

Installation and User Manual | IVD **MAGPIX**[®] **Hardware**



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August 2017



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89-30000-00-186 Rev E

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Chapter 1: About This Manual

Overview

Read this manual carefully before using the MAGPIX[®] system. It provides vital information about the following aspects of MAGPIX:

- Safety issues
- Regulatory considerations and labeling
- Installation
- Operation
- Maintenance
- Troubleshooting
- Storage
- Shipping
- Part Numbers

Warnings and Notes

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 may 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 may result in incorrect performance, instrument failure, invalid results, or hazard to the operator.
DANGER:	This message is used in cases where significant risk of serious injury or death is present.
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.

Symbols

You will encounter these symbols throughout this manual. They represent warnings, conditions, identifications, instructions, and regulatory agencies.

TABLE 1. Key to Symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
**	Puncture/Pinch Point Warning	0434B [‡]	Caution To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	5.4.1*	Biological risks Indicates that there are potential biological risks associated with the medical device.
**	Hand Crush / Force From Above	5041†	Caution, hot surface To indicate that the marked item can be hot and should not be touched without taking care.	**	Burn Hazard / Hot Surface
	Caution, possibility of electric shock To identify equipment, for example, the welding power source, that has risk of electric shock.	W004#	Warning; Laser Beam To warn of a laser beam	5.4.3*	Consult instructions for use Indicates the need for the user to consult the instructions for use.
5019†	Protective earth; protective ground To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.	5032†	Alternating Current To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	5.1.6*	Catalog(ue) Number Indicates the manufacturer's catalogue number so that the medical device can be identified.

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
5.5.1*	In vitro diagnostic medical device Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	5.1.7*	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.	5.1.5*	Batch Code Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.4*	Use-by date Indicates the date after which the medical device is not to be used.	5.3.7*	Temperature Limit Indicates the temperature limits to which the medical device can be safely exposed.	#	WEEE Symbol Separate collection for electrical and electronic equipment
5.1.3*	Date of manufacture Indicates the date when the medical device was manufactured.	5.1.1*	Manufacturer / Date of manufacture Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/ EC.	° CE	Conformite Europeenne (EU CE Marking of Conformity) CE conformity marking
5.1.2* EC REP	Authorized representative in the European Community Indicates the Authorized representative in the European Community	TUDE US	TÜV SÜD NRTL Certification Mark TÜV SÜD America is an OSHA-recognized Nationally Recognized Testing Laboratories (NRTL) capable of providing electrical safety certification services to North American requirements for Medical Devices, and Laboratory Test & Measurement Equipment.	5009 [†]	Stand-by Power on/off To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand- by condition, and to identify the control to shift to or to indicate the state of low power consumption. Each of different states of power consumption may be indicated using a corresponding color.
		LISTING NO.	MET Mark	5016 [†]	Fuse To identify fuse boxes or their location

* ANSI/AAMI/ISO 15223-1:2012, Medical devices—Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements.

† IEC 60417:2002 DB, graphical symbols for use on equipment. (General I (QS/RM))

‡ ISO 7000: Fifth edition 2014-01-15, graphical symbols for use on equipment - registered symbols. (General I (QS/RM))

§ Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)

|| 61010-1: 2010, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements [including: Corrigendum 1 (2011)]

IEC 60825-1-2007 Safety of Laser Products - Part 1: Equipment classification and requirements

** ISO 3864-1:2011, Graphical symbols -- Safety colors and safety signs -- Part 1: Design principles for safety signs and safety markings

‡‡ DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Chapter 2: Safety and Regulatory Considerations

Become familiar with the safety information in this chapter before using MAGPIX[®]. This system contains electrical and mechanical components that, if handled improperly, are potentially harmful. In addition, biological hazards may be present during system operation. Therefore, Luminex recommends that all system users become familiar with the specific safety advisories below in addition to adhering to standard laboratory safety practices. Do not perform procedures on MAGPIX that are not specifically described in this manual, unless you are directed to do so by *"Technical Support"* on page 54.

Intended Use

The MAGPIX[®] system is a clinical multiplex test system intended to measure and sort multiple signals generated in an in vitro diagnostic assay from a clinical sample. This instrument system is used with a specific assay to measure multiple analytes that aid in diagnosis. The device includes a signal reader unit, raw data storage mechanisms, data acquisition software and software to process detected signals.

Regulatory Labels and Warnings

The following fuse caution label appears on MAGPIX[®].

FIGURE 1. Fuse Caution Label



A voltage label appears on the back of MAGPIX. It displays the MAGPIX serial number, model number, power requirements, and manufacturer's information.

FIGURE 2. Serial Number and Voltage Label

Luminex Corporation 12212 Technology Blvd. Austin, Texas 78727 USA, 2016-10-20 d i Model: MAGPIX SN MAGPX16294725 100-120V~, 2.0A 50/60 Hz or 200-240V~, 1.0A 50/60 Hz The WEEE (Waste Electrical and Electronic Equipment) label appears.

FIGURE 3. WEEE Symbol



Because MAGPIX complies with European Union safety requirements, it displays an EC representative label.

FIGURE 4. EC Representative



Testing and Certifications

The MAGPIX[®] has been tested and complies with the safety requirements for the United States and Canada. One of the following agency marks will be on the instrument.

FIGURE 5. Safety Label





In addition, MAGPIX complies with European Union (EU) safety requirements and therefore may be marketed in the Europe Single Market. The following European Union compliance label appears on the back of the MAGPIX instrument.

F

FIGURE 6. European Union Compliance Label

Safety Practices



In any situation in which you encounter this symbol, consult this manual or other Luminex[®] documentation to determine the nature of the potential hazard and any necessary actions you must take.

CAUTION: The protection provided by the equipment can be impaired or the warranty voided if the Luminex MAGPIX[®] system is used in a manner not specified by the instructions or by Luminex Corporation.

General

Keep the side access door closed and latched during normal operations.



DANGER: Do not, under any circumstances, remove the housing of the instrument. Use of controls or adjustments or performance of procedures other than those specified in Luminex[®] MAG-PIX[®] documentation can result in exposure to hazards.

Always observe standard laboratory safety practices.

Mechanical



MAGPIX[®] has parts that move during operation. Risk of personal injury is present. The moving parts present puncture and pinching hazards. Keep your hands and fingers away from the plate carrier slot, syringe pump, and sample probe during operation. The plate carrier ejects without warning, especially during multiplate batches. Observe all warnings and cautions. Keep the access door closed and latched during normal operations.

Electrical



Do not perform any maintenance or cleaning of the electrical components in the system, with the exception of replacing fuses.

Observe the fuse caution stated on the fuse caution label. See *Figure 1, "Fuse Caution Label"* on page 5. Be aware of the voltage of the instrument. See *Figure 2, "Serial Number and Voltage Label"* on page 5.

Power cords must be replaced with cords of the same type and ratings as originally provided. Contact "*Technical Support*" on page 54 for correct replacement power cords.

Electromagnetic Compatibility

MAGPIX[®] complies with the emission and immunity requirements described in IEC 61326-1 and IEC 61326-2-6. The electromagnetic environment should be evaluated prior to operation.



WARNING: Do not use this instrument in close proximity to sources of strong electromagnetic radiation, for example, unshielded intentional RF sources, as these may interfere with the proper operation.



WARNING: Always handle MAGPIX according to Luminex[®] instructions to avoid any possible interference from its electromagnetic fields.

Bar Code Reader Laser

The accessory bar code reader is classified under FDA 21 CFR 1040.10 and 1040.11 as a Class II laser product. In accordance with IEC 60825-1, the accessory bar code reader is classified as Class 2.

The bar code reader laser presents a potential hazard to eyesight.



WARNING: Do not stare into the barcode reader beam or shine it into other people's eyes.

Heat

The heater plate, used to warm the plate carrier of the Y platform, can be heated between 35°C and 60°C.



CAUTION: Do not use the heater plate as an incubator. Its purpose is to maintain the temperature of the microtiter plate while the plate is in the MAGPIX[®] instrument. Monitor the heater plate temperature while it is in use. If it overheats, discontinue use and contact "*Technical Support*" on page 54.



WARNING: The heater plate of the MAGPIX plate carrier may be hot and can cause personal injury if touched. Do not touch the heater plate.

Fluids

This instrument contains fluids. In the event of a fluid leak, turn off all power to the system and disconnect all power cords. The on/off switch is not a method of disconnection; the power cord must be removed from the outlet. Contact "*Technical Support*" on page 54 for further information.



DANGER: Do not operate the instrument in the presence of leaking fluid.

Monitor waste fluid levels periodically as a precaution. Do not allow the waste fluid container to overflow. Empty the waste fluid container each time you replace the Drive Fluid container.

Biohazard

Human and animal samples may contain biohazardous infectious agents. To avoid pressurization problems, the waste fluid container is vented, so beware of biohazardous aerosol material.



WARNING: Where exposure to potentially biohazardous material, including aerosol, exists, follow appropriate biosafety procedures and use personal protective equipment (PPE). PPE includes gloves, gowns, laboratory coats, face shields or mask and eye protection, respirators, and ventilation devices. Observe all local, state, federal and country-specific biohazard handling regulations when disposing of biohazardous waste material.

Indicator Light

The lights inside the front panel of MAGPIX[®] indicate the status of the system and are harmless. The blue light-emitting diodes (LEDs) do not emit light in the UV spectrum.

Decontamination Procedure

Occasions may arise when it becomes necessary to decontaminate the entire MAGPIX[®] instrument. If you must decontaminate the instrument, sanitize the accessible surfaces and the internal fluidics system. This is particularly important when biohazardous samples have been run.



WARNING: Wear appropriate personal protective equipment when handling parts that come into contact with potentially biohazardous samples.

To decontaminate MAGPIX:

- 1. Remove all specimens and all Luminex[®] MAGPIX[®] reagents. Leave distilled water and household bleach solution diluted to 10% to 20% in water in the off-plate reagent block of the system.
- 2. Use the software to run a sanitize command with the diluted (10% to 20%) household bleach solution followed by two wash commands with distilled water.
- 3. Empty the off-plate reagent block and the waste container and clean each with a 10% to 20% bleach solution followed by a distilled water rinse.
- 4. Turn off MAGPIX and unplug the power cord.
- 5. Clean all exterior surfaces with mild detergent followed by a household bleach solution diluted to 10% to 20%.
- 6. Open the side access door of the instrument.
- 7. Clean all accessible surfaces with detergent followed by the household bleach solution (10% to 20%).

Disposal of Instrument



Within the European Union, the Waste Electrical and Electronic Equipment Directive requires that you properly dispose of electrical and electronic equipment when it reaches its end of life.

If you are disposing of a Luminex[®] MAGPIX[®] instrument, decontaminate the system. See "*Decontamination Procedure*" on page 9. Next, contact "*Technical Support*" on page 54 for a Return Material Authorization (RMA) number at +1-512-381-4397 (outside of the U.S.). Return the equipment to the following Luminex location:

Luminex Corporation 12201 Technology Blvd., Suite 130 Austin, Texas 78727, USA

For information about disposal of MAGPIX outside of the European Union, contact "*Technical Support*" on page 54. For information about disposal of the barcode scanner, PC, or monitor, refer to the manufacturer documentation.

Chapter 3: Installation Procedure

Before handling or unpacking MAGPIX[®], make certain that the selected site is appropriate. See the "*Installation Diagram*" on page 12 for handling and site installation requirements and detailed dimensions of MAGPIX.

Check for these requirements:

- Indoors
- Operating temperature of 15°C to 35°C (59°F to 95°F)
- Operating relative humidity of 20% to 80%, noncondensing
- Operating altitude up to 2400m (7874 ft) above mean sea level
- Available electrical power outlet with protective earthing and easy accessibility
- Available area of approximately 3' X 3' (91.44cm), including a 2" (5.08cm) clearance between the back of MAGPIX and any wall or vertical surface.
- Stable, level surface

MAGPIX arrives in a large, corrugated cardboard overpack on skids.

FIGURE 7. The MAGPIX® Overpack





CAUTION: This overpack is too heavy to be lifted by one person (approximately 119lbs (53.97kg), a three-person lift) and should be moved mechanically. Be careful the overpack is not punctured during any necessary moving.

Within the overpack are separate cartons for the PC, the monitor, the 2-pack of Drive Fluid, and the MAGPIX instrument. In addition, a divided tray contains the cables, CDs, and printed material. For a complete list of contents, see the "*Shipping Checklist*" on page 28.

FIGURE 8. Inside the Overpack



1.	PC Carton	3.	MAGPIX [®] Carton
2.	Monitor Carton	4.	Accessory Tray (Monitor stand and Drive Fluid cartons are underneath)

Each individual carton can be handled by one person. The MAGPIX carton and the PC carton each weigh less than 40 pounds (18.14 kg).

Installation Diagram



Unpacking and Assembling the PC

Begin the installation process with the PC. The computer and monitor are in the boxes at the end of the overpack (See *Figure 9, "The Assembled PC"* on page 13.); the monitor stand is in a box underneath the accessory tray.

The computer and monitor boxes include all the necessary cords and peripheral devices as well as complete installation instructions. Follow those instructions to set up the PC.

To set up the PC:

- 1. Remove the three boxes containing PC components from the overpack.
- 2. Assemble the components using the instructions provided by the PC vendor.

FIGURE 9. The Assembled PC



Unpacking and Assembling MAGPIX®

To install the MAGPIX[®] instrument:

1. Remove the MAGPIX carton from the overpack.

FIGURE 10. Removing the MAGPIX[®] Carton



The MAGPIX instrument is inside a plastic bag and surrounded by foam inserts attached to a corrugated cardboard insert.

FIGURE 11. The MAGPIX[®] Carton, Opened



2. Remove MAGPIX from its carton by pulling on the handles that extend from the cardboard insert.

NOTE: It is helpful to have another person hold down the carton while you pull out MAGPIX.

FIGURE 12. Pulling MAGPIX[®] from its Carton



- 3. Put the instrument on a stable, flat surface. This may require two people.
- 4. Fold down the cardboard panels from each side of the instrument.

FIGURE 13. Removing the Packing Materials



- 5. Pull the plastic bag down from the top.
- 6. Place MAGPIX onto a lab bench or other flat, stable surface. This may require two people.

Before proceeding with the installation, check the contents of the overpack with the Shipping Checklist and make certain you can locate all listed items. Check contents to make certain no damage has occurred during shipping. If anything is missing or damaged, contact "*Technical Support*" on page 54.

Connecting the Components

To connect the components:

1. Locate the cords in the accessory tray of the overpack.

FIGURE 14. Power Cord and USB Cable



- 2. Plug the power cord into the back of the instrument.
- 3. Connect the USB cable to the PC and to the connector labeled P1 on the back of MAGPIX[®].

FIGURE 15. Power Cord and USB Cable Connected



4. Connect the barcode scanner (if ordered) to the computer, to a USB port on either the front or back.

FIGURE 16. All Components Connected



Preparing MAGPIX®

Preparing MAGPIX[®] includes removing the shipping plug, installing the Drive Fluid, and installing the sample probe.

Removing the Shipping Plug

Inside the side access door of MAGPIX[®], a shipping plug holds the sample probe assembly in place. Use the door access tool included in the accessory tray to open the side access door and remove the plug.



CAUTION: MAGPIX should not be plugged into a power source when you open this compartment.

To open the side access door and remove the shipping plug:

1. Locate the door access tool in a small plastic bag in the accessory tray of the overpack.

FIGURE 17. Door Access Tool



2. Insert the tool in the side access door latch and turn it one quarter turn clockwise.

FIGURE 18. Door Access Tool Inserted and Turned



3. Slide the door to the right.

FIGURE 19. Sliding Open the Door



4. Raise the probe assembly and locate the shipping plug.

FIGURE 20. Shipping Plug in Position



5. Pull the probe holder up, then, holding MAGPIX on the top with one hand to stabilize it, firmly push the probe assembly away from you with your other hand. Be prepared to use some strength.

FIGURE 21. Pushing the Probe Assembly



6. With the probe assembly out of the way, lift out the shipping plug.

FIGURE 22. Lifting Out the Shipping Plug



Installing the Sample Probe

 $MAGPIX^{\textcircled{R}}$ comes with two sample probes, but the probe is not pre-installed. To install the sample probe:

1. Locate the sample probe, which is shipped in a tube in the accessory tray.

FIGURE 23. The Sample Probe and Its Container



- 2. Pull the probe assembly toward you and push it down.
- 3. Completely unscrew the probe fitting on top of the probe holder by turning it counterclockwise.

FIGURE 24. Unscrewing the Probe Fitting



4. Put the probe into the opening left by the probe fitting. It should slip down and catch at the bottom of the opening.

FIGURE 25. Inserting the Sample Probe



5. Reinstall the probe fitting, tightening it until it clicks into place.

FIGURE 26. The Sample Probe in Position



6. Close and latch the side access door.

Installing the Drive Fluid

The overpack includes a carton containing two containers of Drive Fluid. Open the carton and remove one container to install in the instrument.

To install the Drive Fluid container:

1. Locate the carton of Drive Fluid containers.

FIGURE 27. Drive Fluid Carton and Container



- 2. Open the carton and remove a container of Drive Fluid.
- 3. Open the door of the fluid compartment on the front of MAGPIX[®].

FIGURE 28. Fluid Compartment



4. Pull the Drive Fluid tube and plug (1) in the left side of the fluid compartment forward until it extends outside the compartment. Pull it to the left to allow room to insert the Drive Fluid container.

FIGURE 29. Pulling Out the Drive Fluid Tube and Plug



5. Insert the Drive Fluid container part of the way into the fluid compartment opening and remove the seal.

FIGURE 30. Removing the Foil Seal



6. Connect the Drive Fluid tube and plug to the opening on the top of the Drive Fluid container.

FIGURE 31. Connecting the Tube and Plug to the Container Opening



7. Slide the container into the tray on the left side of the fluid compartment. The container tray is constructed to hold the container in place.

FIGURE 32. Sliding in the Drive Fluid Container



8. After the container is fully inserted, check the valve on the front of the waste fluid container to make certain it is securely attached and close the door of the fluid compartment.

Powering Up MAGPIX®

MAGPIX[®] has two on/off switches: a hard power switch and a soft power switch.

To power on MAGPIX:

1. Plug the power cord from the back of the instrument into a power outlet.

NOTE: Luminex recommends the use of a surge protector or UPS device with MAGPIX. For more information, see "Uninterruptible Power Supply (UPS) or Surge Protector" on page 40.

2. Turn on the hard power switch (1). This is the toggle switch at the lower right corner of the back of MAGPIX.

NOTE: The hard power switch controls flow of power to the instrument.

FIGURE 33. Hard Power Switch



3. When you are ready to begin testing, turn on the soft power switch (2) on the front of MAGPIX. The blue LED in the hexagonal window lights up as confirmation that the power is on. MAGPIX requires approximately 45 seconds to start up.

FIGURE 34. Soft Power Switch



- NOTE: The soft power switch activates and deactivates the unit.
- 4. After MAGPIX is powered on, use the software to eject the tray carrier to put the off plate reagent block in place.

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. Calibration/Verification

Adjust the Sample Probe Height

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

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

- 1. On the Home page, click Probe and Heater under Daily Activities. The Probe & Heater tab opens.
- 2. Use well D6 (this is the center of a standard 96-well plate).
- 3. Ensure that the well location is selected on the plate image. A green pin marks the selected well.

- 4. Based on the type of plate you are using, place alignment disks or an alignment sphere in the well.
 - For a standard 96-well plate none
 - For a Filter-bottom plate two 5.08 mm disks
 - For a Mylar-bottom plate two 5.08 mm disks
 - For a conical (v-shaped) plate one sphere
- 5. Click **Eject** to eject the plate carrier.
- 6. Place the off plate reagent block on the plate carrier. Make sure it is well seated so that it clips into place.
- 7. Place a strip well (provided with the Calibration and the Performance Verification kit) in the off-plate reagent block.
- 8. In the Strip Wells section, click SD1.
- 9. Verify that the reservoir is empty.
- 10. In the **Reservoir** section, click well **RB1**.
- 11. Verify that the plate is not warped. Warped plates can lead to incorrect probe height adjustment.
- 12. Place the plate on the plate carrier with well A1 positioned as indicated on the plate carrier.
- 13. Click Retract to retract the plate carrier.
- 14. Type a name for the plate in the Plate Name box.
- 15. Click Auto Adjust Height. The probe automatically adjusts itself to the locations you selected.

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

- 16. Click Eject to eject the plate holder. If you used alignment disks or spheres, remove them from the plate.
 - **NOTE:** When you adjust and save the probe height settings for all three areas under a plate name, all areas retain the adjustment.



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



FIGURE 35. Sample Probe Height Adjustment



Revive After Storage Routine

- **NOTE:** The **Revive After Storage** routine is necessary when the system runs for the first time and when the system has been idle for more than a week. After you have adjusted the sample probe height, run the **Revive After Storage (Luminex)** routine.
- 1. Open the Maintenance page, then the Cmds & Routines tab.
- 2. Select **Revive After Storage (Luminex)** from the **Routine Name** drop-down list. The **Revive After Storage** routine performs the following commands:
 - Prime
 - Rinse
 - Alcohol Flush
 - Rinse
- Add 70% isopropanol or 70% ethanol to reservoir RB1 on the off-plate reagent block as indicated on the Cmds & Routines tab.

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

- 4. Click Retract.
- 5. Click Run.

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

Calibration-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 Home page, click System Initialization under Daily Activities. The Auto Maint tab opens.
- 2. Click the **Calibration/Verification** option under **Automated Maintenance Options** section.

3. 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 "Adding or Importing CAL and VER Kit Information" on page 27 for instructions on how to import the kit.

4. 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 "Adding or Importing CAL and VER Kit Information" on page 27 for instructions on how to import the kit.

- 5. 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.
- 6. 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.

- 7. Add 6 drops of each reagent into the designated well.
- 8. Verify that reservoir RB1 is ³/₄ filled with 70% isopropanol or ethanol.

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

- 9. Click **Retract**.
- 10. 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.

Shipping Checklist

The MAGPIX $^{\ensuremath{\text{\scriptsize R}}}$ overpack contains the following items:

	Quantity	Part Number
MAGPIX [®] Instrument	1	
PC	1	
Monitor	1	
All-in-One Monitor Stand	1	
Drive Fluid 2-pack	1	40-50014
Waste Bottle	1	CN-0261-01
Sample Probe	2	CN-0221-01
Power Cord	1	CN-P0XX-01
USB Cable	1	CN-0271-01
Side Access Door Tool	1	CN-0264-01
Sample Probe Height Adjustment Kit	1	CN-0263-01
Off-plate Reagent Block	1	CN-0260-01
xPONENT [®] 4.2 Software for MAGPIX [®] (DVD)	1	CN-SWXX-XX
Installing MAGPIX [®]	1	89-30000-00-236
xPONENT [®] for MAGPIX [®] IVD Quick Guide	1	CN-M083-01
IVD MAGPIX [®] Installation and Hardware User Manual (CD)	1	CN-M082-01
IVD xPONENT [®] for MAGPIX [®] Software User Manual (CD)	1	CN-M088-01
PC Installation Instructions	1	89-30000-00-263
96-wellplate Heater Block (optional)	1	CN-0224-01
Barcode reader (optional)	1	CN-PC03-01

NOTE: A MAGPIX Calibration Kit and a MAGPIX Performance Verification Kit are shipped separately.

Chapter 4: Technical Overview

This chapter describes the operation, components, subsystems, and technical specifications of MAGPIX[®].

How MAGPIX[®] Operates

MAGPIX[®] combines a fluidics system, a mechanical system, an electronic system and an optical system with magnetic microspheres and complex computer analysis to perform multiplex assays.

The mechanical system begins the process. An operator places a 96-well microtiter plate on the plate carrier, which transports the plate into the instrument. The carrier moves along the y-axis, to allow the sample probe access to each column of the microtiter plate. The sample probe assembly moves along the x and z axes, allowing it to access each row of the microtiter plate. Between the y-axis movement of the carrier and the x-axis movement of the sample probe, all wells of the microtiter plate are accessible.

The fluidics system handles the acquisition and transportation of the sample. The sample probe descends into each well, drawing a sample for testing and drawing Drive Fluid from the Drive Fluid container. The sample moves through the fluid tubing to the optics module, transported by the Drive Fluid.

In the optics module, a magnet holds the magnetic microspheres in place while first a red (classification) LED and then a green (reporter) LED illuminate them. They are imaged during each illumination. After the images are recorded, the magnet withdraws, releasing the microspheres for transport to the waste fluid container and to clear the way for the next sample.

xPONENT[®] software analyzes the images, the red-illuminated images to classify the microspheres and the green-illuminated images to determine what elements of the sample have bonded to their surfaces. It reports the results to the operator.

FIGURE 36. MAGPIX[®] Front and Right Side



1.	Status Indicator Light	4.	Access Door for Fluid Compartment. For a more detailed illustration, see " <i>The Fluid Compartment</i> " on page 36.
2.	Soft On/Off Switch	5.	Side Access Door
3.	Access Door for Plate Carrier	6.	Side Access Door Latch
FIGURE 37. MAGPIX[®] Back and Left Side



System Components

The following topics describe details of the three components of the Luminex[®] MAGPIX[®] system: software, reagents, and hardware.

Software

Luminex[®] xPONENT[®] for MAGPIX[®] software provides complete control of the MAGPIX instrument and performs the analysis. The software requires a dedicated PC. For updated information about the PC or operating system, see the appropriate software user manual or access *http://www.luminexcorp.com*.

Under most circumstances, the PC that comes with the MAGPIX system is preloaded with xPONENT for MAGPIX software. Luminex provides a software DVD to use if you need to reinstall the software or need to install it on another computer. If you install the software on another PC, be sure that the PC meets the minimum specifications, including 4.0 GB of RAM and a 2.66 GHz processor. The number of installations you can perform is limited by your license.

The software DVD automatically installs the basic software only. To install the various upgrades, contact "*Technical Support*" on page 54. A Technical Support representative can supply you with the correct license number to install upgrades.



CAUTION: If you need to uninstall the software, follow carefully the procedure provided by "*Technical Support*" on page 54.

The software is documented in two ways: in online help, which can be accessed from within the application itself, and in PDF form, which is available on the Luminex website and on a CD included with the shipped system.



CAUTION: Luminex recommends that you do not install additional software on the PC that runs xPONENT for MAGPIX, with the exception of Adobe Acrobat. Acrobat is required to view the PDFs and is included on the installation DVD. The operation of xPONENT for MAGPIX has been validated only when it is the only program running on the dedicated PC.

Hardware

The Luminex[®] MAGPIX[®] system includes the following hardware:

- The MAGPIX instrument
- · Personal computer (PC) and necessary peripherals, including a monitor, keyboard and mouse
- Power cable to connect MAGPIX to power outlet
- USB communication cable to connect MAGPIX to PC
- Two sample probes
- Sample probe height adjustment kit
- Off-plate reagent block
- · Additional empty waste fluid container
- Side door access tool
- Barcode reader (optional)
- Heater block (optional)

The hardware is shipped with a quick installation guide, a quick software user guide, a CD containing both the software user manual and the hardware installation and user manual, and a DVD containing the software.

Reagents

Luminex[®] xMAP[®] technology requires two kinds of reagents: common laboratory reagents and reagents created especially for Luminex instruments.



CAUTION: Adhere to standard laboratory safety practices when handling hazardous, toxic, or flammable reagents and chemicals. Contact "*Technical Support*" on page 54 when in doubt about compatibility of cleaning and decontamination agents or materials.



CAUTION: Only use reagents, assays, or other consumables that are within their expiration date. Dispose of all expired reagents, assays, or consumables in the appropriate waste container.

Required Laboratory Reagents

- 10% to 20% household bleach solution
- 70% isopropanol or 70% ethanol solution
- 0.1N NaOH
- Sporicidin[®] Disinfectant
- Mild detergent

Distilled water



WARNING: Isopropanol and ethanol are flammable liquids. Keep them away from heat, open flames, and sparks in a well-ventilated area. Remove them from the instrument when they are not in use.

xMAP[®] Technology Reagents

- Drive Fluid (unit volume sufficient to run eight 96-well plates)
- MAGPIX[®] Calibration Kit (to normalize the CL1 and CL2 classification channels and the RP1 reporter channel parameters)
- MAGPIX Performance Verification Kit (to verify system integrity associated with the CL1 and CL2 classification channels, the RP1 reporter channel, and the system fluidics)



CAUTION: Protect MAGPIX calibration and verification reagents from light at all times to avoid photobleaching of the microspheres.



WARNING: Luminex[®] Drive Fluid contains ProClin[®] as a preservative. This can cause allergic reactions in some people. Additional information is available in the Drive Fluid MSDS.

MAGPIX is shipped with a 2-pack of Drive Fluid. A MAGPIX Calibration Kit and a MAGPIX Performance Verification Kit are shipped separately.

Subsystems

MAGPIX[®] includes four subsystems: electronic, fluidics, mechanical, and optical.

Electronic Subsystem

The electronics subsystem provides the power for operation and control of the MAGPIX[®] system and communication between its parts.

Power Input Module

The power input module contains the input power plug, hard power toggle switch, and fuses. This is the protective earthing point for the MAGPIX[®] system. The mating power cord connector type is IEC-320-C13. The mating power cord provides electrical power to the instrument when it is connected to an electrical outlet and is the means of disconnection. The power input auto-senses the voltage range.

FIGURE 38. Power Input Module





WARNING: Do not obstruct this means of disconnection. Connect only to outlets that contain protective earthing. Before changing a fuse, turn off the instrument and unplug the power cord to avoid any danger of electrical shock.

Communications Port

The communications port connects MAGPIX[®] to the computer. It is a USB port, labeled P1.

FIGURE 39. Communications Port



Printed Circuit Board Assemblies

MAGPIX[®] requires a series of printed circuit board assemblies (PCBAs), including four major boards: optics control, XY controller, imaging, and processor. These PCBAs are all contained within the same area as the optical system, are not accessible to the user, and require no user maintenance.

Fluidics Subsystem

The fluidics subsystem handles the flow of liquid through MAGPIX[®]. MAGPIX has two doors that access its fluidics system: a side access door and a front door to the fluid compartment.

Side Compartment and its Components

The side access door, at the upper front of the right side, provides access to the side compartment, which contains the sample probe assembly, the sample valve, the tube between the probe and the sample valve, the filter for the Drive Fluid, and the syringe pump.

The side access door is secured with a latch that requires a door access tool to open.



CAUTION: Keep the side access door closed and latched during normal operation. Unlatch it only to perform maintenance on the user maintainable parts of the fluidics system.

FIGURE 40. Side Access Door



FIGURE 41. Interior of Side Access Door



Syringe Pump and Drive Fluid Filter

The syringe pump draws fluid from the Drive Fluid container, in the bottom compartment of the instrument. The fluid first passes through the Drive Fluid filter, which removes particles greater than 35 microns in diameter.

The pumping action results from the up-and-down movement of the plunger guide in its mounting bracket, which moves the plunger up and down in the glass cylinder, drawing Drive Fluid in through the filter and into the valve and forcing it out into the sample loop.

FIGURE 42. Syringe Pump and Drive Fluid Filter



1.	Drive Fluid filter	5.	Mounting bracket
2.	Plunger	6.	Plunger guide
3.	Tube from Drive Fluid container	7.	Syringe pump valve
4.	Glass cylinder	8.	Sample loop



WARNING: Avoid contact with moving parts.

Sample Probe Assembly

The stainless steel sample probe fits inside a holder. A probe fitting screws into the top of the holder, keeping the probe in place. From the probe, through the fitting, extends a tube that passes through a strain relief and attaches to the sample valve. The sample loop from the syringe pump also enters the sample value, and a tube extends from it into the optical chamber, carrying the sample mixed with Drive Fluid.

A wheel pulley, covered by a protective shield, moves the probe assembly along the x-axis.

FIGURE 43. Sample Probe Assembly



1.	Sample loop	6.	Sample valve
2.	Strain relief	7.	Protective cover on wheel pulley
3.	Probe-to-valve tube (coded black)	8.	Probe holder
4.	Valve-to-optical chamber tube (coded red)	9.	Probe fitting
5.	Sample probe		



WARNING: Avoid contact with moving parts.



WARNING: Wear appropriate personal protective equipment when handling parts that come into contact with potentially biohazardous samples.

The Fluid Compartment

At the bottom of the front panel of MAGPIX[®], a door folds down to provide access to the fluid compartment. Within that compartment, two trays hold the Drive Fluid and waste fluid containers. Internal sensors monitor the fullness of the waste fluid container and the emptiness of the Drive Fluid container. When either container reaches an unacceptable level, MAGPIX stops. The appropriate software user manual provides instructions for setting up an alert to warn you about unacceptable fluid levels.

FIGURE 44. Door to Fluid Compartment



The Drive Fluid container comes pre-filled and is disposable. The reusable waste fluid container receives waste from the system. The waste and Drive Fluid tubes connect to the waste fluid and Drive Fluid containers using clear tubing.



WARNING: Wear appropriate personal protective equipment when handling parts that come into contact with potentially biohazardous samples. Make certain the waste fluid container is properly vented.

FIGURE 45. Fluid Compartment, Interior



1.	Drive Fluid container in place	3.	Valve attaching waste tubing to waste fluid container
2.	Waste fluid container in place		

Mechanical Subsystem

x-Axis and y-Axis Movement

The MAGPIX[®] mechanical subsystem includes the plate carrier and the assembly that moves the sample probe. The carrier moves along the y-axis, to allow the sample probe access to each row of the microtiter plate. The sample probe assembly moves along the x and z axes, allowing it to access each column of the microtiter plate. Between the y-axis movement of the carrier and the x-axis and z-axis movement of the sample probe, all wells of the microtiter plate are accessible.

FIGURE 46. MAGPIX[®] Plate Carrier Assembly



1.	Microtiter plate area
2.	Off-plate reagent block area

FIGURE 47. MAGPIX[®] Sample Probe Assembly



2. Sample probe

Air Filters

MAGPIX[®] has two air filters, one on the bottom of the instrument and one on the back of the instrument. These filters require periodic cleaning to perform optimally.

The filter on the bottom of MAGPIX[®] can be slid out of its holder toward the front of the instrument. This requires lifting up or tilting the instrument. The filter on the back of MAGPIX can be slid up out of its holder.



CAUTION: Before lifting the instrument, remove all liquid from the off plate reagent block and remove the fluid containers.

FIGURE 48. Bottom of MAGPIX[®] Showing Filter in Place in Holder



FIGURE 49. Back of MAGPIX[®] Showing Filter in Place in Holder



1

Optical Subsystem

The MAGPIX[®] optical subsystem consists of red and green LED illumination, a CCD-based imager, an imaging chamber, and a magnet to hold the magnetic microspheres in place during the imaging process. The optical subsystem is contained in the same area as the PCBAs. It is not accessible by the user and requires no user maintenance.

Recommended Additional Equipment

Successful operation of theLuminex[®] MAGPIX[®] system may require additional equipment.

Uninterruptible Power Supply (UPS) or Surge Protector

Luminex recommends using either an uninterruptible power supply (UPS) or a surge protector to protect your system from power outages. Use a UPS that provides 585 Watts/960 VA for at least 60 minutes. Select a surge protector that fits your requirements with regard to electrical environment, endurance, suppressed voltage rating, and method of protection. The surge protector requires three outlets and a minimum rating of 585 Watts. Either piece of equipment should bear an appropriate safety certification mark for your region, for example, Underwriters Laboratory (UL), Canadian Standards Association (CSA), or Conformité Europeénne (CE).

Printer

Use a printer compatible with Microsoft[®] Windows[®] XP Pro Service Pack 3 or Microsoft Windows 7, 32-bit.

Barcode Labels

Use Code 128 barcode label type when scanning barcode labels into the system.

Vortex

Use VWR product number 58816-12, with a speed range of 0 to 3200 rpm, or equivalent.

Bath Sonicator

Use Cole-Parmer[®] product number 08849-00, with an operating frequency of 55 kHz, or equivalent.

System Specifications

General Specifications

- Start-up time: Under 15 minutes, including flushing system lines, system calibration, and system verification
- System verification: 5 minutes
- Shutdown time: Under 15 minutes
- Time to complete one 96-well microtiter plate: Under 1 hour with 50 regions, 2000 microspheres per region per well, counting 50 microspheres in each region, aspirating 30 μL out of a 75 μL sample
- Physical Dimensions: 20.3 cm (8") width, 66 cm (26") depth, 43.2 cm (17") height
- Weight: 40 lbs. (18.0 kg)
- Installation Category II
- Pollution degree 2
- Temperature control: maintains samples using the heater block at a constant temperature from 35°C to 60°C (95°F to 131°F) +/- 1°C of setpoint.
- Automatic transfer of assay protocols and new reagent information into the system using a large capacity read/write DVD
- Automatic sampling from a 96-well microtiter plate, beginning from any well position
- Automatic real-time analysis
- Analysis of multiple assay protocols per microtiter plate

- Barcode reader entry of sample IDs
- Produces sound pressure levels below 85 dBA

Environmental Conditions

- Indoor use only
- Operating temperature: 15°C to 35°C (59°F to 95°F)
- Operating relative humidity: 20% to 80%, noncondensing
- Operating altitude: up to 2400m (7874 ft) above mean sea level
- Shipping temperature: 0°C to 50°C (32°F to 122°F)
- Storage temperature: 10°C to 40°C (50°F to 104°F)

Electronics

- USB 2.0-compatible communications link for fast data transfer
- Input voltage range: either 100-120 V~, 2.0 A 50/60 Hz or 200-240 V~, 1.0 A 50/60 Hz

Optics

- Reporter channel detection: A/D resolution 16 bits
- Reporter detector: CCD, detection bandwidth of 566 to 614 nm
- Classification detector: CCD
- Limit of Detection (LOD): For the reporter channel, using a blank microsphere from region 078, ≤ 700 molecules of phycoerythrin (PE) per microsphere
- Dynamic Range: For the reporter channel, using a microsphere from region 078, ≥ 3.0 decades
- Efficiency: Classification Channels: ≥ 80%

Fluidics

- Sample load rate: 20 µL to 500 µL per second
- Sample uptake volume: 20 µL to 200 µL
- Well-to-well carryover: ≤ 4%
- Sample uptake accuracy: +/- 5%

Microtiter Plates

- Microtiter plate must be 96-well, not to exceed 1" (2.54cm) in height, including heater block.
- Microtiter plate must be compatible with the microtiter heater block temperature when the heater block is in use.
- All microtiter plates have standard width (85.5mm) and length (127.9 mm). Depth varies depending on the type of well. Maximum allowable depth is 1" (2.54cm). Plates must have minimum 0.06" (1.5mm) lip height, standard distance from well center to well center (9mm) and standard distance from A1 center to plate center in both length and width. To be compatible in size with the microtiter heater block, the plate must fit into the heater block so that the top is flush with the heater block.

Microspheres

- Distinguishes 1 to 50 unique MagPlex[®] microspheres in a single sample
- Misclassification Rate ≤ 2%
- Classification Rate ≥ 80%
- Detects and distinguishes surface reporter fluorescence emissions at 590 nm +/- 24 nm on the surface of 1 to 50 unique MagPlex microsphere in a single sample
- Soluble background fluorescence emission at 590 nm +/- 24 nm automatically subtracted from fluorescence intensity values

Chapter 5: Operational and Maintenance Procedures

To ensure accurate test results, properly clean and maintain MAGPIX[®]. Read and follow all instructions in this chapter. To facilitate your maintenance process, print out and use the "*Maintenance Logs*" on page 52.

General Maintenance Precautions

Observe the following general maintenance precautions, which were explained in more detail in the previous chapters:



Personnel who use, maintain, or clean $MAGPIX^{\mbox{\sc 8}}$ should be trained in standard laboratory safety practices and should follow those practices when handling the instrument.



Samples and waste fluid can contain biohazardous material. Where exposure to biohazardous material, including in an aerosol form, exists, follow appropriate biosafety procedures, use personal protective equipment, and use ventilation devices.



Avoid contact with moving parts. Disconnect the instrument from the power source when the procedure instructs you to do so.

Do not remove the cover of MAGPIX. All maintenance can be performed from the outside of the instrument, within the fluid compartment, or within the compartment that is accessible by opening the side access door.

Assessing the Side Compartment

The side compartment of MAGPIX[®] contains the majority of user-maintainable components. The access door to this compartment must remain latched during operation of the instrument. Opening the access door requires a special tool provided with the MAGPIX system.

FIGURE 50. Side Access Door Latch



To open the latch:

- 1. Turn off and unplug the MAGPIX.
- 2. Insert the latch tool into the slot of the latch and turn it clockwise.
- 3. Slide the door to the right.

Daily Procedures

Most of the daily maintenance tasks for MAGPIX[®] can be performed using available software commands. For details about performing these commands, refer to the appropriate software user manual or online help.

Initializing MAGPIX®

Initialize MAGPIX[®] at the start of each day using the xPONENT[®] for MAGPIX software. Refer to the appropriate software user manual or online help. Initialization requires less than five minutes and includes a quick system self-check.

Verifying MAGPIX®

Perform verification using the xPONENT[®] for MAGPIX[®] software. Refer to the appropriate software user manual or online help.

Maintaining Fluids

MAGPIX[®] has a built-in compartment to hold a single-use disposable Drive Fluid container and a reusable waste fluid container. It comes with two waste fluid containers and a two-pack of Drive Fluid containers. All fluid tubing is contained within the instrument.

Monitor fluid levels daily. Replace the empty Drive Fluid container as needed. If MAGPIX operates with an empty Drive Fluid container, the lack of Drive Fluid may interrupt a sample and prevent further samples from being collected.



CAUTION: Use only xMAP[®] Drive Fluid. Use of any other Drive Fluid constitutes improper use and can void the warranty provided by Luminex[®], its authorized partner, or both.

Empty the waste fluid container whenever it is full. Use the following guidelines:

- Replace the newly emptied waste fluid container with the second, dry waste fluid container so the moisture remaining in the first waste fluid container does not trigger a "waste bottle full" message.
- Before removing the waste fluid container, make certain all other fittings and tubes are firmly attached to avoid any contamination from dripping waste fluid.

To empty the waste fluid container:

- 1. Open the fluid compartment at the bottom front of MAGPIX.
- 2. Disconnect the orange waste fluid line from the waste fluid container.
- 3. Carefully remove the waste fluid container from its tray.
- 4. Unscrew the cap on top of the waste fluid container to drain out the fluid.

NOTE: Discard the waste fluid in accord with all local, state, federal, and country-specific biohazard handling regulations.

- 5. Insert the second, dry waste fluid container in the fluid compartment
 - **NOTE:** Make sure the empty waste fluid bottle is dry or the empty bottle will continue to send a "Waste Bottle Full" message.



WARNING: Waste fluid can contain biohazardous infectious agents. Where exposure to potentially biohazardous materials (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), respirators, and ventilation devices.

Shutting Down MAGPIX®

Like initialization, shutdown is a standardized procedure in xPONENT[®] for MAGPIX[®] software. It includes sanitize, clean (with 0.1N NaOH), wash, and soak routines. Refer to the appropriate software user manual or online help for instructions to perform shutdown.



WARNING: Sodium hydroxide is extremely caustic. If it comes into contact with skin, it can burn and cause tissue damage without causing pain. Always wear gloves and goggles when working with sodium hydroxide.

Weekly Procedure

Cleaning MAGPIX®

Clean MAGPIX[®] weekly using a 0.1N sodium hydroxide (NaOH) solution. Refer to the software manual for instructions for running the **Clean** command.

Cleaning the Sample Probe



WARNING: Avoid contact with moving parts. If a plate is running, use the software to execute Stop to avoid the possibility of exposure to moving parts. MAGPIX[®] must not be performing any operations while you carry out this maintenance procedure.

To clean the sample probe:

- 1. Execute STOP if a plate is running. Refer to the software manual for instructions.
- 2. Turn off MAGPIX[®] and unplug the power cord.
- 3. Remove the sample probe.
 - a.Open the side access door of MAGPIX.
 - b. Unscrew the probe fitting on top of the probe completely.
 - c. Grasp the probe gently and push up.
 - d. Lift the probe out of the top of the probe holder.

FIGURE 51. Probe Assembly



1.	Probe fitting (Unscrew and remove)	3.	Probe - Push up gently and lift out of holder
2.	Probe holder		

- 4. Clean the sample probe using either a bath sonicator or a 10 mL syringe, or both. If you are using a bath sonicator, place the tip of the sample probe in the bath sonicator for 2 to 5 minutes. If you are using a syringe, force distilled water through the tip of the sample probe to its large end. This dislodges any debris clogging the tip.
- 5. Replace the sample probe and tightly screw in the probe fitting until it clicks.
- 6. Use the software to perform an automatic probe height adjustment.

NOTE: Perform an automatic probe height adjustment any time the probe is reinstalled after removal.

Performing a Visual Inspection

Inspect MAGPIX[®] weekly. Make sure the instrument is idle, so there are no moving parts. Open the MAGPIX side access door and fluid compartment door and visually inspect for leaks, corrosion, and other signs of improper function. Check all visible tubing connections.

Calibrating and Verifying MAGPIX®

Calibration, with a follow-up verification, is another weekly procedure that can be performed using the xPONENT[®] for MAGPIX[®] software. Refer to the appropriate software user manual or online help for instructions.

Removing Clogs

If you frequently use MAGPIX[®] to test concentrated serum or other debris-ridden samples, Luminex recommends that you perform a clog removal routine weekly. Otherwise, you can perform this procedure as needed. See the appropriate software user manual for instructions. Run the **Remove Clog** routine, using sodium hydroxide (0.1N NaOH) in the Clean reservoir.

To remove clogs:

- 1. Put sodium hydroxide (0.1N NaOH) in the Clean reservoir of the off-plate reagent block.
- 2. Run the **Remove Clog** routine.



WARNING: Sodium hydroxide is extremely caustic. If it comes into contact with skin, it can burn and cause tissue damage without causing pain. Always wear gloves and goggles when working with sodium hydroxide.

Monthly Procedures

Clean the exterior surfaces monthly.

To clean exterior surfaces:

- 1. Turn off MAGPIX[®] and unplug the power cord.
- 2. Clean all exterior surfaces with mild detergent, followed by a household bleach solution diluted to 10% to 20%, followed by distilled water.
- 3. Open the side access door of the instrument.
- 4. Clean all accessible surfaces with detergent, followed by the household bleach solution (10% to 20%), followed by distilled water.



WARNING: Avoid contact with the tubing and electronic parts of the instrument.

- 5. Dry any unpainted metal surfaces to prevent corrosion.
- 6. Plug in the power cord and turn on MAGPIX.

Semi-Annual Procedures

Maintaining Air Filters

MAGPIX[®] has two air filters, one on the bottom of the instrument and one on the back of the instrument. Every six months, remove these air filters, clean them, and reinstall them.

To clean MAGPIX air filters:

- 1. Turn off MAGPIX and unplug the power cord.
- 2. Slide the back filter up out of its holder.
- 3. Lift MAGPIX and slide the bottom filter out of its holder toward the front of the instrument.



CAUTION: Before removing the bottom air filter, remove both the waste fluid and Drive Fluid containers, the off-plate reagent block, and any microtiter plates in the instrument.

4. Clean the filters with a vacuum or with distilled water. Stand the filters upright to air dry.



CAUTION: Filters must be completely dry prior to re-installation.

5. Locate the small incised arrow on the frame of the filter. This indicates air flow. The filter must be installed with the arrow pointing inward.

FIGURE 52. Arrow on Air Filter Frame



- 6. Reinstall the filters.
- 7. Plug in the power cord and turn on MAGPIX.

FIGURE 53. Bottom of MAGPIX[®], Filter Holder



FIGURE 54. Back of MAGPIX[®]. Before and After Filter Removal



Replacing the Syringe Seal

When you replace a syringe seal, also replace the black O-ring that fits inside it. One package contains four of each. To replace the syringe seal:

1. Turn off MAGPIX[®] and unplug the power cord.



WARNING: The plunger guide does NOT deactivate while the seal is being changed; unplugging is necessary to avoid injury.

- 2. Open the side access door of MAGPIX.
- 3. Locate the syringe (glass cylinder with a metal rod plunger).
- 4. Push the plunger guide down. The syringe may fill with clean Drive Fluid.

NOTE: The plunger guide is tight. Be prepared to use some force to push it down.

- 5. Unscrew the syringe from the top of its housing and carefully remove it.
- 6. Pull the plunger out of the syringe and dispose of any Drive Fluid.
- 7. Using a pair of pliers, remove the white plunger seal (at the top of the plunger) and discard it.
- 8. Place the black O-ring inside the new white plunger seal and press the seal down on the top of the plunger.
- 9. Return the plunger to the syringe.
- 10. Screw the syringe back into its housing.

FIGURE 55. The Syringe



1.	Syringe Housing	4.	Glass Cylinder
2.	Metal Rod Plunger	5.	Plunger Guide
3.	Syringe Seal (contains black O-ring)		

- 11. Return the plunger guide to its original position. The bottom of the plunger fits into the indentation in the plunger guide.
- 12. Plug in the power cord and turn on MAGPIX.
- 13. Use the software to run the prime command twice, watching for any leaks in the syringe area.

14. Close the side access door.

Annual Procedures

Replacing the Sample Probe Tube

The tube that connects the sample probe to the valve is subject to wear because of the constant motion of the sample probe. Consequently, maintenance requires replacing it on a yearly basis.

FIGURE 56. Sample Probe Tube



1.	Sample Probe Tube (color-coded black at valve end)	4.	Strain Relief
2.	Valve	5.	Probe Fitting
3.	1/4-28 flat-bottom fittings		

FIGURE 57. Sample Probe Tube Assembly



To replace the sample probe tube:

1. Turn off MAGPIX[®] and unplug the power cord.

- 2. Open the side access door on MAGPIX and locate the probe assembly.
- 3. Unscrew the probe fitting completely. The sample probe tube is connected to it.
- 4. Unscrew the ¼-28 flat-bottom fitting at the valve end of the sample probe tube. The sample probe tube is connected to it. Use pliers to disconnect the ¼-28 flat-bottom fitting if necessary.
- 5. Pull the loose tube through the strain relief to remove it.
- 6. Thread the new piece of tube through the strain relief.
- 7. Screw the ¹/₄-28 flat-bottom fitting on the end of the new sample probe tube assembly into the valve where you removed the fitting in the above step. Tighten the fitting until it clicks.
- 8. Screw the probe fitting on the end of the new sample probe tube assembly into the top of the probe assembly where you removed the probe fitting in the above step. Tighten the fitting until it clicks.

Replacing the Drive Fluid Filter

To replace the Drive Fluid filter on MAGPIX[®]:

- 1. Turn off MAGPIX and unplug the power cord.
- 2. Open the side access door on MAGPIX and locate the Drive Fluid filter at the left of the syringe pump.
- 3. Gently pull the filter from the mounting bracket.
- 4. Unscrew the **Top Tube Attachment** and the **Bottom Tube Attachment** from the top and bottom of the filter, see *Figure 58, "Drive Fluid Filter"* on page 50.
- 5. Ensure that the Drive Fluid filter orientation (top and bottom) matches the following *Figure 58, "Drive Fluid Filter*" on page 50 and reattach the tubing to the ends of the new filter. Tighten both fittings until they click.

FIGURE 58. Drive Fluid Filter



1.	Top Tube Attachment	3.	Bottom Tube Attachment
2.	Filter	4.	Mounting Bracket

- 6. Press the new filter into the mounting bracket.
- 7. Close the side access door.
- 8. Plug in the power cord and turn on MAGPIX.
- 9. Use the software to run the prime command twice. Ensure that the Drive Fluid is being pulled into the syringe during the Prime.

As Needed Maintenance

Replacing Fuses

Periodically, you may need to replace a fuse on MAGPIX[®]. Use fuses with the following specifications:

• F2A, 250 V

The fuse cartridge will accept either 5 mm x 20 mm or 0.25" x 1.25" fuses. Fuses are available from Luminex Corporation. Replacing a fuse requires access to the back of MAGPIX.



DANGER: To avoid serious injury or death by electric shock, turn off MAGPIX and unplug it from the wall before replacing a fuse.

To replace a fuse:

- 1. Unplug the power cable from the instrument.
- 2. Use a small, flat blade screwdriver to open the power module door on the lower right corner of the back of the instrument. The door opens downward. Inside is a red cartridge.
- 3. Use the screwdriver to remove the cartridge.

FIGURE 59. Power Module



1. Insertion Point for Screwdriver or Blade

- 4. Check both of the fuses in the cartridge for damage. A fuse can display physical evidence of damage, for example, broken wire or blackened glass; if it displays no physical evidence, test it for continuity with a voltmeter.
- 5. Replace any damaged fuse with the correct type of fuse.
- 6. Replace the cartridge.
- 7. Shut the module door.
- 8. Plug in the power cord and turn on MAGPIX.

Maintenance Logs

Reproduce the following forms as necessary and use them to record maintenance information. Fill in the dates in the first line of the table. The first table includes a sufficient number of columns for one week (7 days). The second table includes a sufficient number of columns for monthly maintenance (one task monthly), semi-annual maintenance (two tasks twice yearly), and annual maintenance (two tasks yearly). For each item listed at the left, enter your initials under each date on which you perform the task.

Short Term Maintenance - One Week

Date:				
Daily Maintenance				
Initialize with Alcohol Flush				
Verify				
Check Fluid Levels				
Shut Down with Sanitize				
Weekly Maintenance				
Clean MAGPIX [®]				
Clean Probe				
Calibrate and Verify				
Perform Visual Inspection				
Remove Clogs (If necessary)				

Long Term Maintenance - One Year

Date:								 	
Monthly Maintenance									
Clean Exterior Surfaces									
Semi-Annual Maintenance									
Clean Air Filter									
Replace Syringe Seal									
Annual Maintenance									
Replace Drive Fluid Filter									
Replace Sample Probe Tube									

Chapter 6: Troubleshooting Procedures

Troubleshooting procedures help users identify and remedy problems with the instrument.

Overview

To troubleshoot a problem, locate the problem in one of the sections in this chapter, explore the possible causes, and take the described corrective action.

This chapter supplies information about the following topics:

- Power Supply Problems
- Communication Problems
- Clogs
- Fluid Leaks
- Sample Probe Problems
- Calibration Slowness and Failure
- Verification Slowness and Failure
- Acquisition Slowness and Failure
- Carryover Problems
- Bead Detail Irregularities

Technical Support

Contact Luminex Technical Support in the U.S. and Canada by calling 1-877-785-BEAD (-2323). Outside of the U.S. and Canada, call +1 512-381-4397. Contact Luminex Technical Support in Europe by calling +31 162 408 333. Email inquiries to *support* @*luminexcorp.com*.

Additional information is available on the Luminex website. Search the desired topic or navigate through menus. Also, review the website's Technical Support section. Enter *http://www.luminexcorp.com* in your browser's address field. Navigate to the FAQ section.

This chapter does not troubleshoot problems with the PC. For help with PC problems, contact the technical support department for the manufacturer of your PC.

Power Supply Problems

Power supply problems often involve a blown fuse, faulty electronic component, or disconnected cable.



CAUTION: Whenever you deal with a potential electrical problem, be careful to avoid electrical shocks.

Problem	Possible Cause	Corrective Action
MAGPIX [®] will not turn on.	The power cord is disconnected	Plug in the power cord.
	The hard power switch on the back of the instrument is not turned on.	Turn on the switch.
	No voltage is coming from the electrical outlet.	Change to a different outlet. If MAGPIX is plugged into a surge protector, make certain the surge protector is turned on.
	The power supply is faulty.	Contact " <i>Technical</i> Support" on page 54
	A fuse has burned out.	See " <i>Replacing Fuses</i> " on page 51.
Fuses continue to open (blow).	A component has a short circuit.	Contact " <i>Technical</i> <i>Support</i> " on page 54.

Communication Problems

Communication problems described in this section involve the links between the data system (PC and software) and MAGPIX. "Communication" refers to the transfer of data between the PC and MAGPIX, including the current status of the instrument, instrument control, sample acquisition, session uploading, and start, stop, and pause features.

Problem	Possible Cause	Corrective Action
The PC cannot establish a connection with MAGPIX [®] .	The communication cable is unplugged or plugged into the wrong port.	Plug in or move the communications cable.
	MAGPIX is not turned on.	Turn off the PC. Turn on the MAGPIX and then turn on the PC.

Clogs

Often, a clog somewhere in MAGPIX[®] is the cause of a problem with calibration, verification, or data acquisition. To determine whether there is a clog, run performance verification to see if the fluidics function is operating properly. In the event you encounter a problem that is clog-related, use the following procedure.

To troubleshoot a possible clog:

- 1. Clean and adjust the sample probe. See "*Cleaning the Sample Probe*" on page 44.
- 2. Perform the procedure for removing clogs. See "*Removing Clogs*" on page 45.
- 3. Run calibration and verification.

If this procedure is unsuccessful, call "Technical Support" on page 54.

Fluid Leaks

There are numerous places in MAGPIX[®] where fluid can leak. Most leaks can be easily fixed; for the remainder, call *"Technical Support"* on page 54.

Problem	Possible Cause	Corrective Action
Fluid is pooled around MAGPIX [®] .	Fittings, fluid tubes, or components are damaged, loose, or faulty.	Turn off and disconnect the instrument to avoid electrical shock, Check for possible sources of leaking and correct them. if leaking continues, contact " <i>Technical</i> <i>Support</i> " on page 54.
Fluid leaks within the instrument:		
A fluid tube leaks.	The tube is damaged.	If it is the sample probe tube, replace it. See the " <i>Replacing the Sample Probe</i> <i>Tube</i> " on page 49 for assistance. Otherwise, contact " <i>Technical Support</i> " on page 54.
The waste bottle leaks.	The waste bottle fitting is loose.	Reset the waste bottle fitting.
The Drive Fluid filter leaks.	The Drive Fluid filter fittings are loose.	Hand-tighten the Drive Fluid filter fittings.
The sample probe leaks.	The sample probe is clogged.	See " <i>Clogs"</i> on page 55.
	The sample probe is loose.	Tighten the fitting.
The sample valve leaks.	The sample valve has one or more loose fittings.	Hand-tighten the sample valve fittings.
	The sample valve is faulty.	Contact "Technical Support" on page 54.
The syringe seal leaks.	The seal is worn out or faulty.	Replace the syringe seal. See " <i>Replacing the Syringe Seal</i> " on page 47.
The syringe valve leaks.	The valve is loose or faulty.	Hand-tighten the syringe connection (silver knob) on the syringe valve. Run a Prime command. If leaking continues, contact " <i>Technical Support</i> " on page 54.

Sample Probe Problems

Problems with the sample probe can lead to both fluid leaks and acquisition failure.

Problem	Possible Cause	Corrective Action
The sample probe leaks.		See " <i>Fluid</i> s" on page 8.
The sample arm is stuck in the up or down position.	The sample probe motor connections are loose.	Contact " <i>Technical Support</i> " on page 54.
	The sample probe motor is faulty.	Contact " <i>Technical Support</i> " on page 54.
The sample arm does not go down smoothly.	The microtiter plate is incorrectly seated.	Adjust the microtiter plate.
	The microtiter plate is warped.	Replace the microtiter plate.
	The sample probe is bent.	Remove the sample probe from the instrument and roll it on a flat surface to straighten. If a sample probe has been bent and rolled straight more than once, discard it and replace it with a new sample probe. Perform an automatic sample probe height adjustment using the software.

Calibration Slowness and Failure

Calibration problems can result from a variety of causes, many of them easily correctable human errors.

Problem	Corrective Action	
Possible Calibration Microsphere Causes:		
The calibration microspheres are not fully resuspended.	Vortex the calibration vials to resuspend the microspheres.	
The wrong lot number or target values were entered in the software.	Correct the lot number and target values in the software.	
The calibration microspheres are in the wrong well.	Change the well setting in the software.	
There are not enough calibration microspheres in the well.	Add at least five drops of calibration microspheres to the well. For accurate drop volume, hold the vial upside down at a 90 degree angle to the microtiter plate while dispensing them.	
You are using the incorrect calibration microspheres.	Use the xMAP [®] MAGPIX [®] Calibration Kit.	
The calibration microsphere lot is expired.	Substitute an unexpired bottle of calibrator microspheres.	
Possible Sample Probe Causes:		
The sample probe height is incorrect.	Perform an automatic sample probe height adjustment.	
The sample probe is clogged.	See "Clogs" on page 55.	
The probe fitting is loose.	Tighten the probe fitting.	
Other Possible Causes:		
There is a partial clog in the instrument.	See "Clogs" on page 55.	

There is air in the instrument.	Perform an automatic sample probe height adjustment. Use the software to run a prime command three times, an alcohol flush command twice, then a wash command three times with distilled water.	
	Make sure the Drive Fluid coil is not pinched.	
The sample valve is faulty.	Contact "Technical Support" on page 54.	
There is a problem internal to the instrument.	Review the log of calibration reports. Check for dramatic changes in temperature or voltage. If any of these are present, contact " <i>Technical Support</i> " on page 54.	
No events are being collected during calibration.	Check the drive and waste fluid levels. Verify that tubing for both containers is tightly connected.	
	Check for sample probe problems.	

Verification Slowness and Failure

Like calibration problems, verification problems can have a variety of causes..

Problem	Corrective Action	
Possible Verification Microsphere Causes:		
The verification microspheres are not fully suspended.	Vortex the verification vials to resuspend the microspheres.	
The wrong lot number or target values were entered in the software.	Correct the lot number and target values in the software.	
The instrument verification microspheres are in the wrong well.	Change the well setting in the software.	
There are not enough verification microspheres in the well.	Add at least five drops of verification microspheres to the well. For accurate drop volume, hold the vial upside down at a 90 degree angle to the microtiter plate while dispensing them.	
You are using the incorrect verification microspheres.	Verify that you are using the xMAP [®] MAGPIX [®] Performance Verification Kit.	
The verification lot is expired.	Use an unexpired bottle of verification microspheres.	
The verification microspheres have been diluted.	Substitute undiluted verification microspheres.	
The verification microspheres are photobleached.	Use a different bottle of verifications microspheres, one which has been protected from light during storage.	
Possible Sample Probe Causes:		
The sample probe height is incorrect.	Perform an automatic sample probe height adjustment.	
The sample probe is clogged.	See "Clogs" on page 55.	
The sample valve is faulty.	Contact "Technical Support" on page 54.	
Other Possible Causes:		
There is carryover from the calibrators or the previous assay.	See "Carryover Problems" on page 59.	

There is air in the instrument.	Verify the sample probe height. Use the software to run a prime command three times, an alcohol flush command twice, then a wash command three times with distilled water.	
	Make sure the Drive Fluid coil is not pinched.	
There is a problem internal to the instrument.	Review the log of calibration reports. Check for dramatic changes in temperature or voltage. If any of these are present, contact " <i>Technical Support</i> " on page 54.	

Acquisition Slowness and Failure

Acquisition failure can result from many of the same causes as calibration and verification failure, in addition to sample and volume problems.

Problem	Corrective Action	
Possible xMAP [®] Microsphere Causes:		
The xMAP [®] microspheres are not fully suspended.	Gently vortex the microtiter plate or resuspend beads with a multichannel pipette to ensure that the microspheres are present in the solution.	
The wrong lot number or target values are entered in software.	Correct the lot number and target values in the software.	
The wrong wells are selected for the xMAP [®] microspheres.	Change the well setting in the software.	
The xMAP [®] microspheres have expired.	Substitute an unexpired bottle of xMAP [®] microspheres.	
The xMAP [®] microspheres are photobleached.	Substitute xMAP [®] microspheres that are not photobleached.	
Possible Sample Probe Causes:		
The sample probe height is incorrect.	Perform an automatic sample probe height adjustment.	
The sample probe is clogged.	See "Clogs" on page 55.	
Other Possible Causes:		
The Drive Fluid or waste line is not fully connected.	Disconnect and reconnect the lines.	
Air is present in the instrument.	Verify the sample probe height. Use the software to run a prime command three times, an alcohol flush command twice, then a wash command three times with distilled water.	
	Make sure the Drive Fluid coil is not pinched.	
The acquisition volume is set too high.	Set the acquisition volume to at least 25 μ L less than the actual volume in your wells. This enables the probe to acquire sample more efficiently with less chance of incorporating air in the sample.	
The sample is too concentrated.	Dilute concentrated biological fluids, such as serum or plasma, at least 1:5.	

Carryover Problems

Carryover from calibration can interfere with verification; likewise, carryover from an assay can interfere with correct reading of the following assay. Take the following steps to eliminate carryover:

- Begin by performing four rinse cycles.
- If that fails, run the Clean command twice using a 0.1N sodium hydroxide solution.
- If running the Clean command twice fails, run the Enhanced Startup Up Routine.

Bead Irregularities

Use these tools to assist in diagnosing instrument and kit-related problems:

- MAGPIX[®] calibrators
- MAGPIX performance verifiers
- Assay standards
- Assay controls
- Error messages

Review the log of calibration reports routinely to detect trends.

Use MAGPIX performance verifiers to check the success of the instrument calibration and to troubleshoot. If there is a problem with kit results, MAGPIX performance verifiers can help determine if the problem is related to the instrument. If calibration and verification are successful, contact the kit manufacturer.

The following table identifies the three possible categories of microsphere dot plots: normal, irregular due to photobleaching of the microspheres, and irregular due to MAGPIX being out of calibration.

Appearance	Description	Possible Problem	Solution
Normal Bead Grouping			
	MagPlex [®] verifiers form a tight bead population within the boundaries of the gray region.		
Irregular Bead Grouping: Photoblea	ched Microspheres vs. C	out-of-Calibration Instrum	nent
*	MagPlex [®] verifiers are outside of their region (above or to the right).	Instrument is out of calibration.	Recalibrate and verify.

Appearance	Description	Possible Problem	Solution
	MagPlex [®] verifiers are outside of their region (below or to the left).	MagPlex [®] calibrators are photobleached.	Recalibrate with new MagPlex [®] calibrators and verify.
Irregular Bead Grouping due to Out	-of-Calibration Instrumen	t	
	MagPlex [®] verifiers are anywhere outside of their region.	MAGPIX [®] is out of calibration.	Recalibrate and verify.
	The dot plot is elongated, horizontally or vertically.		
	MagPlex [®] beads fail to form a tight population within their regions. The dot plot is wide and possibly extends horizontally, vertically, or diagonally to the left.		

Appendix A: Storage

If you need to put MAGPIX[®] in long-term storage for any period longer than a month, or if you are preparing it for use after removing it from long-term storage, use the following procedures.

Storing MAGPIX®

This procedure explains the steps you should take before placing MAGPIX® into long-term storage

- 1. Use the software to perform a preparation for storage routine.
- 2. Remove the sample probe from the instrument and flush it with distilled water from the narrow end out through the larger end.
- 3. Replace the sample probe in the probe holder and wrap the end of the probe with Parafilm[®].
- 4. Remove the Drive Fluid container and empty the waste fluid container.
- 5. Eject the plate carrier and remove the microtiter plate and the off-plate reagent block from the plate carrier.

Preparing MAGPIX® for Use After Storage

Follow this procedure before you begin using MAGPIX[®] after its removal from long-term storage.

To prepare MAGPIX for use after storage:

- 1. Make sure that the drive fluid container has a sufficient amount of Drive Fluid and that the waste fluid container is empty.
- 2. Remove the Parafilm[®] from the end of the sample probe.
- 3. Turn on MAGPIX and watch for the following indications of correct response:
 - Air blows out of the fans.
 - The syringe inside the side access door of MAGPIX initializes.
- 4. Turn on the PC and start up the software.
- 5. Use the software to run a **Revive After Storage** routine.

Appendix B: Shipping

If a serious problem arises with MAGPIX[®], it may be necessary to return it to Luminex Corporation for repairs. If Luminex Technical Support directs you to return MAGPIX, the Technical Support representative will provide you with all necessary information as well as a Return Material Authorization (RMA) number.

Storing MAGPIX®

This procedure explains the steps you should take before placing MAGPIX[®] into long-term storage.



CAUTION: Before the instrument is returned, perform two procedures: Decontaminate the instrument and prepare the instrument for shipping. For the decontamination procedure, see *"Decontamination Procedure"*. For instructions for preparing the instrument for shipping, see below.

Preparing MAGPIX® for Shipping

To prepare MAGPIX[®] for shipping:

- 1. Disconnect and remove the Drive Fluid container.
- 2. Remove the off plate reagent block and any microtiter plates.
- 3. Perform two Prime commands. This should remove fluid from the lines.
- 4. Empty the waste container.
- 5. Remove the probe.
- 6. Reinsert the red shipping plug. The Luminex-provided shipping materials include this.

Shipment Checklist

Complete the following checklist, sign and date it, and return it with MAGPIX[®].

1. Remove all specimens from the instrument.

2. Decontaminate the instrument.

3. Prepare the instrument for shipping.

Was there	an internal	leak in the	system?
YES			

NO

Printed Name:	
Signature:	
Company/Institution:	
Date:	
Instrument Serial Number:	

Appendix C: Part Numbers

Hardware

Product Description	Customer Number
Access Door Tool	CN-0264-01
Fuse 2AMP 250V Fast Acting (Qty 1)	CN-0019-01
Sample Probe Needle	CN-0221-01
Heater Block, 96 Wellplate	CN-0224-01
Cable, USB (A to B)	CN-0271-01
Air Filter 4.5 x 4.5	CN-0257-01
Drive Fluid Filter	CN-0258-01
Sample-to-Valve Tubing Assembly	CN-0259-01
Off-Plate Reagent Block	CN-0260-01
Waste Bottle Assembly	CN-0261-01
Syringe, 500 μL Ball End	CN-0262-01
Sample Probe Height Adjustment Kit	CN-0263-01
Barcode Scanner	CN-PC03-01
Cable, Power	CN-PXXX-01*

*XXX is a country specific part number. For more information, contact "Technical Support".

Reagents

Product Description	Customer Number
MAGPIX [®] Calibration Kit, 25 Uses, IVD	MPXIVD-CAL-K25
MAGPIX [®] Performance Verification Kit, 25 Uses, IVD	MPXIVD-PVER-K25
MAGPIX [®] Drive Fluid, 4PK, IVD	MPXDF-4PK-1