

# PA 800 Plus Pharmaceutical Analysis System

**Overview Guide** 



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## **Operational Precautions and Limitations**

Note: Before operating the system, carefully read all of the sections of this guide.

This section contains information about general safety and regulatory compliance. This section gives descriptions of possible hazards and the related warnings for the system, and the precautions that should be obeyed to minimize the hazards.

In addition to this section, for information about the symbols that are used in the laboratory environment, on the system, and in this documentation, refer to the section: Glossary of Symbols. For site requirements, refer to the document: *Site Planning Guide*.

## **General Safety Information**

To prevent personal injury or system damage, read, understand, and obey all of the safety precautions and warnings in this document, the manufacturer chemical safety data sheets (SDSs), and product label information. Labels are shown with internationally recognized symbols. Failure to heed these warnings could result in serious injury.

This safety information is intended to supplement federal, state, provincial, and local environmental health and safety (EHS) regulations. It does not include every safety procedure that should be practiced. Ultimately, the user and the organization are responsible for compliance with federal, state, provincial, and local EHS regulations and for maintaining a safe laboratory environment.

Refer to the correct laboratory reference material and standard operating procedures.

### **Documentation Symbols and Conventions**

The following symbols and conventions are used throughout the guide.



DANGER! Danger identifies an action that can cause severe injury or death.



WARNING! Warning identifies an action that can cause personal injury if precautions are not obeyed.

CAUTION: Caution identifies an operation that can cause damage to the system or corruption or loss of data if precautions are not obeyed.

Note: Notes supply important information in a procedure or description.

**Tip!** Tips supply information that helps to apply the techniques in a procedure or gives a shortcut, but that is not essential to the completion of a procedure.

## **Regulatory Compliance**

This system complies with the regulations and standards listed in this section. For dated references, refer to the declaration of conformity included with the system and the individual system components. Applicable labels have been affixed to the system.

#### Australia and New Zealand

- Electromagnetic Compatibility (EMC): Radio Communications Act 1992 as implemented in these standards:
  - Electromagnetic Interference—AS/NZS CISPR 11/ EN 55011/ CISPR 11 (Class A). Refer to the section: Electromagnetic Interference.

#### Canada

- Electromagnetic Interference (EMI): CAN/CSA CISPR11. This ISM device complies with Canadian ICES-001. Refer to the section: Electromagnetic Interference.
- · Safety:
  - CAN/CSA C22.2 No. 61010-1

#### Europe

- Electromagnetic Compatibility (EMC): Electromagnetic Compatibility Directive 2014/30/EU as implemented in these standards:
  - EN 61326-1
  - EN 55011 (Class A)

Refer to the section: Electromagnetic Compatibility.

- Safety:
  - EN 61010-1
- Waste Electrical and Electronic Equipment (WEEE): Waste Electrical and Electronic Equipment Directive 2012/19/EU, as implemented in EN 40519. Refer to the section: Waste Electrical and Electronic Equipment.
- **Packaging and Packaging Waste (PPW):** Packaging and Packaging Waste Directive 94/62/EC

RoHS Restriction of Hazardous Substances: RoHS Directive 2011/65/EU and 2015/863/EU

#### **United States**

- Radio Emissions Interference Regulations: 47 CFR 15, as implemented in FCC Part 15 (Class A)
- **Safety:** Occupational Safety and Health Regulations, 29 CFR 1910, as implemented in these standards:
  - UL 61010-1

#### International

- Electromagnetic Compatibility (EMC):
  - IEC 61326-1
  - IEC CISPR 11 (Class A)

Refer to the section: Electromagnetic Compatibility.

- Safety:
  - IEC 61010-1

## **Electrical Precautions**



WARNING! Electrical Shock Hazard. Do not remove the covers. If the covers are removed, then injury or incorrect system operation can occur. Removal of the covers is not required for routine maintenance, inspection, or adjustment. Contact a SCIEX field service employee (FSE) for repairs that require removal of the covers.

- Obey the required electrical safe work practices.
- Use cable management practices to control electrical cables and decrease the risk of a tripping hazard.

For information about system electrical specifications, refer to the document: *Site Planning Guide*.

### Mains Supply

Connect the system to a compatible mains supply as instructed in this guide.



WARNING! Electrical Shock Hazard. Use only qualified personnel for the installation of all of the electrical supplies and fixtures, and make sure that all of the installations adhere to local regulations and safety standards.



WARNING! Electrical Shock Hazard. Make sure that the system can be disconnected from the mains supply outlet in an emergency. Do not block the mains supply outlet.



WARNING! Electrical Shock Hazard. Use only the mains supply cables that are supplied with the system. Do not use mains supply cables that are not correctly rated for the operation of this system.

### **Protective Earth Conductor**

The mains supply must include a correctly installed protective earth conductor. The protective earth conductor must be installed or examined by a qualified electrician before the system is connected.



WARNING! Electrical Shock Hazard. Do not intentionally interrupt the protective earth conductor. Any interruption of the protective earth conductor causes an electrical shock hazard.

## **Chemical Precautions**



WARNING! Ionizing Radiation Hazard, Biohazard, or Toxic Chemical Hazard. Before cleaning or maintenance, identify whether decontamination is required. If radioactive materials, biological agents, or toxic chemicals have been used with the system, then the customer must decontaminate the system before cleaning or maintenance.



WARNING! Environmental Hazard. Do not discard system components in municipal waste. To discard components correctly, obey local regulations.

- Before servicing and regular maintenance, identify the chemicals that have been used in the system. For the health and safety precautions that must be obeyed for a chemical, refer to the safety data sheet (SDS). For storage information, refer to the certificate of analysis. To find a SCIEX SDS or certificate of analysis, go to sciex.com/tech-regulatory.
- Always wear assigned personal protective equipment, including powder-free gloves, protective eyewear, and a laboratory coat.

Note: Nitrile or neoprene gloves are recommended.

• Do work in a well-ventilated area or fume hood.

- When flammable materials such as isopropanol, methanol, and other flammable solvents are in use, do not go near ignition sources.
- Be careful with the use and disposal of any chemicals. If the correct procedures for chemical handling and disposal are not obeyed, then personal injury can occur.
- During cleaning, do not let chemicals touch the skin. Wash hands after use.
- Collect all spent liquids and discard them as hazardous waste.
- Obey all of the local regulations for the storage, handling, and disposal of biohazardous, toxic, and radioactive materials.

#### System Safe Fluids

CAUTION: Potential System Damage. Do not use any other fluid until confirmation is received from SCIEX that it does not cause a hazard. This is not an exhaustive list.

Any substance in a PA 800 Plus reagent kit, or referenced in a PA 800 Plus application guide, can safely be used with the system. In addition, the following fluids can also be used with the system. To determine compatibility with other chemicals, contact sciex.com/request-support.

#### Acids and Bases

The pH range is from 2 to 12.

- Acetic acid, up to 10%
- Sodium hydroxide, up to 1 M
- Hydrochloric acid, up to 1 M
- Reagents
  - CE Grade Water

## **Physical Precautions**



WARNING! Lifting Hazard. Use a mechanical lifting device to lift and move the **IN** system. If the system must be moved manually, then at least four people are required to move the system safely. Follow established safe lifting procedures. We recommend the use of a professional moving service.

## **Environmental Precautions**

Use gualified personnel for the installation of electrical mains, heating, ventilation, and plumbing supplies and fixtures. Make sure that all of the installations comply with local bylaws and biohazard regulations. For information about the required environmental conditions for the system, refer to the document: Site Planning Guide.

When the system is set up, make sure that there is sufficient access space around the equipment.



WARNING! Biohazard. For biohazardous material use, always obey local regulations for hazard assessment, control, and handling. Neither this system nor any part is intended to be used as a biological containment.



WARNING! Environmental Hazard. Obey established procedures for disposal of biohazardous, toxic, radioactive, and electronic waste. The customer is responsible for the disposal of hazardous substances, including chemicals, waste oils, and electrical components, in accordance with local laws and regulations.

#### Electromagnetic Environment Electromagnetic Compatibility

**Basic Electromagnetic Environment:** Environment existing at locations characterized by being supplied directly at low voltage from the public mains network.

The equipment is intended for use in a basic electromagnetic environment.

Make sure that a compatible electromagnetic environment for the equipment can be maintained so that the device will operate as intended. If the power supply line is subject to high electrical noise, then install a surge protector.

#### **Electromagnetic Interference**

**Group 1 Equipment:** This equipment is classified as industrial, scientific, and medical (ISM) equipment that might use RF energy for internal operation.

**Class A Equipment:** Equipment which is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. [Derived from CISPR 11:2009, 5.3] Class A equipment shall meet Class A limits.

CAUTION: Potential Radio Interference. This equipment is not intended for use in residential environments and may not supply adequate protection to radio reception in such environments.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC (Federal Communications Commission) Compliance Rules.

These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the operator's manual, can cause harmful interference to radio communications.

Operation of this equipment in a residential area is likely to cause harmful interference in which case you will be required to correct the interference, at your own expense. Changes or modifications not expressly approved by the manufacturer could void your authority to operate the equipment.

#### **Decommissioning and Disposal**



WARNING! Environmental Hazard. Obey established procedures for disposal of biohazardous, toxic, radioactive, and electronic waste. The customer is responsible for the disposal of hazardous substances, including chemicals, waste oils, and electrical components, in accordance with local laws and regulations.

Before decommissioning, obey local regulations to decontaminate the entire system.

When the system is removed from service, obey national and local environmental regulations to divide and recycle different materials.

**Note:** SCIEX will not accept any system returns without a completed *Decontamination Form*. Contact an FSE to get a copy of the form.

Do not discard system components or subassemblies, including computer parts, as unsorted municipal waste.

#### Waste Electrical and Electronic Equipment

Obey local municipal waste ordinances for the correct disposal provisions to decrease the environmental impact of waste, electrical, and electronic equipment (WEEE). To discard this equipment safely, contact a local Customer Service office for complimentary equipment pick-up and recycling.

## **UV Radiation Precautions**



WARNING! Ultraviolet Radiation Hazard. Prevent exposure to direct or reflected UV radiation. Ultraviolet radiation is harmful to the eyes and skin. Do not operate the UV source without the required system safety interlocks.

## **Laser Precautions**

This section is applicable for systems that have a laser-induced fluorescence (LIF) detection system.



WARNING! Laser Hazard. Obey all local codes, regulations, and standards, and internal requirements that are applicable to laser safety.



WARNING! Laser Hazard. To prevent exposure to hazardous laser radiation, do not use different equipment and controls or do procedures differently than what is documented in this guide.



WARNING! Personal Injury Hazard. Do not look directly into the anticipated path of the laser beam or at any specular reflections of the laser beam. Invisible ultraviolet radiation from the laser can cause injury to the eyes.



WARNING! Personal Injury Hazard. To prevent exposure to hazardous laser radiation, always turn off the PA 800 Plus system before any of the LIF detector modules are removed.

The LIF detection system contains a Class I laser system in a sealed module. The module contains an embedded Class 3B laser component. The 3B classification means that direct intrabeam viewing of this type of laser is always hazardous to personnel.

The laser assembly contains the laser and several other components in a sealed housing, and has no user-serviceable parts. Service of the laser assembly is restricted to qualified SCIEX field service employees (FSEs). Therefore, the overall laser classification of the system is Class 1, defined as lasers that are safe under reasonably foreseeable conditions of operation.

## **Qualified Personnel**

Only qualified SCIEX personnel are permitted to install, examine, and supply servicing for the equipment. After the system has been installed, the field service employee (FSE) uses the document: *Installation Qualification* to help the customer become familiar with system operation, cleaning, and basic maintenance. If a system under warranty is serviced by personnel who are not authorized by SCIEX, then SCIEX is not responsible to repair any damage caused by the servicing.

### Laboratory Conditions Safe Environmental Conditions

The system is designed to operate safely in these conditions:

- Indoors
- Altitude: Up to 2,000 m (6,560 ft) above sea level
- Ambient temperature: 15 °C (59 °F) to 40 °C (104 °F)
- Relative humidity: 20% to 80%, noncondensing
- Mains supply voltage fluctuations: ±10% of the nominal voltage
- Transient overvoltages: Up to the levels of Overvoltage Category II

- Temporary overvoltages on the mains supply
- Pollution Degree 2

#### **Performance Specifications**

The system is designed to meet specifications in these conditions:

• An ambient temperature of 15 °C to 30 °C (59 °F to 86 °F).

Over time, the temperature must stay approximately 4 °C (7.2 °F), with the rate of the change in temperature not more than 2 °C (3.6 °F) per hour. Ambient temperature fluctuations that are more than the limit might cause shifts in migration time.

• Relative humidity from 30% to 70%, noncondensing.

## **Equipment Use and Modification**



WARNING! Electrical Shock Hazard. Do not remove the covers. If the covers are removed, then injury or incorrect system operation can occur. Removal of the covers is not required for routine maintenance, inspection, or adjustment. Contact a SCIEX field service employee (FSE) for repairs that require removal of the covers.



WARNING! Personal Injury Hazard. Use SCIEX-recommended parts only. The use of parts that are not recommended by SCIEX or the use of parts for any purpose other than their intended purpose can put the user at risk of harm or have a negative effect on system performance.



WARNING! Lifting Hazard. Use a mechanical lifting device to lift and move the system. If the system must be moved manually, then at least four people are required to move the system safely. Follow established safe lifting procedures. We recommend the use of a professional moving service.

Use the system indoors in a laboratory that has the environmental conditions recommended in the document: *Site Planning Guide*, or contact an FSE.

If the system is used in an environment or in a method that is not approved by the manufacturer, then the performance and protection that is supplied by the equipment might be decreased.

Contact an FSE for information about servicing the system. Unauthorized modification or operation of the system might cause personal injury and equipment damage, and might void the warranty. If the system is operated outside the recommended environmental conditions or with unauthorized modifications, then the acquired data might be inaccurate.



WARNING! Electrical Shock Hazard. Connect the high-voltage input and output cables at both ends before the PA 800 Plus system is turned on or operated.

The PA 800 Plus system has these main components:

- · Trays that hold sample vials, buffers, and other solutions
- An interface block
- · A high-voltage power supply and electrodes
- A source optics module and one or more detectors. Options are:
  - Photodiode array (PDA) detector
  - Ultraviolet (UV) detector
  - Laser-induced fluorescence (LIF) detectors
- Temperature control hardware
- A sample injection mechanism

The main power switch is on the bottom right side of the front of the system. All of the connections for external components are on the top left side panel of the system, except for the AC inlet and the fuse holder. Three fans supply cooling air flow for the internal system components. Air exhaust goes through the vents at the side and back of the system. To supply sufficient air flow, make sure that each vent has least 6 inches of clearance.

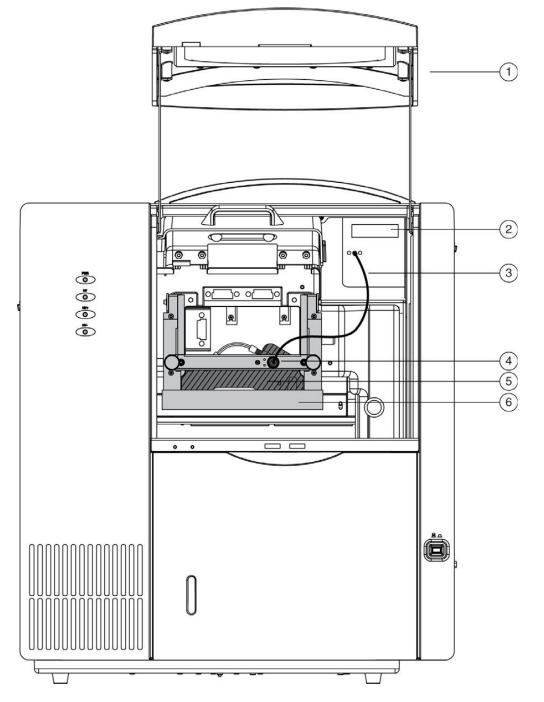


Figure 2-1 PA 800 Plus System with a UV Detector

ltem	Description
1	Outer door (open)
2	UV detector

ltem	Description
3	Two-ended fiber optic cable
4	Clamp bar and cable connection
5	Capillary cartridge
6	Interface block

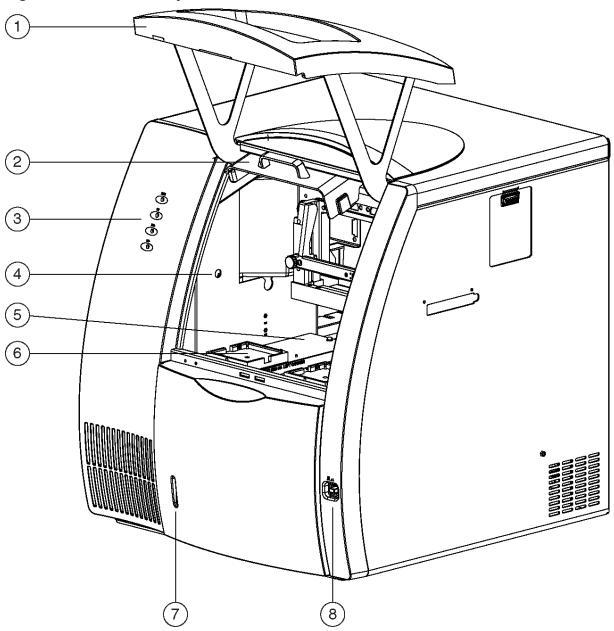


Figure 2-2 PA 800 Plus System Side View

ltem	Description
1	Outer door or sample cover (open)
2	Inner door or cartridge cover (open)
3	Indicators
4	Coolant fill port

Item	Description
5	Sample trays
6	Buffer trays
7	Coolant sight glass
8	Power switch

## Sample-Handling System

WARNING! Personal Injury Hazard. When the sample cover is opened, wear protective eyewear, a lab coat, and gloves.

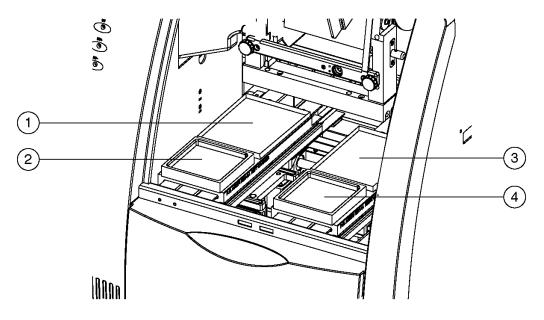
CAUTION: Potential System Damage. To decrease the risk of breakage and expelled particles, use only SCIEX vials that are designed for the PA 800 Plus system. Examine every vial for damage before use. Do not use any vial that shows cracks or other damage.



DANGER! Explosion Hazard. Do not use volatile solvents in 96-well plates. Volatile solvents might damage the system. Volatile solvents might also release hazardous or flammable vapors, which might cause fire or explosion.

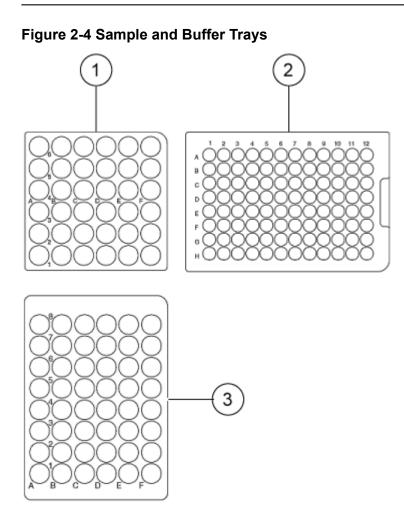
The sample-handling system holds four trays: two sample trays (inlet and outlet) and two buffer trays (inlet and outlet). The sample trays are used for samples. The buffer trays hold the other solutions that are required for electrophoresis. The trays are on two parallel tracks. In normal conditions of operation, the trays on the left are inlet trays for sample and buffer, and the trays on the right are outlet trays for sample and buffer.

Figure 2-3 PA 800 Plus System Trays



ltem	Description
1	Inlet sample tray (48 vials) or 96-well plate
2	Inlet buffer tray (36 vials)
3	Outlet sample tray (48 vials) or 96-well plate
4	Outlet buffer tray (36 vials)

Each buffer tray has slots for 36 universal vials. The sample tray holds either 48 universal vials or a 96-well plate. The trays are numbered from the front to the back, starting with 1, and a letter from left to right, starting with A.

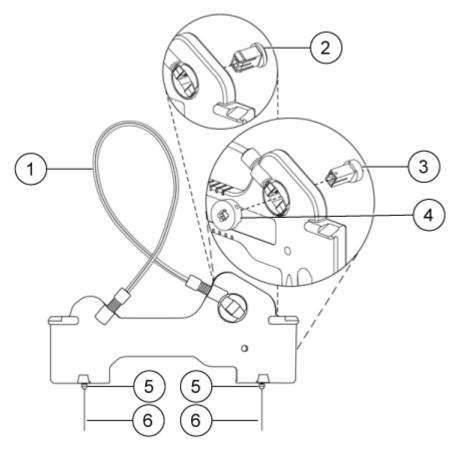


ltem	Description
1	Buffer tray
2	96-well sample plate
3	48-vial sample tray for universal vials
	<b>Note:</b> Universal vials can also be used as holders for micro vials that contain samples.

## **Capillary Cartridge**

The separation capillary is installed in a cartridge. The cartridge design protects the capillary and supplies a path for liquid coolant. The following figure shows the components of the cartridge.





ltem	Description
1	Coolant tubing with capillary inside
2	Aperture (UV and PDA detectors)
3	Aperture (LIF detector)
4	Probe guide (LIF detector)
5	Double seal
6	Capillary ends

The detection window is an area of the capillary where the polyimide coating is removed to show the transparent fused silica. This capillary detection window passes by the cartridge window used by the optical system. The capillary is held in place with the aperture. The UV and PDA detectors use the same aperture. The LIF detector uses a different aperture and also requires a probe guide to hold the LIF probe in position.

The capillary temperature is controlled with an inert liquid that moves through the cartridge. The temperature is controlled in a range from  $10^{\circ}$  C below ambient temperature (with a minimum of  $15^{\circ}$  C) to  $60^{\circ}$  C. Coolant goes into the cartridge through two openings in the bottom of the housing between the ends of the capillary. The coolant removes the heat that is generated by electrophoresis.

For the procedures to install a capillary in a cartridge, refer to the document: *Maintenance Guide*.

## Syringe Pump

The PA 800 Plus system uses an internal pump mechanism to supply 0.1 psi to 25 psi to do pressure injections or low-pressure mobilizations. The pump can apply a maximum of 100 psi to move the fluids through the capillary. Vacuum injections can be done from 0.1 psi to 5 psi. Pressure can be applied to both ends of the capillary at the same time to prevent the outgassing of gels.

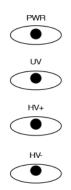
## **High-Voltage Power Supply**

The high-voltage power supply can deliver a maximum of 30 kV with a maximum current of 300  $\mu$ A. The voltage programming range is from 1 kV to 30 kV in increments of 100 V. The polarity is configured in the 32 Karat software. The current programming range is from 3.0  $\mu$ A to 300  $\mu$ A in increments of 0.1  $\mu$ A. The user supplies values for current, voltage, or power operation. During operation, the system increases the current, voltage, or power in increments to the programmed value. Limits for current, voltage, and power can be set to protect the capillary. For example, if the user supplies a voltage setting for 30 kV, but the setting for maximum current is only 3.0  $\mu$ A, then the system can get to the current limit before getting to the programmed voltage.

## **LED Indicators**

The front panel of the system has LED indicators for power, ultraviolet (UV), high voltage (HV+ and HV–).

#### Figure 2-6 LED Indicators on the Front Panel



ltem	Description
PWR	Identifies if system power is on or off
UV	For service only
HV+	Identifies that high voltage is set to normal polarity
HV–	Identifies that high voltage is set to reverse polarity

## **Cartridge and Sample Cover Interlocks**



WARNING! Personal Injury Hazard. When the sample cover is opened, wear protective eyewear, a lab coat, and gloves.

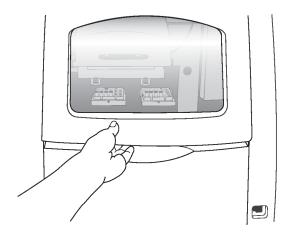
CAUTION: Potential Wrong Result. Do not open the cartridge cover during a run. The run will stop and the separation will fail.

The hinged doors of the PA 800 Plus system have interlock sensors that prevent unsafe access to the inside of the system. The outer door is the sample cover. The inner door is the cartridge cover.

When the sample cover is opened, this occurs:

- · Any tray movement stops immediately.
- Any programmed event that requires tray movement is prevented.
- A method or sequence stops when a step that requires tray movement occurs.
- If a method is running or if high voltage is applied while the tray is not moving, then a system beep occurs every 5 s.

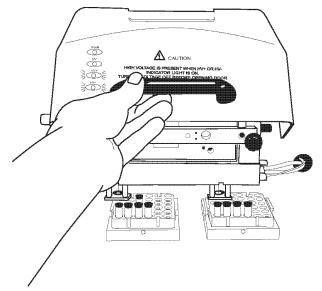
Figure 2-7 Sample Cover (Outer Door)



When the cartridge cover is opened, this occurs:

- If high voltage is on, then it turns off.
- The pump that supplies the capillary coolant turns off.
- The detector filter wheel moves to the closed position.

Figure 2-8 Cartridge Cover (Inner Door)



## **UV Detector**

The ultraviolet (UV) detector includes the following components:

- UV light source
- Wavelength filters
- Aperture
- Capillary
- Photodiode detector

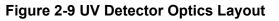
The UV light source is a deuterium lamp with a wavelength range of 190 nm to 600 nm. Two lenses focus and direct the output of the lamp through one of the wavelength-selecting filters that are in a rotating wheel behind the capillary cartridge. The light continues through the aperture and through a section of the capillary where the polyimide coating has been removed to make the detection window. For more information, refer to the section: Cartridge and Sample Cover Interlocks.

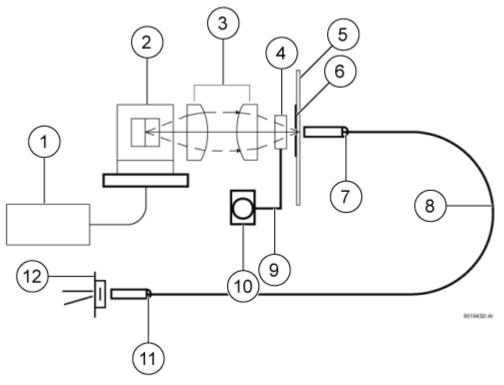
The unabsorbed light then continues through a fiber optic cable to a photodiode. The light signal is converted to an electrical signal, digitized, and then sent to the 32 Karat workstation to be processed by the software. This signal is also available as an analog output through a connection on the left side of the system.

The design of the system makes sure that the optical system is in alignment. The user is not required to align the optical system.

There are eight positions on the UV filter wheel. UV detector systems are supplied with four standard filters: 200 nm, 214 nm, 254 nm, and 280 nm (10 nm bandwidth). The filters are installed on the filter wheel in positions 2, 3, 4, and 5, respectively. Position 1 is opaque, and operates as a shutter for the detection system.

To get more wavelengths, install filters in positions 6, 7, and 8. If the system is used with a PDA detector, then position 8 must be kept open (no filter). The filter wheel can use  $\frac{1}{2}$  inch (12.7 mm) diameter filters with wavelengths from 190 nm to 600 nm.





Item	Description
1	Deuterium lamp power supply
2	Deuterium lamp
3	Lenses
4	Filter
5	Capillary
6	Capillary aperture
7	Fiber optic connection
8	Fiber optic cable
9	Filter wheel
10	Filter wheel motor
11	Fiber optic connection
12	Photodiode

## **PDA Detector**

The photodiode array (PDA) detector, like the UV detector, uses the absorbance of light to detect sample components as the sample moves past the detection window. Unlike the UV detector, the PDA detector can do spectral analysis of samples.

The PDA detector uses the same aperture as the UV detector. For a description of the cartridge, refer to the section: Capillary Cartridge.

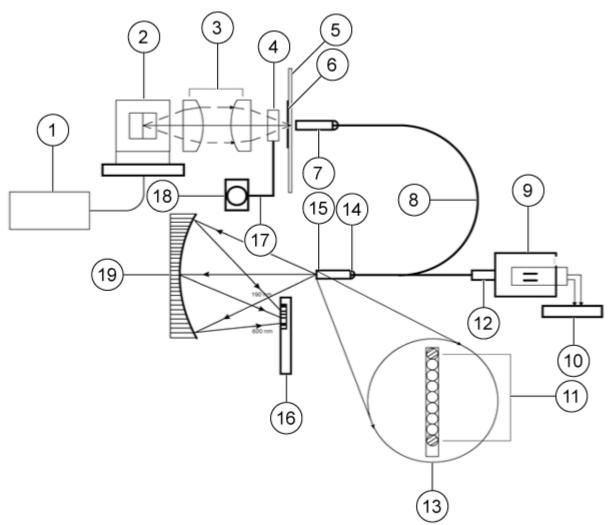
In PDA detection, the full spectrum of light from the deuterium lamp illuminates the capillary. Light that is not absorbed by samples is delivered by a fiber optic cable to a diffraction grating that breaks the light into a spectrum. This spectrum is projected onto an array of 256 photodiodes. This design is used to measure the absorbance profile of the sample. The PDA detector also measures light at the same time at different discrete wavelengths. The photodiode array converts the light signal into an electrical signal. The electrical signal is digitized and then sent to the 32 Karat workstation to be processed by the software.

The PDA detector always uses filter wheel position 8. When the PDA detector is in use, make sure that there is no filter in position 8.

The PDA detector is calibrated with discrete emission wavelength bands generated by a mercury lamp. The mercury lamp is an important part of the detector system. When requested by the user, the calibration is done automatically.



WARNING! Toxic Chemical Hazard. Do not discard the mercury lamp in the regular trash. Mercury is a hazardous material. Obey local, state, and federal laws to discard the mercury lamp.



#### Figure 2-10 PDA Detector Optics Layout

ltem	Description
1	Deuterium lamp power supply
2	Deuterium lamp
3	Lenses
4	Filter wheel in position 8
5	Capillary
6	Capillary aperture
7	Fiber optic connector

Item	Description
8	Fiber optic Y-cable
9	Mercury lamp
10	Mercury lamp power supply
13	9 μm by 200 μm fiber array (slit)
11	Mercury calibration fibers
12	Fiber optic connector
14	Fiber optic connector
15	Monochromator entrance slit
16	256 element diode array
17	Filter wheel
18	Filter wheel motor
19	Concave holographic grating

## **LIF Detector**

The optional laser-induced fluorescence (LIF) detector has an LIF detector module and a laser module.

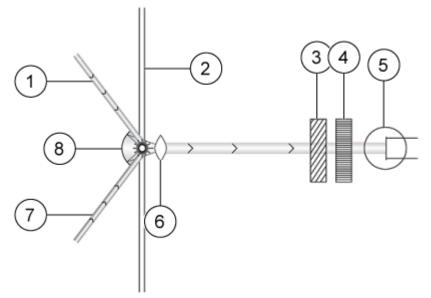
The LIF detector uses a different aperture than the UV and PDA detector. For a description of the cartridge, refer to the section: Capillary Cartridge.

The LIF detector uses an integrated 488 nm laser light source. A fiber optics cable transmits excitation light from the laser to the capillary in the cartridge. Substances in the capillary that fluoresce when excited at the laser wavelength are detected. The LIF detector measures and records this fluorescence, which shows as a peak on the electropherogram.

The initial installation of the LIF detector is done by a SCIEX field service employee (FSE). Because the detector components are modular, a user can easily change between the LIF and UV/PDA detectors.

For the procedures to install and calibrate the LIF detector, refer to the document: *Maintenance Guide*.





ltem	Description
1	Laser 1
2	Capillary
3	Laser filters
4	Emission filters
5	Photomultiplier tube
6	Ball lens
7	Laser 2
8	Spherical mirror

#### 488 nm Laser Module

#### WARNING! Personal Injury Hazard. To prevent exposure to hazardous laser radiation, always turn off the PA 800 Plus system before any of the LIF detector modules are removed.

The SCIEX solid-state 488 nm laser module is mounted inside the PA 800 Plus system. The laser module has a fiber optic connector and an electrical interlock connector for an external laser connection. These connectors are on the right side of the system. The external laser connection is compatible with a fiber-coupled external laser source for laser-induced fluorescence (LIF) detection. During normal operation of the LIF detector, laser light cannot be seen by the user. To prevent the emission of possibly harmful laser light from the end of the fiber cable, if the laser fiber optic cable is disconnected from the interconnect module or if the cartridge cover is opened, then an interlock mechanism turns off the laser.

#### **Other Lasers for the LIF Detector**

If required, then other lasers can be added to the PA 800 Plus system.

For third party lasers, the fiber optic cable must be silica fiber, with a 100  $\mu$ m core diameter, 140  $\mu$ m cladding, and a numerical aperture (NA) of 0.2. To connect the laser to the LIF detector, the cable must have an SMA 906 connector with hole concentricity less than 20  $\mu$ m.

For instructions to add a second laser, contact SCIEX Technical Support at sciex.com/requestsupport.

## **Supported Applications**

SCIEX supplies kits that are designed and validated for different types of analyses. To purchase a kit, go to store.sciex.com or contact the local SCIEX representative. SCIEX research and development continuously works to supply new workflows and kits. To see the latest product developments, go to sciex.com.

At the time of publication, the following kits are available.

- **SDS-MW Analysis Kit** (PN 390953): Used to do the separation and sizing of therapeutic proteins in the range of 10 kDA to 250 kDa. The separation is done with a replaceable sieving gel matrix.
- **IgG Purity and Heterogeneity Kit** (PN A10663): Used to assess the purity and heterogeneity of therapeutic proteins with a replaceable sieving gel matrix. Samples can be reduced or nonreduced.
- **RNA 9000 Purity & Integrity Kit** (PN C48231): Used to assess the purity and integrity of RNA therapeutics, vaccines, and other large, single-stranded oligonucleotides.
- dsDNA 1000 Kit (PN 477410): Used to do purity and integrity analysis of double-stranded linear nucleic acid species between 100 and 15,000 base pairs. Can also be used for the separation of plasmid isoforms. To increase the detection limit, the LIFluor EnhanCE dsDNA 1000 Dye Kit (PN 477409) can be used to label the samples.
- **ssDNA 100-R Kit** (PN 477480): Used to do purity and integrity analysis of single-stranded oligonucleotides between 10 and 150 base pairs. The separation has single-base resolution.
- **CZE Rapid Charge Variant Analysis Kit** (PN C44790): Used to do the separation of charge variants of a molecule by their mobility in a native state.
- **Capillary Isoelectric Focusing (cIEF) Kit** (PN A80976): Used to do the determination of an isoelectric point (pl) and charge variants of a molecule.

- Fast Glycan Labeling and Analysis Kit (PN B94499PTO): Used to do the separation and analysis of N-glycans that are released from therapeutic proteins. The N-glycans are labeled with the fluorophore APTS. Uses a magnetic bead clean-up.
- **Carbohydrate Labeling and Analysis Kit** (PN 477600): Used to do the separation and analysis of oligosaccharides and monosaccharides that are released from therapeutic proteins. The oligosaccharides and monosaccharides are labeled with the fluorophore APTS.

## **Controller and System Start-Up**

#### **Controller and Network Login**

The default network identification for the controller is 32 Karat. The work group name is WORKGROUP. If the PA 800 Plus system is installed on a network, then the network administrator must supply the user name and password.

If more than one PA 800 Plus system will be installed on the network, then a unique network name is required for each workstation. Usually, the network administrator assigns the names.

### License Key

A license key for the 32 Karat software is required to acquire data and to open and analyze data files. The license key is supplied on a flash drive that must be installed in a USB port on the PA 800 Plus controller. Without the license key, the 32 Karat software can only operate in demo mode.

In demo mode, only the data supplied with the 32 Karat software in the Default project can be opened and analyzed. Data acquisition is not possible.

If required, the license key can be uninstalled on one controller and installed on another.

CAUTION: Potential Wrong Result. Do not remove the flash drive with the license key from the PA 800 Plus system controller when the 32 Karat software is in operation. If the flash drive is removed, then the software changes to demo mode.

#### System Start Up

- 1. While the system power is off, open the sample and cartridge covers, and then do the following:
  - a. If a different detector is required, then change the detector. Refer to the document: *Maintenance Guide*.
  - b. If no cartridge is installed, then install the OPCAL cartridge.

**Note:** A cartridge is required for the system to fully initialize. If a different cartridge is required for a separation, it can be installed later.

c. To examine the coolant level for the capillary cooling system, look through the coolant sight glass.

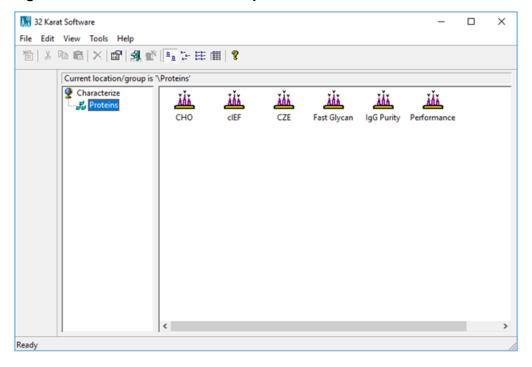
If the coolant level is low, then add coolant. Refer to the document: Maintenance Guide.

- d. Close the cartridge and sample covers.
- Push the power button on the front of the system and then wait for the system to initialize. The time required might be up to 5 minutes. Sounds will occur as the filter wheel, transport, and pressure systems initialize. When initialization is complete, the system can be controlled with the 32 Karat software.

#### **Open the 32 Karat Software**

- 1. On the Windows desktop, double-click the 32 Karat software icon. The 32 Karat Software Enterprise window opens.
- Click View > Hierarchy Pane.
   The Proteins group is shown in the left pane.
- 3. To see the available instruments, click **Proteins**.

In the 32 Karat software, an instrument is a software representation of a configuration of a PA 800 Plus system. Refer to the section: About Instruments and Projects in the 32 Karat Software.



#### Figure 3-1 32 Karat Software Enterprise Window

#### About Instruments and Projects in the 32 Karat Software

In the 32 Karat software, an instrument is a software representation of a configuration of a PA 800 Plus system. It includes the detector, the tray configuration, and whether options for system suitability, Caesar integration, and qualitative analysis are available.

When an instrument is opened, the user must select a project. All files are saved to this project. A project is a set of folders for files that are used by the 32 Karat and PA 800 Plus software. For example, if carbohydrate analysis with LIF detection and protein analysis with diode array detection are done, keep the method and report files for each type of analysis in different projects.

When the 32 Karat software is installed, projects are provided for supported applications for the PA 800 Plus system. Refer to the section: Supported Applications.

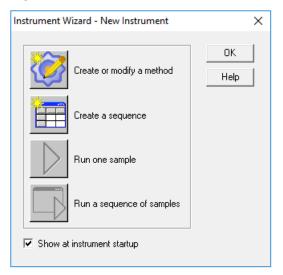
Note: The instruments and projects that are provided with the software have the same names.

**Note:** A user who has opened an instrument can open files in any project to which they have access.

Instruments and projects are created with the System Administration Wizard, available from 32 Karat Software Enterprise window. For information, refer to the document: *System Administration Guide*. If more than one detector is available, then SCIEX recommends creating at least one instrument for each detector.

When an instrument is opened, the Instrument Wizard dialog is shown.

#### Figure 3-2 Instrument Wizard - New Instrument Dialog



### **Online and Offline Modes**

The 32 Karat software has two modes of operation:

- Online mode gives the user full control of the system and the ability to acquire data, open and analyze existing data files, and create methods and sequences. To open an instrument online, in the 32 Karat Software Enterprise window, double-click the **Instrument** icon.
- Offline mode lets the user open and analyze existing data files, and create methods and sequences, but not control the system. To open any instrument offline, right-click the **Instrument** icon, and then click **Open Offline**.

If an instrument is open in online mode, then a second window for the same instrument can be opened in offline mode.

### **System Administration**

The system administration feature is used to control access to the 32 Karat software and the PA 800 Plus system. Access can be configured for a user, instrument, or project. When system administration is enabled, it also keeps customized settings for each instrument.

By default, system administration, including user login and other security features, is disabled.

A system administrator user name and password are required for any system changes or to get access to any instrument. The administrator can give access to more users. Make sure that at least one user is assigned the system administrator role. Depending on the roles assigned to the other users, some or all software features can be inaccessible if there is no system administrator.

The default system administrator user name is pa800. The default password is plus.

### **Enable System Administration**

Use this procedure to enable system administration and set up user access to the 32 Karat software.

- 1. In the 32 Karat Software Enterprise window, click **Tools > Enterprise Login**.
- 2. When a prompt is shown, type pa800 in the User name field, and plus in the Password field.

Figure 3-3 System Administration Login Dialog

Login	
<b>P</b>	User name: pa800 Password: x***
	Login Cancel Help

- 3. Click **Tools** > **Options**.
- 4. Open the Enterprise tab.

#### Figure 3-4 Options Dialog

Options	×				
Workstation Enterprise E-mail General					
Instrument control mode     Stand-alone     C Client/Server					
Enable user logins and permissions					
Obtain user lists from: Internal data system Data system users:	-				
Add User					
<ul> <li>Allow passwords to be saved</li> <li>Enable single user login mode</li> <li>Automatically login as the current domain user.</li> </ul>					
OK Cancel Apply	Help				

5. Select **Enable user logins and permissions** and then select the location of the user list:

- Internal data system: The list of users is maintained locally in the 32 Karat software. The software administrator adds the user names and passwords. Users can be added or removed locally.
- **Windows domain controller**: The 32 Karat software controller must be on a network. The list of potential users is the list of users assigned to a particular network domain.

When the software is run under a domain controller, the user names and passwords are those already assigned to that domain. To add or remove users, a 32 Karat system administrator must also be a domain administrator.

- Windows local PC: The 32 Karat software uses the local computer administrative tools for user lists and administrative accounts.
- 6. If Internal data system is selected, click **Add User** and complete the fields in the User Information dialog box.
- 7. If required, select Allow passwords to be saved.

This option saves the password of the user after initial logon. Subsequent logons will not require the user to enter a password unless the 32 Karat software is closed. This option is designed for systems where only one user will use the workstation.

8. If required, select **Enable single user login mode**.

This option lets users log on to all instruments once and not individually.

9. Click **OK**. System administration is enabled.

After adding users, customize project access and assign administrator roles with the System Administration wizard. For information, refer to the document: *System Administration Guide*.

### PA 800 Plus Software

The PA 800 Plus software operates with the 32 Karat software. On the PA 800 Plus system, the PA 800 Plus software guides the system operator through the tasks of running methods and sequences that have been developed by a 32 Karat software user. Methods and sequences cannot be created or changed directly in the PA 800 Plus software.

The PA 800 Plus software gets the electronic controls that are necessary for 21 CFR part 11 compliance from the 32 Karat software.

The license key used for the 32 Karat software is required to operate the PA 800 Plus software. Refer to the section: License Key.

If required, the 32 Karat software can be opened from the side menu in the PA 800 Plus software.

For information about the PA 800 Plus software, refer to the document: Help System.

## Workflow

Note: The following steps assume that samples have been prepared.

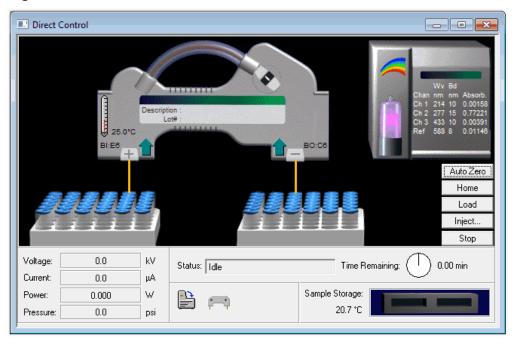
Step	To Do This	Refer To
1	Start the controller and open the 32 Karat software.	Open the 32 Karat Software
2	Make sure that a detector is installed.	Refer to the document: <i>Maintenance Guide</i> .
3	If required, install the capillary in the cartridge.	Refer to the document: <i>Maintenance Guide</i> .
4	Install the cartridge.	Load the Cartridge and Samples
5	Turn on the power to the system.	System Start Up
6	In the 32 Karat Software Enterprise window, open the instrument in online mode.	Online and Offline Modes
7	Prepare the sample and buffer vials, install the vials in the trays, and then put the trays in the system.	Load the Cartridge and Samples
8	Do the run.	Start a Method
9	Analyze the results and then save the parameters to the method.	Analyze the Data
10	Create a sequence to acquire data for more than one sample and then do the analysis.	Create a Sequence to Run the Method Multiple Times
11	View or print a report.	View or Print a Report

Table 3-1	Run a	a Method	Workflow
	I CULL C		

## Load the Cartridge and Samples

After the instrument and controller have been initialized, make sure that system performance is correct.

- 1. Open the instrument in online mode.
- 2. If the instrument opens with a project other than Performance, then click **File > Select Project > Performance Tests**.
- 3. Click **Control > Direct Control**.



#### **Figure 3-5 Direct Control Window**

The Direct Control window lets the user control the system manually and shows the status of the system. Status icons for the sample cover and cartridge show at the bottom of the window. Make sure that the icons show that the sample cover is closed and a cartridge is installed. If the sample cover is open, or if a cartridge is not installed, then the trays cannot move.

- 4. To move the trays to the front of the sample compartment, click **Load**.
- Use an angled mirror and penlight to examine the interface block.
   For the procedure to clean the interface block, refer to the document: *Maintenance Guide*.
- 6. Install the correct capillary in the cartridge.
- 7. Prepare the vials with the samples, buffer, and any other solutions, and then put them in the trays.

For instructions on preparing solutions and fill in the vials, refer to the correct PA 800 Plus application guide.

8. Install the cartridge and the trays, and then close the sample cover. The instrument automatically detects the trays and moves to the home position. The instrument is ready to run the method.

## Start a Method

1. In the instrument window, click **Control > Single Run**.

Tip! As an alternative, on the toolbar, click (Single Run).

#### Figure 3-6 Single Run Acquisition Window

Single Run Acquisition		×
Run information         Sample ID:         Method:       C:\32Karat\projects\Performance\Method\Perfo         Data path:       C:\32Karat\Projects\Performance\Data	Calibrate Calibration level: Calibration Clear all calibration Clear calibration for level	Start Cancel Help
Data file: Number of reps: 1 Amount values	<ul> <li>Print calibration report</li> <li>Clear replicates</li> <li>Average replicates</li> </ul>	
Sample amount:     1       Internal standard amount:     1       Multiplication factors:     1     1       Dilution factors:     1     1	Begin run	
Sample inject (override) Inlet vial: Inlet Tray Duration (sec): Outlet vial: Outlet Tray		Description

- 2. To the right of the **Method** field, click <sup>𝒴</sup> (**Folder**) and then select a method. The projects provided when the 32 Karat software was installed include methods.
- 3. If required, to the right of the **Data path** field, click 🖆 (**Folder**) and then select a folder for the data file.

By default, this field is set to the path to the data folder in the current project.

4. In the **Data file** field, type a unique data file name.

**Tip!** To the right of the **Data file** field, click **b** and then select fields for the data file name.

5. Click **Start**. The instrument runs the selected method.

Note: During a run, the Start button changes to the Submit button.

Sample ID:	Calibrate	Submit
Method:	:\32Karat\projects\Performance\Method\Perfo	Submit Priority
Data path: 🛛	:\32Karat\Projects\Performance\Data	Cancel
Data file:	Print calibration report	Help
Number of reps:	Print method report     Clear replicates	
Amount values — Sample amount: Internal standard a Multiplication factor Dilution factors:		
Sample inject (ove Inlet vial: Outlet vial:	ride) Inlet Tray Duration (sec): Outlet Tray	Description

Figure 3-7 Single Run Acquisition Window: Running a Method

**Note:** Another run can be started before the method that is running completes. Use the same steps to start a single run. When the run is submitted, it is added to the run queue.

6. To see the run queue, in the instrument window, click **Control > Run Queue**.

## Analyze the Data

**Note:** The following steps analyze a data file that was acquired with a PDA detector. For data from a different type of detector, skip steps 3 and 4. Also, the window titles will be different.

Do the following steps to analyze the data:

- 1. Click File > Data > Open.
- 2. Open the data file that was collected in the previous section.
- If the electropherogram is minimized, then click Window > PDA- 214 nm. An electropherogram with two large peaks is shown. An electropherogram is a plot with migration time on the X-axis and absorbence data on the Y-axis.

Make sure that the title on the electropherogram window shows PDA - 214 nm.

4. In the Data Channel list in the Main toolbar, select **1: PDA - 214nm**.

#### Figure 3-8 Data Channel List

1: PDA - 214nm	Ŧ
1: PDA - 214nm	
2: PDA - 254nm	
3: PDA - 280nm	
4: PDA - 250nm	
5: Spectrum Max Plo	ot

The Data Channel list shows the different channels collected during data acquisition. The selected channel is the data that will be analyzed.

**Note:** The items in the Data Channel list depend on the settings on the PDA Detector Initial Conditions tab in the method.

Starting with item 1 in the list, the following channels might be shown:

- From zero to three electropherogram channels.
- The peak detect channel.
- The spectrum max channel.
- If a multi-electropherogram is present in the method, then a channel for each wavelength in the multi-electropherogram is shown in the list.

For information about the different channels in PDA data, refer to the documents: *Methods Development Guide* and *32 Karat Software Help System*.

5. On the toolbar, click 🚨 (Integration Events).

#### Figure 3-9 Integration Events Window

Integration Events PDA - 214nm					×			
	#		Event		Start Time	Stop Time	Value	
	1	V	Width	•	0.000	0.000	0.5	5
F	2	V V	Threshold		0.000	0.000	500	2
ŀ								

**Note:** Make sure that the title bar of the Integration Events window shows Integration Events -- PDA - 214nm. If another channel shows, then go to step 4 and change the analysis channel to 1: PDA - 214 nm.

6. Close all windows except for the Integration Events -- PDA - 214nm and PDA - 214nm windows and then click **Window** > **Tile Horizontally**.

The windows are arranged so that they are all above or below one another in one column. The position of the windows lets users see how changes to the Integration Events table affect how peaks are detected in the electropherogram.

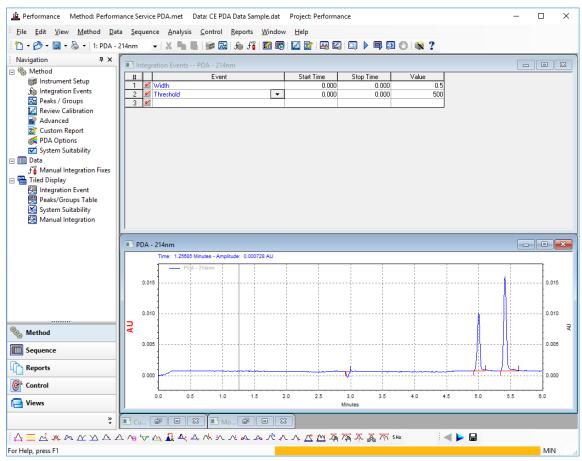


Figure 3-10 PDA - 214nm and Integration Events -- PDA - 214nm Windows, Tiled

7. In the Integration Events window, type values for the following parameters.

**Tip!** If the integration event is not shown in the table, click  $\frown$  in the **Events** cell and then select the event from the list.

- Width: Sets the peak-detection sensitivity to changes in the baseline. Set this parameter to the width of the smallest peak in the electropherogram. The default value is 0.2.
- Threshold: Sets the distance from the baseline at which a point becomes a cluster point.
- **Shoulder Sensitivity**: Measures the curvature of the up slope and down slope of the peak.

• **Minimum Cluster Distance**: Sets the number of data points to be grouped together before the software identifies the group of cluster points as a peak. If a sufficient number of cluster points are grouped together, then the software identifies this group of points as a peak. A curve is drawn through these points and extends to the baseline. The points where the curve meets the baseline are the start and stop points.

The Width and Threshold parameters are both required for integration. Shoulder Sensitivity and Minimum Cluster Distance are recommended.

For information about the integration parameters, refer to the documents: *Methods Development Guide* and *32 Karat Software Help System*.

### 8. Click 🤷 (Analyze).

The data is integrated and the electropherogram updates to show markers for peak start, baseline, and peak stop.

9. Make sure that the markers for peak start, baseline, and peak stop correctly identify the baseline segments and the peaks. If they are not correct, change the values for the

parameters in the Integration Events window and then click 🔤 (Analyze) again.

- 10. If required, to show additional information such as the peak name or migration time on the electropherogram, add annotations. Refer to the section: Add Annotations.
- 11. Click **File > Method > Save**.

The integration events are saved to the method.

### About Peak Area and Corrected Peak Area

In addition to calculating the baseline, peak start, peak apex, and peak stop, the integration algorithm calculates the area of the peak. The area of the peak is calculated for each data point and then all of the areas for the data points of a peak are added together to calculate the area of the peak.

In capillary electrophoresis, each component of the sample migrates with a different mobility so each component spends a different amount of time in front of the detector. Faster migrating compounds spend less time in front of the detector compared to slower migrating compounds. Consequently, a faster migrating compound will have an artificially lower peak area compared to a slower migrating compound (which will also have an artificially higher peak area).

To correct for the influence of mobility on peak area, the 32 Karat software also calculates the corrected peak area. Corrected peak area is the peak area divided by the peak velocity. The velocity is calculated from the total length of the capillary and the length to the detector. These parameters are set in the Advanced Method Options dialog. To eliminate any peak area bias, report corrected peak area not peak area.

Capillary Information Capillary length:	0.602	• meters O cm	
Capillary length to detec	· · · · · · · · · · · · · · · · · · ·	C meters 📀 cm	
Capillary lot number:			
Capillary installation date	e 📃		
Capillary description:			
Calculate performance	parameters for this	channel	
Calculation method(s):	<b>I</b> USP □EMG		
	DAB, BP, EP,	ASTM	
	DAOH		

Figure 3-11 Advanced Method Options Dialog: Capillary/Performance Tab

### **Add Annotations**

- In the top right corner of the PDA Electropherogram window, click 
   If the data has been analyzed, then the peak start, peak end, and baseline are shown on the electropherogram.
- 2. Right-click the graph, and then click **Annotations**.

Trace Annotation Properties	×
Annotation	
Trace: 1: (Current Data) - PDA	- 214nm 💌
Peaks 💌	
Available Annotations: Migration Time Area Area Percent Height Height Percent ESTD concentration ISTD concentration	Show the following annotations:          Pk #         Name
NORM concentration Width	Decimals: 2
Other	
I USP Width	<ul> <li>MT Window</li> <li>MT Windo</li></ul>
<	>
OK Cancel	Apply Apply To All Help

Figure 3-12 Trace Annotation Properties Dialog

The **Available Annotations** list contains parameters that can be shown for each peak. In the Other section, the **Baseline** and **Show undetected named peaks** check boxes are selected by default.

- 3. In the **Available Annotations** list, click **Peak #**, and then click **I** to move the selection to the right pane.
- 4. Do 3 again for **Name**, and then click **Apply**.

The peak numbers and peak names are shown above the peaks. The peak names are from the Named Peaks tab in the Peak / Group Tables window for the method. If the quality of the separation is poor, then the peak names might not be assigned to the correct peaks.

### **About Peak Identity**

For peaks to be identified in the data, values for the peak name, the migration time, and the migration time window must be present in the table on the Named Peaks tab in the Peak / Group Tables window. Refer to the document: *Methods Development Guide*.

For the methods that are supplied with the PA 800 Plus system, peak information is included on the Named Peaks tab in the Peak / Group Tables window. For applications with unknown samples, peak information should be added to the table.

# Create a Sequence to Run the Method Multiple Times

After the method and analysis are optimized, the method can be run again with different samples, or multiple times on a single sample to calculate performance. To automate this process, use the Sequence Wizard to create a sequence to use the same method multiple times to acquire data.

For information about the Sequence Wizard, refer to the document: *Methods Development Guide*.

- 1. Use the Sequence Wizard to create a sequence for acquisition.
  - a. Click File > Sequence > Sequence Wizard.

Sequence Wizard - Method		×
32 Karat™	Method : Data File Type	
52 Rarat	Multiplication factors :     1     1       Dilution factors:     1     1	
<b>SCIEX</b>		
	Cancel < Back Next > Fini	sh

#### Figure 3-13 Sequence Wizard - Method Page

- b. To the right of the **Method** field, click 🖻 (**Folder**), and then select the method.
- c. In the Data File Type section, click **For acquisition**, and then click **Next**.

Note: Do not make any changes in the Amount values section.

The Sequence Wizard - Unknowns page opens.

d. Type a sample ID in the **Sample ID** field.

**Tip!** To use unique sample IDs, append one or more fields to the sample ID in the **Sample ID** field. To show the available fields, click the arrow to the right of the sample ID field.

#### Figure 3-14 Field List for Sample ID

Line Number	
Increment Number	
User Name	
Method Name	
Instrument Name	
Date and Time	

e. Type a data file name in the **Data file** field.

When the sequence is run, the data is saved to a file with this name.

**Tip!** To prevent the overwriting of data, append one or more fields to the file name in the **Data file** field. To show the available fields, click the arrow to the right of the file name field.

Sequence Wizard - Unknowns	>	×
	Sample ID :       Image: C:\32Karat\projects\Performance\Data         Data path :       C:\32Karat\projects\Performance\Data         Data file : <u><d>         Number of unknown runs in sequence :       1         Repetitions per run :       1</d></u>	Line Number Increment Number Sample ID
32 Karat™	Create a separate row in the sequence for each repetition	User Name Method Name Instrument Name Date and Time
<b>SCIEX</b>		Open File
	Cancel         < Back	_

Figure 3-15 Sequence Wizard - Unknowns Page, with Field List for Data File Name Shown

- f. Click Next.
- g. Use the Vials page to set the vial incrementing and then click **Next**.

Figure 3-16 Sequence Wizard- Vials Page

Sequence Wizard - Vials	×
First unknown vials of sequence :         Inlet :       Inlet :         Outlet :       BO:C1         Trays       Image: Advance         First calibration vials of sequence :         Inlet :       BI:C2         Trays       Image: Advance         Outlet :       BO:C1         Trays       Image: Advance         Outlet :       BI:C2         Trays       Image: Advance         Outlet :       BO:C1         Trays       Image: Advance         Outlet :       BO:C1         Trays       Image: Advance	
32 Karat <sup>™</sup> Injection duration: 10.0 sec Advance direction:	
SCIEX	
Cancel < Back Next > Finis	1

At this point the sequence has all the required information for a run.

- 2. Do either of the following:
  - Click Finish.
  - If required, to add calibration or reports, click **Next** and then make any changes in the Calibration page or Reports page and then click **Finish**.

The sequence opens in a table.

- 3. Click **Sequence** > **Save**.
- 4. If required, add a summary report to the sequence. Refer to the section: Add a Summary Report to a Sequence.
- 5. In the instrument window, click **Sequence** > **Process**.

Figure 3-17 Process Sequence Dialog

Process Sequence		×
Sequence information Sequence name: C:\32Karat\proje	cts\Performance\Sequence\Performance	Start Cancel
Run range	Mode Tower: N/A Processing mode: Reintegrate Bracketing: None	Help
Printing Print method reports Print sequence reports	C Results review (pause after each run) C Calibration review (pause after each calibration set)	

- 6. Set the parameters in the Process Sequence dialog.
  - a. To the right of the **Sequence name** field, click 🖆 (**Folder**), and then select the sequence.
  - b. In the Run range section, click All to acquire data for the complete sequence. To acquire data for only some of the sequence, click Range, and then in the Range field, type the row numbers of the rows of interest. Separate ranges with dashes and commas. For example, to run lines 2, 3, 4, and 6, type 2-4, 6.
  - c. Select Review, and then click Results review [pause after each run].
- 7. Click Start.

The data is acquired. As each file is acquired, the sequence updates.

### Add a Summary Report to a Sequence

To add a summary report to the sequence, do the following:

- 1. To open the sequence, click **File > Sequence > Open**.
- 2. Click the **Run Type** row header, then right-click and select **Set Run Types > Summary**.

**Tip!** If not all samples should be included in the report, select the range of samples to be included by dragging in the **Run #** cells.

The first cell in the range is set to Summary Begin and the last cell is set to Summary End. The other cells are set to Summary Run.

Figure 3-18 Sequence Window

Run # Status Run Type Level Conc Ove		Conc Oiverride		
1		Summary Begin	0	n/a
2		Summary Run	0	n/a
3		Summary Run	0	n/a
4		Summary Run	0	n/a
5		Summary End	0	n/a
6				
7				
8				

- 3. To specify the type of summary, double-click the **Summary Begin** cell.
- 4. Click the text next to right of the **Begin Summary** check box. The **Report Template** field shows the report template. The default template for a summary report is Summary.tpl.

#### Figure 3-19 Sample Run Type(s) Dialog: Begin Summary Selected

Sample Run Type(s)	×
Clear All Calibration Clear Calibration at Level Print Calibration Report Average Replicates Clear Replicates Begin Loop End Loop Shutdown Print Additional Reports Begin System Suitability System Suitability Standard End System Suitability Wegin Summary Summary Run End Summary Vial Summary Vial Summary QC Check Standard Unspiked Spiked Spike 1 of 2 Spike 2 of 2 Duplicate Begin Calibration End Calibration Baseline File	Report Template : Summary.tpl
	OK Cancel Help

5. If required, click  $\stackrel{\text{\tiny left}}{=}$  (**Folder**), and then select a different report template file.

### 6. Click OK.

## **Create a Sequence to Analyze Multiple Files**

After the data files are acquired, they can be analyzed. To automate this process, use the Sequence Wizard to create a sequence to analyze the data with the same method.

For information about the Sequence Wizard, refer to the document: *Methods Development Guide*.

- 1. Use the Sequence Wizard to create a sequence for analysis.
  - a. Click File > Sequence > Sequence Wizard.
  - b. To the right of the **Method** field, click 🖻 (**Folder**), and then select the method.
  - c. In the Data File Type section, click **From existing data files**, and then click **Next**.

#### Figure 3-20 Sequence Wizard - Method Page

Sequence Wizard - Method		×
	Method : Data File Type For acquisition From existing data files Amount values Sample amount : 1	
32 Karat™	Internal standard amount :     1       Multiplication factors :     1     1       Dilution factors:     1     1	-
SCIEX		
	Cancel < Back Next > Fir	nish

Sequence Wizard - Select File	25	×
	Data files:	
32 Karat™		
<b>SCIEX</b>		
	Cancel < Back	Next > Finish

Figure 3-21 Sequence Wizard - Select Files Page

- d. Click 🖻 (Folder), and then select the data files to be analyzed.
- e. (Optional) Click a file name and then click 1 (**Up**) or 1 (**Down**) to change the order of the data files in the sequence.
- 2. Click **Finish**.

The sequence opens in a table.

- 3. Click **Sequence** > **Save**.
- 4. If required, add a summary report to the sequence. Refer to the section: Add a Summary Report to a Sequence.
- 5. In the instrument window, click **Sequence** > **Process**.

#### Figure 3-22 Process Sequence Dialog

Process Sequence		×
Sequence information Sequence name: C:\32Karat\pri	ojects\Performance\Sequence\Performance	Start Cancel
Run range	Mode Tower: N/A Processing mode: Reintegrate Bracketing: None	Help
Printing Print method reports Print sequence reports	C Results review (pause after each run) C Calibration review (pause after each calibration set)	

- 6. Set the parameters in the Process Sequence dialog.
  - a. To the right of the **Sequence name** field, click 🖆 (**Folder**), and then select the sequence.
  - b. In the Run range section, click **All** to analyze the complete sequence.

To analyze only some of the sequence, click **Range**, and then in the **Range** field, type the row numbers for the rows of interest. Separate ranges with dashes and commas. For example, to run lines 2, 3, 4, and 6, type 2-4, 6.

c. Select Review, and then click Results review [pause after each run].

#### 7. Click Start.

The data files are analyzed. As each file is analyzed, the sequence updates.

The electropherogram shows the analyzed date for each data file until the next line of the sequence is processed. When the run is complete, the electropherogram shows the last data file.

## **View Reports**

### **Standard Reports**

By default, each project contains standard method reports. After data analysis, parameters for selected peaks are reported.

- For the Area % report, all of the detected peaks are included.
- For the External Standard, Internal Standard, and Normalization normalization reports, only the detected peaks that are listed on the Named Peaks tab in the Peak / Group Tables window are reported.

Standard reports cannot be edited.

### **Method Custom Reports**

Method custom reports can be edited to show custom information and then saved as a new report. If a method custom report is included with a method, then a method custom report is created each time data is analyzed.

Do the following steps to make a method custom report:

- 1. Click File > Report Template Open.
- 2. Select the report template, for example, the External Standard.Srp file.
- 3. Right-click to edit any section of the report and make the required changes
- 4. Click File > Report Template > Save as, and then save the report with the file name CRPtrain.srp.

### **Sequence Custom Reports**

Sequence custom reports are similar to method custom reports, but the parameters are related to the sequence rather than the data. If a report template is specified as part of the sequence, then the sequence custom report is created after the sequence is processed.

### **Advanced Reports**

**Note:** The report that is created with this procedure is an example. As required, select different options.

For information about advanced reports, refer to the document: 32 Karat Software Online Help.

Do the following steps to make an advanced report:

- 1. Click File > Advanced Reports > New.
- 2. In the Report window, right-click cell A1 and then click **Table Wizard**.
- 3. Click Sequence Summary Table, and then click Next.

Table Wizard - Parameters		×
	What parameters would you like t	to summarize?
	ACH Resolution AOH Theoretical Plates AOH Theoretical Plates Area % ASTM LOD ASTM LOD ASTM LOQ Asymmetry at 10% Capacity Factor Centroid Time CurveCoeff(A) CurveCoeff(C) CurveCoeff(D)	Trace index: 1
	Cancel < Back	Next > Finish

Figure 3-23 Table Wizard - Parameters Page

- 4. Set the parameters in the Table Wizard Parameters page:
  - a. In the list on the left, click **Area** and then click **b**.
  - b. If required, to set the number of digits after the decimal point, type a value in the **Precision** field.
  - c. Do 4.a and 4.b again for **Migration Time**.
  - d. Click ... next to the Trace index field and select which data trace will be reported for the selected peak or group.
  - e. Click Next.

The Table Wizard - Types page opens.

5. To report all of the named peaks in the active window, select **Named peaks that were detected** and **Named peaks that were not detected** and then click **Next**.

Table Wizard - Run Parameters		Х
	What parameters would you like to include for each run?          Analysis Date         BCD Value         Data Description         Dilution Factor 1         Dilution Factor 2         Dilution Factor 3         Data Filename         Data Filename         Instrument Name         ISTD Amount         Last Method Filename         Multiplier Factor 1         Multiplier Factor 2         Multiplier Factor 3         Original Method Filenan         Original Method Filename         Sample Amount         System Wide Paramete	
	Cancel < Back Next > Finish	n

Figure 3-24 Table Wizard - Run Parameters Page

- 6. Click **Data Filename**, click **!**, and then click **Next**. The Table Wizard Run Direction page opens.
- 7. To accept the default value (Down), click **Next**. The Table Wizard - Statistics page opens.
- 8. Cick **Yes**, and then click **Finish**. The Template Editor updates to show the fields for the report.
- 9. Click File > Advanced reports > Save as. Save the report as a template with the file name RSD.tpl.

### **Suitability Reports**

A suitability report is a special type of sequence report.

Do the following steps to make a suitability report:

- 1. Create a sequence that contains a rows with the samples for the system suitability report.
  - a. Click the **Run Type** row header, then right-click and select **Set Run Types > System Suitability**.

**Tip!** If not all samples should be included in the report, select the range of samples to be included by dragging in the **Run #** cells.

The first cell in the range is set to System Suit Begin and the last cell is set to System Suit End. The other cells are set to System Suit Std..

- b. To specify which type of summary is reported, double-click the System Suit Begin cell.
- c. Click the text next to right of the **Begin System Suitability** check box. The **Report Template** field shows the report template. The default template for a summary report is SysSuit.rep.

Figure 3-25 Sample Run Type(s) Dialog: Begin System Suitability Selected

Sample Run Type(s)		
Sample Run Type(s)  Clear All Calibration Clear Calibration at Level Print Calibration Report Average Replicates Clear Replicates Begin Loop End Loop Shutdown Print Additional Reports Begin System Suitability System Suitability System Suitability Begin Summary Summary Run End Summary QC Check Standard Unspiked	Run Type Parameters Report Template : SysSuit.rep	
Spiked Spike 1 of 2 Spike 2 of 2 Duplicate Begin Calibration End Calibration Baseline File	OK Cancel Help	

- d. Click OK.
- 2. To change the suitability parameters that are included in the report, click **Method** > **System Suitability**, and then edit the parameters in the window.

**Note:** System Suitability is only shown on the **Method** menu if **System Suitability** is selected when the instrument is configured. To add system suitability, in the 32 Karat Software Enterprise window, right-click the instrument and then select **Configure** > **Instrument**. By default, System Suitability is only enabled for the Performance instrument that is provided when the software is installed.

3. Click (Sequence Run).

### View or Print a Report

- 1. To view a report in the instrument window, click **Reports > View**.
- 2. To print a report, in the instrument window, click **Reports > View**.

If the **Print Reports** option is selected in the Run window, then method and sequence reports are printed automatically.

## Maintenance

For installation instructions for the cartridge and detectors, and calibration and maintenance procedures, refer to the document: *Maintenance Guide*.

## **PA 800 Plus System Specifications**

Dimensions (H × W × D)	99.1 cm (cover open), 73.7 cm (cover closed) × 63.5 cm × 72.4 cm
	(39 in. (cover open), 29 in. (cover closed) × 25 in. × 28.5 in.)
Weight	85.3 kg (188 lb)
Electrical	Power requirement: 100 VAC to 240 VAC, 8.0 A, 50 Hz or 60 Hz
	Power consumption: Supply voltage must not exceed 10% of nominal
	Fuses:
	• 8.0 A slow blow, 1/4 in. (2 each), 100 VAC to 120 VAC
	• 6.3 A time delay, 20 mm (2 each), 200 VAC to 240 VAC
	Installation (overvoltage) category: Category II
Working environment	Altitude: Up to $\leq$ 2,000 m (6,562 ft)
	Humidity:
	<ul> <li>&lt; 80% (noncondensing) at 15 °C to 30 °C (59 °F to 86 °F)</li> </ul>
	<ul> <li>&lt; 60% (noncondensing) at 30 °C to 40 °C (86 °F to 104 °F)</li> </ul>
	Temperature: 15 °C to 40 °C (59 °F to 104 °F), 15 °C to 30 °C (59 °F to 86 °F) recommended
Maximum heat dissipation	400 W (1,024 BTU/hr)
Pollution degree	2
I/O	TTL: 2
	Contact closures: 2

## **Supplied Controller Configuration**

Note: Specifications are subject to change without notice.

**Note:** SCIEX fully validates and supports the controllers supplied with the system. Only limited support is available for customer-supplied computers.

Item	Details
Operating system	Windows 10 Enterprise LTSC, language set to English (United States)
CPU	Intel Core i7-10700 4.7 GHz processor
Random access memory (RAM)	16 GB
Hard drive	500 GB
Optical drive	DVD-RW drive
Serial ports	1
Ethernet ports	2
USB ports	8
Monitor	24 inch wide-screen monitor with 1920 × 1080 resolution

 Table A-2 Supplied Controller Configuration

## **Sample Temperature Control Specifications**

Range	20 °C below the ambient temperature to 60 °C (140 °F)	
	Minimum value: 4 °C (39 °F)	
Stability	±1 °C at 25 °C (77 °F)	
	±3 °C at 4 °C (39 °F) and 60 °C (140 °F)	
Accuracy	±2 °C within a range of ±15 °C from the ambient temperature	
	±3 °C outside a range of ±15 °C from the ambient temperature	

## **Capillary Temperature Control Specifications**

#### **Table A-4 Capillary Temperature Control Specifications**

Range	10 °C below the ambient temperature to 60 °C (140 °F)
	Minimum setting: 15 °C (59 °F)
Stability	±1 °C at 25 °C (77 °F)
Accuracy	±1 °C within a range of ±1 °C from the ambient temperature
	$\pm 2$ °C outside a range of $\pm 5$ °C from the ambient temperature

## **Pressure and Vacuum System Specifications**

Range	Injection: 0.1 psi to 25 psi (pressure) or 0.1 psi to 5.0 psi (vacuum)
	Rinse: 0.1 psi to 100 psi (pressure) or 0.1 psi to 5.0 psi (vacuum)
Stability	±0.3 psi at 25 psi
	±1.0 psi at 100 psi
Direction	Applied at inlet or outlet for all pressure functions, rinses, and injections
	This parameter is set by the user in the software.

#### Table A-5 Pressure and Vacuum System Specifications

## **Detector Specifications**

### **UV Detector Specifications**

#### **Table A-6 UV Detector Specifications**

Available filters	214 nm
	Positions for 6 additional filters
Filter bandwidth	25 nm nominal
Filter dimensions	Diameter: 12.7 mm (0.5 in.)
	Thickness: 5 mm (0.2 in.)

UV source	30 W pre-aligned deuterium lamp
UV source lifetime	1,000 hours

#### Table A-6 UV Detector Specifications (continued)

### LIF Detector Specifications

Table A-7 LIF	Detector	<b>Specifications</b>
---------------	----------	-----------------------

Baseline drift	< 0.2 RFU/hr	
Baseline noise	< 0.005 RFU peak to peak	
Dynamic range (at a setting of 1,000)	> 10 <sup>4</sup>	
Filters	488 nm notch filter and 520 nm bandpass filter	
Filters (optional)	For 488 nm laser: 488 nm notch filter and 520 nm bandpass filter	
	For user-supplied lasers, two filters are required: a laser filter to block stray laser light and an emission filter to select the wavelength of the emitted light.	
	Filter dimensions must be:	
	• Outer diameter: 12.7 mm to 0.25 mm (0.5 in. to 0.01 in.)	
	<ul> <li>Thickness: ≤ 0.89 mm (0.35 in.)</li> </ul>	
	<ul> <li>For multiple filters used in a single channel, total thickness: ≤ 0.89 mm (0.35 in.)</li> </ul>	
Laser	3 mW, 488 nm solid state	
Laser life span	10,000 hours	
RFU range	0 RFU to 1,000 RFU	
Sensitivity	1 × 10 <sup>11</sup> M sodium fluorescein with signal-to-noise > 2	
Wavelength range (for	Excitation: 300 nm to 700 nm	
optics)	Detection: 350 nm to 750 nm	

## **PDA Detector Specifications**

### **Table A-8 PDA Detector Specifications**

Bandwidth	6 mm minimum (absorbance averaging)
Detector type	256 element diode array
Scan collection frequency	0.5 Hz to 32 Hz
UV source	30 W pre-aligned deuterium lamp
UV source lifetime	1,000 hours
Wavelength accuracy	2 nm
Wavelength range	190 nm to 600 nm

Note: Not all of the symbols in the following table are applicable to every instrument.

Symbol	Description
	Australian Regulatory Compliance Mark. Indicates that the product complies with Australian Communications Media Authority (ACMA) EMC and Electrical Safety Requirements.
$\sim$	Alternating current
A	Amperes (current)
	Asphyxiation Hazard
EC REP	Authorized representative in the European community
	Biohazard
CE	CE Marking of Conformity
C S B B B B B B B B B B B B B B B B B B	cCSAus mark. Indicates electrical safety certification for Canada and USA.
REF	Catalog number

Symbol	Description
	Caution. Consult the instructions for information about a possible hazard.
	<b>Note:</b> In SCIEX documentation, this symbol identifies a personal injury hazard.
	China RoHS Caution Label. The electronic information product contains certain toxic or hazardous substances. The center number is the Environmentally Friendly Use Period (EFUP) date, and indicates the number of calendar years the product can be in operation. Upon the expiration of the EFUP, the product must be immediately recycled. The circling arrows show the product is recyclable. The date code on the label or product indicates the date of manufacture.
O	China RoHS logo. The device does not contain toxic and hazardous substances or elements above the maximum concentration values and the device is an environmentally-friendly product that can be recycled and reused.
Ĩ	Consult instructions for use.
	Crushing Hazard
C BATH American US	cTUVus mark for TUV Rheinland of North America
	Data Matrix symbol that can be scanned by a barcode reader to obtain a unique device identifier (UDI)
	Environmental Hazard

Symbol	Description
쁍	Ethernet connection
	Explosion Hazard
	Eye Injury Hazard
	Fire Hazard
	Flammable Chemical Hazard
Ţ	Fragile
	Fuse
Hz	Hertz
	International safety symbol "Caution, risk of electric shock" (ISO 3864), also known as High Voltage symbol If the main cover must be removed, then contact a SCIEX representative to prevent electric shock.
	Hot Surface Hazard
IVD	In Vitro Diagnostic Device

Symbol	Description
	Ionizing Radiation Hazard
<u></u>	Keep dry.
Ţ.	Do not expose to rain.
	Relative humidity must not exceed 99%.
<u>     1 1     1     1     1     1 </u>	Keep upright.
	Lacerate/Sever Hazard
	Laser Radiation Hazard
	Lifting Hazard
	Magnetic Hazard
	Manufacturer
	Moving Parts Hazard
	Pacemaker Hazard. No access to people with pacemakers.

Symbol	Description
	Pinching Hazard
	Pressurized Gas Hazard
	Protective Earth (ground)
	Puncture Hazard
	Reactive Chemical Hazard
SN	Serial number
	Toxic Chemical Hazard
66 kPa	Transport and store the system within 66 kPa to 103 kPa.
101 kPa 75 kPa	Transport and store the system within 75 kPa to 101 kPa.
min% max%	Transport and store the system within the specified minimum ( <b>min</b> ) and maximum ( <b>max</b> ) levels of relative humidity, noncondensing.
-30 -30	Transport and store the system within –30 °C to +45 °C.

Symbol	Description
-30°C	Transport and store the system within –30 °C to +60 °C.
•	USB 2.0 connection
s <del>s (</del> •	USB 3.0 connection
	Ultraviolet Radiation Hazard
UK CA	United Kingdom Conformity Assessment Mark
UKRP	United Kingdom Responsible Person
VA	Volt Ampere (apparent power)
V	Volts (voltage)
	WEEE. Do not dispose of equipment as unsorted municipal waste. Environmental Hazard
W	Watts (power)
~	<i>yyyy-mm-dd</i> Date of manufacture

**Note:** If any of the labels used to identify a component become detached, then contact a SCIEX field service employee (FSE).

Label	Translation (if applicable)
FOR RESEARCH USE ONLY. NOT FOR USE	FOR RESEARCH USE ONLY. NOT FOR USE
IN DIAGNOSTIC PROCEDURES.	IN DIAGNOSTIC PROCEDURES.

## **Contact Us**

## **Customer Training**

- In North America: NA.CustomerTraining@sciex.com
- In Europe: Europe.CustomerTraining@sciex.com
- Outside the EU and North America, visit sciex.com/education for contact information.

## **Online Learning Center**

SCIEX Now Learning Hub

## **Purchase Supplies and Reagents**

Reorder SCIEX supplies and reagents online at store.sciex.com. To set up an order, use the account number, found on the quote, order confirmation, or shipping documents. Currently, customers in the United States, Canada, United Kingdom, Belgium, Netherlands, France, Germany, and Switzerland have access to the online store, but access will be extended to other countries in the future. For customers in other countries, contact a local SCIEX representative.

## **SCIEX Support**

SCIEX and its representatives maintain a staff of fully-trained service and technical specialists located throughout the world. They can answer questions about the system or any technical issues that might arise. For more information, visit the SCIEX website at sciex.com or contact us in one of the following ways:

- sciex.com/contact-us
- sciex.com/request-support

## CyberSecurity

For the latest guidance on cybersecurity for SCIEX products, visit sciex.com/productsecurity.

## Documentation

This version of the document supercedes all previous versions of this document.

To see this document electronically, Adobe Acrobat Reader is required. To download the latest version, go to https://get.adobe.com/reader.

#### **Contact Us**

To find software product documentation, refer to the release notes or software installation guide that comes with the software.

To find hardware product documentation, refer to the documentation that comes with the system or component.

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