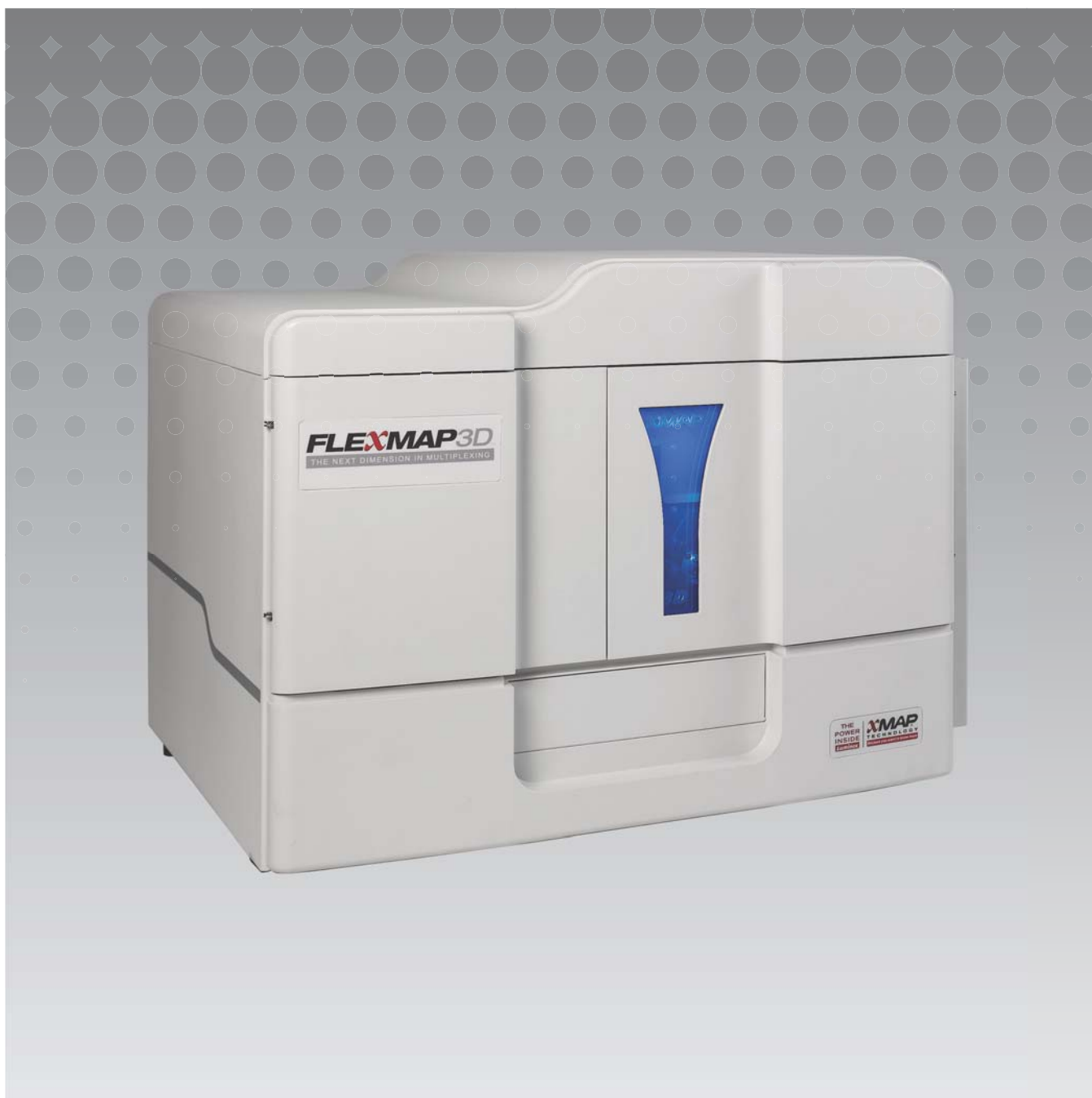


**Luminex**

*Software User Manual* | IVD

# Luminex<sup>®</sup> xPONENT<sup>®</sup> 4.2

IVD



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# Chapter 1: Introduction

The Luminex® system was developed to improve workflow and efficiency in the clinical laboratory. End users in the laboratory must run microtiter plates using xMAP®-based assay kits developed for use with xMAP technology.

**NOTE:** The primary language of the user interface is English. xPONENT® uses the host PC's locale settings for displayed time, date, and numeric values. If you choose the export data in US regionalization format only, you can change this setting in the CSV and Batch Export Options in the Admin section. Otherwise, data will be exported per your PC's locale settings.

## Intended Use

The Luminex® FLEXMAP 3D® system with xPONENT® software is a clinical multiplex test system intended to measure and sort multiple signals generated in an *in vitro* diagnostic assay from a clinical sample. This instrumentation is intended for use with specific IVD cleared or approved assays citing its use, to measure multiple similar analytes that establish a single indicator to aid in diagnosis.

## Software Packages

The Luminex® xPONENT® software has different levels of functionality:

- **Basic** - Basic package allows you to acquire data, perform analysis, create protocols and batches, review and print reports, and perform Luminex system maintenance.
- **Secure** - Secure has all of the Basic functionality, plus it allows the administrator to set up user access levels.
- **21 CFR Part 11** - Has all of the Secure functionality, and also requires electronic signatures to perform certain tasks. Electronic signatures are listed in the system log. Electronic signatures for batch functions are also listed in the batch audit log.

Other licensable software features are:

- **Automation** - Includes the ability to communicate with external hardware.
- **LIS** - Includes the ability to communicate with an external Laboratory Information System (LIS) database. The LIS edition allows the export of patient result data in ASTM file format and the import of patient information in ASTM format.

You will need an instrument control license to operate the instrument.

For more information on purchasing upgraded packages, or to obtain specific package documentation, contact your vendor.

## About this Guide

The conventions in this document assume a basic familiarity with computers and a knowledge of Microsoft® Windows® software. Commands are often available through more than one method, such as from the toolbar and from menus that appear when right-clicking an area of the screen. However, for ease of use the individual procedures in this manual describe only one method for accessing commands.

This guide is formatted as a PDF, and can be printed. However, the guide is best viewed online due to the bookmarks and hypertext included in the text.

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**NOTE:** This message is used to provide general helpful information. No safety or performance issues are involved.



**CAUTION:** This message is used in cases where the hazard is minor or only a potential hazard is present. Failure to comply with the caution may result in hazardous conditions.








**WARNING:** This message is used in cases where danger to the operator or to the performance of the instrument is present. Failure to comply with the warning may result in incorrect performance, instrument failure, invalid results, or hazard to the operator.



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You may encounter these symbols during the use of xPONENT® software. They represent warnings, conditions, identifications, instructions, and regulatory agencies.

**TABLE 1. Symbols**

	Warning, Biological Hazard		Heat/Hot Surface Warning
	General Warning, Caution, Risk of Danger		Authorized representative in the European Community
	Manufacturer		<i>In vitro</i> diagnostic medical device
	European Union Conformity		

## General Guidelines

Modifying or deleting xPONENT® system files may cause degradation to system performance. You can repair modified or deleted xPONENT system files by uninstalling and re-installing the xPONENT software.

Use of unauthorized third party software with xPONENT software may result in corruption or failure of the xPONENT software. Use third party software at your own risk.

If using a screen saver on the xPONENT system, be aware that xPONENT will prevent it from activating. A dialog box will display each time xPONENT is launched, recommending that the screen saver and any power management settings are turned off.

This system contains electrical, mechanical, and laser components that, if handled improperly, are potentially harmful. In addition, biological hazards may be present during system operation. Therefore, Luminex® recommends that all system users adhere to standard laboratory safety practices. The protection provided by the equipment may be impaired or the warranty voided if Luminex FLEXMAP 3D® is used in a manner not specified by the instructions or by Luminex Corporation.

## Biological Samples

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 - gloves, gowns, laboratory coats, face shields, or mask and eye protection - and ventilation devices. Observe all local, state, and federal biohazard handling regulations when disposing of biohazardous waste material.

## Bead Handling

xMAP® beads come in various configurations. Avoid excessive agitation of the product to reduce foaming and surface precipitation. The xMAP beads will settle if left undisturbed. Always ensure that the xMAP beads are homogeneously resuspended prior to dispensing. The uncoupled xMAP beads are not monodispersed and tend to aggregate until coated. Multiple pipetting from the original container may affect bead concentrations. Protect the xMAP beads from light at all times. Store xMAP beads at 2°C to 8°C.

**NOTE:** Refer to the product information sheet that accompanies your xMAP beads or assay for additional information.

## Limitations

xMAP® beads are susceptible to photobleaching; photobleaching effects are cumulative. To maintain the integrity of the xMAP-based kit minimize its exposure to light.

xMAP beads are hydrophobic in the aqueous medium provided and will settle if left undisturbed. Resuspend prior to dispensing.

Do not use this product with strong organic solvents. For information on specific compatibility, visit the Luminex® Technical Support website at [www.luminexcorp.com](http://www.luminexcorp.com). From the main page, click **Support**.

## Safety Precautions

All samples should be regarded as potentially contaminated and treated as infectious. These samples should be handled at the Biosafety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Center for Disease Control/ National Institutes of Health Manual, "Biosafety in Microbiological and Biomedical Laboratories" 1984.

Although beads do not contain hazardous or carcinogenic components at toxic levels, they may be toxic if swallowed. Contact with acids liberates toxic gases. If product comes in contact with skin, wash immediately with copious amounts of water. In case of accident, seek medical advice immediately and show the product label or container to your medical provider. A Material Safety Data Sheet is available upon request.



**WARNING:**

Reagents may 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 material safety data sheet (MSDS) health hazard 4. 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).



**CAUTION:**

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

## Bead Concentration

The concentration of beads in an assay is a factor in system speed. If running an xMAP®-based kit, follow the instructions found on the kit's product insert or use the provided software protocol.

## Repetitive xMAP® Bead Measurements

In an xMAP® assay, the reporter signal is the result of the assay. Due to small bead size, xMAP bead suspension exhibits near solution phase reaction kinetics. This means that each set of xMAP beads used for a particular assay will show a statistically even distribution of reporter molecules bound to the surface of each bead. During data acquisition, numerous beads of each set are analyzed and the median statistic is computed for that set by the software. The more beads of a set measured, the more confidence that can be given for that particular measurement. If running an xMAP-based kit, follow the kit's product insert or use the provided software protocol.

## Classification and Reporter Fluorochromes

Each xMAP® bead set is internally dyed with two classification dyes, or three dyes for beads above 100-plex. The fluorescence signal of these dyes allows for classification of each bead set. Since each bead is analyzed individually, even when the sets are

mixed in a multiplex assay they can still be distinguished by their emission signals. The fluorescence signal of reporter molecules bound to the surface of each bead set is measured and used to determine the result of each assay in a multiplex. Again, since each bead is analyzed individually, reporter signals for each bead set can be accurately quantified.

The following table displays acceptable reporter fluorochromes and their excitation and emission wavelengths.

**TABLE 2. Reporter Fluorochromes Wavelengths**

	R-Phycoerythrin	Alexa 532
Formula weight (Daltons)	240,000	470
Absorbance max (nm)	480,546,565	531
Extinction max (M-1cm-1)	1,960,000	83,800
Emission max (nm)	578	554
Quantum yield	0.82	0.8

## Sample Volume

Sample volume or sample sizes range from 10 µL to 200 µL. Ensure that some of the sample remains in the well after aspiration; about 25 µL greater than the sample volume. This amount may vary depending on the type of plate used. After acquisition, the Luminex® analyzer washes the sample lines resulting in ejection of approximately 45 µL of sheath fluid back into the well for a 96 and 384-well plate. Ensure that there is room to add this amount to the well without overflowing and contaminating other wells.

The volume restrictions on the assay design can be expounded by the following formula:

Total well volume (µL) - Sample uptake volume (µL) + 45 (µL) <Maximum Well Volume (µL)

- Total well volume = Starting sample volume of a well before the unit samples for acquisition. Well volume is determined by the consistency of the bead set.
- Sample uptake volume = Uptake volume for acquisition (program this in the protocol as sample volume).
- 45 (µL) = Volume expelled back into the well.
- Maximum well volume plate = The maximum volume capacity of the wells in a selected 96 and 384-well microtiter plate.

**NOTE:** This sample volume information is for a 96 and 384-well plate.

## Sample Dilution

Dilute concentrated biological samples, such as plasma or serum, at least 1:5 with reagents as part of assay setup or as a final dilution step. If running an xMAP®-based kit, follow the dilution instructions found on the kit's product insert.

## Reagents

Formulated reagents must be free of particulates other than xMAP® beads. Do not dilute xMAP calibrators or verifiers.

## Gating

Gate positions are dependent upon buffer composition. Any changes made to the buffer composition in an assay may result in a different optimal gate location.

Determine the gating on the Doublet Discriminator channel for the assay during assay development. The numeric values appear on the left side of the histogram. Use the numerical gate position, as determined during assay development, to set the gate location in the protocol.

Gating information may change with a new lot of xMAP® beads. Each time you receive a new lot of xMAP beads, evaluate them with the current protocols. If gating information changes, create a new protocol identical to the current protocol, but with a new version number and new gating information. If running an xMAP-based kit, follow the instructions found on the kit's product insert or use the provided software protocol.

## Plates

When using uncovered plates, use black opaque plates, if possible, to reduce photobleaching.

Select a 96-well plate with an overall height no greater than 1 inch (25.4 mm).

## Help

English-language help is available at all times while you are using xPONENT®. To display online help for the page or tab in which you are currently working, click the blue “i” icon at the upper-right of the xPONENT window. This opens a help window with information specific to that page or tab.



To display system-level help, click the blue question mark at the top of the xPONENT window, then click **Contents and Index**. The online help opens, where you can navigate to any available topic.



To display quick start information, click the blue question mark at the top of the xPONENT window, then click **Quick Start**. This displays information about the basic steps to start the system.

To display software information, click the blue question mark at the top of the xPONENT window, then click **About Luminex xPONENT**. The xPONENT information dialog box opens, displaying the software version information.

## Quick Start

The five steps to starting and using xPONENT® are the following:

**TABLE 3. Starting and Using xPONENT®**

To	Go to	Expanded Help
Adjust the sample probe height	<b>Home &gt; Probe and Heater</b>	<i>“Adjusting the Sample Probe Height”</i>
Initialize the system	<b>Home &gt; System Initialization</b>	<i>Running the “System Initialization” Routine</i>
Run an assay	<b>Home &gt; Create a new Batch using the highlighted protocol below</b>	<i>“Create a New Batch from an Existing Protocol”</i>
Analyze	<b>Results &gt; Saved Batches</b>	<i>“Performing Analysis”</i>
Print reports	<b>Results &gt; Reports</b>	<i>“Reports Tab”</i>

## Chapter 2: Exploring the Software

This chapter explores the software, its functionality, and default views. Please note that views can be changed and functionality can be disabled by the xPONENT® system administrator.

### Basic Procedures

#### Starting xPONENT®

- On the PC desktop, click the Luminex® xPONENT® icon, or click **Start > All Programs > Luminex > xPONENT> Luminex xPONENT**.
- If you have a trial license, contact Luminex Technical Support to obtain a full license, or click **OK** in the dialog box to continue.
- If this is the first time you have started the software, the **User License Agreement** may display. Read the license agreement. Select **I accept the terms of this license agreement**, then click **OK**.

**NOTE:** For safety and legal information, refer to the *Hardware User Manual* that you received with the instrument.

#### Adding a New License Key

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

#### Logging On to xPONENT®

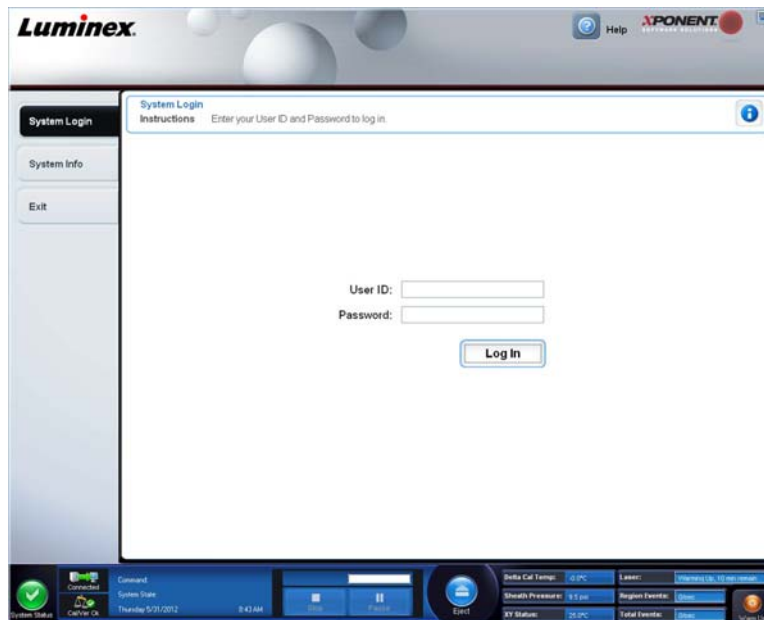
To log in, type your user ID at the System Login tab. If you are using the secure version of the software, type your password. Once you have logged in, the Home page opens. The xPONENT® system administrator must set up the User ID and initial logon passwords. Contact your xPONENT system administrator if you have not been assigned a user ID and password.



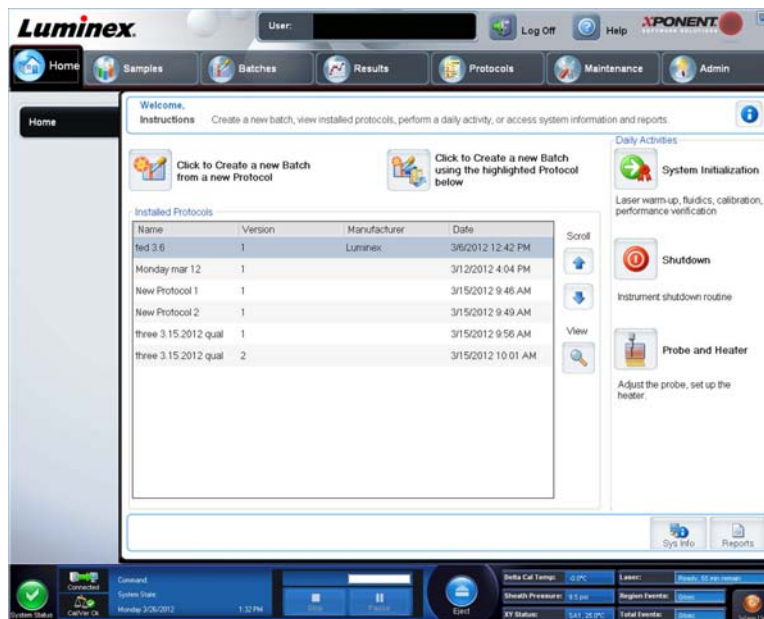
**CAUTION:** Use of this software by untrained personnel can result in inaccurate data and test results. Users of xPONENT must read the documentation thoroughly before operating the software.



1. On the **System Login** tab, type your **User ID**.



2. If you are using a secure version of the software, type your password. The **Home** page opens.



**NOTE:** If a user is locked out of the application, each time the Admin user logs in, a dialog box opens to notify the Admin user that a user is locked out.

## Logging Off

Click **Log Off** to log out of the software, then click **OK** in the **Confirm Logout** dialog box.

## Exiting

After you log out, click **Exit**, then **Yes** to exit the software completely.

## Screen Elements

This section shows screen elements and the terms used in this book to describe them.



1	Page
2	Tab
3	Subtab

## Navigation Elements

**Page** - Across the top of the window, there is a content pane with page tabs. Click a page to go to that part of xPONENT®.

**Tab** - On the left side of the window, along the left side of the content pane, are tabs. Click a tab to go to that subsection of the software.

**Subtab** - A tab can have one or more subtabs. These are located below the tab, are smaller, and are identified by the circle on the left end of the subtab. The circle is red when the subtab is open. For some workflows, you must move through the subtabs of a tab sequentially, completing the work on one subtab and clicking **Next** to move to the next subtab.

## Right-Click Menu

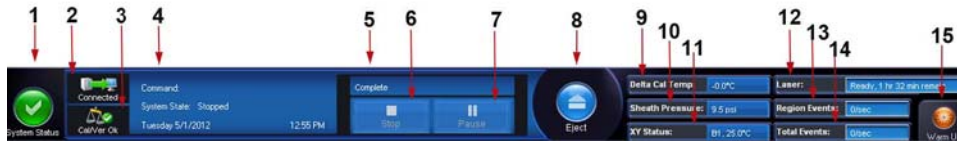
Certain sections of the software such as tables, lists, and text boxes have right-click option menus. Menus are different depending upon the item you right-clicked.

- **Apply Dilution Down** - sets the dilution levels for the sample.
- **Print All** - Prints all sections or cells of the item.
- **Print Selection** - Prints only the selected section or cell.
- **Import** - Imports a file.
- **Export Grid Contents** - Opens a **File** dialog box. Use the **Browse** button to select a location, file name, and file type (either a text or CSV file) for the export. This 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 box.
- **Delete** - Erases text or data from the selection.

## System Monitor

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



1	System Status button	2	Connection Status	3	Check Cal/Ver Ok
4	Command Display	5	Progress Bar and buttons	6	Stop button
7	Pause button	8	Eject button	9	Delta Cal Temp Status
10	Sheath Pressure	11	XY Status	12	Laser Status
13	Region Event Status	14	Total Events Status	15	Warm Up button

**System Status** - This button has two functions: When clicked, it opens the system log. 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.

**Connection Display** - Displays the connection status.

**Cal/Ver Ok** - This will be lit up if the calibrations and verifications are current. When you click the **Cal/Ver** button, it takes you to **Maintenance > System Setup**.

**Command** - Displays the following:

- The command currently running.
- The system state (i.e. running, idle, etc.).
- Date and time.

**Progress** - 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**.

**Pause** - 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, store the pending batch and then resume exactly where it left off.

**Stop** - Stops the system, regardless of command status. Use this only if it does not matter whether the data from the current well is lost.

**Eject** - 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 in degrees Celsius between the current reading and the reading when the system was calibrated. If the temperature is out of tolerance, this shows a high or low arrow. When clicked, it opens the **Auto Maint** tab.

**Sheath Pressure** - Displays the sheath pressure in psi. A high or low arrow is displayed if the pressure is trending up or down versus the calibration pressure it turns yellow. When clicked, it opens the **System Info** tab.

**XY Status** - Displays the current location of the command and the temperature of the plate heating block in degrees Celsius. When clicked, it opens the **Probe & Heater** tab.

**Laser** - Displays the laser status, including the time remaining until you must warm up the laser again. The **Laser status** box is blue. The button turns yellow when the lasers are turned off and about 10 minutes before they turn off. Clicking the **Warm Up** button restarts the active clock for the laser.

**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 Button** - Starts or schedules a warmup.

## System Info Tab

**System Information**  
View, copy, or save information and diagnostics about this instrument.

Software	Luminex xPONENTB for FLEMAP 3D
Version	4.2 Build 1424
Operating System	Windows XP (S 1.3600.196608 Service Pack 3)
Licensing	Base Software*, LIS*, 21 CFR Part 11*, Automation*, Security*, Allelic Ratios*, Instrument Control*, Remote Web Monitoring*, 500 Analyte Support*
Instrument Type	FLEMAP 3D
Serial Number	SIMFMDET
Firmware Version	3.0.274 3/25/2011 12:00:00 AM
XYP Heater Temperature	Heater Off
Sheath Pressure	9.48 psi (Tolerance: 0.00 ± 0.00)
Calibration/Verification Status	OK
Last F3DCAL1 Calibration	Passed: 5/22/2012 12:00:00 AM
Last F3DeCAL1 Calibration	Passed: 5/22/2012 12:00:00 AM
Last F3DCAL2 Calibration	Passed: 5/22/2012 12:00:00 AM
Last F3DCAL3 Calibration	Passed: 5/22/2012 12:00:00 AM
Last F3DVER1 Verification	Passed: 5/22/2012 12:00:00 AM
Last F3DVER2 Verification	Passed: 5/22/2012 12:00:00 AM
Last Fluidics Test	Not yet run
Delta Calibration Temp	-0.0° C (Calibration Temperature: 25.00° C, Tolerance: ±5.00° C)
System Temperature	25.0° C
DD Temperature	25.0° C
CL1 Temperature	25.0° C
CL2 Temperature	25.0° C
CL3 Temperature	25.0° C
CL1 Voltage	110.0
CL2 Voltage	110.0
CL3 Voltage	110.0
DD Voltage	110.0
RP1 Voltage	110.0
Number of Syringes	2

Delta Cal Temp: -0.0°C    Laser: Ready, 2 hr 34 min remain  
 Sheath Pressure: 9.5 psi    Region Events: 0/sec  
 XY Status: 25.0°C    Total Events: 0/sec    Warm Up

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

This tab contains the following information:

- Software
- Version
- Operating System
- Licensing
- Instrument Type
- Serial Number
- Firmware Version
- XYP Heater Temperature
- Sheath Pressure
- Calibration/Verification Status
- Last F3DCAL1 Calibration
- Last F3DeCAL1 Calibration

- Last F3DCAL2 Calibration
- Last F3DCAL3 Calibration
- Last F3DVER1 Verification
- Last F3DeVER1 Verification
- Last F3DVER2 Verification
- Last Fluidics Test
- Delta Calibration Temp
- System Temperature
- DD Temperature
- CL1 Temperature
- CL2 Temperature
- CL3 Temperature
- CL1 Voltage
- CL2 Voltage
- CL3 Voltage
- DD Voltage
- RP1 Voltage
- Number of Syringes

Items in this list relating to calibration and verification (CAL/VER) have one of the following states:

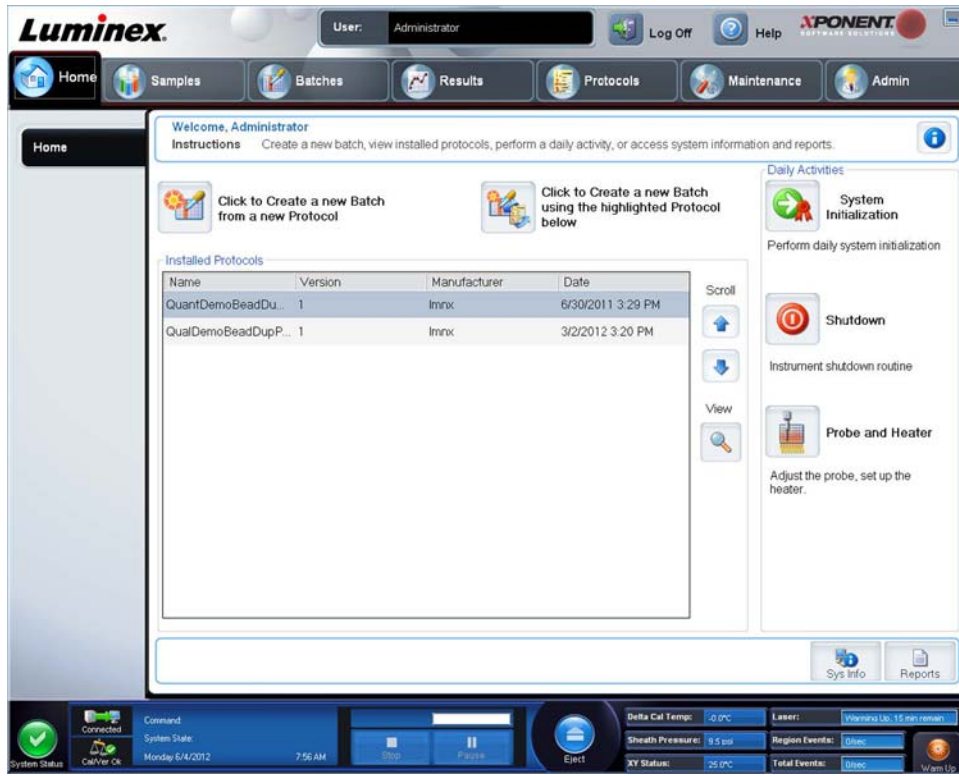
- **Passed** - Indicates that the process completed successfully.
- **Failed** - Indicates that the process was not completed successfully. Failed items appear in red.
- **Not Current** - Indicates that verifiers are not current. Verifiers are not current if you have not calibrated the system since the 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.

## 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. This page contains the following:

**Click to Create a new Batch using the highlighted Protocol below** - Creates a new batch using a selected protocol from the **Installed Protocols** list. For more information about creating a batch from an existing protocol, see [“Create a New Batch from an Existing Protocol”](#).

**Installed Protocols** - Displays a list of protocols. The list contains the following information about each protocol:

- Name
- Version
- Manufacturer
- Date

**Scroll** - Use the arrows on the right to move through the list of protocols.

**View** - Opens the **Settings** tab of the **Protocols** page to view the selected protocol. This tab enables viewing the settings, analytes, and plate layout for the selected protocol.

**Daily Activities** - Contains shortcut buttons to common commands in the Luminex® xPONENT® software:

- **System Initialization** - Opens the routine specified in the **Maintenance Options** on the **Admin** page. For more information about this tab, see [“Auto Maintenance \(Auto Maint\) Tab”](#).
- **Shutdown** - Opens the **System Shutdown** command in the **Auto Maint** tab on the **Maintenance** page. For more information about this tab, see [“Auto Maintenance \(Auto Maint\) Tab”](#).
- **Probe and Heater** - Opens the **Probe and Heater** tab on the **Maintenance** page. For more information about this tab, see [“Probe and Heater Tab”](#).

**Sys Info** - Opens the **System Info** tab of the **Maintenance** page. For more information, see [“System Info Tab”](#).

**Reports** - Opens the **Reports** tab of the **Results** page. For more information, see [“Reports Tab”](#).

## Initial Startup

When you turn on the system for the first time, perform the following procedures:

1. Adjusting the Sample Probe Height
2. System Initialization

### Adjusting the Sample Probe Height

Adjust the sample probe height to ensure that the probe drops far enough into 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.



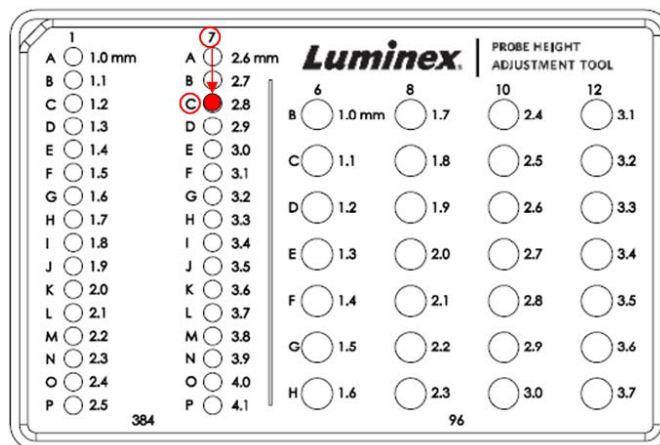
**WARNING:**

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.

1. On the **Home** page, click **Probe and Heater** under **Daily Activities**. The **Probe & Heater** tab opens.
2. Based on the type of plate you are using, you may have to place an alignment disk or sphere in the well:
  - **Filter-bottom plate** - 1 disk
  - **Mylar-bottom plate** - 1 disk
  - **V-bottom (conical) plate** - 1 sphere
  - **Flat-bottom plate** - no disks or spheres
  - **Round-bottom plate** - no disks or spheres

**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.

- **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:** These instructions enable the probe height to be set correctly in the vast majority of cases where a plate is being used having wells with rigid bottoms. However, in the case of plates having a filter bottom or a Mylar-

bottom, the instructions in Appendix C of the *FLEXMAP 3D® Hardware User Manual IVD* may help avoid perforating the bottom of the well during probe-height adjustment.

3. Verify that the microtiter is not warped. Warped plates can lead to incorrect probe height adjustment.
4. Click **Eject** to eject the plate carrier.

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

5. Place the plate on the plate holder with **A1** in the top left corner. Place the off-plate reagent block on the plate carrier. Place a well-strip (provided with the Calibration and the Performance Verification kits) in column **S1** of the block.

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

6. Click **Retract** to retract the plate carrier.
7. Type a name for the plate in the **Plate Name** box, or select a saved plate from the **Plate Name** list.

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

8. In the Plate section, click **D6** for the 96-well plate.
9. In the **Reservoir** section, click **RB1**.
10. In the **Strip-Wells** section, click **SD1**.
11. Click **Auto Adjust Height**. The probe automatically adjusts itself and saves it to the plate you selected.

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



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



**WARNING:** Correct sample probe height is critical to successful sample acquisition and calibration. Problems with the sample probe can lead to fluid leaks and inhibit sample acquisition.



**CAUTION:** Ensure that the probe height is set correctly before calibrating the system.



## Revive After Storage Routine

**NOTE:** The Revive After Storage routine is recommended for new systems starting up for the first time or when the system has been idle for more than one week.

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

1. Open the **Maintenance** page, then the **Cmnds & Routines** tab.
2. Select **Revive After Storage (Luminex)** from the **Routine Name** drop-down list. The **Revive After Storage** routine performs the following commands:
  - Warmup
  - Backflush (x2)
  - Drain RA2 (x3)
  - Alcohol Flush RB1 (x2)
  - Backflush
  - Wash RA1 (x3)
3. Add 70% isopropanol or 70% ethanol to reservoir **RB1** on the off-plate reagent block as indicated on the **Cmnds & Routines** tab. Add DI Water to reservoir **RA1**.

**NOTE:** The drain reservoir (RA2) should be empty.

4. Click **Run**.

After the **Revive After Storage** routine is complete, run the **System Initialization** routine.

## System Initialization

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.

- On the **System Status** bar, click the **Warm Up** button.

OR

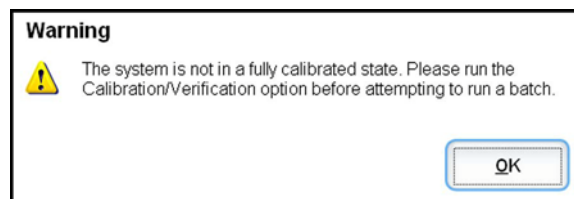
- Open the **Maintenance** page, and then the **Cmnds & Routines** tab. Click **Warmup** in the **Commands** section at the left of the screen, and then click the **Run** button at the bottom right to begin the procedure. The warmup process takes 30 minutes to complete.

Calibrate the system before use. Open the **Maintenance** page and then the **Auto Maint** tab and select the **Calibration Verification** button and follow the instructions provided on the screen.

**NOTE:** See the [“Defining the System Initialization”](#) section for more information.

Calibrator xMAP® beads are used to normalize the settings for the reporter channel, all classification channels, and the Doublet Discriminator channel. Verification xMAP beads are used to verify calibration and optical integrity of the system.

If the system is not fully calibrated, a warning message opens.



Once calibrated, the values remain until you recalibrate. You can track system calibration and verification results through the **Calibration and Verification** report.

Luminex recommends that you calibrate your system once a week. In addition, recalibrate the system if any of the following things occur:

- The delta calibration temperature exceeds  $\pm 5^{\circ}\text{C}$ .
- You move the instrument.
- You experience sample acquisition problems.
- The instrument undergoes hardware maintenance, such as replacement of a part.

Luminex recommends that you verify system performance on a daily basis.

The daily system initialization routine can be set to include calibration and or verification under the **Admin** page, **System Setup** tab, **Maintenance Options** section.

Before you can calibrate or verify the system, you must import FLEXMAP 3D® calibrator and verification bead lot information. Do this using the **Lot Management** tab of the **Maintenance** page. This information is available on the CD that accompanies the Performance Verification Kit and the Calibration Kit, and also available on the Luminex® website at <http://www.Luminexcorp.com/Support/index.htm>.

**NOTE:** Ensure that the Luminex analyzer lasers are warmed up and the probe height is set correctly before calibrating the system. Do not move the system waste line while calibrating.

## Shutting Down the Analyzer

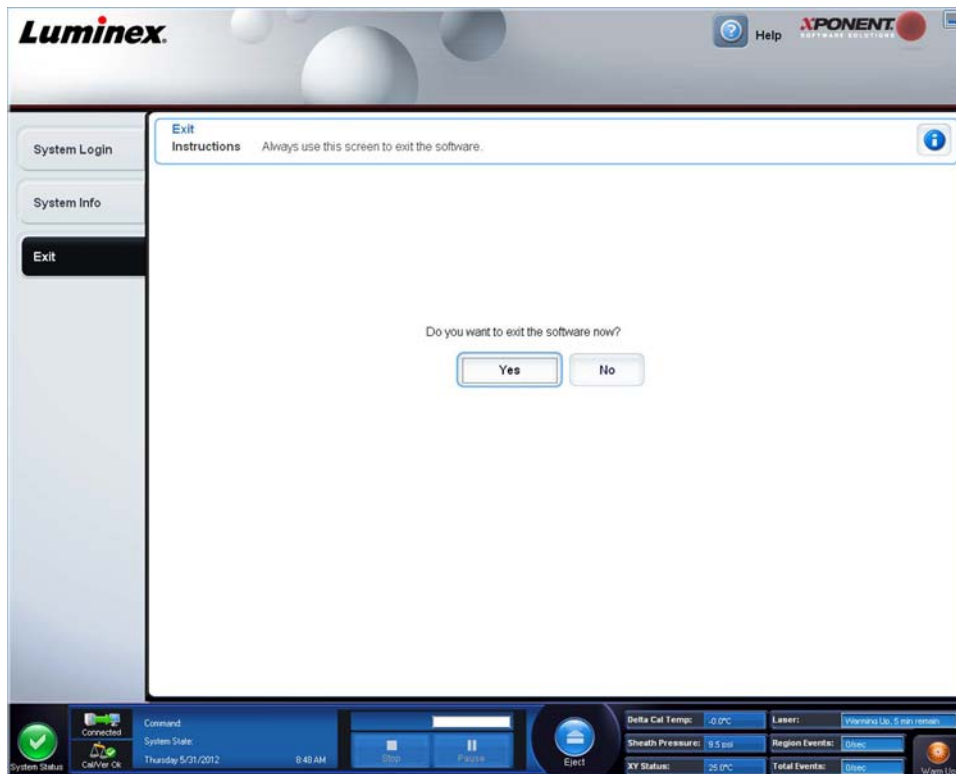
Run the daily shutdown routine to prevent clogs and crystallization of salt in the sample probe. Clogs and crystallization of salt in the sample probe can cause problems with calibration, verification, and data acquisition; they can also cause sample splashing. Shut down the system properly to ensure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

## Logging Off and Exiting

To log off and exit xPONENT®:

1. Click **Logoff** at the top of the page.
2. When the **Confirm** dialog box opens, click **OK**. This opens the **Log In** page, with **Exit** on the left tab.

- Click **Exit** to exit the application.



## Using Online Help

English-language help is available at all times while you are using xPONENT®. To display online help for the page or tab in which you are currently working, click the blue “i” icon at the upper-right of the xPONENT window. This opens a help window with information specific to that page or tab.



To display system-level help, click the blue question mark at the top of the xPONENT window, then click **Contents and Index**. The online help opens, where you can navigate to any available topic.



To display quick start information, click the blue question mark at the top of the xPONENT window, then click **Quick Start**. This displays information about the basic steps to start the system.

To display software information, click the blue question mark at the top of the xPONENT window, then click **About Luminex xPONENT**. The xPONENT information dialog box opens, displaying the software version information.

## Luminex® Support

### Viewing the Luminex® Website

Additional information is available on the Luminex® website at [http:// www.luminexcorp.com/Support/](http://www.luminexcorp.com/Support/).

## Contacting Technical Support

Luminex® Technical Support representatives are ready to help you. If the question or problem relates to materials from the assay kit, contact the kit provider directly.

Luminex Technical Support is available to users in the U.S. and Canada by calling 1-877-785-BEAD (2323). Users outside of the U.S. and Canada can contact us at +1 512-381-4397. Inquiries may also be sent by email to [support@luminexcorp.com](mailto:support@luminexcorp.com).

## Software Modules

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

- **Basic** - Allows instrument control.

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.
- **Remote Web Monitoring** - Enables you to view alerts and system status using a webpage.
- **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.

You must have an instrument control license to operate the instrument.

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

## Chapter 3: Running Assays with FLEXMAP 3D®

### General Guidelines



**WARNING:** 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.



**WARNING:** 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.

**NOTE:** 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.



**CAUTION:** This system contains electrical and mechanical components that, if handled improperly, are potentially harmful. Adhere to standard laboratory safety practices.



**CAUTION:** Protection provided by the equipment can be impaired or the warranty voided if the Luminex system is used in a manner not specified by Luminex documentation or Luminex Corporation.

### Biological Samples



**WARNING:** 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 such as gloves, gowns, laboratory coats, face shields, or mask and eye protection. Use ventilation devices. Observe all local, state, and federal biohazard handling regulations when disposing of biohazardous waste material.

### Bead (Microsphere) Handling

MicroPlex® and MagPlex® beads come in various configurations. To reduce foaming and precipitation, avoid agitating the beads until you are ready to vortex and use them. Beads settle and must be resuspended by vortexing before use. In addition:

- Multiple pipetting from the original container can affect bead concentrations.
- Protect MagPlex and MicroPlex beads from light at all times to prevent photobleaching. Photobleaching effects are cumulative. To maintain the integrity of the xMAP-based kits, minimize their exposure to light.
- Store MagPlex and MicroPlex beads at 2°C to 8°C.

**NOTE:** Refer to the product information sheet or IVD package insert that accompanies your xMAP beads or assay for additional information.

### Sample Volume

Sample volume or sample sizes range from 10 µL to 200 µL. Ensure that some of the sample remains in the well after aspiration; about 25 µL greater than the sample volume. This amount may vary depending on the type of plate used. After

acquisition, the Luminex® analyzer washes the sample lines resulting in ejection of approximately 45 µL of sheath fluid back into the well for a 96 and 384-well plate. Ensure that there is room to add this amount to the well without overflowing and contaminating other wells.

The volume restrictions on the assay design can be expounded by the following formula:

Total well volume (µL) - Sample uptake volume (µL) + 45 (µL) < Maximum Well Volume (µL)

- Total well volume = Starting sample volume of a well before the unit samples for acquisition. Well volume is determined by the consistency of the bead set.
- Sample uptake volume = Uptake volume for acquisition (program this in the protocol as sample volume).
- 45 (µL) = Volume expelled back into the well.
- Maximum well volume plate = The maximum volume capacity of the wells in a selected 96 and 384-well microtiter plate.

**NOTE:** This sample volume information is for a 96 and 384-well plate.

## Plates

Follow the IVD assay manufacturer's instructions in the selection of plates. If not specified, follow these guidelines when choosing plates:

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

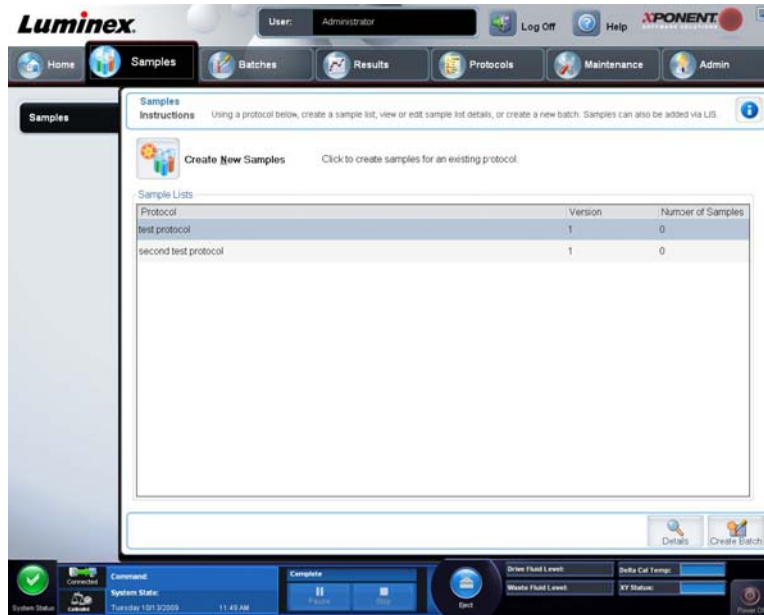


**CAUTION:** The heater block or plate can be hot and can cause personal injury when touched. Use care when you are working with it and do not touch it.

See the recommended consumables list on the Luminex® website at <http://www.luminexcorp.com/Support/index.htm> and click **Recommended Materials** from the **Support Resources** section for more information.

## Chapter 4: Samples Page

### Samples Page Overview



Use this tab for the following:

**Create New Samples** - Click to create a new sample.

**Protocol** - Displays the protocol selected in the **Samples** tab. If xPONENT® has a Laboratory Information System (LIS) license enabled, any sample details provided by the LIS also appear in the **Sample** list.

**Version** - Displays the protocol version number.

**Number of Samples** - Displays the number of samples that are in the protocol.

**NOTE:** If a protocol is created using the same name and version as a previously deleted protocol, previous, or pending are relinked to the added protocol.

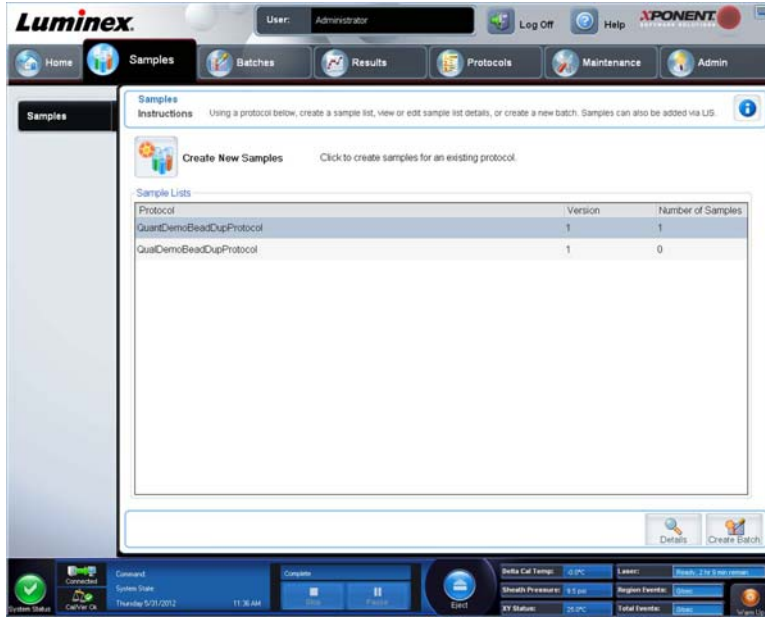
**Details** - Displays the details of the selected protocol.

**Create Batch** - Creates a new batch from the selected protocol.

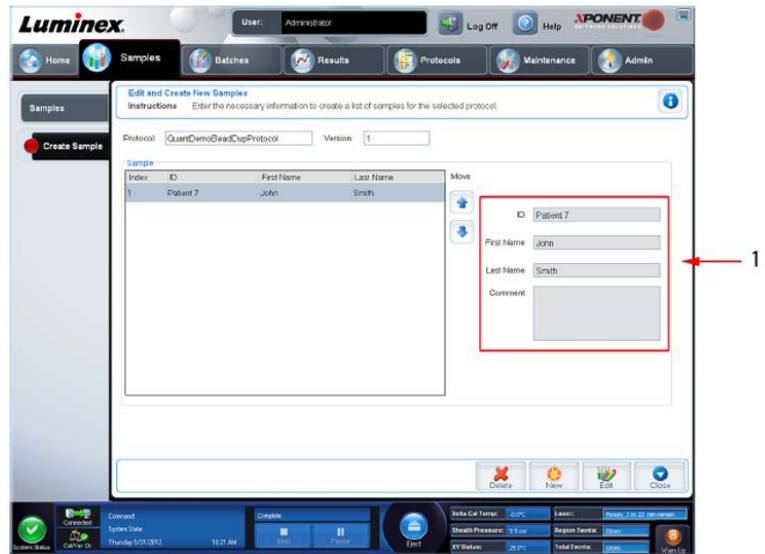
### Creating New Samples

Follow these steps to create a new sample list.

1. Open the **Samples** page.



2. In the **Sample Lists** section, select the protocol you are using for the sample list, then click **Create New Samples**. The **Create Sample** tab opens.



3. In the **ID** box, type the sample ID.



**WARNING:** You will not be warned if you create a sample ID that is the same as another.

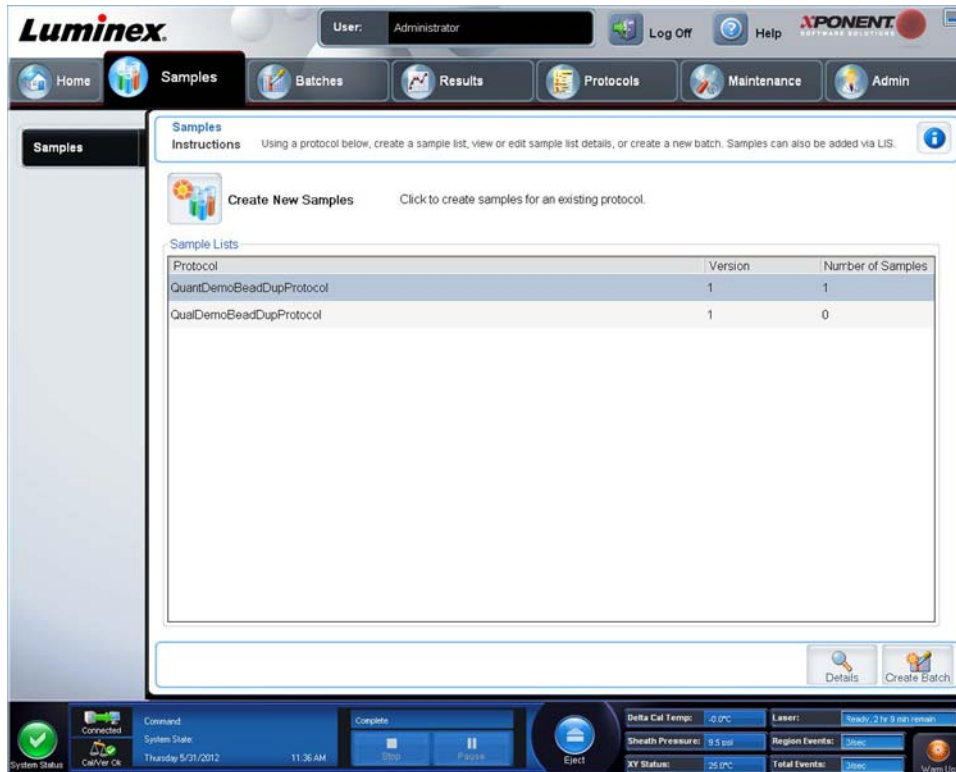
4. Type a patient first name in the **First name** box (optional).
5. Type a patient last name in the **Last name** box (optional).
6. Type any comments (optional).
7. Click **Save** to add the sample to the **Sample** list.
8. To add more samples, click **New**. Repeat the above until you have added all of the samples you want in your samples list.
9. Once you have added all the desired samples, click **Close**.



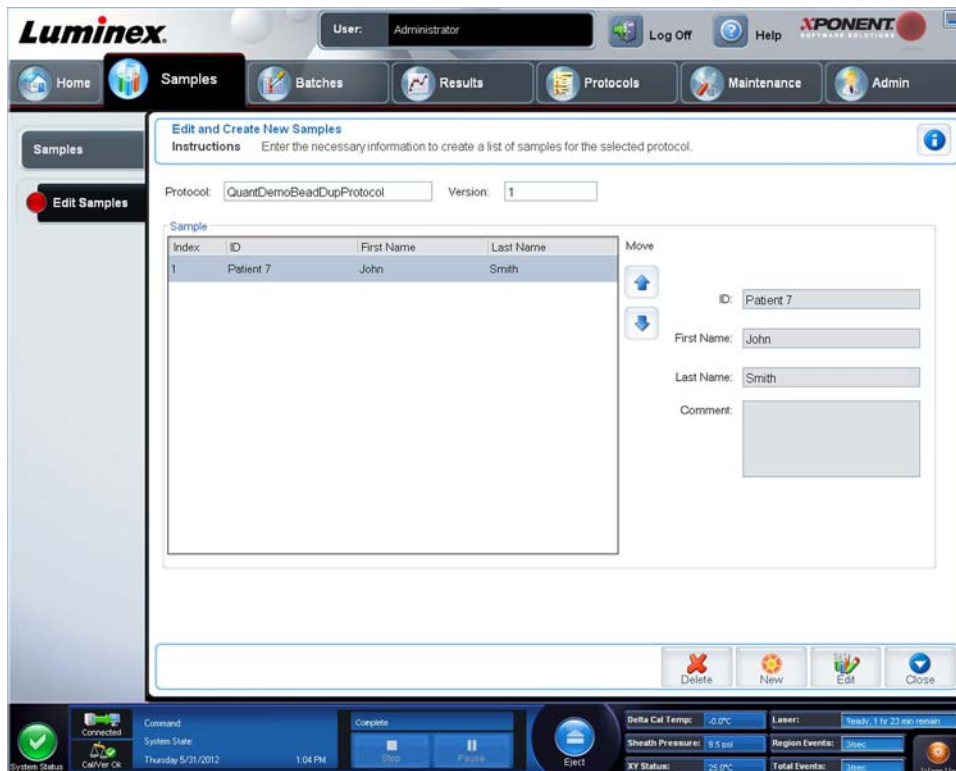
**NOTE:** Samples can also be added using an LIS.

## Editing a Sample List

1. Open the **Samples** page.



2. In the **Samples** list section, choose the protocol you want to edit, then click **Details**. The **Edit Samples** subtab opens.



3. Click a sample, then use the **Move** arrows to move it up or down in the sample list, changing the order in which they will be acquired.
4. To add a new sample to the list, click **New**, then perform the following steps:
  - a. In the **ID** box, type the sample ID.
  - b. Type a patient first name in the **First name** box if desired
  - c. Type a patient last name in the **Last name** box if desired.
  - d. To add a comment about the sample, type it in the **Comment** box; this is optional.
  - e. Click **Save** to add the sample to the **Sample** list.
5. To edit an existing sample, click the sample, then click **Edit**.
6. Once you have completed editing the sample list, click **Close**.

## Chapter 5: Batches Page

### Batches Page Functionality

The screenshot shows the Luminex xPONENT software interface. The top navigation bar includes tabs for Home, Samples, Batches, Results, Protocols, Maintenance, and Admin. The user is logged in as Administrator. The main content area is titled 'Batches' and contains the following sections:

- Instructions:** Create new batches with or without a protocol, or manage and run a pending batch.
- Create a New Batch from an existing Protocol:** Click to create a new batch from an existing protocol.
- Create a New Batch from a new Protocol:** Click to create a new batch without using a protocol.
- Create a New Multi-Batch:** Click to create a new multi-batch from pending batches.
- Pending Batches:** A table with columns: Name, Protocol, Protocol Version, Date, and Status. The table contains one entry: 'New Batch 1' with Protocol 'QualDemoBeadDupProto...', Protocol Version '1', Date '5/31/2012 2:35 PM', and Status 'Pending'.

At the bottom of the interface, there are buttons for 'Save Prtcl', 'Plate Layout', 'Import', 'Export', 'Delete', 'Edit', and 'Run'. The system status bar at the very bottom shows 'System Status' as 'Connected', 'Command' as 'System State', and 'Thursday 5/31/2012 2:35 PM'.

Options on the **Batches** tab on the **Batches** page are:

- Create a New Batch from an existing Protocol
- Create a New Multi-Batch

**NOTE:** These tabs (except New MultiBatch) are sequential. You must complete each screen in a specific order.

The **Pending Batches** list displays the name of the protocol used with the batch, the protocol version, date, and status for each pending batch. The following buttons only appear if the pending batches have data:



**WARNING:** Performing this action may result in varying results due to decreased bead counts, potential carry over effects, and time-sensitive reagents.

**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**.

**Import** - Imports a batch not previously run in xPONENT® from a folder on the PC into xPONENT.

**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.

**Delete** - Deletes a batch.

**Edit** - Edits a batch.

**Run** - Runs a batch.

## 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.

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



**WARNING:**

Human and animal samples may contain biohazardous infectious agents. Where exposure (including aerosol) to potentially biohazardous material exists, follow appropriate biosafety procedures and use personal protective equipment, such as gloves, gowns, laboratory coats, face shields, or mask and eye protection, and ventilation devices. Observe all local, state, and federal biohazard handling regulations when disposing of biohazardous waste material.

When setting up a batch, if the number of samples exceeds the number of wells in one microtiter plate, you can add additional plates in the **Add and Change Plate** secondary window. 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.

## Using the Batches Page

1. Open the **Batches** page.
2. Click one of the following:
  - **Create a New Batch from an Existing Protocol**
  - **Create a New Multi-Batch**
3. Type the batch name in the **Batch Name** box.
4. Type an optional description of the batch in the **Enter Optional Description** box.
5. If you are creating a batch from an existing protocol, select the protocol in the list. Click **Next**. If the protocol uses standards and/or controls, the **Stds & Ctrl**s tab displays.

**NOTE:** If you are creating a batch from a new protocol, the next steps do not apply. You have to add Acquisition Settings and Analysis Settings before moving to the next screen.

6. The **Stds & Ctrl**s tab appears. View the details of the active reagents, apply different assay standards/controls, or manually enter new information. Click **Next**.
7. On the **Plate Layout** tab, assign well commands for this batch.
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.

**NOTE:** If the batch spans more than one plate, the tray ejects automatically when all defined wells have been acquired. A dialog box displays prompting you to insert the next plate.

## Create a New Batch from an Existing Protocol

Read the instructions provided with the assay kit you are using.

1. Open the **Batches** page.
2. Click **Create a New Batch from an existing Protocol**.
3. Type the batch name in the **Batch Name** box.
4. Type a description about the batch in the **Enter Optional Description** box.
5. Click a protocol you wish to use in the **Select a Protocol** list.
6. Click **Next**. If the protocol uses standards, controls, or both, the next tab that opens is the **Stds & Ctrl**s tab. View the details of the active reagents or apply different assay standards, controls, or both or manually enter new information.

Select **Next**. If the selected protocol does not use standards, controls, or both, the next tab that opens is the **Plate Layout** tab.

7. On the **Plate Layout** tab, assign well commands for this batch. See *“Plate Layout Subtab”* for a complete description of the commands and options on this tab.
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.

**NOTE:** If the batch spans more than one plate, the tray ejects automatically when all defined wells have been acquired. A dialog box opens, prompting you to insert the next plate.

## Protocol Subtab

The screenshot shows the Luminex xPONENT software interface. The top navigation bar includes Home, Samples, Batches, Results, Protocols, Maintenance, and Admin. The Batches tab is selected, and the Protocol Subtab is active. The subtab displays the following information:

- Step 1: Select Protocol for "Protein Demo"**
- Instructions:** Name this batch and select a protocol. Press Next to continue.
- Batch Name:** Protein Demo
- Batch Description:** Example Assay
- Select a Protocol:**

Name	Version	Manufacturer	Date
QualDemoBeadDupProtocol	1	Imnx	3/2/2012 3:20 PM
QuantDemoBeadDupProtocol	1	Imnx	6/30/2011 3:29 PM
- Active Reagents:**
  - Stds/Ctrls Kit Name – Lot #: <None>
  - Standard Lots: <None>
  - Control Lots: <None>

At the bottom of the subtab, there are **Cancel** and **Next** buttons. The status bar at the bottom of the interface shows system information such as System Status, Connected, Command, System State, Thursday 5/21/2012, 1:10 PM, and various instrument parameters like Delta Cal Temp, Sheath Pressure, XY Status, Laser, Region Events, Total Events, and Warm Up.

Use this tab to name a batch, type a batch description, select a protocol, and view active reagents. This tab contains the following:

**Batch Name/Description** - Used to name and describe a batch.

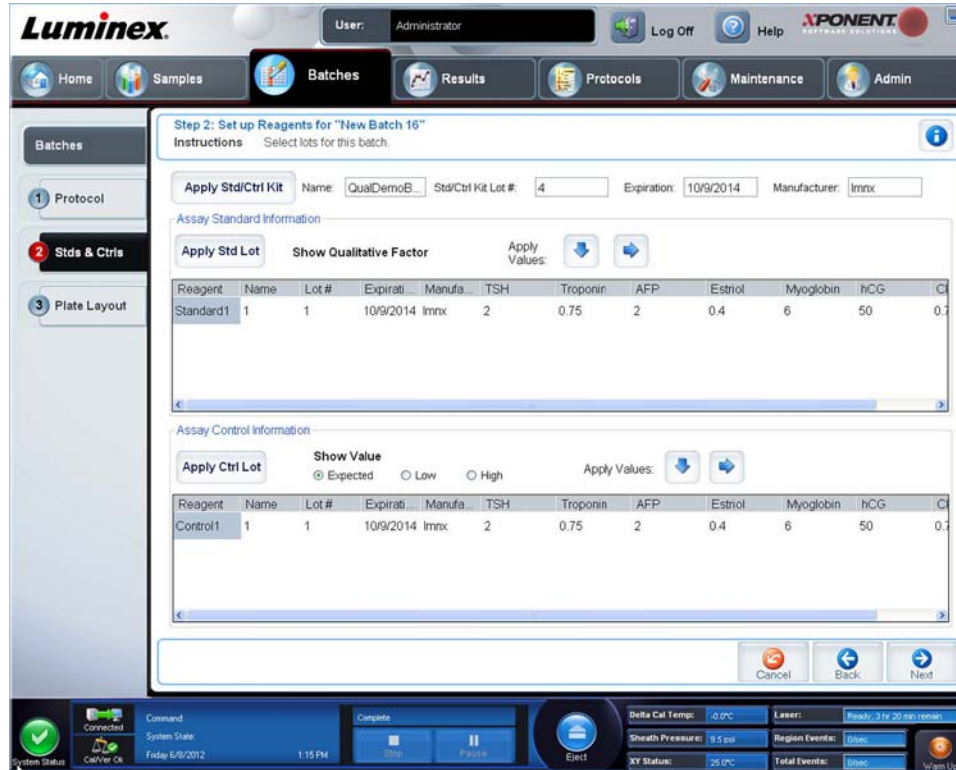
**Select a Protocol** - Contains the protocol name, version, manufacturer, and creation date for each protocol.

**Active Reagents** - Displays assay and control lots/kits associated with the selected protocol. The Standard/Ctrls Kit Name - Lot# field displays the assay **Stds/Ctrls Kit Name - Lot #** currently associated with the selected protocol. The **Standard Lots** and **Control Lots** fields display any standard or control lots associated with the selected protocol.

**Cancel** - Returns to the main **Batches** tab.

**Next** - If you have selected a protocol with no standards or controls (displayed as **None** in the **Active Reagents** section), clicking **Next** continues to the **Plate Layout** tab. If you have selected a protocol with standards and controls, clicking **Next** continues to the **Stds & Ctrls** tab.

## Standards and Controls (Stds &amp; Ctrls) Subtab



Use this tab to apply a kit or lot to the batch. This tab contains the following:

**Apply Std/Ctrl Kit** - Opens the **Select Std/Ctrl Kit** dialog box. The dialog box displays the **Std/Ctrl Kit Lot #**, **Std/Ctrl Kit Name**, **Expiration**, and **Manufacturer** for the kit. Select a **Std/Ctrl** kit from the list and then click **OK** to close the dialog box. The kit information will display in the boxes to the right of the **Apply Std/Ctrl Kit** button. The selected kit must be associated with the same analyte names. You can also type information by clicking in the **Name**, **Std/Ctrl Kit Lot #**, **Expiration**, and **Manufacturer** boxes and typing the information.

**Assay Standard Information** - Displays the selected standard reagents in a list. The list displays the **Reagent**, **Name**, **Lot #**, **Expiration**, **Manufacturer**, and expected concentration value of each analyte.

**NOTE:** Click a **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** - Opens the **Select Lot** dialog box.

Reagent	Name	Lot #	Expiration	Manufacturer	Std/Ctrl Kit N...	Std/Ctrl Kit #

Select a lot from the list and then click **OK** to apply the lot.

**Apply Values** - Applies a value across or down the **Reagent**, **Name**, **Lot #**, **Expiration**, and **Analyte** fields. Type a value in these fields by double-clicking on them, and then using one of the two **Apply Values** arrows to apply that value down or across the list of analytes.

**Dilution** - Contains the following dilution options:

- 1:2 - Halves the standard from each previous iteration.
- 1:10 (Log) - Computes a value of one-tenth of the standard from each previous iteration.
- 1/2 Log - Creates a 1:3.16 dilution, or half of each 1:10 (Log) from each previous iteration.

**Apply Dilution** - Applies the dilution selected in the **Dilution** list.

**NOTE:** The Dilution list and Apply Dilution button are displayed only if a quantitative analysis has been selected.

**NOTE:** You can also manually type a number to set your own dilution factor. It must be a whole number.

**Assay Control Information** - Lists the selected control reagents. The list displays the **Reagent, Name, Lot Number, Expiration,** and **Manufacturer.** Existing control lot information can be applied or new information can be typed manually.

- **Apply Ctrl Lot** - Opens the **Select Lot** dialog box. Select a lot from the list and then click **OK.**
- **Show Concentration** - 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.

**Cancel** - Returns to the **Batches** tab.

**Back** - Returns to the previous tab.

**Next** - Continues to the **Plate Layout** tab.

## Plate Layout Subtab

The screenshot displays the 'Plate Layout' subtab in the Luminox xPONENT software. The interface is divided into several sections:

- Navigation:** A top menu bar with icons for Home, Samples, Batches (active), Results, Protocols, Maintenance, and Admin. A user profile 'Administrator' is visible in the top right.
- Subtab Selection:** On the left, a vertical menu shows '1 Protocol', '2 Stds &Ctrls', and '3 Plate Layout' (selected).
- Instructions:** A text box at the top left of the main area provides instructions for adding samples and maintenance commands to the plate.
- Plate Grid:** A 96-well plate grid (8 rows A-H, 12 columns 1-12) is shown. Some wells are highlighted with colored circles (blue, green, red) corresponding to the command sequence.
- Command Sequence Table:** A table titled 'Command Sequence: Plate 1' lists the commands for each well.
 

Well	Type	ID	Dilution
1,A1	B	Background0	
1,B1	B	Background0	
1,C1	S1	Standard1	
1,D1	S1	Standard1	
1,E1	C1	Control1	1
1,F1	C1	Control1	1
- Controls:** Below the grid and table are various control buttons and options, including 'Replicate Count' (set to 2), 'Grouping' (1,2,3,1,2,3), 'Commands and Routines' (Add, Delete, Pre Batch Routine, Post Batch Routine), 'Plate' (Add Plate, Delete Plate), 'Direction' (Wash, Aspirate), 'Plate Navigation', and 'Off Plate Area'.
- Footer:** A status bar at the bottom shows system information like 'System Status', 'Command', 'System State', 'Wednesday 6/6/2012', '12:29 PM', 'Delta Cal Temp: 0.0°C', 'Laser: Ready 3.1r 30 rpm/min', 'Sheath Pressure: 9.5 psi', 'Region Events: Blank', 'XY Status: 25.0°C', 'Total Events: Blank', and a 'Warm Up' indicator.

Use this tab to define commands that apply to one or more wells. You can also define off-plate and maintenance commands. This tab contains the following:

**Plate Image** - This is a representation of the plate. Each well is displayed 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. The list includes all active wells, the type of command (Unknown, Standard, Control, Background, or assigned maintenance command), ID, and dilution factor. Double-click the **ID** field to type an ID. Double-click the **Dilution** field to type a dilution factor.

**NOTE:** A command's ID and Dilution fields have a blue border around them if they can be double-clicked to type information.

**Move Command** - These arrows move a selected command up or down in the Command sequence list, changing the acquisition order.

**Import List** - Opens the **Open** dialog box to import an existing command sequence list.

**NOTE:** A list of unknowns must be specified before importing a list without locations specified.

**Replicate Count** - Defines a quantity of replicate sets from one to nine.

**NOTE:** 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.

**NOTE:** Grouping selection must be made before adding a well command.

The options are:

- **123123123**. . . Lays out one of each replicate set at a time in numerical order.
- **111222333**. . . Lays out all the replicates in a set before moving on to the next set in numerical order.

You can assign the following well commands. Each command is associated with a color. You can 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.

- **Unknown (U):** Yellow
- **Background (B):** Purple
- **Control (C):** Red
- **Standard (S):** Green

The **Delete** and **Start at Well** commands are also available to assign as well commands. Delete removes the well command for the selected well. The **Start at Well** command enables you to begin acquisition at a well other than **A1**.

**NOTE:** 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.

**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.

**Commands and Routines** - Allows you to add and delete commands and routines, and to create pre and post batch routines. Select a well and then select the appropriate command:

- **Add**
- **Delete**
- **Pre Batch Routine**
- **Post Batch Routine**

**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.

Clicking either **Pre Batch Routine** or **Post Batch Routine** opens the **Commands and Routines** dialog box, where you can select the command or routine you want before or after running the batch. Clicking **Add** after selecting a well opens the same box for you to select a command or routine for that well. Clicking **Delete** after selecting a well deletes any commands or routines associated with that well.

**Plate** - Specifies the plate to display in the plate image in the list. Add Plate adds a new plate to the batch, and 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.

**NOTE:** All batches within a multi-batch must have the same direction and the same plate type.

**Plate Navigation** - Displays a smaller plate image for the current batch.

**Single Step** - Instructs the system to acquire one well and then stop. Use this to ensure the system is working correctly before you run the whole batch.

**Off-Plate Area** - Designates an alternate location for maintenance commands in the Commands and Sequence list.

**Save Prtcl** - Opens the **Save Protocol** dialog box to save the protocol and/or kit.

- Select **Save Protocol** and/or **Save Std/Ctrl Kit** to save the protocol and/or kit.
- Type information in the following boxes and click **Save** to save the protocol or kit.
  - **Protocol Name**
  - **Version**
  - **Manufacturer**
  - **Optional Description**
  - **Std/Ctrl Kit Name**
  - **Std/Ctrl Kit Lot#**
  - **Expiration**
  - **Manufacturer**
  - **Lots**

**Save** - Saves the information as a pending batch.

**Cancel** - Returns to the **Batches** tab.

**Back** - Returns to the previous window.

**Run Batch** - Runs the batch and opens the **Current Batch** tab, where you can monitor the batch as it runs.

## Settings Subtab

Use this tab to name your new batch and configure acquisition settings. For existing batches, you can view the acquisition parameters of the selected saved batch and print the batch settings report.

This tab contains the following:

- **Name** box and box for description - Type a name and a description in the appropriate boxes.
- **Acquisition Settings** - Use this section to set the following:
  - **Volume** - This is the volume the instrument will aspirate into the system for analysis. Type the desired sample volume in microliters. Use values from 20  $\mu$ L to 200  $\mu$ L. To avoid air intake, add at least 25  $\mu$ L to the sample well in addition to the sample size. The default value is 50  $\mu$ L.
  - **XY heater** - Select to enable the XY heater. In the box, type the desired value in degrees Celsius. The temperature range is 35°C to 60°C.



**CAUTION:** Acquiring data before the heater has reached the proper temperature can compromise test results.

- **Timeout** - Select the **Enabled** box to enable the Timeout.
- **Bead Type** - Check the **Bead Type** box. From the drop-down menu you can select MicroPlex® or MagPlex®.
- **Plate Name** - Select the plate name from the drop-down menu. Select **Current 96-well plate** or a plate that you have created.
- **DD Gating (Doublet Discriminator)** - 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** - Select Standard PMT from the drop-down menu to decrease the reporter gain.
- **Analysis Settings** - Displays the analysis type to be used for the batch.
  - Analysis Type** - Use this list to choose from the following analysis types:

- **None** - No analysis. Select 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.

$$(FI_{\text{sample}})/(FI_{\text{standard}}) = K_i$$

Where FI = Fluorescent Intensity and  $K_i$  = 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**. Type the desired values for standards and controls in the **Number of Standards** and **Number of Controls** boxes. Select either **Fit of All Standards** or **Mean of Replicates** for the calculation of the curve fit.

**NOTE:** 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** - Click to type the number of standards for the protocol.
- **Number of Controls** - Click to type the number of controls for the protocol.
- **Fit of All Standards** - The standard curve is determined by using each individual standard replicate when calculating the standard curve. For example, if you run duplicates of a 7-point standard curve, the software will calculate the standard curve by using 14-points.
- **Mean of Replicates** - The standard curve will be determined by averaging the individual standard replicates when calculating the standard curve. For example, if you run duplicates of a 7-point standard curve, the software will calculate the standard curve by using 7-averaged points.
- **Analyze Results While Acquiring Samples** - The software allows for real-time viewing of the results as the instrument analyzes samples.
- **Use External Analysis Program** - Select this check box to use a third-party program to analyze the data. The **Analysis Program** list becomes active when this is selected.
- **Analysis Program** - Use this list to select which program to use for data analysis.
- **Cancel** - Click to return to the main **Batches** tab.
- **Next** - Click to advance to the **Analytes** tab.

## Analytes Tab

Use this tab to select or edit analytes used in the batch or protocol.



This tab contains the following:

**Default Analysis** - The default analysis changes based on the **Analysis Type** selected in the **Settings** tab. You can change the analysis settings for all analytes by clicking **Change** if this button is enabled in this tab. This displays the **Analysis Settings** dialog box:



If you selected **Quantitative** on the **Settings** tab, the default analysis formula is 5P Weighted. To change the default, select one of the following from the **Method** list:

- No Analysis
- Cubic Spline
- Linear Fit
- Logistic 4P
- Logistic 5P

If you selected **Logistic 4P** or **Logistic 5P**, select a weight type of either **None** or **1/y<sup>2</sup>**.

If you selected **Qualitative** on the **Settings** tab, the default analysis is **Luminex Qualitative**. Change the default value by selecting either **Luminex Qualitative** or **No Analysis**.

Click **Apply to All Analytes** to apply your selection to all selected analytes. Click **OK** to change the default analysis to the analysis you selected. Click **Cancel** to close the dialog box without saving. For more information, see the “*Analysis Settings*” section.

**Units** - Type the desired units for the analytes in this box.

**Count** - Type the desired bead count for the analytes by clicking in the **Count** box. 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. If you select bead sets that are not present, the analyzer continues to acquire, trying to reach the number of events per bead for bead sets that are not in the sample. Therefore, choose only the bead sets present in your sample.

**Apply All** - Applies the information in the **Units** and **Counts** boxes to all analytes.

**Total Count** - Select **Stop** after bead count reaches: to stop acquisition when the bead count reaches a certain number determined by the user. Type the desired value in the box. The default value is 100.

You can also specify the minimum allowable bead count per well that the xPONENT® software analyzes. This excludes data from any beads carried over during acquisition.

**Selected Analytes List** - Selected analytes appear in a list on the right side of the analyte grid. This list includes the following information:

- **Name** - The name of the analyte. Click and type to rename the analyte.
- **Analysis** - To change the type of analysis for an analyte, click this field to open the **Analysis Settings** dialog box and select another analysis from the list.
- Select a method from the **Method** list.
- If necessary, select a weight type from the **Weight Type** list.
- Apply the analysis to all analytes in the list by clicking **Apply to All Analytes**.
- Select **Mark as Intra-Well Normalization Bead** to make the analyte an intra-well normalization bead.
- Add a range to the analysis by clicking **Add Range**.
- Select **Use Threshold Ranges** to enable ranges for the analysis.
- Click **Add Range** to add a range.
- Type a **Range Name**, a **Low Value**, a **High Value**, and select **Inclusive** if you wish to include the low and high values in the range. Click **OK** to exit the dialog box.
- **Units** - The unit of measurement you specified in the **Unit** box. Click this box to type a value for the analyte.

**Cancel** - Click **Cancel** to return to the **Batches** tab.

**Back** - Click **Back** to return to the **Settings** tab.

**Next** - Click to go to the next tab. If the **Analysis Type** selected in the **Settings** tab was **None**, this takes you to the **Plate Layout** tab. If the **Analysis Type** selected was **Quantitative** or **Qualitative**, this button takes you to the **Stds & CtrlIs** tab.

## Standards and Controls (Stds &amp; Ctrls) Subtab

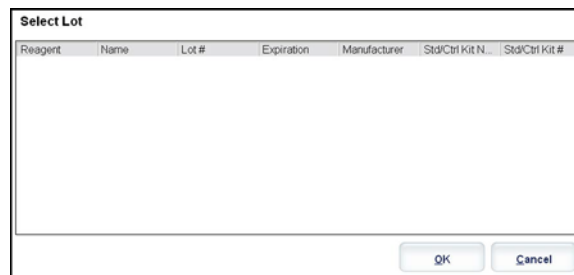


Use this tab to apply a kit or lot to the batch. This tab contains the following:

- **Apply Std/Ctrl Kit** - Opens the **Select Std/Ctrl Kit** dialog box. The dialog box displays the **Std/Ctrl Kit Lot #**, **Std/Ctrl Kit Name**, **Expiration**, and **Manufacturer** for the kit. Select a **Std/Ctrl** kit from the list and then click **OK** to close the dialog box. The kit information will display in the boxes to the right of the **Apply Std/Ctrl Kit** button. The selected kit must be associated with the same analyte names. You can also type information by clicking in the **Name**, **Std/Ctrl Kit Lot #**, **Expiration**, and **Manufacturer** boxes and typing the information.
- **Assay Standard Information** - Displays the selected standard reagents in a list. The list displays the **Reagent**, **Name**, **Lot #**, **Expiration**, **Manufacturer**, and expected concentration value of each analyte.

**NOTE:** Click a **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** - Opens the **Select Lot** dialog box.



- Select a lot from the list and then click **OK** to apply the lot.
- **Apply Values** - Applies a value across or down the **Reagent**, **Name**, **Lot #**, **Expiration**, and **Analyte** fields. Type a value in these fields by double-clicking on them, and then using one of the two **Apply Values** arrows to apply that value down or across the list of analytes.
- **Dilution** - Contains the following dilution options:
  - 1:2 - Halves the standard from each previous iteration.
  - 1:10 (Log) - Computes a value of one-tenth of the standard from each previous iteration.
  - 1/2 Log - Creates a 1:3.16 dilution, or half of each 1:10 (Log) from each previous iteration.
- **Apply Dilution** - Applies the dilution selected in the **Dilution** list.

**NOTE:** The **Dilution** list and **Apply Dilution** button are displayed only if a quantitative analysis has been selected.

**NOTE:** You can also manually type a number to set your own dilution factor. It must be a whole number.

- **Assay Control Information** - Lists the selected control reagents. The list displays the **Reagent, Name, Lot Number, Expiration, and Manufacturer**. Existing control lot information can be applied or new information can be typed manually.
  - **Apply Ctrl Lot** - Opens the **Select Lot** dialog box. Select a lot from the list and then click **OK**.
  - **Show Concentration** - **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.
- **Cancel** - Returns to the **Batches** tab.
- **Back** - Returns to the previous tab.
- **Next** - Continues to the **Plate Layout** tab.

## Plate Layout Subtab

The screenshot displays the 'Plate Layout' subtab in the Luminex xPONENT software. The interface is divided into several sections:

- Navigation:** A top menu bar with 'Home', 'Samples', 'Batches', 'Results', 'Protocols', 'Maintenance', and 'Admin'. A left sidebar shows '1 Protocol', '2 Stds & Ctrls', and '3 Plate Layout' (selected).
- Instructions:** A text box at the top of the main area: "Step 3: Plate Layout for 'New Batch 14'. Instructions: Select wells to add samples and maintenance commands to the plate. Edit the sample ID and Dilution factor in the command list, and choose the direction in which to run the plate."
- Plate Grid:** A 96-well grid (rows A-H, columns 1-12). Well 1,A1 is highlighted with a blue circle. Other wells have colored circles: 1,B1 (blue), 1,C1 (green), 1,D1 (green), 1,E1 (red), 1,F1 (red).
- Command Sequence Table:**

Well	Type	ID	Dilution	Move Command
1,A1	B	Background0		↑
1,B1	B	Background0		↓
1,C1	S1	Standard1		
1,D1	S1	Standard1		
1,E1	C1	Control1	1	
1,F1	C1	Control1	1	
- Controls:**
  - Replicate Count:** Set to 2.
  - Grouping:** 1 2 3 1 2 3.
  - Commands and Routines:** Add, Delete, Add Plate, Delete Plate, Pre Batch Routine, Post Batch Routine, Start at Well.
  - Plate:** Set to 1.
  - Direction:** Wave icon selected.
  - Off Plate Area:** A small grid with colored bars.
- Bottom Status Bar:** Shows 'System Status' (green), 'Command' (Completed), 'System State' (Ready), 'Date/Time' (Wednesday 6/6/2012 12:29 PM), 'Delta Cal Temp: 0.0°C', 'Sheath Pressure: 9.5 psi', 'XY Status: 25.0°C', 'Laser: Ready, 3 hr 30 min remain', 'Region Events: Blank', 'Total Events: Blank', and 'Warm Up' button.

Use this tab to define commands that apply to one or more wells. You can also define off-plate and maintenance commands. This tab contains the following:

- **Plate Image** - This is a representation of the plate. Each well is displayed 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. The list includes all active wells, the type of command (Unknown, Standard, Control, Background, or assigned maintenance command), ID, and dilution factor. Double-click the **ID** field to type an ID. Double-click the **Dilution** field to type a dilution factor.

**NOTE:** A command's ID and Dilution fields have a blue border around them if they can be double-clicked to type information.

- **Move Command** - These arrows move a selected command up or down in the **Command Sequence** list, changing the acquisition order.
- **Import List** - Opens the **Open** dialog box to import an existing command sequence list.  
**NOTE:** A list of unknowns must be specified before importing a list without locations specified.
- **Replicate Count** - Defines a quantity of replicate sets from one to nine.  
**NOTE:** 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.  
**NOTE:** Grouping selection must be made before adding a well command.

The options are:

- **123123123**. . . Lays out one of each replicate set at a time in numerical order.
- **111222333**. . . Lays out all the replicates in a set before moving on to the next set in numerical order.

You can assign the following well commands. Each command is associated with a color. You can 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.

- **Unknown (U):** Yellow
- **Background (B):** Purple
- **Control (C):** Red
- **Standard (S):** Green

The **Delete** and **Start at Well** commands are also available to assign as well commands. **Delete** removes the well command for the selected well. The **Start at Well** command enables you to begin acquisition at a well other than **A1**.

**NOTE:** 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.

**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.

**Commands and Routines** - Allows you to add and delete commands and routines, and to create pre and post batch routines. Select a well and then select the appropriate command:

- **Add**
- **Delete**
- **Pre Batch Routine**
- **Post Batch Routine**

**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.

Clicking either **Pre Batch Routine** or **Post Batch Routine** opens the **Commands and Routines** dialog box, where you can select the command or routine you want before or after running the batch. Clicking **Add** after selecting a well opens the same box for you to select a command or routine for that well. Clicking **Delete** after selecting a well deletes any commands or routines associated with that well.

- **Plate** - Specifies the plate to display in the plate image in the list. **Add Plate** adds a new plate to the batch, and **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.
- **Single Step** - Instructs the system to acquire one well and then stop. Use this to ensure the system is working correctly before you run the whole batch.
- **Off-Plate Area** - Designates an alternate location for maintenance commands in the **Commands and Sequence** list.
- **Save Prtcl** - Opens the **Save Protocol** dialog box to save the protocol and/or kit.
  - Select **Save Protocol** and/or **Save Std/Ctrl Kit** to save the protocol and/or kit.
  - Type information in the following boxes and click **Save** to save the protocol or kit.
    - **Protocol Name**
    - **Version**
    - **Manufacturer**
    - **Optional Description**
    - **Std/Ctrl Kit Name**
    - **Std/Ctrl Kit Lot#**
    - **Expiration**
    - **Manufacturer**
    - **Lots**
  - **Save** - Saves the information as a pending batch.
  - **Cancel** - Returns to the **Batches** tab.
  - **Back** - Returns to the previous window.
  - **Run Batch** - Runs the batch and opens the **Current Batch** tab, where you can monitor the batch as it runs.

## Create a New Multi-Batch

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

You must ensure that the batches fit on one plate. After you add each batch, the software automatically adds the next batch to the first well of the next column or row (depending on your plate orientation) as long as space is available on the plate. You can also select a well first, which places the next batch in your chosen location. If space limitations create an overlap, an error message appears. Results for each batch are saved as individual batch files.

**NOTE:** You cannot add a batch that forces multiple plates to a multi-batch operation. When creating or adding batches, ensure your batches fit on one plate. All batches must use the same plate name previously defined and adjusted. All batches must also specify the same direction.

This tab contains the following:

**Select Pending Batch** - Contains a list of all pending batches. The list includes name, protocol, protocol version, date, and status information for each pending batch. Select the batch you want to add to the plate. Click **OK**. A plate layout diagram automatically populates the wells for the batch. Click **Add** to open this box again and add additional batches.

**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 that contains:

- **Page** - Use these arrows to scroll through the report pages.
- **Zoom** - Select from the list to change the report magnification.
- **Print** - Prints report.
- **Save** - Saves report.
- **Close** - Closes 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** - Opens the **Create New Batch** tab. Create your new batch. Click **Save** to return to the **New Multi-batch** tab.

**Add** - Opens the **Select Pending Batch** box. Add a batch from the available options, including batches newly created. The selected batch then appears on the plate layout. If the batches selected do not fit on the plate, a **Multi-Batch** error dialog box opens, indicating you must edit one or more of the selected batches. The Multi-batch feature will automatically set the batches

side-by-side if space remains on the plate. 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.

**Cancel** - Returns to the main **Batches** tab without saving.

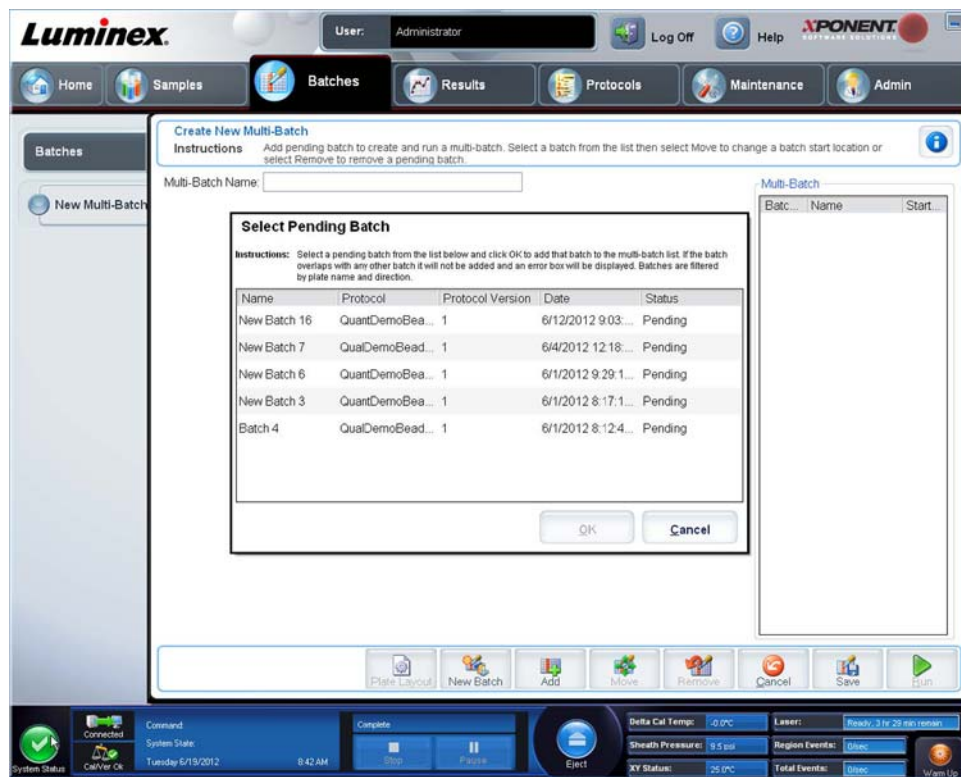
**Save** - Saves the batch.

**Run** - Runs the batch

## Creating a New Multi-Batch

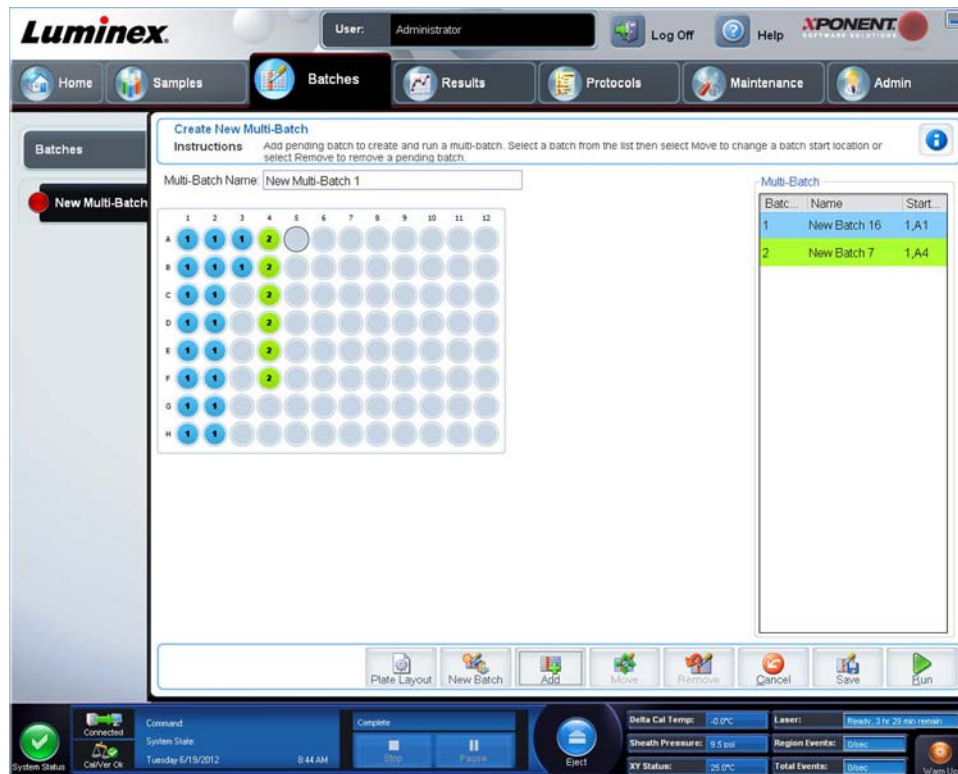
Use the **Create a New Multi-Batch** button to add or remove batches to the multi-batch set up and to run a multi-batch.

1. Select the pending batch from the **Select Pending Batch** dialog box.



2. Once you have selected a batch click **OK**.

- On the next screen, select a well location for the next batch and click **Add**.



- Once the batches are created, click **Run**.

After creating a multi-batch, you can save it to the **Select Pending Batch** list. When saved to this list, the protocol appears as “Multibatch.”

To save a Multi-Batch:

- Create a new Multi-Batch.
- Select a pending batch.
- Type the name for the **Multi-Batch Name** field.
- Click **Save**. You are returned to the **Batches** page, and the multi-batch is added to the pending batches list.

**NOTE:** Batches saved to a multi-batch cannot be edited or deleted unless they are removed from the multi-batch. However, you can edit the multi-batch itself. To remove a batch from a multi-batch, click a well in the plate layout, and click **Remove**.

## Batch Procedures

### Running a Pending Batch

Open the **Batches** page. Select the pending batch that you want to run, then click **Run**.

**NOTE:** 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.

### Importing a Batch

You only need to import batches to the system once. You must type 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.

To import a batch:

- Open the **Batches** page.

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

### Exporting a Batch

1. Open the **Batches** page.
2. In the **Pending Batches** section, click the batch you want to export, then click **Export**. The **Export Batch** dialog box opens.
3. Click **Browse**. The **Select File** dialog box opens.
4. Navigate to the location to which you want to save the file, then click **Save**.
5. Click **OK** in the **Export Batch** dialog box.

**NOTE:** When exporting a large batch and including the LXB files, such as a batch with hundreds of wells or hundreds of analytes, the export process can take 10 minutes or more.

### Editing a Batch

1. Open the **Batches** page.
2. Click the batch you want to edit, then click **Edit**. The **Protocol** tab opens.
3. Edit the information as needed on the **Protocol**, **Std & Ctrl**s, and **Plate Layout** tabs.
4. Click **Save** on the **Plate Layout** tab.

### Deleting a Batch

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

To delete a batch:

1. Open the **Batches** page.
2. In the **Pending Batches** section, click the batch you want to delete, then click **Delete**. The **Delete Pending Batch** dialog box opens.
3. Click **Yes**.

**NOTE:** You can remove a batch that includes results only through the Archive Utility. See [“Archive Utility”](#).

## Chapter 6: Results Page

### Results Page

Once data is collected in a batch, observation and analysis take place in the **Results** page. This page contains the following tabs:

**Current Batch** - View statistics for the current run and progress per well.

**Saved Batches** - View information about already processed batches and if necessary, replay them or recalculate their data.

- From the **Saved Batches** tab, select the **Open** button located at the bottom right of the screen. Four subtabs will open:
  - **Results** - Shows the results of a new or saved batch.
  - **Settings** - Shows the report type you selected.
  - **Log** - Information about acquisition.
  - **Sample Details** - Details about the sample.
- From the **Saved Batches** tab, select the **Replay** button located at the bottom right of the screen. A dialog box will display **Recalculate data** and **Replay batch**. Select either **Replay batch** or **Recalculate data**. Three subtabs will open:
  - **Protocols**
  - **Stds & Ctrl**s
  - **Plate Layout**

**LIS Results** - View a batch or transmit a batch that contains LIS results.

**Reports** - This enables you to select a report to view.

From the **Report** drop-down box you can choose the **Type** of report to view.

- **Batches Reports**
  - **Data Interpretation**
  - **Batch Settings**
  - **Plate Layout**
  - **Batch Audit**
  - **Patient Report**
- **Protocol Reports**
  - **Protocol Settings**
  - **Plate Layout**
  - **Protocol Audit**
- **Calibration and Verification Reports**

**NOTE:** **Calibration and Verification Reports** gives you **Dates** fields to select which dates to view the report.

- **All**
- **F3DCAL1**
- **F3DeCAL1**
- **F3DCAL2**
- **F3DCaL3**
- **F3DVER1**
- **F3DeVER1**
- **F3DVER2**

- Fluidics
- Performance Verification Reports

**NOTE: Performance Verification Reports** gives you **Dates** fields to select which type of report you want to view between specified dates. You can specify the type of report you want from the drop-down menu. You can choose from:

- Condensed
- Detailed
- System Log Reports
  - All
  - Maintenance
  - Security
  - Warning and Errors
- Advanced Reports
  - User Report

## Performing Analysis

You may 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.

For Quantitative batches, quantitative results can be viewed on the Standard Curve.



## Current Batch Tab

Use this 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 intrawell 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 one to maximize the pane. After clicking, the clicked button becomes a minimize button. Click minimize to return the pane to its standard size.

**NOTE:** The buttons on this tab change based on settings chosen on other application pages.

The screenshot shows the Luminex xPONENT 4.2 software interface. The top navigation bar includes Home, Samples, Batches, Results (selected), Protocols, Maintenance, and Admin. The main content area is titled 'Current Batch' and displays 'Now displaying batch "New Batch 8"'. Below this, there are instructions and a 'Results' section with a table of data. The table has columns for Well, Sample, Run Sta., Normalized..., TSH, Troponin, AFP, Estriol, Myoglobin, and hCG. The data rows are: 1,A1 Background0 Error NaN NaN NaN NaN NaN NaN NaN; 1,B1 Background0 Error NaN NaN NaN NaN NaN NaN NaN; 1,C1 Standard1; and 1,D1 Standard1. Below the table are two histograms: 'Double Discriminator' and 'Classification 1'. At the bottom, there is a message log with two entries: 'Batch "New Batch 8" aborted.' and 'Batch "New Batch 8" results exported to "C:\Documents and Settings\All Users\Application Data\Luminex\XPONENT42\Output"'. The Windows taskbar at the bottom shows the system status, date (Tuesday 6/5/2012), time (3:20 PM), and various system icons.

The **Current Batch** tab has the following features:

- **Statistic** - To view a particular statistic for analytes in a batch, select one of the options on the drop-down list. The statistical options displayed change according to the type of analysis.
  - **Median (MFI)** - The point is a data set where there are as many values occurring above it as there are below it.
  - **Net MFI (Median Background)** - Net MFI median background.
  - **Count** - Gated events, if gates are set.
  - **% CV of microspheres** - The measure of relative dispersion within the distribution.
  - $\%CV = 100 \times \text{Std Dev} / \text{Mean}$
  - **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.
  - **Trimmed Count**
  - **Trimmed % CV of Microspheres**
  - **Trimmed Standard Deviation**
  - **Trimmed Peak**

\* Trimmed statistics remove the lower and upper 5% of the extreme statistic values, then use the remaining values for the **Standard Deviation**, or **%CV** calculations.

The statistics displayed change according to the analysis type selected.

- **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** - Instrument analyzes one well at a time. Click to turn function on or off. This is useful to run prior to running an entire batch to confirm that the system is set up correctly.
- **Results** pane - 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 **maximize/minimize** toggle button expands the batch table and returns it to the standard size.

**Plate** - Select the plate you want to view, if there is more than one plate.



**WARNING:** 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 pane** - This pane displays a representation of the plate and the status of acquired wells. Each well displays one of three possible states:

- **Histogram/Dot Plot** - Displays real-time monitoring of batch sampling during acquisition. Both the histogram and the dot plot have buttons that enable you to change the default view:
  - Click the **maximize** button to maximize the graph to fill the whole window. In the maximized view, use sliders to zoom in or zoom out. To return to the standard view, click the **minimize** button. If the histogram or dot plot display have been changed to another view (e.g. **Progress, Well Report**), click **Default** to return to the default histogram and dot plot displays.
  - 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.
- **Histogram** - The default location of the histogram is the lower left section of the **Current Batch** tab. The **Doublet Discriminator (DD)** displays on the X-axis. Events display on the Y-axis. Doublets appear when two beads stick together, creating undesired results. When you select the gate, two vertical dashed red lines appear. These represent gate positions determined by the protocol. Once the gate is set, everything outside of it is ignored. For batches created using an existing protocol, the gate cannot be changed while running the batch. For new batches created from new protocols, the gate can be changed while running the batch. Any changes made to the gate while running new protocol batches immediately affect the visual display of the dot plot and histogram. In addition, changes made to the gate while running new protocol batches affect the acquisition for all wells initiated after the change is made. When viewing saved batch data, the gate can be changed to visually inspect the effect. Only the visual display of the dot plot and histogram is affected for saved batches, not the acquired data.

**NOTE:** Gate positions are dependent upon buffer composition. Any changes made to your assay buffer composition may result in a different optimal gate location.

Right click inside the histogram area to access the following options:

**X-Axis** - Use this function to change the X-axis to the following: Doublet Discriminator, Reporter 1, Classification 1, Classification 2, and Classification 3. Doublet Discriminator is the default.

**NOTE:** You can change the X-axis of the histogram for troubleshooting purposes. Use only the default settings in all other instances.



- **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** - The **Set Scale** dialog box displays. Set the maximum number of events and click **OK**. The default number of events is 60.
- **View** - You can choose to view all events or only gated events.
- **Display Mode** - Opens the **Histogram Options** dialog box. Click either **Logarithmic** or **Linear** display. **Logarithmic** display is the default. Select the **Zoom** check box for a magnified view of the histogram.
- **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. Luminex recommends using the default settings to collect data.

Right-click inside the dot plot area to access the following options:

- **X-Axis** - Changes the X-axis to the following: Doublet Discriminator, Reporter 1, Classification 1, Classification 2, and Classification 3.

**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.
- **View** - Choose to view all events or only gated events.
- **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.

**NOTE:** The Density Plot allows the visual elimination of data values that are determined to be insignificant to the display. Luminex recommends collecting data in Density Plot mode to observe all collected events.

You can only view the Decaying Plot during batch acquisition.

Right-click inside the dot plot area to access the following options:

- **Log** - Displays a log of system processes. The log includes the following information:
  - **Date**
  - **Message**
  - **Code**

Log entries indicating warnings are highlighted in yellow. Errors are highlighted in red. Other log entries are not highlighted. Click the maximize button to maximize the log. The log expands to fill the whole window. Click minimize to return to the standard size.

- **Save Image** - Opens a **Save As** dialog box to save a screen capture.
- **Details** - Opens the **Results** tab, enabling more analysis and results.
- **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** displays scrolls through the analyte list.
  - **Maximize** - Maximizes the **Progress** display to fill the window.
  - **Zoom** - Enable a closer look at the analyte progress.
  - **Save Image** - Opens a **Save As** dialog box to save a screen capture.
  - **Default** - Returns to the histogram and dot plot display.
- **Well Report** - Displays a representation of the plate and the status of acquired well. Wells will display one of three possible states:

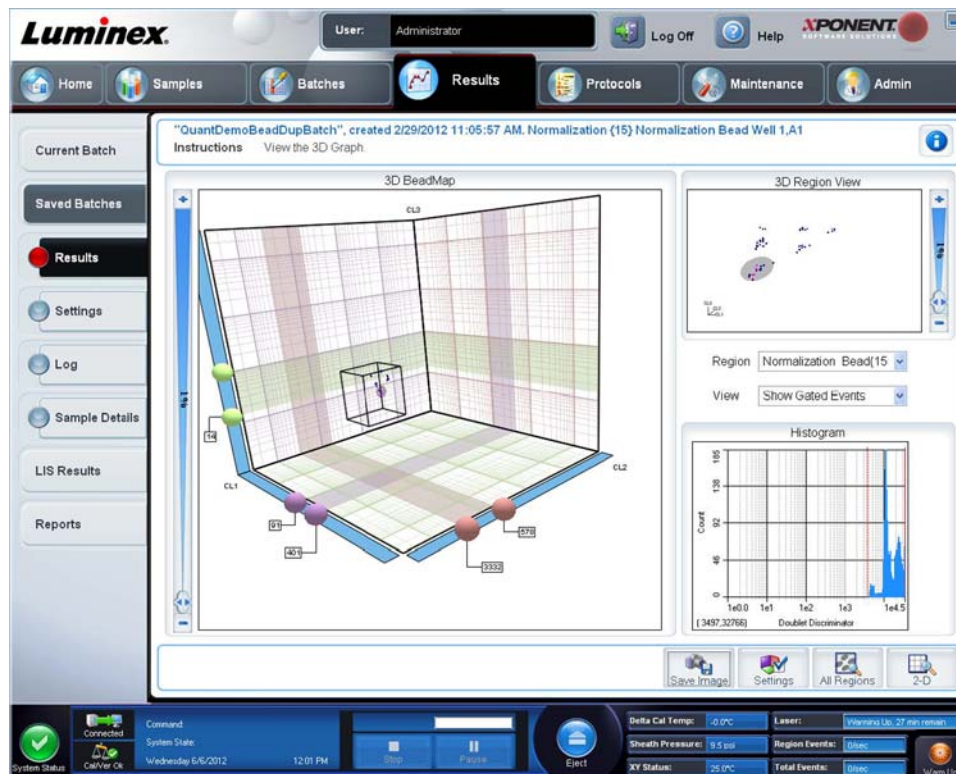
- **Yellow** - Well acquired, but the system detects a possible problem (select the **Log** tab for more information).
- **Green** - Well acquired successfully.
- **Red** - Well acquisition unsuccessful, the system may have stopped, depending on the circumstances (select **Log** tab for more information).

- **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.

**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.

Click the **Settings** button at the bottom to display:

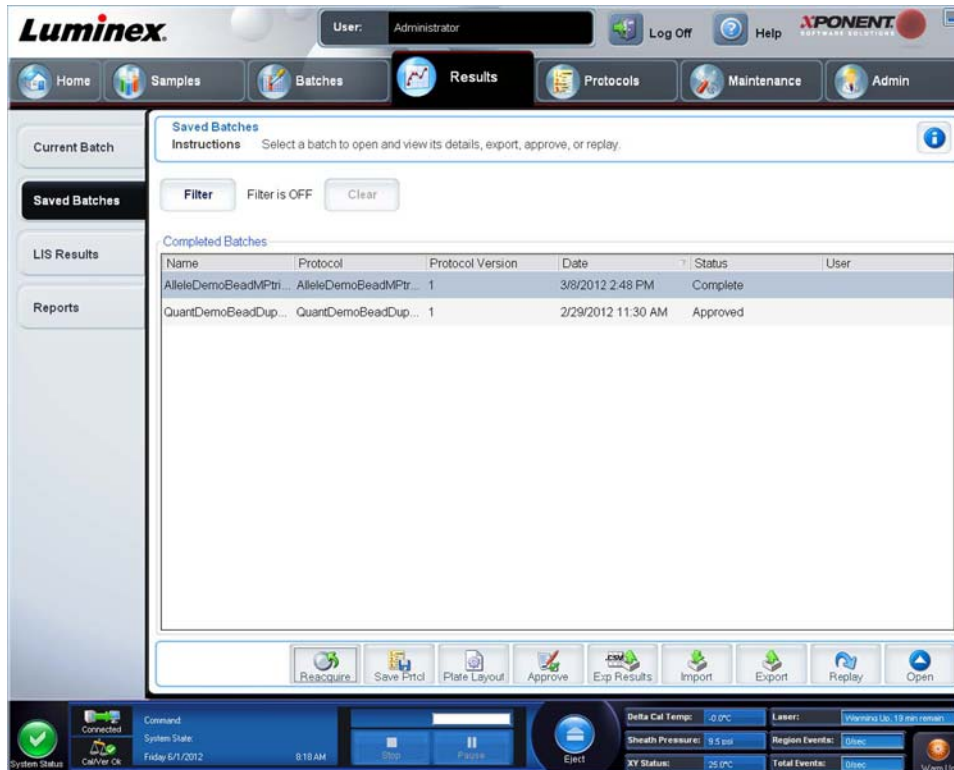
- **Show Regions**
  - 3D
  - CL1/CL3 Plane
  - CL2/CL3 Plane
  - CL1/CL2 Plane
- **Show Beads**
  - 3D

- **CL1/CL3 Plane**
- **CL2/CL3 Plane**
- **CL1/CL2 Plane**
- **View**
  - **Show Cursors**
  - **Show Region Labels**
  - **Show 3D Region View Box**
- **Display Mode**
  - **Logarithmic**
  - **Linear**
- **Display Position**
  - **3D View**
  - **CL1/CL3 Plane**
  - **CL2/CL3 Plane**
  - **CL1/CL2 Plane**
- **View**
  - **All Events**
  - **Gated Events**
- **Show Cursors**
- **Show Region Labels**
- **Show 3D Region View Box**
- **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** - A list that 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 the following options:

These settings are also available on the toolbar of the main 3D display:

- **Save Image** - Saves the current 3D image.
- **Settings** - Saves the settings to view different angles.
- **All Regions** - Displays all regions of the batch.
- **2D** - Returns to the default display.

## Saved Batches Tab



Use this tab to open a batch that has been run and view its details, and to export, approve, or replay a batch.

Select a **Completed Batch** and click **Open** to view the batch details.

The **Saved Batches** tab has four subtabs:

- Click the **Results** subtab to view statistical information about the batch.
- Click the **Settings** subtab to view the batch settings report.
- Click the **Log** subtab to view a log for the activity that occurred during acquisition of the selected batch.
- Click the **Sample Details** tab to view sample details for each sample in the batch.

When the **Saved Batches** tab opens, it includes the following features:

**Filter** - Click **Filter** to open the **Filter Setup** dialog box.

**Filter Setup**

Batch Specific Details

Batch Name:   Lot ID:

Protocol:   Kit ID:

Batch Status:   Analyte:

Sample Details

Sample ID:   First Name:

Last Name:

Others

User ID:

Date: From  To

This dialog box lets you choose the saved batches you want to display in the **Completed Batches** list, based on options you select or clear in these check boxes:

- **Batch Name**

- **Protocol**
- **Batch Status**
- **Lot ID**
- **Kit ID**
- **Analyte**
- **Sample ID**
- **First Name**
- **Last Name**
- **User ID**
- **Date**
- **Reset** - Clears all check boxes.
- **OK** - Closes the dialog box and applies any changes you made.
- **Cancel** - Closes the dialog box and cancels any changes that you made.

When you fill in the **Filter Setup** box and click **OK**, the message **Filter is on** is displayed on the **Saved Batches** page. To turn off the filter, click **Clear**.

**Completed Batches** table - This displays a list of completed batches, including the **Name, Protocol, Protocol Version, Date, Status,** and **User information** for each batch. This list does not include batches that have not been run.

There are more **Results** options at the bottom of the **Saved Batches** screen.



**WARNING:** Performing this action may result in varying results due to decreased bead counts, potential carry effects, and time-sensitive reagents.

**Save Prtcl** - Opens the **Save Protocol** dialog box, displaying the kit information for the selected batch.

**Save Protocol**

Save Protocol

---

Protocol Name:

Version:  Manufacturer:

*Enter optional description here*

---

Save Std/Ctrl Kit

Std/Ctrl Kit Name:  Std/Ctrl Kit Lot#:

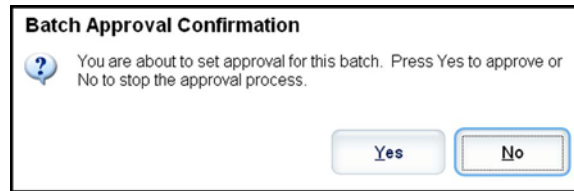
Expiration:  Manufacturer:

Lots:

Reagent	Name	Lot #	Expiration	Manufacturer
Standard1		3	12/31/2012	av
Control1		3	12/31/2012	aaabb
Control2		4	12/31/2012	ab

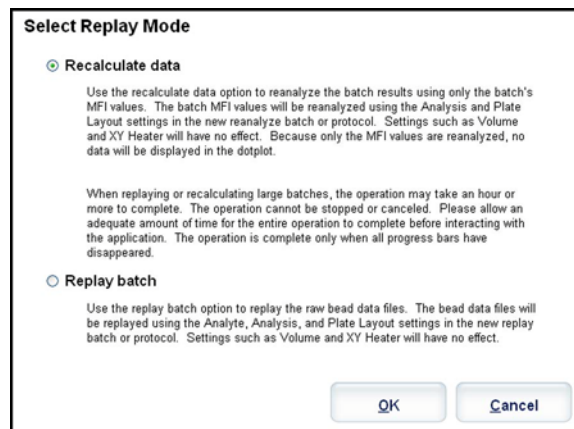
- **Plate Layout** - Opens the **Report** dialog box, which contains the **Batch Plate Layout Report**.

- **Approve** - Opens the **Batch Approval Confirmation** dialog box to approve the selected batch.



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 **Sample Results** tab. After you have approved a batch, the status of the batch changes to **Approved** in the **Complete Batches** list.

- **Exp Results** - Opens the **Save As** dialog box to choose an export destination for the .CSV file containing your results.
- **Import** - Opens the **Open** dialog box so you can select a batch file (.mdf) to import. Select **Include Raw Files (LXB)** to include raw files in the import. Select **Overwrite** to overwrite existing files.
- **Export** - Opens the **Export Batch** dialog box, where you can choose a location for the file you selected to export. Select **Include Raw Files (LXB)** to include raw files in the export. Select **Overwrite** to overwrite existing files.
- **Replay** - Opens the **Select Replay Mode** dialog box. This box 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. A batch can be reprocessed 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. This sequence varies based on whether or not you created a new batch from a new protocol or a new batch from an existing protocol. 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.



- **Replay batch** - Use to replay raw bead data files. The bead data files are replayed using the gate, analyte, analysis settings, and plate layout that were selected in the new or updated protocol. Settings such as bead type, volume, timeout, XY heater, and report gain have no effect on the replayed results.
  - **Recalculate data** - Reanalyze the batch results using only the batch MFI values. The batch MFI values are recalculated using the analysis settings and plate layout selected in the new recalculated batch or protocol. Settings such as bead type, volume, timeout, XY heater, and report gain have no effect on the replayed results. Because only the MFI values are reanalyzed, no data is displayed in the dot plot.
  - **OK** - Saves your changes.
  - **Cancel** - Cancels your changes and closes the box.
- **Results** - Opens the **Results** tab. Use this tab to view the saved batch results for the selected batch. When you click **Open**, the **Results** subtab opens.

## Replaying a Batch

**Replay batch** uses the raw bead data files from the initial acquisition to reprocess 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 in the usual manner, with new .lxb and .csv files.

Replaying or recalculating a large batch can take 1 hour or more to complete. Batch replay cannot be stopped while in progress. Allow adequate time for the operation to complete. The operation is complete when all progress bars have disappeared.

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

The initial batch data and output file always remain intact and unchanged. Each time you replay or recalculate a batch, the system handles it as if it is a new batch, creating a separate batch entry and output file.

If you select to replay or recalculate a batch that was originally run without a saved protocol, you have to modify the settings on the following subtabs:

- **Settings**
- **Analytes**
- **Stds & Ctrl**s
- **Plate Layout**

These subtabs appear under the **Saved Batches** tab. After you have completed them in order, click **Replay Batch** on the **Plate Layout** subtab to perform the replay or recalculate procedure.

## Results Subtab



This subtab displays the following features:

There are three maximize buttons in this window, one for each major pane. Click the appropriate one to maximize the pane. After clicking, the clicked button becomes a minimize button. Click minimize to return the pane to its standard size.

This tab has the following features:

- **Statistic** - To view a particular statistic for analytes in a batch.

**NOTE:** The statistics displayed change according to the analysis type selected.

- **Median (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 to outliers and carry-over.
- **Test Result** - The calculated analysis value for quantitative or qualitative assays derived from standards with known values.
- **Count** - Gated events, if gates are set.
- **Net MFI (Median Background)** - Net MFI median Background.
- **% 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.
- **Trimmed Count**
- **Trimmed%CV of microspheres**
- **Trimmed Standard Deviation**
- **Trimmed Peak**
- **%CV of Replicates**
- **% Recovery**
- **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 New Median**
- **Units**
- **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 graph.
- **Results** pane - 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.
  - **Plate** - Select the plate you want to view, if there is more than one plate.



**CAUTION:** 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.

- **Save 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 to the default view.
- **Edit Patients** - Updates patient information.
- **3D** - Ability to look at a region map in three dimensions.

**NOTE:** The 3D option must be enabled on the **Admin > System Settings** page.

- **Approve** - Opens the **Batch Approval Confirmation** dialog box, which contains the data for analytes selected in the **Results** tab. Click **Yes** to approve the batch. The dialog box confirms the approval.
- **Validate** - Validates an entire selected row or cell in the **Results** table. 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. Your xPONENT system administrator must give you privileges to invalidate standards if you are using the Secure xPONENT package.



- **Invalidate** - Invalidates an entire selected row or cell in the **Results** table. The selection will turn red when invalidated. Select the same item and click **Validate** to remove the invalidation status.
- **Close** - Closes the batch and reopens the **Saved Batches** tab.
- **Save** - Saves the batch. This button only appears if a change has been made to the batch.
- **Analyze** - Analyzes data that has been invalidated. This button only appears if you have clicked **Invalidate** on a portion of the data, or if you have clicked **Validate** on an invalidated portion of the data. This will analyze the data again with the invalidated standard removal.

### 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. Open the **Results** page.
2. Open the **Saved Batches** tab.
3. Click the batch name, then click **Open**. The **Results** tab opens.
4. Click the square area next to left of the standard you wish to validate, then click **Validate**.

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

### 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 regarding accepting or rejecting control values, contact the assay kit manufacturer.

To invalidate standards and controls:

1. Open the **Results** page, then open the **Saved Batches** tab.
2. Open the **Saved Batches** tab.
3. Click the batch name, then click **Open**. The **Results** tab opens.
4. Click the square area to the left of the well you wish to invalidate, then click **Invalidate**. The whole row turns red.

### Settings Subtab

Use this tab to view the acquisition parameters of the selected saved batch and print the batch settings report.

**Page** - Scrolls through the **Batch Settings** report.

**Save** - Opens the **Save As** dialog box to save the **Batch Settings** report. Select a location and click **OK** to save the file. The default save type is a .pdf file.

**Print** - Prints the report.

**Close** - Returns to the **Saved Batches** tab.

### Viewing Batch Settings

1. Open the **Results** page, then open the **Saved Batches** tab.
2. Click **Saved Batches**, then click the batch for which you want to view details.
3. Click **Open**, then click the **Settings** tab.
4. Click the left and right **Page** arrows to view the pages of the batch settings report.
5. Click **Save** to open the **Save As** dialog box. Navigate to the location where you want to save the batch settings report, and click **Save**.

## Log Subtab

This tab displays a log of the activity which occurred during the acquisition of the selected batch; you can print the log:

The screenshot shows the Luminex xPONENT software interface. The 'Results' tab is selected, and the 'Log' subtab is active. The log displays a list of activities for the batch 'AlleleDemoBeadMPtriBatch', created on 3/8/2012 at 11:50:48 AM. The log entries are as follows:

Date	Message	Code
3/8/2012 1:34:09 PM	Well 1,D5 completed.	53F
3/8/2012 1:35:21 PM	Move Eject command started.	0
3/8/2012 1:35:27 PM	Move Eject command completed with status SUCCEEDED.	0
3/8/2012 1:41:32 PM	The command is pausing.	0
3/8/2012 1:41:32 PM	Well 2,A1 started.	540
3/8/2012 1:42:03 PM	Well 2,B1 started.	540
3/8/2012 1:42:16 PM	Well 2,A1 completed.	53F
3/8/2012 1:42:32 PM	The command has been paused.	0
3/8/2012 1:42:32 PM	Plate command completed with status SUCCEEDED. The command was cancelled. (0x4FF01052)	4FF01052
3/8/2012 1:42:32 PM	Well 2,B1 completed.	53F
3/8/2012 1:42:32 PM	Batch 'AlleleDemoBeadMPtriBatch' paused.	552
3/8/2012 2:06:19 PM	The command is pausing.	0
3/8/2012 2:06:19 PM	Well 2,C1 started.	540
3/8/2012 2:06:52 PM	Well 2,D1 started.	540
3/8/2012 2:07:06 PM	Well 2,C1 completed.	53F
3/8/2012 2:07:24 PM	The command has been paused.	0
3/8/2012 2:07:24 PM	Plate command completed with status SUCCEEDED. The command was cancelled. (0x4FF01052)	4FF01052
3/8/2012 2:07:24 PM	Well 2,D1 completed.	53F
3/8/2012 2:07:24 PM	Batch 'AlleleDemoBeadMPtriBatch' paused.	552
3/8/2012 2:35:56 PM	Well 2,E1 started.	540
3/8/2012 2:36:24 PM	xPONENTBeadController application has device control access.	0
3/8/2012 2:36:24 PM	xPONENTBeadController application has released device control access.	0
3/8/2012 2:36:28 PM	Well 2,F1 started.	540
3/8/2012 2:36:45 PM	Well 2,E1 completed.	53F
3/8/2012 2:36:45 PM	Well 2,G1 started.	540

At the bottom of the interface, there is a status bar showing system information: Delta Cal Temp: 0.0°C, Laser: Wavelength: 16 mW (lower), Sheath Pressure: 9.5 psi, Region Events: 0, XY Status: 25.0°C, Total Events: 0, and a 'Warm Up' indicator.

The following information is displayed about each activity:

- **Date**
- **Message**
- **Code**

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.

## Viewing Batch Logs

1. Open the **Results** page, then open the **Saved Batches** tab.
2. Click **Saved Batches**, then click the batch for which you want to view details.
3. Click **Open**. The **Results** tab opens.
4. Click **Log** to open the **Log** tab.

## Sample Details Subtab

The following information is shown on this tab:

- **SampleID**
- **Samples Status**

- Analyte

The screenshot shows the Luminex xPONENT software interface. The top navigation bar includes 'Home', 'Samples', 'Batches', 'Results', 'Protocols', 'Maintenance', and 'Admin'. The 'Results' page is active, showing a batch named 'AlleleDemoBeadMPTriBatch' created on 3/8/2012 at 11:50:48 AM. The 'Sample Details' tab is selected, displaying a table of sample results. The table has columns for SampleID, Sample Status, and four analyte columns (Analyte 52, 54, 56, and an unlabeled one). The status for all samples is 'Complete'. The results for the analytes are: Analyte 52 (NEG), Analyte 54 (NEG), Analyte 56 (POS), and the unlabeled analyte (POS). The interface also includes a 'Transmit' button and a 'Close' button at the bottom right of the table area.

SampleID	Sample Status	Analyte 52	Analyte 54	Analyte 56	Analyte ?
Unknown1	Complete	NEG	NEG	POS	POS
Unknown2	Complete	NEG	NEG	POS	POS
Unknown3	Complete	NEG	NEG	POS	POS
Unknown4	Complete	NEG	NEG	POS	NEG
Unknown5	Complete	NEG	NEG	POS	NEG
Unknown6	Complete	POS	POS	POS	NEG
Unknown7	Complete	POS	NEG	POS	POS
Unknown8	Complete	NEG	NEG	POS	POS
Unknown9	Complete	NEG	POS	NEG	POS
Unknown10	Complete	POS	POS	POS	NEG
Unknown11	Complete	POS	POS	POS	POS
Unknown12	Complete	NEG	NEG	POS	POS
Unknown13	Complete	NEG	NEG	POS	POS

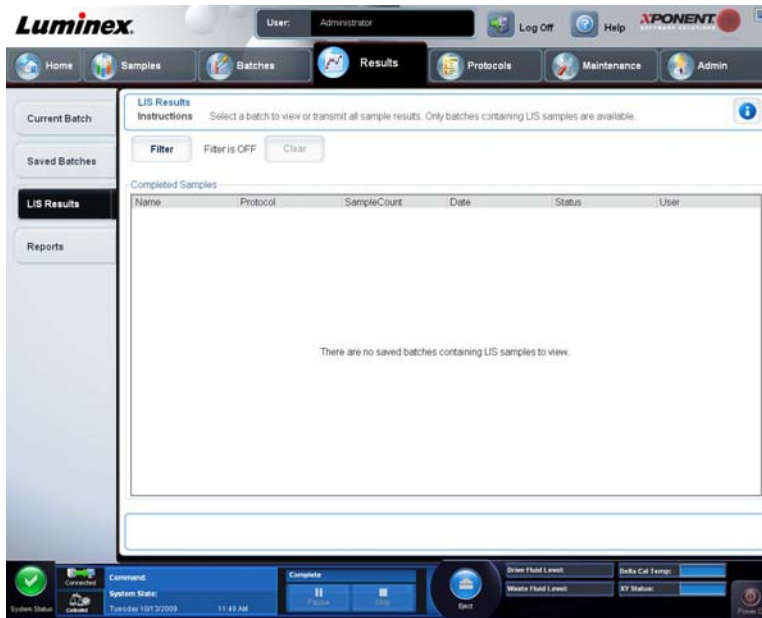
- **< and > Arrows** - Scroll left to right through the sample details.
- **^ and v Arrows** - Scroll up and down through the sample details.
- **Transmit** - For systems configured for LIS transmission, select a single analyte or the entire sample and click **Transmit** to send the results.
- **Close** - Reopens the **Saved Batches** tab.

### Viewing Sample Details

1. Open the **Results** page, then open the **Saved Batches** tab.
2. Click **Saved Batches**, then click the batch for which you want to view details.
3. Click **Open**, then click **Sample Details**. The **Sample Details** tab opens. 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.

## LIS Results Tab

This tab displays information about saved batches that contain LIS samples.



- **Filter** - Opens the **Filter Setup** dialog box.

### Batch-Specific Details

- **Batch Name**
- **Protocol**
- **Batch Status**
- **Lot ID**
- **Kit ID**
- **Analyte**

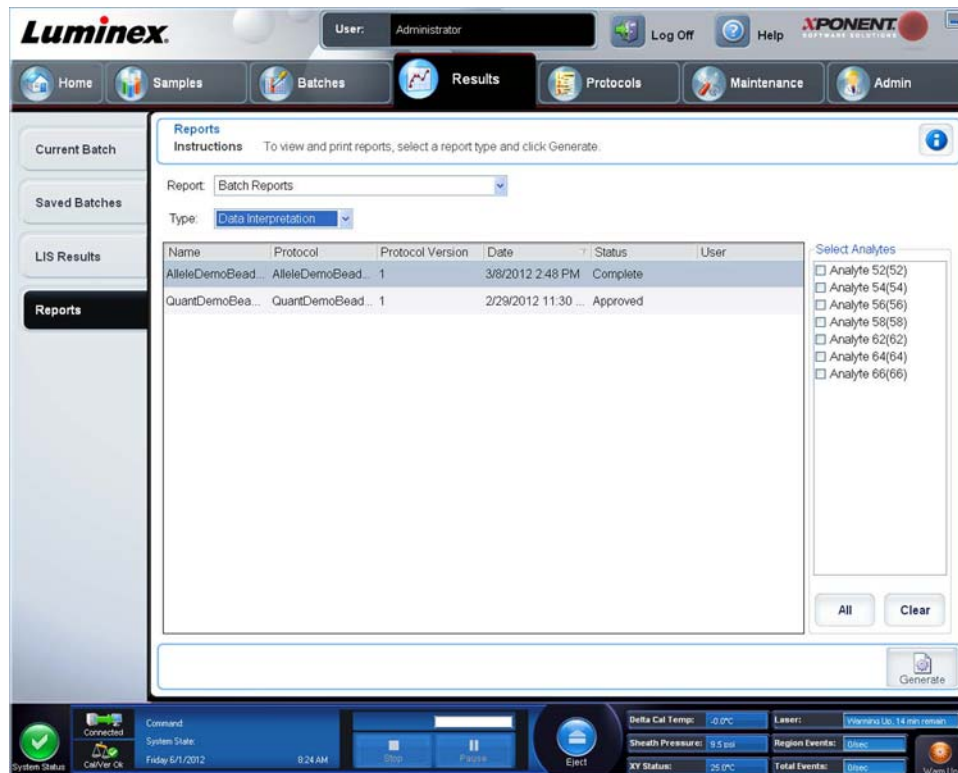
### Sample Details

- **Sample ID**
- **First Name**
- **Last Name**

### Others

- **User ID**
- **Date**
- **Reset**
- **OK / Cancel**
- **Clear** - Click to turn off the filter.
- **Completed Samples** - Displays **Name**, **Protocol**, **Sample Count**, **Date**, **Status**, and **User** information for each batch displayed in this list.
- **Transmit** - Transmits a batch to a LIS if xPONENT is connected to one.
- **Details** - Opens the **Sample Details** tab to view sample results.

## Reports Tab



Use this tab to view, generate, and print reports.

**Report and Type** lists - **Report** lists the categories of reports. The selections in the **Type** list change depending on the selection you made from the **Report** list. Depending on the choice you make, various other changes occur on the **Reports** tab:

**Batch Reports** - A list of batches appears below the **Type** list. This includes **Name**, **Protocol**, **Protocol Version**, **Date**, **Status**, and **User** information. Choose from the following reports:

- **Data Interpretation**
- **Batch Settings**
- **Plate Layout**
- **Batch Audit**
- **Patient Report**

If you choose **Data Interpretation**, a **Select Analysis** section appears on the right and displays a list of the analytes in the batch. Select the analytes you want to include in the report. Select **All** to select all the analytes in the list. Select **Clear** to clear all the analytes in the list.

A series of new buttons appears when you click **Generate Report**.

- **Analyte arrows** - This feature is directly below the **Report** list. Use the left and right arrows to display information for individual analytes of those selected for the report.
- **Page arrows** - Use the arrows to scroll through the pages being displayed.
- **Save All** - Click to open the **Browse For Folder** dialog box. Select a location to save the file, and click **OK**. This file includes all selected analytes.
- **Print All** - Click to print the analyte information for all the analytes in the report.
- **Save** - Click to open the **Save As** dialog box. Select a location and click **Save**. This saves only the analyte information currently displayed.
- **Print** - Click to print the analyte information currently being viewed.
- **New Report** - Click to return to the main **Reports** window.

- **Protocol Reports** - A list of protocols displays. Choose from the following reports:
  - **Protocol Settings**
  - **Plate Layout**
  - **Protocol Audit**

Select a protocol and then click **Generate to generate the report**.

- **Calibration and Verification Reports** - Displays a list of calibrations and verifications. Choose from the following selections:
  - **All**
  - **F3DCAL1**
  - **F3DeCAL1**
  - **F3DCAL2**
  - **F3DCAL3**
  - **F3DVER1**
  - **F3DeVER1**
  - **F3DVER2**

Select a calibration component, a date from the **Date** list, and click **Generate to generate the report**.

**Performance Verification Reports** - Displays two report types. Choose either of the following:

- **Condensed**
- **Detailed**

Select a report type, a date range from the **Date** list, and then click **Generate to generate the report**.

**System Log Reports** - Displays a list of system log reports. Choose from the following selections:

- **All**
- **Maintenance**
- **Security**
- **Warnings and Errors**

Select a system log report, a date from the **Date** list, and then click **Generate to generate the report**.

**Advanced Reports** - Enables a single option, **User Report**, in the list.

Click **Generate** to generate the report.

## Generating a Report

1. Open the **Results** page, then the **Reports** tab.
2. In the **Report** drop-down list, select 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 can be displayed in the window.
3. Select the specific report from the **Type** list.
4. If you selected either a batch report or a protocol report, select the specific batch or protocol from the list.
5. If the report you selected requires a date range (calibration and verification, performance verification, and system log), use the calendars available when you click the **Start** and **Through** buttons to establish the date range.
6. If the report you selected requires a choice of analytes, select them from the **Select Analytes** box. Select them all using the **All** button; clear your selections using the **Clear** button.
7. Click **Generate**.

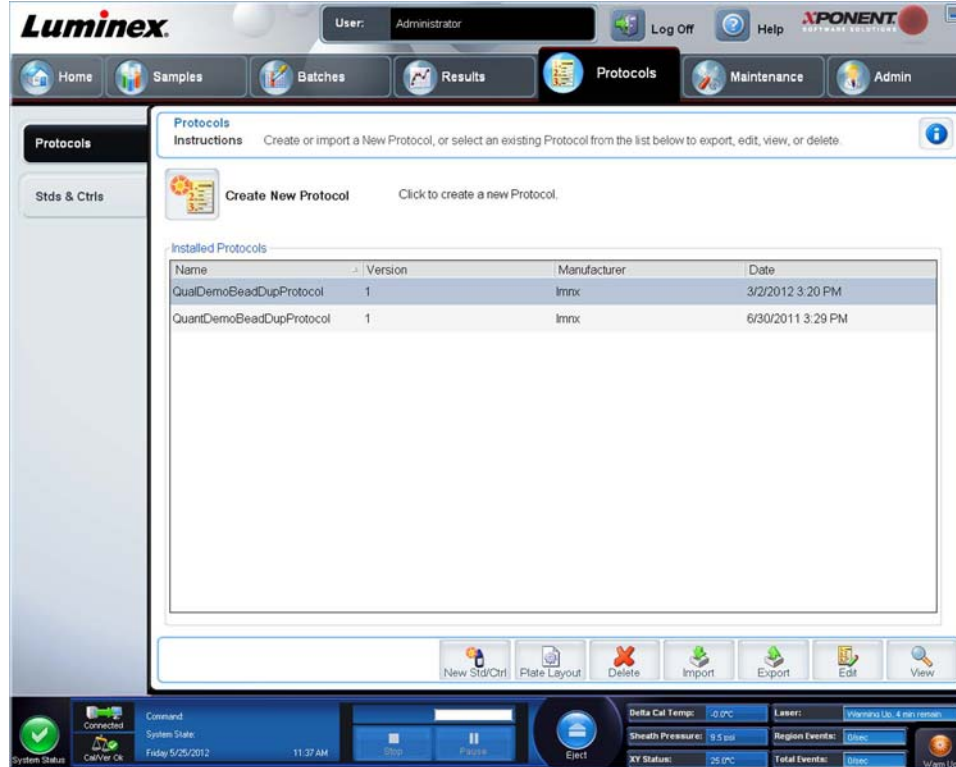
If the report includes multiple analytes, use the arrows above the report to move through the list of analytes.

If the report is lengthy, use the **Page** arrows to scroll through the pages in the report.

Use the **Zoom** button to focus on a particular part of the report.

## Chapter 7: Protocols Page

### Protocols Page Functionality



The **Protocols** page enables you to create or import a new protocol, or select an existing protocol from the **Installed Protocols** list.

The following installed protocol information is shown on the page:

- **Name**
- **Version**
- **Manufacturer**
- **Date**

Click the **Create New Protocol** button or click **Stds/Ctrls** to move to those pages.

There are action buttons at the bottom of the page. Most of these buttons are not displayed unless you are working with a saved protocol. While you are creating a protocol, only **Cancel** and **Next** buttons are displayed. After saving a protocol or opening a saved protocol, the following buttons are displayed:

- **New Std/Ctrl**
- **Plate Layout**
- **Delete**
- **Import**
- **Export**
- **Edit**
- **View**



**NOTE:** The buttons are only visible when there is an existing protocol in the system. If no protocols have been created or imported, then only the **Import** button is visible

## Protocol Procedures

### Deleting a Protocol

1. Open the **Protocols** page, then open the **Protocols** tab.
2. Select a protocol.
3. Click **Delete**. The **Delete Protocol** dialog box opens.
4. Click **Yes**.

### Exporting a Protocol

1. Open the **Protocols** page, then open the **Protocols** tab.
2. Select a protocol.
3. Click **Export**. The **Save as** dialog box opens.
4. Select a location to export the file to, and click **Save**.

### Importing a Protocol

1. Open the **Protocols** page, then open the **Protocols** tab. Click **Import**.
2. In the **Open** dialog box, navigate to the protocol file you want to import, then click **Open**.
3. The imported protocol displays in the **Installed Protocols** list.

### Adding a New Lot for Protocol

1. Open the **Protocols** page.
2. Click the **Stds & Ctrls** tab.
3. Click **Create New Std/Ctrl Lots** and select a protocol from the drop-down list in the **Select Protocol** dialog box, then click **OK**. The **Std/Ctrl Details** tab opens.
4. Click **Apply Std/Ctrl Kit** to associate a kit with the protocol. If you are not using a kit, type the appropriate Standard and Controls information in the **Assay Standard Information** and **Assay Control Information** sections.
5. Click **Save**.

## Lots and Kits Procedures

You can edit standard and control lot information. Once a lot is used, changing or modifying it will prompt you for a new lot name.

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.

Assay kits include standards and/or controls. Once you enter the assay kit information, it can be used in multiple protocols. However, you should create separate kits specific for use with each protocol.

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

### Creating a Lot

To create lots, you must use a protocol that uses either **Quantitative** or **Qualitative** analysis settings.

To create a lot:

1. Open the **Stds & Ctrls** tab from the **Protocols** page, then open the **Create New Std /Ctrl Lots** button.
2. In the **Select Protocol** dialog box, select the protocol you want to use for this lot, then click **OK**. The **Std/Ctrl Details** tab opens.
3. If the protocol uses standards, type the appropriate information for each standard in the **Assay Standard Information** section. In each analyte column, type the expected concentration for the analyte.

4. Alternatively, click **Apply Std/Ctrl Kit** and select a lot from the **Select Lot** dialog box. Click **OK** to apply the lot.
5. If your batch uses controls, select **Expected**, **Low**, or **High** from the **Show Value** options. Use the **Apply Values** arrows to apply values down or across the range of analytes.
6. Click **Save**.

## Editing a Lot

To edit a lot:

1. Open the **Protocols** page, then open the **Stds & Ctrls** tab.
2. In the **Installed Kits And Lots** section, select a lot and then click **Edit**. The **Std/Ctrl Details** tab opens. Change the lot information as appropriate.

## Deleting a Lot

To delete a lot:

1. Open the **Protocols** page, then open the **Stds & Ctrls** tab.
2. In the **Installed Kits And Lots** section, click the lot you want to delete, then click **Delete**.

## Exporting a 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.

To export a lot:

1. Open the **Protocols** page, then open the **Stds & Ctrls** tab.
2. In the **Installed Kits And Lots** section, click the lot you want to export, then click **Export**. The **Save As** dialog box opens.
3. Navigate to the location you want to export the file to, then click **Save**.

## Importing a Lot

To import a lot:

4. Open the **Protocols** page, open the **Stds & Ctrls** tab, and then click **Import**.
5. In the **Open** dialog box, navigate to the file, then click **Open**.

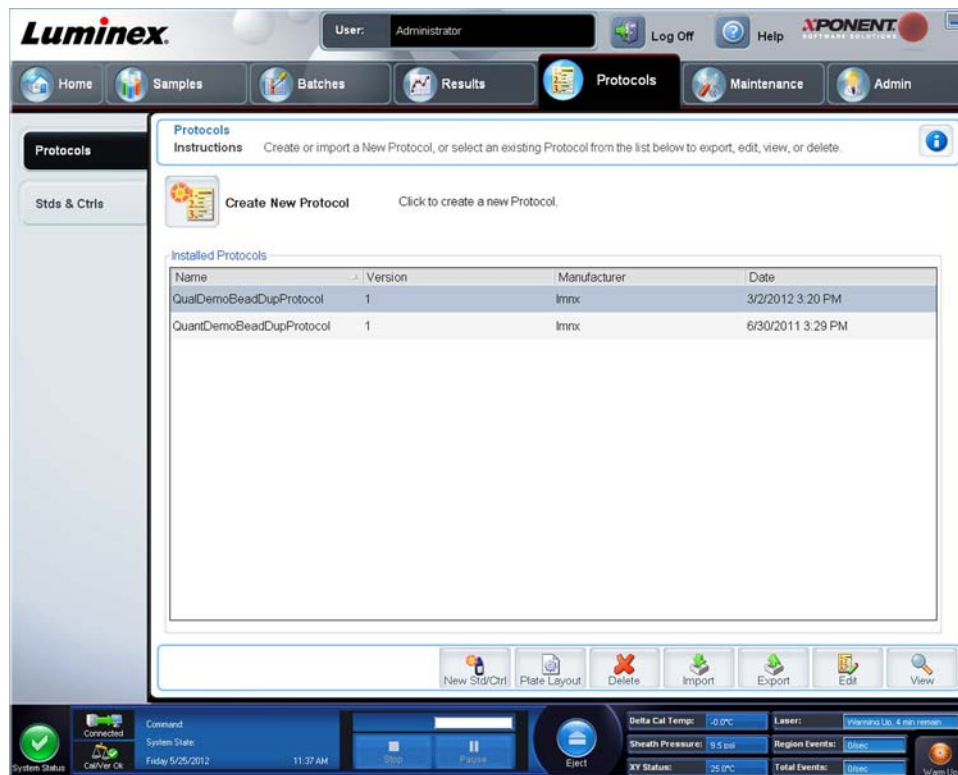
## Creating a Kit

To create a kit:

1. Open the **Protocols** page, then open the **Protocols** tab.
2. Select the protocol that you want to use for the kit, then click **New Std/Ctrl**. The **Std/Ctrl Details** tab opens.
3. Type the name of the kit in the **Name** box, the lot number in the **Std/Ctrl Kit Lot#** box, the expiration date using MM/DD/YYYY format in the **Expiration** box, and the manufacturer in the **Manufacturer** box.
4. Click **Apply Std Lot** if you want to apply a standard lot. The **Select Lot** dialog box opens. Click a lot and select **OK**.
5. Click **Apply Ctrl Lot** to apply a control lot. The **Select Lot** dialog box opens. Select a lot and click **OK**.
6. Alternatively, type 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, select **Expected**, **Low** or **High** from the **Show Value** options. Use the **Apply Values** arrows to apply values down or across the range of analytes.
7. Click **Save**.

## Protocols Tab

Use this tab to create, export, or delete a protocol. You can also add new assay standard and/or control information using one of the installed protocols.



This tab contains the following:

**Create New Protocol** - Opens the **Settings** tab to create a new protocol. For more information, see “Settings Subtab”.

**Installed Protocols** - Displays installed protocols. The list includes **Name**, **Version**, **Manufacturer**, and **Date** information for each protocol.

**New Std/Ctrl** - Opens the **Std/Ctrl Details** tab.

**Plate Layout** - Open the **Report** dialog box, which includes the **Plate Layout Report**.

**Delete** - Opens the **Delete Protocol** dialog box to delete a protocol selected in the **Installed Protocol** list. Click **Yes** to delete the selected protocol.

**Import** - Opens the **Open** dialog box to select a protocol (.lxt file) to import. Navigate to the protocol file you wish to import and click **Open**.

**Export** - Opens the **Save As** dialog box to export a selected protocol. Choose an export destination and name, and select **Save**.

**Edit** - Opens the **Settings** tab to edit a selected protocol.

**View** - Opens the **Settings** tab to view the protocol. Click **Next** to advance the tab, and **Next** again to advance to the **Plate Layout** tab. Click **Close** at any time to return to the main **Protocols** tab, or **Back** to return to a preceding tab. The **View** option does not allow any changing of the protocol settings.

## Settings Subtab

The screenshot displays the 'Settings' subtab within the 'Protocols' section of the Luminex xPONENT software. The interface includes a top navigation bar with 'Home', 'Samples', 'Batches', 'Results', 'Protocols', 'Maintenance', and 'Admin' tabs. The 'Protocols' subtab is active, showing 'Step 1: Protocol Settings for "Nov 2013"'. The 'Name' field is filled with 'Nov 2013'. The 'Version' is '1' and 'Manufacturer' is empty. Under 'Acquisition Settings', 'Volume' is '50 microliters', 'XY Heater' is 'Enabled' with a value of '0 degrees C', 'Timeout' is 'Enabled' with a value of '200 seconds', 'Bead Type' is 'MicroPlex', and 'Plate Name' is 'Current 96-well plate'. 'DD Gating' is set from '7500' to '15000', and 'Reporter Gain' is 'Enhanced PMT (High)'. The 'Apply MFI Divider' checkbox is checked. Under 'Analysis Settings', 'Analysis Type' is 'Quantitative', 'Number of Standards' is '8', and 'Number of Controls' is '2'. The 'Fit of all Standards' radio button is selected. 'Min MFI Enabled' is unchecked. The 'Analyze results while acquiring samples' checkbox is checked, and 'Use External Analysis Program' is unchecked. The 'Analysis Program' dropdown is empty. 'Cancel' and 'Next' buttons are at the bottom right.

Click **Create a New Protocol** on the **Protocols** tab to open the **Settings** subtab.

**Name and description boxes** - Type the name and description in the appropriate box.

### Acquisition Settings

- **Volume** - This is the volume the instrument aspirates into the system for analysis. Type the desired sample volume in microliters. Use values from 10  $\mu$ L to 200  $\mu$ L. To avoid air intake, add at least 25  $\mu$ L to the sample well in addition to the sample size. The default value is 45  $\mu$ L.
- **XY heater** - Select **Enabled** to enable the XY heater. In the box type the desired value in degrees Celsius. The temperature range is 35°C to 60°C.



**CAUTION:** Acquiring data before the heater has reached the proper temperature can compromise test results.

- **Timeout** - Check the **Enabled** box to enable the **Timeout**.
- **Bead Type** - Select the **Bead Type** box. From the drop-down menu you can choose MicroPlex® or MagPlex®.
- **Plate Name** - Select the plate name from the drop-down menu. Select **Current 96-well plate** or a plate that you have created.
- **DD Gating** (Doublet Discriminator) - 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** - Select **Standard PMT** from the drop-down menu to decrease the reporter gain.
- **MFI Divider** - For information on this function, contact Luminex® Technical Support.

**Analysis Settings** - Use this section to set the analysis type, set the number of standards and controls, select an external analysis program, and choose whether or not to analyze results while acquiring samples.

- **Analysis Type** - Use this list to choose from the following analysis types:
  - **None** - No analysis. Select if you have your own data post-processing program. 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.
 
$$(FI_{\text{sample}})/(FI_{\text{standard}}) = Ki$$
 Where FI = Fluorescent Intensity and Ki = a “Quali” value entered in lot information to determine the value or the qualitative assay standard.
 

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.
  - The “Quali” value determines a cutoff or threshold. This, in conjunction with ranges using the Lum Quali formula or an edited range specific for your assay, helps to determine qualitative results for unknown samples.
  - **Quantitative** - Determines the sample concentrations from standard curves using regression methods. Cubic Spline, Linear, Logistic 4P, and Logistic 5P. Type the desired values for standards and controls in the **Number of Standards** and **Number of Controls** boxes. Select either **Fit of All Standards** or **Mean of Replicates** for the calculation of the curve fit.

**NOTE:** 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** - Click to type the number of standards for the protocol. Applies only to qualitative and quantitative analysis.
- **Number of Controls** - Click to type the number of controls for the protocol. Applies only to qualitative and quantitative analyses.
- **Fit of All Standards** - The standard curve will be determined by using each individual standard replicate when calculating the standard curve. For example, if you run duplicates of a 7-point standard curve, the software will calculate the standard curve by using 14 points. Applies only to quantitative analysis.
- **Mean of Replicates** - The standard curve will be determined by averaging the individual standard replicates when calculating the standard curve. For example, if you run duplicates of a seven-point curve, the software calculates the standard curve by using 7-averaged points. Applies only to 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.
- **Use External Analysis Program** - Select this check box to use a third-party program to analyze the data. The **Analysis Program** list becomes active when this is selected. Applies only to qualitative and quantitative analysis. Use this list to select which program to use for data analysis.

**Cancel** - Returns you to the main **Batches** tab.

**Next** - Click to advance to the **Analytes** tab.

### Editing Qualitative Analysis Settings

1. Open the **Protocols** page, then open the **Protocols** tab. Select a protocol and click **Edit**.
2. In the **Settings** tab, enter a new version number before clicking the **Analytes** subtab.
3. From the **Analytes** subtab, click on any analyte in the **Analysis** field to open the **Analysis Settings** dialog box.
4. From the **Method** list, click **Luminex Qualitative** or **No Analysis**. Check **Mark as Intra-Well Normalization Bead** if you want to use a 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. An analyte used as a normalization bead will appear blue in the analyte grid.

5. From the **Formulas** list, click **Lum Qual** or **Adv Qual**.
6. Type a new name for the edited formula in the **Formula Name** box.

## Plate Layout Subtab



- **Plate Image** - This is a representation of 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. 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** box to display different portions of the plate.
- **Command Sequence** - Contains the command sequence for the active plate. The list includes all active wells, the type of command (Unknown, Standard, Control, Background, or assigned maintenance command), ID, and dilution factor. Double-click the ID field to type an ID. Double-click the **Dilution** field to type a dilution factor.

**NOTE:** A command's ID and Dilution fields have a blue border around them if they can be double clicked to type information.

- **Move Command** - These arrows move a selected command up or down in the **Command Sequence** list, changing the acquisition order.
- **Import List** - Opens the **Open** dialog box to import an existing command sequence list.

**NOTE:** The import feature allows you to import patient information into unknown wells or wells with specified locations.

- **Replicate Count** - Defines a quantity of replicate sets from one to nine.
- **Grouping** - Selects the sequence in which the replicates are laid out in plate wells. The options are:
  - **123123123** - This displays one of each replicate set at a time in numerical order.
  - **111222333** - This displays all the replicates in a set before moving on to the next set in numerical order.

You can assign the following well commands. Each command is associated with a color. You can click and drag to highlight a series of wells, click a column or row header to highlight the entire column or row, or simply click and highlight different wells and then click a command below to assign that command to all the highlighted wells.

- **Unknown (U):** Yellow
- **Background (B):** Purple
- **Control (C):** Red
- **Standard (S):** Green

The **Delete** and **Start at Well** commands are also available to assign as well commands. **Delete** removes the well command for the selected well. The **Start at Well** command enables you to begin acquisition at a well other than **A1**.

**NOTE:** You should first delete all standards from the plate layout if any of the standards need to be rearranged, and all controls from the plate layout if any of the controls need to be rearranged.

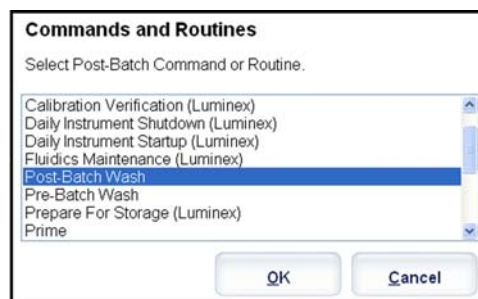
**NOTE:** Wells and routine names you assign to the protocol plate layout are saved into the protocol settings. The routine itself must exist on the instrument. Standards and controls associated with a given protocol typically remain constant, while the number of unknown wells often vary. You can assign a specific number of unknown wells to the plate when setting up a batch.

**Commands and Routines** - Assigns maintenance commands and routines to a well after you select it in the **Command Sequence** area.

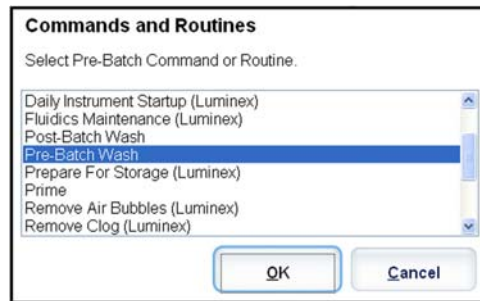
- **Add** - Opens the **Commands and Routines** dialog box so you can select a command or routine.



- **Delete** - Deletes the selected command or routine.
- **Post Batch Routine** - Opens the **Commands and Routines** dialog box so you can select a post-batch command or routine.



- **Pre Batch Routine** - Opens the **Commands and Routines** dialog box so you can select a pre-batch command or routine.



- **Plate Name** - Specifies the plate you want to display in the plate image in the list. **Add Plate** adds a new plate to the batch, and **Delete Plate** deletes the plate highlighted in the list.

**Plate Name** - This list displays the available plates to use for the selected routine or procedure.



**WARNING:** When using multiple plates, use them in the proper order. Failure to do so can result in inaccurate data and test results.

- **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.
- **Off-Plate Area** - Designates an alternate location for maintenance commands in the **Commands and Routines** list.
- **Cancel** - Returns to the main **Protocols** tab without saving.
- **Back** - Returns to the **Analytes** tab
- **Save** - Saves the protocol and returns to the main **Protocols** tab.



## Analytes Subtab



Use this tab to select or edit analytes used in the batch or protocol. This tab contains the following:

This tab contains the following:

- **Analytes grid** - A grid representing each analyte from 1 to 500. **Select All** selects all analytes, and **Deselect All** deselects all analytes. Click a numbered analyte to select it; click the analyte again to deselect it. You can also click and drag to select groups of analytes. Selected analytes are red. Deselected analytes are gray. An analyte marked as an intra-well normalization bead is blue.
- **Default Analysis** - The default analysis changes based on the **Analysis Type** selected in the **Settings** tab. You can change the analysis settings for all analytes by clicking **Change** if this button is enabled in this tab. This displays the **Analysis Settings** dialog box.
  - If you selected **Quantitative** on the **Settings** tab, the default analysis formula is **5P Weighted**.
  - If you selected **Qualitative** on the **Settings** tab, the default analysis is **Luminex Qualitative**. Change the default value by selecting either **Luminex Qualitative** or **No Analysis**.
  - Click **Apply to All Analytes** to apply your selection to all selected analytes. Click **OK** to change the default analysis to the analysis you selected. Click **Cancel** to close the dialog box without saving.
- **Units** - Type the desired units for the analytes in this box.
- **Count** - Type the desired bead count for the analytes by clicking in the **Count** box. 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. If you select bead sets that are not present, the analyzer continues to acquire, trying to reach the number of events per bead for bead sets that are not in the sample. Therefore, choose only the bead sets present in your sample.
- **Apply All** - Applies the information in the **Units** and **Counts** boxes to all analytes.
- **Total Count** - Select **Stop after bead count reaches:** to stop acquisition when the bead count reaches a certain number determined by the user. Type the desired value in the box. The default value is 50. You can also specify the minimum allowable bead count per well that the xPONENT software analyzes. This excludes data from any beads carried over during acquisition.
- **Selected Analytes list** - Selected analytes are displayed in a list on the right side of the analyte grid. This list includes the following information:

- **Name** - The name of the analyte. Click and type to rename the analyte.
- **Analysis** - To change the type of analysis for an analyte, click this field to open the **Analysis Settings** dialog box and select another analysis from the list.

In the **Analysis Settings** dialog box:

**Analysis Settings**  
Analyte: Analyte 45

Method: Logistic 5P  
Logistic5P:  $y = a + \frac{b-a}{1 + (x/c)^d)^f}$

WeightType:  $1/x^2$  Apply to All Analytes

Mark as Intra-Well Normalization Bead

Use Threshold Ranges

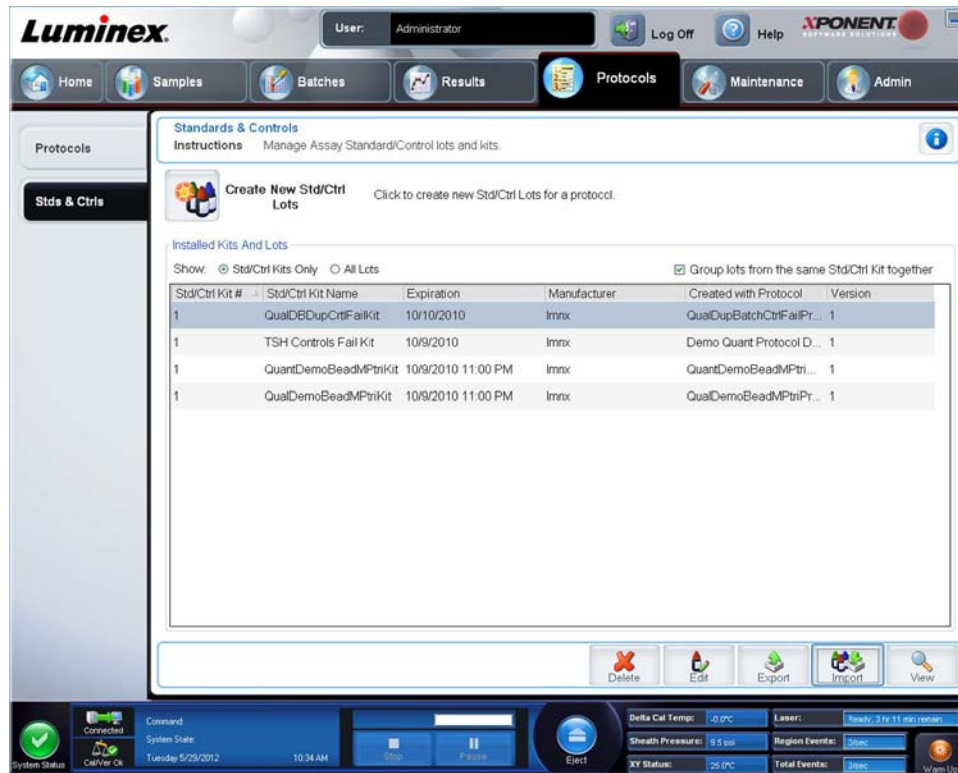
Range Name	Low Value	Inclusive	High Value	Inclusive
Lower	4	<input checked="" type="checkbox"/>	20	<input checked="" type="checkbox"/>

Add Range Delete Range OK Cancel

1. Select a method from the **Method** list.
2. If necessary, select a weight type from the **WeightType** list.
3. Apply the analysis to all analytes in the list by clicking **Apply to All Analytes**.
4. Select **Mark as Intra-Well Normalization Bead** to make the analyte an 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.
5. Add a range to the analysis by clicking **Add Range**.
6. Select **Use Threshold Ranges** to enable ranges for the analysis.
7. Click **Add Range** to add a range.
8. Type a **Range Name**, a **Low Value**, a **High Value**, and select **Inclusive** if you want to include the low and high values in the range. Click **OK** to exit the dialog box.
  - **Units** - The unit of measurement you specified in the **Unit** box. Select this box to type a value for the analyte.
  - **Count** - Type the desired bead count for the analytes by clicking in the **Count** box. 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. This is a number between 12 and 78.
- **Cancel** - Click **Cancel** to return to the **Batches** tab.
- **Back** - Click **Back** to return to the **Settings** tab.
- **Next** - Click to go to the next tab.

**NOTE:** If the **Analysis Type** selected in the **Settings** tab was **None**, this takes you to the **Plate Layout** tab. If the **Analysis Type** selected was **Quantitative** or **Qualitative**, this button takes you to the **Stds & Ctrl** tab.

## Standards and Controls (Stds & Ctrl) Tab



Use this tab to delete, edit, export, import, and create standards and controls.

This tab contains the following:

- **Create New Std/Ctrl Lots** - Opens the **Select Protocol** box.

**Select Protocol**

Protocol Qualitative Version: 1

After you select from this box, the **Std/Ctrl Details** tab opens 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.
  - Group lots from the same **Std/Ctrl Kit** together - Select to group lots from the same kit together.

Select **All Lots** in the **Show** selections to display the following information about each installed lot:

- **Reagent**
- **Lot #**
- **Expiration**
- **Name**
- **Manufacturer**
- **Protocol**
- **Versions**
- **Std/Ctrl Kit #**

- **Std/Ctrl Kit Name**

Select **Std/Ctrl Kits Only** in the **Show** selections to display the following information about the **Installed Std/Ctrl Kits**:

- **Std/Ctrl Kit #**
- **Std/Ctrl Kit Name**
- **Expiration**
- **Manufacturer**
- **Created with Protocol**
- **Version**
- **Delete** - Deletes a selected lot. The **Delete Lot(s) Confirmation** dialog box opens. Click **Yes** to delete the lot.
- **Edit** - Opens the **Std/Ctrl Details** tab to edit the lot information.
- **Export** - Opens the **Save As** dialog box to export the selected lot. Select a location to save the lot file, and click **Save**.
- **Import** - Opens the **Open** dialog box. Select a **Std/Ctrl Kit** or lot file to import, and click **Open**.
- **View** - Opens the selected **Std/Ctrl Kit#**.

## Chapter 8: Maintenance Page

Use the **Maintenance** page to maintain and calibrate your system. This page contains the following tabs:

- **Auto Maint**
- **Lot Management**
- **Cmds & Routines**
- **Probe & Heater**
- **System Info**
- **System Status**
- **Schedule**
- **Support Utility**

### Auto Maintenance (Auto Maint) Tab

The screenshot displays the 'Automated Maintenance - Performance Verification' section of the software. It features a table of commands and a reagents section.

Command	Location	Reagent	Status	Information
Warmup		None	Pending	
Prime		None	Pending	
Alcohol Flush	RB1	70% Alcohol	Pending	
Wash	RA1	DI H2O	Pending	
Wash	RA1	DI H2O	Pending	
F3DVER1	SA2	F3DVER1	Pending	
F3DeVER1	SB2	F3DeVER1	Pending	
F3DVER2	SC2	F3DVER2	Pending	
Wash	RA1	DI H2O	Pending	
Fluidics1	SD2	Fluidics1	Pending	
Fluidics2	SE2	Fluidics2	Pending	
Wash	RA1	DI H2O	Pending	

The reagents section includes a legend and a keypad. The legend lists reagents such as Alcohol Flush, Sterilize, Wash, Soak, Clean, F3DCAL1, F3DCAL2, F3DCAL3, F3DVER1, F3DVER2, Fluidics1, Fluidics2, and Multiple. The keypad is a 4x4 grid with letters A-D, numbers 1-4, and symbols for W and AF.

This tab contains routines to initialize, verify, and maintain the analyzer.

**Automated Maintenance Options** - Provides buttons for commonly used maintenance routines for the machine. Select from the following:

- **Calibration/Verification** - Select this routine to use with the Calibration/Verification kit.
- **Performance Verification** - Select this routine to use with the Performance Verification kit.
- **Fluidics Prep** - Select this routine to use with Fluidics Prep.
- **System Shutdown** - Select this routine to perform a pre-defined system shutdown.

The commands for these routines display in the command list below the buttons. This list is used to view the name of the current command, its well location, the reagent, status, and information about the command. Only the current commands are listed in the box.

- **Reagents** - Displays the reagents and well locations necessary for the selected routine. You can select kits for the routines from:

- The **Calibration Kit** drop-down menu.
- The **Performance Verification Kit** drop-down menu.
- **Report** - Opens the **Reports** tab, with the **Performance Verification Reports** selection displayed in the **Report:** list.
- **Import Kit** - Opens the **Import Calibration or Performance Kit** dialog box. Select a kit and click **Open** to import a kit.
- **Run** - Initiates the selected routine.

## Running Calibration and Verification

Before running Calibration/Verification from the **Auto Maint** tab, you need to import Cal and Ver kit information. Perform that procedure from the **Lot Management** tab. See [“Importing CAL or VER Kits”](#).

Run the Calibration/Performance Verification routine as part of your weekly maintenance routine:

1. On the **Home** page, click **System Initialization** under **Daily Activities**. The **Auto Maint** tab on the **Maintenance** page opens.
2. Click the **Calibration Verification** button under Automated Maintenance options.
3. Add the appropriate reagents to the off-plate reservoir and the strip well, using the diagram in the Reagents pane of the **Auto Maint** tab to guide you.
4. Click **Run**.

## Running the Performance Verification Routine

Run the **Performance Verification** routine as part of your daily startup routine.

1. On the **Home** page, click **System Initialization** under **Daily Activities**. The **Auto Maint** opens.
2. On the **Auto Maint** tab, click **Performance Verification**.
3. Add the appropriate reagents to the off-plate reservoirs and the strip well, using the diagram in the **Reagents** pane of the **Auto Maint** tab to guide you.
4. Click **Run**.

## Lot Management Tab

Use this tab to manage calibration and verification kits.

The screenshot shows the Luminex xPONENT 4.2 software interface. The top navigation bar includes Home, Samples, Batches, Results, Protocols, Maintenance, and Admin. The Lot Management tab is active, displaying instructions for managing calibration and verification kits. The interface is divided into several sections:

- Active Reagents:** Contains fields for Calibration Kit (B21519), Performance Verification Kit (B22400), and their respective Expiration Dates (8/24/2012 and 4/15/2012). There are 'Delete Kit' buttons for each.
- Active Reagents Table:** A table with columns: Lot Type, Active Lot Number, and Expiration Date.
 

Lot Type	Active Lot Number	Expiration Date
F3DCAL1	B21345	12/15/2012
F3DeCAL1	B18709	8/24/2012
F3DCAL2	B20005	11/16/2012
F3DCAL3	B20550	11/16/2012
F3DVER1	B17851	7/2/2012
F3DeVER1	B18843	1/18/2013
F3DVER2	B17879	8/26/2012
Fluidics1		
Fluidics2		
- Lot Details:** Contains fields for Lot Type (F3DCAL1), Lot # (B21345), and Expiration (12/15/2012). Below is a table for Channel and Target values.
 

Channel	Target
DD	9818
CL1	3427
CL2	3566
CL3	3447
- Sheath Fluid:** Fields for Current Lot # (Not Set) and Expiration (Not Set), with an Edit button.
- Buttons:** Import Kit, Import, Export, Add New, and Delete.

**Active Reagents** - Use this section to change calibration or performance verification kits, lot numbers and expiration dates, or to delete a kit.

- **Calibration Kit** - Select a calibration kit from this list. Details of the selected kit display in the **Lot Type**, **Active Lot Number**, and **Expiration Date** fields.
- **Performance Verification Kit** - Select a performance verification kit from this list. Details of the selected kit display in the **Lot Type**, **Active Lot Number**, and **Expiration Date** fields.
- **Delete Kit** - These buttons delete the selected calibration or performance verification kit.
- **Active Reagents table** - This 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** area. The choice changes what columns appear in the table in the **Lot Details** area.

**NOTE:** Select an active lot number for the selected reagent from this list.

- **Lot Details** - Displays lot information for the lot selected in the **Active Reagent** area.
  - **Lot Type** - Displays the lot type selected.
  - **Lot #** - Enter the lot number after clicking **Add New**.
  - **Expiration** - Select this to edit the expiration date after clicking **Add New**.
  - **Lot Details table** - This table enables you to enter target MFI values for the type of lot you selected in the **Active Reagents** area. 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.
- **Add New** - Adds a new lot. Add information in the Lot Details section on the right side of the window. Type a Lot #, Expiration, and target in the appropriate boxes and fields. Click Save to save the lot, or select. Cancel to cancel the entry.
- **Delete** - Deletes a lot selected in the Active Reagents list.

## Importing CAL or VER Kits

Follow these steps to import a CAL or VER kit.

1. Open the **Maintenance** page, then open the **Lot Management** tab.
2. Click **Import Kit**. The **Import Calibration or Performance Kit** dialog box opens.
3. Select the kit you want to import, then click **Open**.

## Deleting CAL and VER Kit Information

1. Open the **Maintenance** page, then open the **Lot Management** tab.
2. In the **Active Reagents** section, select the kit you want to delete from the **Calibration Kit** or **Performance Verification Kit** lists.
3. Click **Delete Kit**.



**CAUTION:** There is no confirmation dialog box when you delete a kit.

## Commands and Routines

**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. Additionally, you can create custom routines on this tab, which display in the **Routine Name** list once you save the routine. To create a custom routine, start with **None** and add the desired commands. You can also modify a Luminex® routine and save it as a new routine. Select from the following routines:

- **<None>**
- **Calibration Verification (Luminex)**
- **Daily Instrument Shutdown (Luminex)**
- **Daily Instrument Startup (Luminex)**
- **Fluidics Maintenance (Luminex)**
- **Prepare for Storage (Luminex)**
- **Remove Air Bubbles (Luminex)**
- **Remove Clog (Luminex)**
- **Revive After Storage (Luminex)**
- **Verification (Luminex)**
- **Weekly Maintenance (Luminex)**

**Commands** - This section contains the following commands:

- **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.
- **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.
- **F3DCAL1** - Calibrates DD, CL1, CL2, and CL3 for original non-magnetic xMAP beads.
- **F3DVER1** - Verifies DD, CL1, CL2, and CL3 for non-magnetic xMAP beads.



- **Alcohol Flush** - Removes air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The alcohol flush takes about five minutes. **Alcohol Flush** uses the off-plate reservoir because it can accommodate the amount of fluid necessary to flush the instrument.
- **Warm-up** - Warms the system to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn 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.
- **F3DeCAL1** - Calibrates DD, CL1, CL2, and CL3 for original magnetic MagPlex beads.
- **F3DeVER1** - Verifies DD, CL1, CL2, and CL3 for magnetic MagPlex beads.
- **Sanitize** - Uses the off-plate reagent block, 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 solution to decontaminate sample lines and the cuvette after biohazard contact. Sanitize as part of your daily shutdown routines.
- **Prime** - Removes air 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.
- **F3DCAL2** - Calibrates xMAP reporters.
- **F3DVER2** - Verifies RP1 at normal and high PMT and extended ranges for all xMAP Bead Types.
- **Drain** - Helps remove debris from the bottom of the cuvette during troubleshooting. You do not need to supply solution. Draining takes approximately two 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.



**WARNING:** Do not run three backflush commands in a row. This will use the sheath fluid faster than the system can replenish.

- **F3DCAL3** - Calibrates extended RP1 ranges for all xMAP beads.
- **Fluidics** - Fluidics calibrates sample carry over from well to well.

**NOTE:** You should perform a Self Test as part of your scheduled weekly maintenance.

Click a command to add it to a new routine, to modify an existing routine, or to run the single command. It will appear in the plate image to the right of the **Commands**. You can also select a location first, which places the command where you choose. To change the location of a command already on the plate, select it in the **Command Sequence**, and then click a different well or reservoir in the plate image.

**NOTE:** When you modify an existing routine, by adding or clearing a command, the routine name defaults to None in the Routine Name drop-down menu and the Save As button appears. Remember to save your new routine to make it available for future use.

**Command Sequence** - When you select a routine, the individual commands in the routine appear in order in the **Command Sequence** list. The list includes the name of each command, location, status, and any additional information.

- **Self Test** - Performs a self-diagnostic to see if the system and all operations are functioning correctly.

**NOTE:** You should perform a Self Test as part of your scheduled weekly maintenance.

- **Report** - Opens the **Reports** tab with **Calibration and Verification Reports** selected in the **Report:** list. Click **Generate** to view the selected report.
- **Import** - Displays the **Open** dialog box to select a routine file to import. Select a file and click **Open** to import it.
- **Cancel** - Cancels changes made to the default location of one of the commands in the **Command Sequence**. Click it to cancel those changes. This button only appears if changes have been made to the command sequence.

## Creating a New 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 analyzer operations and maintenance requirements. See the *Hardware User Manual* for more information.

To create a new routine:

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.
2. In the **Routine Name** list, click **None**.
3. In the **Plate Name** list, select the plate that you will use for the new routine.
4. 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.
5. 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 incompatible 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 reservoir.

6. Click **Save As** to save the new routine. The **Save Routine** dialog box opens.
7. Type the routine name in the **Routine Name** box, then click **OK**.

## Editing a Routine

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab. Click the routine that you want to edit from the **Routine Name** list.
2. 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 modify a routine, the routine name automatically defaults to None in the Routine Name list.

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

**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.

## Deleting a Routine

You can delete a routine that you created, but you cannot delete predefined routines. Predefined routines have (Luminex) after the routine name.

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.
2. Click the routine that you want to delete from the **Routine Name** list.
3. Click **Delete**.

**NOTE:** Do not delete routines that are used by protocols as pre- and postbatch routines.

## Running a Routine

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.
2. Select a routine to run from the **Routine Name** list.
3. Click **Eject** on the system monitor.
4. Add the appropriate reagents to the plate, reservoirs, and well strips 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 opens when the routine is complete.

7. Click **OK**.

## Importing a Routine

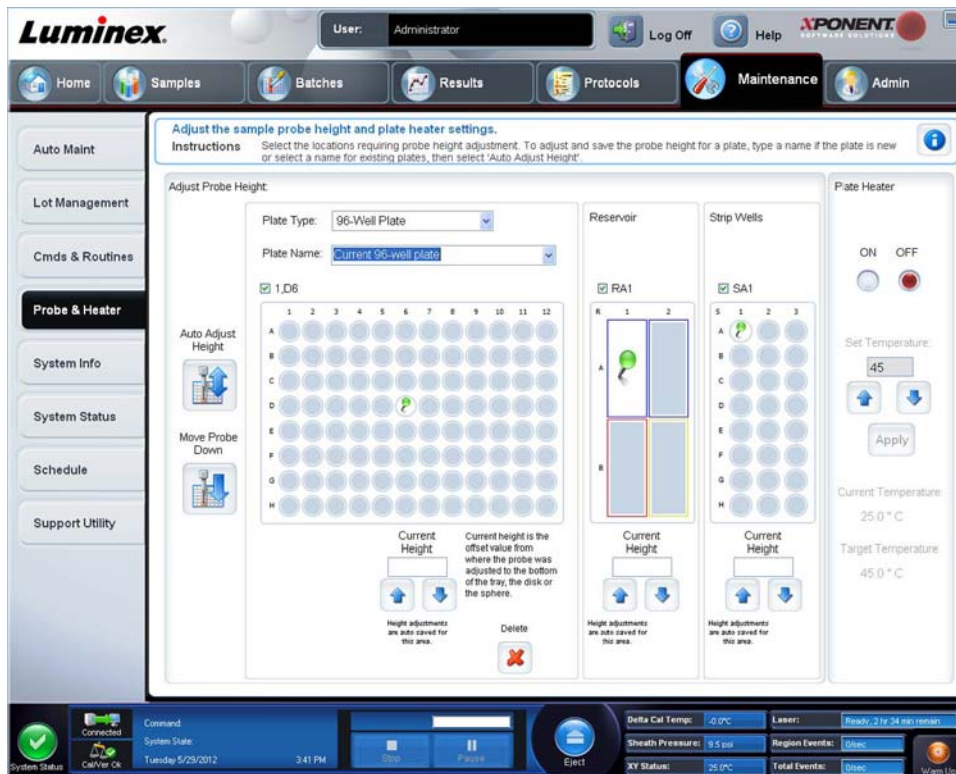
1. Open the **Maintenance** page, then open the **Cmnds & Routines** tab.
2. Click **Import**.
3. In the **Open** dialog box, browse for the file you want to import, then click **Open**. The routine becomes the active routine.

## Exporting a Routine

1. Open the **Maintenance** page, then open the **Cmnds & Routines** tab.
2. Click **Export**.
3. In the **Save As** dialog box, navigate to the folder where you want to store the routine file, then click **Save**.

**NOTE:** If you have not previously saved a routine, the **Export** button will not display.

## Probe and Heater Tab



Use this tab to adjust the probe height and plate heater settings.

- **Auto Adjust Height** - Automatically adjusts the probe height using the specified location(s) in the main plate, reservoir, and strip wells.

**NOTE:** Luminex recommends that you calibrate the probe height using well **D6**.

- **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 96-well plate is well **D6**.
  - The main plate depicts a 96-well microtiter plate. For information about the plates used in assays, see “Plates”.
  - **Strip Well** depicts the strip well added to the off-plate reagent block when extra wells are required. A strip well is equivalent to one column of a microtiter plate, and, like a microtiter plate, its wells can be flat-bottomed, v-bottomed, etc.

- **Reservoir** depicts the reservoir added to the off-plate reagent block when procedures require larger amounts of a reagent such as alcohol or distilled water.
- **Move Probe Down** - Moves the probe down in the specified well(s).
- **Plate Type** - 96-well.
- **Plate Name** - Type a name for a plate for future use or select an existing plate from the list.

**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 send to someone else, click **Save**. Otherwise, click **Cancel** and perform an auto adjust.

## Adjusting the Sample Probe Height

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

**NOTE:** For additional instructions on adjusting the probe height, see the *“Initial Startup”* section in Chapter 2.

**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.



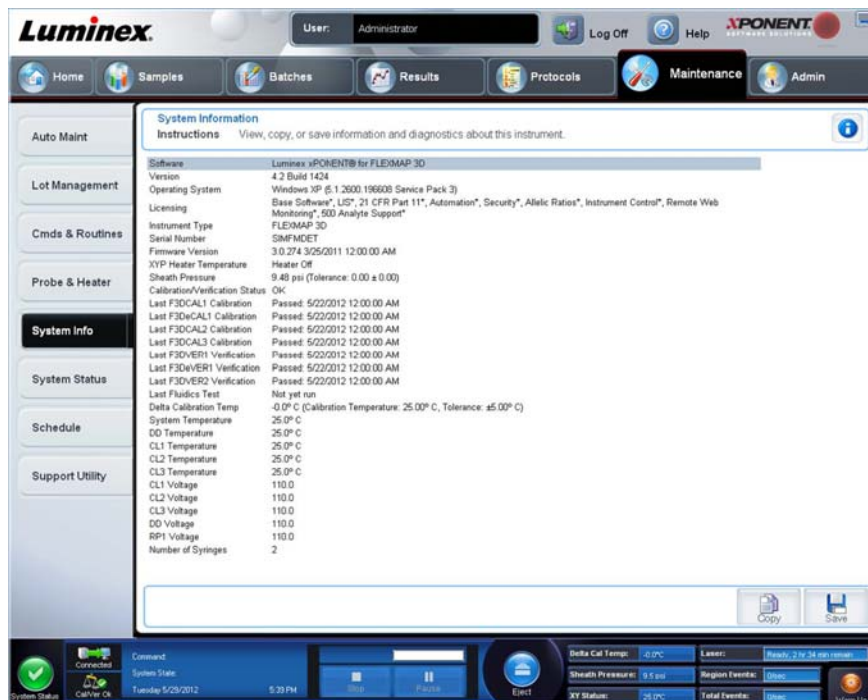
**WARNING:** Correct sample probe height is critical to successful sample acquisition and calibration. Problems with the sample probe height can lead to fluid leaks and inhibit sample acquisition.

1. On the **Home** page, click **Probe and Heater** under **Daily Activities**. The **Probe & Heater** tab opens.
2. Select a plate from the **Plate Type** list.
3. If you are using a filter or mylar bottom plate, place a large (5.08) alignment disk into a well. For other plates, no disk is required. Ensure that the well location is selected on the plate image, (a green pin marks the location). To change the well location, click on the desired well in the plate image.
4. Verify that the microtiter is not warped. Warped plates can lead to incorrect probe height adjustment.
5. **Eject** the plate holder and add the desired plate.
6. Click **Retract** to retract the plate holder.
7. Type a name for the plate in the **Plate Name** box, or select a saved plate from the **Plate Name** list.
8. In the **Reservoir** section, click in an off-plate position.
9. In the **Strip-Wells** section, click on a well location.
10. Click **Auto Adjust Height**. The probe automatically adjusts itself to the plate you selected.

11. Click **Save** plate.



## System Info Tab



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

This tab contains the following information:

- **Software**
- **Version**
- **Operating System**

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

Items in this list relating to calibration and verification (CAL/VER) 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

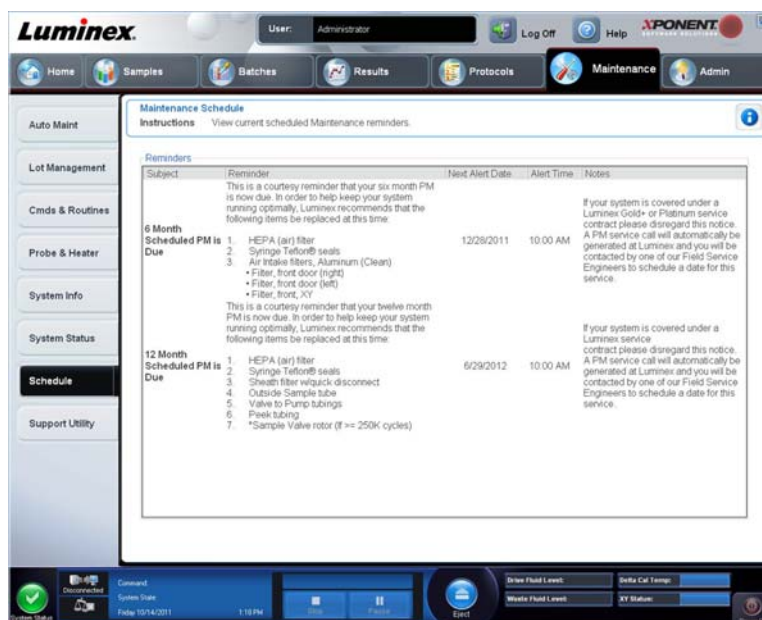
Use this tab to view, print, and save system status log information. You can also access this information by clicking the **System Status** button on the **System Monitor**.

This tab contains the following:

- **Search By Log Type** - Filters the type of log information. Select **All**, **Maintenance**, **Security**, or **Warnings and Errors**.
- **Search By Log Date** - Enables using a date range to display a log of system activities.
- **Advanced** - Displays the following added information in the system log:
  - **Log Type**

- **User ID**
- **Error Level**
- **Log** - Displays a list of information about each system process. The following information appears in the list:
  - **Log Date**
  - **Message**
  - **Code**
- **Export** - Opens the **Export System Log** dialog box. Select a name and location for the system log export and click **OK**. Select **Overwrite** to overwrite a pre-existing file. This button exports the file in .csv format.
- **Print** - Click to print the log file.
- **Save** - Click to open the **Save As** dialog box. This saves the file as a .pdf. Pick a file name and location to save the file, and click **Save**.

## Schedule Tab



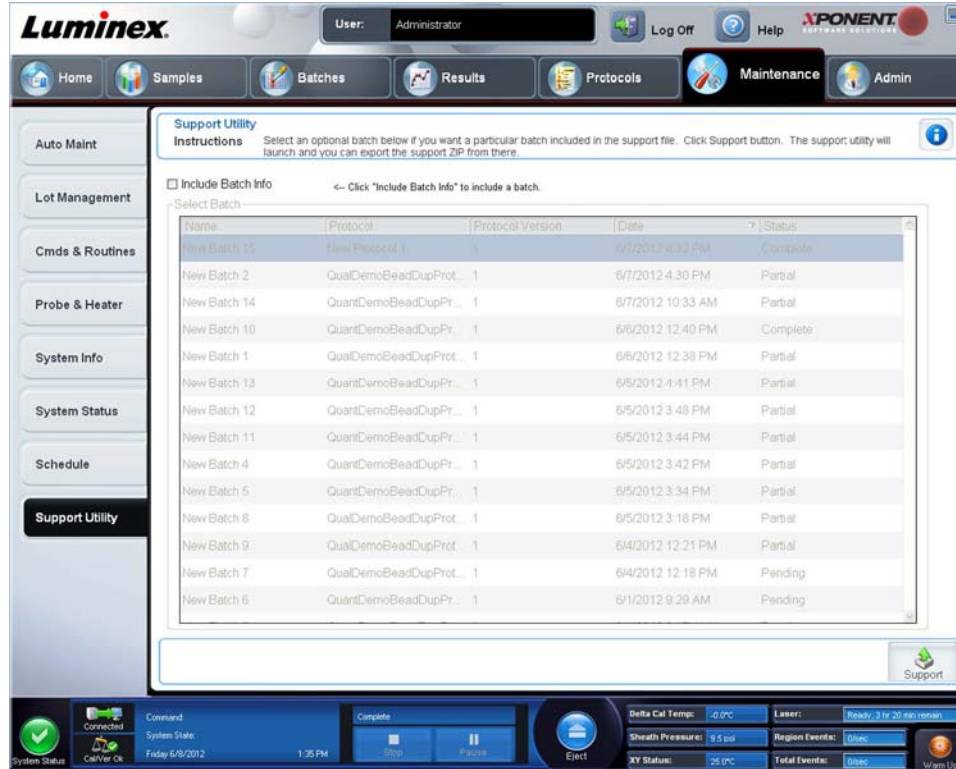
Use this tab to view reminders for scheduled maintenance due to be performed on the analyzer.

The **Reminders** section displays:

- **Subject**- The maintenance occasion scheduled for an alert.
- **Reminder** - A description of the maintenance that you need to perform on that occasion.
- **Next Alert Date** - The date on which xPONENT® alerts you about the maintenance occasion.
- **Alert Time** - The time at which xPONENT alerts you about the maintenance occasion.
- **Notes** - Any additional information you want to know about the maintenance occasion.

**NOTE:** This is a view-only page when accessed from Maintenance. Access the Schedule tab through the Admin page to change settings.

## Support Utility Tab



Use this tab to type information that will be useful in the event you need to contact Luminex® Technical Support. On this tab, you can type your contact information and comments, as well as create and export a .zip file containing system logs and optional batch files. This file can be sent to Luminex Technical Support, who can use the information in the event of a service call.

This tab contains the following:

- **Include Batch Info.** - Included batch information from a selected batch in the **Support Utility.zip** export folder.
- **Select Batch** - Displays a list of all batches. The list includes:
  - **Name**
  - **Protocol**
  - **Protocol Version**
  - **Date**
  - **Status**

After you select the Support button, the dialog box contains:

- **Name, Phone, Company, and Email** - Type your information in these boxes so that Luminex Technical Support can contact you.
- **Clear** - Clears all the information in the **Name, Phone, Company, Email, and Comment** boxes.
- **Browse** - Opens the **Browse for Folder** dialog box to choose an alternate destination folder for the utility .zip file.

### Sending a Support.zip File

1. If you want to include a batch file, select it and check **Include Batch Information**.
2. Press **Support**. The Support Utility launches.



3. Type your name in the **Name** box.

**Support Utility** About

**Instructions:** Select an application on the list to view default support files. Click the "Add More Files" or "Take Screen Shot" button to add additional support files. When you are done, click "Save File" to generate the support file.

**Select Application**

xPONENT 4.2

**User Info**

Name  Company Name   
*Enter a name.* *Enter a company.*

Phone Number  Email   
*Enter a valid phone number.* *Enter a valid email address.*

Comment   
*Please enter a comment.*

**Support Files** Double-click file below to view.

C:\Documents and Settings\All Users\Application Data\Luminex\Common\LMNX\Support\SupportFiles\_2012531\_14192\aystermin  
C:\Documents and Settings\All Users\Application Data\XPONENT\Setup.log  
C:\Documents and Settings\All Users\Application Data\LUMINEX\XPONENT42\Log\startup.1.log  
C:\Documents and Settings\All Users\Application Data\LUMINEX\XPONENT42\Log\startup.10.log  
C:\Documents and Settings\All Users\Application Data\LUMINEX\XPONENT42\Log\startup.2.log  
C:\Documents and Settings\All Users\Application Data\LUMINEX\XPONENT42\Log\startup.3.log  
C:\Documents and Settings\All Users\Application Data\LUMINEX\XPONENT42\Log\startup.4.log

**Directory Configuration**

Output Directory

4. Type your company name in the **Company** box.
5. Type your phone number in the **Phone** box.
6. Type your email address in the **Email** box.
7. In the **Comment** box, type a detailed description about the problem you are experiencing.
8. Verify the location where you want to store the file. To change the location, click **Browse**, then navigate to the new folder and click **OK**.
9. Click **Save File**. The saved file includes date and time information.
10. Send an email to support@luminexcorp.com and attach the support file (**xPONENTSupportFile.zip**) to the email.

## Chapter 9: Admin Page

You must have the appropriate license to view some of the features of in the **Admin** page. This page contains the following tabs:

- **System Setup**
- **Group Setup**
- **User Setup**
- **Batch Options**
- **Alert Options**
- **CSV Options**
- **Archive**
- **Licensing**
- **Schedule**
- **Report Options**

### System Setup Tab



Use this tab to configure system settings such as application settings, LIS settings, maintenance page options, and external analysis program settings.

### Application Settings

These settings change some of the basic ways that xPONENT® works, allowing customization of many of the basic functions.

- **Enable Virtual Keyboard** - Enables the touchscreen 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 will 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 Lab Information System (LIS).

- **Connect to LIS** - Enables connection to the LIS.
- **Browse** - Opens the **Browse For Folder** dialog box. Select a location for the system to watch for incoming orders.

## 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** box, and the name displays in the **Name** box.
  - **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.
  - **OK** - Saves the chosen settings and exits the dialog box.
  - **Cancel** - Cancels changes and exits the dialog box.
- **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 Third Party Analysis when batches complete for all protocols** - Disables the automatic launch of the third-party analysis program after batch acquisition.

## Arrange Main Page Headers

These options enable the customizing of the main page headers at the top of the xPONENT® window.

- **Arrange Main Navigation Buttons** - Select or clear the check boxes to display or remove main page headers. The **Home** page header cannot be removed. 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.
- **Main Navigation Button Arrows** - Click a main page header and then click an up or down arrow to change the selected header's order of appearance at the top of the window. The **Home** page cannot be moved.
- **Default** - Restores the software to the default page header arrangement.

## Maintenance Options

This section displays procedures to use when initializing the system.

- **System Initialization Procedure** - Displays the available selections to use as the default system initialization procedure. After selecting an option, click **Save** at the bottom right portion of the window to save the selection as the default 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.
- **Calibration expiration days** - Allows to set how often the system will need to be recalibrated.

## Adding an External Analysis Program

To 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. Click **Add New** to open the **New External Analysis Program** dialog box.
3. Type a name for the external analysis program.
4. Click **Browse** to navigate to the .exe file for that program. Double-click the file name.
5. Type 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.

## Editing an Analysis Program

1. In the **Installed Analysis Programs** list, click the program you want to edit.
2. Click **Edit**. The **Edit External Analysis Program** dialog box opens.
3. 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.

## Removing an Analysis Program

To remove an analysis program from the **Installed Analysis Programs** list:

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

## Arranging Main Navigation Buttons

Use this section to arrange the main pages at the top of the xPONENT® screen.

**NOTE:** The Home page, and in some instances the Admin page, cannot be moved.

To arrange the main navigation buttons:

1. Select or clear the check boxes by each page name to hide or display the page.
2. Click a page name and use the up and down arrows to change the order in which the pages display, from left to right.
3. Click **Save**.
4. Click **Default** if you want to restore the main navigation.

## Maintenance Options

This section allows you to define the **System Initialization** Routine.

Run one of the **System Initialization** procedures as part of your daily startup routine.

**NOTE:** See Daily Activities on the “[Home Page](#)” for daily maintenance routines.

Luminex recommends that you verify daily and calibrate weekly. You should also verify and calibrate if any of the following occurs:

- The delta calibration temperature exceeds  $\pm 5^{\circ}\text{C}$ .
- You move the instrument.
- You experience sample acquisition problems.
- You perform maintenance on the instrument, for example, replacing a hardware component.

Available system initialization procedures are as follows:

- Fluidics preparation, calibration, performance verification
- Fluidics preparation, performance verification
- Fluidics preparation

## Defining the System Initialization

**NOTE:** Luminex® recommends daily performance verification and weekly calibration of the FLEXMAP 3D® system. You can set up the system initialization routine to include calibration and verification on the Admin page, System Setup tab, Maintenance Options section.

1. Open the **Admin** page.
2. Click **System Setup**.



3. Under **Maintenance Options**, you can select a procedure from the drop-down list.
  - Laser warm-up, fluidics prep, calibration, performance verification
  - Laser warm-up, fluidics prep, performance verification
  - Warmup, fluidics prep
4. Click **Save**.

## 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. 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. These users then have permissions granted to their group.

**NOTE:** Assign permissions directly to an individual by assigning the user to a specific Group Profile on the User Setup tab.

This tab contains the following:

**Group Profile** - The following user groups are predefined:

- **Administrator**
- **Supervisor**
- **Service**
- **Technician2**
- **Technician1**
- **Reviewer**

The user will belong to the group you select.

**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

- **System Administration**
- **Batch Management**
- **Protocol Management**
- **Lot and Std/Ctrl Kit management**
- **Import and export data**
- **Archiving**

The **Allowed** check box next to the desired permission in the **Features** section enables the selected group to perform that task. The **Signature Required** check box next to the desired permission requires a digital signature whenever a user in the selected group performs that task.

Clear the **Allowed** check box 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.

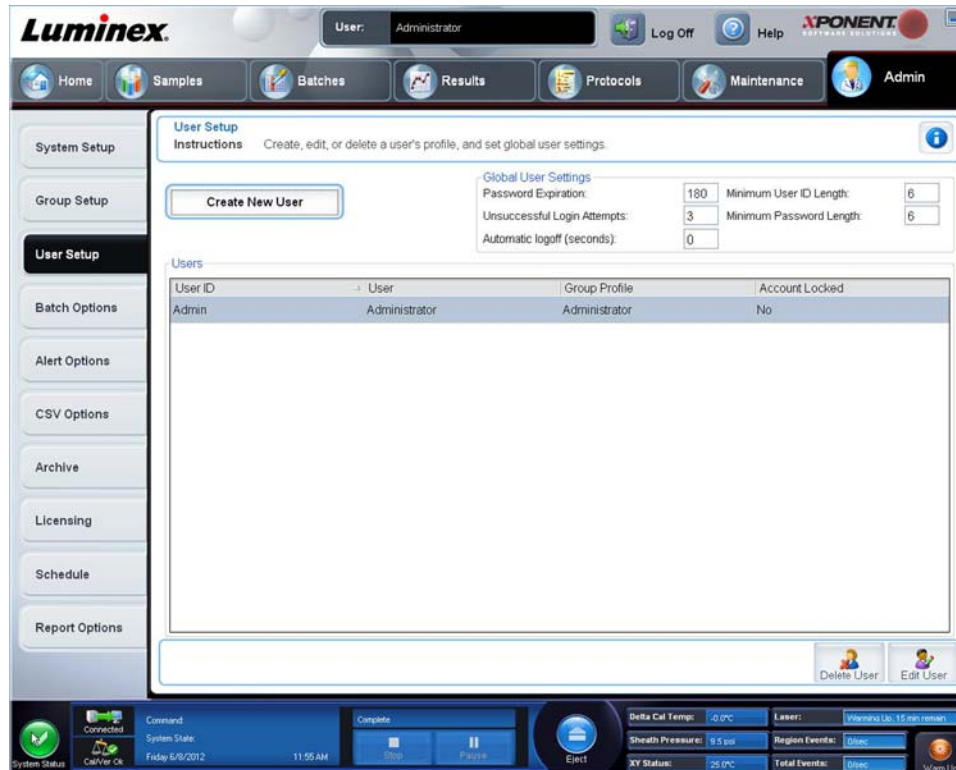
The following permissions are available for these groups:

- **System Administration**
  - **System Administration Manage Users (add, edit, or delete users)**
  - **Manage System Configuration**
  - **Perform Calibration and Verification**
  - **Manage Alerts**
  - **Manage scheduled maintenance**
  - **Change batch and CSV options**
  - **Allow exit software**
  - **Batch run override system**
  - **Create, delete, activate CAL and VER Lots and Kits**
- **Batch Management**
  - **Create Batch**

- **Edit Batch**
- **Delete Batch**
- **Run Batch**
- **Validate and Invalidate Results**
- **Approve Batch**
- **Reanalyze Results**
- **Save Batch after changing results**
- **Change Formula**
- **View Processed Batch Results**
- **Export Processed Batch Results**
- **Change Sample Load Volume During Run**
- **Protocol Management**
  - **Delete Protocol**
- **Lot and Std/Ctrl Kit management**
  - **Create Std/Ctrl Kit and Lots**
  - **Edit Std/Ctrl Kit and Lots**
  - **Delete Std/Ctrl Kit and Lots**
- **Import and Export Data**
  - **Export Batch, Protocol, Kit or Lot Files**
  - **Import Batch, Protocol, Kit or Lot Files**
- **Archiving**
  - **Backup/Restore**
  - **Import/Archive**

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

## User Setup Tab



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

- **Create New User** - Opens the **Create User Account** screen.
- **Global User Settings** - This section contains the following:
  - **Password Expiration** - Type 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.

### Editing User Permissions

In the **Users** list, click the user ID, then click **Edit User**. In the **Edit User Account** screen, edit the desired information, then click **Save**.

### Restoring Account Status

If users attempt to log in unsuccessfully more than the number of times allowed, they will be locked out. In the **User** list, click the user ID, then click **Edit User**. Clear the **Account status: Locked** check box, then click **Save**.



## Create User Account Window

Use this tab to set the options for a new user. Any user with access to this tab can assign rights to any and all groups.

This tab contains the following:

- **User ID** - Type a User ID in this box. The User ID is not case-sensitive. You can change the required number of characters on the **User Setup** tab. Once you create and delete a User ID, you cannot use that User ID again in the future.
- **User** - Type the user's name.
- **Account Status** check box - Select this check box to lock the amount. Clear this check box to unlock the account. When an account is locked, the check box is selected.
- **Group Profile** list - Select:
  - **Administrator**
  - **Supervisor**
  - **Service**
  - **Technician2**
  - **Technician1**
  - **Reviewer**
- **Password** - Type a unique password for the user in this box.
- **Reenter Password** - This becomes active when you type a password in the **Password** box. Type the password again in the **Reenter Password** box to confirm it.
- **Change password after next login** - Requires the user to change the password after the first login. This check box is enabled by default.
- **Save** - Saves and returns to **User Setup**.
- **Cancel** - Returns to **User Setup** without saving.
- **Global User Settings** - This section contains the following:
  - **Password Expiration** - Type 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.
- **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 **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.

### Creating a New User

1. Click **Create New User**. The **Create User Account** window opens.
2. Type the user ID in the **User ID** box.
3. Type the user's name in the **User** box.
4. Type a password for the user Password box, then re-type it in the **Reenter Password** box. If you want the user to change the password on first login, select **Change password after first login**. The required length for passwords is set on the **Group Setup** tab.
5. In the **Group Profile** list, select the role for the user you are creating.
6. Click **Save** to cancel to return to **User Setup** without saving.

### Edit User Account Window

On this page, users can modify the information of the user who was selected from the **User Setup** tab.

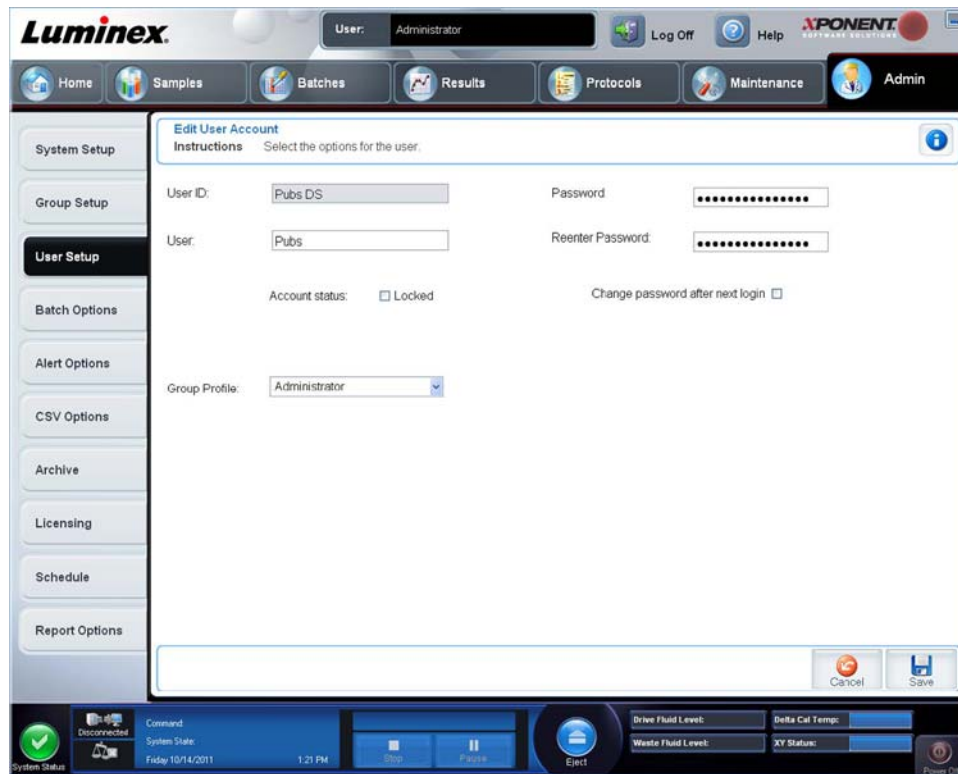
The **Edit User** page contains the following:

- **User ID** - The identification of the user.
- **Name** - The user's name.
- **Group Profile** - The user's group or category.
- **Change Password After Next Login** - A box that, when checked, indicates that the user will change his or her password at the next login.
- **Account Status** - Locked or functioning. A check in the **Locked** box indicates that the account is locked due to the maximum number of unsuccessful login attempts.
- **Password** - The user's current password.
- **Reenter Password** - The user's current password, repeated.
- **Save** - Click to save the changes made within the **Edit User Account** window.
- **Cancel** - Click to cancel the process and return to the **User Setup** tab.

### Editing User Permissions

1. In the **Users** list, click the user ID, then click **Edit User**.
2. In the **Edit User Account** window, edit the desired information.

3. Click **Save**.



## Batch Options Tab

Use this tab to set options for analysis and acquisition of batches.

This tab contains the following:

**Batch Options** - This section displays the following options:

- **Allow running a batch if the instrument is not warmed up** - Allows batches to run if the instrument is not warmed up.
- **Allow running or saving a batch with expired reagents and fluids** - Allows batches to run with expired reagents and fluids.
- **Allow running a batch if XY temperature is not in range** - Allows batches to run if the XY temperature is not in range.
- **Allow running a batch if the instrument is not calibrated or verified** - Allows batches to run if the instrument is not calibrated.
- **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** - Type the number of digits the system displays. The default number of digits is three.
- **Minimum bead count for obtaining results** - Type 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 analyzer does not display data for bead sets not generating events equal to or less than this value. Type 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 Batch Routines**

- **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. Select this option to specify a particular routine to run before running a batch.
- **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 Analysis Graph Axes**

- **Log X-axis**
- **Log Y-axis**

**Batch Thresholds** - Displays the following options:

- **Low bead count detection**
  - **Detection Enabled** - When this box is checked it enables low bead count detection.
  - **Well Count**
  - **Total Bead Count**
  - **Error (Stop)** - Stops the batch.
  - **Warning (Pause)** - Pauses the batch.
  - **Warning (Log)** - Logs a warning if the number of successive wells in the Well Count box are run without reaching the number of beads in the Bead Count box.
  - **Run Routine** - Displays a drop-down box which allows you to select the routine you want to run when a low bead count is detected.

Click in either box to type a number other than the default.

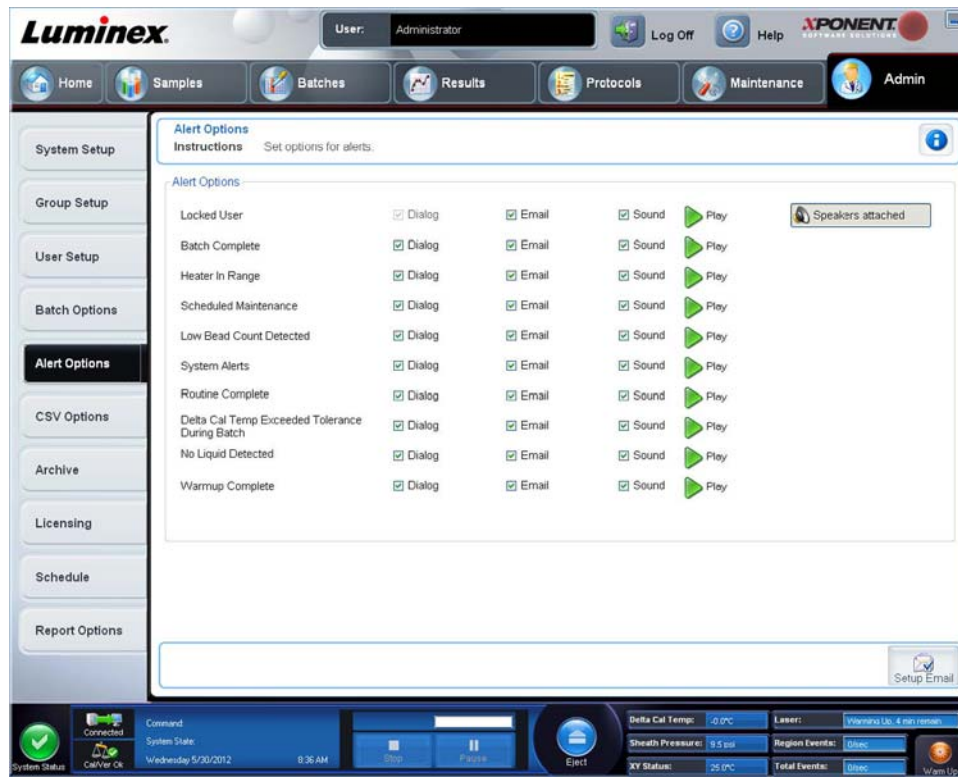
- **Liquid Detection** - Selecting either **Error** or **Warning** stops the batch or logs a warning if no liquid is detected in the well.

**Cancel** - Cancels changes.

**Save** - Saves changes.

## Alert Options Tab

Use this tab to set options for alerts about various system events.



**Alert Options** - Offers three check boxes for each alert - **Dialog**, **Email**, and **Sound**. This section displays the following events:

- **Locked User** - The user is locked out of the login.
- **Batch Complete** - The batch is finished.
- **Heater In Range** - The plate heater is warmed to the designated range.
- **Scheduled Maintenance** - A scheduled maintenance routine is now due.
- **Low Bead Count Detected** - A bead count below the accepted range is encountered.
- **System Alerts** - One of the following events has occurred:
  - Overloaded syringe pump plunger
  - Probe step loss
  - Sheath pressure error
  - X step loss
  - Y step loss
- **Routine Complete** - The currently running routine is complete.
- **Delta Cal Temp Exceeded Tolerance During Batch** - The delta cal temperature fell outside the designated range during the running of the batch.
- **No Liquid Detected** - There is no liquid detected.
- **Warmup Complete** - The laser is warmed up.

Select the appropriate check boxes to display a pop-up message, send an email, or play a sound to alert you when the event occurs. All check boxes are selected by default. **Cancel** and **Save** buttons display if you change a setting.

**Speakers Attached/Speakers Not Attached** - Enables sounds to be played through speakers. Click this button if you have speakers attached to your system. The button title will alternate between attached/not attached status when you click it.

**Setup Email** - Opens the **Setup Email** dialog box.

Enable or disable email notification by selecting or clearing the **Email Active** check box.

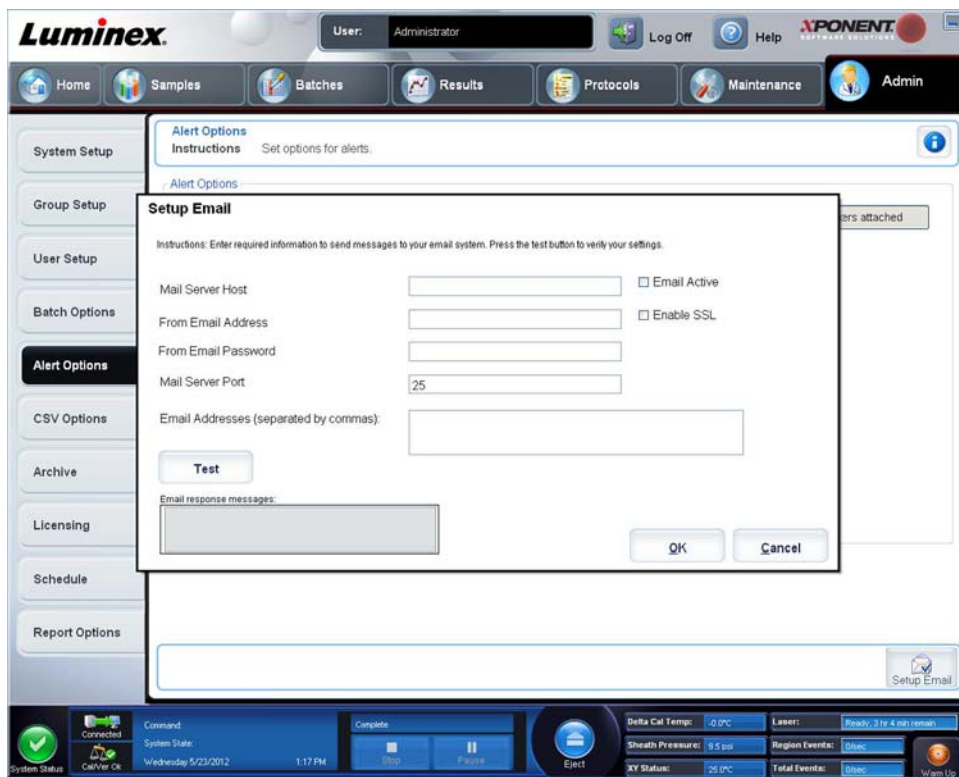
Contact your network administrator to determine the information needed in the **Mail Server Host**, **From Email Address**, **From Email Password**, and **Mail Server Port** boxes, and if you need to select the **Enable SSL (Secure Sockets Layer)** check box.

The **Test** button tests the email settings. Select **Apply** to initiate the settings you have selected, or click **OK** to use the settings and exit the dialog box. **Cancel** exits the dialog box without saving the settings.

## Alert Options Tasks

To set notification options for various events:

- Select **Dialog** if you want a dialog box to open for a specific event.
- Select **Email** if you want to send an email notification for a specific event.
- Select **Sound** if you want a sound to play for a specific event.
- 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 checking or clearing the **Email Active** check box.
- Contact your system administrator to determine the correct information for the **Mail Server Host**, **From Email Address**, **From Email Password**, and **Mail Server Port** boxes, and if you need to check the **Enable SSL (Secure Sockets Layer)** check box.
- Type addresses you wish to be sent alert notifications in the **Email Addresses** box.
- Click **Test** to send a test email to the addresses you have typed.
- Click **OK** to apply any changes and close the dialog box or **Apply** to apply any changes but remain in the **Setup Email** dialog box.

## CSV Options Tab



### CSV and Batch Export Options

This tab contains the following:

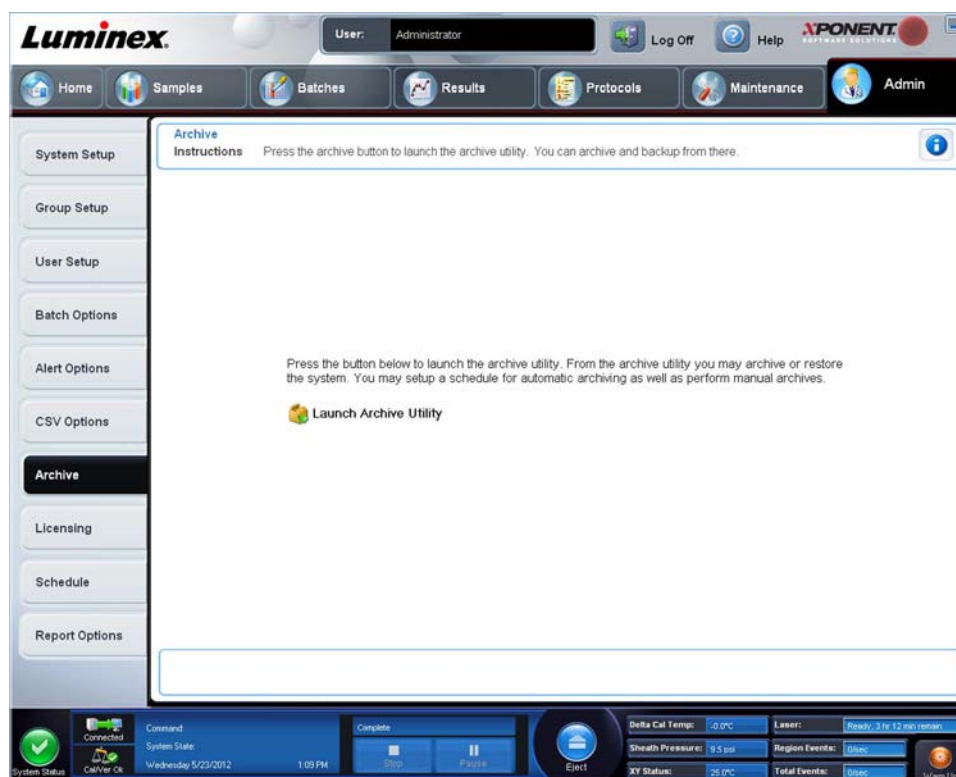
- **Automatically export results CSV file when batch is complete** - Automatically export the results .CSV file when the system finishes analyzing the batch. This allows running programs on exported data without having to manually start the export.
- **Automatically export batch when batch is complete** - 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.
- **Use US regionalization format only** - Exports data only in US regionalization format.
- **Include Advanced Statistics** - Exports advanced and additional statistics, for example, trimmed counts, in the CSV file.
- **CSV Export Folder and Automatically Exported Batch File** - 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.
- **Test Sort Order** - Defines a method to sort the test data. The options are **By Analyte Name**, **By Region ID**, or **By Setup Order**.

### Raw Run Files Export Options

- **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 LXB 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** - Click the check box if you want the automatic conversion.

- **Cancel** - Cancels changes.
- **Save** - Saves changes.

## Archive Options Tab

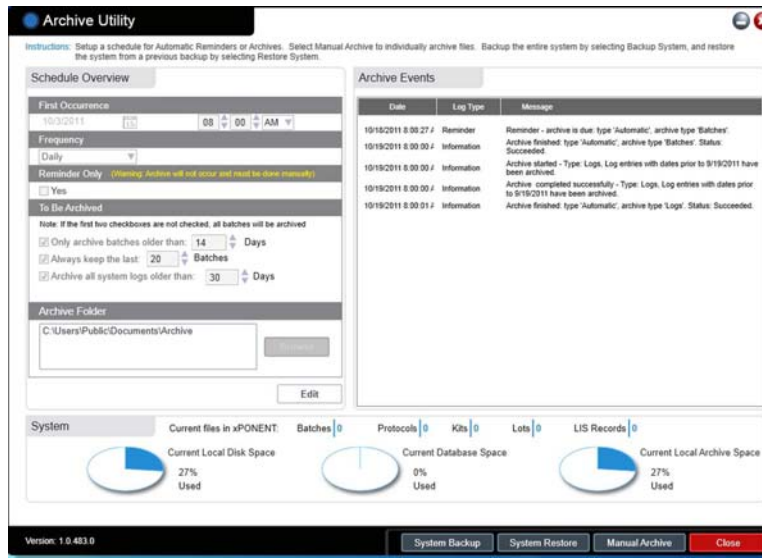


Use this tab to archive all file types - batches, protocols, kits, lots, and LIS records. When you click the **Launch Archive Utility** button, the **Archive Utility** opens.

**NOTE:** To back up or restore xPONENT® files, quit the application and select xPONENT ARCHIVE.



## Archive Utility



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

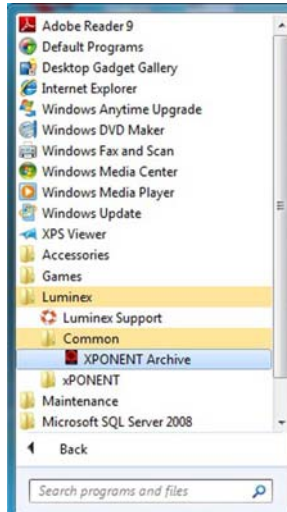
The Archive Utility runs continuously. If automatic archives are scheduled, they occur whether xPONENT is running or not.

When you want to backup or restore xPONENT, quit the application and run the Archive Utility from the **Start** menu.

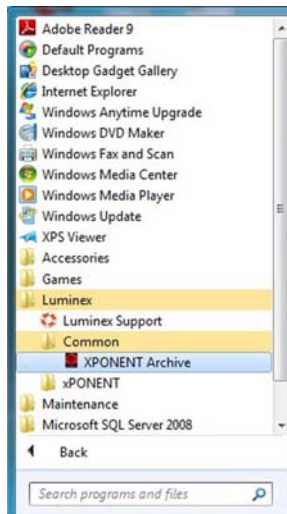
The **Archive Utility** includes the following elements:

- **Schedule Overview** - Use the selections in this dialog box to schedule archiving.
  - **First Occurrence** - Use this to select the date and time for the first automatic archive.
  - **Frequency** - Use this to establish how frequently the system performs the archive process.
  - **Reminder Only** - Use this to establish whether you want a regular reminder from the system so that you can perform archiving manually.
  - **To Be Archived** - Use these choices to establish which files are archived.
  - **Archive Folder** - Use this to 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** - This lists all events related to archiving activity, including **Date**, **Log Type** (Reminder, Warning, or Information), and **Message**.
- **System** - This displays how many files of each type are currently in xPONENT: Batches, Protocols, Kits, Lots, LIS Records. It also shows, in the form of pie charts, how much local disk space, database space, and local archive space is in use.

- **System Backup** - Click this to back up your system. It requires a log in and then instructs you to shutdown the xPONENT software and launch the **Archive Utility** from the **Start** menu.



- **System Restore** - Click this to restore your system. It requires a log in and then refers you to the **Start** menu to restore your system.

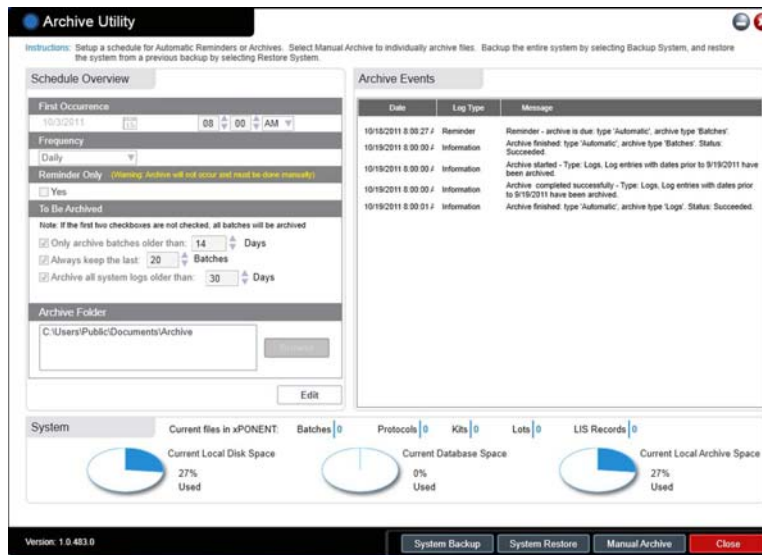


- **Manual Archive** - Click this to perform a manual archive process. It requires a log in and then opens the **Manual Archive** window.
- **Close** - Click this to close the **Archive Utility**.

### Setting Up Automatic Archiving

Click **Edit** in the **Schedule Overview** box to enable the fields to accept your edits and to enable the **Browse** button. The label on the button changes to **Save**.

1. Specify when you want your archives to begin using the calendar.



2. Using the drop-down list, select how often you want to perform archives.
3. 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.
4. In the **To Be Archived** drop-down list, select 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
5. In the **Archive Folder dialog** box, 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** dialog box reflects that same location when you import those archived files.

6. Click **Save** to save your settings.

## Performing a Manual Archive

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

1. In the **Archive Utility**, click **Manual Archive** to open the **Manual Archive** window.



2. Using the tabs on the left side of the window, select the type of files you want to archive:

- Batches
- Logs
- Protocols
- Kits
- Lots
- LIS Records

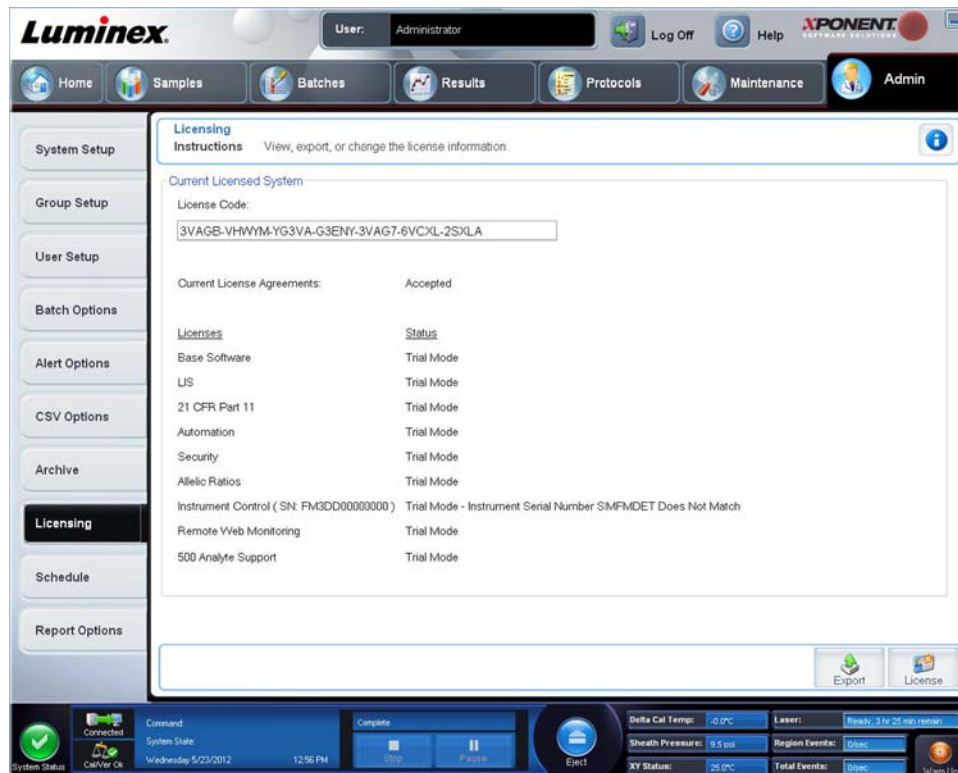
Each tab opens a list of files available for archiving, except **Logs**, which requires only a choice of how old, in days, a file has to be archived.

3. Select 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.
4. 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 lose the information in the **To Be Archived** box.

5. Click **Close** to close the **Manual Archive** window.

## Licensing Tab



Contact Luminex® Technical Support to upgrade xPONENT® for FLEXMAP 3D® or to obtain a new license.

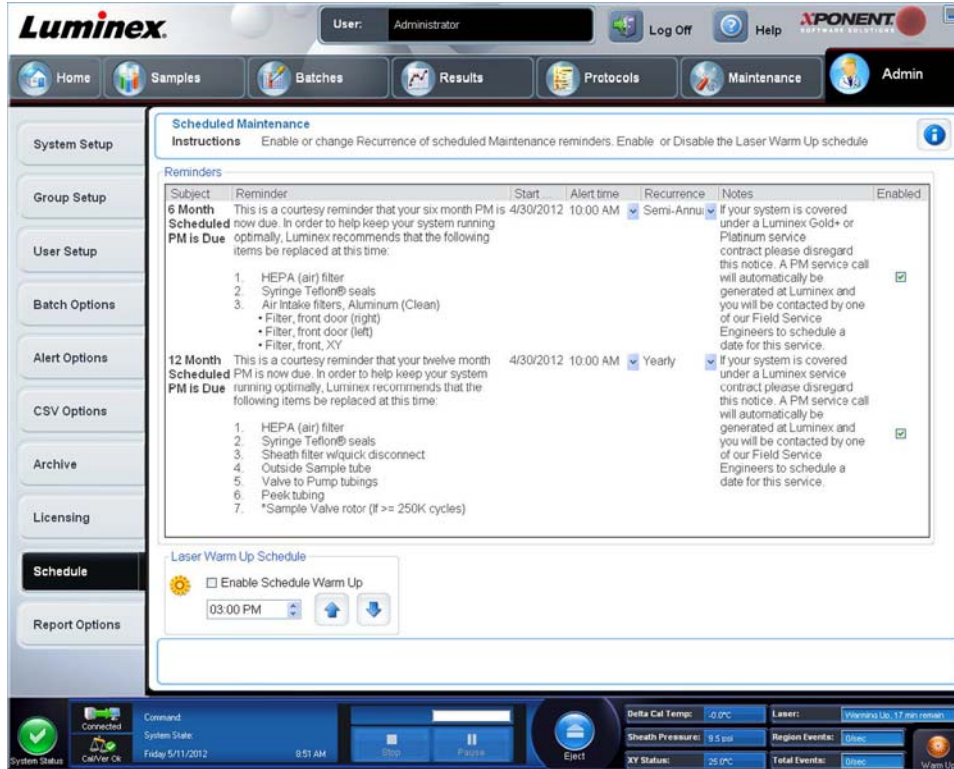
**NOTE:** You must restart the computer for the new license to take effect.

### Adding a New License Key

1. Access the **Admin** page, then the **Licensing** tab.
2. Click **License** (bottom right corner of window).
3. Copy and paste the new key into the **License Code** field. The **License File** field remains blank.
4. Click **OK**. This closes xPONENT®, applies the license, and restarts xPONENT.

Contact Luminex® Technical Support if you have any difficulty saving or adding a new license key.

## Schedule Tab



Use the **Schedule** tab to enable or change the recurrence of scheduled maintenance reminders.

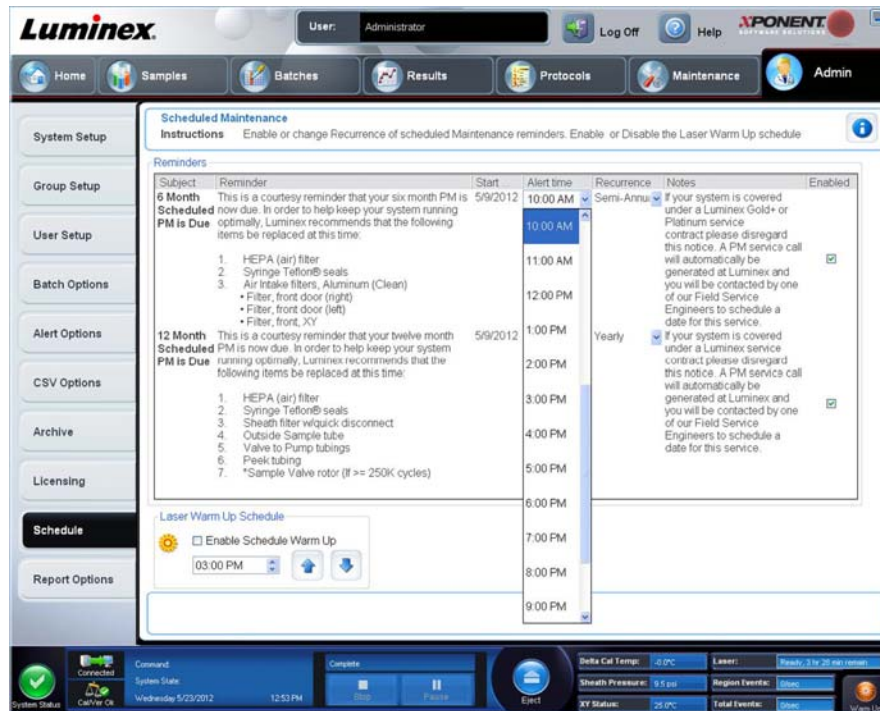
- Choose the time of day that you want to receive alerts in the **Alert Time** list.
- Choose how often you want to receive reminders in the **Recurrence** list.
- Enable or disable the reminders by selecting or clearing the **Enabled** check box.

### Editing Maintenance Schedule Settings

Edit maintenance settings on the **Schedule** tab accessed from the **Admin** page. The **Schedule** tab can also be accessed from the **Maintenance** page, but the settings cannot be edited from there.

1. Access the **Admin** page, then the **Schedule** tab.
2. On the **Schedule** tab, use the drop-down menus to edit the following items for any scheduled activity:
  - **Alert Time** - the time of day that you want to receive alerts.
  - **Recurrence** - how often you want to receive reminders.

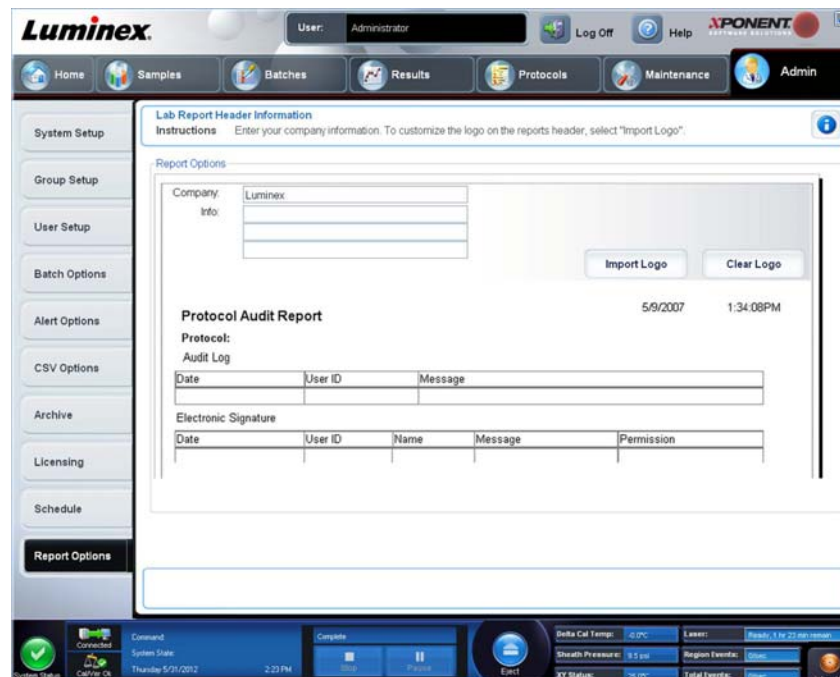
- **Laser Warm Up Schedule** - Schedule the time you want the lasers to warm up. You can either enable or disable this option.



3. Enable or disable the reminders by selecting or clearing the **Enabled** check box.

## Report Options Tab

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



1. Type a company name in the **Company** box, and any additional information in the **Info:** field.

- NOTE:** The logo file should be 920 x 125 pixels. If you want the logo to appear 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 appear behind the company information.
2. Click **Import Logo** to open the **Open** dialog box and select the file you want to use for the logo at the top of reports.
  3. Click **Clear Logo** to return to the default logo.
  4. Click **Save**.