

Software Quick Guide **xPONENT[®] for FLEXMAP 3D[®] Version 4.2**



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Starting xPONENT®

To start 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 End User License Agreement may display. Read the license agreement. Select I accept the terms of this license agreement, then click OK.

Start-up Indicators

When you turn on the Luminex[®] FLEXMAP 3D[®] instrument, the following start-up indicators occur:

- The blue light and power supply fan turn on.
- The compressor and MAC valve cycle on (MAC valve makes a distinct sound).
- Immediately, the sample valve cycles (distinct sound).
- Immediately, the probe actuator cycles.
- Immediately, the right syringe pump takes a stroke.
- Immediately, the exhaust fans turn on.
- The left syringe pump takes a stroke.
- Drip to waste occurs.
- The sample valve cycles again approximately 15 seconds to 30 seconds after the left syringe pump completes stroke.

Common Daily Activities

This flowchart illustrates the flow of common daily tasks. For more information about any task, see the Luminex[®] FLEXMAP $3D^{®}$ Installation and Hardware User Manual or the xPONENT[®] for FLEXMAP $3D^{®}$ Software User Manual.

NOTE: For safety and legal information, refer to the *xPONENT*[®] for FLEXMAP 3D[®] Hardware Version User *Manual* that you received with your instrument.

FIGURE 1. Common Daily Activities Flowchart



Software Overview

xPONENT[®] software is organized into a series of pages. As you click each page, applicable tabs open on the left-hand side of the window.

xPONENT opens to the **Home** page. You can access most tasks from the **Home** page.

xPONENT includes the following pages:

- Home Access most commonly used features
- Samples Import or enter sample data (optional)
- Batches Set up batches
- Results Analyze previously acquired batches; view current and saved reports
- Protocols Displays protocols, Stds & Ctrls, and Lot information
- Maintenance Calibrate, verify, and maintain the application
- Admin Perform administrative tasks
- Log Off Log out of software
- Help Access help file

FIGURE 2. xPONENT[®] Home Page

	Click to Cre from a new	Daily Activities				
	Installed Protocols					Laser warm-up, fluidics, calibration
	Name	Version	Manufacturer	Date	Scroll	
	Friday 4.6	2	lmnx	4/6/2012 1:47 PM		6 Shutdown
	NoAnalysisDemoBea	2	Imnx	4/6/2012 2:06 PM		
	NoAnalysisDemoBea	1	Imnx	4/6/2012 2:04 PM		Instrument shutdown routine
	rtg	1	Imnx	4/10/2012 4:46 PM		
	quan v2	1	lmnx	4/10/2012 4.55 PM	View	1
	quan v2	2	Imne	4/10/2012 4:56 PM		Probe and Heater
	Friday 4.6	3	Imnx	4/11/2012 9:14 AM		Adjust the probe, set up the
	arg	1	lmnx	4/12/2012 9:07 AM		heater.
	quan v2	5	lmnx	4/20/2012 10:15 AM		
	quan v2	7	Imnx	4/20/2012 10:16 AM		
	quan v2	7	lmnx	4/20/2012 10:16 AM		

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.

FIGURE 3. xPONENT® System Monitor



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

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

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

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

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

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

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

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

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

Region Events Status - Displays the number of bead events detected per second that are classified in a region.

Total Events Status - Displays the number of total events detected per second.

Warm Up Button - Starts or schedules a warm up.

Initial Startup

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

- 1. "Adjusting the Sample Probe Height"
- 2. "Initializing the System"

Adjusting the Sample Probe Height

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

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

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



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

- 1. On the Home page, click Probe and Heater under Daily Activities. The Probe & Heater tab opens.
- 2. Select a plate in the Plate Type list.
 - 96-well and 384-well Hard Bottom Plates No disk is required. Ensure that the well location is selected on the plate image. Use well D6 for the 96-well plate and well H12 for the 384-well plate (a green pin marks the location). To change the well location, click on the desired well in the plate image.
 - 96-well, 384-well Filter, or Mylar Bottom Plates Use the Probe Height Adjustment Tool (not supplied).



NOTE: You can order the Probe Height Adjustment Tool (P/N CN-0298-01) at http://www.luminexcorp.com.

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

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

5. Place the plate on the plate holder with A1 in the top left corner. Place the reagent block on the plate carrier. Place a wellstrip (provided with the Calibration and the Performance Verification kits) in column S1 of the block. **NOTE:** Make sure there is no liquid in the plate or the off-plate reagent block.

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

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

- 8. In the **Plate** section, click **D6** for the 96-well plate. Click **H12** for the 384-well plate.
- 9. In the **Reservoir** section, click **RB1**.
- 10. In the Strip-Wells section, click SD1.
- 11. Click Auto Adjust Height. The probe automatically adjusts itself and saves it to the plate you selected.
 - **NOTE:** The probe height is automatically set to 0.49 mm. The probe automatically adjusts this distance from the bottom of the plate or calibration disks.



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



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

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

Revive After Storage Routine

NOTE: The Revive After Storage routine is necessary 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. Choose **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.

Initializing the System

xPONENT[®] enables you to customize system initialization using one of these three options:

- Laser warm-up, fluidics prep, calibration, performance verification
- · Laser warm-up, fluidics prep, performance verification
- Warm-up fluidics prep

NOTE: Verify the system daily and calibrate weekly to check system integrity and to ensure that calibration is still valid.

To run the system initialization routine:

- 1. On the **Home** page, click **System Initialization**.
- 2. Choose the performance verification kit from the Performance Verification Kit list.
- 3. Choose the calibration kit from the Calibration Kit list.
- 4. Vortex the xMAP[®] calibrator, verification, and fluidics containers for 30 seconds to ensure homogeneity. Do not dilute xMAP calibrator, verification, or fluidics agents.
- 5. Click Eject on the status bar.
- 6. Place the off-plate reagent block on the plate holder. Load a strip well into the block.
- 7. Load wells with at least 5 drops of the Calibration, Verification, and Fluidics beads, as indicated on the plate image and in the kit insert instructions.
 - **NOTE:** To ensure you get the necessary bead count, invert the calibrator and verifier vials perpendicular to the plate as you add drops to the wells. This ensures the maximum fluid drop size is dispensed into the wells.
- 8. Click Retract.

9. Click Run.

Auto Maint	Instructions	s Select th	he Automated N	faintenance C	ption or Maintenanc	e Command. Then, s	elect the appropria	te kit if applicable.	
Lot Management	Automated Main System Initialization	renance Option (Perfo Verifi	emance cation	Calibration / Verification	System Shutdown				
Cmds & Routines	Command	Location	Reagent	Status	Information	Reagents			
	Warmup		None	Pending		Calibration Kit		Performance Verification	
Probe & Heater	Prime		None	Pending		B21519	~	B22400	_
TODO GITIORET	Alcohol Flush	RB1	70% Alcohol	Pending		Alcohol Fix	ush Vortex each reage	ent vial for 30 seconds. Place	5 drops of e
	Wash	RA1	DI H2O	Pending		Sanitize	with DI H20, 70%	Isopropanol, 10 - 20% house	shold bleach
System Info	Wash	RA1	DI H2O	Pending		Wash Vesh	erc, a appricacie	to the chosen rousine.	
	F3DCAL1	SA1	F3DCAL1	Pending		Sock	R 1 2	5 1 2 3	
System Status	F3DeCAL1	SB1	F3DeCAL1	Pending		F3DCAL1		^ 😳 💿 🥘	
	F3DCAL2	SC1	F3DCAL2	Pending		F3DeCAL	. w	• 😋 🛞 🍈	
Schedule	F3DCAL3	SD1	F3DCAL3	Pending		F3DCAL2		c 🙂 🧐 🥘	
	Wash	RA1	DI H2O	Pending		G F3DCAL3		• 🙂 😻 🔘	
Support Utility	F3DVER1	SA2	F3DVER1	Pending		F3DVERI			
	F3DeVER1	SB2	F3DeVER1	Pending		F3DVER2	I AF		
	F3DVER2	SC2	F3DVER2	Pending		Fluidics1		-000	
	Wash	RA1	DI H2O	Pending		Fluidics2			
	 A.1100240 					Multiple			

Running, Saving, and Printing Reports

xPONENT[®] can provide information in six different report types:

- Batch
- Protocol
- Calibration and Verification (Often used when troubleshooting CAL/VER failures)
- Performance Verification
- System Log
- Advanced (User)

xPONENT can also format your batch or multibatch results in a variety of export formats.

To run, print, and/or save a report:

- 1. Open the **Results** page.
- 2. Click the **Reports** tab.
- 3. In the **Report** drop-down list, choose the report that you want to view.
- 4. In the **Type** drop-down list, choose the type of report you want to view.

NOTE: Select dates if applicable.

- 5. Select the item for which you want to generate the report. If you are creating a **Batch Report**, select the analytes to include in the report.
- 6. Click Generate.

7. Click **Print** to print the report, or **Save** to save the report as a PDF file.

Lumine	🗶 User: Administrator 🧐 Log Off 💿 Help	
🙆 Home 👔	Samples 🕜 Batches 🧭 Results 👔 Protocols 🔗 Maintenance	Admin
Current Batch	Reports Instructions To view and print reports, select a report type and click Generate.	•
Saved Batches	Report: Batch Reports	Zoom: 100% 💌
LIS Results	Hain Report	^
Reports	Luminex Data Interpretation Report Batch Name: Demo Quant Dup Batch xPO40 Protocol Name: Demo Quant Dup Potocol xPO40 Protocol Version: 1 Test Name: Topoini Nemalization Bead Normalization Bead Report Claibration and verification results: Calibration results used for batch : Calibration results used for batch :	
	Save All Print All Save	Print New Report
System Salus	Connand Golden State: Monday 4/23/2012 5 11 PM Display Pages Epide Monday 4/23/2012 5 11 PM Total Pages Total Tevente	Ready, 1 tr 26 min renain

Creating a Protocol

You can create protocols with four types of analysis:

Quantitative - Analyzes unknown data generated with a standard curve.

Qualitative - Analyzes unknown data generated with cutoff ranges based on one standard.

Allele Call - Analyzes data generated as either heterozygotes or homozygotes, based on specific cutoff ratios.

None - Used when analysis of the data will be carried out in another program. (xPONENT[®] reports are unavailable for data acquired with a protocol of type "none".)

You can create each quantitative, qualitative, and allele call protocols using one product composed of a definable number of standards and controls.

There are three steps to creating a protocol. All three are accessible from the **Protocols** page, **Protocols** tab. The three steps are:

- Define settings
- · Select the analysis type
- Define the plate layout

To create a protocol:

- 1. Open the **Protocols** page.
- 2. Click Create New Protocol. The Settings tab opens.
- 3. Type the protocol Name, Version, and Manufacturer, and add an optional description in the empty field.
- 4. Type the following information in the **Acquisition Settings** panel:
 - Volume (10 μL to 200 μL)
 - XY Heater (35°C to 60°C)
 - Timeout (1 second to 250 seconds)

- Bead Type
- Plate Name
- DD Gating
- Reporter Gain
- 5. Choose the analysis type (**Qualitative**, **Quantitative**, **Allele Call**, or **None**), and enter the number of standards and controls.
- 6. Select Fit of all Standards or Mean of Replicates.
- 7. Select Analyze results while acquiring samples if you want to view real-time analysis.
- 8. Click **Next** to open the **Select Analytes** tab. Select analytes by clicking the bead number. The table allows you to name the analyte and to select the analysis type, the units to be measured, and the count.

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🖻 Home 🛛 👔	Samples	Batches	Results	Protocols	Mainte	inance	() A	imin
frotocols	Step 2: Select Instructions	t Analytes for "New Pr Select analytes. Edit an	otocol 1" alyte name, analysis formula, u column to channe analysis or	nits, counts, and select an in	tra-well normalization b	ead, if desired	Select an	
Settings	Analytes Select All			Default Analysis Logistic 5P Weighte	Change	Units: C	Count	Apply
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Analytes			88888	Name	Analysis	Units	Count	Regi
	Ter 1			Analyte 33	Logistic 5P Wei	ghted	100	33
Plate Layout	1-		00000	Analyte 44	Logistic 5P Wei	ghted	100	44
	1240	0000		Analyte 45	Logistic 5P Wei	ghted	100	45
is & Ctris				Analyte 46	Logistic 5P Wei	ghted	100	46
			<u>ăăăăă</u>	Analyte 30	Logistic 5P Wei	ghted	100	36
				Analyte 26	Logistic 5P Wei	ghted	100	26
				Analyte 35	Logistic 5P Wei	ghted	100	35
				Analyte 25	Logistic 5P Wei	ghted	100	25
				Analyte 24	Logistic 5P Wei	ghted	100	24
				Analyte 14	Logistic 5P Wei	ghted	100	14
				Analyte 15	Logistic 5P Wei	ghted	100	15
				Analyte 16	Logistic 5P Wei	ghted	100	16
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	orimand	Corp	aete -	T _ Detta C	al Temp: 10.01C	Laser:	Ready, 1 h	r 53 min re
Connected	ystem State: Stopped			Sheath	Pressure: 95 psi	Region Events	Usec	

- 9. Click **Change** to change the analysis settings.
- 10. Click Next. The Plate Layout tab opens.
- 11. Add standards, controls, unknowns, and maintenance steps to the plate layout.

12. Click **Save** to save the protocol.



Creating a Kit

To create a kit:

- 1. Open the **Protocols** page, then open the **Protocols** tab.
- 2. Select the protocol that you want to use for the kit, then click New Std/Ctrl. The Std/Ctrl Details tab opens.
- 3. Type the name of the kit in the **Name** box, the lot number in the **Std/Ctrl Kit Lot#** box, the expiration date using MM/DD/ YYYY format in the **Expiration** box, and the manufacturer in the **Manufacturer** box.
- 4. Click Apply Std Lot if you want to apply a standard lot. The Select Lot dialog box opens. Select a lot and click 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.

Creating a Batch

There are three batch creation options:

- Create a New Batch from an Existing Protocol (uses a protocol; described in this section)
- Create a New Batch from a New Protocol
- Create a New Multi-batch (runs multiple batches on a single plate at one time)

To create a new batch from an existing protocol:

- 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 of the batch in the **Enter Optional Description** box.

- 5. Click the protocol you want to use in the **Select a Protocol** list. If the protocol you select uses standards and/or controls, the active reagents are shown on the bottom of the screen. Verify that these are the correct standards and controls.
- 6. Click Next.
 - If the protocol you selected uses standards and controls, the **Stds & Ctrls** tab opens. View the details of the active reagents and verify that they are correct; apply different assay standards and controls, or manually enter new information. Click **Next**. The **Plate Layout** tab opens. Confirm that the plate layout conforms to your specific assay instructions.
 - If the protocol you selected does not use standards and/or controls, the **Plate Layout** tab opens. Confirm that the plate layout conforms to your specific assay instructions. Continue with this step.
- 7. On the **Plate Layout** tab, add samples to the plate layout if needed.
- 8. Click **Run Batch** to begin batch acquisition, or click **Save** to save the 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 prompts you to insert the next plate.
 - **NOTE:** If running a Multi-batch, ensure the Plate Name type is the same when setting up the Batch protocol(s).

Viewing Batches

You can observe and analyze current and previously run batches on the **Results** page.

To view batch data:

- 1. Open the **Results** page.
- 2. Click the Current Batch or Saved Batches tab.
- 3. If you want to open a saved batch, highlight the batch and click **Open**.

Current Batch	No Ins Resul	w displ truction Its tic: Me	aying batch "Ins View cum Saved Ba	New Batch ent run stati tches when	e Select an Ar	e progress per w n completes.	ell. For more :	analysis and result	t options for thi Single	s batch, select D	etails or go to	
Saved Batches		Well	Sample	Run Sta	Normalizati	TSH	Troponin	AFP	Step Step	Myoglobin	hCG	
IS Results		1,A1	Background0	Error	NaN	NaN	NaN	NaN	NaN	NaN	NaN	
		1,B1	Background0	Error	NaN	NaN	NaN	NaN	NaN	NaN	NaN	
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Shutting Down the Instrument

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 may cause problems with calibration, verification, and data acquisition; they may 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. Fill the labeled area of the off-plate reagent block (**RB2**) with a 10% to 20% household bleach and water solution.
- 3. Add deionized water to the labeled area of the off-plate reagent block (RA1).
- 4. Click Run.

Technical Support

For more information, visit the Luminex FAQ page at http://www.luminexcorp.com.

You can access the Technical Support website using a user name and password at http://www.luminexcorp.com.

Contact Luminex Technical support at:

- Phone: 512-381-4397
- Toll Free: 1-877-785-2323
- International: + 800-2939-4959
- Fax: 512-219-5114
- Email: *support@luminexcorp.com*.
 - **NOTE:** When contacting Technical Support, have the instrument serial number available for reference. It is also recommended that you generate a Support Utility File (SUF) for submission to Technical Support. For information on sending a support file, see the "Support Utility Tab" section within the Luminex[®] xPONENT[®] 4.2 Software User Manual IVD.