

Luminex

User Quick Guide | IVD

MAGPIX[®]

IVD



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MAGPIX® User Quick Guide



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Chapter 1: Starting the MAGPIX System for the First Time

Detailed instructions on how to install the MAGPIX System are provided in the *PC Installation Instructions* (89-30000-00-263) and *Installing MAGPIX* (89-30000-00-236) foldouts that you received with the instrument.

This manual provides step-by-step instructions on how to start your MAGPIX system for the first time, how to perform daily operations, and how to properly maintain the instrument.

WARNING: Improper installation or use of the MAGPIX System can result in injury, damage to the instrument, and/or incorrect results. Before installing or using MAGPIX you must complete the training modules located in the **Training** tab at <http://www.luminexcorp.com/MAGPIX>.

Additional "How-To" videos describing specific operations can be found on the same page under the **Support** tab.

Starting xPONENT

Perform the following steps if xPONENT does not launch automatically after you turn on the computer.

- On the PC desktop, click the Luminex xPONENT icon, or click **Start > All Programs > Luminex > xPONENT > Luminex xPONENT**.
- If you have a trial license, click **OK** in the dialog box that opens.
- 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* and the *Software User Manual* that you received with your instrument.

Start-up Indicators

When you turn on the Luminex MAGPIX system, the following start up indicators occur:

- Blue light indicator turns on.
- Fans turn on.
- Syringe pump initializes.
- The filter wheel initializes.
- Software connects to the instrument.

NOTE: It may take several minutes for the instrument to initialize and connect to the software.

The Software Connectivity indicator is located on the lower left corner of the software screen.

Log On to xPONENT

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



CAUTION: Use of this software by untrained personnel can result in inaccurate data and test results. Personnel who will use xPONENT must read this manual thoroughly before operating the software.

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

Initial Startup

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

1. Adjust the Sample Probe Height
2. Revive After Storage (Luminex) Routine
3. System Initialization
 - Fluidics Preparation
 - Calibration
 - Performance Verification

Adjusting the Sample Probe Height

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

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

1. On the **Home** page, click **Probe and Heater** under **Daily Activities**. The **Probe & Heater** tab opens.
2. Based on the type of plate you are using, place alignment disks or an alignment sphere from the Height Alignment Kit in the well.

NOTE: Luminex recommends that you use well **D6** (this is the center of a standard 96-well plate).

- Filter-bottom plate - two (2) 5.08mm disks
- Mylar-bottom plate - two (2) 5.08mm disks
- Conical (V-shaped) plate - one (1) sphere

If you are using a standard 96-well plate, you do not need to use any of the disks or spheres in the Height Alignment Kit.

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

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

15. Click **Eject** to eject the plate holder. If you used alignment disks or spheres, remove them from the plate.
16. Click **Save** to save the probe height settings for the plate and the well.

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

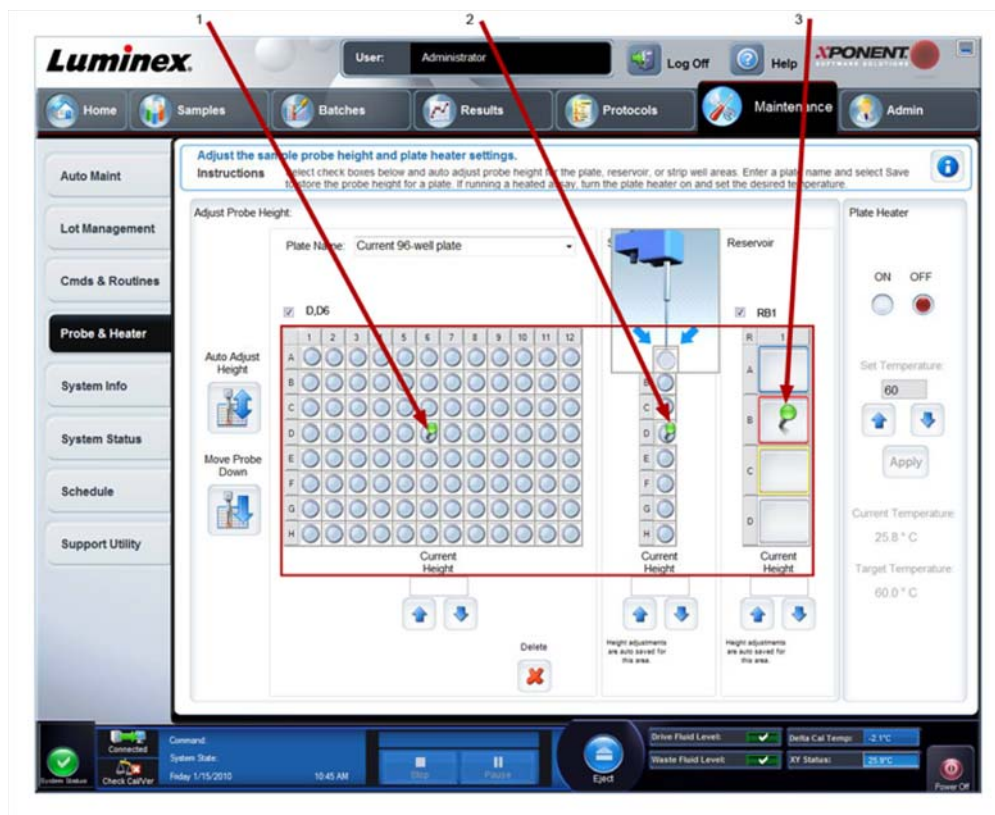


CAUTION: Ensure that the probe height is set correctly before calibrating the system.



CAUTION: 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. To adjust the height of the sample probe, follow the steps above.

FIGURE 1. Sample Probe Height Adjustment



1. Well D6	2. Strip well SD1	3. Reservoir RB1
------------	-------------------	------------------

Revive After Storage Routine

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

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

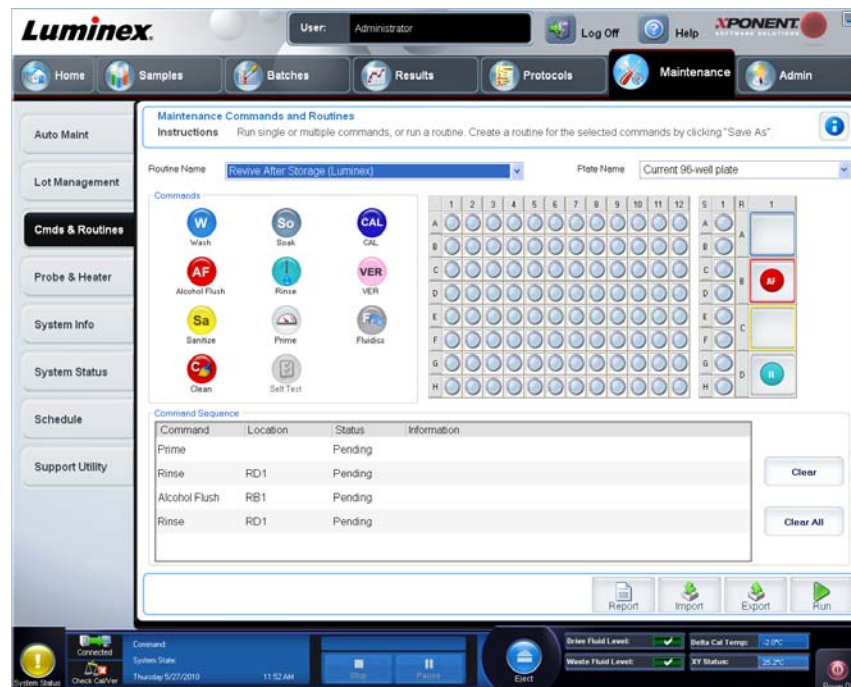
1. Open the **Maintenance** page, then the **Cmnds & Routines** tab.
2. Select **Revive After Storage (Luminex)** from the drop-down list. The **Revive After Storage** routine performs the following commands:
 - Prime

- Rinse
 - Alcohol Flush
 - Rinse
3. On the **Cmds & Routines** tab, select **Prime** from the **Commands** option section and perform a Prime.
 4. Add 70% isopropanol or ethanol to reservoir RB1 on the off-plate reagent block as indicated on the **Cmds & Routines** tab.

NOTE: The rinse reservoir (RD1) should be empty.

5. Click **Retract**.
6. Click **Run**.

FIGURE 2. Revive After Storage (Luminex) Routine



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

System Initialization

System initialization prepares the system for data acquisition. On initial startup, the System Initialization should consist of:

- Fluidics Prep
- Calibration
- Performance Verification

Calibration normalizes the settings for the system and ensures optimal and consistent microsphere classification. Verification uses system controls to ensure that the analyzer is functioning properly with current calibration settings.

1. On the **Admin** page, select the **System Setup** tab.
2. In the **Maintenance Options** section, select the **System Initialization** procedure that contains **Fluidics Prep, Calibration, and Performance Verification**.
3. Click **Save**.
4. On the **Home** page, click **System Initialization** under **Daily Activities**. The **Auto Maint** tab opens.
5. Import the **Calibration Kit** lot information from the CD provided with the kit or select the appropriate kit from the drop down menu if the kit information has been preloaded.

NOTE: See the “Adding or Importing CAL and VER Kit Information” on page 5 on how to import the kit.

6. Import the **Performance Verification Kit** lot information from the CD provided with the kit or select the appropriate kit from the drop down menu if the kit information has been preloaded.

NOTE: See the “Adding or Importing CAL and VER Kit Information” on page 5 on how to import the kit.

7. Vortex the xMAP calibrator, verification, and fluidics containers at a medium speed for approximately 10 seconds to ensure homogeneity. Do not dilute xMAP calibrator, verification, or fluidics agents.
8. Click **Eject** on the status bar.

NOTE: To ensure that you get the necessary bead count, invert the calibrator and verifier vials perpendicular to the strip well as you add drops to the wells. This ensures that the maximum fluid drop size is dispensed into the wells.

9. Luminex recommends adding 6 drops of each reagent into the designated well.
10. Verify that reservoir RB1 is 3/4 filled with 70% isopropanol or ethanol.

NOTE: The rinse reservoir (RD1) should be empty.

11. Click **Retract**.
12. Click **Run**.

Adding or Importing CAL and VER Kit Information

You can add CAL and VER Kit information from the **Home** page.

To add or import CAL and VER kit information:

1. Load the CAL/VER CD (provided with the kit) on the computer.
2. On the **Home** page, click **System Initialization**.
3. Click **Import Kit** at the bottom right side of the window. The **Import Calibration or Performance Kit** dialog box opens.
4. Select **Locate the CD** in the appropriate drive and select the *.mpx folder and click **Open**.
5. Select the *.lxl file and click **Open**.
6. Click **OK**.

Creating Calibration and Verification Reports

1. Open the **Results** page, then open the **Reports** tab.
2. In the **Report** drop-down list, select **Calibration and Verification Reports**.
3. In the **Type** drop-down list, select **ALL**, **CAL**, **VER**, or **Fluidics**.
4. Type a **Start** date and a **Through** date for the date range you want to view.
5. Click **Generate** to display the report.
6. Use the left or right **Page** arrows to navigate to the different report pages.
7. Click **Print** to print the report, or **Save** to save the report.
8. Click **New Report** to generate another report.

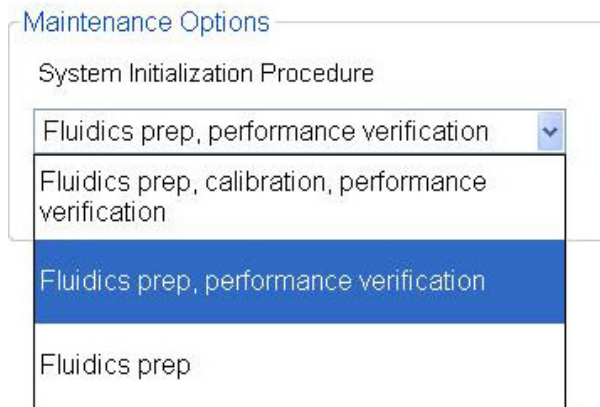
Chapter 2: Daily Start-Up Activities

Defining the System Initialization Routine

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

1. Open the **Admin** page.
2. Click **System Setup**.
3. Under **Maintenance Options**, select **Fluidics prep, performance verification** from the drop-down list.

FIGURE 3. **Setting System Initialization Routine**



4. Click **Save**.

Running the System Initialization Routine

1. On the **Home** page, click **System Initialization** under **Daily Activities**. The **Auto Maint** tab opens.
2. On the **Auto Maint** tab, the **System Initialization** option is automatically selected.
3. Verify that the correct lot kit is displayed in the **Calibration and Performance Verification** drop-down field and that the correct reagents (Ex: VER and Fluidics reagents) have been added to the off-plate reagent block.
4. Fill reservoir RB1 3/4 full of 70% isopropanol or ethanol.
5. Verify that the **Rinse** reservoir **RD1** is empty.
6. Click **Retract**.
7. Click **Run**.

FIGURE 4. Automated Maintenance - System Initialization

Luminex User: Administrator Log Off Help **XPONENT** SOFTWARE SOLUTIONS

Home Samples Batches Results Protocols Maintenance Admin

Automated Maintenance - System Initialization

Instructions Select the Automated Maintenance Option or Maintenance Command. Then, select the appropriate kit if applicable.

Automated Maintenance Options

System Initialization Performance Verification Calibration / Verification System Shutdown Alcohol Flush Sanitize

Command	Location	Status	Information
Rinse	RD1	Pending	
Alcohol Flush	RB1	Pending	
Rinse	RD1	Pending	
Rinse	RD1	Pending	
VER	SB1	Pending	
Rinse	RD1	Pending	
Fluidics1	SC1	Pending	
Fluidics2	SD1	Pending	
Rinse	RD1	Pending	
Rinse	RD1	Pending	

Reagents: Calibration Kit: PD101-165 Performance Verification Kit: PD101-166

Legend: Alcohol Flush, Sanitize, Rinse, Wash, Clean, Soak, CAL, VER, Fluidics1, Fluidics2, Multiple

Vortex each reagent vial for 30 seconds. Place 6 drops of each reagent into the designated well. Fill the designated reservoirs with DI H₂O, 70% Isopropanol, 10 - 20% household bleach, etc. if applicable to the chosen routine.

Report Import Kit Run

System Status: Disconnected Command: Complete System State: Complete Monday 7/19/2010 10:41 AM

Drive Fluid Level: Delta Cal Temp: Waste Fluid Level: XY Status: Power Off

Chapter 3: Running Assays

Create a New Batch from an existing Protocol

This option creates a new batch using a selected protocol from the **Installed Protocols** list.

When you click this option, the following tabs appear:

1. **Protocols**
2. **Stds & Ctrl**s
3. **Plate Layout** - Confirm that the plate layout conforms to your specific assay instructions.

These tabs are numbered because you must complete the steps on each tab sequentially. For example, you must complete the **Protocols** tab before you can access the **Stds & Ctrl**s tab.

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

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

NOTE: Luminex recommends that you analyze the manufacturer's assay kit controls with each batch.

To create a new batch from an existing protocol:

1. Read the instructions provided with the assay kit you are using.
2. Open the **Batches** page.
3. Click **Create a New Batch from an existing Protocol**.
4. Type the batch name in the **Batch Name** box.
5. If you want a description for the batch, type it in the **Enter Optional Description** box.
 - Click the existing protocol that you want to use. If the protocol uses standards and/or controls, you can view the active reagents. If the selected protocol uses standards/controls, the next tab that appears is the **Stds & Ctrl**s tab. You can view details about the active reagents, apply different standards/controls, or manually add new information on this tab.
 - If the selected protocol does not use standards/controls, the next tab that appears is the **Plate Layout** tab. You can assign well commands for this batch on this tab. Confirm that the plate layout conforms to your specific assay instructions.
6. Click **Next**.
7. Click **Run Batch** to begin batch acquisition, or click **Save** to save the batch information as a pending batch. Pending batches can be run at any 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.

Run, Save, and Print Reports

xPONENT can provide information in three different report types:

- Batch
- Protocol
- Advanced (User)

It 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, select the report that you want to view.
4. In the **Type** drop-down list, select the type of report you want to view.
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**. The report appears in the lower part of the **Reports** tab.
7. Click **Print** to print the report, or **Save** to save the report as a PDF file.

FIGURE 5. **Data Interpretation Report**

The screenshot displays the Luminex software interface. At the top, the user is logged in as 'Administrator'. The navigation bar includes 'Home', 'Samples', 'Batches', 'Results', 'Protocols', 'Maintenance', and 'Admin'. The 'Results' tab is active, showing a 'Reports' section. The 'Reports' section has a sidebar with 'Current Batch', 'Saved Batches', 'LIS Results', and 'Reports'. The main area shows a table of reports with the following data:

Name	Protocol	Protocol Version	Date	Status	User
QualSwellBatch	None	1	10/12/2009 6:53 ...	Complete	
New Batch 2	None	1	10/12/2009 5:20 ...	Complete	Admin

Below the table, there is a 'Select Analytes' section with an 'All' button and a 'Clear' button. At the bottom right, there is a 'Generate' button. The bottom status bar shows 'System State: Connected', 'Time: 10/13/2009 2:44 PM', and various system indicators like 'Drive Fluid Level', 'Delta Cal Temp', 'Waste Fluid Level', and 'XY Station'.

Chapter 4: Shutdown

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 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. Click **Eject**.
3. Fill reservoir **RA1** with 3/4 of DI water.
4. Fill reservoir **RB1** with 3/4 of NaOH 0.1N.
5. Fill reservoir **RC1** with 3/4 of 10%-20% household bleach solution.
6. Verify that reservoir **RD1** is empty.
7. Click **Retract**.
8. Click **Run**.

Chapter 5: Troubleshooting

MAGPIX New System Initialization Troubleshooting

This section provides you with information to troubleshoot issues that may be encountered during the MAGPIX installation and system startup. The procedures are presented as step-by-step instructions and assume basic knowledge of xPONENT software and xMAP Technology.

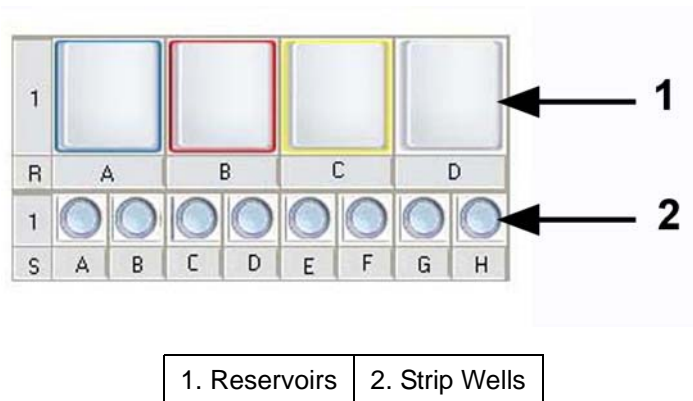
System Startup

Verify that the following procedures were performed when the MAGPIX system was turned on for the first time.

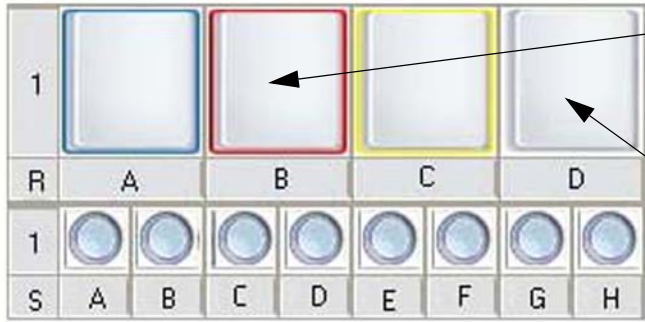
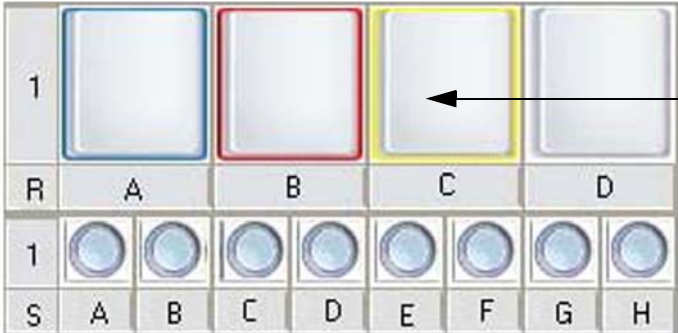
1. Adjusting the Sample Probe Height
2. Revive After Storage Routine (Luminex)
3. System Initialization

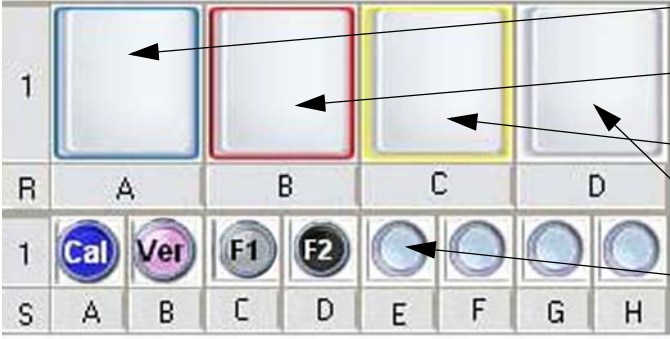
All system startup routines are run from the MAGPIX Off-Plate Reagent Block. For detailed instructions on how to perform these operations, refer to the section “Starting the MAGPIX System for the First Time” on page 1 of this manual.

FIGURE 6. MAGPIX Off-Plate Reagent Block



MAGPIX New System Startup Errors

Problem Summary	Resolution	Notes
<p>Calibration Failure</p>	<p>Sonicate and flush the sample probe. Observe the probe calibration for positional accuracy. Verify all fittings are secured in place (reference the <i>MAGPIX Calibration and Performance Verification Trouble Shooting Guide Flowchart</i> below).</p>	<p>Refer to the <i>MAGPIX Calibration and Performance Verification Trouble Shooting Guide Flowchart</i> below for detailed information on the fittings.</p>
	 <p>Fill reservoir B with 70% alcohol</p> <p>Leave reservoir D empty</p>	
	<p>(2x) Clean with 70% isopropanol or ethanol alcohol (reservoir B)</p>	
	<p>(2x) Alcohol Flush with 70% isopropanol or ethanol alcohol (reservoir B)</p>	
	<p>(3x) Rinse (reservoir D)</p>	
	<p>(3x) Prime</p>	
	<p>Run Calibration Routine</p>	<p>Verify that reagent is freshly vortexed. Use 6 drops of reagent.</p>
	<p>If Calibration continues to fail run the following routine:</p>	<p>Create routines in the xPONENT “Maintenance” Tab “Cmds & Routines” page Approx run time: Five minutes</p>
	 <p>Fill reservoir C with 0.1 N NaOH</p>	
	<p>(1x) Clean with 0.1 N NaOH (reservoir C)</p>	
	<p>(3x) Rinse (reservoir D)</p>	
	<p>(3X) Prime</p>	
	<p>Run Calibration Routine</p>	<p>Verify that reagent is freshly vortexed. Use 6 drops of reagent.</p>
<p>If problem is not solved, contact Luminex Technical Support</p>		

Problem Summary	Resolution	Notes
Performance Verification Failing	Sonicate and flush the sample probe. Observe the probe calibration for positional accuracy. Verify all fittings are secured in place (reference the MAGPIX Calibration and Performance Verification Trouble Shooting Guide flowchart below).	Refer to the MAGPIX Calibration and Performance Verification Trouble Shooting Guide flowchart below for detailed information on the fittings.
	If system continues to fail run the enhanced start-up routine outlined below:	Create routines in the xPONENT "Maintenance" Tab, "Cmds & Routines" page Approx run time: Thirty minutes
		Fill reservoir A with DI water Fill reservoir B with 70% alcohol Fill reservoir C with 0.1 N NaOH Leave reservoir D empty Add Calibration and Verification reagents as necessary
	Sonicate and flush the sample probe (flush from narrow to wide end).	
	(4x) Rinse (reservoir D)	
	(3x) Alcohol Flush with 70% isopropanol or ethanol alcohol (reservoir B)	
	(1x) Alcohol Flush with DI water (reservoir A)	
	(1x) Sanitize with 0.1N NaOH (reservoir C)	
	(2x) Clean with 0.1N NaOH (reservoir C)	
	(2x) Rinse (reservoir D)	
	(1x) Alcohol Flush with 70% isopropanol or ethanol alcohol (reservoir B)	
	(1x) Prime	
	(4x) Rinse (reservoir D)	
	CAL (strip well A)	Verify that reagent is freshly vortexed. Use 6 drops of reagent.
	(3x) Rinse (reservoir D)	
	VER (strip well B)	Verify that reagent is freshly vortexed. Use 6 drops of reagent.
	(1x) Rinse (reservoir D)	
	Fluidics 1 (strip well C)	Verify that reagent is freshly vortexed. Use 6 drops of reagent.
	Fluidics 2 (strip well D)	Verify that reagent is freshly vortexed. Use 6 drops of reagent.
	(3x) Rinse (reservoir D)	


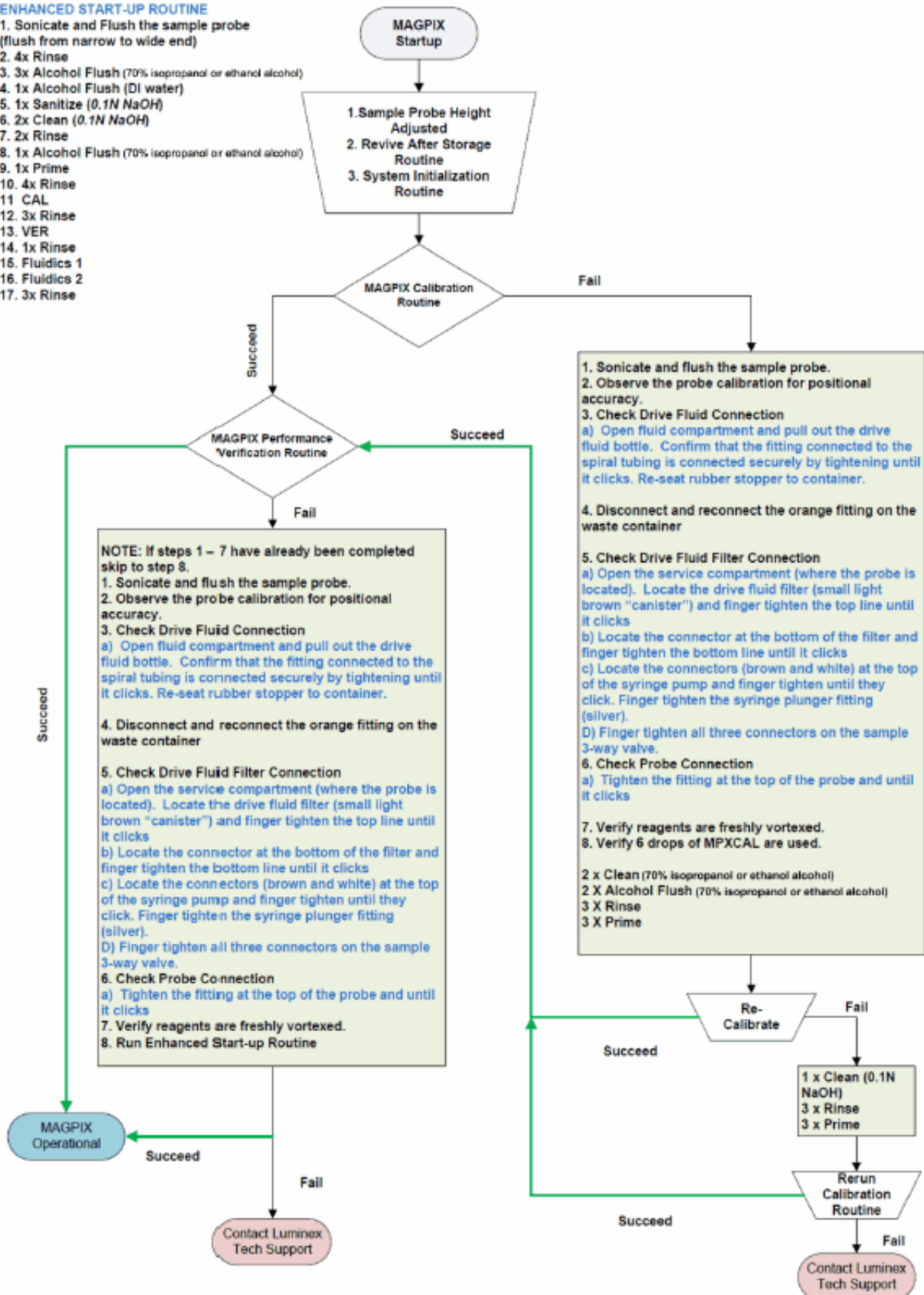
Problem Summary	Resolution	Notes
	 <p>The image shows two icons from the xPONENT software interface. On the left is a green circular icon with a white checkmark, labeled 'System Status'. On the right is a blue square icon with a white checkmark and the text 'Connected' above a scale icon, labeled 'Cal/Ver'.</p>	Check the Cal/Ver Icon in the System Monitor Bar located at the bottom of the xPONENT screen to confirm that the operation has been completed successfully.
If problem is not solved, contact Luminex Technical Support		
1st Well “Low Bead Count”	Under the Admin Tab. Verify that “Run Rinse Before Batch Starts” is checked.	
	Rerun the plate	
	Close and restart xPONENT.	
Error at xPONENT start	If you have configured your PC to auto-start xPONENT when booting, please disable this function.	

FIGURE 7. **MAGPIX Calibration and Performance Verification Troubleshooting Guide**

ENHANCED START-UP ROUTINE

1. Sonicate and Flush the sample probe (flush from narrow to wide end)
2. 4x Rinse
3. 3x Alcohol Flush (70% isopropanol or ethanol alcohol)
4. 1x Alcohol Flush (DI water)
5. 1x Sanitize (0.1N NaOH)
6. 2x Clean (0.1N NaOH)
7. 2x Rinse
8. 1x Alcohol Flush (70% isopropanol or ethanol alcohol)
9. 1x Prime
10. 4x Rinse
11. CAL
12. 3x Rinse
13. VER
14. 1x Rinse
15. Fluidics 1
16. Fluidics 2
17. 3x Rinse



Chapter 6: Technical Support

On the Web

For more information, visit the Luminex Support page at <http://www.luminexcorp.com/support/>.

By Phone Inside the U.S. and Canada

Contact Luminex Technical support at:

- Toll Free: 1-877-785-BEAD (-2323)
- Fax: 512-219-5114

By Phone Outside the U.S. and Canada

Contact Luminex Technical support at:

- International Toll Free: +800 2939 4959
- Direct Phone: +1 512-381-4397
- Fax: +1 512-219-5114

Email

Email questions to support@luminexcorp.com.