Luminex®

xPONENT for MAGPIX 4.2
Software User Manual
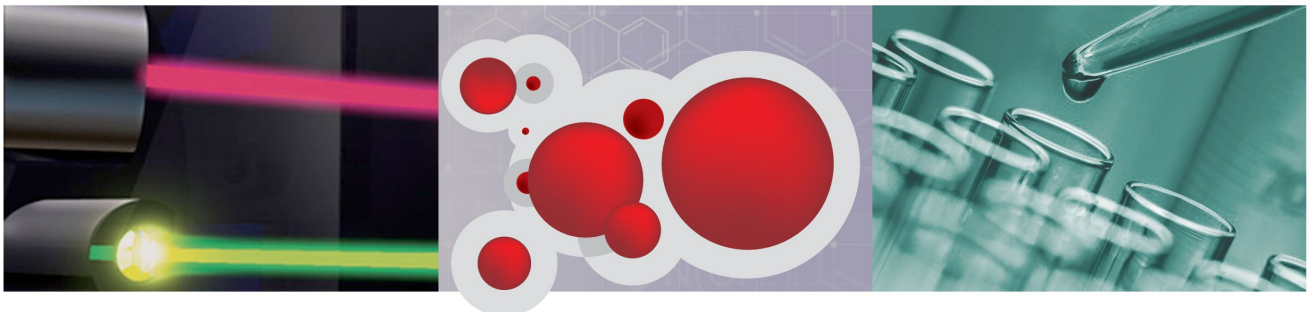
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xPONENT 4.2 for MAGPIX Software User Manual

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89-30000-00-254 Rev. B

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Table of Contents

Chapter 1: Introduction

Safety Precautions

DANGER: Samples and waste fluid can contain biohazardous infectious agents. Handle them at Biosafety level 2, as recommended for any potentially infectious human serum or blood specimen in the DCE/NIH manual, *Biosafety in Microbiological and Biomedical Laboratories*, 1984.

CAUTION: Although beads do not contain hazardous or carcinogenic components at toxic levels, they can be toxic if swallowed. In addition, contact with acids liberates toxic gases. If beads come into contact with skin, wash immediately with copious amounts of water. In case of an accident, seek medical advice immediately and show the product label or container to your medical provider. A material safety data sheet (MSDS) is available upon request.

CAUTION: Luminex reagents can contain ProClin® as a preservative. This can cause an allergic reaction in some people. Use personal protective equipment (PPE), including gloves and safety glasses. Check the assay package insert for assay component information.

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

Elements of the Software

Home Page

Home > **Home**

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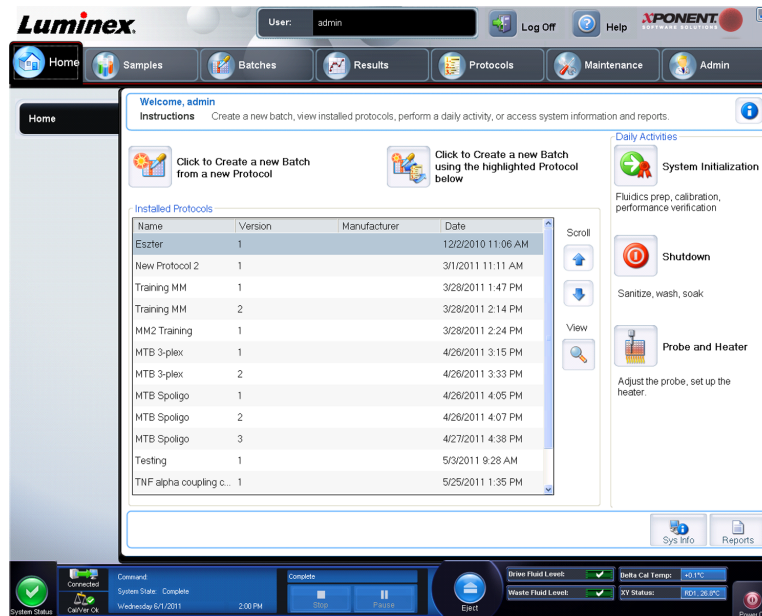
Return to the **Home** page at any time by clicking **Home** in the **Navigation** toolbar. This page contains the following:

- **Click to Create a new Batch from a New Protocol** - Creates a new batch from a new protocol. This allows you to create a new protocol while you are creating the batch. Choose this function if you want to quickly create a batch and run it and you do not already have a protocol that is appropriate for use. This is useful for one time batches you do not expect to rerun frequently. However, you always have the option of saving a protocol once a batch is created.

- **Click to Create a new Batch using the highlighted Protocol below** - Creates a new batch using a selected protocol from the **Installed Protocols** list.

- **Installed Protocols** - Displays a list of protocols. 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.
  - **Shutdown** - Opens the **System Shutdown** command in the **Auto Maint** tab on the **Maintenance** page.
  - **Probe and Heater** - Opens the **Probe and Heater** tab on the **Maintenance** page.
- **Sys Info** - Opens the **System Info** tab of the **Maintenance** page.
- **Reports** - Opens the **Reports** tab of the **Results** page.

Screen Elements

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

Navigation Elements

1. **Page** - Across the window, above the content pane, are pages. Click a page to go to that part of xPONENT.

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

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

Right-Click Menu

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

- **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** dialog box. Use the **Browse** button to select a location, file name, and file type (either a text or CSV file) for the export. This exports all data from the right-clicked item.
- **Cut** - Cuts the selected data.
- **Copy All** - Copies all data.
- **Copy** - Copies only the selected data.
- **Paste** - Pastes previously copied text or data into the box.
- **Delete** - Erases text or data from the selection.

System Monitor

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

1. **System Status** Button	2. Connection Status
3. Check Cal/Ver Status	4.**Command** Display
5. Progress bar, **Stop** button, **Pause** button	6. **Eject** Button for plate carrier
7. **Drive Fluid Level**	8. **Waste Fluid Level**

9. **Delta Cal** Temperature   10. **XY Status**

11. **Power Off** button

System Status Button - This button has two functions: When clicked, it opens the system log. It also displays the current status of the system. If there are no warnings or errors, the **System Status** button is green with a check mark. If there is a warning, out of calibration condition, or other important user notification, the button is yellow with an exclamation point.

Connection Status - Displays the status of the analyzer's connection to the PC (**Connected** or **Disconnected**). To ensure the analyzer connects to the PC, turn on the analyzer before you start xPONENT.

Check Cal/Ver - If this displays a white X, there is a failed calibration or verification. Click the scales to open the **System Information** tab to see details about the last calibration and other important instrument information.

Command Display - Displays the following:

- The command currently running.

- The system state (i.e. running, idle, etc.).

- Date and time.

Progress - Displays a bar graph showing the progress of the current command or routine; if the command or routine is finished, it displays a full progress bar and the command status as **Complete**.

Pause - Pauses the system after the current command completes. **Pause** does not stop the system in the middle of running a command. You cannot run another command while the system is paused. Pause the system before stopping it so that it will finish the current command and store the pending batch and then resume exactly where it left off.

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

Eject - Ejects the plate. Once the plate is ejected, the **Eject** button changes to **Retract**. Retract retracts the plate, and the **Retract** button changes back to **Eject.**

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

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

Drive Fluid Level - The Drive Fluid liquid level sensor warns you when the Drive Fluid is low. There can be enough Drive Fluid left in the container to finish a plate. The system does NOT stop until a air bubble is detected in the line coming from the Drive Fluid container.

Waste Fluid Level - The waste fluid container liquid level sensor stops the current plate if the waste container is full.

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 and 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.

Quick Start

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

To	Go to	Expanded Help
Adjust the sample probe height	**Home** > **Probe and Heater**	*Adjusting the Sample Probe*
Initialize the system	**Home** > **System Initialization**	*Running the System Initialization Routine*
Run an assay	**Home** > **Create a new Batch from a new protocol**, or **Home** > **Create a new Batch using the highlighted protocol below**	*Create a New Batch from a New Protocol* *Create a New Batch from an Existing Protocol*
Analyze	**Results** > **Saved Batches**	*Performing Analysis*
Print reports	**Results** > **Reports**	*Reports Tab*

System Info Tab

Maintenance > **System Info**

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

This tab contains the following information:

• **Software**

• **Version**

• **Operating System**

• **Licensing**

- **Instrument Type**
- **Serial Number**
- **Firmware Version**
- **XYP Heater Temp**
- **Calibration/Verification Status**
- **Delta Calibration Temp**
- **System Temperature**
- **Last CAL Calibration**
- **Last VER Verification**
- **Last Fluidics Test**
- **Drive Fluid**
- **Waste Fluid**

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

- **Passed** - Indicates that the process completed successfully.
- **Failed** - Indicates that the process was not completed successfully. Failed items appear in red.
- **Not Current** - Indicates that verifiers are not current. Verifiers are not current if you have not calibrated the system since the last time you ran the verifiers.
- **Not Yet Run** - Indicates that this process has not yet been run on the machine.

Copy - Copies the system information to the Windows clipboard. You can then paste it into a text editor such as Notepad.

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

Basic Procedures

Starting xPONENT

Perform the following steps to launch xPONENT:

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

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

Adding a New License Key

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

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

Logging On to xPONENT

If your version of xPONENT is licensed for 21 CFR Part 11, Security, or both, an application administrator must set up user IDs (and passwords, if required). If you are not using a version with 21 CFR Part 11, the security module, or both, users can log in with any username or with no username.

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

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

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

Luminex ? Help **XPONENT**

System Login

System Login
Instructions   Enter your User ID to log In.

System Info

Exit

User ID: [   ]

Log In

Disconnected Command: Complete Drive Fluid Level: Delta Cal Temp:
System State: Stop Pause Waste Fluid Level: XY Status:
System Status Thursday 7/7/2011 2:52 PM Eject Power Off
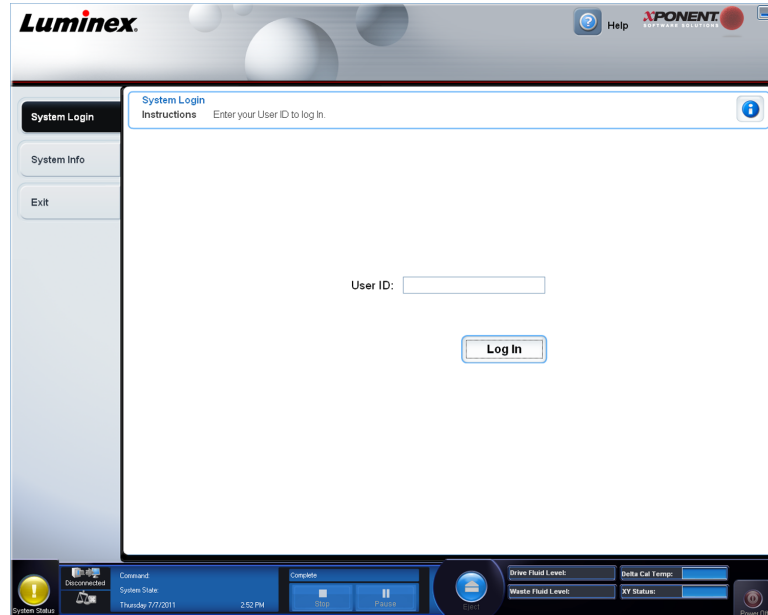
2. If you are using a secure version of the software, type your password. The **Home** page opens.

Luminex User: admin Log Off ? Help **XPONENT**

Home Samples Batches Results Protocols Maintenance Admin

Welcome, admin
Instructions   Create a new batch, view installed protocols, perform a daily activity, or access system information and reports.

Home

Click to Create a new Batch from a new Protocol

Click to Create a new Batch using the highlighted Protocol below

Daily Activities

System Initialization

Fluidics prep, calibration, performance verification

Installed Protocols

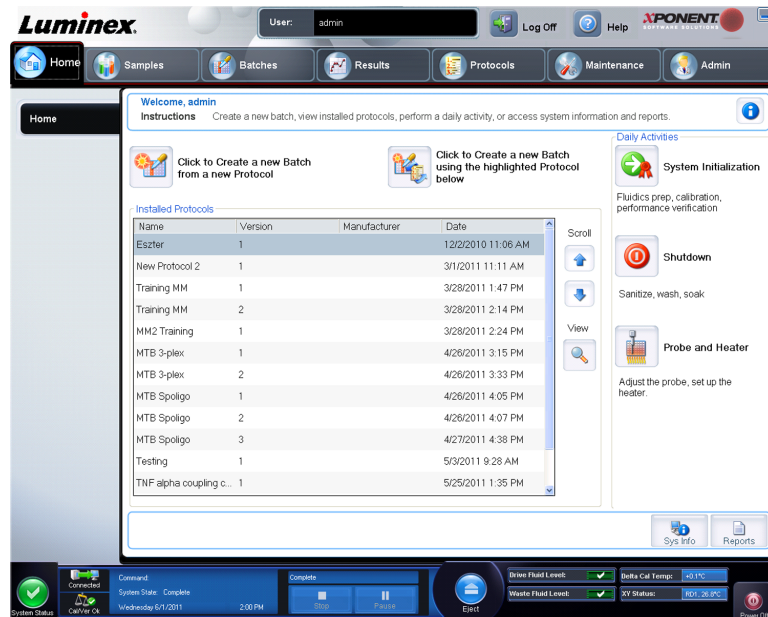| Name	Version	Manufacturer	Date
Eszter	1		12/2/2010 11:06 AM
New Protocol 2	1		3/1/2011 11:11 AM
Training MM	1		3/28/2011 1:47 PM
Training MM	2		3/28/2011 2:14 PM
MM2 Training	1		3/28/2011 2:24 PM
MTB 3-plex	1		4/26/2011 3:15 PM
MTB 3-plex	2		4/26/2011 3:33 PM
MTB Spoligo	1		4/26/2011 4:05 PM
MTB Spoligo	2		4/26/2011 4:07 PM
MTB Spoligo	3		4/27/2011 4:38 PM
Testing	1		5/3/2011 9:28 AM
TNF alpha coupling c...	1		5/25/2011 1:35 PM

Scroll

View

Shutdown

Sanitize, wash, soak

Probe and Heater

Adjust the probe, set up the heater.

Sys Info Reports

Connected Command: Complete Drive Fluid Level: Delta Cal Temp: +0.1°C
Cal/Ver Ok System State: Complete Stop Pause Waste Fluid Level: XY Status: RD1: 26.8°C
System Status Wednesday 6/1/2011 2:00 PM Eject Power Off

Initial Startup

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

1. **Adjusting the Sample Probe Height**
2. **Revive After Storage (Luminex) Routine**
3. **Calibration/Verification**

Adjusting the Sample Probe Height

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

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

1. On the **Home** page, click **Probe and Heater** under **Daily Activities**. The **Probe & Heater** tab opens.
2. Use well **D6** (this is the center of a standard 96-well plate).
3. Ensure that the well location is selected on the plate image. A green pin marks the selected well.
4. Based on the type of plate you are using, place alignment disks or an alignment sphere in the well.

   • For a standard 96-well plate - none

   • For a Filter-bottom plate - two 5.08 mm disks

   • For a Mylar-bottom plate - two 5.08 mm disks

   • For a conical (v-shaped) plate - one sphere

5. Click **Eject** to eject the plate carrier.
6. Place the off plate reagent block on the plate carrier. Make sure it is well seated so that it clips into place.
7. Place a strip well (provided with the Calibration and the Performance Verification kit) in the off-plate reagent block.
8. In the **Strip Wells** section, click **SD1**.
9. Verify that the reservoir is empty.
10. In the **Reservoir** section, click well **RB1**.
11. Verify that the plate is not warped. Warped plates can lead to incorrect probe height adjustment.
12. Place the plate on the plate carrier with well A1 positioned as indicated on the plate carrier.
13. Click **Retract** to retract the plate carrier.
14. Type a name for the plate in the **Plate Name** box.
15. Click **Auto Adjust Height**. The probe automatically adjusts itself to the locations you selected.

    > **NOTE:** The probe height is automatically set to 0.98 mm. The probe automatically adjusts this distance from the bottom of the plate, or calibration disks or spheres.

16. Click **Eject** to eject the plate holder. If you used alignment disks or spheres, remove them from the plate.

NOTE: When you adjust and save the probe height settings for all three areas under a plate name, all areas retain the adjustment.
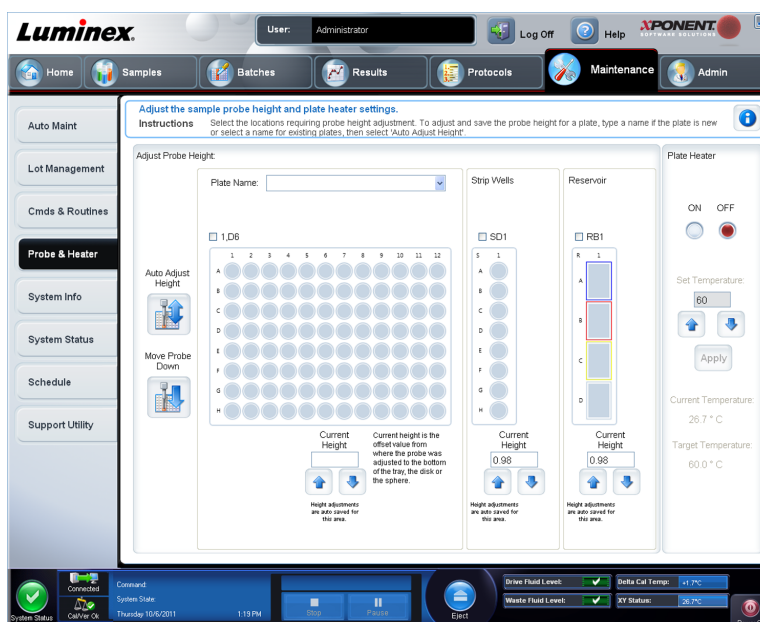
WARNING: Correct sample probe height is critical to successful sample acquisition and calibration. Problems with the sample probe can lead to fluid leaks and inhibit sample acquisition.

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

FIGURE 1. **Sample Probe Height Adjustment**

Revive After Storage Routine

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

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

1. Open the **Maintenance** page, then the **Cmds & Routines** tab.

2. Select **Revive After Storage (Luminex)** from the drop-down list. The **Revive After Storage** routine performs the following commands:

   • **Prime**

   • **Rinse**

   • **Alcohol Flush**

   • **Rinse**

3. Add 70% isopropanol or ethanol to reservoir RB1 on the off-plate reagent block as indicated on the **Cmds & Routines** tab.

   NOTE: The rinse reservoir (RD1) should be empty.
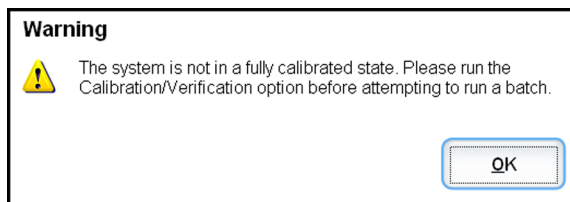
4. Click **Retract.**

5. Click **Run.**

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

System Initialization

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

Calibrator magnetic beads are used to normalize the settings for the reporter channel and classification channels. Verification magnetic beads are used to verify calibration and optical integrity of the system. Fluidics beads are used to assess well-to-well carryover.

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

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

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 any of the following things occur:

• The delta calibration temperature exceeds ± 5° C.

• You move the instrument.

• You experience sample acquisition problems.

• The instrument undergoes hardware maintenance, such as replacement of a part.

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.

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

Running the System Initialization Routine

1. On the **Home** page, click **System Initialization** under **Daily Activities**. The **Auto Maint** tab opens. On the **Auto Maint** tab, the **System Initialization** option is automatically selected.

2. Verify that the correct lot kit is displayed in the **Calibration and Performance Verification** drop down field and that the correct reagents (for example, VER and Fluidics reagents) have been added to the off-plate reagent block.

3. Fill reservoir RB1 3/4 full of 70% isopropanol or ethanol.

4. Verify that the **Rinse** reservoir **RD1** is empty.

5. Click **Retract**.

6. Click **Run**.

Daily Activities

System Initialization - Perform a system initialization routine.

> **NOTE:** Luminex recommends weekly calibration and daily verification. For daily use, verify your System Initialization setting is set to Fluidics Prep and Performance Verification in the Admin System Setup tab. Refer to *Maintenance Page* for detailed maintenance instructions.

Shutdown - Perform the shutdown routine.

Probe and Heater - Adjust the probe height or plate heater.

Drive Fluid Lot - Enter the Drive Fluid lot number, which is printed on the box in which the fluid container was shipped. This information is optional.

Create a New Batch from a new Protocol - Creates a new batch from a new protocol by opening the **Settings** tab of the **Batches** page. You can create protocols while creating a batch, and can save the protocol before or after you run the batch.

Create a New Batch from the highlighted Protocol below - Creates a new batch using a selected protocol from the **Installed Protocols** list. This button displays the same fields as the **Create a new batch from existing Protocol** button on the **Batches** page.

Scroll - Use the up and down arrows to scroll through the list of installed 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.

Sys Info - Opens the **System Info** tab of the **Maintenance** page. If the instrument is connected and powered on, the **System Information** page displays licensing information, the instrument serial number, the date of the last Calibration, Verification, Fluidics tests, and other important information.

Reports - Opens the **Reports** tab of the **Results** page.

Return to the **Home** page at any time by clicking **Home** at the top of the screen.

Shutting Down the Analyzer

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

1. On the **Home** page, click **Shutdown**. The **Auto Maint** tab opens, with **System Shutdown** selected.

2. Click **Eject**.

3. Fill reservoir **RA1** with 3/4 of DI water.

4. Fill reservoir **RC1** with 3/4 of 10%-20% household bleach solution.

5. Verify that reservoir **RD1** is empty.

6. Click **Retract**.

7. Click **Run**.

Logging Off and Exiting

To log off and exit xPONENT:

1. Click **Logoff** at the top of the page.

2. When the **Confirm** dialog box opens, click **OK**. This opens the **Log In** page, with **Exit** on the left tab.

3. Click **Exit** to exit the application.
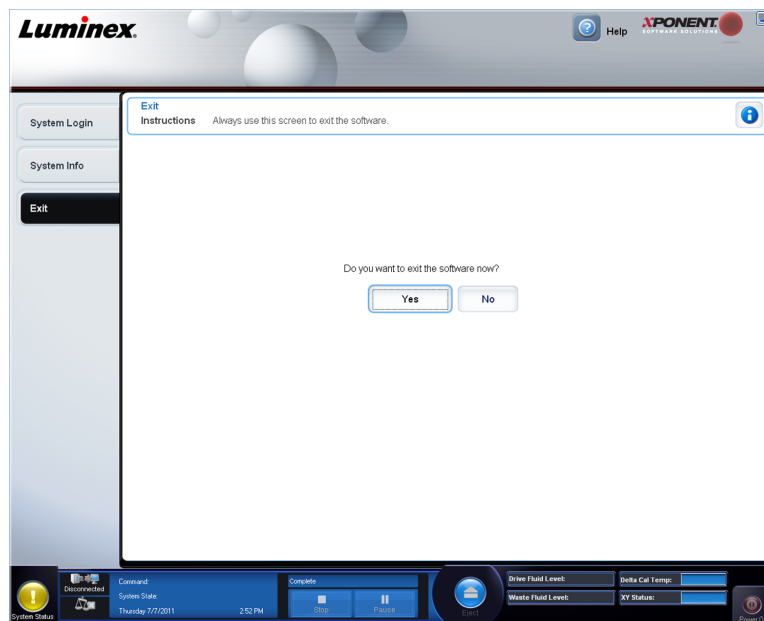
Using Online Help

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

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

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

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

Luminex Support

Luminex Website

Additional information is available on the Luminex website. FAQs are available at http://www.luminexcorp.com/Support/index.htm.

You can access the Technical Support Website using a user name and password at https://oraweb.luminexcorp.com/OA_HTML/jtflogin.jsp.

Contacting Technical Support

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

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

Software Packages

Multiple levels of user access can be licensed for xPONENT.

> **Basic** - Allows instrument control.

Additional features for which you can obtain a license:

• **Secure** - Includes all of the Basic functions as well as administrator-controlled user permission levels.

• **21 CFR Part 11** - Includes all of the Secure package features as well as the option to require electronic signatures to perform certain tasks. (Electronic signatures are listed in the system log.)

• **Automation** - Includes the ability to communicate with external hardware.

• **Allele** - Enables you to use allelic ratios.

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

- **LIS** - Enables the system to communicate with an external Laboratory Information System (LIS) database. The LIS package enables you to export and import patient result data in ASTM file format.

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

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

MAGPIX Technology

The MAGPIX system operates by using magnetic beads (microspheres) that are coated with a reagent specific to a particular bioassay, enabling the capture and detection of specific analytes from a sample. The sample mixture is aspirated by the sample probe and conveyed via Drive Fluid into the camera chamber, where the beads are pulled down into a monolayer by the magnet, immobilized, and imaged. Within the chamber, beads are exposed to a red LED and a green LED, which excite both the internal dyes that identify each bead's color signature and the reporter fluorescence from the surface of the beads. The red LED is responsible for classifying the beads. The CL1 and CL2 filters function to categorize the beads based on color signature and place them properly on the bead map as well as throw out any doublets that may exist. The green LED with the RP1 filter excites the reporter fluorescence, which identifies the quantity of analyte captured for each bead region. The beads are then flushed to the waste container, clearing room for the next sample.

Calibration is important to ensure that the optical system functions effectively and that different Luminex MAGPIX systems report similar results. Calibrating the MAGPIX system normalizes the settings for the classification channels (CL1 and CL2) and the reporter channel (RP1). Use the Luminex MAGPIX Calibration Kit to accomplish this.

Following calibration, use the Luminex MAGPIX Performance Verification Kit to check all of the optical channels in the system for correct calibration. It is essential to verify every time you calibrate. If there is a problem with optical integrity or fluidics, MAGPIX may pass calibration but fail performance verification. The Luminex MAGPIX Performance Verification Kit includes reagents to verify the calibration and optical integrity for the Luminex MAGPIX system as well as reagents to verify the fluidics channels using observations of bead count and well-to-well carryover.

FIGURE 2. **LED Image-Based Analysis**
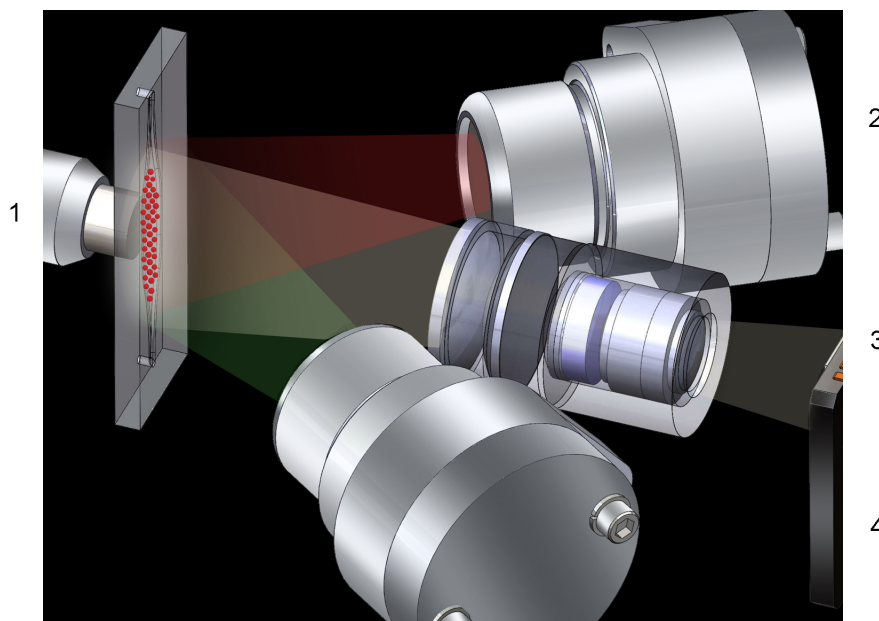
1 Beads in chamber

2 Red LED (635 nm)

3 CCD Imager

4 Green LED (525 nm)

Running Assays with MAGPIX

General Guidelines

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

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

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

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

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

Biological Samples

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

Dilute concentrated biological samples, such as plasma or serum, at least 1:5 with reagents as part of assay setup or as a final dilution step to reduce the chance of system clogs. If you are running a MagPlex® kit, follow the dilution instructions in the kit's product insert.

Bead (Microsphere) Handling

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

- Multiple pipetting from the original container can affect bead concentrations.

- Protect MagPlex beads from light at all times to prevent photobleaching. Photobleaching effects are cumulative. To maintain the integrity of the beads, minimize their exposure to light during your development and manufacturing phases.

- Store MagPlex beads at 2°- 8°C.

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

Repetitive MagPlex Bead Measurements

In a MagPlex assay, the reporter signal is the result of the assay. Due to small bead size, MagPlex bead suspension exhibits near solution-phase reaction kinetics. This means that each set of beads used for a particular assay shows a statistically even distribution of reporter molecules bound to the surface of each bead. 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. During data acquisition, numerous beads of each set are analyzed and the median statistic is computed for that set by xPONENT. The more beads of a set measured, the more confidence that can be given for that particular measurement. Luminex recommends that you use R-Phycoerythrin as your reporter fluorophore.

If you are running a calibration and verification kit, follow the kit's product insert or use the software protocol provided.

Classification and Reporter Fluorochromes

MagPix beads in the calibration kit are used to autofocus the camera and calibrate the CL1, CL2, and RP1 channels. The beads in the verification kit are a mix of 6 different regions that cover the range of the 50-plex map. Both calibration and verification beads are triple-dyed, and the fluorescence signal of these dyes enables classification of each bead set.

TABLE 1. **MAGPIX Active Bead Regions (by Region)**

Region	Region	Region
MC10012	MC10013	MC10014
MC10015	MC10018	MC10019
MC10020	MC10021	MC10022
MC10025	MC10026	MC10027
MC10028	MC10029	MC10030
MC10033	MC10034	MC10035
MC10036	MC10037	MC10038
MC10039	MC10042	MC10043
MC10044	MC10045	MC10046
MC10047	MC10048	MC10051
MC10052	MC10053	MC10054
MC10055	MC10056	MC10057
MC10061	MC10062	MC10063
MC10064	MC10065	MC10066
MC10067	MC10072	MC10073
MC10074	MC10075	MC10076
MC10077	MC10078	

Fluidics 1 and Fluidics 2

Although it undergoes a wash step in between wells, the probe can be susceptible to carry-over from well-to-well. Fluidics 1 contains one bead set. Fluidics 2 contains a buffer solution and a different control bead. The function of this maintenance procedure is to measure how much (as a percentage) of the first bead set in Fluidics 1 is found in the well where Fluidics 2 has been loaded.

Sample Volume

Sample volumes range in size from 20 µL to 200 µL. Ensure that approximately 25 µL more than the sample volume remains in the well after aspiration. This amount may vary depending on the type of plate used. Your sample volume must be large enough to prevent aspirating air into the fluid line when acquiring sample, and small enough to prevent spill-over

when the analyzer flushes the sample lines after sample acquisition and expels approximately 75 µL of sample back into the well.

Examples

- If you use a sample volume of 50 µL and aspirate 50 µL, you acquire air bubbles.

- If you use a sample volume of 200 µL and a standard sample pickup of 50 µL, the well overflows when the analyzer washes the sample lines after acquisition and expels fluid back into the well, because the amount of fluid expelled back into the well is approximately 75 µL.

> **CAUTION:** Sample volume is critical to the proper functioning of your MAGPIX instrument. Aspirating too few beads can result in insufficient bead count or insignificant data results. Aspirating too many beads can result in saturation of the chamber and prevent proper bead classification, which may also result in low bead counts or inconclusive data.

This formula quantifies the volume restrictions on the assay design:

Total well volume (µL) - Sample uptake volume (µL) + 75 (µL) <Maximum Well Volume (µL)

Where:

- Total well volume = Starting sample volume before the instrument acquires sample. Sample 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).

- 75 (µL) = Volume expelled back into the well.

- Maximum well volume = The maximum volume capacity of the wells in a selected 96-well microtiter plate.

You can change the sample size while running a batch using the **Change Volume** button on the **Current Run** tab.

If you are running a MagPlex kit, follow the kit's product insert or use the software protocol provided.

Do not dilute MagPix Calibration or Verification beads, or the Fluidics 1 and Fluidics 2 beads.

Plates

Follow these guidelines when choosing plates:

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

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

- For unheated assays, use a 96-well plate with an overall height no greater than 0.75 inches (19 mm).

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

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

Chapter 2: Samples Page

Samples Page Functionality
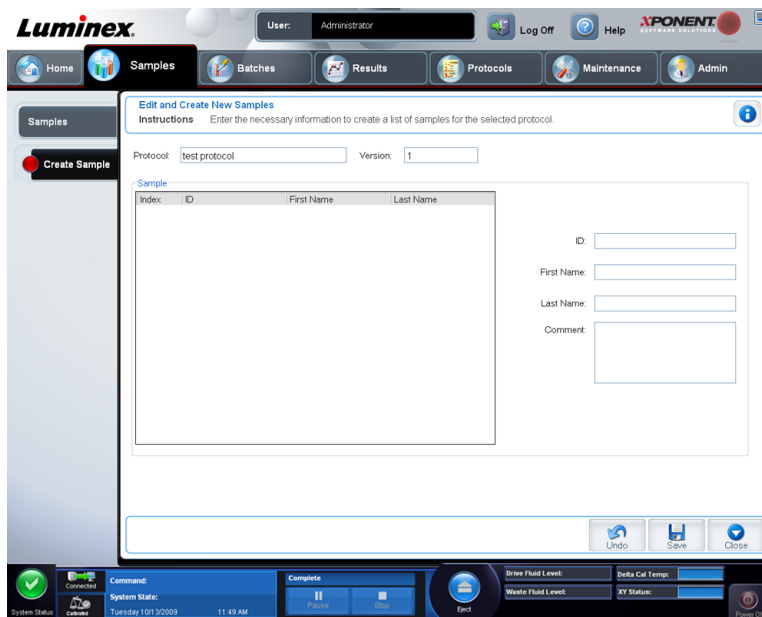
Samples > **Samples**
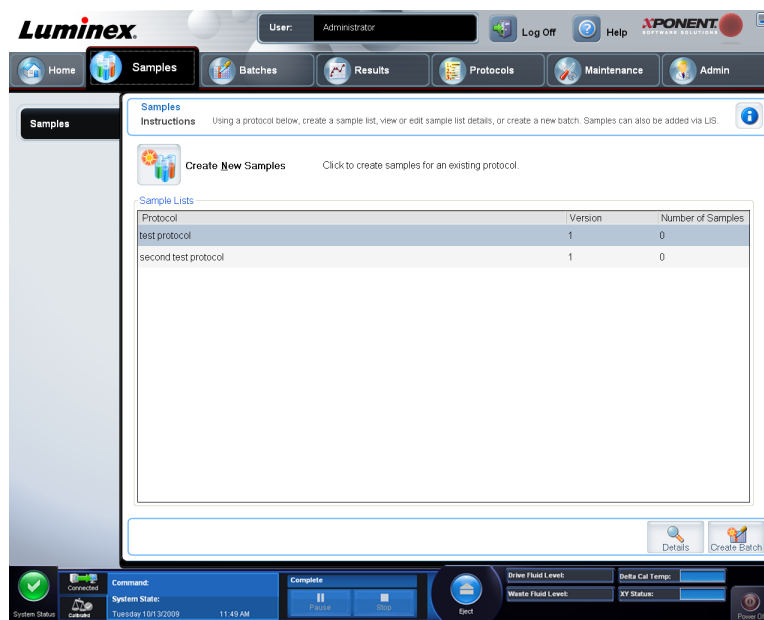
Use this tab for the following:

- Click **Create New Samples** to display the **Create Samples** subtab, on which you can create a new sample.

- View sample lists, including a list of protocols with version number and the number of samples associated with each protocol.

- Click **Details** to display the **Edit Samples** subtab, on which you can view or edit sample details for the selected protocol.
- Click **Create Batch** to name the LIS batch for a protocol. This opens the **Batches** page, **Batches** tab, with the following subtabs displayed:
  - **Protocol**
  - **Stds & Ctrls**
  - **Plate Layout**

Edit Samples and Create Sample Subtab

Samples > **Samples** > **Edit Samples** or **Create Sample**

Click **Create Samples** on the **Samples** tab to display this subtab. Use this subtab to type and view sample information.

This tab contains the following:

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

Version - Displays the protocol version number. This cannot be edited.

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

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. Use **Create New Samples** to create a new sample. After 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.
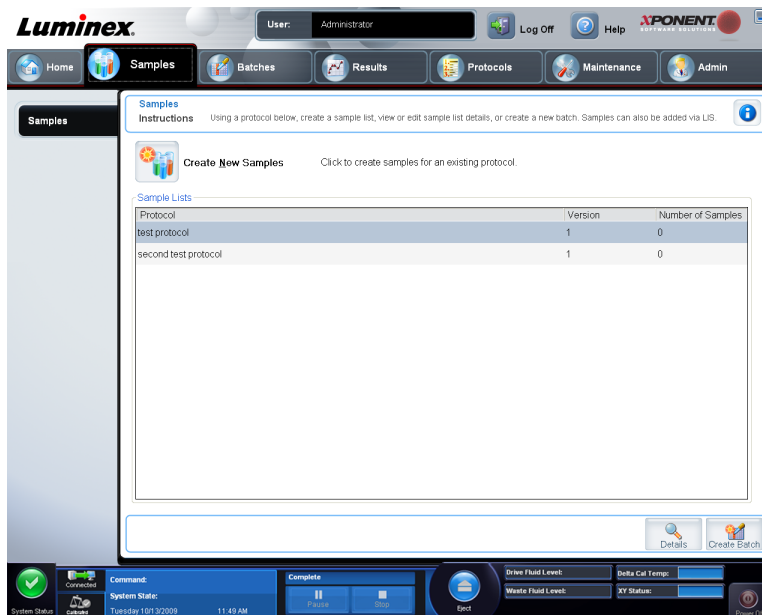
Save - Saves changes made to the **Sample** list.
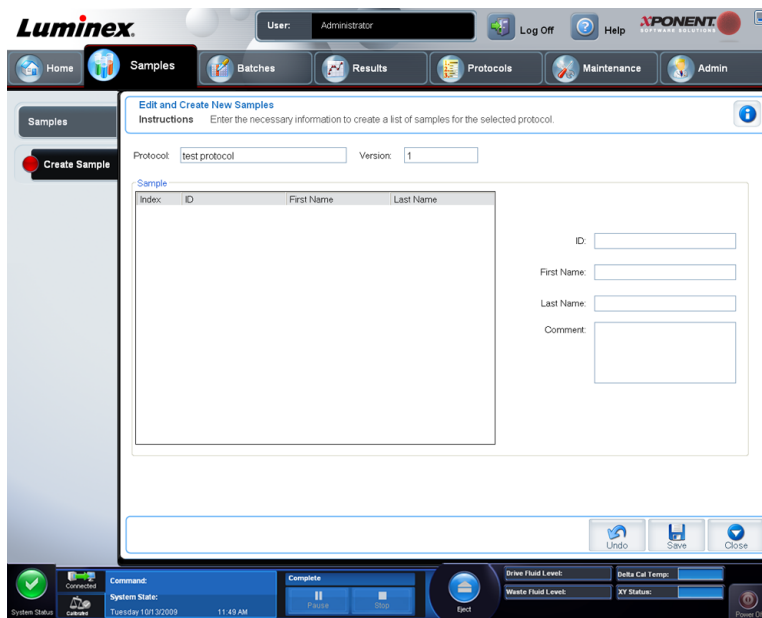
Close - Returns to the **Samples** tab.

Creating a New Sample List

Follow these steps to create a new sample list.

1. Open the **Samples** page.

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

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

4. Type a patient first name in the **First** name box (optional).

5. Type a patient last name in the **Last** name box (optional).

6. 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 3-7 until you have added all of the samples you want in your samples list.

9. Once you have added all the desired samples, click **Close**.

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

Editing a Sample List

1. Open the **Samples** page.
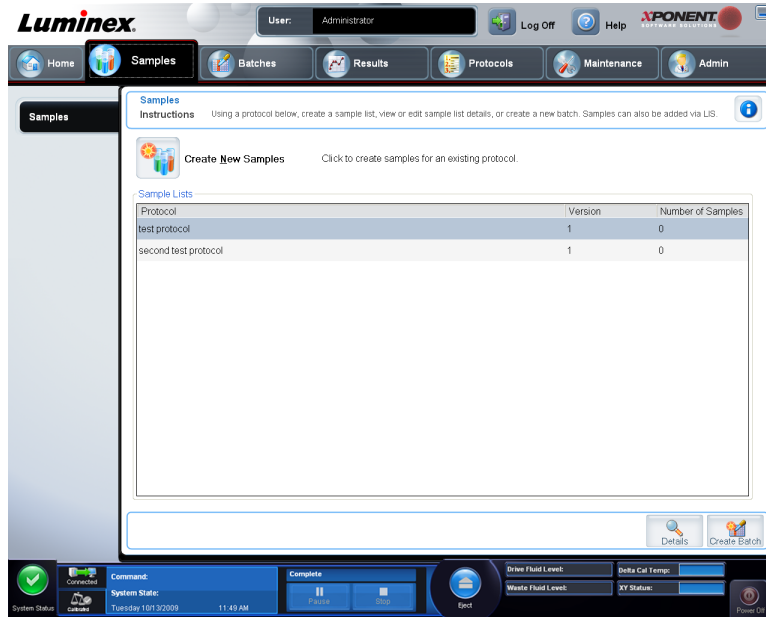
2. In the **Samples** list section, choose the protocol you want to edit, then click **Details**. The **Edit Samples** subtab opens.
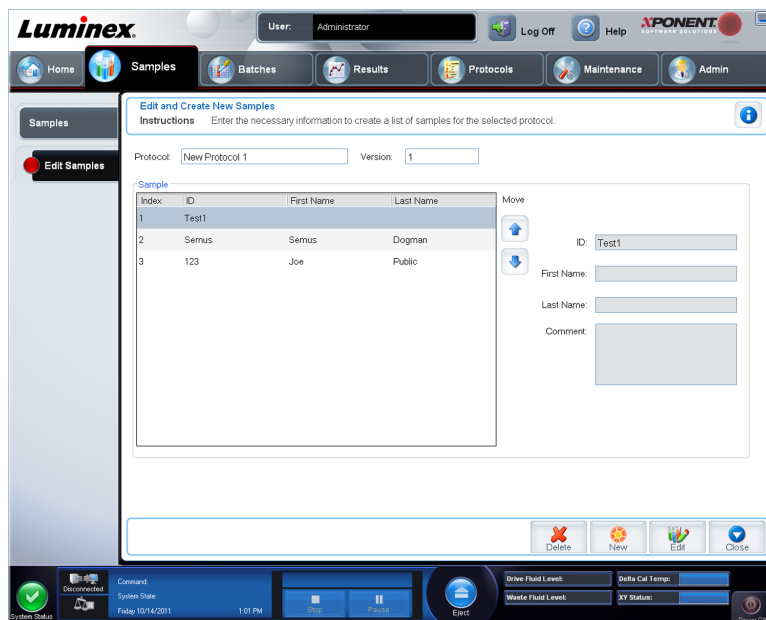
3. Click a sample, then use the **Move** arrows to move it up or down in the sample list, changing the order in which they will be acquired.

4. To add a new sample to the list, click **New**, then perform the following steps:

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

   b. Type a patient first name in the **First name** box (optional).

   c. Type a patient last name in the **Last name** box (optional).

   d. To add a comment about the sample, type it in the **Comment** box; this is optional.

   e. Click **Save** to add the sample to the **Sample** list.

5. To edit an existing sample, click the sample, then click **Edit**.

6. Once you have completed editing the sample list, click **Close**.

Chapter 3: Batches Page

Batches Page Functionality

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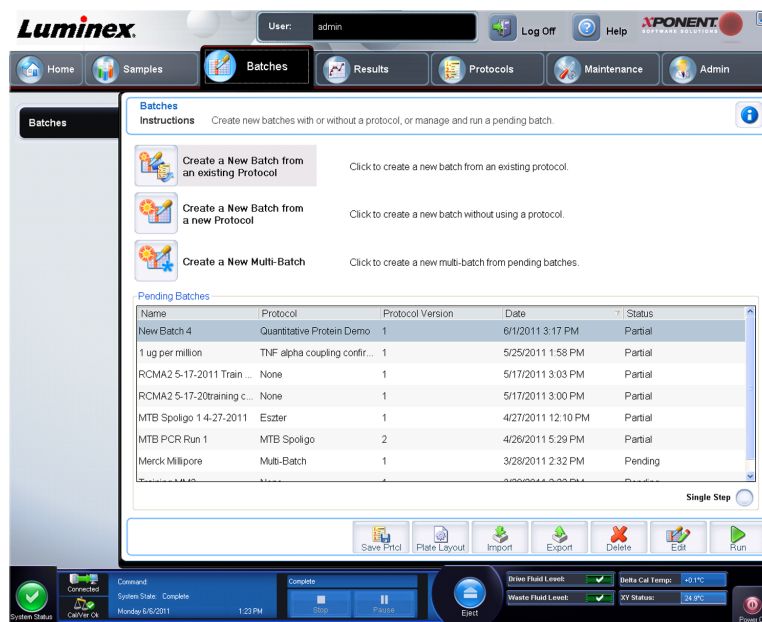
Options on the **Batches** tab on the **Batches** page are:

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

Depending on your selection, this page displays the following tabs:

- **Protocols** - Displays when **Create a New Batch from an existing Protocol** is clicked.
- **Stds & Ctrls** - Displays when **Create a New Batch from an existing Protocol** and **Create a New Batch from a new Protocol** are clicked.

- **Analytes** - Displays when **Create a New Batch from a new Protocol** is clicked.
- **Plate Layout** - Displays when **Create a New Batch from an existing Protocol** and **Create a New Batch from a new Protocol** are clicked.
- **New MultiBatch** - Displays when **Create a New Multi-Batch** is clicked.

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

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

- **Single Step** - Instructs the system to acquire one well and then pause. If Single Step is activated during a batch, the batch pauses at the end of the current well. This ensures that the system is working correctly before you run an entire batch.
- **Save Prtcl.** - Saves protocol and/or assay information for a standard/control.
- **Plate Layout** - Opens the **Report** dialog box, which includes the **Batch Plate Layout Report**.
- **Import** - Imports a batch not previously run in xPONENT 4.2 from a folder on the PC into xPONENT.
- **Export** - Exports the batch information in order to move it to another computer, make a copy of the data, and then import it into xPONENT on another computer.
- **Delete** - Deletes a batch.
- **Edit** - Edits a batch.
- **Run** - Runs a batch.

Setting Up Batches

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

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

Assay kit manufacturers may provide protocols in their kits which are distributed on a CD. 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.

Using the Batches Page

1. Open the **Batches** page.

2. Click one of the following:
   • **Create a New Batch from an Existing Protocol**
   • **Create a New Batch from a new Protocol** - if you select this option, you can save the prootocol and/or stds/ctrls information.
   • **Create a New Multi-Batch**

3. Type the batch name in the **Batch Name** box.

4. Type an optional description of the batch in the **Enter Optional Description** box.

5. If you are creating a batch from an existing protocol, select the protocol in the list. Click **Next**. If the protocol uses standards and/or controls, the **Stds & Ctrls** tab displays.

6. If you selected **Create a New Batch from a new Protocol**, the **Stds & Ctrls** tab displays.

7. The **Plate Layout** tab appears. View the details of the active reagents, apply different assay standards/controls, or manually enter new information. Click **Next.**

8. On the **Plate Layout** tab, assign well commands for this batch.

9. Click **Run Batch** to begin batch acquisition, or click **Save** to save batch information to the **Pending Batch** list to be run at a later time.

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

# Create a New Batch from an existing Protocol

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

1. Open the **Batches** page.

2. Click **Create a New Batch from an existing Protocol**.

3. Type the batch name in the **Batch Name** box.

4. Type a description about the batch in the **Enter Optional Description** box.

5. Click a protocol you wish to use in the **Select a Protocol** list.

6. Click **Next**. If the protocol uses standards, controls, or both, the next tab that opens is the **Stds & Ctrls** tab. View the details of the active reagents or apply different assay standards, controls, or both or manually enter new information. Select **Next**. If the selected protocol does not use standards, controls, or both, the next tab that opens is the **Plate Layout** tab.

7. On the **Plate Layout** tab, assign well commands for this batch. See *Plate Layout 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 opens, prompting you to insert the next plate.

Protocol Subtab

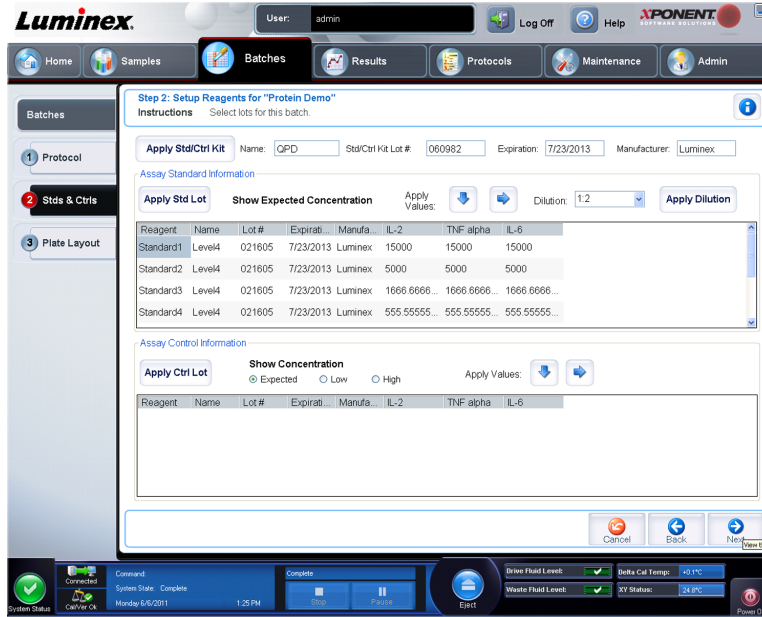**Batches** > **Batches** > **Protocol**
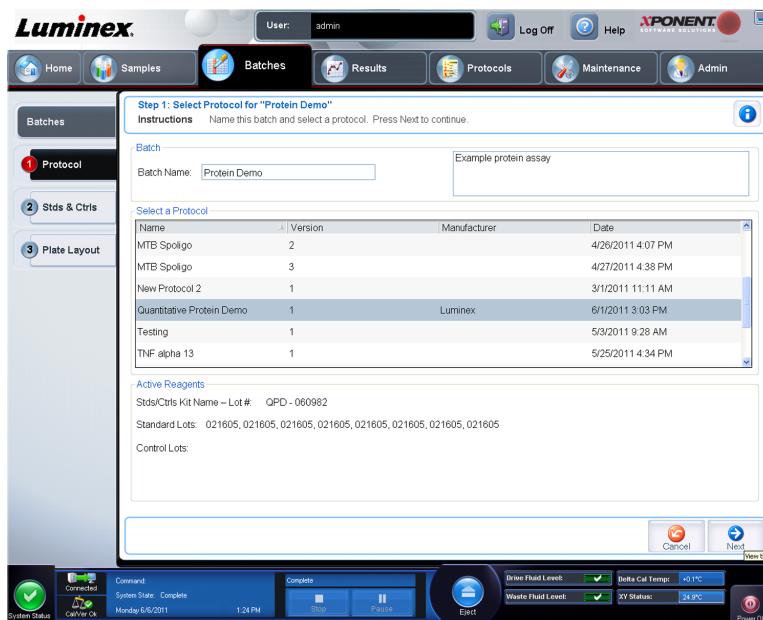
Use this tab to name a batch, type a batch description, select a protocol, and view active reagents. This tab contains the following:

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

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

- **Active Reagents** - Displays assay and control lots/kits associated with the selected protocol. The **Standard/Ctrls Kit Name - Lot#** field displays the assay 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.

Standards and Controls (Stds & Ctrls) Subtab

Batches > **Batches** > **Stds & Ctrls**

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

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

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

  > **NOTE:** Click a **Reagent** column header to re-sort the order from the highest number standard to standard number one. This is useful for applying dilutions in which the last standard is the highest standard.

- **Apply Std Lot** - Opens the **Select Lot** dialog box.

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

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

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

  - 1:2 - Halves the standard from each previous iteration.

  - 1:10 (Log) - Computes a value of one-tenth of the standard from each previous iteration.

  - 1/2 Log - Creates a 1:3.16 dilution, or half of each 1:10 (Log) from each previous iteration.

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

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

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

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

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

    - **Show Concentration** - **Expected**, **Low**, and **High** set the expected, lowest, or highest acceptable concentration of the analyte in the sample.

    - **Apply Values** - Applies a value down or across the list of analytes.

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

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

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

Plate Layout Subtab

Batches > **Batches** > **Plate Layout**

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

- **Plate Image** - This is a representation of the plate. Each well is displayed as a circle on the grid. Well commands appear in the appropriate circles as you assign them to wells on the plate.

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

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

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

- **Import List** - Opens the **Open** dialog box to import an existing command sequence list.
- **Replicate Count** - Defines a quantity of replicate sets from one to nine.

> **NOTE:** Replicate count selection must be made before adding a well command.

- **Grouping** - Selects the sequence in which the replicates are laid out in plate wells.

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

The options are:

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

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

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

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

> **NOTE:** Before adding well commands, delete all standards from the plate layout if any of the standards need to be rearranged. Delete all controls from the plate layout if any of the controls need to be rearranged.

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

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

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

> **NOTE:** If you select a routine you created, that routine must also exist on any system to which you import this protocol. The system displays an error when attempting to run a batch on a system where the routine does not exist.

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

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

- **Direction** - Specifies the direction to run the plate commands. Select either horizontally or vertically. The selected direction also dictates how wells are added to the plate when assigning multiple unknowns, standards, and controls at one time.

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

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

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

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

  - Select **Save Protocol** and/or **Save Std/Ctrl Kit** to save the protocol and/or kit.

  - Type information in the following boxes and click **Save** to save the protocol or kit.

    - **Protocol Name**
    - **Version**
    - **Manufacturer**
    - **Optional Description**
    - **Std/Ctrl Kit Name**
    - **Std/Ctrl Kit Lot#**
    - **Expiration**
    - **Manufacturer**
    - **Lots**

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

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

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

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

Create a New Batch from a New Protocol

Click this option to create a new batch from a new protocol. This option enables you to create a protocol while you are creating the batch.

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. These are **Volume**, **XY Heater** (enable/disable and set temperature), **Plate Name**, and enable/disable **Sample Wash**.

> **NOTE:** Final washes are required for proper analysis. If you are not performing a final wash step on your plate before acquisition on the MAGPIX instrument, enable **Sample Wash** here. This automatically washes each sample.

If you select **Qualitative**, **Quantitative**, or **Allele Call** from the **Analysis Type** list, you can select **Analyze results while acquiring samples** to view real-time analysis.

6. Next, complete the Analysis Settings. These include **Analysis Type**, **MFI** enable/disable (used for Allele Call analysis), # of standards, # of controls, either **Fit all Standards** or **Mean of Replicates**.

7. Click **Next**. The **Analytes** tab opens. Click the analytes of interest in the numbered grid. Information about the analytes opens in a list on the right side of the grid. Name the analytes.

8. To change the **Default Analysis**, click **Change**. The **Analysis Settings** dialog box opens.

9. 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.

10. Type a unit of measurement in the **Units** box.

11. Type the desired bead count for each analyte in the **Count** box.

12. If you click **Apply All**, this applies to all analytes.

13. To change individual units or counts, change them in the analyte table.

14. Click **Next**. The **Stds & Ctrls** tab opens if you selected an analysis type other than **None**.

   - 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, but you can also manually type the information.

   - 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 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 for a custom batch unless you want to use the analysis feature.

15. 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.

   - As you add commands to your plate, they are listed 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 plate location.

16. Click **Single Step** to acquire the first well, then pause acquisition.

17. Click **Run Batch** to start acquisition, or **Save** to save the batch for a later time. You can also save the protocol and/or standard and control information by clicking **Save Prtcl**.

> 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.

Settings Subtab

Batches > **Batches** > **Settings**

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

This tab contains the following:

- **Name** box and box for description - Type a name and a description in the appropriate boxes.
- **Acquisition Settings** - Use this section to set the following:
  - **Volume** - This is the volume the instrument will aspirate into the system for analysis. Type the desired sample volume in microliters. Use values from 20 to 200 µl. To avoid air intake, add at least 25 µl to the sample well in addition to the sample size. The default value is 50 µl.
  - **XY heater** - Select **Enabled** to enable the XY heater. In the box, type the desired value in degrees Celsius. The temperature range is 35 to 60°C in 0.5 increments.

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

  - **Plate Name** - The name assigned to the plate during sample probe height adjustment. You can select a different plate from the list.
  - **Sample wash** - Select this option for assays without a final wsh step prior to reading the plate on the instrument. This automatically washes each sample within the instrument. Final washes are required for proper analysis.

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

  Analysis Type - Use this list to choose from the following analysis types:

  - **None** - No analysis. Select if you have your own data post-processing program and want to obtain only fluorescent intensity results. You cannot apply standards or controls when you select **None**. You cannot analyze acquisitions with this setting.

  - **Qualitative** - Qualitative analysis determines results as either positive or negative, reactive or non-reactive. The software is flexible in defining custom result ranges, such as negative, low positive, or high positive. Determinations are based on a single standard. For qualitative analysis the Luminex software uses a specific algorithm, shown below.

    $$(FI_{sample})/(FI_{standard}) = Ki$$

    Where FI = Fluorescent Intensity and Ki = a "Quali" value entered in lot information to determine the value or the qualitative assay standard.

  - The "Quali" value determines a cutoff or threshold. This, in conjunction with ranges using the Lum Qual formula or an edited range specific for your assay, helps to determine qualitative results for unknown samples.

  - Two predefined formulas using the algorithm are included in the system. You can use them as is or edit their range values to meet your requirements.

  - **Quantitative** - Determines the sample concentrations from standard curves using regression methods **Cubic Spline**, **Linear**, **Logistic 4P**, and **Logistic 5P**, **Luminex Logistic 4P**, and **Luminex Logistic 5P**. Type the desired values for standards and controls in the **Number of Standards** and **Number of Controls** boxes. Select either **Fit of All Standards** or **Mean of Replicates** for the calculation of the curve fit.

    NOTE: Luminex recommends **Fit of All Standards** as the most accurate calculation of the curve fit .
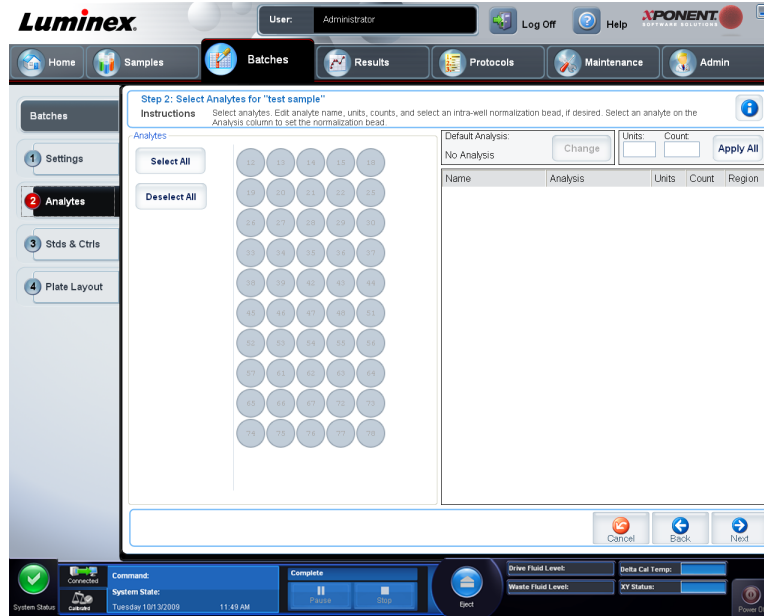
  Based on a range of quantitative, numerical results, a threshold range can be applied to a quantitative analysis, for example, high, low, saturated, and expected.

  - **Allele Call** - Sets analysis for an allele call. Analytes must be put in groups of 2, 3, or 4 analytes.

  - **Min MFI Enabled** - Select this box to enable a minimum MFI for the Allele Call analysis. Type a value in this box to set the minimum MFI for analysis.

  - **Number of Standards** - Click to type the number of standards for the protocol.

  - **Number of Controls** - Click to type the number of controls for the protocol.

  - **Fit of all Standards** - The standard curve is determined by using each individual standard replicate when calculating the standard curve. For example, if you run duplicates of a 7 point standard curve, the software will calculate the standard curve by using 14 points.

  - **Mean of Replicates** - The standard curve will be determined by averaging the individual standard replicates when calculating the standard curve. For example, if you run duplicates of a 7-point standard curve, the software will calculate the standard curve by using 7 averaged points.

  - **Analyze Results While Acquiring Samples** - The software allows for real-time viewing of the results as the instrument analyzes samples.

- **Use External Analysis Program** - Select this check box to use a third-party program to analyze the data. The **Analysis Program** list becomes active when this is selected.

- **Analysis Program** - Use this list to select which program to use for data analysis.

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

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

Analytes Subtab

Batches > **Batches** > **Analytes**

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

This tab contains the following:

- **Analytes** grid - A grid representing each analyte from 12 to 78. **Select All** selects all analytes, and **Deselect All** deselects all analytes. Click a numbered analyte to select it; click the analyte again to deselect it. You can also click and drag to select groups of analytes. Selected analytes are red. Deselected analytes are gray. An analyte marked as an intra-well normalization bead is blue.

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

FIGURE 3. **Analysis Settings Dialog Box**

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

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

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

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

Click **Apply to All Analytes** to apply your selection to all selected analytes. Click **OK** to change the default analysis to the analysis you selected. Click **Cancel** to close the dialog box without saving.

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

- **Count** - Type the desired bead count for the analytes by clicking in the **Count** box. If each selected bead set does not acquire this number of events, a warning is added to the log that not enough bead events were acquired. If you select bead sets that are not present, the analyzer continues to acquire, trying to reach the number of events per bead for bead sets that are not in the sample. Therefore, choose only the bead sets present in your sample.

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

- **Total Count** - Select **Stop after bead count reaches:** to stop acquisition when the bead count reaches a certain number determined by the user. Type the desired value in the box. The default value is 50. You can also specify the minimum allowable bead count per well that the xPONENT® software analyzes. This excludes data from any beads carried over during acquisition.

- Selected Analytes list - Selected analytes are displayed in a list on the right side of the analyte grid. This list includes the following information:
  - **Name** - The name of the analyte. Click and type to rename the analyte.
  - **Analysis** - To change the type of analysis for an analyte, click this field to open the **Analysis Settings** dialog box and select another analysis from the list.

  In the **Analysis Settings** dialog box:

  FIGURE 4. **Analysis Settings Dialog Box**

  1. Select a method from the **Method** list.
  2. If necessary, select a weight type from the **Weight Type** list.
  3. Apply the analysis to all analytes in the list by clicking **Apply to All Analytes**.
  4. Select **Mark as Intra-Well Normalization Bead** to make the analyte an intra-well normalization bead. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run.
  5. Add a range to the analysis by clicking **Add Range**.
  6. Select **Use Threshold Ranges** to enable ranges for the analysis.
  7. Click **Add Range** to add a range.
  8. Type a **Range Name**, a **Low Value**, a **High Value**, and select **Inclusive** if you want to include the low and high values in the range. Click **OK** to exit the dialog box.
- **Units** - The unit of measurement you specified in the **Unit** box. Click this box to type a value for the analyte.
- **Count** - Type the desired bead count for the analytes by clicking in the **Count** box. If each selected bead set does not acquire this number of events, a warning is added to the log that not enough bead events were acquired.
- **Region** - Refers to the specific analyte selected. This is a number between 12 and 78.
- **Group** - If you have selected **Allele Call** from the **Analysis Type** in the **Settings** tab, this button is displayed. Click **Group** to group 2, 3, or 4 analytes for the group. Multiple groups can be defined.

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

Standards and Controls (Stds & Ctrls) Subtab

Batches > **Batches** > **Stds & Ctrls**

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

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

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

  > **NOTE:** Click a **Reagent** column header to re-sort the order from the highest number standard to standard number one. This is useful for applying dilutions in which the last standard is the highest standard.

- **Apply Std Lot** - Opens the **Select Lot** dialog box.

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

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

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

  - 1:2 - Halves the standard from each previous iteration.

  - 1:10 (Log) - Computes a value of one-tenth of the standard from each previous iteration.

  - 1/2 Log - Creates a 1:3.16 dilution, or half of each 1:10 (Log) from each previous iteration.

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

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

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

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

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

  - **Show Concentration** - **Expected**, **Low**, and **High** set the expected, lowest, or highest acceptable concentration of the analyte in the sample.

  - **Apply Values** - Applies a value down or across the list of analytes.

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

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

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

Plate Layout Subtab

Batches > **Batches** > **Plate Layout**

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

- **Plate Image** - This is a representation of the plate. Each well is displayed as a circle on the grid. Well commands appear in the appropriate circles as you assign them to wells on the plate.

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

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

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

- **Import List** - Opens the **Open** dialog box to import an existing command sequence list.
- **Replicate Count** - Defines a quantity of replicate sets from one to nine.

> **NOTE:** Replicate count selection must be made before adding a well command.

- **Grouping** - Selects the sequence in which the replicates are laid out in plate wells.

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

The options are:

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

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

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

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

> **NOTE:** Before adding well commands, delete all standards from the plate layout if any of the standards need to be rearranged. Delete all controls from the plate layout if any of the controls need to be rearranged.

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

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

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

> **NOTE:** If you select a routine you created, that routine must also exist on any system to which you import this protocol. The system displays an error when attempting to run a batch on a system where the routine does not exist.

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

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

- **Direction** - Specifies the direction to run the plate commands. Select either horizontally or vertically. The selected direction also dictates how wells are added to the plate when assigning multiple unknowns, standards, and controls at one time.

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

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

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

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

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

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

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

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

Create a New Multi-Batch

Batches > **Batches** > **New Multibatch**

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

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. This feature enables you to conserve plates.

You must ensure that the batches fit on one plate. After you add each batch, the software automatically adds the next batch to the first well of the next column or row (depending on

your plate orientation) as long as space is available on the plate. You can also select a well first, which places the next batch in your chosen location. If space limitations create an overlap, an error message appears. Results for each batch are saved as individual batch files.

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

> **NOTE:** There is a limit of 96 batches in a multi-batch.
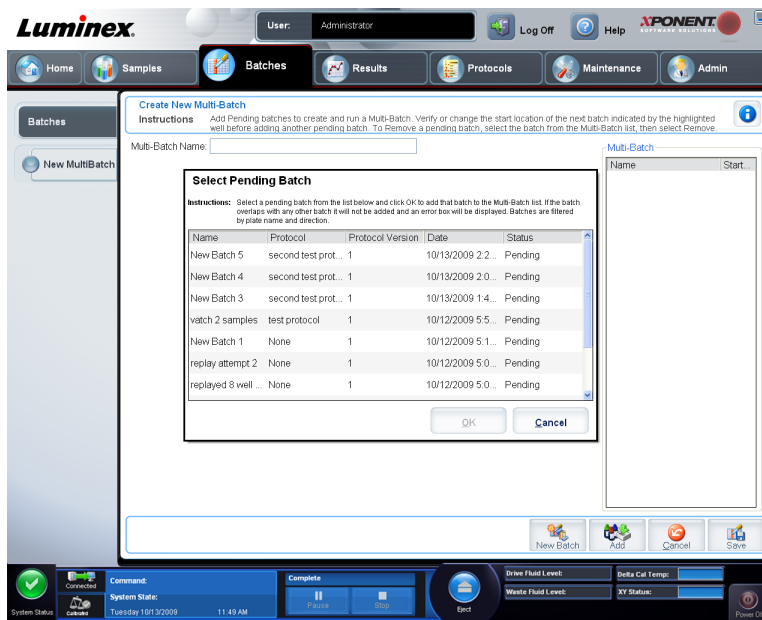
This tab contains the following:

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

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

- **Plate Layout** - Opens the 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.

- **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 still remains in the **Pending Batches** section This button is displayed only if you have added a batch to the **Multi-Batch** list and selected the batch from the list.

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

- **Run** - Runs the 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."

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

To save a multi-batch:

1. Create a new multi-batch.

2. Select a pending batch.

3. Type the name for the multi-batch in the **Multi-Batch Name** field.

4. Click **Save**. You are returned to the **Batches** page, and the multi-batch is added to the pending batches list.

Batch Procedures

Running a Pending Batch

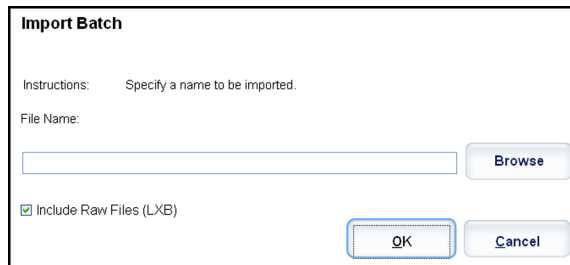Open the **Batches** page. Select the pending batch that you want to run, then click **Run**.

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

Importing a Batch

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

To import a batch:

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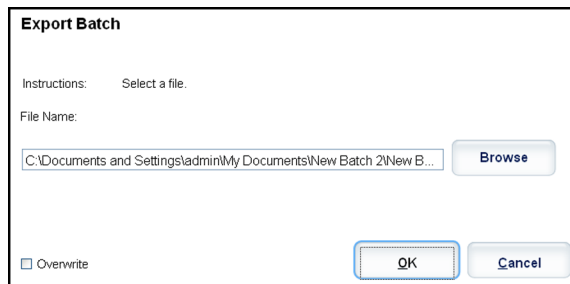

3. Click **Browse** to open the **Select File** dialog box. Navigate to the batch file you want to import, then click **Open**.
4. Click **OK** in the **Import Batch** dialog box. The batch displays in the **Pending Batches** list.

Exporting a Batch

1. Open the **Batches** page.
2. In the **Pending Batches** section, click the batch you want to export, then click **Export**. The **Export Batch** dialog box opens.

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

3. Click **Browse**. The **Select File** dialog box opens.
4. Navigate to the location to which you want to save the file, then click **Save**.
5. Click **OK** in the **Export Batch** dialog box.

   NOTE: When exporting a large batch and including the LXB files, the export process may take ten minutes or more.

Editing a Batch

1. Open the **Batches** page.
2. Click the batch you want to edit, then click **Edit**. The **Protocol** tab opens.

3. Edit the information as needed on the **Protocol**, **Std & Ctrls**, and **Plate Layout** tabs. For the tab, confirm that the plate layout conforms to your specific assay instructions.

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

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

Deleting a Batch

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

To delete a batch:

1. Open the **Batches** page.

2. In the **Pending Batches** section, click the batch you want to delete, then click **Delete**. The **Delete Pending Batch** dialog box opens.

3. Click **Yes**.

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

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

Chapter 4: Results Page

Results Page Functionality

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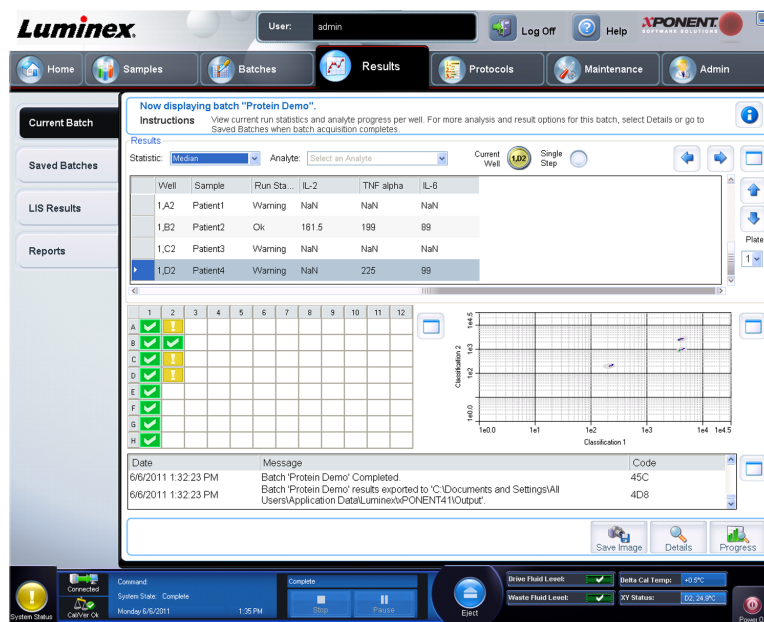
Once data is collected in a batch, observation and analysis take place in the **Results** page. This page contains the following tabs:

- **Current Batch** - View statistics for the current run and progress per well.
- **Saved Batches** - View information about already processed batches and, if necessary, replay them or recalculate their data.
    - Click **Open** from the **Saved Batches** tab to view the following subtabs:
        - **Results**
        - **Settings** - Shows the report type you selected
        - **Log** - Information about acquisition
        - **Sample Details** - Details about the sample
    - Click **Replay** > **Recalculate Data** from the **Saved Batches** tab to view the following subtabs:
        - **Protocols**
        - **Stds & Ctrls**
        - **Plate Layout**
    - Click **Replay** > **Replay Batch** from the **Saved Batches** tab to view the following subtabs:
        - **Settings** - Shows the report type you selected
        - **Analytes**
        - **Stds & Ctrls**
        - **Plate Layout**
- **LIS Results** - View a batch or transmit a batch that contains LIS results.
- **Reports** - This tab enables you to select a report to view:
    - **Batches Reports**
    - **Protocols Reports**
    - **Calibration and Verification Reports**
    - **Performance Verification Reports**
    - **System Log Reports**
    - **Advanced Reports**
    - **Data Interpretation**
    - **Batch Settings**
    - **Plate Layout**
    - **Batch Audit**
    - **Patient Report**

Performing Analysis

If you are using a third-party software to perform analysis, see the user manual provided with that software.

> **NOTE:** Luminex recommends using median statistics for data analysis.

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

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

You can analyze an acquired batch using the analysis features of **Qualitative**, **Quantitative**, and **Allele Call** algorithms.

Qualitative Analysis - Determines results as either positive or negative, reactive or non-reactive, and so on. The system is flexible in defining custom result ranges, such as negative, low positive, and high positive.

Quantitative Analysis - Determines the sample concentrations from standard curves using regression methods, such as 4P or 5P logistic curve fitting. There are two main assay types: non-competitive and competitive. In a non-competitive assay, the slope of a concentration versus Median Fluorescent Intensity (MFI) standard curve is a positive number. That is, low concentrations result in low MFIs and high concentrations result in high MFIs. Conversely, competitive assays generate a standard curve with a negative slope, the endpoints of which are high MFI/low concentration on the left, and low MFI/high concentrations on the right.

Allele Call - Compares groups of analytes in order to determine genotype. Groups can include two, three, or four analytes for comparison. Set the call rate to determine what ratio you want to set as the limit for the analyte comparison.

Current Batch Tab

Results > **Current Batch**
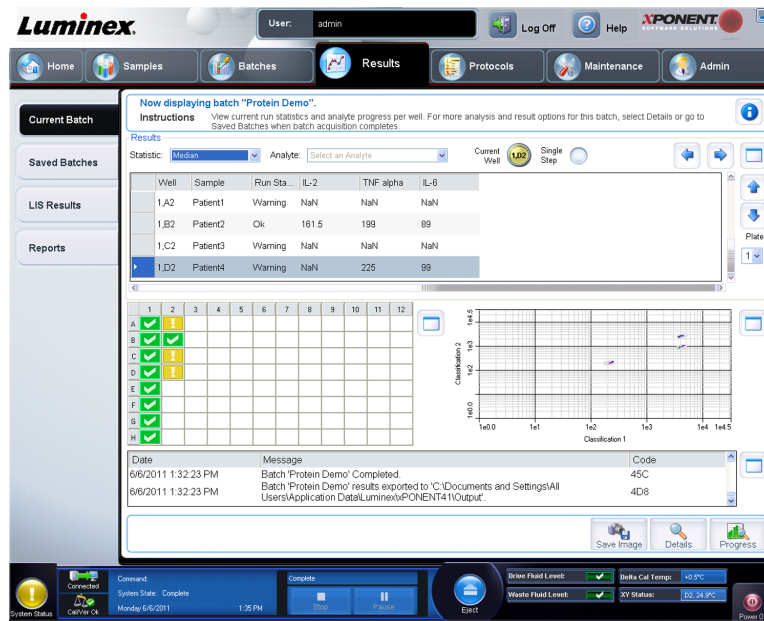
Use this tab to view results, statistics, and log information related to the current batch, and to perform statistical analysis on batch results. This tab offers real-time monitoring of batch sampling during acquisition through a display of sample bead statistics and analytes, and dot

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

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

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

This tab has the following features:

- **Statistic** - To view a particular statistic for analytes in a batch, select one of the options on the drop-down list. The statistical options displayed change according to the type of analysis.

> **NOTE:** Trimmed statistics (indicated by *) remove the lower and upper five percent of the extreme statistic values, then use the remaining values for the **Mean**, **Standard Deviation**, or **%CV** calculations. The point of a trimmed statistic is that it removes outliers, ensuring that the data is more representative of the population.

- **Median** (MFI) - The value (detected signal) that is in the middle of the microsphere population when sorted by reporter value lowest to highest. The mediam value is much less sensitive than the mean value to outliers and carryover.

- **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** - The number of microspheres detected within the specified microsphere region. Microspheres that are not inside the region on the dot plot are not included.

- **Net MFI** (Sample Well MFI - Background Well MFI)) - The NetMFI can be used to eliminate the effect of background signal in an assay.

- **Mean** - Average of all values for the microspheres detected in a region.

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

  %CV = 100 x Std Dev / Mean

- **Standard Deviation** - For calculating sample variability or dispersion, Luminex uses the standard deviation formula.

- **Peak** - The value that is equal to the largest number of data points within the distribution. For example, in data set {1,2,2,3,3,3,4,5}, 3 is the peak because it occurs the most frequently in the distribution list.

- **Trimmed Count***

- **Trimmed Mean***

- **Trimmed%CV of microspheres***

- **Trimmed Standard Deviation***

- **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.

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

- **Well(s) to View**

  - **Current Well** - Displays the statistics of the well currently being displayed (This changes to **Displayed Well** if viewing a batch using the **Open** button of the **Saved Batches** tab).

  - **Single Step** - Instrument analyzes one well at a time. Click to turn function on or off. This is useful to run prior to running an entire batch to confirm that the system is set up correctly.

- **Results** pane - Displays statistics related to the batch.

  - Use the up, down, left, and right arrow buttons to move through the table, or use the scroll bars.

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

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

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

  - **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 might have stopped, depending on the circumstances (select **Log** tab for more information).

- Dot Plot pane - 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. The dot plot default display when using 1 to 50 beads shows **Classification 1** (CL1) and **Classification 2** (CL2). Click within the dot plot to open **Display Mode**, with its two options:

  - **Logarithmic**. This is the default option.

  - **Linear**

- Log pane - This displays a log of system processes. Log entries indicating warnings are highlighted in yellow; errors are highlighted in red. Other log entries are not highlighted. The log includes the following information:

  - **Date**

  - **Message**

  - **Code**

- **Save Image** - Opens a **Save As** dialog box to save a screen capture.

- **Details** - Opens the **Results** tab, enabling more analysis and results.

- **Progress** - Click to display real-time progress of the well acquisition. Analyte counts are displayed in a dynamic bar graph as they are acquired. The scroll bar at the bottom of the **Progress** display scrolls through the analyte list. A zoom feature on the left of the display enables you to enlarge the image.

- **Default** - Appears only when the progress display is active. Click to return to the dot plot display.

Saved Batches Tab

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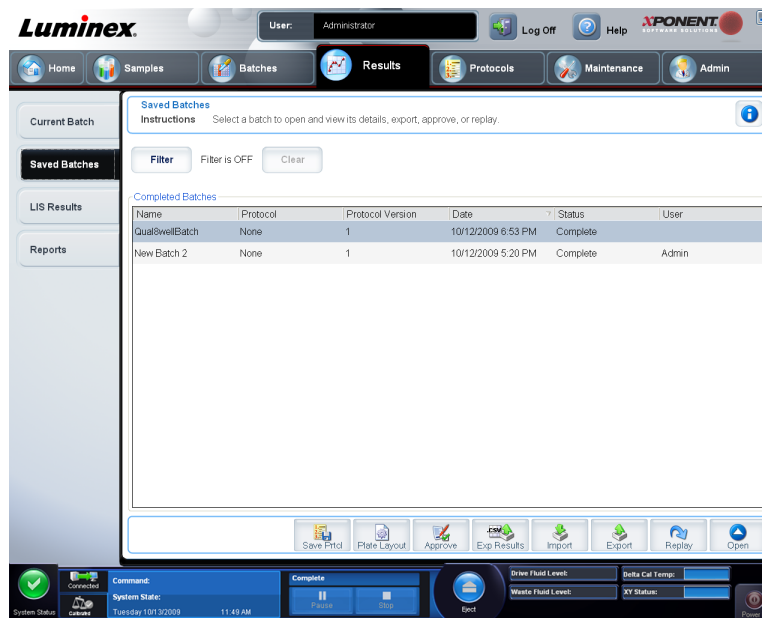
Use this tab to open a batch that has been run and view its details, and to export, approve, or replay a batch.

The **Saved Batches** tab has 4 subtabs:

- Click the **Results** subtab to view statistical information about the batch.

- Click the **Settings** subtab to view the batch settings report.

- Click the **Log** subtab to view a log for the activity that occurred during acquisition of the selected batch.

- Click the **Sample Details** tab to view sample details for each sample in the batch.

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

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

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

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

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

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

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

- **Plate Layout** - Opens the **Report** dialog box, which contains the **Batch Plate Layout Report**.
- **Approve** - Opens the **Batch Approval Confirmation** dialog box to approve the selected batch.


  Only approved batches can be transmitted to the LIS. If your software is licensed for LIS use, you can transmit batches to the LIS from the **Sample Results** tab. After you have approved a batch, the status of the batch changes to **Approved** in the **Complete Batches** list.

- **Exp Results** - Opens the **Save As** dialog box to choose an export destination for the .CSV file containing your results.

  NOTE: If you plan to replay this batch in the future, be sure to include the raw (lxb) files.

- **Import** - Opens the **Open** dialog box so you can select a batch file (.mdf) to import. Select **Include Raw Files (LXB)** to include raw files in the import. Select **Overwrite** to overwrite existing files.
- **Export** - Opens the **Export Batch** dialog box, where you can choose a location for the file you selected to export. Select **Include Raw Files (LXB)** to include raw files in the export. Select **Overwrite** to overwrite existing files.

- **Replay** - Opens the **Select Replay Mode** dialog box. This box enables you to use the data stored in the run files from the initial acquisition to reprocess a batch, creating a new batch output file. A batch can be reprocessed multiple times. When you replay or recalculate a batch, you perform the same steps to create the batch as you did when you created the batch the first time. This sequence varies based on whether or not you created a new batch from a new protocol or a new batch from an existing protocol. The initial batch data and output file always remain intact and unchanged. Each time you replay a batch, the system handles it as if it is new data, and creates a separate batch entry and output file.
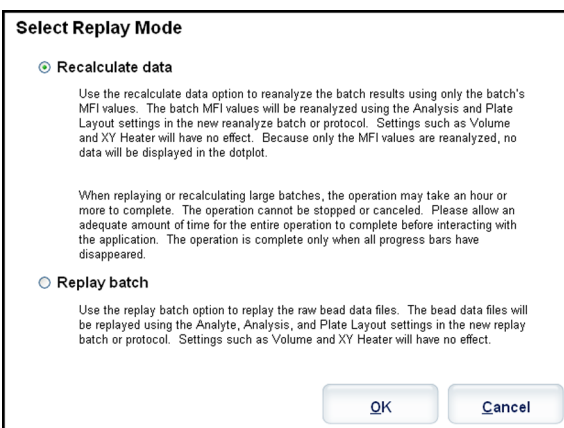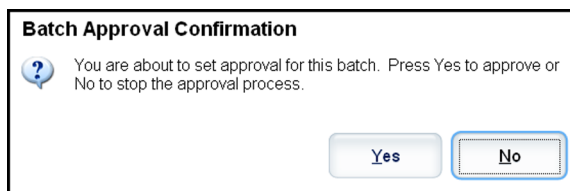

- **Replay batch** - Use to replay raw bead data files. The bead data files are replayed using the gate, analyte, analysis settings, and plate layout that were selected in the new or updated protocol. Settings such as bead type, volume, timeout, XY heater, and report gain have no effect on the replayed results.

- **Recalculate data** - Reanalyze the batch results using only the batch MFI values. The batch MFI values are recalculated using the analysis settings and plate layout selected in the new recalculated batch or protocol. Settings such as bead type, volume, timeout, XY heater, and report gain have no effect on the replayed results. Because only the MFI values are reanalyzed, no data is displayed in the dot plot.

- **OK** - Saves your changes.

- **Cancel** - Cancels your changes and closes the box.

- **Open** - Opens the **Results** tab. Use this tab to view the saved batch results for the selected batch. When you click Open, the buttons change:

  - **Save Image** - Opens a **Save As** dialog box to save a screen capture.

  - **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.

- **Progress** - Click to display real-time progress of the well acquisition. Analyte counts are displayed in a dynamic bar graph as they are acquired. The scroll bar at the bottom of the **Progress** display scrolls through the analyte list. A zoom feature on the left of the display enables you to enlarge the image.

- **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.

- **Close** - Closes the batch and reopens the **Saved Batches** tab.

Replaying a Batch

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

Results from replaying a batch are generated in the usual manner, with new .lxb and CSV files.

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

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

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

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

- **Settings**
- **Analytes**
- **Stds & Ctrls**
- **Plate Layout**

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

Selecting Replay Mode

1. Open the **Results** page, then the **Saved Batches** tab.
2. Select the batch that you want to replay and click **Replay** at the bottom of the screen. This opens the **Select Replay Mode** dialog box. By default, **Recalculate data** is selected.
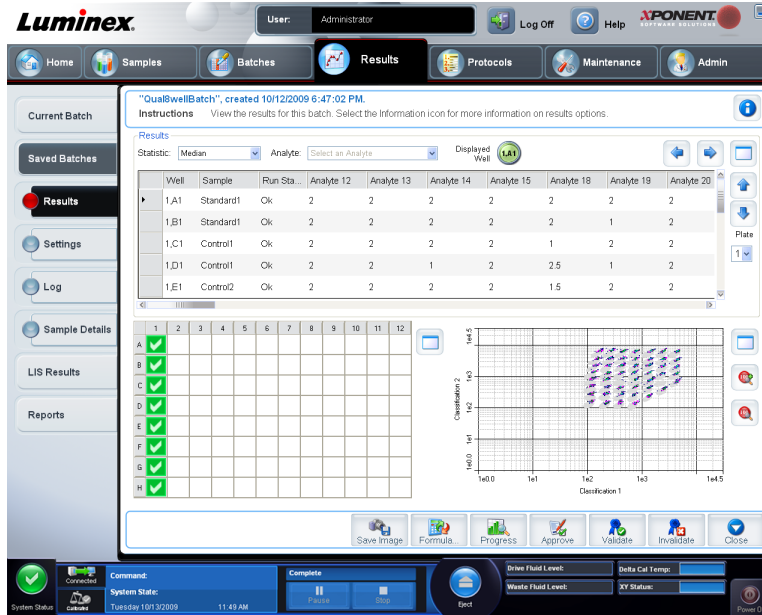3. Select **Replay batch** or **Recalculate data**.

   The information that you must enter to replay or recalculate is the same.
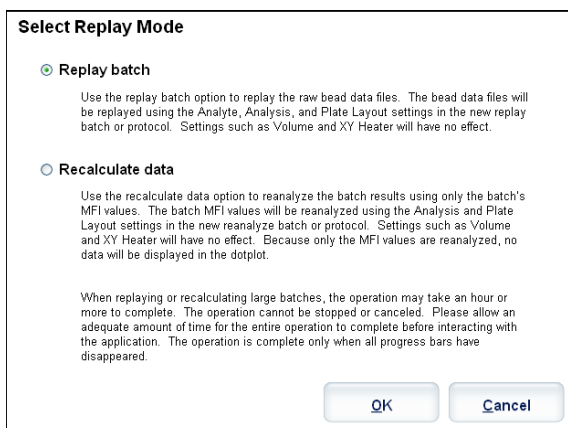
4. Select the correct protocol and click **Next**.
5. Select the wells to be acquired and click **Replay Batch**.

Results Subtab

Results > **Saved Batches** > **Results**

This subtab displays the following features:

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

This tab has the following features:

- **Statistic** - To view a particular statistic for analytes in a batch, select one of the options on the drop-down list. The statistical options displayed change according to the type of analysis.

> **NOTE:** Trimmed statistics (indicated by *) remove the lower and upper five percent of the extreme statistic values, then use the remaining values for the **Mean**, **Standard Deviation**, or **%CV** calculations. The point of a trimmed statistic is that it removes outliers, ensuring that the data is more representative of the population.

- **Median** (MFI) - The value (detected signal) that is in the middle of the microsphere population when sorted by reporter value lowest to highest. The mediam value is much less sensitive than the mean value to outliers and carryover.

- **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** - The number of microspheres detected within the specified microsphere region. Microspheres that are not inside the region on the dot plot are not included.

- **Net MFI** (Sample Well MFI - Background Well MFI)) - The NetMFI can be used to eliminate the effect of background signal in an assay.

- **Mean** - Average of all values for the microspheres detected in a region.

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

  %CV = 100 x Std Dev / Mean

- **Standard Deviation** - For calculating sample variability or dispersion, Luminex uses the standard deviation formula.

- **Peak** - The value that is equal to the largest number of data points within the distribution. For example, in data set {1,2,2,3,3,3,4,5}, 3 is the peak because it occurs the most frequently in the distribution list.

- **Trimmed Count***

- **Trimmed Mean***

- **Trimmed%CV of microspheres***

- **Trimmed Standard Deviation***

- **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.

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

- **Displayed Well** - Displays the n;umber of the well whose contents currently appear in the table.

- **Results** pane - Displays statistics related to the batch.

  - Use the up, down, left, and right arrow buttons to move through the table, or use the scroll bars.

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

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

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

  - **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 might have stopped, depending on the circumstances (select **Log** tab for more information).

- Dot Plot pane - 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. The dot plot default display when using 1 to 50 beads shows **Classification 1** (CL1) and **Classification 2** (CL2). Right click within the dot plot to open **Display Mode**, with its two options:

  - **Logarithmic**. This is the default option.

  - **Linear**

- **Save Image** - Opens a **Save As** dialog box to save a screen capture.

- **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.

- **Progress** - Click to display real-time progress of the well acquisition. Analyte counts are displayed in a dynamic bar graph as they are acquired. The scroll bar at the bottom of the **Progress** display scrolls through the analyte list. A zoom feature on the left of the display enables you to enlarge the image.

- **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. Your xPONENT system administrator must give you privileges to invalidate standards if you are using the Secure xPONENT package.

- **Invalidate** - Invalidates an entire selected row or cell in the Results table. The selection will turn red when invalidated. Select the same item and click **Validate** to remove the invalidation status.

- **Close** - Closes the batch and reopens the **Saved Batches** tab.

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**.

Invalidate Standards and Controls

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

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

To invalidate standards and controls:

1. Open the **Results** page, then open the **Saved Batches** tab.

2. Open the **Saved Batches** tab.

3. Click the batch name, then click **Open**. The **Results** tab opens.

4. Click the square area to the left of the well you wish to invalidate, then click **Invalidate**. The whole row turns red.

Settings Subtab

Results > **Saved Batches** > **Settings**
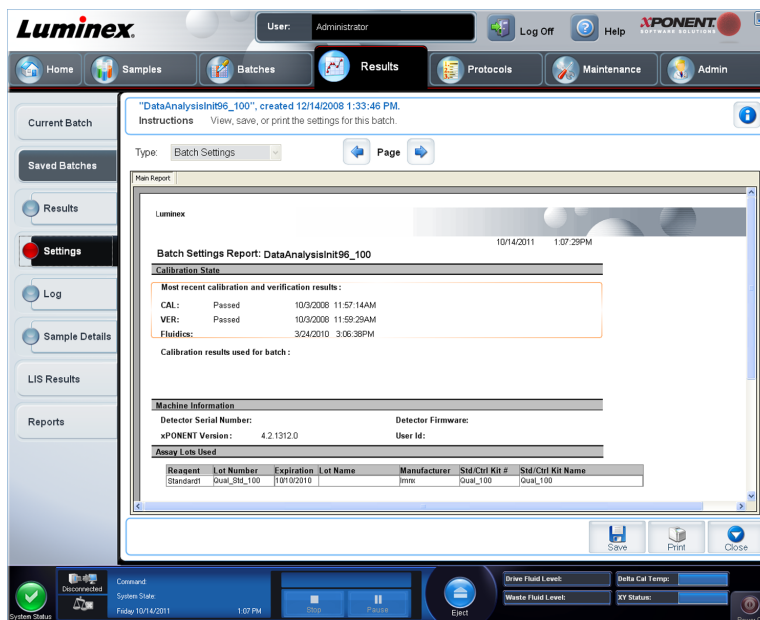
When you click the **Settings** subtab on the **Saved Batches** page, a report opens. This report displays:

- A date and time stamp at the top of the report
- **<** and **>** scroll buttons so that you can view pages in the report
- **Calibration State**
- **Machine Information**
- **Assay Lots Used**

Viewing Batch Settings

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

Log Subtab

Results > **Saved Batches** > **Log**
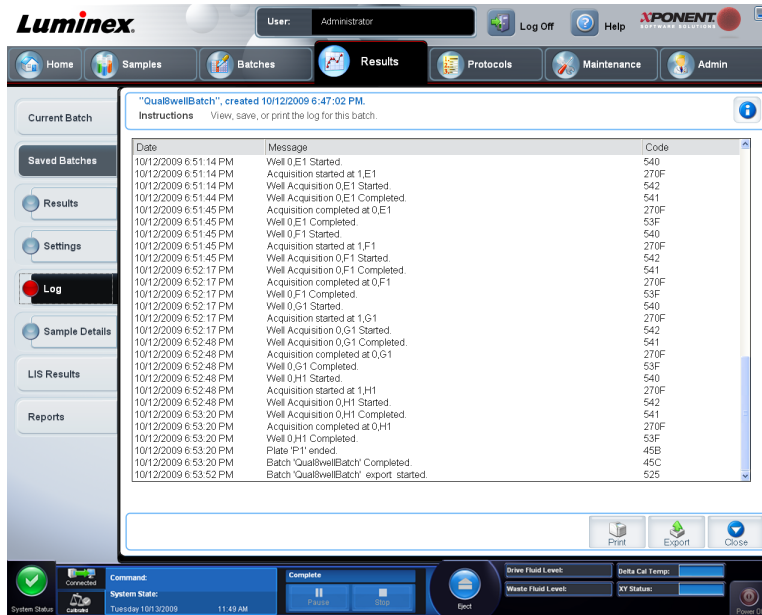
This tab displays a log of the activity which occurred during the acquisition of the selected batch; you can print the log.

The following information is displayed about each activity:

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

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

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

Viewing Batch Logs

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

Sample Details Subtab

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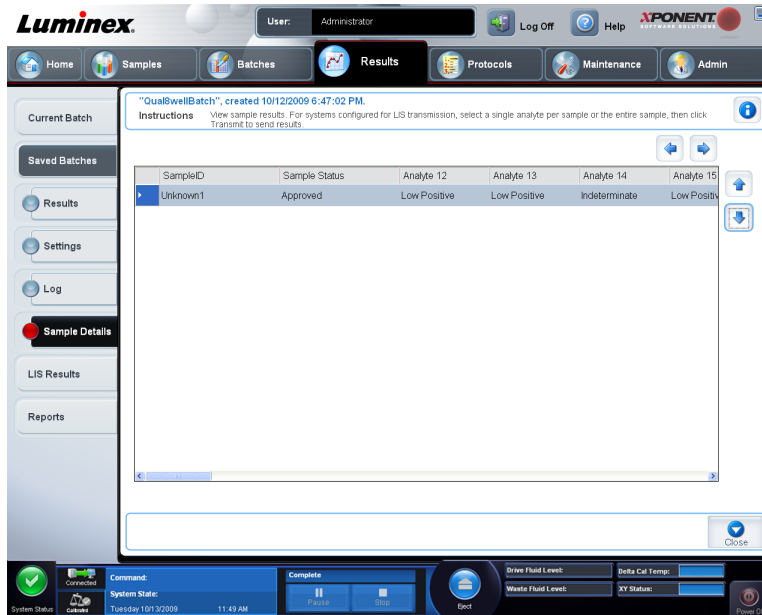
- **< and > Arrows** - Scroll left to right through the sample details.
- **^ and v Arrows** - Scroll up and down through the sample details.
- **Transmit** - For systems configured for LIS transmission, select a single analyte or the entire sample and click **Transmit** to send the results.
- **Close**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

In addition, the following information is shown on this tab:
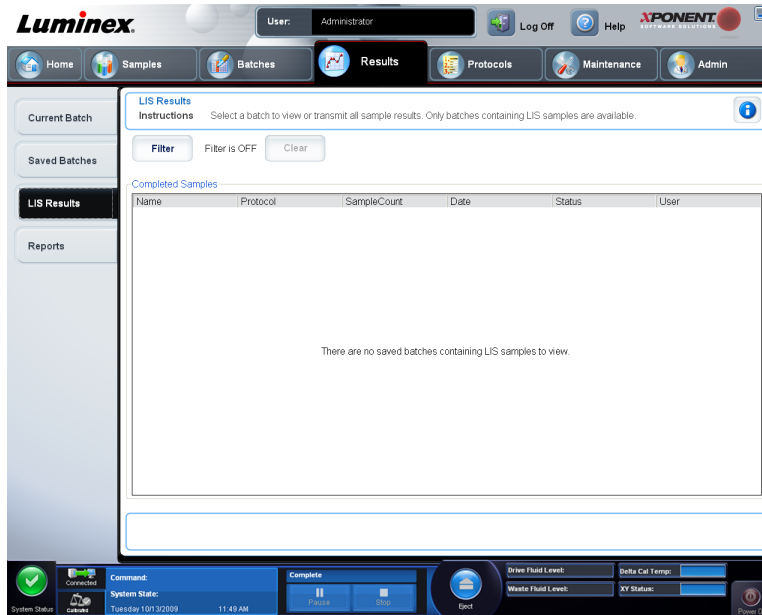
- **SampleID**
- **Samples Status**
- **Analyte**

Viewing Sample Details

1. Open the **Results** page, then open the **Saved Batches** tab.
2. Click **Saved Batches**, then click the batch for which you want to view details.
3. Click **Open**, then click **Sample Details**. The **Sample Details** tab opens. If you are using an LIS licensed package of the software, click **Transmit** to transmit sample details to the LIS database. You can transmit either a single analyte per sample or the entire sample.

LIS Results Tab

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

Results > **LIS Results**

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

    Batch-Specific Details

        • **Batch Name**

        • **Protocol**

        • **Batch Status**

        • **Lot ID**

        • **Kit ID**

        • **Analyte**

    Sample Details

        • **SampleID**

        • **First Name**

        • **Last Name**

    Others

        • **User ID**

        • **Date**

        • **Reset**

        • **OK** / **Cancel**

• **Clear** - Click to turn off the filter.

• **Completed Samples** - Displays **Name**, **Protocol**, **Sample Count**, **Date**, **Status**, and **User information** for each batch displayed in this list.

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

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

Reports Tab

Results > **Reports**
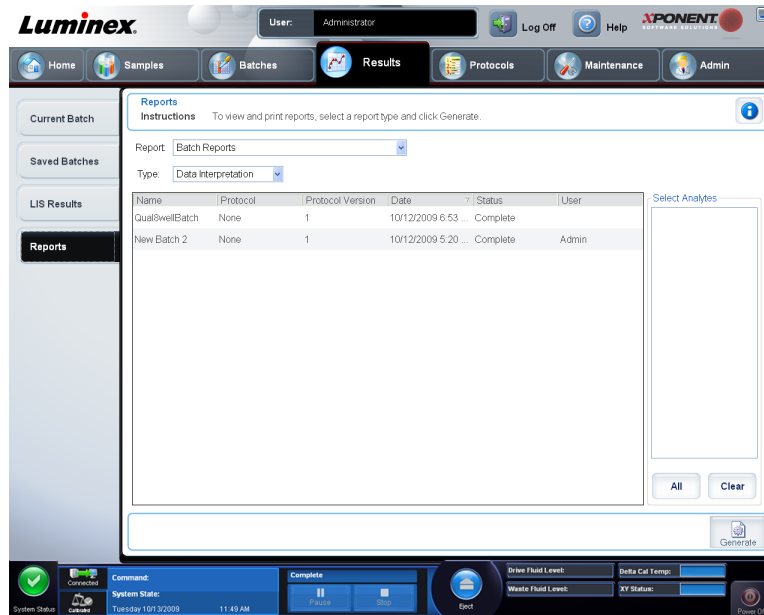
Use this tab to view, generate, and print reports.

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

    - **Batch Reports** - A list of batches opens, so that you can select one. In addition, a Select Analytes box opens to the right of the reports list. You can select the analytes you want to include. Select them all using the **All** button; clear your selections using the **Clear** button.

        > **NOTE:** If running a data interpretation of an allele call batch report, be aware that when choosing analytes from the **Select Analytes** list, selecting one analyte selects all analytes in that group.

    - **Protocol Reports** - A list of protocols opens, so that you can select one.

    - **Calibration and Verification Reports** - A **Start** field and a **Through** field open. Use these to define the date range.

    - **Performance Verification Reports** - A **Start** field and a **Through** field open. Use these to define the date range.

    - **System Log Reports** - A **Start** field and a **Through** field open. Use these to define the date range.

    - **Advanced Reports**

- **Generate** - Use this button to generate the report.

After you click **Generate**, additional buttons are displayed or can be displayed, depending on the nature and size of the report:

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

Generating a Report

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

If the report includes multiples analytes, use the arrows above the report to move through the list of analytes.
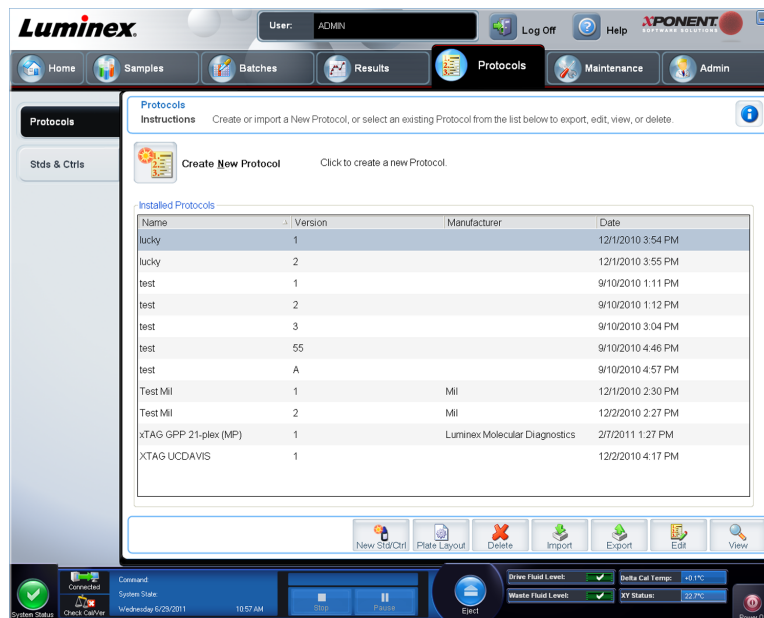
If the report is lengthy, use the **Page** arrows to scroll through the pages in the report.

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

Chapter 5: Protocols Page

Protocols Page Functionality

Protocols > Protocols

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

The following installed protocol information is shown on this page:

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

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

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

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

Protocol Procedures

Creating an Allele Call Protocol

Protocols > Protocols > Create New Protocol

This protocol contains no standards or controls. An allele call protocol compares groups of two, three, or four analytes to identify genotypes.

To create an allele call protocol:

1. Open the **Protocols** page, then open the **Protocols** tab. Click **Create New Protocol**. The **Protocol Settings** tab opens.

2. In the **Name** box, type the name of the protocol.

3. In the **Description** box, type a description of the protocol.

4. In the **Version** box, type the version of the protocol.

5. In the **Manufacturer** box, type the manufacturer information for the protocol.

6. Define the settings in the **Acquisition Settings** section.

    > **NOTE:** Final washes are required for proper analysis. If you are not performing a final wash step on your plate before acquisition on the MAGPIX instrument, enable **Sample Wash** here. This automatically washes each sample.

7. Define settings in the **Analysis Settings** section, selecting **Allele Call** as the analysis type.

8. Click **Next**. The **Analytes** tab opens.

9. Click the desired analyte (bead ID) in the numbered grid. Information about the analytes is displayed in a list on the right side of the grid. For an allele call analysis, you must select a group of two, three, or four analytes.

10. Click **Group** to group analytes for the allele call. The grouped analytes display in a list to the right. Select more analytes and then click **Group** again if you want to add another group to the analysis.

11. Click and type an analyte name in the **Name** column to the right of the analyte grid.

12. In the **Count** box, type the desired bead count for each analyte. Click **Apply All**.

13. To set a bead count and the units for a single analyte, click in the **Units** and **Count** columns directly to the right of the analyte grid, and type a units value and bead count.

14. Click in the **Call %** column and type a value to set an individual analyte's call percentage.

15. Click **Next**. The **Plate Layout** tab opens.

    - To add well commands, select 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.

    - Delete a command by clicking the well, and clicking **Delete**. The **Delete Options** dialog box opens. Select **Delete** just the selected wells to delete a single well command, or **Delete** all wells containing these samples to delete all wells with the same command.

        NOTE: The **Post Batch** routine runs after the batch is complete. This routine is selected by default when the protocol or batch is set up. The default **Post Batch** routine can be changed in the **Batch Options** tab of the **Admin** page.

        NOTE: For more information about the commands and settings on the **Plate Layout** tab, see the *Plate Layout Tab*.

Creating a Quantitative Assay Protocol

The protocol must contain multiple standards. The standards are assigned lot value information for each test. A standard curve is generated according to the lot values. Including controls in the protocol is optional, but recommended for judging the acceptability of batch results.

To create a quantitative assay protocol:

1. Open the **Protocols** page, then open the **Protocols** tab. Click **Create New Protocol**. The **Settings** tab opens.

2. In the **Name** box, type the name of the protocol.

3. Type a description in the **Enter optional description here** box.

4. In the **Version** box, type the version of the protocol.

5. In the **Manufacturer** box, type the manufacturer information for the protocol.

6. Define settings in the **Acquisition Settings** section.

7. Define settings in the **Analysis Settings** section, selecting **Quantitative** as the analysis type. The protocol for a quantitative assay must contain multiple standards. Controls are optional in a quantitative assay protocol.

8. Click **Next**. The **Analytes** tab opens.

9. Click the desired analytes (bead ID) in the numbered analyte grid. Information about the analyte displays to the right side of the grid.

10. Click and type an analyte name in the **Name** column to the right of the analyte grid.

11. Click and type the desired unit of measurement in the **Units** box to the left of the **Apply All** button.

12. Click and type the desired bead count for each analyte in the **Count** box. Click **Apply All**.

13. To set a bead count and the units for a single analyte, click in the **Units** and **Count** columns directly to the right of the analyte grid, and type a bead count and units value.

14. To change the default analysis for all analytes, click **Change**. The **Analysis Settings** dialog box opens.

15. In the **Analysis Settings** dialog box, select the analysis method from the **Method** list, and the weighting in the **Weight Type** list. Click **Apply to All Analytes** to apply the selection to all analytes.

16. To change the analysis for a single analyte, click the **Analysis** field for the analyte you want to modify. The **Analysis Settings** dialog box opens.

17. Select an analysis method in the **Method** list.

18. Select a weight type in the **Weight Type** list (**Weight Type** may not display, depending on the analysis method selected in the **Method** list).

19. Check **Mark as Intra-Well Normalization Bead** if you want to use the analyte as a normalization bead. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run.

20. Check **Use Threshold Ranges** if you want to use a range for the analysis.

21. Click **Add Range** to setup the threshold range.

22. Type a name for the range in the **Range Name** field.

23. Type low and high range values in the **Low Value** and **High Value** fields.

24. Select the check box in the **Inclusive** column to include the value in the range, or leave it clear to make the range value one unit higher than the low value, and one unit lower than the high value.

25. Highlight a range and click **Delete Range** to delete the range.

26. Click **OK** to apply the new settings to the analyte first clicked, or **Apply to All Analytes** to apply them to all the analytes in the protocol.

27. Click **Next**. The **Plate Layout** tab opens.

  • To add well commands, highlight the appropriate wells and mark them as unknown, standard, control, background, or wash. You can also delete commands that you have 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.

  > **NOTE:** Select the **Replicate Count** and **Grouping** settings before adding a well command.

  • To add maintenance commands, choose a command from the list. Highlight the well that you want to apply it to, and then choose **Pre Batch Routine** or **Post Batch Routine**. The **Commands and Routines** dialog box opens.
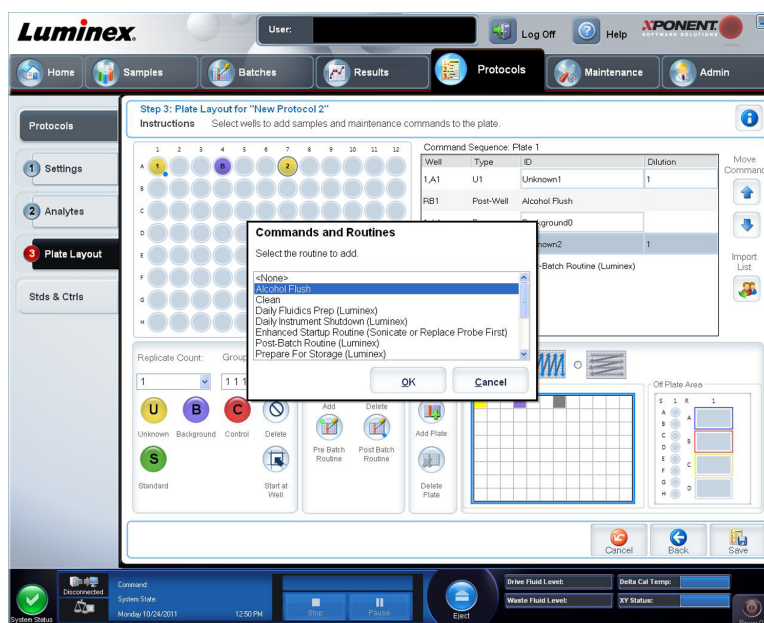
  If you are working with more than one plate, choose **Add & Change Plate**. Here, you can add a plate, change the order of the plates, and scroll through all plates.

  • Delete a command by clicking the well, and clicking **Delete**. The **Delete Options** dialog box opens. Select **Delete just the selected wells** to delete a single well command, or **Delete all wells containing these samples** to delete all wells with the same command.

  • As you add commands to your plate, they appear in the **Command Sequence** list. Type a well ID in the **ID** field. Here, you can give each of your wells an ID. You can also import a protocol file by clicking **Import List**.

  • Move commands up or down in the sequence by highlighting a command and using the **Move Command** arrows to move the command up or down in the list.

28. Click **Save**.

  > **NOTE:** The **Pre Batch** routine runs before the batch begins. This routine is selected by default when the protocol or batch is set up. The default **Pre Batch** routine can be changed in the **Batch Options** page.

  > **NOTE:** The **Post Batch** routine runs after the batch is complete. This routine is selected by default when the protocol or batch is set up. The

default **Post Batch** routine can be changed in the **Batch Options** tab of the **Admin** page.

# Creating a Qualitative Assay Protocol

You define each Qualitative assay protocol using a single kit. The kit must contain one standard. The standard is assigned a "Quali" value for each test. Controls are optional, but are recommended for judging the acceptability of batch results.

To create a Qualitative Assay Protocol:

1. Open the **Protocols** page, then open the **Protocols** tab. Click **Create New Protocol**. The **Settings** tab opens.

2. In the **Name** box, type the name of the protocol.

3. In the **Version** box, type the version of the protocol.

4. In the **Manufacturer** box, type the manufacturer information for the protocol.

5. Define settings in the **Acquisition Settings** section.

6. Define settings in the **Analysis Settings section**, selecting **Qualitative** as the analysis type. The protocol for a qualitative assay contains a single standard.

7. Click **Next**. The **Analytes** tab opens.

8. Click the desired analytes (bead IDs) 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. In the **Analysis Settings** dialog box, click the analysis method from the **Analysis Method** list. Click **OK** to change the default analysis to a single analyte. Click **Apply to All Analytes** to apply the selection to all analytes. Skip this step if you do not want to change the default analysis or if you chose **No Analysis** on the **Settings** tab.

11. In the **Units** box, type the desired unit of measurement.

12. In the **Count** box, type the desired bead count for each analyte. Click **Apply All**.

13. Click **Next**. The **Plate Layout** tab opens.

- To add well commands, highlight 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 a command from the list. Highlight the well that you want to apply it to, and then choose **Pre Batch Routine** or **Post Batch Routine**. The **Commands and Routines** dialog box opens.
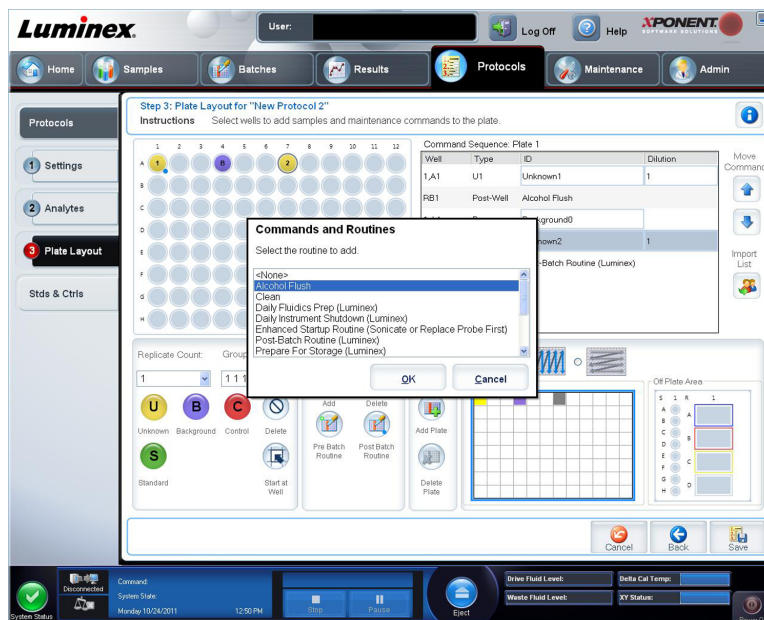
If you are working with more than one plate, choose **Add & Change Plate**. Here, you can add a plate, change the order of the plates, and scroll through all plates.

14. Click **Save**.

Deleting a Protocol

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

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**.

Exporting a Protocol

1. Open the **Protocols** page, then open the **Protocols** tab.

2. Select a protocol.

3. Click **Export**. The **Save as** dialog box opens.

4. Select a location to export the file to, and click **Save**.

Importing a Protocol

1. Open the **Protocols** page, then open the **Protocols** tab. Click **Import**.

2. In the **Open** dialog box, navigate to the protocol file you want to import, then click **Open**.

3. The imported protocol displays in the **Installed Protocols** list.

Adding a New Lot for Protocol

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

2. Open the **Stds & Ctrls** tab.

3. Click **Create New Std/Ctrl Lots** and select a protocol from the drop down list in the **Select Protocol** dialog box, then click **OK**. The **Std/Ctrl Details** tab opens.

4. Click **Apply Std/Ctrl Kit** to associate a kit with the protocol. If you are not using a kit, type the appropriate Standard and Controls information in the **Assay Standard Information** and **Assay Control Information** sections.

5. Click **Save**.

Lots and Kits Procedures

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

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

Creating a Lot

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

To create a lot:

1. Open the **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**.

Editing a Lot

To edit a lot:

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

2. In the **Installed Kits And Lots** section, select a lot and then click **Edit**. The **Std/Ctrl Details** tab opens. Change the lot information as appropriate.

Deleting a Lot

To delete a lot:

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

2. In the **Installed Kits And Lots** section, click the lot you want to delete, then click **Delete**.

Exporting a Lot

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

To export a lot:

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

2. In the **Installed Kits And Lots** section, click the lot you want to export, then click **Export**. The **Save As** dialog box opens.

3. Navigate to the location you want to export the file to, then click **Save**.

Importing a Lot

1. Open the **Protocols** page, then open the **Protocols** tab. Click the **Stds & Ctrls** tab, and then click **Import**.

2. In the **Open** dialog box, navigate to the file, then click **Open**.

Creating a Kit

To create a kit:

1. Open the **Protocols** page, then open the **Protocols** tab.

2. Select the protocol that you want to use for the kit, then click **New Std/Ctrl**. The **Std/Ctrl Details** tab opens.

3. Type the name of the kit in the **Name** box, the lot number in the **Std/Ctrl Kit Lot#** box, the expiration date using MM/DD/YY format in the **Expiration** box, and the manufacturer in the **Manufacturer** box.

4. Click **Apply Std Lot** if you want to apply a standard lot. The **Select Lot** dialog box opens. Click a lot and select **OK**.

5. Click **Apply Ctrl Lot** to apply a control lot. The **Select Lot** dialog box opens. Select a lot and click **OK**.

6. Alternatively, type the appropriate information in the **Assay Standard Information** and **Assay Control Information** sections. The number of standards, controls, or both in these sections is defined in the protocol. If your batch uses controls, select **Expected**, **Low** or **High** from the **Show Value** options. Use the **Apply Values** arrows to apply values down or across the range of analytes.

7. Click **Save**.

Protocols Tab

Protocols > **Protocols**

The following installed protocol information is shown on this page:

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

In addition, these action buttons are available at the bottom of the page:

- **New Stds & Ctrls** - Click this button to open the **Std/Ctrls Details** page.
- **Plate Layout** - Click to open the **Plate Layout** tab.
- **Delete**

- **Import**
- **Export**
- **Exit**
- **View**

Settings Subtab

Protocols > **Protocols** > **Settings**

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

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

Acquisition Settings

- **Volume** - This is the volume the instrument aspirates into the system for analysis. Type the desired sample volume in microliters. Use values from 20 to 200 µl. To avoid air intake, add at least 25 µl to the sample well in addition to the sample size. The default value is 50 µl.

- **XY heater** - Select **Enabled** to enable the XY heater. In the box type the desired value in degrees Celsius. The temperature range is 35° to 60° C.

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

- **Plate name** - The name assigned to the plate. You can select a different plate from the list.

- **Sample wash** - Select this option for assays without a final wash step prior to reading the plate on the instrument. This automatically washes each sample within the instrument. Final washes are required for proper analysis.

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

- **Analysis Type** - Use this list to choose from the following analysis types:

  - **None** - No analysis. Select if you have your own data post-processing program. You cannot apply standards or controls when you select **None**. You cannot analyze acquisitions with this setting.

  - **Qualitative** - Qualitative analysis determines results as either positive or negative, reactive or non-reactive. The software is flexible in defining custom results ranges, such as negative, low positive, or high positive. Determinations are based on a single standard. For qualitative analysis the Luminex software uses a specific algorithm, shown below:

    Where:

    FI = Fluorescent Intensity

    Ki - a "Quali" value determines a cutoff or threshold. This, in conjunction with ranges using the Lum Qual formula or an edited range specific for your assay, helps to determine qualitative results for unknown samples.

    Two predefined formulas using the algorithm are included in the system. You can use them as-is or edit their range values to meet your requirements.

  - **Quantitative** - Determines the sample concentrations from standard curves using regression methods. Cublc Spline, Linear, Logistic 4P, and Logistic 5P. Type the desired values for standards and controls in the **Number of Standards** and **Number of Controls** boxes. Select either **Fit of All Standards** or **Mean of Replicates** for the calculation of the curve fit.

    > **NOTE:** Luminex recommends **Fit of All Standards** as the most accurate calculation of the curve fit.

    Based on a range of quantitative, numerical results, a threshold range can be applied to a quantitative analysis, for example, high, low, saturated, and expected.

  - **Allele Call** - Sets analysis for an allele call. Analytes must be put in groups of 2, 3, or 4.

- **Min MFI Enabled** - Select this box to enable a minimum MFI for the **Allele Call** analysis. Type a value in this box to set the minimum MFI for analysis.

- Analyze results while acquiring samples - The software allows real-time viewing of the results as the instrument analyzes samples. This feature is not available if you select **None** as your analysis type.

- **Number of Standards** - Click to type the number of standards for the protocol. Applies only to qualitative and quantitative analysis.

- **Use External Analysis Program** - Select this check box to use a third-party program to analyze the data. The **Analysis Program** list becomes active when this is selected. Applies only to qualitative and quantitative analysis. Use this list to select which program to use for data analysis

- **Number of Controls** - Click to type the number of controls for the protocol. Applies only to qualitative and quantitative analyses.

- **Fit of all Standards** - The standard curve will be determined by using each individual standard replicate when calculating the standard curve. For example, if you run duplicates of a seven-point standard curve, the software will calculate the standard curve by using 14 points. Applies only to quantitative analysis.

- **Mean of Replicates** - The standard curve will be determined by averaging the individual standard replicates when calculating the standard curve. For example, if you run duplicates of a seven-point curve, the software calculates the standard curve by using 7 averaged points. Applies only to quantitative analysis.

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

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

Editing Quantitative Analysis Settings

To edit quantitative analysis settings:

1. Open the **Protocols** page, then open the **Protocols** tab. Select a protocol and click **Edit**.

2. From the **Analytes** tab, click an analyte's **Analysis field** to open the **Analysis Settings** dialog box.

3. From the **Method** list, click **No Analysis, Cubic Spline, Linear Fit, Logistic 4P**, or **Logistic 5P**.

4. From the **Weight** list, click **None** or **1/Y$^{\wedge 2}$**.

   NOTE: The **Weight** options are only available if the chosen **Method** is **Logistic 4P** or **Logistic 5P**.

5. Check **Mark as Intra-Well Normalization Bead** if you want to use a normalization bead. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run.

6. Check **Use Threshold Ranges** if you want to use a range for the analysis.

7. Click **Add Range** to setup the threshold range.

8. Type a name for the range in the **Range Name** field.

9. Type low and high range values in the **Low Value** and **High Value** fields.

10. Select the check box in the **Inclusive** column to include the value in the range, or leave it clear to make the range value one unit higher than the low value, and one unit lower than the high value.

11. Highlight a range and click **Delete Range** to delete the range.

12. Click **OK** to apply the new settings to the analyte first clicked, or **Apply to All Analytes** to apply them to all the analytes in the protocol.

Editing Qualitative Analysis Settings

1. Open the **Protocols** page, then open the **Protocols** tab. Select a protocol and click **Edit**.

2. On the **Analytes** tab, click an analyte's **Analysis** field on the right side of the window to open the **Analysis Settings** dialog box.

3. From the **Method** list, click **Luminex Qualitative** or **No Analysis**.

4. From the **Formulas** list, click **Lum Qual** or **Adv Qual**.

5. Type a new name for the edited formula in the **Formula Name** box.

6. If you selected **Lum Qual** in the **Formulas** list, edit the values for each range under **Negative**, **Low Positive**, or **High Positive**. If you selected **Adv Qual** in the **Formulas** list, edit **Negative**, **Low Positive**, **Moderate Positive**, or **Strong Positive**. Select the check box in the **Inclusive** column to include the value in the range. If you clear the check box, the value will be one unit higher than the low value, and one unit lower than the high value.

7. Click **Add Range** if you want to add a new range. Type a **Range Name**, **Low Value**, **High Value**, and check or clear the **Inclusive** check boxes.

8. If you want to delete a range, click a range to highlight it, and click **Delete Range**.

9. Check **Mark as Intra-Well Normalization Bead** if you want to use a normalization bead. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run. An analyte used as a normalization bead will appear blue in the analyte grid.

10. Type a name for the new formula in the **Formula Name** box.

11. Click **Save Formula**. The new formula displays in the **Formulas** list.

12. Click **Apply to All Analytes** to apply the new formula to all analytes in the list, or click **OK** to apply the new formula to the single analyte you first clicked.

Plate Layout Subtab

Protocols > **Protocols** > **Plate Layout**
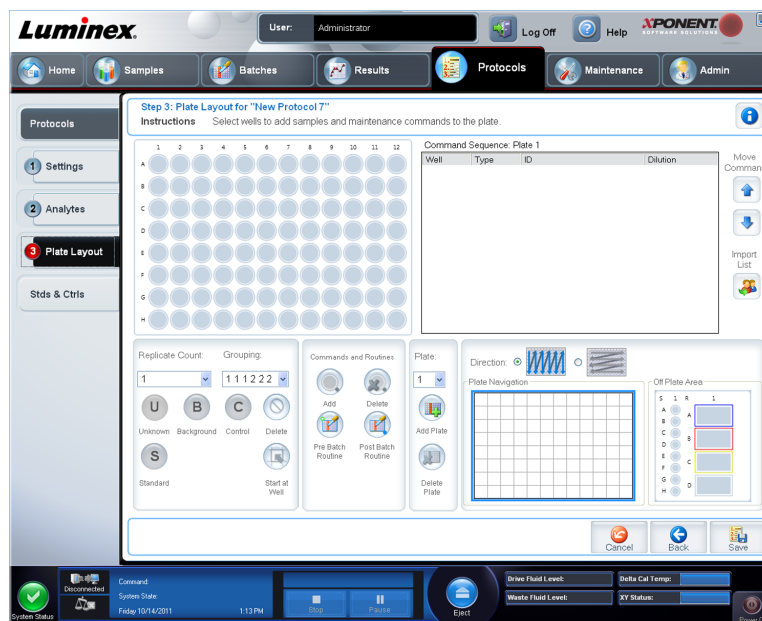
- **Plate Image** - This is a representation of the plate. Each well appears as a circle on the grid. Well commands appear in the appropriate circles as you assign them to wells on the plate. The **Plate Navigation** section in the lower right part of the window can be used to display all the wells in the plate image. Click and drag in the **Plate Navigation** box to display different portions of the plate.

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

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

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

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

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

Commands and Routines - Assigns maintenance commands and routines to a well after you select it in the **Command Sequence** area.
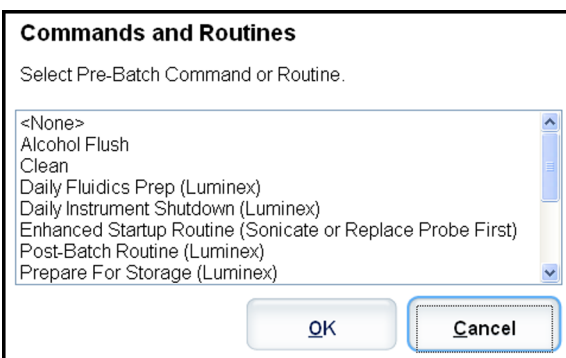
- **Add** - Opens the **Commands and Routines** dialog box so you can select a command or routine.
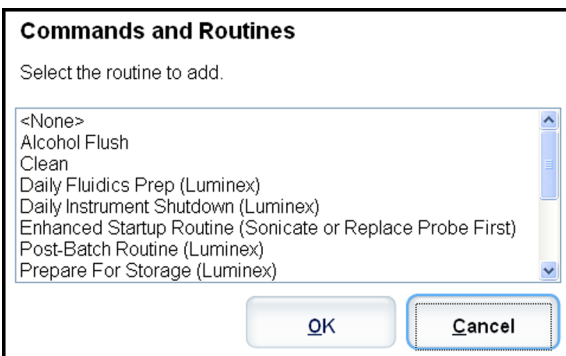
- **Delete** - Deletes the selected command or routine.
- **Post Batch Routine** - Opens the **Commands and Routines** dialog box so you can select a post-batch command or routine.
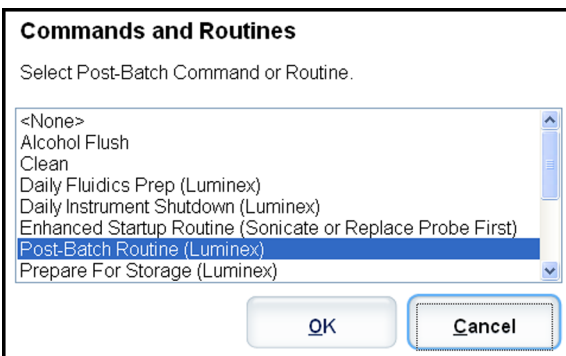
- **Pre Batch Routine** - Opens the **Commands and Routines** dialog box so you can select a pre-batch command or routine.

- **Plate** - Specifies the plate you want to display in the plate image in the list. **Add Plate** adds a new plate to the batch, and **Delete Plate** deletes the plate highlighted in the list.
- **Direction** - Specifies the direction to run the plate commands. Select either horizontally or vertically. The selected direction also dictates how wells are added to the plate when assigning multiple unknowns, standards, and controls at one time.

- **Plate Navigation** - Displays a smaller plate image for the current batch. Click and drag in the box to select wells to display.

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

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

- **Back** - Returns to the **Analytes** tab

- **Save** - Saves the protocol and returns to the main **Protocols** tab.

Standards and Controls (Stds/Ctrls) Details Subtab

Protocols > **Protocols** > **Std/Ctrl Details**

Click **New Std/Ctrl** on the **Protocols** tab of the **Protocols** page to open the **Standards and Controls (Stds/Ctrls) Details** subtab.

Use this tab to create or edit a kit. The following fields are available:

- **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.

  As an alternative, you can type a number (must be a whole number) for your own dilution factor.

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

  NOTE: Click a column header to re-sort 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 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.

Analytes Subtab

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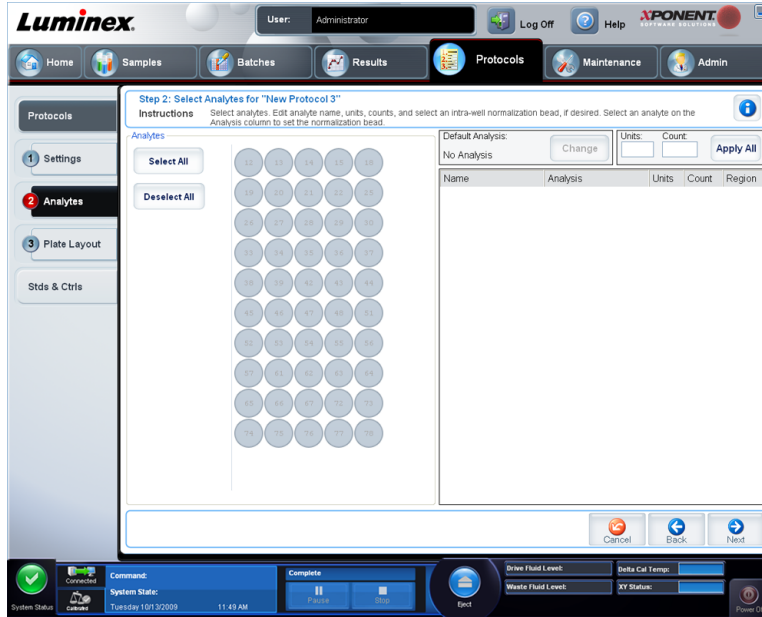
Use this tab to select or edit analytes used in the batch or protocol.This tab contains the following:

This tab contains the following:

- **Analytes** grid - A grid representing each analyte from 12 to 78. **Select All** selects all analytes, and **Deselect All** deselects all analytes. Click a numbered analyte to select it; click the analyte again to deselect it. You can also click and drag to select groups of analytes. Selected analytes are red. Deselected analytes are gray. An analyte marked as an intra-well normalization bead is blue.

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

FIGURE 5. **Analysis Settings Dialog Box**

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

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

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

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

Click **Apply to All Analytes** to apply your selection to all selected analytes. Click **OK** to change the default analysis to the analysis you selected. Click **Cancel** to close the dialog box without saving.

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

- **Count** - Type the desired bead count for the analytes by clicking in the **Count** box. If each selected bead set does not acquire this number of events, a warning is added to the log that not enough bead events were acquired. If you select bead sets that are not present, the analyzer continues to acquire, trying to reach the number of events per bead for bead sets that are not in the sample. Therefore, choose only the bead sets present in your sample.

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

- **Total Count** - Select **Stop after bead count reaches:** to stop acquisition when the bead count reaches a certain number determined by the user. Type the desired value in the box. The default value is 50. You can also specify the minimum allowable bead count per well that the xPONENT® software analyzes. This excludes data from any beads carried over during acquisition.

- Selected Analytes list - Selected analytes are displayed in a list on the right side of the analyte grid. This list includes the following information:
  - **Name** - The name of the analyte. Click and type to rename the analyte.
  - **Analysis** - To change the type of analysis for an analyte, click this field to open the **Analysis Settings** dialog box and select another analysis from the list.

  In the **Analysis Settings** dialog box:

FIGURE 6. **Analysis Settings Dialog Box**

1. Select a method from the **Method** list.
2. If necessary, select a weight type from the **Weight Type** list.
3. Apply the analysis to all analytes in the list by clicking **Apply to All Analytes**.
4. Select **Mark as Intra-Well Normalization Bead** to make the analyte an intra-well normalization bead. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run.
5. Add a range to the analysis by clicking **Add Range**.
6. Select **Use Threshold Ranges** to enable ranges for the analysis.
7. Click **Add Range** to add a range.
8. Type a **Range Name**, a **Low Value**, a **High Value**, and select **Inclusive** if you want to include the low and high values in the range. Click **OK** to exit the dialog box.

- **Units** - The unit of measurement you specified in the **Unit** box. Click this box to type a value for the analyte.
- **Count** - Type the desired bead count for the analytes by clicking in the **Count** box. If each selected bead set does not acquire this number of events, a warning is added to the log that not enough bead events were acquired.
- **Region** - Refers to the specific analyte selected. This is a number between 12 and 78.
- **Group** - If you have selected **Allele Call** from the **Analysis Type** in the **Settings** tab, this button is displayed. Click **Group** to group 2, 3, or 4 analytes for the group. Multiple groups can be defined.

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

Standards and Controls (Stds & Ctrls) Tab

Protocols > **Stds & Ctrls**
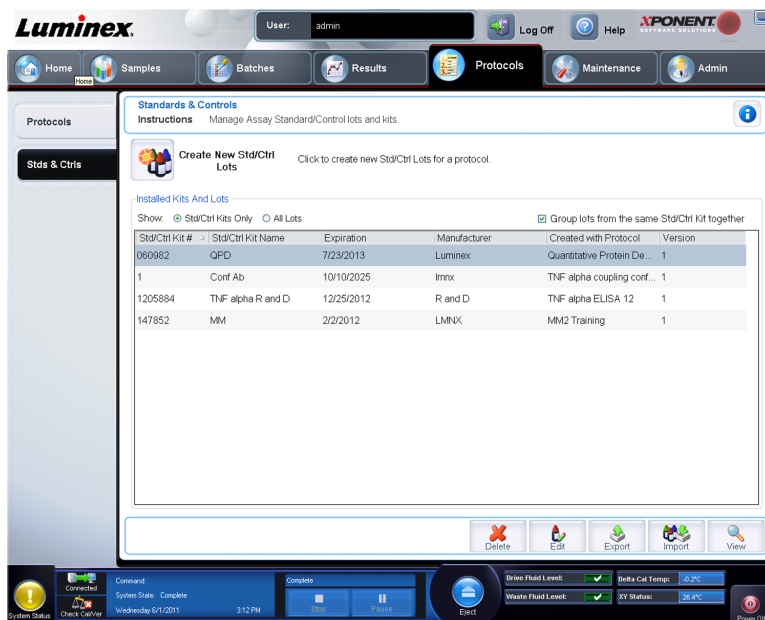
Use this tab to delete, edit, export, import, and create standards and controls.

This tab contains the following:

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

After you select from this box, the **Std/Ctrl Details** tab opens so you can create a new lot or kit.

- **Installed Kits And Lots** - Displays information about the kits and lots currently installed on the system.

  - **Show** - Click either **Std/Ctrl Kits Only** or **All Lots** to choose what to display.

  - Group lots from the same **Std/Ctrl Kit** together - Select to group lots from the same kit together.

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

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

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

- **Std/Ctrl Kit #**
- **Std/Ctrl Kit Name**
- **Expiration**
- **Manufacturer**
- **Created with Protocol**
- **Version**

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

Standards and Controls (Stds/Ctrls) Details Subtab

Protocols> **Stds & Ctrls**> **Std/Ctrl Details**

Click **Create New Std/Ctrl Lots** on the **Standards and Controls (Stds & Ctrls)** tab of the **Protocols** page to open the **Standards and Controls Details** tab.

Use this tab to create or edit a kit. The following fields are available:

- **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.

    As an alternative, you can type a number (must be a whole number) for your own dilution factor.

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

    > **NOTE:** Click a column header to re-sort 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 click **OK**.
  - **Show Value** - **Expected**, **Low**, and **High** set the expected, lowest, or highest acceptable concentration of the analyte in the sample.
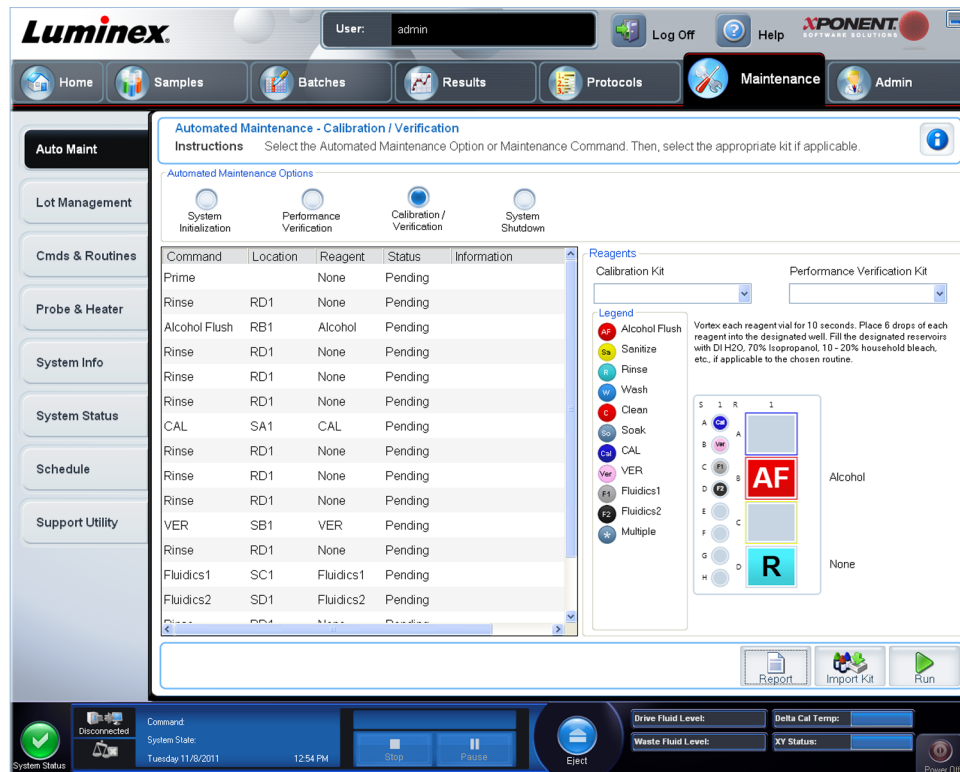 - **Apply Values** - Applies a value down or across the list of analytes.

Chapter 6: Maintenance Page

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

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

Auto Maintenance (Auto Maint) Tab

Maintenance > **Auto Maint**

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

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

- **System Initialization** - Select this routine to perform System Initialization.
- **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.

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 are listed in the box.
- **Reagents** - Displays the reagents and well locations necessary for the selected routine. You can select kits for the routines from the **Calibration Kit** and **Performance Verification Kit** lists.
- **Report** - Opens the **Reports** tab, with the **Performance Verification Reports** selection displayed in the **Report:** list.
- **Import Kit** - Opens the **Import Calibration or Performance Kit** dialog box. Select a kit and click **Open** to import a kit.
- **Run** - Initiates the selected routine.

System Initialization

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

Calibrator magnetic beads are used to normalize the settings for the reporter channel and classification channels. Verification magnetic beads are used to verify calibration and optical integrity of the system. Fluidics beads are used to assess well-to-well carryover.

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

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

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 any of the following things occur:

- The delta calibration temperature exceeds ± 5° C.

- You move the instrument.

- You experience sample acquisition problems.

- The instrument undergoes hardware maintenance, such as replacement of a part.

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.

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

Running the Performance Verification Routine

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

1. On the **Home** page, click **System Initialization** under **Daily Activities**. The **Auto Maint** opens.

2. Add the appropriate reagents to the off-plate reservoirs and the strip well, using the diagram in the **Reagents** pane of the **Auto Maint** tab to guide you.

3. On the **Auto Maint** tab, click **Performance Verification**.

4. Click **Run**.

Running Calibration and Verification

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

For information about what calibration and verification accomplish, see *Magpix Technology*.

For complete procedures for performing calibration and verification, refer to the package inserts that are included with Luminex Calibration and Verification kits.

Lot Management Tab

Use this tab to manage calibration and verification kits.

Maintenance > **Lot Management**

- **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.

    - Active Reagents table - This displays information about the selected reagent. It allows you to choose whether the lot is **CAL**, **VER**, **Fluidics 1**, or **Fluidics 2**. That choice is displayed in the **Lot Details** area. The choice changes what columns appear in the table in the **Lot Details** area.

- **Lot Details** - Displays lot information for the lot selected in the **Active Reagent** area.

    - **Lot Type** - Displays the lot type selected.

    - **Lot #** - Enter the lot number after clicking **Add New**.

    - **Expiration** - Select this to edit the expiration date after clicking **Add New**.

    - Lot Details table - This table enables you to enter target MFI values for the type of lot you selected in the **Active Reagents** area. If your choice was **CAL**, enter targets for CL1, CL2, and RP1. If it was **VER**, enter targets for each channel for each reagent. If it was Fluidics 1 or 2, you cannot enter any targets.

- **Drive Fluid** - Provides information about the drive fluid.

    - **Current Lot #** - Displays the lot number. After you click **Edit**, it allows you to fill in a lot number.

    - **Expiration** - Displays the expiration date. After you click **Edit**, it allows you to open a calendar and select an expiration date.

    - **Edit** - Allows you to add or change the current lot # and expiration.

- **Import Kit** - Opens the **Import Calibration or Performance Kit** dialog box to import a kit.

- **Import** - Opens the **Import Calibrator or Verification Lot** dialog box to import a lot.

- **Export** - Opens the **Export Calibrator or Verification Lot** dialog box. Select a name and location to save the calibrator or verification lot and click **Save**.

- **Add New** - Adds a new lot. Add information in the **Lot Details** section on the right side of the window. Type a **Lot #**, **Expiration**, and target in the appropriate boxes and fields. Click **Save** to save the lot, or select. **Cancel** to cancel the entry.

- **Delete** - Deletes a lot selected in the **Active Reagents** list.

Importing CAL or VER Kits

Follow these steps to import a CAL or VER kit.

1. Open the **Maintenance** page, then open the **Lot Management** tab.

2. Click **Import Kit**. The **Import Calibration or Performance Kit** dialog box opens.

3. Select the kit you want to import, then click **Open**.

Deleting CAL and VER Kit Information

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

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

Commands and Routines (Cmds & Routines) Tab

Maintenance > **Cmd & Routines**

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 Drive 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.

This tab contains the following:

- **Routine Name** - This list of pre-set routines and commands can be used for system maintenance. Some of these commands are also available on the **Auto Maint** tab. You can also create custom routines which appear in the **Routine Name** list after you save the routine. To create a custom routine, start with **None** and add commands. You can also modify a Luminex routine and save it as a new routine. Select from the following routines:
  - **Daily Fluidics Prep (Luminex)**
  - **Daily Instrument Shutdown (Luminex)**
  - **Enhanced Startup Routine (Sonicate or Replace Probe First)**
  - **Post-Batch Routine (Luminex)**
  - **Prepare for Shipping Part 1 (Luminex)**
  - **Prepare for Shipping Part 2 (Remove Drive Fluid Stem First)**
  - **Prepare for Storage (Luminex)**
  - **Revive After Storage (Luminex)**
  - **Weekly Maintenance (Sonicate or Replace Probe First)**
- **Plate Name** - This list displays the available plates to use for the selected routine or procedure.

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

Commands - This section contains the following commands:

- **Wash** - Sends distilled water through the fluidic lines in the system. It pulls the fluid from a well or from the reservoir and runs it completely through the system to the waste receptacle.

- **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.

- **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.

- **Clean** - Aspirates a cleaning reagent such as bleach or sodium hydroxide.

- **Soak** - Prevents salt crystals from forming in the probe due to air exposure. Soaking the probe replaces Drive 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.

- **Rinse** - Performs a rinse.

- **Prime** - Removes air bubbles from the systems fluidic pathways by drawing Drive Fluid from the Drive Fluid container. You do not need to supply solution in a plate.

- **CAL** - Performs a calibration.

- **VER** - Performs a verification.

- **Fluidics** - Runs fluidics.

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 buttons are located to the right of the **Command Sequence** box:

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

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

Different buttons appear at the bottom right of the window, depending on your selections in the window:

- **Command Sequence** - 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.

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

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

- **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 appears in the **Routine Name** list. This button only appears if a routine has been customized or 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.

- **Run** - Runs the selected routine or command.

Creating a New Routine

Create maintenance routines to facilitate your startup procedure, shutdown procedure, troubleshooting, or calibration. Ensure that the maintenance routine you create is consistent with the Luminex analyzer operations and maintenance requirements. See the *MAGPIX Installation and Hardware User Manual* for more information.

To create a new routine:

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.

2. In the **Routine Name** list, click **None**.

3. In the **Plate Name** list, select the plate that you will use for the new routine.

4. In the **Commands** section, click one or more commands to add to the routine. These commands display in the plate image and in the **Command Sequence** list.

   NOTE: When you choose the **CAL** command, a **Rinse** command is performed prior to the **CAL**. When the **CAL** is complete, two additional **Rinse** commands are performed. This prevents a bubble from loading into the chamber. Verify that you have sufficient room in the reservoir to complete these **Rinse** commands.

   When you choose the **VER** command, a **Rinse** command is performed prior to the **VER**. When the **VER** is complete, an additional **Rinse** command is performed. This prevents a bubble from loading into the chamber. Verify that you have sufficient room in the reservoir to complete these **Rinse** commands.

5. To change a location (well or reservoir) for a command, click the command in the **Command Sequence** list, then click the new location in the plate image.

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

6. Click **Save As** to save the new routine. The **Save Routine** dialog box opens.

7. Type the routine name in the **Routine Name** box, then click **OK.**

Editing a Routine

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

2. Click a command in the **Command Sequence** list that you want to edit. Click **Clear** to delete the command, or click in a different well in the plate image to change the location of that command.

> **NOTE:** When you modify a routine, the routine name automatically defaults to **None** in the **Routine Name** list.

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

> **NOTE:** When you choose the **CAL** command, a **Rinse** command is performed prior to the **CAL**. When the **CAL** is complete, two additional **Rinse** commands are performed. This prevents a bubble from loading into the chamber. Verify that you have sufficient room in the reservoir to complete these **Rinse** commands.
>
> When you choose the **VER** command, a **Rinse** command is performed prior to the **VER**. When the **VER** is complete, an additional **Rinse** command is performed. This prevents a bubble from loading into the chamber. Verify that you have sufficient room in the reservoir to complete these **Rinse** commands.

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

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

Deleting a Routine

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

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.

2. Click the routine that you want to delete from the **Routine Name** list.

3. Click **Delete.**

Running a Routine

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.

2. Select a routine to run from the **Routine Name** list.

3. Click **Eject** on the system monitor.

4. Add the appropriate reagents to the plate, reservoirs, and well strips as indicated in the plate image and set the plate on the plate holder.

5. Click **Retract.**

6. Click **Run**. The **Routine Message** dialog box opens when the routine is complete.

7. Click **OK.**

Importing a Routine

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.

2. Click **Import**.

3. In the **Open** dialog box, browse for the file you want to import, then click **Open**. The routine becomes the active routine.
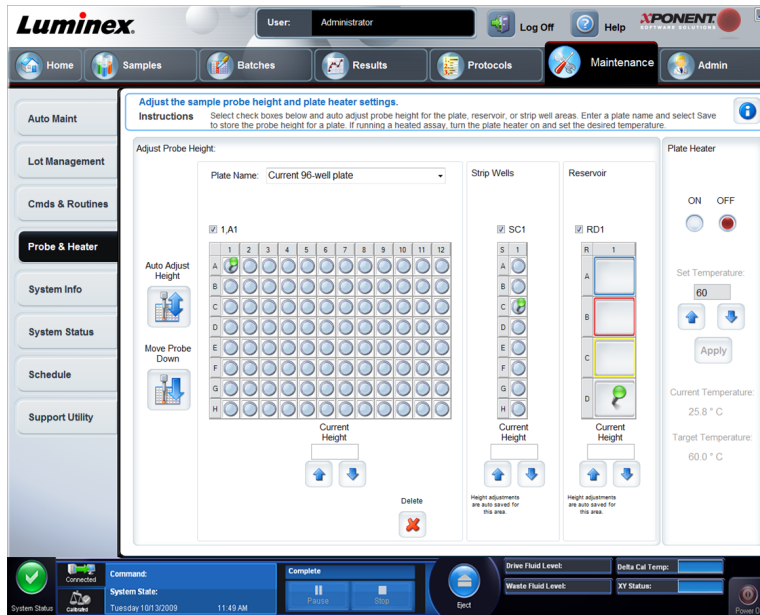
Exporting a Routine

1. Open the **Maintenance** page, then open the **Cmds & Routines** tab.

2. Click **Export**.

3. In the **Save As** dialog box, navigate to the folder where you want to store the routine file, then click **Save**.

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

Probe and Heater Tab

Maintenance > Probe & Heater

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

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

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

- **Plate Location** pin - A green pin that shows the well location used to auto adjust the probe height for the main plate, reservoir, and/or strip wells. The default (and recommended) location for the main plate is well D6.

  - The main plate depicts a 96-well microtiter plate. For information about the plates used in assays, see *Plates*.

  - **Strip Well** depicts the strip well added to the off-plate reagent area when extra wells are required. A strip well is equivalent to one column of a microtiter plate, and, like a microtiter plate, its wells can be flat-bottomed, v-bottomed, etc.

  - **Reservoir** depicts the reservoir added to the off-plate reagent area when procedures require larger amounts of a reagent such as alcohol or distilled water.

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

- **Plate Name** - Type a name for a plate for future use, or select an existing plate from the list.

- **Plate Images** - Assigns a particular well to use for probe height adjustment in the main plate, reservoir, and strip wells. Clicking in a well displays a green pin to denote its use for the height adjustment.

- **Current Height** - Used to fine tune the probe height after an auto-adjust. It displays the current height of the probe, and the arrows below allow for adjustments up or down.

- **Plate Heater** - Enable and disable the Plate Heater by clicking **ON** or **OFF**. Also used to set the temperature of the plate to the number typed in the **Set Temperature** box. Up and down arrows allow half-degree increments. Click **Apply** to apply the new temperature settings. **Current** and **Target** temperatures display at the bottom of this section.

> **NOTE:** The temperature range is 35 to 60° Celsius.

> **WARNING:** The plate heater can become hot enough to cause injury. Use caution when handling after heating.

- **Delete** - Deletes the current plate from the available plates in the **Plate Name** list.
- **Save Plate** - Appears when you have typed a new plate name in the **Plate Name** list, and is used to save the current plate. A warning message opens.
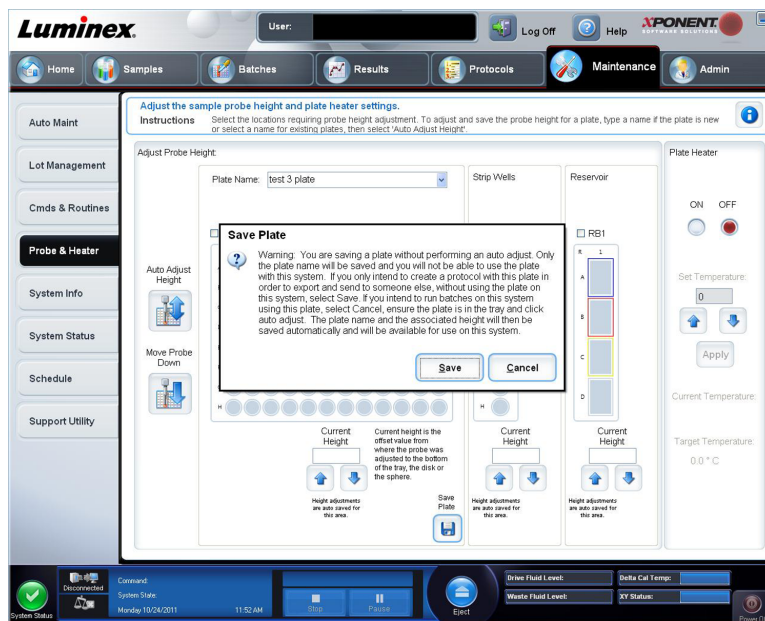
> **NOTE:** If you save a plate without performing an auto adjust, the plate name is saved, but the probe height adjustment is not. If you do this, you cannot use the plate with this instrument. If your purpose is to save this plate to use it when you create a protocol to export and send to someone else, click **Save**. Otherwise, click **Cancel** and perform an auto adjust.

Adjusting the Sample Probe Height

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

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

1. On the **Home** page, click **Probe and Heater** under **Daily Activities**. The **Probe & Heater** tab opens.

2. Use well **D6** (this is the center of a standard 96-well plate).

3. Ensure that the well location is selected on the plate image. A green pin marks the selected well.

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

   - For a standard 96-well plate - none
   - For a Filter-bottom plate - two 5.08 mm disks
   - For a Mylar-bottom plate - two 5.08 mm disks
   - For a conical (v-shaped) plate - one sphere

5. Click **Eject** to eject the plate carrier.

6. Place the off plate reagent block on the plate carrier. Make sure it is well seated so that it clips into place.

7. Place a strip well (provided with the Calibration and the Performance Verification kit) in the off-plate reagent block.

8. In the **Strip Wells** section, click **SD1**.

9. Verify that the reservoir is empty.

10. In the **Reservoir** section, click well **RB1**.

11. Verify that the plate is not warped. Warped plates can lead to incorrect probe height adjustment.

12. Place the plate on the plate carrier with well A1 positioned as indicated on the plate carrier.

13. Click **Retract** to retract the plate carrier.

14. Type a name for the plate in the **Plate Name** box.

15. Click **Auto Adjust Height**. The probe automatically adjusts itself to the locations you selected.

> **NOTE:** The probe height is automatically set to 0.98 mm. The probe automatically adjusts this distance from the bottom of the plate, or calibration disks or spheres.

16. Click **Eject** to eject the plate holder. If you used alignment disks or spheres, remove them from the plate.

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

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

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

FIGURE 7. **Sample Probe Height Adjustment**

System Info Tab

Maintenance > **System Info**

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

This tab contains the following information:
- **Software**
- **Version**

- **Operating System**
- **Licensing**
- **Instrument Type**
- **Serial Number**
- **Firmware Version**
- **XYP Heater Temp**
- **Calibration/Verification Status**
- **Delta Calibration Temp**
- **System Temperature**
- **Last CAL Calibration**
- **Last VER Verification**
- **Last Fluidics Test**
- **Drive Fluid**
- **Waste Fluid**

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

- **Passed** - Indicates that the process completed successfully.
- **Failed** - Indicates that the process was not completed successfully. Failed items appear in red.
- **Not Current** - Indicates that verifiers are not current. Verifiers are not current if you have not calibrated the system since the last time you ran the verifiers.
- **Not Yet Run** - Indicates that this process has not yet been run on the machine.

Copy - Copies the system information to the Windows clipboard. You can then paste it into a text editor such as Notepad.

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

System Status Tab

Maintenance > **System Status**
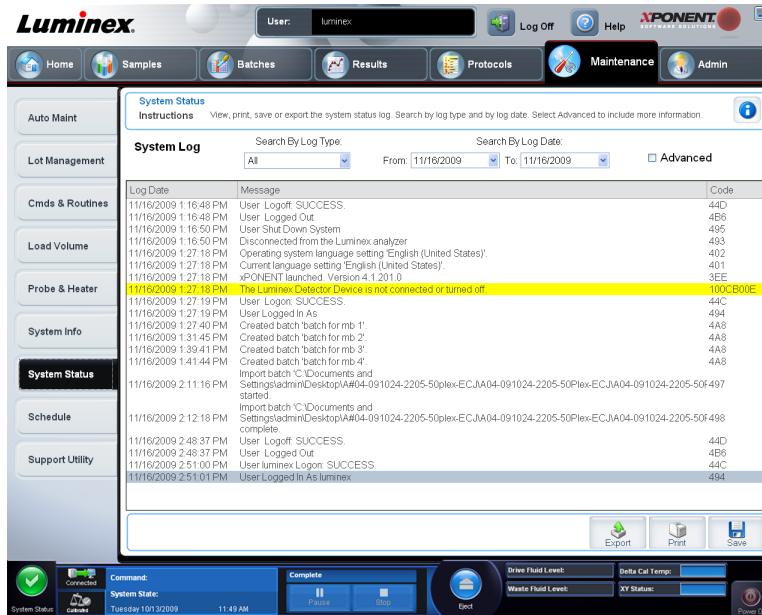
Use this tab to view, print, and save system status log information.

This tab contains the following:

- **Search By Log Type** - Filters the type of log information. Select **All**, **Maintenance**, **Security**, or **Warnings and Errors**.

- **Search By Log Date** - Enables using a date range to display a log of system activities.

- **Advanced** - Displays the following added information in the system log:

  - **Log Type**

  - **User ID**

  - **Error Level**

- **Log** - Displays a list of information about each system process. The following information appears in the list:

  - **Log Date**

  - **Message**

  - **Code**

- **Export** - Opens the **Export System Log** dialog box. Select a name and location for the system log export and click **OK**. Select **Overwrite** to overwrite a 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

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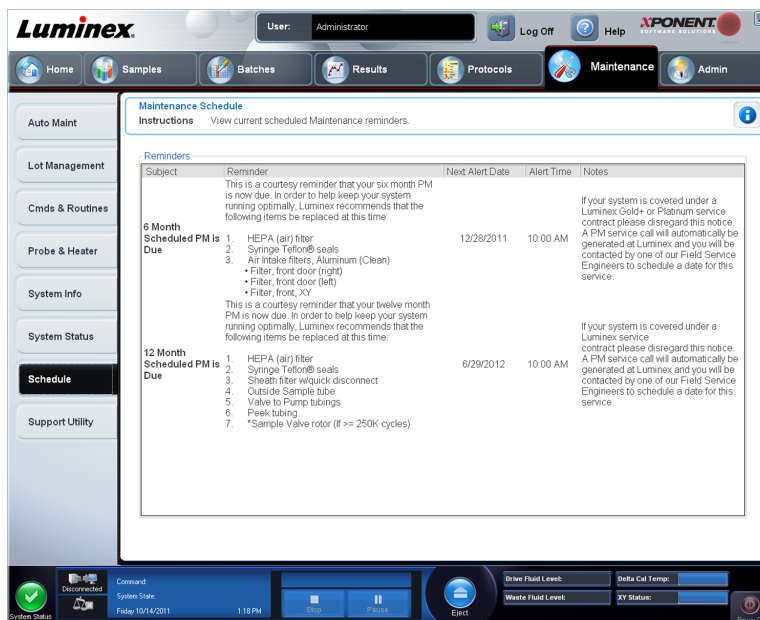
Use this tab to view reminders for scheduled maintenance due to be performed on the analyzer.

Reminders - This section displays reminders for scheduled maintenance.

- **Subject** - The maintenance occasion scheduled for an alert.

- **Reminder** - A description of the maintenance that you need to perform on that occasion.

- **Next Alert Date** - The date on which xPONENT alerts you about the maintenance occasion.

- **Alert Time** - The time at which xPONENT alerts you about the maintenance occasion.

- **Notes** - Any additional information you want to know about the maintenance occasion.

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

Support Utility Tab

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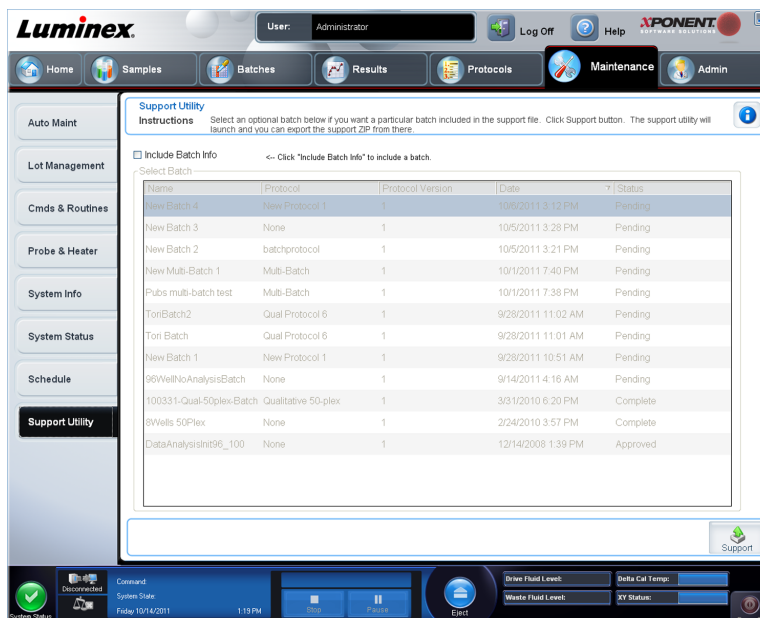
Use this tab to create a support file that you can send to Luminex Technical Support. To include batch information in the support file, use the **Include Batch Information** button and the **Select Batch** table.

- **Include Batch Information** - Select this to include batch infromation with the support file. It actives the **Select Batch** table.

- **Select Batch** - This table includes columns for the following information about a batch:

  - **Name**

  - **Protocol**

  - **Protocol Version**

  - **Date** - Click the arrowhead to sort the batches by date, ascending or descending.

  - **Status**

- **Support** - Click this button to launch the **Support Utility**.

Sending a Support.zip File

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

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

4. Type your company name in the **Company** box.

5. Type your phone number in the **Phone** box.

6. Type your email address in the **Email** box.

7. In the **Comment** box, type a detailed description about the problem you are experiencing.

8. Verify the location where you want to store the file. To change the location, click **Browse**, then navigate to the new folder and click **OK.**

9. Click **Save File**. The saved file includes date and time information.

10. Send an email to support@luminexcorp.com and attach the support file (**xPONENTSupportFile.zip**) to the email.
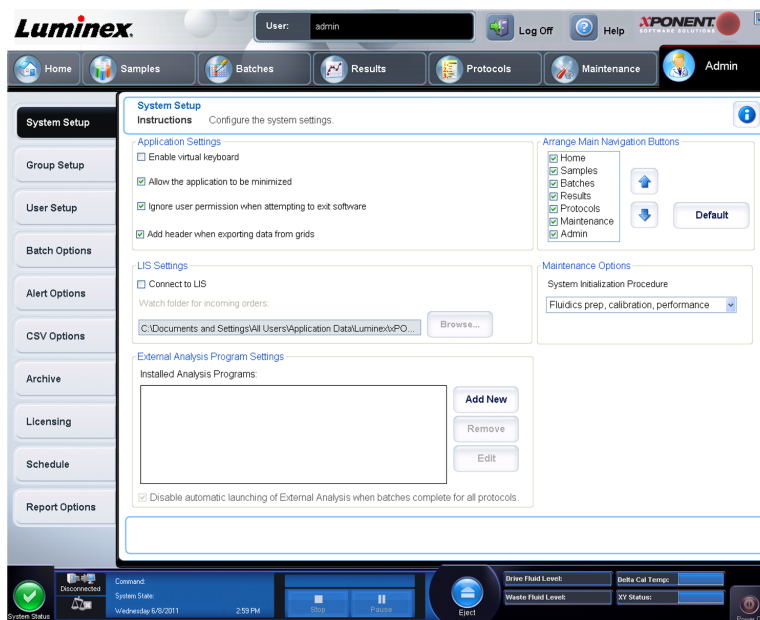
Chapter 7: Admin Page

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

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

System Setup Tab

Admin > **System Setup**

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

Application Settings

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

- **Enable Virtual Keyboard** - Enables the touchscreen virtual keyboard.

- **Allow the application to be minimized** - Enables minimization of the xPONENT software so that the computer's desktop can be accessed. If this check box is clear, the application's minimize button does not function.

- **Ignore user permission when attempting to exit software** - Enables the user to exit the xPONENT software, regardless if permission has been granted in the **User Setup** tab.

- **Add header when exporting data from grids** - Adds a header row when exporting the data.

Select the options you want to enable and click **Save**.

LIS Settings

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

- **Connect to LIS** - Enables connection to the LIS.

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

External Analysis Program Settings

This option is for those using a program other than xPONENT to analyze collected data.

- **Installed Analysis Programs** - Lists the analysis programs currently installed.

- **Add New** - Opens the **New External Analysis Program** dialog box.

- **Browse** - Opens another dialog box to select the file location for the third-party analysis program. The selected location appears in the **Path** box, and the name displays in the **Name** box.

- **Command Line Parameters** - To keep the default command line settings, leave **Command Line Parameters** blank. Otherwise, type the command line parameter for which parameters you want xPONENT to use with the external analysis program. If the information is supplied with the external analysis program documentation, use that information. Otherwise, you can type the following parameters built into xPONENT, in any order:

    - **#c - Output.csv, full file path**

    - **#p - Protocol name**

    - **#b - Batch name**

    - **#u - Logged in user name**

- **Set Default** - Sets the chosen analysis program as the default analysis program for xPONENT.

- **OK** - Saves the chosen settings and exits the dialog box.

- **Cancel** - Cancels changes and exits the dialog box.

- **Remove** - Removes the selected program from the **Installed Analysis Programs** list.

- **Edit** - Opens the New **External Analysis Program** dialog box where you can edit the settings for the selected program.

- **Disable Automatic launching of External Third Party Analysis when batches complete for all protocols** - Disables the automatic launch of the third-party analysis program after batch acquisition.

Arrange Main Page Headers

These options enable you to customize the order in which the Main Navigation Buttons (pages) display.

- **Arrange Main Navigation Buttons** - Select or clear the check boxes to display or remove main page headers. The **Home** page header cannot be removed. The **Admin** page cannot be removed if a security license is not being used, or if the user currently logged in is set up as a member of the Administrator group profile.

- **Main Navigation Arrows** - Click a main page header and then click an up or down arrow to change the selected header's order of appearance at the top of the window. The **Home** page cannot be moved.

- **Default** - Restores the software to the default page header arrangement.

Maintenance Options

This section displays procedures to use when initializing the system.

System Initialization Procedure - Displays the available selections to use as the default system initialization procedure. After selecting an option, click **Save** at the bottom right portion of the window to save the selection as the default procedure.

Adding an External Analysis Program

To add an external analysis program:

1. If the program is on an external media such as a CD or flash drive, insert the media.

2. Click **Add New** to open the **New External Analysis Program** dialog box.

3. Type a name for the external analysis program.

4. Click **Browse** to navigate to the .exe file for that program. Double-click the file name.

5. Type the command line parameter for the parameters you want xPONENT to use with the external analysis program. If the information is supplied with the external analysis program documentation, use that information. Otherwise, you can type the following parameters built into xPONENT, in any order:

   • **#c** - Output.csv, full file path.

   • **#p** - Protocol name.

   • **#b** - Batch name.

   • **#u** - Logged in user name.

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

Editing an Analysis Program

1. In the **Installed Analysis Programs** list, click the program you want to edit.

2. Click **Edit**. The **Edit External Analysis Program** dialog box opens.

3. Edit the **Name**, **Path**, or **Command Line Parameters**, or make this the default analysis program if there are two or more programs installed. The default analysis program name displays in bold text.

Removing an Analysis Program

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

1. In the **Installed Analysis Programs** list, select the program you want to uninstall.

2. Click **Remove.** To prevent the external analysis program from starting automatically, select **Disable automatic launching of External Analysis when batches complete for all protocols**.

Arranging Main Navigation Buttons

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

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

To arrange the main navigation buttons:

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

2. Click a page name and use the up and down arrows to change the order in which the pages display, from left to right.

3. Click **Save**.

4. Click **Default** if you want to restore the main navigation.

Maintenance Options

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

NOTE: See "Daily Activities" on the **Home** page for daily maintenance routines.

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

• The delta calibration temperature exceeds ± 5° C.

• You move the instrument.

• You experience sample acquisition problems.

• You perform maintenance on the instrument, for example, replacing a hardware component.

Available system initialization procedures are as follows:

• Fluidics preparation, calibration, performance verification

• Fluidics preparation, performance verification

• Fluidics preparation

## Defining the System Initialization Routine

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

1. Open the **Admin** page.

2. Click **System Setup**.
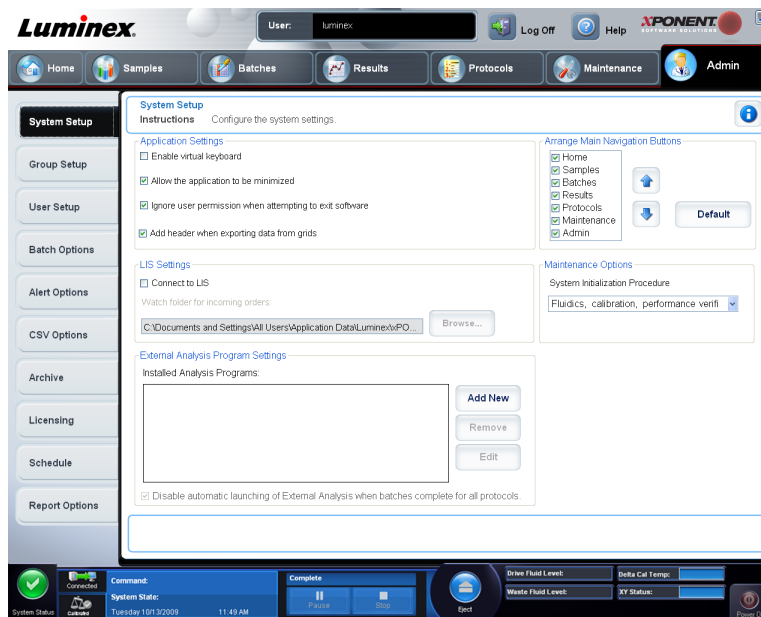
3. Under **Maintenance Options**, select **Fluidics prep, performance verification** from the drop-down list.
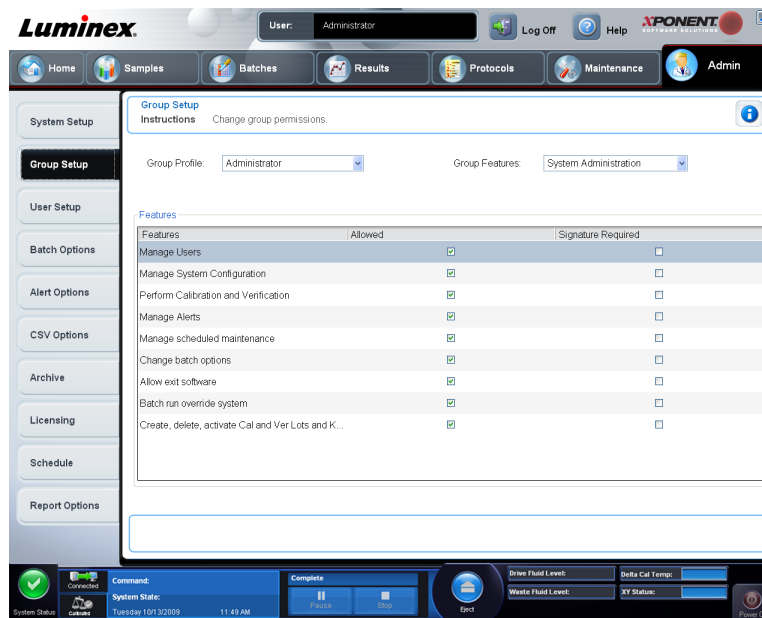
FIGURE 8. **Setting System Initialization Routine**
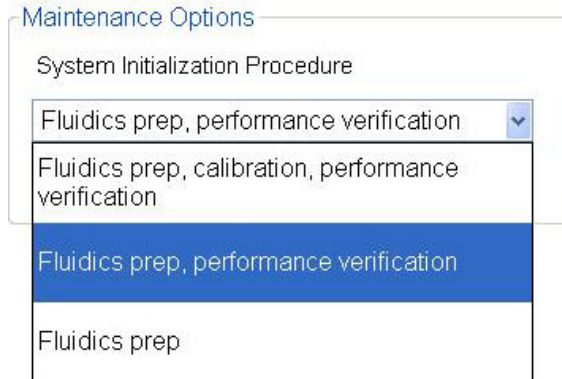
4. Click **Save**.

Group Setup Tab

Admin > **Group Setup**

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

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

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

Group Features - In this **Group Profile** list, select the group profile you want to set up. In the list, select the features you want to assign to the **Group Profile** you selected. Finally, **Features** are used to assign a specific feature to a group. To select a feature, select the check box.

> **Group Profile** - These user groups are predefined:

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

The user belongs to the group to which you assign them.

> **Group Features** - The **Group Features** list contains permission categories. When you select a category from the list, the **Features** section displays the individual tasks that are a part of that category. The following categories are available:

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

The **Allowed** check box next to the a permission in the **Features** section enables the selected group to perform that task. The **Signature Required** check box next to the 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. Activities performed with "Signature Required" are tracked in the **System Log**.

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**
  - **Batch run override system**
  - **Create, delete, activate Cal and Ver Lots and Kits**
- **Batch Management**
  - **Create Batch**
  - **Edit Batch**
  - **Delete Batch**
  - **Run Batch**
  - **Validate and Invalidate Results**
  - **Replay Batch/Recalculate Data**
  - **Approve Batch**
  - **Reanalyze Results**
  - **Save Batch after changing results**
  - **Change Formula**
  - **View Processed Batch Results**
  - **Export Processed Batch Results**
- **Protocol Management**
  - **Create Protocol**
  - **Edit Protocol**
  - **Delete Protocol**
- **Lot and Std/Ctrl Kit Management**
  - **Create Std/Ctrl Kit and Lots**
  - **Edit Std/Ctrl Kit and Lots**
  - **Delete Std/Ctrl Kit and Lots**
- **Import and Export Data**
  - **Export Batch, Protocol, Kit or Lot Files**
  - **Import Batch, Protocol, Kit or Lot Files**
- **Archiving**
  - **Backup/Restore**
  - **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.

Setting Up Group Permissions

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, enable the **Signature Required** check box next to the desired permission to require a digital signature whenever a user in the selected group performs that task. These tasks are tracked in the **System Log**.
4. Click **Save**.

User Setup Tab

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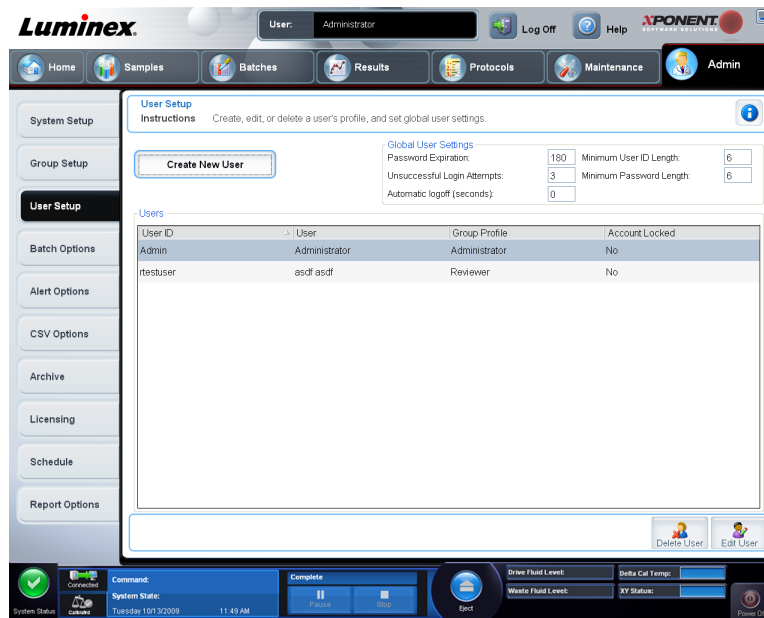
Use this tab to create or edit a user account, remove a user from the system, or view a list of authorized users and their profile details.

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

This tab contains the following:

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

Editing User Permissions

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

Restoring Account Status

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

Create User Account Window

Admin > **User Setup** > **Create User Account**

Use this tab to set the options for a new user. Admin users can assign rights to any and all groups. Either the 21 CFR Part 11 or the Secure package is required.
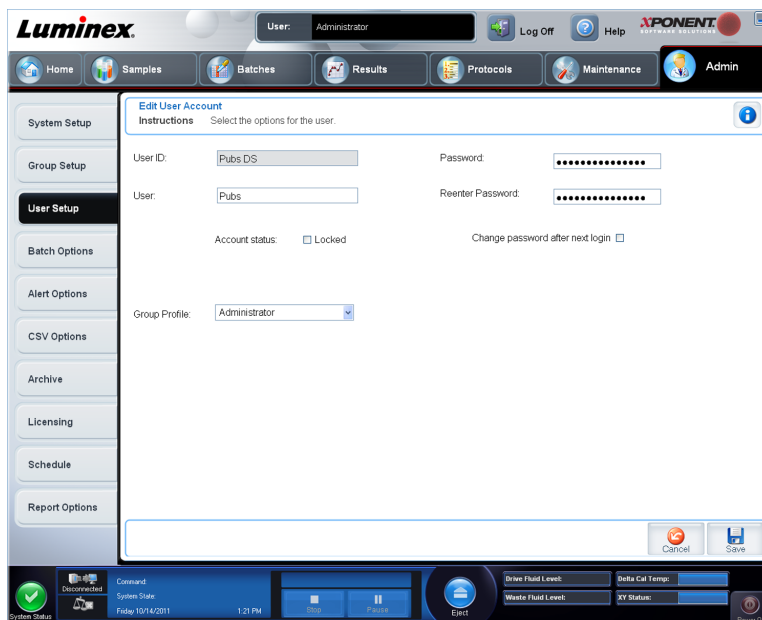
This tab contains the following:

- **User ID**
- **User**
- **Account Status check box**
- **Group Profile** list
- **Password**
- **Reenter Password**
- **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.

Creating a New User

1. Click **Create New User**. The **Create User Account** window opens.
2. Type the user ID in the **User ID** box. The user ID is not case-sensitive. You can change the required number characters for a user ID on the **User Setup** tab. Once you create and delete a user ID, you cannot use that user ID again.
3. Type the user's name in the **User** box.
4. Select the **Account Status** check box to lock the account, or clear this check box to unlock the account.
5. Type a password for the user Password box, then re-type it in the **Reenter Password** box. If you want the user to change the password on first login, select **Change password after first login**. The required length for passwords is set on the **Group Setup** tab.
6. In the **Group Profile** list, select the role for the user your are creating.
7. Click **Save** to cancel to return to **User Setup** without saving.

Edit User Account Window

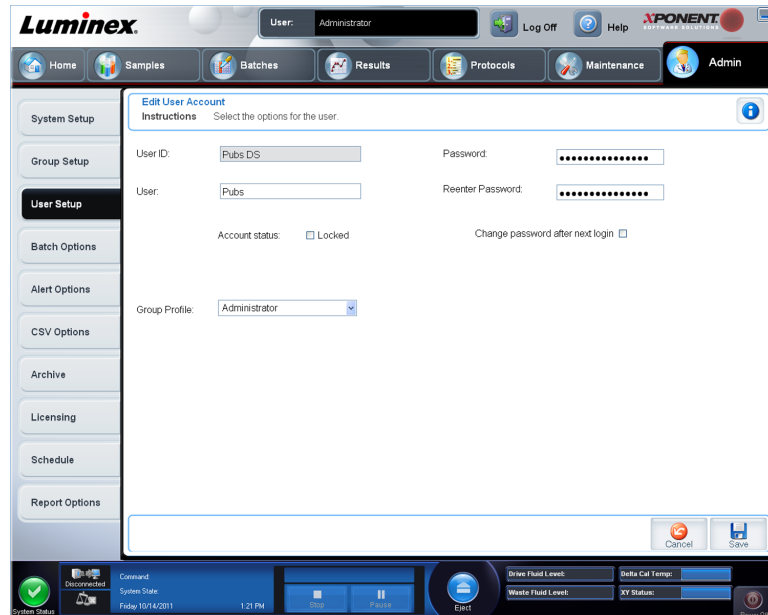**Admin** > **User Setup** > **Edit User Account**

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

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

- **User ID** - The identification of the user.

- **Name** - The user's name.

- **Group Profile** - The user's group or category.

- **Change Password After Next Login** - A box that, when checked, indicates that the user will change his or her password at the next login.

- **Account Status** - Locked or functioning. A check in the **Locked** box indicates that the account is locked due to the maximum number of unsuccessful login attempts.

- **Password** - The user's current password.

- **Reenter Password** - The user's current password, repeated.

- **Save** - Click to save the changes made within the **Edit User Account** window.

- **Cancel** - Click to cancel the process and return to the **User Setup** tab.

Editing User Permissions

1. In the **Users** list, click the user ID, then click **Edit User**.

2. In the **Edit User Account** window, edit the desired information.

3. Click **Save**.

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**.

Batch Options Tab

Admin > **Batch Options**
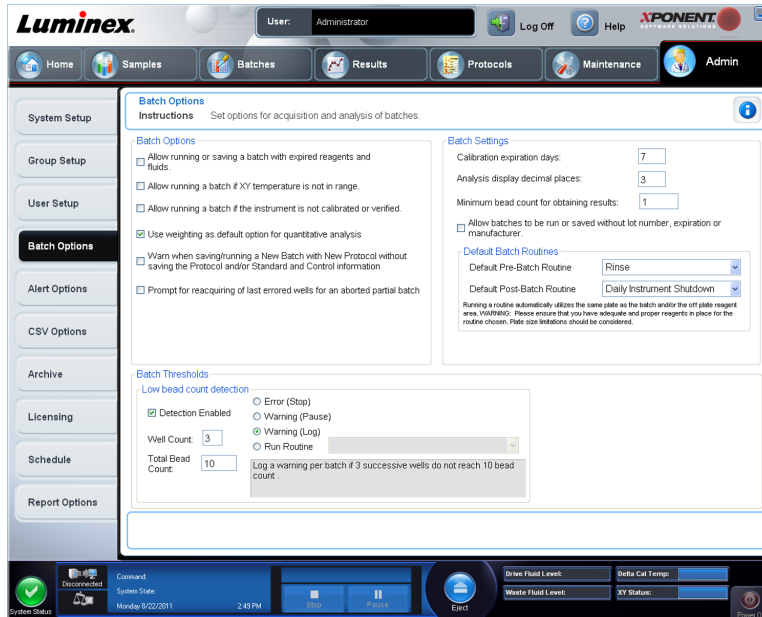
Use this tab to set options for analysis and acquisition of batches.

This tab contains the following:

- **Batch Options** - This section displays the following options:
    - **Allow running or saving a batch with expired reagents and fluids** - Allows batches to run with expired reagents and fluids.
    - **Allow running a batch if XY temperature is not in range** - Allows batches to run if the XY temperature is not in range.
    - **Allow running a batch if the instrument is not calibrated or verified** - Allows batches to run if the instrument is not calibrated.

        > **NOTE:** Settings to enable running/saving with expired agents, running with XY temperature out of range, and running a batch if the instrument is not calibrated or verified are managed at the system level. If one or more of these options is enabled, you cannot run batches while the condition exists. However, if you have the group permission **Batch run override system**, you can run a batch with the condition present. Without **Batch run override system** you are unable to override any or all of these conditions and therefore cannot run or save batches.

    - **Use Weighting as default option for quantitative analysis** - Sets the weighting for quantitative analysis to default to **ON** for new protocols.
    - **Warn when saving/running a New Batch with New Protocol without saving the Protocol and/or Standard and Control information** -Opens a dialog box warning when saving or running a new batch with a new protocol when you haven't saved the protocol and/or standard and control information.
    - **Prompt for reacquiring of the last errored wells for an aborted partial batch** - Allows users to choose to reacquire aborted wells when resuming a stopped/partial batch or to start with the next unacquired well.
- **Batch Settings** - This section displays the following options:
    - **Calibration expiration days** - Type the desired number of days a system calibration remains active before expiring. The default number of days is seven.
    - **Analysis display decimal places** - Type the number of digits the system displays. The default number of digits is three.
    - **Minimum bead count for obtaining results** - Type any whole number from 0 to 1000000. This is the minimum bead count that must be observed by the instrument for a particular analyte before this data is used in statistical calculations and is displayed on the graphs and results table. When set to a number greater than 0, the analyzer does not display data for bead sets not generating events equal to or less than this value. Type 0 to display all events. The default setting is 1.
    - **Allow batches to be run or saved without lot number, expiration or manufacturer** - Allows saving lots without normal required information.
    - **Default Pre-Batch Routine** - System maintenance routines like wash, flush, or clean can be programmed at different points in a batch to prevent clog formation and maintain peak system performance. Pre-batch routines, specifically, are recommended for challenging sample matrices like viscous material or material containing particulates in suspension because these matrices can clog the instrument. Select this option to specify a particular routine to run before running a batch.

   > **NOTE:** A **Rinse** command runs after all pre-batch routines.

    - **Default Post-Batch Routine** - A Luminex Post-Batch routine automatically runs at the end of each batch to clean the sample chamber and maintain peak system performance.

This cannot be deleted or modified and runs by default. However, you can turn off this routine or use a different routine. Luminex recommends cleaning the system with 0.1N NaOH.

- **Default Analysis Graph Axes** - Either Log X Axis or Log Y.

• **Batch Thresholds**

- **Detection enabled** - Enable or disable low bead count detection.

- **Well Count** - When this number of consequetive wells acquire a bead count lower than the number specified in the **Total Bead Count** box, the low bead count action is taken.

- **Total Bead Count** - The number of beads that must be counted per well for the well to pass.

- Action - Select either **Error (Stop)**, **Warning (Pause), Warning (Log)**, or **Run Routine**.The selected action is taken when the number of wells in the **Well Count** box are run without reaching the number of beads in the **Bead Count** box.

• **Cancel** - Cancels changes.

• **Save** - Saves changes.

Alert Options Tab

Admin > **Alert Options**
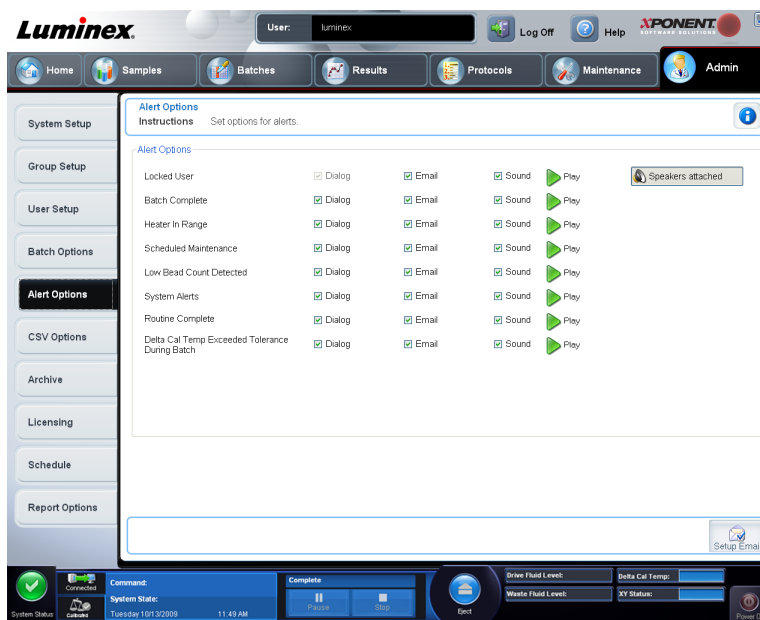
Use this tab to set options for alerts about various system events.

This tab contains the following:

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 xPONENT.
- **Batch Complete** - The batch is finished.
- **Heater In Range** - The plate heater is warmed to the designated range.
- **Scheduled Maintenance** - A scheduled maintenance routine is now due.
- **Low Bead Count Detected** - A bead count below the accepted range is encountered.
- **System Alerts** - One of the following system events has occurred:
  - Empty Sheath fluid
  - Low Sheath fluid
  - Full waste container
  - Activated bubble sense
  - Overloaded syringe pump plunger
  - Probe step loss
  - Sheath pressure error
  - X step loss
  - Y step loss
- **Routine Complete** - The currently running routine is complete.
- **Delta Cal Temp Exceeded Tolerance During Batch** - The delta cal temperature fell outside the designated range during the running of the batch.

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. This is a toggle button.

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

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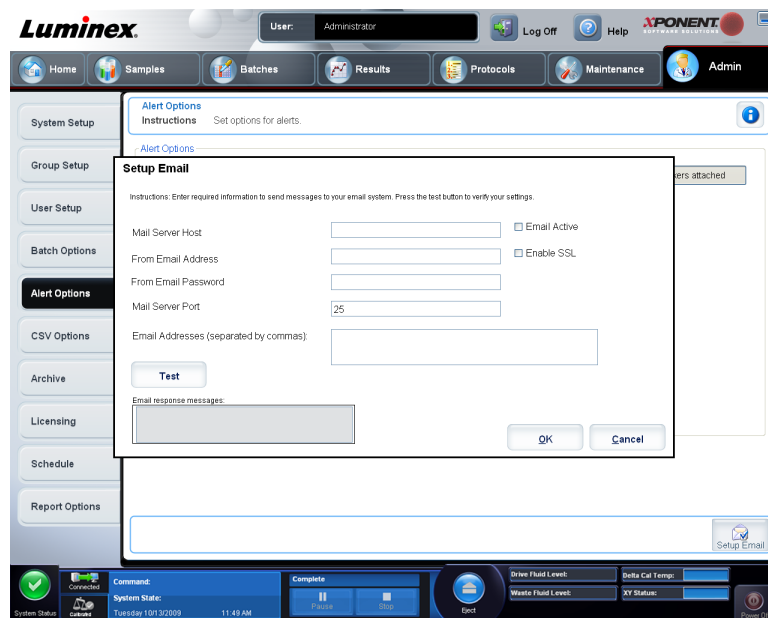
Contact your network administrator to determine the information needed in the **Mail Server Host**, **From Email Address**, **From Email Password**, and **Mail Server Port** boxes, and if you need to select the **Enable SSL (Secure Sockets Layer)** check box.

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

Alert Options Tasks

To set notification options for various events:

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**.

CSV Options Tab

Admin > **CSV Options**
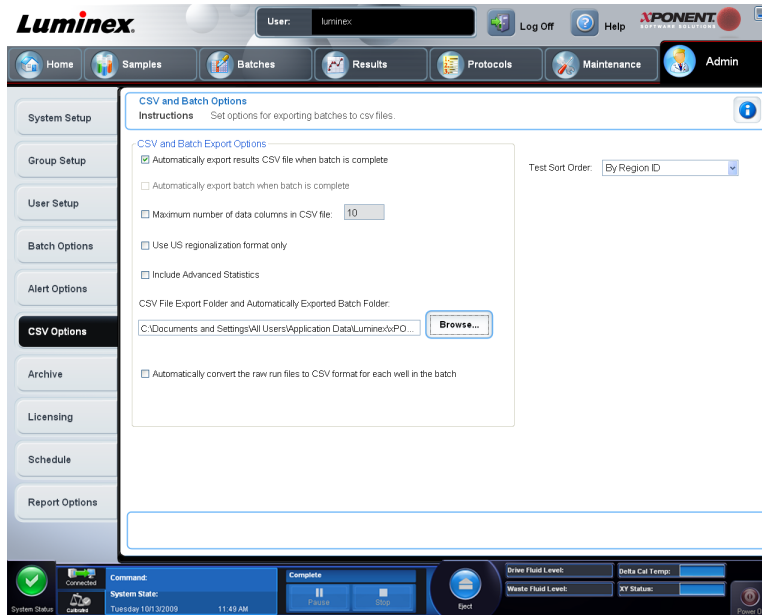
You must have administrative privileges to perform this task if you are using the 21 CFR Part 11 or Secure package. Use this tab to define what the CSV (comma-separated values) file will contain and where it will be stored.

This tab contains the following:

CSV and Batch Export Options

- **Automatically export results CSV file when batch is complete** - Automatically export the results .CSV file when the system finishes analyzing the batch. This allows running programs on exported data without having to manually start the export.

- **Automatically export batch when batch is complete** - Exports batch information automatically when a batch has completed.

- **Maximum number of data columns in CSV file** - Sets the number of individual values in each line of the comma-separated value output file. Each value is separated from the previous and following value by a comma.

- **Use US regionalization format only -** Exports data only in US regionalization format. Use this option if your external analysis program requires a CSV output file with US delimiters.

- **Include Advanced Statistics** - Exports advanced and additional statistics, for example, trimmed counts, in the CSV file. See the CSV file specification for details.

- **CSV Export Folder and Automatically Exported Batch 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.
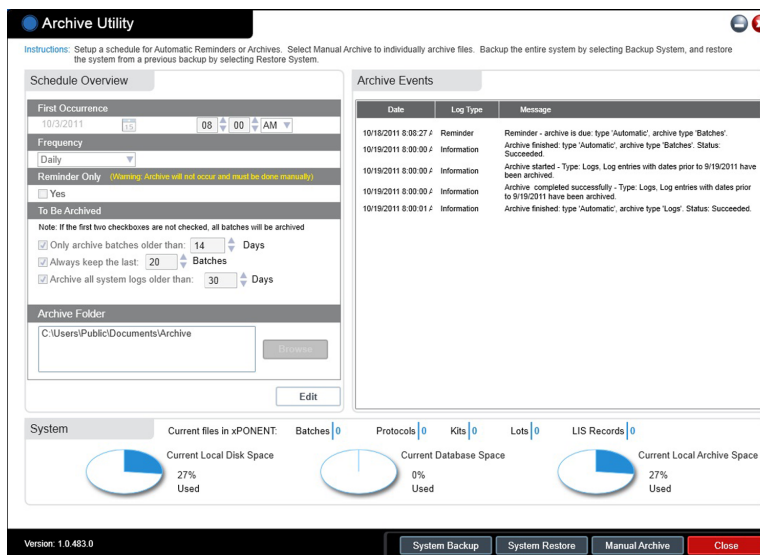
Archive Options Tab

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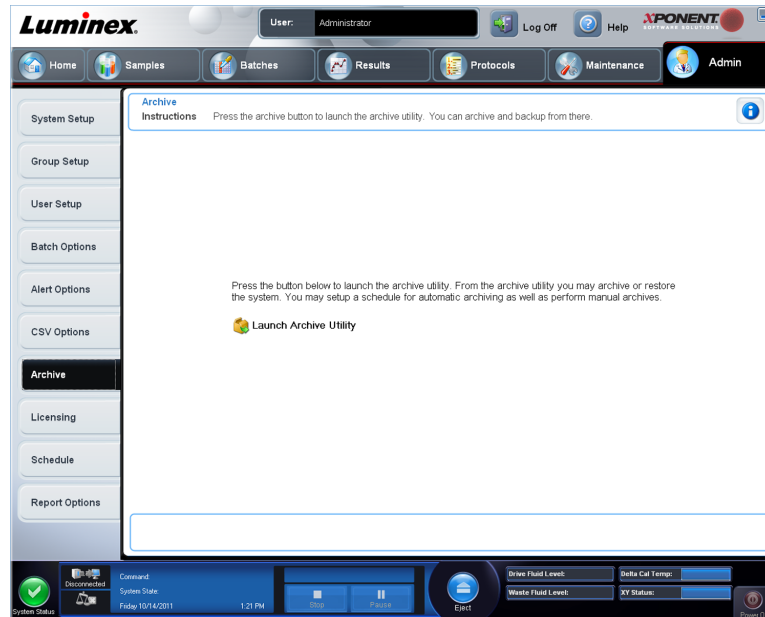
Use this tab to archive all file types - batches, protocols, kits, lots, and LIS records. When you click the **Launch Archive Utility** button, the **Archive Utility** opens.

> **NOTE:** To back up or restore xPONENT files, quit the application and select **XPONENT ARCHIVE** from the Windows **start** menu.

Archive Utility

Admin > Archive > Archive Utility

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

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

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

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

- **Schedule Overview** - Use the selections in this box to schedule archiving.

  - **Edit/Save** - This button toggles between these two settings. Click **Edit** to enable yourself to write over the current settings; click **Save** to save your new settings.

  - **First Occurrence** - Use this to select the date and time for the first automatic archive.

  - **Frequency** - Use this to establish how frequently the system performs the archive process.

  - **Reminder Only** - Use this to establish whether you want a regular reminder from the system so that you can perform archiving manuallly.

  - **To Be Archived** - Use these choices to establish which files are archived.

  - **Archive Folder** - Use this to select the folder in which files are archived. If the output folder is on a network share and the share becomes unavailable, the system archives locally and sends you a note where the archived files are.

- **Archive Events** - This lists all events related to archiving activity, including **Date**, **Type** (Reminder, Warning, or Information), and **Message**.

- **System** - This displays how many files of each type are currently in xPONENT: Batches, Protocols, Kits, Lots, LIS Records. It also shows, in the form of pie charts, how much local disk space, database space, and local archive space is in use.

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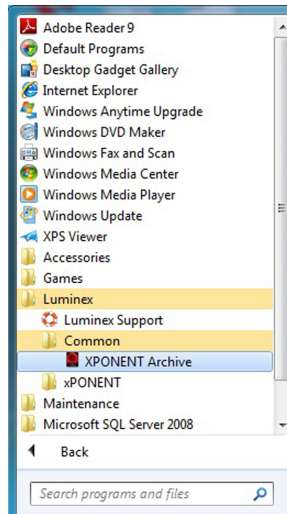
- **System Restore** - Click this to restore your system. It requires a log in and then refers you to the **Start** menu to restore your system.
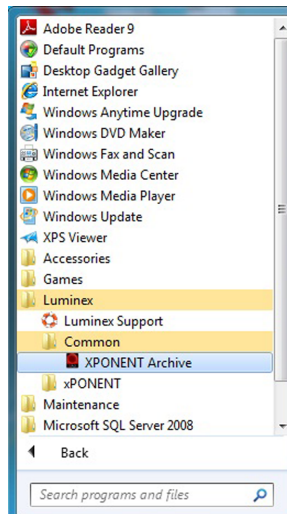

- **Manual Archive** - Click this to perform a manual archive process. It requires a log in and then opens the **Manual Archive** window.
- **Close** - Click this to close the **Archive Utility**.

Setting Up Automatic Archiving

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

1. Specify when you want your archives to begin using the calendar.
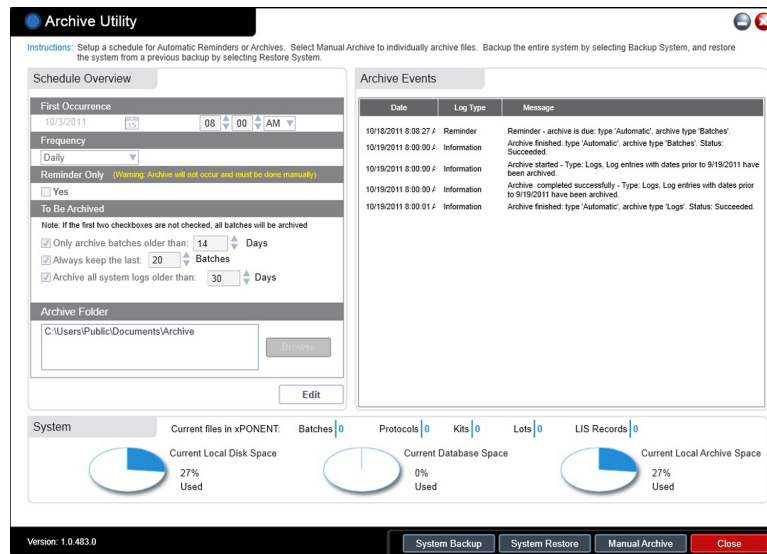
2. Using the drop-down list, select how often you want to perform archives.

3. Select **Reminder Only** to be reminded of the need to archive, after which you must archive manually. Clear this check box to enable automatic archives.

4. In the **To Be Archived** drop-down list, select the date and batch parameters for the files you want to archive:

    • **Only archive batches older than: [*x*] Days**

    • **Always keep the last: [*x*] Batches**

    • **Archive all system logs older than:[*x*] Days**

5. In the **Archive Folder** box, verify the location to which you want to archive the file(s). To change the location, click **Browse**, then navigate to the new location and click **OK**. **Note:** If you change the default archive location, ensure that the **Archive Folder** box reflects that same location when you import those archived files.

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

Performing a Manual Archive

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

1. In the **Archive Utility**, click **Manual Archive** to open the **Manual Archive** window.
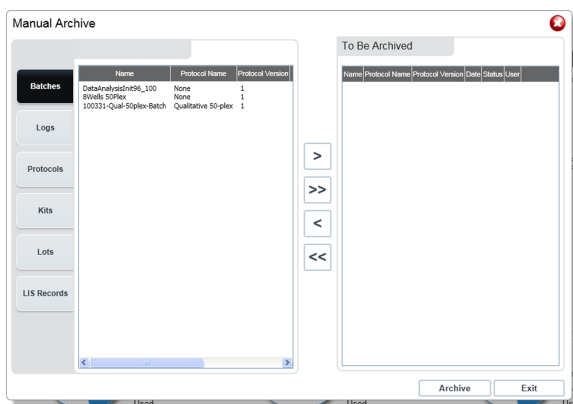
2. Using the tabs on the left side of the window, select the type of files you want to archive:

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

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

3. Select the files you want to archive from the list on the left and use the arrow keys to move those files to the **To Be Archived** box on the right. For log files, select the age of the files, in days.

4. Click **Archive** to move the selected files to the archive.

   NOTE: You must archive each groups of files separately. If you select a different tab without archiving first, xPONENT warns you that you lose the information in the **To Be Archived** box.

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

Licensing Tab

Admin > **Licensing**
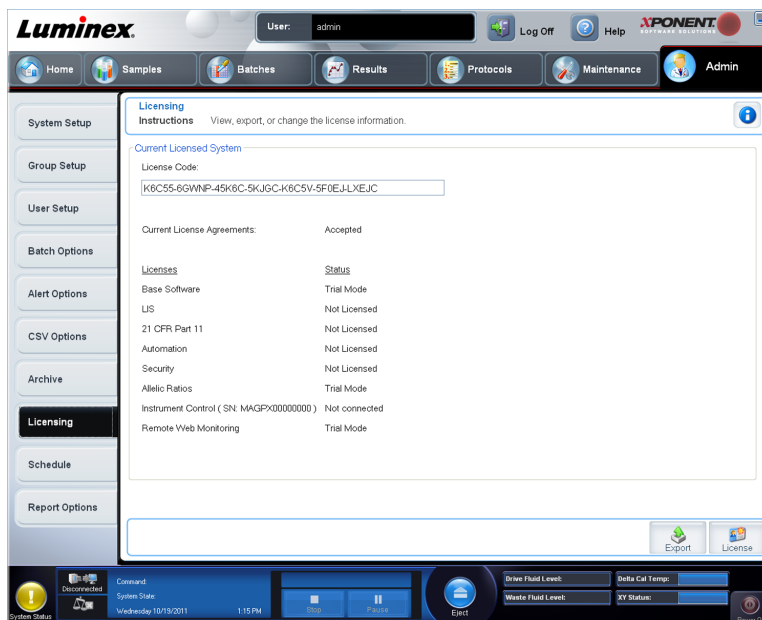
Contact Luminex Technical Support to upgrade xPONENT for MAGPIX or to obtain a new license.

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

Adding a New License Key

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

1. Access the **Admin** page, then the **Licensing** tab.

2. Click **License** (bottom right corner of window).

3. Copy and paste the new key into the **License Code** field. The **License File** field remains blank.

4. Click **OK**. This closes xPONENT, applies the license, and restarts xPONENT.

Schedule Tab

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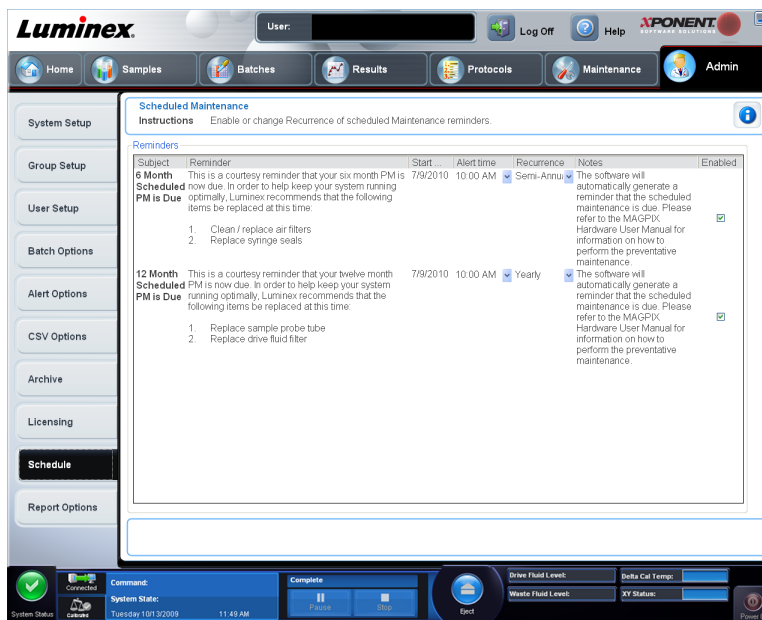
Use the **Schedule** tab to enable or change the recurrence of scheduled maintenance reminders.

- Select the time of day that you want to receive alerts in the **Alert Time** list.

- Select how often you want to receive reminders in the **Recurrence** list.

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

Editing Maintenance Schedule Settings

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

1. Access the **Admin** page, then the **Schedule** tab.

2. On the **Schedule** tab, use the dropdown menus to edit the following items for any scheduled activity:

   • **Alert Time** - the time of day that you want to receive alerts.

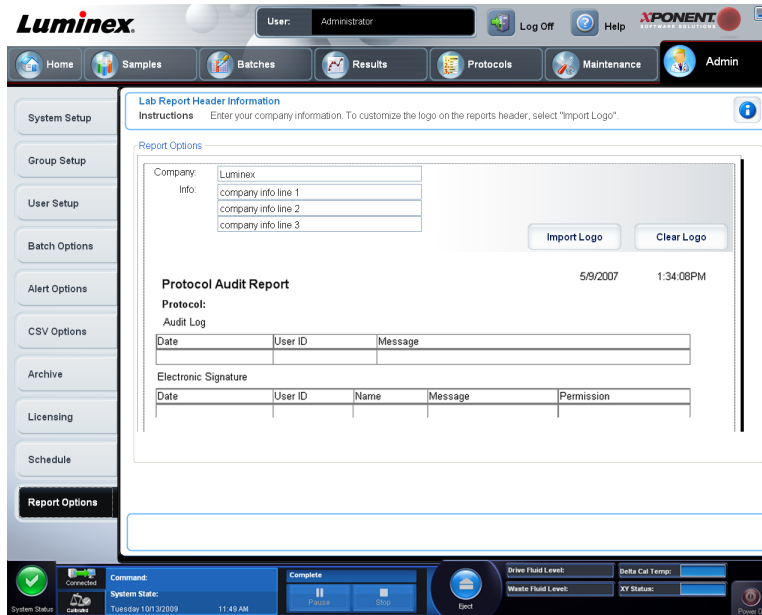   • **Recurrence** - how often you want to receive reminders.
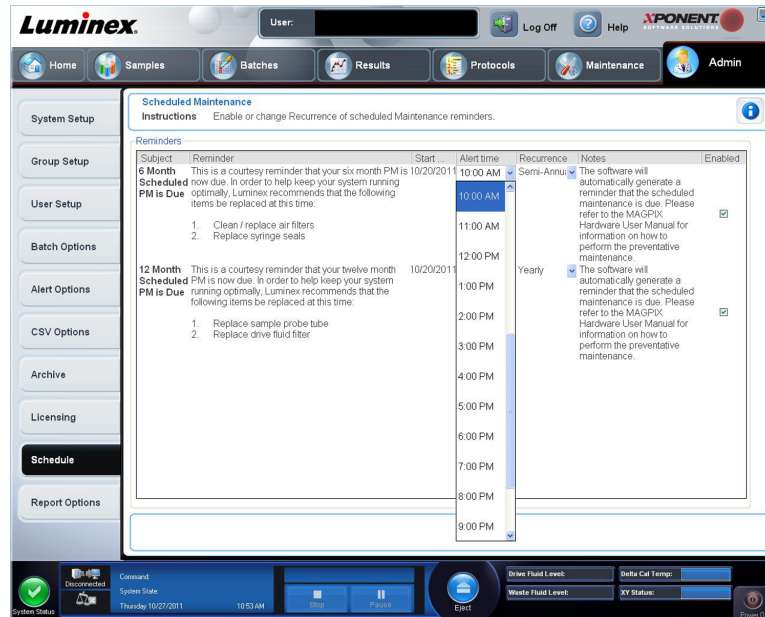
3. Enable or disable the reminders by selecting or clearing the **Enabled** check box.

Report Options Tab

Admin > **Report Options**

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

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

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

2. Click **Import Logo** to open the **Open** dialog box and select the file you want to use for the logo at the top of reports.

3. Click **Clear Logo** to return to the default logo.

4. Click **Save**.

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