

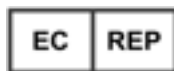
Luminex[®] 200[™] User Manual

For Research Use Only. Not for use in diagnostic procedures.

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Chapter 1: System and Software Introduction

Instrument Overview

The Luminex® 200™ system contains electrical, mechanical, and laser components that, if handled improperly, are potentially harmful.

Luminex® xMAP® Technology is based on flow cell fluorometry with Luminex-developed innovations. The fluidics, optics, robotics, temperature control, software, and xMAP microspheres work together to enable simultaneous analysis of up to 100 analytes in a single test sample. Assay analysis requiring temperature control is provided through the Luminex® XYP™ instrument heater block.

The Luminex 200 is designed to run with xMAP Technology.

Software Overview

xPONENT® software runs, maintains, and troubleshoots the Luminex® 200™ instrument. The software collects, saves, and can export assay data to review the results.

The primary language of the user interface is English. xPONENT uses the host PC's regional settings for displayed time, date, and numeric values. If you choose to export data in U.S. regionalization format only, you can change this setting on the Admin page > CSV Options tab and Admin page > Batch Options tab. Otherwise, data will be exported per your PC's regional settings.

Consumables Overview

Luminex® xMAP® Technology requires two kinds of reagents: common laboratory reagents and reagents created only for Luminex instruments.

Luminex Technical Support

Contact Luminex Technical Support by telephone in the U.S. and Canada by calling: 1-877-785-(2323)

Contact outside the U.S. and Canada by calling: +1 512-381-4397

International: + 800-2939-4959

Fax: 512-219-5114











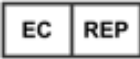






Email: support@luminexcorp.com.



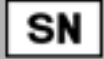



Additional information is available on the Luminex website. Search on the desired topic, navigate through menus. Also, review the website's FAQ section. Enter <http://www.luminexcorp.com> in your browser's address field.

This manual can be updated periodically. To ensure that you have a current version, contact Technical Support.

Symbols Glossary

You will encounter these symbols throughout this manual. They represent warnings, conditions, identifications, instructions, and regulatory agencies.

Symbol	Meaning	Symbol	Meaning
	Caution.		Ionizing Radiation
	Biological risks.		Caution hot surface.
	Puncture/Pinch Point Warning		Burn Hazard/Hot Surface
	Warning Laser Beam.		Hand Crush/Force From Above
	Fuse.		Use-by date.
	Alternating Current.		Authorized representative in the European Community.
	For Research Use Only. Not for use in diagnostic procedures.		Batch Code.
	Conformite Europeenne (EU CE Marking of Conformity) CE conformity marking		Manufacturer.
	Temperature Limit.		Date of manufacture.
	Stand-by Power on/off.		Protective earth; protective ground.

Symbol	Meaning	Symbol	Meaning
	Consult instructions for use.		Catalog(ue) Number.
	Serial number.		TÜV SÜD NRTL Certification Mark.
	WEEE Symbol. Separate collection for electrical and electronic equipment.		UL Mark.

Chapter 2: Regulatory and Safety Considerations

Luminex recommends that all system users become familiar with the specific safety advisories and adhere to standard laboratory safety practices. Biological hazards may be present during system operation.



The system contains electrical and mechanical components that, if handled improperly, can be harmful.

Description

The Luminex® 200™ system is a life science research multiplex test system intended to measure and sort multiple signals generated in an assay from a biological sample. The Luminex 200 system is for research use only and is not for use in diagnostic procedures. The Luminex 200 system is for indoor laboratory and professional use only.

Safety Testing and Certifications

The Luminex® 200™ has been tested and complies with the safety requirements for the United States and Canada and is marked with the UL label or the TUV label. Review the Symbols Glossary to determine what the labels look like.

The Luminex 200 complies with the European Union (EU) safety requirements and therefore may be marketed in the Europe Single Market.

Regulatory and Safety Labels

The following labels appear on the back of the Luminex® 200™ instrument.

Figure 1: Laser Warning Label

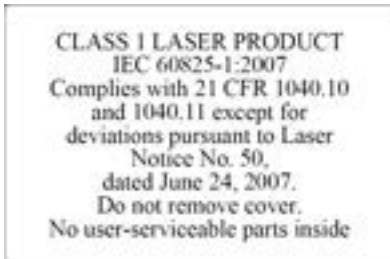
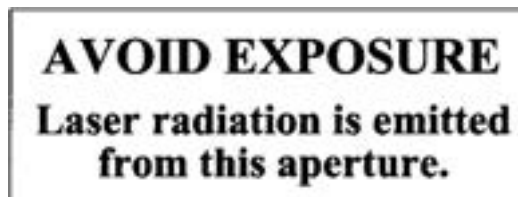


Figure 2: Laser Class Label



The following label appears above the laser apertures located inside the optics enclosure inside the Luminex 200.

Figure 3: Avoid Exposure Label



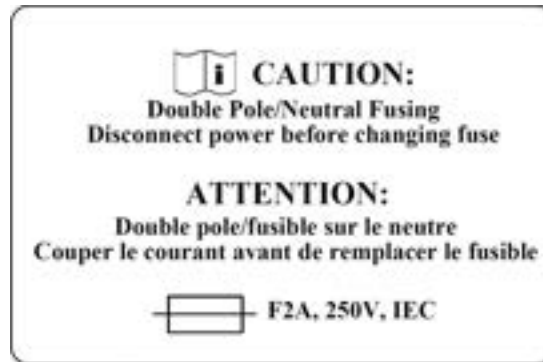
The following label appears on the optics cover inside the Luminex 200.

Figure 4: Optics Laser Label



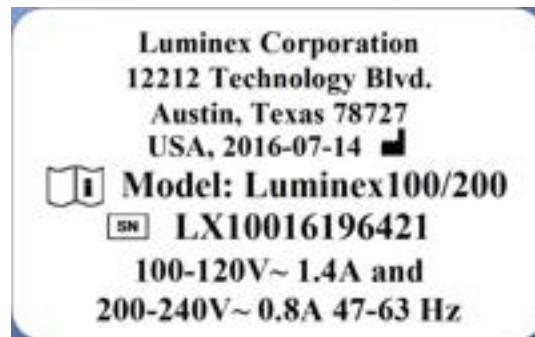
The following fuse caution label appears on the back of the system.

Figure 5: Fuse Caution Label



A voltage label appears on the back of the system and displays the serial number, model number, power requirements, and manufacturer's information.

Figure 6: Serial Number and Voltage Label



Warnings and Precautions



USA Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the State in which he practices, to use or order the use of the device.



In any situation that you encounter a symbol shown below, consult this manual or other Luminex documentation to determine the nature of the potential hazard and any necessary actions you should take.

General Safety




The protection provided by the equipment can be impaired or the warranty voided if the system is used in a manner not specified by the Luminex documentation or by Luminex Corporation.

Mechanical Safety



	<p>The system has parts that move during operation. Risk of personal injury is present. The moving parts present puncture and pinching hazards.</p>
	<p>Keep hands and fingers away from the Luminex® XYP™ instrument slot and sample probe during operation. Observe all warnings and cautions. Keep the access doors closed during normal operations. The operator must be present during operation.</p>

Electrical Safety

	<p>Observe the fuse caution stated on the fuse caution label. Be aware of the instrument voltage.</p>
	<p>Power cords must be replaced with cords of the same type and ratings as originally provided. Contact <i>Luminex Technical Support</i> for correct replacement power cords.</p>


Electromagnetic Compatibility

The Luminex® 200™ complies with the emission and immunity requirements described in IEC 61326-1. The electromagnetic environment should be evaluated prior to operation.


	<p>Do not use this instrument in close proximity to sources of strong electromagnetic radiation, for example, unshielded intentional RF sources, as these may interfere with the proper operation.</p>
	<p>Always handle the instrument according to Luminex instructions to avoid any possible interference from its electromagnetic fields.</p>

Luminex® 200™ Analyzer Laser

The Luminex® 200™ instrument is classified under FDA 21 CFR 1040.10 and 1040.11 as a Class 1 laser product consisting of two Class 3B lasers within the instrument. The accessory barcode reader is classified as Class 2. In accordance with IEC 60825-1:2014, the instrument is classified as Class 1, containing two Class 3B lasers, and including an accessory Class 2 barcode reader. The Luminex 200 complies with IEC 60825-1:2014 and 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

	<p>Under NO circumstances should you remove the Luminex® 200™ analyzer cover. When performing routine maintenance, turn power to the Luminex 200 analyzer OFF and disconnect the power cord.</p>
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All laser apertures are located within the Luminex 200 analyzer and are contained within a protective housing.

	<p>Use of controls or adjustments or performance of procedures other than those specified herein can result in hazardous radiation exposure.</p>
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Barcode Reader Laser

See the barcode reader operating instructions provided with the barcode reader for more safety information.



Do not stare into the barcode reader beam or shine it into other people's eyes.

Heat Safety



The heater plate of the Luminex® XYP™ may be hot and can cause personal injury if touched. Do not touch the heater plate.

Fluids Safety

This system contains fluids. In the event of a fluid leak, turn off all power to the system and disconnect all power cords. The on/off switch is not a method of disconnection; the power cord must be removed from the outlet. Contact *Luminex Technical Support* for further information.

Monitor waste fluid levels manually. Do not allow the waste container to overflow. Empty the waste fluid container each time you replace or fill the sheath fluid container. Do not place the waste fluid container on top of the instrument. Contact *Luminex Technical Support* before relocating the waste fluid container or rerouting the waste line.



Do not operate the instrument in the presence of leaking fluid.

If biological samples have been tested with the system, use your standard laboratory safety practices when handling system waste.

Biohazard/Biological Safety

Human and animal samples may contain biohazardous infectious agents. To avoid pressurization problems, the waste fluid bottle is vented, so beware of biohazardous aerosol material.



Where exposure to potentially biohazardous material, including aerosol, exists, follow appropriate biosafety procedures and use personal protective equipment (PPE). PPE includes gloves, gowns, laboratory coats, face shields or mask and eye protection, respirators, and ventilation devices. Observe all local, state, federal and country-specific biohazard handling regulations when disposing of biohazardous waste material.



Reagents can contain sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. It is also highly toxic and rates a safety data sheet (SDS) health hazard 4. On disposal, flush drains with a generous amount of cold water to prevent azide buildup. Consult the manual guideline "*Safety Management No. CDC-22, Decontamination of Laboratory Sink Drains to remove Azide salts*" (Centers for Disease Control, Atlanta, Georgia, April 30, 1976).

The sheath fluid and the solution in which microspheres are stored contain ProClin®, which may cause an allergic reaction. Use personal protective equipment, including gloves and safety glasses.

NOTE: Do not use strong organic solvents with the system. Contact *Luminex Technical Support* when in doubt about compatibility of cleaning and decontamination agents or materials.

Indicator Light

The blue light above the Luminex[®] 200[™] analyzer sample arm indicates the on/off status of the Luminex 200 analyzer, and is harmless. The blue light-emitting diode (LED) does not emit light in the UV spectrum.

Chapter 3: Performance Specifications and System Components

General System Workflow

The mechanical system. A user places a plate on the plate carrier, which transports the plate into the instrument. The plate carrier moves along the x and y-axis, to allow the sample probe access to each column of the plate. The sample probe assembly moves along the z-axis, allowing the sample probe to access each well of the plate. Between the x and y-axis movement to the plate carrier and the z-axis movement of the sample probe, all wells of the plate are accessible.

The fluidics system. There are two fluidics paths in the Luminex® 200™ analyzer. The first path involves a syringe-driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The syringe-driven system transports a specified volume of sample from a sample container to the cuvette. The sample is injected into the cuvette at a steady rate for analysis. Following analysis, the sample path is automatically purged with Luminex® xMAP® sheath fluid by the second fluidics path. This process removes residual sample within the tubing, valves, and probe. The second fluidics path is driven by positive air pressure and supplies sheath fluid to the cuvette and sample path.

xMAP sheath fluid is the delivery medium of the sample to the optics component. The analysis sample is acquired using a sample probe from a 96-well plate via the Luminex® XYP™ instrument and injected into the base of the cuvette. The sample then passes through with sheath fluid at a reduced rate resulting in a narrow sample core to ensure that each microsphere is illuminated individually. The sample injection rate is such that the xMAP microspheres are introduced to the optics path as a series of single events.

The optics system. The optics assembly consists of two lasers. One laser excites the dye mixture inside the xMAP microspheres and the second laser excites the fluorophore bound to the surface of the xMAP microspheres. Avalanche photo diode detectors measure the excitation emission intensities of the color coding classification dye mixtures inside the xMAP microspheres, and a photomultiplier tube detects the excitation emission intensity of the reporter molecule bound to the surface of the xMAP microspheres. High speed digital signal processors and advanced computer algorithms provide analysis of the xMAP microspheres as they are processed through the Luminex 200 analyzer. Results of the analyses are processed and provided in a report format.

The Luminex® SD™. The Luminex® SD™ system lets you run samples continuously without refilling sheath bottles. It automatically draws sheath from a non pressurized bulk sheath container to constantly maintain a reservoir of pressurized sheath fluid. A single 20 liter sheath container provides enough fluid for 48 hours or more of normal operation.

Environmental Conditions

Luminex® 200™, Luminex® XYP™, and Luminex® SD™

- Indoor and professional use only
- Operating temperature: 15°C to 30°C (59°F to 86°F)
- Shipping and Operating relative humidity: 20% to 80%, non-condensing
- Operating altitude: up to 2400 m (7874 ft) above mean sea level

Performance Specifications

Luminex® 200™ Analyzer General Specifications

- Physical dimensions: 43 cm (17 inches) W x 50.5 cm (20 inches) D x 24.5 cm (9.5 inches) H
- Weight: maximum of 25 kg (60 lbs.)
- Installation Category II
- Pollution Degree 2
- Shipping and storage: The allowable shipping and storage temperature and humidity ranges are 0°C to +50°C and 20% to 80% non-condensing, respectively
- Input voltage range: 100 V to 120 V~ +/- 10%, 1.4 Amp, and 200 V to 240 V~ +/- 10%, 0.8 Amp, 47 Hz to 63 Hz
- AC inlet fuse: 2 Amp, 250 V~, fast acting, IEC Approved

Luminex® 200™ Speed Specifications

- USB connection 2.0
- System calibration: < 10 minutes
- System controls: < 10 minutes
- Barcode reader entry of sample IDs
- Analyze one 96-well plate/hour depending on manufacturer's kit
- Up to 100 xMAP® microspheres sets per sample
- System warm up: 30 minutes. Systems that remain inactive for at least four hours will require a warm up to restart the lasers. After acquiring sample, running system calibrators, running system controls, and warming up the instrument, the system resets the four-hour internal clock.

Accuracy and Precision Specifications

- Sample uptake volume: +/- 5%
- Classification of xMAP® microspheres: > 80%
- Misclassification of xMAP microspheres: ≤ 2% - can vary by xMAP microsphere product lines. Refer to the specific product information sheet for further details.
- Temperature control: +/- 2°C of target

- Internal sample carry over: < 0.9%
- Soluble background fluorescence emission at 575 nm automatically subtracted from fluorescence intensity values

Sensitivity Specifications

- Detect 1000 fluorochromes R-Phycoerythrin (PE) per xMAP® microsphere
- Reporter channel dynamic range: 3.5 decades of detection

Capacity Specifications

The specifications below reflect minimum capacity values:

- Analyze multiple 96-well plates per batch
- Analyze multiple assay templates per plate
- Distinguish a minimum of 1 to a maximum of 100 unique xMAP® microsphere sets in a single sample
- Detect and distinguish surface reporter fluorescence emissions at 575 nm on the surface of 1 to 100 unique xMAP microsphere sets in a single sample
- Sample core: 15 µm to 20 µm core at 1 µL/sec. sample inject rate
- Maintain samples at a constant temperature from 35°C to 55°C (95°F to 131°F)
- Automatic sampling from a 96-well plate
- Start sampling from any well position
- Sheath container and waste fluid container hold enough volume to run up to two 96-well plates between refills

Luminex® XYP™ Instrument General Specifications

- Physical dimensions: 44 cm (17.25 inches) W x 60 cm (23.5 inches) D x 8 cm (3 inches) H
- Weight: 15 kg (33 lbs.)
- Installation Category II
- Pollution Degree 2
- Heater operating range: 35°C to 55°C (95°F to 131°F) with tolerance +/- 2°C
- Input voltage range: 100 V to 240 V~ +/- 10%, 1.8 Amps, 47 Hz to 63 Hz
- AC inlet fuse: 2 Amp, 250 V~, fast acting, IEC Approved

Luminex® SD™ System General Specifications

- Physical dimensions: 20 cm (8 inches) W x 30 cm (11.75 inches) D x 24.75 cm (9.75 inches) H
- Weight: 9 kg (20 lbs)
- Installation Category II
- Pollution Degree 2
- Input voltage range: 100 V to 240 V~ +/- 10%, 0.4 Amps, 47 Hz to 63 Hz
- AC inlet fuse: 2 Amp, 250 V~, time lag, IEC Approved

Electronics Specifications

- Reporter channel detection: A/D resolution 14 bits
- Communications interface: USB
- Luminex® XYP™ instrument, communications interface: RS 232
- Luminex® SD™ communication cable

Optics Specifications

- Reporter laser: 532 nm, nominal output 10 mW to 15 mW maximum 500 mW, frequency-doubled diode; mode of operation, continuous wave (CW)
- Classification laser: 635 nm, 9.1 mW +/- 6% , maximum output 25 mW, diode; mode of operation, continuous wave (CW)
- Reporter detector: Photomultiplier tube, detection bandwidth of 565 nm to 585 nm
- Classification detector: Avalanche photo diodes with temperature compensation
- Doublet discrimination detector: Avalanche photo diodes with temperature compensation

Plates Specifications

- Plate must be 96-well, not to exceed 1 inch (2.54 cm) in height, including heater block.
- Plate must be compatible with the heater block temperature when the heater block is in use.
- All plates have standard width (85.5 mm) and length (127.9 mm).
- Depth varies depending on the type of well. Maximum allowable depth is 1 inch (2.54 cm).
- Plates must have minimum 0.06 inch (1.5 mm) lip height, standard distance from well center to well center (9 mm) and standard distance from A1 center to plate center in both length and width.
- To be compatible in size with the heater block, the plate must fit into the heater block so that the top is flush with the heater block.
- Plates with 96 wells must be compatible with the Luminex® XYP™ instrument plate holder.
- The following plate types are compatible with the Luminex XYP instrument plate holder: flat-bottom, conical, round, filter bottom, half plates, overall height no more than 0.75 inch (19 mm), any color.
- Plates with 96 wells must be compatible with Luminex XYP instrument heater block temperature from 35°C to 55°C (95°F to 131°F) when performing heated assays and using the heater block.

System Components

The three components of the Luminex® 200™ system are: software, hardware, and reagents.

Software Component

xPONENT® software provides complete control of the system and performs the analysis. The software requires a dedicated PC. For updated information about the PC or operating system, refer to the software release notes, or access <http://www.luminexcorp.com>.

Under most circumstances, the PC that comes with the Luminex® 200™ system is preloaded with xPONENT for Luminex 200 software. Luminex provides software on media to use if you need to reinstall the software or need to install it on another computer.

The software media automatically installs the 21 CFR and Security modules on a temporary license. The 21 CFR and Security modules are only active for 90 days. If you do not purchase a permanent license key for 21 CFR and Security modules, then you will not need a user ID and password to access the basic functions of the software. Contact *Luminex Technical Support* if you choose to purchase the 21 CFR and Security Modules.



If you need to uninstall the software, follow the procedure provided by *Luminex Technical Support*.

The software is documented in online help, which can be accessed from within the application itself, in PDF form, which is available on the Luminex website, and on media included with the shipped system.



Luminex recommends that you do not install additional software on the PC that runs xPONENT, with the exception of Adobe Acrobat. Acrobat is required to view the PDFs and is included on the installation DVD. The operation of xPONENT for Luminex 200 has been validated only when it is the only program running on the dedicated PC.

Hardware Components

The Luminex® 200™ system includes the following hardware:

- Luminex 200 analyzer
- Luminex® XYP™ instrument
- Luminex Sheath Delivery System (Luminex® SD™)
- Power connector cables
- Two long sample probes
- XYP Reagent Reservoir
- Probe Shield
- Heater block
- Empty sheath bottle
- Waste bottles
- Sheath fluid container
- Waste container
- Sheath fluid line
- Air line
- sheath fluid intake line
- Communications: 1 serial "RS232" communication cable
- Communications: 1 serial "RS232 to USB" communication cable OR 1 USB communication cable
- Communications: 1 CAN-bus cable
- Barcode reader (optional)
- Sample probe height alignment kit (optional)
- Automated Maintenance Plate (AMP) (optional)

Consumable Components

xMAP® Technology Reagents



Adhere to standard laboratory safety practices when handling hazardous, toxic, or flammable reagents and chemicals. Contact *Luminex Technical Support* when in doubt about compatibility of cleaning and decontamination agents or materials.

Only use reagents, assays, or other consumables that are within their expiration date. Dispose of all expired reagents, assays, or consumables in the appropriate waste fluid container.

- Calibration Kit (CAL) - PN: LX2R-CAL-K25
- Verification Kit (VER) - PN: LX2R-PVER-K25
- Luminex® xMAP® sheath fluid - PN: 40-50015

Required Laboratory Reagents

- 10% to 20% household bleach
- 70% isopropanol or 70% ethanol solution
- Mild detergent
- Distilled water



Isopropanol and ethanol are flammable liquids. Keep them away from heat, open flames, and sparks in a well-ventilated area. Remove them from the instrument when they are not in use.

Subsystems

Mechanical Subsystem

Air Intake Filter

A replaceable air intake filter cleans the air used to pressurize the sheath fluid. The air intake filter is enclosed behind an access door located on the back of the Luminex® 200™ analyzer.

Luminex® 200™ Analyzer Ventilation Filter

The Luminex® 200™ analyzer ventilation filter is located on the bottom of the Luminex 200 analyzer. The Luminex 200 analyzer ventilation filter must be checked and cleaned as necessary. For proper ventilation, do not obstruct the area below the Luminex 200 analyzer ventilation filter, and allow at least two inches (5 cm) of clearance around the Luminex 200 analyzer.

Luminex[®] XYP[™] Instrument Ventilation Filter

The Luminex[®] XYP[™] instrument ventilation filter cleans the air that cools the internal parts of the Luminex XYP instrument.

Electrical Subsystem

The electrical subsystem provides the power for operation and control of the Luminex[®] 200[™] system and communication between its parts.

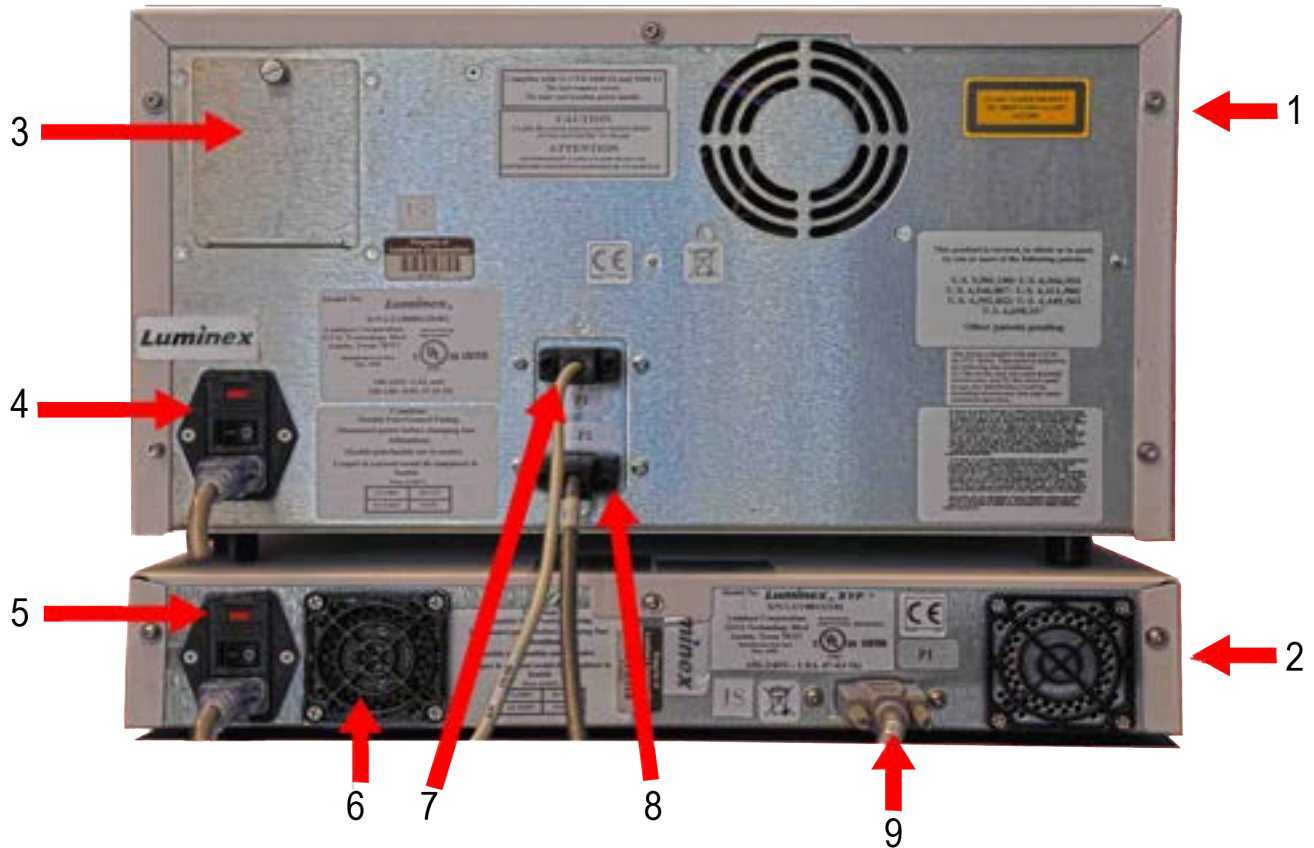
Power Input Module

The power input modules contain the on/off switch and fuses.

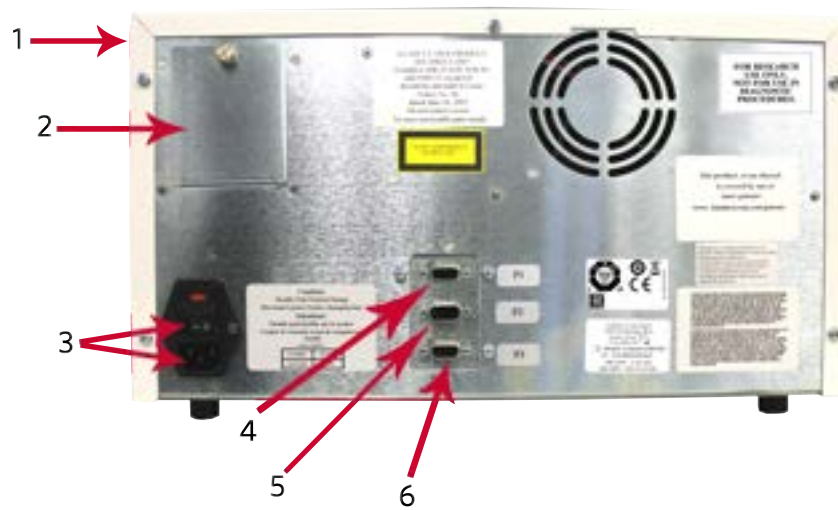
Communications Ports (DB9-PIN)

The communications ports connect the PC to the Luminex[®] 200[™] analyzer, Luminex 200 analyzer to the Luminex[®] XYP[™] instrument, and the Luminex[®] SD[™] system to the Luminex 200 analyzer.

Figure 7: Luminex 200 Analyzer Connections - Configuration A



1.	Luminex® 200™ Analyzer	6.	Luminex® XYP™ ventilation filter
2.	Luminex® XYP™ Instrument	7.	USB cable communication
3.	Air intake filter access door	8.	Luminex® SD™ communication cable
4.	Luminex® 200™ Analyzer power outlet and on/off switch	9.	Luminex® XYP™ communication cable
5.	Luminex® XYP™ power outlet and on/off switch.		

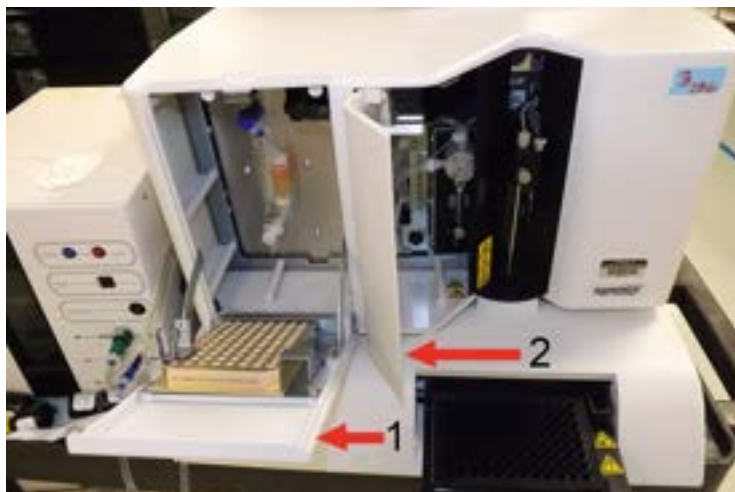
Figure 8: Luminex 200 Analyzer Connections - Configuration B

1.	Luminex [®] 200 [™] Analyzer	4.	USB communication port
2.	Air intake filter access door	5.	Luminex [®] SD [™] communication port
3.	Luminex [®] 200 [™] Analyzer power outlet and on/off switch	6.	Luminex [®] XYP [™] communication port

Fluidics Subsystem

Access Doors

The Luminex[®] 200[™] analyzer has three access doors. Two of the access doors are on the front, and the third is on the back. The front left access door supplies access to the sheath filter. The front center access door supplies access to the syringe. The rear access door supplies access to the air intake filter.

Figure 9: Luminex 200 Analyzer Access Doors

1. Left door, access to service panel

2. Center door, access to syringe

Sample Probe

A stainless steel sample probe acquires the sample.



During operation, this system contains exposed moving parts that can result in a puncture hazard. Risk of personal injury is present. Keep hands and fingers away from the sample probe. The shield should be in place.

Cheminert® Fitting

This Cheminert® fitting attaches the sample probe to the sample tubing. Disconnect the Cheminert fitting when you remove the sample probe.

Figure 10: Fluidics Components

1.	Cheminert® fitting	3.	Front thumbscrew
2.	Probe holder	4.	Sample probe

Syringe

The syringe allows for the fluidic drive to deliver a sample, acquired by the sample probe, from the 96-well plate to the cuvette.

Figure 11: Syringe

Proper Placement of the Luminex® SD™

For proper operation, place the Luminex® SD™ system at the same level as the base of the Luminex® XYP™ instrument. Do not put it on top of the Luminex® 200™ analyzer. If you are not using the Luminex SD system, sheath fluid levels must be monitored manually. Check the sheath fluid level before starting a run or procedure.

Sheath Filter

The sheath filter removes particles greater than 10 microns in diameter from the sheath fluid.

Waste Fluid Container

The waste fluid container receives waste from the system. To maintain a stable flow rate, do not move the waste line or waste fluid container during system operation and make certain the waste fluid container is properly vented. Contact *Luminex Technical Support* before you relocate the waste fluid container.



If biological samples have been tested with the system, use your standard laboratory safety practices.



The waste fluid container should not be placed on top of the instrument. Ensure that the waste tubing is not elevated above the level of the Luminex® 200™ at any point.

Waste levels must be manually monitored. Do not allow the waste fluid container to overflow.

Air, Waste, and Sheath Fluid Connectors

The air, waste, and sheath fluid connectors, located on the left side of the analyzer, connect to the Luminex® SD™ system and waste fluid containers using clear tubing. The air connector is green, the sheath fluid connector is blue, and the waste fluid connector is orange.

Optical Subsystem

The optical subsystem consists of the optical assembly and the excitation lasers. The optical components do not require manual adjustment by the user.

PC Specifications

For updated information regarding the PC operating system, go to: www.luminexcorp.com.

Recommended Additional Equipment

Successful operation of the system may require additional equipment.

Uninterruptible Power Supply (UPS) or Surge Protector - Luminex recommends using either an uninterruptible power supply (UPS) or a surge protector to protect your system from power outages. Use a UPS that provides 1050 Watts for at least 45 minutes. Choose a surge protector that fits the requirements for electrical environment, endurance, suppressed voltage rating, and method of protection. The surge protector requires three outlets and a minimum rating of 1500 Watts. Both pieces of equipment should include appropriate safety certification marks for your region, for example, Underwriters Laboratory (UL) or a similar listing body, certified by Canadian Standards Association (CSA), or Conformité Européenne (CE) for non-domestic use. The UPS should be CE marked when used internationally.

Printer - Use a printer compatible with the version of Microsoft® Windows® running your PC with xPONENT®. Refer to the xPONENT release notes for the specific version of Windows.

Barcode Labels - Use Code 128 barcode label type when scanning barcode labels into the system.

Vortex - Use VWR product number 58816-12, with a speed range of 0 to 3200 rpm, or equivalent.

Bath Sonicator - Use Cole-Parmer® product number 08849-00, with an operating frequency of 55 kHz, or equivalent.

Chapter 4: Preparing the System

xPONENT® for Luminex® 200™ contains pre-defined routines to prepare the instrument for data acquisition.

Power on the System

To power on the Luminex® 200™ and Luminex® XYP™:

1. Plug the power cord from the back of the instruments into a power outlet.
NOTE: Luminex recommends the use of a surge protector or UPS device.
2. Turn on the power switch, which is located at the lower left back corner of the Luminex 200 and Luminex XYP. Blue LEDs will light up on the front of the instruments to indicate they are powered on.
NOTE: The power switch controls flow of power to the instruments.
 - a. If you have a Luminex® SD™, plug the power cord into a power outlet, and turn on the power switch, located at the lower left back corner of the instrument.

Log into the Software

If you ordered a PC from Luminex, xPONENT® will be installed with 21 CFR and Security Modules on a temporary license. Use the default user ID and password to access the software:

User ID: admin

Password: xponent

Once an application administrator updates the user ID and password, the default user ID and password will not be active.

The 21 CFR and Security modules are only active for 90 days. If you do not purchase a permanent license key for 21 CFR and Security modules, then you will not need a user ID and password to access the basic functions of the software.

NOTE: Contact *Luminex Technical Support* if you have problems logging on. If you want to purchase a license for 21 CFR Part 11 or the security module, contact Luminex to place an order.



Use of this software by untrained personnel can result in inaccurate data and test results. Users of xPONENT must read the documentation thoroughly before operating the software.

1. On the PC desktop, double-click the Luminex xPONENT icon.

2. If this is the first time you have started the software, read the User License Agreement. Select **I accept the terms of this license agreement**, then click **OK**.
3. Enter your User ID on the **System Login** tab.
4. Enter your password if you are using a secure version of the software.
5. Click **Log In**. The **Home** page displays.

Adjust the Sample Probe Height

Adjust the sample probe height to ensure that the sample probe drops far enough in the well to acquire sample.

Adjust the sample probe height:

- as part of weekly maintenance,
- if the sample probe is removed and replaced for troubleshooting or cleaning purposes, or
- if sample acquisition is slow or sporadic.

NOTE: If the probe height is adjusted for use with a round or flat bottom plate, the probe height does not have to be readjusted for use with the verification strip well in the Automated Maintenance Plate.

NOTE: Readjust probe height for all other plates.



Problems with the sample probe height can lead to fluid leaks and inhibit sample acquisition.

Ensure that the sample probe height is set correctly before calibrating the system.

1. From the **Home** page, under **Daily Activities**, click **Probe and Heater**.
 2. Remove the clear plastic shield that covers the sample probe area.
 3. On the **Probe and Heater** tab select a well on the plate image. A green pin marks the selected well.
 4. In a 96-well plate where overall height is no more than 19 mm (0.75 inches), place the appropriate alignment tool in the plate.
 - For a standard plate with flat-bottom wells - stack two of the larger (5.08 mm diameter) alignment discs together and place them into the selected well.
 - For a filter bottom plate - stack three of the larger (5.08 mm diameter) alignment discs together and place them into the selected well.
 - For a plate with conical wells (v-bottom) - place one alignment sphere into the selected well.
 - For a round-bottom (U-bottom) plate - stack two of the smaller (3.35 mm diameter) alignment discs in the selected well.
 - For a half-volume plate with flat-bottom wells - stack two of the smaller (3.35 mm diameter) alignment discs together and place them into the selected well.
- NOTE:** Verify that the plate is not warped. Warped plates can lead to incorrect sample probe height adjustment.
5. Click **Eject**.
 6. Place the 96-well plate on the Luminex® XYP™ plate holder with A1 in the top left corner.
 7. Verify that the correct well location is selected in xPONENT, and that you are using the appropriate number of alignment discs or sphere.

8. Click **Retract**.
9. Loosen the front thumbscrew on the probe holder one-third to one-half turn. Pull the sample probe upward until it touches the top of the adjustment slide. Tighten the thumbscrew.
10. Click **Move Probe Down** to lower the sample probe.
11. Loosen the front thumbscrew. Gently push the sample probe down until it just touches the top of the alignment discs or sphere.
12. Tighten the front thumbscrew.
13. Using xPONENT, raise the sample probe. Replace the clear plastic shield to cover the sample probe area.

Run the Revive After Storage Routine

NOTE: The Revive After Storage routine is necessary when the system runs for the first time and is recommended when the system has been idle for more than a week.

After you have adjusted the sample probe height, run the Revive After Storage (Luminex) routine.

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. From the **Routine Name** drop-down menu, choose **Revive After Storage (Luminex)**. The Revive After Storage routine performs the following commands:
 - Warmup
 - Backflush (x2)
 - Drain (x3)
 - Alcohol Flush (x2)
 - Backflush
 - Wash (x3)
3. Click **Eject**.
4. Fill reservoir RA1 3/4 full of 70% isopropanol or 70% ethanol.
5. Fill the appropriate well 3/4 full of DI water.

NOTE: The drain well should be empty.

6. Click **Retract**.
7. Click **Run**.

Import Calibration or Performance Verification Kits

1. Load the CAL/VER CD (provided with the kit) on the computer.
2. From the **Home** page, click **System Initialization**.
3. Click **Import Kit** at the bottom right side of the window. The **Import Calibration or Performance Kit** dialog box opens.
4. Navigate to the kit folders and choose the *.lxl file and click **Open**.
5. Click **OK**.

Delete Calibration or Performance Verification Kits

1. Navigate to the **Maintenance** page > **Lot Management** tab.
2. In the **Active Reagents** section, choose the kit you want to delete from the Calibration Kit or Performance Verification Kit drop-down menus.

3. Click **Delete Kit**.
4. Click **OK** in the **Delete Kit** dialog box to confirm you want to delete the kit.

Calibrate the System

Calibration is important to ensure the optical system functions effectively and different Luminex[®] 200[™] systems report similar results. Calibrating the Luminex 200 system normalizes the settings for the classification channels (CL1 and CL2), the doublet discriminator (DD), and the reporter channel (RP1). Use the Luminex 200 Calibration Kit to calibrate the system. After calibration, perform verification. Following calibration, use the Luminex[®] 200[™] Performance Verification Kit to check all of the optical channels in the system for correct calibration. Be sure to verify every time you calibrate. If there is a problem with optical alignment or fluidics, Luminex 200 may pass calibration but fail performance verification.

If the system is not fully calibrated, a warning message displays. Track the system calibration and verification results through the Calibration and Verification report. Target value information for calibration and verification microspheres is available on the media that comes with the calibration kit and on the Luminex website at www.luminexcorp.com.

Calibrate the system at least once a week using the Calibration Verification button on the Maintenance page > Auto Maint tab. In addition, recalibrate the system if any of the following occur:

- The delta calibration temperature exceeds +/- 3°C.
- The instrument is moved.
- You experience sample acquisition problems.
- The instrument undergoes hardware maintenance, such as replacement of a part.

Control xMAP[®] microspheres are used to verify the calibration and optical integrity for the system. Do not dilute calibrators or controls.

NOTE: Ensure the lasers are warmed up before starting calibration.

1. From the **Home** page, click **System Initialization**. The **Auto Maint** tab displays.
2. Select **Calibration Verification** option under **Automated Maintenance Options**.
3. Choose the appropriate calibration kit from the drop-down menu.
4. Click **Eject**.
5. Add two clean strip wells into the Automated Maintenance Plate.

NOTE: The plate layout in the software indicates reagent locations.

6. Fill the appropriate reservoirs 3/4 full of DI water and 3/4 full of 70% isopropanol or 70% ethanol.

NOTE: The plate layout in the software indicates reagent locations.

7. Invert the bottle and add five complete drops of each calibration reagent to the first strip well. (CAL1, MCAL1, and CAL2)
8. Add five complete drops of each performance verification reagent (CON1, MCON1, CON2, Fluidics1, and Fluidics2) to the second strip well.

NOTE: Luminex recommends checking the label on the bottles to ensure you are dispensing the correct reagents.

9. Click **Retract**.
10. Click **Run**. Once complete, click **OK**.

Verify the System

The Luminex® 200™ Performance Verification Kit includes reagents to verify the calibration and optical integrity for the Luminex 200 system as well as reagents to verify the fluidics channels using observations of pressure, flow rate, and well-to-well carryover.

Run the Performance Verification routine as part of your daily startup routine. Refer to your assay kit instructions for additional calibration frequency requirements.

Verification uses system controls to ensure that the instrument is functioning properly with current calibration settings.

NOTE: Ensure the lasers are warmed up before starting calibration.

1. From the **Home** page, click **System Initialization**. The **Auto Maint** tab displays.
2. Select the **Performance Verification** option under **Automated Maintenance Options**.
3. Choose the appropriate performance verification kit from the drop-down menu.
4. Vortex the performance verification reagents for approximately 10 seconds to ensure homogeneity. Do not dilute the xMAP verification or fluidics agents
5. Click **Eject**.
6. Add one clean strip well to the second strip well location into the Automated Maintenance Plate .
NOTE: The plate layout in the software indicates reagent locations.
7. Fill the appropriate reservoirs 3/4 full of DI water and 3/4 full of 70% isopropanol or 70% ethanol.
NOTE: The plate layout in the software indicates reagent locations.
8. Completely invert the bottle and add 5 complete drops each of the performance verification reagents (CON1, MCON1, CON2, Fluidics1, and Fluidics2) to the second strip well.
NOTE: The plate layout in the software indicates reagent locations.
NOTE: Luminex recommends checking the label on the bottles to ensure you are dispensing the correct reagent.
9. Click **Retract**.
10. Click **Run**.

Chapter 5: Running the Assay

General Software Guidelines

Modifying or deleting xPONENT® system files can cause degradation of system performance. Repair modified or deleted xPONENT system files by uninstalling and re-installing the xPONENT software. Luminex recommends that you contact *Luminex Technical Support* before uninstalling and reinstalling xPONENT.



Using unauthorized third-party software with xPONENT software can result in corruption or failure of the xPONENT software. Use third-party software at your own risk. The operation of the system software is validated only when it runs alone on the dedicated PC.

If you are using a screen saver on the PC on which xPONENT is installed, xPONENT prevents it from activating. A dialog box opens each time xPONENT is launched, recommending that the screen saver and any power management settings be turned off.

Plates

Follow these guidelines when choosing plates:

- When using uncovered plates, use black opaque plates, if possible, to reduce photobleaching.
- For heated assays, use Costar® Thermowell® 96-well, thin-wall polycarbonate, model P plates.
- For non-heated assays, select a 96-well plate with an overall height no greater than 0.75 inches (19 mm).



The heater block or plate can be hot and can cause personal injury when touched. Use care when you are working with it and do not touch it.

Define the Protocol

NOTE: When running a kit with a provided protocol, the protocol for the assay must be run as instructed in the assay's package insert.

Create a New Protocol

1. Navigate to the **Protocols** page > **Protocols** tab > click **Create New Protocol**.

2. On the **Settings** subtab, fill in the details of the assay for proper analysis.
 - a. Enter the **Name** of the protocol.
 - b. The **Version** field defaults to 1.
 - c. Enter the **Manufacturer**.
 - d. Enter a **Description**.
 - e. Enter the **Volume** for the instrument to aspirate into the system.
 - f. Select **Enabled** to enable the **XY Heater** and then enter the value in **degrees C**.
 - g. Select **Enabled**, to enable **Timeout** and then enter the amount in **seconds** the instrument will try to acquire the sample.
 - h. For **Bead Type**, choose **Microplex®** or **MagPlex®**.
 - i. For **DD Gating**, enter the minimum and maximum value.
 - j. For **Reporter Gain**, choose **Default** or **PMT (High)**.
 - k. For **Analysis Type**, choose the type of protocol you want - **None**, **Qualitative**, or **Quantitative**.
 - l. If you chose quantitative analysis type, enter the **Number of Standards** that apply to the protocol. If you chose qualitative analysis type, the field defaults to 1 and is un-editable.
 - m. If you chose qualitative or quantitative analysis type, enter the **Number of Controls** that apply to the protocol.
 - n. If you chose quantitative analysis type, select the option of **Fit of All Standards** or **Mean of Replicates** to apply to the protocol.
 - o. Select **Analyze results while acquiring samples** to view the results while the samples are being analyzed.
 - p. Select **Use External Analysis Program**, if you plan to use an external analysis program to analyze the results.
 - i. If you chose to use an external analysis program, the **Analysis Program** drop-down menu enables for you to choose a program.
 - q. Once all the settings have been chosen on the **Settings** subtab, click **Next**.
3. On the **Analytes** subtab, fill in the details of the assay for proper analysis.
 - a. Select the analytes in the analytes grid.
 - b. For **Default Analysis**, click **Change** to change the default analysis.
 - c. For **Units**, enter the desired units for the analytes. If the units applies to all analytes, click **Apply All**.
 - d. For **Count**, enter the desired bead count the instrument will analyze from the sample until it has reached the count chosen for each bead region. If the bead count applies to all analytes, click **Apply All**.
 - e. If you want to stop acquisition once a certain number of beads have been counted, then select the option and enter the number for when you want the instrument to stop acquiring beads.
 - f. Click in the **Name** field of each analyte, and enter a new name if you choose.
 - g. Once you are done setting up the **Analytes** tab, click **Next**.
4. On the **Plate Layout** subtab, fill in the details of the assay for proper analysis, or click **Save** if you chose **None** for the analysis type.
 - a. Select the wells in the plate image, assign well commands to the selected wells, and then choose the **Replicate Count** and **Grouping**.
 - b. If you have more than one plate, click **Add Plate** to add another plate.
 - c. Choose the **Direction** to run the plate commands.
 - d. Click **Import List** to import an existing command sequence list.
 - e. Click **Save**.

Edit Quantitative Analysis Settings

1. Navigate to the **Protocols** page > **Protocols** tab.
2. Choose a quantitative protocol from the **Installed Protocols** list and click **Edit**.
3. If desired, enter a new protocol name and description in the appropriate fields.
4. Enter a new version number in the **Version** field.
5. Edit the manufacturer if needed.
6. Edit the **Acquisition Settings** and **Analysis Settings** as necessary.
7. Click **Next** to display the **Analytes** subtab.
8. From the **Analytes** subtab, click an analyte's **Analysis** field to open the **Analysis Settings** dialog box, and edit as needed.
 - a. Choose an analysis method in the **Method** drop-down menu.
 - b. Choose a weight type in the **Weight Type** drop-down menu (Weight Type may not display, depending on the analysis method selected in the **Method** list).

NOTE: If you want an analyte to be an Intra-Well Normalization Bead, select **Mark as Intra-Well Normalization Bead**. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run.
 - c. Click **OK** to apply the new settings to only the analyte selected, or **Apply to All Analytes** to apply the settings to all of the analytes in the protocol.
9. If you want to use a range for the analysis, click the **Analysis** field for the analyte you want to modify. The **Analysis Settings** dialog box displays.
 - a. Select **Use Threshold Ranges** if you want to use a range for the analysis.
 - b. Click **Add Range** to setup the threshold range.
 - c. Enter a name for the range in the **Range Name** field.
 - d. Enter low and high range values in the **Low Value** and **High Value** fields.
 - e. Select the check box in the **Inclusive** columns to include the value in the range, or leave it clear to make the range value one unit higher than the low value, and one unit lower than the high value.
 - f. If you need to delete a range, highlight a range and click **Delete Range**.
 - g. Click **OK** to apply the threshold range to the analyte.
10. Click **Next**. The **Plate Layout** subtab displays.

11. Assign commands and routines to the plate layout.
12. Click **Save**.

The screenshot shows the 'Analysis Settings' dialog box for 'Analyte 12'. The 'Method' dropdown is set to 'Logistic 5P' with the formula $y = a + (b-a)/(1 + \exp(-cx/dg^f))$. The 'WeightType' dropdown is set to '1/n^2'. There are checkboxes for 'Mark as Intra-Well Normalization Bead' and 'Use Threshold Ranges'. Below these is a table for 'Threshold Ranges' with columns: Range Name, Low Value, Inclusive, High Value, Inclusive. At the bottom are 'Add Range' and 'Delete Range' buttons, and 'OK' and 'Cancel' buttons. Red arrows point from labels on the left to the 'Method', 'WeightType', 'Mark as Intra-Well Normalization Bead', 'Use Threshold Ranges', 'Range Name' (in the table header), and 'Add Range' buttons. A red arrow on the right points to the 'Apply to All Analytes' button.

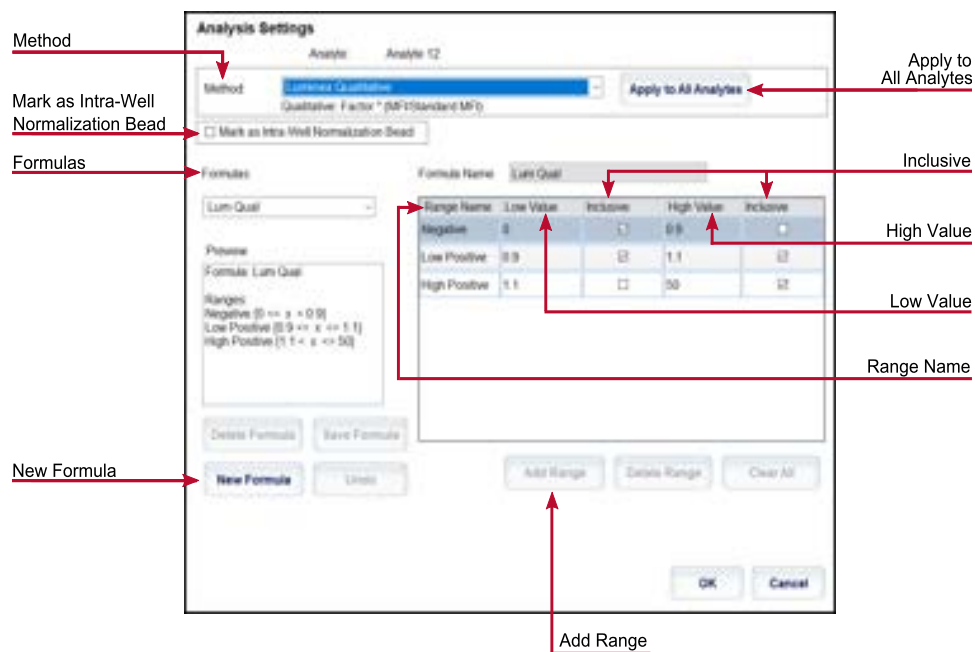
Edit Qualitative Analysis Settings

1. Navigate to the **Protocols** page > **Protocols** tab.
2. Choose a qualitative protocol from the **Installed Protocols** list and click **Edit**.
3. If desired, enter a new protocol name and description in the appropriate fields.
4. Enter a new version number in the **Version** field.
5. Edit the manufacturer if needed.
6. Edit the **Acquisition Settings** and **Analysis Settings** as necessary.
7. Click **Next** to display the **Analytes** subtab.
8. From the **Analytes** subtab, click an analyte's **Analysis** field to open the **Analysis Settings** dialog box.
 - a. Choose **Luminex Qualitative** or **No Analysis** from the **Method** drop-down menu.

NOTE: If you want an analyte to be an Intra-Well Normalization Bead, select **Mark as Intra-Well Normalization Bead**. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run. Click **OK** or continue with the steps.

- b. Choose **Lum Qual**, **Adv Qual**, or another saved formula, from the **Formulas** drop-down menu.
- c. Click **New Formula** to add a new formula.
 - i. Edit the name in the **Formula Name** field.

- ii. If you chose **Lum Qual** in the **Formulas** drop-down menu, edit the values for each range under **Negative**, **Low Positive**, and/or **High Positive**. If you chose **Adv Qual** in the **Formulas** drop-down menu, edit **Negative**, **Low Positive**, **Moderate Positive**, and/or **Strong Positive**.
 - iii. Select the check box in the **Inclusive** columns to include the value in the range. If you clear the check box, the value will be one unit higher than the low value, and one unit lower than the high value.
 - iv. Click **Add Range** if you want to add a new range.
 - v. Enter a **Range Name**, **Low Value**, **High Value**, and select or clear the **Inclusive** check boxes.
 - d. If you want to delete a range, highlight the range, and click **Delete Range**.
 - e. Click **Save Formula**. The new formula displays in the **Formulas** drop-down menu.
 - f. Click **Apply to All Analytes** to apply the settings to all of the analytes in the protocol, or click **OK** to apply the new formula to the single analyte you selected.
9. Click **Next**. The **Plate Layout** subtab displays.
 10. Assign commands and routines to the plate layout.
 11. Click **Save**.



Import a Protocol

1. Navigate to the **Protocols** page > **Protocols** tab.
2. Click **Import**.
3. In the **Open** dialog box, choose a protocol file (.lxt2) to import, then click **Open**.
4. In the **Imported Protocol File** dialog box, click **OK**. The imported protocol displays in the **Installed Protocols** section.

Export a Protocol

1. Navigate to the **Protocols** page > **Protocols** tab.
2. Choose a protocol.
3. Click **Export**.

4. In the **Save As** dialog box, choose a location to export the file to, and click **Save**.
5. In the **Export File** dialog box, click **OK**.

Delete a Protocol

1. Navigate to the **Protocols** page > **Protocols** tab.
2. Choose a protocol.
3. Click **Delete**.
4. In the **Delete Protocol** dialog box, click **Yes**.

Define the Standards and Controls

Standards and Controls

Assay kits may include standards and/or controls. After you enter the assay kit information, it can be used in multiple protocols. For assay reagents specified in protocols, you can create new lots, edit lot information, select pre-existing lots for reuse, import lots, and export lots.

On the **Stds &Ctrls** tab in the **Installed Kits And Lots** section, before deleting, exporting, importing, or editing a kit and/or lot, select the correct radio button for **Std/Ctrl Kits Only** or **All Lots**. Selecting **All Lots** will display all standard and control reagents and any associated Std/Ctrl Kit.

Once a lot is used, changing or modifying the lot will prompt you for a new lot or name.

Create a Standard/Control Kit

To create a standard and control kit, you must use a protocol that uses either Quantitative or Qualitative analysis settings; complete the following:

1. Navigate to the **Protocols** page > **Protocols** tab.
2. Select the protocol that you want to use for the kit, then click **New Std/Ctrl**. The **Std/Ctrl Details** subtab displays.
3. Enter the name of the kit in the **Name** field, the lot number in the **Std/Ctrl Kit Lot #** field, the expiration date using MM/DD/YY format in the **Expiration** field, and the manufacturer in the **Manufacturer** field.
4. Click **Apply Std Lot** if you want to apply a standard lot. The **Select Lot** dialog box displays.
 - a. Choose a lot and click **OK**.
5. Click **Apply Ctrl Lot** to apply a control lot. The **Select Lot** dialog box displays.
 - a. Choose a lot and click **OK**.
6. Alternatively, enter the appropriate information in the **Assay Standard Information** and **Assay Control Information** sections. The number of standards, controls, or both in these sections is defined in the protocol. If your batch uses controls, enter values for **Expected**, **Low** and **High** from the **Show Concentration** options. To apply the same values to multiple analytes, use the **Apply Values** arrows to apply values down or across the range of analytes.
7. Click **Save**.

Create a Standard/Control Lot

To create a standard and control lot, you must use a protocol that uses either Quantitative or Qualitative analysis settings; complete the following:

1. Navigate to the **Protocols** page > **Stds & Ctrls** tab > click **Create New Std/Ctrl Lots**.
 - a. In the **Select Protocol** dialog box, choose the protocol you want to use for this lot, then click **OK**. The **Std/Ctrl Details** subtab displays.
 - b. Click **Apply Std Lot** if you want to apply a standard lot. The **Select Lot** dialog box displays.
 - i. Choose a lot and click **OK**.
 - c. Click **Apply Ctrl Lot** to apply a control lot. The **Select Lot** dialog box displays.
 - i. Choose a lot and click **OK**.
2. Enter the appropriate information for each standard in the **Assay Standard Information** section.
3. In each analyte column, enter the expected concentration for the analyte. To apply the same values to multiple analytes, use the **Apply Values** arrows to apply values down or across the range of analytes.
4. To apply a dilution, choose the value or create a dilution, then click **Apply Dilution**.

NOTE: The Dilution list and Apply Dilution button only display if a quantitative analysis has been selected.
5. If your batch uses controls, enter the appropriate information for each control in the **Assay Control Information** section.
6. Enter values for **Expected**, **Low**, and **High** from the **Show Concentration** options. To apply the same values to multiple analytes, use the **Apply Values** arrows to apply values down or across the range of analytes.
7. Click **Save**.

Import a Kit/Lot

1. Navigate to the **Protocols** page > **Stds & Ctrls** tab > click **Import**.
2. In the **Open** dialog box, navigate to the location that you want to import from and click **Open**.

Edit a Kit/Lot

1. Navigate to the **Protocols** page > **Stds & Ctrls** tab.
2. In the **Installed Kits And Lots** section, choose a kit or lot and then click **Edit**.
3. If you chose a kit, edit the information as appropriate on the **Std/Ctrl Details** subtab.

NOTE: If you choose to edit a standard lot, then only the Assay Standard Information section is editable. If you choose to edit a control lot, then only the Assay Control Information is editable.

- a. To apply the standard lot and control lot to a kit, enter the name of the kit in the **Name** field, and click **Apply Std/Ctrl Kit**.

NOTE: The chosen kit must be associated with the same analyte names.
- b. Click **Apply Std Lot**. Select a lot from the list and click **OK**.
- c. Apply values across or down the **Reagent**, **Name**, **Lot #**, **Expiration**, and **Analyte** fields by double-clicking the fields to enter a value, and then using one of the two **Apply Values** arrows to apply that value down or across the list of analytes.

NOTE: The **Dilution** list and **Apply Dilution** button only appear if a quantitative analysis has been selected.
- d. Click **Apply Ctrl Lot**. Select a lot from the list and click **OK**.

- e. Apply values across or down the **Reagent, Name, Lot #, Expiration,** and **Analyte** fields by double-clicking the fields to enter a value, and then use one of the two **Apply Values** arrows to apply that value down or across the list of analytes.
4. Click **Save**.

Export a Kit/Lot

NOTE: Lots and kits can only be exported if the protocol they were originally created with exists within the system. If the protocol has been deleted, the lot or kit cannot be exported.

1. Navigate to the **Protocols** page > **Stds & Ctrls** tab.
2. In the **Installed Kits And Lots** section, choose the kit or lot you want to export, then click **Export**.
3. In the **Save As** dialog box, navigate to the location you want to export the file to, then click **Save**.

Delete a Kit/Lot

1. Navigate to the **Protocols** page > **Stds & Ctrls** tab.
2. In the **Installed Kits And Lots** section, choose the kit or lot you want to delete, then click **Delete**.
3. Click **Yes** in either the **Delete Std/Ctrl Kit(s) Confirmation** or **Delete Lot(s) Confirmation** dialog box.

Invalidate Standards and Controls

NOTE: It is possible to invalidate or remove a control in data analysis. However, Luminex does not recommend invalidating controls.

For information on assay controls and guidelines for accepting or rejecting control values, contact the assay kit manufacturer.

To invalidate standards, controls, and samples:

1. Navigate to the **Results** page > **Saved Batches** tab.
2. Choose the completed batch, then click **Open**.
3. In the **Results** section on the **Results** subtab, click the square area to the left of the well you want to invalidate and click **Invalidate**. The whole row turns red. Or click the analyte results in a well and click **Invalidate**.

NOTE: Select the same item and click **Validate** to remove the invalidation status.

Validate Standards

Your xPONENT® system administrator must give you privileges to validate standards if you are using the Secure xPONENT® package. All standards are assumed to be valid unless explicitly invalidated.

1. Navigate to the **Results** page > **Saved Batches** tab.
2. Choose the completed batch, then click **Open**.
3. In the **Results** section, click the square area to left of the well you want to validate and click **Validate**.

NOTE: Average rows or cells cannot be selected. If you have not selected an item or the item you selected does not need to be validated, a warning dialog box displays.

Define the Samples

Create a New Sample List

NOTE: Creating a new sample list is intended for LIS users. If you are not using an LIS, you may want to import a sample list when creating the batch or editing the protocol.

1. Navigate to the **Samples** page > **Samples** tab.
2. In the **Sample Lists** section, choose the protocol you are using for the sample list, then click **Create New Samples**.
3. Add the following information for your sample in the Create Sample subtab:
 - a. Enter the sample ID in the **ID** field.

NOTE: Sample IDs are limited to 30 characters.
 - b. Enter a patient first name in the **First Name** field (optional).
 - c. Enter a patient last name in the **Last Name** field (optional).
 - d. Enter a comment in the **Comment** field (optional).
 - e. Click **Save** to add the sample to the **Sample** list.
4. Click **New** to create more samples or **Edit** to edit the sample.
5. Click **Close** after you add your samples.

NOTE: Samples can also be added using an LIS.

Edit a Sample List

1. Navigate to the **Samples** page > **Samples** tab.
2. In the **Sample Lists** section, choose the protocol you want to edit, then click **Details**.
3. Choose a sample in the **Edit Samples** subtab, then use the **Move** arrows to move the sample up or down in the sample list, changing the order in which the samples will be acquired.
4. Click **Edit**.
5. Edit the appropriate fields or click **Undo** to undo any changes.
6. Click **Save** when you are done editing the sample.
7. Click **Close** when you have completed editing the sample.

Define the Batch

Create a New Batch from an Existing Protocol

When running a kit with a provided protocol, the protocol for the assay must be run as instructed in the assay's package insert.

1. Navigate to the **Batches** page > **Batches** tab > click **Create a New Batch from an existing Protocol**.
2. Enter the batch name in the **Batch Name** field.
3. Enter a description about the batch in the **Enter Optional Description** field.
4. Choose a protocol in the **Select a Protocol** list.

5. Click **Next**. If the protocol uses standards, controls, or both, the **Stds & Ctrls** subtab displays the details of the active reagents. Click **Next**. If the chosen protocol does not use standards or controls, the **Plate Layout** subtab displays.
6. Assign standards, controls, samples, or well commands for this batch on the **Plate Layout** subtab.
 - a. If you need to define a replicate count, choose the **Replicate Count** before adding a well command.
 - i. Choose the **Grouping** - 123123123 OR 111222333 - to define how the replicate count is laid out in the plate wells. Grouping selection must be made before adding a well command.
 - b. In the plate image, click and drag to highlight a series of wells, click a column or row header to highlight the entire column or row, or click and highlight different wells and then click a command to assign that command to the highlighted wells. Each command is associated with a color.
 - i. Before adding well commands, delete all standards from the plate layout if any of the standards need to be rearranged. Delete all controls from the plate layout if any of the controls need to be rearranged.
 - ii. If you need to change the acquisition order of a command in the plate, select the command in the **Command Sequence** list, and click the **Move Command** arrows, up or down.
 - iii. To begin acquisition at a well other than A1, select the well you want to begin acquisition, and click **Start at Well**.
 - c. Select a well and then choose **Add**, **Delete**, **Pre-Batch Routine**, or **Post-Batch Routine**, as applicable.

NOTE: Wells and commands you assign to the protocol plate layout are saved into the protocol settings and execute each time you use the protocol to run a batch. Standards and controls associated with a given protocol typically remain constant, while the number of unknown wells often varies. You can assign a specific number of unknown wells to the plate when setting up a batch.

NOTE: If you need to add multiple plates to the batch, click **Add Plate** to add another plate.

7. Specify the direction to run the plate commands by selecting either vertically or horizontally. The selected direction also dictates how wells are added to the plate when assigning multiple unknowns, standards, and controls at one time.
8. Click **Run Batch** to begin batch acquisition, or click **Save** to save batch information to the **Pending Batch** list to be run at a later time.
 - a. If the batch spans more than one plate, the tray ejects automatically when all defined wells have been acquired. A dialog box displays, prompting you to insert the next plate.

Create a Multi-Batch

The Multi-batch feature automatically sets the batches side-by-side if space remains on the plate. Ensure that the batches fit on one plate. If space limitations create an overlap, an error message displays. Results for each batch are saved as individual batch files. Batches must be created first, before they can be combined on one plate to create a multi-batch.

NOTE: There is a limit of 96 batches in a multi-batch.

NOTE: You cannot add a batch that forces multiple plates to a multi-batch operation. All batches must use the same plate name previously defined and adjusted.

1. Navigate to the **Batches** page > **Batches** tab > click **Create a New Multi-Batch**. The **New Multi-Batch** subtab displays.
 - a. If the **Select Pending Batch** dialog box displays, choose the batch you want to add to the new multi-batch list.
 - b. Click **OK**.
2. Click **Add** to add a batch. The **Select Pending Batch** dialog box displays.
3. Choose a batch from the available options, including batches newly created.
4. Click **OK**. The selected batch will then display on the plate layout.

NOTE: After you add each batch, the software automatically adds the next batch to the first well of the next column or row (depending on the plate direction). You can also select a well first, which places the next batch in your chosen location.

NOTE: If the batches chosen do not fit on the plate, a **Multi-Batch Error** dialog box opens, indicating you must edit one or more of the selected batches.

Save a Multi-Batch

After creating a multi-batch, save it to the **Pending Batches** list. When saved to this list, the protocol appears as **Multi-Batch**.

1. Navigate to the **Batches** page > **Batches** tab.
2. Choose a pending multi-batch and click **Edit**. The **New Multi-Batch** subtab displays.
3. Enter the name for the multi-batch in the **Multi-Batch Name** field.
4. Click **Save**. The multi-batch is now added to the pending batches list.

Edit a Batch

1. Navigate to the **Batches** page > **Batches** tab.
2. In the **Pending Batches** list, choose the batch you want to edit, then click **Edit**. The **Protocol** subtab displays.
3. Enter a new **Batch Name** and **Description** if needed.
4. Choose a protocol and click **Next**.
5. Edit the information as needed on the **Stds & Ctrl**s and **Plate Layout** subtabs. On the **Plate Layout** subtab, confirm that the plate layout conforms to your specific assay instructions.
6. Click **Save** on the **Plate Layout** subtab.

NOTE: Batches saved to a multi-batch cannot be edited unless they are removed from the multi-batch.

NOTE: Only run a batch from the Batches page > Batches tab.

Import a Batch

You only need to import batches to the system once. Enter the lot information for the standard and control reagents as specified in the protocol. This lot information is used for every batch set up using the protocol, until it is changed.

1. Navigate to the **Batches** page > **Batches** tab > click **Import**. The **Import Batch** dialog box displays.

NOTE: Batch files are MDF files. The MDF file allows importing batch data from one xPONENT® to another.

2. Click **Browse**. The **Select File** dialog box displays.
3. Navigate to the batch file you want to import, then click **Open**.
4. Click **OK**. The batch displays in the **Pending Batches** list.

Export a Batch

1. Navigate to the **Batches** page > **Batches** tab.
2. In the **Pending Batches** list, choose the batch you want to export, then click **Export**. The **Export Batch** dialog box displays.

NOTE: You can export batches, but not multi-batches.

3. Click **Browse**. The **Select File** dialog box displays.
4. Navigate to the location where you want to save the file, then click **Save**.
NOTE: If you plan to replay this batch in the future, be sure to include the raw (.lxb) files.
5. In the **Export Batch** dialog box, select **Overwrite** to overwrite the previous file that you may have exported.
6. In the **Export Batch** dialog box, click **OK**.
NOTE: When exporting a large batch and including the LXB files, the export process may take 10 minutes or more.
7. When the export is complete, click **OK** in the **Export Batch File** dialog box.

Delete a Batch

You can only delete unprocessed batches. Batches are deleted from the **Open Batch** list and moved to the **Open Incomplete Batch** list.

1. Navigate to the **Batches** page > **Batches** tab.
2. In the **Pending Batches** list, choose the batch you want to delete, then click **Delete**.
3. Click **Yes** in the **Delete Pending Batch** dialog box.

NOTE: Batches saved to a multi-batch cannot be deleted unless they are removed from the multi-batch. To remove a batch from a multi-batch, click a well in the plate layout, then click **Remove**.

NOTE: You can remove a batch that includes results only through the **Archive Utility**.

Run a Pending Batch

1. Navigate to the **Batches** page > **Batches** tab.
2. Choose the pending batch that you want to run, then click **Run**.

NOTE: If the batch spans more than one plate, the instrument automatically ejects the first plate after acquiring all of the wells. Insert the next plate when the dialog box prompts you to.

Chapter 6: Analyzing the Results

View the Results

1. Navigate to the **Results** page > **Current Batch** tab.
2. On the **Current Batch** tab you can view results, statistics, and log information related to the current batch, and perform statistical analysis on the batch results.

View Sample Details

1. Navigate to the **Results** page > **Saved Batches** tab.
2. Choose the desired batch from the **Completed Batches** list and click **Open**.
3. Click the **Sample Details** subtab.
4. If you are using an LIS-licensed package of the software, click **Transmit** to transmit sample details to the LIS database. You can transmit either a single analyte per sample or the entire sample.

View Batch Settings

1. Navigate to the **Results** page > **Saved Batches** tab.
2. Choose the desired batch from the **Completed Batches** list and click **Open**.
3. Click the **Settings** subtab, click the left and right **Page** arrows to view the pages of the batch settings report.
4. If desired, click **Save** to open the **Save As** dialog box.
5. Navigate to the location where you want to save the batch settings report, and click **Save**.
6. In the **Report Save Success** dialog box, click **OK**.

View Batch Logs

1. Navigate to the **Results** page > **Saved Batches** tab.
2. Choose the desired batch from the **Completed Batches** list and click **Open**.
3. Click **Log** on the **Results** tab to open the **Log** subtab.

Generate Reports

1. Navigate to the **Results** page > **Reports** tab.

- From the **Report** drop-down menu, choose the category of report: Batch, Protocol, Calibration and Verification, Performance Verification, System Log, or Advanced. Depending on what you choose in the **Report** list, the content of the **Type** list changes and other features will display in the window.
- From the **Type** drop-down menu, choose the specific report type.
 - If you chose either a Batch report or a Protocol report, select the specific batch or protocol from the list.
 - If the report you chose requires a date range (Calibration and Verification, Performance Verification, and System Log), use the calendars available to establish the date range.
- Batch reports require a choice of analytes; select them from the **Select Analytes** section. Select them all using the **All** button; clear your selections using the **Clear** button.
- Click **Generate**. If the report includes multiple analytes, use the arrows above the report to move through the list of analytes.
- Use the **Zoom** drop-down menu to increase the size of the report.

Export the Batch Results

- Navigate to the **Results** page > **Saved Batches** tab.
- Choose the completed batch to export and click **Exp Results**.
- In the **Save As** dialog box, choose an export destination for the .csv file containing your results.

NOTE: The CSV files are the only human readable files. These files can be opened with Excel or similar program to analyze/view data.

- Click **Save**.
- In the **Export Complete** dialog box, click **OK**.

Transmit Results to the LIS

Only approved batches can be transmitted to the LIS. If your software is licensed for LIS use, you can transmit batches to the LIS from the Saved Batches tab.

- Navigate to the **Results** page > **LIS Results** tab.
- Select a single analyte or the entire sample.
- Click **Transmit** to send the results to the LIS.

Reacquire Wells from a Batch

Reacquire is performed at the end of a run if a well needs to be reanalyzed. xPONENT® creates a copy of the original file (this new file contains the reacquired values).

- Navigate to the **Results** page > **Saved Batches** tab.
- Choose the completed batch from the **Completed Batches** table.
- Click **Reacquire**.

4. Select the **Reacquire** check box for the desired well(s) on the **Results** subtab.
5. Click **Run** to have the instrument reanalyze the well(s) selected.
6. Click **Yes** on the **Save Copy of Original Batch** dialog box. You also have the option to change the file name.

Replay a Batch

Replaying a batch uses the raw bead data files from the initial acquisition to reanalyze the batch, and creates a new batch output file. The bead data files are replayed using the analyte, analysis settings, and plate layout selected in the new batch or protocol. Settings such as Bead Type, Volume, and XY Heater have no effect.

Results from replaying a batch are generated with new .lxb and .csv files.

Replaying a large batch can take one hour or more to complete. Allow adequate time for the operation to complete; batch replay cannot be stopped while in progress. The operation is complete when all progress bars have disappeared.

A batch can be reanalyzed multiple times. When you replay or recalculate a batch, you perform the same steps to create the batch as you did when you created the batch the first time. The initial batch data and output file always remain intact and unchanged. Each time you replay a batch, the system handles it as if it is new data, and creates a separate batch entry and output file.

If you choose to replay a batch that was originally run without a saved protocol, you have to modify the settings. After you have modified the settings, click **Replay Batch** on the **Plate Layout** subtab to perform the replay or recalculate procedure.

If the system crashes but the plate finished, the data can be recovered by replaying the batch.

1. Navigate to the **Results** page > **Saved Batches** tab.
2. Choose the batch to replay in the **Completed Batches** section, and click **Replay**. This opens the **Select Replay Mode** dialog box. By default, **Recalculate data** is selected, select **Replay Batch**. Click **OK**.

NOTE: When replaying data, if there is a saved protocol associated with the batch, the **Protocols** subtab will display. Select the preferred protocol to replay batch MFI values. If an amended or new protocol is needed, create the protocol before replaying the batch data. If there is not a protocol associated with the data, the **Settings** subtab will display to create a protocol. Analysis settings and plate layout are required by xPONENT® to replay batch MFI values.

NOTE: After you have approved a batch, the status of the batch changes to **Approved** in the **Completed Batches** list.

3. Enter a batch name and description on the **Settings** subtab.

NOTE: You cannot edit the **Acquisitions Settings**.

4. Edit the **Analysis Settings** section as needed to create a new protocol.
5. Click **Next**.
6. Edit the necessary information on the **Analytes** subtab.
7. Click **Next**.
8. Edit the necessary information on the **Stds & Ctrl** subtab.
9. Click **Next**.
10. Edit the necessary information on the **Plate Layout** subtab.
 - a. Choose the wells you wish to replay on the **Plate Layout** subtab. Only wells previously read will be available to replay.

11. Click **Replay Batch**.
12. Click **OK** once the batch is complete.

Recalculate Batch Data

Recalculating data reanalyzes the batch results using only the batch's MFI values.

The batch MFI values will be recalculated using the analysis settings and plate layout selected in the new recalculated batch or protocol. Settings such as Volume, Timeout, and XY Heater have no effect. Because only the MFI values are reanalyzed, no data will be displayed in the dot plot. Recalculating data from a large batch can take one hour or more to complete.

1. Navigate to the **Results** page > **Saved Batches** tab.
2. Choose the data to recalculate in the **Completed Batches** section, and click **Replay**.
3. Ensure **Recalculate data** is selected in the **Select Replay Mode** dialog box and click **OK**.

NOTE: When recalculating data, if there is a saved protocol associated with the batch, the **Protocols** subtab will display. Select the preferred protocol to recalculate batch MFI values. If an amended or new protocol is needed, create the protocol before recalculating the batch data. If there is not a protocol associated with the data, the **Settings** subtab will display to create a protocol. Analysis settings and plate layout are required by xPONENT® to recalculate batch MFI values.

4. Enter a name and description for the batch.
5. Choose a protocol with the data you want to recalculate from the **Select a Protocol** section.
6. Click **Next**.
7. Edit the necessary information on the **Stds & Ctrl**s subtab.
8. Click **Next**.
9. Edit the necessary information on the **Plate Layout** subtab.
 - a. Choose the wells you wish to recalculate on the Plate Layout subtab. Only wells previously read will be available to replay.
10. Click **Replay Batch**.

Chapter 7: Troubleshooting

Troubleshooting procedures help users isolate, identify, and remedy problems with the system. This chapter does not troubleshoot problems with the PC. For help with PC problems, please contact the technical support system for your PC's manufacturer.

Generate and Send the Support Utility File

The Support Utility tab creates a support file that you can send to Technical Support. The file also contains calibration and verification reports.

NOTE: Ensure the instrument is powered on and connect to xPONENT® before generating a Support Utility File.

1. Navigate to the **Maintenance** page > **Support Utility** tab.
2. Choose the batch you want to generate a support utility file for, and then select the **Include Batch Information** check box to include the batch information with the support file.
3. Click **Support** to launch the **Support Utility** dialog box.
4. Enter your name in the **Name** field.
5. Enter your company name in the **Company Name** field.
6. Enter your phone number in the **Phone Number** field.
7. Enter your email in the **Email** field.
8. In the **Comment** field, type a detailed description of the problem you are experiencing.
9. In the **Directory Configuration** section, verify the location where you want to store the file in the **Output Directory** field.
 - a. To change the location, click **Browse**, then navigate to the new folder and click **OK**.
10. Click **Save File**. The saved file includes date and time information.
11. In the **Save As** dialog box, enter the file name and then click **Save**.
12. Send an email to support@luminexcorp.com and attach the support file (xPONENTSupportFile.zip) to the email.

You can save and/or print the report, if desired.

Calibration/Performance Verification Failures

Calibration and Control Problems

Table 1. Calibration and Control Problems

Symptom	Possible problem	Solution
Calibration is slow or fails.	The calibration microspheres are not fully suspended.	Vortex the calibration vials to re-suspend the microspheres.
	Wrong lot number or target values are entered.	Verify that correct lot number and target values are used.
	The system calibrators are in the wrong well on the plate.	Verify that calibrators are in the correct well.
	Not enough calibrator microspheres added to the well.	Add at least 5 drops of calibrator microspheres to the well. Hold the vial upside down, completely inverted to the plate while dispensing the reagents.
	Calibrator lot is expired.	Use a fresh bottle of calibrator microspheres.
	The sample probe height is incorrect.	Adjust the sample probe height.
	The sample probe is clogged.	Clean the sample probe.
	There is a partial clog in the system.	Clean the sample probe, then flush the system.
	There is air in the system.	Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, then three Wash commands with water.
	The waste fluid container is not vented.	Check that the seal in the waste fluid container cap is dry and that the waste fluid container cap is vented.
	The waste line was moved during system operation, resulting in unstable flow rate.	Stabilize the waste line during instrument operation.

Symptom	Possible problem	Solution
	Possible problem with the laser.	View the calibration trend report. Check for dramatic changes in temperature, sheath pressure, or voltages. If any of these are evident on the report, contact <i>Luminex Technical Support</i> .
Zero events collected during calibration.	There is a problem with fluid levels.	Check the sheath and waste fluid levels. Verify that tubing for both bottles is tightly connected to the instrument. Check that the waste bottle cap is vented.
	Laser-related issue.	Verify fluid is moving through the system by performing a Wash command, which causes fluid to go out to waste. If no fluid is going to waste, clean the sample probe, then flush the system. If the issue does not resolve, contact <i>Luminex Technical Support</i> .
	The waste fluid container is not vented.	Check that the seal in the waste fluid container cap is dry and that the waste fluid container cap is vented.
	The Cheminert® fitting is loose.	Tighten the Cheminert® fitting.
Analyzer fails Controls.	The control microspheres are not fully suspended.	Vortex the control vials to re-suspend the microspheres.
	Wrong control lot number or target values are entered.	Verify that the correct lot number and target values are used.
	The system controls are in the wrong well on the plate.	Verify that control microspheres are in the correct well.
	Not enough control microspheres added to the well.	Add at least 5 drops of control microspheres to the well. Hold the vial upside down, completely inverted to the plate while dispensing the reagents.
	Control lot is expired.	Use a fresh bottle of control microspheres.
	Control microspheres have been diluted.	Do not dilute the control microspheres.
	The sample probe height is incorrect.	Adjust the sample probe height.
	The sample probe is clogged.	Clean the sample probe.

Symptom	Possible problem	Solution
	There is air in the system.	Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, then three Wash commands with water.
	The waste fluid container is not properly vented.	Verify that the waste fluid container is properly vented and that the seal is not wet or soiled.
	The waste line was moved during system operation, resulting in unstable flow rate.	Verify that the waste line is not moved during system operation.
	Possible problem with the lasers.	Check the system control trend report for consistent failures. If any are evident on the report, contact <i>Luminex Technical Support</i> .

Instrument Errors

Communication Problems

Communication problems described in this section involve the links between the data system (PC and software) and Luminex® 200™ and the Luminex® XYP™.

The term “Communication” refers to:

- The transfer of data between the PC and the Luminex 200.
- The current status of the Luminex 200 and Luminex XYP.
- Instrument control, sample acquisition, session uploading, and start, stop and pause features.

Table 2. Communication Problems

Problem	Possible Causes	Corrective Action
The PC cannot establish communication with the analyzer.	The communication cable is unplugged or plugged into the wrong port.	Check the communication's cable connections.
	The Luminex® 200™ or the Luminex® XYP™ is not turned on.	Turn off the PC. Turn on the Luminex® 200™ and the Luminex® XYP™ and then turn on the PC. Ensure you see the three blue indicator lights on the front of the Luminex® 200™, Luminex® XYP™, and the Luminex® SD™, if you are using one.
	The Luminex® Windows Driver is not installed.	Check the PC Control Panel to see if the Luminex® Windows Driver is installed.
	The Luminex® Windows Driver is installed but system still does not connect.	Contact <i>Luminex Technical Support</i> to determine the COM port.
	Incorrect firmware installed on the system.	Check the firmware on the system.
	The PC and analyzer are connected but xPONENT® software still displays a disconnect.	Unplug the USB from the instrument and plug it back in. Power on the PC. Wait for the system to boot up. Power on the instrument.

Power Supply Problems

Power supply problems often involve a blown fuse, faulty electronic component, or disconnected cable.



Whenever you deal with a potential electrical problem, be careful to avoid electrical shocks.

Table 3. Power Supply Problems

Problem	Possible Cause	Corrective Action
Analyzer will not turn on, or Luminex® XYP™ will not turn on.	The power cord is disconnected.	Verify that the power cord is plugged in.
	No voltage is coming from the electrical outlet.	Verify that the electrical outlet is operational.
	The power supply is faulty.	Contact <i>Luminex Technical Support</i> .
	A fuse has burned out.	Replace the fuse.
Fuses continue to open (blow).	A component has a short circuit.	Contact <i>Luminex Technical Support</i> .

Fluid Leaks

Fluid leaks can result in poor pressurization and failed sample acquisition.

Table 4. Fluid Leaks

Problem	Possible Cause	Corrective Action
Pressure is too low.	The sample probe is clogged.	Clean the sample probe.
	The syringe seal leaks.	Replace the syringe seal.
	The syringe valve leaks.	Hand-tighten the syringe connection (silver knob) on the syringe valve. Run a Prime command. If leaks continue, contact <i>Luminex Technical Support</i> .
Large amount of fluid pooled around instrument.	Fittings or fluid lines are damaged.	Contact <i>Luminex Technical Support</i> .
Fluid dripping from the sample probe.	The sample probe is clogged	Clean the sample probe.
	The sample three-way valve is faulty.	Contact <i>Luminex Technical Support</i> .
Fluid is leaking from the front of the analyzer.	The syringe seal leaks.	Replace the syringe seal.
	The syringe valve leaks.	Hand-tighten the syringe connection (silver knob) on the syringe valve. Run a Prime command. If leaks continue, contact <i>Luminex Technical Support</i> .

Low Bead Count

Pressurization Problems

Normal air and sheath pressure readings vary between 6 psi to 9 psi while the compressor runs. If the system pressure is out of range, your sample acquisition will fail or return inadequate results.

Table 5. Pressurization Problems

Symptom	Possible problem	Solution
Pressurization fails or pressure is too low.	The sheath and waste lines are not fully connected.	Make sure the lines between the sheath and waste bottles and the system are fully connected.
	The sheath or waste bottle fittings are cracked.	Inspect the fittings to be sure they form a tight seal.
	The system has a leak.	Check for system leaks. A leak will be obvious if there is fluid on the surface on which the system sits.
	The compressor does not engage.	Run a Prime command. If you do not hear the compressor turn on, contact <i>Luminex Technical Support</i> .
	The Cheminert® fitting is loose.	Ensure that the fitting connects tightly above the sample probe, below the blue light.
	Fluid leaks in the system.	Refer to topic Troubleshooting > Fluid Leak Problems .
	The sheath bottle has an air leak.	Disconnect the sheath and waste bottle connections from the analyzer. Run a Prime command. If pressure builds, remove and re-tighten the sheath fluid bottle cap, then reconnect fluid lines to the analyzer. If pressurization fails again, replace the sheath bottle.
Pressure too high.	The sheath bottle is overfilled.	Ensure that the sheath bottle is not filled above the fill line.
	The Sheath Delivery System is overfilled.	Drain the Luminex SD reservoir and refill it.

Sample Probe Problems

Problems with the sample probe can lead to fluid leaks, pressurization problems, and acquisition failure.

Table 6. Sample Probe Problems

Problem	Possible Cause	Corrective Action
The sample probe leaks.	The sample probe is clogged.	Clean the sample probe.
The sample arm is stuck in the up position.	The system is not properly pressurized.	Ensure that the sample probe is not clogged and there are no leaks in the syringe seal or syringe valve.
The sample arm does not go down smoothly.	The 96-well plate is incorrectly seated in the Luminex® XYP™ instrument.	Adjust the plate.
	The plate is warped.	Inspect the plate. Replace the plate if it is warped.
	The sample probe is bent.	Remove the sample probe from the instrument and roll it on a flat surface. If the sample probe does not roll smoothly, replace it with a new sample probe. Adjust the sample probe height.
	The sample arm is misaligned.	Contact <i>Luminex Technical Support</i> .

Acquisition Problems

Table 7. Acquisition Problems

Symptom	Possible problem	Solution
Acquisition fails or slows.	The air pressure is out of range.	Refer to topic Troubleshooting > Pressurization Problems .
	The sample probe height is incorrect.	Adjust the sample probe height.
	The sample probe is clogged.	Clean the sample probe.
	The sheath bottle has a leaky seal.	Make sure that the sheath bottle lid is tightened. Remove and replace the sheath bottle lid.
	The sheath or waste lines are not fully connected.	Disconnect and reconnect the lines; you should hear them click.
	The calibration microspheres have expired.	Replace old microspheres with a fresh (unexpired) lot.
	The wrong wells are selected for the calibration microspheres.	Ensure that the microspheres have been dispensed into the correct wells.
	The calibration lot number or target values selected in setup is incorrect.	Verify the correct calibration lot number and target values.
	Air is present in the system.	Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, then three Wash commands with water.
	The acquisition volume is set too high.	Set the acquisition volume to at least 25 µL less than the actual volume in your wells. This enables the sample probe to acquire sample more efficiently with less chance of incorporating air in the sample.
	The xMAP® microspheres are not fully suspended.	Gently vortex the plate or re-suspend microspheres with a multichannel pipettor to ensure that the microspheres are present in the solution.
	You are using photobleached microspheres.	Replace the microspheres with unphotobleached microspheres.
There is an insufficient number of microspheres in the sample.	Ensure that there are 2000 to 5000 microspheres per beadset per well.	
The sample is too concentrated.	Dilute concentrated biological fluids, such as serum or plasma, at least 1:5.	

Bead Detail Irregularities

Use these tools to assist in diagnosing instrument and assay-related problems:



- System calibrators
- System controls
- Assay standards
- Assay controls
- Error messages

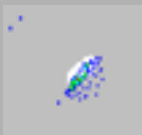
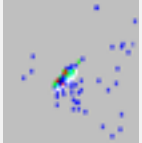
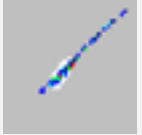
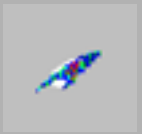

Review calibration/control reports routinely to detect trends.

Use system xMAP® control microspheres (from the performance verification kit) to check the success of the system calibration and for troubleshooting purposes. If there is a problem with your kit results, xMAP controls can help determine if the problem is analyzer-related. If Calibration and Controls are successful, contact the kit manufacturer.

A normal bead detail depicts a tight bead population within a white region.

Table 8. Bead Details

Symptom	Possible problem	Solution
xMAP® microspheres classify too high. 	You could be using photobleached calibration microspheres.	Replace the calibration microspheres with a fresh batch. To avoid photobleaching, protect your microspheres from light.
xMAP® microspheres hit the lower right of the region. 	You could be using photobleached xMAP® microspheres.	Replace microspheres with a fresh batch. To avoid photobleaching, protect your microspheres from light.
Beads appear scattered.		

Symptom	Possible problem	Solution
	Air is in the system.	Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, and three Wash commands with distilled water.
	The sheath fluid container is empty.	Make sure there is sheath fluid in the sheath container. Prime the system until all air is out of the system.
Microspheres appear as a long diagonal line.		
	The xMAP® microspheres have agglutinated.	Add additional detergent to the assay buffer. For example, add 0.02% to 0.1% Tween-20, Triton® X100, or SDS.
	The solvent is incompatible.	Contact <i>Luminex Technical Support</i> to request a list of incompatible solvents. If the solvent you are using is listed, switch solvents.
	You are using incompatible sheath fluid.	Use only Luminex sheath fluid in the Luminex® 200™ analyzer. Other fluids can damage your analyzer and can void your warranty.

Luminex® SD™ Problems

If an empty sheath fluid container is not replaced and the system continues to operate, the Luminex® SD™ system eventually vents pressure to prevent air from being introduced into the Luminex® 200™ analyzer. This can interrupt a sample and prevent further samples from being collected.

Filter Clog

If the filter attached to the sheath intake line becomes clogged from extended use, an alarm will sound even though the bulk sheath container is not empty. If this happens, replace the filter, part number CN-0037-01.

Malfunction With the Luminex® SD™

If the alarm sounds even though the bulk sheath container has fluid and the sheath filter is in good condition, the system is reporting a malfunction. If this happens, contact *Luminex Technical Support*.

Run a Self Test

Perform a Self Test to evaluate the hardware component of the system and all operations are functioning properly. When running the self test, the lasers will turn off and you will need to warm up the system before running calibration and verification, or samples.

If there is a failure you can try to cycle the power to correct the failure. If that does not fix the issue, then call *Luminex Technical Support*.

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. Click **Self Test**.
3. Click **Run**.

Customer Orderable Part Numbers

Table 9. Hardware Part Numbers

Product Description	Customer Number
Rear Air Filter	CN-0001-01
Bottom Air Filter	CN-0002-01
Air Filter, Intake	CN-0027-01
Bar Code Scanner	CN-PC03-01
Serial Cable, (2.5 feet)	CN-0374-01
Serial Cable, (5 feet)	CN-0415-01
Heater Block, Luminex® XYP™	CN-0017-01
Power Cord	CN-PXXX-01*
Reservoir, Luminex® XYP™	CN-0022-01
Sample Needle Height Alignment Kit [Sample Probe Alignment Kit]	CN-0015-01
Long Sample Probe	CN-0007-01
Sample Tube Holder, Large, 1.5 mL	CN-0008-01
Sample Tube Holder, Small, 1.2 mL	CN-0009-01

Product Description	Customer Number
Sheath Filter with Quick Disconnect	CN-0010-01
Sheath Bottle	CN-0011-01
Syringe Cylinder with Seal	CN-0013-01
Syringe Seal	CN-0014-01
Cable, USB	CN-0018-01
Cable, USB A to USB B	CN-0271-01
Waste Bottle	CN-0012-01
Solvent Inlet Filter	CN-0037-01
2A Fuse, 250V, Fast Acting (Luminex® 200™ and Luminex® XYP™)	CN-0430-01
2A Fuse, 250V, SloBlo (SDS)	CN-0172-01

* XXX is a country specific part number. For more information, contact *Luminex Technical Support*.

Table 10. Reagent Part Numbers

Product Description	Customer Number
Calibration Kit, Luminex® 200™	LX2R-CAL-K25
Verification Kit, Luminex® 200™	LX2R-PVER-K25
xMAP® Sheath Fluid, 20L	40-50015

Chapter 8: Maintaining the System

To ensure accurate test results, properly clean and maintain the Luminex® 200™. Read and follow all instructions in this chapter. To facilitate your maintenance process, print out and use the *Maintenance Log*.

It is important to use only xMAP® sheath fluid or other Luminex-approved sheath fluid.



Use of non-Luminex approved sheath fluid shall constitute “Improper Use” and can void warranty rights provided by Luminex and its authorized partner.

When analyzing potentially infectious biological samples on the Luminex® 200™, follow standard laboratory safety practices. These safety precautions should also be taken when cleaning or maintaining the analyzer.

General Maintenance Precautions

Observe the following general maintenance precautions.



Personnel who use, maintain, or clean the Luminex® 200™ should be trained in standard laboratory safety practices and should follow those practices when handling the instrument.

Samples and waste fluid can contain biohazardous material. Where exposure to biohazardous material, including in an aerosol form, exists, follow appropriate biosafety procedures, use personal protective equipment, and use ventilation devices.

Avoid contact with moving parts. Disconnect the instrument from the power source when the procedure instructs you to do so.

Do not remove the cover of the Luminex 200 under any circumstances.

Maintenance Commands and Routines

Wash	Sends distilled water through the fluidic lines in the system. It pulls the fluid from a well or reservoir and runs it completely through the system to the waste fluid container.
Alcohol Flush	Removes air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The alcohol flush takes about 5 minutes.
Warmup	Warms the system to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn the power on. The process takes 30 minutes. You will need to use the Warmup command if the system is idle for four hours or longer.
Soak	Perform the soak function at the end of each day. The system uses at least 250 µL of distilled water. Prevents salt crystals from forming in the probe due to air exposure. Soaking the probe replaces sheath fluid in the probe with water.
Sanitize	Performs a similar function as the alcohol flush command, but uses 10% to 20% household bleach and water solution to decontaminate sample lines and the cuvette after biohazard contact.
Prime	Removes air bubbles from the system's fluidic pathways by drawing sheath fluid from the sheath fluid container. You do not need to supply solution in a plate.
Self-Test	Performs a self-diagnostic test to see if the system and all operations are functioning properly. The self-test evaluates the sample delivery and the optics module.
CAL1	Calibrates DD, CL1, and CL2 for original non-magnetic xMAP® microspheres.
CON1	Verifies DD, CL1, and CL2 for non-magnetic xMAP microspheres.
MagCAL1	Calibrates DD, CL1, and CL2 for original magnetic MagPlex microspheres.
MagCON1	Verifies DD, CL1, and CL2 for magnetic MagPlex microspheres.
CAL2	Calibrates xMAP reporters (RP1).
CON2	Verifies RP1 at normal and high PMT for all xMAP bead types.
Fluidics	Calibrates sample carry over from well to well.
Drain	Helps remove debris from the bottom of the cuvette during troubleshooting. You do not need to supply solution. Draining takes approximately 2 minutes and should be followed by an alcohol flush with 70% isopropanol or 70% ethanol.
Backflush	Removes obstructions from the fluidics pathways by drawing sheath fluid from the sheath fluid container.

Create a New Maintenance Routine

Create maintenance routines to facilitate your startup procedure, shutdown procedure, troubleshooting, or calibration. Ensure that the maintenance routine you create is consistent with the Luminex® instrument operations and maintenance requirements.

To create a new maintenance routine:

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. Choose **None** in the **Routine Name** drop-down menu.
3. In the **Commands** section, click one or more commands to add to the routine. These commands display in the plate image and in the **Command Sequence** list.
4. To change a location (well or reservoir) for a command, click the command in the **Command Sequence** list, then click the new location in the plate image.

NOTE: If you attempt to place two or more commands in the same well; a message displays instructing you to change the location of the command. Some commands can be run from the same location, for example, multiple washes can be run from the same reservoir.

5. Click **Save As** to save the new routine. The **Save Routine** dialog box displays.
6. Enter the routine name in the **Routine Name** field, then click **OK**.

Run a Maintenance Routine

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. Choose a routine from the **Routine Name** drop-down menu.
3. Click **Eject**.
4. Add the appropriate reagents to the plate, reservoirs, and strip wells, as indicated in the plate image and set the plate on the plate holder.
5. Click **Retract**.
6. Click **Run**. The **Routine Message** dialog box displays when the routine is complete.
7. Click **OK**.

Import a Maintenance Routine

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab > click **Import**.
2. In the **Open** dialog box, browse for the file you want to import, then click **Open**.
3. In the **Import Routine File** dialog box, click **OK**. The routine becomes the active routine.

Edit a Maintenance Routine

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. Choose a routine from the **Routine Name** drop-down menu.
3. Click a command in the **Command Sequence** list that you want to edit. Click **Clear** to delete the command, or click in a different well in the plate image to change the location of that command.

NOTE: When you add or remove a command, the routine name automatically defaults to **None** in the **Routine Name** drop-down menu.

4. Add, delete, or change commands as necessary, then click **Save As**.

NOTE: You can only add commands to the end of a routine. You cannot insert new commands before commands that are already part of a routine.

5. Enter a different name for the routine to create a new routine, or type the existing name of the routine to keep the edited routine using the existing routine name.

Delete a Maintenance Routine

You can delete a routine that you created, but you cannot delete pre-defined routines.

1. Navigate to the **Maintenance** page > **Cmnds & Routines** tab.
2. Choose a routine from the **Routine Name** drop-down menu.
3. Click **Delete**.
4. In the **Delete Maintenance Routine Confirmation** dialog box, click **Yes** to delete.

Export a Maintenance Routine

1. Navigate to the **Maintenance** page > **Cmnds & Routines** tab.
2. Choose a routine from the **Routine Name** drop-down menu.
3. Click **Export**.
4. In the **Save As** dialog box, navigate to the folder where you want to store the routine file, then click **Save**.

NOTE: The export option is only available for routines that have been saved.

5. In the **Export Routine** dialog box, click **OK**.

Maintain Instrument Fluids

Replace the sheath fluid and empty the waste bottle as required. Manually monitor the waste bottle and waste fluid container levels.

Sheath and Waste Fluid Bottles

Be careful not to touch the seal in the waste bottle cap or allow it to become wet or dirty. This could cause the bottle to become pressurized, causing pressure errors in the system. If the seal gets wet, let it air-dry. Touching the seal can contaminate it. If it gets dirty, replace the waste bottle cap.

If using the waste line, do not move it while the system is running. While along a horizontal surface, do not permanently reroute the waste line elevation without first contacting *Luminex Technical Support*. You can move the line temporarily for cleaning and maintenance purposes.

Refill the Sheath Fluid Bottle

1. Release system pressure by removing the lid from the sheath fluid bottle.
2. Refill the sheath fluid bottle.
3. Screw the lid back on the bottle, but not too tightly, so the bottle can vent.

If the sheath bottle ever runs dry, prime the system at least twice until the air is removed from the system.

Empty the Waste Bottle



If biological samples have been tested with the system, use your standard laboratory safety practices when handling system waste.

1. Disconnect the waste bottle from the Luminex® 200™ analyzer.
2. Unscrew the waste bottle lid, being careful not to touch the Gore-Tex™ seal. If the seal becomes wet or soiled, it can impair venting.
3. Discard the waste from the waste bottle by appropriate means.
4. Reconnect the waste bottle to the Luminex analyzer and replace the cap.

NOTE: There is NO warning of a high waste volume. Empty the waste bottle each time you fill the sheath bottle.

Any time the sheath bottle is disconnected from the Luminex 200 analyzer, you must remove air from the sample lines by priming.

Sheath Delivery System (SD System)

Replace the sheath fluid and empty the waste container as required. Do not move the waste line while the system is running. Sheath fluid and waste boxes should always be placed below the instrument. You can move the lines temporarily for cleaning and maintenance purposes.

Replace the Sheath Fluid Box

1. Unscrew the cap and remove the sheath fluid intake line.
2. Remove the empty sheath box. The empty sheath box can be used as the new waste box.
3. Replace with a new sheath fluid box.
4. Replace sheath fluid intake line and screw in the cap. Do not touch the filter on the sheath intake line. Ensure the filter is near the bottom of the container.

Empty the Waste Fluid Container

To empty the waste fluid container:

1. Remove the waste line from the waste fluid container.
2. Discard the waste from the waste fluid container in accordance with lab protocols.
3. Attach the waste line to the new empty waste fluid container.

NOTE: There is NO warning of a high waste volume. Empty or replace the waste fluid container each time you fill the sheath container.

Maintain Instrument Hardware

Daily Maintenance

If the system is powered on, but idle for more than 4 hours, click **Warmup**. Wait 30 minutes for the Luminex® 200™ analyzer and the optics system to warm up.

Shut Down the System

System shutdown is a standardized procedure in xPONENT® for Luminex® 200™ software.



Sodium hydroxide is extremely caustic. If it comes into contact with skin, it can burn and cause tissue damage without causing pain. Always wear gloves and goggles when working with sodium hydroxide.

Run the **Daily Shutdown** routine to prevent clogs and crystallization of salt in the fluidics lines. Clogs and crystallization of salt in the sample probe can cause problems with calibration, verification, and data acquisition; they can also cause sample splashing. Shut down the system properly to ensure system integrity.

1. From the **Home** page, click **Shutdown**. The **Auto Maint** tab displays.
2. Click **Eject**.
3. Fill reservoir B7 on the AMP 3/4 full of DI water.
4. Fill reservoir H7 on the AMP 3/4 full of 10% to 20% household bleach.
5. Click **Retract**.
6. Click **Run**.

Weekly Maintenance

Perform a Visual Inspection

Inspect the Luminex® 200™ weekly. Make sure the instrument is idle, so there are no moving parts. Open all of the Luminex® 200™ doors.

- Visually inspect for leaks, corrosion, and other signs of improper function.
- Check all visible tubing connections.
- Check the Luminex® XYP™ instrument air intake filter for buildup of dust.
- Check the Luminex® SD™ system and its connection for leaks. If you see a leak, turn off the power to the Luminex® SD™ system and contact Luminex Corporation.

Clean the Sample Probe



Be sure that the system is not performing an operation when you remove the sample probe.

The Luminex® 200™ analyzer sample probe should slide up easily while removing it from the sample arm. If you feel resistance, do not force the sample probe up. Contact *Luminex Technical Support*.

1. Remove the sample probe as follows:
 - a. Unsnap the light housing located above the sample probe.
 - b. Unscrew the Cheminert® fitting on top of the sample probe completely.
 - c. Loosen the thumbscrew.
 - d. Gently grasp the sample probe and push up.
 - e. Remove the sample probe out of the top of the sample arm.
2. Remove the sample probe and place the narrow end of the sample probe in a bath sonicator for 2 to 3 minutes. Keep the larger end out of the sonication fluid.
3. Use the syringe to flush the sample probe with distilled water from the narrow end out through the larger end.
4. Replace the sample probe and readjust the height for the plates you are using.
5. Run three **Backflush** commands, three **Drain** commands, two **Alcohol Flush** commands, and three **Wash** commands with distilled water.

Flush the System

Run three **Backflush** commands, three **Drain** commands, two **Alcohol Flush** commands, and three **Wash** commands with distilled water.

Monthly Maintenance

Clean the Exterior Surfaces

1. Turn off the power switches and unplug the power cords to the Luminex® 200™ analyzer, the Luminex® XYP™ instrument, and the Luminex® SD™ system.
2. Clean all exterior surfaces with mild detergent, followed by a 10% to 20% household bleach, followed by distilled water.
3. Open both doors of the system.
4. Clean all accessible surfaces with detergent, followed by a 10% to 20% household bleach, followed by distilled water.
5. Dry any unpainted metal surfaces to prevent corrosion.
6. Plug in the power cords and power on the Luminex 200 analyzer, the Luminex XYP instrument, and the Luminex SD system.

Semi-Annual Maintenance

Replace the Luminex® 200™ Analyzer Air Intake Filter

NOTE: Hold on to the tubing. Do not allow the tubing to fall inside the instrument.

1. Disconnect the Luminex® 200™ analyzer from AC power by turning off the power switch on the rear of the analyzer, then unplugging the power cord from the wall source.
2. On the back of the Luminex 200 analyzer, in the upper left corner, remove the screw at the top of the panel and open the panel door.
3. Grasp the tubing and pull the Luminex 200 air intake filter 3 to 4 inches from the unit.



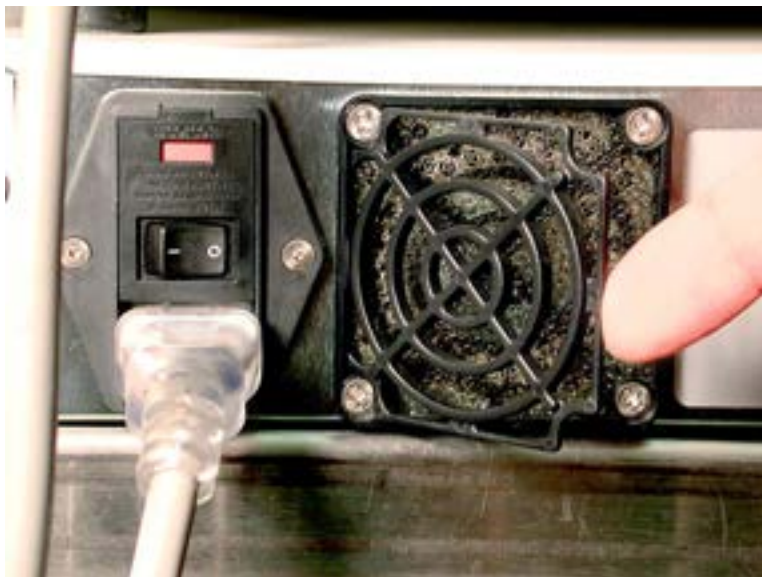
4. Remove the Luminex 200 air intake filter with one hand, and hold the tubing with the other hand.
5. Connect a new Luminex 200 air intake filter to the tubing and position the filter inside the panel.
6. Reattach the panel door to the unit using the thumb screw.
7. Plug in and power on the Luminex 200 analyzer.

Replace Luminex® XYP™ Instrument Air Intake Filter

1. Disconnect the Luminex® XYP™ instrument from AC power by turning off the power switch on the rear of the Luminex XYP instrument, then unplugging the Luminex XYP instrument power cord from the wall source.

2. On the back of the Luminex XYP instrument, to the left side, gently remove the screen from the Luminex XYP air intake filter.

NOTE: Do not remove the screws.



3. Replace the Luminex XYP air intake filter and replace the screen.

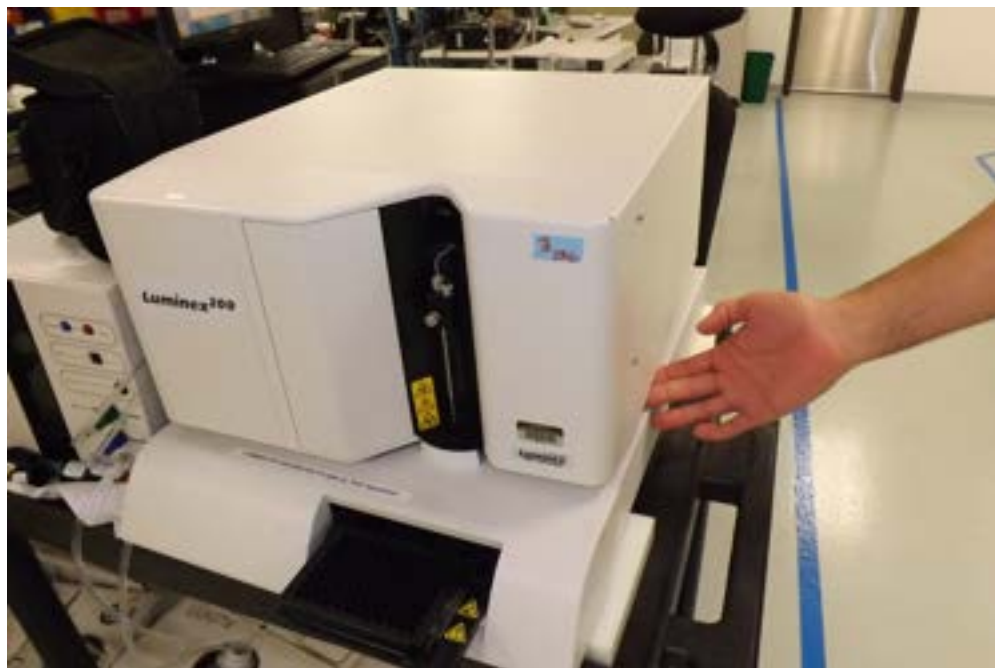


4. Plug in and power on the Luminex XYP instrument.

Clean the Analyzer's Ventilation Filter

1. Disconnect the Luminex® 200™ analyzer from AC power by turning off the power switch on the rear of the analyzer, then unplug the analyzer power cord from the wall source.

2. While facing the Luminex 200 analyzer, place your index finger up under the right side of the analyzer (in the space between the Luminex 200 analyzer and the Luminex® XYP™ instrument). When you feel the ventilation filter, push the ventilation filter toward the left of the analyzer.



3. Remove the ventilation filter from the left side of the Luminex 200 analyzer.
4. Clean the ventilation filter with a vacuum or with distilled water. Stand the ventilation filter upright to air dry.
5. Re-install ventilation filter with the arrows facing up. The ventilation filter should click into place.
6. Plug in and power on the Luminex 200 analyzer.

Replace the Syringe Seal

When you replace a syringe seal, also replace the black O-ring that fits inside it.

To replace the syringe seal:

1. Turn off the power switch on the back of the analyzer.

2. Open the door on the front center of the analyzer to gain access to the syringe. The syringe is the glass cylinder with a metal plunger inside.



3. At the base of the syringe, loosen the thumbscrew by turning it counter-clockwise six quarter-turns.
4. Turn on the analyzer and immediately watch the syringe pump.
5. Within a few seconds, the syringe arm will go down, then start going up again. As soon as it begins traveling upward, turn off the analyzer.



Do not turn off the analyzer as the arm is going down. The syringe pump valve will not be in the correct position, allowing sheath fluid to drain out of the valve when you remove the syringe.

6. If the base of the plunger did not come out of the arm when it cycled, loosen the thumbscrew a little more and very lightly attempt to lift the plunger away from the base. If the problem persists, contact *Luminex Technical Support*.

7. Unscrew the syringe from the top of its housing.



8. Pull the plunger out of the syringe.
9. Remove and replace the plunger seal and the black O-ring.
10. Replace the plunger into the glass syringe.



The syringe arm does not deactivate when changing the plunger; injury could result if the system is not unplugged.

Replace the Syringe

1. Screw the syringe into place.
2. Grab the base of the syringe plunger and gently pull down on it until it is fully seated into the opening of the arm.
3. Tighten the thumbscrew at the base of the syringe completely. If the thumbscrew does not go in as far as it did before, reposition the plunger and try again.
4. Power on the analyzer. The syringe will return to its home position before the analyzer begins its normal start up process.
5. Run two **Prime** commands, and watch for any leaks in the syringe area.
6. When the **Prime** finishes, close the analyzer door.

Annual Maintenance

Replace the Sheath Filter

1. Turn off the Luminex® 200™ and unplug the power cord.
2. Disconnect the sheath fluid tubing before changing the sheath filter.
3. Open the left door on the Luminex 200.

4. Disconnect the sheath filter by pushing down on the metal clamps on each connection.



5. Connect the new sheath filter, matching up the color-coded fittings. The arrow on the sheath filter should be pointing up.
6. Reconnect the sheath fluid tubing.
7. Close the left door.
8. Plug in and power on the Luminex 200.
9. Run two **Prime** commands.

As Needed Maintenance

Replace the Fuses

Periodically, you may need to replace a fuse on the Luminex® 200™. Use fuses with the following specifications:
F2A, 250 V



To avoid serious injury or death by electric shock, turn off the system and unplug the power cord from the wall before replacing a fuse.

To replace a fuse:

1. Turn off the Luminex 200 and unplug the power cord.
2. Use a small, flat blade screwdriver to open the module door on the lower left corner of the back of the system.

3. Use the screwdriver to remove the red cartridge.



4. Check both of the fuses in the cartridge for damage. A fuse can display physical evidence of damage, for example, broken wire or blackened glass; if the fuse displays no physical evidence, test the fuse for continuity with a voltmeter.
5. Replace any damaged fuse with the type specified on the sticker to the right of the power input module.
6. Replace the red cartridge.
7. Shut the module door.
8. Plug in the power cord and turn on the Luminex 200.

Replace the Luminex® SD™ with a Sheath Bottle

You will need to replace the Sheath Delivery System (Luminex® SD™) with sheath bottles for maintenance or troubleshooting.

1. With the Luminex SD still connected, perform **Warm Up** using the software.
2. When the pressure has stabilized, note the sheath pressure in the software.
3. Use a screwdriver to turn the regulator on the Luminex SD approximately five full turns to the left (counterclockwise).
4. Shut down the Luminex SD. Disconnect the Luminex SD system and air, sheath fluid, and waste fluid tubing from the analyzer.
5. Attach the sheath bottles (preferably full) to the analyzer.
6. Open and close the sheath bottle caps in order to release any remaining pressure within the system.
7. Perform **Warm Up** using the software if the compressor has turned off.
8. When the pressure has stabilized, note the sheath pressure.
9. If the pressure is equal to the value noted above (within +/- 0.1psi), then the set up is complete. If not, continue with the next step. After each adjustment, you will have to release the pressure and let it build back up again in order to obtain an accurate pressure reading. Any time the compressor turns off while making adjustments, perform another warm up to maintain pressure in the system.
10. On the analyzer, turn the regulator clockwise (right) to increase the pressure or counterclockwise to decrease the pressure. There is no exact measurement of pressure increase or decrease for each turn of the regulator. Try one full turn in the required direction to start.
11. Release the pressure by opening and closing the sheath bottle cap.
12. Repeat the following steps until you obtain the original sheath pressure reading noted in step 2, within +/- 0.1 psi.

- a. On the analyzer, turn the regulator clockwise (right) to increase the pressure or counterclockwise to decrease the pressure. There is no exact measurement of pressure increase or decrease for each turn of the regulator. Try one full turn in the required direction to start.
- b. Release the pressure by opening and closing the sheath bottle cap.

NOTE: Do not move the sheath bottle or sheath line while the system is in use.

Back up the System

Before uninstalling xPONENT® software, perform a back up of the system. You can also schedule regular backups of the data.

1. Log off and exit out of xPONENT before performing a backup of the system.
2. Navigate to the **Windows logo** > **Luminex** folder > **xPONENT Archive**. The **Archive Utility** dialog box displays.
3. Click **System Backup**.
 - a. In the **Login** dialog box, enter the admin **User name** and **Password** if you have the secure version of the software. Click **OK**.
 - b. In the **Browse For Folder** dialog box, navigate to the **Backup** folder - which should automatically be chosen. Click **OK**.

NOTE: The **System Backup Started** dialog box displays at the bottom right of the screen.

4. Click **Close** in the **Archive Utility** dialog box.
5. When the backup is complete, navigate to the desktop and double-click the **Backup** shortcut folder. You will see the backup zip file and the name includes the date and time.

Archive Data

Set Up Automatic Archiving

1. Navigate to the **Admin** page > **Archive** tab.
2. Click **Launch Archive Utility**. The **Archive Utility** dialog box displays.
3. Click **Edit** under **Schedule Overview**. The **Login** dialog box displays.
 - a. Enter your **User name** and **Password**, if you have the secure version of the software.
 - b. Click **OK**.
4. Specify when you want your archives to begin, using the calendar.
5. Using the drop-down menu, choose the frequency of how often you want to perform archives.

NOTE: The default frequency to archive is daily.

6. Select **Reminder Only** to be reminded of the need to archive, after which you must archive manually. Clear this check box to enable automatic archives.
7. In **To Be Archived**, choose the date and batch parameters for the files you want to archive:

- Only archive batches older than: [x] Days
 - Always keep the last: [x] Batches
 - Archive all system logs older than: [x] Days
8. In the **Archive Folder** section, verify the location to which you want to archive the file(s). To change the location, click **Browse**, then navigate to the new location and click **OK**.
- NOTE:** If you change the default archive location, ensure that the **Archive Folder** section reflects that same location when you import those archived files.
9. Click **Save** to save your settings.

Perform a Manual Archive

Use **Manual Archive** only when you need to archive specific individual files.

1. Navigate to the **Admin** page > **Archive** tab > click **Launch Archive Utility**. The **Archive Utility** dialog box displays.
2. In the **Archive Utility** dialog box, click **Manual Archive**.
3. In the **Login** dialog box, enter the username and password, and click **OK**.
4. Use the tabs on the left side of the window to choose the type of files you want to archive.
NOTE: Each tab opens a list of files available for archiving, except **Logs**, which requires only a choice of how old, in days, a file has to be archived.
5. Choose the files you want to archive from the list on the left and use the arrow keys to move those files to the **To Be Archived** box on the right. For log files, select the age of the files, in days.
6. Click **Archive** to move the selected files to the archive.
NOTE: You must archive each group of files separately. If you select a different tab without archiving first, xPONENT® warns you that you will lose the information in the **To Be Archived** box.
7. Click **Close**.

Maintenance Log

Reproduce the following form as necessary and use them to record maintenance information.

MONTH: _____ YEAR: _____

Luminex® 200™ Maintenance Log

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Day of the Month																															
Daily																															
Warm up laser																															
Check fluid levels																															
Run performance verification																															
Run system shutdown																															
Turn off system (optional)																															
Weekly																															
Perform visual inspection																															
Clean sample probe																															
Calibrate																															
Flush the system																															
Monthly																															
Clean exterior surfaces																															
Semi-annual maintenance																															
Replace analyzer air intake filter	Yes		No																												
Replace XYP™ air intake filter	Yes		No																												
Clean analyzer ventilation filter	Yes		No																												
Replace syringe seal or syringe	Yes		No																												
If Yes, Date: _____																															
If Yes, Date: _____																															
If Yes, Date: _____																															
If Yes, Date: _____																															
Annual maintenance																															
Replace sheath filter	Yes		No																												
If Yes, Date: _____																															
If Yes, Date: _____																															
If Yes, Date: _____																															
If Yes, Date: _____																															

Chapter 9: Storing the System

Store the System

To prepare the Luminex® 200™ for long-term storage:

1. Run a **Sanitize** command with 10% to 20% household bleach.
2. Run a **Sanitize** command with distilled water.
3. Run four **Wash** commands with distilled water.
4. Remove the sample probe from the instrument, flush with distilled water from the narrow end out through the larger end, replace it in the sample arm, and wrap the end with PARAFILM®.

Prepare the System for Use After Storage

To prepare the system for use after long-term storage:

1. Turn on the Luminex® 200™ and XY Platform and watch for the following indications of correct response:
 - The light above the sample probe on the Luminex® 200™ and the light next to the door of the XY platform are lit.
 - The compressor starts in the Luminex® 200™. It is a low rumbling sound.
 - Place your hand behind the Luminex® 200™ to feel air coming out of the rear fan.
 - Observe movement of the syringe inside the front middle door of the Luminex® 200™ shortly after the instrument is powered on.
2. Turn on the PC and start xPONENT®.
3. Run a **Warmup** command, which will take 30 minutes.
4. Remove the PARAFILM® from the end of the sample probe.
5. After warmup is complete, run three **Backflush** commands, three **Drain** commands, two **Alcohol Flush** commands, and three **Wash** commands with distilled water. Make sure that the sheath bottle or Luminex® SD™ has a sufficient amount of sheath fluid and that the waste fluid container is empty. Verify that the pressure during each of the maintenance commands reads between 6 psi and 9 psi.

Chapter 10: Shipping and Decontaminating the System

If a serious problem arises with the Luminex® 200™, you may need to return the system to Luminex Corporation for repairs. If *Luminex Technical Support* directs you to return the system, the Technical Support representative will provide you with all the necessary information as well as a Return Material Authorization (RMA) number.



Before the instrument is returned, perform two procedures: Decontaminate the instrument and prepare the instrument for shipping.

Decontaminate the System

Occasions may arise when it becomes necessary to decontaminate the entire Luminex® 200™ system. If you must decontaminate the system, sanitize the accessible surfaces and the internal fluidics system. This is particularly important when biohazardous samples have been run.



Wear appropriate personal protective equipment when handling parts that come into contact with potentially biohazardous samples.

To decontaminate the Luminex 200 system:

1. Remove all specimens, disposables, and reagents from the system.
2. Disconnect the sheath line going from the Luminex® SD™ system to the analyzer.
3. Connect a sheath bottle filled with a solution of 10% to 20% household bleach and waste bottle to the analyzer.
4. Run a **Sanitize** command with 10% to 20% household bleach followed by two **Wash** commands with distilled water.
5. Disconnect the system from AC power by turning off the power switch on the rear of the system, then unplugging the analyzer power cord from the wall source.
6. Disconnect the Luminex SD system and waste and sheath fluid containers.
7. Rinse the waste fluid container with 10% to 20% household bleach and drain.
8. Clean all exterior surfaces with mild detergent followed by 10% to 20% household bleach, then wipe down with distilled water.
9. Open the front doors of the analyzer.
10. Clean all accessible surfaces with mild detergent, followed by 10% to 20% household bleach, then wipe down with distilled water.

Drain the Reservoir

If you need to ship the Luminex® SD™ system back to Luminex Corporation, drain the reservoir before you pack the system.

1. Perform a **Warmup** command to pressurize the system.
2. Leave the green air tubing connected between the Luminex® 200™ analyzer and the Luminex SD system.
3. On the Luminex SD front panel, disconnect the blue tubing from the intake labeled **Sheath Out** and disconnect the white tubing from the intake labeled **Sheath In**.
4. Insert the white tubing into the intake labeled **Sheath Out** and insert the blue tubing into the intake labeled **Sheath In**.
5. Turn the unit off and then on again.
6. Press the **Prime** button on the front panel of the Luminex SD system.
7. Sheath fluid will pump from the Sheath Delivery System reservoir into the 20 L Sheath Box.

To refill the Sheath Delivery System, reconnect the tubing according to color coding and press the **Prime** button on the Luminex SD. Contact *Luminex Technical Support* for additional information.

Prepare the System for Shipping

Luminex Technical Support will give you a Return Material Authorization (RMA) number if they direct you to return the system. They will explain how to return the system according to Luminex procedures.

1. Pack the system within a biohazard bag, place it in the corrugated box, then insert it in its original packaging or an approved shipping container.
2. Attach the shipment checklist to the top of the corrugated box prior to packaging in the crate.

Shipment Checklist

Complete the following checklist, sign and date it, and return it with the Luminex® 200™.

1. Remove all specimens from the instrument.
2. Decontaminate the instrument.

NOTE: It is the user's responsibility to decontaminate the instrument before shipment.
3. Prepare the instrument for shipping.
4. Was there an internal leak in the system? YES NO

Printed Name:	
Signature:	
Company/Institution:	
Date:	
Instrument Serial Number:	

Dispose of the System



Within the European Union, the Waste Electrical and Electronic Equipment Directive requires that you properly dispose of electrical and electronic equipment when it reaches its end of life.

If you are disposing of a Luminex® 200™ system, decontaminate the system. Next, contact *Luminex Technical Support* for a Return Material Authorization (RMA) number at +1-512-381-4397 (outside of the U.S.). Return the equipment to the following Luminex location:

Luminex Corporation
 12201 Technology Blvd., Suite 130
 Austin, Texas 78727, USA

For information about disposal of the system outside of the European Union, contact *Luminex Technical Support*. For information about disposal of the barcode scanner, PC, or monitor, refer to the manufacturer documentation.

Appendix A: Software Functionality

Software Packages

Multiple levels of user access can be licensed for xPONENT®.

The Basic license key includes:

- **Basic Software** - Allows the end user to perform analysis from protocols and batches, review and print reports, and perform Luminex system maintenance.
- **Instrument Control** - Allows the application to connect to and communicate with an instrument identified by a specific serial number.
- **Remote Web Monitoring** - Allows the end user to view alerts and system status from a different computer using a webpage.

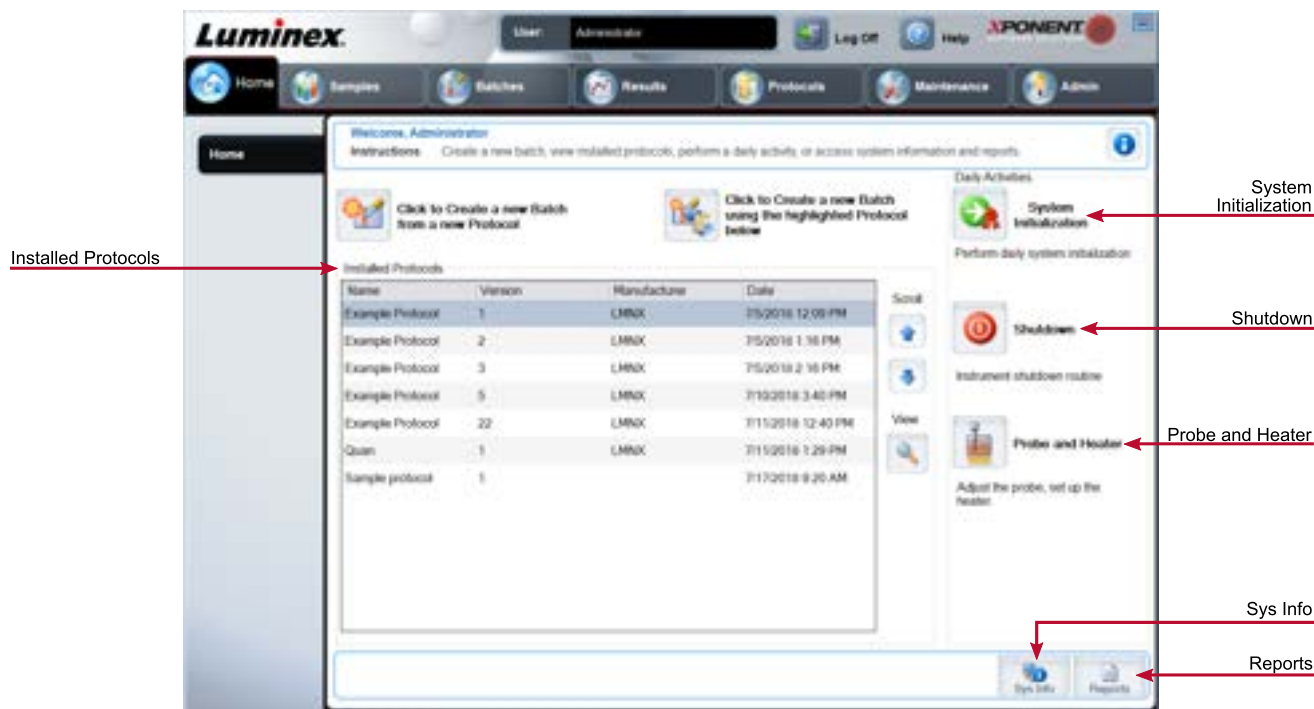
Additional features for which you can obtain a license:

- **Secure** - Includes all of the Basic functions as well as administrator-controlled user permission levels.
- **21 CFR Part 11** - Includes all of the Secure package features as well as the option to require electronic signatures to perform certain tasks. (Electronic signatures are listed in the system log.)
- **Automation** - Includes the ability to communicate with external hardware.
- **LIS** - Enables the system to communicate with an external Laboratory Information System (LIS) database. The LIS package enables you to export and import patient result data in ASTM file format.

For more information about purchasing additional features, or to obtain specific package documentation, contact your vendor.

Home Page

Figure 12: Home Page



The **Home** page displays a welcome message, batch creation buttons, **Daily Activities** shortcuts, and the **Installed Protocols** list. Return to the **Home** page at any time by clicking **Home** in the navigation toolbar.

Table 11. Home Page Screen Elements

Click to Create a new Batch using the highlighted Protocol below	Creates a new batch using a selected protocol from the Installed Protocols list.
Installed Protocols	Displays a list of protocols.
Scroll	Scrolls through the list of protocols.
View	Opens Protocols tab > Settings subtab to view the chosen protocol.
Sys Info	Opens Maintenance page > System Info tab.
Reports	Opens Results page > Reports tab.
System Initialization	Opens Maintenance page > Auto Maint tab.

Certain sections of the software such as tables, lists, and text boxes have right-click option menus. Menus are different depending upon the item you right-clicked.

Table 12. Right-Click Menu Screen Elements

Print All	Prints all sections or cells of the item.
Print Selection	Prints only the selected section or cell.
Import	Imports a file.
Export/Export Grid Contents	Exports all data from the right-clicked item.
Cut	Cuts the selected data.
Copy All	Copies all data.
Copy	Copies only the selected data.
Paste	Pastes previously copied text or data into the field.
Delete	Erases text or data from the selection.

Online Help

English-language help is available at all times while you are using xPONENT®.

To display online help for the page or tab you are currently working in, click the "i" icon, in the upper-right corner of the xPONENT window. A help window displays information specific to that page or tab.

To display system-level help, click the "?" at the top of the xPONENT window, then click **Contents and Index**. A help window displays so you can navigate to any available topic.

To display quick start information, click the "?" at the top of the xPONENT window, then click **Quick Start**. A help window displays information about the basic steps to start the system.

To display software information, click the "?" at the top of the xPONENT window, then click **About Luminex® xPONENT**. The xPONENT information dialog box displays the software version information.

System Monitor Overview

The **System Monitor** is located at the bottom of all xPONENT® windows. The System Monitor displays the physical state of the Luminex® system. Values are reported directly from the Luminex system.

System Status button	When clicked, the System Log displays. It also displays the current status of the system. If there are no warnings or errors, the System Status button is green with a check mark. If there is a warning, out of calibration condition, or other important user notification, the button is yellow with an exclamation point.
Connected Status	Displays the status of the instrument's connection to the PC (Connected or Disconnected).

Check Cal/Ver Status	Displays a white X if there is a failed calibration or verification.
Command display	Displays the command currently running, the system state (i.e., running, idle, etc.), and date and time.
Progress bar	Displays a bar graph showing the progress of the current command or routine; if the command or routine is finished, it displays a full progress bar and the command status as Complete .
Stop button	Stops the system, regardless of command status. Use this only if it does not matter whether the data from the current well is lost.
Pause button	Pauses the system after the current command completes. Pause does not stop the system in the middle of running a command. You cannot run another command while the system is paused. Pause the system before stopping it so that it will finish the current command and store the pending batch and then resume exactly where it left off.
Eject button	Ejects the plate. Once the plate is ejected, the Eject button changes to Retract . Retract retracts the plate, and the Retract button changes back to Eject .
Delta Cal Temp	Displays the difference in temperature between the current reading and the reading when the system was calibrated, in degrees Celsius.
XY Status	Displays the current location of the command, and the temperature of the plate heating block in degrees Celsius.
Sheath Pressure	Sheath pressure is displayed in PSI, an arrow will indicate if pressure is above or below expected pressure range for the instrument. When clicked on, the Maintenance page > System Info tab opens.
Laser	Indicates laser's current status.
Region Events	Displays the number of bead events detected per second that are classified in a region.
Total Events	Displays the number of total events detected per second.
Warm Up	Starts or schedules a laser warmup.

Arrange Main Navigation Pages

NOTE: The Home page cannot be moved. The Admin page cannot be removed if a security license is not being used, or if the user currently logged in is set up as a member of the Administrator group profile.

To arrange the main navigation buttons:

1. Navigate to the **Admin** page > **System Setup** tab.
2. In the **Arrange Main Navigation Button** section, select or clear the check boxes by each page name to hide or display the page.
3. Click a main page header and then click the up and down arrows to change the order in which the pages display, from left to right.

4. Click **Save**.
5. Click **Default** if you want to restore the main navigation.
6. In the **Settings Saved** dialog box, click **OK**.

Samples Page

Samples Tab

Use the Samples tab to create new samples, view the sample list, create a batch, and to view and edit samples for protocols. The Samples tab is intended to be used with an LIS. If you want to import a sample list, use the Import List function when creating the batch or editing the protocol.

Figure 13: Samples Tab

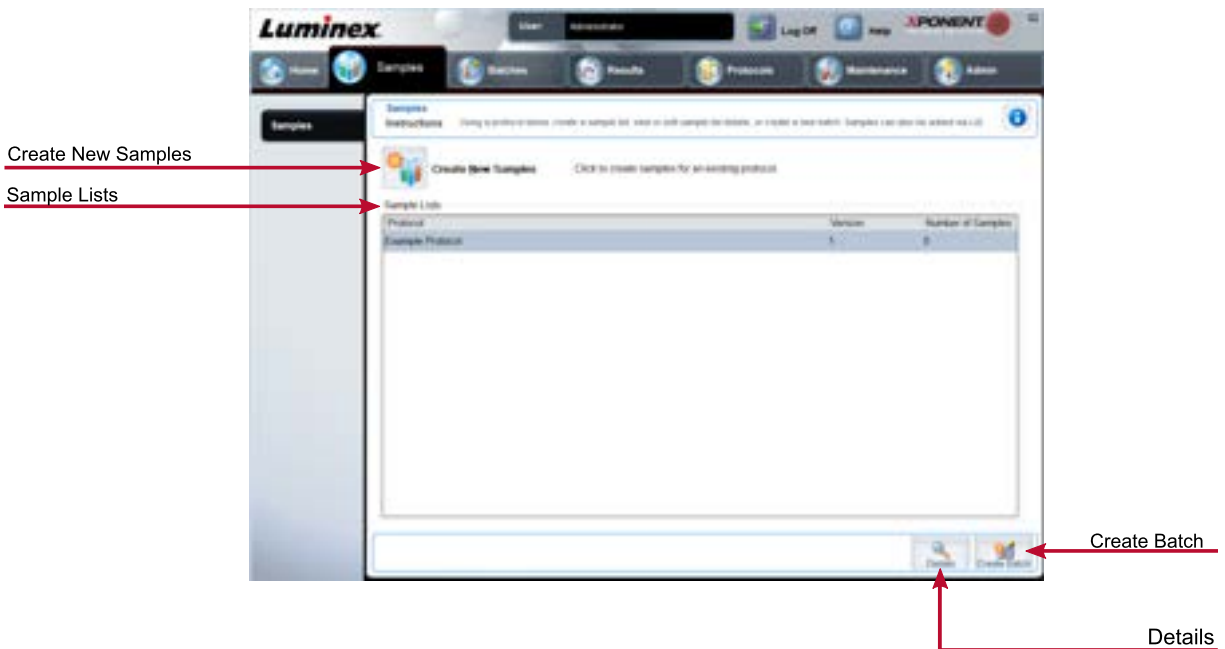


Table 13. Samples Tab Screen Elements

Create New Samples	Creates a new sample.
Details	View and edit sample details for the chosen protocol.
Create Batch	Creates a LIS batch for the protocol.

Create Sample Subtab

Use the Create Sample subtab to enter and view sample information.

Click Create New Samples from the Samples tab to display the Create Sample subtab. In the Sample section, if you have the LIS-enabled version of the software and are currently connected to the LIS, the sample list auto-populates when the LIS provides sample orders. You can only view or run a sample list created in the LIS; you cannot edit it.

Edit Samples Subtab

Use the Edit Samples subtab to edit a sample for the chosen protocol.

Batches Page

Batches Tab

Use the Batches tab to create a new batch from an existing protocol, and create a new multi-batch.

Figure 14: Batches Tab

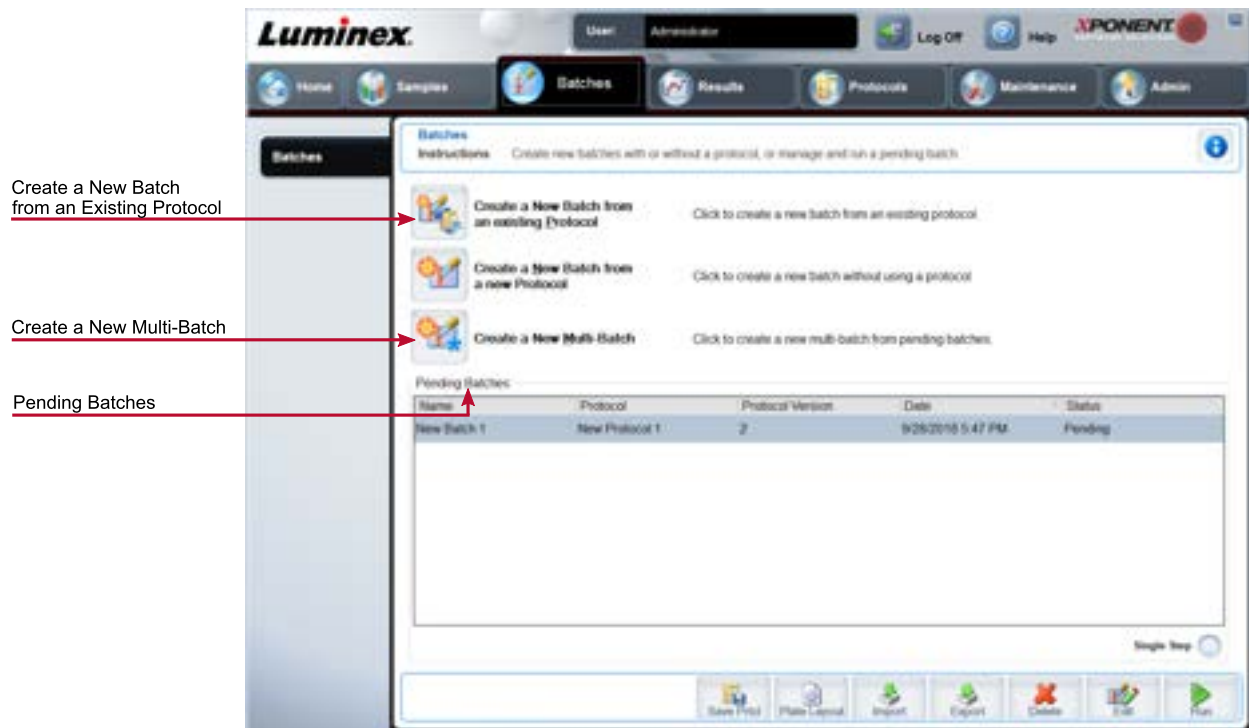


Table 14. Batches Tab Screen Elements

Create a New Batch from an existing Protocol	Creates a new batch from an existing protocol.
Create a New Multi-Batch	Creates a new multi-batch.

Pending Batches	Displays the name of the protocol used with the batch, the protocol version, date, and status for each pending batch.
Single Step	Instructs the system to acquire one well and then pause. If Single Step is activated during a batch, the batch pauses at the end of the current well. This ensures that the system is working currently before you run an entire batch.
Save Prtcl	Saves protocol and/or assay information for a standard/control
Plate Layout	Opens the Report dialog box, which includes the Batch Plate Layout Report. Confirm that the plate layout conforms to your specific assay instructions.
Import	Imports a batch, not previously run in xPONENT®, from a folder on the PC.
Export	Exports the batch information in order to move it to another computer, make a copy of the data, and then import it into xPONENT on another computer.

Batches Tab > Protocol Subtab

Use the Protocol subtab to name a batch, enter a batch description, choose the protocol needed for running the batch, and view active reagents.

Figure 15: Protocol Subtab

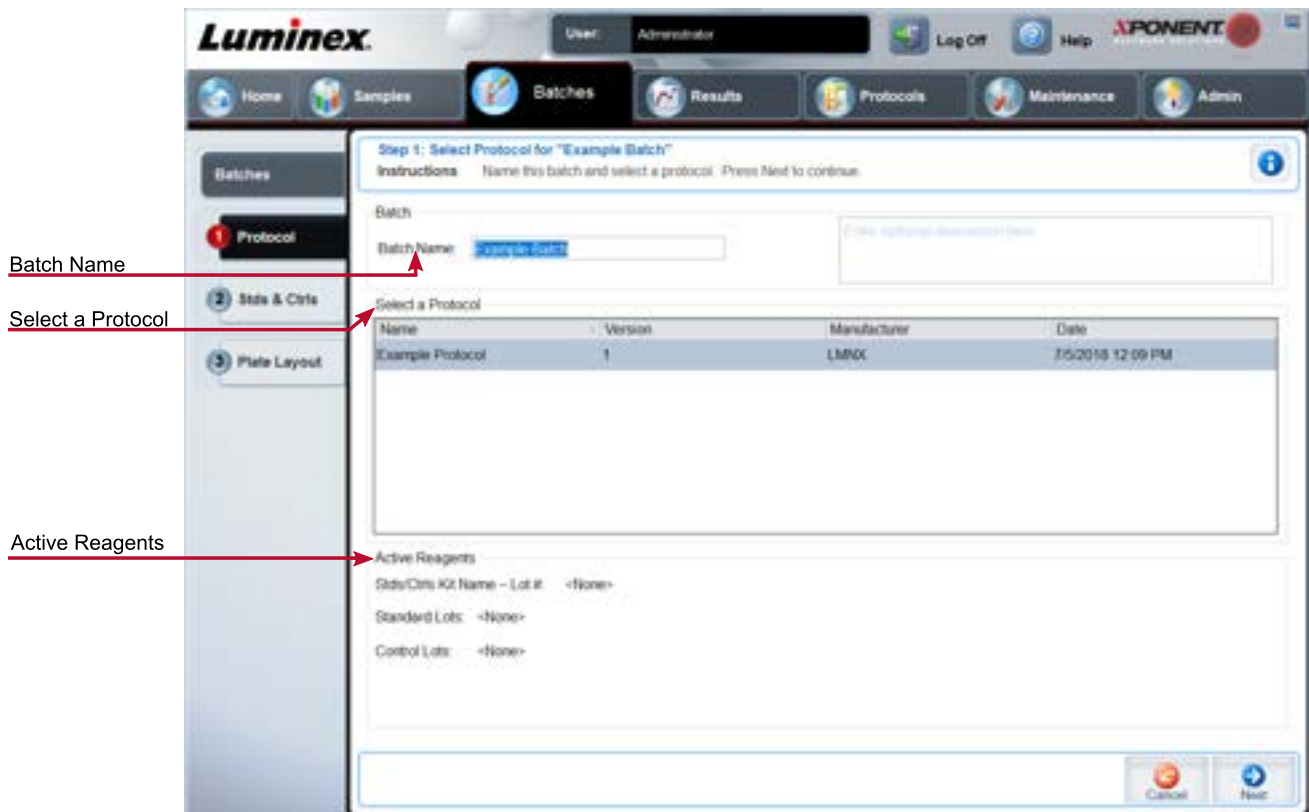


Table 15. Protocol Subtab Screen Elements

Batch Name/Description	Batch name and batch description.
Select a Protocol	Contains the protocol name, version, manufacturer, and creation date for each protocol.
Active Reagents	Displays assay and control lots/kits associated with the selected protocol. The Standard/Ctrl Kit Name - Lot# field displays the assay standard/control kit/ lot name and lot number currently associated with the selected protocol.

Batches Tab > Stds & Ctrls (Standards and Controls) Subtab

Use the Stds & Ctrls subtab to apply a kit or lot.

Figure 16: Stds & Ctrls Subtab

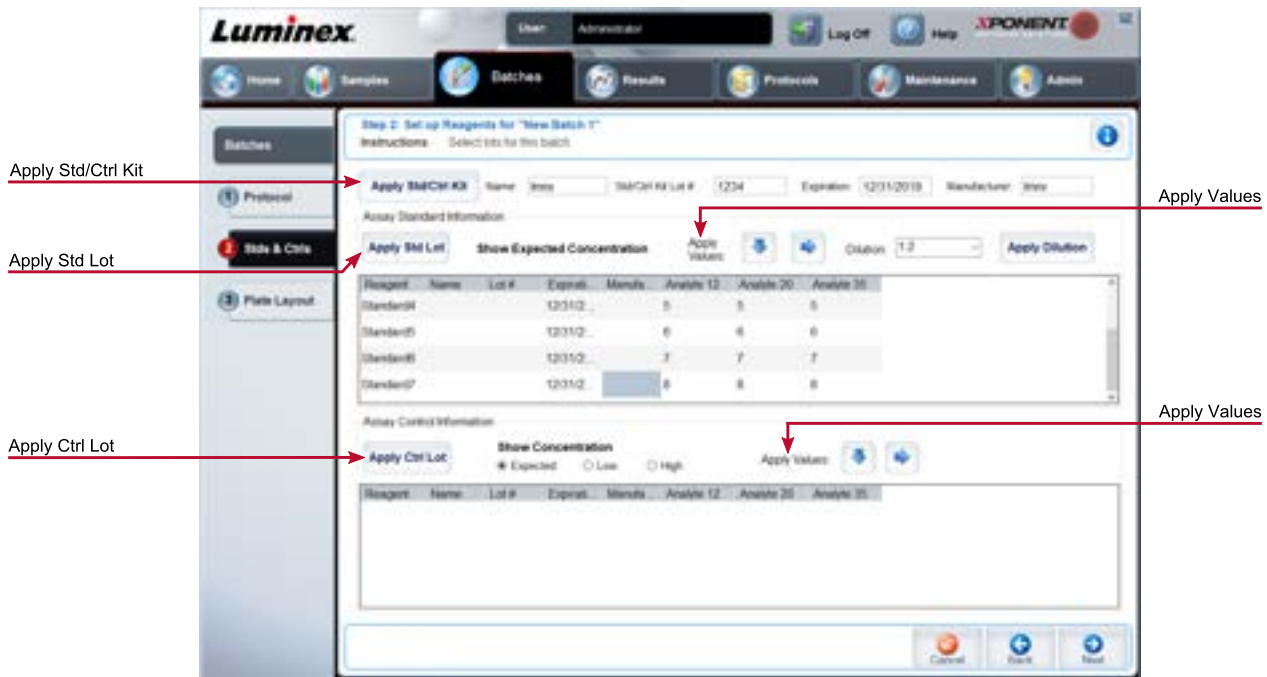


Table 16. Stds & Ctrls Subtab Screen Elements

Apply Std/Ctrl Kit	Applies a Std/Ctrl Kit. The chosen kit must be associated with the same analyte names.
---------------------------	----------------------------------------------------------------------------------------

Assay Standard Information	Displays the chosen standard reagents in a list. Click the Reagent column header to re-sort the order from the highest number standard to standard number one. This is useful for applying dilutions in which the last standard is the highest standard.
	Apply Std Lot - Applies a standard lot.
	Apply Values arrow buttons - Applies a value down or across the list of analytes.
Assay Control Information	Lists the selected control reagents. Existing control lot information can be applied or new information can be entered manually.
	Apply Ctrl Lot - Applies a control lot.
	Show Value - Expected, Low, and High set the expected, lowest, or highest acceptable concentration of the analyte in the sample.
	Apply Values arrow buttons - Applies a value down or across the list of analytes.

Batches Tab > Plate Layout Subtab

Use the Plate Layout subtab to define commands that apply to one or more wells, define off-plate and maintenance commands, and define well locations for samples, standards, controls, and background.

Figure 17: Plate Layout Subtab

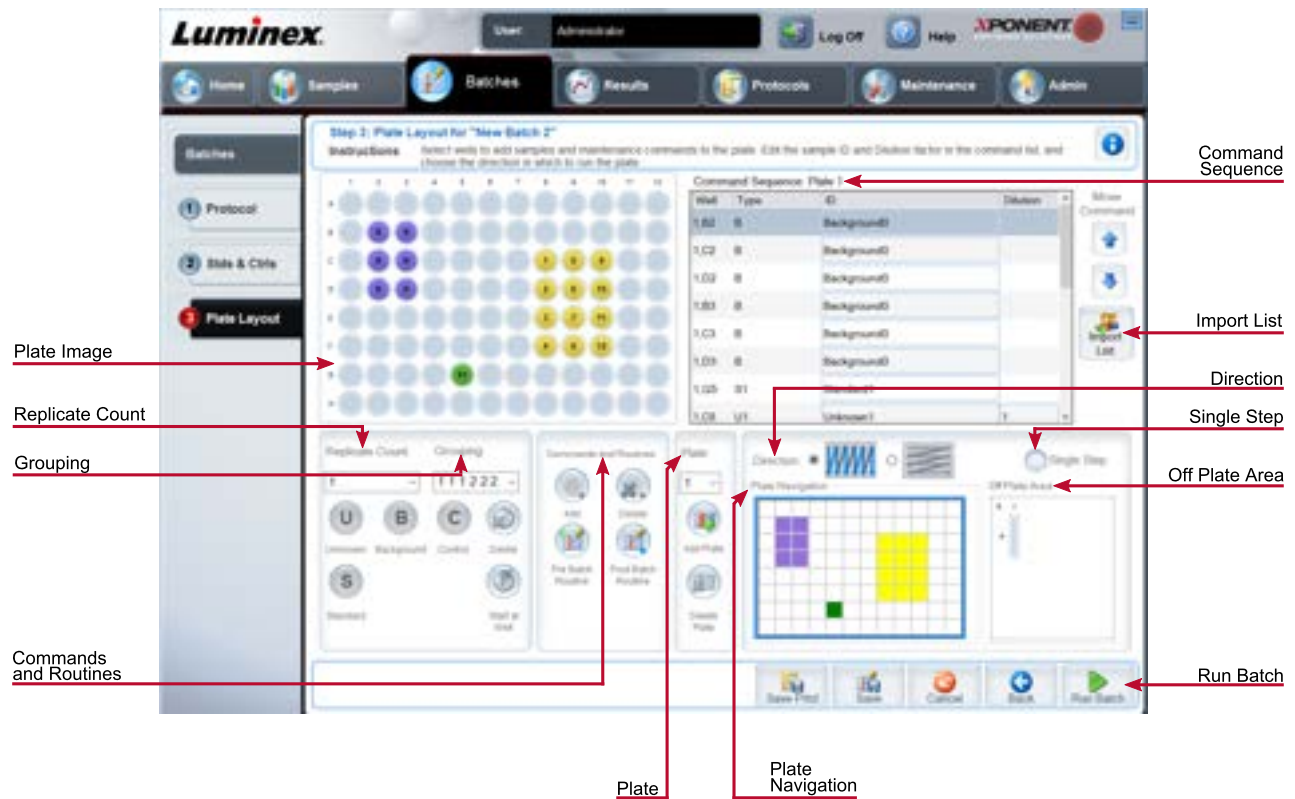


Table 17. Plate Layout Subtab Screen Elements

Plate Image	Represents the plate. Each well appears as a circle on the grid. Well commands appear in the appropriate circles as you assign them to wells on the plate.
Command Sequence	Contains the command sequence for the active plate. A command's ID and Dilution fields have a blue border around them if they can be double-clicked to enter information.
Move Command	Changes the acquisition order of a command.
Replicate Count	Defines a quantity of replicate sets from one to nine. Replicate count selection must be made before adding a well command

Grouping	<p>Selects the sequence in which the replicates are laid out in plate wells. Options for Grouping are:</p> <ul style="list-style-type: none"> • 123123123. . . Lays out one of each replicate set at a time in numerical order. • 111222333. . . Lays out all the replicates in a set before moving on to the next set in numerical order. <p>Each command is associated with a color. Click and drag to highlight a series of wells; click a column or row header to highlight the entire column or row, or click and highlight different wells and then click a command below to assign that command to all the highlighted wells.</p> <ul style="list-style-type: none"> • Unknown (U): Yellow • Background (B): Purple • Control (C): Red • Standard (S): Green
	<p>Delete - Removes the well command from the selected well.</p>
	<p>Start at Well - Enables you to begin acquisition at a well other than A1.</p>
	Commands and Routines
<p>Add - Adds a command or routine to the selected well.</p>	
<p>Delete - Deletes any command or routine associated with the selected well.</p>	
<p>Pre-Batch Routine - Adds the command or routine before running the batch.</p>	
<p>Post-Batch Routine - Adds the command or routine for running the batch.</p>	


Plate	Specifies the plate to display in the plate image in the list.
	Add Plate - Adds a new plate to the batch.
	Delete Plate - Deletes the plate highlighted in the list.
Direction	Specifies the direction to run the plate commands. The selected direction also dictates how wells are added to the plate when assigning multiple unknowns, standards, and controls at one time.
Plate Navigation	Displays a smaller plate image for the current batch.
Single Step	Instructs the system to acquire one well and then pause. If Single Step is activated during a batch, the batch pauses at the end of the current well. This ensures that the system is working currently before you run an entire batch.
Off Plate Area	Displays the location for maintenance commands in the Command Sequence list.
Save Prtcl (When creating a batch)	Opens the Save Protocol dialog box to save the protocol and/or kit.
Run Batch	Runs the batch and opens the Current Batch tab, where you can monitor the batch as it runs.
Import List	Imports a sample list into the Command Sequence section.

Batches Tab > Settings Subtab

Use the Settings subtab to name your new batch and configure acquisition settings, view the acquisition parameters of the selected saved batch (for existing batches), and print the batch settings report.

NOTE: When running a kit with a provided protocol, the protocol for the assay must be run as instructed in the assay's package insert.

Table 18. Settings Subtab Screen Elements

Volume	The instrument acquires from the sample well the desired sample volume (µL). Use values ranging from 20 µL to 200 µL. To avoid air intake, add an additional 25 µL to the sample volume in each well. The default value is 50 µL.
XY heater	Select Enabled to enable the XY heater. In the field, type the desired value in degrees C . The temperature range is 35°C to 60°C in 0.5 increments.
	Acquiring data before the heater has reached the proper temperature can compromise test results.
Timeout	The maximum number of timeout seconds when setting up a batch or protocol in xPONENT® is 250.

Bead Type	You can choose Microplex® or MagPlex®.
DD Gating (Doublet Discriminator)	Sets the minimum and maximum DD Gating values. In the first box, enter the minimum value. In the second box, enter the maximum value. The default is 7500 to 15000.
Reporter Gain	Choose Default from the drop-down menu to decrease the reporter gain or Enhanced PMT (High) .
Analysis Type	<p>Use this list to choose from the following analysis types:</p> <p>None - No analysis. Choose if you have your own data post-processing program and want to obtain only fluorescent intensity results. You cannot apply standards or controls when you select None. You cannot analyze acquisitions with this setting.</p> <p>Qualitative - Qualitative analysis determines results as either positive or negative, reactive or non-reactive. The software is flexible in defining custom result ranges, such as negative, low positive, or high positive. Determinations are based on a single standard. For qualitative analysis the Luminex software uses a specific algorithm, shown below.</p> $(FI_{\text{sample}})/(FI_{\text{standard}}) = K_i$ <p>Where FI = Fluorescent Intensity and K_i = a "Quali" value entered in lot information to determine the value or the qualitative assay standard.</p> <p>The "Quali" value determines a cutoff or threshold. This, in conjunction with ranges using the Lum Qual formula or an edited range specific for your assay, helps to determine qualitative results for unknown samples.</p> <p>Two predefined formulas using the algorithm are included in the system. You can use them as is or edit their range values to meet your requirements</p> <p>Quantitative - Determines the sample concentrations from standard curves using regression methods. Cubic Spline, Linear, Logistic 4P, and Logistic 5P. Enter the desired values for standards and controls in the Number of Standards and Number of Controls fields. Select either Fit of All Standards or Mean of Replicates for the calculation of the curve fit.</p> <p>Luminex recommends Fit of All Standards as the most accurate calculation of the curve fit.</p> <p>Based on a range of quantitative, numerical results, a threshold range can be applied to a quantitative analysis, for example, high, low, saturated, and expected.</p>

Number of Standards	The number of standards for the protocol. Applies only to qualitative and quantitative analysis.
Number of Controls	The number of controls for the protocol. Applies only to qualitative and quantitative analysis.
Fit of all Standards	Determines the standard curve by using each individual standard replicate when calculating the standard curve. For example, if you run duplicates of a 7-point standard curve, the software will calculate the standard curve by using 14 points. Applies only to quantitative analysis.
Mean of Replicates	Averages the individual standard replicates when calculating the standard curve. Applies only to quantitative analysis. For example, if you run duplicates of a 7-point standard curve, the software will calculate the standard curve by using 7-averaged points.
Analyze results while acquiring samples	The software allows real-time viewing of the results as the instrument analyzes samples. This feature is not available if you chose None as your analysis type.
Use External Analysis Program	Use a third-party program to analyze the data. The Analysis Program list becomes active. Applies only to qualitative and quantitative analysis.

Batches Tab > Analytes Subtab

Use the Analytes subtab to select or edit analytes used in the batch or protocol.

Figure 18: Analytes Subtab

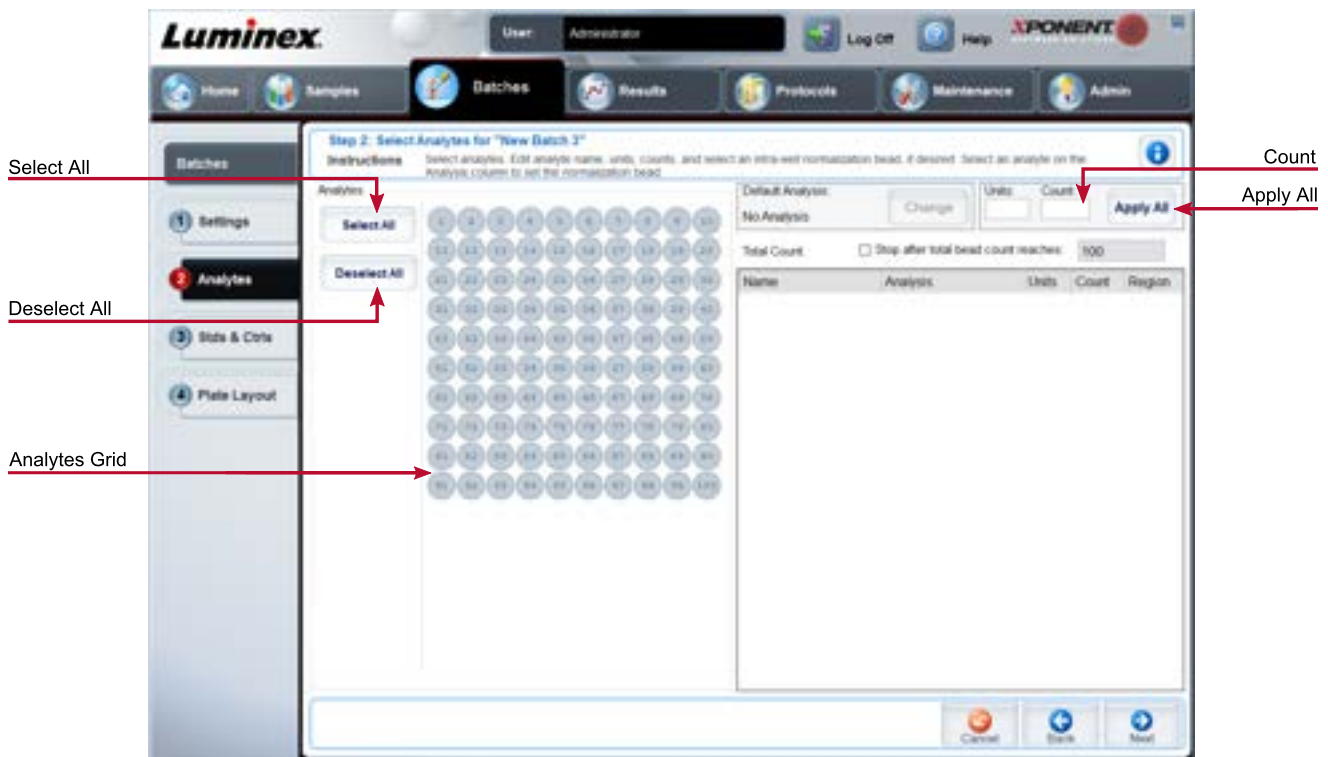


Table 19. Analytes Subtab Screen Elements

Analytes grid	A grid representing each analyte from 1 to 100.
	Select All - Selects all analytes.
	Deselect All - Deselects all analytes.
	<p>Default Analysis - The default analysis changes based on the Analysis Type selected in the Settings tab. You can change the analysis settings for all analytes by clicking Change if this button is enabled in this tab.</p> <p>If you selected Quantitative on the Settings tab, the default analysis formula is 5P Weighted. To change the default, select one of the following from the Method list:</p> <ul style="list-style-type: none"> • No Analysis • Cubic Spline • Linear Fit • Logistic 4P • Logistic 5P
Count	The desired bead count for the analytes. The instrument will analyze the sample until it has analyzed the count chosen for each bead region or until the timeout is reached if that feature was enabled.
Units	Enter the desired units for the analytes in this box.
Apply All	Applies the information in the Units and Counts fields to all analytes.
Stop after total bead count reaches:	Stops acquisition when the bead count reaches a certain number determined by the user. Enter the desired value in the box. The default value is 100.

Setting Up Batches

Batches consist of protocols and samples for acquisition and can span more than one plate. Protocols contain predefined commands that must be included in every batch acquisition. You can group batches together as a multi-batch. Multi-batches can consist of any number of batches that have been set up from different protocols and are processed consecutively. Multi-batches cannot be run on multiple plates.

When setting up a batch, if the number of samples exceeds the number of wells in one plate, you can add additional plates in the Add and Change Plate section. Additional plates are identified on the bottom of the plate image as Plate a of b, where a is the plate number and b is the total number of plates.

NOTE: Luminex recommends that the manufacturer assay kit controls are analyzed with each plate.

Assay kit manufacturers may provide protocols in their kits which are distributed on media. Protocols typically include assay values for standards and controls, and maintenance commands (such as washes or primes to acquire along with samples). Assay reagents are included in assay kits. You must provide information about these reagents, such as lot numbers and concentration values for the standards and assay controls.

New Multi-Batch Subtab

Use the Create New Multi-Batch button to add or remove batches to the multi-batch set up and to run a multi-batch.

A multi-batch is a set of batches that you want to process consecutively. Add batches to the multi-batch from pending batches in your database. You can also create a new batch to add to the database for the multi-batch. Include as many batches as you need, up to 96 batches. This feature enables you to conserve plates.

Ensure that batches fit on one plate. If space limitations create an overlap, an error message displays. Results for each batch are saved as individual batch files.

Table 20. New Multi-Batch Subtab Screen Elements

Select Pending Batch	Contains a list of all pending batches. Select the batch you want to add to the plate.
Multi-Batch	Lists pending batches selected for the multi-batch. The list includes name and "Start at" well.
Plate Layout	Opens the Multi-batch Report dialog box
Multi-batch Plate Layout Report	Includes the multi-batch plate layout, command number, plate location, command type, sample ID and dilution. The report is date and time stamped.
New Batch	Creates your new batch.
Add	Adds a batch from available options. The selected batch then appears on the plate layout. After you add each batch, the software automatically adds the next batch to the first well of the next column or row (depending on the plate direction). You can also select a well first, which places the next batch in your chosen location.
Remove	Removes a selected batch in the Multi-Batch list. The batch still remains in the Pending Batches section This button is displayed only if you have added a batch to the Multi-Batch list and selected the batch from the list.

Results Page

Once a batch has begun running, observation and analysis take place in the **Results** page. This page contains the following tabs and subtabs:

- **Current Batch** tab - View statistics for the current run and analyte progress per well.
- **Saved Batches** tab - View information about already processed batches and, if necessary, replay them or recalculate their data.
 - Click **Replay > Recalculate Data** from the **Saved Batches** tab.
 - Click **Replay > Replay Batch** from the **Saved Batches** tab.
- **LIS Results** tab - View a batch or transmit a batch that contains LIS results.
- **Reports** tab - This tab enables you to select a report to view.

Performing Analysis

If you are using a third-party software to perform analysis, see the user manual provided with that software. Follow the assay's package insert when running a kit with data analysis instructions.

NOTE: Luminex recommends using median statistics for data analysis.

You can direct the system to acquire samples in replicate regardless of batch type. For qualitative batches, qualitative results for replicates are averaged, and the reported interpretation is determined from this replicate average.

Replicates in quantitative batches are based on a standard curve that is generated by either the "Fit of all standards" or "Mean of replicates." The default is "Fit of all standards." Unknown samples are calculated from the standard curve. Test results for replicate samples are averaged to determine the reported quantitative result denoted as "AVG."

You can analyze a batch using the analysis features of **Qualitative** and **Quantitative** or **None**.

Current Batch Tab

Use the Current Batch tab to view results, statistics, and log information related to the current batch, and to perform statistical analysis on batch results. This tab offers real-time monitoring of batch sampling during acquisition through a display of sample bead statistics and analytes, and dot plot data. The statistics available on this tab are individual well bead statistics. They do not describe replicate well assay results.

There are four maximize buttons in this window, one for each major pane. Click the appropriate button to maximize the pane. Click the minimize button at the top right of the pane to return to its standard size.

Figure 19: Current Batch Tab

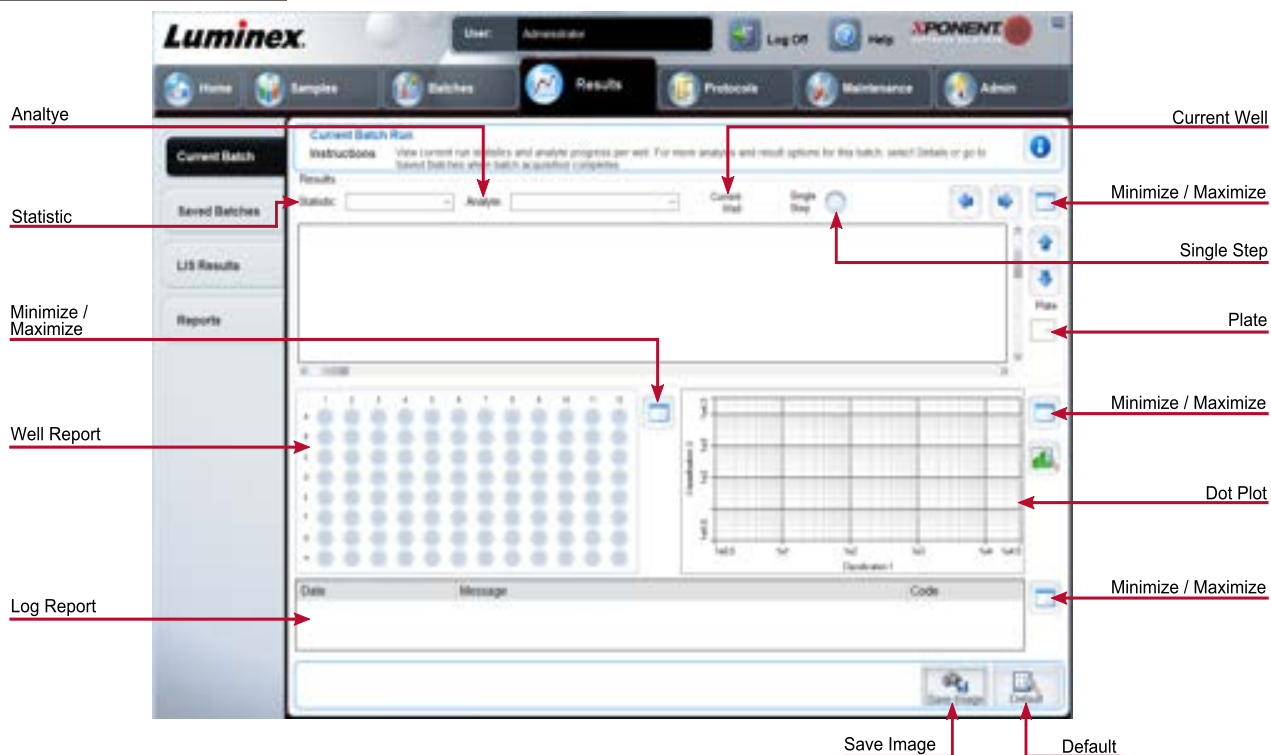



Table 21. Current Batch Tab Screen Elements

Statistic	To view a particular statistic for analytes in a batch, choose one of the options on the drop-down menu. The statistical options displayed change according to the type of analysis.
	<p>NOTE: Trimmed statistics remove the lower and upper 5% of the extreme statistic values, then use the remaining values for the Mean, Standard Deviation, or %CV calculations. Trimmed statistics remove outliers, ensuring that the data is more representative of the population.</p> <p>Median Fluorescence Intensity (MFI) - The value (detected signal) that is in the middle of the microsphere population when sorted by reporter value, lowest to highest. The median value is much less sensitive than the mean value, due to outliers and carryover.</p>
	Test Result - The calculated analysis value for quantitative or qualitative assays derived from standards with known values.
	Range - A semi-quantitative result for a particular numerical result falling between a predefined set of values such as Normal or Negative.
	Net MFI (Sample Well MFI - Background Well MFI) - The Net MFI can be used to eliminate the effect of background signal in an assay.
	Count - The number of microspheres detected within the specified microsphere region. Microspheres that are not inside the region on the dot plot are not included.
	Mean - Average of all values for the microspheres detected in a region.
	<p>Trimmed Mean - (Optional) The sum of the data points in the trimmed distribution divided by the number of data points.</p> <p>Trimmed Mean = $\sum xi / Nt$</p>
	<p>% CV of microspheres - The measure of relative dispersion within the distribution.</p> <p>$\% CV = 100 \times \text{Std Dev} / \text{Mean}$</p>
	Standard Deviation - For calculating sample variability or dispersion, Luminex uses the standard deviation formula.
	Peak - The value that is equal to the largest number of data points within the distribution. For example, in data set {1,2,2,3,3,3,4,5}, 3 is the peak because it occurs the most frequently in the distribution list.

	<p>% CV of Replicates - The measure of relative dispersion within the distribution of results for replicate samples.</p> $\% \text{ CV} = 100 \times \text{Std Dev} / \text{Mean}$
	<p>% Recovery - A measure of how accurately your observed results match your expected results following regression analysis.</p> $(\text{Observed concentration}) / (\text{Expected concentration}) \times 100\%$
	<p>Expected Result - The known or expected test result value for a standard or control.</p>
	<p>Control Range - Low - The lowest value for an assay control used to determine pass/fail criteria for an assay.</p>
	<p>Control Range - High - The highest value for an assay control used to determine pass/fail criteria for an assay.</p>
	<p>Normalized Net - Median - For each analyte in a well, the Normalized Net Median (NNM) = (net median of analyte) / (net median of normalization bead)</p>
	<p>Units - The unit of measure for an analyte, for example, pg/mL.</p>
	<p>Trimmed Count - (Optional) The number of data points in the trimmed distribution (Nt).</p>
	<p>Trimmed % CV of microspheres</p>
	<p>Trimmed Standard Deviation - (Optional) The measure of dispersion within the trimmed distribution.</p> $\text{Trimmed Std Dev} = ((Nt \sum x_i^2 - \sum x_i)^2) / Nt (Nt - 1))^{1/2}$
	<p>Trimmed Peak - (Optional) The value that is equal to the largest number of data points within the trimmed distribution.</p>
Analyte	Contains a list of analytes run in the batch. Select an analyte to view all statistics for that analyte.
Well(s) to View:	<p>Current Well - Displays the statistics of the well currently being displayed. (This changes to Displayed Well if viewing a batch using the Open button of the Saved Batches tab.</p> <p>Single Step - Instructs the system to acquire one well and then pause. If Single Step is activated during a batch, the batch pauses at the end of the current well. This ensures that the system is working correctly before you run an entire batch.</p>

Results	Displays statistics related to the batch. Use the up, down, left, and right arrow buttons to move through the table, or use the scroll bars. The Results will only display when a batch is actively running or when a batch is replayed and not recalculated.
Plate	Select the plate you want to view, if there is more than one plate.
	If using multiple plates, ensure that plates are used in the proper order. Failure to do so can result in inaccurate data and test results.
Well Report	<p>This pane displays a representation of the plate and the status of acquired wells on the left side of the page. Each well displays one of three possible states:</p> <ul style="list-style-type: none"> • Yellow - Well acquired, but the system detects a possible problem. • Green - Well acquired successfully. • Red - Well acquisition unsuccessful; the system might have stopped, depending on the circumstances.
Dot Plot	<p>The default location of the dot plot is the lower-right section of the Current Batch tab. The dot plot is a graphical display of real-time data collection. When using 1 to 50 beads, the dot plot default display shows Classification 1 (CL1) and Classification 2 (CL2).</p> <p>The dot plot default displays when using 1 to 100 bead regions Classification 1 and Classification 2. To view the dot plot, you must use the default axis. To display the bead set information, hover over the desired region. Click the upper view classification button immediately below the maximize button to change the display to show Classification 2. This view displays a series of buttons on the right side of the dot plot. When one of the buttons is clicked, the bead regions in view are those in a fixed range of CL1 values plotted against CL2. Click the bottom view classification button to change back to the default classification display.</p>

	<p>The default location of the histogram is the lower left section of the Current Batch tab. The Doublet Discriminator (DD) displays on the X-axis. Events display on the Y-axis. Doublets appear when two beads stick together, creating undesired results. When you select the gate, two vertical dashed red lines appear. These represent gate positions determined by the protocol. Once the gate is set, everything outside of it is ignored. For batches created using an existing protocol, the gate cannot be changed while running the batch. Any changes made to the gate while running new protocol batches immediately affect the visual display of the dot plot and histogram. In addition, changes made to the gate while running new protocol batches affect the acquisition for all wells initiated after the change is made. When viewing saved batch data, the gate can be changed to visually inspect the effect. Only the visual display of the dot plot and histogram is affected for saved batches, not the acquired data.</p> <p>NOTE: Gate positions are dependent upon buffer composition. Any changes made to your assay buffer composition can result in a different optimal gate location.</p>
Histogram	<p>Right-click inside the histogram area to access the following options:</p>
	<p>Gate - Show, create, delete, or move the gate. You can also move the gates by clicking and dragging the red lines on the histogram.</p>
	<p>Autoscale - Click to automatically adjust the maximum number of events shown on the Y-axis. Click during acquisition to readjust the Y-axis scale.</p>
	<p>Set Scale - Sets the maximum number of events. The default number of events is 60.</p>
	<p>View - View all events or only gated events.</p>
	<p>X-Axis - Changes the X-axis to the following: Doublet Discriminator, Reporter 1, Classification 1, and Classification 2.</p> <p>NOTE: You can change the X-axis of the dot plot for troubleshooting purposes. Use only the default settings in all other instances.</p>
	<p>Display Mode - Select either Logarithmic or Linear display. The software defaults to Logarithmic display. Click maximize for a magnified view of the dot plot.</p> <p>Plot Type - Select either Density Plot or Decaying Plot. The software defaults to Density Plot, which displays a constant accumulation of events. Contrasting colors indicate increasing density. The Decaying Plot plots only the last 100 events.</p> <p>Custom Regions - The Density Plot allows the visual elimination of data values that are determined to be insignificant to the display. Luminex recommends collecting data in Density Plot mode to observe all collected events.</p> <p>NOTE: You can only view the Decaying Plot during batch acquisition.</p>

Log	<p>This pane displays a log of system processes at the bottom of the Current Batch page. Log entries indicating warnings are highlighted in yellow; errors are highlighted in red. Other log entries are not highlighted. The log includes the following information:</p> <ul style="list-style-type: none"> • Date • Message • Code
Progress	<p>Click to display real-time progress of the well acquisition. Analyte counts are displayed in a dynamic bar graph as they are acquired. The scroll bar at the bottom of the Progress display scrolls through the analyte list. A zoom feature on the left of the display enables you to enlarge the image.</p>
Save Image	<p>Opens a Save As dialog box to save a screen capture.</p>
Default	<p>Appears only when the progress display is active. Click to return to the dot plot display.</p>
Chg. Vol	<p>Changes the sample load volume for the batch.</p>
Reacquire	<p>Reacquires data from selected wells in the bath.</p>

Saved Batches Tab

Use the Saved Batches tab to open a completed batch, view completed batch details, import, export, or approve a batch, and replay or reacquire a batch.

On the Saved Batches tab click Open to display the following subtabs on the left side of the page: Results, Settings, Log, and Sample Details.

Figure 20: Saved Batches Tab

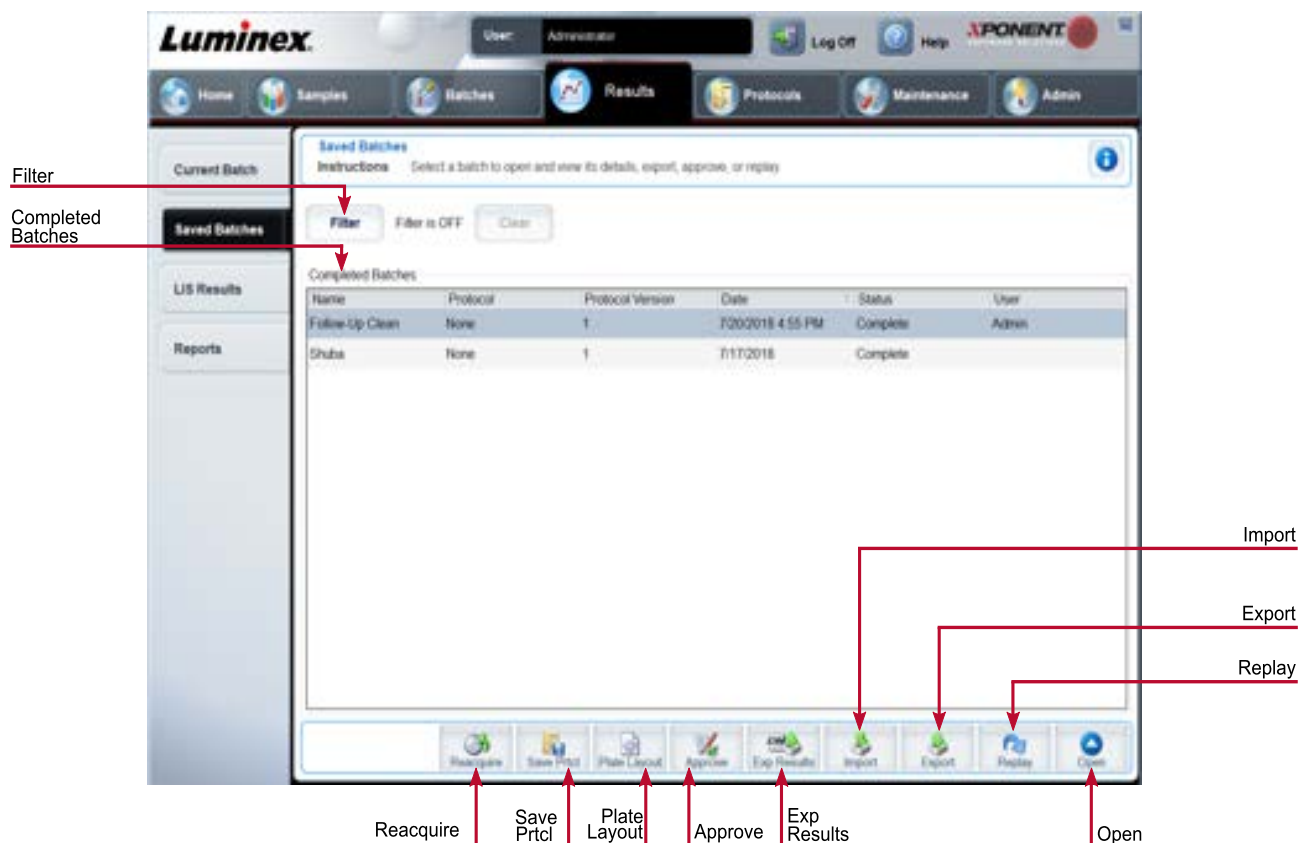


Table 22. Saved Batches Tab Screen Elements

Filter	Displays the saved batches you want to display in the Completed Batches list.
Clear	Turns off the filter.
Completed Batches	Displays a list of completed batches.
Reacquire	Reacquires the selected batch.
Save Prtcl	Opens the Save Protocol dialog box, displaying the kit information for the selected batch.
Plate Layout	Displays the Batch Plate Layout Report .
Approve	Approves the batch.
Exp Results	Choose an export destination for the .csv file containing your results.
Import	Imports a batch file (.mdf). Select Include Raw Files (LXB) to include raw files in the import.
Export	Exports a file. Select Include Raw Files (LXB) to include raw files in the export.


Replay	Enables you to use the data stored in the run files from the initial acquisition to reprocess a batch, creating a new batch output file.
Open	Displays the saved batch results for the selected batch.

Saved Batches Tab > Results Subtab

Table 23. Results Subtab Screen Elements

	<p>To view a particular statistic for analytes in a batch, select one of the options on the drop-down menu. The statistical options displayed change according to the type of analysis.</p> <p>NOTE: Trimmed statistics (indicated by *) remove the lower and upper five percent of the extreme statistic values, then use the remaining values for the Mean, Standard Deviation, or %CV calculations. The point of a trimmed statistic is that it removes outliers, ensuring that the data is more representative of the population.</p>
Statistic	<p>Median Fluorescence Intensity (MFI) - The value (detected signal) that is in the middle of the microsphere population when sorted by reporter value, lowest to highest. The median value is much less sensitive than the mean value, due to outliers and carryover.</p>
	<p>Test Result - The calculated analysis value for quantitative or qualitative assays derived from standards with known values.</p>
	<p>Range - A semi-quantitative result for a particular numerical result falling between a predefined set of values such as Normal or Negative.</p>
	<p>Net MFI (Sample Well MFI - Background Well MFI) - The Net MFI can be used to eliminate the effect of background signal in an assay.</p>
	<p>Count - The number of microspheres detected within the specified microsphere region. Microspheres that are not inside the region on the dot plot are not included.</p>
	<p>Mean - Average of all values for the microspheres detected in a region.</p>
	<p>Trimmed Mean - (Optional) The sum of the data points in the trimmed distribution divided by the number of data points.</p> <p>Trimmed Mean = $\Sigma xi / Nt$</p>
	<p>% CV of microspheres - The measure of relative dispersion within the distribution.</p> <p>% CV = $100 \times \text{Std Dev} / \text{Mean}$</p>

	<p>Standard Deviation - For calculating sample variability or dispersion, Luminex uses the standard deviation formula.</p>
	<p>Peak - The value that is equal to the largest number of data points within the distribution. For example, in data set {1,2,2,3,3,3,4,5}, 3 is the peak because it occurs the most frequently in the distribution list.</p>
	<p>% CV of Replicates - The measure of relative dispersion within the distribution of results for replicate samples.</p> <p>$\% \text{ CV} = 100 \times \text{Std Dev} / \text{Mean}$</p> <p>% Recovery - A measure of how accurately your observed results match your expected results following regression analysis.</p> <p>$(\text{Observed concentration}) / (\text{Expected concentration}) \times 100\%$</p>
	<p>Expected Result - The known or expected test result value for a standard or control.</p>
	<p>Control Range - Low - The lowest value for an assay control used to determine pass/fail criteria for an assay.</p>
	<p>Control Range - High - The highest value for an assay control used to determine pass/fail criteria for an assay.</p>
	<p>Normalized Net - Median - For each analyte in a well, the Normalized Net Median (NNM) = (net median of analyte) / (net median of normalization bead)</p>
	<p>Units - The unit of measure for an analyte, for example, pg/mL.</p>
	<p>Trimmed Count - (Optional) The number of data points in the trimmed distribution (Nt).</p>
	<p>Trimmed%CV of microspheres</p>
	<p>Trimmed Standard Deviation - (Optional) The measure of dispersion within the trimmed distribution.</p> <p>$\text{Trimmed Std Dev} = ((Nt \sum xi^2 - \sum xi)^2) / Nt (Nt - 1))^{1/2}$</p>
	<p>Trimmed Peak - (Optional) The value that is equal to the largest number of data points within the trimmed distribution.</p>
Analyte	<p>Contains a list of analytes run in the batch. Select an analyte to view all statistics for that analyte.</p>

Displayed Well	Displays the number of the well whose contents currently appear in the table.
Results pane	Displays statistics related to the batch.
Save Image	Saves a screen capture.
	Select the plate you want to view, if there is more than one plate.
Plate	 <p>If using multiple plates, ensure that plates are used in the proper order. Failure to do so can result in inaccurate data and test results.</p>
Well Report	<p>This pane displays a representation of the plate and the status of acquired wells on the left side of the page. Each well displays one of three possible states:</p> <ul style="list-style-type: none"> • Yellow - Well acquired, but the system detects a possible problem • Green - Well acquired successfully • Red - Well acquisition unsuccessful; the system might have stopped, depending on the circumstances
Dot Plot	The default location of the dot plot is the lower-right section of the Current Batch tab. The dot plot is a graphical display of real-time data collection. When using 1 to 50 beads, the dot plot default display shows Classification 1 (CL1) and Classification 2 (CL2).
Log	<p>This pane displays a log of system processes at the bottom of the Current Batch page. Log entries indicating warnings are highlighted in yellow; errors are highlighted in red. Other log entries are not highlighted. The log includes the following information:</p> <ul style="list-style-type: none"> • Date • Message • Code
Progress	Click to display real-time progress of the well acquisition. Analyte counts are displayed in a dynamic bar graph as they are acquired. The scroll bar at the bottom of the Progress display scrolls through the analyte list. A zoom feature on the left of the display enables you to enlarge the image.
Formula	Opens the Change Analysis dialog box with a list of analytes used in the batch. Click an analyte to open the Analysis Settings dialog box from which you can select a new analysis setting for the analyte.
Default	Returns view to Results page.
Approve	Opens the Batch Approval Confirmation dialog box to approve the batch.

Validate	Validates an entire selected row or cell in the Results table.
Invalidate	Invalidates an entire selected row or cell in the Results table.

Saved Batches Tab > Settings Subtab

When you click the Settings subtab, a report generates displaying the following:

- A date and time stamp at the top of the report
- Left and right **Page** arrow buttons so that you can view pages in the report
- **Calibration State**
- **Machine Information**
- **Assay Lots Used**
- **Tests**
- **Protocol Settings**

Saved Batches Tab > Log Subtab

The Log subtab displays a log of the activity which occurred during the acquisition of the selected batch.

The following information is displayed about each activity:

- **Date** - date and time well was acquired
- **Message** - log message about the well
- **Code** - command and error codes

Log entries display yellow if a well was acquired but there was a possible problem, and red if acquisition failed.

- **Print** - Prints the log
- **Export** - Opens the Save As dialog box to save the batch log file. Select a location and click Save
- **Close** - Reopens the Saved Batches tab

Saved Batches Tab > Sample Details Subtab

Table 24. Sample Details Subtab Screen Elements

< and > Arrows	Scroll left to right through the sample details.
^ and v Arrows	Scroll up and down through the sample details.
Transmit	Sends the results.

Reports Tab

Use the Reports tab to generate, view, and print reports.

Table 25. Reports Tab Screen Elements

Report and Type list	Report lists the categories of reports. The selections in the Type list change depending on the selection you made from the Report list.
Generate	Generates the report, The Data Interpretation Report displays, with additional buttons, depending on the size of the report.
	Page - Use the arrows to scroll through the pages being displayed.
	Save - Saves the analyte information currently displayed.
	Print - Prints the analyte information currently being viewed.
	New Report - Returns you to the main Reports window.

Protocols Page

Protocols Tab

Use the Protocols tab to choose an existing protocol.

Figure 21: Protocols Tab

Installed Protocols

Name	Version	Manufacturer	Date
Example Protocol	1	LMNX	7/5/2018 12:09 PM
Example Protocol	2	LMNX	7/5/2018 1:16 PM
Example Protocol	3	LMNX	7/5/2018 2:16 PM
Example Protocol	5	LMNX	7/10/2018 3:40 PM

Import Export

Protocols Tab > Settings Subtab

Figure 22: Settings Subtab

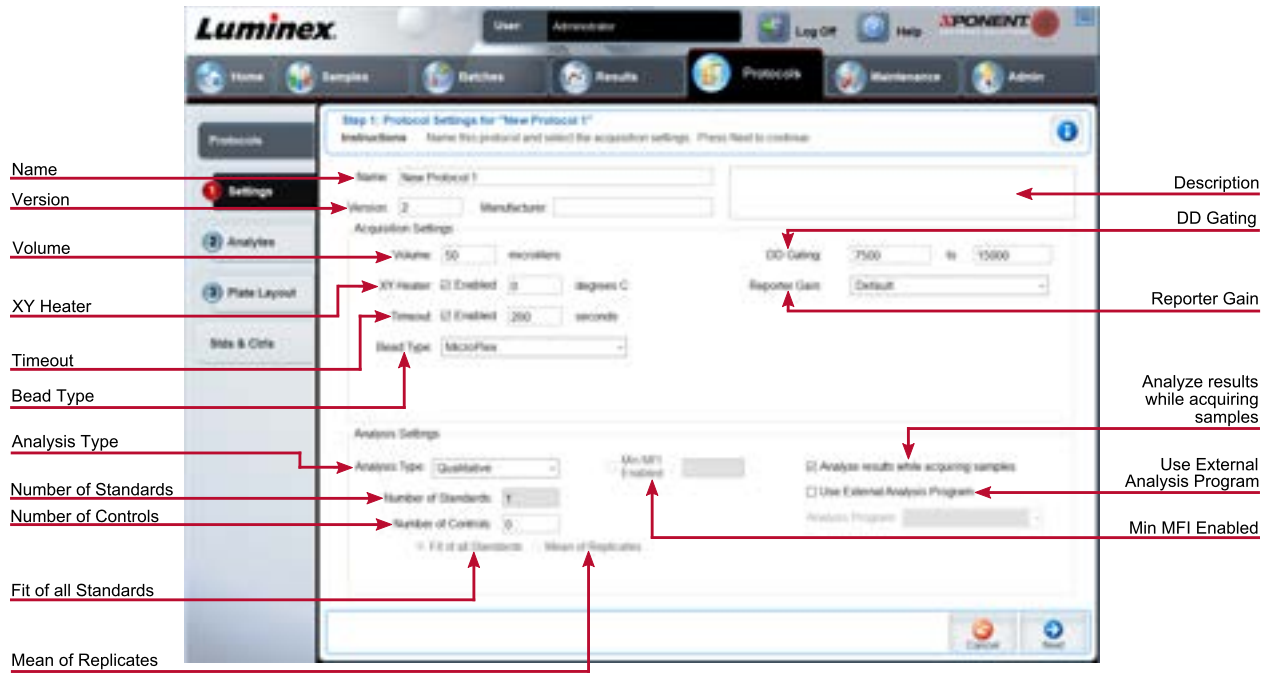


Table 26. Protocols Tab > Settings Subtab Screen Elements

Name and Description fields	The name and description of the protocol.
Version	Version number of the protocol.
Manufacturer	Manufacturer of the protocol.
Volume	The volume the instrument aspirates in to the system for analysis. Enter the desired sample volume in microliters. Use values from 20 µl to 200 µl. To avoid air intake, add at least 25 µl to the sample well in addition to the sample size. The default value is 50 µl.
XY heater	Select Enabled to enable the XY heater. In the field, type the desired value in degrees C . The temperature range is 35°C to 60°C in 0.5°C increments. NOTE: Acquiring data before the heater has reached the proper temperature can compromise test results.
Timeout	The amount of seconds the instrument will try to acquire sample until it will timeout and move to the next sample.
Bead Type	Choose between Microplex® and MagPlex®.

DD Gating	Use this to set the minimum and maximum DD Gating values. In the first box, type the minimum value. In the second box, type the maximum value. The default is 7500 to 15000.
Reporter Gain	Choose Default from the drop-down menu to decrease the reporter gain or Enhanced PMT (High) .
Analysis Type	Use this list to choose from the following analysis types:
	None - No analysis. Choose if you have your own data post-processing program and want to obtain only median fluorescent intensity results. You cannot apply standards or controls when you select None . You cannot use xPONENT® to analyze acquisitions with this setting.
	Qualitative - Qualitative analysis determines results as either positive or negative, reactive or non-reactive.
	Quantitative - Quantitative analysis determines the sample concentrations from standard curves using regression methods: Cubic Spline , Linear , Logistic 4P , and Logistic 5P .
Number of Standards	Number of standards for the protocol. Applies only to qualitative and quantitative analyses.
Number of Controls	Number of controls for the protocol. Applies only to qualitative and quantitative analyses.
Fit of all Standards	Use each individual standard replicate when calculating the standard curve. Applies only to quantitative analysis.
Mean of Replicates	Average the individual standard replicates when calculating the standard curve. Applies only to quantitative analysis.
Use External Analysis Program	This option is for those using a program other than xPONENT® to analyze collected data. Applies only to qualitative and quantitative analysis.
Analyze results while acquiring samples	The software allows real-time viewing of the results as the instrument analyzes samples. This feature is not available if you select None as your analysis type.

Protocols Tab > Analytes Subtab

Use the Analytes subtab to select or edit analytes used in the batch or protocol.

Figure 23: Analytes Subtab

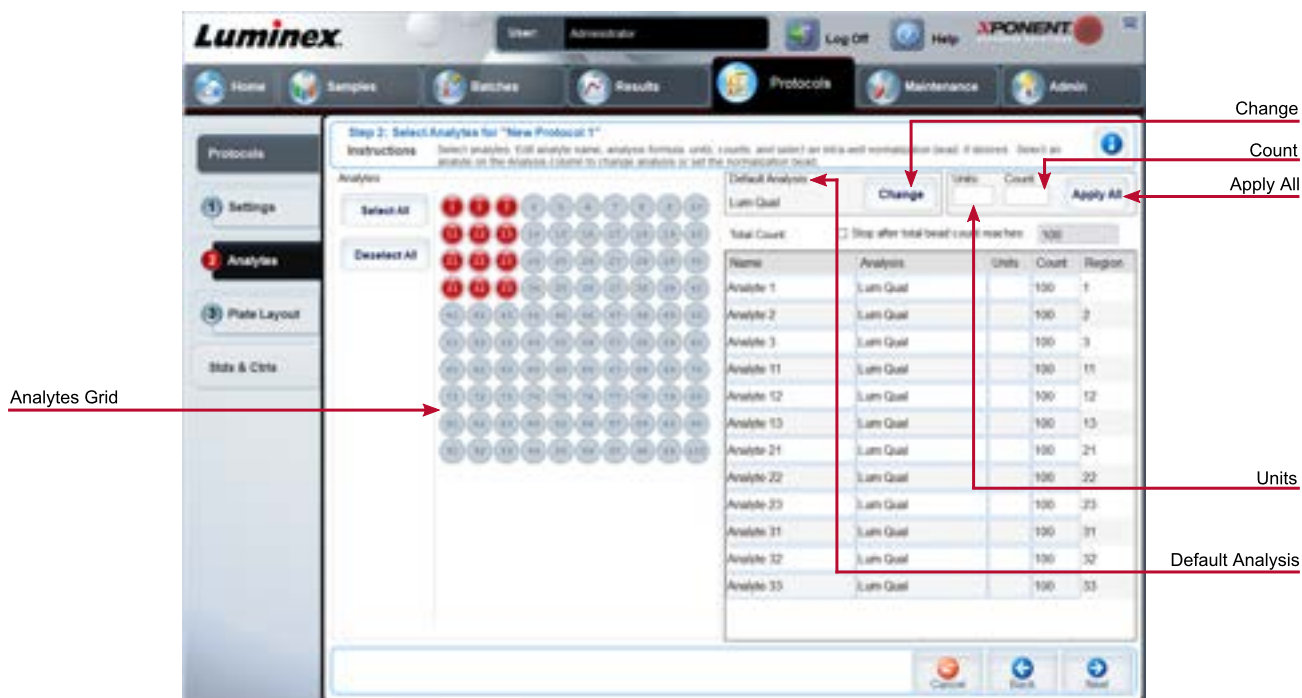


Table 27. Analytes Subtab Screen Elements

Analytes grid	A grid representing each analyte from 1 to 100.
Select All	Selects all analytes.
Deselect All	Deselects all analytes.
Default Analysis	The default analysis changes based on the Analysis Type selected in the Settings subtab. If Qualitative or Quantitative was chosen on the Settings subtab, click Change to change the analysis settings for all analytes.
Count	The desired bead count for the analytes. The instrument will analyze the sample until it has analyzed the count chosen for each bead region or until the timeout is reached if that feature was enabled.
Units	Enter the desired units for the analytes in this box.
Apply All	Applies the information in the Units and Count fields to all analytes.

Selected analytes are displayed in a list on the right side of the Analytes grid. This list includes the following information:	Name - The name of the analyte. Click and type to rename the analyte.
	Analysis - Click this field and choose another analysis from the list, if you want to change it.
	Units - The unit of measurement you specified in the Unit box. Click this box to enter a value for the analyte.
	Count - Enter the desired bead count for the analytes. If each selected bead set does not acquire this number of events, a warning is added to the log that not enough bead events were acquired.
	Region - Refers to the specific analyte selected.
Total Count	Stops acquisition once a certain number of beads have been counted, regardless of which region they fall into.
Stop after total bead count reaches:	Stops acquisition when the bead count reaches a certain number determined by the user. Enter the desired value in the box. The default value is 100.

Protocols Tab > Plate Layout Subtab

Figure 24: Plate Layout Subtab

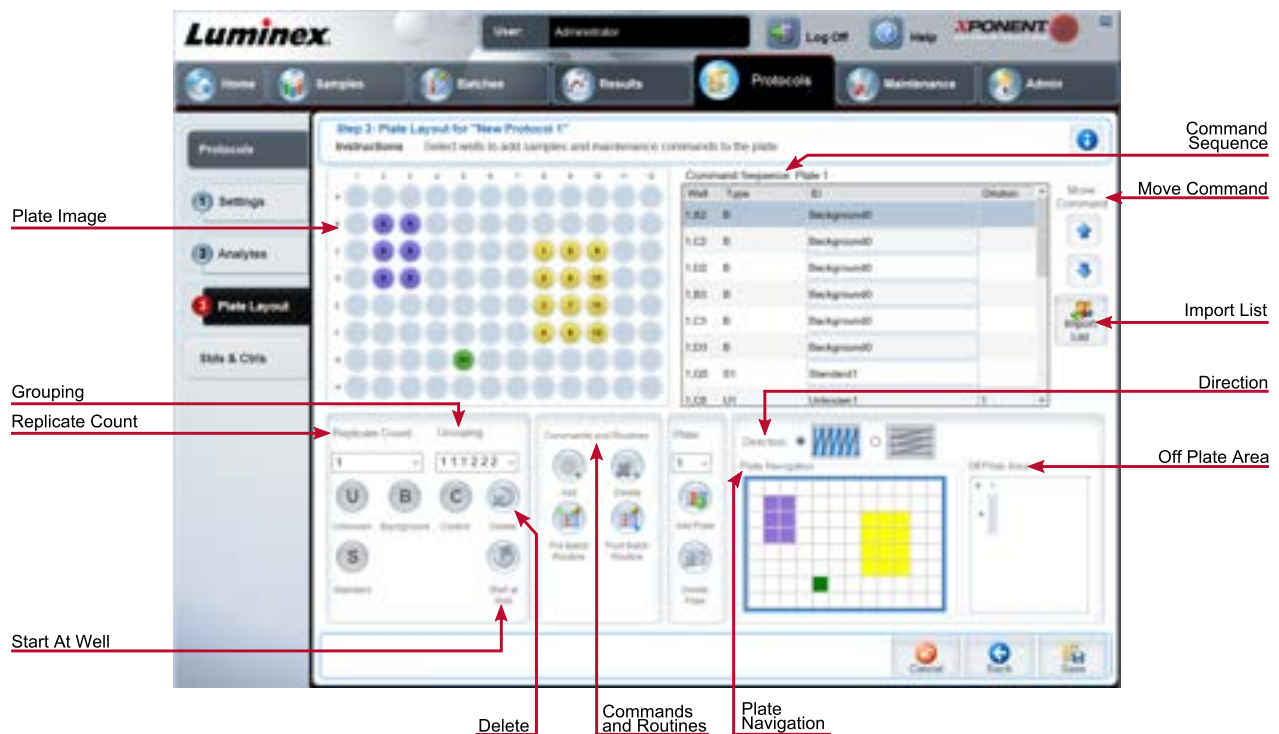


Table 28. Plate Layout Subtab Screen Elements

Plate Image	Represents the plate. Each well appears as a circle on the grid.
Command Sequence	Contains the command sequence for the active plate. A command's ID and Dilution fields have a blue border around them if they can be double-clicked to enter information.
Move Command	Moves a selected well command in the plate up or down in the Command Sequence list, changing the acquisition order.
Import List	Imports an existing command sequence list. NOTE: The import feature allows you to import sample information into unknown wells or wells with specified locations.
Replicate Count	Defines a quantity of replicate sets from one to nine. Replicate count selection must be made before adding a well command.
Grouping	<p>Selects the sequence in which the replicates are laid out in plate wells. Grouping selections must be made before adding a well command. Options for grouping are:</p> <p>123123123. . . Lays out one of each replicate set at a time in numerical order.</p> <p>111222333. . . Lays out all the replicates in a set before moving on to the next set in numerical order.</p> <p>Each command is associated with a color. Click and drag to highlight a series of wells, click a column or row header to highlight the entire column or row, or click and highlight different wells and then click a command below to assign that command to all of the highlighted wells.</p> <p>Delete - Removes the well command for the selected well.</p> <p>Start at Well - Enables you to begin acquisition at a well other than A1.</p>

Commands and Routines	Assigns maintenance commands and routines to a well after you select it in the Command Sequence or plate image area.
	NOTE: If you select a routine you created, that routine must also exist on any system to which you import this protocol. The system displays an error when attempting to run a batch on a system where the routine does not exist.
	Add - Opens the Commands and Routines dialog box so you can choose a command or routine.
	Delete - Deletes the chosen command or routine.
	Post-Batch Routine - Adds the command or routine before running the batch.
	Pre-Batch Routine - Adds the command or routine for running the batch.
Plate	Specifies the plate you want to display in the plate image.
	Add Plate - Adds a new plate to the batch.
	Delete Plate - Deletes the plate highlighted in the list.
Direction	Specifies the direction to run the plate commands. Select either horizontally or vertically. The selected direction also dictates how wells are added to the plate when assigning multiple unknowns, standards, and controls at one time.
Plate Navigation	Displays a smaller plate image for the current batch. Click and drag in the plate layout to select wells to display. The Plate Navigation section in the lower right part of the window can be used to display all the wells in the plate image. Click and drag in the Plate Navigation dialog box to display different portions of the plate.
Off Plate Area	Designates an alternate location for maintenance commands in the Command Sequence list.
Save Prtcl (When creating a batch)	Opens the Save Protocol dialog box to save the protocol and/or kit. Click Save Protocol and/or Save Std/Ctrl Kit to save the protocol and/or kit. Enter the appropriate information in the fields and click Save to save the protocol or kit.
Run Batch	Runs the batch.

Stds & Ctrl (Standards and Controls) Tab

Use the Stds & Ctrl tab to delete, edit, export, import, and create standards and controls.

Figure 25: Stds & Ctrl Tab

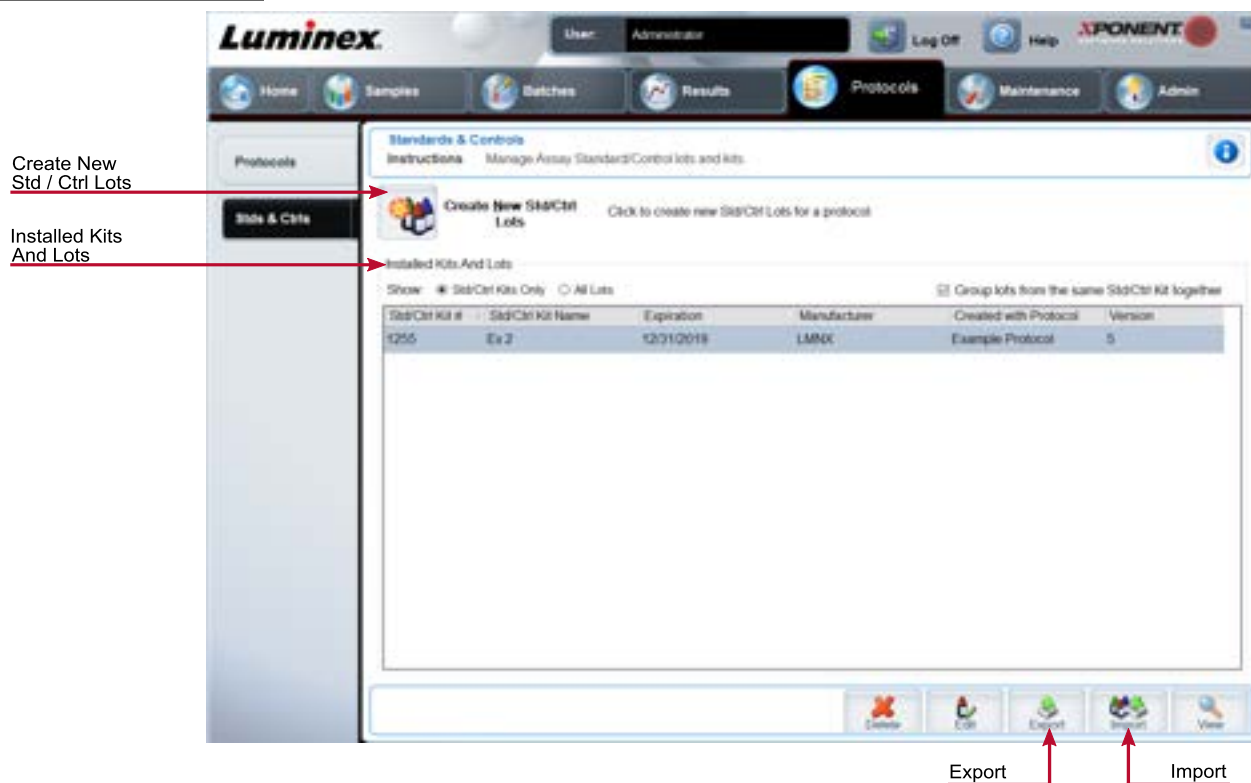


Table 29. Stds & Ctrl Tab Screen Elements

<p>Create New Std/Ctrl Lots</p>	<p>Opens the Select Protocol dialog box. After you choose the protocol, the Std/Ctrl Details subtab displays so you can create a new lot or kit.</p>
<p>Installed Kits And Lots</p>	<p>Displays information about the kits and lots currently installed on the system.</p> <p>Show - Click either Std/Ctrl Kits Only or All Lots to choose what to display.</p> <p>Select All Lots to display the following information about each installed lot: Reagent, Lot #, Expiration, Name, Manufacturer, Protocol, Versions, Std/Ctrl Kit #, and Std/Ctrl Kit Name.</p> <p>Select Std/Ctrl Kits Only to display the following information about the Installed Std/Ctrl Kits: Std/Ctrl Kit #, Std/Ctrl Kit Name, Expiration, Manufacturer, Created with Protocol, and Version.</p> <p>Group lots from the same Std/Ctrl Kit together - Groups lots from the same kit together.</p>

Export	Exports the selected lot. Select a location to save the lot file, and click Save .
Import	Select a Std/Ctrl Kit or lot file to import, and click Open .

Protocols Tab > Stds/Ctrls Details (Standards and Controls) Subtab

Use the Std/Ctrl Details subtab to create, edit, or view a kit.

Table 30. Std/Ctrl Details Subtab Screen Elements

Apply Std/Ctrl Kit	Applies a Std/Ctrl kit.
Assay Standard Information	Displays the selected standard reagents in a list.
	Apply Std Lot - Applies the standard lot.
	Apply Values - Applies a value across or down the Reagent, Name, Lot #, Expiration, and Analyte fields.
	NOTE: The Dilution list and Apply Dilution button only appear if a quantitative analysis has been selected.
Assay Control Information	Lists the selected control reagents. Existing control lot information can be applied or new information can be typed manually.
	Apply Ctrl Lot - Applies the control lot.
	Show Value - Expected, Low, and High set the expected, lowest, or highest acceptable concentration of the analyte in the sample.
	Apply Values - Applies a value down or across the list of analytes.
Dilution	Dilute concentrated biological samples, such as plasma or serum, reagents as part of assay setup or as a final dilution step.
Apply Dilution	Applies the dilution selected in the Dilution list.
Assay Control Information	Lists the selected control reagents.
	Apply Ctrl Lot - Applies a control lot.
	Show Value - Expected, Low, and High set the expected, lowest, or highest acceptable concentration of the analyte in the sample.
	Apply Values - Applies a value down or across the list of analytes.

Maintenance Page

Use the Maintenance page to maintain and calibrate your system.

Auto Maint (Auto Maintenance) Tab

Use the Auto Maint tab to initialize, verify, and maintain the instrument.

Figure 26: Auto Maint Tab



Table 31. Auto Maint Tab Screen Elements

Automated Maintenance Options	<p>Provides buttons for commonly used maintenance routines for the machine.</p> <ul style="list-style-type: none"> • Calibration/Verification • Performance Verification • Fluidics Prep • System Shutdown
Reagents	<ul style="list-style-type: none"> • Calibration Kit • Performance Verification Kit
Report	The Reports tab displays with the Performance Verification Report chosen in the Report: list.
Import Kit	Displays the Calibration and/or Performance Verification kits to choose to import.

Run	Initiates the chosen run.
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Lot Management Tab

Use the Lot Management tab to manage calibration and verification kits.

Figure 27: Lot Management Tab



Table 32. Lot Management Tab Screen Elements

	Changes calibration or performance verification kits, lot numbers and expiration dates, or deletes a kit.
Active Reagents	Calibration Kit - Choose a calibration kit from this list.
	Performance Verification Kit - Choose a performance verification kit from this list.
	Delete Kit - Deletes the chosen calibration or performance verification kit (s).
	Active Lot Number - Choose an active lot number for the chosen reagent from this list.
	Active Reagents table - Displays information about the selected reagent. It allows you to choose whether the lot is CAL1, MagCAL1, CAL2, CON2, MagCON1, CON2, Fluidics 1, or Fluidics 2. That choice is displayed in the Lot Details section. The choice changes what columns appear in the table in the Lot Details section.

Lot Details	Displays lot information for the lot chosen in the Active Reagents section.
	Lot Type - Displays the lot type selected.
	Lot # - Enter the lot number after clicking Add New .
	Expiration - Edit the expiration date after clicking Add New .
	Lot Details table - Enter target MFI values for the type of lot you chose in the Active Reagents section. If your choice was CAL, enter targets for CL1, CL2, and RP1. If it was VER, enter targets for each channel for each reagent. If it was Fluidics 1 or 2, you cannot enter any targets.
	Calibrator - If a calibration reagent is selected, the Lot Details table displays Channel and Target information.
	Verifier - If a verification reagent is selected, the Lot Details table displays target information.
	Sheath Fluid - Click Edit, enter the Current Lot# and Expiration date.
Import Kit	Opens the Import Calibration or Performance Kit dialog box to import a kit.
Import	Opens the Import Calibrator or Verification Lot dialog box to import a lot.
Export	Opens the Export Calibrator or Verification Lot dialog box. Select a name and location to save the calibrator or verification lot and click Save . You must have a lot chosen in order to Export.
Add New	Adds a new lot. Add information in the Lot Details section on the right side of the window. Enter a Lot # , Expiration , and target in the appropriate boxes and fields. Click Save to save the lot, or click Cancel to cancel the entry.
Delete	Deletes a lot selected in the Active Reagents list.

Commands and Routines (Cmds & Routines) Tab


Use the Cmds & Routines tab to create a routine or to edit, delete, or run a selected routine or command and run one or more maintenance commands with or without saving them as a routine.

Figure 28: Cmds & Routines Tab



Table 33. Cmds & Routines Tab Screen Elements

Routine Name	This list of pre-set routines and commands can be used for system maintenance. Some of these commands are also available on the Auto Maint tab. You can also create custom routines which appear in the Routine Name drop-down menu after you save the routine.
Commands	Commands you can add to routines.
	Wash - Sends distilled water through the fluidic lines in the system. It pulls the fluid from a well or from the reservoir and runs it completely through the system to the waste receptacle.
	Alcohol Flush - Removes air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The alcohol flush takes about 5 minutes.
	Warmup - Warms the system to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn the power on. The process takes 30 minutes. You will need to use the Warm-up command if the system is idle for four hours or longer.
	Sanitize - Uses the off-plate reagent area, because only the reservoir can accommodate the amount of fluid necessary to sanitize the instrument. The sanitize command performs a similar function as the alcohol flush command, but uses 10% to 20% household bleach and water to decontaminate sample lines and the cuvette after biohazard contact. Sanitize as part of your daily shutdown routine after biohazard contact.

	Soak - Prevents salt crystals from forming in the probe due to air exposure. Soaking the probe replaces sheath fluid in the probe with water. You should perform the soak function at the end of each day. The system uses at least 250 µL of distilled water.
	Prime - Removes air bubbles from the system's fluidic pathways by drawing sheath fluid from the sheath fluid container. You do not need to supply solution in a plate.
	CAL1 - Calibrates DD, CL1, and CL2 for original non-magnetic xMAP® microspheres.
	CON1 - Verifies DD, CL1, and CL2 for non-magnetic xMAP microspheres.
	MagCAL1 - Calibrates DD, CL1, and CL2 for original magnetic MagPlex® microspheres.
	MagCON1 - Verifies DD, CL1, and CL2 for magnetic MagPlex beads.
	CAL2 - Calibrates xMAP reporters (RP1).
	CON2 - Verifies RP1 at normal and high PMT for all xMAP Bead Types.
	VER - Performs a verification.
	Fluidics - Fluidics calibrates sample carry over from well to well.
	Drain - Helps remove debris from the bottom of the cuvette during troubleshooting. You do not need to supply solution. Draining takes approximately 2 minutes and should be followed by an alcohol flush with 70% isopropanol or 70% ethanol.
	Backflush - Removes obstructions from the fluidics pathways by drawing sheath fluid from the sheath fluid container.
	Do not run three backflush commands in a row. This will use the sheath fluid faster than the system can replenish.
Clear	Clears the highlighted command in the Command Sequence list.
Clear All	Clears all commands in the Command Sequence list.
Different buttons appear at the bottom right of the window, depending on your selections in the window.	

Command Sequence	Lists the routines in order in the Command Sequence list. The list includes the name of each command, location, reagent status, and any additional information.
	Self Test - Performs a self-diagnostic to see if the system and all operations are functioning correctly.
	Report - Opens the Reports tab with Calibration and Verification Reports selected in the Report drop-down menu. Click Generate to view the selected report.
	Import - Imports the routine file.
	Cancel - Cancels changes made to the default location of one of the commands in the Command Sequence. Cancel only displays if changes have been made to the command sequence.

Probe and Heater Tab


Use the Probe & Heater tab to adjust the probe height and plate heater settings.

Figure 29: Probe & Heater Tab



Table 34. Probe & Heater Tab Screen Elements

Plate Type	Defines the selection of either a 96-well plate or an Automated Maintenance Plate.
Plate Images	Assigns a particular well to use for probe height adjustment in the main plate, reservoir, and strip wells. Selecting a well displays a green pin to denote its use for the height adjustment.

Move Probe Down	Moves the probe down in the specified well(s).
Plate Location pin	<p>A green pin that shows the well location used to adjust the probe height for the main plate or automated maintenance plate, reservoir, and/or strip wells. The default (and recommended) location for the main plate is well D6.</p> <p>The main plate depicts a 96-well plate.</p>
Plate Heater	Enables and disables the Plate Heater by clicking ON or OFF. Also used to set the temperature of the plate to the number typed in the Set Temperature field. Up and down arrows allow half-degree increments. Click Apply to apply the new temperature settings. Current and Target temperatures display at the bottom of this section. The temperature range is 35°C to 60°C.
	The plate heater can become hot enough to cause injury. Use caution when handling after heating.

System Info Tab

Use the System Info tab to view information and diagnostics about the Luminex® instrument.

This tab contains the following information:

Software	
Version	
Operating System	
Licensing	Last Con1 Verification
Instrument Type	Last Fluidics Test
Serial Number	Delta Calibration Temp
Firmware Version	System Temperature
XY Serial Number	DD Temperature
XY Firmware Version	CL1 Temperature
XYP Heater Temperature	CL2 Temperature
Air Pressure	CL1 Voltage
Sheath Pressure	CL2 Voltage
Calibration/Verification Status	DD Voltage
Last CAL1 Calibration	RP1 Voltage
Last MagCAL1 Calibration	
Last CAL2 Calibration	

Table 35. System Info Tab Screen Elements

Items in the list relating to calibration and verification have one of the following states:

Passed	Indicates that the process completed successfully.
Failed	Indicates that the process was not completed successfully. Failed items appear in red.
Not Current	Indicates that verifiers are not current. Verifiers are not current if you have not calibrated the system since the last time you ran the verifiers.
Not Yet Run	Indicates that this process has not yet been run on the machine.
Copy	Copies the system information to the Windows® clipboard. You can then paste it into a text editor such as Notepad.

Save	Opens the Save As dialog box to specify a file name and location to save the system information file.
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System Status Tab

Use the System Status tab to view, print, and save system status log information.

Table 36. System Status Tab Screen Elements

Search By Log Type	Filters the type of log information.
Search By Log Date	Enables using a date range to display a log of system activities.
System Log table	Displays a list of information about each system process.
Export	Enter a name and choose a location for the system log to export to. Select Overwrite to overwrite a pre-existing file. This button exports the file in .CSV format.

Schedule Tab

Use the Schedule tab to view reminders for scheduled maintenance due to be performed on the instrument.

Table 37. Schedule Tab Screen Elements

Reminders	Subject - The scheduled maintenance.
	Reminder - A description of the scheduled maintenance.
	Next Alert Date - The date xPONENT® alerts you about the scheduled maintenance.
	Alert Time - The time xPONENT alerts you about the scheduled maintenance.
	Notes - Any additional information you want to know about the scheduled maintenance.
Laser Warmup Schedule	Enables a schedule to warm up the lasers.

Support Utility Tab

Use the Support Utility tab to create a support file that you can send to *Luminex Technical Support*. To include batch information in the support file, use the Include Batch Information button and the Select Batch table.

Table 38. Support Utility Tab Screen Elements

Include Batch Information	Select this check box to include batch information with the support file. It activates the Select Batch table.
Select Batch	This table includes columns for the following information about a batch - Name, Protocol, Protocol Version, Date, Status.
Support	Launches the Support Utility dialog box.

Admin Page

You must have the appropriate licenses to view some of the features on the Admin page.

System Setup Tab

Use the System Setup tab to configure system settings such as application settings, LIS settings, maintenance options, and external analysis program settings. These settings change some of the basic ways that xPONENT® works, allowing customization of many of the basic functions. Select the options you want to enable and click **Save**.

Table 39. System Setup Tab Screen Elements

Application Settings	Enable Virtual Keyboard - Enables the touch screen virtual keyboard.
	Allow the application to be minimized - Enables minimization of the xPONENT software so that the computer's desktop can be accessed. If this check box is clear, the application's minimize button does not function.
	Ignore user permission when attempting to exit software - Enables the user to exit the xPONENT software, regardless if permission has been granted in the User Setup tab.
	Add header when exporting data from grids - Adds a header row when exporting the data.
	Require Fluidics as part of successful verification - Verification will only be marked as complete if the system attempts and passes the fluidics check. That check involves testing carryover from one well to the next.

LIS Settings	This setting is only for those using xPONENT with a Laboratory Information System (LIS).
	Connect to LIS - Enables connection to the LIS.
	Browse - Opens the Browse For Folder dialog box. Choose a location for the system to watch for incoming orders. This button does not work if LIS is not enabled.
External Analysis Program Settings	This option is for those using a program other than xPONENT to analyze collected data.
	Installed Analysis Programs - Lists the analysis programs currently installed.
	Add New - Opens the New External Analysis Program dialog box.
	Browse - Opens another dialog box to select the file location for the third-party analysis program. The selected location appears in the Path window, and the name displays in the Name field.
	Command Line Parameters - To keep the default command line settings, leave Command Line Parameters blank. Otherwise, type the command line parameter for which parameters you want xPONENT to use with the external analysis program. If the information is supplied with the external analysis program documentation, use that information. Otherwise, you can type the following parameters built into xPONENT, in any order: #c - Output.csv, full file path, #p - Protocol name, #b - Batch name, #u - Logged in user name
	Set Default - Sets the chosen analysis program as the default analysis program for xPONENT.
Remove	Removes the selected program from the Installed Analysis Programs list.
Edit	Opens the New External Analysis Program dialog box where you can edit the settings for the selected program.
Disable Automatic launching of External Analysis when batches complete for all protocols	Disables the automatic launch of the third-party analysis program after batch acquisition.

Arrange Main Navigation Pages	These options enable you to customize the order in which the Main Navigation buttons (pages) display.
	Main Navigation Arrows - Moves the selected header's order of appearance at the top of the window.
	Default - Restores the software to the default page header arrangement.
Maintenance Options	System Initialization Procedure - Displays the available selections to use as the default system initialization procedure.
	Allow running calibration or verification if the instrument is not warmed up - You can enable or disable this feature by selecting the check box.
	NOTE: Luminex does not recommend running calibration and verification if the lasers are not warmed up.
	Calibration expiration days - Choose the number of days in which the calibration of the system will expire.

Add an External Analysis Program

1. If the program is on an external media such as a CD or flash drive, insert the media.
2. Navigate to the **Admin** page > **System Setup** tab.
3. Click **Add New** to open the **New External Analysis Program** dialog box.
4. Enter a name for the external analysis program.
5. Click **Browse** to navigate to the .exe file for that program. Double-click the file name.
6. Enter the command line parameter for the parameters you want xPONENT® to use with the external analysis program. If the information is supplied with the external analysis program documentation, use that information. Otherwise, you can type the following parameters built into xPONENT, in any order:
 - #c - Output.csv, full file path
 - #p - Protocol name
 - #b - Batch name
 - #u - Logged in user name

To keep the default command line settings, leave **Command Line Parameters** blank.

Edit an Analysis Program

1. Navigate to the **Admin** page > **System Setup** tab.
2. In the **Installed Analysis Programs** list, click the program you want to edit.
3. Click **Edit**. The **Edit External Analysis Program** dialog box displays.
4. Edit the **Name**, **Path**, or **Command Line Parameters**, or make this the default analysis program if there are two or more programs installed. The default analysis program name displays in bold text.

Remove an Analysis Program

1. Navigate to the **Admin** page > **System Setup** tab.
2. In the **Installed Analysis Programs** list, select the program you want to uninstall.
3. Click **Remove**.
4. To prevent the external analysis program from starting automatically, select **Disable automatic launching of External Analysis** when batches complete for all protocols.

Group Setup Tab

This tab is accessible only in the Security or 21 CFR Part 11 packages. Use this tab to assign permissions to different groups of users. Additionally, if you have the 21 CFR Part 11 package, you can require an electronic signature in order to perform selected tasks.

NOTE: The 21 CFR Part 11 package also provides full access to the Secure Package functionality.

Users are assigned to groups and permissions are granted to each group. Do not assign permissions directly to individual users. Use this tab to unlock accounts for users who have locked themselves out of the system.

Table 40. Group Setup Tab Screen Elements

Group Profile	<p>These user groups are predefined:</p> <ul style="list-style-type: none"> • Administrator • Supervisor • Service • Technician2 • Technician1 • Reviewer <p>The user belongs to the group to which you assign them.</p>
Group Features	<p>The Group Features list contains permission categories. When you select a category from the list, the Features section displays the individual tasks that are a part of that category. The following categories are available:</p> <ul style="list-style-type: none"> • System Administration • Batch Management • Protocol Management • Lot and Std/Ctrl Kit management • Import and export data • Archiving
Allowed check box	Enables the selected group to perform that task.
Signature Required check box	Requires a digital signature whenever a user in the selected group performs that task.

Clear **Allowed** and select **Signature Required** to require the electronic signature of another user whose account is configured to allow the action. When you do this, the current user cannot complete the action without this electronic signature. Activities performed with “Signature Required” are tracked in the **System Log**.

Permissions Available by Group

- **System Administration**
 - Manage Users (add, edit, or delete users)
 - Manage System Configuration
 - Perform Calibration and Verification
 - Manage Alerts
 - Manage scheduled maintenance
 - Change batch options and CSV options
 - Allow exit software
 - Batch run override system
 - Create, delete, activate Cal and Ver Lots and Kits
- **Protocol Management**
 - Create Protocol
 - Edit Protocol
 - Delete Protocol
- **Batch Management**
 - Create Batch
 - Edit Batch
 - Delete Batch
 - Run Batch
 - Validate and Invalidate Results
 - Replay Batch/Recalculate Data
 - Approve Batch
 - Reanalyze Results
 - Save Batch after changing results
 - Change Formula
 - Reacquire errored wells for partial batch
 - View Processed Batch Results
 - Export Processed Batch Results
 - Change Sample Load Volume During Run
- **Lot and Std/Ctrl Kit Management**
 - Create Std/Ctrl Kit and Lots
 - Edit Std/Ctrl Kit and Lots
 - Delete Std/Ctrl Kit and Lots
- **Archiving**
 - Backup/Restore
 - Archive
- **Import and Export Data**

- Export Batch, Protocol, Kit or Lot Files
- Import Batch, Protocol, Kit or Lot Files

When you perform an action that requires an electronic signature, the **Electronic Signature** dialog box displays. The user ID auto-populates. Enter your password and any comments. Click **OK** to complete the electronic signature, or **Cancel** to cancel the signature.

Set Up Group Permissions

1. Navigate to the **Admin** page > **Group Setup** tab.
2. In the **Group Profile** drop-down menu, click the group profile you want to set up.
3. In the **Group Features** drop-down menu, choose each group feature you want to set for the group profile you chose.
4. In the **Features** section, select the **Allowed** check box next to the desired permission to enable the selected group to perform that task. If you are using the 21 CFR Part 11 package, enable the **Signature Required** check box next to the desired permission to require a digital signature whenever a user in the selected group performs that task.

NOTE: These tasks are tracked in the **System Log**.

NOTE: Depending on the features you choose for the group, the list of permissions change.

5. Click **Save**.
6. In the **Settings Saved** dialog box, click **OK**.

User Setup Tab

Use the User Setup tab to create or edit a user account, remove a user from the system, or view a list of authorized users and their profile details.

NOTE: You must have administrative privileges and be using the Secure version of xPONENT or the 21 CFR Part 11 version to perform these tasks.

Table 41. User Setup Screen Elements

Create New User	Opens the Create User Account window.
Global User Settings	Password Expiration - Enter a length of time in days. The default is 180 days.
	Unsuccessful Login Attempts - The default number of allowed unsuccessful logins is three attempts.
	Automatic Logoff (seconds) - How many seconds pass until an automatic logoff. Default is 0.
	Minimum User ID Length - The default minimum User ID length is six characters.
	Minimum Password Length - The default minimum password length is six characters.
Users	Displays a list of all users. The list includes ID , Name , and Group Profile information, and indicates whether or not a user account is locked.
Delete User	Removes a selected user from the list.

Edit User

Opens the **Edit User Account** screen. This screen has the same options as the **Create User Account** screen.

Create a New User Account

1. Navigate to the **Admin** page > **User Setup** tab.
2. Click **Create New User**. The **Create User Account** window displays.
 - a. Enter the user ID in the **User ID** field. The user ID is not case-sensitive.

NOTE: You can change the required number characters for a user ID on the **User Setup** tab. Once you create and delete a user ID, you cannot use that user ID again.
 - b. Enter the user's name in the **User** field.
 - c. Select the **Account Status** check box to lock the account, or clear this check box to unlock the account.
 - d. Enter a password for the user **Password** field, then re-enter it in the **Reenter Password** field.
 - i. If you want the user to change the password on first login, select **Change password after next login**. The required length for passwords is set on the **Group Setup** tab.
 - e. In the **Group Profile** drop-down menu, choose the role for the user you are creating.
3. Click **Save** to return to **User Setup**.
4. Click **Cancel** to return to **User Setup** without saving.

Define Global User Settings

The settings in the **Global User Settings** section affect all users in all user groups. You can retain the default settings or type your own values.

To define Global User Settings, complete the following:

1. Navigate to the **Admin** page > **User Setup** tab.
2. In the **Global User Settings** section, type a length of time (in days) for the **Password Expiration**.
3. Set the number of allowed **Unsuccessful Login Attempts**.
4. Set how many seconds pass before an **Automatic Logoff (seconds)** is initiated.
5. Enter the **Minimum User ID Length**.
6. Enter a **Minimum Password Length**.
7. Click **Save**.
8. In the **Settings Saved** dialog box, click **OK**.

Edit User Permissions

1. Navigate to the **Admin** page > **User Setup** tab.
2. In the **Users** section, choose the **user ID**, then click **Edit User**.
3. In the **Edit User Account** window, edit the desired information.
4. Click **Save**.

Restore Account Status

If users attempt to log in unsuccessfully more than the number of times allowed, they will be locked out.

1. Navigate to the **Admin** page > **User Setup** tab.
2. In the **Users** section, choose the **user ID**, and click **Edit User**.
3. Clear the Account status: **Locked** check box.
4. Click **Save**.

Batch Options Tab

Use the Batch Options tab to set options for analysis and acquisition of batches.

Table 42. Batch Options Tab Screen Elements

Batch Options	Allow running a batch if the instrument is not calibrated or verified. - Allows batches to run if the instrument is not calibrated.
	Allow running or saving a batch with expired reagents.
	Allow running a batch if XY temperature is not in range.
	Allow canceling the warmup time to run batch
	Use weighting as default option for quantitative analysis. - Sets the weighting for quantitative analysis to default to ON for new protocols.
	Warn when saving/running a New Batch with New Protocol without saving the Protocol and/or Standard and Control information. - Opens a dialog box warning when saving or running a new batch with a new protocol when you have not saved the protocol and/or standard and control information.

Batch Settings	Analysis display decimal places - Enter the number of digits the system displays. The default number of digits is three.
	Minimum bead count for obtaining results - Enter any whole number from 0 to 1000000. This is the minimum bead count that must be observed by the instrument for a particular analyte before this data is used in statistical calculations and is displayed on the graphs and results table. When set to a number greater than 0, the instrument does not display data for bead sets not generating events equal to or less than this value. Enter 0 to display all events. The default setting is 1.
	Allow batches to be run or saved without lot number, expiration or manufacturer - Allows saving lots without normal required information.
	Default Routines - System maintenance routines like wash, flush, or clean can be programmed at different points in a batch to prevent clog formation and maintain peak system performance. Pre-batch routines, specifically, are recommended for challenging sample matrices like viscous material or material containing particulates in suspension because these matrices can clog the instrument. Select this option to specify a particular routine to run before running a batch.
	Default Analysis Graph Axes - Either Log X Axis or Log Y Axis.
Batch Thresholds	Detection enabled - Select or clear for low bead count detection.
	Well Count - When this many consecutive wells acquire a bead count lower than the number specified in the Total Bead Count field, the low bead count action is taken.
	Total Bead Count - The number of beads that must be counted per well to not receive a warning message.
	Error (stop) - Stops the batch.
	Warning (Pause) - Pauses the batch.
	Warning (Log) - Logs a warning if the number of successive wells in the Well Count text box are run without reaching the number of beads in the Bead Count box.
	Run Routine - Allows you to select the routine you want to run when a low bead count is detected.

Alert Options Tab

Use the Alert Options tab to set options for alerts about various system events.

Set Up Notification Options

To set notification options for various events:

1. Navigate to the **Admin** page > **Alert Options** tab.
2. Select **Dialog** if you want a dialog box to open for a specific event.

3. Select **Email** if you want to send an email notification for a specific event.

NOTE: Make sure the PC is connected to a network before trying to send an email.
4. Select **Sound** if you want a sound to play for a specific event.
5. If you choose to send an email notification for a specific event, and the email address is not already set up, click **Setup Email** to open the **Setup Email** dialog box. Turn email notifications on or off by selecting or clearing the **Email Active** check box.
 - a. Contact your system administrator to determine the correct information for the **Mail Server Host**, **From Email Address**, **From Email Password**, and **Mail Server Port** fields, and if you need to select the **Enable SSL** (Secure Sockets Layer) check box.
 - b. Enter email addresses in the **Email Addresses (separated by commas)** field that you want to send alert notifications to.
 - c. Click **Test** to send a test email to the addresses you have entered.
6. Click **OK** to apply any changes.
7. In the **Save Settings** dialog box, click **OK**.

CSV Options Tab

NOTE: You must have administrative privileges to perform this task if you are using the 21 CFR Part 11 or Secure package.

Use the CSV Options tab to define what the CSV (comma-separated values) file will contain and where it will be stored.

Table 43. CSV Options Tab Screen Elements

Automatically export results CSV file when batch is complete	Automatically exports the results to a CSV file when the system finishes analyzing the batch. This allows running programs on exported data without having to manually start the export.
Automatically export batch when batch is complete	Exports batch information automatically when a batch has completed.
Maximum number of data columns in CSV file	Sets the number of individual values in each line of the comma-separated value output file. Each value is separated from the previous and following value by a comma.
Use US regionalization format only	Exports data only in US regionalization format. Use this option if your external analysis program requires a CSV output file with US delimiters.
Include Advanced Statistics	Exports advanced and additional statistics, for example, trimmed counts, in the CSV file. See the CSV file specification for details.
CSV Export Folder and Automatically Exported Batch Folder	Displays the path and location where the CSV file or automatically exported batch file will be exported. Click Browse to change the file export location.
Automatically Export LXB files	Displays the path and location where the LXB file will be exported. Click Browse to change the file export location.

Automatically Export Run CSV files	Displays the path and location where the Run CSV file will be exported. Click Browse to change the file export location.
Automatically convert the raw run files to CSV format for each well in the batch	Automatically converts raw run files to CSV format for each well in the batch. This option creates a CSV formatted file for the raw bead data of each well.
Test Sort Order	Defines a method to sort the test data. The options are By Analyte Name , By Region ID , or By Setup Order .

Archive Tab

Use the Archive tab to archive all file types - batches, protocols, kits, lots, and LIS records.

When you click the Launch Archive Utility button, the Archive Utility dialog box displays.

NOTE: To back up or restore xPONENT® files, quit the application and select xPONENT ARCHIVE from the Windows® Start menu.

Archive Utility Dialog Box

Click the Launch Archive Utility button to open the Archive Utility dialog box.

The Archive Utility can be used within xPONENT® to set up the frequency and types of files to back up. Statistics about disk space and archive space used, as well as the types of files to back up, appear on this page.

The archive utility runs continuously. If automatic archives are scheduled, they occur whether xPONENT is running or not. When you want to backup or restore xPONENT, quit the application and run the Archive Utility from the Start menu.

Schedule Overview	Schedules archiving.
First Occurrence	Select the date and time for the first automatic archive.
Frequency	Establishes how frequently the system performs the archive process.
Reminder Only	Establishes whether you want a regular reminder from the system so that you can perform archiving manually.
To Be Archived	Establishes which files are archived.
Archive Folder	Select the folder in which files are archived. If the output folder is on a network share and the share becomes unavailable, the system archives locally and sends you a note where the archived files are.
Archive Events	Lists all events related to archiving activity.
System	Displays how many files of each type are currently in xPONENT®.
System Backup	Backs up your system. It requires a log on and then instructs you to shutdown the xPONENT software and launch the Archive Utility from the Start menu.

System Restore	Restores your system. It requires a log on and then refers you to the Start menu to restore your system.
Manual Archive	Performs a manual archive process. It requires a log on and then opens the Manual Archive window.

Licensing Tab

Contact *Luminex Technical Support* to obtain a license key for xPONENT® for software.

NOTE: You must restart the computer for the new license to take effect.

Add a New License Key

1. Navigate to the **Admin** page > **Licensing** tab.
2. Click **License** (bottom right corner of window).
3. Copy and paste the new key into the **Your new License Code** field. The **License File** field remains blank.
4. Click **OK**. This closes xPONENT®, applies the license, and restarts xPONENT.
5. Contact *Luminex Technical Support* if you have any difficulty saving or adding a new license key.

Schedule Tab

Use the Schedule tab to view reminders for scheduled maintenance due to be performed on the instrument.

Table 44. Schedule Tab Screen Elements

Reminders	Subject - The scheduled maintenance.
	Reminder - A description of the scheduled maintenance.
	Next Alert Date - The date xPONENT® alerts you about the scheduled maintenance.
	Alert Time - The time xPONENT alerts you about the scheduled maintenance.
	Notes - Any additional information you want to know about the scheduled maintenance.
Laser Warmup Schedule	Enables a schedule to warm up the lasers.

Edit Maintenance Schedule Settings

1. Navigate to the **Admin** page > **Schedule** tab.

NOTE: The **Schedule** tab can also be accessed from the **Maintenance** page, but the settings cannot be edited from there.
2. On the **Schedule** tab, use the drop-down menus to edit the **Alert Time** and **Recurrence** frequency for any scheduled activity.

3. Enable or disable the reminders by selecting or clearing the **Enabled** check box.
4. Click **Save**.
5. In the **Settings Saved** dialog box, click **OK**.

Enable Laser Warm Up Schedule

1. Navigate to the **Admin** page > **Schedule** tab.
2. Select **Enable Schedule Warm Up** to schedule the warm up.
3. Click the up or down arrows to change the schedule time.
4. Click **Save**.
5. In the **Settings Saved** dialog box, click **OK**.

Report Options Tab

Use the Report Options tab to set how reports are displayed and printed.

Customize How the Report Looks

1. Navigate to the **Admin** page > **Report Options** tab.
2. Enter a company name in the **Company** field, and any additional information in the **Info** field.
3. Click **Import Logo** to open the **Windows® Open** dialog box and select the file you want to use for the logo at the top of reports. Click **Open**.

NOTE: The logo file should be 920 x 125 pixels. If you want the logo to display to the right of your company name, include 120 pixels of white space to the left of the logo in the graphic file. If you do not include white space, the logo may display behind the company information.

4. Click **Clear Logo** to return to the default logo. (Optional)
5. Click **Save**.
6. In the **Settings Saved** dialog box, click **OK**.

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