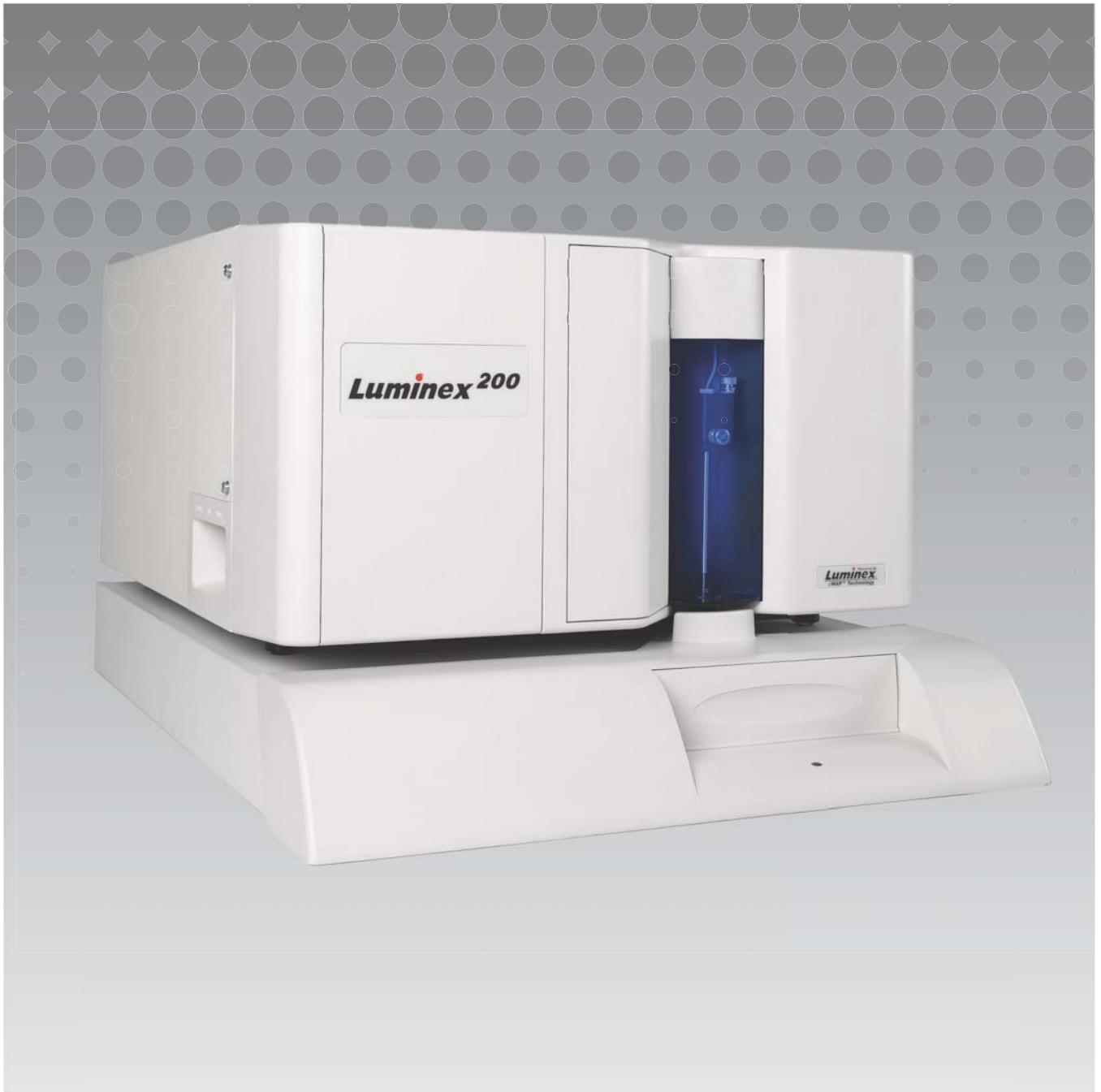


Luminex

Software User Manual | IVD

xPONENT[®] 3.1 Rev. 2

IVD



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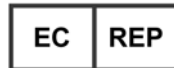
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xPONENT[®] 3.1 Rev. 2 Software User Manual



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Chapter 1: Introduction

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

Software Packages

xPONENT[®] software has different levels of functionality:

- Allows you to perform analysis from IVD protocols and batches, review and print reports, and perform Luminex system maintenance.
- Instrument Control - Allows the application to connect to and communicate with an instrument identified by a specific serial number.
- Secure - Includes all of the Basic functionality, as well as administrator-controlled user permission levels.
- 21 CFR Part 11 - Includes all of the Secure functionality as well as requiring 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.
- Remote Web Monitoring - Allows you to view alerts and system status using a webpage.
- 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 sample 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.

This guide will be updated periodically. To ensure that you have a current version, visit <http://www.luminexcorp.com/>. The most recent version of this guide, as well as all translations of this guide, are available for download on the Resources page.

Warnings, Notes and Symbols

The following informational notes and warning appear as necessary in this manual.

TABLE 1. **Definitions**








Type of Note	Meaning
NOTE:	This message is used to provide general helpful information. No safety or performance issues are involved.

TABLE 1. Definitions

Type of Note	Meaning
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 can result in hazardous conditions
WARNING:	This message is used in cases when danger to the operator or to the performance of the instrument is present. Failure to comply with the warning can result in incorrect performance, instrument failure, invalid results, or hazard to the operator.

You will encounter these symbols during the use of xPONENT software. They represent warnings, conditions, identifications, instructions, and regulatory notations as follows.

TABLE 2. Symbols

	Warning, Biological Hazard		Heat/Hot Surface Warning
	General Warning, Caution, or Risk of Danger		Authorized Representative in the European Community
	Manufacturer		In-vitro Diagnostic Device
	Conformité Européenne (European Union Conformity)		

General Guidelines

Modifying or deleting Luminex® xPONENT® system files can 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 can 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 can be present during system operation. Therefore, we recommend that all system users adhere to standard laboratory safety practices. The protection provided by the equipment can be impaired or the warranty voided if the Luminex® 100/200™ is used in a manner not specified by the instructions or by Luminex Corporation.

Biological Samples

Human and animal samples can 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

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 can 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. Minimize exposure of xMAP beads to light to maintain product integrity.

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 <http://www.luminexcorp.com/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 can 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 can contain sodium azide as a preservative. Sodium azide can 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 can 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 and 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 IVD kit, follow the kit's product insert and 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 3. 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 volumes or sample sizes range from 10 µL to 200 µL. Ensure that some sample remains in the well after aspiration; about 25 µL greater than the sample volume. This amount can vary depending on the type of plate used. After acquisition, the Luminex analyzer washes the sample lines resulting in ejection of approximately 165 µL of sheath fluid back into the well for a 96-well plate. Ensure that there is room to add this amount to the well without overflowing and contaminating other wells. Follow the IVD kit package insert instructions for use.

The volume can be expounded by the following formula:

$$\text{Total well volume } (\mu\text{L}) - \text{Sample uptake volume } (\mu\text{L}) + 165 (\mu\text{L}) < \text{Maximum Well Volume } (\mu\text{L})$$

- 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).
- 165 (µL) = Volume expelled back as stated in the above paragraph.
- Maximum well volume plate = The maximum volume capacity of the wells in a selected 96- well microtiter plate.

Sample Dilution

Dilute concentrated biological samples such as plasma or serum following the IVD kit package insert instructions for use. If running an xMAP-based kit, follow the dilution instructions in the kit's product insert.

Reagents

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

Plates

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

For heated assays, use CoStar[®] Thermowell[®] 96-well, thin-wall polycarbonate, model P plates.

For non-heated assays, select a 96-well plate with an overall height no greater than 0.75 inches (19 mm). Follow the xMAP based IVD kit instructions for use. See the Bead Concentration section.

See the recommended consumables list on the Luminex website at <http://www.luminexcorp.com/Support/SupportResources/> for more information.

Chapter 2: Touring the Software

This chapter explores each section of the software and its functionality. For information about using the software, see “Using the Software” on page 57.

This chapter describes default views. Please note that views can be changed and functionality can be disabled by the xPONENT system administrator.

Log In

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.

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.



WARNING: Use of this software by untrained personnel can result in inaccurate data and test results. It is highly advised that users read this manual thoroughly before operating the software.

Help

English-language help is available for each window in the software by clicking the blue “i” button in the upper-right portion of the window in which you are working. You can also access the complete system-wide help by clicking **Help** at the very top of the screen, and then clicking **Contents** and **Index**.

Log Off

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

Exit

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

Screen Elements

The following section details the screen elements and the common terms used in this manual to describe them.

FIGURE 1. **Screen Elements**



1. Page

2. Tab

3. Right-click Menu

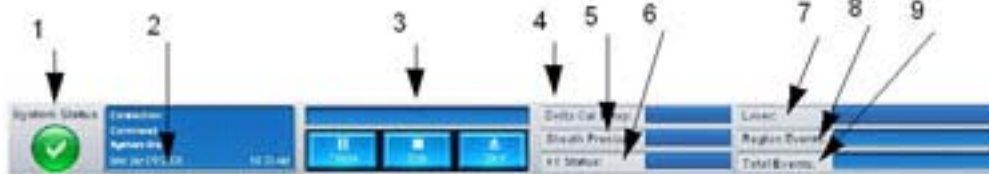
- **Page** - The main elements at the top of the window are “Pages”. Click a page to go to that section of the software. All but the **Home**, and in some cases the **Admin**, page can be moved or deleted. For more information, see “Arrange Main Navigation buttons” on page 47.
- **Tab** - The elements on the left side of the window are “Tabs”. Click a tab to go to that section. Some tabs require you to go in order, and will not let you click a tab further down without performing a task on the current tab.
- **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.
 - **Print All** - Prints all sections or cells of the item.
 - **Print Selection** - Prints only the selected section or cell.
 - **Import** - Imports a file.
 - **Export** - Opens a **File** dialog box. Use the **Browse** button to select a location, and type a file name. The export is in .CSV format. 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 remains at the bottom of all xPONENT windows. It displays the physical state of the Luminex analyzer. The values displayed are reported directly from the Luminex system.

FIGURE 2. **System Monitor**



- | | |
|---------------------------------|-------------------------|
| 1. System Status button | 6. XY status |
| 2. Command display | 7. Laser status |
| 3. Progress bar and buttons | 8. Region Events status |
| 4. Delta Cal Temp status button | 9. Total Events status |
| 5. Sheath Pressure status | |

- **System Status** - This button has two functions: When clicked, it opens the system log (see System Status Tab). 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, error, or other important user-notification, the button turns yellow with an exclamation point.
- **Command** - Displays the command currently running on the system.

NOTE: A yellow **Check Calibration** button is visible in the command display if the calibration or verification command has failed, when any verification is not current, or when the calibration or verification was performed prior to the calibration expiration setting.

- **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.
- **Stop** - Stops the system, regardless of command status.
- **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**.
- **Temp** - Displays the difference in temperature between the current reading and the reading when it was calibrated, in degrees Celsius. If the temperature is out of tolerance, it 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 and 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 and Heater** tab.
- **Laser** - Displays the laser status, including the time remaining until you must warm up the laser again. The **Laser status** button is blue. The button turns yellow when the lasers are turned off and about ten minutes before they turn off. When clicked, it 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.

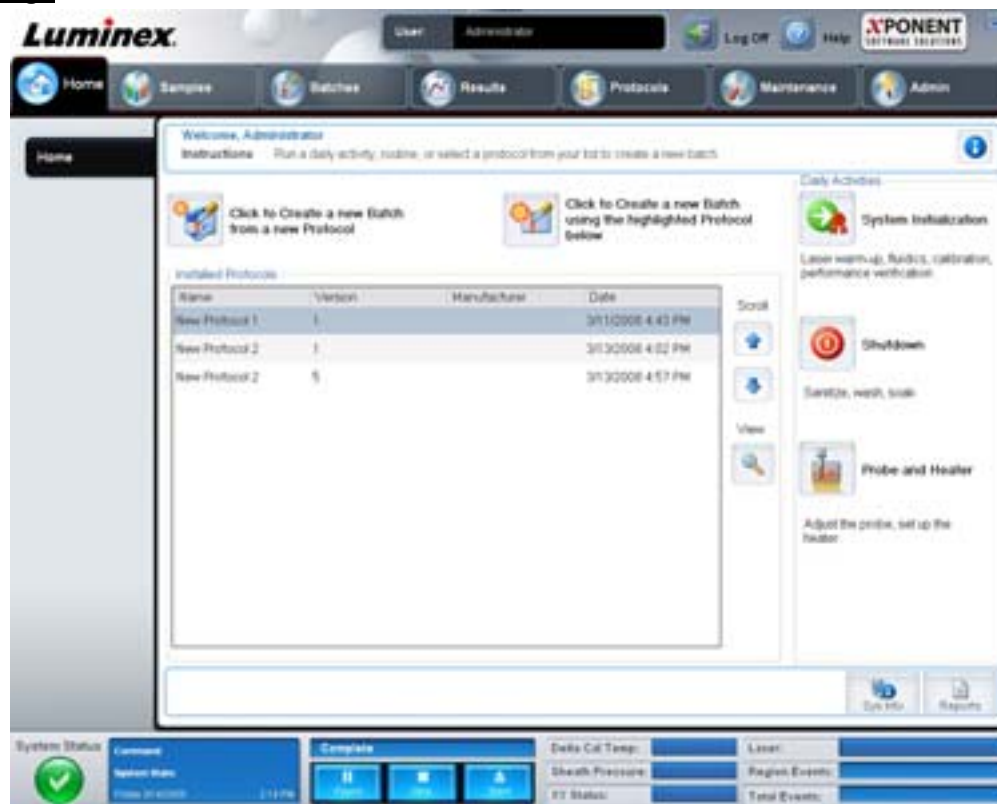
Home

The **Home** page displays a welcome message, batch creation buttons, **Daily Activities** shortcuts, and the **Installed Protocols** list.



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

FIGURE 3. Home Page



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” on page 12.
- **Installed Protocols** - Displays a list of protocols. The list contains the following information about each protocol:
 - Name
 - Version
 - Manufacturer
 - Date

Use the up and down 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 xPONENT software:
 - **System Initialization** - Opens the **System Initialization** command in the **Auto Maint** tab on the Maintenance page. For more information about this tab, see “Auto Maint Tab” on page 36.

- **Shutdown** - Opens the **System Shutdown** command in the **Auto Maint** tab on the **Maintenance** page. For more information about this tab, see “Auto Maint Tab” on page 36.
- **Probe and Heater** - Opens the **Probe and Heater** tab on the **Maintenance** page. For more information about this tab, see “Probe and Heater Tab” on page 41.
- **Sys Info** - Opens the **System Info** tab of the **Maintenance** page. For more information, see “System Info Tab” on page 42.
- **Reports** - Opens the **Reports** tab of the **Results** page. For more information, see “Reports Tab” on page 30.

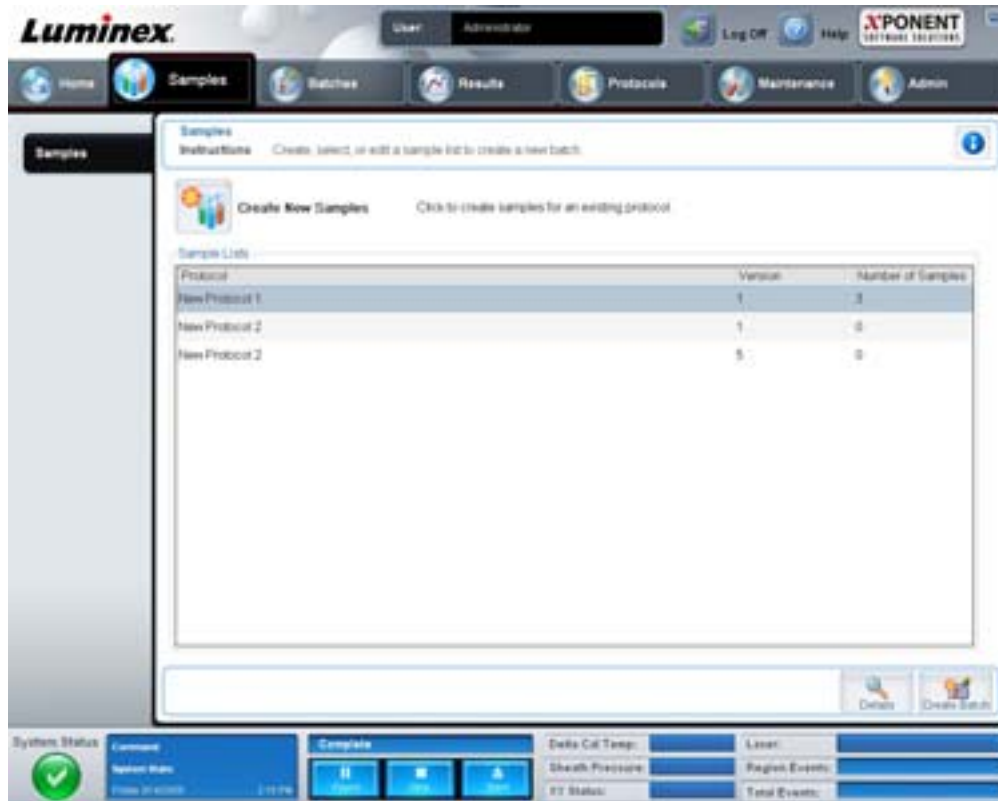
Samples

Use this page to create new samples, view the details of a sample list, or to create a new batch. Samples can also be added via a Lab Information System (LIS), if your software is licensed for a LIS.

This page contains the following tabs:

- **Create Sample** - Displays when the **Create New Samples** button is clicked.
- **Edit Samples** - Displays when the **Details** button is clicked.
- **Protocol** - Displays when the **Create Batch** button is clicked.
- **Stds & Ctrls** - Displays when the **Create Batch** button is clicked.
- **Plate Layout** - Displays when the **Create Batch** button is clicked.

FIGURE 4. **Samples Tab**



This tab contains the following:

- **Create New Samples** - Opens the **Create Sample** tab.
- **Sample Lists** - Contains a list of protocols, including the version number and the number of samples associated with each protocol.
- **Details** - Opens the **Edit Samples** tab to view or edit sample details for the selected protocol.

- **Create Batch** - Opens the **Protocol** tab to create a batch.

Create Sample Tab

Use this tab to type and view sample information.

FIGURE 5. Create Sample Tab



This tab contains the following:

- **Protocol** - Displays the protocol selected in the **Samples** tab. If xPONENT has an LIS license enabled, any sample details provided by the LIS also appear in the **Sample** list.
- **Version** - Displays the protocol version number. It is not editable.
- **Sample** - If you have the LIS-enabled version of the software and are currently connected to the LIS, the sample list autopopulates when the LIS provides samples orders. You can only view or run a sample list created in the LIS; you cannot edit it. Otherwise, use **Create New Samples** to create a new sample. Once you have typed and saved the sample information, it appears in the list to the left. This list displays the samples you have already created. To reorder the sample's acquisition location, use the move arrows.

The following **Delete**, **New**, **Edit**, and **Undo** buttons only display depending on actions taken in the **Create Sample** tab.

- **Delete** - Deletes a highlighted sample.
- **New** - Creates a new sample.
- **Edit** - Edits a highlighted sample.
- **Undo** - Reopens the **Create Sample** tab without saving any changes made using the **Edit** or **New** buttons.
- **Save** - Saves changes made to the **Sample** list.
- **Close** - Returns to the **Samples** tab.

Batches

Use the **Batches** page to create and run a new batch from an existing protocol or a new multi-batch. This page contains the following tabs:

- **Protocol** - Displays when the **Create a New Batch from an existing Protocol** button is clicked.
- **Stds & Ctrl** - Displays when the **Create a New Batch from an existing Protocol** button is clicked.
- **Plate Layout** - Displays when the **Create a New Batch from an existing Protocol** button is clicked.
- **New MultiBatch** - Displays when the **Create a New Multi-Batch** button is clicked.

Batches Tab

The **Batches** tab displays the following:

- **Create a New Batch from an existing Protocol** - Opens the Protocol tab, where you can create a new batch from an existing protocol. For more information, see “Create a New Batch from an Existing Protocol” on page 64.
- **Create a New Multi-Batch** - Simultaneously opens the **New Multibatch** tab and the **Select Pending Batch** dialog box, where you can create a multi-batch from pending batches. For more information, see “Create a Multi-Batch” on page 66.
- **Pending Batches** - Displays a list of pending batches. It includes the batch name, protocol, protocol version, date, and status for each pending batch. If there is no data in the list of pending batches, the following buttons do not appear on the screen.
- **Single Step** - Instructs the system to acquire a well and then pause. This ensures the system is working correctly before running an entire batch.
- **Save Prtcl** - Saves a protocol and or assay standard/control information.
- **Plate Layout** - Opens the **Report** dialog box, which includes the **Batch Plate Layout Report**.

FIGURE 6. **Batch Plate Layout Report**



- **Import** - Imports a batch.
- **Export** - Exports a batch.

- **Delete** - Deletes a batch.
- **Edit** - Edits a batch.
- **Run** - Runs a batch.

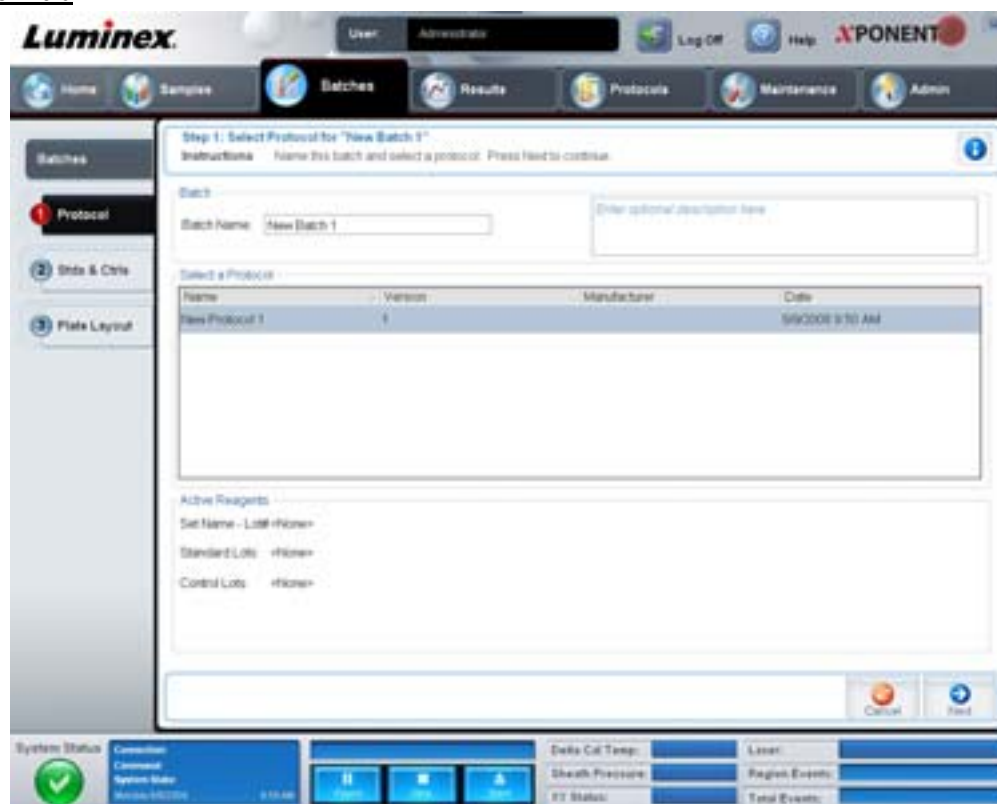
Create a New Batch from an existing Protocol

Creates a **New Batch** from an existing protocol. The **Protocol** tab opens.

Protocol Tab

Use this tab to name a batch, type a description, select a protocol, and view active reagents.

FIGURE 7. **Protocol Tab**



This tab contains the following:

Batch Name/Description - Contains the protocol name, version, manufacturer, and creation date for each protocol.

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

Active Reagents - Displays assay and control lots/kits associated with the selected protocol. The **Standard/Ctrls Kit Name - Lot#** field displays the assay standard/control kit/lot name and lot number currently associated with the selected protocol. The **Standard Lots and Controls 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.

Stds & Ctrls Tab

Use this tab to apply a kit or lot to the batch.

FIGURE 8. **Stds & Ctrls Tab**

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.

Manually 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

- **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.

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

- **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.
 - Alternatively, type a number for your own dilution factor.
- **Apply Dilution** - Applies the dilution selected in the **Dilution** list.

NOTE: Click a column header to resort the display.

NOTE: Click the **Reagent** column header to resort 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.

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 Value - Expected, Low, and High** set the expected, lowest, or highest acceptable concentration of the analyte in the sample.
- **Apply Values** - Applies a value down or across the list of analytes.

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

Back - Returns to the previous tab.

Next - Opens the **Plate Layout** tab.

Plate Layout Tab

Use this tab to define commands that apply to one or more wells. You can define off-plate and maintenance commands.

FIGURE 9. **Plate Layout Tab**



This tab contains the following:

- **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.
- **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. 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.
- **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. . . 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 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 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 vary. You can assign a specific number of unknown wells to the plate when setting up a batch.

Commands - Assigns maintenance commands that run before or after single wells, ranges of wells, and rows or columns of wells. Select a well, and then select one of the following commands:

- Alcohol Flush
- Prime
- Sanitize
- Soak
- Wash

NOTE: These commands are run from a reservoir in the Off-Plate Area.

After selecting a maintenance command, click one of the following buttons:

- **Before Well** - The system performs the command before acquiring the well. An open dot appears in the upper left corner of the selected well on the plate image. The command appears in the command sequence list before the selected well.
- **After Well** - The system performs the command after acquiring the well. A closed dot appears in the lower right corner of the selected well on the plate image. The command appears in the command sequence list after the selected well.
- **Clear Command** - Select a well and click **Clear Commands** to remove all maintenance commands from the 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.

Off Plate Area - Highlight a command and click a either a Reservoir in the **Off Plate Area** to select a location for the command.

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

FIGURE 10. **Save Protocol Dialog Box**

Save Protocol

Save Protocol

Protocol Name:

Version: Manufacturer:

Save Std/Ctrl Kit

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

Expiration: Manufacturer:

Lots:

Reagent	Name	Lot #	Expiration	Manufacturer
Standard1		234	12/25/2009	Acme

- 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

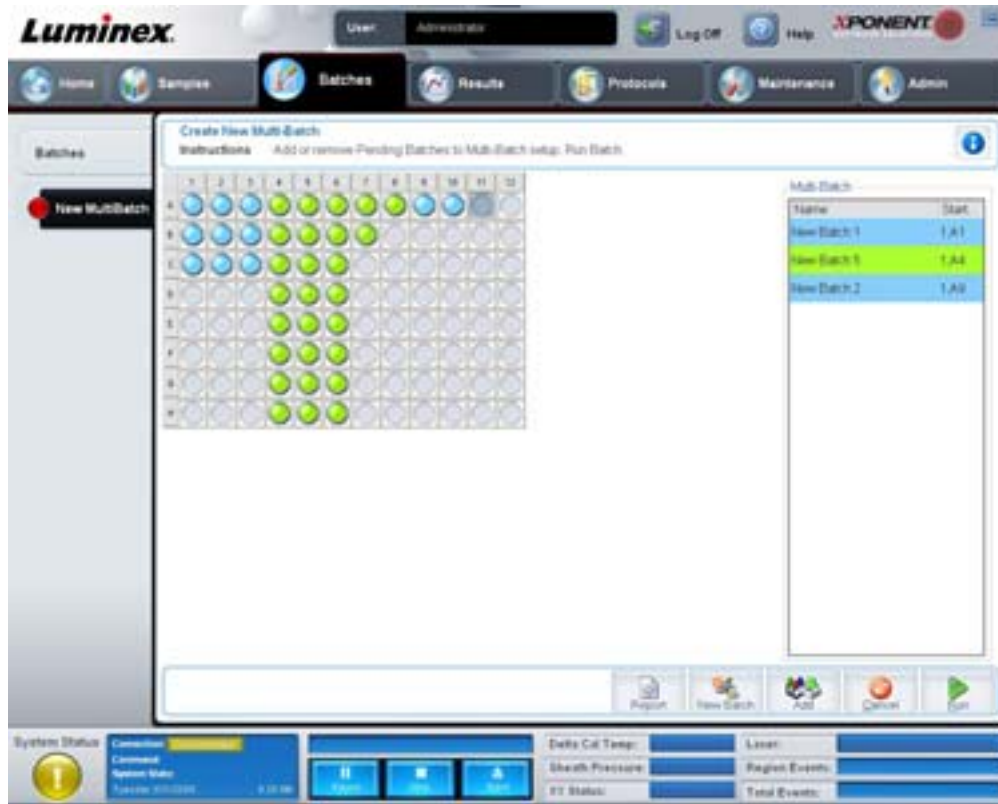
Save - Saves the information as a pending batch.

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.

FIGURE 11. Create a New Multibatch



Use this button to add or remove pending batches to the multi-batch set up and to run a multi-batch. A multi-batch is composed of one or more pending batches which, together, will fit on one plate. Use the multi-batch feature to conserve plates.

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.

FIGURE 12. **New Multibatch Tab**



This tab contains the following:

Multi-Batch name - Use this field to create a name for new multi-batches you want to save.

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.

FIGURE 13. **Select Pending Batch dialog box**

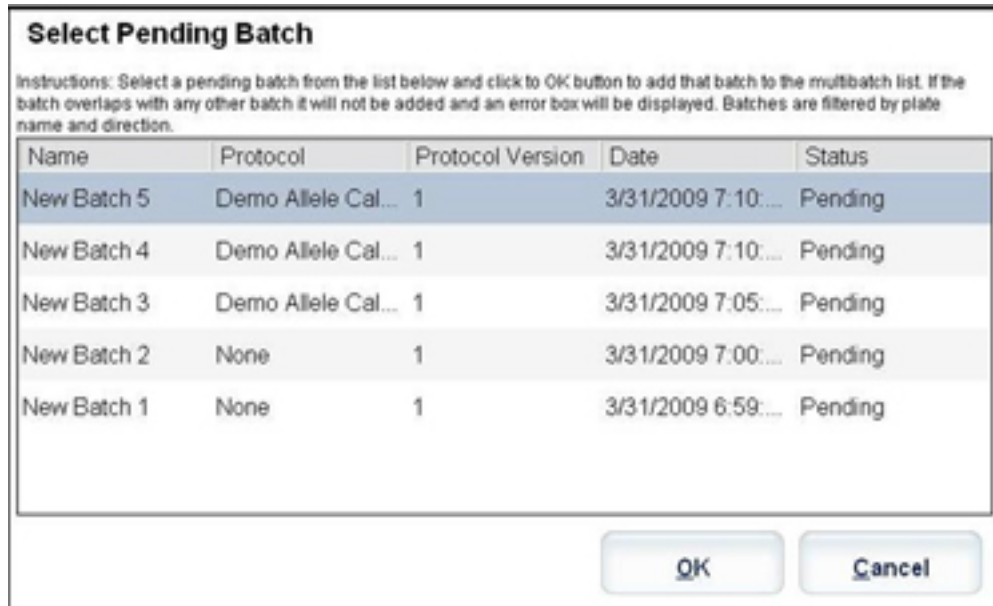
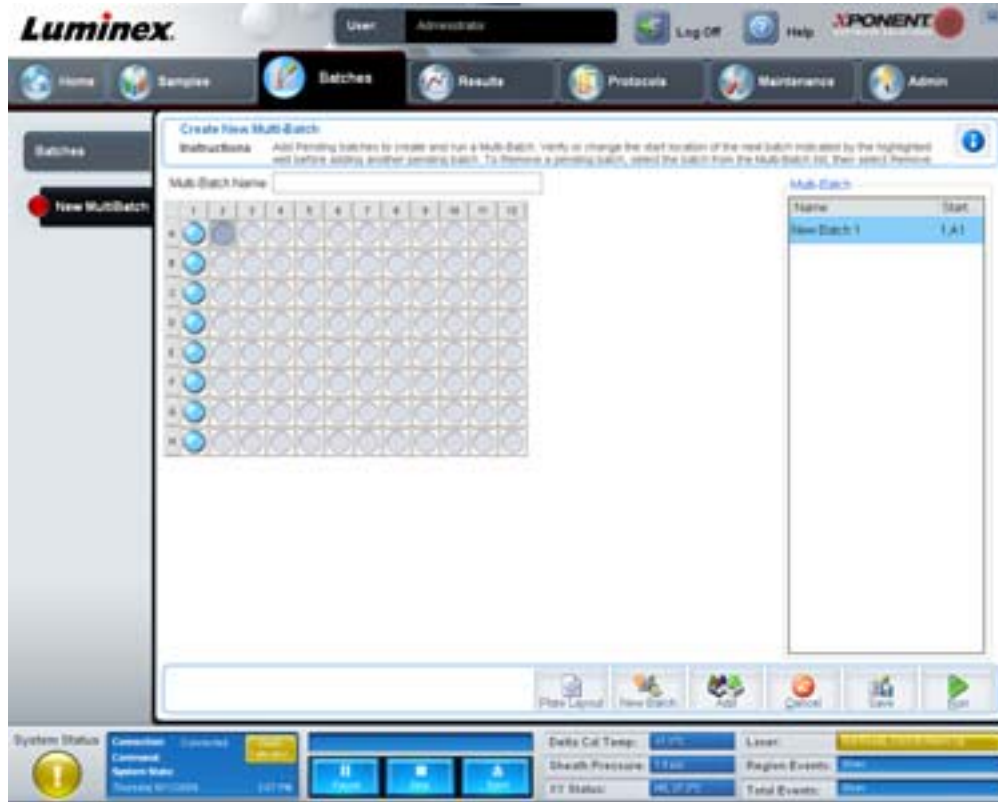


Plate layout - Depicts where batches are located on the plate.

FIGURE 14. New Multibatch tab with plate layout displayed

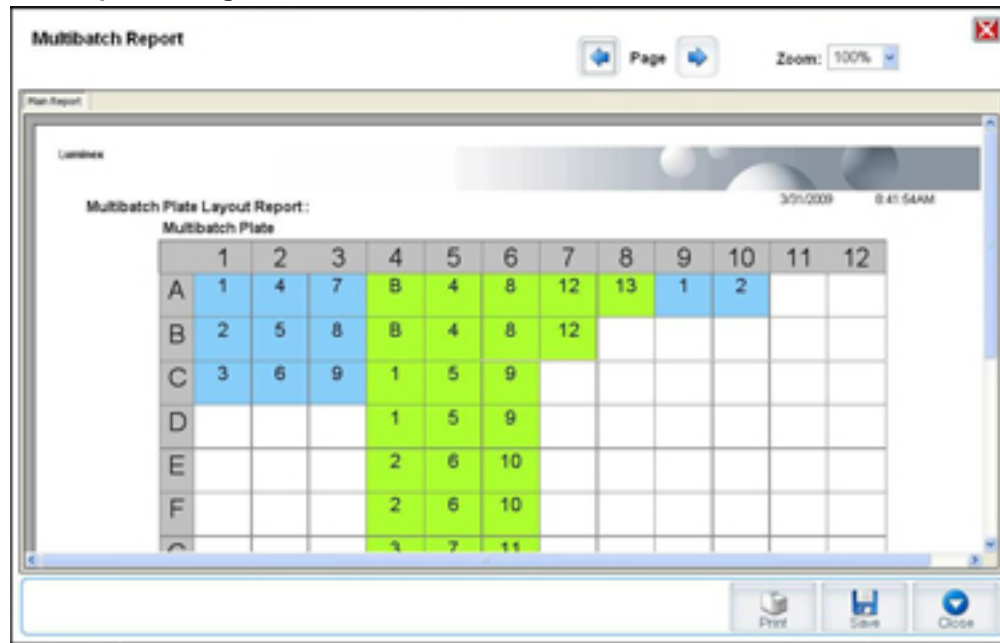


Multi-Batch - Lists pending batches selected for the multi-batch. The list includes name and “Start at” well.

Plate Layout - Opens the Multibatch 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.

The **Multibatch Plate Layout Report** includes the multibatch plate layout, command number, plate location, command type, sample ID and dilution. The report is date and time stamped.

FIGURE 15. **Multibatch Report dialog box**

New Batch - Opens the **Create New Batch** tab. Create your new batch. Click **Save** to return to the **New Multibatch** 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 will still remain in the **Pending Batches** section (This button only appears 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 a newly created multibatch and adds it to the **Select Pending Batchlist**.

NOTE: When a batch is saved to a multibatch, you cannot edit or delete it unless it is removed from the multibatch.

Run - Runs the batch.

Results

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

- Current Batch
- Saved Batches
- Results
- Settings
- Log
- Sample Details
- LIS Results
- Reports

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, histogram, and dot plot data. The statistics available on this tab are intrawell bead statistics. They do not describe replicate well assay results.

NOTE: The buttons on this tab can change based on settings chosen by the user.

FIGURE 16. **Current Batch Tab**



Statistic - To view a particular statistic for analytes in a batch, select one of the following:

- **Median** - The point in a data set where there are as many values occurring above it as there are below it.
- **Test Result** - The calculated analysis value for quantitative or qualitative assays derived from standards with known values.
- **Range** - A semi-quantitative result for a particular numerical result falling between a predefined set of values such as "Normal" or "Negative".
- **Count** - Gated events.
- **Net MFI (Median Background)** - Net MFI median background.
- **Mean** - Average of all values in a set of results.
- **% 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 largest number of times in the distribution list.
- **Trimmed Count** - The number of data points in the trimmed distribution (Nt).
- **Trimmed Mean** - The sum of the data points in the trimmed distribution divided by the number of data points. $\text{Trimmed Mean} = \sum Xi / Nt$.
- **Trimmed%CV of microspheres** - The measure of relative dispersion within the trimmed distribution.

- **Trimmed %CV** = 100 x Trimmed Std Dev / Trimmed Mean.
- **Trimmed Standard Deviation** - The measure of dispersion within the trimmed distribution.
- **Trimmed Std Dev** = $(((Nt \sum xi^2 - \sum xi)^2) / Nt (Nt -1))^{1/2}$
- **Trimmed Peak**
- **% CV of Replicates** - The measure of relative dispersion within the distribution of results for replicate samples. %CV = 100 X Std Dev / Mean.
- **% Recovery** - A measure of how accurately your observed results match your expected results following regression analysis. (Observed concentration) / (Expected concentration) x 100%.
- **Expected Result** - The known or expected test result value for a standard or control.
- **Control Range - Low** - The lowest value for an assay control used to determine pass/fail criteria for an assay.
- **Control Range - High** - The highest value for an assay control used to determine pass/fail criteria for an assay.
- **Normalized Net Median** - For each analyte in a well the Normalized Net Median (NNM) = (net median of analyte) / (net median of normalization bead).
- **Units** - The unit of measure for an analyte, for example, pg/mL.

Trimmed statistics remove the lower and upper five percent of the extreme statistical values, then use the remaining values for the **Mean**, **Standard Deviation**, or **%CV** calculations.

The trimmed distribution represents the events that were collected for an individual test in a single sample with the lowest 5% and highest 5% of the data points removed to help eliminate outliers.

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.
- **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** - Allows analysis one well at a time. Click to turn function on or off.
- **Results** - Displays statistics related to the batch. Use the up, down, left, and right arrow buttons to move through the table, or use the scroll bars. The **maximize/minimize** toggle button expands the batch table and returns it to the standard size.
- **Plate** - A list of the available plates (if more than one).



WARNING: If using multiple plates, be careful to ensure that plates are used in the proper order. Failure to do so can result in inaccurate data and test results.

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 the 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.

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.

Display Mode - Select either **Logarithmic** or **Linear** display. The software defaults to **Logarithmic** display. Click maximize for a magnified view of the dot plot.

- **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, and Classification 2.

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, and Classification 2.
- **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 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. For more information, see ““Results Tab” on page 26

Progress - Click to display real-time progress of the well acquisition. Analyte counts are displayed in a dynamic bar graph as they are acquired. The scroll bar at the bottom of the **Progress** display scrolls through the analyte list.

- **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 wells. 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).

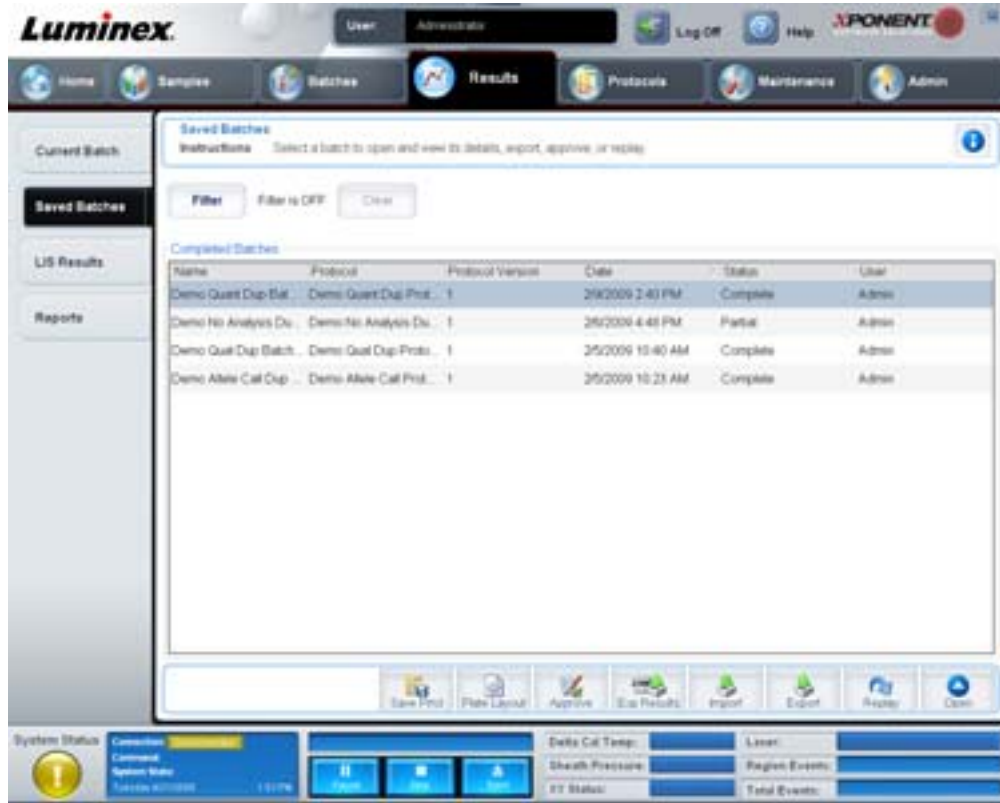
Default - Returns to the histogram and dot plot display.

Saved Batches Tab

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

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

FIGURE 17. **Saved Batches Tab**



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

FIGURE 18. **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 the following 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.

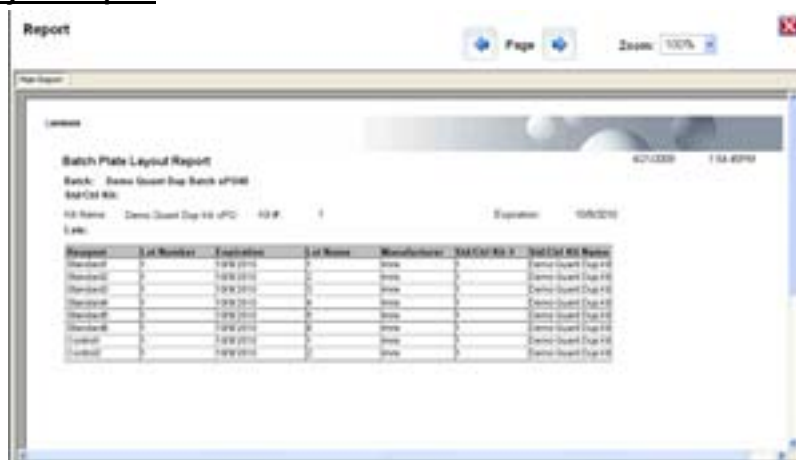
OK - Closes the dialog box and cancels any changes you made.

Cancel - Closes the dialog box and cancels any changes you made.

Save Prtcl - Saves the protocol and kit information for the selected batch.

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

FIGURE 19. 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. Once you have approved a batch, the status of the batch changes to **Approved** in the **Completed 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 to choose a batch file (.mdf) to import. Select **Include Raw Files (LXB)** to import the raw data file as well.

Export - Opens the **Export Batch** dialog box to choose a destination for the batch file (.mdf). Select **Include Raw Files (LXB)** to include the raw file in the export. Select **Overwrite** to overwrite pre-existing files.

Replay - Opens the **Select Replay Mode** dialog box.

Replay a batch to replay the raw bead data files. The bead data files will be replayed using the gate, analyte, analysis settings, and plate layout selected in the protocol. Settings such as bead type, volume, timeout, XY Heater, and report gain will have no effect.

Open - Opens the **Results** tab. Use this tab to view the saved batch results for the selected batch.

Results Tab

FIGURE 20. Results Tab



The **Results** tab has the same **Save Image**, **Progress**, and **Well Report** buttons as the **Current Batch** tab. For more information about these buttons, see “Current Batch Tab” on page 21. The following buttons are added to the **Results** tab:

- **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. For more information, see “Create a Multi-Batch” on page 66.
- **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 haven’t selected an item or the item you selected does not need to be validated, a warning dialog box displays.
- **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.
- **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 removed.
- **Close** - Closes the batch and reopens the **Saved Batches** tab.

Settings Tab

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

FIGURE 21. **Settings Tab**



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.

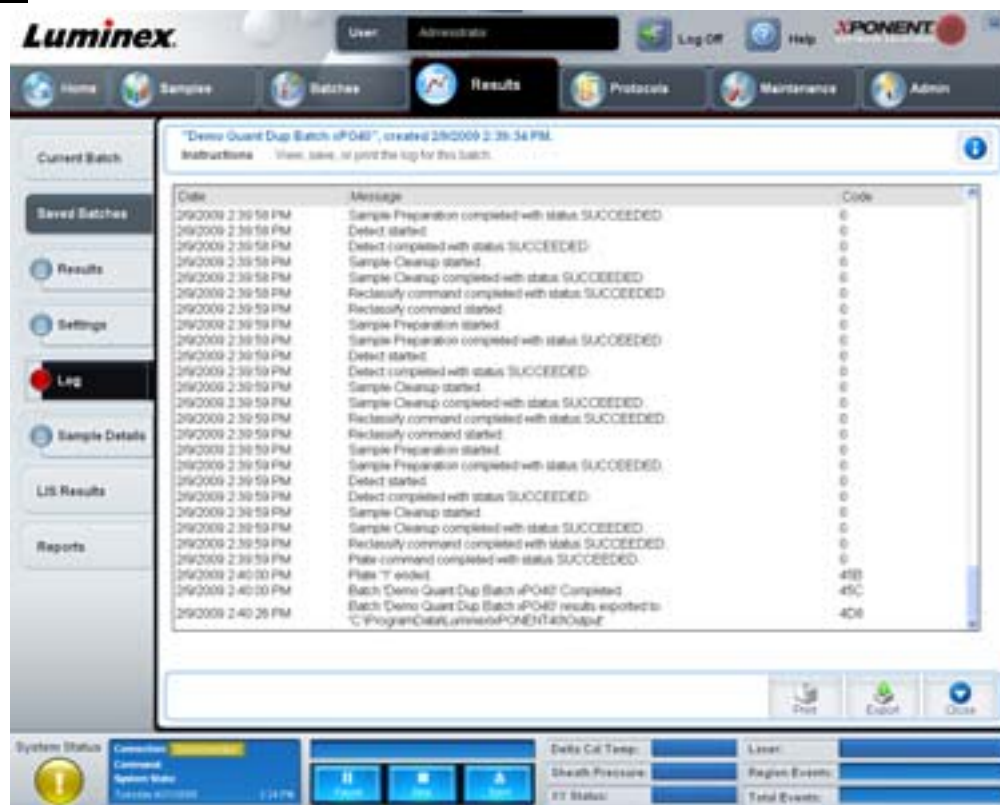
Print - Prints the report.

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

Log Tab

This tab displays a log of the activity which occurred during the acquisition of the selected batch.

FIGURE 22. Log Tab



This tab displays the following information about each activity:

- Date
- Message
- Code

Log entries display yellow if a well was acquired but there was a possible problem. They display red if a problem occurred during the acquisition.

Print - Prints the log.

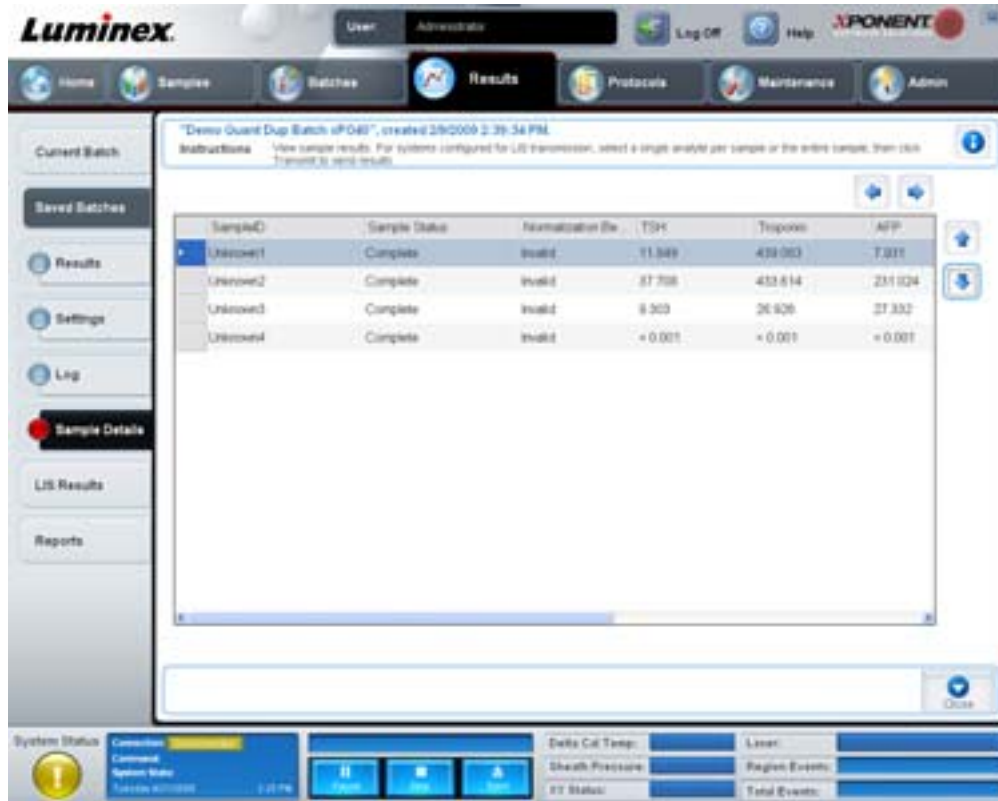
Export - Opens the **Save As** dialog box to save the batch log file. Select a location and click **Save**.

Close - Reopens the **Saved Batches** tab.

Sample Details Tab

Use this tab to view sample results.

FIGURE 23. **Sample Details tab**



Arrows - Scrolls through the sample details.

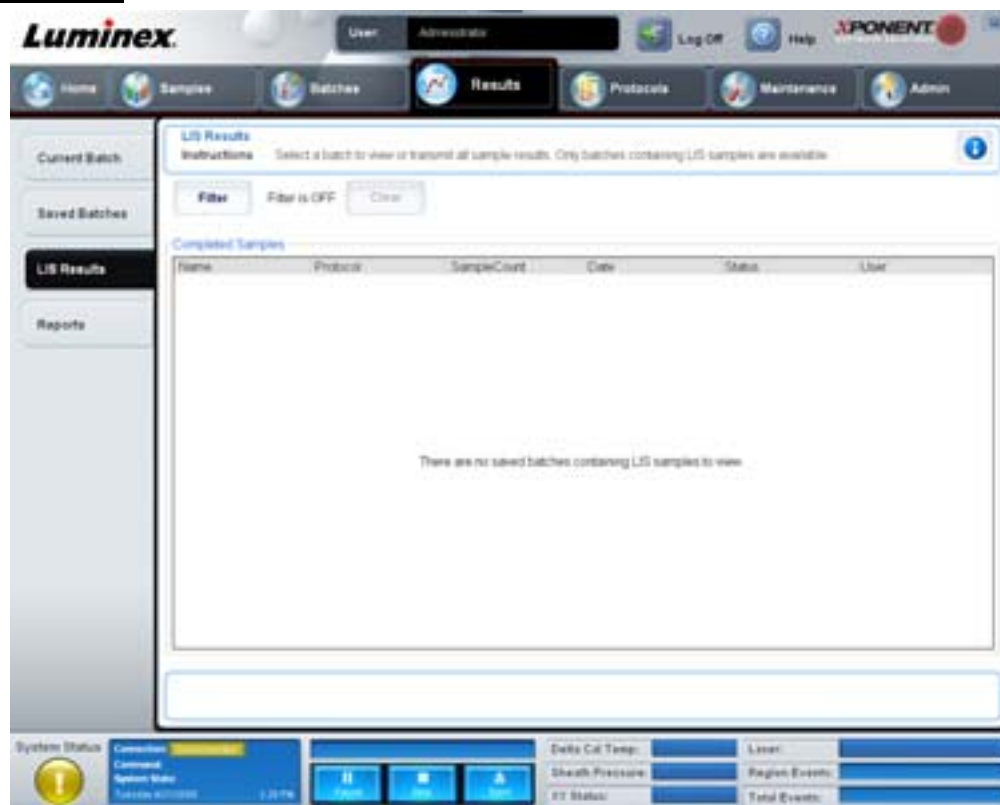
Transmit - For systems configured for LIS transmission, select a single analyte or the entire sample and click **Transmit** to send the results.

Close - Reopens the **Saved Batches** tab.

LIS Results Tab

This tab displays saved batches containing LIS samples.

FIGURE 24. LIS Results Tab



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

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.

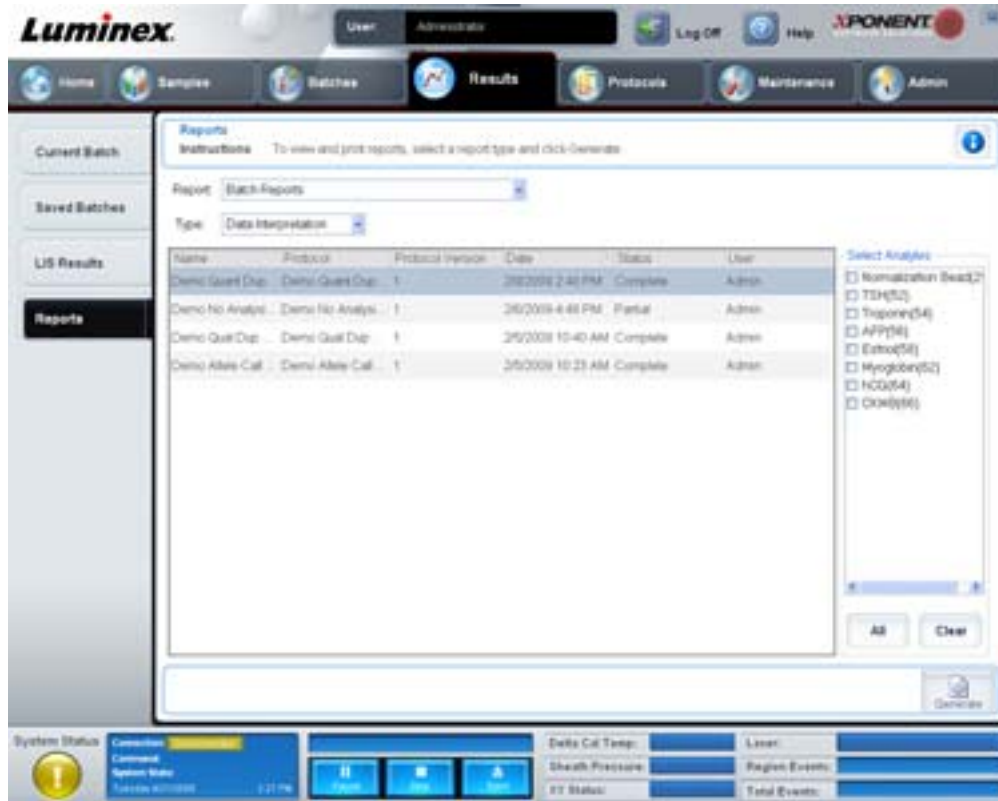
Transmit - Transmits a batch to an LIS if xPONENT is connected to one.

Details - Opens the **Sample Details** tab to view sample results.

Reports Tab

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

FIGURE 25. Reports Tab



Report and Type lists. Choose a report from one of the following categories:

- **Batch Reports** - A list of batches appears below the **Type** list. The list includes **Name**, **Protocol**, **Protocol Version**, **Date**, **Status**, and **User** information. 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:
 - CAL1
 - MagCAL1
 - CAL2
 - CON1
 - MagCON1
 - CON2

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 click **Generate** to generate the report.

- **System Log Reports** - Displays a list of system log reports. Choose from the following selections:
 - All
 - Maintenance
 - Security
 - Warning and Errors

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

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

Click **Generate** to generate the report.

Protocols

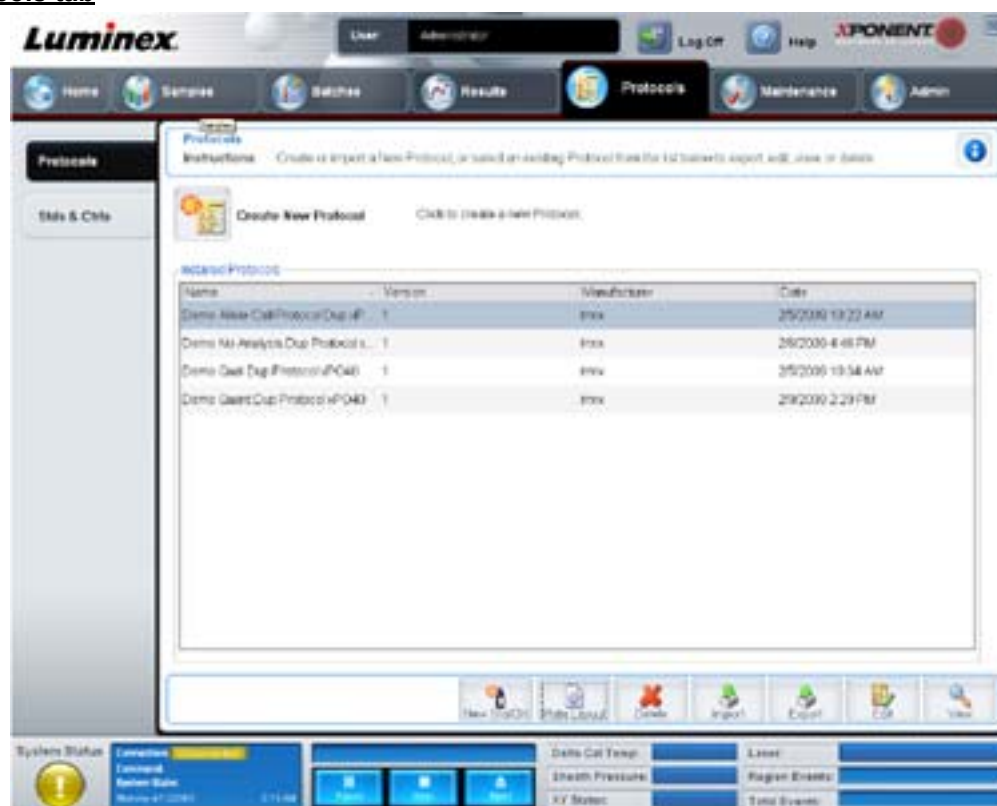
The Protocols page enables you to add standards and controls. This page contains the following tabs:

- Protocols
- Settings
- Analytes
- Plate Layout
- Stds & Ctrl

Protocols Tab

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

FIGURE 26. **Protocols tab**



This tab contains the following:

- **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. For more information, see “Stds & Ctrl Details Tab” on page 35
- **Plate Layout** - Opens the **Report** dialog box, which includes the **Plate Layout Report**. For more information see “Saved Batches Tab” on page 24.

FIGURE 27. **Protocols Plate Layout Report**

Report

Page Zoom: 100%

Plate Layout Report:

Protocol: Some Abile Call Protocol Step xPOM

Plate: 1

	1	2	3	4	5	6	7	8	9	10	11	12
A	B	4	8	12								
B	B	4	8	12								
C	1	5	9									
D	1	5	9									
E	2	6	10									
F	2	6	10									

Print Save Close

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

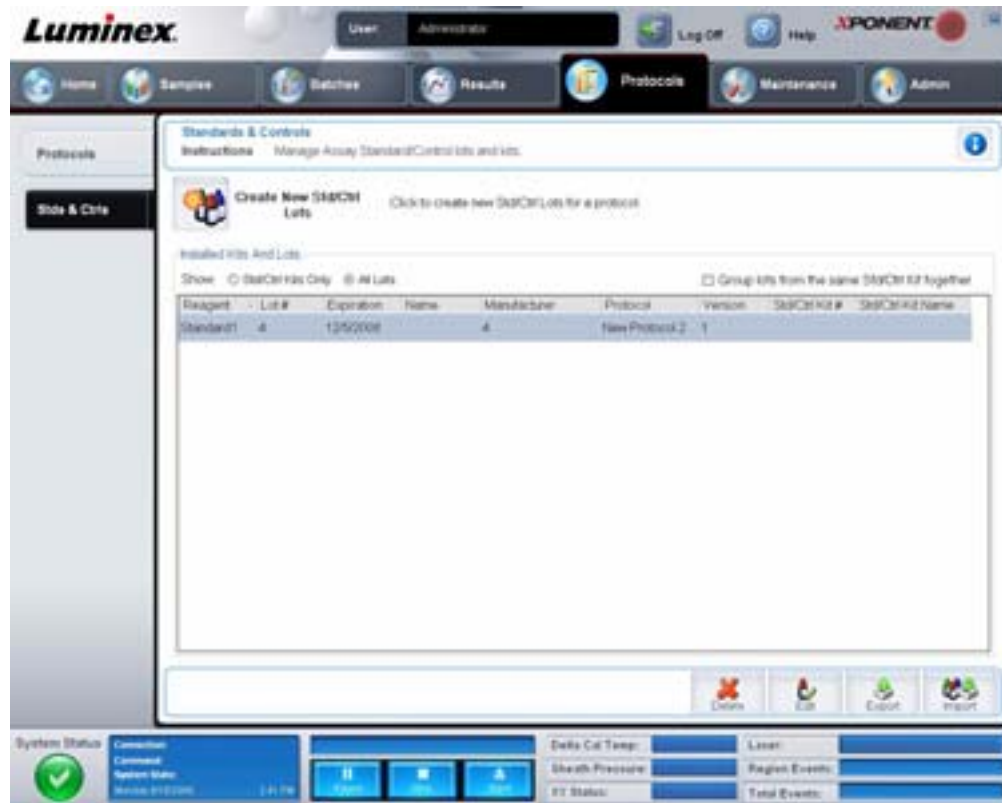
Import - Opens the **Open** dialog box to select a protocol (.lxt file) to import. Navigate to the protocol file you wish to import and click **Open**.

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

View - Opens the **Settings** tab to view the protocol. Click **Next** to advance to the **Analytes** tab, and **Next** again to advance to the **Plate Layout** tab. Click **Close** at any of the three tabs 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.

Stds & Ctrl's Tab

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

FIGURE 28. **Stds &Ctrls Tab**

This tab contains the following:

Create New Std/Ctrl Lots - Opens the **Std/Ctrl Details** tab to create a new lot or kit. For more information, see “Stds & Ctrls Details Tab” on page 35.

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
- Version
- 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**.

Stds & Ctrls Details Tab

The Std/Ctrl Details tab lets you create or edit a standard and control lot. You can also group a lot as a kit.

FIGURE 29. **Stds/Ctrls Details Tab**



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.

Manually 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.

- **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.

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

- **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.
 - Alternatively, type a number for your own dilution factor.
- **Apply Dilution** - Applies the dilution selected in the **Dilution** list.

NOTE: Click a column header to resort the display.

NOTE: Click the **Reagent** column header to resort 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.

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 Value - Expected, Low,** and **High** set the expected, lowest, or highest acceptable concentration of the analyte in the sample.
- **Apply Values** - Applies a value down or across the list of analytes.

Cancel - Reopens the **Protocols** tab.

Save - Saves the lot and kit information for the selected protocol.

Maintenance

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 Maint Tab

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

FIGURE 30. **Auto Maint Tab**

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

- **System Initialization** - Select this routine to initialize the system.
- **Performance Verification** - Select this routine to use with the Performance Verification kit.
- **Calibration / Verification** - Select this routine to use with the Calibration/Verification kit.
- **System Shutdown** - Select this routine to perform a pre-defined system shutdown.
- **Alcohol Flush** - Select this routine to run a single alcohol flush.
- **Sanitize** - Select this routine to run a sanitize command.

The commands for these routines display in the command list below the buttons.

Command - This list is used to view the name of the current command, its well location, its status, and information about the command. Only the current commands appear 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** and **Performance Verification Kit** lists. In the lower right section of the Reagents area is a depiction of the Automated Maintenance Plate. Place reagents in the wells of the Automated Maintenance Plate the way they are placed in the depiction.

Report - Opens the **Reports** tab, with the **Performance Verification Reports** selection displayed in the **Report:** list. See "Reports Tab" on page 30.

Import Kit - Opens the **Import Calibration** or **Performance Kit** dialog box. Select a kit and click **Open** to import it.

Run - Initiates the selected routine.

Lot Management Tab

Use this tab to manage calibration and verification kits.

FIGURE 31. **Lot Management Tab**



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 Lot Number** - Select an active lot number for the selected reagent from this list.

Lot Details - Displays lot information for the selected reagent in the **Active Reagents** section.

- **Lot Type** - Displays the lot type selected in the **Active Reagents** section to the left.
- **Lot #** - Displays the lot number selected in the **Active Reagents** section to the left.
- **Expiration:** - Displays the expiration date for the lot type selected in the **Active Reagents** section to the left.
- **Calibrator** - If a calibration reagent is selected, the **Lot Details** table displays **Channel** and **Target** information.
- **Target Verifier** - If a verification reagent is selected, the **Lot Details** table displays target information.

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 to export a lot.

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.

Cmds & Routines Tab

Use this tab to create a routine or to edit, delete, or run a selected routine or command. You can also run one or more maintenance commands with or without saving them as a routine.



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.

This tab contains the following:

FIGURE 32. **Maintenance Commands and Routines Tab**



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 routines on this tab, which display in the **Routine Name** list once you save the routine. To create a 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:

- Alcohol Flush (Luminex)
- Daily Instrument Shutdown (Luminex)
- Daily Instrument Startup (Luminex)
- Fluidics Maintenance (Luminex)
- None
- Prepare for Storage (Luminex)
- Remove Air Bubbles (Luminex)
- Remove Clog (Luminex)
- Revive After Storage (Luminex)
- Sanitize(Luminex)
- Weekly Maintenance (Luminex)

Commands - This section contains the following commands:

- **Wash** - Sends distilled water through the fluidics 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.
- **CAL1** - Calibrates DD, CL1, and CL2 for original non-magnetic xMAP beads.
- **CON1** - Verifies DD, CL1, and CL2 for original 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 Luminex XYP reservoir because only the reservoir 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 the power on. The process takes about thirty minutes. You will need to use the **Warm-up** command if the system is idle for four hours or longer.
- **MagCAL1** - Calibrates DD, CL1, and CL2 for MagPlex beads.
- **MagCON1** - Verifies DD, CL1, and CL2 for MagPlex beads.
- **Sanitize** - Uses the off plate reagent area, because only the reservoir can accommodate the amount of fluid necessary to sanitize the instrument. The **Sanitize** command performs a similar function as the alcohol flush command, but uses 10% to 20% household bleach and water solution to decontaminate sample lines and the cuvette after biohazard contact. Sanitize as part of your daily shutdown routine after biohazard contact.
- **Prime** - Removes air from the system's fluidics pathways by drawing sheath fluid from the sheath fluid container. You do not need to supply solution in a plate.
- **CAL2** - Calibrates xMAP reporters (RP1).
- **CON2** - Verifies RP1 at normal and high PMT 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. Any fluid that drains from the system drains to the Luminex XYP reservoir as the default. However, you can set the system to drain to any unused well on the microtiter plate. The drain function normally expels 125 µL of fluid.
- **Backflush** - Removes obstructions from the fluidics pathways by drawing sheath fluid from the sheath fluid container. You do not need to supply solution.
- **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.

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.

Clear - Clears the highlighted command in the **Command Sequence** list.

Clear All - Clears all commands in the **Command Sequence** list.

Report - Opens the **Reports** tab with the **Calibration Summary** selected in the **Report:** list. Click **Generate** to view the selected report.

Import - Displays the **Open** dialog box to select a routine file (.lxd) to import. Select a file and click **Open** to import it.

Export - Opens the **Save As** dialog box to specify a file name and location to save a **Routine** file.

Save As - Opens the **Save Routine** dialog box. Choose a routine name to save the routine under. After saving, the new routine will then appear in the **Routine Name** list. This button only appears if a new routine has been made.

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.

Delete - Opens the **Delete Maintenance Routine Confirmation** dialog box. Click **Yes** to delete the routine. Once deleted, it will no longer appear in the **Routine Name** list. This button appears if you have selected a non-Luminex routine in the **Routine Name** list.

Run - Runs the selected routine or command.

Probe and Heater Tab

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

FIGURE 33. **Probe and Heater Tab**



Move Probe Down - Moves the probe down in the specified well(s).

Plate Type - Defines the selection of either a 96-well plate or an Automated Maintenance plate.

Plate Image - Identifies the location to be used to adjust the probe height. Clicking a well selects it and marks it with a blue pin.

Plate Heater - Sets the temperature of the plate to the number typed in the **Set Temperature** box. Up and down arrows allow half-degree adjustments of the temperature, and Apply activates the adjustment. Current and Target temperatures display at the bottom of this section.

NOTE: The temperature range is 35°C to 60°C.



WARNING: Be advised that the plate heater can become hot enough to cause injury. Use caution when handling after heating.

System Info Tab

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

FIGURE 34. **System Info Tab**



This tab contains the following information:

- Software
- Version
- Operating System
- Licensing
- Instrument Type
- Serial Number
- Firmware Version
- XY Serial Number
- XY Firmware Version
- XYP Heater Temperature
- Air Pressure
- Sheath Pressure
- Calibration Status
- Last CAL1 Calibration
- Last MagCAL1 Calibration
- Last CAL2 Calibration
- Last CON1 Verification
- Last MagCON1 Verification
- Last CON2 Verification
- Delta Calibration Temp

- System Temperature
- DD Temperature
- CL1 Temperature
- CL2 Temperature
- CL1 Voltage
- CL2 Voltage
- DD Voltage

RP1 Voltage - Items in this list relating to CAL/Verification, CON calibration, and controls 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 calibrated the system since the last time you ran the controls.
- **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**.

FIGURE 35. **System Status Tab**



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 for each system process. The following information appears in this 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 preexisting 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.

FIGURE 36. The Schedule Tab



The **Reminders** section displays **Subject**, **Reminder**, **Next Alert Date**, **Alert Time**, and **Notes**. This schedule can be changed using the **Schedule** tab of the **Admin** page. For more information, see “Schedule Tab” on page 56.

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 to troubleshoot.

FIGURE 37. **Support Utility Tab**

Support Utility
Instructions: Enter contact information and select an optional batch to export a file for technical support.

Name: Company: Clear

Phone: Email:

Comment:

Include Batch Info Click "Include Batch Info" to include a batch

Select Batch:

Name	Protocol	Protocol Version	Date	Status	BatchID
New Batch 3	Archive Test 1	1	8/28/2008 10:35 AM	Pending	7c918b19-54aa-429-
New Batch 2	New Protocol 5	1	8/27/2008 3:14 PM	Pending	3ac95ba4-5a8e-48e-
Archive Batch Test	Archive Test 1	1	8/25/2008 4:17 PM	Pending	a1271017a-8902-445-
New Batch 1	New Protocol 1	1	8/24/2008 9:18 PM	Pending	e3747aa5-1ab0-494-
Demo Assay Batch 4 - Demo Assay Proba...	Demo Assay Proba...	1	8/27/2008 12:18 PM	Approved	9688d6c-3594-438-

Support utility zip export folder:
C:\Documents and Settings\jgale\My Desktop

This tab contains the following:

Name, Phone, Company, and Email - Type your information in these boxes so that Luminex Technical Support can contact you.

Clear - Clears all information in the **Name, Phone, Company, Email, and Comment** boxes.

Comment - Type any comments in this box.

Include Batch info - Includes 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, and Batch ID** information. Selecting a batch automatically selects the **Include Batch Info** check box.

Browse - Opens the **Browse for Folder** dialog box to choose an alternate destination folder for the utility zip file.

Export - Opens the **Save Support File As** dialog box. Select a name and location for the support .zip file and click **Save**.

Admin

You must have the appropriate license to view some of the windows in the **Admin** section. 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.

FIGURE 38. System Setup Tab



Application Settings

These settings change some of the basic ways that xPONENT works, for graphical user interface preferences.

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.

LIS Settings

This setting is only for those using xPONENT with a Lab Information System (LIS).

Connect to LIS - Enables connection the LIS.

Browse - Opens the **Browse for Folder** dialog box. Select a location for the system to watch for incoming orders.

Arrange Main Navigation buttons

These options enable you to rearrange 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 setup as a member of the **Administrator** group profile. For further information about the user setup, see “Group Setup Tab” on page 47.

Arrange 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, it always appears as the first main page header.

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.

Data Conversion

This section contains options to use when converting data from an earlier version of xPONENT.

Open - Opens a dialog box to select a data file from an earlier version of the xPONENT software to convert to the current version. For information about the file types and procedures to convert older data, see the Data Conversion section.

Cancel - Cancels changes made to the **System Setup** tab.

Save - Save changes made to the **System Setup** tab.

Group Setup Tab

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

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

FIGURE 39. **Group Setup Tab**

Users are assigned to groups. These users then have permissions granted to their group. Do not assign permissions directly to an individual user. On this tab, you can reinstate users who lock themselves out of the system at the **System Login** 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 **Allow** 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

- Manage Users (add, edit, or delete users)
- Manage System Configuration
- Perform Calibration and Verification
- Manage Alerts
- Manage scheduled maintenance
- Change batch options
- Allow exit software
- Ignore warm-up
- 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
- Approve Batch
- Reanalyze Results
- Save Batch after changing results
- Change Formula
- Reacquire errored wells for partial batch
- View Processed Batch Results
- Export Processed Batch Results

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, Std/Ctrl Kit/Lot Files
- Import Batch, Protocol, Std/Ctrl Kit/Lot Files

Archiving

- Backup/Restore
- Import/Archive

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

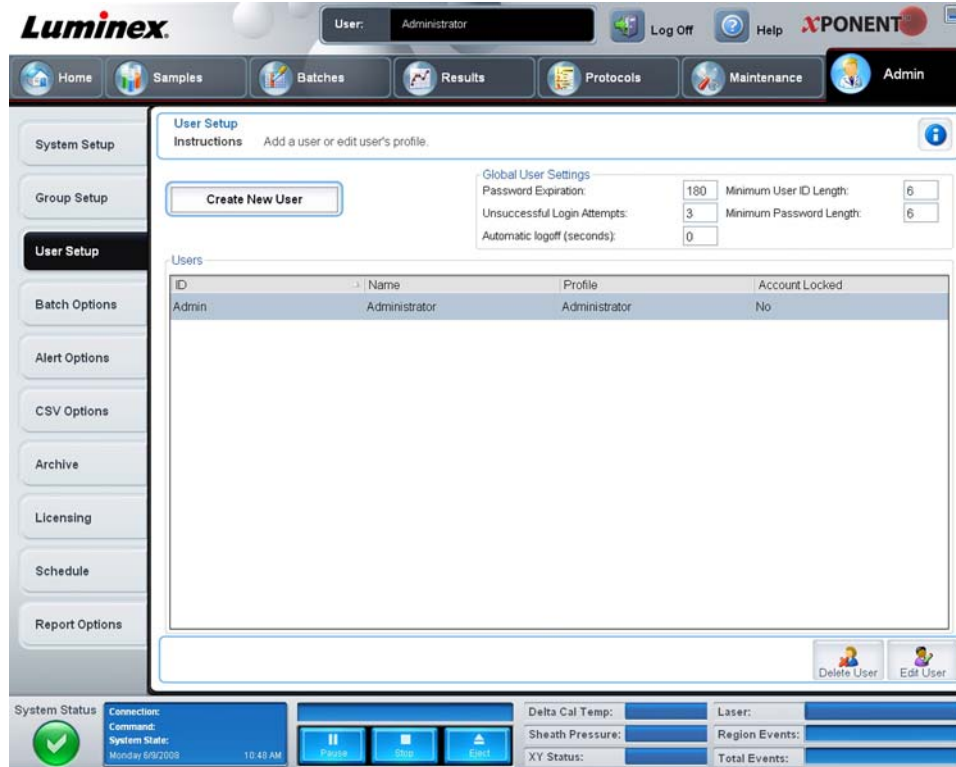
Cancel - Cancels changes

Save - Saves changes

User Setup Tab

Use this tab to create or edit a user account, remove a user from the system, or view a list of authorized users, along with their profile details.

FIGURE 40. **User Setup Tab**



This tab contains the following:

Create New User - Opens the **Create User Account** screen.

Create User Account Screen

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.

FIGURE 41. **Create User Account Screen**

The screenshot shows the 'Create User Account' screen in the Luminox software. The interface includes a top navigation bar with 'Home', 'Samples', 'Batches', 'Results', 'Protocols', 'Maintenance', and 'Admin' tabs. A left sidebar contains a 'System Setup' menu with options like 'System Setup', 'Group Setup', 'User Setup' (highlighted), 'Batch Options', 'Alert Options', 'CSV Options', 'Archive', 'Licensing', 'Schedule', and 'Report Options'. The main content area is titled 'Create User Account' and contains the following fields and options:

- User ID:** A text input field.
- Name:** A text input field.
- Password:** A text input field.
- Reenter Password:** A text input field.
- Account Status:** A checkbox labeled 'Locked'.
- Change password after next login:** A checkbox.
- Group Profile:** A dropdown menu currently showing 'Administrator'.

At the bottom of the screen, there are 'Save' and 'Cancel' buttons. The bottom status bar shows system information like 'System Status', 'Connection', 'Command', 'System Mode', and 'Delta Cal Temp'.

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 account. 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**, or **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. For more information, see “User Setup Tab” on page 50.

Alert Options Tab

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

FIGURE 42. Alert Options Tab



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.
- **Warmup Complete** - The laser is warmed up.
- **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.
- **Sheath Empty** - A problem with the sheath fluid is encountered.
- **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.

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.

CSV Options Tab

Use this tab to set options for exporting batches to .CSV (comma separated values) files.

FIGURE 43. **CSV Options Tab**



This tab contains the following:

CSV and Batch Export Options

Automatically export results CSV file when batch is complete - Automatically exports the .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 columns into which your CSV output file will be organized.

Use US regionalization format only - Exports data only in US regionalization format.

Include Advanced Statistics - Exports advanced statistics 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.

Automatically convert the raw run files to CSV format for each well in the batch - Automatically converts raw run files to CSV format for each well in the batch. This option creates a CSV formatted file for the raw bead data of each well.

Test Sort Order - Defines a method to sort the test data. The options are **By Analyte Name**, **By Region ID**, or **By Setup Order**.

Cancel - Cancels changes.

Save - Saves changes.

Archive Tab

Use this tab to set options for backing up and restoring files.

FIGURE 44. Archive Tab



This tab contains the following:

Archive - Use this section to define archive locations for specific file types.

- **File Type** - Choose from **Protocols**, **Batches**, **Std/Ctrl Kits**, **Lots**, **Patient Samples**, or **Log**. The selected information appears in the list below the **Archive Folder** path.
- **Keep data after archive** - Retains data instead of deleting after you archive it.
- **Exclude Raw Data Files** - Select this option if you have selected **Batches** in the **File Type** list to exclude files that contain only raw data.
- **Browse** - Chooses the network or local PC destination folder for the exported archive file. The selected file displays in the **Archive file export folder** box.

NOTE: Files are restored from the path displayed in the **Archive file export folder** box. Use the **Browse** button to select the file path if necessary.

The list below the **Archive Folder** path displays all the files of the type selected in the **File Type** list. This list displays information for each file.

Current Storage Utilized - Displays the amount of space currently in use, as well as the amount of space left, in the database and on the hard disk.

Backup System - Enables backups and restores for the xPONENT software.

- **Backup** - Backs up the entire system (Click **View Backup Log** to view information about the backup).
- **Restore** - Restores all information in the archive file to the system. This will overwrite all information.

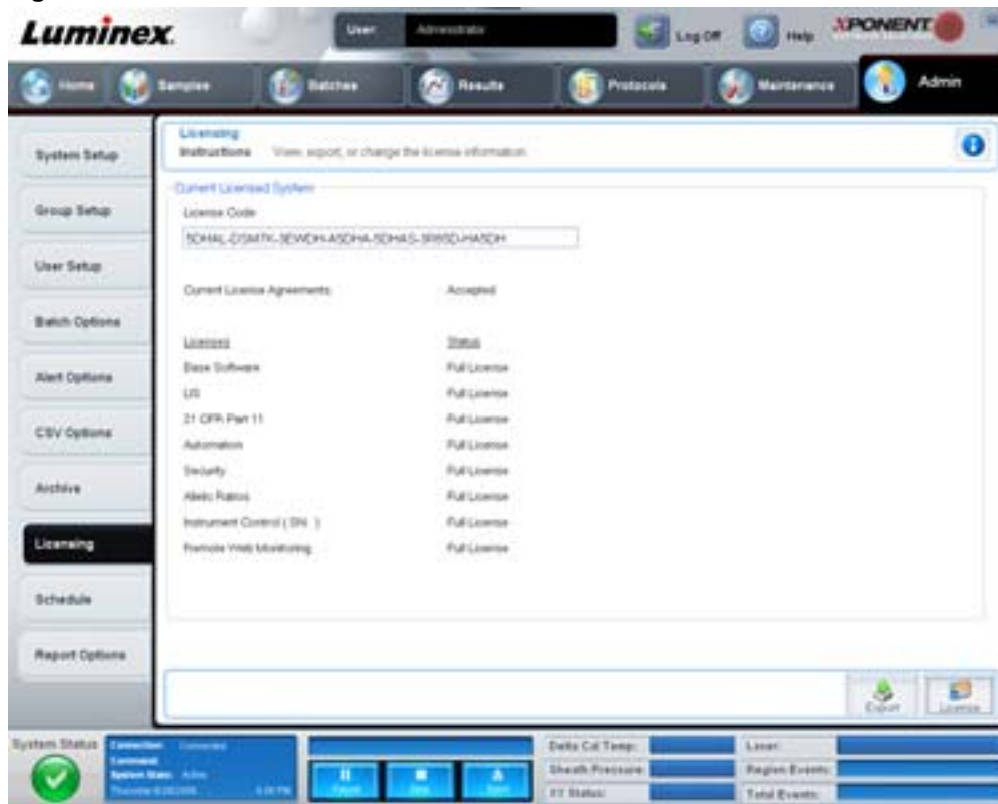
Import - Select a file type to import in the **File Type** list and click **Import** to import all files of that type from the archive. The imported files will then display in the list below the **Archive Folder** path.

Archive - Select a file type in the **File Type** list, and then select a file in the list below the **Archive Folder** path and click **Archive** to archive the file. If you have selected **Keep data after archive**, the file will still display in the list, otherwise it will no longer be displayed.

Licensing Tab

Use this tab to configure or change your license information.

FIGURE 45. Licensing Tab



This tab contains the following:

License Code - The current license code being used on the system.

Current License Agreements - You cannot start the software unless the license agreements are accepted. Therefore, the current license agreements will always display as Accepted.

Status - Displays the status of the licensing agreements.

Export - Opens the Save As dialog box to select an export name and location.

License - Opens the **Change License** dialog box.

- Type the file path for the license file in the **License File** box, or use the **Browse** button to display the **Open License** dialog box and navigate to the file. You can also update the xPONENT license status by manually typing the license code in the **License Code** box. It is not necessary to update both the license file and the license code. Updating either will serve to update the license.
- Select **Accept License Agreement at next start** for the agreement to take effect the next time you launch the software.
- Click **OK** to open the End User License Agreement (EULA). Select the appropriate radio button to either accept or decline the terms of the EULA and click **OK** to exit.

Schedule Tab

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

FIGURE 46. **Schedule Tab**



Reminders - This section displays reminders for scheduled maintenance.

- **Alert Time** - Select a time from this list to display maintenance reminders.
- **Recurrence** - Select **Daily**, **Weekly**, **Bi-Weekly**, **Monthly**, **Bi-Annually**, or **Yearly** recurring reminders from this list.
- **Enabled** - Select or clear this check box to enable or disable the reminders.

Cancel - Cancels changes.

Save - Saves changes.

Chapter 3: Using the Software

This chapter describes the steps needed to successfully use the xPONENT software.

Starting the Software

When you turn on the computer for your Luminex system, xPONENT® should launch automatically. If it does not, click the **Luminex xPONENT** icon on the PC desktop, or click **Start > Programs > Luminex > xPONENT > Luminex xPONENT**.

If you have a trial license, a dialog box opens. Click **OK** to close the dialog box.

If this is the first time you are using the software, the User License Agreement will display. Read the license agreement. Select **I accept the terms of this license agreement**, then click **OK**.

At the **System Login** page, type your username, and password if required. The **Home** page opens, from which you can perform many different tasks. For more information on the **Home** page, see “Home” on page 8.

Using Online Help

To display online help for the 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 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 seven 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.

Setting Administrative Options

Click **Admin** on the toolbar to display the tabs used to set administrative options.

System Setup

You must have xPONENT administrative privileges to perform **System Setup** tasks.

Application Settings

Use **Application Settings** to define how the software runs and displays.

1. Select the options you want to enable in the software. For a description of each option, see “Application Settings” on page 46.
2. Click **Save**.

Arrange Main Navigation Buttons

Use this section to rearrange the main pages at the top of the xPONENT software.

1. Select or clear the check boxes by each page name to hide or display the main pages.
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**.

Click **Default** if you want to restore the default navigation.

LIS Settings

You must have the LIS version of the software to perform this task.

To connect to the LIS, check **Connect to LIS**. Type the location where the incoming orders are stored in the **Watch folder for incoming orders** box, or click **Browse** to choose a destination.

Maintenance Options

To choose a system initialization option:

1. In the **System Initialization Procedure** list, click the option you wish to use.
2. Click **Save**.

Data Conversion

Convert earlier versions of data with the data conversion feature. The following formats can be converted:

- xPONENT 3.0 protocols (LXT files) into xPONENT 3.1 protocols (LXT files).
- xPONENT 3.0 assay lots (LXK files) into xPONENT 3.1 assay lots (LXK files).
- xPONENT 3.0 batches (LXD files) into xPONENT 3.1 batches (MDF).
- xPONENT 3.0, 3.1 .CSV files and specially formatted text files containing MFI values into xPONENT 3.1 batch files (MDF).

The data conversion utility is xCONVERT. For additional information about using the xCONVERT utility, see the Appendix A: Converting IS 2.3 .idt Files to xPONENT 3.1 .lxt Files section.

Group Setup

You must have xPONENT administrative privileges and be using the Secure package of the software to perform group setup tasks. Additionally, you must have the 21 CFR Part 11 package to require electronic signatures.

1. In the **Group Profile** list, click the group profile you want to set up.
2. In the **Group Features** list, click which group features you want to set for the group profile you selected.
3. In the **Features** section, select the **Allowed** check box next to the desired permission to enable the selected group to perform that task. If you are using the 21 CFR Part 11 package, move the **Signature Required** check box next to the desired permission to require a digital signature whenever a user in the selected group performs that task. These tasks are tracked in the **System Log**.

For more information on the Group Setup tab, see “Group Setup Tab” on page 47.

User Setup

You must have xPONENT administrative privileges and be using either the 21 CFR Part 11 or Secure package of the software to perform user setup tasks.

Define Global User Settings

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

To define Global User Settings:

1. In the **Global User Settings** section, type a length of time (in days) for the **Password Expiration**.
2. Set the number of allowed **Unsuccessful Login Attempts**.
3. Set how many seconds pass before an **Automatic Logoff** is initiated.
4. Type the **Minimum User ID Length**.
5. Type a **Minimum Password Length**.

For a description of each of these settings, see “User Setup Tab” on page 50.

Adding a User

1. Click **Create New User**. The **Create User Account** screen opens.
2. Type the user ID in the **User ID** box.
3. Type the user's name in the **Name** box.
4. Type a password for the user in the **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**.
5. In the **Group Profile** list, select the role for the user you are creating.
6. Click **Save**.

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**.

Alert Options

To set notification options about various system events:

1. Select **Dialog** if you want a dialog box to open for a specific event.
2. Select **Email** if you want to send an email notification for a specific event.
3. Select **Sound** if you want a sound to play for a specific event.
4. 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've typed.
5. 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.

For more information about each event in the **Alert Options** tab, see "Alert Options Tab" on page 52.

CSV Options

You must have xPONENT administrative privileges to perform this task if you are using the 21 CFR Part 11 or Secure package. Use the commands on this tab to define what the CSV file will contain, and where it will be stored. For more information on this tab, see "CSV Options Tab" on page 53.

To set CSV Options:

1. In the **CSV and Batch Export Options** section, select the CSV Options you want to apply to the CSV file. If you select **Maximum number of data columns in CSV file**, type the maximum number of columns.
2. In the **CSV File Export Folder and Automatically Exported Batch Folder** box, type the location to which you want the file sent, or click **Browse** to navigate to the folder.
3. In the **Test Sort Order** box, select the method that you want to use to sort the tests in the protocols.
4. Click **Save**.

Archive

Use the settings on the **Archive** tab to set options for backing up, exporting and restoring files.

To archive a file:

1. In the **File Type** list, click the file type you want to archive.
2. Click the files you want to archive in the list below the **Archive Folder** box (this list displays all files of the selected file type in the internal database).
3. In the **Archive Folder** box, verify the location to which you want to archive the file. To change the location, click **Browse**, then navigate to the new location and click **OK**.

NOTE: If you change the default archive location, you will need to ensure that the **Archive Folder** box reflects that same location when you import those archived files.

4. Select **Keep data after archive** if you want to keep the file in the list after archiving rather than deleting it.
5. If you have selected **Batches** in the **File Type** list, select **Exclude Raw data files** if you wish to exclude the raw data from archiving.
6. Click **Archive** at the bottom right corner of the tab. A progress bar displays, then the **Archive Successful** dialog box opens. Click **OK**.

To add a previously archived file back into the database:

1. In the **File Type** list, click the file type you want to import.
2. Click **Browse** and navigate to the archived file location if you previously changed the location in the **Archive Folder** box.
3. Click **Import**. An **Import Complete** dialog box displays after the files have imported. All archived files of the type selected in the **File Type** list will now display in the list below the **Archive Folder** box, and be available for use with xPONENT.
4. Click **OK**.

To back up all xPONENT data and settings:

1. Click **Backup**. A Warning dialog box displays.
2. Click **OK** to continue with the backup. A progress bar displays.

NOTE: The backup file outputs by default to C:\Documents and Settings\All Users\Documents\Backup\xPONENT.zip

To restore the system using a backup file:

1. Click **Restore**. A Warning dialog box displays.



CAUTION: All data and settings will be overwritten, and xPONENT will restart once the restore task completes.

2. Click **OK** to continue restoring the system. The **File Dialog** box opens. The most recent backup file displays in the **File Name** box. To use a different backup file, click **Browse** to navigate to a different file.
3. Click **OK** to start the restore. A progress bar displays, followed by a **Warning** dialog box stating that xPONENT needs to be restarted.
4. Click **OK** to restart xPONENT.

Licensing

You can use the functions on the **Licensing** tab to change your license information if you are upgrading to a different software package (from Basic to Secure, for example). If you are using a trial license and it has expired, contact Luminex Technical support.

To obtain a new license:

1. Click **Export**. The **Save As** dialog box opens.

2. Select the folder in which you want to save the license file, then click **Save**.
3. Send an email, with the license file attached, to Luminex Technical Support (support@luminexcorp.com). Please include the analyzer serial number in the body of the email. Tech Support needs this in addition to the license key in order to generate a permanent license.
4. Luminex Technical Support will create a new license file and E-mail it to you. Save the new license file to your PC or other storage device.

To use the new license:

1. Click **License**. The **Change License** dialog box opens. Click **Browse**, navigate to the new license file, and then click **Open**.
2. Read the license agreement.
3. Select **Accept License Agreement at next start**, then click **OK**.

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

Schedule

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

1. Select the desired reminder time in the **Alert Time** list.
2. Select how often you want the reminder with the **Recurrence** list.
3. Enable or disable the reminders by checking or clearing the **Enabled** check box.

Adjusting the Sample Probe

Adjust the sample probe to ensure that it drops far enough into the well to acquire sample without impacting the plate.

NOTE: Ensure that there is no liquid in the wells or reservoirs.

NOTE: You should adjust the probe height using row 1 unless you are using the Automated Maintenance Plate. In that case, the probe automatically moves to the specified well.

1. On the **Home** page, click **Probe & Heater**. The Probe & Heater tab opens.
2. Review the adjustment location for the well that you will use for alignment. Click a well on the plate image if you want to use a different well. A blue pin notes the well selected for alignment.
3. Remove the clear plastic shield that covers the sample probe area.
4. In a 96-well microtiter plate where overall height is no more than 0.75 inches (19 mm), place the appropriate alignment tool in the plate:
 - For a standard plate with flat bottom wells - stack two of the larger (5.08 mm diameter) alignment discs into the selected well.
 - For a filter bottom plate - stack three of the larger (5.08 mm diameter) alignment discs into the selected well.
 - For a half-volume plate with flat-bottom wells - stack two of the smaller (3.35 mm diameter) alignment discs into the selected well.
 - For a round-bottom (U-bottom) plate - stack two of the smaller (3.35 mm diameter) alignment discs into the selected well.
 - For a plate with conical wells - place one alignment sphere into the selected well.
5. Verify that the microtiter plate is not warped. Warped plates can lead to incorrect probe height adjustment
6. Click **Eject** to eject the plate holder. Place the plate on the plate holder with well A1 in the top left corner.
7. Click **Retract** to retract the plate holder.
8. Loosen the probe adjustment screw on the probe holder one-third to one-half turn. Pull the sample probe upward until it touches the top of the adjustment slide. Tighten the probe adjustment screw.
9. Click **Move Probe Down** to lower the sample probe.
10. Gently loosen the probe adjustment screw. Push the probe down until it just touches the top of the alignment discs or sphere.

11. Tighten the probe adjustment screw.

NOTE: Use caution not to move the probe up accidentally when tightening the probe adjustment screw.

12. Click **Move Probe Up**.
13. Replace the plastic shield that covers the sample probe area.
14. Click **Eject** to eject the plate holder. Remove the alignment tools from the plate.

System Initialization

xPONENT Software contains a pre-defined startup routine to prepare the analyzer for data acquisition. This section describes warmup, calibration, and performance verification of the system.

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 **Laser:** button if it is yellow. OR
- Open the **Maintenance** page, and then the **Cmds & 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.

Calibrator xMAP beads are used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel. Verification xMAP beads are used to verify calibration and optical integrity of the system.

NOTE: When you run MagPlex® Microspheres, it is essential to use both regular calibration reagents (CAL1 and CAL2) and magnetic calibration reagents (MagCAL1) every time the system is calibrated. Both must pass for the system to be fully calibrated and ready for running magnetic beads.

Once calibrated, the values remain until you recalibrate. You can track system calibration and verification results through the **Calibration** report. Target value information for calibration and verification beads is available on the Luminex website at <http://www.luminexcorp.com/Support/SupportResources/>.

Calibrate your system at least once a week using the **Calibration/Verification** button on the **Auto Maint** tab of the **Maintenance** page. In addition, recalibrate the system if the delta cal temperature exceeds +/-3° C. Verify the system daily using the **Performance Verification** button on the **Auto Maint** tab of the **Maintenance** page. Refer to your assay kit instructions for additional calibration frequency requirements.

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

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.

Run System Initialization

1. On the **Home** page, click **System Initialization**. The **Auto Maint** page opens.
2. Select the performance verification kit from the **Performance Verification** kit list at the right of the tab.
3. Select the calibration kit from the **Calibration Kit** list.
4. Vortex the xMAP calibrator, verification, and fluidics containers to ensure homogeneity. Do not dilute xMAP calibrator or verification agents.
5. Click **Eject** on the status bar, then place the microtiter plate on the plate holder.
6. Load a microtiter plate with at least five drops of the beads in the Calibration and Performance Verification kit as indicated on the plate image and in the kit insert instructions.
7. Click **Retract**.
8. Click **Run**.

Add CAL or VER Kits

Before you can calibrate the system, you will need to add xMAP calibrator and verification bead lot information. This information is on the CD that accompanies the performance verification kit and is also available on the Luminex website at <http://www.luminexcorp.com/Support/SupportResources/>.



WARNING: Inaccurate data entry can invalidate the results of these procedures. Careful entry of data in each field is necessary to ensure accurate results.

1. On the **Home** page, click **System Initialization**.
2. Click **Import Kit** at the bottom right side of the window. The **Import Calibration or Performance Kit** dialog box opens.
3. Locate the xMAP calibrator or verification kit information file (.ixl) and click **Open**.

Import CAL or VER Kits

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 wish to import, then click **Open**.

Export CAL or VER Kits

1. Open the **Maintenance** page, then open the **Lot Management** tab.
2. In the **Active Reagents** section, select the kit you want to export from the **Calibration Kit or Performance Verification Kit** lists.
3. Click **Export**.
4. In the **Export Calibrator or Verification Lot** dialog box, select an export location for the kit.
5. Type the kit name for the exported kit into the **File Name** box.
6. Click **Save**. The dialog box closes.

Delete 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.

Create Calibration Reports

1. Open the **Results** page, then open the **Reports** tab.
2. In the **Report** list, click **Calibration Summary**.
3. In the **Type** list, click the calibrator or verifier for which you want to create a report.
4. In the **Dates** list, select a start date for the date range you want to view.
5. In the **Through** list, select the end date for the date range you want to view.
6. Click **Generate** to display the desired report.
7. Use the left or right **Page** arrows to navigate to the different report pages.
8. Click **Print** to print the report, or **Save** to save the report.
9. Click **New Report** to generate another report.

Managing Sample Lists

Use the **Samples** page to create a sample list, view or edit sample list details, or create a batch.

Create 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
4. Type a patient first name in the **First name** box if desired.
5. Type a patient last name in the **Last name** box if desired.
6. To add a comment about the sample, type it in the **Comment** box; this is optional.
7. Click **Save** to add the sample to the **Sample** list.
8. To add more samples, click **New**. Repeat Steps 3 through 7 until you have added all of the samples you want in your samples list.
9. Once you have added the all desired samples, click **Close**.

NOTE: Samples can also be added via a LIS if your software is licensed for LIS.

Edit Sample Lists

1. Open the **Samples** page.
2. In the **Samples Lists** section, choose the protocol you want to edit, then click **Details**. The **Edit Samples** tab opens.

NOTE: If the number in the **Number of Samples** column is 0, there are no samples attached to the protocol.

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 follow steps 3 through 7 in “Create New Sample List” above.
5. To edit an existing sample, click the sample, then click **Edit**.
6. Once you have completed editing the sample list, click **Close**.

Setting Up Batches

A batch consists of a group of samples processed under control of a protocol. 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 can only be run on one plate.

Protocols are provided on CD as part of your assay kit. Protocols typically include assay standards, controls, and maintenance commands (such as washes or primes to acquire along with samples). Assay reagents are included in assay kits. You must provide information about these reagents, such as lot numbers and concentration values for the standards and assay controls.

WARNING: Human and animal samples can 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 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.

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. If the protocol uses standards and/or controls, view the active reagents.
6. Click **Next**. If the protocol uses standards and/or controls, the next tab that appears is the **Stds & Ctrl**s tab. Otherwise, the **Plate Layout** tab appears. View the details of the active reagents or apply different assay standards/controls or manually enter new information. Select **Next**.
7. On the **Plate Layout** tab, assign well commands for this batch. See “Plate Layout Tab” 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 displays prompting you to insert the next plate.

Create a New Batch from a New Protocol

This option creates a new batch to acquire data without using an existing protocol. It writes raw data results to a simple “.csv” file format. You can define parameters for samples, gates, regions, events, and commands.

1. Open the **Batches** page.
2. Click **Create a New Batch from a new Protocol** to open the **Settings** tab.
3. Type a name in the **Name** box.
4. Type a description in the **Description** box.
5. Define the settings in the **Acquisition Settings** section.

NOTE: For information about each of these settings, see the Settings Tab section.

6. Define the settings in the **Analysis Settings** section. For more information about each of these settings, see the **Analysis Settings** information within the Settings Tab section. If you select **Quantitative** or **Qualitative** from the **Analysis Type** list, you can select **Analyze results while acquiring samples** to view real-time analysis. The xPONENT Analysis Package can only analyze batches acquired using qualitative or quantitative protocols.
7. Click **Next**. The Analytes tab opens.
8. Click the desired analyte in the numbered grid. Information about the analyte displays in a list on the right side of the grid.
9. To change the **Default analysis**, click **Change**. The **Analysis Settings** dialog box opens.
10. Select the analysis method from the **Method** list. Click **OK** to change the default analysis for analytes to be selected. Click **Apply to All Analytes** to apply the selection to all analytes. The Analysis dialog box closes.
11. Type the units of measurement you want to use in the **Units** box. If you click **Apply All**, this choice is applied to all analytes. To change individual units, change them in the analyte table in the dialog box.
12. Type the desired bead count for each analyte in the **Count** box. If you want to change individual bead counts, change them in the analyte table in the dialog box.
13. Click **Next**. The **Stds & Ctrl**s tab opens. This tab does not open if no analysis is selected.
14. If you are using an assay standard/control kit, click **Apply Std/Ctrl Kit**. In the **Select Std/Ctrl Kit** dialog box, click the kit from the list and click **OK**. Applying a kit only works for kits already installed, however, you can manually type the information.
15. If you are not using a kit, type the appropriate information in the **Standard Information** and **Control Information** sections. The number of standards and/or controls in these sections is defined on the **Settings** tab in the **Analysis Settings** section. If your batch uses controls enter the high value for each analyte. Reagent information is not required for a custom batch unless you want to use the analysis feature.
16. Click **Next**. The **Plate Layout** tab opens.
 - To add well commands, click the appropriate wells and mark them as unknown, standard, control, background, or wash. You can also delete commands that you’ve added and change the starting location on the plate. If you want to run in replicate, change the **Replicate Count** to the appropriate number and the **Grouping** to your preferred grouping method.

- To add maintenance commands, choose the desired command from the list. Choose the well that you want to apply it to, and then choose **Before well command** or **After well command**. If you are working with more than one plate, choose the **Plate** list. Here, you can add a plate, change the order of the plates, and scroll through all plates.
 - As you add commands to your plate, they appear in the **Command Sequence** list. Here you can give each of your wells an ID. You can also import an ID list and move your commands up and down to change the order in which they will be acquired. For additional information, see “Plate Layout Tab” on page 14.
17. Click **Single Step** to acquire the first two wells, then pause acquisition.
 18. Click **Run Batch** to run the acquisition, or **Save** the batch for 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 Multi-Batch

A multi-batch is a set of batches that you want to process consecutively. You add batches to the multi-batch from pending batches in your database. You can also create a new batch to add to the database for the multi-batch. You can include as many batches as you need. The software does not limit you to a certain number of batches per multi-batch.

You must ensure 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 the plate direction) as long as space remains 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. For more information, see Create a Multi-Batch.

1. Open the **Batches** page.
2. Click **Create a New Multi-Batch**. The **New MultiBatch** tab and **Select Pending Batch** dialog box open simultaneously.
3. In the **Select Pending Batch** list, select the batch to add. Click **OK**. Click **Add** to open the **Select Pending Batch** dialog box. Select the new batch that appears and click **OK**. Repeat for all batches to be run.
4. Click **New Batch** to open. Select **Protocol for New Batch** tab or just **Protocol** tab. Follow the steps for creating a new batch from a new or existing protocol. Click **Save** and you return to the **New Multibatch** tab.
5. Click **Run** to run the multi-batch.

Save Multi-batch

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.”

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.

1. Create a new multi-batch.
2. Select a pending batch.
3. Enter the name for the multi-batch in the **Multi-batch Name** field.
4. Click **Save**.

Import Batch

You need to import batches to the system only 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 setup using the protocol until it is changed.

1. Open the **Batches** page.
2. Click **Import**. The **Import Batch** dialog box opens.
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.

Export 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 in which you want to save the file, then click **Save**. Click **OK** in the Export Batch dialog box.

NOTE: When exporting a large batch and including the LXP files, such as a batch with hundreds of wells or hundreds of analytes, the export process may take ten minutes or more.

Delete Batch

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

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**.

Edit Batch

1. Open the **Batches** page.
2. Click the batch you want to edit, then click **Edit**. The Protocol tab opens, (this includes the batch name, the protocol used, and the active reagent).
3. Edit the information as needed on the **Protocol, Std & Ctrl**s, and **Plate Layout** tabs.

NOTE: This does not allow editing of the assay protocol.

4. Click **Save** on the Plate Layout tab.

See “Settings Tab” on page 26 for more information on batch settings.

NOTE: You cannot delete or edit a batch included in a saved multi-batch. Remove the batch from the multibatch to make changes.

Run 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.

Add a Patient List

You can apply a Patient List to any batch or multi-batch during batch setup from the Batches Page on the Plate Layout tab.

You can create a Patient List text file using Windows Notepad or a text editor. The text file must include a line or lines of text containing Patient ID/Name, Dilution Factor, Well location (optional).

The Patient ID/Name can contain the following characters: a-z, A-Z, 0-9, -,_, or space. The dilution factor is a number greater than or equal to 1.0, depending on the assay specifications.

Patient List files can optionally contain a location identifier. When using a list without locations, as shown in Example 1 below, the unknown sample wells must be added to the plate layout graphic first. When the list is imported, the names and dilution factors of the existing unknown wells on the plate will be updated with the information contained in the list. If dilution factors are not present in the list, as indicated by “Patient 1” in Example 1 below, a dilution factor of 1 (effectively no dilution factor) will automatically be applied.

Example 1: Typical patient list file without well locations:

Patient 1

Patient 2, 5

Patient 3, 10

If a Patient List file contains locations, as shown in Example 2 below, the plate layout graphic should not contain unknown sample wells. The list must specify the plate and well using Plate Number, Plate Row, and Plate Column. When a list with locations is imported, the unknown sample wells will be added to the plate layout and the names and dilution factors will be assigned. Dilution factors should always be present in Patient List files that contain locations. For unknown sample wells that are not diluted, a dilution factor of 1 should be specified.

Example 2: Typical patient list file with well locations:

Patient 1, 1, P1A1

Patient 2, 1, P1B1

Patient 2, 10, P1C1

To add a Patient List file while creating a batch or multi-batch, follow these steps:

1. When creating a batch, on the **Plate Layout** tab, click the **Import List** button. The Import List window opens.
2. Browse to the location of the patient list and click **Open**.

Performing Analysis

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

Analyze Current Batch

When you run a batch, the **Current Batch** tab opens. Here, you can view real-time analysis of acquired analytes.

To view a single statistic type for all analytes click the statistic you want to view from the **Statistic** list. To view all statistic types for a single analyte, click the analyte from the **Analyte** list.

Click **Single Step** if you want to set the DD Gate during sample acquisition. Click **Resume** to acquire the next sample. Clear **Single Step** if you want to run all subsequent samples without pausing.

Manage Saved Batches

Replay Batch

You can replay a batch to reprocess batches multiple times. This function uses the data stored in the run files from the initial acquisition to reprocess a batch and create a new batch output file.

1. Open the **Results** page, then open the **Saved Batches** tab.
2. Click the batch you want to replay.
3. Click **Replay**. The Select Replay Mode dialog box opens. Click **Replay batch**.
4. In the **Settings** tab, type a batch name in the **Batch Name** box.
5. Type a description in the **Description** box.
6. Click **Next**.
7. On the **Stds & Ctrls** tab, type the appropriate information in the **Standard Information** and **Control Information** sections. The number of Standards and/or Controls in these sections is defined on the **Settings** tab in the **Analysis Settings** section. If your batch uses controls, enter the appropriate values for **Expected Values**. Click **Low Value** from the **Show** list, and enter the low value for each analyte. Click **High Value** from the **Show** list, and enter the high value for each analyte. Reagent information is not required to replay a custom batch, unless you want to use the analysis feature.
8. Click **Next**.
9. In the **Plate Layout** tab, you can do the following:

- To add well commands, choose the appropriate wells and mark them as unknown, standard, control, background, or wash. You can also delete commands that you've added, and change the starting location on the plate. If you wish to run in replicate mode, change the **Replicate Count** to the appropriate number and the **Grouping** to your preferred grouping method.
- To add maintenance commands, choose the desired command from the list. Choose the well that you want to apply it to, and then choose **Before Well** or **After Well**. If you are working with more than one plate, choose the **Add & Change Plate** drop down list. Here, you can add a plate, change the order of the plates, and scroll through all plates.
- As you add commands to your plate, they appear in the command sequence list. Here, you can give each of your wells an ID. You can also import an ID list and move your commands up and down in the command sequence chart.

NOTE: Only wells that were acquired in the original batch can be replayed.

10. Click **Replay Batch**. The **Current Batch** tab opens, where you can view the data as it is replayed.

Analyze Saved Batch

Click **Results** on the xPONENT toolbar, then open the **Saved Batches** tab. Click the batch name, then click **Open**. The **Results**, **Settings**, **Log**, and **Sample Details** tabs appear.

- Click the **Results** tab to view statistical information about the batch. See "Sample Details Tab" on page 28.
- Click the **Settings** tab to view the batch settings report. See "Settings Tab" on page 26.
- Click the **Log** tab to view a log for the activity that occurred during acquisition of the selected batch. See "Log Tab" on page 27.
- Click the **Sample Details** tab to view sample details for each sample in the batch. If you are using the LIS package, click **Transmit** to transmit the data to the LIS.

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**.

View 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 you wish to save the batch settings report, and click **Save**.

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.

View Sample Details

1. Open the **Results** page and 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.

View and Print Reports

The Luminex xPONENT software can format your batch or multi-batch results in a variety of export formats and provide different types of information in different types of reports. Three types of reports are available. See “Reports Tab” on page 30 for a description of available reports.

NOTE: Install the printer before initiating the **Print** command.

1. Open the **Results** page, then open the **Reports** tab.
2. In the **Report** list, click the report you want to view.
3. In the **Type** list, select the report type you want to view.
4. Select the item for which you want to generate the report. If you are creating a batch report, select the analyte to include in the report.
5. Click **Generate**. The report displays in the lower part of the **Reports** tab.
6. Click **Print** to print the report, or **Save** to save the report as a .pdf file.

Transmit Batch

You can only perform this task if you are using an xPONENT package licensed for LIS.

1. Open the **Results** page, then open the **LIS Results** tab.
2. Select a batch, then click **Open**.
3. Click **Yes** to approve and transmit the batch to the LIS database.

Using Protocols, Lots, and Kits

Protocols

Protocols for your assay are provided with your assay kit.

WARNING: Human and animal samples can 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.

Import 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.

Add New Lot for Protocol

1. Open the **Protocols** page, then open the **Protocols** tab. Click the protocol to which you want to add a lot.
2. Open the **Stds & Ctrl** 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**.

Delete 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**.

Export 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**.

Editing a Protocol

1. Open the **Protocols** page, then open the **Protocols** tab.
2. Select a protocol.
3. Click **Edit**. The Settings tab opens.
4. Define settings and click **Next**. The Analytes tab opens.
5. Define analytes and click **Next**. The Plate Layout tab opens.
6. Define the plate layout.
7. Click **Save**.

Lots and Kits

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.

Create Kit

1. Open the **Protocols** page, then open the **Protocols** tab.
2. Click on 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/YY format in the **Expiration** box, and the manufacturer in the **Manufacturer** box.
4. Click **Apply Std Lot** if you wish 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. Click 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 and/or controls 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**.

Create Lot

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

1. Open the **Protocols** page, then open the **Protocols** tab. Click the **Stds & Ctrls** tab, then click **Create New Std/Ctrl Lots**.
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**.

Import Lot

1. Open the **Protocols** page, then open the **Protocols** tab. Click the **Stds & Ctrl**s tab, and then click **Import**.
2. In the **Open** dialog box, navigate to the file, then click **Open**.

Delete Lot

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

Export Lot

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

1. Open the **Protocols** page, then open the **Protocols** tab. Click the **Stds & Ctrl**s 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 wish to export the file to, then click **Save**.

Edit Lot

1. Open the **Protocols** page, then open the **Protocols** tab. Click the **Stds & Ctrl**s 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.

Performing System Maintenance

Perform Individual Maintenance Command

Open the **Maintenance** page, then click the **Auto Maint** tab to display the automated maintenance options. To perform an individual maintenance command, click on the appropriate button in the **Cm**ds & **R**outines tab. For a description of each of these commands, see “Cmds & **R**outines Tab” on page 39.



WARNING: Lack of proper maintenance can lead to inaccurate test results and failure of system components. Please follow all scheduled maintenance routines to ensure proper functioning of equipment.

Perform System Calibration

Perform system calibration weekly. In addition, recalibrate the system if the delta cal temperature exceeds +/-3°C. For further information, see “System Initialization” on page 62.

Manage Maintenance Routines

You can manage maintenance routines at the **Cm**ds & **R**outines tab on the **Maintenance** page. Open the **Maintenance** page, then click the **Cm**ds & **R**outines tab.

Create 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 Luminex System Manual for more information.

1. Open the **Maintenance** page, then open the **Cm**ds & **R**outines tab.
2. In the **Routine Name** list, click **None**.

3. In the **Commands** section, click one or more commands to add to the routine. These commands display in the plate image and in the **Command Sequence** list.
4. To change a location (well or reservoir) for a command, click the command in the **Command Sequence** list, then click the new location in the plate image.

NOTE: If you attempt to place two or more incompatible commands in the same well, a message will display 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.

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

Edit Routine

You can also edit routines.

1. Open the **Maintenance** page, then open the **Cmnds & 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 wish 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 them before commands that are already part of a routine.

Run Routine

1. Open the **Maintenance** page, then open the **Cmnds & Routines** tab.
2. Select a routine to run from the **Routine Name** list.
3. Click **Eject** on the status bar.
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**.

Delete Routine

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

On the **Cmnds & Routines** tab of the **Maintenance** page, click the routine that you want to delete from the **Routine Name** list, then click **Delete**.

Import Routine

On the **Cmnds & Routines** tab of the **Maintenance** page, click **Import**. In the **Open** dialog box, browse for the routine file (.lxd) you want to import, then click **Open**. The routine becomes the active one.

Export Routine

On the **Cmnds & Routines** tab of the **Maintenance** page, click **Export**. In the **Save As** dialog box, navigate to the folder where you want to store the routine file, then click **Save**.

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

Support Utility

Use the options on the **Support Utility** tab to create a support file to send to Luminex Technical Support.

1. Type your name in the **Name** box.
2. Type your company name in the **Company** box.
3. Type your phone number in the **Phone** box.
4. Type your e-mail address in the **Email** box.
5. In the **Comment** box, type a detailed description about the problem you are experiencing.
6. To include information about a batch, click **Include Batch Info**, then click the batch name.
7. 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**.
8. Click **Export**.
9. Send an email to support@luminexcorp.com and attach the support file (xPONENTSupportFile.zip) to the email.

Shutting Down the Analyzer

1. On the **Home** page, click **Shutdown**. The Auto Maint tab opens, with System Shutdown selected.
2. Refer to the Automated Maintenance plate depiction in the lower right of the **Auto Maint** tab. Fill the well indicated in this depiction the (off-plate reagent area RB2) with a 10% to 20% household bleach and water solution.
3. Add deionized water to the RA1 reservoir.
4. Click **Run**.

Logging Out of the Software

To log out of xPONENT, click the **Log Off** icon in the upper right corner of the software window. The **Confirm Logout** dialog box opens. Click **OK**.

NOTE: This only logs you out of the software; it does not exit the software.

Exiting the Software

Log out of the software. The System Log-in page displays. Click the **Exit** tab, then click **Yes**.

Technical Support

Luminex Technical Support representatives are ready to help you, particularly when the system or software cause any questions or problems. If the question or problem relates to materials from the assay kit, you should 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 can also be sent by email to support@luminexcorp.com.

Luminex Website

Additional information is available on the Luminex website, <http://www.luminexcorp.com>. Search on the desired topic or navigate through menus.

Appendix A: Glossary

Term	Definition
21 CFR Part 11	21 CFR Part 11 sets the criteria under which the Food and Drug Administration (FDA) considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.
agglutination	The coalescing of small particles that are suspended in solution; these larger masses are then (usually) precipitated.
ambient temperature	The temperature of the surrounding environment.
analyte	A substance that is detected through assay analysis. Each test or bead set will test for a specific analyte.
analyzer	This term is used to refer to the Luminex analyzer.
APD	Avalanche Photo Diode; Measures the excitation emission intensity of the color coding classification dye mixtures inside the microsphere and the amount of light scattered as particles pass by the lasers.
assay	A substance or analyte or a group of substances or analytes undergoing evaluation or analysis.
background (noise)	That portion of a bead set result that can be attributed to excess reporter molecules in the solution, nonspecific binding, or fluorescent spillover from another fluorochrome into the reporter channel.
batch	A group of samples that are processed using a selected protocol.
bead	Shorthand terminology for an xMAP microsphere.
bead map	A collection of bead sets with defined classification coordinates.
bead set	A set of xMAP microspheres that have a uniquely identifiable ratio of two classification dyes. The unique ratio is identified by a unique spectral address. Also sometimes called microsphere set, microsphere region, or test by the software during acquisition.
calibration	A process used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel for the Luminex System. Calibration ensures optimal and consistent microsphere classifications and reporter readings.
calibrators	xMAP microspheres used to normalize the settings for the reporter channel, both classification channels, and the doublet discriminator channel for the Luminex System.
CL1	Refers to dyes embedded in the microsphere. Also see classification channel.
CL1 Target	Used for calibration purposes. This is the target value for the Classification Channel 1 for the CAL1 microspheres.
CL2	Refers to dyes embedded in the microsphere. Also see classification channel.
CL2 Target	Used for calibration purposes. This is the target value for the Classification Channel 2 for the CAL1 microspheres.

Term	Definition
classification channel	A specific range of wavelengths in which light intensity is measured. Includes the fluorescence emission of a given classification dye. Classification channels are abbreviated as CL1 and CL2.
CSV	Comma separated value file format used to output data from the application.
cuvette	Fluid pathway within the optics component of the system through which the sample is read.
data reduction	The analysis of acquired batch data.
DD temperature	The current temperature of the doublet discriminator avalanche photo diode.
delta cal temperature	The difference between the current temperature of the Doublet Discriminator APD and its temperature at your last calibration. Once the delta cal temperature exceeds +/- 3°C, the system must be recalibrated.
dot plot	Graphical representation of microsphere analysis classification data displayed by frequency and intensity.
doublet discriminator (DD)	A classification channel measuring side scatter; used to filter for single bead events based on size.
emission spectrum	Wavelength range that an excited fluorochrome emits when its electrons fall from a higher to a lower energy state. Expressed in nanometers (nm).
event	Occurs when the signal processor determines that a particle of any size has passed through the lasers.
excitation spectrum	Wavelength range that excites a molecule's electrons to a higher energy state. Expressed in nanometers (nm).
fluorescence	Light emission that occurs when the electrons of a fluorochrome drop to a lower energy state.
fluorochrome	A fluorescent molecule.
fluorophore	See fluorochrome.
histogram	The representation of frequency distribution for analyte results. The DD channel results are often displayed in a histogram format.
immunofluorescence	A technique which uses a covalently linked fluorochrome-antibody complex to detect or quantify a particular antigen.
kit	A group of standards and controls used to create a protocol. They are used in the protocol's definition for the multi-analyte assays that will be performed. Formerly called "product" in previous releases of Luminex software.
Luminex xMAP microsphere set	Luminex multi-analyte microspheres containing a unique mixture of two distinctly colored fluorochromes to distinguish them from other multi-analyte microspheres.
laser	Light Amplification by Stimulated Emission of Radiation. This highly purified source of light is an efficient way to excite fluorochrome electrons.
LIS	Laboratory Information System; A system for storing sample records and test requests.
lot	A reagent with specific target values used for analysis or calibration.
median fluorescence intensity (MFI)	Used to denote how much fluorescence a given particle population carries; expressed and compared in linear numbers.
microparticle	A solid substance with a diameter in the micrometer range. Often used as a synonym for a microsphere.

Term	Definition
microspheres	Polystyrene spheres with a diameter in the micrometer range. Also called beads.
multi-analyte	Several assays or tests performed simultaneously in the same reaction container.
multi-batch	A set of batches to be processed consecutively on a single plate.
panel	A panel is a grouping of related functions and text fields on the xPONENT user interface.
pending batch	A batch that has been set up, but not yet run.
photobleaching	The process in which light absorption converts the fluorochromes on the beads into different fluorescent or nonfluorescent compounds. Photobleaching prevents beads from being properly classified.
plate	A 96-well tray in which analytes and samples are placed for organized acquisition.
plate heater	An aluminum block used in the Luminex analyzer to maintain sample temperature.
PMT	Photomultiplier tube, measures the excitation emission intensity of the reporter dye bound to the surface of the xMAP microspheres.
probe	See Sample Probe.
protocol	A file containing a sequence of commands and predetermined settings provided with your assay kit.
Qual	A value that determines a cutoff or threshold. This, in conjunction with ranges using the Lum Qual Formula, Adv Qual Formula, or an edited range specific for your assay, helps to determine qualitative results for unknown samples.
qualitative	Pertaining to calculations that determine the absence or presence of an analyte.
quantitative	Pertaining to calculations that determine the precise numerical measurement of an analyte.
reagent	A substance used to detect or measure other substances.
region event	A gated event that exhibits the correct classification fluorescence values to fall into one of the bead regions. Region events are used to calculate the median fluorescence intensity (MFI) which is the final data generated by the system. Any other event is excluded from data analysis.
reporter	A molecule (or combination of molecules) with a specific range of excitation and emission wavelengths that is used to identify or quantify an analyte. Examples of acceptable reporters are Phycoerythrin and Alexa 532. Reporter signals are the final result of each assay.
reporter channel (RP or RP1)	A specific range of wavelengths that includes the emission wavelength of a designated reporter molecule.
RP	See reporter channel.
RP1	Refers to the dyes bound to the surface of the xMAP microsphere. Also see reporter channel.
sample	The mixture of assay components (microspheres, reporter, patient dilutant) that are analyzed.
sample probe	The probe, or needle, on the Luminex analyzer that acquires sample from the 96-well plate.
sample reaction	The reaction that occurs between reagents and beads.

Term	Definition
sheath fluid	Luminex xMAP Sheath Fluid is the delivery medium of the sample to the optics component. Only Luminex-approved sheath fluid should be used when operating the Luminex analyzer.
signal	Detectable measurement unit of the reporter molecule.
standards microspheres, assay	Assay standards are substances of known concentrations used to derive a standard curve with which unknown samples and controls are compared to determine their concentration or quantity.
suspension	Solution consisting of homogeneously dispersed microspheres in an aqueous medium.
system controls	Include the xMAP reporter and classification control microspheres. They are used to verify the calibration of the Luminex analyzer.
template	This is now called a protocol.
test	Each test represents an analyte and corresponds to a bead set. Each bead set falls into a particular location on the bead map.
total event	Everything passing through the cuvette and analyzed by the instrument. This includes single beads, aggregates of beads, debris, and air bubbles.
verification	The process using system controls to ensure the analyzer is functioning properly with current calibration settings.
Verifier microspheres, assay	Used to verify standards within the kit. Tells you that the curve or thresholds are correct.
Verifier microspheres, system	xMAP microspheres used to verify the calibration and optical integrity for the Luminex analyzer.
xMAP	See Luminex xMAP microsphere set.