Luminex®

User Manual | RUO

xPONENT® 4.2 for FLEXMAP 3D Software

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

© 2012 - 2017 Luminex Corporation. All rights reserved. No part of this publication may be reproduced, transmitted, transcribed, or translated into any language or computer language, in any form or by any means without prior express, written consent of Luminex Corporation.


Luminex Corporation

12212 Technology Blvd.

Austin, TX 78727

U.S.A.

Technical Support

Telephone: 512-381-4397

North America Toll Free: 1-877-785-2323

International Toll Free: + 800-2939-4959

Email: *support@luminexcorp.com*

www.luminexcorp.com

xPONENT® 4.2 for FLEXMAP 3D Software User Manual

89-00002-00-535 Rev A

April 2017

Luminex Corporation (Luminex) reserves the right to modify its products and services at any time. This guide is subject to change without notice. Although prepared to ensure accuracy, Luminex assumes no liability for errors or omissions, or for any damages resulting from the application or use of this information.

Luminex, xMAP, xPONENT, FLEXMAP 3D, MagPlex, MicroPlex are trademarks of Luminex Corporation, and registered in the U.S. and other countries.

All other trademarks, including ProClin®, Cheminert®, Costar®, and Microsoft® Windows® are trademarks of their respective companies.

This product, or use thereof, is covered, in whole or in part, or made by processes covered by one or more patents: *www.luminexcorp.com/patents*.

End-User License Agreement (EULA) for Luminex® Software

This Luminex End-User License Agreement ("EULA") is a legal agreement between you (either an individual or a single entity, also referred herein as "you") the end-user and Luminex Corporation and its affiliates (collectively, "Luminex") regarding the use of Luminex or third party software product provided to you by Luminex or its authorized reseller, which includes computer software, scripts, algorithms, and online or electronic documentation and may include associated media and printed materials (if any) ("SOFTWARE"). The terms also apply to any updates, supplements, web content or Internet-based services, such as remote access.

BY USING, INSTALLING, OR ACCESSING THE SOFTWARE, YOU ACCEPT THESE TERMS. IF YOU DO NOT ACCEPT THESE TERMS, DO NOT USE, INSTALL, AND/OR ACCESS THE SOFTWARE. INSTEAD, RETURN IT TO LUMINEX OR THE LUMINEX AUTHORIZED RESELLER FROM WHICH YOU PURCHASED OR OBTAINED THE SOFTWARE (IF APPLICABLE, FOR A REFUND OR CREDIT). IF YOU COMPLY WITH THESE LICENSE TERMS, YOU HAVE THE RIGHTS TO USE THE SOFTWARE AS SPECIFICALLY SET FORTH BELOW.

1. **OVERVIEW.** The SOFTWARE is protected by copyright laws and international copyright treaties, as well as other intellectual property laws and treaties. The SOFTWARE is licensed, not sold.
2. **ADDITIONAL LICENSING REQUIREMENTS AND/OR USE RIGHTS**.
   a. **Trial and Conversion.** Some or all of the SOFTWARE may be licensed on a trial basis. Your rights to use trial SOFTWARE are limited to the trial period. The trial SOFTWARE and length of the trial period are set forth during the activation process or otherwise set forth in a written agreement between Luminex and you. The SOFTWARE may be used for evaluation purposes only during the trial period and not for any commercial use, including without limitation to any diagnostic use. You may have the option to convert your trial rights to perpetual rights. Conversion options will be presented to you at the expiration of your trial period.
   b. **Activation.** For certain SOFTWARE, you can activate the SOFTWARE by obtaining a license key provided by Luminex Technical Support at support@luminexcorp.com or 1-877-785-2323 or 1-512-381-4397.
   c. **Branding.** You may only add additional branding or other graphics to SOFTWARE with Luminex's express written consent. For certain SOFTWARE, Luminex may permit you to upload your logo onto the SOFTWARE pursuant to the instructions and terms provided by Luminex.
   d. **Upgrades.** You may only obtain updates or upgrades for the SOFTWARE from Luminex Technical Support at orders@luminexcorp.com or authorized resellers. For certain SOFTWARE, Luminex may permit downloading updates or upgrades from a Luminex authorized Website. For more information on obtaining updates from authorized resellers, see *http://www.luminexcorp.com*.
3. **GRANT OF LICENSE.** Subject to the terms and conditions of this EULA, Luminex hereby grants to you a non-exclusive, non-transferable, non-assignable license (without right to sublicense) under Luminex's copyrights and trade secrets to use the SOFTWARE on a single computer running with a single unit of a specific model of Luminex instrument, as such model is identified on the packaging included with the SOFTWARE. For certain SOFTWARE that is not integrated into a Luminex instrument and provided on a separate medium and/or does not require activation, you may make one (1) copy of the SOFTWARE for backup or archival purposes only. For some of such SOFTWARE, you may also install the SOFTWARE on up to two (2) additional computers for purposes of performing ancillary tasks (i.e. preparing templates/protocols, performing further analysis or re-running previous data), provided such computers are at a single location and are NOT connected with a Luminex instrument. In addition, you may purchase the right to use the SOFTWARE on additional computers, as agreed to in writing with Luminex or its authorized reseller, for purposes of performing ancillary tasks (i.e. preparing templates/protocols, performing further analysis or re-running previous data), provided such computers are at a single location and are NOT connected with a Luminex instrument. Although no rights or licenses under any of Luminex's patents are granted by or shall be implied from the license of the SOFTWARE or the sale of a Luminex instrument to you, the purchaser, you may obtain a license under Luminex's patents, if any, to use a Luminex instrument with microsphere beads or cassettes, as applicable, authorized by Luminex, or with kits developed, manufactured, and distributed by licensees authorized in writing by Luminex, by purchasing such beads, cassettes, or kits from Luminex or an authorized Luminex reseller or licensee.
4. **RESTRICTIONS**.
   a. SOFTWARE must only be installed and operated on a single computer running with or in connection with a Luminex instrument, as set forth above.

b. You may not use this SOFTWARE for any commercial purpose, including in the performance of testing services, unless expressly agreed to in writing by Luminex or as authorized in writing by Luminex through an authorized reseller of the SOFTWARE.

c. You may only use the SOFTWARE with microspheres or cassettes, as applicable, authorized by Luminex or with kits developed, manufactured and distributed by licensees authorized in writing by Luminex.

d. You must maintain all proprietary notices on all copies of the SOFTWARE.

e. You may not distribute copies of the SOFTWARE to third parties.

f. You may not reverse-engineer, decompile, disassemble, or otherwise attempt to derive source code from the SOFTWARE.

g. You may not copy (other than one backup or archival copy), sell, distribute, sublicense, rent, lease, transfer or grant any rights in or to all or any portion of the SOFTWARE.

h. You must comply with all applicable laws and regulations, including Food and Drug Administration requirements, regarding the use of the SOFTWARE.

i. You may not modify or prepare derivative works of the SOFTWARE, including modifying any branding or graphics.

j. You may not use the SOFTWARE in a computer-based service business, in the operation of a service bureau, or otherwise for the benefit of any third party, or publicly display visual output of the SOFTWARE.

k. You may not transmit the SOFTWARE over a network, by telephone, or electronically by any means.

l. You acknowledge your obligation to inform your employees, consultants, and associates who will be using the SOFTWARE, of Luminex's labeling literature, warnings, instructions, notices, and other materials regarding proper use that Luminex has provided or may hereafter provide to you.

5. **TERM AND TERMINATION.** Your rights under this EULA are effective until termination. You may terminate this EULA at any time by destroying the SOFTWARE, including all computer programs and documentation, and erasing any copies residing on your computer equipment. Luminex may terminate this EULA upon thirty (30) days written notice to you. Your rights under this EULA automatically terminate without further action on the part of Luminex if you do not comply with any of the terms or conditions of this EULA. Upon any termination of this EULA, you agree to destroy the SOFTWARE and erase any copies residing on your computer equipment.

6. **RIGHTS IN SOFTWARE.** All rights and title in and to the SOFTWARE and any copies thereof are owned by Luminex or its suppliers. This EULA is not a sale and does not transfer to you any title or ownership interest in or to the SOFTWARE or any patent, copyright, trade secret, trade name, trademark or other intellectual property right therein. You shall not remove, alter, or obscure any proprietary notices contained on or within the SOFTWARE and shall reproduce such notices on any back-up copy of the SOFTWARE. All title and intellectual property rights in and to the content which may be accessed through use of the SOFTWARE is the property of the respective content owner and may be protected by applicable copyright or other intellectual property laws and treaties. This EULA grants you no rights to use such content.

7. **EXPORT RESTRICTIONS.** You agree that you will not export or re-export the SOFTWARE to any country, person, entity, or end-user subject to U.S.A. export restrictions or in a manner that is contrary to any local, provincial, state, national, international, and foreign laws or regulations applicable to you. You hereby warrant no state or federal agency has suspended, revoked, or denied your export privileges.

8. **NO WARRANTY.** THE SOFTWARE IS LICENSED "AS IS, WHERE IS.**"** ANY USE OF THE SOFTWARE IS AT YOUR OWN RISK WITHOUT WARRANTY OF ANY KIND. THE SOFTWARE IS PROVIDED FOR USE ONLY WITH LUMINEX PRODUCTS. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, LUMINEX AND ITS SUPPLIERS DISCLAIM ALL CONDITIONS, TERMS, REPRESENTATIONS, AND WARRANTIES, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING BUT NOT LIMITED TO IMPLIED WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY.

9. **LIMITATION OF LIABILITY.** IN NO EVENT SHALL LUMINEX, ITS AFFILIATES, LICENSORS, AUTHORIZED DISTRIBUTORS, OR SUPPLIERS BE LIABLE FOR ANY SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES WHATSOEVER (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, LOSS OF BUSINESS INFORMATION, OR ANY OTHER PECUNIARY LOSS) ARISING OUT OF THE USE OF OR INABILITY TO USE THE SOFTWARE, OR THE RESULTS OF THE USE OF THE SOFTWARE, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR ANY OTHER LEGAL THEORY, AND EVEN IF LUMINEX, ITS AFFILIATES, LICENSORS, AUTHORIZED DISTRIBUTORS, OR SUPPLIERS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. YOU ACKNOWLEDGE THAT

THE “AS IS” AND LIMITATION ON LIABILITY PROVISIONS CONTAINED IN THIS AGREEMENT CONSTITUTE MATERIAL TERMS OF THE CONTRACTUAL BARGAIN BETWEEN THE PARTIES AND THAT NO LICENSE WOULD BE PROVIDED IN THE ABSENCE OF SUCH PROVISIONS.

10. **YOUR REPRESENTATION AND INDEMNITY**. You represent and warrant that you shall use the Software in accordance with the terms of this Agreement, and that any such use of the Software will not violate any law, regulation, judicial order or injunction. You agree to defend, indemnify and hold Luminex and its authorized resellers and licensors, and each of their respective officers, directors, employees, agents, successors and assigns harmless from and against any loss, damage, claim, cost, expense or other liability (including, without limitation, legal fees and amounts reasonably paid in settlement) suffered or incurred by Luminex as a result of any claim or cause of action by a third party arising out of, based upon or relating to: (i) your use of the SOFTWARE, (ii) your use of or reliance on any evaluation, analytic results or other data derived from the SOFTWARE, or (iii) any breach by you or any of your representatives of the terms of this Agreement.
11. **MISCELLANEOUS.** This EULA is governed by the laws of the State of Texas, U.S.A., without reference to conflicts of laws principles. You shall not assign or sublicense or otherwise transfer the rights or license granted hereunder, by agreement or by operation of law, without the prior written consent of Luminex, and all assignments in violation of this prohibition shall be null and void. This EULA is the complete and exclusive agreement of Luminex and you and supersedes all other communications, oral or written, relating to the subject matter hereof. No change to this EULA shall be valid unless in writing and signed by the party against whom enforcement is sought. The waiver or failure of Luminex or you to exercise in any respect any right or rights provided for herein shall not be deemed a waiver of any further right hereunder. If any provision of this EULA is held unenforceable, the remainder of this EULA will continue in full force and effect.
12. **LANGUAGE.** The parties hereto confirm their express wish that this Agreement, as well as all other documents related hereto, including notices, be drawn up in the English language only and declare themselves satisfied therewith; les parties aux présentes confirment leur volonté que cette convention, de même que tous les documents qui s'y rattachent, y compris tout avis, soient rédigés en langue anglaise et s'en déclarent satisfaits.

89-30000-00-419 Rev. D

Table of Contents

Chapter 1: Introduction

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

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

Software Packages

The xPONENT® software has different levels of functionality:

- **Basic** - allows you to acquire data, perform analysis, create protocols and batches, review and print reports, and perform Luminex® system maintenance.
- **Secure** - includes all of the Basic functionality as well as allows the administrator-controlled user permission levels.
- **21 CFR Part 11** - includes all of the Secure functionality, and also requires electronic signatures to perform certain tasks. Electronic signatures are listed in the system log. Electronic signatures for batch functions are listed in the batch audit log.

Other licensable software features are:

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

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

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

About this Manual

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

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

This manual is updated periodically. To ensure that you have a current version, contact Luminex Technical Support. Inquiries can also be sent by email to *support@luminexcorp.com.* The most recent version of this manual, as well as all translations of this manual, are available from Luminex Technical Support.

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 displays 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 displays, 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 displays, displaying the software version information.

Quick Start

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

TABLE 1. **Starting and Using xPONENT®**

To	Go to	Expanded Help
Adjust the sample probe height	**Home > Probe and Heater**	*"Adjusting the Sample Probe Height" on page 27*
Initialize the system	**Home > System Initialization**	Running the *"System Initialization" on page 11* Routine
Run an assay	**Home > Create a new Batch using the highlighted protocol below**	*"Creating a New Batch from an Existing Protocol" on page 15*
Analyze	**Results > Saved Batches**	*"Performing Analysis" on page 18*
Print reports	**Results > Reports**	*"Generating a Report" on page 20*

Warnings, Notes, and Symbols

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

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

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

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

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

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

TABLE 2. **Symbols**

	Biological risks		Caution, hot surface
	Caution		Manufacturer / Date of manufacture

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 displays 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.

Bead Handling

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

Bead (Microsphere) Handling

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

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

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

Limitations

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

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

Do not use this product with strong organic solvents. For information on specific compatibility, visit the Luminex Technical Support website at *www.luminexcorp.com*.

Bead Concentration

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

Repetitive xMAP® Bead Measurements

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

Classification and Reporter Fluorochromes

Each xMAP® bead set is internally dyed with two classification dyes, or three dyes for beads above 100-plex. The fluorescence signal of these dyes allows for classification of each bead set. Since each bead is analyzed individually, even when the sets are mixed in a multiplex assay they can still be distinguished by their emission signals. The fluorescence signal of reporter molecules bound to the surface of each bead set is measured and used to determine the result of each assay in a multiplex. Again, since each bead is analyzed individually, reporter signals for each bead set can be accurately quantified.

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

TABLE 3. **Reporter Fluorochromes Wavelengths**

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

Sample Volume

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

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

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

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

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

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

Sample Dilution

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

Reagents

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

Gating

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

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

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

Plates

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

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

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

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

Chapter 2: Basic Procedures

Starting xPONENT®

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

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

Adding a New License Key

1. Access the **Admin** page **> 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.

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

Logging On to xPONENT®

To log in, enter your user ID at the **System Login** tab. If you are using the secure version of the software, enter your password.

Once you have logged in, the **Home** page displays. The xPONENT® system administrator must set up the User ID and initial logon passwords. Contact your xPONENT system administrator if you have not been assigned a user ID and password.

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

1. On the **System Login** tab, enter your **User ID**.
2. If you are using a secure version of the software, enter your password. The **Home** page displays.

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

Navigation Screen Elements

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

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.

Apply Dilution Down	Sets the dilution levels for the sample.
Print All	Prints all sections or cells of the item.
Print Selection	Prints only the selected section or cell.
Import	Imports a file.
Export Grid Contents	Opens a **File** dialog box. Use the **Browse** button to select a location, file name, and file type (either a text or CSV file) for the export. This exports all data from the right-clicked item.
Cut	Cuts the selected data.
Copy All	Copies all data.
Copy	Copies only the selected data.
Paste	Pastes previously copied text or data into the field.
Delete	Erases text or data from the selection.

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

2. **Connection** Status	Displays the status of the instrument's connection to the PC (Connected or Disconnected). To ensure the instrument connects to the PC, turn on the instrument before you start xPONENT®.
3. Check **Cal/Ver** Status	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.
4.**Command** display	Displays the following: • The command currently running. • The system state (i.e. running, idle, etc.). • Date and time.
5. Progress bar **Stop** button	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**. Stops the system, regardless of command status. Use this only if it does not matter whether the data from the current well is lost.

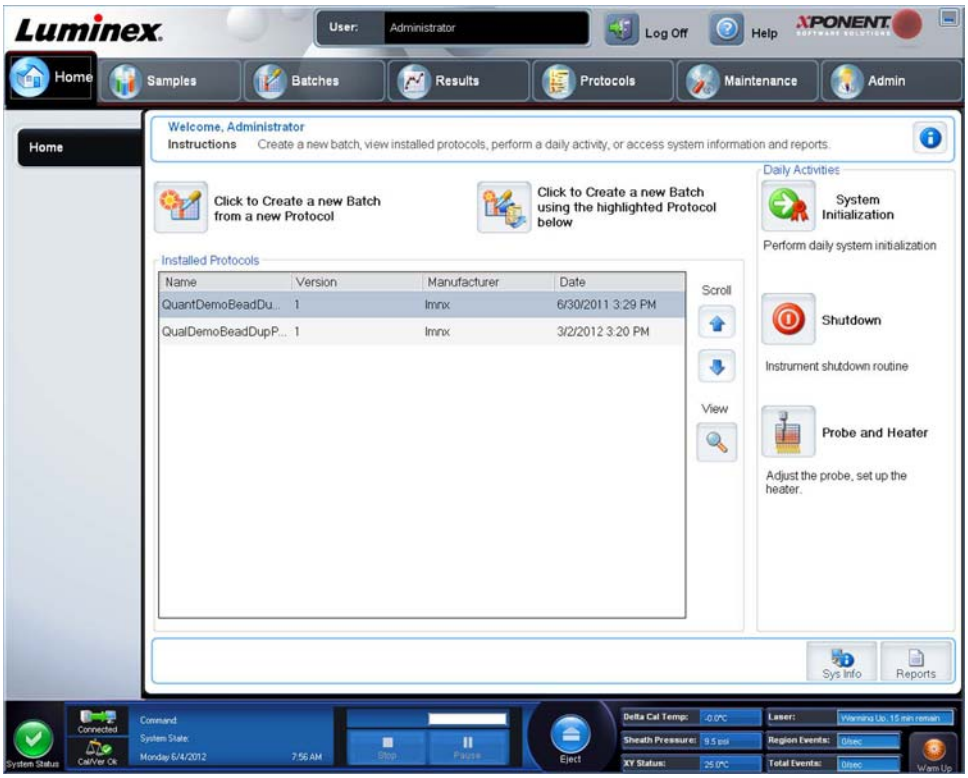
Pause button	Pauses the system after the current command completes. Pause does not stop the system in the middle of running a command. You cannot run another command while the system is paused. Pause the system before stopping it so that it will finish the current command and store the pending batch and then resume exactly where it left off.
6. **Eject** button for plate carrier	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**.
7. **Sheath Pressure**	Displays the sheath pressure in psi. A high or low arrow is displayed if the pressure is trending up or down versus the calibration pressure it turns yellow. When clicked, it displays the **System Info** tab.
8. **Waste Fluid Level**	The waste fluid container liquid level sensor stops the current plate if the waste container is full.
9. **Delta Cal 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 displays the **Auto Maint** tab.
10. **XY Status**	Displays the current location of the command, and the temperature of the plate heating block in degrees Celsius. When clicked, it displays the **Probe & Heater** tab.
Laser	Displays the laser status, including the time remaining until you must warm up the laser again. The **Laser status** box is blue. The button turns yellow when the lasers are turned off and about 10 minutes before they turn off. Clicking the **Warm Up** button restarts the active clock for the laser.
11. **Power Off** button	Powers off the instrument.
Region Events	Displays the number of bead events detected per second that are classified in a region.
Total Events	Displays the number of total events detected per second.
Warm Up Button	Starts or schedules a warmup.

System Info Tab

See *"Sending a Support.zip File" on page 28* regarding information and diagnostics about the Luminex® instrument.

Home Page

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



Initial Startup

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

1. Adjusting the Sample Probe Height - See *"Adjusting the Sample Probe Height" on page 27*.
2. System Initialization - See *"System Initialization" on page 11*.

Revive After Storage Routine

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

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

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

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

4. Click **Run.**

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

System Initialization

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

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

  OR

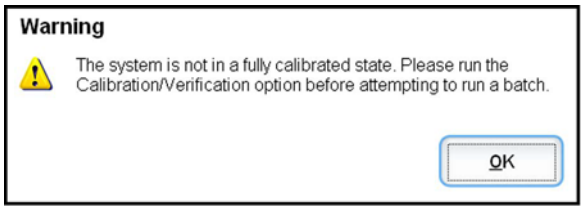
- Open the **Maintenance** page, and then the **Cmds & Routines** tab. Click **Warmup** in the **Commands** section at the left of the screen, and then click the **Run** button at the bottom right to begin the procedure. The warmup process takes 30 minutes to complete.

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

NOTE: See the *"Defining the System Initialization" on page 30* section for more information.

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

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



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

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

- The delta calibration temperature exceeds ± 5°C.
- You move the instrument.
- You experience sample acquisition problems.
- The instrument undergoes hardware maintenance, such as replacement of a part.

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

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

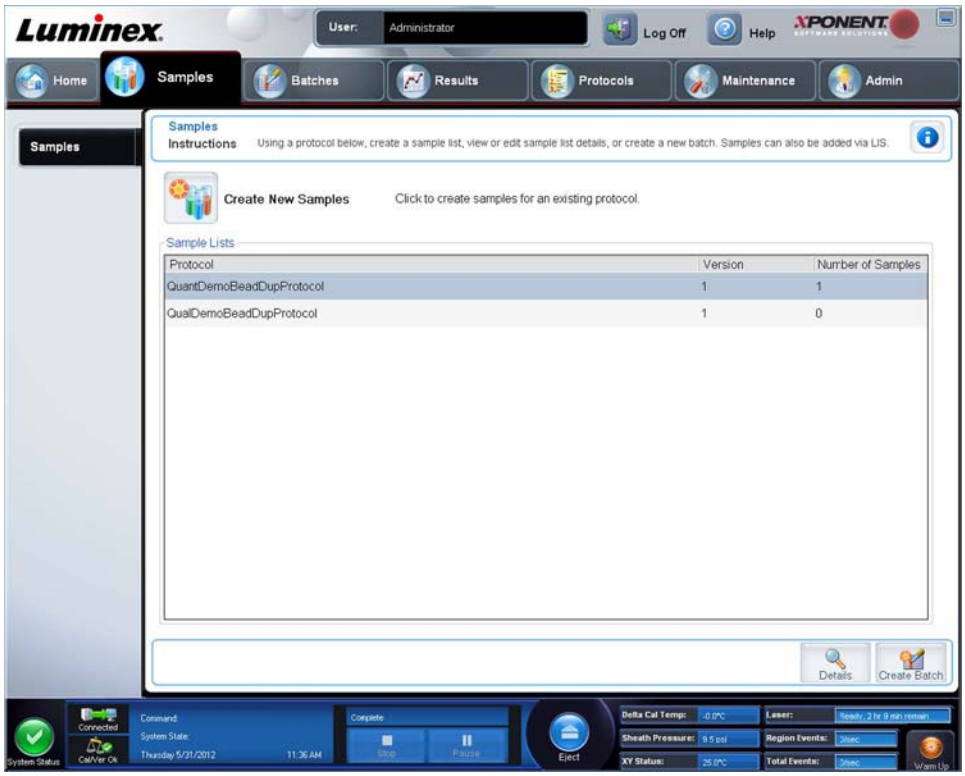
Before you can calibrate or verify the system, you must import FLEXMAP 3D® calibrator and verification bead lot information. Do this using the **Lot Management** tab of the **Maintenance** page. This information is available on the CD that accompanies the Performance Verification Kit and the Calibration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

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

Shutting Down the Analyzer

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

Chapter 3: Samples Page



Creating a New Sample List

1. Open the **Samples** page.
2. In the **Sample Lists** section, choose the protocol you are using for the sample list, then click **Create New Samples**. The **Create Sample** subtab displays.
3. Perform the following steps until you have added all of the samples you want in your samples list.
   a. In the **ID** field, enter the sample ID.

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

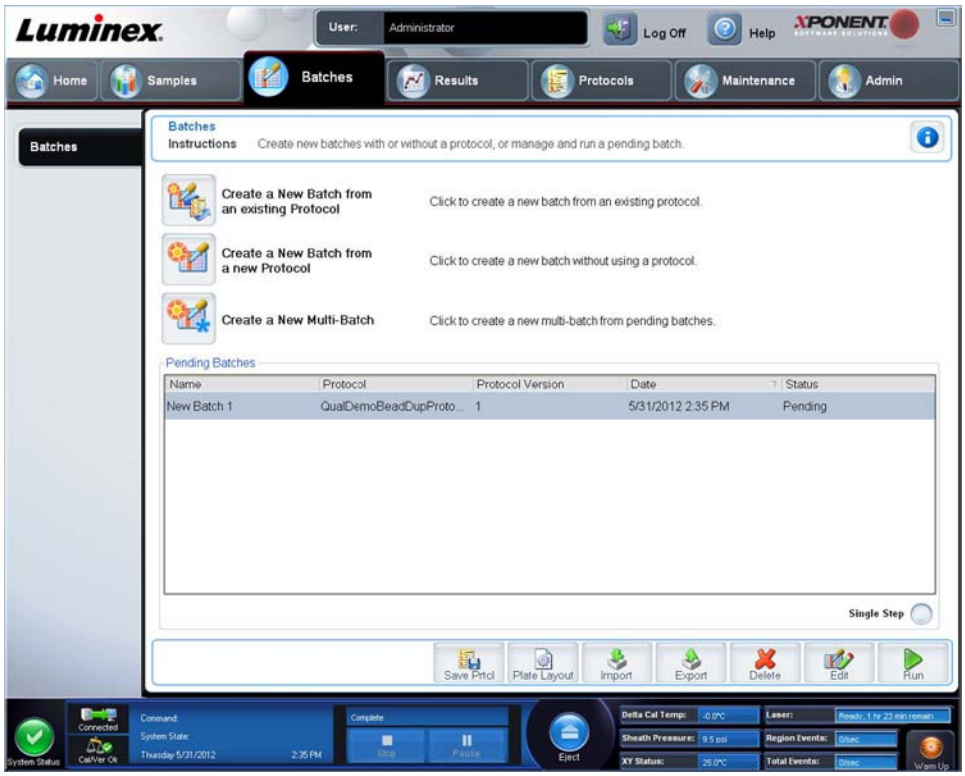
   b. In the **First name** field, enter a patient first name (optional).
   c. In the **Last name** field, enter a patient last name (optional).
   d. In the **Comment** field, enter any comments (optional).
   e. Click **Save** to add the sample to the **Sample** list.
4. After clicking **Save**, click **New** to add more samples.
5. 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 Lists** section, choose the protocol you want to edit, then click **Details**. The **Edit Samples** subtab displays.
3. Click a sample, then use the **Move** arrows to move the sample up or down in the sample list, changing the order in which the sample will be acquired.
4. Click the sample, then click **Edit**.
5. Edit the appropriate fields.
6. Click **Close** once you have completed editing the sample list.

Chapter 4: Batches Page



Setting Up Batches

Batches consist of protocols and samples for acquisition and can span more than one plate. Protocols contain predefined commands that must be included in every batch acquisition.

You can group batches together as a multi-batch. Multi-batches can consist of any number of batches that have been set up from different protocols and are processed consecutively. Multi-batches cannot be run on multiple plates.

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

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

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

Creating 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. Enter the batch name in the **Batch Name** field.
4. Enter a description about the batch in the **Enter Optional Description** field.
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 subtab that displays is the **Stds & Ctrls** subtab. View the details of the active reagents or apply different assay standards, controls, or both or manually enter new information. Click **Next**. If the chosen protocol does not use standards, controls, or both, the next tab that displays is the **Plate Layout** subtab.
7. On the **Plate Layout** tab, assign well commands for this batch.
8. Click **Run Batch** to begin batch acquisition, or click **Save** to save batch information to the **Pending Batch** list to be run at a later time.

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

Creating a New Multi-Batch

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

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 the chosen location. If space limitations create an overlap, an error message displays. Results for each batch are saved as individual batch files.

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

To save a Multi-Batch:

1. Create a new Multi-Batch.
2. Select a pending batch.
3. Enter the name for the **Multi-Batch Name** field.
4. Click **Save**. The **Batches** page displays, and the multi-batch is added to the pending batches list.

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

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. Enter the lot information for the standard and control reagents as specified in the protocol. This lot information is used for every batch set up using the protocol, until it is changed.

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

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

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

Editing a Batch

1. Open the **Batches** page.
2. Click the batch you want to edit, then click **Edit**. The **Protocol** subtab displays.
3. Edit the information as needed on the **Protocol**, **Std & Ctrls**, and **Plate Layout** subtabs.
4. Click **Save** on the **Plate Layout** subtab.

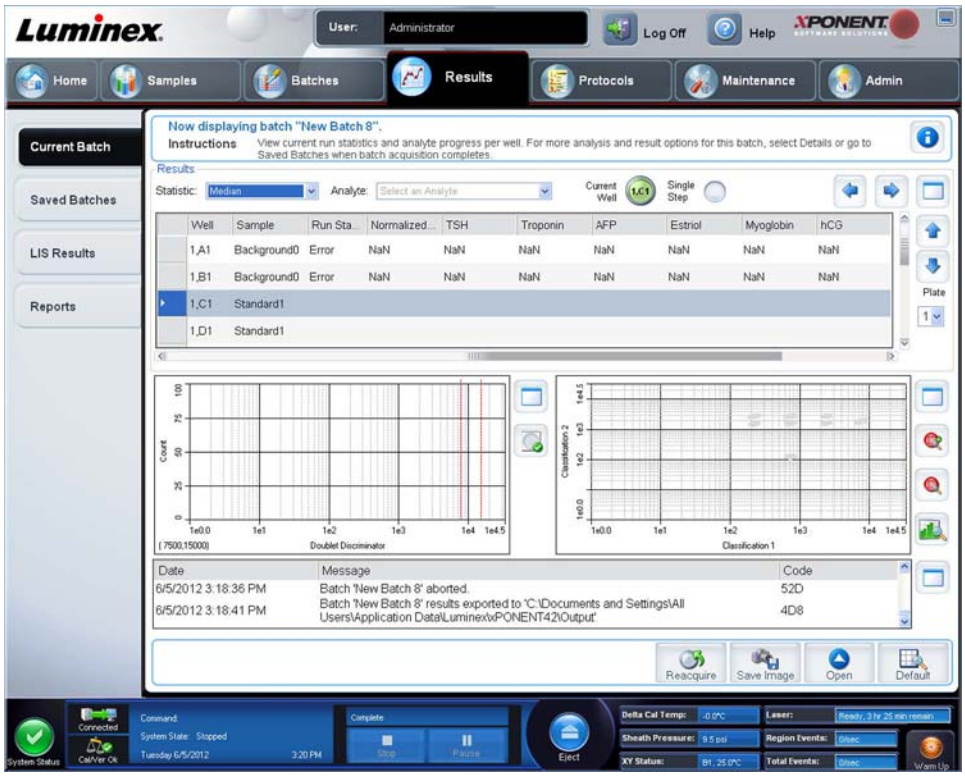
Deleting a Batch

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

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 displays.
3. Click **Yes**.

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

Chapter 5: Results Page



Performing Analysis

The system can be directed to acquire samples in replicate regardless of batch type.

For qualitative batches, qualitative results for replicates are averaged and the reported interpretation is determined from this replicate average.

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

Current Batch Tab

Use the **Current Batch** tab to view results, statistics, and log information related to the current batch, and to perform statistical analysis on batch results. The **Current Batch** 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. The statistics 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 the **Current Batch** tab change based on settings chosen on other application pages.

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 chosen 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.

Validating Standards

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

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

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

Invalidating Standards and Controls

NOTE: You can 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. Navigate to **Results** page **> Saved Batches** tab.
2. Click the batch name, then click **Open**. The **Results** tab displays.
3. Click the square area to the left of the well you wish to invalidate, then click **Invalidate**. The whole row turns red.

Viewing Batch Settings

1. Navigate to **Results** page **> Saved Batches** tab.
2. 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.
6. Navigate to the location where you want to save the batch settings report, and click **Save**.

Viewing Batch Logs

1. Navigate to **Results** page **> Saved Batches** tab.
2. Click the batch for which you want to view details.
3. Click **Open**. The **Results** tab displays.

4. Click **Log** to open the **Log** tab.

Viewing Sample Details

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

Generating a Report

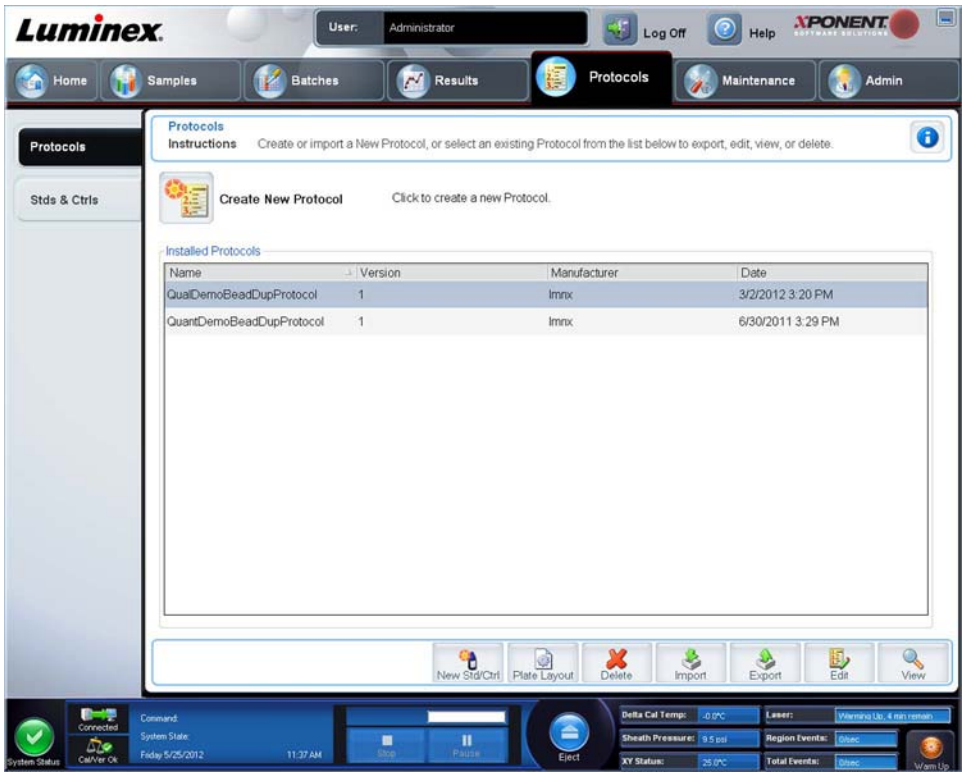
1. Navigate to **Results** page **> Reports** tab.
2. In the **Report** drop-down list, select the category of report: batch, protocol, calibration and verification, performance verification, system log, or advanced. Depending on what you choose in the **Report** list, the content of the **Type** list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

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

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

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

Chapter 6: Protocols Page



Deleting a Protocol

1. Navigate to **Protocols** page **> Protocols** tab.
2. Choose a protocol.
3. Click **Delete**. The **Delete Protocol** dialog box displays.
4. Click **Yes**.

Exporting a Protocol

1. Navigate to **Protocols** page**> Protocols** tab.
2. Choose a protocol.
3. Click **Export**. The **Save as** dialog box displays.
4. Select a location to export the file to, and click **Save**.

Importing a Protocol

1. Navigate to **Protocols** page**> 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. Navigate to **Protocols** page**> Stds & Ctrls** tab.

2. Click **Create New Std/Ctrl Lots** and choose a protocol from the drop-down list in the **Select Protocol** dialog box, then click **OK**. The **Std/Ctrl Details** tab displays.
3. Click **Apply Std/Ctrl Kit** to associate a kit with the protocol. If you are not using a kit, enter the appropriate Standard and Controls information in the **Assay Standard Information** and **Assay Control Information** sections.
4. Click **Save**.

Lots and Kits Procedures

You can edit standard and control lot information. Once a lot is used, changed or modified xPONENT® prompts you for a new lot name.

For assay reagents specified in protocols, you can create new lots, edit lot information, select pre-existing lots for reuse, import lots, and export lots.

Assay kits include standards, controls, or both. Once you enter the assay kit information, the information can be used in multiple protocols. Create separate kits specific for use with each protocol.

Once a lot is used, changed or modified 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.

1. Navigate to **Protocols** page**> Protocols** tab, then click the **Create New Std /Ctrl Lots** button.
2. In the **Select Protocol** dialog box, choose the protocol you want to use for this lot, then click **OK**. The **Std/Ctrl Details** subtab displays.
3. If the protocol uses standards, enter the appropriate information for each standard in the **Assay Standard Information** section. In each **Analyte** column, enter the expected concentration for the analyte.
4. Alternatively, click **Apply Std/Ctrl Kit** and choose 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

1. Navigate to **Protocols** page**> Stds & Ctrls** tab.
2. In the **Installed Kits And Lots** section, choose a lot and then click **Edit**. The **Std/Ctrl Details** tab displays. Change the lot information as appropriate.

Deleting a Lot

1. Navigate to **Protocols** page**> 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.

1. Navigate to **Protocols** page**> 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 displays.
3. Navigate to the location you want to export the file to, then click **Save**.

Importing a Lot

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

Creating a Kit

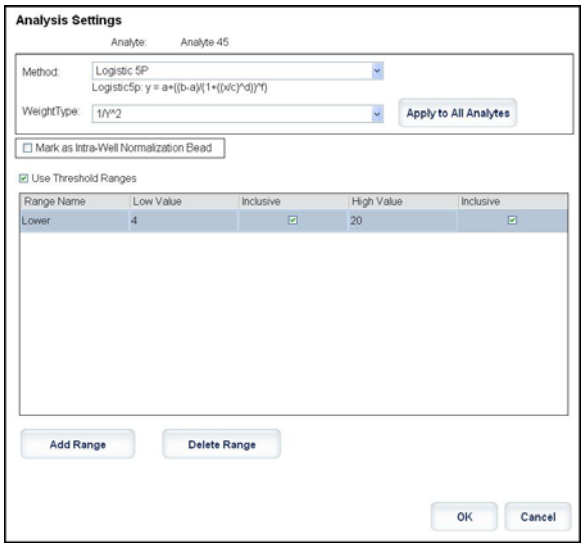
1. Navigate to **Protocols** page**> Protocols** tab.
2. Choose the protocol you want to use for the kit, then click **New Std/Ctrl**. The **Std/Ctrl Details** tab displays.
3. Enter the name of the kit in the **Name** field, the lot number in the **Std/Ctrl Kit Lot#** field, the expiration date using MM/DD/YYYY format in the **Expiration** field, and the manufacturer in the **Manufacturer** field.
4. Click **Apply Std Lot** if you want to apply a standard lot. The **Select Lot** dialog box displays. Click a lot and click **OK**.
5. Click **Apply Ctrl Lot** to apply a control lot. The **Select Lot** dialog box displays. Choose a lot and click **OK**.
6. Alternatively, enter the appropriate information in the **Assay Standard Information** and **Assay Control Information** sections. The number of standards, controls, or both in these sections is defined in the protocol. If your batch uses controls, 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**.

Editing Qualitative Analysis Settings

1. Navigate to **Protocols** page > **Protocols** tab. Choose a protocol and click **Edit**.
2. In the **Settings** tab, enter a new version number before clicking the **Analytes** subtab.
3. From the **Analytes** subtab, click on any analyte in the **Analysis field** to open the **Analysis Settings** dialog box.
4. From the **Method** list, click **Luminex Qualitative** or **No Analysis**. Check **Mark as Intra-Well Normalization Bead** if you want to use a normalization bead. The normalization bead is a microsphere set that is included in the assay as an internal control. It controls for sample variation and can be used to normalize data between samples in a run. An analyte used as a normalization bead will appear blue in the analyte grid.
5. From the **Formulas** list, click **Lum Qual** or **Adv Qual**.
6. Enter a new name for the edited formula in the **Formula Name** field.

Changing the Type of Analysis for an Analyte

To change the type of analysis for an analyte, click this field to open the **Analysis Settings** dialog box and choose another analysis from the list. In the **Analysis Settings** dialog box:



1. Choose a method from the **Method** list.
2. If necessary, choose 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. Enter 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.

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

Chapter 7: Maintenance Page

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" on page 26*.

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

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

Running the Performance Verification Routine

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

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

Importing CAL or VER Kits

Follow these steps to import a CAL or VER kit.

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

Deleting CAL and VER Kit Information

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

CAUTION: A confirmation dialog box will NOT display when deleting a kit.

Creating a New Routine

Create maintenance routines to facilitate your startup procedure, shutdown procedure, troubleshooting, or calibration. Ensure that the maintenance routine you create is consistent with the Luminex® analyzer operations and maintenance requirements. See the Hardware User Manual for more information.

To create a new routine:

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

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

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

Editing a Routine

1. Navigate to **Maintenance** page**> 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 modifying a routine, the routine name automatically defaults to **None** in the **Routine Name** list.

3. Add, delete, or change commands as necessary, then click **Save As**.
4. Enter a different name for the routine to create a new routine, or enter 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. Navigate to **Maintenance** page**> Cmds & Routines** tab.
2. Click the routine that you want to delete from the **Routine Name** list.
3. Click **Delete.**

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

Running a Routine

1. Navigate to **Maintenance** page**> 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 displays when the routine is complete.
7. Click **OK.**

Importing a Routine

1. Navigate to **Maintenance** page**> 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. Navigate to **Maintenance** page**> 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: If you have not previously saved a routine, the **Export** button will not display.

Adjusting the Sample Probe Height

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

NOTE: For additional instructions on adjusting the probe height, see *“Initial Startup” on page 10*.

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

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

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

1. On the **Home** page, under **Daily Activities** click **Probe and Heater**. The **Probe & Heater** tab displays.
2. Select a plate from the **Plate Type** list.
3. If you are using a filter or mylar bottom plate, place a large (5.08) alignment disk into a well. For other plates, no disk is required. Ensure that the well location is selected on the plate image, (a green pin marks the location). To change the well location, click on the desired well in the plate image.
4. Verify that the microtiter plate is not warped. Warped plates can lead to incorrect probe height adjustment.
5. **Eject** the plate holder and add the desired plate.

6. Click **Retract** to retract the plate holder.
7. Enter a name for the plate in the **Plate Name** field, or select a saved plate from the **Plate Name** list.
8. In the **Reservoir** section, click in an off-plate position.
9. In the **Strip-Wells** section, click on a well location.
10. Click **Auto Adjust Height**. The probe automatically adjusts itself to the plate you selected.
11. Click **Save** plate.

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. Enter your name in the **Name** field.
4. Enter your company name in the **Company** field.
5. Enter your phone number in the **Phone** field.
6. Enter your email address in the **Email** field.
7. In the **Comment** field, enter 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 8: Admin Page

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. Enter 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. Enter the command line parameter for the parameters you want xPONENT® to use with the external analysis program. If the information is supplied with the external analysis program documentation, use that information. Otherwise, you can enter 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 displays.
3. Edit the **Name**, **Path**, or **Command Line Parameters**, or make this the default analysis program if there are two or more programs installed. The default analysis program name displays in bold text.

Removing an Analysis Program

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

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

Arranging Main Navigation Buttons

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

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

To arrange the main navigation buttons:

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

Maintenance Options

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

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

NOTE: See Daily Activities on the *"Home Page" on page 10* 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:

- Warmup, fluidics preparation, calibration, performance verification
- Warmup, fluidics preparation, performance verification
- Warmup, fluidics preparation

Defining the System Initialization

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

1. Navigate to **Admin** page **> System Setup** tab.
2. Under **Maintenance Options**, you can select a procedure from the drop-down list.
   - Laser warm-up, fluidics prep, calibration, performance verification
   - Laser warm-up, fluidics prep, performance verification
   - Warmup, fluidics prep
3. Click **Save**.

Group Setup Tab

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

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

Users are assigned to groups. These users then have permissions granted to their group.

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

This tab contains the following:

Group Profile - The following user groups are predefined:

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

The user will belong to the group you select.

Group Features - The **Group Features** list contains permission categories. When you select a category from the list, the **Features** section displays the individual tasks that are a part of that category. The following categories are available

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

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

Clear the **Allowed** check box and select **Signature Required** to require the electronic signature of another user whose account is configured to allow the action. When you do this, the current user cannot complete the action without this electronic signature.

The following permissions are available for these groups:

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

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

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

Editing User Permissions

1. In the **Users** list, click the user ID, then click **Edit User**.
2. 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.

1. In the **User** list, click the user ID, then click **Edit User**.
2. Clear the **Account status: Locked** check box, then click **Save**.

Creating a New User

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

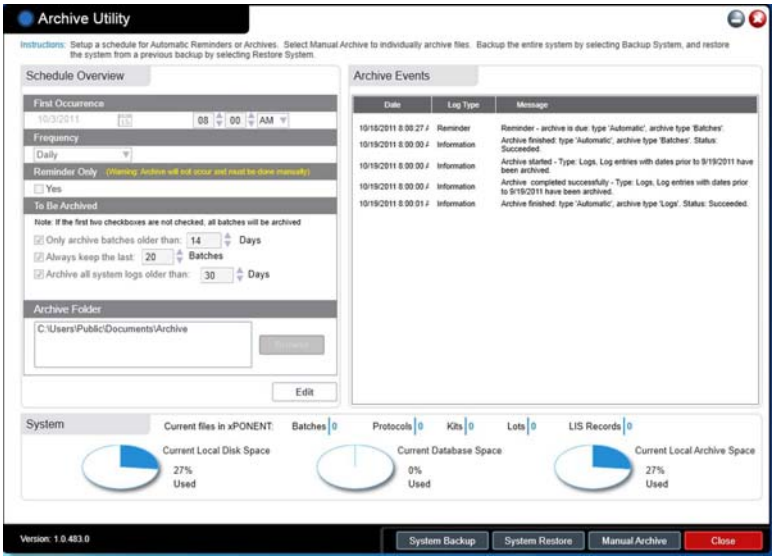
Editing User Permissions

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**.

Setting Up Automatic Archiving

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

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



2. Using the drop-down list, select how often you want to perform archives.
3. Select **Reminder Only** to be reminded of the need to archive, after which you must archive manually. Clear this check box to enable automatic archives.
4. In the **To Be Archived** drop-down list, select the date and batch parameters for the files you want to archive:
   - Only archive batches older than: [*x*] Days
   - Always keep the last: [*x*] Batches
   - Archive all system logs older than:[*x*] Days
5. In the **Archive Folder dialog** box, verify the location to which you want to archive the file(s). To change the location, click **Browse**, then navigate to the new location and click **OK**.

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

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

Performing a Manual Archive

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

1. In the **Archive Utility**, click **Manual Archive** to open the **Manual Archive** window.
2. Using the tabs on the left side of the window, select the type of files you want to archive. Each tab displays a list of files available for archiving, except **Logs**, which requires only a choice of how old, in days, a file has to be archived.
3. Select the files you want to archive from the list on the left and use the arrow keys to move those files to the **To Be Archived** box on the right. For log files, select the age of the files, in days.
4. Click **Archive** to move the selected files to the archive.

   NOTE: You must archive each group of files separately. If you select a different tab without archiving first, xPONENT® warns you that you lose the information in the **To Be Archived** box.

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

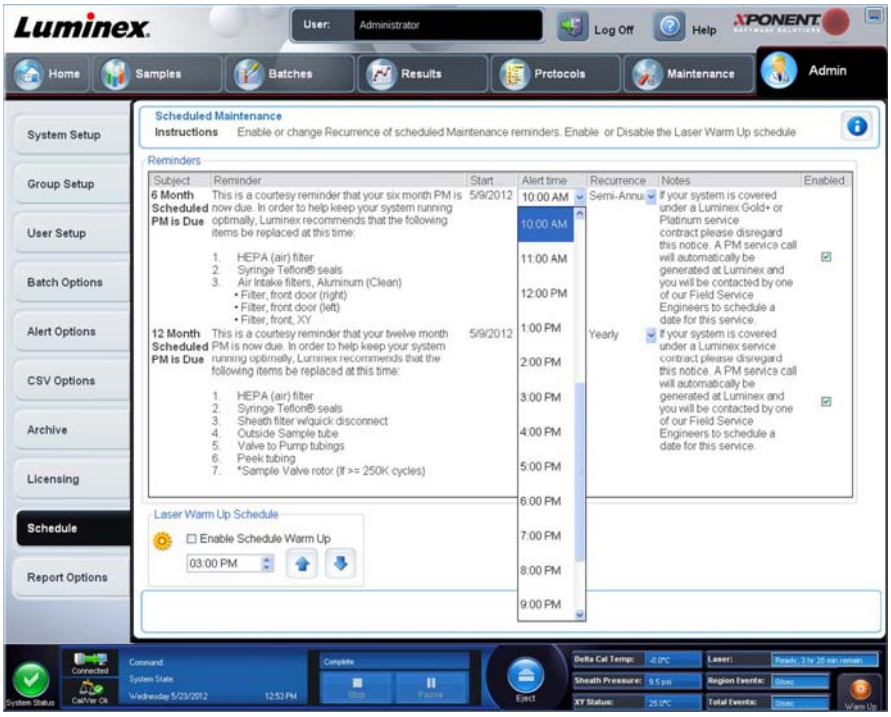
Adding a New License Key

See section *“Adding a New License Key” on page 6* for instructions.

Editing Maintenance Schedule Settings

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

1. Navigate to **Admin** page **> Schedule** tab.
2. On the **Schedule** tab, use the drop-down menus to edit the following items for any scheduled activity:
   - **Alert Time** - the time of day that you want to receive alerts.
   - **Recurrence** - how often you want to receive reminders.
   - **Laser Warm Up Schedule** - Schedule the time you want the lasers to warm up. You can either enable or disable this option.



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

Setting Reports to Display and Print

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

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

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

2. Click **Import Logo** to open the **Open** dialog box and select the file you want to use for the logo at the top of reports.
3. Click **Clear Logo** to return to the default logo.
4. Click **Save**.