# Luminex®

## complexity simplified.

# FLEXMAP 3D® User Manual

CE

| EC | REP |
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# Chapter 1: System and Software Introduction

## Instrument Overview

The FLEXMAP 3D®, in combination with xMAP® (Multi-Analyte Profiling) Technology, will simultaneously measure up to 500 analytes from a single sample. xMAP Technology incorporates microspheres, proprietary dyeing processes, flow-cytometry based fluidics, lasers, the latest in high-speed digital signal and advanced computer algorithms, enabling a multi-analyte detection system that demonstrates excellent sensitivity and specificity.

An established proprietary process created by Luminex to internally dye same-size polystyrene microspheres with multiple fluorophores facilitates the creation of 500 distinguishable microspheres when these fluorophores are combined in varying concentrations. The microspheres, discriminated by color, are excited by two lasers in the FLEXMAP 3D instrument. The resulting emission is detected by avalanche photo diodes (APDs) in three classification channels (CL1, CL2, and CL3) that is then further analyzed using a separate APD in a doublet discriminator (DD) channel, which measures bead size through side-scatter.

Analytes are bound to xMAP microspheres using the same surface chemistry used with earlier Luminex instruments. Reporters, tagged with fluorescent labels excited at a different wavelength than the internal dyes, bind to the analyte of interest and are detected by a photomultiplier tube (PMT) in a reporter channel (RP1), allowing for quantitative analysis. As the microspheres in a fluid stream pass rapidly through the laser beams, high speed digital signal and computer algorithms discriminate which analyte is being carried on each microsphere and quantifies the reaction based on fluorescent reporter signal. The results are analyzed by the system software and presented in a readable format for analysis.

## Software Overview

xPONENT® software runs, maintains, and troubleshoots the FLEXMAP 3D® 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
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Email: support@luminexcorp.com.
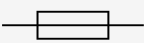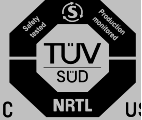
Additional information is available on the Luminex website. Search on the desired topic, navigate through menus. Also, review the website's FAQ section. Enter http://www.luminexcorp.com in your browser's address field.

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. | | Caution possibility of electric shock. |
| | 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. | EC REP | Authorized representative in the European Community. |

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|---|
| **RUO** | For Research Use Only. Not for use in diagnostic procedures. | **LOT** | Batch Code. |
| CE | Conformite Europeenne (EU CE Marking of Conformity) CE conformity marking | | Manufacturer. |
| | Temperature Limit. | | Date of manufacture. |
| I | On (Power). To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved. | | Protective earth; protective ground. |
| ◯ | Off (Power). To indicate disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. | MET® UL 61010-1 | MET Mark |
| | Consult instructions for use. | **REF** | Catalog(ue) Number. |
| **SN** | Serial number. | TÜV SÜD NRTL | TÜV SÜD NRTL Certification Mark. |
| | WEEE Symbol. Separate collection for electrical and electronic equipment. | | |

# 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® FLEXMAP 3D® system with xPONENT® software is a clinical multiplex test system that measures and sorts multiple signals generated in an assay from a clinical sample. This instrumentation is for research use only and is not for use in diagnostic procedures. The FLEXMAP 3D system is for laboratory and professional use only.

# Safety Testing and Certifications

The FLEXMAP 3D® has been tested and complies with the safety requirements for the United States and Canada and is marked with the MET label or the TUV label. Review the Symbols Glossary to determine what the labels look like.

The FLEXMAP 3D 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 FLEXMAP 3D® instrument.

Figure 1: Laser Warning Label

CLASS 1 LASER PRODUCT
IEC 60825-1:2007
Complies with 21 CFR 1040.10
and 1040.11 except for
deviations pursuant to Laser
Notice No. 50,
dated June 24, 2007.
Do not remove cover.
No user-serviceable parts inside
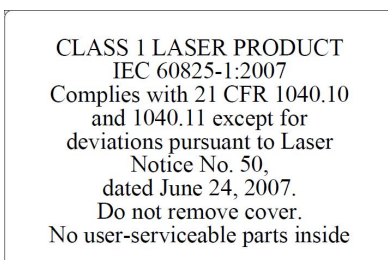
Figure 2: Laser Class Label



CLASS 1 LASER PRODUCT
IEC 60825-1:2014

The following label appears above the laser apertures located inside the optics enclosure inside the FLEXMAP 3D.

Figure 3: Avoid Exposure Label



**AVOID EXPOSURE**
**Laser radiation is emitted**
**from this aperture.**
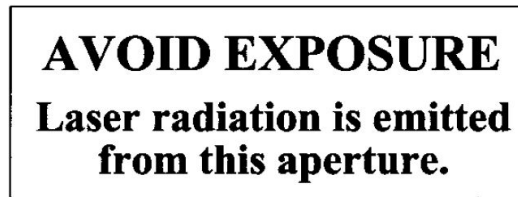
The following fuse caution label appears on the back of the system.

Figure 4: Fuse Caution Label



CAUTION:
Double Pole/Neutral Fusing
Disconnect power before changing fuse

ATTENTION:
Double pole/fusible sur ie neutre
Couper le courant avant de remplacer le fusible

F6A, 250V
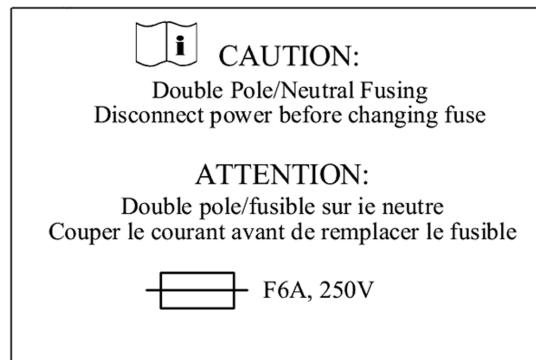
A voltage label appears on the back of the system and displays the serial number, model number, power requirements, and manufacturer's information.

Figure 5: Serial Number and Voltage Label



**Luminex Corporation**
**12212 Technology Blvd.**
**Austin, Texas 78727**
**USA, 2016-07-14**
**Model: FLEXMAP 3D**
**SN FM3DD16196021**
**100-120V~, 6.0A, 50/60 Hz or**
**200-240V~, 3.0A, 50/60 Hz**
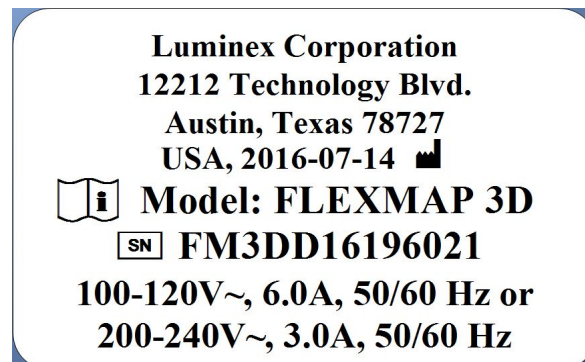
# Warnings and Precautions

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.

Keep access doors closed during normal operation. Always observe standard laboratory safety practices

## Mechanical Safety

The system has parts that move during operation. Risk of personal injury is present. The moving parts present puncture, hand-crushing hazards, and pinching hazards.

Keep hands and fingers away from the XY slot, syringe pumps, and sample probe during operation. Observe all warnings and cautions. Keep the access doors closed during normal operations.

## Electrical Safety

Observe the fuse caution stated on the fuse caution label. Be aware of the instrument voltage.

Do not perform any maintenance or clean the electrical components in the system, with the exception of replacing fuses.

Power cords must be replaced with cords of the same type and ratings as originally provided. Contact *Luminex Technical Support* for correct replacement power cords.

## Electromagnetic Compatibility

The FLEXMAP 3D® complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6. The electromagnetic environment should be evaluated prior to operation.

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.

⚠️ Always handle the instrument according to Luminex instructions to avoid any possible interference from its electromagnetic fields.

## Laser Safety

The FLEXMAP 3D® 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 optional 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 optional accessory Class 2 barcode reader. The FLEXMAP 3D 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.

All Class 3B per IEC standard laser apertures are located within the FLEXMAP 3D and are contained within a protective housing, accessible only to trained field service technicians. When performing routine maintenance, turn power to the system off and unplug the power cord.

⚠️ Do not, under any circumstances, remove the FLEXMAP 3D instrument cover. Use of controls or adjustments or performance of procedures other than those specified in this manual can result in hazardous radiation exposure.

## Barcode Reader Laser

The barcode reader laser presents a potential hazard to eyesight.

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

## Heat Safety

The heater plate, used to warm the plate carrier of the XY platform, can be heated between 35°C and 60°C.

⚠️ The heater plate of the FLEXMAP 3D® XY platform 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.

Route the waste line to a laboratory drain. The volume of the waste fluid container should be at least as large as the volume of the sheath container. Do not move the waste line vertically while the FLEXMAP 3D is running, and make certain the waste fluid container is properly vented. Contact Luminex 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, user your standard laboratory safety practices when handling system waste.

## Biohazard/Biological Safety

Human and animal samples may contain biohazardous infectious agents.

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.

## Swivel Base Safety

The optional swivel base available with the FLEXMAP 3D® includes moving parts and possible pinch points. Those factors present the possibility of injury.

Use care when handling the swivel base to avoid pinch point injuries.

Make certain the swivel base sits securely on a stable surface, to avoid any possibility of falling over.

## Indicator Light

The lights inside the front door of the FLEXMAP 3D® indicate the on/off status of the system and are 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. To aid in reducing the overall plate run time, the XYP in the FLEXMAP 3D® system also moves in the diagonal direction. 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 FLEXMAP 3D. The first path involves a dual syringe-driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The dual 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 or 384-well plate 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 FLEXMAP 3D. Results of the analyses are processed and provided in a report format.

## Environmental Conditions

- 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

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- Shipping temperature: 0°C to 50°C (32°F to 122°F)
- Storage temperature: 0°C to 50°C (32°F to 122°F)
- Altitude: Operation up to 2400 m (7874 ft.) above mean sea level
- Operating Shock: The instrument can operate while experiencing limited shock.
    - Pulse amplitude: 1 m/s$^2$ maximum
    - Pulse direction: along any axis defined by a rear corner of the instrument, in either direction
    - Reference IEC 60068-2-27 Basic Environmental Testing Procedures Part 2: Tests -Test Ea and Guidance: Shock

    NOTE: This specification is not meant to comprehensively describe all forms of shock the instrument can be exposed to in use; it is only intended to serve as a measure of the system's robustness.

- Although the system can withstand a shock pulse as described above without compromising reliable operation, extended exposure to shock whether or not it exceeds the pulse defined above is not recommended and can result in instrument failure.
    - Operating Vibration: The instrument can operate while experiencing limited vibration.
        - Direction is along any axis defined by a rear corner of the instrument.
        - Sinusoidal, limited to frequency ranges
    - Frequency Range Limit Type of Limit
        - 0 Hz to 10 Hz 0.35 mm +/- 10% (0.7 mm peak-to-peak) Displacement
        - 10 Hz to 100 Hz 1 m/s$^2$ +/- 10% peak Acceleration
        - Reference IEC 60068-2-6 Environmental Testing Procedures Part 2: Tests - Test Fc: Vibration (Sinusoidal).

            NOTE: Although the instrument can operate while experiencing vibration as described above, extended exposure to vibration whether or not it exceeds these limits is not recommended and can result in instrument failure.

# Performance Specifications

## General System Specifications

- System verification: 5 minutes
- Time to complete one 96-well plate: Approximately 20 minutes with 2500 microspheres per region per well
- Physical Dimensions: 58.4 cm (23 in) W x 65.3 cm (25.7 in deep, including the required 1.25 in for proper cooling) D x 45.7 cm (18.0 in) H. Additional space required for the arm, monitor, keyboard, mouse, and optional barcode scanner does not exceed 64.8 cm (25.5 in) W x 61 cm (24.0 in) D.
- Weight: Up to 91 kg (200 lbs), including the instrument, monitor arm, monitor and accessories such as the keyboard, mouse, and barcode scanner.
- Installation Category II
- Pollution degree 2
- Temperature control: maintains samples using the heater block at a constant temperature from 35°C to 60°C (95°F to 131°F) +/- 1°C of setpoint.
- Automatic transfer of assay protocols and new reagent information into the system using a large capacity read/write DVD

- Automatic sampling from a 96-well or 384-well plate, beginning from any well position
- Automatic real-time analysis
- Analysis of multiple assay protocols per plate
- Barcode reader entry of sample IDs
- Produces sound pressure levels below 85 dBA
- System initialization: < 45 minutes (including laser warmup, required software procedures, and weekly calibration)
- FLEXMAP 3D® warmup: 30 minutes. A system that remains inactive for at least 4 hours requires a warm-up to restart the lasers. The system resets the 4 hour internal clock after acquiring the sample, running system calibrators, running system controls, or warming up the instrument.

# Electronics Specifications

- USB 2.0-compatible communications link for fast data transfer
- Input voltage range:  100 V~ to 120 V~, 6.0 A, 50 Hz to 60 Hz or, 200 V~ to 240 V~, 3.0 A, 50 Hz to 60 Hz

# Optics Specifications

- Reporter channel detection: A/D resolution 16 bits
- Reporter Channel Dynamic Range: ≥ 4.5 decades of detection (verified with microspheres dyed with high levels of organic dyes)
- Reporter laser: 532 nm, nominal output 15.0+5%/-0% mW, diode-pumped; mode of operation, continuous wave (CW); maximum output power 50 mW
- Classification laser: 638 nm, nominal output 12.0 mW to 12.5 mW, maximum output power 15 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

# Fluidics Specifications

- Cuvette: 200 micron square flow channel
- Sample injection rate: 2 µL/second
- Sample uptake volume: 10 µL to 200 µL
- Sheath flow rate: 7.9 (+/- 0.9) mL/minute
- Sheath pressure: 8 psi to 13 psi for normal operations; 15 psi maximum

# Microspheres Specifications

- Distinguishes 1 to 500 unique xMAP® microspheres in a single sample
- Misclassification Rate ≤ 4%
- Classification Rate ≥ 80%
- Detects and distinguishes surface reporter fluorescence emissions at 575 nm on the surface of 1 to 500 unique xMAP microsphere in a single sample

- Soluble background fluorescence emission at 575 nm automatically subtracted from fluorescence intensity values
- Internal sample carryover: < 1.5%
- Detects a minimum of 500 fluorochromes of Phycoerythrin (PE) per xMAP microsphere

## Plates Specifications

- The FLEXMAP 3D® system processes a 96-well plate in ~20 minutes and a 384-well plate ~ 1 hour and 15 minutes, with 2500 microspheres per region per well, counting 100 microspheres in each region.
- Plate must be 96-well or 384-well, not to exceed 1 inch (2.54 cm) in height, including heater block.
- Plate must be compatible with the heater block temperature (35°C to 60°C or 95°F to 131°F) 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.

# System Components

The three components of the FLEXMAP 3D® 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 FLEXMAP 3D® system is preloaded with xPONENT for FLEXMAP 3D 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 FLEXMAP 3D has been validated only when it is the only program running on the dedicated PC.

# Hardware Components

- FLEXMAP 3D® instrument
- Personal computer (PC) and accessories
- Stereo speakers
- Power cables
- Three sample probes
- Off-plate reagent block
- Empty cubitainer for waste
- Sheath fluid intake line
- Waste fluid outtake line
- USB communication cable
- Barcode reader (optional)
- Monitor arm

# 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.

- F3DCAL1 - Classification Calibrator (calibrates DD, CL1, CL2, CL3 - for all xMAP® microsphere applications other than MagPlex® microspheres)
- F3DeCAL1 - Classification Calibrator (calibrates DD, CL1, CL2, CL3 - for MagPlex microsphere-based applications only)
- F3DCAL2 - Reporter Calibrator (calibrates RP1 standard and enhanced range - for all xMAP microspheres)
- F3DCAL3 - EDR Calibrator (calibrates RP1 extended range - for all xMAP microspheres)
- F3DVER1 - Classification Verifier (verifies DD, CL1, CL2, CL3 - for all xMAP microsphere based applications other than MagPlex microspheres)
- F3DeVER1 - Classification Verifier (verifies DD, CL1, CL2, CL3 - for MagPlex microsphere based applications only)
- F3DVER2 - Reporter Verifier (verifies RP1 standard and enhanced PMT and extended range - for all xMAP microspheres)
- Fluidics1 - xMAP Fluidics 1 (verifies fluidic integrity and well-to-well microsphere carryover)

- Fluidics2 - xMAP Fluidics 2 (verifies fluidic integrity and well-to-well microsphere carryover)
- xMAP sheath fluid

> ⚠️ Protect xMAP reagents from light at all times to avoid photobleaching of the microspheres. Luminex reagents contain ProClin® as a preservative. This can cause allergic reactions in some people.
>
> Luminex calibrators and verifiers contain sodium azide. Sodium azide is toxic and can also react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush drains with a generous amount of cold water to prevent azide build-up. 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).

## Required Laboratory Reagents

- 10% to 20% household bleach
- 70% isopropanol or 70% ethanol solution
- 0.1N NaOH
- Sporicidin® Disinfectant
- Mild detergent
- Deionized 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.
>
> Formulated reagents must be free of particulates other than xMAP® microspheres. Do not dilute xMAP calibrators or verifiers.

# Subsystems

## Mechanical Subsystem

### Filter System

The mechanical subsystem of the FLEXMAP 3D® system includes a filter system.

Replaceable ventilation filters clean the air used to cool the system and pressurize sheath fluid. The four filters must be checked and cleaned.

Figure 6: Front Door Ventilation Filters
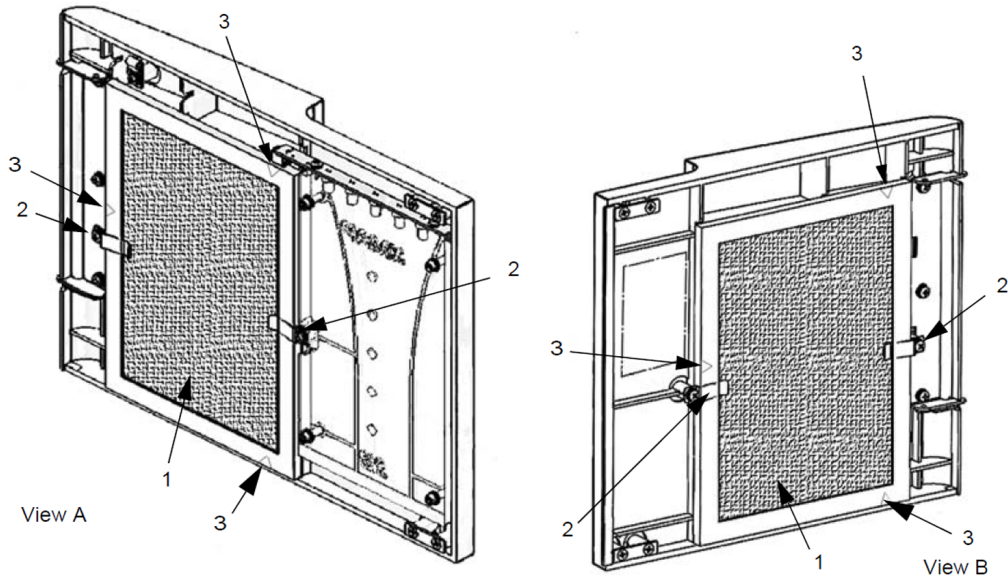


| View A | Right front door, viewed from inside |
|--------|--------------------------------------|
| View B | Left front door, viewed from inside |
| 1 | Filter |
| 2 | Holding clamp |
| 3 | Filter arrows |

Figure 7: XY and HEPA Filters
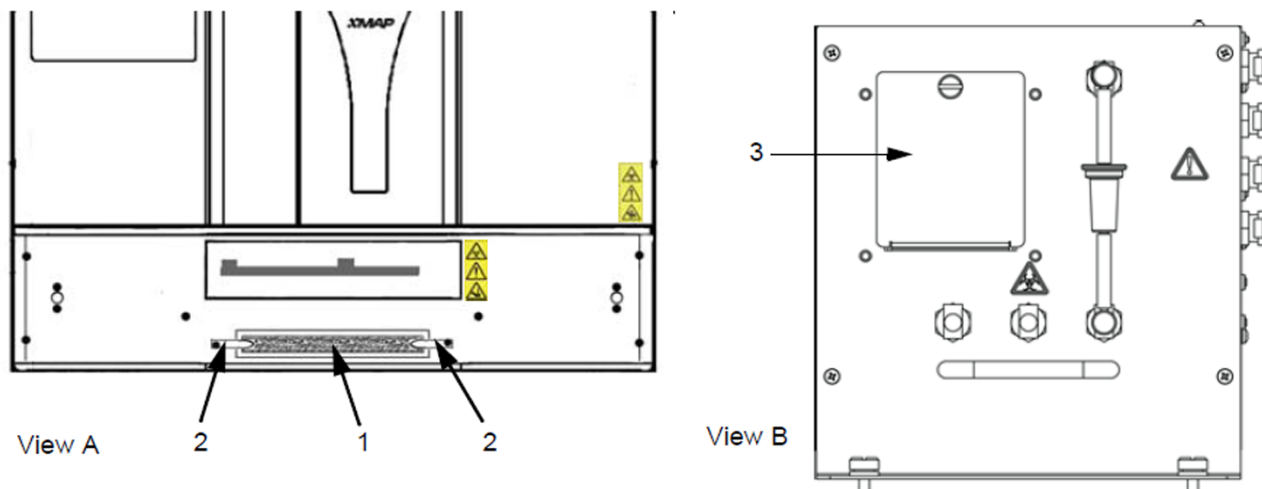


| View A | Front of XY, with XY cover removed |
|---|---|
| View B | Front of fluidics bay, behind left front door |
| 1 | XY filter |
| 2 | Holding clamp |
| 3 | Cover over HEPA filter |

# Electrical Subsystem

The electrical subsystem provides the power for operation and control of the FLEXMAP 3D® system and communication between its parts.

## Power Input Module

The power input module contains the input power plug and fuses. The power input module is the protective earthing point for the FLEXMAP 3D® system. The mating power cord connector type is IEC-320-C13. The mating power cord provides electrical power to the instrument when it is connected to an electrical outlet and is the means of disconnection. The power input automatically senses the voltage range.

Do not obstruct this means of disconnection. Connect only to outlets that contain protective earthing. Before changing a fuse, turn off the instrument and unplug the power cord to avoid any danger of electrical shock. Before changing a fuse, turn off the instrument and unplug the power cord to avoid any danger of electrical shock.

## Communications Ports (USB Type B Connector)

The communications port connects the FLEXMAP 3D® to the computer.

**Figure 8: Back of the FLEXMAP 3D**
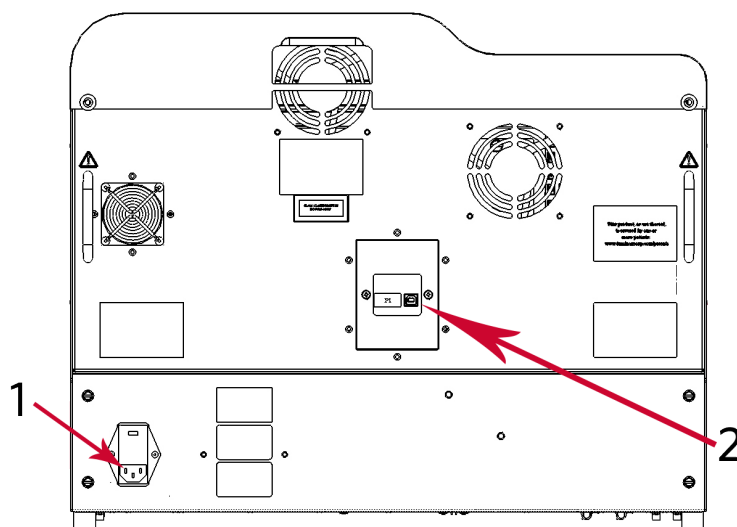


| 1 | Power Input Module |
|---|---|
| 2 | Communications Port P1 (USB type B) |

# Fluidics Subsystem

The fluidics subsystem handles the flow of liquid through the FLEXMAP 3D®.

## Access Doors

The FLEXMAP 3D® has two front access doors. The left door supplies access to a door ventilation filter and the sheath filter. The right door supplies access to a door ventilation filter, the sample probe, and the syringe pumps.

**Figure 9: Front of the System**
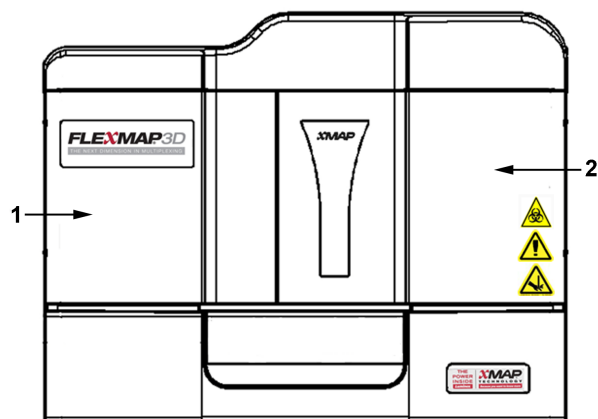


| 1 | Left door, with access to sheath filter and door ventilation filter |
|---|---|
| 2 | Right door, with access to door ventilation filter, sample probe, and syringe pumps |

## Fluidics Bay

The waste and sheath connectors, located on the front of the fluidics bay, connect to the sheath fluid and waste fluid containers using clear tubing. The sheath fluid connector is blue and the waste connector is orange.

> Wear appropriate PPE when handling parts that come into contact with potentially biohazardous samples.

Figure 10: Fluidics Bay
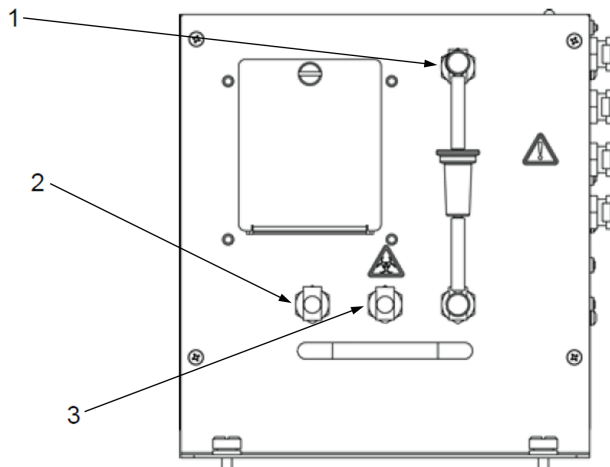


| | |
|---|---|
| 1 | Sheath filter |
| 2 | Blue tubing attached to sheath fluid container |
| 3 | Orange tubing attached to waste fluid container |

## 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.

## Cheminert® Fitting

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

Figure 11: Fluidics Components
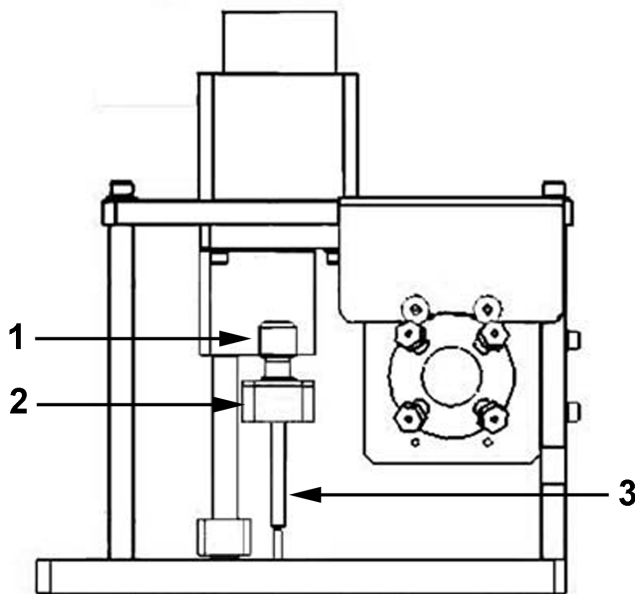


| 1 | Cheminert® fitting |
|---|---|
| 2 | Attachment point on Cheminert fitting for sample tubing |
| 3 | Sample probe, in the up position |

## Syringe Pump

The syringe delivers a sample from the plate to the cuvette.

> ⚠️ Avoid contact with moving parts.

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

20
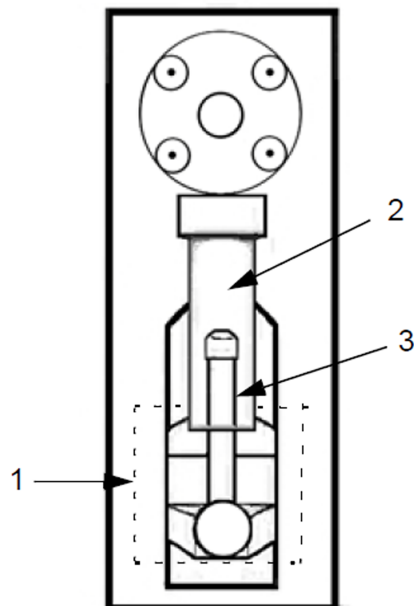
| 1 | Syringe arm (within dotted lines) |
|---|---|
| 2 | Glass syringe barrel |
| 3 | Syringe plunger |

## 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. Place the waste fluid container at least 3 feet below the surface on which the system sits. Place the waste fluid container as far away from the system as the tubing allows. Contact *Luminex Technical Support* before you relocate the waste fluid container.

> ⚠️ 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 FLEXMAP 3D® at any point.
>
> Waste levels must be manually monitored. Do not allow the waste fluid container to overflow.

# 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 1300 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 Europeénne (CE) for non-domestic use.

**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 FLEXMAP 3D® contains pre-defined routines to prepare the instrument for data acquisition.

## Power on the System

To power on the FLEXMAP 3D®:

1.  Plug the power cord from the back of the instrument into a power outlet.

    **NOTE:** Luminex recommends the use of a surge protector or UPS device.

2.  Turn on the power switch on the right side of the instrument, toward the back.

    **NOTE:** The power switch controls flow of power to the instrument.

    **NOTE:** There are several startup indicators when you turn on the FLEXMAP 3D, but the easiest to hear is the fan and to see is the blue light on the front 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.

**NOTE:** Ensure that there is no liquid in the wells or reservoirs before adjusting the sample probe height.

**NOTE:** When you adjust and save the probe height settings for all three areas under a plate name, all areas retain the adjustment.

| | |
|---|---|
| ⚠️ | Correct sample probe height is critical to successful sample acquisition and calibration. Problems with the sample probe height can lead to fluid leaks and inhibit sample acquisition.<br><br>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. Choose a plate from the **PlateType** drop-down menu.

3. Based on the type of plate you are using, place alignment disks or an alignment sphere in the well.

   - 96-well Hard Bottom Plates - No disk is required. Ensure that the well location is selected on the plate image. Luminex recommends the use of well D6 (a green pin marks the location). To change the well location, click on the desired well in the plate image.
   - 96-well Filter or Mylar Bottom Plate - Place one (5.08) alignment disk into a well. Ensure that the well location is selected on the plate image. Luminex recommends using well D6 for 96-well plates.
   - 384-well Filter or Mylar Plate - Use the Probe Height Adjustment Tool.

     **NOTE:** Verify that the plate is not warped. Warped plates can lead to incorrect sample probe height adjustment.

     **NOTE:** Alignment disks and spheres are included in the Sample Probe Height Adjustment Kit (CN-0263-01) shipped with the instrument. Likewise, the Probe Height Adjustment Tool (CN-0298-01) is also shipped with the instrument.

     **NOTE:** These instructions enable the sample probe height to be set correctly in the vast majority of cases where a plate is being used having wells with rigid bottoms.

4. Click **Eject**.

5. Place the off-plate reagent block on the plate carrier. Place the plate on the plate holder with A1 in the top left corner.

6. Place a strip well (provided with the Calibration and Performance Verification kit) in column S1 of the block

   **NOTE:** If using a strip-well plate, ensure that a strip is present in the selected well location, prior to calibration.

   **NOTE:** Make sure there is no liquid in the plate or the off-plate reagent block.

7. In the **Strip Wells** section, select **SD1**.

8. In the **Reservoir** section, select well **RB1**.

9. Click **Retract**.

10. Enter a name for the plate in the **Plate Name** box, or choose a saved plate from the **Plate Name** drop-down menu.

   **NOTE:** If a saved plate is chosen, the results of the new calibration will override the previous calibration.

11. Click **Auto Adjust Height**. The sample probe automatically adjusts itself and saves it to the plate you chose.

   **NOTE:** The sample probe height is automatically set to 0.49 mm. The sample probe automatically adjusts this distance from the bottom of the plate, or calibration disks or spheres.

# Adjust the Sample Probe Height with the Sample Probe Adjustment Tool

**NOTE:** The Probe Height Adjustment Tool is primarily designed to be used with 96-well or 384-well plates on the FLEXMAP 3D® instrument.

- 384 well plates - Only use wells A1-P1 and A7-P7.
- 96 well plates - Only use wells B6-H6 and B8-H8.

To determine which well to use for with the tool, perform the following steps:

1. Use the data sheet for the plate you intend to adjust the probe height to; subtract the "well depth" from the "plate height" as shown in the Example 1 or Example 2.

   **Example 1:**
   **Plate Type:** Corning 384-well plate (Catalog #3703)
   **Plate Height:** 14.2 mm - **Well Depth:** 11.43 mm = 2.77 mm (2.8 mm).

| | Representative microplate (Corning Cat. #) | Well Volume (uL) | Well Depth (mm) | Well Diameter (top/bottom) (mm) | Plate Length (mm) | Plate Width (mm) | Plate Height (mm) |
|---|---|---|---|---|---|---|---|
| **384 Well Microplates** | | | | | | | |
| **Solid black, white, and clear polystyrene plates** | | | | | | | |
| 384 well flat bottom | 3640, 3652, 3654, 3844, 3680, 3700, 3701, 3702, 3703, 3704, 3705, 3708, 3709, 3710, 3723, 3844 | 112 | 11.43 | 3.63 / 2.67 (width) | 127.8 | 85.5 | 14.2 |

   **NOTE:** Numbers rounded to the nearest tenth of a millimeter.

In this calculation, well C7 on the tool should be used to adjust the probe height for the 384-well plate.
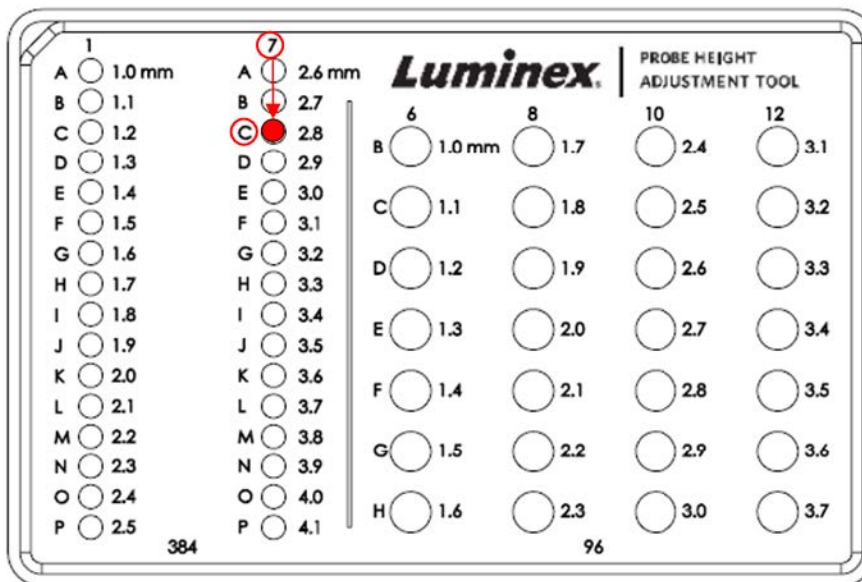


**Example 2:**

**Plate Type:** Greiner Bio One 96-well flat bottom plate (Catalog #655094)

**Plate Height:** 14.40 mm - **Well Depth:** 10.90 mm = 3.50 mm

In this calculation, well F12 on the tool should be used to adjust the sample probe height for the 96-well plate.
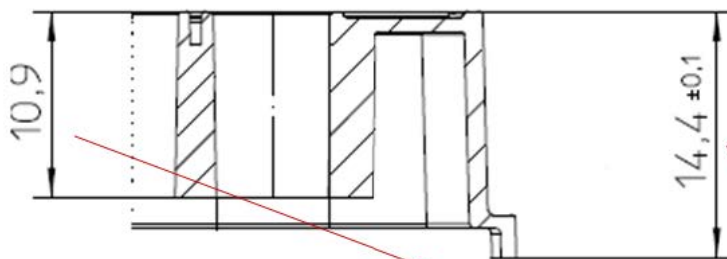


| | Microplate | Catalog # | Well Volume (µL) | Well Depth (mm) | Plate Height (mm) |
|---|---|---|---|---|---|
| **96-well flat bottom** | Greiner Bio-One | 655090, 655094 655095, 655096 655097, 655098 | 392 | 10.90 | 14.40 |
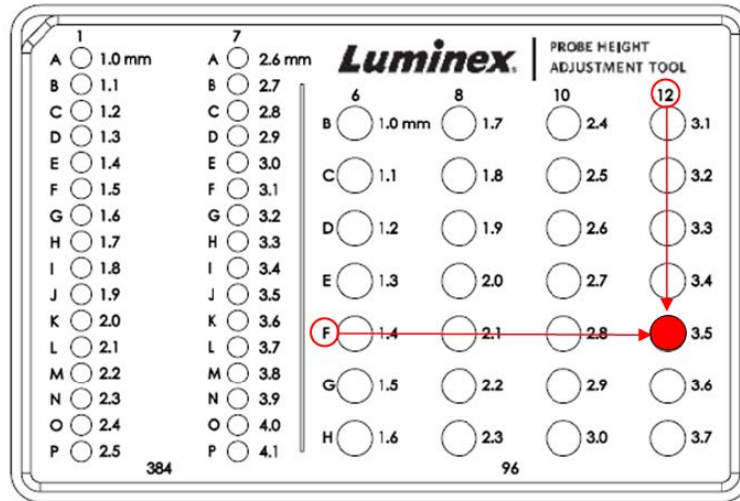
2. From the **Home** page, under **Daily Activities**, click **Probe and Heater.**
3. Choose a plate from the **Plate Type** drop-down menu.
4. Click **Eject**, place the tool onto the tray, and click **Retract**.
5. Enter a name for the plate in the **Plate Name** box, or choose a saved plate from the **Plate Name** drop-down menu.
6. In the **Plate** section, select the well determined to adjust the sample probe height.
7. Click **Auto Adjust Height**. The sample probe automatically adjusts itself.
8. Click **Eject**, remove the tool, and load the sample plate to be read.

# 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 RA2 (x3)
   - Alcohol Flush RB1 (x2)
   - Backflush
   - Wash RA1 (x3)

3. Click **Eject.**
4. Fill reservoir RB1 3/4 full of 70% isopropanol or 70% ethanol.
5. Fill reservoir RA1 3/4 full of DI water.

   NOTE: The drain reservoir (RA2) 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 FLEXMAP 3D® systems report similar results. Calibrating the FLEXMAP 3D system normalizes the settings for the classification channels (CL1, CL2, and CL3), the doublet discriminator (DD), and the reporter channel (RP1). Use the FLEXMAP 3D Calibration Kit to calibrate the system. After calibration, perform verification. Following calibration, use the FLEXMAP 3D® 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, FLEXMAP 3D 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 +/- 5°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. Vortex the xMAP® calibrator and fluidics bottles at a medium speed for approximately 10 seconds to ensure homogeneity. Do not dilute the xMAP calibrator or fluidics agents.
5. Click **Eject**.
6. Add two clean strip wells into the off plate reagent area.

> **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. Invert the bottle and add five complete drops of each calibration reagent to the first strip well. (F3DCAL1, F3DeCAL1, F3DCAL2, and F3DCAL3)
9. Add five complete drops of each performance verification reagent (F3DVER1, F3DeVER1, F3DVER2, 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.

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

# Verify the System

The FLEXMAP 3D® Performance Verification Kit includes reagents to verify the calibration and optical integrity for the FLEXMAP 3D 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 off plate reagent area.

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

7. Completely invert the bottle and add 5 complete drops each of the performance verification reagents (F3DVER1, F3DeVER1, F3DVER2, 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.

8. Click **Retract**.
9. Click **Run**.

# Chapter 5: Running the Assay

Warm up the lasers to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn power on; however, you will need to use the Warmup command if the system is idle for four hours or longer. Failure to properly warm up the lasers will affect assay results and system performance.

## 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. Choose the **Plate Name** that was assigned to the plate during probe height adjustment.

   j. For **DD Gating**, enter the minimum and maximum value.

   k. For **Reporter Gain**, choose **Standard PMT** or **Enhanced PMT (High)**.

   l. For **Analysis Type**, choose the type of protocol you want - **None**, **Qualitative**, or **Quantitative**.

   m. 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.

   n. If you chose qualitative or quantitative analysis type, enter the **Number of Controls** that apply to the protocol.

   o. If you chose quantitative analysis type, select the option of **Fit of All Standards** or **Mean of Replicates** to apply to the protocol.

   p. Select **Analyze results while acquiring samples** to view the results while the samples are being analyzed.

   q. 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.

   r. 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**.
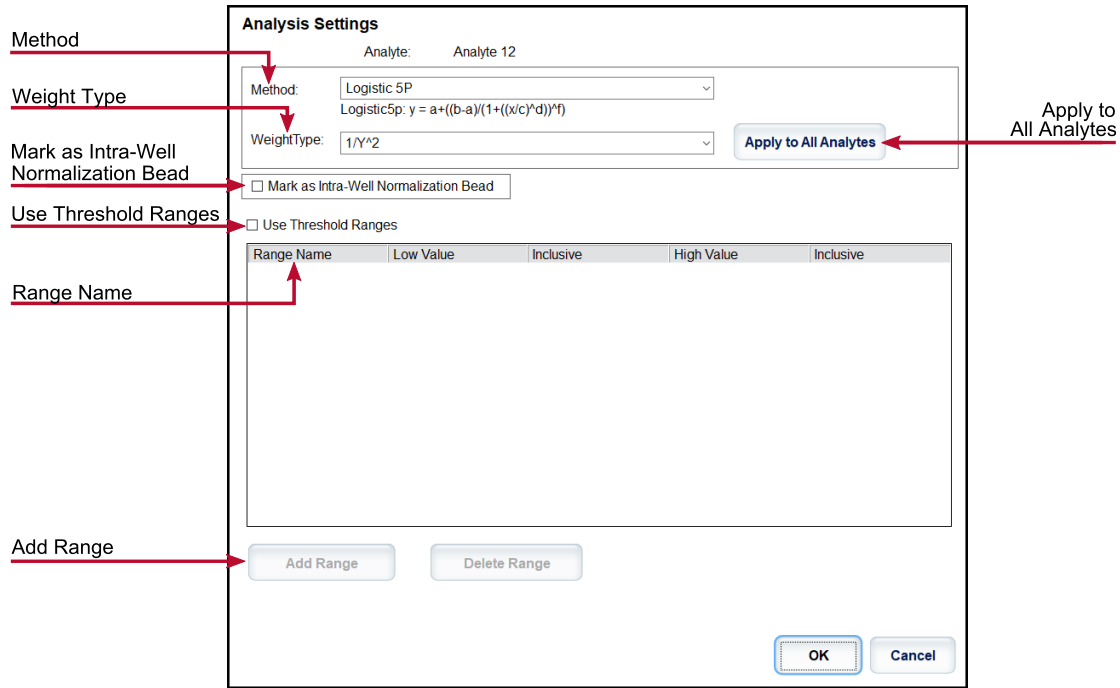


# Edit Qualitative Analysis Settings

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 Normal-ization 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 con-tinue 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**.
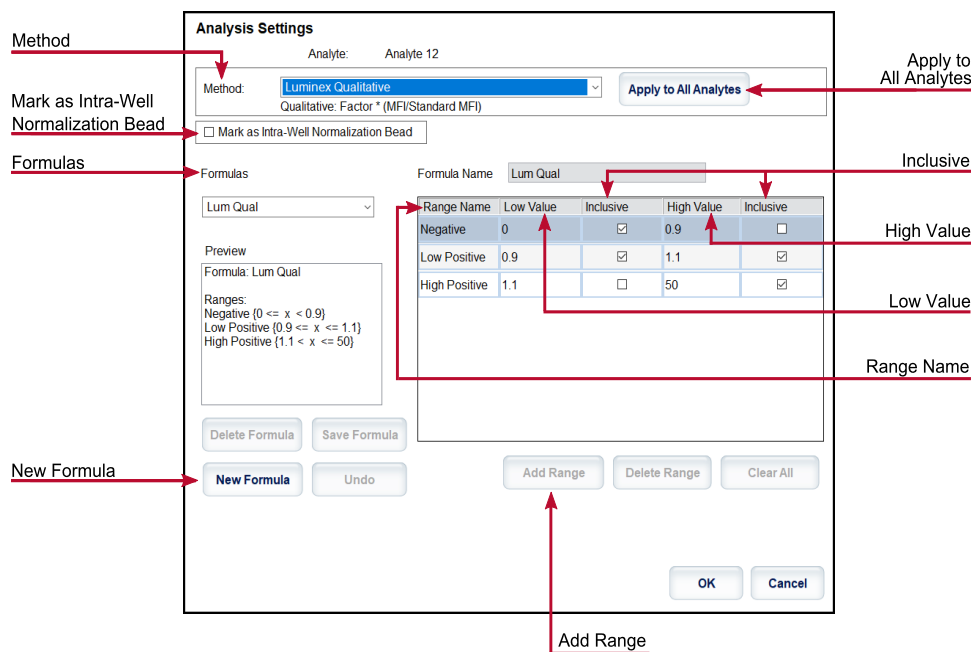


# Import a Protocol

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.

# 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 & Ctrls** 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 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.

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# 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.

2.  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.

3.  From the **Type** drop-down menu, choose the specific report type.

    a.  If you chose either a Batch report or a Protocol report, select the specific batch or protocol from the list.

    b.  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.

4.  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.

5.  Click **Generate**. If the report includes multiple analytes, use the arrows above the report to move through the list of analytes.

6.  Use the **Zoom** drop-down menu to increase the size of the report.

# Export the Batch Results

1.  Navigate to the **Results** page > **Saved Batches** tab.
2.  Choose the completed batch to export and click **Exp Results**.
3.  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.

4.  Click **Save**.
5.  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.

1.  Navigate to the **Results** page > **LIS Results** tab.
2.  Select a single analyte or the entire sample.
3.  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).

1.  Navigate to the **Results** page **> Saved Batches** tab.
2.  Choose the completed batch from the **Completed Batches** table.
3.  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 & Ctrls** 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 & Ctrls** 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 micro-spheres. |
| | 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 incor-rect. | Perform the automatic sample probe height adjustment. |
| | The sample probe is clogged. | Clean the sample probe. |
| | There is a partial clog in the system. | Refer to topic **Troubleshooting > Clogs**. |
| | There is air in the system. | Verify sample probe height. Perform the automatic sample probe height adjustment. Run three **Prime** commands, two **Alcohol Flush** commands, then three **Wash** commands with deionized water. |
| | The waste line was moved during system operation, resulting in unstable flow rate. | Stabilize the waste line during instrument operation. |
| Zero events col-lected 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 instru-ment. Check that the waste bottle cap is vented. |
| | The Cheminert® fitting is loose. | Tighten the Cheminert® fitting. |

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| Symptom | Possible problem | Solution |
|---|---|---|
| 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. |
| | 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 *Luminex Technical Support*. |

# Instrument Errors

## Communication Problems

Communication problems described in this section involve the links between the data system (PC and software) and FLEXMAP 3D®.

The term "Communication" refers to:

- The transfer of data between the PC and the FLEXMAP 3D.
- The current status of the FLEXMAP 3D.
- 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. | Plug in or move the communications cable. |
| | The FLEXMAP 3D® is not turned on. | Turn off the PC. Turn on the FLEXMAP 3D® and then turn on the PC. |

# 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 |
|---|---|---|
| FLEXMAP 3D® will not turn on. | The power cord is disconnected | Plug in the power cord. |
| | No voltage is coming from the electrical outlet. | Change to a different outlet. |
| | The power supply is faulty. | Contact *Luminex Technical Support* |
| | A fuse has burned out. | Replace the fuse. |
| Fuses continue to open (blow). | A component has a short circuit. | Contact *Luminex Technical Support.* |

# Fluid Leaks

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

<u>Table 4. Fluid Leaks</u>

| Problem | Possible Cause | Corrective Action |
|---|---|---|
| Fluid is pooled around the FLEXMAP 3D®. | Fittings, fluid tubes, or components are damaged, loose, or faulty. | Turn off and disconnect the instrument to avoid electrical shock. Contact *Luminex Technical Support*. |
| Fluid dripping from the sample probe. | The sample probe is clogged | Refer to topic **Troubleshooting > Clogs**. |
| | The sample path is clogged. | Refer to topic **Troubleshooting > Clogs**. |
| | The internal component is faulty. | Contact *Luminex Technical Support*. |
| 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 *Luminex Technical Support*. |

# Low Bead Count

## Pressurization Problems

Normal air and sheath pressure readings vary between 8 psi and 13 psi while the compressor runs. If the system pressure is out of range, your sample acquisition will fail or return inadequate results.

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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 fittings are cracked. | Inspect the fittings to be sure they form a tight seal. Contact *Luminex Technical Support*. |
| | 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 *Luminex Technical Support*. |

# Clogs

Often, a clog somewhere in the FLEXMAP 3D® is the cause of a fluid leak, a pressurization or sample probe problem, or a problem with calibration, verification, or data acquisition. To determine if there is a clog, check the bead count during calibration. During calibration you should see 300 bead events per second or more. If there are fewer than that, there is probably a clog in the instrument. In the event you encounter a problem that is clog-related, use the following procedure.

To troubleshoot a possible clog:

1. Clean and adjust the sample probe.
2. Remove the clogs.
3. Replace all fluids.
4. Run the weekly maintenance routine.
5. Run calibration and verification.

If this procedure is unsuccessful, contact *Luminex Technical Support*.

# Sample Probe Problems

Problems with the sample probe can lead to fluid leaks 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. |

| Problem | Possible Cause | Corrective Action |
|---|---|---|
| The sample arm is stuck in the up position. | Internal component is faulty. | Contact *Luminex Technical Support*. |
| | The probe is not calibrated. | Perform the automatic sample probe height adjustment |
| The sample arm does not go down smoothly. | The plate is incorrectly seated. | 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 a sample probe has been bent and rolled straight more than once, discard it and replace with a new sample probe. Adjust the sample probe height. |
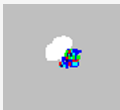
# Bead Detail Irregularities
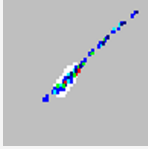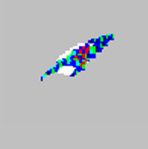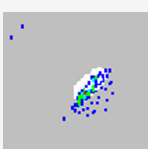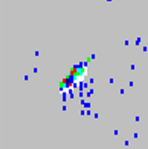
Use these tools to assist in diagnosing instrument and assay-related problems:

- System calibrators
- 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.

| Symptom | Description | Possible Problem | Solution |
|---|---|---|---|
| xMAP® and calibrator microspheres form a group in the wrong location | | | |
|  | Calibrator microspheres group together at the top of the region. | The calibrator microspheres are photobleached. | Replace the calibrator microspheres with unphotobleached calibrator microspheres. To avoid photobleaching, protect microspheres from light. |
|  | xMAP microspheres group together at the lower right of the region. | The xMAP microspheres are photobleached. | Replace the xMAP microspheres with unphotobleached xMAP microspheres. To avoid photobleaching, protect microspheres from light. |
| xMAP microspheres form an unusual shape | | | |

| Symptom | Description | Possible Problem | Solution |
|---|---|---|---|
|  | xMAP microspheres form a long diagonal line. | The xMAP microspheres have agglutinated. | Contact Luminex Technical Support. |
|  | xMAP microspheres form a group with extending tails. | The solvent is incompatible. | The Luminex Technical Support website lists incompatible solvents. If the solvent you are using is listed, switch solvents. |
| xMAP microspheres fail to form a group | | | |
|  | xMAP microspheres do not form a cohesive group. | The sheath fluid is incompatible. | Use only xMAP sheath fluid in the FLEXMAP 3D. Other fluids can damage the system and void your warranty. |
|  | xMAP microspheres do not form a cohesive group and are somewhat scattered. | There is air in the instrument. | Verify the sample probe height. Run three **Prime** commands, two **Alcohol Flush** commands, then three **Wash** commands with deionized water. |
|  | xMAP microspheres are widely scattered. | The sheath fluid is empty. | Make sure there is sheath fluid in the sheath container. Run a **Prime** command until all air is pushed out of the instrument. |

# 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 7. Hardware Part Numbers

| Product Description | Customer Number |
|---|---|
| Barcode Scanner | CN-PC03-01 |
| Air Filter: Access Door | CN-0222-01 |
| Air Filter: XY Platform | CN-0229-01 |
| Air Filter: HEPA | CN-0001-01 |
| Syringe Cylinder with seal, 500 uL | CN-0013-01 |
| Syringe Seal | CN-0014-01 |
| Sheath Filter with quick disconnect | CN-0010-01 |
| Sample Probe Height Adjustment Kit | CN-0263-01 |
| Cable, USB (A to B) | CN-0227-01 |
| Cable, Power | CN-PXXX-01* |
| Fuse (6 amp) | CN-0226-01 |
| Sample Probe Needle | CN-0221-01 |
| Off-plate Block | CN-0225-01 |
| 6 Month PM (Preventive Maintenance) Kit | CN-0215-01 |
| Probe Height Adjustment Plate | CN-0298-01 |
| Heater Block for 96-Well Plates | CN-0224-01 |
| Heater Block for 384-Well Plates | CN-0223-01 |

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

Table 8. Reagent Part Numbers

| Product Description | Customer Number |
|---|---|
| xMAP® Sheath Fluid, 20 L | 40-50000 |

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| Product Description | Customer Number |
|---|---|
| xMAP® Sheath Fluid Concentrate (20x), 1 L | 40-75680 |
| FLEXMAP 3D® Calibration Kit | F3DIVD-CAL-K25 |
| FLEXMAP 3D® Performance Verification Kit | F3DIVD-PVER-K25 |

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# Chapter 8: Maintaining the System

To ensure accurate test results, properly clean and maintain the FLEXMAP 3D®. 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 FLEXMAP 3D®, 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 FLEXMAP 3D® 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 FLEXMAP 3D 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 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. |
| 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. |
| F3DCAL1 | Calibrates DD, CL1, CL2, and CL3 for original non-magneticxMAP microspheres. |
| F3DVER1 | Verifies DD, CL1, CL2, and CL3 for non-magnetic xMAP microspheres. |
| F3DeCAL1 | Calibrates DD, CL1, CL2, and CL3 for original magnetic MagPlex® microspheres. |
| F3DeVER1 | Verifies DD, CL1, CL2, and CL3 for magnetic MagPlex microspheres. |
| F3DCAL2 | Calibrates xMAP reporters. |
| F3DVER2 | Verifies RP1 at normal and high PMT and extended ranges for all xMAP Bead Types. |
| F3DCAL3 | Calibrates extended RP1 ranges for all xMAP microspheres. |
| Fluidics1 | xMAP fluidics 1. Verifies fluidic integrity and well to well microsphere carryover. |
| Fluidics2 | xMAP fluidics 2. Verifies fluidic integrity and well to well microsphere carryover. |

# 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 > **Cmds & 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 > **Cmds & 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

Periodically monitor fluid levels. Replace the empty sheath fluid container as needed. If FLEXMAP 3D® operates with an empty sheath fluid container, the lack of sheath fluid may interrupt a sample and prevent further samples from being collected.

> ⚠️ Use only xMAP® sheath fluid. Use of any other sheath fluid constitutes improper use and can void the warranty provided by Luminex, its authorized partner, or both.

### 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.

> ⚠️ Do not place the waste fluid container on top of the system. Do not move the waste line vertically while the FLEXMAP 3D® system is running.

Contact Luminex before relocating the waste fluid container or rerouting the waste line. Only move the line temporarily for cleaning and maintenance.

# Maintain Instrument Hardware

## Daily Maintenance

Most of the daily maintenance tasks for FLEXMAP 3D® can be performed using available software commands.

### Warm Up the FLEXMAP 3D® Instrument

Warm up the lasers to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn power on; however, you will need to use the Warmup command if the system is idle for four hours or longer. Failure to properly warm up the lasers will affect assay results and system performance.

Click the **Warmup** button on the bottom right of the screen if the instrument has been idle for more than four hours.

### Shut Down the System

System shutdown is a standardized procedure in xPONENT® for FLEXMAP 3D® 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 RA1 3/4 full of DI water.
4. Fill reservoir RB2 3/4 full of 10% to 20% household bleach.
5. Click **Retract**.
6. Click **Run**.

## Weekly Maintenance

Some of the weekly maintenance tasks for the FLEXMAP 3D® can be performed using available software commands. Weekly maintenance includes using the software to perform a weekly maintenance routine, removing clogs, cleaning the sample probe, calibrating the system, and visually inspecting the system.

### Run the Weekly Maintenance Routine

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. Choose **Weekly Maintenance** from the **Routine** drop-down menu.
3. Click **Eject**.

4. Fill reservoir RA1 3/4 full of DI water.
5. Fill reservoir RB1 3/4 full of 70% alcohol or 70% ethanol.
6. Click **Retract**.
7. Click **Run**.

## Perform a Visual Inspection

Inspect the FLEXMAP 3D® weekly. Make sure the instrument is idle, so there are no moving parts. Open all of the FLEXMAP 3D doors.

- Visually inspect for leaks, corrosion, and other signs of improper function.
- Check all visible tubing connections.

## Clean the Sample Probe

⚠️ Avoid contact with moving parts. If a plate is running, use the software to execute Stop to avoid the possibility of exposure to moving parts. The system must not be performing any operations while you carry out this maintenance procedure.

To clean the sample probe:

1. Click **STOP** if a plate is running.
2. Turn off the FLEXMAP 3D® and unplug the power cord.
3. Remove the sample probe.
   a. Open the right front door of the FLEXMAP 3D.
   b. Unscrew the sample probe fitting on top of the probe completely.
   c. Grasp the sample probe gently and push up.
   d. Lift the sample probe out of the top of the sample probe holder.
4. Clean the sample probe using a bath sonicator or a 10 mL syringe. If you are using a bath sonicator, place the tip of the sample probe in the bath sonicator for 2 to 5 minutes of water flowing through the probe syringe. If you are using a syringe, force distilled water through the tip of the sample probe and out the large end. This dislodges any debris clogging the tip.
5. Replace the sample probe and tightly screw in the sample probe fitting until it clicks.
6. Perform an automatic probe height adjustment.

   **NOTE:** Perform an automatic probe height adjustment any time the probe is reinstalled after removal.
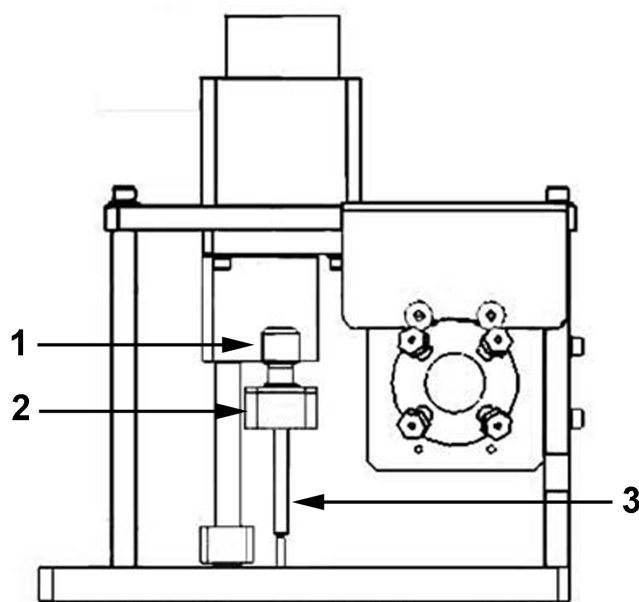
| 1 | Cheminert® fitting |
|---|---|
| 2 | Sample probe holder |
| 3 | Sample probe - Push up and out of sample probe holder |

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

## Remove Clogs

If you frequently use the FLEXMAP 3D® to test concentrated serum or other debris-ridden samples, Luminex recommends that you perform a clog removal weekly. Otherwise, perform this procedure as needed.

To remove clogs:

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. Choose **Remove Clog** from the **Routine Name** drop-down menu.
3. Click **Eject**.
4. Fill reservoir RB2 3/4 full of sodium hydroxide (0.1N NaOH) in the of the off-plate reagent block.
5. Fill reservoir RA1 3/4 full of DI water.
6. Click **Retract**.
7. Click **Run**.

⚠ 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.

# Monthly Maintenance

## Clean the Exterior Surfaces

1. Turn off the FLEXMAP 3D® and unplug the power cord.
2. Clean all exterior surfaces with mild detergent, followed by a 10% to 20% household bleach, followed by deionized water.
3. Open both doors of the system.

> ⚠️ Avoid contact with the tubing and electronic parts of the instrument.

4. Dry any unpainted metal surfaces to prevent corrosion.
5. Plug in the power cord and turn on the FLEXMAP 3D.

# Semi-Annual Maintenance

## Replace the HEPA Filter

The HEPA filter is the round filter behind the panel on the left side of the front of the fluidics bay. Tubing from the interior of the fluidics bay is attached to the stem in the center back of the filter.

To replace the HEPA filter:

1. Turn off the FLEXMAP 3D® and unplug the power cord.
2. Open the left door and locate the HEPA filter panel on the front of the fluidics bay.
3. Remove the screw at the top of the panel and open the panel door.
4. Grasp the tubing and pull the filter 3 to 4 inches from the unit.
5. Remove the filter with one hand and hold the tubing with the other hand.

> ⚠️ Do not allow the tubing to fall inside the system.

6. Connect a new filter to the tubing and position the filter inside the panel.
7. Reattach the panel door to the unit and close the access door.
8. Plug in the power cord and turn on the FLEXMAP 3D.

View A        View B
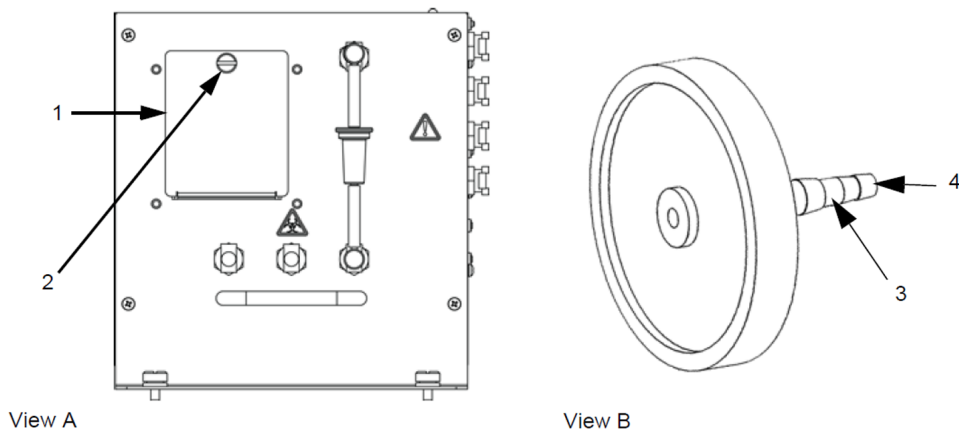
| View A | Front of fluidics bay | View B | HEPA filter |
|---|---|---|---|
| 1 | Filter panel | 3 | Filter stem |
| 2 | Screw | 4 | Attachment point for tubing |

## Clean the Ventilation Filters

Each ventilation filter has at least one imprinted arrow on its metal frame. The arrow indicates the direction of the air flow. Install the filters so that the arrows are at the correct locations and point in the correct direction.

To clean the FLEXMAP 3D® ventilation filters:

1. Turn off the FLEXMAP 3D and unplug the power cord.
2. Open the front doors. Slide clamps off the left and right silver door filters and remove the filters.
3. Remove the XY cover by gently grasping the ventilation holes along the top of the cover and pulling the cover straight out.
4. Clean the filters with a vacuum or with deionized water.
5. Stand the filters upright to air dry.

> ⚠️ Filters must be completely dry prior to reinstallation.

6. Reinstall filters. The arrows on the door filters should point to the inside of the door; the arrow on the XY filter should point up.
7. Reinstall the XY cover and close the access doors.
8. Plug in the power cord and turn on the FLEXMAP 3D.
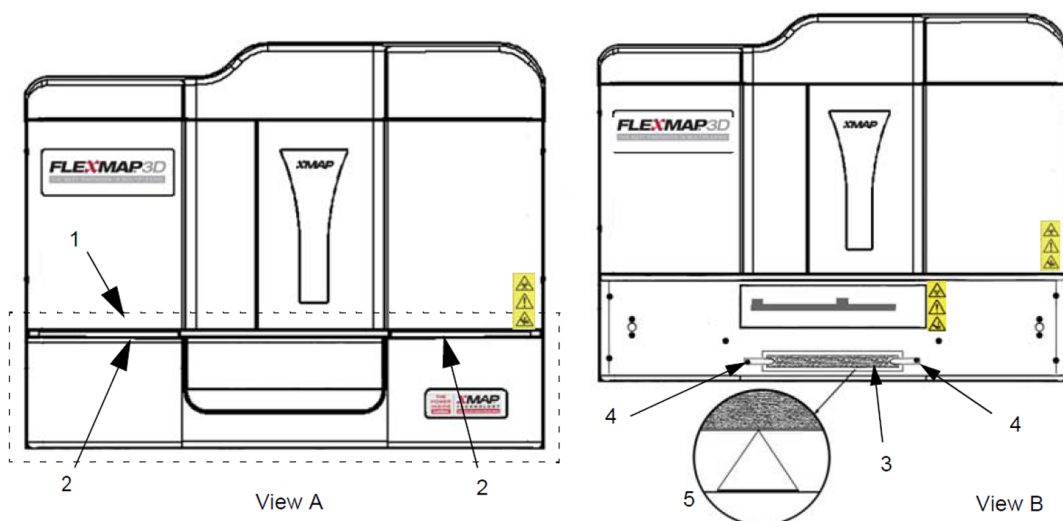
| View A | Front of the FLEXMAP 3D® system with XY cover in place | View B | Front of the FLEXMAP 3D® system with XY cover removed |
|---|---|---|---|
| 1 | XY cover (inside dotted lines) | 3 | Filter |
| 2 | Location of ventilation holes on top of XY cover (visible only when doors are open) | 4 | Filter clamp |
| | | 5 | Incised arrow |

| | |
|---|---|
| View A | Right front door, viewed from inside |
| View B | Left front door, viewed from inside |
| 1 | Filter |
| 2 | Filter clamp |
| 3 | Incised arrow |
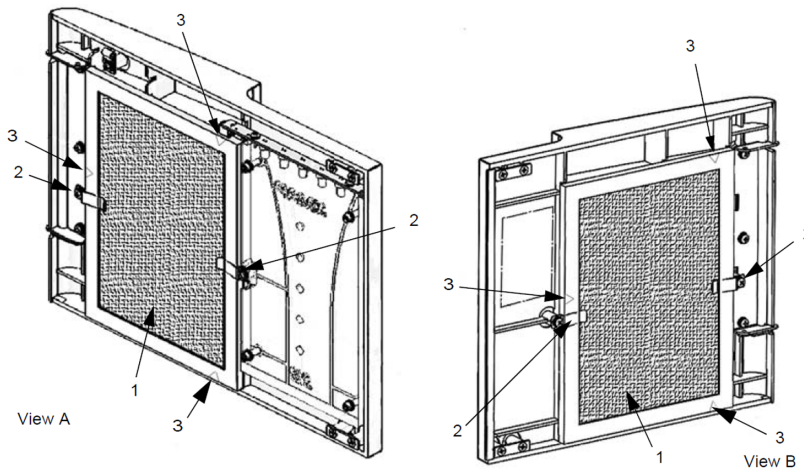
## Replace the Syringe Teflon Seal

To replace each syringe seal:

1. Turn off the FLEXMAP 3D® and unplug the power cord.

⚠️ The syringe arm does NOT deactivate while the seal is being changed; unplugging is necessary to avoid injury.

2. Open the right front door of the FLEXMAP 3D.
3. Locate the syringe (glass cylinder with a metal rod plunger).
4. Loosen the set screw on the syringe arm (at the bottom of the syringe) and push the syringe arm down.

    NOTE: The syringe arm is tight. Be prepared to use some force to push it down.

5. Unscrew the syringe from the top of its housing.
6. Pull the plunger out of the syringe.
7. Remove and replace the white plunger seal (at the top of the plunger) and the black O-ring inside the seal.
8. Return the plunger to the syringe.
9. Screw the syringe back into its housing.
10. Return the syringe arm to its original position. The bottom of the plunger fits into the indentation in the syringe arm.
11. Hand-tighten the set screw on the syringe arm.
12. Plug in the power cord and turn on the FLEXMAP 3D.
13. Run two **Prime** commands, watching for any leaks in the syringe area.

14. Close the right front door.
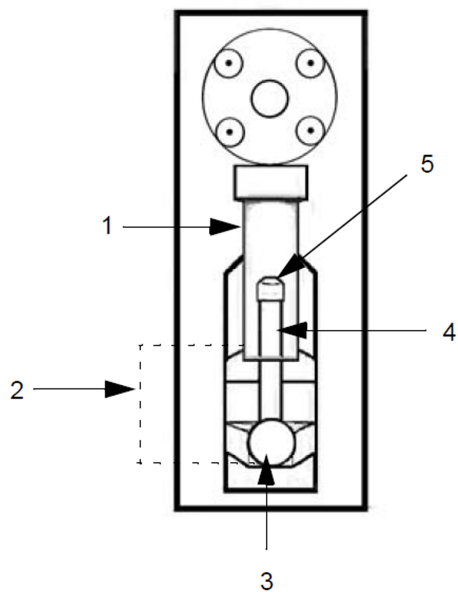


| | |
|---|---|
| 1 | Glass Syringe Barrel |
| 2 | Syringe Arm (between dotted lines) |
| 3 | Set Screw |
| 4 | Syringe Plunger |
| 5 | Plunger Seal (contains O-ring) |

# Annual Maintenance

## Replace the Sheath Filter

1. Turn off the FLEXMAP 3D® and unplug the power cord.
2. Open the left door on the FLEXMAP 3D and locate the sheath filter on the front of the fluidics bay.
3. Disconnect the sheath filter by pushing down on the metal clamps at each quick-disconnect point.
4. Connect the new sheath filter, matching up the color-coded fittings. The arrow on the sheath filter should be pointing up.
5. Close the left door.
6. Plug in and power on the FLEXMAP 3D.
7. Run two **Prime** commands.

# As Needed Maintenance

## Replace the Fuses

Periodically, you may need to replace a fuse on the FLEXMAP 3D®. Use fuses with the following specifications:

F6A, 250 V

The fuse cartridge will accept either 5 mm x 20 mm or 0.25 inch x 1.25 inch fuses. Fuses are available from Luminex Corporation. Replacing a fuse requires access to the back of the FLEXMAP 3D. Be aware before attempting any necessary lifting or movement of the system that the FLEXMAP 3D weighs approximately 91 kg (200 lbs) and requires five people to lift it.

> 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 FLEXMAP 3D 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. The door opens downward. Inside are two cartridges, a red one on top and a black one on the bottom.
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 FLEXMAP 3D.

   **NOTE:** If your FLEXMAP 3D is not on a swivel base and requires moving in order for you to access the back of the system, use the software to re-calibrate and re-verify the system after the system is restored to its original location.
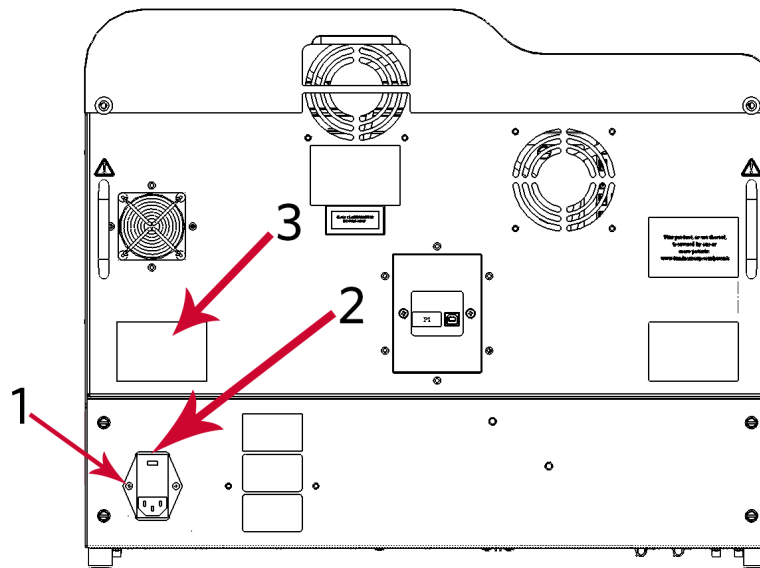
| 1 | Power Module |
|---|---|
| 2 | Location to insert screwdriver to open module door, as referenced above |
| 3 | Fuse Information |

# 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**.

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# Maintenance Log

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

# FLEXMAP 3D® Maintenance Log

MONTH: _____        YEAR: _____

**Day of the Month** | 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 |

**Daily**

| Warm up laser |
| Run performance verification |
| Check fluid levels |
| Run system shutdown |

**Weekly**

| Clean sample probe |
| Calibrate |
| Perform visual inspection |
| Run weekly maintenance |
| Run clog removal |

**Monthly**

| Clean exterior surfaces |

**Semi-annual maintenance**

| Clean ventilation filters | Yes | No | If Yes, Date: _____ |
| Replace HEPA filter | Yes | No | If Yes, Date: _____ |
| Replace syringe seal | Yes | No | If Yes, Date: _____ |

**Annual maintenance**

| Replace sheath filter | Yes | No | If Yes, Date: _____ |

**As needed maintenance**

| Replace fuses | Yes | No | If Yes, Date: _____ |

**Luminex®**
complexity simplified.

# Chapter 9: Storing the System

## Store the System

To prepare the FLEXMAP 3D® for long-term storage:

1. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
2. From the **Routine** name drop-down menu, choose the **Prepare for Storage** routine.
3. Click **Run**.
4. Remove the sample probe from the instrument and flush the sample probe with deionized water from the narrow end out through the larger end.
5. Replace the sample probe in the sample arm and wrap the end of the probe with PARAFILM®.

## Prepare the System for Use After Storage

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

1. Make sure that the sheath fluid container has enough sheath fluid that the system is not giving you an error, and that the waste fluid container is empty.
2. Remove the PARAFILM® from the end of the sample probe.
3. Turn on the FLEXMAP 3D® and watch for the following indications of correct response:

   - The compressor starts. It has a low rumbling sound.
   - Air blows out of the rear fans. Place your hand behind the FLEXMAP 3D, on the upper right back, to feel it.
   - The syringes inside the right door of the system initialize

4. Turn on the PC and start xPONENT®.
5. Navigate to the **Maintenance** page > **Cmds & Routines** tab.
6. From the **Routine** name drop-down menu, choose **Revive After Storage** routine.
7. Click **Eject**.
8. Add the appropriate reagents to the reservoirs.
9. Click **Retract**.
10. Click **Run**.

# Chapter 10: Shipping and Decontaminating the System

If a serious problem arises with the FLEXMAP 3D®, 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.

## Decontaminate the System

Occasions may arise when it becomes necessary to decontaminate the entire FLEXMAP 3D® 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 FLEXMAP 3D system:

1. Remove all specimens and reagents from the system.
2. Leave distilled water and 10% to 20% household bleach in the system.
3. Run a **Sanitize** command with 10% to 20% household bleach followed by two **Wash** commands with distilled water.
4. Turn off the FLEXMAP 3D and unplug the power cord.
5. Clean all exterior surfaces with mild detergent followed by 10% to 20% household bleach.
6. Open the front doors of the system.
7. Clean all accessible surfaces with mild detergent, followed by 10% to 20% household bleach.

## Drain the Reservoir

1. Make sure the waste fluid container can hold at least one additional liter of fluid.
2. Open the front doors.
3. Disconnect the sheath fluid tubing from the sheath fluid container to prevent additional sheath fluid from entering the reservoir.
4. Disconnect the sheath filter tubing (white connector) from its bottom quick disconnect point (white connection) on the fluidics bay.
5. Disconnect the waste fluid tubing (orange connector) from the orange connection on the fluidics bay.
6. Disconnect the sheath fluid tubing (blue connector) from the blue connection on the fluidics bay.

7. Connect the waste fluid tubing (orange connector) to the bottom quick disconnect point (white connection) of the sheath filter tubing.

8. Perform a **Warmup** command. The warmup starts the compressor, which drains the sheath fluid from the reservoir into the waste fluid container.

NOTE: To refill the reservoir, reconnect each connector to its color-matched connection and run a **Prime** command.
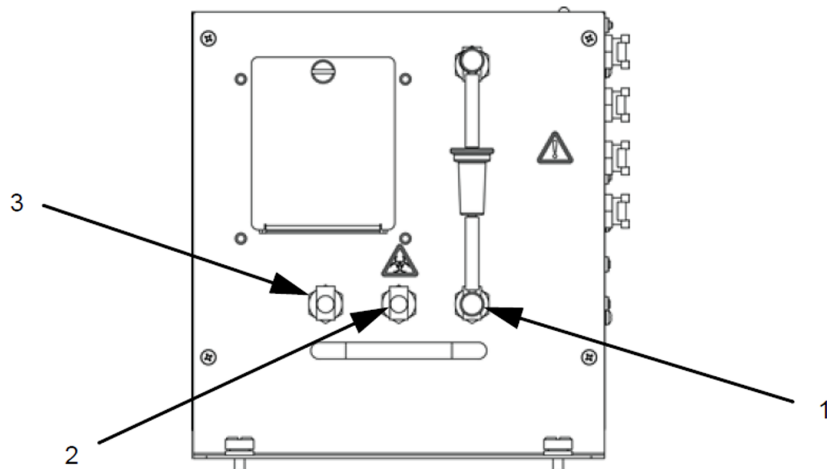


| 1 | White connection for sheath fluid tubing |
|---|---|
| 2 | Orange connection for waste fluid tubing |
| 3 | Blue connection for sheath filter tubing |

# Prepare the System for Shipping

Contact Luminex Technical Support before preparing the instrument for shipping. They will explain how to return the system according to Luminex procedures.

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# Shipment Checklist

Complete the following checklist, sign and date it, and return it with the FLEXMAP 3D®.

1. Remove all specimens from the instrument.
2. Decontaminate the instrument.
3. Drain the reservoir.
4. Prepare the instrument for shipping.
5. 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 FLEXMAP 3D® 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.
- **500 Analyte Support** - Allows use of the 500-plex bead map.

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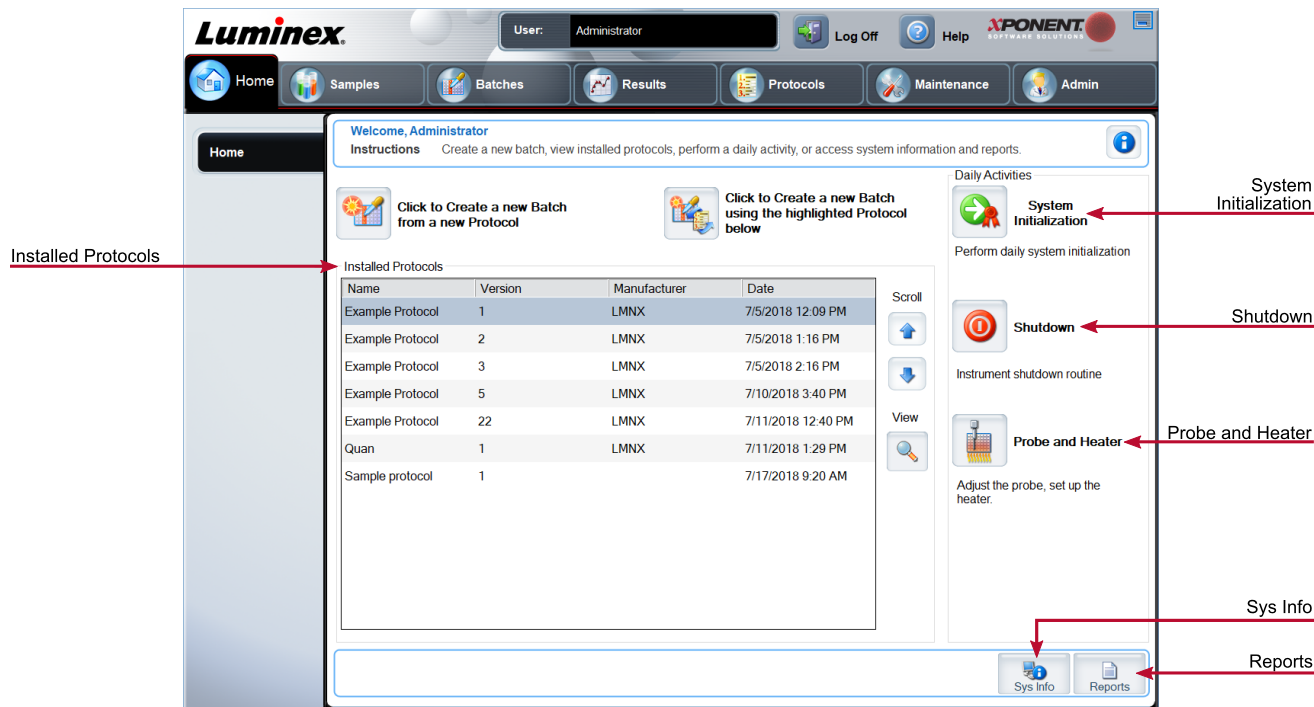
The **Home** page displays a welcome message, batch creation buttons, **Daily Activities** shortcuts, and the **Installed Protocols** list. Return to the **Home** page at any time by clicking **Home** in the navigation toolbar.

### Table 9. 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 10. 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 14: Samples Tab
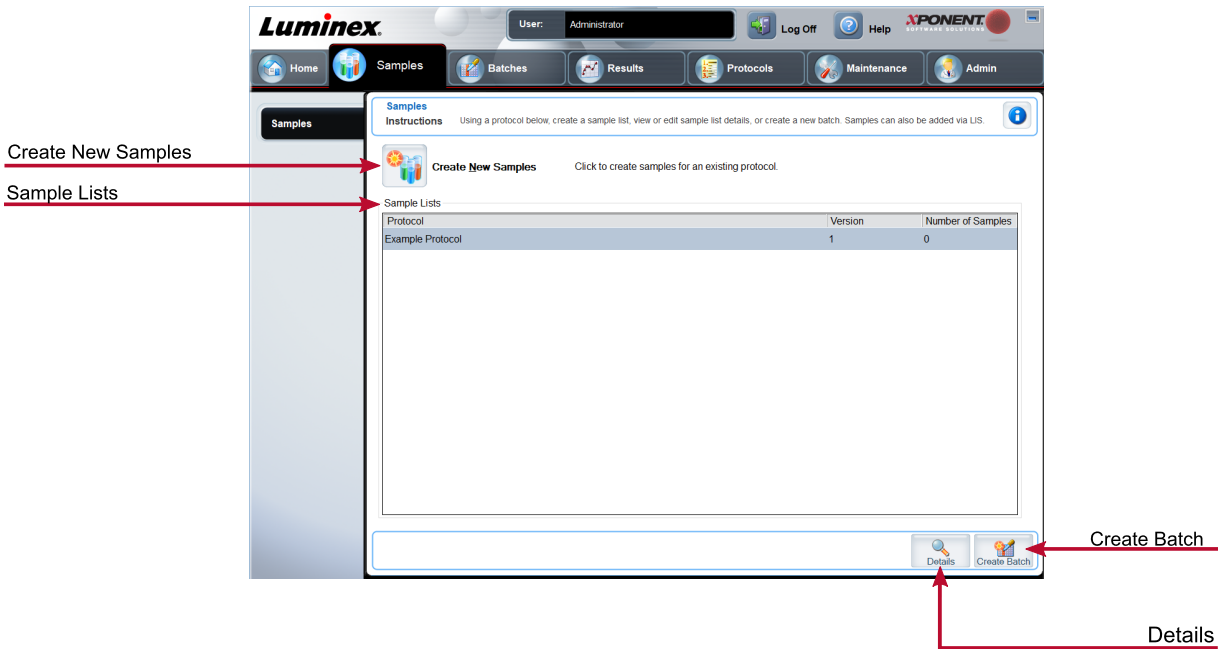


Table 11. Samples Tab Screen Elements

| 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 15: Batches Tab
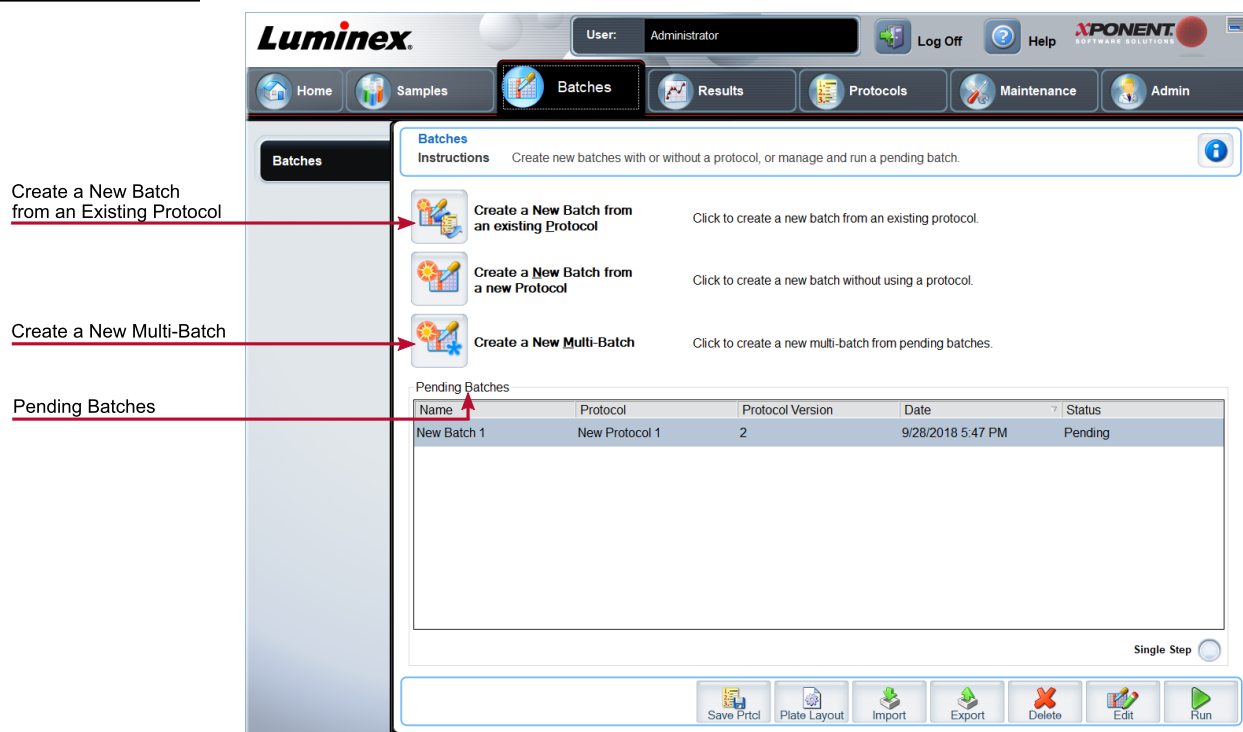


Table 12. Batches Tab Screen Elements

| 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 16: Protocol Subtab
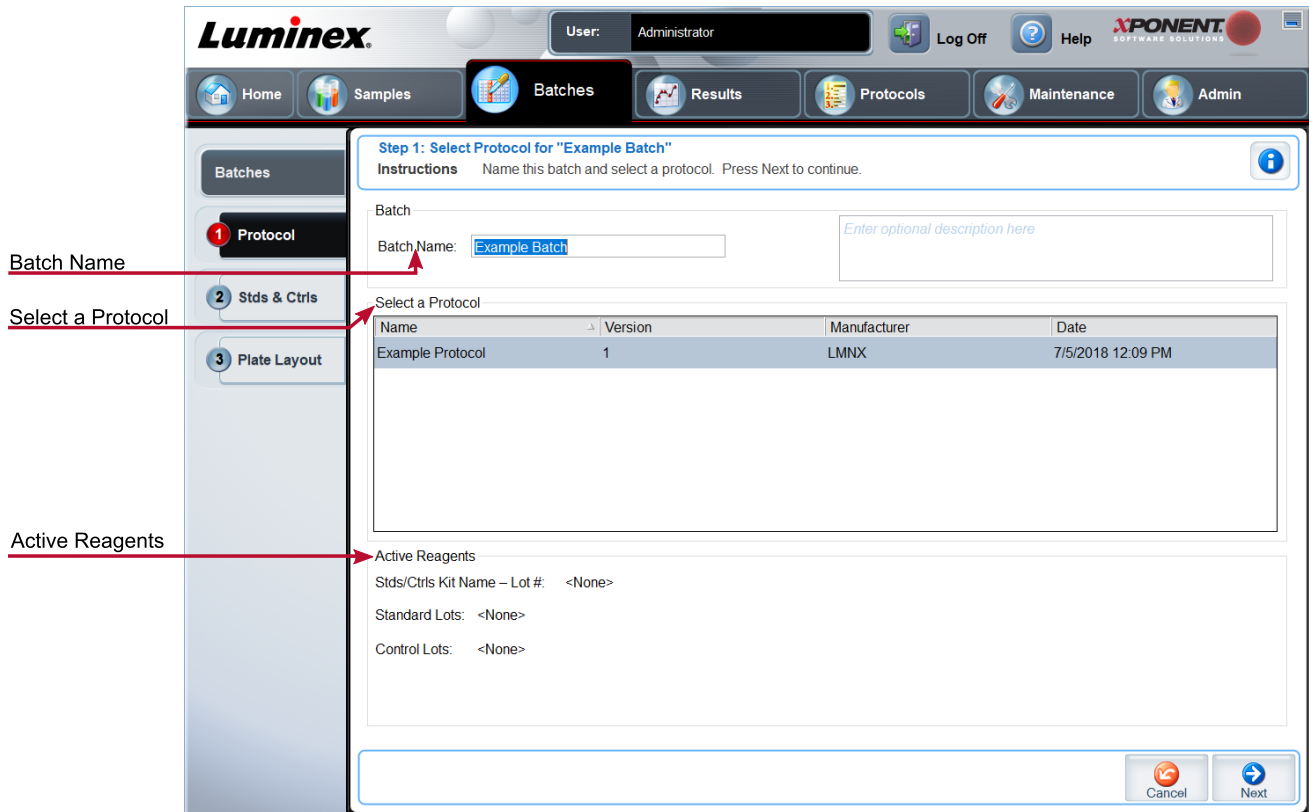
**Table 13. Protocol Subtab Screen Elements**

| 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/Ctrls 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 17: Stds & Ctrls Subtab**
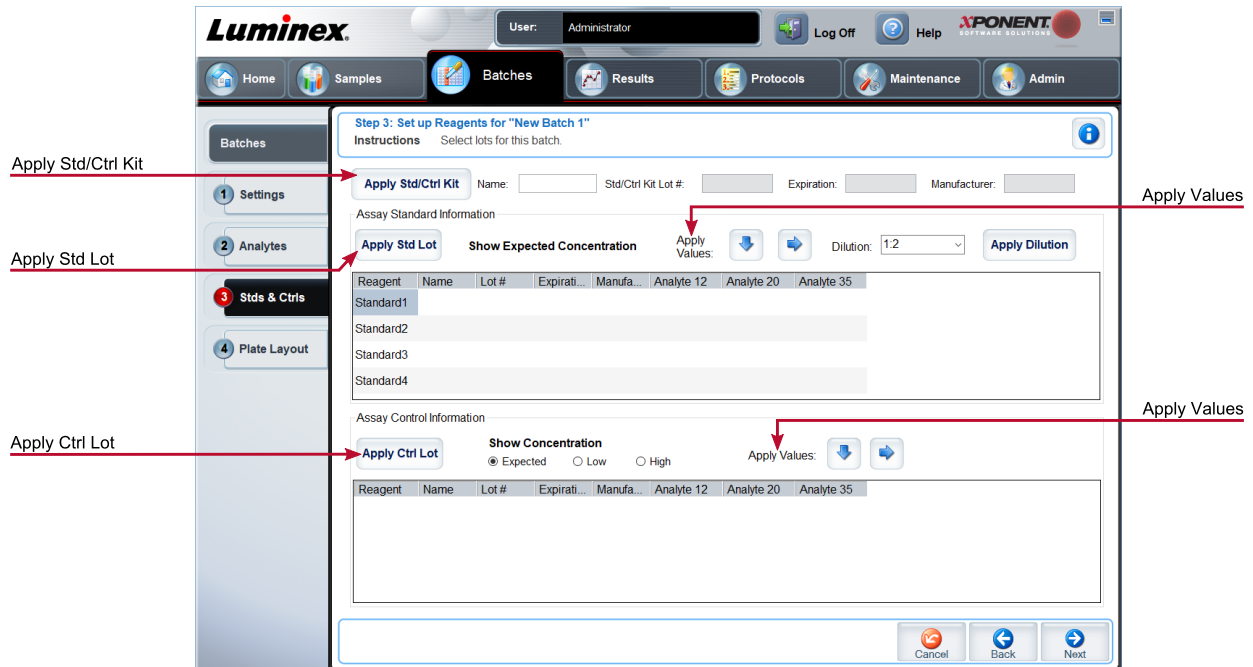


**Table 14. Stds & Ctrls Subtab Screen Elements**

| 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.<br><br>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.

<u>Figure 18: Plate Layout Subtab</u>
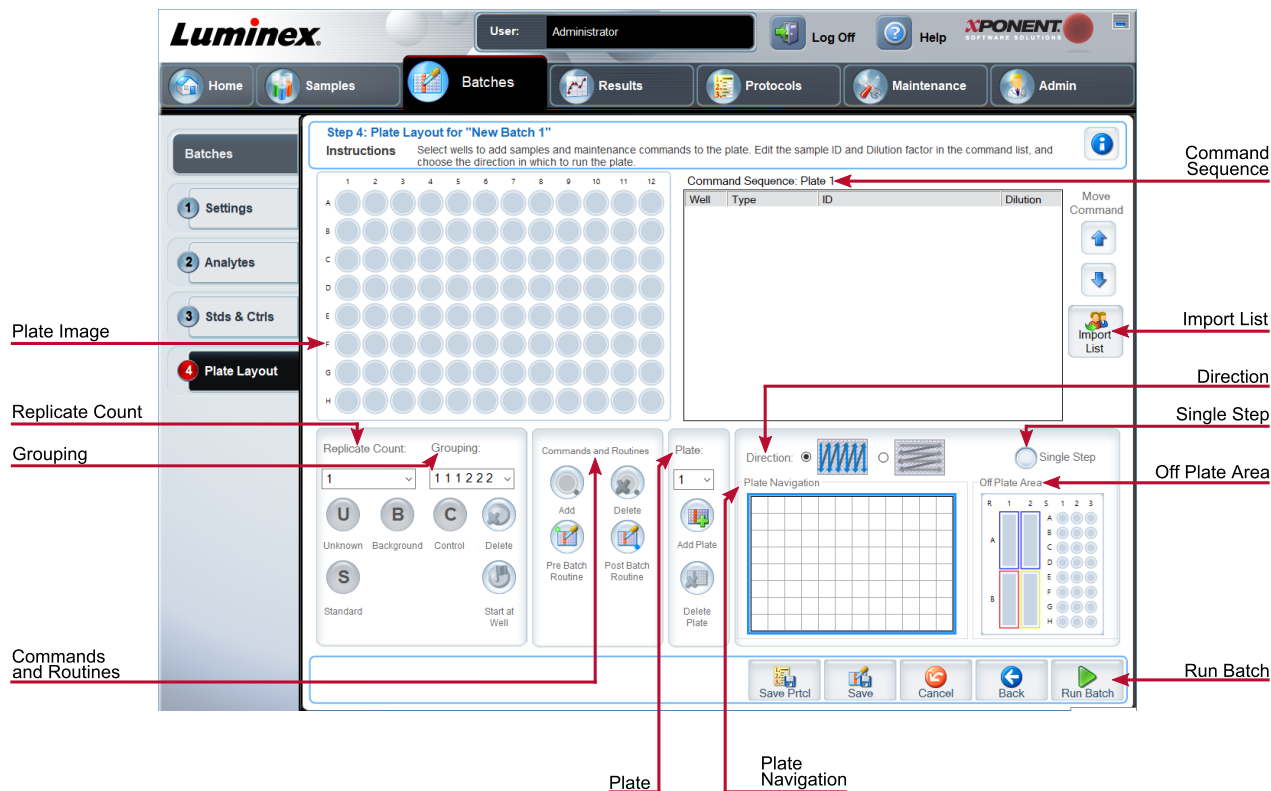


<u>Table 15. Plate Layout Subtab Screen Elements</u>

| 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** | Selects the sequence in which the replicates are laid out in plate wells. Options for Grouping are:<br><br>• 123123123. . . Lays out one of each replicate set at a time in numerical order.<br>• 111222333. . . Lays out all the replicates in a set before moving on to the next set in numerical order.<br><br>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.<br><br>• Unknown (U): Yellow<br>• Background (B): Purple<br>• Control (C): Red<br>• Standard (S): Green |
| | **Delete** - Removes the well command from the selected well. |
| | **Start at Well** - Enables you to begin acquisition at a well other than A1. |
| **Commands and Routines** | Allows you to add and delete commands and routines, and to create pre and post batch routines. 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.<br><br>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.<br><br>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. |
| | **Add** - Adds a command or routine to the selected well. |
| | **Delete** - Deletes any command or routine associated with the selected well. |
| | **Pre-Batch Routine** - Adds the command or routine before running the batch. |
| | **Post-Batch Routine** - Adds the command or routine for running the batch. |

| 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 16. 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 | 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 fluorescent intensity results. You cannot apply standards or controls when you select None. You cannot analyze acquisitions with this setting. |
| | **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. |
| | $(FIsample)/(FIstandard) = Ki$ |
| | Where FI = Fluorescent Intensity and Ki = a "Quali" value entered in lot information to determine the value or the qualitative assay standard. |
| | 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. |
| | 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 |
| | **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. |
| | Luminex recommends **Fit of All Standards** as the most accurate calculation of the curve fit. |
| | 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. |

| | |
|---|---|
| **Number of Standards** | The number of standards for the protocol. Applies only to qualitative and quantitative ana-lysis. |
| **Number of Controls** | The number of controls for the protocol. Applies only to qualitative and quantitative ana-lysis. |
| **Fit of all Standards** | Determines the standard curve by using each individual standard replicate when cal-culating 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 19: Analytes Subtab

Table 17. Analytes Subtab Screen Elements

| | |
|---|---|
| Analytes grid | A grid representing each analyte from 1 to 500. |
| | **Select All** - Selects all analytes. |
| | **Deselect All** - Deselects 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 **Counts** fields to all analytes. |

## 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 18. 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 20: Current Batch Tab
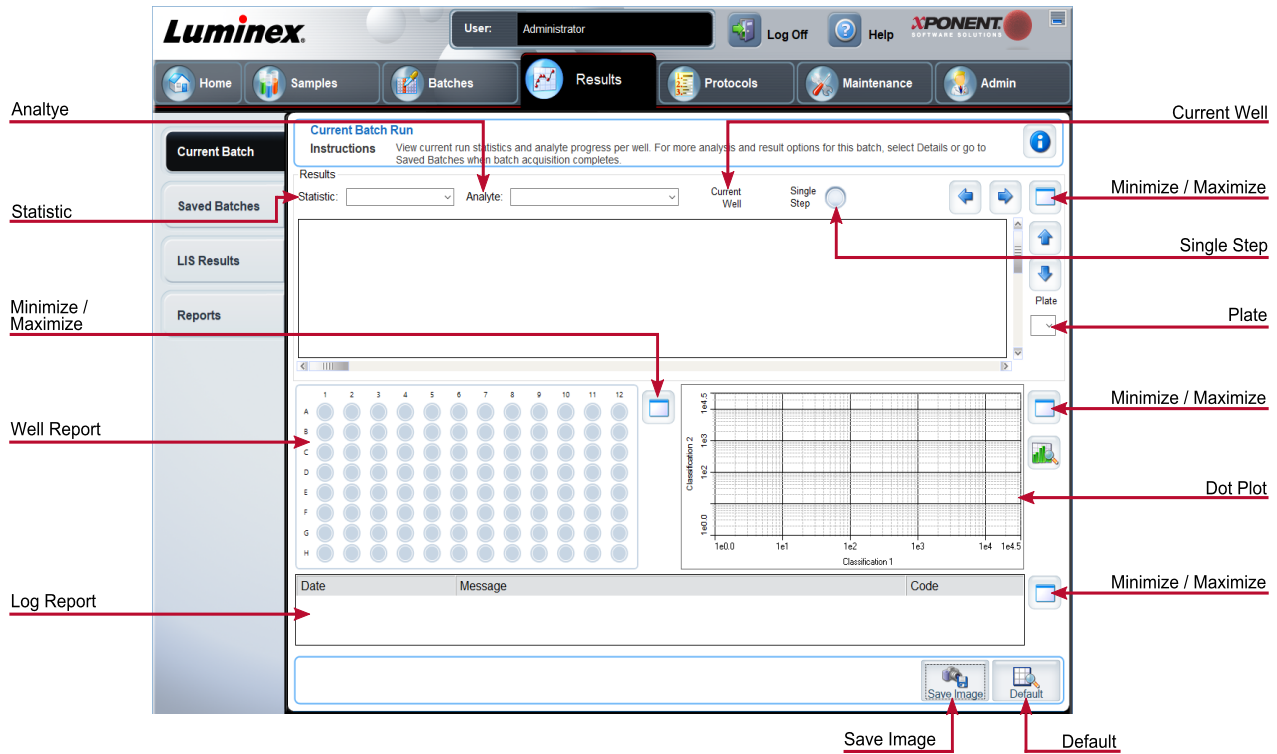


Table 19. Current Batch Tab Screen Elements

| | |
|---|---|
| **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. |
| | **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. |
| | **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. |

**Test Result** - The calculated analysis value for quantitative or qualitative assays derived from standards with known values.

**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.

**Trimmed Mean -** (Optional) The sum of the data points in the trimmed distribution divided by the number of data points.

Trimmed Mean = $\Sigma x_i$ / Nt

**% CV of microspheres** - The measure of relative dispersion within the distribution.

% CV = 100 x Std Dev / Mean

**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.

**% CV of Replicates** - The measure of relative dispersion within the distribution of results for replicate samples.

% CV = 100 X Std Dev / Mean

**% Recovery** - A measure of how accurately your observed results match your expected results following regression analysis.

(Observed concentration) / (Expected concentration) x 100%

**Expected Result** - The known or expected test result value for a standard or control.

**Control Range** - Low - The lowest value for an assay control used to determine pass/fail criteria for an assay.

| | |
|---|---|
| | **Control Range** - High - The highest value for an assay control used to determine pass/fail criteria for an assay. |
| | **Normalized Net** - Median - For each analyte in a well, the Normalized Net Median (NNM) = (net median of analyte) / (net median of normalization bead) |
| | **Units** - The unit of measure for an analyte, for example, pg/mL. |
| | **Trimmed Count -** (Optional) The number of data points in the trimmed distribution (Nt). |
| | **Trimmed % CV of microspheres** |
| | **Trimmed Standard Deviation -** (Optional) The measure of dispersion within the trimmed distribution.<br><br>Trimmed Std Dev = ((Nt Σxi 2 - Σxi)2) / Nt (Nt -1))1/2 |
| | **Trimmed Peak -** (Optional) The value that is equal to the largest number of data points within the trimmed distribution. |
| **Analyte** | Contains a list of analytes run in the batch. Select an analyte to view all statistics for that analyte. |
| **Well(s) to View:** | **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. |
| | **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. |
| **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** | 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:<br><br>• Yellow - Well acquired, but the system detects a possible problem.<br>• Green - Well acquired successfully.<br>• 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).<br><br>The dot plot default displays when using 1 to 100 bead regions Classification 1 and Classification 2. When running regions greater than 100 beads, the default is Classification 2 and Classification 3 axes, and radio buttons are displayed on the right for the Classification 1 axis slices. 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 and Classification 3. This view displays a series of radio buttons on the right side of the dot plot. When one of the radio buttons is selected, the bead regions in view are those in a fixed range of CL1 values plotted against CL2 and CL3. Click the bottom view classification button to change back to the default classification display. |
| | **Gate** - Show, create, delete, or move the gate. You can also move the gates by clicking and dragging the red lines on the histogram. |
| | **Autoscale** - Click to automatically adjust the maximum number of events shown on the Y-axis. Click during acquisition to readjust the Y-axis scale. |
| | **Set Scale** - Sets the maximum number of events. The default number of events is 60. |
| | **View** - View all events or only gated events. |
| | **X-Axis** - Changes the X-axis to the following: Doublet Discriminator, Reporter 1, Classification 1, Classification 2, and Clasification 3.<br><br>**NOTE:** You can change the X-axis of the dot plot for troubleshooting purposes. Use only the default settings in all other instances. |
| | **Y-Axis** - Changes the Y-axis to the following: Doublet Discriminator, Reporter 1, Classification 1, Classification 2, and Classification 3. |
| | **Display Mode** - Select either Logarithmic or Linear display. The software defaults to Logarithmic display. Click maximize for a magnified view of the dot plot. |
| | **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. |

| | |
|---|---|
| **Log** | 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:<br><br>• Date<br>• Message<br>• 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. |
| **Save Image** | Opens a **Save As** dialog box to save a screen capture. |
| **Default** | Appears only when the progress display is active. Click to return to the dot plot display. |
| **3D View** | The 3D view enables a three dimensional look at the batch results. This view can be manipulated in a variety of ways to view regions, specific events, and results outside expected parameters.<br><br>**NOTE:** The 3D View must be enabled in the Admin > System Setup screen. |

# 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 21: Saved Batches Tab
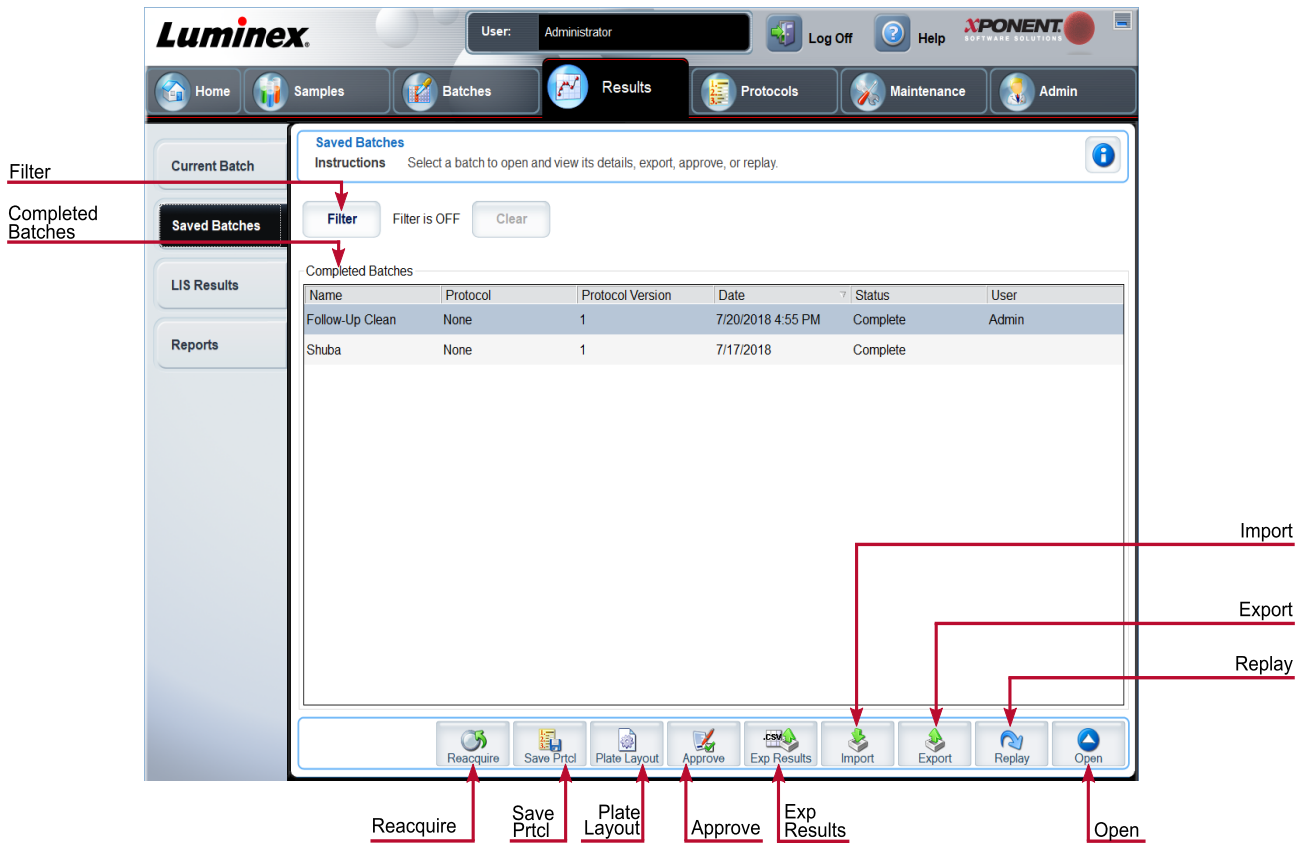


## Table 20. Saved Batches Tab Screen Elements

| 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 21. Results Subtab Screen Elements**

| | |
|---|---|
| **Statistic** | 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.<br><br>**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.<br><br>**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.<br><br>**Test Result** - The calculated analysis value for quantitative or qualitative assays derived from standards with known values.<br><br>**Range** - A semi-quantitative result for a particular numerical result falling between a predefined set of values such as Normal or Negative.<br><br>**Net MFI** (Sample Well MFI - Background Well MFI) - The Net MFI can be used to eliminate the effect of background signal in an assay.<br><br>**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.<br><br>**Mean** - Average of all values for the microspheres detected in a region.<br><br>**Trimmed Mean -** (Optional) The sum of the data points in the trimmed distribution divided by the number of data points.<br><br>Trimmed Mean = Σxi / Nt<br><br>**% CV of microspheres** - The measure of relative dispersion within the distribution.<br><br>% CV = 100 x Std Dev / Mean<br><br>**Standard Deviation** - For calculating sample variability or dispersion, Luminex uses the standard deviation formula.<br><br>**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. |

**% CV of Replicates** - The measure of relative dispersion within the distribution of results for replicate samples.

% CV = 100 X Std Dev / Mean

**% Recovery** - A measure of how accurately your observed results match your expected results following regression analysis.

(Observed concentration) / (Expected concentration) x 100%

**Expected Result** - The known or expected test result value for a standard or control.

**Control Range** - Low - The lowest value for an assay control used to determine pass/fail criteria for an assay.

**Control Range** - High - The highest value for an assay control used to determine pass/fail criteria for an assay.

**Normalized Net** - Median - For each analyte in a well, the Normalized Net Median (NNM) = (net median of analyte) / (net median of normalization bead)

**Units** - The unit of measure for an analyte, for example, pg/mL.

**Trimmed Count -** (Optional) The number of data points in the trimmed distribution (Nt).

**Trimmed%CV of microspheres**

**Trimmed Standard Deviation -** (Optional) The measure of dispersion within the trimmed distribution.

Trimmed Std Dev = $((Nt \, \Sigma xi \, 2 - \Sigma xi)2) / Nt \, (Nt -1))1/2$

**Trimmed Peak -** (Optional) The value that is equal to the largest number of data points within the trimmed distribution.

| | |
|---|---|
| **Analyte** | Contains a list of analytes run in the batch. Select an analyte to view all statistics for that analyte. |
| **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. |

| | |
|---|---|
| **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** | 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: <br><br>• Yellow - Well acquired, but the system detects a possible problem <br>• Green - Well acquired successfully <br>• 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** | 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: <br><br>• Date <br>• Message <br>• 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. |

| | |
|---|---|
| **3D View** | The 3D view enables a three dimensional look at the batch results. This view can be manipulated in a variety of ways to view regions, specific events, and results outside expected parameters.<br><br>**NOTE:** The 3D View must be enabled in the Admin > System Setup screen. |
| | Move the green, purple, and red balls to display only a selection of Classification 3, 2, and 1 data. As you move the balls, a square forms in the middle of the 3D view and excludes data outside that range. |
| **3D BeadMap** | The main display is the 3D BeadMap. The display shows the CL1, CL2, and CL3 axes. Left-click and drag your mouse to move the display for better viewing of a particular section. Right-click anywhere in the display to select from the following viewing options. |
| **3D Region View** | This view in the upper right of the window displays a small 3D representation of the regions. The three axes are shown in the bottom left corner of the display and can be manipulated by left-clicking and dragging the mouse. Move the slider on the right to zoom in or out. Enable the 3D View Box by clicking Settings for an easier way to manipulate the viewing angles. |
| **Region** | Enables viewing of specific region. |
| **View** | A list with the options to Show All Events, or Show Gated Events. |
| **Histogram** | A smaller histogram displays identical to the histogram display in the 2D view. |
| **Save Image** | Displays the Save As dialog box to save a screen capture of the 3D display. |
| **Settings** | Opens the 3D Settings dialog box. |

## 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 22. 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 23. 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 22: Protocols Tab
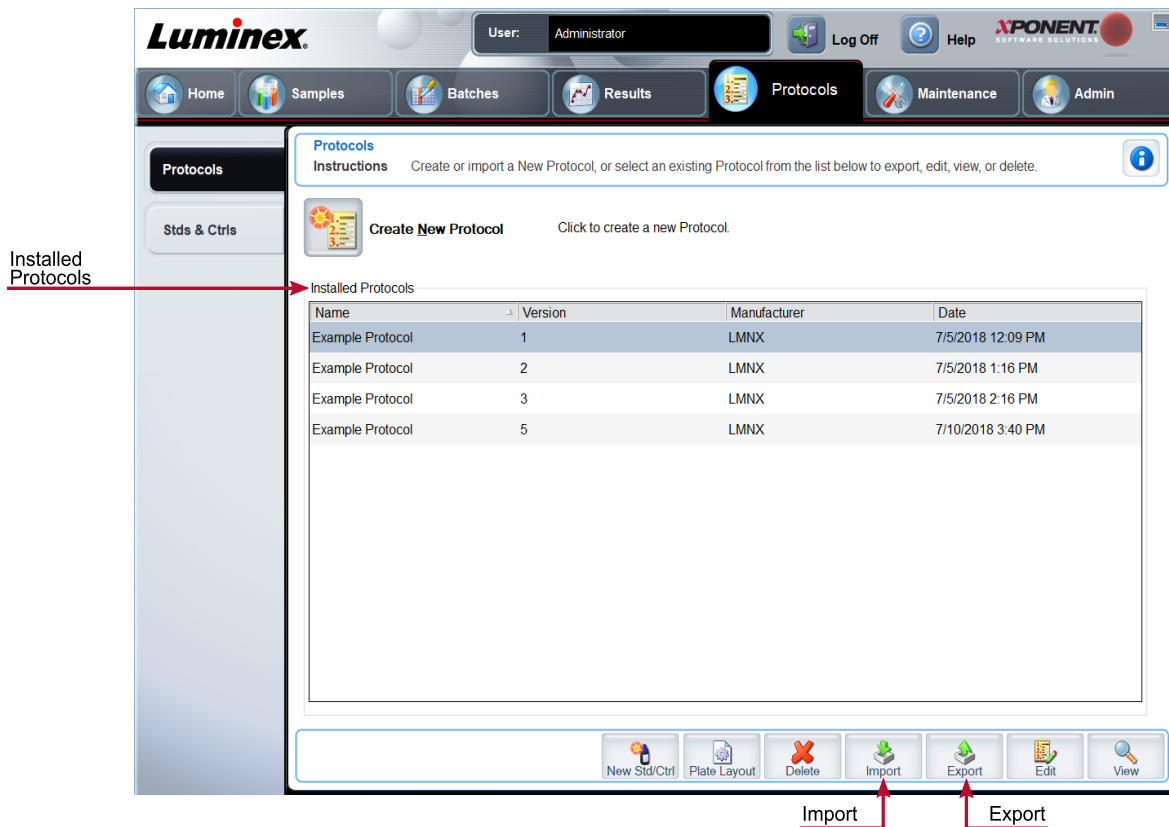
# Protocols Tab > Settings Subtab

**Figure 23: Settings Subtab**
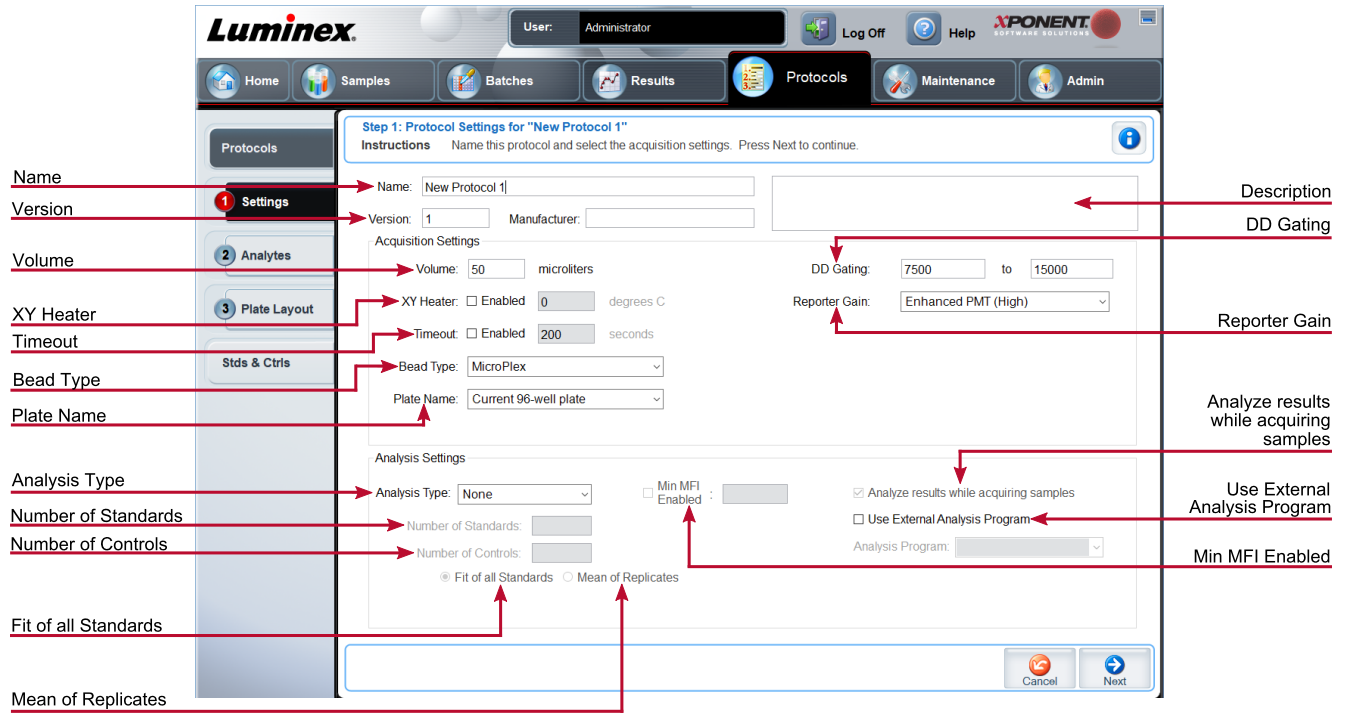


**Table 24. Protocols Tab > Settings Subtab Screen Elements**

| | |
|---|---|
| **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.<br><br>**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)**. |
| Plate Name | Choose the current 96-well plate or a plate that you have created. |
| Analysis Type | Use this list to choose from the following analysis types:<br><br>**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.<br><br>**Qualitative -** Qualitative analysis determines results as either positive or negative, reactive or non-reactive.<br><br>**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 24: Analytes Subtab
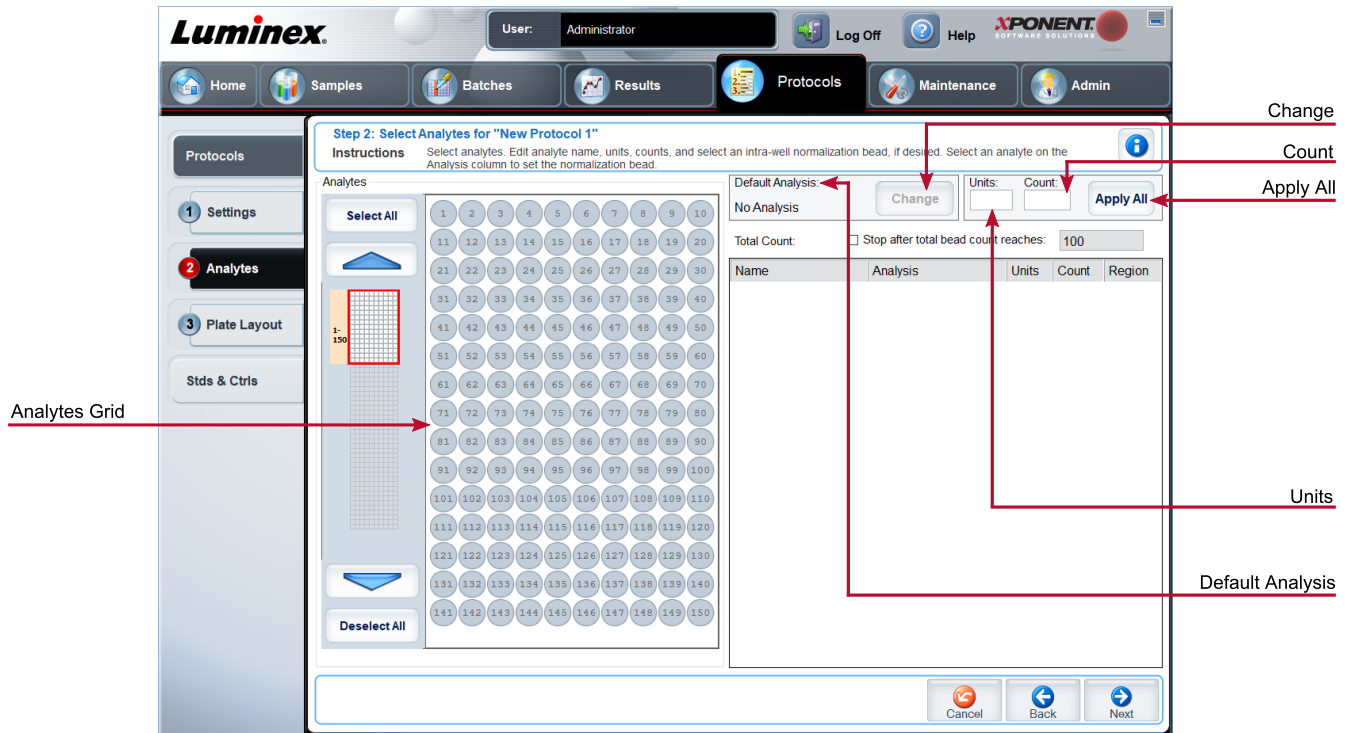


Table 25. Analytes Subtab Screen Elements

| Analytes grid | A grid representing each analyte from 1 to 500. |
|---|---|
| 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. |

# Protocols Tab > Plate Layout Subtab

Figure 25: Plate Layout Subtab
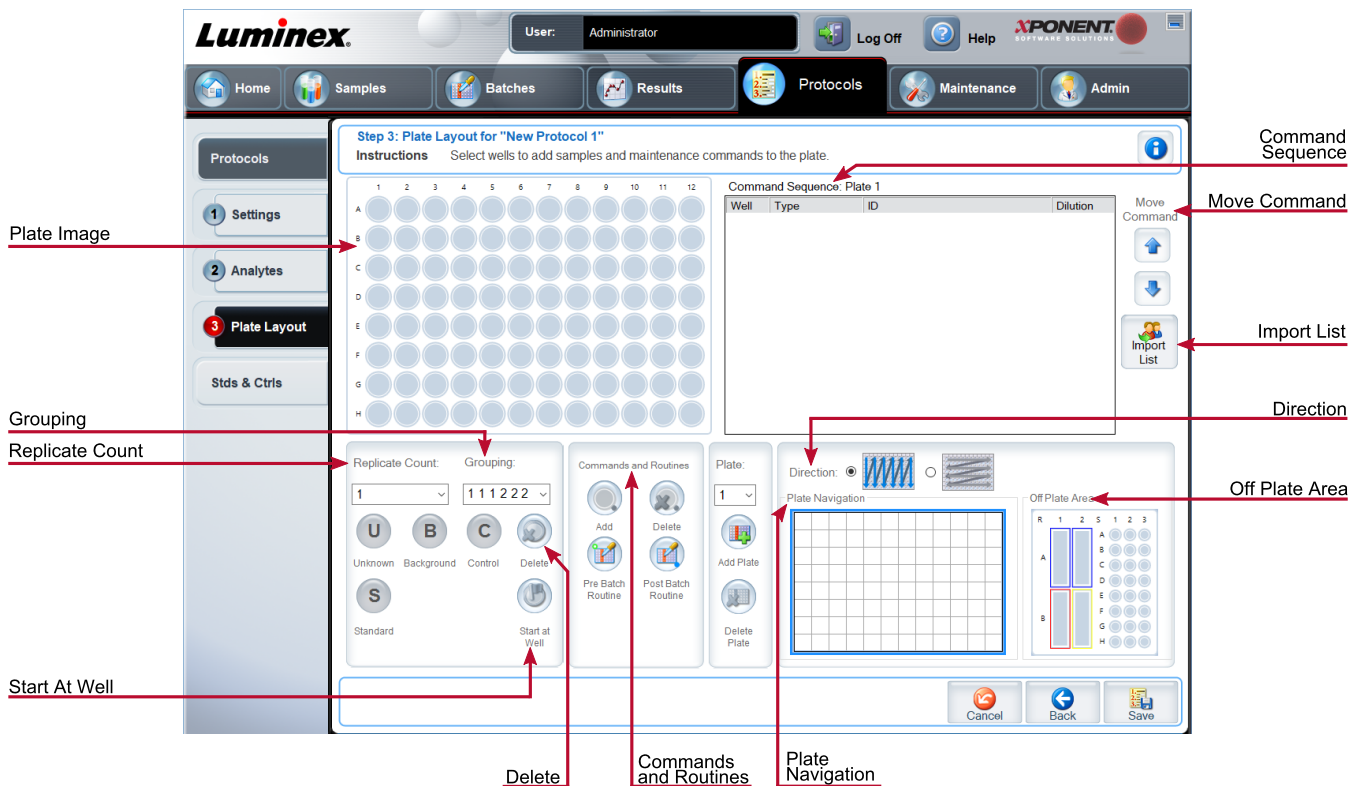
Table 26. Plate Layout Subtab Screen Elements

| | |
|---|---|
| **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.<br><br>**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** | 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:<br><br>123123123. . . Lays out one of each replicate set at a time in numerical order.<br><br>111222333. . . Lays out all the replicates in a set before moving on to the next set in numerical order.<br><br>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. |
| | **Delete** - Removes the well command for the selected well. |
| | **Start at Well** - Enables you to begin acquisition at a well other than A1. |

| | |
|---|---|
| **Commands and Routines** | Assigns maintenance commands and routines to a well after you select it in the Command Sequence or plate image area.<br><br>**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.<br><br>Enter the appropriate information in the fields and click **Save** to save the protocol or kit. |
| **Run Batch** | Runs the batch. |

# Stds & Ctrls (Standards and Controls) Tab

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

Figure 26: Stds & Ctrls Tab
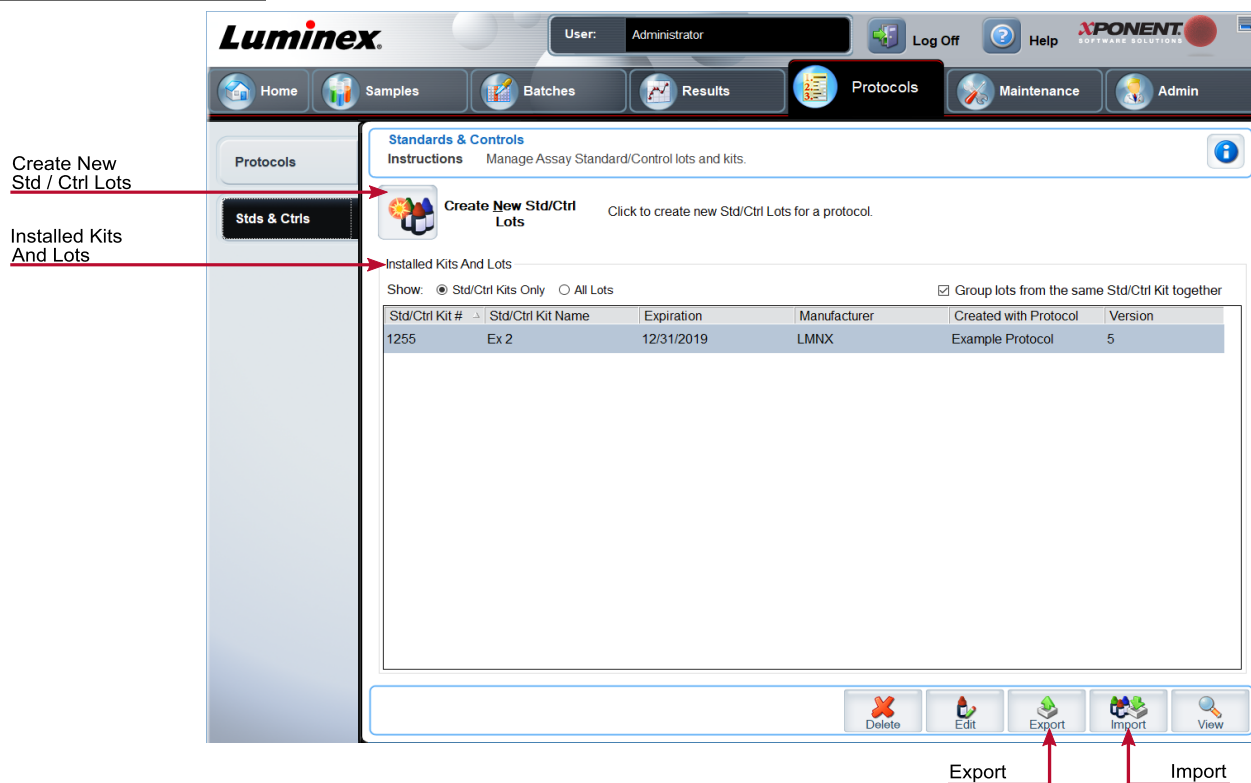


Table 27. Stds & Ctrls Tab Screen Elements

| Create New Std/Ctrl Lots | 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. |
| --- | --- |
| **Installed Kits And Lots** | Displays information about the kits and lots currently installed on the system. |
| | **Show -** Click either Std/Ctrl Kits Only or All Lots to choose what to display. |
| | 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. |
| | 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. |
| | **Group lots from the same Std/Ctrl Kit together** - Groups lots from the same kit together. |

| 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.

Figure 27: Stds/Ctrls Details Subtab
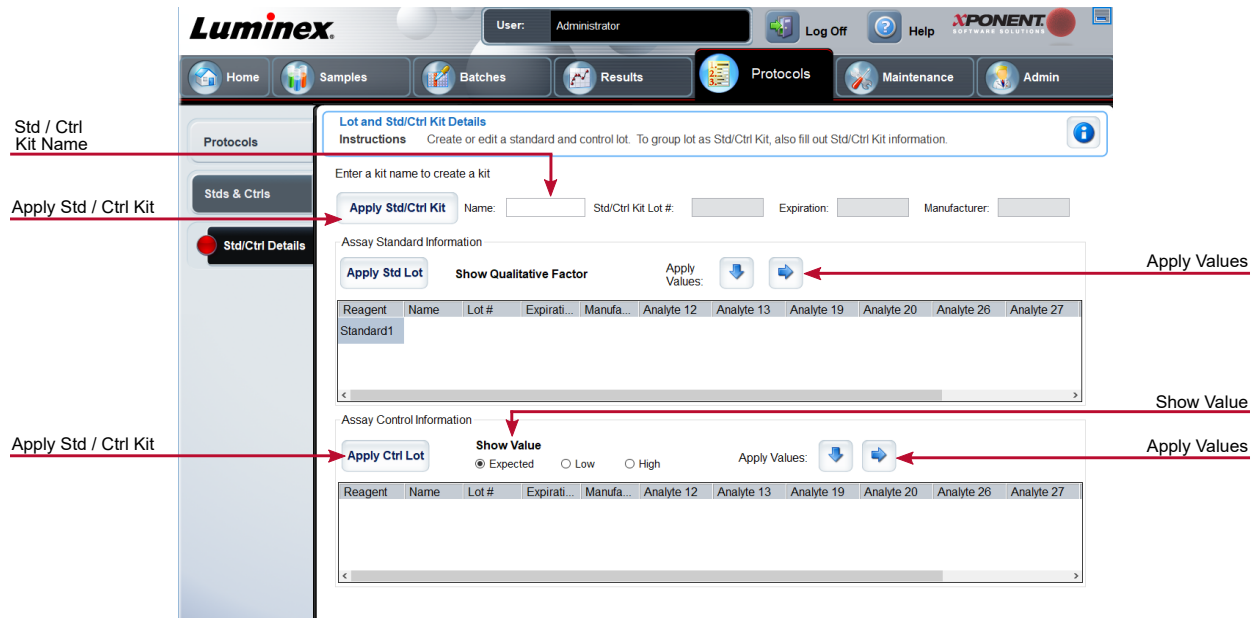


Table 28. Std/Ctrl Details Subtab Screen Elements

| 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** | |
| **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 28: Auto Maint Tab
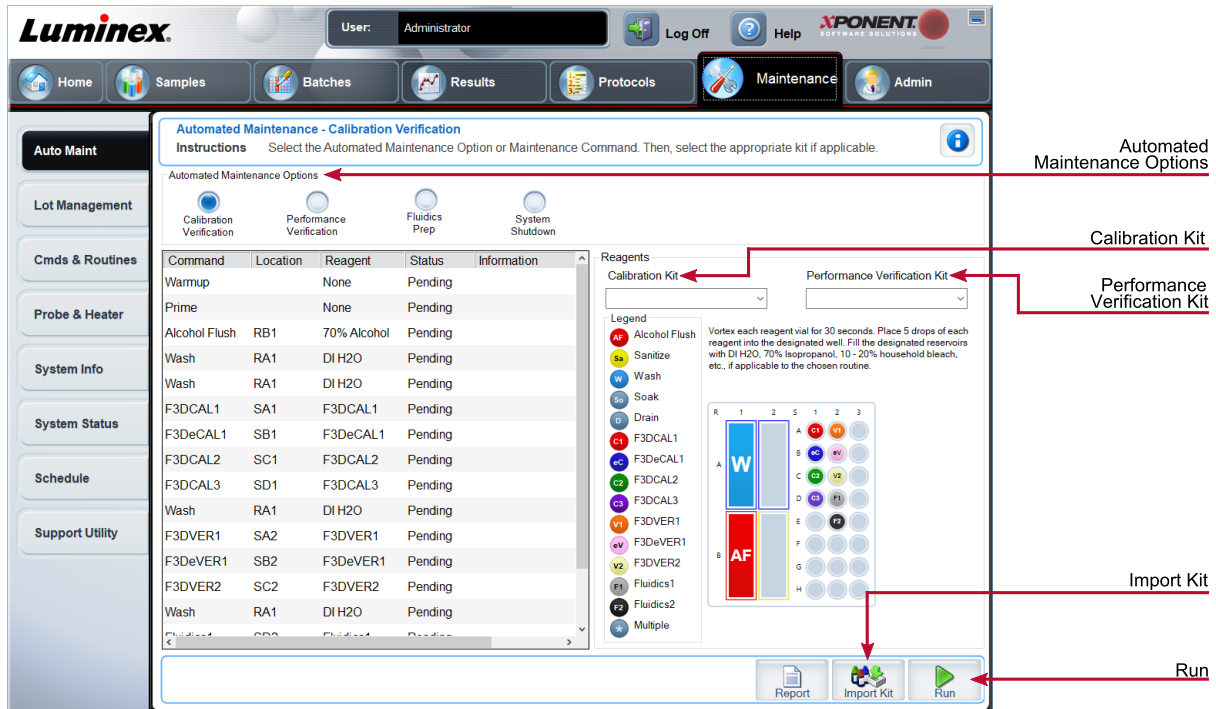


Table 29. Auto Maint Tab Screen Elements

| | |
|---|---|
| **Automated Maintenance Options** | Provides buttons for commonly used maintenance routines for the machine.<br><br>• **Calibration/Verification**<br>• **Performance Verification**<br>• **Fluidics Prep**<br>• **System Shutdown** |
| **Reagents** | • **Calibration Kit**<br>• **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. |

# Lot Management Tab

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

**Figure 29: Lot Management Tab**
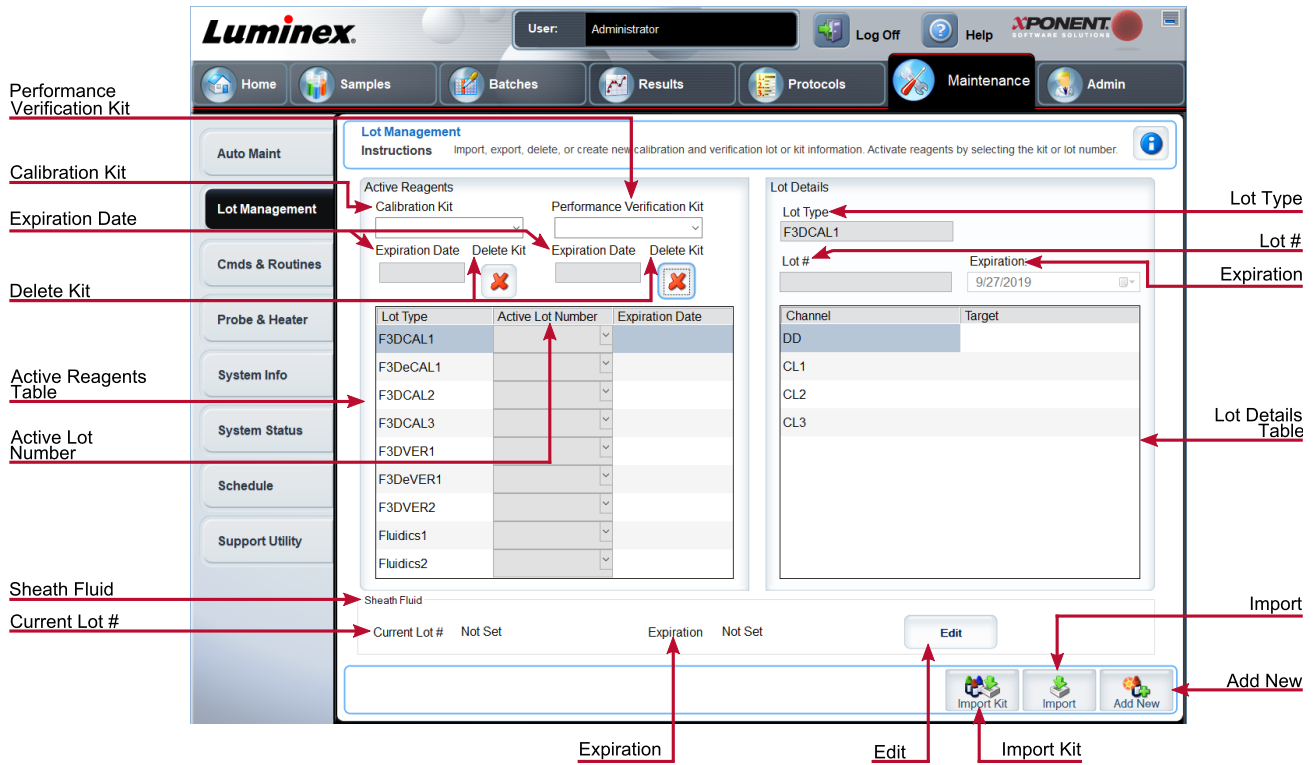


**Table 30. Lot Management Tab Screen Elements**

| | |
|---|---|
| Active Reagents | Changes calibration or performance verification kits, lot numbers and expiration dates, or deletes a kit. |
| | **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 CAL, VER, 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, CL3, and RP1 and EDR. 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.
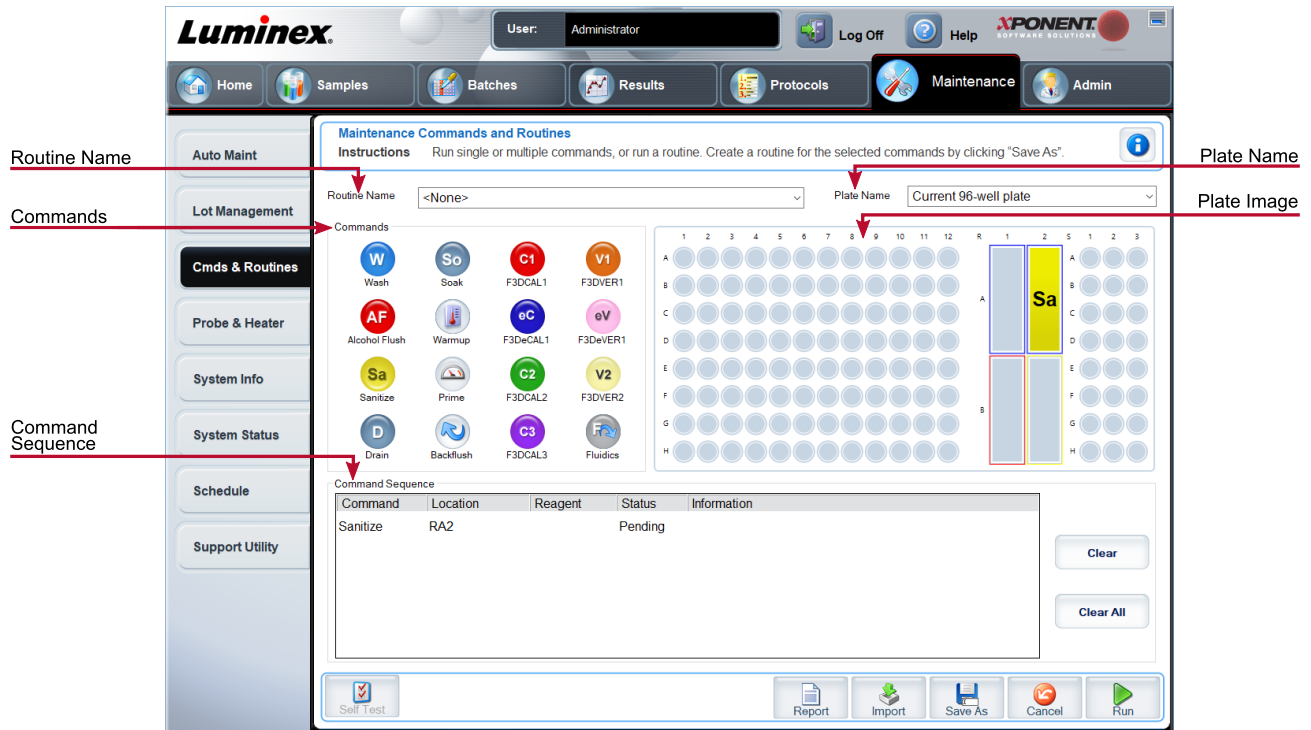
### Figure 30: Cmds & Routines Tab



### Table 31. 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 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. |
| **Commands** | **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. |
| | **F3DCAL1** - Calibrates DD, CL1, CL2, and CL3 for original non-magnetic xMAP microspheres. |
| | **F3DVER1** - Verifies DD, CL1, CL2, and CL3 for non-magnetic xMAP microspheres. |
| | **F3DeCAL1** - Calibrates DD, CL1, CL2, and CL3 for original magnetic MagPlex microspheres. |
| | **F3DeVER1** - Verifies DD, CL1, CL2, and CL3 for magnetic MagPlex microspheres. |
| | **F3DCAL2** - Calibrates xMAP reporters. |
| | **F3DVER2** - Verifies RP1 at normal and high PMT and extended ranges for all xMAP Bead Types. |
| | **F3DCAL3** - Calibrates extended RP1 ranges for all xMAP microspheres. |
| | **Fluidics -** Fluidics calibrates sample carry over from well to well. |
| **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.<br><br>**Self Test** - Performs a self-diagnostic to see if the system and all operations are functioning correctly.<br><br>**Report** - Opens the Reports tab with Calibration and Verification Reports selected in the Report drop-down menu. Click Generate to view the selected report.<br><br>**Import** - Imports the routine file.<br><br>**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 31: Probe & Heater Tab



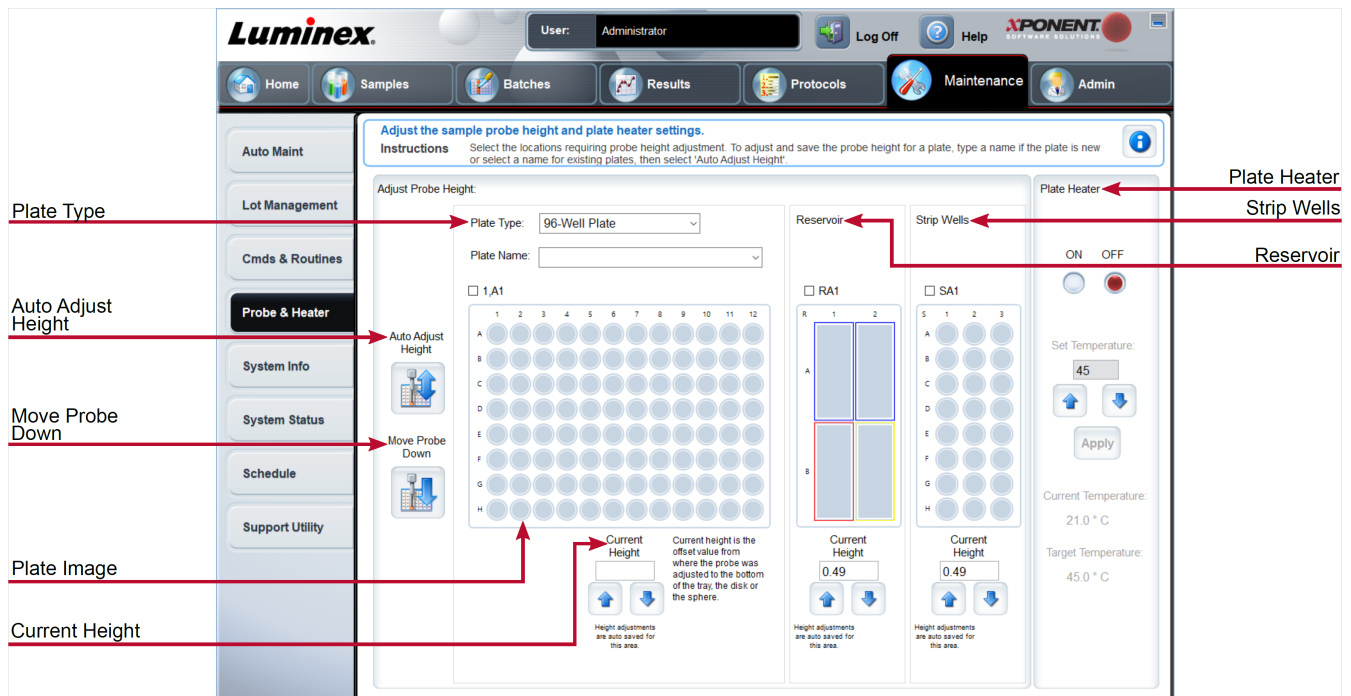Table 32. Probe & Heater Tab Screen Elements

| | |
|---|---|
| **Plate Name** | Enter a name for a plate for future use, or choose an existing plate from the list. |
| Plate Type | Defines the selection of either a 96-well plate or a 384-well 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. |
|---|---|
| Current Height | Used to fine tune the probe height after an auto-adjust. Displays the current height of the probe, and the arrows below allow for adjustments up or down. |
| Auto Adjust Height | Automatically adjusts the probe height using the specified location(s) in the main plate, reservoir, and strip wells.<br><br>Luminex recommends that you calibrate the probe height using well D6. |
| Move Probe Down | Moves the probe down in the specified well(s). |
| Plate Location pin | A green pin that shows the well location used to auto adjust the probe height for the main plate, reservoir, and/or strip wells. The default (and recommended) location for the main plate is well D6.<br><br>The main plate depicts a 96-well plate.<br><br>**Strip Wells** depicts the strip well added to the off-plate reagent area when extra wells are required. A strip well is equivalent to one column of a plate, and, like a plate, its wells can be flat-bottomed, v-bottomed, etc.<br><br>**Reservoir** depicts the reservoir added to the off-plate reagent area when procedures require larger amounts of a reagent, such as alcohol or distilled water. |
| 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. |
| Save Plate | Appears when you have typed a new plate name in the **Plate Name** list, and is used to save the current plate. A warning message displays. |

**NOTE:** If you save a plate without performing an auto adjust, the plate name is saved, but the probe height adjustment is not. If you do this, you cannot use the plate with this instrument. If your purpose is to save this plate to use it when you create a protocol to export and, click **Save**. Otherwise, click **Cancel** and perform an auto adjust.

# System Info Tab

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

This tab contains the following information:

| | Last F3DCAL2 Calibration |
|---|---|
| | Last F3DCAL3 Calibration |
| | Last F3DVER1 Verification |
| Software | Last F3DeVER1 Verification |
| Version | Last F3DVER2 Verification |
| Operating System | Last Fluidics Test |
| Licensing | Delta Calibration Temp |
| Instrument Type | System Temperature |
| Serial Number | DD Temperature |
| Firmware Version | CL1 Temperature |
| Sheath Pressure | CL2 Temperature |
| Calibration/Verification Status | CL3 Temperature |
| Last F3DCAL1 Calibration | CL3 Voltage |
| Last F3DeCAL1 Calibration | DD Voltage |
| | RP1 Voltage |
| | Number of Syringes |

Table 33. 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. |

# System Status Tab

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

Table 34. 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 35. 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. |

# 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 36. 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 37. 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. |
| | **Allow 3D View** - Enables the 3D view in the Current Batch tab of the Results page. |
| **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.<br><br>**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 38. Group Setup Tab Screen Elements

| | |
|---|---|
| **Group Profile** | These user groups are predefined:<br><br>● Administrator<br>● Supervisor<br>● Service<br>● Technician2<br>● Technician1<br>● Reviewer<br><br>The user belongs to the group to which you assign them. |
| **Group Features** | 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:<br><br>● **System Administration**<br>● **Batch Management**<br>● **Protocol Management**<br>● **Lot and Std/Ctrl Kit management**<br>● **Import and export data**<br>● **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
  - View Processed Batch Results
  - Export Processed Batch Results
- **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 39. 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 your 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 40. 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.** |
| | **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 Pre-Batch Routine -** 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. Choose the Pre Batch Routine to specify a particular routine to run before running a batch.<br><br>NOTE: A **Rinse** command runs after all pre-batch routines. |
| | **Default Post-Batch Routine -** A Luminex Post-Batch routine automatically runs at the end of each batch to clean the sample chamber and maintain peak system performance. This cannot be deleted or modified and runs by default. However, you can turn off this routine or use a different routine. Luminex recommends cleaning the system with 0.1N NaOH. |
| | **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. |

# Alert Options Tab

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

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

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## 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 41. 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 Auto-matically 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 42. 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. |

## 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**.