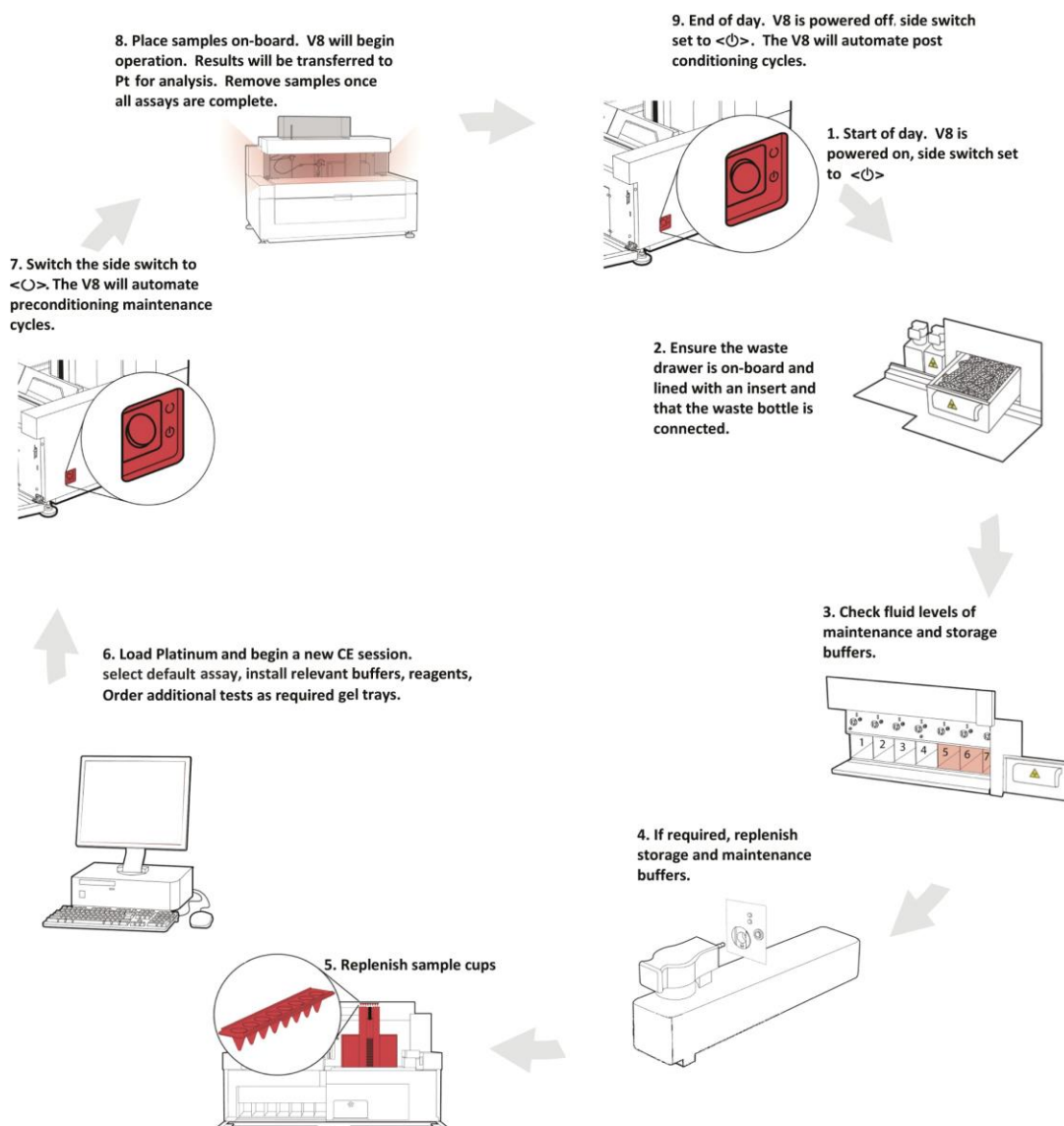
- BD Vacutainer (L x D) – 100 mm x 16 mm, 100 mm x 13 mm, 75 mm x 13 mm
- Greiner Vacuette (L x D) - 100 mm x 16 mm, 100 mm x 13 mm, 75 mm x 13 mm

The V8 system is designed to be simple to use. As such, the daily routine of operation can be broken down into the following steps. It is strongly advised that these are conducted everyday so as to maintain the optimum performance of the instrument.

For more information on how best to maintain the condition of the instrument, please refer to Part 9: Maintenance of the V8. For information on individual assays, please refer to the IFU located on the web, directions and password can be found in each kit box.

5.1

Quick user guide to daily operation



5.2

Daily operating instructions


The following section describes how to prepare the V8 for operating and shutting the system down after use.


5.2.1


Switching the V8 on and off

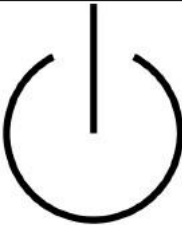
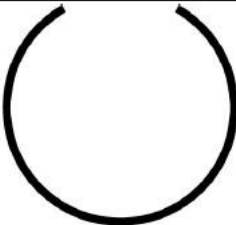
Power to the V8 is controlled by a main *ON/OFF* switch located at the rear of the instrument. This switch is used to power the instrument.

Daily operation of the V8 should be controlled solely by the *SLEEP/AWAKE* switch on the right hand side of the instrument. It is recommended that the rear power switch only be used when the V8 is being unused for a period of three days or more.



In order to turn the V8 on for operation and to initiate the preconditioning cycle, set the side switch it to .


To put the V8 back into SLEEP mode after operation, set the side switch to . This will initiate the post-conditioning cycle.

N.B. The V8 MUST be switched off at the side switch (position ) and allowed to complete the post-conditioning cycle before it is switched off using the rear switch (failure to do so WILL cause irreparable damage to the capillaries).

Stand-by IEC 5009, JTC1 010 To identify the switch or switch position by means of which part the equipment is switched on in order to bring it into the standby-by condition.		Ready ISO 1140, JTC1 009 To indicate the machine is ready for operation.	
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5.3 Preparing the V8 for operation

The power switch located at the rear of the V8 will be ON and the side switch set to . The V8 must be ready for the pre-conditioning cycle. Therefore, before setting the side switch to  the user must check the following protocols:

- The relevant test mode is selected (5.4.1)
- The required default assay is selected from Platinum (5.4.2) and the relevant buffers are on-board.
- The reflex test priority is selected. (5.4.3)
- The clinical waste drawer is on-board and lined with an insert (refer to section 9.14.1).
- The waste bottle is connected to port 7 of the fluid bottle compartment or port 1 if using the V8 Piercing and Agitation Upgrade (800020) (refer to section 9.14.2)
- V8 Storage Buffer and V8 Maintenance Buffer are on-board in ports 5 and 6 respectively (refer to section 5.7.1).
- Sample cup load tower is filled.
- To initiate pre-conditioning and capillary preparation for use, set the side switch to  once all checks are complete.

5.4 Programming Platinum

At the start of every session, it is important that the user checks and/or sets the test mode and selects the default assay as the V8 will pre-condition to the default assay automatically.

5.4.1 Setting the V8 test mode

The V8 has 2 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

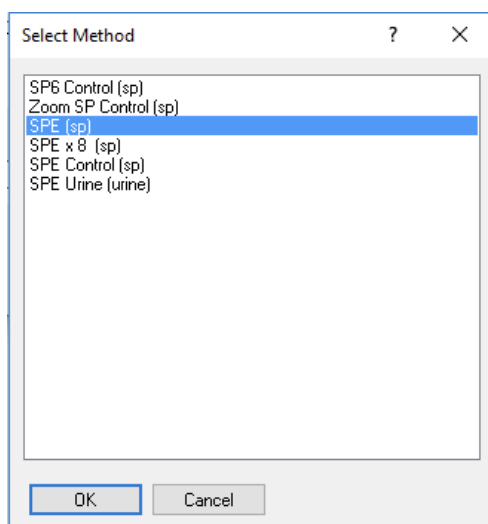
In this mode, the V8 will only process and analyse those samples that have been flagged for reflex testing (and appear in the test list within Platinum), or those that have been individually ordered. Other samples within the sample rack will be ignored.

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

5.4.2 Selecting default assay

To choose the default assay:

Choose **V8 System > Select Default Method** to open the **Select Method** dialogue box. Choose the desired default assay from the Method to Use list. Advanced customisation options are available for each defined assay, however, it is recommended that these are set to default.



5.4.3

Reflex test priority

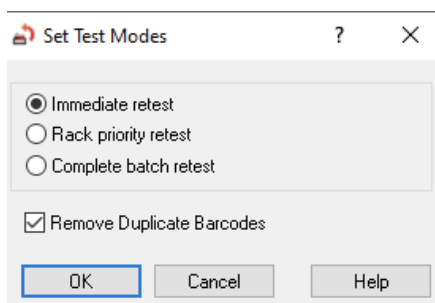
The reflex test priority determines when the V8 performs reflex tests, whether these have been ordered manually or automatically. For more information on reflex testing please refer to section 5.9.3.4

There are three Reflex Test priority modes: Immediate, Rack Priority and Batch.

- Immediate mode will perform each ordered test immediately, thus moving racks back into the sample handling area, 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 tests per rack.
- Complete batch retest mode will hold all ordered tests until prompted to perform analyses at the user's discretion. This mode should be selected when optimising workflow and instrument throughput.

To set the Reflex Test mode:

Choose **V8 System > V8 Mode Selection...** to open the **V8 mode selection** dialogue box. Select the desired reflex mode. Note – reflex mode can only be selected ONCE per CE session and cannot be changed throughout an active session.



5.5

Running in Multi-Assay mode

The V8 is capable of automating assay switching with minimum instrument downtime. To run the V8 in multi assay mode, the following steps should be followed:


- All relevant buffers and reagents should be on-board and installed as per instructions (see section 5.7.1).
- Select the required default assay (see section 'Selecting Default Assay', 5.4.2) and run samples as required.
- Serum Proteins, Urines and Immunodisplacement tests can be run simultaneously in one rack.
- To do this, ensure that the additional sample types are ordered appropriately.
 - Default assay set to run Serum Protein e.g. SPE (sp). All serum samples will run as default.
 - Order Urine and Immunodisplacement tests through Test Ordering (section 5.9.3.1).
 - Place samples on-board the V8 for simultaneous analysis.
- For multiple assay switching e.g. SPE and Haemoglobin UltraScreen and Hb A1c, the V8 will automatically perform pre-conditioning of the capillaries to run the new buffer.
- To do this, select one method as the default assay. All racks on-board will be analysed using this assay.
- For those samples that require analysis using the different assay, either change the default method after all other samples have been analysed, or, order the required tests through Test Ordering (section 5.9.3.1).
- For multi-assay switching between SP, Haemoglobin UltraScreen, Hb A1c, CDT and Glyco Liver Profile assays, samples should be batch loaded, using separate racks per test.

N.B. Assay switching between SP, Haemoglobin UltraScreen, Hb A1c, CDT and Glyco Liver Profile will require capillary preconditioning. This will take approximately 20 minutes. Helena Biosciences recommends that you batch load samples according to assay.

5.6 Shutting down the V8 after use

It is important that the V8 is shut down correctly after use to maintain optimum performance. The system MUST post-condition fully to ensure capillary integrity.


To shut the V8 down:

Remove all sample racks from the sample rack loading bay. Remove and cap all reagents in the reagent block. If required these should be refrigerated. Switch the side switch to .



The V8 will begin post conditioning with the voice command 'PREPARING FOR SLEEP MODE' and pulse yellow. This takes around 15 minutes.

When post-conditioning has finished, the V8 lights will turn off. This indicates that the instrument is now in SLEEP mode.

N.B The V8 will automatically shut down after a period of inactivity, this period is user definable, the default setting is 4 hrs.

If the V8's side switch is switched to  whilst it still has racks onboard to be tested, the V8 will complete all necessary testing before automatically beginning the shutdown procedure. If the operator intends to use this method for shutting down the V8 they must first ensure that all necessary buffers, reagents, sample cups and provision for waste is made to allow the instrument to complete its testing and shutdown correctly, otherwise the instrument may be prevented from shutting down.

5.6.1 Shutting down the V8 without the necessary buffers onboard

If the V8 is shut down without all the buffers onboard necessary for post conditioning to occur the V8 will stay in the yellow light maintenance mode indefinitely. It will speak the "OUT OF LIQUID" error and will display onscreen the details of the buffer that needs to be replaced in order for post conditioning to occur. If this happens the missing liquid(s) need to be replaced, then the instrument side switch must be set to  then back to . Post conditioning will then be carried out automatically.

It is important that Platinum remains open during the post-condition process.

5.7 General instrument instructions

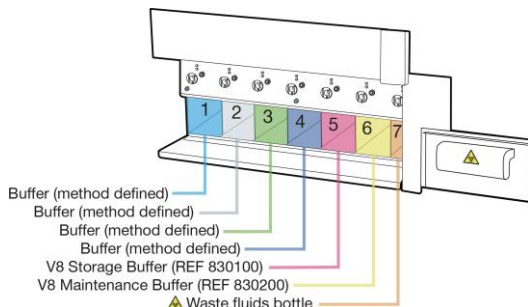
The following section describes the general instrument instructions and procedures for effective running of the system.

5.7.1 Installation of buffer bottles

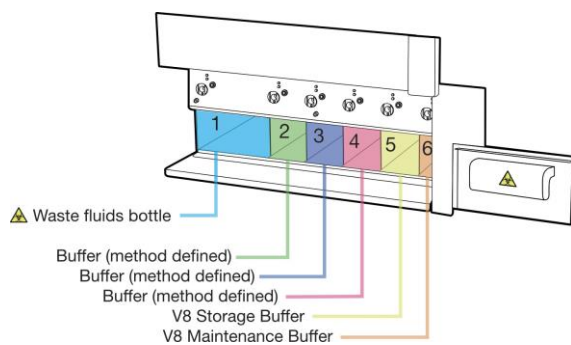
The V8 will only accept Helena Biosciences V8 buffers and reagents. Each bottle has a unique barcode and this information MUST be entered when the user is prompted before the buffer will be accepted on-board. Once a bottle has been exhausted, it cannot be refilled and placed back on-board. This is to ensure QC and system integrity.

If installing a bottle before operation please ensure the system is in standby mode. Once installed, start a new V8 session and wait until prompted to enter all barcode information. If installing a bottle during operation, there is no need to start a new session.

The V8 fluid bottle compartment contains space for seven buffer bottles. Three of these positions are not user-definable and should always be loaded with the appropriate bottle: V8 Storage Buffer in port 5; V8 Maintenance Buffer in port 6.



V8 Nexus



V8 Nexus fitted with the Piercing and Agitation Upgrade

The V8 has active liquid level sensing, and as such will always notify the user when a buffer bottle is empty or when the waste bottle is full. The waste cap designated with the biohazard sticker should ONLY be used with port 7 OR port 1 when using the V8 Nexus Piercing and Agitation Upgrade.

5.7.2

To install a new buffer

- Attach a new filter unit to the inlet pipe of the bottle connector cap. The narrow end of the filter unit should be carefully inserted inside the pipe and securely fitted.



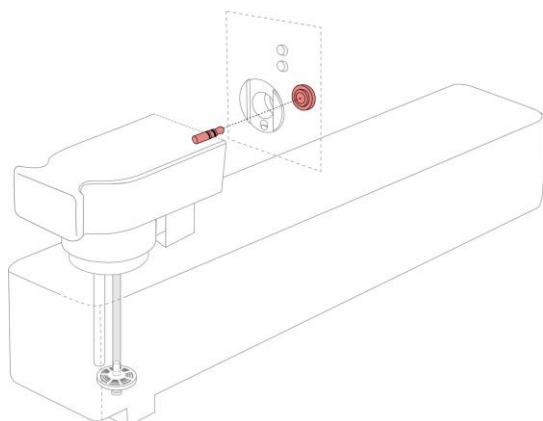
- Access the fluid bottle compartment by opening the *Front Cover*.
- Remove any exhausted buffer bottles by holding the bottle connector and pulling backwards gently, but firmly.



CAUTION

N.B. Care must be taken when installing and removing bottles. Do not pull on the bottle to remove as this can lead to damage of the cap. Do not invert the fluid cap after removal.

- Dispose of the old buffer bottle, filter unit and any excess liquid.
- Carefully place the bottle connector into the buffer port ensuring the cap is firmly located within the buffer unit. The LED light will change to Green.



- The V8 will audio prompt '*UNKNOWN LIQUID.*' The **Define Buffer** window will open, with one of the buffer ports highlighted in blue.
- Scan or enter the barcode information into the highlighted barcode box using the hand-held barcode scanner. Click **OK** to close the window.

N.B. If installing multiple bottles do not attempt to scan all barcodes at once. Wait until prompted to do so. Do not manually open the [Define Buffer] windows, always wait until prompted.

- The blue highlight will move to the next port that has been changed and the V8 will announce '*UNKNOWN LIQUID.*' Scan or enter the barcode for this buffer. Click OK to close the window. This process will continue until all new buffers have been identified to the Platinum software.

- i. Close the front panel. The V8 will then purge all new liquids, accompanied by the voice command '*PURGING NEW LIQUID*'. Depending upon how many liquids have been changed, this process should take approximately 2-6 minutes.
N.B. In sites with multiple V8 instruments, partially used bottles cannot be taken off one V8 and installed on another. When switching assays, it is recognised by Helena Biosciences that partially used bottles will be removed and re-installed on the V8 at a later time. Re-installation is the same as if you were installing a new bottle, as Platinum will recognise the barcode and extract stored information on previous use. However, this information is stored only on the system which was first loaded with the buffer. Another instrument cannot retrieve this information, and thus, the bottle is likely to run dry and air introduced into the system.

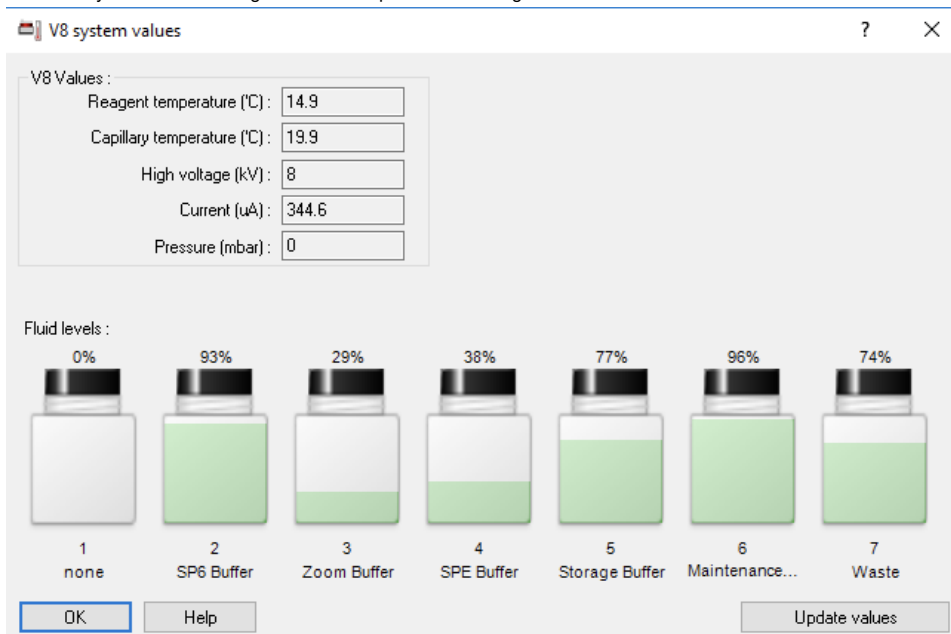
5.7.3

Checking buffer levels

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

To check the buffer fluid levels:

- a. Choose **V8 System > V8 System Actual Values** or click .
- b. In the V8 system values dialogue box click Update values to gain a measurement of fluid levels within the fluid bottle compartment.



V8 system values [?] [X]

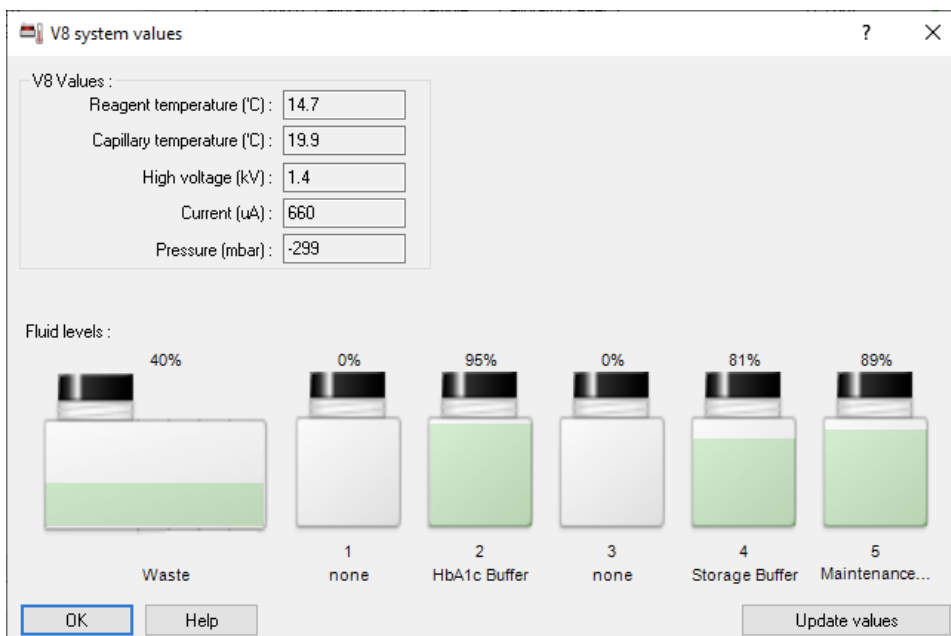
V8 Values :

Reagent temperature (°C) :	14.9
Capillary temperature (°C) :	19.9
High voltage (kV) :	8
Current (uA) :	344.6
Pressure (mbar) :	0

Fluid levels :

0%	93%	29%	38%	77%	96%	74%
1 none	2 SP6 Buffer	3 Zoom Buffer	4 SPE Buffer	5 Storage Buffer	6 Maintenance...	7 Waste

[OK] [Help] [Update values]



V8 system values [?] [X]

V8 Values :

Reagent temperature (°C) :	14.7
Capillary temperature (°C) :	19.9
High voltage (kV) :	1.4
Current (uA) :	660
Pressure (mbar) :	-299

Fluid levels :

40%	0%	95%	0%	81%	89%
Waste	1 none	2 HbA1c Buffer	3 none	4 Storage Buffer	5 Maintenance...

[OK] [Help] [Update values]

N.B. Fluid levels in "V8 System Actual Values" may vary slightly to real world levels and are therefore primarily for indication purposes only

5.7.4

Loading reagents

V8 antisera and supplementary reagents/diluents can be placed on-board the V8 for automated Immunodisplacement and sample preparation. The V8 has the capacity to hold on-board ten different reagents with open access positions. Positions are user defined

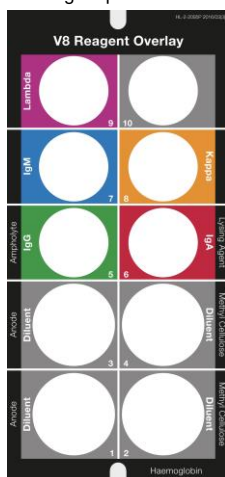
and dependent upon the assay being performed. However, to ensure correct loading, the V8 comes with an overlay for the reagent bottle area. This is supplied with the V8.


The reagent block is Peltier temperature controlled ensuring that the reagents can remain on-board throughout the day and without a compromise to reagent stability. It is suggested that reagents are placed on-board at the start of the day before any sample analysis commences.

N.B. Installation of reagents is not an automated process. The user MUST enter the barcode information into Platinum for the V8 to recognise the reagents on-board.

To install reagents:

- a. Access the reagent panel by raising the top cover to the sample preparation and analysis area.
- b. Antisera, haemoglobin lysing agent and haemoglobin ampholyte solution can be placed in locations 5-10 of the reagent panel and in any combination.
- c. Assay diluents, V8 Anode Buffer, V8 Methyl Cellulose Solution and V8 CDT Auto Diluent can be placed into position 1, 2, 3 or 4 of the reagent panel.



- d. Choose **V8 System > Define Reagents** to open the Reagents window or click .
- e. 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.
- f. Multiple reagents can be entered in one go.
- g. Once entered, close the lid to the sample preparation and handling area. The V8 will commence analysis.

V8 Reagents

	Reagent 1	Reagent 2	Reagent 3	Reagent 4	Reagent 5
Barcode :	JK1245TY00	0000000000	0000000000	0000000000	126TYBDPL0
Product reference :	SPE Diluent				IgG (Green)
Expiry :	1121				1220
Lot :	9				8
Batch index :	207				1
Tests Left :	167				9
Max tests :	167				10
Cap Opened on :	05/05/2020				30/04/2020
Open Stability (days left) :	182				24

	Reagent 6	Reagent 7	Reagent 8	Reagent 9	Reagent 10
Barcode :	86KJW4BG69	LO45HB22NP	99RTU23TNK	OJT3499CBT	0000000000
Product reference :	IgA (Red)	IgM (Blue)	IgK (Orange)	IgL (Purple)	
Expiry :	1220	1220	1220	1220	
Lot :	8	8	8	8	
Batch index :	1	1	1	1	
Tests Left :	9	9	9	9	
Max tests :	10	10	10	10	
Cap Opened on :	30/04/2020	30/04/2020	30/04/2020	30/04/2020	
Open Stability (days left) :	24	24	24	24	

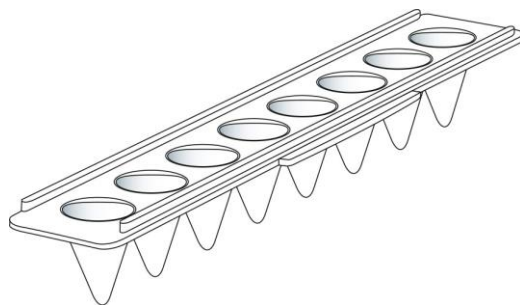
OK Cancel Help

5.7.5

Loading sample cups

The sample cups have eight wells and an asymmetric orientation. They contain a flat edge and a lipped edge. They are packed in clusters of eighteen all in the same orientation. It is important when loading the sample cup load tower to keep all cups in this orientation.

Sample cups are provided in every kit except V8 Storage Buffer and V8 Maintenance Buffer kits. Every time buffer and reagents are loaded onto the V8, please ensure the Sample Cup Dispenser is equipped with the sample cups provided within your kits.

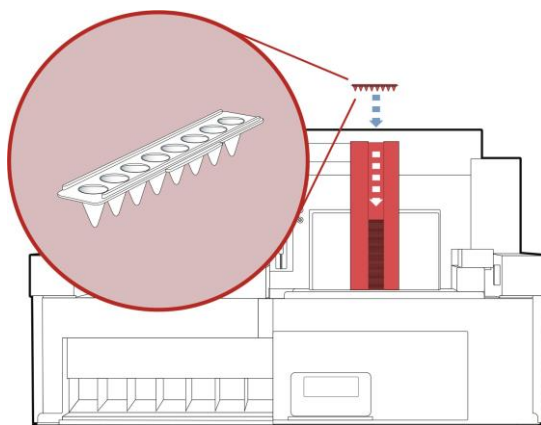


To load sample cups:

- Access the sample cup load tower by raising the top cover to the sample preparation and analysis area.

N.B. If the V8 is in operation, raising this top cover will cause the V8 to 'PAUSE' all sample handling activity. Once closed, normal operation will continue.

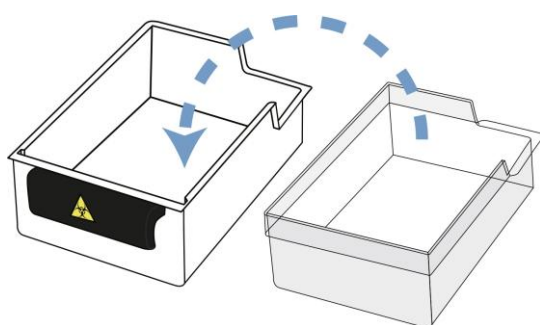
- Remove stacked sample cups from packaging; ensuring cups remain in the same orientation.
- Hold the stacked cups between thumb and forefinger, with the lipped edge facing forward.
- Carefully slide the stack from the top of the sample cup load tower, down to the bottom, ensuring that the cups remain stacked and level, and that the lipped edge of the sample cup appears through the sample cup dispenser window. It is recommended that they are not dropped from the top, but guided down to the bottom.
- Continue to fill the cups in this manner until the load tower is full and close the top cover.



5.7.6

Clinical waste drawer

It is important to change the clinical waste drawer when prompted by the V8. The waste drawer inserts are designed to hold circa 100 sample cups and can be disposed of as clinical waste in accordance with local waste guidelines. The clinical waste drawer inserts are orientation specific. Please ensure the insert fits neatly inside the waste drawer to avoid interference with internal mechanical movements.



5.7.7

Sample racks and sample tubes

The V8 is supplied with 14 custom-moulded sample racks capable of holding 8 sample tubes. The maximum number of sample racks that the V8 can hold is 14 totalling 112 samples at full on-board capacity. Each sample rack is individually barcoded (R01 – R14) for identification by the V8. These barcodes must not be removed or changed.

Sampling is direct from uncapped primary tubes.

The range of sample tube size is:

Diameter:	max-16mm
Height:	max-100mm

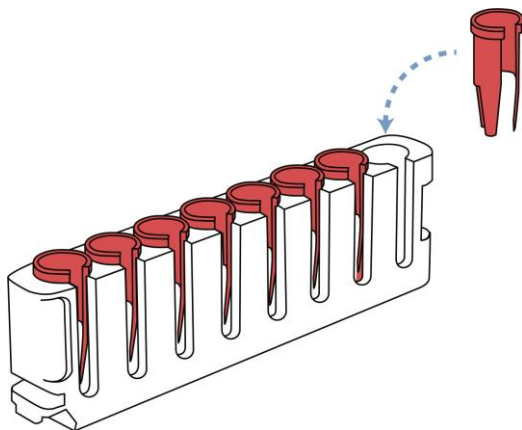
When using the V8 Nexus Piercing and Agitation Upgrade (800020) sampling is direct from capped primary tubes.

Tube specifications when using the V8 Nexus Piercing and Agitation Upgrade:

BD Vacutainer (L × D) – 100 mm × 16 mm, 100 mm × 13 mm, 75 mm × 13 mm

Grenier Vacuette (L × D) - 100 mm × 16 mm, 100 mm × 13 mm, 75 mm × 13 mm

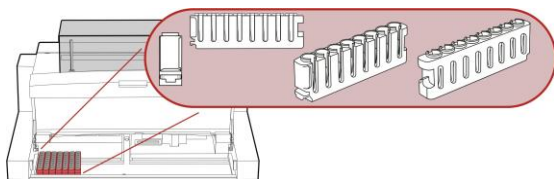
Barcodes must be within the height of 2cm and 8cm from the bottom of the sample tube in order for the internal V8 barcode reader to be able to read the barcode.



5.7.7.1

Placing samples on-board V8

Sample racks are loaded on to the left hand side of the sample rack transport area ensuring that the rack barcode is facing the top left hand corner of the sample rack transport area.



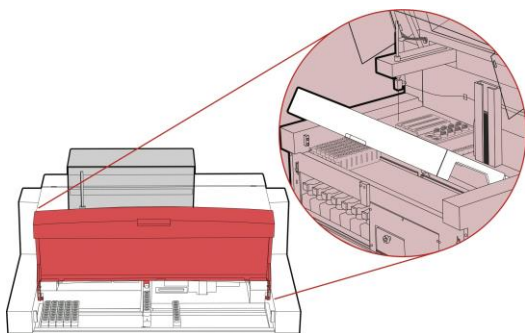
Racks can only be loaded in one orientation. At the barcoded end of the rack is a lip that slots in to the side of the sample rack transport area base plate. This is to ensure that the V8 can move the racks safely and efficiently. The V8 will move sample racks into the rack loading bay for sampling. Once samples have been prepared, the rack will be placed to the right hand side of the sample rack transport area.

Due to the continuous loading and multi-assay functions of the V8, samples can be loaded in any order, and as such there is no specific batch loading option. Up to 14 racks can be loaded at one time. Once the samples in a rack have been processed by the default assay, the user or the Expert System will determine if there are any further tests to be conducted. If there are no further ordered tests or reflex assays assigned to that rack, the rack can be removed.

However, if there are outstanding tests for the analysed rack, then the V8 will recall the rack for further analysis on the samples. The time at which this happens is determined by the Set Test Priority as defined by the user (see 5.4.3).

To load a sample rack:

- a. Open the rack cover to the sample transport area. The V8 will pause sample handling.



- b. Place the sample racks onto the left hand side of the sample rack transport area, ensuring that the rack barcode is facing the top left hand corner and the tube barcodes are facing left. Close the rack cover to the sample rack transport area. The V8 will begin scanning the rack and sample tube bar codes.

N.B. The racks can only be loaded onto the system in one orientation, with the rack barcode facing the left and to the top of the sample rack transport area.

5.7.8


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.

- Barcodes present: the V8 will process each sample individually and will be driven preferentially by barcode; not rack number and position.

- Barcodes 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 holds the tube identification encoded in the barcode in the navigation work list under the column 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 will be left blank.

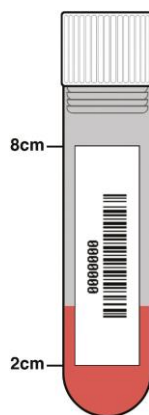
To avoid disruption to the workflow, the V8 will process all the samples, performing the default assay for any unlabelled or mis-read tubes. When an unknown tube (missing or misread barcode) is detected, the tube will appear in the missing bar code work list (MWL) and is identified by .

Rack	1	2	3	4	5	6	7	8	Remove rack
R04									<input type="button" value="Remove R04"/>
R05									<input type="button" value="Remove R05"/>
R08									<input type="button" value="Remove R08"/>

If all barcodes are read the rack will not appear in this list.

The V8 will check all positions in the rack for samples, and so tubes with unread barcodes will be sampled.

N.B. The barcode must be placed onto the tube between 2cm and 8cm from the bottom of the sample tube.



V8 Tube Specification


No tube greater in height than 100 mm (or 106mm with a cap) should be used on the V8 system. The sample racks can accommodate tubes with an outer diameter of 13 mm when using red inserts or < 16 mm with the inserts removed.

75 mm tubes with no cap will not be detected by the tube stripper when using the V8 Nexus Piercing and Agitation Upgrade.

5.7.8.1

Adding a tube ID to processed samples

Sample tubes with no barcode or ones that have been mis-read 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, click on the Tube ID column of the unlabelled sample.
- This will enable the user to scan the tube with the barcode scanner, or to manually enter a tube ID.
- It is also possible to enter sample barcode information from the worklist. To access this, choose [Worklist > Set Up Worklist](#) or click the  toolbar button.

5.7.8.2

To remove a “Sample Missing Barcode” flag from Platinum

Sample tubes with missing barcodes or mis-read barcodes will be listed in the 'Missing Barcode' 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 correct assay has been performed and to notify the system that the user has changed the samples in the rack.

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

5.7.8.3

How to remove a rack from the worklist

To remove the rack click the [Remove Rxx](#) button and if required any outstanding test.

Rack	1	2	3	4	5	6	7	8	Remove rack
R04									
R05									
R08									

N.B. Do not click the remove rack button until the data is visible on screen.

5.7.8.4

Skip position barcode

If you wish to run a rack containing empty sample positions, skip position barcodes should be used. These barcodes are made up of a series of 6 or 7 zeros (depending if a check digit is used). When the V8 pulls a rack into the sample handling area and this barcode is detected, the V8 will not sample from this position and this position will not appear in the Platinum worklist.

This is particularly useful when running Immunodisplacement as a default method with unfilled racks to save on unnecessary ID reagent wastage, when using the gel integration feature of the system with a 9 position IFE gel to save time, or when using the control methods to save on wastage of CETrol control material.

5.7.9

V8 gel tray handling

The V8 automates sample handling and preparation of recalled samples for analysis by agarose gel electrophoresis. The sample handler is able to aliquot samples into a removable gel sample tray which can then be transferred onto one of Helena Biosciences SAS/SPIFE instruments for further analysis. The gel tray must contain a V8 gel tray identifying label (supplied as part of the V8) and a paired tray barcode.

5.7.9.1

To affix V8 gel tray identifying label

SAS SAMPLE TRAY STICKER for the 0030-650 SAS 3 Sample Tray 60 pos.



SAS SAMPLE TRAY STICKER for the 0030-653 SAS 3 Sample Tray 100 pos.



SAS SAMPLE TRAY STICKER for the 0030-652 SAS 3 Sample Tray 80 pos.



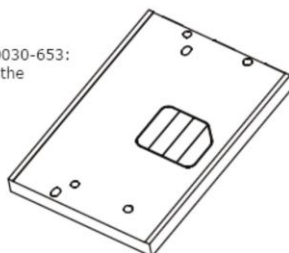
TRAY STICKER for use of the 0012-022: Adapter 96 well tray holder



All stickers can be placed on the specified Tray

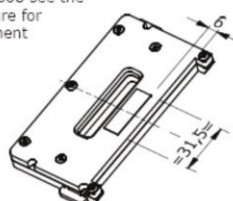
SAS 3 SAMPLE TRAY'S

For the 0030-650 , 0030 652 & 0030-653:
The picture shows the bottom of the Tray the sticker needs to be positioned in the special similar shaped area



SAS1+ SAMPLE TRAY

For the 0030-608 see the following picture for correct placement of the sticker



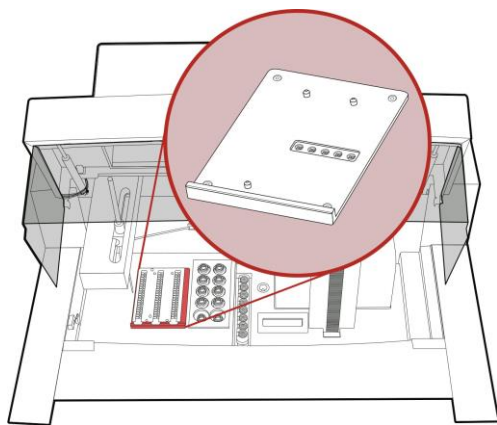
SAS SAMPLE TRAY STICKER for the 0030-608 SAS 1 Sample Tray 24 pos.



5.9.1.2

To load a SAS gel tray:

- Access the sample tray docking station by raising the top cover to allow access to the sample preparation and analysis area.
- Prepare the required SAS sample tray as per SAS operation manual.
- Place the SAS tray onto the sample tray docking station ensuring the locator pins are engaged into the SAS tray.



- d. The V8 optical sensors will detect the type of SAS tray placed on-board and will adjust all sample handling and preparation accordingly.
- e. Scan or enter the SAS tray ID number in the window prompt in Platinum.

N.B. paired barcode stickers can be ordered from Helena Biosciences (catalogue number 312300) for gel tray identification. IFU will be included.

- f. Order the required assay from Platinum – either by reflexing the sample in question or by going to the test ordering window. Alternatively for methods consisting of a larger number of samples the default method may be changed.

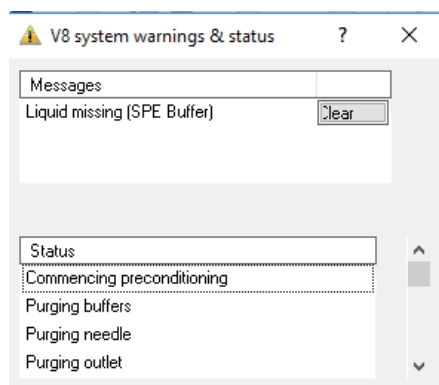
5.7.10

V8 System warnings and status

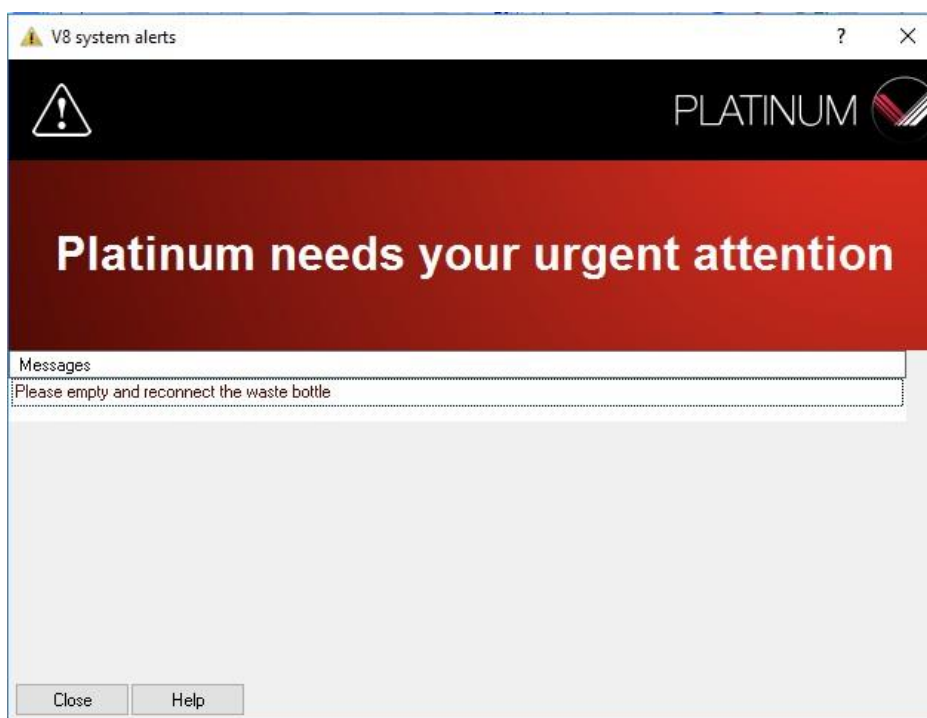
Platinum software contains a dialogue box that continually informs the user of the instrument status, or action, and of any warning or error messages. All information regarding the status of the instrument can be found here. It is strongly recommended that this box remain open during V8 operation.

To access V8 system warnings and status choose **V8 System > Show Status** or click on the  in the toolbar.

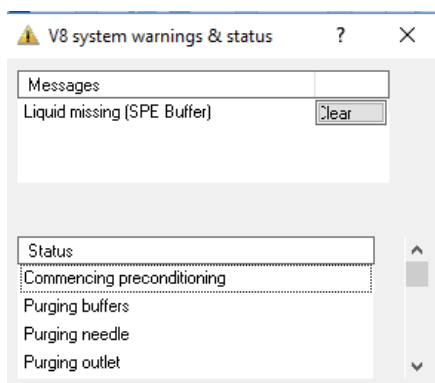
Critical messages will appear in a larger, more visible warning dialogue box.



If an item that has appeared in the **Messages** box requires user input before the V8 can continue to operate a larger more visible warning message will appear on screen this will clearly state the issue encountered and what needs to be done to resolve this issue.



Once the operator has resolved the identified issue, the warning indication will disappear from the screen and also be removed from the attention box in the system status window. In certain circumstances however; e.g. if the instrument runs out of serum protein diluent; the instrument is unable to detect that the necessary resolution action has been carried out. In this situation the user must click the clear button that appears in the system status [Messages](#) box.



5.7.11

List of attention messages and actions required

Attention message	Machine pauses	Action required
Liquid missing (specified)	Yes	Replace missing liquid if necessary click clear button
10% liquid remaining in bottle	No – Though will imminently	Change depleted buffer bottle or load a second bottle into an available port.
Unknown liquid, please scan bottle barcode	Yes	Scan bottle barcode of new bottle added to system
Sample cup load tower nearly empty	No – Though will imminently	Sample cups will need to be replenished soon.
Cup load tower empty, please load sample cups	Yes	Sample cups need replenished in sample cup load towers
Front cover open	No	Close front cover of instrument
Top cover open	Yes – Sample handling	Close top cover to resume sample handling
Rack cover open	Yes – Sample handling	Close rack cover
Please replace the waste bin	No	Replace waste drawer to continue testing
Please empty the waste bin	No	The waste drawer needs to be emptied and replaced

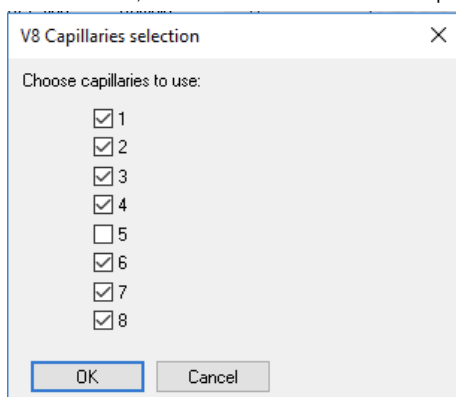
Attention message	Machine pauses	Action required
Please replace the waste bottle	Yes	Replace the waste bottle
Please empty and reconnect the waste bottle	Yes	The waste bottle is full and needs to be emptied and replaced
Empty sample tray required	Yes	Sample tray held on board full, to prepare further gel samples remove the full tray and place a new sample tray on board for gel tray preparation to continue
Sample tray missing	Yes	Need to place sample tray onboard for gel tray preparation to continue

5.7.12

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.

- Choose **V8 System > Manage Capillaries**.
- 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 next to the capillary of interest. To switch the capillary on, ensure the checkbox is ticked.

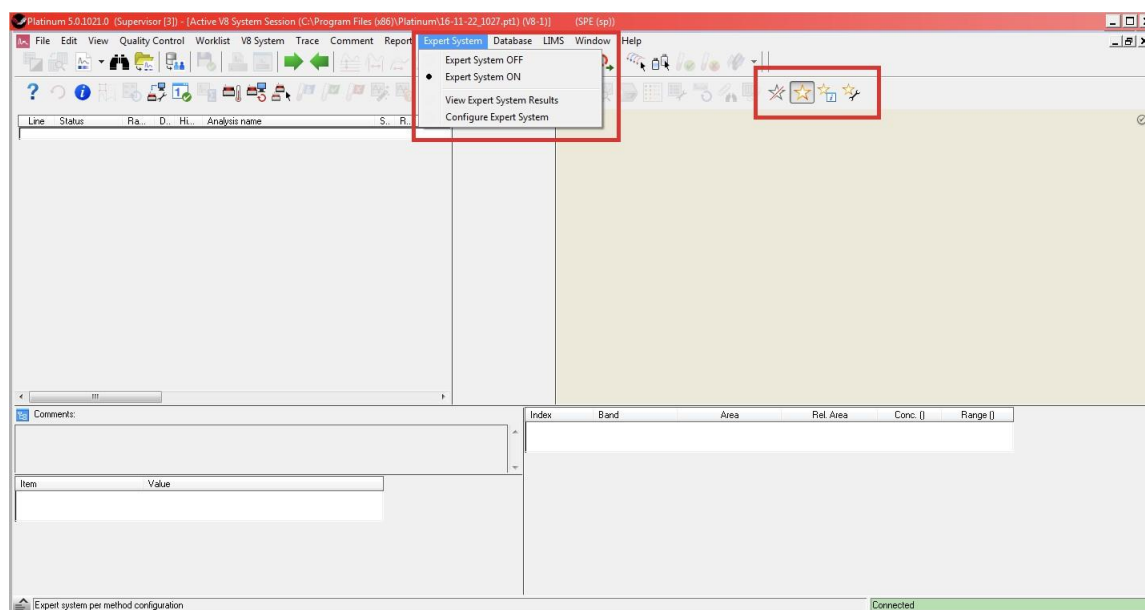


N.B. This dialogue box can also be accessed by right-clicking a processed sample in the navigation work list and choosing **Disable Capillary**.

5.8

Accessing the Expert System

The Expert System can be turned on, turned off, configured or results viewed only when viewing an active session or any previous sessions, via the relevant Expert System icons or the Expert System menu options:



- **Expert System OFF** – This option turns off the Expert System and no interpretation will be performed
- **Expert System ON** – This option turns on the Expert System for automatic interpretation
- **View Expert System Results** – This option opens a floating window that informs the user what parameters has caused a sample to be flagged up or assigned as normal

- **Configure Expert System** – This option opens the configuration for the Expert System for the user to adapt the settings and parameters that are used

Configuring the Expert System

When the Configure Expert System option or icon is selected, a new window appears with all the settings and parameters that can be used to fully configure the Expert System:

★ Configure Expert System for SPE ✕

Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein
Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	

☒ Activate Expert System

☒ Activate Expert System for :
 Method : SPE (sp) ▼

☐ Activate Automatic Reflex Testing

☐ Exclude patients from auto reflex if : ☒ Patient has been historically immunotyped
☐ Patient has been previously seen

Reflex : ▼

☐ Activate Reflex on Warnings

5 Or more.

Full Session Report

Save As

To Clipboard

☐ Add normal results to the LIMS queue.

☐ Activate Relative Area Analysis

☐ Activate Absolute Area

☐ Activate Peak Time

☐ Activate Peak Height

☐ Activate Chemistry Values

☐ Activate Chemistry Totals

☐ Activate Peak Sharpness

☐ Activate Total Protein

Peak Ratios

☐ Activate Area Ratio

☐ Activate Height Ratio

☐ Activate Timing Ratio

☐ Activate Relative Area Ratio

☐ Activate Peak Symmetry

☐ Activate Formula

☐ Activate Peak Number

OK
Help

Once the Expert System is activated, many more tabs are available and the Configuration tab can be set up:

★ Configure Expert System for SPE

Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein
1 Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	

☒ Activate Expert System
 2 ☐ Activate Expert System for :
 Method : SPE (sp)

3 ☐ Activate Automatic Reflex Testing
 4 ☐ Exclude patients from auto reflex if :
 5 ☒ Patient has been historically immunotyped
 ☐ Patient has been previously seen

6 Reflex :

7 ☐ Activate Reflex on Warnings
 5 Or more.

8 ☐ Activate Relative Area Analysis
☐ Activate Absolute Area
☐ Activate Peak Time
☐ Activate Peak Height
☐ Activate Chemistry Values
☐ Activate Chemistry Totals
☐ Activate Peak Sharpness
☐ Activate Total Protein

9 ☐ Add normal results to the LIMS queue.

Full Session Report

Peak Ratios
☐ Activate Area Ratio
☐ Activate Height Ratio
☐ Activate Timing Ratio
☐ Activate Relative Area Ratio
☐ Activate Peak Symmetry
☐ Activate Formula
☐ Activate Peak Number

OK Help

- The tabs that run along the configuration window are for each set of parameters that can be configured to assign samples to being normal, warning, abnormal or wrong number of bands.
- The 'Activate Expert System for:' section allows the user to turn the Expert System on only for relevant methods. Therefore multiple methods can be selected for use with the Expert System, each with differing parameters. The Method dropdown menu is only populated with methods set as Main and Reflex in the Configure V8 Methods section of Platinum.
- Automatic reflex testing can be turned on for use on samples which are assigned as definite abnormal samples. Leave Automatic Reflex testing unselected if you don't wish to reflex test abnormally marked samples.
- Should automatic reflex testing be selected, the Expert System has the ability to not reflex test under certain circumstances. If you don't want to automatically reflex patient samples, ensure "Exclude Patients Form Auto Reflex Test" is selected.
- If it is selected to exclude results from automatic reflex testing, the user can base this on two variables (1) the patient has an immunodisplacement or immunofixation result in the database or (2) the patient has any previous result in the database. This aspect will only work if a unique identifier which is used for similar data is configured in the demographics configuration part of Platinum.
- If automatic reflex testing has been selected, the user can select which test to use for the reflex test. The dropdown menu is only populated with 'Main and Reflex' and 'Reflex Only' methods from the Configure V8 Methods section of Platinum.
- The Expert System works on three main principal results: normal sample, abnormal sample, warning sample. Warning samples have unusual traits compared to normal results, but not indicative of a definite abnormal sample. The user can select to assign a result as abnormal should the result have at least a preset number of warnings. The user turns this aspect on and sets the warning number here.
- Each set of parameters used for assigning sample results must be turned on to be used in the analysis. Each of the parameters can be activated either in the parameter tab or on the configuration page.
- The results of a session can be saved or copied for pasting into a particular program. This will list all sample results from the Platinum file and the Expert System status linked to each.
- If required, all the results assigned as normal can be added to the LIMS queue ready for approval. Should Platinum be set up, these results can then also be sent directly to the LIMS without validation.

Configuring Parameters – Area, Position, Heights, Sharpness, Symmetry and Total Protein

The configuration tabs for Relative Area, Absolute Area, Peak Timings Peak Heights, Peak Sharpness, Symmetry and Total Protein are all the same and allow configuration for all of the six bands:

Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein
Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	

1 ☐ Activate Relative Area Analysis

2 Active	3 Abnormal <	4 Warning <	5 Band	6 > Warning	7 > Abnormal
<input type="checkbox"/>	40.00	45.00	Albumin	75.00	80.00
<input type="checkbox"/>	3.00	4.00	Alpha-1	8.00	10.00
<input type="checkbox"/>	7.00	7.50	Alpha-2	14.50	16.00
<input type="checkbox"/>	4.00	5.50	Beta-1	10.00	15.00
<input type="checkbox"/>	2.00	2.50	Beta-2	6.00	8.50
<input type="checkbox"/>	6.00	8.50	Gamma	18.50	30.00

OK Help

1. The activate button at the top of the tab is linked to the activate button on the configuration page and turns on the use of the parameters selected.
2. The active column allows for only certain bands to have parameters activated for analysing results.
3. The low abnormal column allows the user to input the lowest value before which the result is definitely abnormal.
4. The low warning column allows users to input the lowest value that is deemed normal. Any values that fall between this and the low abnormal are deemed as a warning. Any values that fall between this and the high warning are deemed as normal. This value cannot be lower than the low abnormal value or higher than the high warning value.
5. The band column lists the band that the parameters are being set for.
6. The high warning column allows users to input the highest value that is deemed normal. Any values that fall between this and the low warning are deemed normal. Any values that fall between this and the high abnormal are deemed as a warning. This value cannot be higher than the high abnormal value or lower than the low warning value.
7. The high abnormal column allows users to input the highest value after which the result is definitely abnormal.

When activated, each value can be changed to ensure optimal settings are in place for determining the state of each result. Default values are in place, but it is recommended that each laboratory fine tunes the settings:

Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein
Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	
<input checked="" type="checkbox"/> Activate Relative Area Analysis						
Active	Abnormal <	Warning <	Band	> Warning	> Abnormal	
<input checked="" type="checkbox"/>	40.00	45.00	Albumin	75.00	80.00	
<input checked="" type="checkbox"/>	3.00	4.00	Alpha-1	8.00	10.00	
<input checked="" type="checkbox"/>	7.00	7.50	Alpha-2	14.50	16.00	
<input checked="" type="checkbox"/>	4.00	5.50	Beta-1	10.00	15.00	
<input checked="" type="checkbox"/>	2.00	2.50	Beta-2	6.00	8.50	
<input checked="" type="checkbox"/>	6.00	8.50	Gamma	18.50	30.00	

Configuring Parameters – Ratios

The peak ratios tab allows the user to select certain ratios based on relative area, absolute area, peak timings (position) and peak heights:

★ Configure Expert System for SPE

×

Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein
Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	
<div> <div> <div>1</div> <div> <input type="checkbox"/> Activate Area Ratio <input type="checkbox"/> Activate Height Ratio <input type="checkbox"/> Activate Timing Ratio <input type="checkbox"/> Activate Relative Area Ratio </div> </div> <div> <div>2</div> <div>Peak Height Ratios</div> </div> </div>						
	3	4	5	6	7	8
Active	Band 1	Band 2	> / <	Warning	Abnormal	
<input type="checkbox"/>	Beta-2	Beta-1	>	1.50	2.00	
<input type="checkbox"/>	Albumin	Gamma	>	8.00	10.00	
<input type="checkbox"/>	Beta-1	Beta-2	<	1.10	1.00	
<input type="checkbox"/>	Beta-1	Beta-2	>	2.20	2.40	
<input type="checkbox"/>	Albumin	Gamma	<	5.00	4.00	

1. The activation option allows the user to activate some or all of the peak ratio parameters.
2. The drop down menu allows the user to select which ratio parameter is selected for editing.

3. The active column allows the user to select the number of ratios for the particular parameter that will be used.
4. Band 1 is the column that will be used first in the ratio calculation (e.g. Albumin as peak 1 and Gamma as peak 2 would see the Albumin peak divided by the Gamma peak).
5. Band 2 is the column that will be used as the divisible in the ratio calculation (e.g. Albumin as peak 1 and Gamma as peak 2 would see the Albumin peak divided by the Gamma peak).
6. The higher than (>) and lower than (<) column allows the user to configure whether the parameters set for the ratio result should be higher than or lower than.
7. The warning value is the lowest or highest value that a normal sample can be (depending on whether it is set to < or >). Any value between the normal and abnormal value will be flagged up as a warning result.
8. The abnormal value is the lowest or highest value a sample can be before it is deemed definitely abnormal. Any value above or below (depending on </>) will be marked as abnormal.

Example:

Albumin peak height = 0.1

Gamma peak height = 0.005

Active	Band 1	Band 2	> / <	Warning	Abnormal
<input checked="" type="checkbox"/>	Albumin	Gamma	>	15.0	25.0

Ratio result = 0.1 : 0.005
= 20

Therefore, the result will be marked as a warning.

Configuring Parameters – Chemistry Values

The chemistry values tab works in a similar way to the area, position, height, sharpness and symmetry tabs. When chemistry data is set up in the Configure V8 methods window, these chemistry names are automatically populated in the Expert System.

★ Configure Expert System for SPE ✕

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios
Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number
<div> <div>1</div> <input type="checkbox"/> Activate Chemistry Values Analysis <div>2</div> <input type="checkbox"/> Ignore Zeros </div>					
3	4	5	6	7	8
Active	Abnormal <	Warning <	Band	> Warning	> Abnormal
<input type="checkbox"/>	5.00	6.00	IgG	17.00	25.00
<input type="checkbox"/>	0.50	0.80	IgA	3.00	5.00
<input type="checkbox"/>	0.20	0.40	IgM	2.50	3.00
<input type="checkbox"/>	0.00	0.00	IgK	0.00	0.00
<input type="checkbox"/>	0.00	0.00	IgL	0.00	0.00

1. The Activate Chemistry Values Analysis button allows the user to select to use chemistry data imported from the LIMS or manually inputted to be included as part of the interpretation.
2. When selected, the Ignore Zeros button does not flag up a sample because the result does not have any chemistry data attached to it (i.e. not downloaded from LIMS or manually inputted).
3. The active column allows for only certain chemistry values to be used for analysing results.
4. The low abnormal column allows the user to input the lowest value before which the result is definitely abnormal.
5. The low warning column allows users to input the lowest value that is deemed normal. Any values that fall between this and the low abnormal are deemed as a warning. Any values that fall between this and the high warning are deemed as normal. This value cannot be lower than the low abnormal value or higher than the high warning value.
6. The band column lists the chemistry data that the parameters are being set for.

- The high warning column allows users to input the highest value that is deemed normal. Any values that fall between this and the low warning are deemed normal. Any values that fall between this and the high abnormal are deemed as a warning. This value cannot be higher than the high abnormal value or lower than the low warning value.
- The high abnormal column allows users to input the highest value after which the result is definitely abnormal.

It is recommended that users assign suitable values for each chemistry data based on the reference ranges for each chemistry value. Default settings in the Expert System for chemistry values cannot be reliably used as different users set up their LIMS settings differently.

Configuring Parameters – Chemistry Totals

The chemistry totals tab works in a similar way to the area, position, height, sharpness and symmetry tabs in terms of set up. When chemistry data is set up in the Configure V8 methods window, the chemistry values can be used as a sum as opposed to using single chemistry values. This is useful, for example, where total immunoglobulin concentration is important, but only the breakdown is available.

★ Configure Expert System for SPE ×

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios
Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number

1 ☒ Activate Chemistry Totals Analysis

2 Active	3 Abnormal <	4 Warning <	5 Chem1 +	6 Chem2 +	7 Chem3	8 > Warning	9 > Abnormal
<input type="checkbox"/>	6.2	7.2	IgG	IgA	IgM	17.0	22.0
<input type="checkbox"/>	6.0	6.4	IgG	IgM		17.5	20.0
<input type="checkbox"/>	6.0	6.8	IgG	IgA		19.0	21.0
<input type="checkbox"/>	0.0	0.0				0.0	0.0
<input type="checkbox"/>	0.0	0.0				0.0	0.0

OK Help

- The Activate Chemistry Totals Analysis button allows the user to select to use a sum of chemistry data imported from the LIMS or manually inputted to be included as part of the interpretation.
- The active column allows for only certain chemistry totals to be set up and used for analysing results.
- The low abnormal column allows the user to input the lowest value before which the result is definitely abnormal.
- The low warning column allows users to input the lowest value that is deemed normal. Any values that fall between this and the low abnormal are deemed as a warning. Any values that fall between this and the high warning are deemed as normal. This value cannot be lower than the low abnormal value or higher than the high warning value.
- The Chem 1 column allows the user to select the first chemistry value to be used in the sum.
- The Chem 2 column allows the user to select the second chemistry value to be used in the sum.
- The Chem 3 column allows the user to select the third chemistry value to be used in the sum (this does not have to be used).
- The high warning column allows users to input the highest value that is deemed normal. Any values that fall between this and the low warning are deemed normal. Any values that fall between this and the high abnormal are deemed as a warning. This value cannot be higher than the high abnormal value or lower than the low warning value.
- The high abnormal column allows users to input the highest value after which the result is definitely abnormal.

It is recommended that users assign suitable values for each chemistry total based on the reference ranges for the chemistry values.

Configuring Parameters – Formula

The formula tab works in a similar way to the ratios in that there is only one warning and abnormal option and the user selects whether the value is less than or greater than (< or >). The formula allows the user to make distinct characteristic assessment based on relative or absolute area, position, height, sharpness and symmetry. The user can select any of the six bands and any of the six parameters to create a 5 ruled formula. For a sample to be assigned as a warning, all parameters must be met, if any are normal, the result will be assigned as normal. However if there are a mix of warning and abnormal results, the sample will be assigned as warning. This is because all characteristics must also be abnormal to be assigned as abnormal. Up to five formulas can be created.

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios
Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Total Protein

1 ☐ Activate Formula Analysis Configure

2 Formula 1 Formula 2 Formula 3 Formula 4 Formula 5

3 ☐ Activate formula

4 Active	5 Criteria	6 Band	7 > / <	8 Warning	9 Abnormal
<input type="checkbox"/>	Relative Area	Gamma	>	15.0000	20.0000
<input type="checkbox"/>	Peak Heights	Gamma	>	0.0010	0.0100
<input type="checkbox"/>	Peak Sharpness	Gamma	<	17.0000	15.0000
<input type="checkbox"/>	Peak Timings	Gamma	<	220.0000	200.0000
<input type="checkbox"/>	Symmetry	Gamma	<	0.0000	-10.0000

OK Help

1. The Activate Formula Analysis button allows the user to select to use a combination of band statistics as a way to interpret an electropherogram.
2. The formula tabs allows the user to select and configure up to 5 different formulas.
3. The activate formula option allows for the particular formula configuration to be activated.
4. The activate column allows for up to five different parameters to be configured for each formula.
5. The criteria column allows for one of the six parameters to be selected (Relative Area, Absolute Area, Peak Timings, Peak Height, Peak Sharpness, Symmetry).
6. The Band column allows for the band in which the parameter is set to be selected.
7. The >/< column allows for the user to select whether the parameter value is to be greater than or less than.
8. The warning value is the lowest or highest value that a normal sample can be (depending on whether it is set to < or >). Any value between the normal and abnormal value will be flagged up as a warning result.
9. The abnormal value is the lowest or highest value a sample can be before it is deemed definitely abnormal. Any value above or below (depending on </>) will be marked as abnormal.

Configuring Parameters – Peak Number

The peak number analysis allows the user to assign the number of bands present that may still give an acceptable trace and the number by which the trace is most likely unacceptable.

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios
Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number
Total Protein					

1 ☒ Activate Peak Number Analysis

2 Peak number expected :

3 ☒ Lower Range: 0 and 4

4 ☒ Higher Range: 8 and 25

OK Help

1. The Activate Peak Numbers Analysis button allows the user to select to use the number of bands in the trace as part of the interpretation.
2. The number of peaks expected is linked to the 'Bands' section of the Configure V8 Methods window. The number of bands that are expected for the method will be populated here. This is not editable.
3. Activating the lower range allows the user to mark results with a band number within the lower range. The low range is set to mark samples where the result is expected to be unusable.
4. Activating the higher range allows the user to mark results with a band number within the higher range. The high range is set to mark samples where the result is expected to be unusable.
5. The bottom value of the lower range can be set in this box. It is recommended that this value be set to 0.
6. The top value of the lower range can be set in this box. Based on the expected number of bands, it is recommended that this value be one to two values below this.
7. The bottom value of the higher range can be set in this box. It is recommended that this value be set one or two values above the expected range.
8. The top value of the higher range can be set in this box. It is recommended that this value be a high number well above the expected band number.

In the above example, any result with a band number of between 0 - 4 or 8 - 25 will be flagged up as an expected unusable result. Any result with five or seven bands will be flagged up as having lower or higher bands than expected respectively, but most likely acceptable.

Viewing the Expert System Results

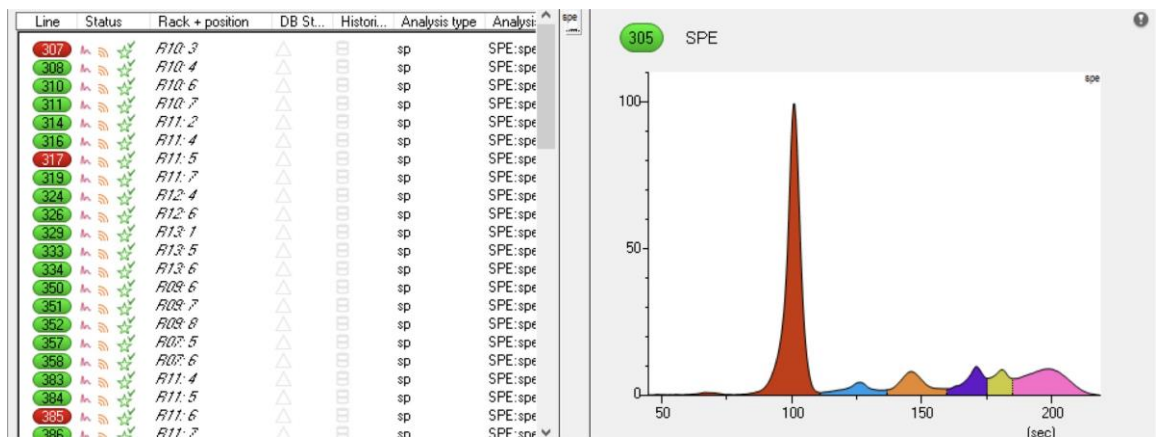
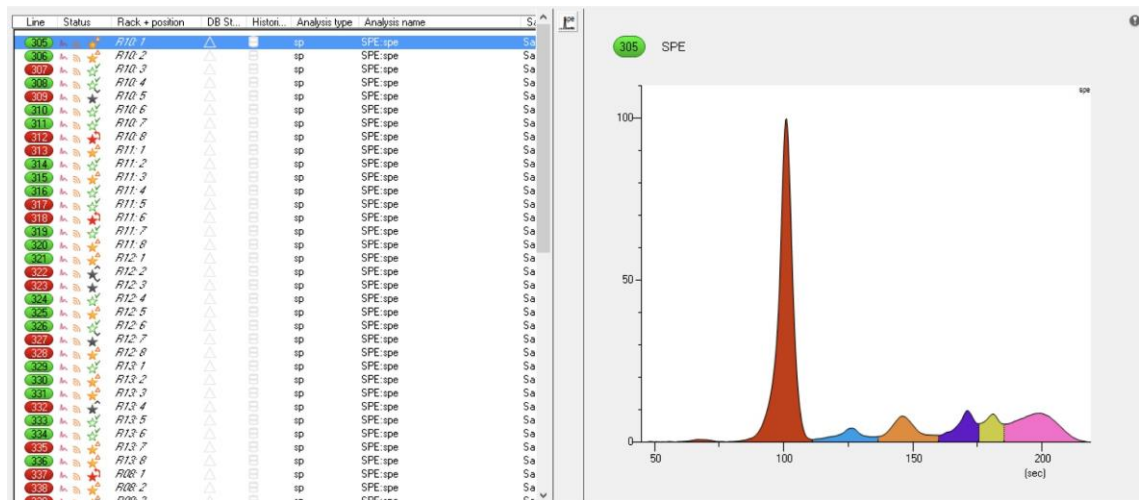
The Expert System alerts the user to the state of the sample result via several icons listed in the navigation worklist.



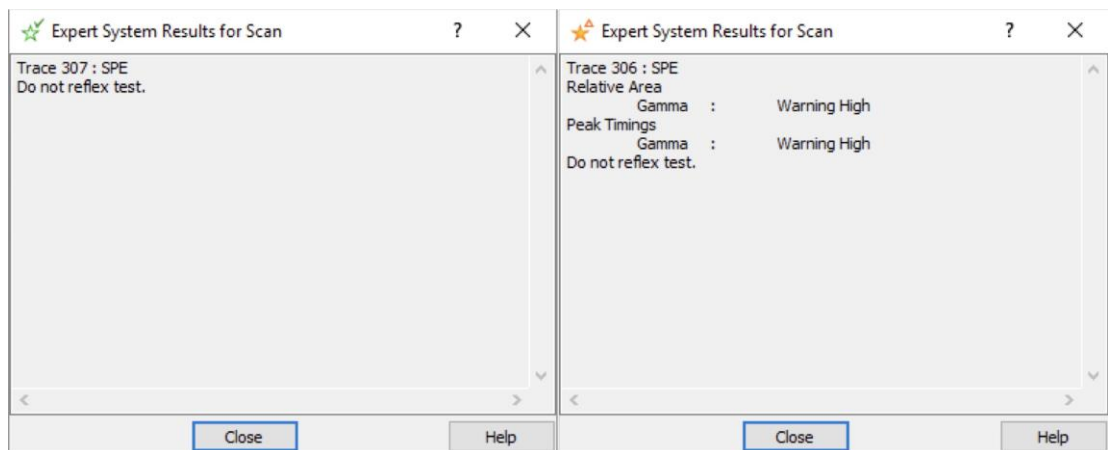
1. The Expert System is turned on but there is no data acquired for the sample or the Expert System is not activated for that method.
2. The Expert System assigns the sample result as normal.
3. The Expert System assigns the sample result as a warning and needs to be reviewed.
4. The Expert System assigns the sample as abnormal. If automatic reflex testing is turned on, the sample will be reflex tested as per the Platinum settings (batch reflex, immediate reflex, rack priority).
5. The Expert System assigns the sample as having extra bands, but the result is probably acceptable.

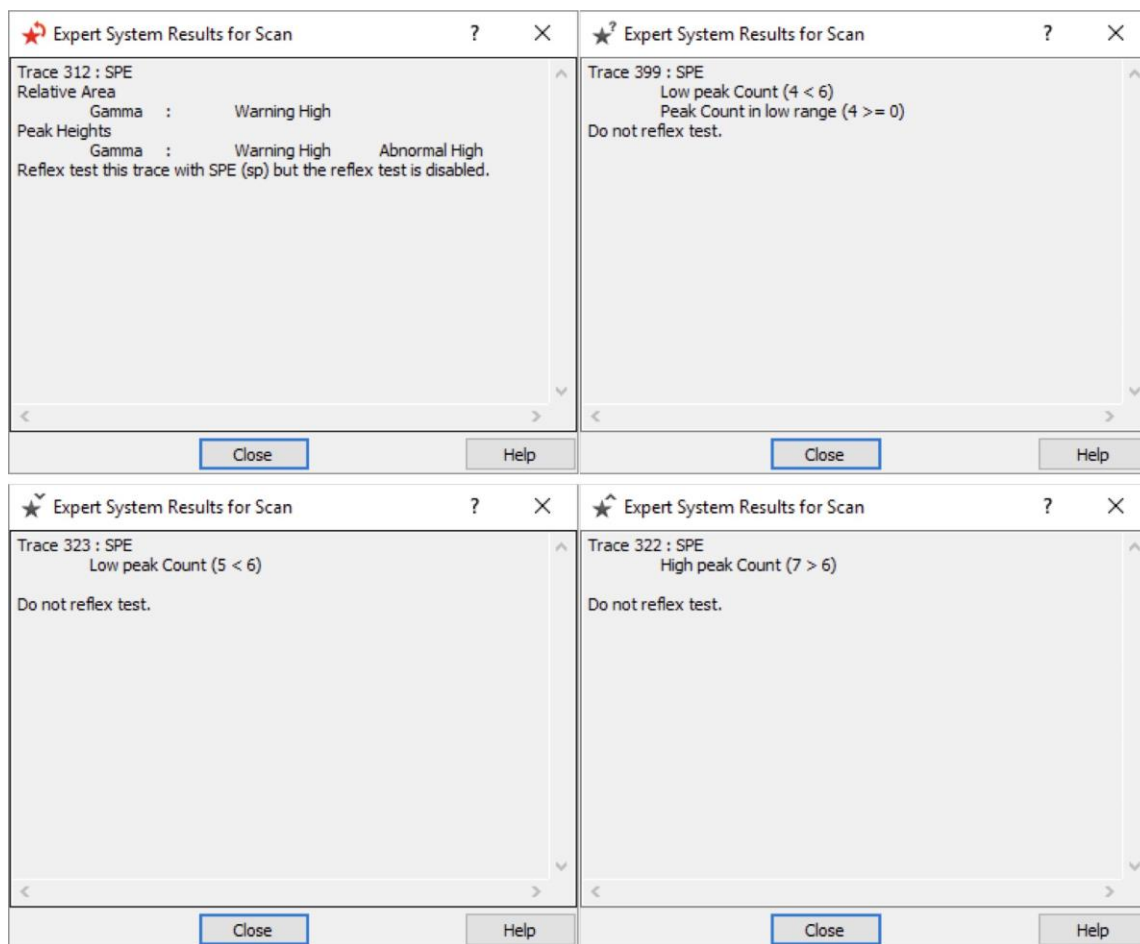
6. The Expert System assigns the sample as having fewer bands, but the result is probably acceptable.
7. The Expert System assigns the sample as have significantly fewer or extra bands and the result is probably unusable.

The results are displayed within the navigation worklist to easily identify the patient result and can be sorted by Expert System status by sorting by the status column:



To view the parameters that have caused a sample to be marked as anything other than normal, the View Expert System Results window can be opened. This is a floating window that sits in front of the main Platinum screen and allows Platinum to continue working so users can progress through all the results to see the failing parameters based on icons 2-7 above:





It is recommended that all Expert System parameters are adjusted and validated prior to relying on the Expert System solely for interpretation.

5.9

Platinum

Platinum is one of the world's most advanced software package for automated clinical capillary electrophoresis. Designed specifically to make the management, analysis and interpretation of clinical test results as simple, accurate and as efficient as possible, Platinum provides a comprehensive set of analytical tools and user-defined options that can meet the data analysis needs of the clinician. Please refer to the following instructions for correct operation of Platinum software.









5.9.1
































Glossary of software icons

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

5.9.1.1


















Basic functions

-  About
-  Cascade
-  View preferences
-  Attach ImmunoTyping
-  Configure bands
-  Usage search
-  Configure V8 system
-  Operator list

-  Customise
-  Backup all
-  Backup changed / new
-  Backup / Archive
-  Restore
-  Attach to scan
-  New
-  Save, Email RTF
-  Open data
-  Find attached scans
-  Search data
-  Help
-  Open similar data
-  Operator
-  Print
-  Preview printer output
-  Redo
-  Save
-  Save as
-  Store screen layout 1
-  Store screen layout 2
-  Store screen layout 3
-  Store screen layout 4
-  Store screen layout 5
-  Tile Horizontally
-  Tile Vertically
-  Screen layout 1
-  Screen layout 2
-  Screen layout 3
-  Screen layout 4
-  Screen layout 5










5.9.1.2

V8 operational functions

-  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
-  Worklist
-  Select gel type
-  Select default method
-  Undo
-  Scan Usage
-  Session Usage
-  V8 mode selection





5.9.1.3

Sample marking

-  Mark as abnormal control
-  Mark as a calibration
-  Mark as normal control
-  Mark as sample
-  Next lane
-  Previous lane
-  Automatically mark
-  Mark normal
-  Mark abnormal




















5.9.1.4

Levey-Jennings

-  Levey- Jennings
-  Accept Levey-Jennings
-  Automatic Levey-Jennings
-  Suspect Levey-Jennings










5.9.1.5










Editing tools

-  Filtering
-  Edit regions / zones
-  Set scale
-  Edit baseline
-  Align gel
-  Match shapes
-  No stretching
-  View as gel
-  View as navigation worklist
-  View as traces
-  Gel contrast
-  Edit peaks
-  Skim
-  Slice
-  Stretch
-  Smoothing
-  Re-interpret scan
-  Select all lanes
-  Optimise scale

5.9.1.6























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




5.9.1.7

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

5.9.1.8

Expert System

-  Expert system OFF
-  Expert system ON
-  Redo external chemistry values

Gel icons

Configure gel



Re-interpret gel



Scan



Mark gel

LIMS icons

Queue pending approval



Unqueue for LIMS



Show LIMS queue window



Approve send to LIMS



Send selected to LIMS



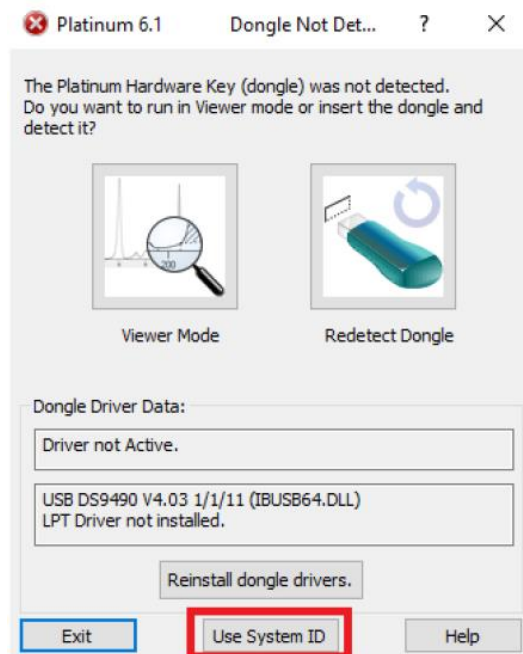
Send all to LIMS

Log in to Platinum**Initial Log-in Screen**

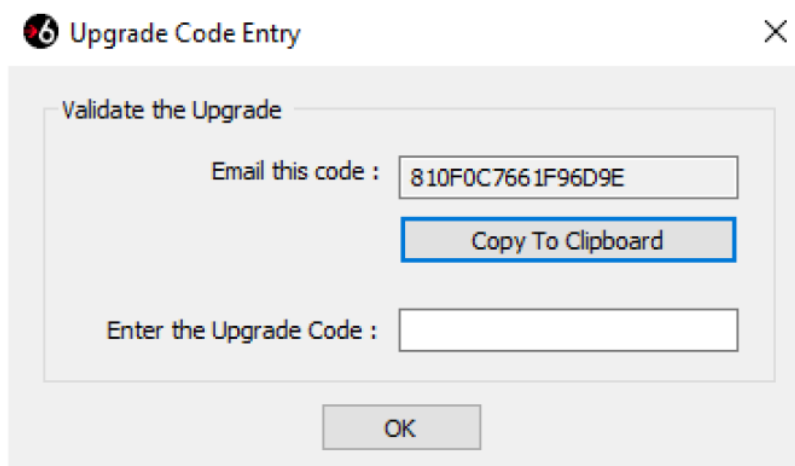
When Platinum is opened, the initial log-in screen will open. A user name and associated password must be entered in order to proceed using the software.

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':

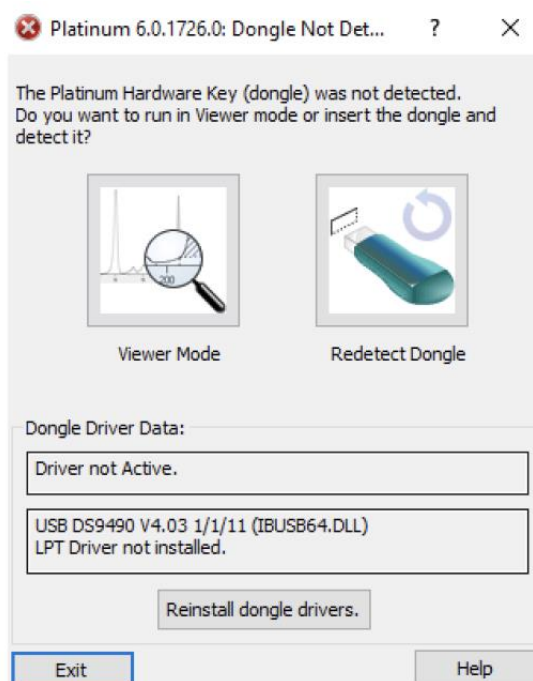


After you have selected 'Use System ID', the Upgrade Code can be sent to V8 Technical Support. V8 Support will then return an Activation Code which can be used in Product Activation.






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.



Initial Window

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 V8 Session or Gel Session 
- Search for previously saved data 
- Or, open a saved file 

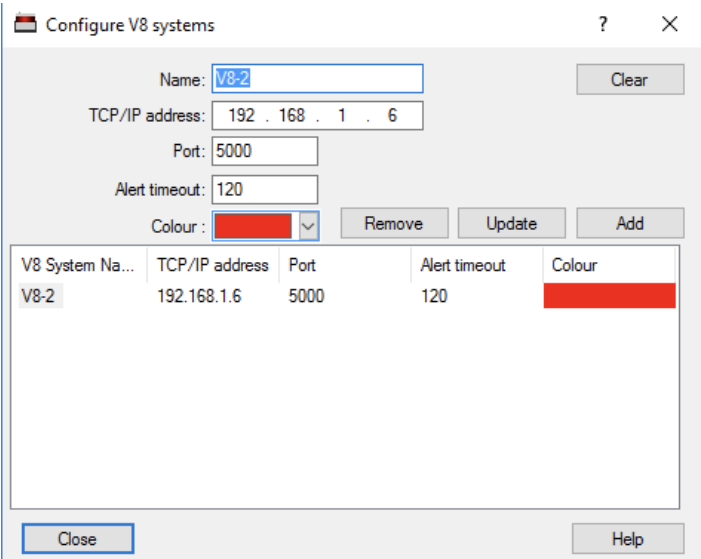


Active Session Window

It is possible to have multiple session windows open in Platinum at any one time. To avoid confusion as to which window is the current active session and inadvertently closing down the active session window, Platinum indicates this by having a different configurable colour top band on the active Pt session. The default colour is set to red. This colour can be configured by:

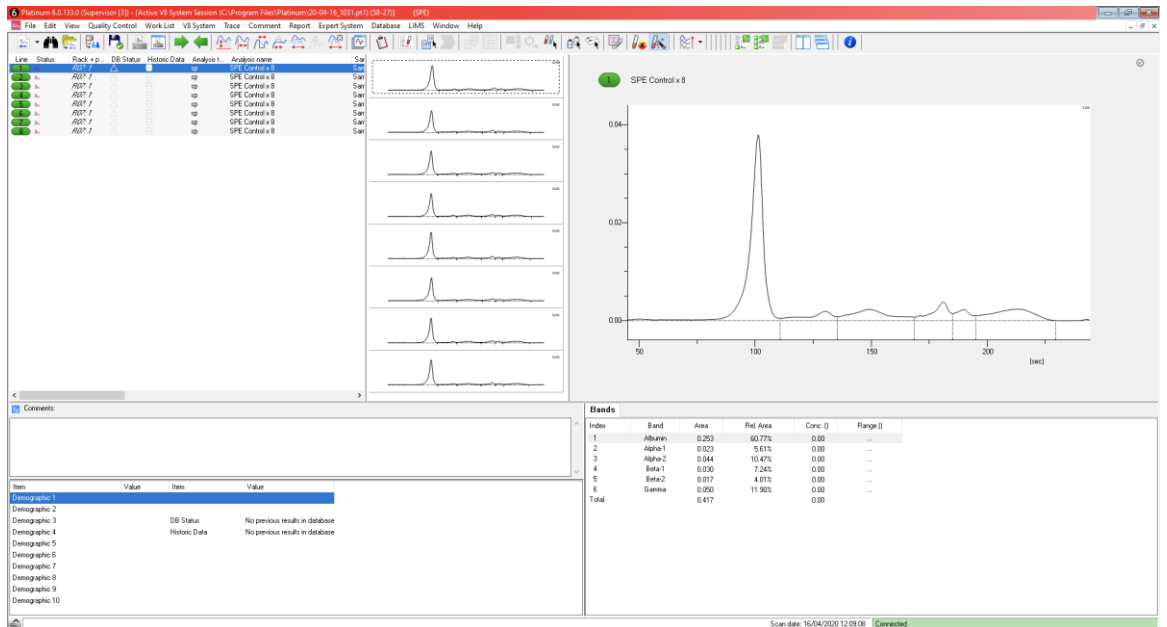
In the V8 session window select **V8 System > Configure V8 Systems**

Press the colour button (below) to configure your preferred colour.

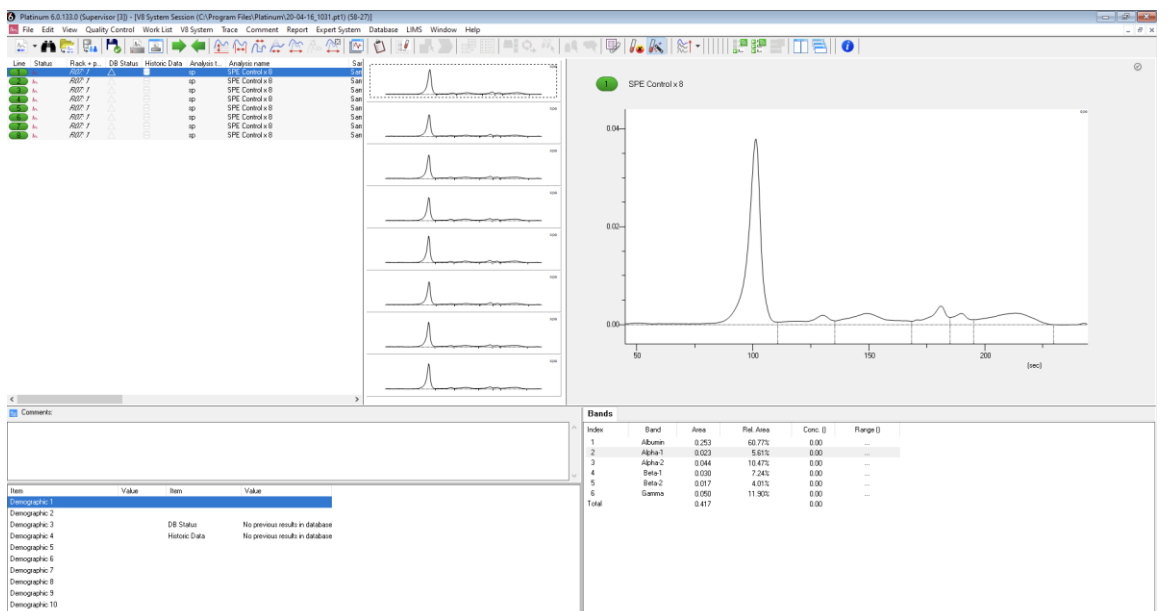


Select **Close**

The set colour will now be the active session top toolbar colour.



Active Platinum session



Inactive Platinum session

5.9.2.4

Performing tasks in Platinum

Once the samples have been processed, the raw data will be shown in Platinum. This sub-section details the functions within the Platinum software that will allow data manipulation and editing. Some tasks are generic to both CE and gel sessions, whilst others are specific to one or the other. Therefore, the tasks are split into the following three groups dependent on where in Platinum they are relevant:

- Tasks common to CE and gel sessions
- Tasks specific to CE sessions
- Tasks specific to gel sessions

5.9.3

Tasks common to V8 and gel sessions

5.9.3.1

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 is required.

5.9.3.2

Ordering a test

In this mode test, ordering will be driven preferentially by barcode and then by Rack ID and Position. If two different specimen types with the same barcode are loaded onto the system both with Reflex tests pending, this may result in the wrong assay being performed on the wrong sample.

- In the V8 session window, choose **Worklist > Manage Test List**

- This will open the **Manage Test List** dialogue box.

Line	Barcode	Rack ID	Position in rack	Tray ID	Scan date	Test name	Tray type	Dilution	Wavelength
1		R01	1			SPE (sp)		1.00	
2		R01	2			SPE (sp)		1.00	
3		R01	3			SPE (sp)		1.00	

- Enter the barcode of the sample being ordered, this can be done manually but it is recommended that tube barcode be scanned in to prevent misidentification. The Rack ID and position of the sample do not need to be included as the V8 will assume that all barcodes are unique and therefore should not appear twice.
- Once the barcode is entered, the desired test can be ordered from the dropdown menu. Any additional dilutions that are required and not set as default can be assigned here.
- Once the information is entered, click **Add** and the test will appear in the **Manage Test List** window. Close the window when test ordering is complete.
- Load the sample(s) into the sample rack transport area and close the lid.
- The V8 will automate the processing of the ordered assay.
- Once complete the sample will no longer appear in the **Manage Test List** window.

N.B. The list of ordered tests will only show tests of the same name. To see all ordered tested: select the box **Search for all ordered tests.**

5.9.3.3

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 re-loaded with new samples.

- Open the **Manage Test List** dialogue box by choosing **Worklist > Manage Test List**.
- Select box **Search for all ordered test names**.
- Once selected click the **Search** button. The test list will display ordered tests and associated information.
- Right click on the test you wish to remove and choose **Remove from Test List**.

5.9.3.4

How to perform a reflex test

The V8 is capable of providing controlled preferences and stipulations. 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 Serum Protein assay. This differs from test ordering as reflex assays are only ordered following the detection of an abnormal result.









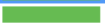












Please refer to SET TEST MODE for information regarding reflex test priority, see sections 5.4.1 and 5.4.3.

It is recommended that reflex test priority is set at complete batch test. The V8 will then store all reflex tests ordered until required by the user to perform all retest analysis.

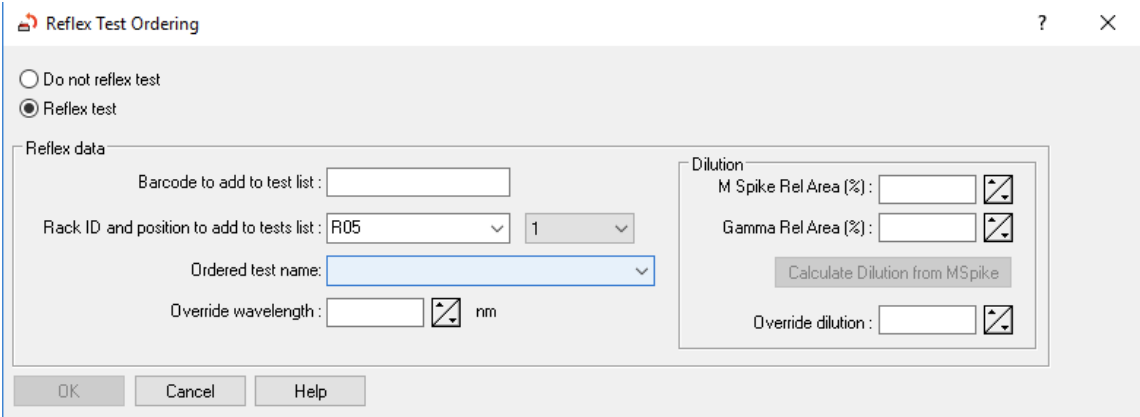
Manual ordering for reflex testing

Manual reflex tests can be ordered whether or not 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 navigation worklist, click on the button  in the Reflex test column on the sample requiring further analysis.

Line	S...	Rack ...	DB St...	Histori...	A...	Analysi...	Sa...	Refle...	Capillary	Progress
9		R05: 1			sp	SPE:spe	Sample		3@V8-2 (50)	
10		R05: 2			sp	SPE:spe	Sample		4@V8-2 (50)	
11		R05: 3			sp	SPE:spe	Sample		5@V8-2 (50)	
12		R05: 4			sp	SPE:spe	Sample		6@V8-2 (50)	
13		R05: 5			sp	SPE:spe	Sample		7@V8-2 (50)	

The following **Test ordering** dialogue box will appear.



The dialog box titled "Reflex Test Ordering" contains the following elements:

- Radio buttons: ☐ Do not reflex test, ☒ Reflex test
- Section "Reflex data":
 - Barcode to add to test list:
 - Rack ID and position to add to tests list: Rack ID: , Position:
 - Ordered test name:
 - Override wavelength: nm
- Section "Dilution":
 - M Spike Rel Area (%): 
 - Gamma Rel Area (%): 
 - Calculate Dilution from MSpike:
 - Override dilution: 
- Buttons: OK, Cancel, Help

Select the **Reflex test** radio button. From the drop down menu choose **Ordered test name**; and then select the appropriate reflex assay.

If there is no barcode present, then the rack number and position are the only factors that can be used to perform analysis. 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 analysis.

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 **V8 System > Allow Reflex Test Batches**, where the V8 will store all reflex tests until required by the user to perform analyses.

Manual entry for using Auto IFE

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 the Helena SAS 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.

Why

Sample 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 applies this 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, also by providing intuitive automation it removes the potential for errors in dilution calculations and streamlines the decision process.

How to use it

Using IFE Auto-dilution with the Reflex Test function

- Select a sample with a monoclonal band and gate the monoclonal band using the skim/slice function see sections 5.9.13 and 5.9.14.
- Order a reflex test on the sample by clicking the icon in the reflex column of the Navigation Worklist or by select Worklist > Test ordering
- Select the (Method In Use = MIU) [MIU] SAS-3 IFE 0-3g/L (IFE) method and select Calculate Dilution from M-Spike.

The image shows the 'Reflex Test Ordering' dialog box. It has two radio buttons: 'Do not reflex test' and 'Reflex test' (selected). Below are input fields for 'Barcode to add to test list', 'Rack ID and position to add to tests list' (R01, 1), 'Ordered test name' (SPE SAS-3 Auto IFE 0-3 g/L (ife)), and 'Override wavelength'. To the right is a 'Dilution' section with 'M Spike Rel Area (%)' (24.65), 'Gamma Rel Area (%)' (30.87), and 'Override dilution' (2.50). A button 'Calculate Dilution from MSpike' is highlighted in the dilution section. At the bottom are 'OK', 'Cancel', and 'Help' buttons.

Reflex Test Ordering Window with the relevant boxes highlighted.

- 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).

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:

- Select Worklist > Manage Test list
- Select the barcode or the rack number and position of the sample to be tested.
- Select the Ordered test name [MIU] SAS-3 IFE 0-3g/L (IFE)
- In the Dilution section of the window input the relative % of the monoclonal band and gamma for the required sample and select calculated dilution from M-Spike.
- Select Add
- When all tests are ordered select close and when the racks with the samples are loaded they will be diluted with the appropriate override dilutions.

The image shows the 'Manage Test List' dialog box. It has input fields for 'Barcode to add to tests list', 'Rack ID and position to add to tests list' (R01, 1), 'Ordered test name' (SPE SAS-3 Auto IFE 0-3 g/L (ife)), and 'Override wavelength'. To the right is a 'Dilution' section with 'M Spike Rel Area (%)' (24.65), 'Gamma Rel Area (%)' (30.87), and 'Override dilution' (2.50). A button 'Calculate Dilution from MSpike' is highlighted. Below the input fields is a 'Search Options' section with a checkbox 'Search for all ordered test names', 'Start date', 'End date', and a 'Search' button. At the bottom is a table with columns: Line, Barcode, Rack ID, Positi..., Tray ID, Scan date, Test name, Tray type, Dilution, Wavele... The first row is highlighted in blue.

Line	Barcode	Rack ID	Positi...	Tray ID	Scan date	Test name	Tray type	Dilution	Wavele...
1		R01	1	1		SPE SAS-3 Auto IFE 0-3 g/L (ife)	SAS-3-60	2.50	

Manage Test List window with the relevant boxes highlighted

5.9.4

Searching for data

To locate previous sample results, whole gels or CE sessions 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 or V8 session, select the [Session](#) radio 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
 ? ×

Search

Search item	(Low) Value	High value
System type	Any source	
Scan type	Any type	
Gel name	Any Name	
Analysis type	Any type	
Measurement time (dd/mm/yyyy)		
Gel ID		
Measurement status	Normal / abnormal	
Tube ID		
Patient ID		
Forename		
Surname		
DOB		
Demographic 6		
Demographic 7		
Demographic 8		
Demographic 9		
Demographic 10		

☒ Sample
☐ Session

Clear

Search

Archive Search

Configure

Help

Close

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 data source (entire gel or V8 session), only 6 of the generic filters are available:

Search
 ? ×

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 CE session or whole 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.

5.9.4.1

Searching the test list

The test list shows ordered and reflex tests. Tests that are displayed are pending and have yet to be performed. Once a test has been performed it is automatically removed from the list.

N.B. At the start of a session the user is offered the option to either clear or review the retest list of outstanding assays. It is useful to check this list prior to clearing.

- Open the **Manage Test List** dialogue box, by selecting **Worklist > Manage Test List**.
- Ordered tests can be searched by selecting the **Search for all ordered test names** checkbox so that all ordered tests are displayed, and optionally also filtering between a specified time period to display results from particular dates and/or times.

- Once selected, click the **Search** button. The test list will display ordered tests and associated information.
- The ordered tests can be sorted by clicking on any of the field headers:

Line	Barcode	Rack ID	Positi...	Tray ID	Scan date	Test name	Tray type	Dilution	Wavele...
------	---------	---------	-----------	---------	-----------	-----------	-----------	----------	-----------

- The original scan or gel for any ordered test can be easily recalled. To view the source data, select the desired ordered test and right-click. Choose **Load Source Data** to view the original gel scan or CE electropherogram.

5.9.4.2

Searching Reagent Statistics

Platinum has a function that allowed the V8 usage logs to be searched intelligently, based on definable criteria. This is done by;

- Quality Control > Reagent statistics.
- Operators can search by Method name, Product reference/kit, and by date to find out how many tests are carried out using a specific buffer, reagent or kit (see window below).
- Details can then be printed or exported as a text file, tabbed file or rich text file.

Archiving Tool

Pre-Archiving Setup

Before an archive is performed, it is recommended to back up your current database and demographics must be configured accordingly in order to allow the archiving process to function as expected.

There must be one demographic which is used for similar data. This demographic should be used to link the archived data within Platinum.

Customise

Sending to LIMS Receiving from LIMS Configure Menus

File locations **Configure Demographics** Institution Data Configure sample handler

Demographics:

Index	Item	Field Type	Used for si...
1	Tube ID	LIS Identifier	No
2	Patient ID	String	Yes
3	Forename	String	No
4	Surname	String	No
5	DOB	Date	No
6	Demographic 6	String	No
7	Demographic 7	String	No
8	Demographic 8	String	No
9	Demographic 9	String	No
10	Demographic 10	String	No

Load Save

Demographics search mode: Global

Archive searching: On

OK Cancel Help

If not already activated, Archive searching must be set to On and the Demographic search mode set to Global.

Merging to a Local Target Database

- Open Platinum and start a new V8 or gel session.
- Open **File > Customise... > File Locations**. Ensure the Network Database field is not selected and the Location for new data pathway is set to `C:\Program Files\Platinum\`. Click **OK** and then close Platinum.

Customise

Sending to LIMS Receiving from LIMS Configure Menus

File locations **Configure Demographics** Institution Data Configure sample handler

Data

Network Database ☐ Slave ☐

Network Database Location: ...

Location for new data: C:\Program Files (x86)\Platinum\

Location for backups and archives: ...

Reports

Main report definition: C:\Program Files (x86)\Platinum\SP Only.rep Edit ..

Report with IDs: C:\Program Files (x86)\Platinum\SP and ID new f Edit ..

Levey-Jennings Report Definition: C:\Program Files (x86)\Platinum\LJ.rep Edit ..

Reassociate Platinum files and icons: ReAssociate

Use old session names: ☐

OK Cancel Help

- Open `C:\Program Files\Platinum\`. Ensure the target database is present whether it is a clean blank database or an existing functioning database. Check that it is split into four component sub-databases; `Baseline.accdb`, `DIB.accdb`, `Platinum.accdb` and `Scan.accdb`.

Windows (C:) > Program Files (x86) > Platinum

Name	Date modified	Type	Size
Archives	14/11/2016 10:20	File folder	
backup	10/11/2016 09:03	File folder	
Drivers	02/11/2016 12:36	File folder	
Languages	09/11/2016 14:04	File folder	
logs	10/11/2016 16:53	File folder	
PDF	10/11/2016 14:47	File folder	
ScannerDlls	09/11/2016 14:04	File folder	
Baseline	14/11/2016 10:20	ACCDB File	1,176
DIB	14/11/2016 10:20	ACCDB File	396
Platinum	14/11/2016 11:05	ACCDB File	1,808
PlatinumCopy	02/11/2016 14:41	ACCDB File	1,168
Reflex	14/11/2016 10:42	ACCDB File	200
Scan	14/11/2016 10:20	ACCDB File	1,752
Platinum	09/11/2016 14:05	Application	14,866
common.dll	25/10/2012 16:27	Application extens...	55

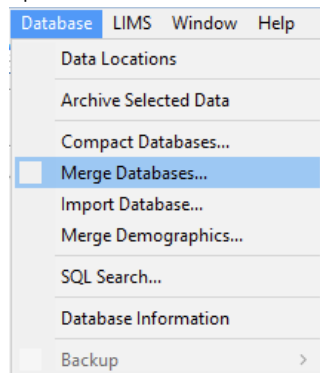
N.B. You will also see two other .accdb files; Reflex.accdb is a local reflex test database and PlatinumCopy.accdb is a full copy of the current database before it was split.

- d. Copy the split historical database and associated Platinum session files to a folder on the target PC desktop. If the historical database has Platinum, 4.0 session files then copy them into `C:\Program Files\Pt\Platinum`. If the historical database has Platinum 4.1, 4.2 or 5.0 session files then copy them into `C:\Program Files\Platinum`. You must leave the 4 split sub-databases in the folder on the desktop.

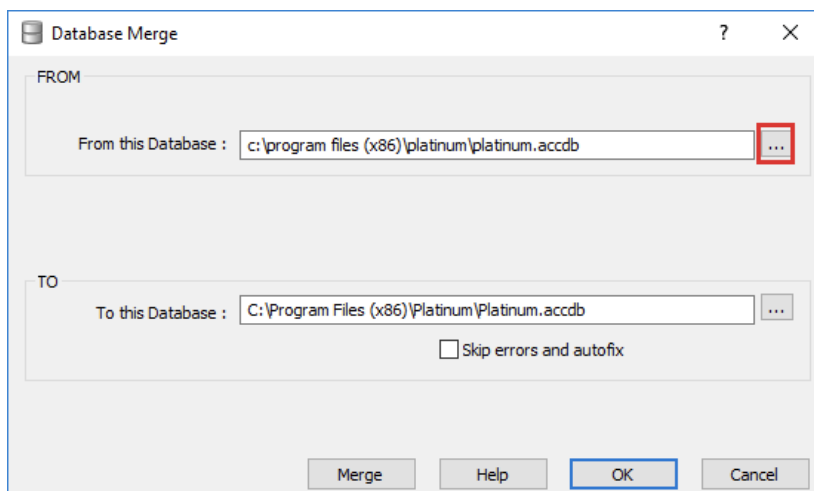
Historical Database

Name	Date modified	Type	Size
Baseline	14/11/2016 10:20	ACCDB File	1,176 KB
DIB	14/11/2016 10:20	ACCDB File	396 KB
Platinum	14/11/2016 11:05	ACCDB File	1,808 KB
Scan	14/11/2016 10:20	ACCDB File	1,752 KB

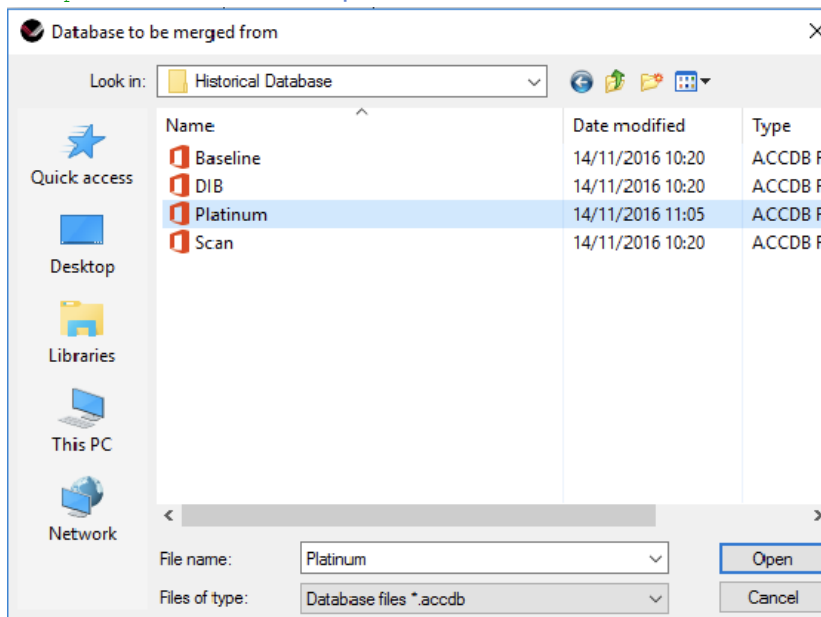
- e. Open Platinum and start a new V8 or Gelscan session. Open **Database > Merge Databases...**



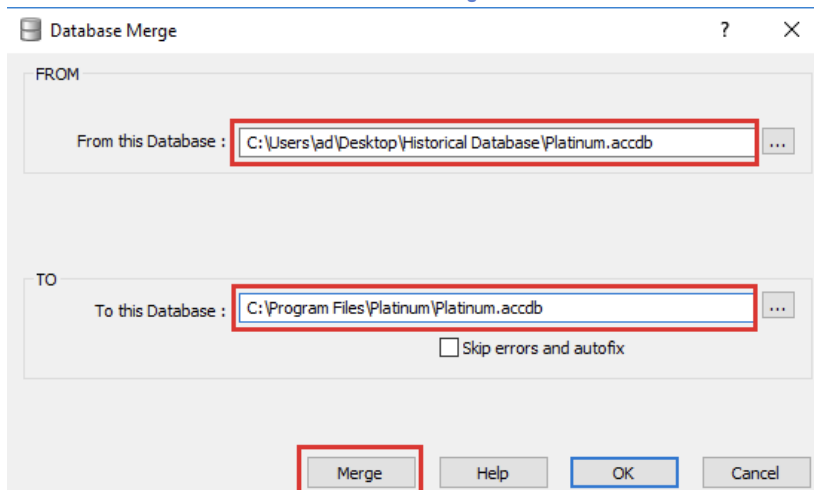
- f. Set the Historical database from the desktop as the **From this Database :** field by clicking the icon. Navigate to Desktop > 'Historical database' folder.



- g. Select **platinum.accdb** and click **Open**.



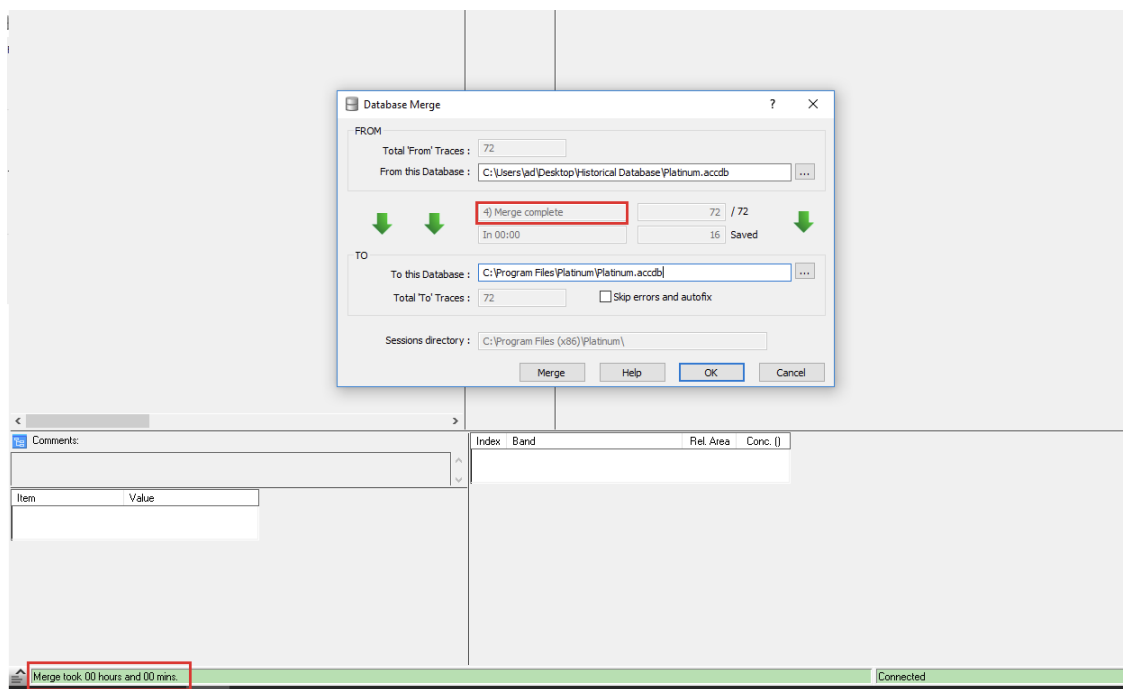
- h. Check that the FROM database is set to the location of the Historical database and the TO database is set to **C:\Program Files\Platinum\Platinum.accdb**. Click **Merge**.



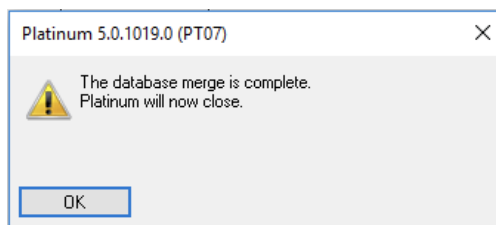
- i. The Database Merge progress window will appear indicating the status of the merging process. 1000 traces are loaded from the historic database and saved to the target database whilst the Platinum session files are moved from the original location to the location for new data configured in Step 2.

N.B. The merging process can be lengthy, for example a database with approximately 88000 traces can take up to 14 hours to complete so it is advisable to run this overnight if the database is particularly large.

- j. Once finished, the window will read 4) Merge complete and a message will display in the bottom left of the Platinum window indicating how long the merge process took.



- k. Click OK. Platinum needs to be restarted so the following message will be displayed. Clicking **OK** will automatically close the software.

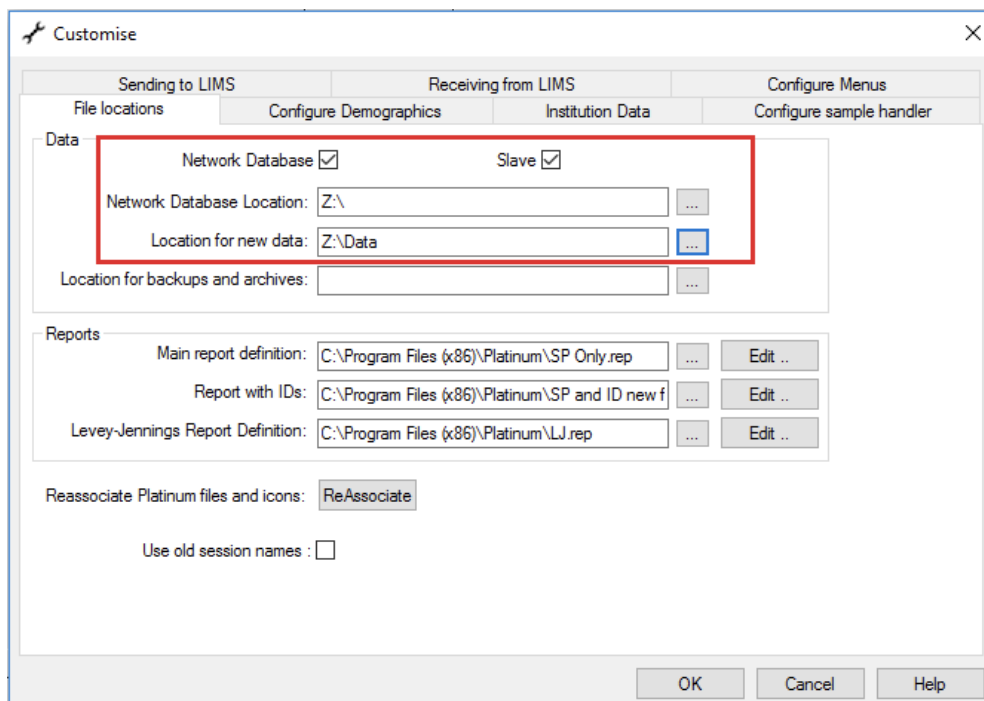


- l. The database merge is complete and Platinum will now run using the combined database. The process can be repeated with more databases if required.

5.9.7

Merging to a Networked Target Database

- Open Platinum and start a new V8 or Gelscan session.
- Open **File > Customise... > File Locations**. Ensure the Network Database and Slave fields are selected and the Network Database Location and Location for new data pathways are set to **Z:** and **Z:\Data** respectively. Click **OK** and then close Platinum.



- Open **Z:**. Ensure the target database is present whether it is a clean blank database or an existing functioning database. Check

that it is split into four component sub-databases; **Baseline.accdb**, **DIB.accdb**, **Platinum.accdb** and **Scan.accdb**.

The screenshot shows a File Explorer window with the address bar set to 'This PC > Platinum Network Folder (\\HELENABIO3) (Z:)'. The search bar contains 'Search Platinum Network Fol...'. The main area displays a list of files and folders:

Name	Date modified	Type	Size
Data	11/11/2016 16:49	File folder	
Baseline	02/11/2016 14:24	ACCDB File	16,020 KB
DIB	07/11/2016 13:25	ACCDB File	3,832 KB
Platinum	09/11/2016 11:39	ACCDB File	3,268 KB
Scan	03/11/2016 09:44	ACCDB File	20,860 KB
PlatinumCopy	02/11/2016 14:41	ACCDB File	1,168 KB

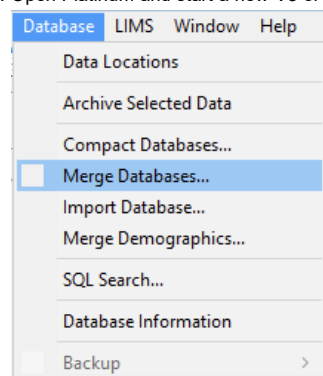
N.B. You will also see two other files; PlatinumCopy.accdb is a full copy of the current database before it was split and Data is the Location for New Data.

- d. Copy the split historical database and associated Platinum session files to a folder on the target PC desktop. If the historical database has Platinum, 4.0 session files then copy them into **C:\Program Files\Pt\Platinum**. If the historical database has Platinum 4.1, 4.2 or 5.0 session files then copy them into **C:\Program Files\Platinum**. You must leave the 4 split sub-databases in the folder on the desktop.

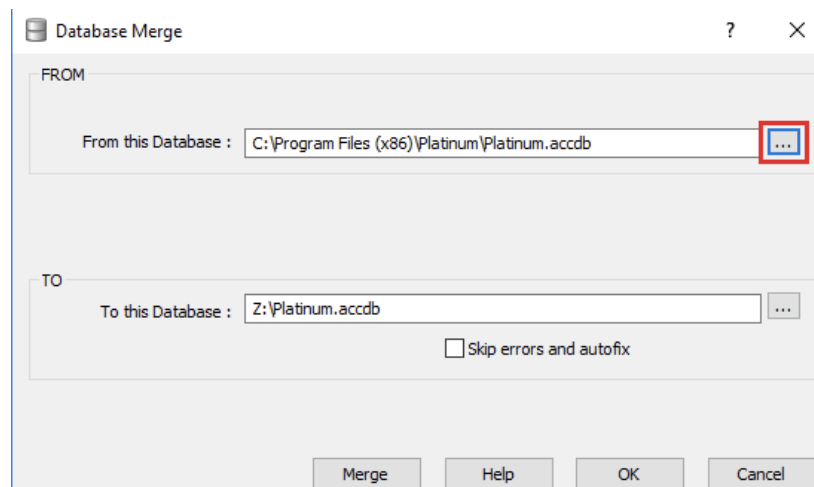
The screenshot shows a File Explorer window with the address bar set to 'Historical Database'. The search bar contains 'Search Historical Database'. The main area displays a list of files:

Name	Date modified	Type	Size
Baseline	14/11/2016 10:20	ACCDB File	1,176 KB
DIB	14/11/2016 10:20	ACCDB File	396 KB
Platinum	14/11/2016 11:05	ACCDB File	1,808 KB
Scan	14/11/2016 10:20	ACCDB File	1,752 KB

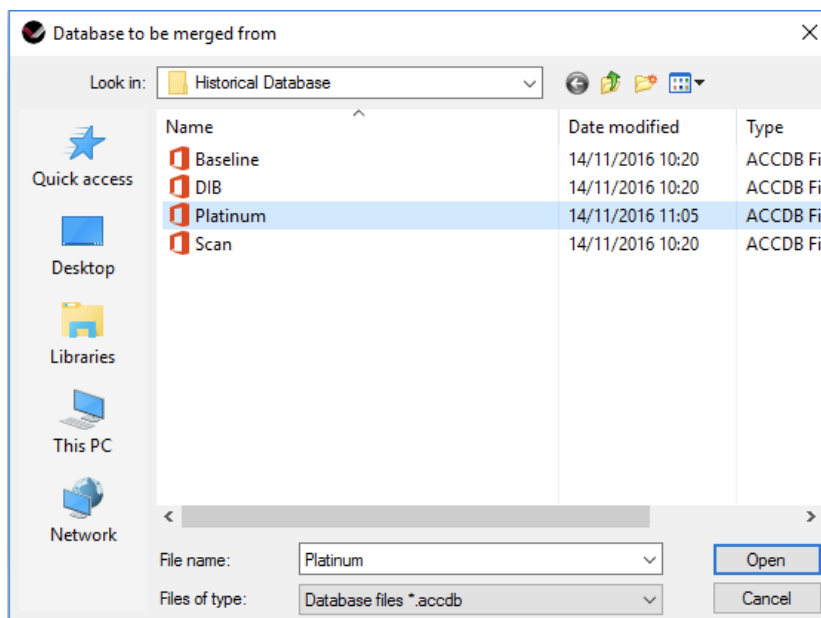
- e. Open Platinum and start a new V8 or Gelscan session. Open **Database > Merge Databases...**



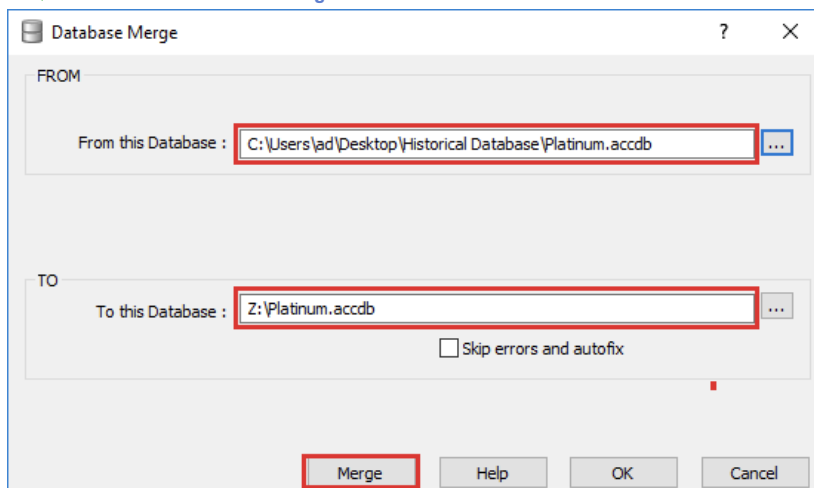
- f. Set the Historical database from the desktop as the **From this Database :** field by clicking the icon. Navigate to Desktop > 'Historical database' folder.



- g. Select **platinum.accdb** and click **Open**.



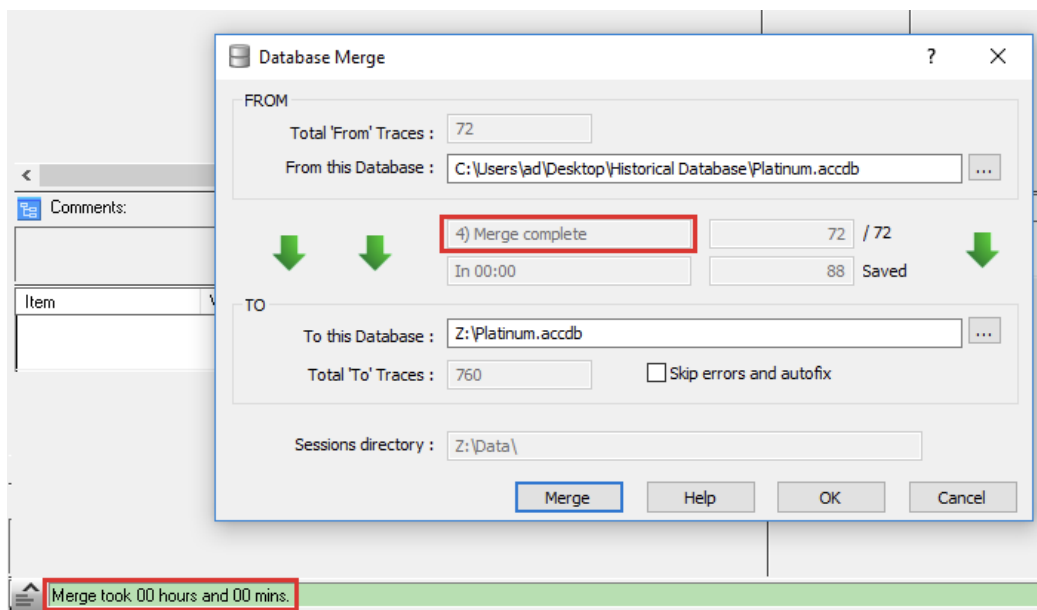
- h. Check that the FROM database is set to the location of the Historical database and the TO database is set to `Z:\Platinum.accdb`. Click **Merge**.



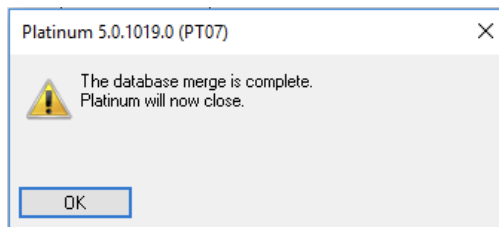
- i. The Database Merge progress window will appear indicating the status of the merging process. 1000 traces are loaded from the historic database and saved to the target database whilst the Platinum session files are moved from the original location to the location for new data configured in Step 2.

N.B. The merging process can be lengthy, for example a database with approximately 88000 traces can take up to 14 hours to complete so it is advisable to run this overnight if the database is particularly large.

- j. Once finished, the window will read 4) Merge complete and a message will display in the bottom left of the Platinum window indicating how long the merge process took.



k. Click **OK**. Platinum needs to be restarted so the following message will be displayed. Clicking **OK** will automatically close the software.



l. The database merge is complete and Platinum will now run using the combined database. The process can be repeated with more databases if required.

5.9.8

Backup and Recovery From Sessions

Platinum supports both MS SQL and MS Access databases. MS SQL offers users increased storage capacity and improves the ability to access the database from multiple PCs, significantly speeding up remote access and making MS SQL ideal for network or track systems. MS SQL databases allow faster searching, loading and saving of data and improvements to the patient history and database status functions.

The 'Backup and Recovery' window allows users to easily backup their database, import session files directly into the database and automatically save sessions from a directory in compatibility mode.

Please note that options in the Database menu are not available if there is an active session open in Platinum.

Importing sessions

Go to **Database > Database Backup... > Database Backup** and **Recovery > Import session files into the Database**.

Database Backup and Recovery ? X

Backup Database

Backup

C:\Program Files\Platinum\Backups\160320\ ...

Recover Database

Recovery

C:\Program Files\Platinum\Backups\ ...

Import session files into the Database

Import Sessions ☐ Update Methods

From Directory

C:\Program Files\Platinum\ ...

To Data Directory :

C:\Program Files\Platinum\

Directory 'Save As' session files

Save As Sessions Save As : ...

From Directory

...

To Directory :

...

☒ Skip errors and autofix
☐ PC shut down when complete

Help OK

In order to import sessions into a new database or current database select the appropriate file location in the 'From Directory'. The 'To Data Directory' will be automatically filled with the location that is set in 'Customise >Database> Location for new data.' It is optional to 'Update Methods' which applies the current method files analysis settings to data that is being imported. If this is to be applied then the 'Update Methods' option should be ticked before selecting 'Import Sessions'.

5.9.9

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, or peaks/bands or values are out of range.
Yellow	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
Green	The lane has been viewed and has the correct number of bands with all values in range.
Blue	The lane has been viewed and edited, and has the correct number of bands with all values in range.

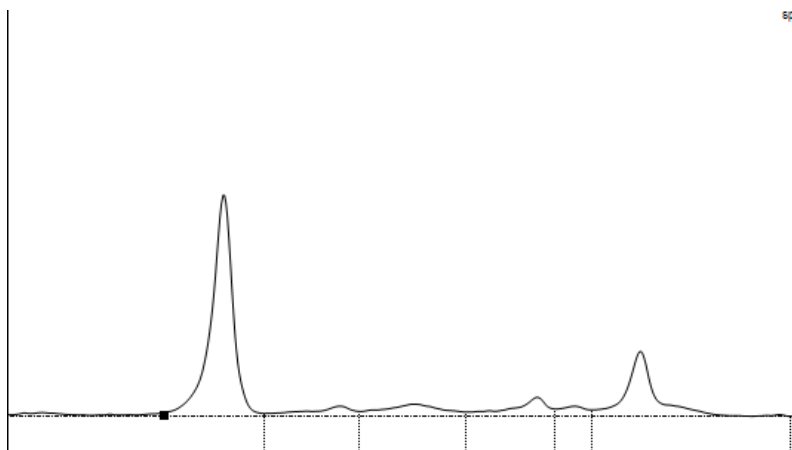
Using this colour code, after editing of a session all normal samples should be green and all reportable samples should be yellow.

5.9.9.1

Editing baseline

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


Moving the cursor 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.



5.9.9.2 Spline node addition:

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

5.9.9.3 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.

5.9.9.4 Add trough marker

To add an additional trough marker to a trace, move the cursor 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).

5.9.9.5 Delete trough marker

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


5.9.9.6 Split peak

To split a peak by addition of a trough marker move the cursor 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).

5.9.9.7 Smoothing

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

5.9.9.8 Filtering


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

5.9.10 Overlay functionality

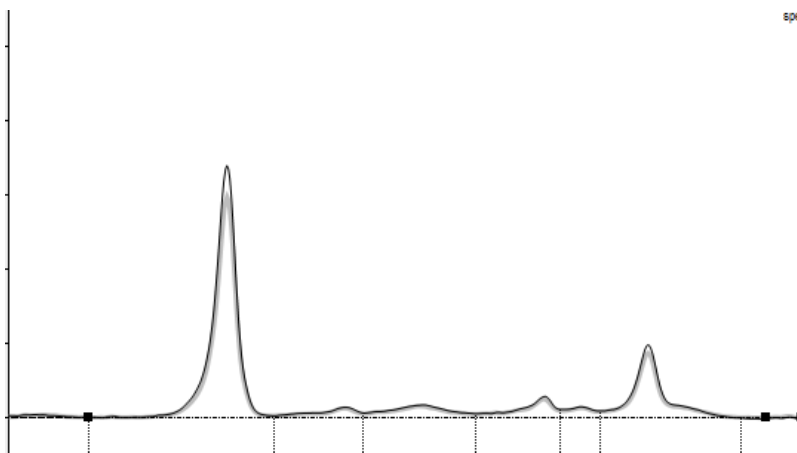
The overlay function enables comparison of a sample trace against a previously specified 'norm' or against another sample.

5.9.10.1 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"**.



5.9.10.2


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.

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.

5.9.10.3


Match Shapes

When Overlaying sample traces in V8 it is often necessary to match the overlay from one sample to another, this is especially apparent 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 click **Edit > Match Shapes** or on the toolbar click the  icon.

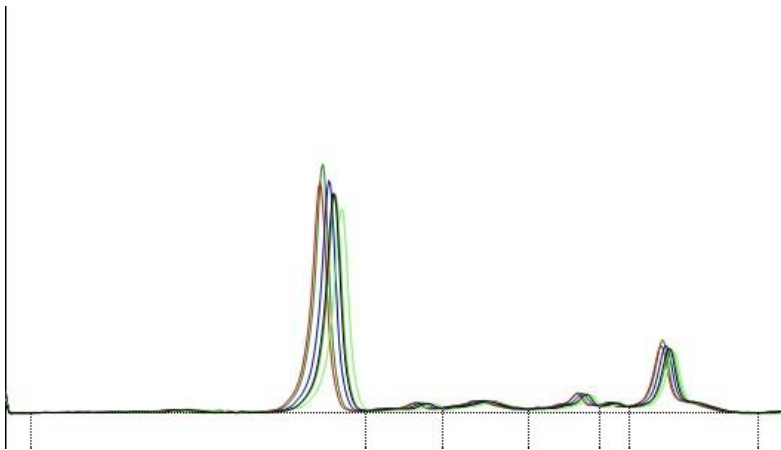
5.9.10.4

Stretching samples to overlay bands

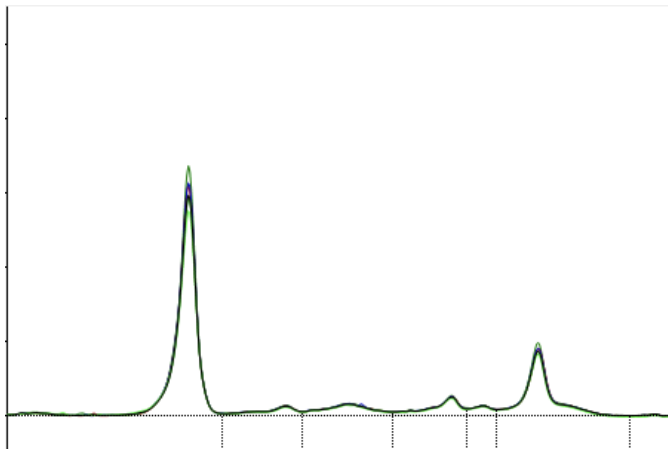
When overlaying samples from different time periods, it may be necessary to stretch a trace to overlay each peak over its corresponding peak in the second trace.

Overlay the required samples by holding down the **Ctrl** key whilst selecting from the navigation worklist, 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.



Pre auto-stretching



Post auto-stretching

5.9.10.5

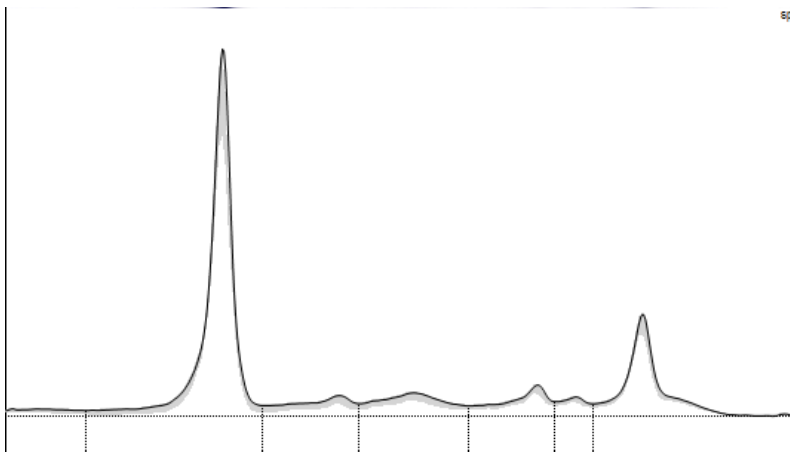
Mean traces

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 Trace List** from the drop down menu.

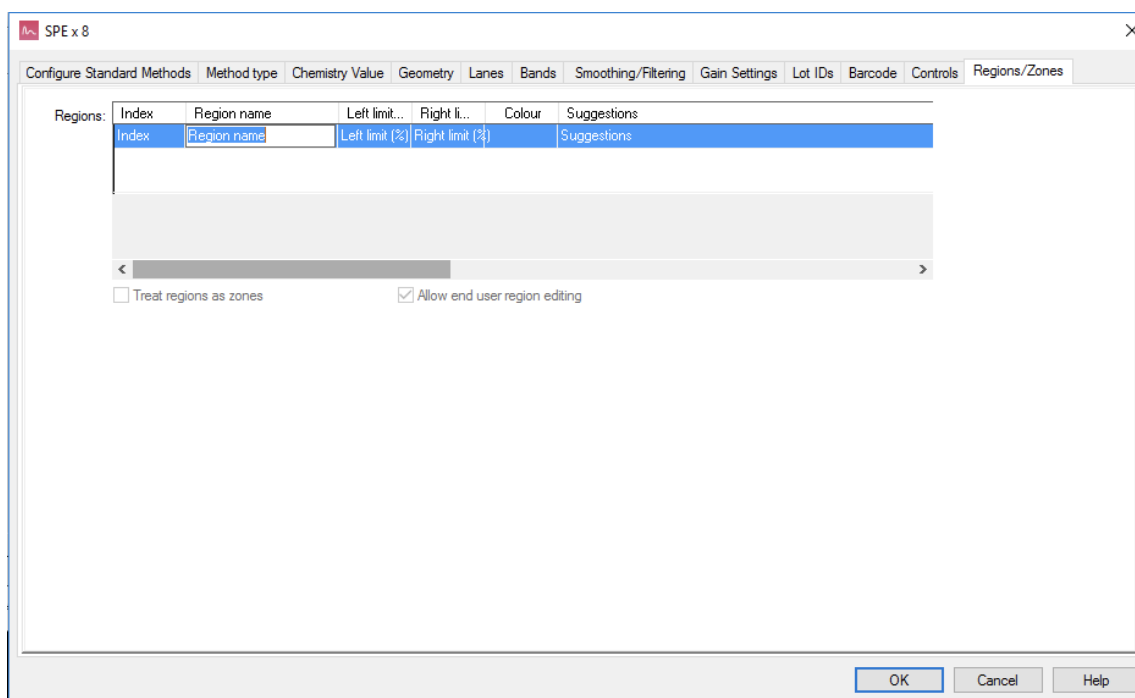
Right clicking on a sample in the list provides an option to remove a specific sample from the mean overlay.



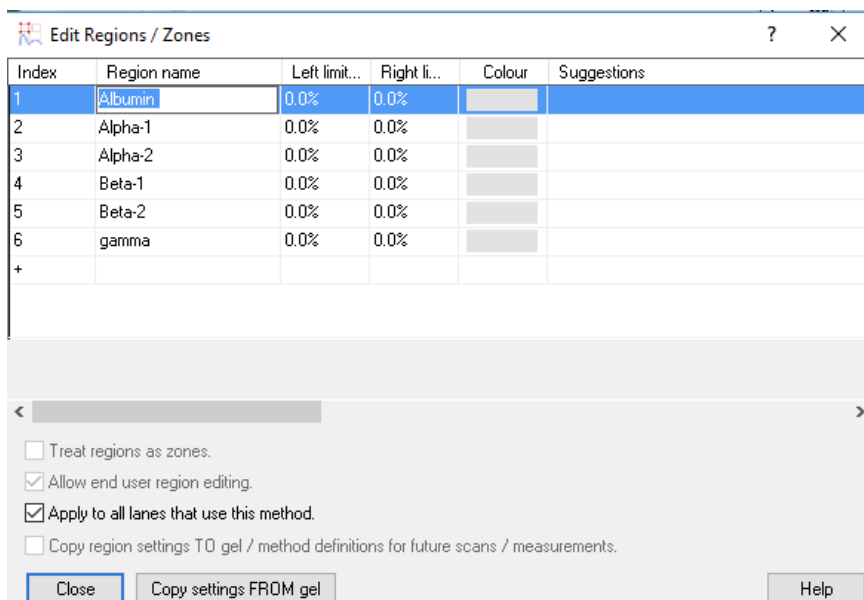
5.9.10.6

Trace regions

Choose **V8 system > Configure V8 Methods > Edit Regions/Zones tab**, and enter the region names and limits. Similarly, with gels, select **Gel > Configure Gel Methods > Edit Regions/Zones** and enter the names. 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 **V8 System > Edit Regions / Zones** or **Gel > Edit Regions / Zones** from the drop down menu.

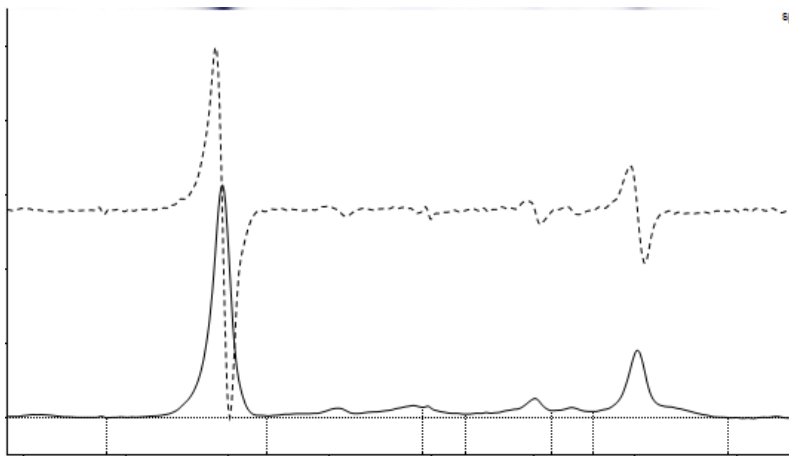


5.9.11

Derivative

Shows the first derivative of the selected trace. This can highlight peaks which may not be immediately apparent in the generated 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.



5.9.12

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, and do not under any circumstances inter-change between methods as this can lead to changes in patient monoclonal quantitation over time, due to the different methods of measurement used.

5.9.13

Skimmed M-spike

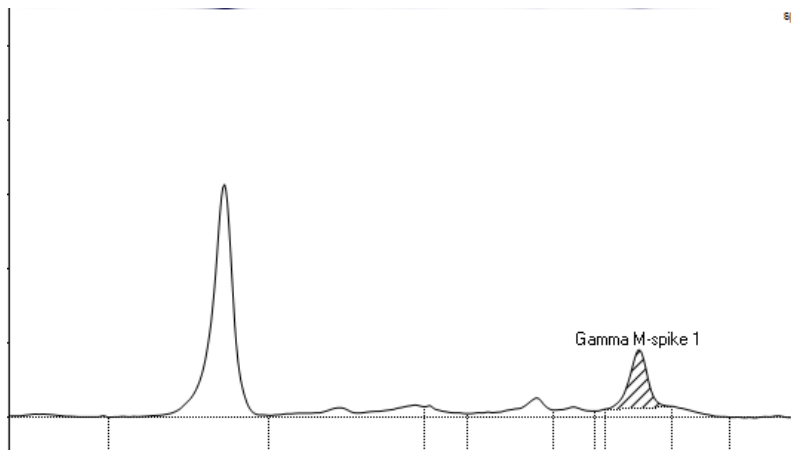
This methodology takes into account the polyclonal background of a sample by allowing the user to estimate the amount of polyclonal background and remove this from the quantitation.

5.9.13.1

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

5.9.13.2

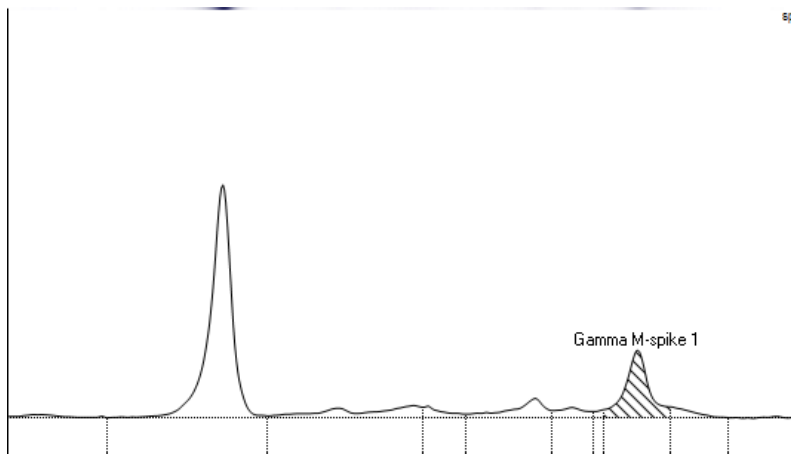
Sliced M-spike

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.

5.9.13.3

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

5.9.13.4

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.


5.9.13.5

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.


5.9.14

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.

5.9.15

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 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).

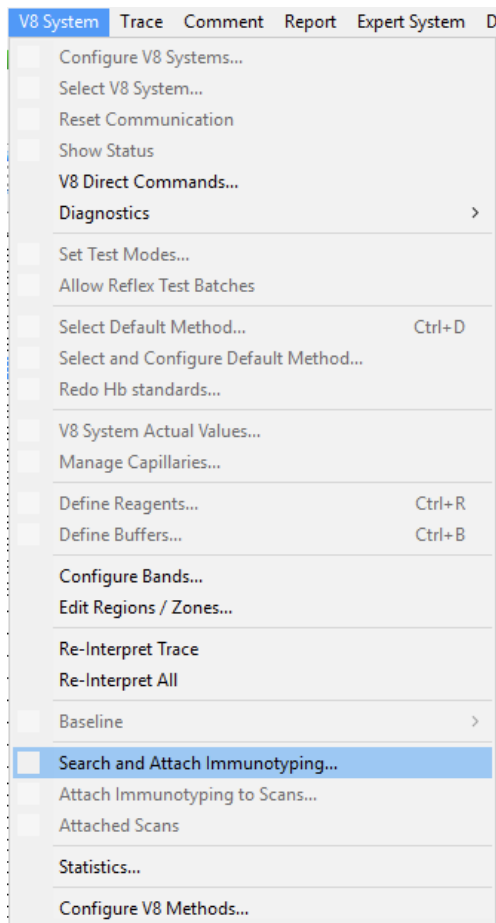
5.9.16

Searching for & attaching an Immunotyping result

It is possible within a single Platinum window to link and display Immunodisplacement traces / IFE traces 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 to be is linked to, and select **V8 System > Search & Attach**

Immunotyping or the 'Attach Immunotyping' icon  (demographic data must be present).



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

The 'Search' window contains a table with the following columns: Search item, (Low) Value, and High value. The table lists various search criteria with dropdown menus for selection.

Search item	(Low) Value	High value
System type	Any source	
Scan type	Any type	
Gel name	Any Name	
Analysis type	Any type	
Measurement time (dd/mm/yyyy)		
Gel ID		
Measurement status	Normal / abnormal	
Tube ID		
Patient ID		
Forename		
Surname		
DOB		
Demographic 6		
Demographic 7		
Demographic 8		
Demographic 9		
Demographic 10		


On the right side of the window, there is a sidebar with the following elements: a radio button for 'Sample', a 'Clear' button, a 'Search' button, an 'Archive Search' button, a 'Configure' button, a 'Help' button, and a 'Close' button.

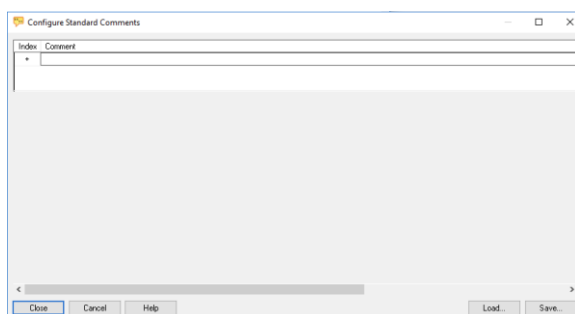
N.B. To detach a linked immunotyping right click on the immunotyping result and select [Detach]

5.9.17 Result comments

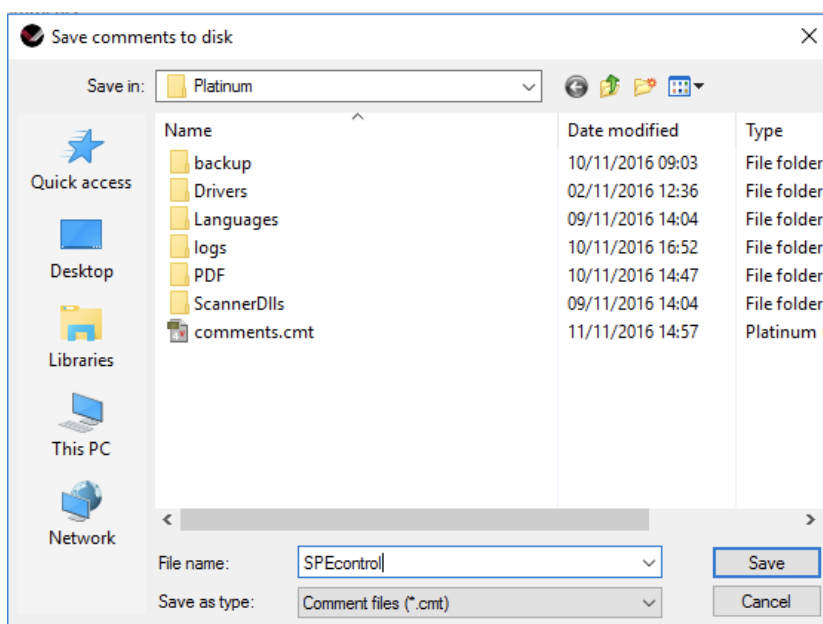
It is possible within Platinum to store predefined comments which can be added to the individual sample records.

5.9.17.1 To compose the standard comments

Choose **Comments > Configure comments** from the drop down menu or click the  icon. A window will appear.




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.

5.9.17.2

Adding a comment to a sample result

To add a comment to a result 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.

5.9.18

Calibration

In order to run a calibration on Platinum:

- Go to **V8 Systems > Configure V8 Methods** and select the method that will be used to run the calibrators. Go to the **Calibration** tab once you have selected the appropriate method. Calibration requires running each calibrator three times. If the user requires a three pick method to be created please contact V8 Support for further assistance. Note – Calibration cannot be applied to the method that was used to run the calibrators.
- Mark **Use Calibration** and select the appropriate base method that is to be calibrated. Eg. for HbA1c select the a1c base method. This will make sure that the calibration is applied to all control and sample methods.
- Input the peak name that is to be calibrated. Eg. A1c or A2.
- Enter the Lot numbers, expiries and calibration targets.
- Select **Warn on Lot Change** to activate a calibration warning when new reagents lots are used to run samples on the system. This is an optional feature. Click **OK** to close the Configure V8 Methods window.

HbA1c Calibration

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

Controls | Carbamylated Albumin | Calibration | Regions/Zones | Analysis

☒ Use Calibration

Calibrated by method:

For base method:

	Lot Number	Expiry date	Calibration Target	Run 1	Run 2	Run 3	Mean Run
Calibrator Level 1:	<input type="text" value="123"/>	<input type="text" value="30/05/2020"/>	<input type="text" value="5.1"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text"/>
Calibrator Level 2:	<input type="text" value="456"/>	<input type="text" value="30/05/2020"/>	<input type="text" value="7.4"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text"/>
Calibrator Level 3:	<input type="text" value="789"/>	<input type="text" value="30/05/2020"/>	<input type="text" value="10.2"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text"/>

☐ Warn on Lot change:

Calibrated peak name:

r^2 :

Calibrant = Mean +

Timer
☐ Use Timer
 Duration: Days
 Time from calibration run: Days

f. With the calibration method as default run the three calibrators.

g. In the navigation worklist or in **Work List > Set Up Work List** mark these samples appropriately as Calibrators 1, 2 or 3.

Set Up Work List

Work List ID: ☐ Display external chemistry values

Line	Sample/Control	Tube ID	Forename	Surname	DOB	Patient ID	Hospital ID
1	Calibrator Level 1	n/a	n/a	n/a	n/a	n/a	n/a
2	Sample	n/a	n/a	n/a	n/a	n/a	n/a
3	Normal Control	n/a	n/a	n/a	n/a	n/a	n/a
4	Abnormal Control	n/a	n/a	n/a	n/a	n/a	n/a
5	Calibrator Level 1	n/a	n/a	n/a	n/a	n/a	n/a
6	Calibrator Level 2	n/a	n/a	n/a	n/a	n/a	n/a
7	Calibrator Level 3	n/a	n/a	n/a	n/a	n/a	n/a
8	Calibrator Level 2	n/a	n/a	n/a	n/a	n/a	n/a
9	Calibrator Level 3	n/a	n/a	n/a	n/a	n/a	n/a

h. Once the calibrators have finished running go to **V8 Systems > Configure V8 Methods > Calibration** tab for the calibration method. Select **Load**. This will fill in the values for each of the calibrator runs. These values can also be input manually or loaded from a previously ran calibration curve. The calibration has now been calculated and the graph will be populated. Click **OK** to close the Configure V8 Methods window.

HbA1c Calibration

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

☒ Use Calibration

Calibrated by method: HbA1c Calibration
For base method: a1c

	Lot Number	Expiry date	Calibration Target	Run 1	Run 2	Run 3	Mean Run	
Calibrator Level 1:	123	30/05/2020	4.6	4.3	4.5	4.3	4.4	Pass
Calibrator Level 2:	456	30/05/2020	7.4	7.1	7.2	7.6	7.3	Pass
Calibrator Level 3:	789	30/05/2020	10.2	10.2	9.9	10.7	10.3	Pass

☐ Warn on Lot change: 0, 0

Calibrated peak name: A1c
r²: 1.00 Pass
Calibrant = 0.95 Mean + 0.46

☐ Use Timer
Duration: 0 Days
Time from calibration run: has expired Days

Load Load Historic

OK Cancel Help

i. All samples and controls that use the same base method will now have the calibration applied.

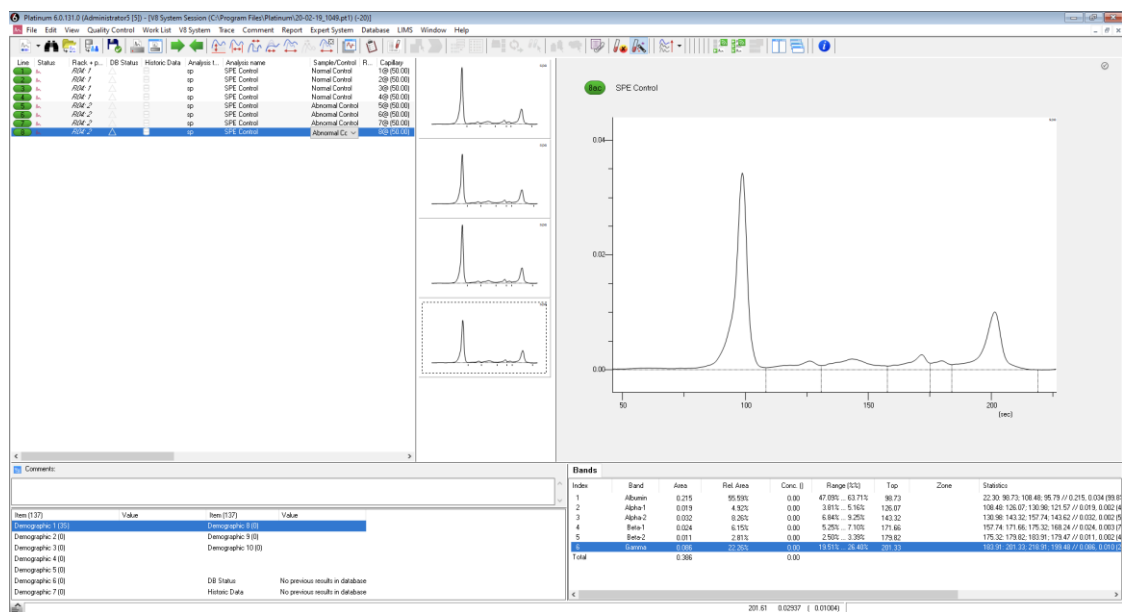
5.9.19

Quality Control

Key Features

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

Quality control menu navigation



Toolbar buttons

Mark as normal control

Mark as abnormal control

Levey Jennings menu

QC status icons

Passed QC and within date

QC out of date

QC failure

Input lot ID

- Lot ID page located in V8 system -> Configure V8 methods
 - Select the appropriate method from the methods list
 - Click on the Lot ID tab
 - Use the assay sheet provided with the control material to fill in the appropriate ranges below, including lot ID and expiry date
- Note if you wish to use peak percentage you should input a % symbol after the value.

Band	Component	Low normal	Upper normal	Low abnormal	Upper abnormal	Mean normal	SD normal	Mean abnormal	SD abnormal
1	Albumin	52.75%	71.37%	0.00%	0.00%	39.59	0.49	0.00	0.00
2	A1AG	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	0.00
3	Alpha-1	5.85%	7.91%	0.00%	0.00%	6.88	0.30	0.00	0.00
4	Pre-Alpha-2	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	0.00
5	Alpha-2	6.66%	9.01%	0.00%	0.00%	7.84	0.23	0.00	0.00
6	LP	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	0.00
7	HPX	0.00%	0.00%	0.00%	0.00%	0.00	0.00	0.00	0.00
8	Beta-1	6.06%	8.20%	0.00%	0.00%	7.13	0.28	0.00	0.00
9	Beta-2	3.58%	4.85%	0.00%	0.00%	4.22	0.28	0.00	0.00
10	Gamma	10.09%	13.66%	0.00%	0.00%	11.87	0.31	0.00	0.00

QC settings

Optional QC settings are defined in the Quality control preferences located on the toolbar when the Levey-Jennings chart is open.

Tick the display Levey-Jennings status function to activate real time tracking of the QC status. The icon will appear in the bottom right corner of the screen and 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 for.

Highlighting 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 Levey-Jennings 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 the force QC failure 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 default box.

Quality Control Preferences ? X

☐ Display Levey-Jennings Status
Active control method :

☐ 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

OK Cancel Help

Levey-Jennings Chart

QC control info

In the Levey-Jennings window go to [View > Preferences](#). Under V8 Auto Control barcodes select [Configure](#).

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.

V8 Auto Control Barcode Setup ? X

☒ Enable Automated V8 Control Barcode

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
CAL 1	Calibrator Level 1	HbA1c Calibration Sample
CAL 2	Calibrator Level 2	HbA1c Calibration Sample
CAL 3	Calibrator Level 3	HbA1c Calibration Sample
	None	None

☒ Show warning for missing Lot ID

OK Help Cancel

How to populate the Levey Jennings chart

- 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.

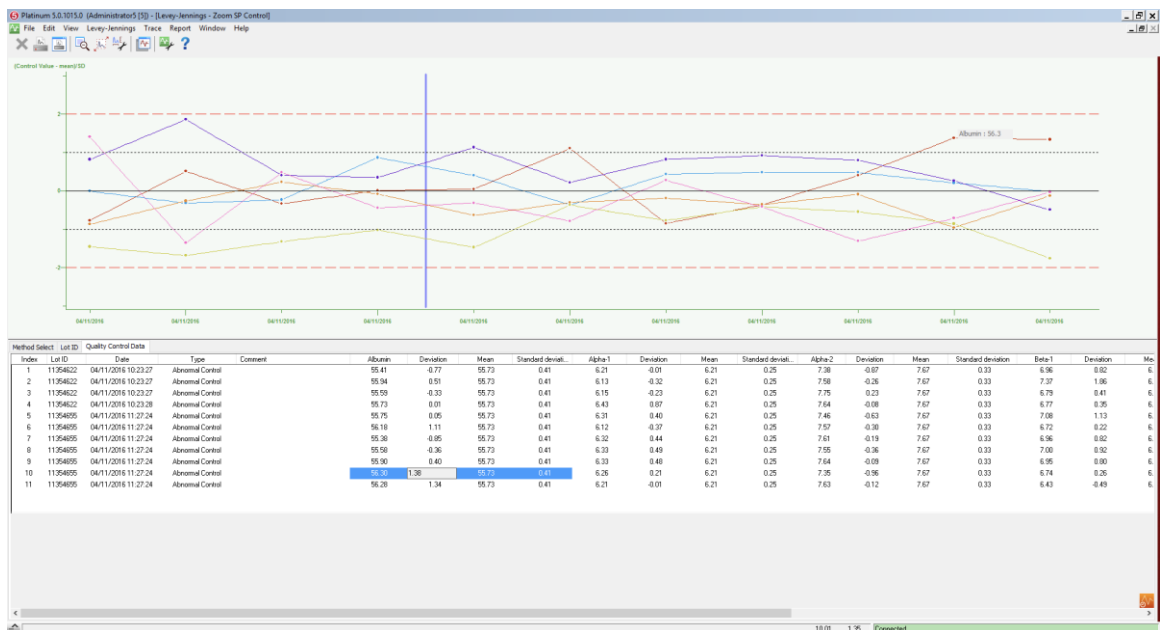
- Interpret trace ensuring all bands are gated correctly
- Highlight the control and mark as either a normal or abnormal control using the icons on the toolbar to populate results into the chart
- This will result in the QC being labelled either normal control or abnormal control in the navigation work list

6 Platinum 6.0.131.0 (Administrator5 [5]) - [V8 System Session (C:\Program Files\Platinum\20-02-19_1049.pt1) (-20)]

Line	Status	Rack + p...	DB Status	Historic Data	Analysis t...	Analysis name	Sample/Control	R...	Capillary
1	h	R04: 1	△		sp	SPE Control	Normal Control		1@ (50.00)
2	h	R04: 1	△		sp	SPE Control	Normal Control		2@ (50.00)
3	h	R04: 1	△		sp	SPE Control	Normal Control		3@ (50.00)
4	h	R04: 1	△		sp	SPE Control	Normal Control		4@ (50.00)
5	h	R04: 2	△		sp	SPE Control	Abnormal Control		5@ (50.00)
6	h	R04: 2	△		sp	SPE Control	Abnormal Control		6@ (50.00)
7	h	R04: 2	△		sp	SPE Control	Abnormal Control		7@ (50.00)
8	h	R04: 2	△		sp	SPE Control	Abnormal Cc		8@ (50.00)

Levey Jennings chart features

- QC method selection, Lot ID and data can all be viewed alongside the QC chart
- Changing control lot will insert a blue vertical line into the chart
- Any result outside of the defined parameter will bring up a comments box
- Hovering the cursor over a result will jump to the data point's values in the results box and highlight them blue.



5.9.20 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 **V8 System > Statistics (or 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 \pm , the standard deviation, and the C.V. for the area, area %, or concentration.

5.9.21 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.

5.9.21.1 Create new report

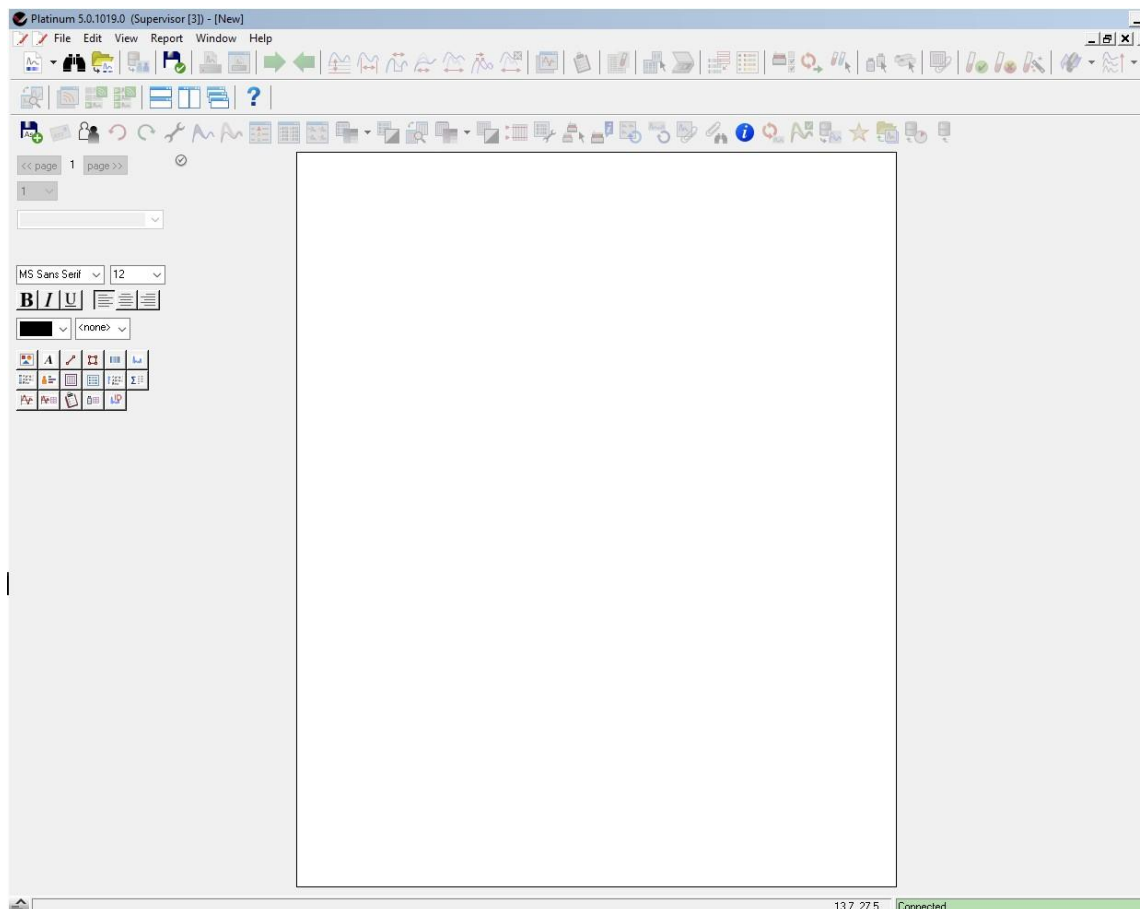
In order to create a new report, choose **Report > New Report Template**.

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 template designations.

5.9.21.2

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 result 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.



5.9.21.3

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 saved reports, and when one is chosen, choose **Open**. This will open the report in a new window with all the required functions to edit the report.

5.9.21.4

Preview report

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

5.9.21.5

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 result unless there is Immunodisplacement results attached to that sample in which case Platinum will default to the Immunodisplacement report. To set a default report:

- Select from the main Platinum window, **V8 System > Configure V8 Methods** or **Gel > Configure Gels**.
- In the report generation area make sure that the Do not report box is unticked.
- Select 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**.

SPE x 8

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

Analysis Type:

Tray type:

Measurement type

☒ Normal

☐ Immunotyping

☐ SP-ID (combination)

Gel scanning mode

☒ Transparent

☐ Reflective (opaque)

Control type

☒ Not a control

☐ Normal control

☐ Abnormal control

☐ Mark abnormal results for reflex testing

Reflex test name:

Default Reflex test name:

Report generation

Report definition: ... Edit ..

Report with IDs: ... Edit ..

☐ Use main reports ☐ Do not report

OK Cancel Help

- d. Repeat the selection for the Reports with IDs.
- e. This report definitions will be applied to all data generated going forward.

5.9.21.6

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:

- a. From the main Platinum window, select, **Reports > Select Reports**.

Select Report

Change reports for:-

☒ Current trace

☐ Current selection

☐ Entire session

Reports used

Report definition: ...

Report with IDs: ...

Help OK Cancel

- b. Select the ... button in the report definitions column, this is the report to be selected for the results without IDs. The default location for the reports files is in the following location: `C:\Program Files\Platinum\Reports`.

Another method to apply report definitions is via configure bands:

- a. From the main Platinum window, select, **V8 System > (or Gel) > Configure Bands**.
- b. Go to 'Report Selection' which will open the Select Report window.
- c. Select the ... button in the report definitions column, this is the report to be selected for the results without IDs. The default location for the reports files is in the following location: `C:\Program Files\Platinum\Reports`.

Set Up Method Interpretation for SPE Control x 8

Re-testing
☐ Mark abnormal results for re-testing
 Retest type : ▼

Smoothing
☒ Smoothing Weight: 5 ↕

Threshold filtering
☒ Filtering Weight: 5 ↕

Slope filtering
☒ Filtering Weight: 5 ↕

Calibration
☐ External Calibration ☐ Internal Calibration

Bands Set-up
☐ Recognise Bands by Tops ☐ Carbamylated Albumin Ratio Setup... Expressions...
☒ Fixed Fraction Mode ☐ Forced Fraction Mode ☒ Use coordinate ranges Carbamylated Alb.

Band	Component	Low are...	Upper ar...	Includ...	Combine with previous/next	Optional band	Limit rel.area
1	Albumin	0.00	0.00	*	Do not combine		
2	A1AG	0.00	0.00	*	Silently combine with next	*	
3	Alpha-1	0.00	0.00	*	Do not combine		
4	Alpha-2	0.00	0.00	*	Do not combine		
5	HPX	0.00	0.00	*	Silently combine with next	*	
6	Beta-1	0.00	0.00	*	Do not combine		
7	Beta-2	0.00	0.00	*	Do not combine		
8	Gamma	0.00	0.00	*	Do not combine		

☒ Recalculate all lanes that use this method Report Selection
☐ Copy settings TO method definitions for future scans / measurements

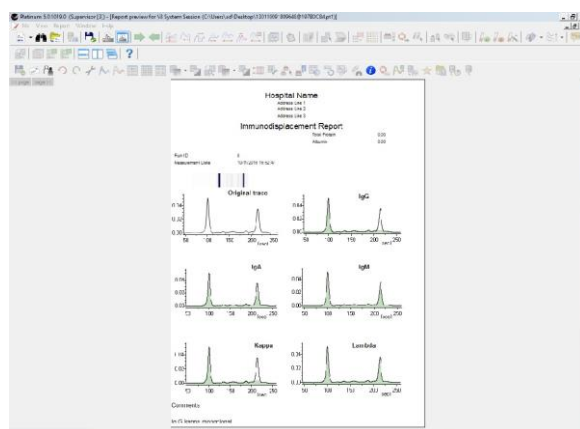
Help Copy settings FROM method Reinterpret All and Exit Cancel

- d. Repeat the selection for the Reports with IDs and Select OK.
- e. If this report definition is to be applied to this session without reinterpreting the traces select **Cancel** in the configure bands window.
 This will close the configure bands window without reinterpreting traces whilst still applying the selected report definitions. Selecting **Reinterpret All and Exit** will reinterpret all traces, applying any changes made in configure bands and in report definitions.
- f. This report definition will be applied to this session only.

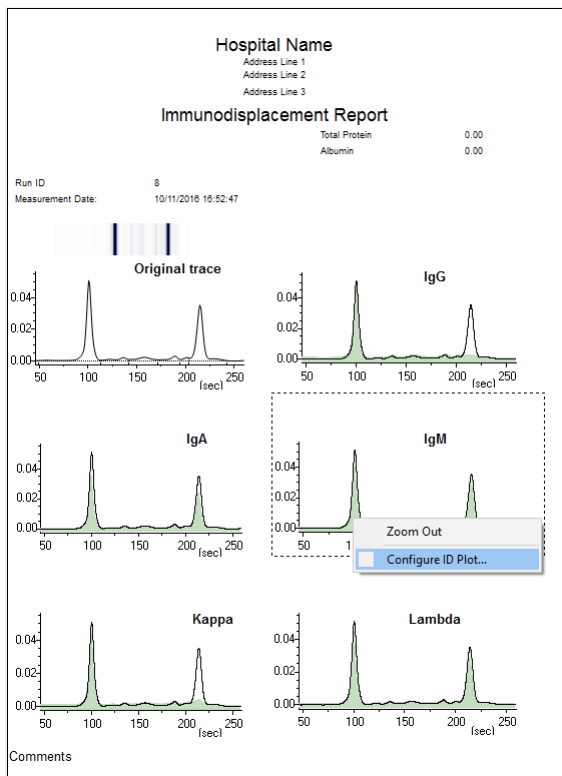
5.9.21.7

Configuring ID reports

ID reports are configured to provide an easy to interpret document (see below).



This can be further customised by the user providing a unique and tailored solution. By right clicking on the individual trace and select **Config ID Plot** (see below).



Each individual trace on the report can be uniquely edited to the user's preferences and requirements (see below).

ID plot configuration

☒ Plot main trace

ID plot items:

1	IgG	1
+		

☒ Match shapes before plotting

☒ Fill second trace

☐ Show method name

Close ☒ Copy settings to report definition

5.9.22

Database

The Platinum database stores all data that is processed and imported. Please note the Database menu options cannot be accessed when an active session is open.

5.9.22.1

Database Maintenance

To validate all sessions, fix corrupted samples or validate the database, go to [Database > Database Maintenance](#).

5.9.22.2

Archive selected data

To archive selected data in Platinum, go to [Database > Archive](#).

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

5.9.22.3

Merge Demographics

To merge previous demographics sets into the current Platinum demographics setup, go to [Database > Demographics Merge](#).

Archiving is not recommended when using SQL databases

5.9.22.4

Backup Selected Data

To back up selected data in Platinum, go to [Database > Backup](#).

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 **Database > Backup and Recovery**.

Compact the Database

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


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

LIMS**Controlling data to the LIMS/LIS**

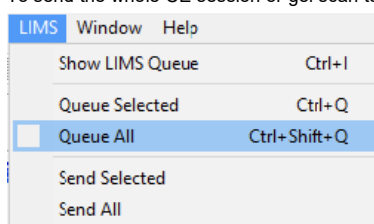
There are two ways to send data to LIMS/LIS. It can either be to a LIMS Queue, where the data can be validated before sending to the LIMS / LIS, or it can be sent directly without validation to the LIMS / LIS.


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 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, click the  icon (**LIMS > Queue Selected**).





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



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

Viewing and releasing data in the LIMS queue

To view those samples in the LIMS queue, choose **LIMS > Show LIMS queue**.

- a. To approve an individual sample to be released from the LIMS queue, click the **Approve sending lane to LIMS** icon  (**Trace > Approve sending lane to LIMS**). A blue tick will appear next to the LIMS icon .
- b. To approve multiple selected samples to be released from the LIMS queue, click the  icon (**Trace > Approve Sending Selected Lanes to LIMS**). A blue tick will appear next to the LIMS icon .
- c. To prevent a previous approved individual sample from being released from the LIMS queue, click (**Trace > Disapprove Sending Lane to LIMS**). The blue tick will disappear.
- d. To prevent multiple previously approved samples from being released from the LIMS queue, click (**Trace > Disapprove Sending Selected Lanes to LIMS**). The blue tick will disappear.
- e. To remove an individual sample from the LIMS queue, click (**Trace > Do Not Send Lane to LIMS**).
To remove multiple samples from the LIMS queue, click (**Trace > Do Not Send Selected Lanes to LIMS**).
- f. Once the appropriate samples have been authorised to be sent to the LIMS database, click either **Send Selected and Approved** or **Send All Approved** depending on the requirement to send the results to the LIMS database.
- g. To display the progress of the LIMS transfer, choose **LIMS > Inspect**.

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.

- a. To send the whole V8 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 2.8.

Usage log

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

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 Session Usage Log**.

Usage log X


Gel ID: V8-3-16-11-03_0936
Gel ID: C:\Users\ad\Desktop\16-11-03_0936.pt1 Close

Li...	User name	Date & time	Type	Subtype	Index on gel
1	Supervisor	07/11/2016 09:27:0	View		1
2	Supervisor	07/11/2016 09:27:2	View		17
3	Supervisor	07/11/2016 09:27:3	View		25
4	Supervisor	07/11/2016 09:27:3	View		28
5	Supervisor	07/11/2016 09:27:3	View		31
6	Supervisor	07/11/2016 09:45:0	View		26
7	Supervisor	07/11/2016 09:45:0	View		29
8	Supervisor	07/11/2016 09:45:1	View		20
9	Supervisor	07/11/2016 09:45:1	View		28
10	Supervisor	07/11/2016 09:45:1	View		25
11	Supervisor	07/11/2016 09:45:1	View		19
12	Supervisor	07/11/2016 09:45:4	View		24
13	Supervisor	07/11/2016 09:46:0	View		33
14	Supervisor	07/11/2016 09:46:0	View		26
15	Supervisor	07/11/2016 09:46:1	View		27
16	Supervisor	07/11/2016 09:46:1	View		15
17	Supervisor	07/11/2016 09:46:1	View		41
18	Supervisor	07/11/2016 09:46:1	View		37
19	Supervisor	07/11/2016 09:46:1	View		29
20	Supervisor	07/11/2016 09:46:4	View		36
21	Supervisor	07/11/2016 09:46:4	View		11

Print...
Export...
Show All

5.9.24.2

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**.

Usage log X

Gel ID: V8-2-16-11-11_1005
Gel ID: C:\Users\ad\Desktop\16-11-11_1005.pt1 Close


Li...	User name	Date & time	Type	Subtype	Index on gel
1	Supervisor	11/11/2016 11:47:1	View		11
2	Supervisor	14/11/2016 08:58:4	View		11

Print...
Export...
Show All

5.9.24.3

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**.

 Search usage log
 ✕

User:
Search
Close

Start date (dd/mm/yyyy):

End date (dd/mm/yyyy):
Clear

Li...	User name	Date & time	Type	Subtype	Index on gel	Gel ID	Gel file

Print...
Export...
Show All

5.9.24.4

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.

Save As

Save in: Platinum

Quick access

- Desktop
- Libraries
- This PC
- Network

Name	Date modified	Type
Archives	14/11/2016 09:32	File folder
backup	10/11/2016 09:03	File folder
Drivers	02/11/2016 12:36	File folder
Languages	09/11/2016 14:04	File folder
logs	10/11/2016 16:53	File folder
PDF	10/11/2016 14:47	File folder
ScannerDlls	09/11/2016 14:04	File folder

File name:

Save as type: Tabbed files (*.txt)

Save Cancel

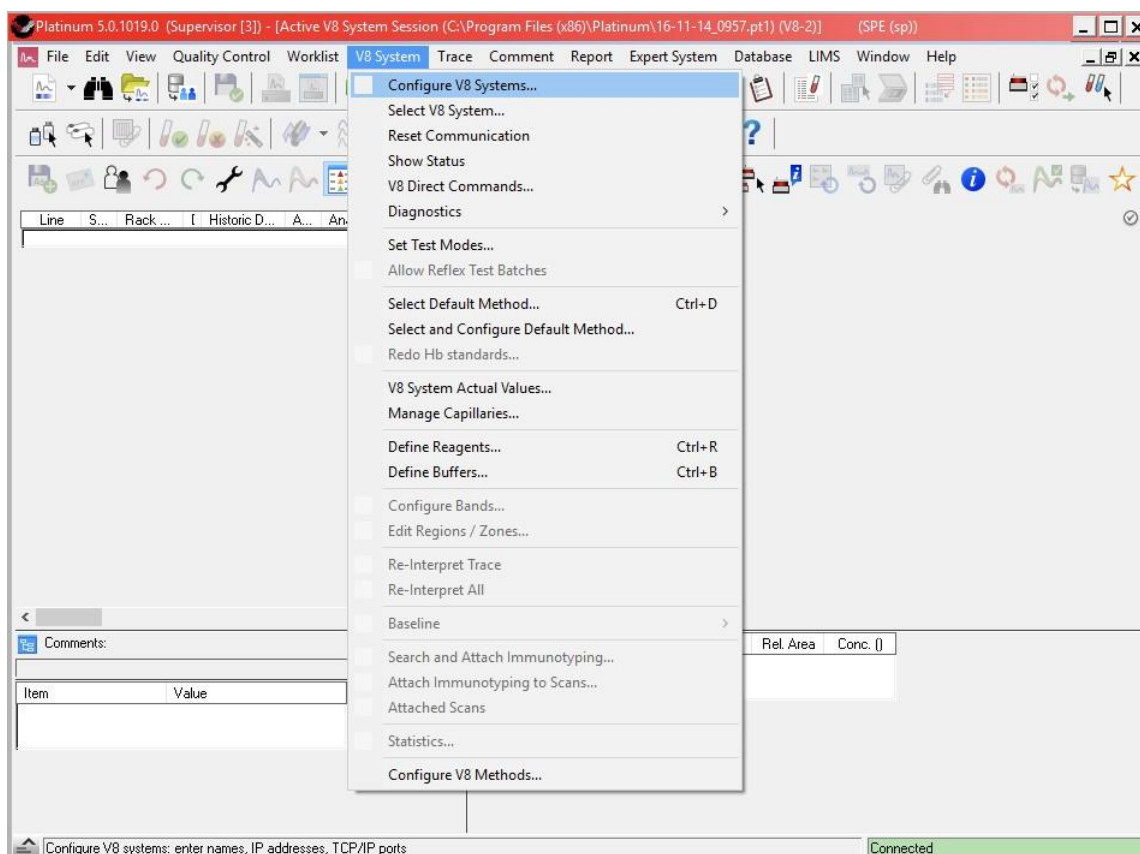
Show All – all data can be loaded in to the search window. By default, only the most recent data is shown without the user having to scroll down the window.

5.9.25

5.9.25.1

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

Choose **V8 System > Configure V8 systems**. The configure V8 systems dialogue box will open. This window will allow for new V8 systems to be attached to the PC, 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

5.9.25.2 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 **V8 System > Select V8 System**.

5.9.25.3 Reset communication

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 communication, select **V8 System > Reset Communication**.

5.9.25.4 Show status

This function allows the user to open a modeless dialogue box that contains all the information pertaining to the current status of the system, and any error messages that have occurred in the session. This window can be kept open without interference to the operation of Platinum or can be opened only when required.

5.9.25.5 Reflex tests


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 complete batch. Immediate and Rack priority will perform each ordered test immediately, thus moving racks back into the sample handling area, switching assay if required. In Complete batch mode, the V8 will hold all ordered tests until prompted to perform analyses at the user's discretion.

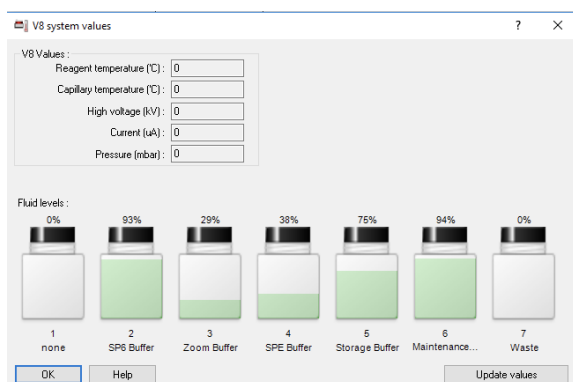
N.B. It is important to define which priority is required before analysis commences.

For more information on reflex testing in a V8 session, see 5.4.3 & 5.9.3.4.

5.9.25.6 V8 system actual values

V8 system actual values show the user the capillary temperature, reagent block temperature, pressure, voltage, current, and levels of fluid in all buffer bottles at that moment in time.

This can be found by selecting **V8 System > V8 System Actual Values** or by clicking the icon . Alternatively, the same information can be obtained for a particular sample in the navigation worklist by right clicking on the trace and choosing **V8 Runtime Parameters**.



V8 system values

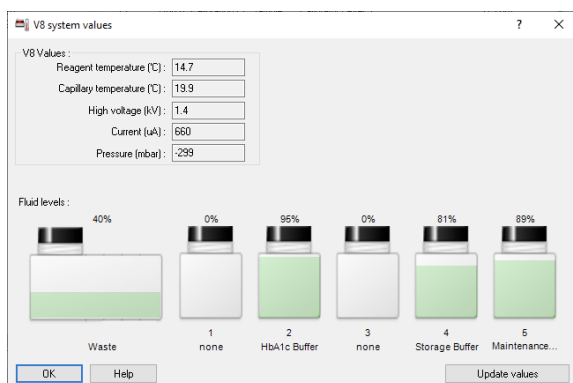
V8 Values:

Reagent temperature (°C):	0
Capillary temperature (°C):	0
High voltage (kV):	0
Current (µA):	0
Pressure (mbar):	0

Fluid levels:

Position	Level (%)	Label
1	0%	none
2	93%	SP8 Buffer
3	29%	Zoom Buffer
4	38%	SPE Buffer
5	75%	Storage Buffer
6	94%	Maintenance...
7	0%	Waste

Buttons: OK, Help, Update values



V8 system values

V8 Values:

Reagent temperature (°C):	14.7
Capillary temperature (°C):	19.9
High voltage (kV):	1.4
Current (µA):	660
Pressure (mbar):	-299

Fluid levels:

Position	Level (%)	Label
Waste	40%	
1	0%	none
2	95%	HbA1c Buffer
3	0%	none
4	81%	Storage Buffer
5	89%	Maintenance...

Buttons: OK, Help, Update values

5.9.25.7

Defining reagents and buffers

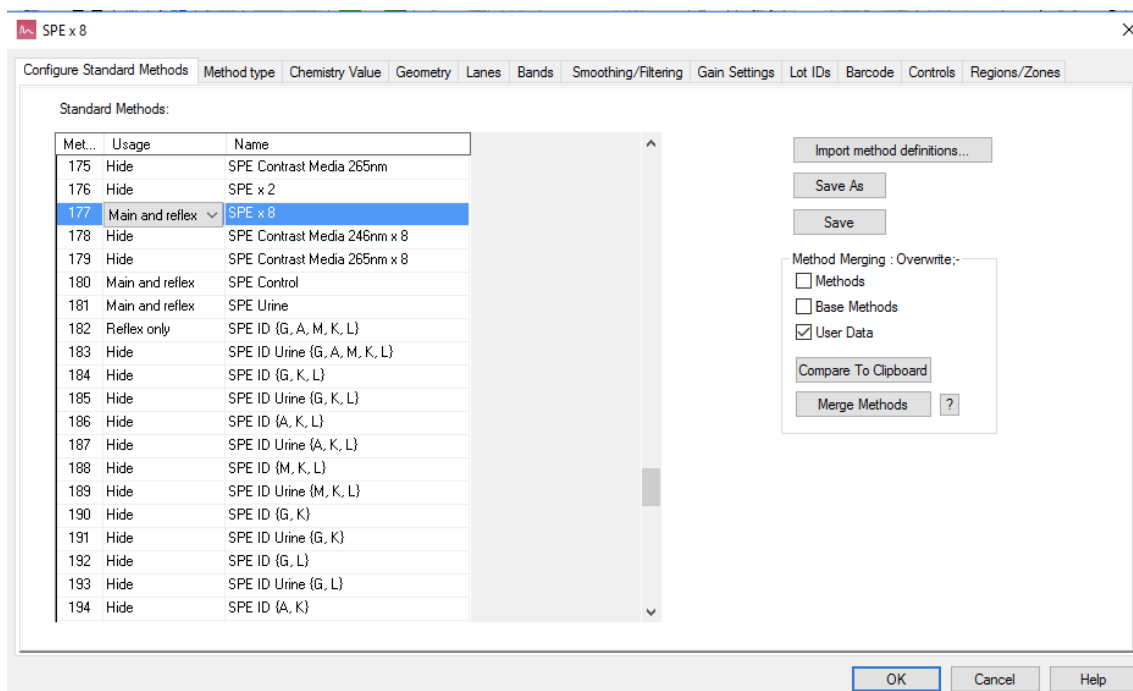
All reagents and buffers used on the V8 are individually barcoded. Using the define reagent or define buffer function allows the user to view what is in use, or in the case of the reagent block in which position. It also permits the user to change buffer bottles or reagents upon prompt from the V8 or upon change of assay.

For information on how to complete this function, please refer to 5.7.1, 5.7.3 & 5.7.4.

5.9.25.8

Configure V8 methods

In Platinum, it is 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 supervisor level.



5.9.25.8.1

To configure V8 methods

- Choose **V8 System > Configure V8 Methods**. This will open the Configure Standard Methods window.
- From the Standard Methods pane, select the method you wish to configure. there is also the option here to choose to '**Show**' or '**Hide**' methods to other user levels by clicking on the '**Usage**' column.
- Once the desired assay is selected there are 11 tabular options available. It is recommended that most of these are left as default.

5.9.26

Tasks specific to gel sessions

5.9.26.1

Select gel

Gel > Select Gel opens a window that allows the user to choose the required gel method to be scanned which specifies geometry and band set up.

5.9.26.2

Scanning configurations

5.9.26.2.1

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 a window that is prompted by choosing **Gel > Select Scanner**.

5.9.26.2.2

Prompting Platinum to scan

Clicking **Gel > Scan** 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 will commence.

5.9.26.2.3

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. 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 require slight adjustments to account for slight individual variations.

5.9.26.2.4

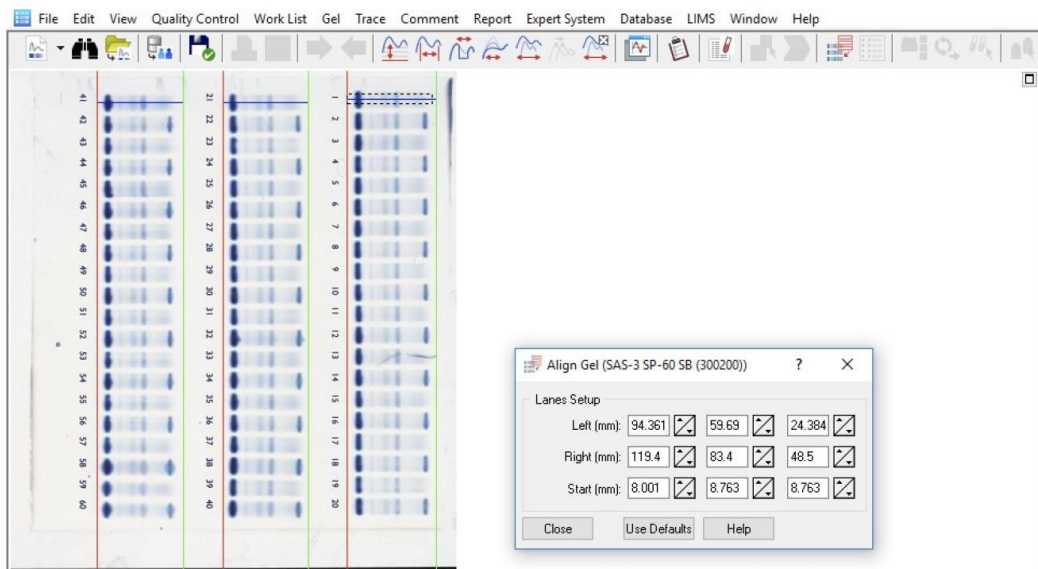
Marking a gel

To see that a template fits correctly on a scanned image, using **Gel > Mark Gel** will 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.

5.9.26.2.5

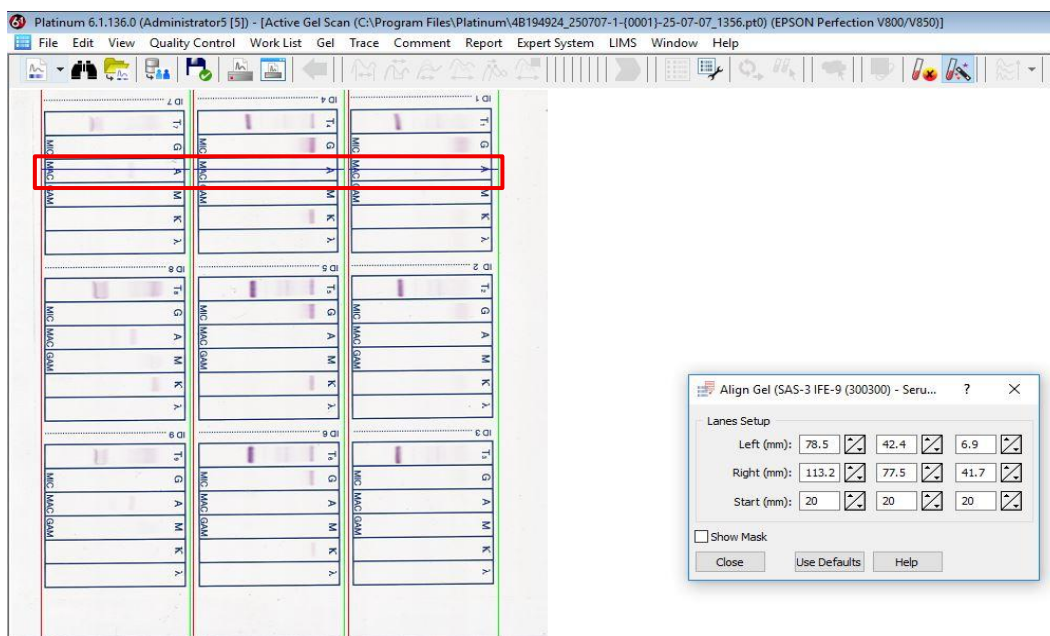
Aligning a gel

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 for each sample row.



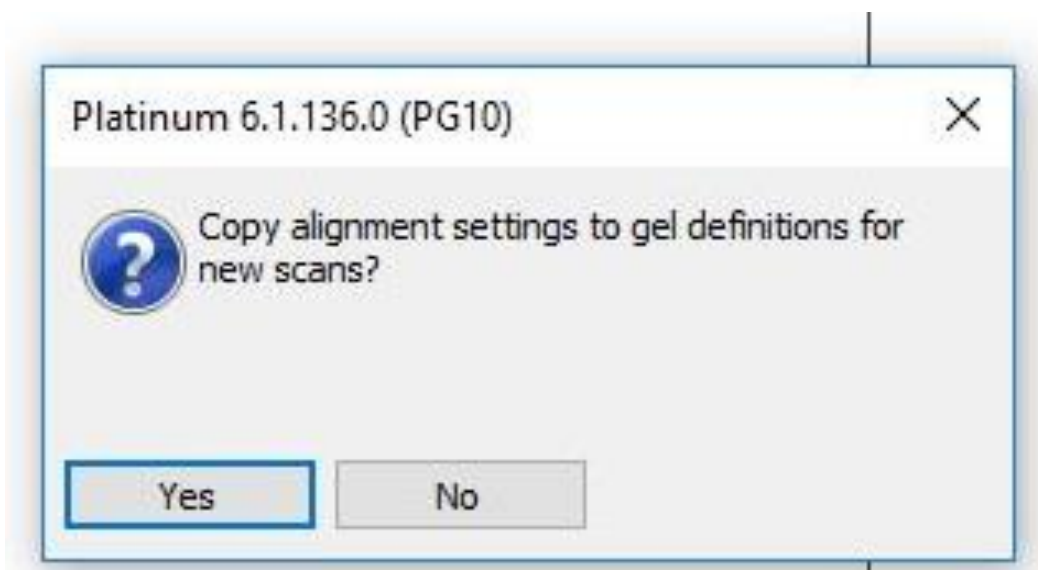
Two vertical markers represent the left and right hand limits of each row and a single horizontal marker indicates the centre position of the first sample in each row. Each marker can be positioned either by clicking and dragging with the cursor, or by altering the values that are displayed in the table. 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.

5.9.26.2.6

Configure gels

In Platinum, it is 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.

6 Calibration procedures

6.1 Instrument calibration

- a. All V8 instrument calibration should be carried out by a Helena Biosciences trained and certified engineer; this will be carried out during scheduled site service visits and at installation.
- b. Any attempts by untrained/unqualified personnel to calibrate the V8 instrument could invalidate the warranty.

6.2 Quality Control calibration checks

- a. It is recommended that Helena Biosciences quality control material are used to perform daily checks on the performance of the V8 instrument. All control kits are supplied with assay sheets which provide details of the expected ranges.
- b. Further details of the quality control procedure can be found in section 5.9.19.

7 Health and Safety information

7.1 Overview

The V8 system has been designed and manufactured to the highest standards of technical excellence, fulfilling the scope of its intended purpose, and incorporating the latest in safety design features satisfying standards for the manufacture of IVD equipment. The V8 system has been designed to ensure the full health and safety of the end-user, and to prevent and limit all possible health and safety risks associated with operating the V8 via in-built protective features, standards and protocols. The following section details all the protective features and user instructions for ensuring health and safety. It is strongly recommended that this section is read thoroughly before system use.

7.1.1 Personal Protective Equipment

It is recommended that suitable Personal Protective Equipment (PPE) is worn at all times. Local regulations should be adhered to for precise instructions of necessary clothing, but as a minimum Helena Biosciences recommends that the following safety equipment is used at all times: safety glasses, gloves and a laboratory coat.

7.2 On-board Health and Safety standards and protocols

7.2.1 Compliance standards

V8 complies with a number of recognised standards and directives for the design, development and manufacture of IVD equipment. Please refer to 7.3.4 to read all of these standards.

7.2.2 Training

All users must demonstrate their competence to operate the V8 fully in accordance with the user instructions of this manual to a certified level. Under no circumstances must anyone operate the V8 without full user training by a qualified instructor representing or associated with Helena Biosciences Europe.

7.2.3 Protective hood



WARNING

The protective hood protects against the mechanical movements of the sample handling system, and environmental contamination from dust particles entering the sample analysis and preparation area. The protective hood should not be removed.

7.2.4 Mechanical movement shut down



WARNING

The V8 is made up of modular components that are integrated with sensors to protect users from hazardous mechanical movements, and to ensure correct and optimal analytical conditions. All mechanical movements linked to the preparation and analysis of samples, including hazardous needle movements, will automatically shut down and remain on stand-by, upon opening of the top cover and rack cover.

7.2.5 Safe loading of samples

The sample rack can be adapted to fit all types of sample tubes, which can be fitted securely to the sample rack. All sample racks must be loaded onto the sample transport area correctly. See section 5.7.7. Appropriate personal protective equipment must be worn.



CAUTION

WARNING: Pinch point hazard

7.2.6 Zero cross contamination

Automatic maintenance procedures ensure that all fluidic and analysis channels are cleaned and decontaminated thoroughly for reproducible results requiring no user intervention between runs, and ensuring zero cross contamination of samples, reagents and buffers.

**WARNING**

All clinical waste is channelled into two removable units held on-board the V8 for the safe and convenient disposal of hazardous substances and material, minimising user interruption to the system and ensuring safe disposal; provided stringent safety protocols are followed as additional measures.

**WARNING**

ALL CLINICAL WASTE SHOULD BE HANDLED WITH CARE AND DISPOSED OF IN ACCORDANCE WITH LOCAL WASTE DISPOSAL RULES.

Analysis security

Platinum is password protected with designated access settings for multiple users, providing a holding pen for all results awaiting: (1) approval by the laboratory manager with Level 3 security access settings, and; (2) data transference to the Hospital's Laboratory Information Management System for official patient records. See section 2.6.

Quality assurance

Full Levey-Jennings capability is available providing quality control data and a graphical indication of how different methods are performing on the system. Within this, Westgard rules define the specific performance limits of the V8, and its assays, which act as a failsafe to detect random and systemic errors.

Audit trail accountability

V8 ensures that the identity of the clinician, and of the patient sample, is logged for audit trail accountability, against the barcode data, lot number and expiry date of each buffer and reagent consumed on the system.

Expert System

Platinum via the Expert System facilitates the positive identification of abnormal results through automated software features for speed and convenience, but does not under any circumstances automate the diagnosis of disease states. It is the responsibility of the clinician to ensure all data is correctly diagnosed. See section 5.8.

Instrument status communication

V8 communicates visually and audibly to the end-user through an on-board lighting and voice command system. This is designed to provide the end-user with information regarding the operational status of the instrument for correct, optimum and safe usage at all times. See Appendix 2 sub-sections 2.2 and 2.3.

Regulatory Information**Proprietary notice**

The information contained in this manual is derived from the patented and proprietary data of Helena Biosciences Europe. Publication of this information does not imply any rights to reproduce or use this manual for purposes other than installing, operating, or maintaining this instrument and software. No part of this manual may be reproduced, transcribed, transmitted, stored in a retrieval system, or translated into any language, in any form or by any means, electronic, magnetic, mechanical, optical, manual, or otherwise, without the prior permission of a representative of the executive management team of Helena Biosciences Europe.

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Warranty

Helena Biosciences Europe warrants each instrument manufactured to be free of defects in materials and workmanship (excluding external power supplies). This warranty shall be fulfilled by the repair or replacement, at the option of Helena Biosciences Europe, of any part or parts, free of charge including labour, F.O.B. it's factory or authorised service centre.

This warranty shall be voided by any repair, alteration, or modification, by persons other than employees of Helena Biosciences Europe, or those expressly authorised by Helena Biosciences Europe to perform repairs, and by any abuse, misuse, or neglect of the product, or by use not in accordance with Helena Biosciences Europe's published instructions.

Helena Biosciences Europe reserves the right to make changes in design and / or improvements to its products without any obligation to include these changes in any products previously manufactured. Correction of defects by repair or replacement shall constitute fulfilment of all warranty obligations on the part of Helena Biosciences Europe.

THIS WARRANTY IS EXPLICITLY IN LIEU OF OTHER EXPRESSED OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. THIS WARRANTY OBLIGATION IS LIMITED TO REPAIR OR REPLACEMENT OF THE UNIT RETURNED TO HELENA BIOSCIENCES EUROPE OR AN AUTHORISED SERVICE CENTRE FOR THAT PURPOSE.

7.3.3

WEEE

As of the 19th February 2007, Helena Biosciences Europe products meet the European Union Waste Electrical and Electronic Equipment (WEEE) directive. Please refer to www.helena-biosciences.com for more information on Helena Biosciences compliance with the WEEE directive.

When supplied as B2B EEE the producer invokes regulation 12.2 and passes all WEEE obligations to the end user.

7.3.4

Applicable standards and directives

The V8 capillary electrophoresis instrument complies with the relevant clauses and articles of the following recognised standards and directives for its development, manufacture and servicing.

COUNCIL DIRECTIVE 2012/19/EU of 4 July 2012 concerning waste electrical and electronic equipment (WEEE)
COUNCIL DIRECTIVE 2011/65/EU of 8 June 2011 concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2)
COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (RoHS3)
EN ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2012 Medical devices — Application of risk management to medical devices
EN IEC 61010-1:2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN IEC 61010-1:2010/A1:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN IEC 61010-2-101:2017 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 61010-2-081:2019 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN IEC 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN IEC 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN IEC 62366-1: 2015 Medical devices - Application of usability engineering to medical devices
EN IEC 62366-2: 2016 Guidance on the application of usability engineering to medical devices
EN IEC 62304:2015 Software for medical devices - Processes for lifecycle of Programs
ISO16142-2:2017 - General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards
EN ISO15223-1:[2016] Medical Devices – Symbols to be used with medical devices, labelling and information supplied – Part 1: General requirements
EN ISO18113 (part 1 & 3) - In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)
EN13612:2003 - Performance evaluation of in vitro diagnostic medical devices
EN14136:2004 - Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
ISO17511:2003 - In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
EN ISO23640 - In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

For instruments that will be sold in the United States of America, all relevant federal regulations of the Food and Drug Administration (FDA) Title 21CFR have been complied with.

7.3.5

Precautions and limitations

1. To fully isolate the system remove the mains power cord from the rear of the instrument. This should be easily accessible by the operator in the event of an emergency.
2. It is the responsibility of the operator to fully read and understand the operator manual and be fully competent on operating the V8 before use.
3. Ensure the fan located at the rear of instrument is not covered and has adequate air circulation (see section 2.4.1).
4. Ensure the top cover is not obstructed when fully opened.
5. Do not use abrasive cleaners on any of the instrument surfaces. Always isolate mains supply before cleaning any spills.
6. Only use cleaning fluids recommended: 70% Ethanol, Isopropanol or 1% hypochlorite solution (see WHO Laboratory biosafety manual) (bleach).
7. Only use the instrument for the intended purpose stated, see section 1.1.
8. The instrument should only be operated when installed by a Helena Biosciences trained engineer.
9. If the system is operated in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
10. Whilst the unit is in operation, the operator should keep clear the area around the reagent bay and gel tray docking station. Reagent bottles should not be stored within this area when not in the reagent bay.

8.1 Residual risks and user protection

In addition to the instrument's on-board safety mechanisms, it is necessary for the user to take adequate protection measures in relation to risks that cannot be eliminated by system design, such as the disposal of clinical waste, or the handling of hazardous reagents and patient samples. Whilst the V8 minimises user risks through expert design, the end-user remains responsible for the safe and correct handling procedures of samples and waste fluids.

Please read the details below that present all residual risks faced by the end-user when using the V8, in addition to the relevant equipment needed to assist with health and safety measures. The manufacturer considers residual risks to mean all potential hazards associated with using the V8, but unprotected by the ergonomic design and in-built safety features of the V8 system;

- Cleaning of sample analysis and preparation area
- Disposal of clinical waste
- High voltage
- Handling of patient samples
- Handling of high risk samples
- Lifting, installation and re-location
- Removal of the protective hood
- Sampling handling arm

8.1.1 Cleaning of sample analysis and preparation area

Please refer to sections 8.1.2 and 9.8 for further information.

8.1.2 Decontamination

Any areas of instrumentation subject to potential biological sample spillage are readily accessible for decontamination procedures and disinfection. In the event of contamination to the system, the operator must post-condition the instrument via the side-switch which will be adequate to fully decontaminate the instrument internally and allow the user to safely deal with any sample spillages.

Decontamination of the system

All samples loaded onto the V8 should be classed as biological contaminated agents and handled appropriately. Samples of known infectious origin, such as HIV positive samples can remain uncapped during sample processing. The V8 can be specifically decontaminated following the analysis of such samples, or as part of the routine maintenance at the discretion of the laboratory.

To decontaminate the system ensure that V8 Storage Buffer (REF 830100) and V8 Maintenance Buffer (REF 830200) are installed. Post condition as normal by switching the side switch from wake to sleep this will post condition the capillaries and decontaminate the V8 system.

- Empty and disinfect the waste collection module.
- Disconnect and dispose of the waste fluids bottle.

Spillages

Mop up any excess material using an appropriate, disposable absorbent towel. Clean all affected surfaces with 70% ethanol solution or 1% hypochlorite solution (see WHO Laboratory biosafety manual) (bleach). The same protocol can be used as a periodic decontamination scheme in the rack transport area and reagent bay.

For further information and advice please contact V8 technical support.

8.1.3 Disposal of clinical waste

Please refer to section 9.5 for further information.

8.1.4 High voltage system



The V8 system is facilitated by a high voltage system. The operator must not modify or attempt to adjust the physical properties forming the design of the V8 instrument. Failure to use the V8 in accordance with its intended purpose set out in this user manual could cause harm or injury to the operator, and compromises the obligations of the warranty.

Handling of patient samples

The user must wear the appropriate clothing and follow the local health and safety regulations for handling ALL patient samples. All patient samples **MUST** be treated as high risk.



Helena Biosciences strongly recommend the routine wearing of laboratory coats, safety glasses and disposable examination gloves when operating the V8 system.

Handling of high risk samples

The user must wear the appropriate clothing and follow the local health and safety regulations for handling known high risk patient samples. All patient samples **MUST** be treated as high risk.

Installation, lifting and re-location

Under no circumstances must the operator attempt to move or re-locate an installed V8 system without notifying a Helena Biosciences certified and trained engineer. Safe installation of the V8 system requires that a trained engineer is on-site to ensure the personal health and safety of all end-users, and third parties, involved in the re-location of the V8 system. To prevent potential bio-hazards, a full decontamination procedure is provided whenever the system is to be removed from the user site. Repositioning or relocation of the V8 system without the aid or assistance of a Helena Biosciences certified and trained engineer could cause serious physical harm and injury, and risk the terms and conditions of the warranty upheld by the manufacturer and/or the distributor, due to system damage.

Removal of the protective hood

The protective hood exists to prevent contamination to the sample and preparation area; and to protect the user from the mechanical movements of the sample handling arm. It should not be removed from the instrument.

Sample handling arm

The sample handling arm is a hazardous component of the instrument and needs to be approached with extreme care. The movement of the sample handling arm pauses immediately for user safety once the top cover and rack cover have been lifted. For maintenance instructions of the sample handling arm, please refer to section 8.1.2 and 9.8.

V8 LED lighting system

Looking directly at lit LEDs can dazzle. Direct eye contact with the diode should be avoided where possible. To avoid hazard the LED lighting system within the V8 is disabled when the top cover is open.

Barcode Reader

The integrated barcode reader incorporates a class 2 laser. Care must be taken to not stare directly into the beam. A warning sticker on the machine is present to indicate this hazard.

This is a brief checklist to ensure the normal operation and optimal efficiency of the V8 adhering to the safety requirements stipulated in this user manual. Please read this checklist before use, or for a reminder of safe operation.

- a. Do not operate the V8 unless trained and authorised for use.
- b. Ensure that all parts of the V8 are undamaged and in good working order.
- c. Do not attempt to relocate the V8 before use, or move the instrument during operation.
- d. Only Helena Biosciences reagents, buffers, sample racks and disposable cups should be used to guarantee system efficiency and normal operation.
- e. Check any tubes, sample cups and bottles before use to ensure they are undamaged and safe for use.
- f. Do not place more than 14 sample racks on-board the V8 at any one time.
- g. Ensure all items for use on-board such as reagents, buffers, sample racks and disposable cups are loaded onto the V8 correctly.
- h. Please remove lids from all reagent bottles placed in the reagent bottle area.
 - i. Do not attempt to repair any faults or hardware malfunctions. Only Helena Biosciences trained engineers can do this.
 - j. Clean up any spills off-board the V8 immediately and follow the local safety guidelines for biological contamination.
- k. Ensure the power supply does not contact any fluid. Should fluid enter the power supply, please switch the V8 off immediately at the mains outlet and call technical support.
 - l. Do not attempt to clean up spills on-board the machine whilst it is running.
- m. Do not switch the V8 off using the switch positioned at the rear of the instrument. This switch should only be initiated when relocating or storing the V8, or in cases of emergency.
- n. Do not attempt to adjust or manually move any moving parts of the machine such as the needle arm or the sample transport system.
- o. Do not remove the protective hood, or any part of the machine that is fixed to the V8.
- p. Failure to adhere to these safety guidelines could invalidate your warranty.

9 Maintenance of the V8

9.1 Overview


V8 automates all daily service and maintenance procedures to ensure optimum performance levels, and to minimise user-intervention. Please refer to this section to understand daily, monthly and annual service and maintenance requirements.

9.2 Daily maintenance

The Helena V8 performs all required daily maintenance automatically. There are two automated processes programmed into the instrument: pre-conditioning and post-conditioning. This is conducted when the instrument is switched to Start-up and Shut-down by the side switch or when there is an idle period of 4 hours. When the V8 is operating in either of these processes, the lights will be YELLOW.


All maintenance solutions are held on-board the instrument at all times. These are V8 Storage Buffer, found in port 5 of the buffer block, and V8 Maintenance Buffer, located in port 6. Should these become low in liquid; the V8 will notify the user with a '**LIQUID LEVEL LOW**' message in Platinum. When an out of liquid voice command and message appear the appropriate buffer should be replaced with a fresh buffer bottle.

9.3 Pre-conditioning

This is initiated when the side switch is set to  at the beginning of every day. This process clears the capillaries of V8 Storage Buffer and prepares them with the default assay buffer that is loaded onto the instrument and set in Platinum. Pre-conditioning is dependent on the default assay and takes around 27 minutes.

N.B. Pre-conditioning is not an optional process and cannot be over-ridden by the user.

9.4 Post-conditioning

This is initiated when the side switch is set to  or when there has been an idle period of 4 hours. This process clears the capillaries of V8 Maintenance Buffer to remove any residual samples or reagents and then fills the capillaries with V8 Storage Buffer until the V8 is switched on again.

N.B. Post-conditioning is not an optional process. Post-conditioning ensures that buffer and residual sample do not crystallize within the capillary and prevents blockage. Filling with V8 Storage Buffer keeps the capillaries wet and prevents them drying out. As such it is ESSENTIAL that the V8 be allowed to carry out this process at the end of every day/use. Failure to do so (by removing power to the instrument using the back power switch) can cause irreparable damage to the capillaries and affect the performance of the system.

9.5 Emptying waste from the instrument

Waste created by the V8 is CLINICAL WASTE and should be treated with caution. There are two areas on the instrument that require emptying of waste: (1) the waste bottle, and; (2) the waste drawer.



Caution needs to be given on the handling of biological samples. Suitable clothing (gloves, glasses, and laboratory coat) must be worn and appropriate handling of all items must be adhered to.

9.6 Emptying the waste fluid bottle

The waste fluid bottle contains buffer, reagent, V8 Maintenance Buffer and sample residues used during the operation and should be treated as clinical waste and disposed of accordingly.

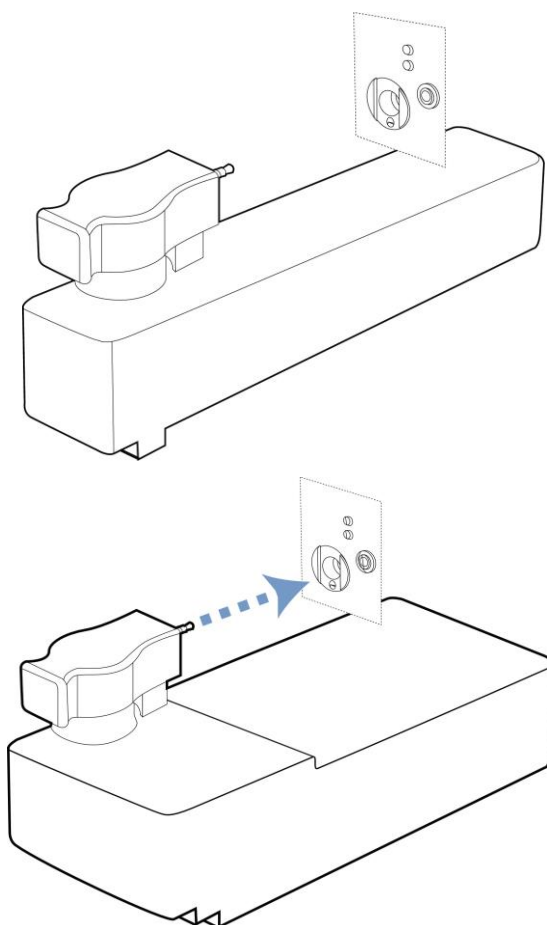
The V8 will notify the user when emptying of the bottle is required by the voice command **'PLEASE EMPTY THE WASTE BOTTLE'**, which will be accompanied by a message window in Platinum. The system will pause and not continue operation until the waste bottle is emptied, if the V8 is undergoing electrophoresis this will continue without any interruption to data generation. The voice command and accompanying message will not be produced until data collection is complete.

To empty the waste bottle:

- a. Ensure appropriate PPE (Personal Protective Equipment) is worn.
- b. Access the fluid bottle compartment by pulling down the Front Cover.
- c. Remove the waste bottle (position 7 or position 1 for the systems with the V8 Nexus Piercing and Agitation Upgrade) by holding the bottle connector and pulling backwards, gently but firmly.
- d. Pull out the bottle connector and decant the waste fluids into an appropriate container for disposal in accordance with local waste disposal rules.
- e. Dry the bottle connector before replacing the bottle connector ensuring that the fluid inlet port and socket is facing down the length of the bottle and is correctly engaged.

N.B. the bottle should NOT be picked up by the bottle connector.

- f. Replace the waste bottle into the correct position, ensuring the bottle connector is fully inserted and connected with the V8. A green LED light will appear over the bottle if installed correctly.



- g. Close the Front Cover. The V8 will continue operation from the point at which it paused.

N.B. Please note that the waste bottle should be emptied when prompted to do so by the V8.

9.7 Emptying the sample cup waste drawer

The V8 will notify the user when the waste drawer requires emptying with the voice command **'PLEASE CHECK THE WASTE BIN'**, accompanied by the message window **'PLEASE EMPTY THE WASTE BIN.'**

The waste drawer contains residual buffer, reagent, diluent and sample waste. The waste contained within this drawer is classified as clinical waste, requiring the user to wear the appropriate clothing, and adhere to the local health and safety standards and precautions. As a minimum Helena Biosciences recommends the use of safety glasses, gloves and laboratory work coat. Maximum volume of solid waste produced per hour will be 24 sample cups. The waste tray will not hold more than 100 sample cups.

To empty the waste drawer:

- Access the sample cup waste drawer by pulling down the *FRONT PANEL*.
- Remove the sample cup waste drawer.
- Dispose of the insert and the contents in accordance with local waste disposal rules.
- Place a fresh insert inside the drawer; in correct orientation.
- Replace the sample cup waste drawer.
- Close the *FRONT PANEL*.

N.B. The clinical waste drawer can be cleaned and decontaminated using sodium hypochlorite solution (see WHO Laboratory biosafety manual) at a concentration of 1% (10,000 ppm) if required.

9.8

Daily maintenance routine

- Switch the V8 ON at the back power switch if not in STAND BY mode (at the side switch). The lights will turn yellow.
- Ensure that the waste bottle, V8 Maintenance Buffer and V8 Storage Buffer are on-board and that the waste drawer is lined with an insert. After checking and/or changing the default assay, ensure that the default buffer required is on-board.
- Switch the V8 to Start-up at the side switch and allow it to pre-condition.
- When the lights on the V8 turn to red, it is ready for use. Run the V8 as required through the day.
- When operation has ceased, remove all sample racks from the loading bay and remove all reagents from the reagent block.
- Set the side-switch to shut-down and wait for the V8 to communicate the voice command '*PREPARING FOR SLEEP MODE*' and for the visual colour to turn to yellow.
- When finished the lights on the V8 will turn off. In Platinum, the V8 status connection bar will turn red. The V8 is ready to be switched off at the back power switch or to be left in stand-by mode.

9.9

Intermittent Use

It is recommended that the V8 is preconditioned and postconditioned twice weekly when not in use.

9.10

Frequent maintenance checks

It is recommended that the operator frequently checks the needle and the sample preparation and analysis area for general cleanliness.



CAUTION

- It is recommended that the needle is cleaned manually with Isopropanol or 70% Ethanol. The V8 should be completely switched off and the needle gently wiped, taking extreme care when touching the tip.
- It is recommended that the sample preparation and analysis area is wiped down with a clean/damp disposable cloth and warm water. The V8 should be switched off completely.
- Any spillage of blood and / or serum should be blotted with an absorbent cloth and then the surface cleaned with a 1% hypochlorite solution (see WHO Laboratory biosafety manual).
- It is recommended that suitable Personal Protective Equipment (PPE) is worn at all times. Local regulations should be adhered to for precise instructions of necessary clothing, but as a minimum Helena Biosciences recommends that the following safety equipment is used: safety glasses, gloves, laboratory coat.

9.11

Monthly maintenance

There are no specific monthly maintenance procedures – providing that daily maintenance routines and frequent checks are carried out.

9.12

Annual maintenance

Annual maintenance of the V8 should only be carried out by a Helena Biosciences trained and certified engineer. Capillaries will be changed and the system will be calibrated and fully serviced. The V8 will notify the end-user when maintenance is required. No user specific intervention is required.

If using a V8 Nexus Piercing and Agitation Upgrade (800020) the needle will need to be replaced after 6,000 piercings.

Any areas of instrumentation subject to potential biological sample spillage are readily accessible for decontamination procedures and disinfection. In the event of contamination to the system, the operator must post-condition the instrument via the side-switch which will be adequate to fully decontaminate the instrument internally and allow the user to safely deal with any sample spillages.

Decontamination of the system

All samples loaded onto the V8 should be classed as biological contaminated agents and handled appropriately. Samples of known infectious origin, such as HIV positive samples can remain uncapped during sample processing. The V8 can be specifically decontaminated following the analysis of such samples, or as part of the routine maintenance at the discretion of the laboratory.

To decontaminate the system ensure that V8 Storage Buffer (REF 830100) and V8 Maintenance Buffer (REF 830200) are installed. Post condition as normal by switching the side switch from wake to sleep this will post condition the capillaries and decontaminate the V8 system.

- Empty and disinfect the waste drawer.
- Disconnect and dispose of the waste fluids bottle.

Spillages

Mop up any excess material using an appropriate, disposable absorbent towel. Clean all affected surfaces with 70% ethanol solution or 1% hypochlorite solution (see WHO Laboratory biosafety manual) (bleach). The same protocol can be used as a periodic decontamination scheme in the rack transport area and reagent bay.

For further information and advice please contact V8 technical support.

Waste container decontamination

Clinical waste drawer

The clinical waste drawer is the point of collection for disposal of the sample cups. The samples cups contain a variety of buffers, reagents and sample components and as such should be disposed of as biologically contaminated solids. The drawer MUST be lined with a waste drawer insert prior to use at all times. The clinical waste drawer is fitted with a sensor, and as such, the V8 will notify the user when it is full and requires a new insert.

In the unlikely event of contamination to the drawer itself, please disinfect with 70% ethanol solution or hypochlorite solution (bleach). Please wear adequate personal protective equipment. Helena Biosciences recommends at a minimum these should include safety glasses, gloves and laboratory coat.

Waste fluids bottle

The waste fluid bottle is designed to be re-usable. Waste fluids should be decanted into an appropriate container for disposal in accordance with local water rules. The full waste fluid bottle must be treated as biologically contaminated waste and handled with care. The cap on the waste bottle has an active liquid level sensor and so the V8 will notify the user when it requires emptying.



WARNING

N.B. The waste bottle should only be rinsed with water. DO NOT use any cleaning agents on the bottle cap or the waste bottle, as these will affect the active liquid level sensor.



WARNING

Adequate personal protective equipment must be used. Helena Biosciences recommends at minimum these should include safety glasses, gloves and laboratory coat.

Re-location and re-installation of the V8

The V8 is a heavy instrument weighing 72kg. The operator must not attempt to move or relocate the instrument for valid health and safety reasons; and for reasons of maintaining the optimum performance of the instrument.

The instrument must be post-conditioned, prepared correctly and packaged in its ORIGINAL packaging. As such, the V8 should not be re-located or re-installed without informing Helena Biosciences, or the official distributor of the company. Failure to do so may invalidate your warranty.

N.B. Please ensure that a Helena Biosciences trained and certified service engineer is contacted to arrange re-location and/or re-installation of the V8.

9.16 Long-term storage of the V8

Helena Biosciences recommend that the instrument is preconditioned at least twice a week. If the system is to be left unused for longer periods, please consult your Helena Biosciences representative for further instructions.

9.17 High-risk samples



WARNING



WARNING

All samples placed on-board the V8 **MUST** be treated as high-risk and containing infectious or innocuous material. It is the responsibility of the user to ensure correct and safe handling of all samples. In the event of sample spillage on the system, please clean immediately with the recommended disinfectant (1% hypochlorite solution (see WHO Laboratory biosafety manual)) as per local guidelines. If required, the needle can be cleaned with alcohol (70% Ethanol or Isopropanol). The needle should only be cleaned when the V8 is switched off.

Adequate personal protective equipment must be worn at all times when operating the V8. Local regulations or requirements should be consulted for precise instructions of correct clothing. Helena Biosciences recommends that at a minimum the following safety equipment is used:

- Safety gloves
- Safety protective glasses
- Laboratory workcoat or gown

9.18 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.

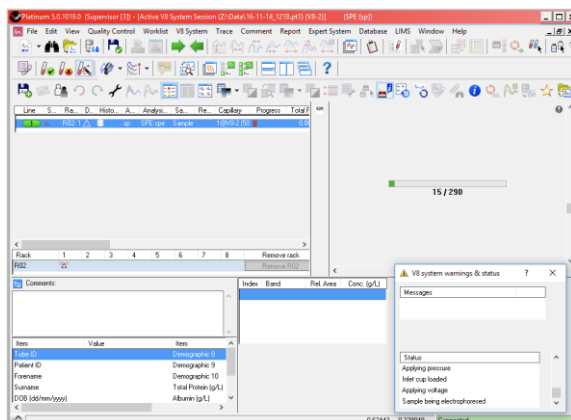
Appendix 1 Toolbar functions in Platinum

1.1 V8 sessions

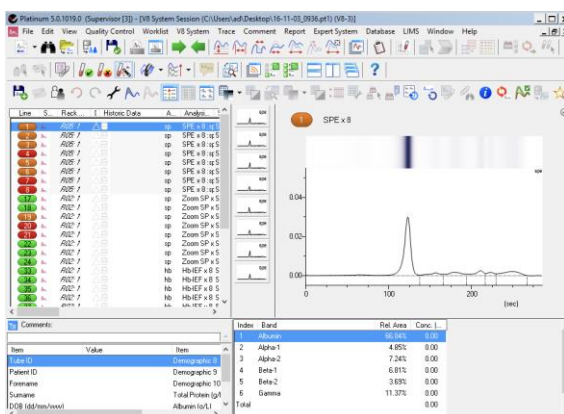
The following toolbar functions apply to V8 functions in Platinum.

1.2 Active analysis window

When Platinum is carrying out active analysis, it will look like this.

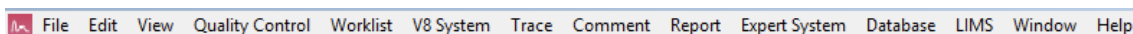


Once a set of samples has been run, or stored data has been opened, then it is displayed in the active analysis window as seen below.



1.3 Menu bar

There are fourteen drop down menus on the top tool bar.



1.4 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 *.w10 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 an 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:** Allows the user to save a file to the Middleware data 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.
- **Print Selection to PDF:** creates PDF reports of selected samples.
- **Print Session to PDF:** creates PDF reports of all samples in the session.
- **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.
 - **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 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.

1.5

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 - 5.9.9'.
- **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 - 5.9.9'.
- **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 or 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 or 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

1.6

View menu

- **As Navigation worklist:** Shows 'normal' worklist windows
- **As Traces:** Shows all result traces filed
- **As Gel Image:** Shows all result gels filed
- **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 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
- **Immuno Window:** Allows the operator to view all linked immunodisplacement traces in a convenient window on screen
- **Show Baseline:** This allows the operator to view the baseline of the trace
- **Show Threshold:** This allows the operator to view the peak detection threshold of the trace
- **Show Derivative:** This allows the operator to view the 2nd 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 on to the selected trace for comparison.
- **Show Normal Overlay:** Allows the operator to select a normal trace from the Navigation Worklist to use as a normal comparison overlay for any other trace in the session
- **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 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.
 - **Show Immuno Window:** Allows the operator to view all linked immunodisplacement traces in a convenient window on screen
- **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 to 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 2" user level access and above.

1.7

Quality Control menu

- **Show Levey-Jennings:** this allows the operator to enter into the Levey-Jennings window. Control data can be searched and displayed in a Levey-Jennings plot.
- **Show Session Usage Log:** this allows the 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.
- **Band Data To Clipboard:** makes a copy of result band data to clipboard for all selected samples to allow for result data value export.
- **Extended Band Data To Clipboard:** makes a copy of result band data to clipboard for all selected samples to allow for result data value export.
- **Excel Formatted To Clipboard:** allows result band data to be viewed in Excel.

1.8

Worklist menu

- **Set Up Worklist:** 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.
- **Show Conflicts:** allows the user to identify conflicts with data imported from LIMS.
- **Manage Test List:** allows the operator to open a test list and to edit the sequence, test type, order tests which are alternative to the default method or view previously ordered test.
- **Show Pending Trays:** opens a window that details the tests that the instrument has been programmed to run.

1.9

V8 System

- **Configure V8 Systems:** enables the operator to configure the TCP/IP address of the V8. This menu can be available to all users, or it can be specific to only 'Level 3' user status operators.
- **Select V8 System:** allows the operator to select which V8 system Platinum will connect to in the session based on all systems that have been entered in to the 'Configure V8 Systems' log.
- **Reset Communication:** this instructs Platinum to reset its communication status with the V8 system, should connection have been lost or disconnected.
- **Show Status:** this opens a modeless dialogue box that shows the user the current status of the instrument and any error messages.
- **V8 Direct Commands:** this allows the operator to skip or force pre-conditioning or purging. Force preconditioning once ordered is triggered by the addition of a sample rack.
- **Diagnostics:** this provides a range of diagnostic materials for the operator.
 - **Show V8 COMS View:** shows a log of the communications from the V8, where it is filed and when it was made.
 - **Show V8 Actuals View:** gives the operator the diagnostic values of the V8, ie the capillary temperature, reagent bay temperature, pressure, voltage, and current and the fluid levels of on-board buffers. The Operator or service engineer can also create a record of these parameters during sample analysis by selecting the Record button. Once started a graphical representation of this data will appear. In the case of system issues, this data can also be copied to the clipboard to be emailed to the Technical Support department or a service engineer. Please note data should be copied to clipboard before selecting Stop Recording.
 - **Show V8 Error Log:** Shows where the error log is filed, when it was created and gives the option of copying it to the clipboard, enabling it to be emailed to a service engineer.
 - **Show LIMS COMS View:** Shows the log of the systems communication with LIMS, where it is filed to, when it was created and gives the operator the option of copying it to the clipboard and stopping the log.
 - **Show LAS COMS View:** Shows the log of the systems communication with LAS when connected to a track system, where it is filed to, when it was created and gives the operator the option of copying it to the clipboard and stopping the log.
- **Set Test Modes:** This allows the operator to set the reflex test priority and determines when the V8 will perform reflex tests, whether these have been ordered manually or automatically.
- **Allow Reflex Test Batches:** when Platinum is set to reflex test complete batches under instruction, this function instigates the procedure.
- **Select Default Method:** this window allows the operator to set the default assay for the session, with smoothing and filtering defaults and the option to automatically mark abnormal results.
- **Select and Configure Default Method:** allows the user to make changes to how the default method is ran, including Smoothing settings, band ranges and default report settings.
- **V8 System Actual Values:** this shows the operator the reagent temperature, capillary temperature, pressure, voltage and current at that point in time.
- **Manage Capillaries:** this shows the operator which capillaries are currently in use by the instrument. If a capillary is showing signs of blockages, the operator can de-select that capillary for use.
- **Define Reagents:** allows the operator to view the reagents that are loaded. Information including barcode, expiry data and number or tests is displayed.

N.B. Reagents that were on the system but have been removed may also still appear if the position has not been subsequently used. Entering 0000000000 will remove the barcode from the display (but will not cancel the information stored on the V8)

- **Define Buffers:** allows the operator to view the buffers that are loaded. Information including barcode, expiry data and number or tests is displayed. This window automatically pops up when a buffer bottle is changed so as the barcode can be scanned to update the information.

N.B. Buffers that were on the system but have been removed may also still appear if the port has not been subsequently used. Entering 000000000 will remove the bar code from the display (but will not cancel the information stored on the V8)

- **Configure Bands:** this enables the operator to configure the bands, and to adjust filtering and smoothing on data that has already been generated.
- **Edit Regions/Zones:** this allows the operator to edit the regions defined on the trace to clarify individual peak regions.
- **Re-Interpret Trace:** this allows the operator to re-interpret a selected trace if the result does not seem right, or the configuration parameters have been changed.
- **Re-Interpret All:** this allows the operator to re-interpret all traces if the result does not seem correct, or the configuration parameters have been changed.
- **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 trace 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.
- **Statistics:** this displays a table of means, standard deviations and CVs for any selected trace data. More than one sample at a time can be selected by keeping the Ctrl key pressed when selecting samples.
- **Configure V8 Methods:** allows the configuration of individual analysis methods including: chemistry values, report definition, QC data input and the configuration of Regions / Zones.

1.10

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 marked 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 Trace List:** 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

1.11 Comment menu

- **Add Comment:** allows the operator to add or remove a comment from the current sample from a list of predefined comments. The user can also add or remove 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.
- **Comments Tree:** allows the operator to add comments to the current sample from a list of predefined comments.

1.12 Report menu

- **New Report Template:** allows the user to create a new report template. 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.

1.13 Database

These functions cannot be used in an active Platinum session.

- **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.
- **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 Platimums database and networking status.
- **Backup:** Backups can be performed on New and changed sessions, all sessions or by customising the backup selected data.

1.14 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.

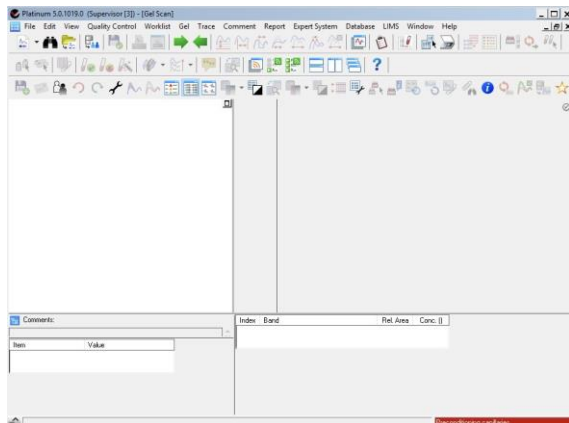
1.15 Window menu

- **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.

1.16 Help menu

- **Platinum Help:** displays help information for using the V8.
- **Open V8 Operator Manual:** Opens the Helena Biosciences V8 operator manual.
- **Open Gel Operator Manual:** Opens the Helena Biosciences gel operator manual.
- **Product Activation:** Allows activation of premium features.
- **About Platinum:** Displays the Platinum version.

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. All are the same as in a V8 session except for the V8 System drop down menu, which is replaced with a drop down menu titled **Gel**.

- **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 or SPIFE) 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 settings.
- **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.
- **Show LIMS COMS View:** Allows the operator to monitor the incoming and outgoing LIMS data transfer traffic.
- **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.
- **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.

Appendix 2 V8 troubleshooting

2.1

Common problems

Problem	Cause	Solution
The V8 turns BLUE	<p>The cause of the blue light can be identified in Platinum in the Status and Error Message window.</p> <p>N.B. Please make a note of any messages that occur as these will help a service engineer.</p>	<p>The first step to resolving a blue light is to restart the instrument. This resets all calibration and mechanical movement.</p> <p>To do this, switch the instrument OFF using the power switch at the back of the instrument, and then switch the side switch to <U>. To restart, turn the power switch at the back to ON and then the side switch to <U> to start a pre-condition.</p> <p>If after a restart the error reoccurs, or the instrument will not restart successfully, please contact the Service Department at Helena Biosciences Europe, or at your local distributor.</p> <p>In this instance, it is important that any error messages displayed in Platinum have been noted down and are passed to the Service Department.</p>
One capillary shows no peaks	No sample	Load sample
	Tube capped	Remove cap unless using the V8 Nexus Piercing and Agitation Upgrade (800020) which allows sampling from capped tubes.
	Insufficient volume	Increase sample volume if possible or transfer sample to a microtube
	Fluid detection error	Rerun sample, if problem persists contact the service department
	Sample contains precipitate	Incubate the sample for 15 minutes at 37°C to remove cryoglobulin
	Capillary blocked	Condition capillaries and rerun sample. If problem persists contact the service department
All capillaries are showing no peaks	No sample	Load sample
	Insufficient volume	Increase sample volume if possible or transfer sample to a micro tube
	Lamp failure	Contact the service department
	Fluid detection error	Contact the service department
	Insufficient injection or high voltage failure	Contact the service department
Slow sample migration on one capillary	Sample build up on capillary wall	Condition capillaries and rerun sample
	Blocked capillary	Contact service department
Slow sample migration on all capillaries	Sample build up on capillary wall	Condition capillaries and rerun samples
	Temperature control error	Contact service department
	High voltage unit failure	Contact service department
	Problems with buffer composition	Try another buffer bottle
Trace has high noise or spikes	Air bubbles in capillary	Rerun sample if problem persists condition capillaries
	Insufficient volume in sample cups	Contact service department
	Capillary lift error	Contact service department

Problem	Cause	Solution
Low signal response	Insufficient volume	Increase sample volume if possible or transfer sample to a microtube
	Low lamp intensity	Contact the service department
	Blocked capillary	Condition capillaries, if the problem persists contact the service department
	Viscous sample	Warm sample to room temperature and rerun

V8 light display

V8 light states are not to be used as an indication of instrument state. Platinum remains the primary user interface for instrument status. The V8 visually communicates system status such as idle, busy, maintenance and fault status through colour coded system illumination. The following light states indicate systems status:

RED



- V8 is ready to accept samples following the pre-conditioning cycle.
- Normal operation/system busy — quick pulsing light.
- V8 is Idle — slow pulsing light.

ORANGE



- Pre-condition maintenance cycle.
- Post-condition maintenance cycle.



BLUE



- System error

V8 audible feedback

Audible status updates will inform the user of automated instrument procedures, or when user intervention is required. Low buffers levels, error messages, maintenance cycles, system status reports and clinical waste limits will be communicated by an appropriate voice update. The following table lists all the audible feedback messages available on the system and explains their meaning:

V8 Audible Command	System Status explanation
Preparing Capillaries	This refers to the pre-conditioning maintenance cycles, when the side switch is set to 
Preparing for Sleep Mode	This refers to post-conditioning maintenance cycles, when the side switch is set to 
Purging New Liquids	This refers to the placing of a new buffer bottle on-board, following entering the barcode information in Platinum.
Please Check the Waste Bin	The waste drawer has been removed or is not correctly inserted.
Empty Waste Bottle Needed	The waste bottle in port 7 (or port 1 when using the 800020 V8 Nexus Piercing and Agitation Upgrade) is full and requires emptying.
Unknown Liquid	The V8 does not recognise the buffer bottle on-board. Ensure that the correct barcode information has been entered in Platinum.
Out of Liquid	Buffer or reagent bottle needs replenishing, or is missing from the system. If not replenished, the V8 will attempt to perform the next available assay – holding other samples in a worklist to be performed once reagents or buffers have been installed.
No Worklist Available	The V8 has scanned the sample rack and barcodes and is awaiting instruction from Platinum. Ensure Platinum is switched on and the default assay has been selected, or the required tests have been ordered.
An Error Occurred	This will be accompanied by the blue light and refers to a system error. The relevant error message will appear in the System Status and Warning Message Window and may require the attention of an engineer.

	Platinum Message	Action
ERROR MESSAGES	"Z motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"X-Motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Y-Motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Rack load motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Finger motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"CE motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Cup motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Pressure leak – Servicing required"	Contact Service Department.
	"Method is not OK"	Restart instrument, if problem persists contact service.
	"Sample handling error - please restart the V8"	Restart instrument, if problem persists contact service.
	"Inlet lift or CE process error – please restart the V8"	Restart instrument, if problem persists contact service.
	"Waste pump stopped too early, trying again"	Restart instrument, if problem persists contact service.
	"Sample rack loading system re-initialising"	Restart instrument, if problem persists contact service.
MESSAGES REQUIRING ACTION	"Unknown liquid, please scan bottle barcode"	Scan barcode of bottle in identified location.
	"Liquid missing"	Load required liquid, outstanding tests will begin with no further intervention.
	"Servicing required"	Contact service department.
	"Please replace the waste bin"	Replace waste drawer.
	"Please empty the waste bin"	Empty the waste drawer and replace onboard.
	"Please replace the waste bottle"	Replace fluid waste bottle and check bottle cap is detected by system (led illuminated).
	"Please empty and reconnect the waste bottle"	Empty waste bottle and replace.
	"Cup load tower empty, please load sample cups"	Refill sample cup load tower immediately
	"Sample cup load tower nearly empty"	Refill sample cup load tower soon
	"Sample tray missing"	Place sample tray onboard the V8
	"10% liquid remaining in bottle"	Place additional buffer onboard the V8 to prevent system stopping due to insufficient reagents
	"Unachievable dilution without a sample tray"	Reduce override dilution
	"Max number of tests achieved – please load a new bottle"	Replace container with a new container
	"Fluid out of expiry date – please load a new bottle"	Replace with an in date product
Sensor Messages	"Front cover open"	Close cover
	"Top cover open"	Close cover
	"Rack cover open"	Close cover
	"Empty sample tray required"	Place a new sample tray onboard the V8.
	"New sample tray"	Enter sample tray ID to enable positive patient ID of samples loaded

	Platinum Message	Action
STATUS MESSAGES	"V8 and Platinum connected"	No action required
	"Starting V8"	No action required
	"Preconditioning Capillaries"	No action required
	"Postconditioning Capillaries and shutting down"	No action required
	"Starting analysis"	No action required
	"Asking for reflex tests"	No action required
	"Starting V8"	No action required
	"Purging outlet"	No action required
	"Purging needle"	No action required
	"Purging inlet"	No action required
	"Conditioning capillaries"	No action required
	"Waiting for front cover to close"	No action required
	"Waiting for top cover to close"	No action required
	"Waiting for rack cover to close"	No action required
	"Waiting for front cover to open"	No action required
	"Waiting for top cover to open"	No action required
	"Waiting for rack cover to open"	No action required
	"Sample rack found, preparing samples"	No action required
	"Liquid not available"	No action required
	"Empty sample tray required"	No action required
	"Saving tests for later"	No action required
	"Returning racks"	No action required
	"Applying pressure"	No action required
	"Applying voltage"	No action required
	"Setting reagent bay temperature"	No action required
	"Setting capillary temperature"	No action required
	"Change of method, need preconditioning"	No action required
	"There are capillaries disabled"	No action required
	"Filling remaining cups with buffer"	No action required
	"No liquid detected in reagent bay"	No action required
	"No liquid detected in sample tray"	No action required
	"Waiting for unknown liquids"	No action required
	"Waiting for conditioning to finish"	No action required
	"Carrying out saved tests"	No action required
	"Immediate reflex tests starting"	No action required
	"Starting re-conditioning"	No action required
	"Cancelling all queued tests"	No action required
	"Unknown analytical method"	No action required
	"Adding queued tests to the worklist"	No action required
	"Max idle time reached - shutting down"	No action required
	"Picking up next cup"	No action required
	"Buffer cup loaded"	No action required
	"Sample cup loaded"	No action required
	"Asking for immediate reflex tests"	No action required
	"Inlet filled with liquid"	No action required
	"Outlet filled with liquid"	No action required

	Platinum Message	Action
	"Applying current"	No action required
	"Adding queued tests to worklist"	No action required
	"Purging buffer lines"	No action required