

Luminex[®]



Luminex[®] 200[™]

System User Manual



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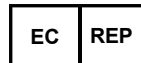
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Luminex® 200™ System User Manual

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GATING PRODUCT TO ANALYTES, THE COMPOSITION OF MATTER OF THE SPECIFIC CHEMISTRIES OF THE ASSAYS DEVELOPED BY BUYER AND METHODS OF PERFORMING THE ASSAYS (I.E., THE PROTOCOL FOR THE ASSAY).

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1

Safety

Please become familiar with the information in this chapter before using the equipment. Do not perform procedures on your Luminex® 200™ system that are not specifically contained in this manual, unless you are directed to do so by Luminex Technical Support.

Intended Use

The Luminex 200 Instrument 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 instrumentation is used with a specific assay to measure multiple similar analytes that establish a single indicator to aid in diagnosis. The device includes a signal reader unit, raw data storage mechanisms, data acquisition software and software to process detected signals.

Warnings and Notes

Informational notes and warnings appear in this manual.

Note: A note provides general helpful information. No safety or performance issues are involved.






















Caution: This message is used in cases where the hazard is minor or only potential hazard is present. Failure to comply with the caution may result in potentially 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.

Symbols

These symbols describe warnings, cautions, and general information used in the operation of this instrument. Some of these symbols are further defined under “Safety Precautions.”

Symbol	Description	Symbol	Description	Symbol	Description
	Alternating current (AC)		Warning (refer to manual)		Warning (refer to manual)
	Protective ground		Warning (refer to manual)		Warning (refer to manual)
	On		Warning (refer to manual)		Warning (refer to manual)
○	Off		Catalog Number		Consult instructions for use
	In vitro Diagnostic Medical Device		Batch Code		Serial Number
	Temperature Limitation		Expiration Date		Date of Manufacture
	Manufacturer		Underwriter’s Laboratory		Canadian Underwriter’s Laboratory
	European Union Conformity		WEEE - Do not throw in trash		

Safety Precautions

Read the following safety information before setting up or using the Luminex 200 analyzer. A user should be present during operation. This system contains electrical, mechanical, and laser components which, if handled improperly, are potentially harmful. In addition, biological hazards may be present during system operation. Therefore, we recommend that all system users become familiar with the specific safety advisories below, in addition to adhering to standard laboratory safety practices. The protection provided by the equipment may be impaired or the warranty voided if the system is used in a manner not specified by the instructions or by Luminex Corporation.

Fluidics

This system contains fluidics. 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 disconnect means; power cords must be removed from the outlet. Contact Luminex Corporation for further information.

You must monitor waste levels manually. Do not allow the waste container to overflow! Empty the waste container each time the sheath fluid container is filled. Do not place the waste container on top of the instrument. Contact Luminex Technical Support before relocating the waste container or rerouting the waste line.

Warning: If biological samples have been tested with the system, use your standard laboratory safety practices when handling system waste.

Electromagnetic Compatibility

The Luminex 200 system complies with the emission and immunity requirements described in EN 61326-1 and EN 61236-2-6. The electromagnetic environment should be evaluated prior to operation.

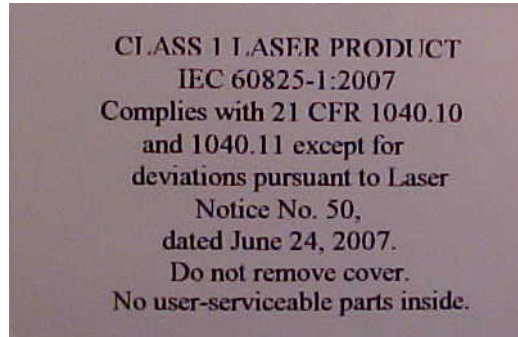
Warning: Do not use this device in close proximity to sources of strong electromagnetic radiation, for example, unshielded intentional RF sources, as these may interfere with proper operation.

Warning: Always handle the Luminex 200 system according to Luminex instructions to avoid any possible interference from its electromagnetic fields.

Luminex 200 Analyzer Laser

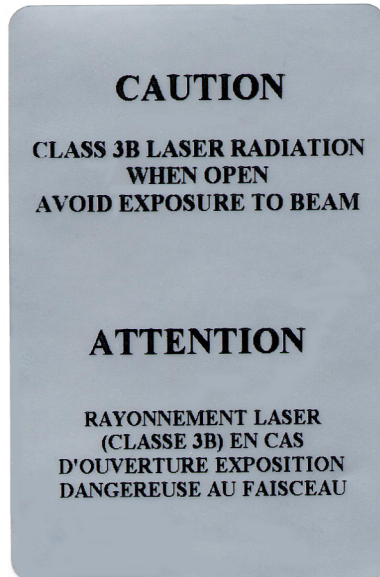
The Luminex 200 instrument is classified under FDA 21 CFR 1040.10 and 1040.11 as a Class I laser product consisting of two Class IIIb lasers within the instrument. The accessory bar code reader is classified as Class II. In accordance with IEC 60825-1, the instrument is classified as Class 1, containing two Class 3b lasers, and including an accessory Class 2 bar code reader. The Luminex 200 complies with IEC 60825-1 and 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.

The following label appears on the back of the Luminex 200 instrument.



Under NO circumstances should you remove the Luminex 200 analyzer cover! When performing routine maintenance, turn power to the Luminex 200 analyzer OFF and disconnect the power cord.

All laser apertures are located within the Luminex 200 analyzer and are contained within a protective housing.



Warning: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Barcode Reader Laser

Do not stare into the beam or shine it into other people's eyes.

Mechanical



Warning: During operation, this system contains exposed, moving parts. Risk of personal injury is present. Observe all warnings and cautions.



Warning: During operation, this system contains exposed, moving parts which could result in puncture hazard. Risk of personal injury is present. Keep hands and fingers away from the Luminex XYP instrument slot during operation.



Warning: During operation, this system contains exposed, moving parts which could result in pinch point hazard. Risk of personal injury is present. Keep hands and fingers away from the Luminex XYP instrument slot during operation.

Access doors must be closed while operating the Luminex 200 analyzer; the operator must be present during operation.

Biological



Warning: Human and animal samples may contain biohazardous infectious agents.

Where exposure (including aerosol) to potentially biohazardous material exists, follow appropriate biosafety procedures and use personal protective equipment, such as gloves, gowns, laboratory coats, face shields, or mask and eye protection, and ventilation devices.

Observe all local, state, and federal biohazard handling regulations when disposing of biohazardous waste material.

Heat



Warning: The heater plate of the Luminex XYP instrument may be hot and could cause personal injury if touched. Do not touch the heater plate.

Blue Indicator Light

The blue light above the Luminex 200 analyzer sample arm indicates the on/off status of the Luminex 200 analyzer, and is harmless. The blue light-emitting diode (LED) does not emit light in the UV spectrum.

Decontaminating the Luminex 200 Analyzer for Return Shipment

Luminex Technical Support will give you a Return Material Authorization (RMA) number if they direct you to return the system. They will explain how to return the system according to Luminex procedures.

The accessible surfaces and the internal fluidics system must be sanitized and decontaminated before returning the analyzer. This is particularly important when biohazardous samples have been run. Make a copy of this page to fill out and return with the system.

Complete the following checklist, signed and dated, and return it with the Luminex 200 analyzer.

Note: It is the user's responsibility to decontaminate the analyzer before shipment.

- 1. Remove all specimens, disposables, and reagents from the system.
- 2. Disconnect the sheath line going from the SD system to the analyzer.
- 3. Connect a sheath bottle filled with a solution of 10% to 20% household bleach solution to the analyzer.
- 4. Sanitize the system using the Sanitize command in the Luminex software. Follow this by washing twice with distilled water.
- 5. Disconnect the system from AC power by turning off the power switch on the rear of the system, then unplugging the analyzer power cord from the wall source.
- 6. Disconnect the SD system and waste and sheath containers.
- 7. Rinse the waste container with 10% to 20% household bleach solution and drain.
- 8. Wash all exterior surfaces with a mild detergent, followed by a 10% to 20% household bleach solution.
- 9. Open the front doors of the analyzer. Clean all accessible surfaces with mild detergent followed by a 10% to 20% household bleach solution.
- 10. Pack the system within a biohazard bag, place it in the corrugated box, then insert it in its original packaging or an approved shipping container. Attach this checklist to the top of the corrugated box prior to packaging in the crate.

Was there an internal leak in the system? Yes No

Print Name: _____

Signature: _____

Date: _____ Instrument Serial No. _____

2

The System

Theory of Operation

Luminex xMAP technology is based on flow cell fluorometry with Luminex-developed innovations. The fluidics, optics, robotics, temperature control, software, and xMAP microspheres work together to enable simultaneous analysis of up to 100 analytes in a single test sample. Assay analysis requiring temperature control is provided through the Luminex XYP instrument heater block.

There are two fluidics paths in the Luminex 200 analyzer. The first path involves a syringe-driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The syringe-driven system transports a specified volume of sample from a sample container to the cuvette. The sample is injected into the cuvette at a steady rate for analysis. Following analysis, the sample path is automatically purged with Luminex xMAP Sheath Fluid by the second fluidics path. This process removes residual sample within the tubing, valves, and probe. The second fluidics path is driven by positive air pressure and supplies sheath fluid to the cuvette and sample path.

Luminex xMAP Sheath Fluid is the delivery medium of the sample to the optics component. The analysis sample is acquired using a sample probe from a 96-well microtiter plate via the Luminex XYP instrument and injected into the base of the cuvette. The sample then passes through with sheath fluid at a reduced rate resulting in a narrow sample core to ensure that each microsphere is illuminated individually. The sample injection rate is such that the xMAP microspheres are introduced to the optics path as a series of single events. The Luminex SD system lets you run samples continuously without refilling sheath bottles. It automatically draws sheath from a non pressurized bulk sheath container to constantly maintain a reservoir of pressurized sheath fluid. A single 20 liter sheath container provides enough fluid for 48 hours or more of normal operation.

The optics assembly consists of two lasers. One laser excites the dye mixture inside the xMAP microspheres and the second laser excites the fluorophore bound to the surface of the xMAP microspheres. Avalanche photo diode detectors measure the excitation emission intensities of the color coding classification dye mixtures inside the xMAP microspheres and a photomultiplier tube detects the excitation emission intensity of the reporter molecule bound to the surface of the xMAP microspheres. High speed digital signal processors and advanced computer algorithms provide analysis of the xMAP microspheres as they are processed through the Luminex 200 analyzer. Results of the analyses are processed and provided in a report format.

Hardware

The Luminex 200 system includes the following hardware:

- Luminex 200 analyzer
- Luminex XYP instrument
- Luminex Sheath Delivery System (Luminex SD™)
- Power cables
- Two long sample probes
- Reservoir
- Shield
- Heater block
- Sheath fluid container
- Waste container
- Sheath fluid line
- Air line
- Sheath fluid intake line
- Communications: 1 serial communication cable
- Communications: 1 USB communication cable
- Communications: 1 CANBUS cable (short cable)
- Barcode reader
- Sample probe height alignment kit

xMAP Technology Reagents

- IS 2.3**
- Classification calibration microspheres (CAL1)
 - Reporter calibration microspheres (CAL2)
 - Classification control microspheres (CON1)

- Reporter control microspheres (CON2)
- Luminex xMAP Sheath Fluid

xPONENT 3.1

- Calibration Kit (CAL)
- Verification Kit (VER)
- Luminex xMAP Sheath Fluid

Required Laboratory Reagents

- Household bleach
- 70% isopropanol or 70% ethanol
- Mild detergent
- Distilled water

Luminex Software

Luminex software provides complete control of the system and performs data analysis. Your Luminex 200 system is preloaded with the Luminex software. However, we supply a software DVD should you need to reinstall the software.

This software requires a dedicated system. Unauthorized additional software is prohibited and may result in improper operation of the system.

Luminex 200 Performance Specifications

Speed

- USB communications link for fast data transfer
- Automatic transfer of assay templates and new reagent information into the system via a large capacity read/write DVD
- Installation: < 4 hours
- System calibration: < 10 minutes
- System controls: < 10 minutes
- Barcode reader entry of sample IDs
- Automatic post-analysis
- Analyze one 96-well plate/hour depending on manufacturer's kit
- Up to 100 xMAP microsphere sets per sample
- System warmup: 30 minutes. Systems that remain inactive for at least four hours will require a warm-up to restart the lasers. After acquiring sample, running system calibrators, running system controls, and warming up the instrument, the system resets the four-hour internal clock.

Accuracy and Precision

- Sample uptake volume: $\pm 5\%$
- Classification of xMAP microspheres: $> 80\%$
- Misclassification of xMAP microspheres: $\leq 2\%$ - may vary by xMAP microsphere product lines. Refer to the specific product information sheet for further details.
- Temperature control: 0°C to $+ 2^{\circ}\text{C}$ of target
- Internal sample carry over: $< 0.9\%$
- Soluble background fluorescence emission at 575 nm automatically subtracted from fluorescence intensity values

Sensitivity

- Detect 1000 fluorochromes phycoerythrin (PE) per xMAP microsphere
- Reporter channel dynamic range: 3.5 decades of detection

Capacity

The specifications below reflect minimum capacity values:

- Analyze multiple 96-well plates per batch
- Analyze multiple assay templates per plate
- Distinguish a minimum of 1 to a maximum of 100 unique xMAP microsphere sets in a single sample
- Detect and distinguish surface reporter fluorescence emissions at 575 nm on the surface of 1-100 unique xMAP microspheres sets in a single sample
- Sample core: 15-20 μm core at 1 $\mu\text{L}/\text{sec}$. sample inject rate
- Maintain samples at a constant temperature from 35°C to 55°C (95°F to 131°F)
- Automatic sampling from a 96-well plate
- Start sampling from any well position
- Sheath container and waste container hold enough volume to run up to two 96-well plates between refills
- Microtiter plates with 96 wells must be compatible with the Luminex XYP instrument plate holder. The following microtiter plate types are compatible with the Luminex XYP instrument plate holder: flatbottom, conical, round, filter bottom, half plates, overall height no more than 0.75" (19 mm), any color.
- Microtiter plates with 96 wells must be compatible with Luminex XYP instrument heater block temperature from 35°C to 55°C (95°F to 131°F) when performing heated assays and using the heater block.

Luminex 200 Analyzer General

- Indoor use only
- Operating temperature: 15°C to 30°C (59°F to 86°F)
- Humidity: 20% to 80%, noncondensing
- Altitude: Operation up to 2400 m (7874 ft.) above mean sea level
- Physical dimensions: 43 cm (17 inches) W x 50.5 cm (20 inches) D x 24.5 cm (9.5 inches) H
- Weight: maximum of 25 kg (60 lbs.)
- UL installation category: UL Installation Category II, as defined in Annex J of UL 61010A-1
- Pollution degree: UL Pollution Degree 2, as defined in Section 3.7.3.2 of UL 61010A-1
- Shipping and storage: The allowable shipping and storage temperature and humidity ranges are 0°C to + 50°C and 20-80% noncondensing, respectively
- Input voltage range: 100 - 120 V~ ± 10%, 1.4 Amp, and 200-240 V~ ± 10%, 0.8 Amp, 47-63 Hz.
- AC inlet fuse: 3 Amp, 250 V~, fast acting

Optics

- Reporter laser: 532 nm, nominal output 10-15 mW, maximum 500 mW, frequency-doubled diode; mode of operation, continuous wave (CW)
- Classification laser: 635 nm, 9.1 mW ± 6%, maximum output 25 mW, diode; mode of operation, continuous wave (CW)
- Reporter detector: Photomultiplier tube, detection bandwidth of 565-585 nm
- Classification detector: Avalanche photo diodes with temperature compensation
- Doublet discrimination detector: Avalanche photo diodes with temperature compensation

Fluidics

- Sheath flow rate 90 μ L ± 5 μ L/second
- Cuvette: 200 micron square flow channel
- Sample injection rate: 1 μ L/second ± 0.05 μ L
- Sample uptake volume: 20-200 μ L

Electronics

- Reporter channel detection: A/D resolution 14 bits
- Communications interface: USB
- Luminex XYP instrument, communications interface: RS 232

Luminex XYP Instrument General

- Ambient temperature: 15°C to 30°C (59°F to 86°F)
- Humidity: 20% to 80%, noncondensing
- Altitude: operation up to 2400 m (7874 ft) above mean sea level
- Physical dimensions: 44 cm (17.25 inches) W x 60 cm (23.5 inches) D x 8 cm (3 inches) H
- Weight: 15 kg (33 lbs.)
- UL installation category: UL Installation Category II, as defined in Annex J of UL 61010A-1
- Pollution degree: UL Pollution Degree 2, as defined in Section 3.7.3.2 of UL 61010A-1
- Heater operating range: 35°C to 55°C (95°F to 131°F) with tolerance 0°C to +2°C
- Input voltage range: 100-240 V~ ± 10%, 1.8 Amps, 47-63 Hz
- AC inlet fuse: 3 A, 250 V~, fast acting

Luminex SD System General

- Ambient temperature: 15°C to 30°C (59° to 86°F)
- Humidity: 20% to 80%, noncondensing
- Altitude: designed to operate at up to 2400m (7874 feet) above mean sea level
- Physical dimensions: 20 cm (8 inches) W x 30 cm (11.75 inches) D x 24.75 cm (9.75 inches) H
- Weight: 9 kg (20 lbs)
- UL installation category: UL Installation Category II, as defined in Annex J of UL 61010A-1
- Pollution degree: UL Pollution Degree 2, as defined in Section 3.7.3.2 of UL 61010A-1
- Input voltage range: 100-240 V~ ± 10%, 0.4 Amps, 47-63 Hz
- AC inlet fuse: 2 Amp, 250 V~, time lag

PC Specifications

For updated information regarding the PC, notebook, or operating system, go to <http://www.luminexcorp.com>, then click on the Support link to open the FAQ list.

Recommended Additional Equipment

Uninterruptible Power Supply (UPS)

Luminex highly recommends using an uninterruptible power supply (UPS) to protect your system from power outages. Choose one that can provide 1050 Watts for at least 45 minutes. The UPS should be

UL listed (or equivalent), CSA certified, and CE marked when used internationally.

Surge Protector

If you do not use a UPS, use a surge protector. Choose a protector that meets your needs. Factors to consider include electrical environment, endurance, suppressed voltage rating, and method of protection. It should have six outlets, rated at least 1500 Watts, and be UL listed, CSA certified, CE marked for nondomestic use when used internationally.

Printer

Printer, HP LaserJet 2300 or available equivalent

Barcode Labels

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

Vortex

VWR product number 58816-121: Speed range 0-3200 rpm or equivalent

Bath Sonicator

Cole-Parmer® product number 08849-00: Operating frequency 55 kHz or equivalent

System Overview

The system consists of three subsystems: electronic, fluidic, and optical. The following section describes the user-accessible components of each subsystem.

Electronics

Power Input Module

The power input modules contain the on/off switch and fuses.

Communications Ports (DB9-PIN)

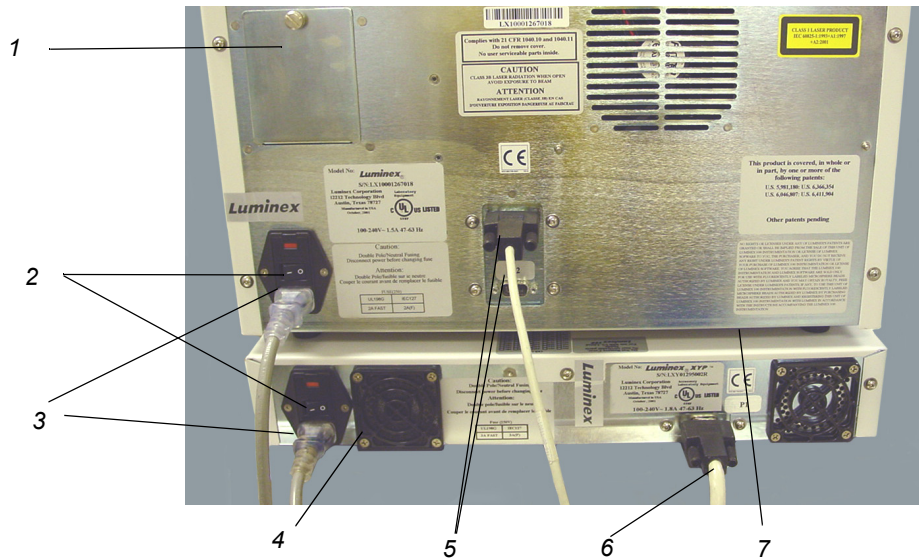
The communications port connects the Luminex 200 analyzer or the Luminex XYP instrument to the computer, and the Luminex SD system to the Luminex 200 analyzer.

Luminex 200 Analyzer Ventilation Filter

Located on the bottom of the Luminex 200 analyzer, the filter must be checked and cleaned as necessary. For proper ventilation, do not obstruct the area below and allow at least two inches (5 cm) of clearance around the Luminex 200 analyzer.

Luminex XYP Instrument Ventilation Filter

The XYP instrument ventilation filter cleans the air that cools the internal parts of the Luminex XYP instrument. See Figure 1.



- | | |
|----------------------------------|---|
| 1. Air intake filter access door | 5. Communication Ports (DB9) |
| 2. Power Switch | 6. XYP Communication Port (DB9) |
| 3. Power Input Module | 7. Analyzer ventilation filter
(on bottom of analyzer) |
| 4. XYP Ventilation Filter | |

Figure 1 Back of the Luminex 200 Analyzer and Luminex XYP Instrument

Fluidics

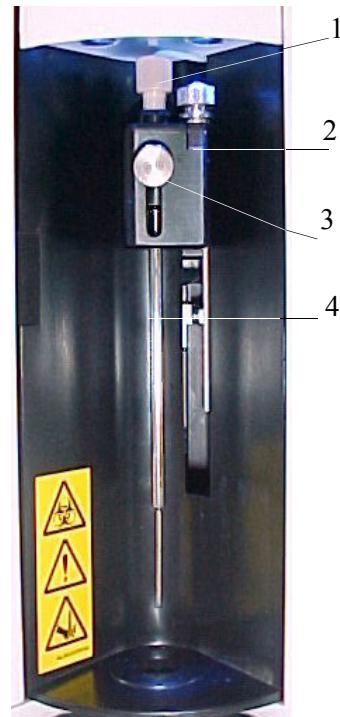
Luminex Instrument Sample Probe

A stainless steel sample probe acquires the sample.

Warning: During operation, this system contains exposed moving parts that can result in a puncture hazard. Risk of personal injury is present. Keep hands and fingers away from the sample probe. The shield should be in place.

Cheminert® Fitting

This fitting attaches the sample probe to the sample tubing. Disconnect this fitting when you remove the sample probe. See Figure 2.

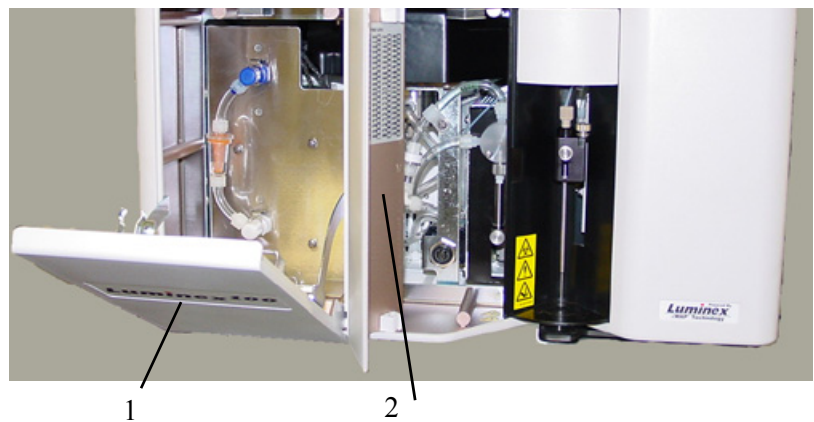


- 1. Cheminert Fitting
- 2. Probe Holder
- 3. Front thumbscrew
- 4. Luminex XYP Instrument Sample Probe

Figure 2 Fluidics Components

Access Doors

The Luminex 200 analyzer has three access doors. Two of the access doors are on the front, and the third is on the back. The front left access door supplies access to the sheath filter. The front center access door supplies access to the syringe. The rear access door supplies access to the air intake filter. See Figure 3.



- 1. Left door, access to service panel
- 2. Center door, access to syringe

Figure 3 Luminex 200 Analyzer Access Doors

Air Intake Filter A replaceable air intake filter cleans the air used to pressurize sheath fluid. This filter is enclosed behind an access door located on the back of the Luminex 200 analyzer.

Syringe The syringe delivers a sample from the 96-well microtiter plate to the cuvette.

Sheath Filter The sheath filter removes particles greater than ten microns in diameter from the sheath fluid.

Air, Waste, and Sheath Fluid Connectors The air, waste, and sheath connectors, located on the left side of the analyzer, connect to the SD system and waste fluid containers using clear tubing. The air connector is green, the sheath fluid connector is blue, and the waste fluid connector is orange.

Luminex Sheath Delivery System For proper operation, place the Luminex SD system at the same level as the base of the Luminex XYP instrument. Do not put it on top of the Luminex 200 analyzer. If you are not using the SD system, sheath fluid levels must be monitored manually. Check the sheath fluid level before starting a run or procedure.

Warning: If biological samples have been tested with the system, use your standard laboratory safety practices.

Waste Fluid Container The waste fluid container receives waste from the system. **The waste container should not be placed on top of the instrument. Ensure that the waste tubing is not elevated above the level of the Luminex 200 analyzer at any point.** Contact Luminex Technical Support before you relocate the waste fluid container. To maintain a stable flow rate, do not move the waste line or container during system operation.

Warning: Waste levels must be manually monitored. Do not allow the waste container to overflow.

Optical

The optical system consists of the optical assembly and the excitation lasers. The optical assemblies do not require manual adjustment by the user.

xMAP Technology Reagents

The xMAP technology reagent system consists of classification calibration microspheres, reporter calibration microspheres, classification control microspheres, and reporter control microspheres.

3

Maintenance and Cleaning

To ensure accurate test results, properly clean and maintain the Luminex 200 system. Read and follow all instructions in this section. For your convenience, a maintenance log form is included at the end of this chapter.

It is important to use only xMAP Sheath Fluid or other Luminex-approved sheath fluid. **USE OF NON-LUMINEX APPROVED SHEATH FLUID SHALL CONSTITUTE “IMPROPER USE” AND MAY VOID WARRANTY RIGHTS PROVIDED BY LUMINEX AND/OR ITS AUTHORIZED PARTNER.**

Warning: When analyzing potentially infectious biological samples on the Luminex 200 analyzer, follow standard laboratory safety practices. These safety precautions should also be taken when cleaning or maintaining the analyzer.

Do not remove the analyzer cover under any circumstances!

Daily Maintenance

If the system is powered on, but idle for more than four hours, click **Warmup**. Wait 30 minutes for the Luminex 200 analyzer and the optics system to warm up.

Before Running Samples

1. Turn the Luminex 200 analyzer on. The laser warms up.
2. Verify the levels of sheath fluid and waste fluid.
3. Tighten the sheath container cap.
4. Prime the analyzer.
5. Perform an alcohol flush using at least 1.2 mL of 70% isopropanol or 70% ethanol in the reservoir.
6. Run two wash commands using distilled water.

Adjust the sample probe vertical height

Note: Verify that the microtiter plate is not warped. Warped plates can lead to incorrect probe height adjustment.

Note: Alignment discs can be placed in any well as long as the well is designated in the software.

7. Verify that the sample probe has been vertically aligned for the plate used in the kit.

Adjust the sample probe vertical height each time you change the type or style of microtiter plate.

1. Remove the clear plastic shield that covers the sample probe area.
2. In a 96-well microtiter plate where overall height is no more than 0.75 inches (19 mm), place the appropriate alignment tool in the plate:

For a standard plate with flat-bottom wells—stack two of the larger (5.08 mm diameter) alignment discs together and place them into the selected well.

For a filter bottom plate—stack three of the larger (5.08 mm diameter) alignment discs together and place them into the selected well.

For a half-volume plate with flat-bottom wells—stack two of the smaller (3.35 mm diameter) alignment discs together and place them into the selected well.

For a round-bottom (U-bottom) plate—stack two of the smaller (3.35 mm diameter) alignment discs in the selected well.

For a plate with conical wells—place one alignment sphere into the selected well.

3. Eject the plate holder. Place the 96-well microtiter plate on the Luminex XYP instrument plate holder with position A1 in the top left corner.
4. Verify that the correct well location is selected in the Luminex software, and that you are using the appropriate number of alignment discs. Retract the plate.
5. Loosen the front thumbscrew on the probe holder one-third to one-half turn. Pull it upward until it touches the top of the adjustment slide. Tighten the thumbscrew.
6. Use the Luminex software to lower the sample probe.
7. Loosen the front thumbscrew. Gently push the probe down until it just touches the top of the alignment discs or sphere.
8. Tighten the front thumbscrew.

9. Raise the sample probe using the Luminex software.
10. Replace the plastic shield that covers the sample probe area.

After Running Samples

- ◆ After running samples:
 1. Sanitize with a 10% to 20% household bleach solution.
 2. Run two Wash cycles with distilled water.
 3. Soak with distilled water. Wait until the soak completes.
 4. If desired, turn off the Luminex 200 analyzer.

Routine Tasks

Sheath and Waste Fluids

Replace the sheath fluid and empty the waste container as required. Be careful not to touch the seal in the waste bottle cap or allow it to become wet or dirty. This could cause the bottle to become pressurized, causing pressure errors in the system. If the seal gets wet, let it air-dry. Touching the seal can contaminate it. If it gets dirty, you should replace the waste bottle cap.

If you are using the waste line, do not move it while the system is running. While you can move the line along a horizontal surface, do not permanently reroute the waste line elevation without first contacting Technical Support. You can move the line temporarily for cleaning and maintenance purposes.

You must manually monitor waste container levels.

Refill the Sheath Fluid Container

- ◆ To refill the sheath fluid container:
 1. Release system pressure by removing the lid from the sheath fluid container.
 2. Refill the sheath fluid container.

If the sheath container ever runs dry, prime the system at least twice until the air is removed from the system.

Empty the Waste Container

Note: There is NO warning of a high waste volume. Empty the waste container each time you fill the sheath container.

- ◆ To empty the waste container:
 1. Disconnect the waste container from the Luminex 200 analyzer.
 2. Unscrew the waste container lid, being careful not to touch the Gore-Tex™ seal. If the seal becomes wet or soiled, it may impair venting.
 3. Discard the waste from the waste container by appropriate means.
 4. Reconnect the waste container to the Luminex 200 analyzer and replace the cap.

Any time the sheath container is disconnected from the Luminex 200 analyzer, you must remove air from the sample lines by priming.

Weekly

Visual Inspection

Open all of the Luminex 200 analyzer doors and visually inspect for leaks, corrosion, and other signs of improper function. Check all visible tubing connections. Check the Luminex XYP instrument air intake filter for buildup of dust. Check the SD system and its connection for leaks. If you see a leak, turn off the power to the Luminex SD system and contact Luminex Corporation.

Clean the Sample Probe

Warning: Be sure that the system is not performing an operation when you remove the sample probe.

Caution: The Luminex analyzer sample probe should slide up easily while removing it from the sample arm. If you feel resistance, do not force the probe up. Contact Luminex Technical Support.

- ◆ To clean the sample probe:
 1. Remove the sample probe as follows: Unsnap the light housing located above the probe. Then, unscrew the Cheminert fitting on top of the probe completely. Next, gently grasp the probe and push up. Remove the probe out of the top of the sample arm.
 2. Remove the sample probe and sonicate the narrow end for 2-3 minutes. Keep the larger end out of the sonication fluid.

3. Using a syringe, flush the sample probe with distilled water from the narrow end out through the larger end.
4. Replace the sample probe and readjust the height for the plates you are using.
5. Run 3 backflushes, 3 drains, 2 alcohol flushes, and 3 washes with distilled water.

Flush the System

Run 3 backflushes, 3 drains, 2 alcohol flushes and 3 washes with distilled water.

Monthly

Clean Exterior Surfaces

- ◆ To clean exterior surfaces, follow these steps:
1. Disconnect the system from AC power by turning off the power switches and unplugging the Luminex 200 analyzer, the Luminex XYP instrument, and the Luminex SD system.
 2. Wipe all exterior surfaces with mild detergent, then a 10% to 20% household bleach solution, and finally with plain distilled water.
 3. Open both doors of the analyzer. Clean all accessible surfaces with detergent followed by a 10% to 20% household bleach solution and then plain distilled water.
 4. Dry the sheet metal surfaces to prevent corrosion.
 5. Plug in and power on the Luminex 200 analyzer, the Luminex XYP instrument, and the Luminex SD system.

Calibrate and Verify the System

You should calibrate and verify the system on a monthly basis as part of regularly scheduled maintenance. For instructions on calibrating the system and verifying calibration, see the Luminex online help or the applicable Luminex software manual.

Clean the Sample Probe

Warning: Be sure that the system is not performing an operation when you remove the sample probe.

Caution: The Luminex analyzer sample probe should slide up easily while removing it from the sample arm. If you feel resistance, do not force the probe up. Contact Luminex Technical Support.

- ◆ To clean the sample probe:
 1. Remove the sample probe as follows: Unsnap the light housing located above the probe. Then, unscrew the Cheminert fitting on top of the probe completely. Next, gently grasp the probe and push up. Remove the probe out of the top of the sample arm.
 2. Remove the sample probe and sonicate the narrow end for 2-3 minutes. Keep the larger end out of the sonication fluid.
 3. Using a syringe, flush the sample probe with distilled water from the narrow end out through the larger end.
 4. Replace the sample probe and readjust the height for the plates you are using.
 5. Run 3 backflushes, 3 drains, 2 alcohol flushes, and 3 washes with distilled water.

Every Six Months

Luminex 200 Analyzer Air Intake Filter

Note: Hold on to the tubing!
Do not allow the tubing to fall inside the instrument.

- ◆ To replace the analyzer air intake filter:
 1. Disconnect the Luminex 200 analyzer from AC power by turning off the power switch on the rear of the analyzer, then unplugging the power cord from the wall source.
 2. On the back of the Luminex 200 analyzer, in the upper left corner, remove the screw at the top of the panel and open the panel door.
 3. Grasp the tubing and pull the filter 3 to 4 inches from the unit. See Figure 4.



Figure 4 Grasping the Tubing

4. Remove the filter with one hand, and hold the tubing with the other hand.
5. Connect a new filter to the tubing and position the filter inside the panel.
6. Reattach the panel door to the unit.
7. Plug in and power on the Luminex 200 analyzer.

Luminex XYP Instrument Air Intake Filter

- ◆ To replace the XYP instrument air intake filter:
 1. Disconnect the Luminex XYP instrument from AC power by turning off the power switch on the rear of the Luminex XYP instrument, then unplugging the Luminex XYP instrument power cord from the wall source.
 2. On the back of the Luminex XYP instrument, to the left side, gently remove the screen from the Luminex XYP instrument filter. **Do not remove the screws.** See Figure 5.

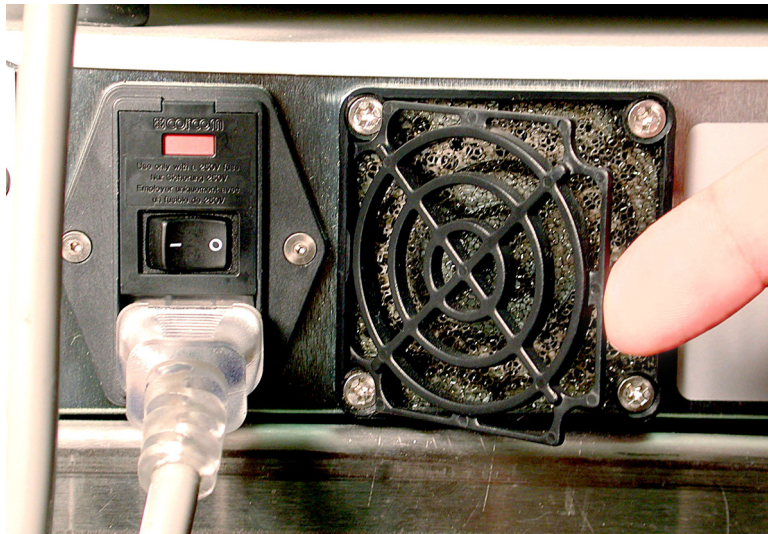


Figure 5 Removing the Screen

3. Replace the filter and replace the screen. See Figure 6.

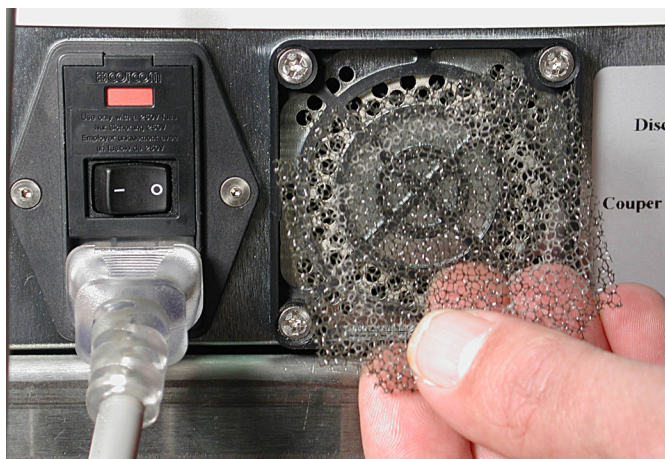


Figure 6 Removing and Replacing the Filter

4. Plug in and turn on Luminex XYP instrument power.

Syringe Seal

- ◆ To replace the syringe plunger seal:

Warning: The syringe arm does not deactivate when changing the plunger; injury could result if the system is not unplugged.

1. Turn the power switch on the back of the analyzer to the off position.

2. Open the door on the front center of the analyzer to gain access to the syringe. The syringe is the glass cylinder with a metal plunger inside, shown in the following graphic.



Frontal view of a Luminex system with door open and syringe exposed.

CAUTION: Do not turn off the analyzer as the arm is going down. The syringe pump valve will not be in the correct position, allowing sheath fluid to drain out of the valve when you remove the syringe.

3. At the base of the syringe, loosen the thumbscrew by turning it counter-clockwise six quarter-turns.
4. Turn on the analyzer and immediately watch the syringe pump.
5. Within a few seconds, the syringe arm will go down, then start going up again. As soon as it begins traveling upward, turn off the analyzer.
6. If the base of the plunger did not come out of the arm when it cycled, loosen the thumbscrew a little more and very lightly attempt to lift the plunger away from the base. If the problem persists, contact Luminex Technical Support.
7. Unscrew the syringe from the top of its housing.
8. Pull the plunger out of the syringe.
9. Remove and replace the plunger seal and the black "O" ring.
10. Replace the plunger into the glass syringe.

◆ To replace the syringe:

1. Screw the syringe into place.

2. Grab the base of the syringe plunger and gently pull down on it until it is fully seated into the opening of the arm.
3. Tighten the thumbscrew at the base of the syringe completely. If the thumbscrew does not go in as far as it did before, reposition the plunger and try again.
4. Turn on the analyzer. The syringe will return to its home position before the analyzer begins its normal start up process.
5. Prime the system twice, watching for any leaks in the syringe area.
6. When the prime finishes, close the analyzer door.

Luminex 200 Analyzer Ventilation Filter

- ◆ To clean the Luminex 200 analyzer ventilation filter:
 1. Disconnect the Luminex 200 analyzer from AC power by turning off the power switch on the rear of the analyzer, then unplug the analyzer power cord from the wall source.
 2. While facing the Luminex 200 analyzer, place your index finger up under the right side of the analyzer (in the space between the Luminex 200 analyzer and the Luminex XYP instrument). When you feel the filter, push the filter toward the left of the analyzer. See Figure 7.
 3. Remove the filter from the left side of the Luminex 200 analyzer.

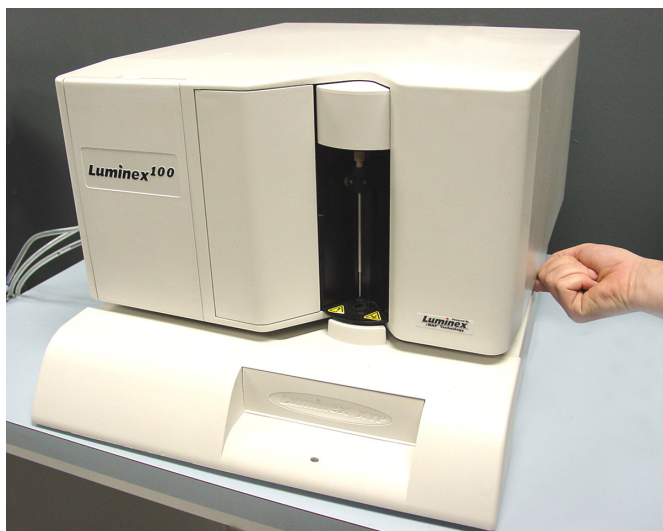


Figure 7 Luminex 200 Analyzer Ventilation Filter

4. Clean the filter with a vacuum or with distilled water. Stand the filter upright to air dry.
5. Re-install it with the arrows facing up. The filter should click into place.
6. Plug in and turn on the Luminex 200 analyzer power.

Annually

Sheath Filter

- ◆ To change the Luminex 200 analyzer sheath filter:
1. Disconnect the Luminex 200 analyzer from AC power by turning off the power switch on the rear of the analyzer, then unplugging the analyzer power cord from the wall source.
 2. Disconnect the sheath fluid tubing before changing the filter.
 3. Open the left door on the Luminex 200 analyzer. Disconnect the filter by pushing down on the metal clamps on each connection. See Figure 8.



Figure 8 Sheath Filter

4. Connect the new sheath filter, matching up the color-coded fittings. The arrow on the sheath filter should be pointing up.
5. Reconnect the sheath fluid tubing.
6. Plug in and power on the Luminex 200 analyzer.

7. Close the left analyzer door.
8. Prime twice.

As required

Fuses

Warning: To avoid serious injury or death by electric shock, you must turn off the system and unplug it from the wall.

- ◆ To replace the fuses in either the Luminex 200 analyzer or the Luminex XYP instrument:
 1. Turn off the power switch on the rear of the analyzer or instrument, then unplug the instrument power cord from the wall source. Remove the power cord from the analyzer or instrument.
 2. With a small, flathead screwdriver, open the module door on the lower left corner of the back of the analyzer or instrument. See Figure 9.



Figure 9 Opening the Module Door

3. Remove the red cartridge (use a flathead screwdriver).
4. Check both fuses for damage.
5. Replace damaged fuses with the type specified on the sticker to the right of the power input module.

6. Replace the module door.
7. Plug in and power on the analyzer or instrument.

Replacing the SD System with a Sheath Bottle

You may need to replace the Sheath Delivery (SD) system with sheath bottles for maintenance or troubleshooting.

◆ To replace the SD system with sheath bottles:

1. With the SD still connected, perform a “Warm Up” via the software.
2. When the pressure has stabilized, note the value of the Sheath pressure in the software.
3. Open the access door on the analyzer. Use a screwdriver to turn the regulator approximately five full turns to the left (counterclockwise).
4. Shut down the SD and disconnect it from the analyzer.
5. Attach the sheath bottle (preferably full) to the analyzer.
6. Open and close the sheath bottle cap in order to release any remaining pressure within the system.
7. Perform a “Warm Up” via the software if the compressor has turned off.
8. When the pressure has stabilized, note the “Sheath” pressure.
9. If the pressure is equal to the value noted in step #2 (within +/- 0.1psi), then the set up is complete. If not, continue with the next step. After each adjustment, you will have to release the pressure and let it build back up again in order to obtain an accurate pressure reading. Any time the compressor turns off while making adjustments, perform another warm-up to maintain pressure in the system.
10. On the analyzer, turn the regulator clockwise (right) to increase the pressure or counterclockwise to decrease the pressure. There is no exact measurement of pressure increase or decrease for each turn of the regulator. Try one full turn in the required direction to start.
11. Release the pressure by opening and closing the sheath bottle cap.
12. Repeat the last two steps until you obtain the original Sheath pressure reading noted in step 2, within +/- 0.1 psi).

Do not move the sheath bottle or sheath line while the system is in use.

Storing the System

This procedure explains the steps you should take before placing the system into long-term storage.

◆ Before storing the system:

1. Run a sanitize with 10% to 20% household bleach solution.
2. Run a sanitize with distilled water.
3. Run four washes with distilled water.
4. Remove the sample probe from the instrument, flush with distilled water from the narrow end out through the larger end, replace it in the sample arm, and wrap the end with Parafilm.

Taking the System out of Storage

Follow this procedure before you begin using the system after it has been stored long-term.

◆ Before using the system:

1. Turn on the Luminex 200 and XY Platform and watch for the following indications that the instruments are responding correctly:
 - The light above the sample probe on the Luminex 200 and the light next to the door of the XY platform are lit.
 - The compressor starts in the Luminex 200. It is a low rumbling sound.
 - Place your hand behind the Luminex 200 to feel air coming out of the rear fan.
 - Observe movement of the syringe inside the front middle door of the Luminex 200 shortly after the instrument is powered on.
2. Turn on the PC and start up the software.
3. Complete a Warmup command, which will take 30 minutes.
4. Remove the Parafilm from the end of the sample probe.
5. After Warmup is complete, run three Backflush commands, three Drain commands, two Alcohol Flush commands, and three Washes with distilled water. Make sure that the sheath bottle or Luminex SD has a sufficient amount of sheath fluid and that the waste container is empty. Verify that the pressure during each of the maintenance commands reads between 6 and 9 psi.

4 *Troubleshooting*

Troubleshooting the Luminex 200 System

Troubleshooting procedures help users isolate, identify, and remedy problems with the Luminex 200 analyzer and Luminex XYP. This chapter does not troubleshoot problems with the PC. For help with PC problems, please contact the technical support system for your PC's manufacturer.

To troubleshoot a problem, select a general symptom. Next, identify the possible problem and remedy it with one of the solutions listed.

This chapter supplies information for the following topics:

- Power Supply Problems
- Communication
- Pressurization
- Fluid Leaks
- Sample Probe
- Calibration Problems
- Acquisition Problems
- Bead Detail Irregularities
- Printing Errors
- Verification

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

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

Power Supply Problems

Power supply problems often involve a blown fuse, faulty electronic component, or even something as simple as a disconnected cable. Use extreme care when you replace a fuse.

Symptom	Possible problem	Solution
Analyzer will not turn on, or XYP will not turn on.	The power cord is disconnected.	Verify that the power cord is plugged in.
	No voltage is coming from the electrical outlet.	Verify that the electrical outlet is operational.
	The power supply is faulty.	Contact Technical Support.
	A fuse has burned out.	See page 28 for instructions on changing fuses.
Fuses continue to open (blow).	A component has a short circuit.	Contact Technical Support.

Communication

Communication problems described in this section involve the links between the data system (PC and software) and the Luminex 200 analyzer and XYP instrument. This section does not address communication issues with other peripheral devices.

The term “Communication” refers to:

- The transfer of data between the PC and the analyzer.
- The current status of the analyzer and XYP instrument.
- Instrument readbacks.
- Instrument control, sample acquisition, session uploading, and start, stop and pause features.

Symptom	Possible problem	Solution
PC cannot initialize communication with analyzer.	The communication cable is unplugged, or plugged into the wrong port.	Check the communications cable connections.
	The XYP or the analyzer power is not turned on.	Turn off the PC and then turn on the analyzer, XYP, and then the PC.

Pressurization

Normal air and sheath pressure readings vary between 6-9 psi while the compressor runs. If the system pressure is out of range, your sample acquisition will fail or return poor results.

Symptom	Possible problem	Solution
Pressurization fails or pressure is too low.	The sheath and waste lines are not fully connected.	Make sure the lines between the sheath and waste bottles and the analyzer are fully connected.
	The sheath or waste bottle fittings are cracked.	Inspect the fittings to be sure they form a tight seal.
	There is a leak in the system.	Check for system leaks. A leak will be obvious if there is fluid on the surface on which the system sits.
	The compressor does not engage.	Run a Prime command. If you do not hear the compressor turn on, contact Technical Support.
	The Cheminert fitting is loose.	Ensure that the fitting connects tightly above the sample probe, below the blue light.
	Fluid leaks in the system.	See Fluid Leak on page 36.
	The sheath bottle has an air leak.	Disconnect the sheath and waste bottle connections from the analyzer. Run a Prime command. If pressure builds, remove and retighten the sheath fluid bottle cap, then reconnect fluid lines to the analyzer. If pressurization fails again, replace the sheath bottle.
Pressure too high.	The sheath bottle is overfilled.	Ensure that the sheath bottle is not filled above the fill line.
	The Sheath Delivery System is overfilled.	Drain the SD reservoir and refill it. See page 45.

Regulator not adjusted properly. If using bottles, open the center door on the Luminex analyzer. Use a screwdriver to adjust the regulator to fit in the center of the green region on the Run Batch tab.

Fluid Leaks

Fluid leaks can result in poor pressurization and failed sample acquisition.

Symptom	Possible problem	Solution
Pressure too low.	The sample probe is clogged.	Clean the sample probe. See page 20.
	The syringe seal leaks.	Replace the syringe seal. See page 24.
	The syringe valve leaks.	Hand-tighten the syringe connection (silver knob) on the syringe valve. Run a Prime command. If leaks continue, contact Technical Support.
Large amount of fluid pooled around instrument.	Fittings or fluid lines are damaged.	Contact Technical Support.
Fluid dripping from the sample probe.	The sample probe is clogged.	Clean the sample probe. See page 20.
	The sample three-way valve is faulty.	Contact Technical Support.
Fluid is leaking from the front of the analyzer.	The syringe seal leaks.	Replace the syringe seal. See page 24.
	The syringe valve leaks.	Hand-tighten the syringe connection (silver knob) on the syringe valve. Run a Prime. If leaks continue, contact Technical Support.

Sample Probe

Problems with the sample probe can lead to fluid leaks and pressurization problems, as well as inhibit sample acquisition.

Symptom	Possible problem	Solution
Sample probe leaks.	The sample probe is clogged.	Clean the sample probe. See page 20.
Sample arm is stuck in the up position.	The system isn't properly pressurized.	Check pressure settings. Ensure that the sample probe is not clogged and there are no leaks in the syringe seal or syringe valve.
Sample arm is stuck in the down position.	The sample probe height is too low, or the path to the well is blocked.	<p>DO NOT turn off the Luminex XYP instrument.</p> <ol style="list-style-type: none"> 1. Remove the blue light housing from the analyzer. 2. Unscrew the Cheminert fitting. The system monitor changes from "Busy" to "Running" and sample acquisition continues. Click Cancel to make adjustments before continuing with the rest of the samples. 3. If the sample arm does not raise, save the data that has been collected. Turn off the analyzer, but keep the XYP instrument on. 4. Exit the Luminex software. 5. Turn the analyzer back on and restart the software. 6. Run a Wash with distilled water to remove air from the system. 7. Verify probe height.

Sample arm does not go down smoothly.	The 96-well plate is incorrectly seated in the XYP instrument.	Adjust the 96-well plate.
	The 96-well plate is warped.	Inspect the 96-well plate. Replace it if it is warped.
	The sample arm is misaligned.	Readjust the sample arm horizontal alignment.
	The sample probe is bent.	Remove the sample probe from the Luminex 200 analyzer. Roll it on a flat surface. If it does not roll smoothly, replace it with a new sample probe. Adjust the sample probe height (see page 18).

Calibration and Control Problems

Symptom	Possible problem	Solution
Calibration is slow or fails.	The calibration microspheres are not fully suspended.	Vortex the calibration vials to resuspend the microspheres.
	Wrong lot number or target values are entered in Update CAL Targets dialog box.	Verify that correct lot number and target values are used.
	The system calibrators are in the wrong well on the plate.	Verify that calibrators are in the correct well.
	Not enough calibrator microspheres added to the well.	Add at least five drops of calibrator microspheres to the well. Hold the vial upside down at a 90 degree angle to the plate while dispensing them.
	Calibrator lot is expired.	Use a fresh bottle of calibrator microspheres.
	The sample probe height is incorrect.	Adjust the sample probe height. See page 18.
	The sample probe is clogged.	Clean the sample probe. See page 20.

	There is a partial clog in the system.	Clean the sample probe, then flush the system. See page 20.
	There is air in the system.	Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, then three Washes with water.
	The waste container is not vented.	Check that the seal in the waste container cap is dry and that the waste container cap is vented.
	The waste line was moved during system operation, resulting in unstable flow rate.	Verify that the waste line is not moved during system operation.
	Possible problem with the laser.	View the calibration trend report. Check for dramatic changes in temperature, sheath pressure, or voltages. If any of these are evident on the report, contact Technical Support.
Zero events collected during calibration.	There is a problem with fluid levels.	Check the sheath and waste fluid levels. Verify that tubing for both bottles is tightly connected to the instrument. Check that the waste bottle cap is vented.
	Laser-related issue.	Verify fluid is moving through the system by performing a Wash, which causes fluid to go out to waste. If no fluid is going to waste, clean the sample probe, then flush the system (see page 20). If the issue does not resolve, contact Technical Support.
	The waste container is not vented.	Check that the seal in the waste container cap is dry and that the waste container cap is vented.
	The Cheminert fitting is loose.	Make sure that the Cheminert fitting is tightened.
Analyzer fails Controls.	The control microspheres are not fully suspended.	Vortex the control vials to resuspend the microspheres.

Wrong control lot number or target values are entered in Update CON Targets box.	Verify that the correct lot number and target values are used.
The system controls are in the wrong well on the plate.	Verify that control microspheres are in the correct well.
Not enough control microspheres added to the well.	Add at least five drops of control microspheres to the well. For accurate drop volume, hold the vial upside down at a 90 degree angle to the plate while dispensing them.
Control lot is expired.	Use a fresh bottle of control microspheres.
Control microspheres have been diluted.	Do not dilute the control microspheres.
The sample probe height is incorrect.	Adjust the sample probe height. See page 18.
The sample probe is clogged.	Clean the sample probe. See page 20.
There is air in the system.	Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, then three Washes with water.
The waste container is not properly vented.	Verify that the waste container is properly vented and that the seal is not wet or soiled.
The waste line was moved during system operation, resulting in unstable flow rate.	Verify that the waste line is not moved during system operation.
Possible problem with the lasers.	Check the system control trend report for consistent failures. If any are evident on the report, contact Technical Support.

Acquisition Problems

Symptom	Possible problem	Solution
Acquisition fails or slows.	The air pressure is out of range.	See Pressurization on page 35.
	The sample probe height is incorrect.	Adjust the sample probe height. See page 18.
	The sample probe is clogged.	Clean the sample probe. See page 20.
	The sheath bottle has a leaky seal.	Make sure that the sheath bottle lid is tightened. Remove and replace the sheath bottle lid.
	The sheath or waste lines are not fully connected.	Disconnect and reconnect the lines; you should hear them click.
	The calibration microspheres have expired.	Replace old microspheres with a fresh lot.
	The wrong wells are selected for the calibration microspheres.	Ensure that the correct wells are selected in the Maintenance tab.
Slow or unsuccessful sample acquisition.	The calibration lot number or target values selected in setup is incorrect.	Enter the correct calibration lot number and target values in the Update CAL Targets box.
	The sample probe is clogged.	Clean the sample probe. See page 20.
	The air pressure is out of range.	See Pressurization on page 35.
	The sample probe is not vertically aligned.	Adjust the sample probe height. See page 18.
	Air is present in the system.	Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, then three Washes with water.
	The acquisition volume is set too high.	Set the acquisition volume to at least 25 μL less than the actual volume in your wells. This setting lets the analyzer acquire sample more efficiently with less chance of acquiring air.

The xMAP microspheres are not fully suspended.	Gently vortex the plate or resuspend beads with a multichannel pipettor to ensure that the microspheres are present in the solution.
You are using photobleached microspheres.	Replace the microspheres with a fresh batch.
There is an insufficient number of beads in the sample.	Ensure that there are 2000-5000 beads per beadset per well.
The sample is too concentrated.	Dilute concentrated biological fluids, such as serum or plasma, at least 1:5.

Bead Detail Irregularities

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

- system calibrators
- system controls
- assay standards
- assay controls
- error messages

Review calibration/control trend reports routinely to detect trends.

Use system xMAP control microspheres to check the success of the system calibration and for troubleshooting purposes. If there is a problem with your kit results, xMAP controls can help determine if the problem is analyzer related. If Calibration and Controls are successful, contact the kit manufacturer.

A normal bead detail display is shown below. It depicts a tight bead population within a white region.

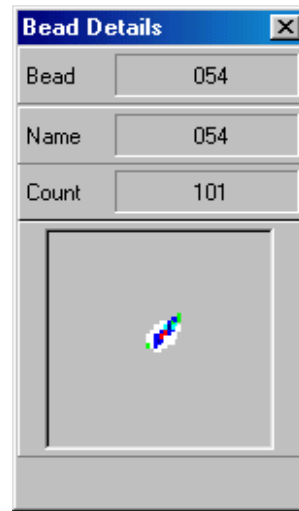


Figure 10 Normal Bead Detail

The histogram for the bead detail above looks like this:

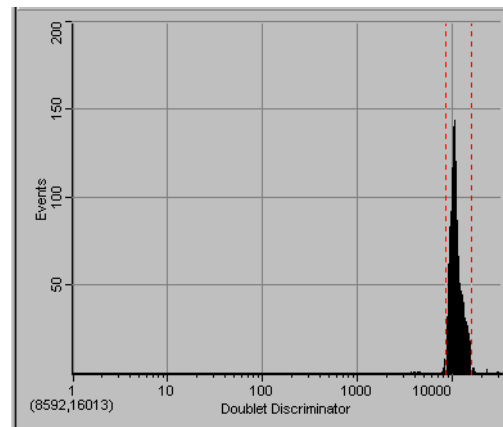



Figure 11 Normal Histogram

Symptom	Possible problem	Solution
<p>xMAP microspheres classify too high.</p> 	<p>You may be using photobleached calibration microspheres.</p>	<p>Replace the calibration microspheres with a fresh batch. To avoid photobleaching, protect your microspheres from light.</p>

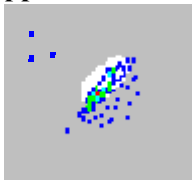
xMAP microspheres hit the lower right of the region.



You may be using photobleached xMAP microspheres.

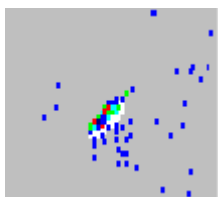
Replace microspheres with a fresh batch. To avoid photobleaching, protect your microspheres from light.

Beads appear scattered.



There is air in the system.

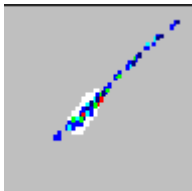
Verify sample probe height. Run three Prime commands, two Alcohol Flush commands, and then three washes with distilled water.



The sheath fluid is empty.

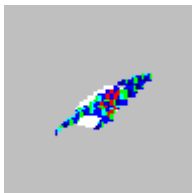
Make sure there is sheath fluid in the sheath container. Prime the system until all air is out of the system.

Microspheres appear as a long diagonal line.



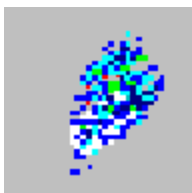
The xMAP microspheres have agglutinated.

Add additional detergent to the assay buffer. For example, add .02% to 0.1% Tween-20, Triton® X100, or SDS.



The solvent is incompatible.

View a list of incompatible solvents at the Luminex Technical Support website - <http://luminexcorp.custhelp.com>. If the solvent you are using is listed, switch solvents.



You are using incompatible sheath fluid.

Use only Luminex sheath fluid in the Luminex 200 analyzer. Other fluids may damage your analyzer and may void your warranty.

Luminex SD Problems

If the empty sheath fluid container is not replaced and the system continues to operate, the Luminex SD system eventually vents pressure to prevent air from being introduced into the Luminex 200 analyzer. This may interrupt a sample and prevent further samples from being collected.

Filter

If the filter attached to the sheath intake line becomes clogged from extended use, an alarm will sound even though the bulk sheath container is not empty. If this happens, replace the filter, part number CN-0037-01.

Malfunction

If the alarm sounds even though the bulk sheath container has fluid and the sheath filter is in good condition, the system is reporting a malfunction. If this happens, contact Luminex Technical Support.

Draining the Reservoir

If you need to ship the Luminex SD system back to Luminex Corporation, drain the reservoir before you pack the system.

1. Perform a warmup to pressurize the system.
2. Leave the green air tubing connected between the Luminex 200 analyzer and the SD system.
3. On the SD front panel, disconnect the blue tubing from the intake labeled Sheath Out and disconnect the white tubing from the intake labeled Sheath In.
4. Insert the white tubing into the intake labeled Sheath Out and insert the blue tubing into the intake labeled Sheath In.
5. Turn the unit off and then on again.
6. Press the Prime button on the front panel of the SD system.
7. Sheath fluid will pump from the Sheath Delivery System reservoir into the 20L Sheath Box.

To refill the Sheath Delivery System, reconnect the tubing according to color coding and press the Prime button on the SD.

Contact Technical Support for additional information.

5

Product Numbers

Hardware

Note: These part numbers are subject to change without notice.

Note: Common description of product is enclosed in brackets.

Product Description	Customer Number
Rear Air Filter	CN-0001-01
Bottom Air Filter	CN-0002-01
Air Filter, Intake	CN-0027-01
Bar Code Scanner	CN-PC03-01
Serial Cable, 5 feet	CN-0005-01
PC, Luminex 200	CN-PC04-01
2 Amp, 250 Volts, Fast Acting Fuse (Qty 10)	CN-0019-01
3 Amp, 250 Volts, Fast Acting Fuse	CN-0051-01
Heater Block, XYP	CN-0017-01
Luminex 200 System with IS 2.3	LX200-IS2.3
Luminex 200 System with IS 2.3 Developer's Workbench	LX200-IS2.3WB
Luminex 100 IS Developer Guide to xMAP Technology Version 2.3	CN-M029-01
Luminex 200 with xPONENT 3.1	LX200-XPON3.1

Power Cord, USA	CN-P001-01
Power Cord, Australia	CN-P002-01
Power Cord, Brazil	CN-P003-01
Power Cord, Denmark	CN-P004-01
Power Cord, Germany, Sweden, France, Belgium, and Spain	CN-P005-01
Power Cord, Switzerland	CN-P006-01
Power Cord, Israel	CN-P007-01
Power Cord, UK	CN-P008-01
Power Cord, Italy	CN-P009-01
Power Cord, Japan	CN-P010-01
Power Cord, China	CN-P012-01
Reservoir, XYP	CN-0022-01
Sample Needle Height Alignment Kit [Sample Probe Alignment Kit]	CN-0015-01
Short Sample Needle	CN-0006-01
Long Sample Needle	CN-0007-01
Sample Holder, Large, 1.5 mL	CN-0008-01
Sample Holder, Small, 1.2 mL	CN-0009-01
Sheath Filter with Quick Disconnect	CN-0010-01
Sheath Bottle	CN-0011-01
Syringe Cylinder with Seal	CN-0013-01
Syringe Seal (Qty 4)	CN-0014-01
Cable, USB	CN-0018-01
Waste Bottle	CN-0012-01
Luminex SD [Luminex Sheath Delivery System]	CN-S001-01

Software

Product Description	Customer Number
Luminex 100 IS Version 2.3 [Software CD]	CN-SW08-01
Luminex xPONENT [Software DVD]	CN-SWI5-01

xMAP Reagents

IS 2.3

Product Description	Customer Number
Microspheres, LX100, CL1 CL2 Calibration (xMAP Classification Calibrator)	L100-CAL1
Microspheres, LX100, RP1 Calibration (xMAP Reporter Calibrator)	L100-CAL2
Microspheres, LX100, CL1 CL2 Control (xMAP Classification Control)	L100-CON1
Microspheres, LX100, RP1 Control (xMAP Reporter Control)	L100-CON2
Microspheres, MagPlex, DD CL1 CL2 Calibrator, 5mL (MagPlex Classification Calibrator Microspheres)	MCAL1-05
Microspheres, MagPlex, DD CL1 CL2 Control, 5mL, (MagPlex Classification Control Microspheres)	MCON1-05
xMAP Sheath Fluid, LX100	40-50000

xPONENT 3.1

Product Description	Customer Number
Calibration Kit, LX200	LX200-CAL-K25
Verification Kit, LX200	LX200-VER-K25
xMAP Sheath Fluid, LX100	40-50000

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