

Luminex[®]

complexity simplified.

xMAP INTELLIFLEX[®] User Manual



RUO

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

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CE

EC REP

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Chapter 1: System and Software Introduction

Instrument Overview

xMAP INTELLIFLEX® Systems are opto-mechanical readers capable of measuring up to 500 analytes per sample and up to 2 parameters per analyte. xMAP INTELLIFLEX Systems are designed to use commercially available Luminex® xMAP microspheres as the substrate on which the assays will be performed, and can accommodate 96-well or 384-well plates. The design reduces the need for optical alignment and is smaller and lighter than other Luminex flow cytometry-based readers.

Software Overview

The xMAP INTELLIFLEX® Software is on-instrument software that operates the instrument hardware, collects data, and allows the user to interact with the instrument.

NOTE: Documents related to IT administration of the system, including guidance on changing the administrator password, configuring networking, and general IT and security best practices, are available upon request from *Luminex Technical Support*. Please contact support@luminexcorp.com for more information.

Consumables Overview

Luminex® xMAP® Technology requires two kinds of reagents: common laboratory reagents and reagents created only for Luminex instruments.

Luminex Technical Support

Contact Luminex Technical Support by telephone in the U.S. and Canada by calling: 1-877-785-2323

Contact outside the U.S. and Canada by calling: +1 512-381-4397

International: + 800-2939-4959

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

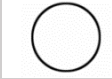





All instrument documentation may be updated without notice. Refer to www.luminexcorp.com or contact Luminex Technical Support for the latest version of manuals, quick guides, release notes, or other documentation.

For previous version of documentation, please contact Luminex Technical Support.

Symbols Glossary

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

Symbol	Meaning	Symbol	Meaning
	Caution.		Caution possibility of electric shock
	Biological risks.		Caution hot surface.
	Hand Crush/Force From Above.		Puncture/Pinch Point Warning.
	Warning Laser Beam.		Ionizing Radiation.
	For Research Use Only. Not for use in diagnostic procedures.		Authorized representative in the European Community.
	Conformite Europeenne (EU CE Marking of Conformity).		Manufacturer.
	Alternating Current.		Use-by-date.
	Batch Code.		WEEE Symbol.
	On (Power).		Protective earth; protective ground.

Symbol	Meaning	Symbol	Meaning
	Off (Power).		Serial number.
	EPUP Symbol.		TÜV SÜD NRTL Certification Mark.
	Consult instructions for use.		Catalog(ue) Number.

Chapter 2: Regulatory and Safety Considerations

Luminex recommends that all system users become familiar with the specific safety advisories and adhere to standard laboratory safety practices. Biological hazards may be present during system operation.



The system contains electrical and mechanical components that, if handled improperly, can be harmful.

Description

The xMAP INTELLIFLEX® System integrates liquid handling capabilities and performs with a sensitivity (LLOQ) of no more than 0.01 pg/mL. The xMAP INTELLIFLEX System is an opto-mechanical analyzer capable of simultaneously measuring up to 500 analytes from a single sample. The xMAP INTELLIFLEX System is for indoor laboratory and professional use only. The xMAP INTELLIFLEX System is for research use only and is not for use in diagnostic procedures.

Safety Testing and Certifications

The xMAP INTELLIFLEX® System has been tested and complies with the safety requirements for the United States and Canada and is marked with the TUV label. Review the Symbols Glossary to determine what the labels look like.

The xMAP INTELLIFLEX System complies with the European Union (EU) safety requirements and therefore may be marketed in the Europe Single Market.

Regulatory and Safety Labels

The following labels appear on the back of the xMAP INTELLIFLEX® Instrument.

Figure 1: Laser Warning Label

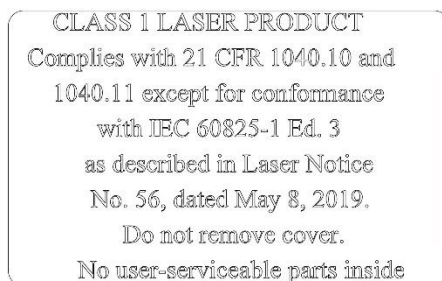
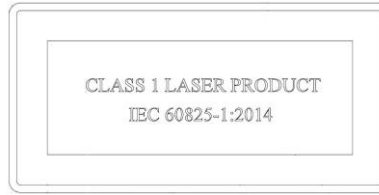


Figure 2: Laser Class Label



The following label appears on the laser module housing inside the xMAP INTELLIFLEX Instrument.

Figure 3: Laser Aperture Warning Label

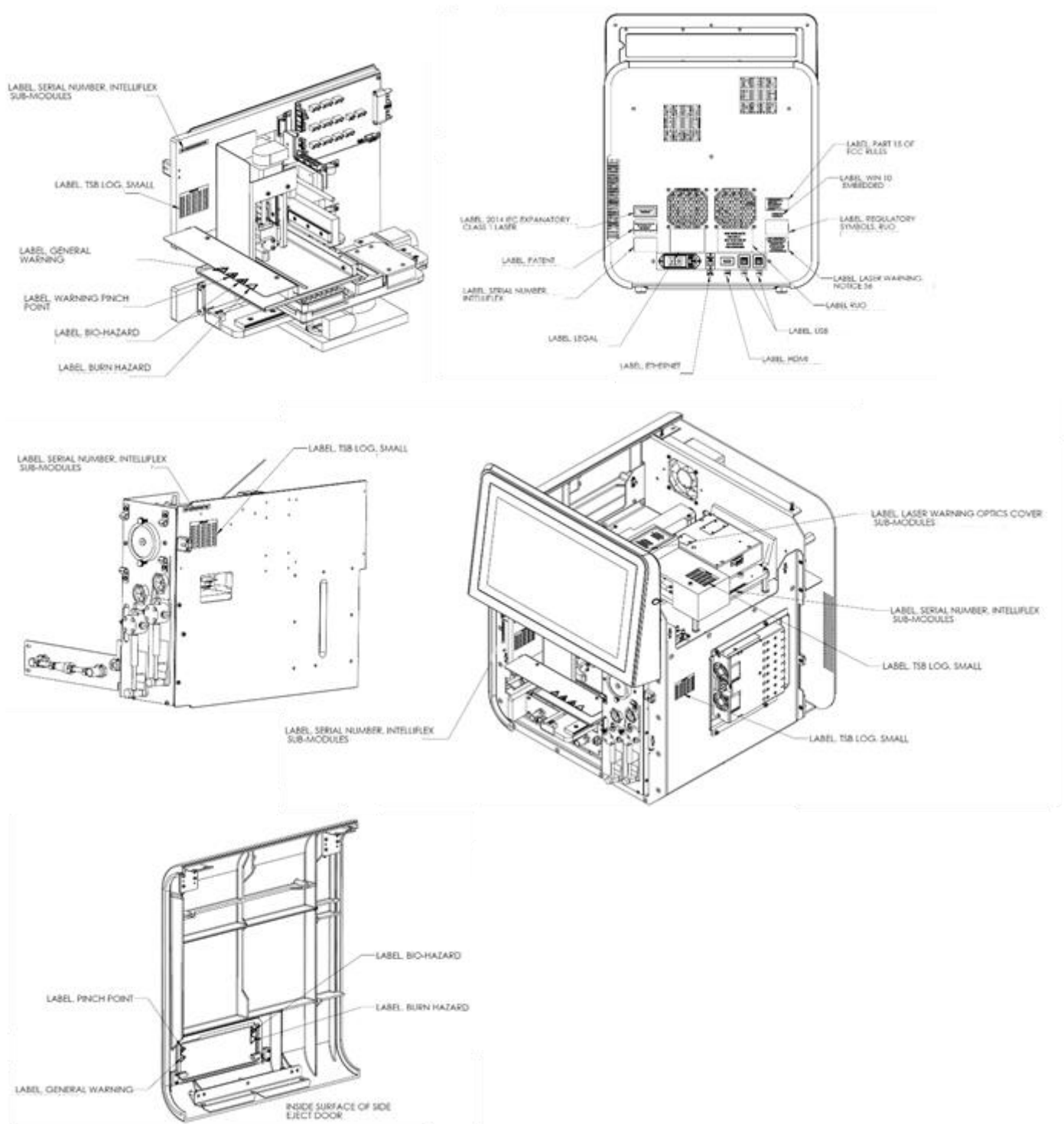


A voltage label appears on the back of the xMAP INTELLIFLEX Instrument and displays the serial number, model number, power requirements, and manufacturer's information.

Figure 4: Serial Number and Voltage Label



Figure 5: Label Placement Diagrams



Warnings and Precautions



Consult safety documentation where the caution symbol is marked.

In any situation that you encounter a symbol shown below, consult this manual or other Luminex documentation to determine the nature of the potential hazard and any necessary actions you shall take.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

General Safety



The protection provided by the equipment can be impaired, or the warranty voided, if the system is used in a manner not specified by the Luminex documentation or by Luminex Corporation.

Keep the access door closed during normal operations. Always observe standard laboratory safety practices.

Do not move the system. If the system needs to be moved, contact *Luminex Technical Support*.

Do not drop or tip the instrument over.

The plate carrier presents a tip risk when it is ejected. If the plate carrier is ejected, do not put any weight on it or use as a brace to support any weight other than the xMAP INTELLIFLEX® reagent block.

Mechanical Safety

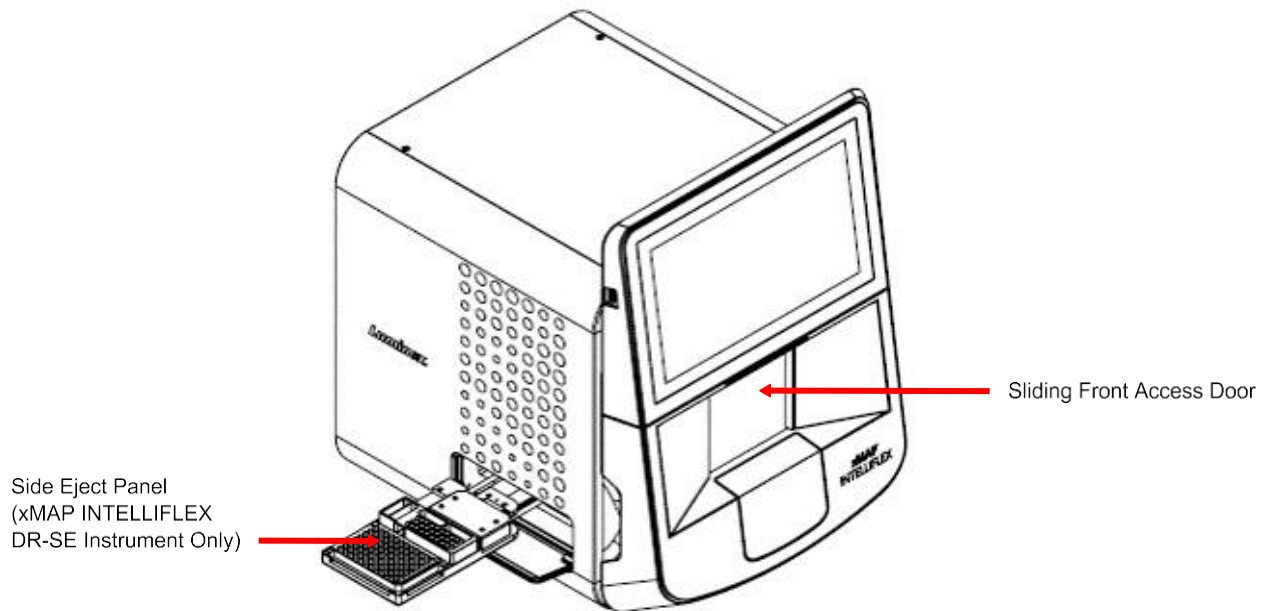


The system has parts that move during operation. Risk of personal injury is present. The moving parts present puncture, hand-crushing hazards, and pinching hazards.



Keep hands and fingers away from the syringe pumps and sample probe during operation. Observe all warnings and cautions. Keep the access door closed and the front cover of the instrument on during normal operations.

Figure 6: Pinch Point Locations



Electrical Safety



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



Avoid spills on or near the electrical components in the xMAP INTELLIFLEX® System.

Electromagnetic Compatibility

The xMAP INTELLIFLEX® System complies with the emission and immunity requirements described in IEC 61326-1. The electromagnetic environment shall be evaluated prior to operation.



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.



Always handle the instrument according to Luminex instructions to avoid any possible interference from its electromagnetic fields.

Laser Safety

The xMAP INTELLIFLEX® Instrument is classified under FDA 21 CFR 1040.10 and 1040.11 as a Class 1 laser product consisting of two or three Class 3B lasers within the instrument. In accordance with IEC 60825-1:2014, the instrument is classified as Class 1, containing two or three Class 3B lasers. The xMAP INTELLIFLEX Instrument complies with IEC 60825-1:2014 and 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 56, dated May 8, 2019.

All Class 3B laser apertures, per IEC standard, are located within the xMAP INTELLIFLEX Instrument and are contained within a protective housing, accessible only to trained field service technicians. When performing routine maintenance, turn power to the system off and unplug the power cord.



Use of controls or adjustments or performance of procedures other than those specified in this manual can result in hazardous radiation exposure.

The risk of skin injury is only likely for highly divergent beams for exposure close to the aperture.

Barcode Reader Laser

The integrated barcode reader laser presents a potential hazard to eyesight.



Do not stare into the barcode reader beam.

Heat Safety

The heater plate of the xMAP INTELLIFLEX® Instrument may be hot and can cause personal injury if touched. Do not touch the heater plate.



The heater plate of the xMAP INTELLIFLEX Instrument automatically turns off after the plate is run and cools passively and slowly. It may continue to be hot after the run is complete.

Ensure the heater plate is off when the xMAP INTELLIFLEX Instrument is not in use.

Do not use the heater plate as an incubator. Its purpose is to maintain the temperature of the plate while the plate is in the xMAP INTELLIFLEX Instrument. Monitor the heater plate temperature while it is in use. If it overheats, discontinue use and contact *Luminex Technical Support*.

Fluids Safety

This system 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 *Luminex Technical Support* for further information.

Monitor waste fluid levels manually. Ensure sufficient capacity of waste container prior to use. Do not allow the waste container to overflow. Empty the waste fluid container each time you replace or fill the xMAP® Sheath Fluid PLUS container.

The volume of the waste fluid container shall be at least as large as the volume of the Sheath Fluid PLUS container. Alternatively, route the waste line to a laboratory drain. Do not move the waste line vertically while the xMAP INTELLIFLEX System is running, and make certain the waste fluid container is properly vented. Contact *Luminex Technical Support* before relocating the waste fluid container or rerouting the waste line.

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



Handle waste disposal in accordance with accepted medical practice and applicable regulations. If spillage occurs immediately, disinfect following appropriate laboratory procedures

Visually inspect the system lines and fittings for leaks prior to use.

Biohazard/Biological Safety

Human and animal samples may contain biohazardous infectious agents.



Where exposure to potentially biohazardous material, including aerosol, exists, follow appropriate biosafety procedures and use personal protective equipment (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.



Luminex reagents contain sodium azide as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. It is also highly toxic and rates a safety data sheet (SDS) health hazard 4. On disposal, flush drains with a generous amount of cold water to prevent azide buildup. Consult the manual guideline "*Safety Management No. CDC-22, Decontamination of Laboratory Sink Drains to remove Azide salts*" (Centers for Disease Control, Atlanta, Georgia, April 30, 1976).

NOTE: Do not use strong organic solvents with the system. Contact *Luminex Technical Support* when in doubt about compatibility of cleaning and decontamination agents or materials.

Indicator Light

The blue light-emitting diode (LED) does not emit light in the UV spectrum.

Chapter 3: Performance Specifications and System Components

General System Workflow

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

The fluidics system. There are two fluidics paths in the xMAP INTELLIFLEX® System. The first path involves a dual syringe-driven mechanism that controls the sample uptake. This mechanism permits small sample uptake volumes from small reaction volumes. The dual 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 xMAP Sheath Fluid PLUS 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 PLUS to the cuvette and sample path.

Sheath Fluid PLUS is the delivery medium of the sample to the optics component. During analysis, Sheath Fluid PLUS is injected into the cuvette at a fast rate. The sample is aspirated from a 96-well or 384-well plate by the sample probe and is injected into the base of the cuvette at a slower rate than the surrounding Sheath Fluid PLUS. The difference in injection rates results in a narrow sample core such that the xMAP microspheres are introduced to the optics path as a series of single events, ensuring each microsphere is illuminated individually.

The optics system. The optics assembly consists of two or three lasers, depending on the instrument model. 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. The third laser allows for workflows that can include a second reporter channel and is only available with the xMAP INTELLIFLEX DR-SE Instrument. Avalanche photodiode detectors (APDs) measure the excitation emission intensities of the dye mixture inside the xMAP microsphere in three separate channels (CL1, CL2, and CL3). A separate APD, called the Doublet Discriminator (DD), measures bead size through side scatter. A pair of photomultiplier tubes detect the fluorescence 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 xMAP INTELLIFLEX System. Results of the analyses are processed and provided in a report format.

Environmental Conditions

- Indoor and professional use only
- Operating temperature: 15°C to 30°C (59°F to 86°F)

- Operating humidity: 20% to 80%, non-condensing
- Altitude: Operation up to 2400 m (7874 ft) above mean sea level
- Shipping and storage temperature: 0°C to 50°C (32°F to 122°F)
- Shipping and storage humidity: 20% to 80%, non-condensing
- Mains supply voltage fluctuations: 90 VAC to 264 VAC
 - Minimum nominal voltage: 100 VAC
 - Maximum nominal voltage: 240 VAC
- Pollution degree: II - As defined in IEC 61010-1:2010 AMD1:2016

Performance Specifications

General System Specifications

- Physical dimensions: 58.4 cm (23 in) W x 61 cm (24 in) D x 76.2 cm (30 in) H; Allow an additional 3.18 cm (1.25 in) clearance to all dimensions for proper cooling.
- Weight: 54.4 kg (120 lbs)
- System warmup time: 30 minutes
 - Systems that remain inactive for at least 4 hours will require a warmup to restart the laser.
 - The system resets the 4-hour internal clock after acquiring the sample, running system calibrators, running system verifiers, or warming up the instrument.
- System initialization: < 45 minutes (including laser warmup and weekly calibration)
- System verification: 5 minutes
- Temperature control: Samples are maintained at a constant temperature when using the heater block (from 35°C to 60°C (95°F to 131°F) +/- 1°C of setpoint).
- Plate run time: 96-well plate in approximately 20 minutes; 384-well plate in approximately 75 minutes
- Side eject door (DR-SE model only): For automation control only (Not currently available)

Electronics Specifications

- USB for data transfer and connection to optional peripherals (keyboard and mouse)
- Input voltage range: 100V~ to 120V~, 6.0 A, 50Hz to 60Hz or 200V~ to 240V~, 3.0 A, 50Hz to 60Hz
- Installation category: II - As defined in IEC 61010-1:2010 AMD1:2016

Fluidics Specifications

- Cuvette: 200 µm square flow channel
- Sample injection rate: 2 µL/second
- Sample uptake volume: 10 µL to 200 µL
- Sheath flow rate: 7.9 (+/- 0.9) mL/minute, temperature viscosity compensated
- Sheath pressure: 8 psi to 13 psi for normal operations; 15 psi maximum
- Piercing probe capability: Yes
- Auto-adjusting probe capability: Yes

Optics Specifications

- Classification laser: 637 nm, nominal operating power 30 mW, diode; mode of operation, continuous wave (CW); maximum output power 50 mW
- Classification detector: Avalanche photodiodes with temperature compensation
- Reporter channel detection: A/D resolution 16 bits
- Reporter channel dynamic range (RP1): ≥ 5.5 decades of detection (verified with xMAP® microspheres dyed with a high concentration of organic dye)
- Reporter channel dynamic range (RP2) (DR-SE model only): ≥ 4.5 decades of detection (verified with xMAP microspheres dyed with a high concentration of organic dye)
- Reporter laser (RP1): 532 nm diode-pumped solid-state laser (DPSS); mode of operation, continuous wave (CW); output power varies based on mode with maximum output power of 50 mW
- Reporter laser (RP2) (DR-SE model only): 405 nm diode laser; mode of operation, continuous wave (CW); nominal output power of 50 mW
- Reporter detector (RP1): Photomultiplier tube, detection bandwidth of 565 nm to 585 nm
- Reporter detector (RP2) (DR-SE model only): Photomultiplier tube, detection bandwidth of 421 nm to 441 nm
- Doublet discrimination detector: Avalanche photodiodes with temperature compensation

Microspheres Specifications

- Distinguishes 1 to 500 unique xMAP® microspheres in a single sample
- Classification of xMAP microspheres: $\geq 80\%$
- Total system misclassification of xMAP microspheres: $\leq 2\%$
- Well-to-well carryover: $< 4\%$
- RP1 detects a minimum of 50 fluorochromes of Phycoerythrin (PE) per xMAP microsphere
- RP2 detects a minimum of 500 fluorochromes per xMAP microsphere
- Soluble background fluorescence emissions are automatically subtracted from fluorescence intensity values

Integrated PC and Integrated Barcode Reader Specifications

- Ports:
 - USB - 1 port on front of system, 4 ports in rear
 - Ethernet - 1 port in rear of system (CAT5 10/100/1000 Mbps)
- Operating system: Microsoft Windows® 10 IoT Enterprise LTSC
- Screen resolution: 1366 x 768 pixels
- Screen size: 39.6 cm (15.6 in)
- Barcode reader: For importing target values from the xMAP INTELLIFLEX® Calibration and Performance Verification Kits

System Components

The three system components of the xMAP INTELLIFLEX® System are: software, hardware, and consumables.

Software Component

The xMAP INTELLIFLEX® Software provides methods to perform sample acquisition and maintenance functions.

For the latest version of the *xMAP INTELLIFLEX® User Manual*, please visit www.luminexcorp.com/intelliflex or contact *Luminex Technical Support*.

Documents related to IT administration of the system, including guidance on changing the administrator password, configuring networking, and general IT and security best practices, are available upon request from Luminex Technical Support.



Using unauthorized third-party software with the xMAP INTELLIFLEX Software may result in corruption or failure of the xMAP INTELLIFLEX Software. Do not use third-party software on the xMAP INTELLIFLEX System.

Hardware Components

The xMAP INTELLIFLEX® System includes the following hardware:

- xMAP INTELLIFLEX Instrument
- Three sample probes
- Off-plate reagent block
- Empty container for waste
- xMAP Sheath Fluid PLUS intake line
- Waste fluid output line
- Keyboard and mouse

Consumable Components

xMAP® Technology Reagents



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

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 fluid container.

- **IFXCAL** - Classification and Reporter Calibrator (calibrates DD, CL1, CL2, CL3, RP1, RP2 - for all MicroPlex® MagPlex® microsphere-based applications)
- **IFXVER** - Classification Verifier (verifies DD, CL1, CL2, CL3, RP1, RP2 - for all MicroPlex and MagPlex microsphere-based applications)
- **Fluidics1** - xMAP® Fluidics 1 (verifies fluidic integrity and well-to-well microsphere carryover)
- **Fluidics2** - xMAP Fluidics 2 (verifies fluidic integrity and well-to-well microsphere carryover)
- xMAP Sheath Fluid PLUS

Protect xMAP reagents from light at all times to avoid photobleaching of the microspheres.

Luminex reagents contain ProClin® as a preservative. This can cause allergic reactions in some people.



Luminex reagents contain sodium azide, as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. It is also highly toxic and rates a safety data sheet (SDS) health hazard 4. On disposal, flush drains with a generous amount of cold water to prevent azide buildup. Consult the manual guideline "*Safety Management No. CDC-22, Decontamination of Laboratory Sink Drains to remove Azide Salts*" (Centers for Disease Control, Atlanta, Georgia, April 30, 1976).

Required Laboratory Reagents

- 10% bleach with no additives

NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.

- 70% isopropanol or 70% ethanol solution
- Sodium hydroxide (0.1N NaOH)
- Mild detergent
- Deionized water (DI water)
- PARAFILM®



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.

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

Subsystems

Mechanical Subsystem

Filter System

The mechanical subsystem of the xMAP INTELLIFLEX® System includes a filter system.

Replaceable ventilation filters clean the air used to cool the system and pressurize xMAP Sheath Fluid PLUS. The HEPA filter must be replaced as part of the required semi-annual maintenance. The front air intake and rear bottom air intake filters will be cleaned during annual maintenance by a Field Service Engineer (FSE).

Figure 7: HEPA Filter

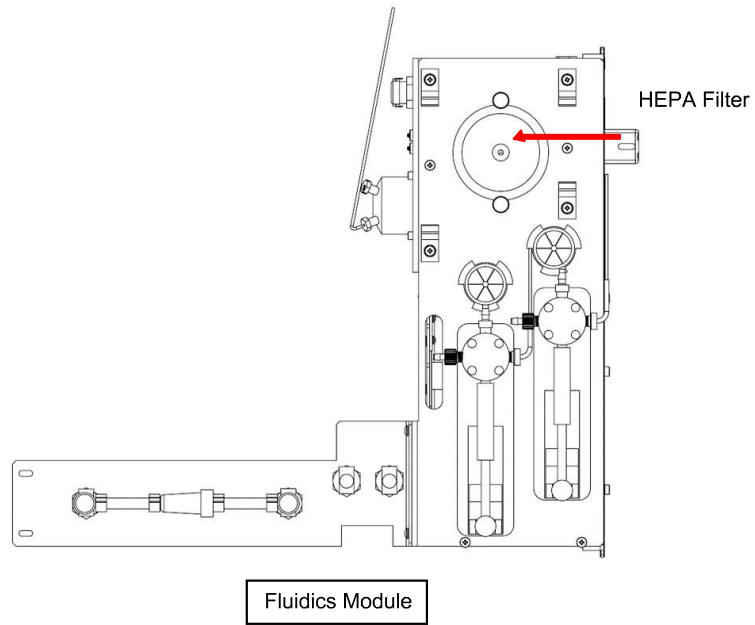


Figure 8: Front Air Intake Filter

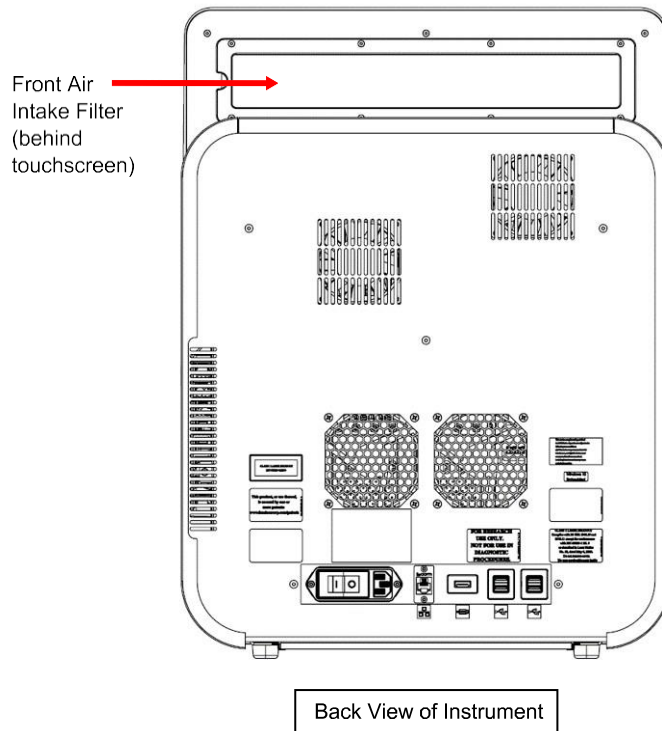
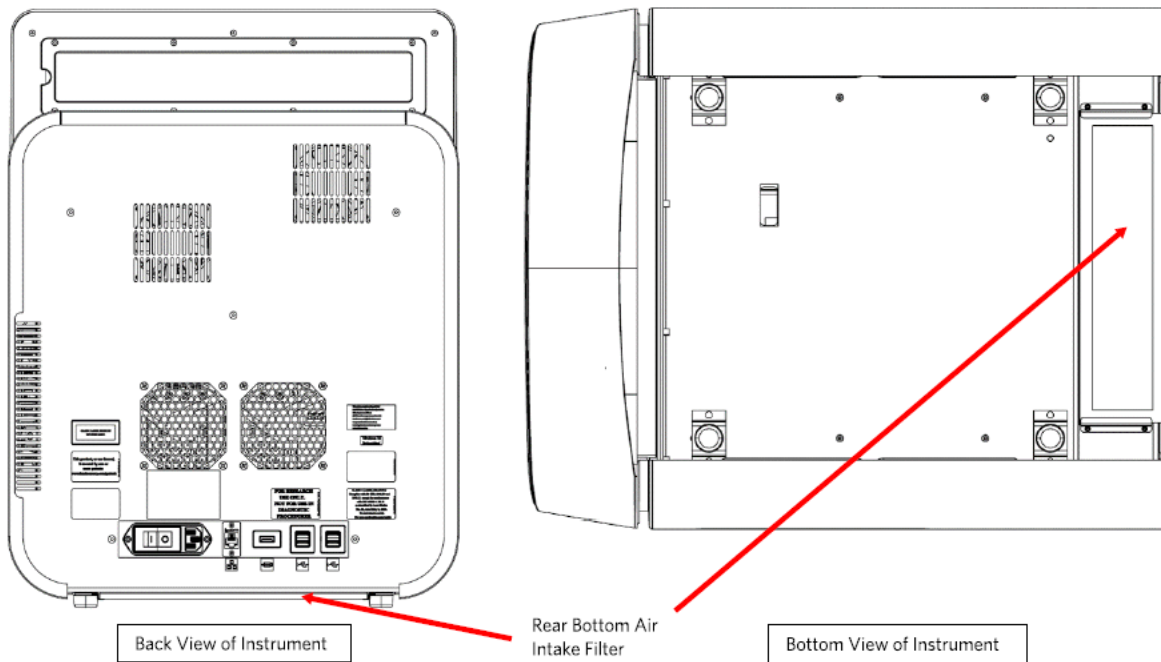


Figure 9: Rear Bottom Air Intake Filter



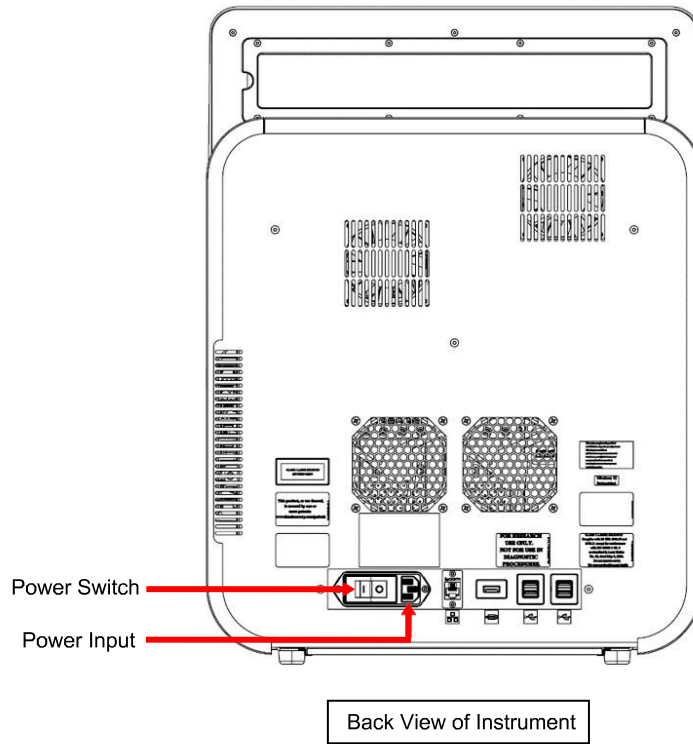
Electrical Subsystem

The electrical subsystem provides the power for operation and control of the xMAP INTELLIFLEX® System and communication between its parts.

Power Input Module

The power input module contains the input power plug and the hard power switch. The power input module is the protective earthing point for the xMAP INTELLIFLEX® 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 automatically senses the voltage range.

Figure 10: Power Input Module



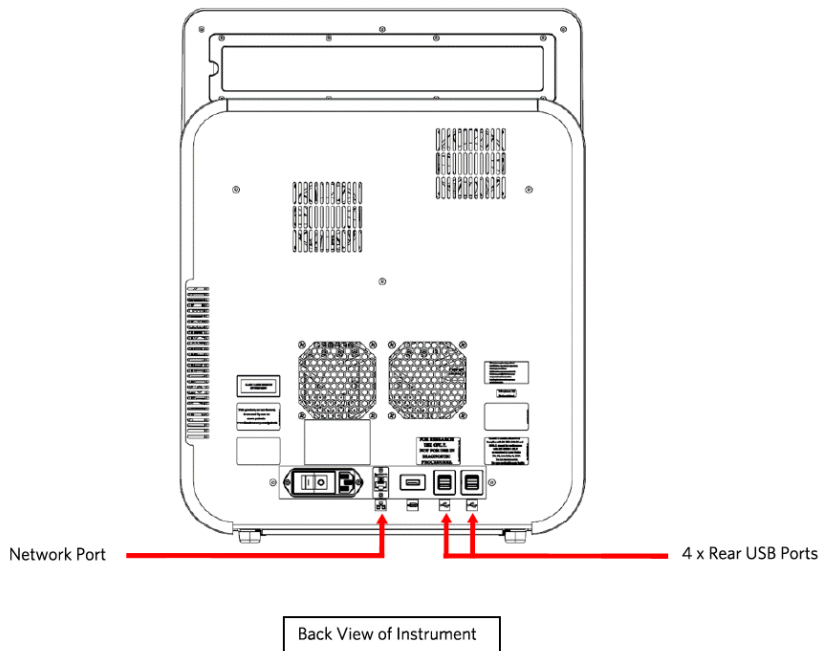
Do not obstruct the power input module as a means of disconnection. Connect only to outlets that contain protective earthing.

Communications Ports

The xMAP INTELLIFLEX® Instrument provides the following communications ports:

- 5 x USB 2.0 connectors (one on the front of the instrument and four on the back)
- 1 x RJ45 network connection

Figure 11: Back of the xMAP INTELLIFLEX® Instrument



Do not plug any external electronic devices into the xMAP INTELLIFLEX Instrument other than those provided by Luminex. Contact *Luminex Technical Support* for more information.

Fluidics Subsystem

The fluidics subsystem handles the flow of liquid through the xMAP INTELLIFLEX® System.

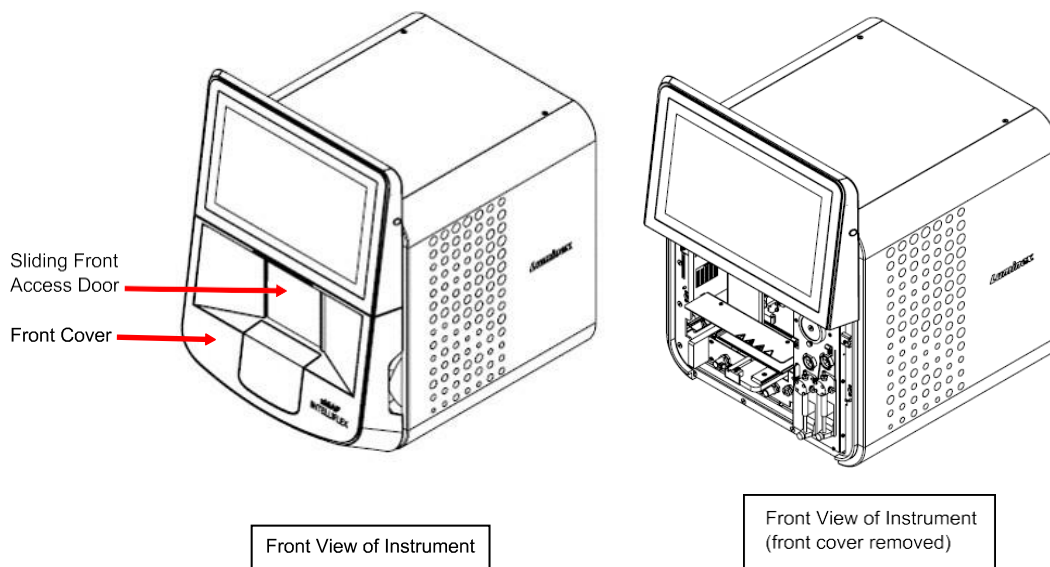
Front Cover and Access Door

The xMAP INTELLIFLEX® Instrument has clear sliding front access door and one front cover. Sliding the access door open supplies easy access to the sample probe for routine maintenance. Removing the front cover supplies access to the sheath filter, sample probe, and syringe pumps for periodic maintenance activities.



Keep hands and fingers away from the syringe pumps and sample probe during operation. Observe all warnings and cautions. Keep the access door closed and the front cover of the instrument on during normal operations.

Figure 12: Front of the xMAP INTELLIFLEX® Instrument



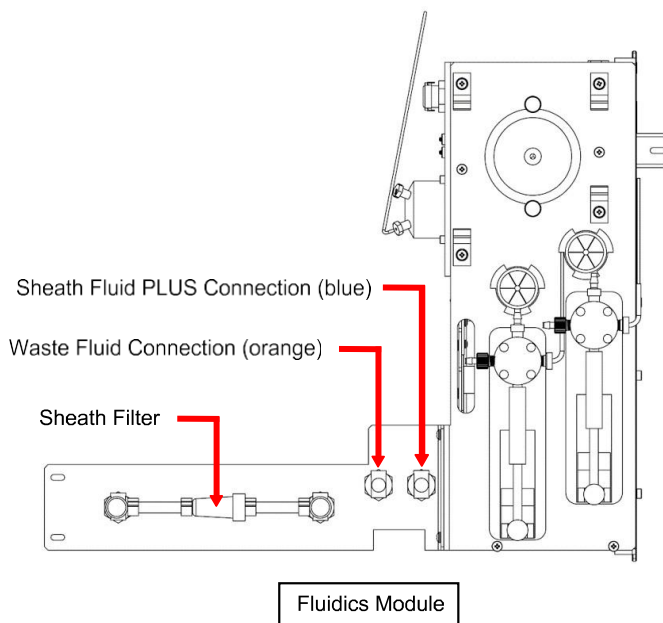
Fluidics Module

The waste and sheath connectors, located on the front of the fluidics module, connect to the xMAP® Sheath Fluid PLUS and waste fluid containers using clear tubing. The Sheath Fluid PLUS connector is blue and the waste connector is orange.



Wear appropriate personal protective equipment (PPE) including a lab coat and disposable gloves, when performing procedures. Fresh clean gloves must be worn in each area and must be changed before leaving that area. Wash your hands thoroughly after performing the test.

Figure 13: Fluidics Module



Sample Probe

A stainless steel sample probe acquires the sample.



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 during operation.

Sample Volume

Sample volume or sample sizes range from 10 μL to 200 μL . Excess dead volume of about 25 μL is required to ensure the full uptake volume is aspirated for analysis. The excess dead volume required may vary depending on the type of plate used.

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

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

$$\text{Total sample volume } (\mu\text{L}) - \text{Sample uptake volume } (\mu\text{L}) + 45 \mu\text{L} < \text{Maximum well volume } (\mu\text{L})$$

- Total sample volume = Starting sample volume of a well before the system samples for acquisition.
- Sample uptake volume = Uptake Volume aspirated from well for acquisition (program this in the acquisition settings as UPTAKE VOLUME).
- 45 μL = Volume expelled back into the well.
- Maximum well volume = The maximum volume capacity of the wells in a selected 96-well and 384-well microtiter plate.

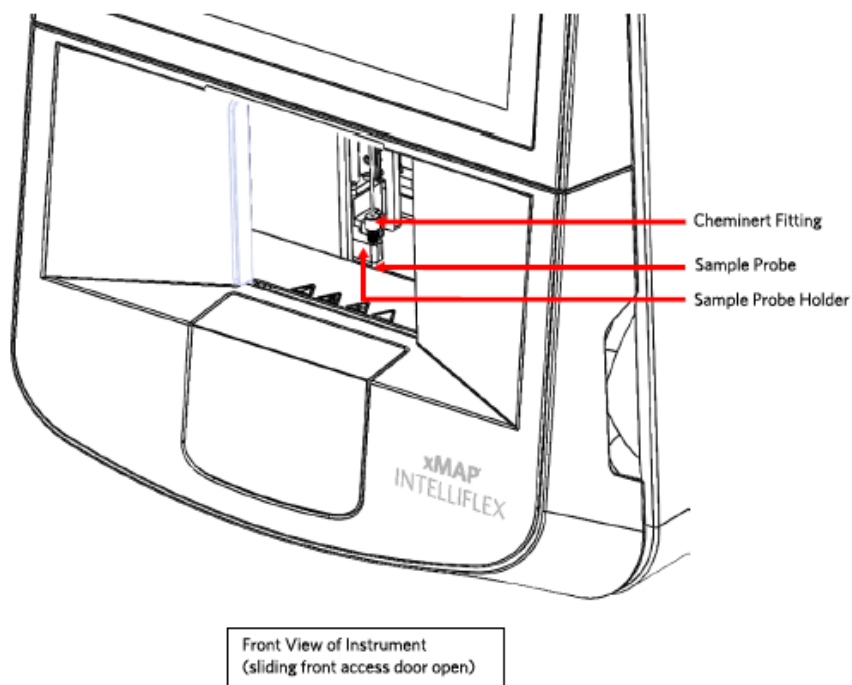
Cheminert® Fitting

The Cheminert® fitting attaches the sample probe to the sample tubing. Disconnect the Cheminert fitting when you remove the sample probe.



Keep hands and fingers away from the syringe pumps and sample probe during operation. Observe all warnings and cautions. Keep the access door closed and the front cover of the instrument on during normal operations.

Figure 14: Fluidics Components



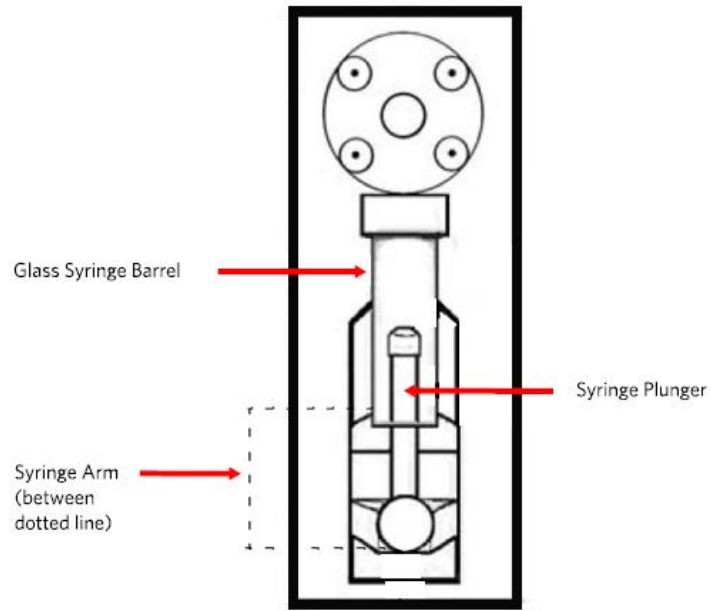
Syringe Pump

The syringe delivers a sample from the plate to the cuvette. The xMAP INTELLIFLEX® Instrument has two syringe pumps.



Avoid contact with moving parts.

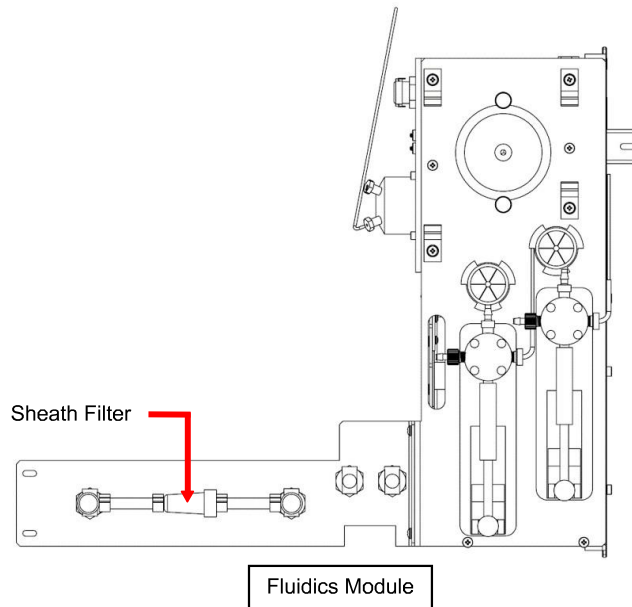
Figure 15: Syringe Pump



Sheath Filter

The sheath filter is capable of filtering particles larger than 5 microns from the xMAP® Sheath Fluid PLUS.

Figure 16: Sheath Filter



Waste Fluid Container

The waste fluid container receives waste from the xMAP INTELLIFLEX® System. To maintain a stable flow rate, do not move the waste line or waste fluid container during system operation and make certain the waste fluid container is properly vented. Place the waste fluid container at least 3 feet below the surface on which the system sits.



Handle waste disposal in accordance with accepted medical practice and applicable regulations. If spillage occurs immediately, disinfect following appropriate laboratory procedures.



Do not place the waste fluid container on top of the instrument. Ensure that the waste tubing is not elevated above the level of the xMAP INTELLIFLEX System at any point.

Monitor waste fluid levels manually. Do not allow the waste fluid container to overflow.

Optical Subsystem

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

Recommended Additional Equipment

Successful operation of the 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 1300 Watts for at least 45 minutes. Choose a surge protector that fits the requirements for electrical environment, endurance, suppressed voltage rating, and method of protection. The surge protector requires a minimum rating of 1500 Watts. Both pieces of equipment shall include appropriate safety certification marks for your region, for example, Underwriters Laboratory (UL) or a similar listing body, certified by Canadian Standards Association (CSA), or Conformité Européenne (CE) for non-domestic use.

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.

Keyboard or Mouse - Users may optionally choose to attach a different USB keyboard and/or mouse from what was provided with the xMAP INTELLIFLEX® System. Peripheral devices must be capable of functioning as a USB human interface device (HID) using standard Microsoft® Windows® drivers and must not require manual installation of additional device driver software.

Chapter 4: Preparing the System

The xMAP INTELLIFLEX® System contains pre-defined routines to prepare the instrument for data acquisition.

Parts of the System

Figure 17: Front and Right Side

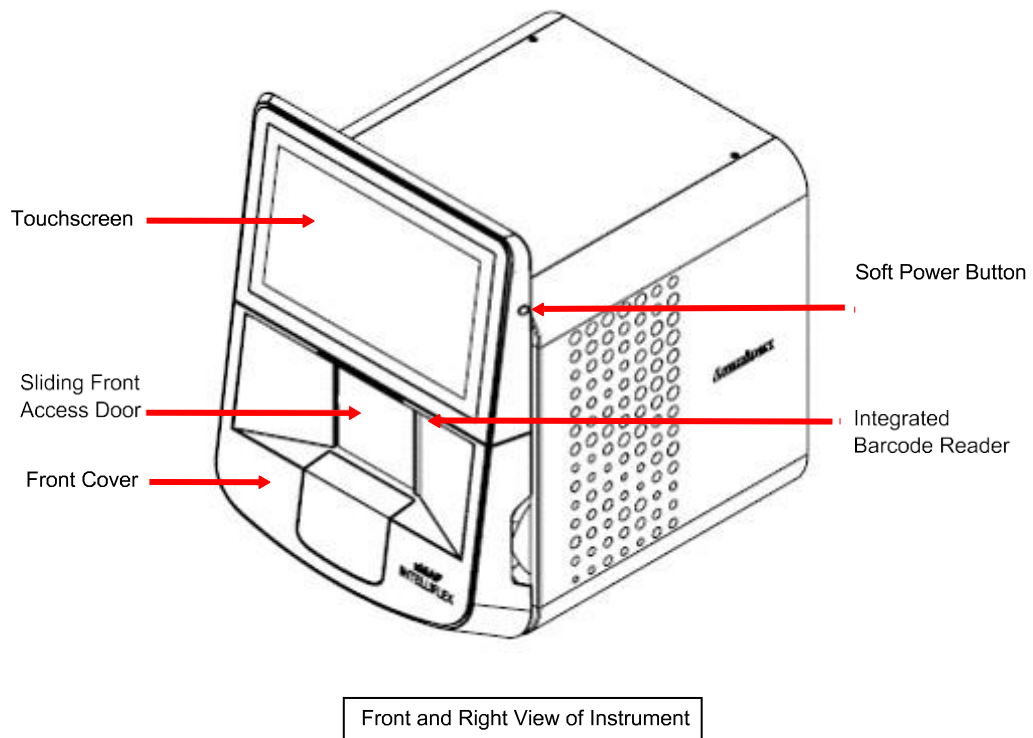


Figure 18: Front and Left Side

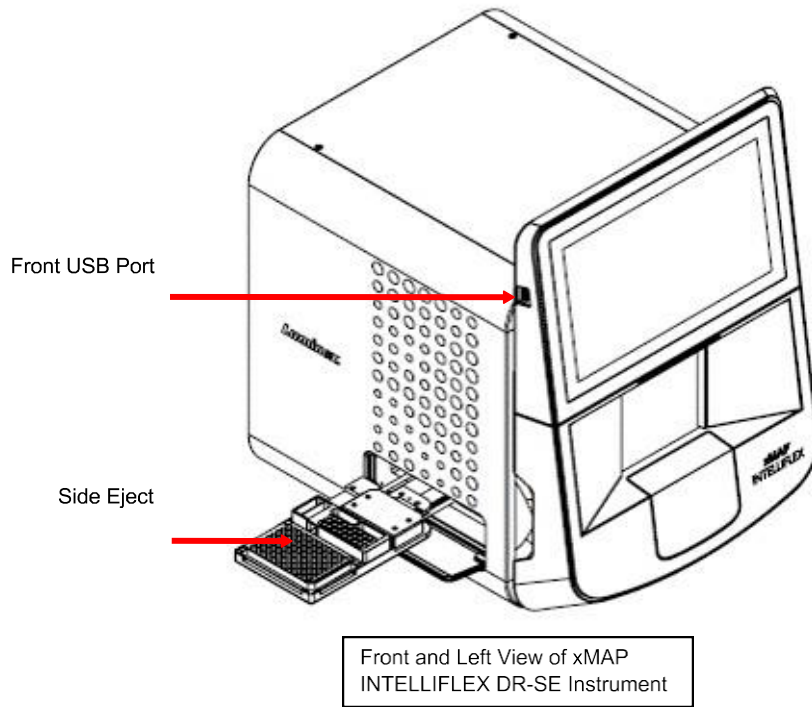
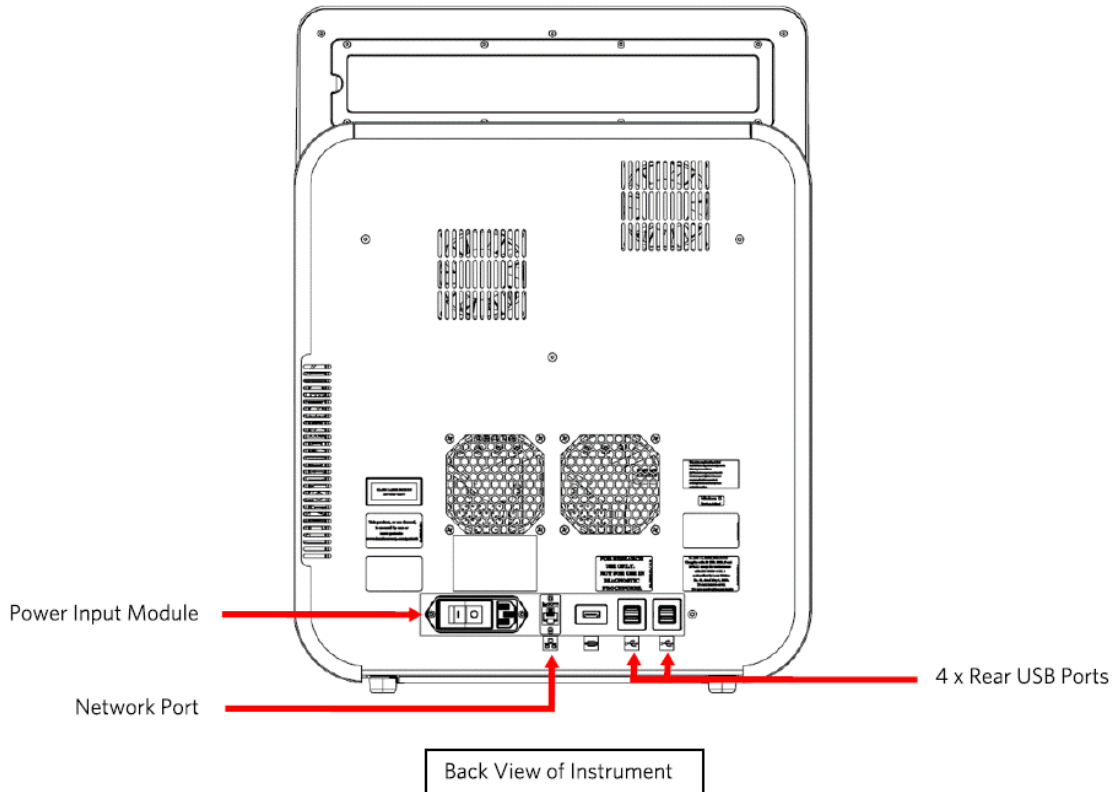


Figure 19: Back Side



Power on the System



Use of this software by untrained personnel can result in inaccurate data and test results. Users of the xMAP INTELLIFLEX® System must read the documentation thoroughly before operating the software.

The xMAP INTELLIFLEX System has a hard power switch and a soft power button. To power on the xMAP INTELLIFLEX System:

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 Uninterruptible Power Supply (UPS) device.
2. Turn on the hard power switch located on the back of the instrument.

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

NOTE: You will hear two clicks when the hard power switch is turned on.
3. Push and hold the soft power button on the right side of the instrument for 2 to 3 seconds to turn on the xMAP INTELLIFLEX System.

NOTE: The soft power button can be used to routinely power the system on and off.

NOTE: There are several startup indicators when you turn on the xMAP INTELLIFLEX System, but the easiest to notice are the sound of the fan and the blue light on the front of the instrument.

Log into the Software


The INTELLIFLEX software supports multiple users either locally or on a network. For more information on user management, refer to [Chapter 10: Administration and Settings](#)

Luminex provides three default user accounts: admin, lablead, and operator. The default password for lablead and operator users is 'password'. Change the password after system installation. For more information on the administrator account, refer to the *xMAP INTELLIFLEX System Administrator Guide*.

1. Once the Status screen displays, display the log in screen by using the mouse or touch screen.
2. Enter the log in credentials for the account displayed or select **Switch Users** to log in as a different user.
 - a. If this is the first time you have started the software, read the End-User License Agreement (EULA).
 - b. Select **Accept**.

NOTE: Documents related to IT administration of the system, including guidance on changing the administrator password, configuring networking, and general IT and security best practices, are available upon request from *Luminex Technical Support*. Please contact support@luminexcorp.com for more information.

Software Navigation

The Software Navigation Menu of the xMAP INTELLIFLEX® Software is located in the upper left-hand corner of the screen. When expanded, it provides access to history, results, maintenance functions, plate configuration, current run information, and settings. To open the Software Navigation Menu, select .

The Dashboard is located on the right side of the screen. The Dashboard displays the physical state of the xMAP INTELLIFLEX System, monitors the current run, and provides shortcuts to common pages. Information displayed in the



Dashboard is dynamically updated as changes are made. To view the Dashboard, select the white Expand arrow  in the lower right-hand corner of the screen to expand to the System Status display, then select the System Status circle .

Figure 20: Software Navigation Menu and Dashboard

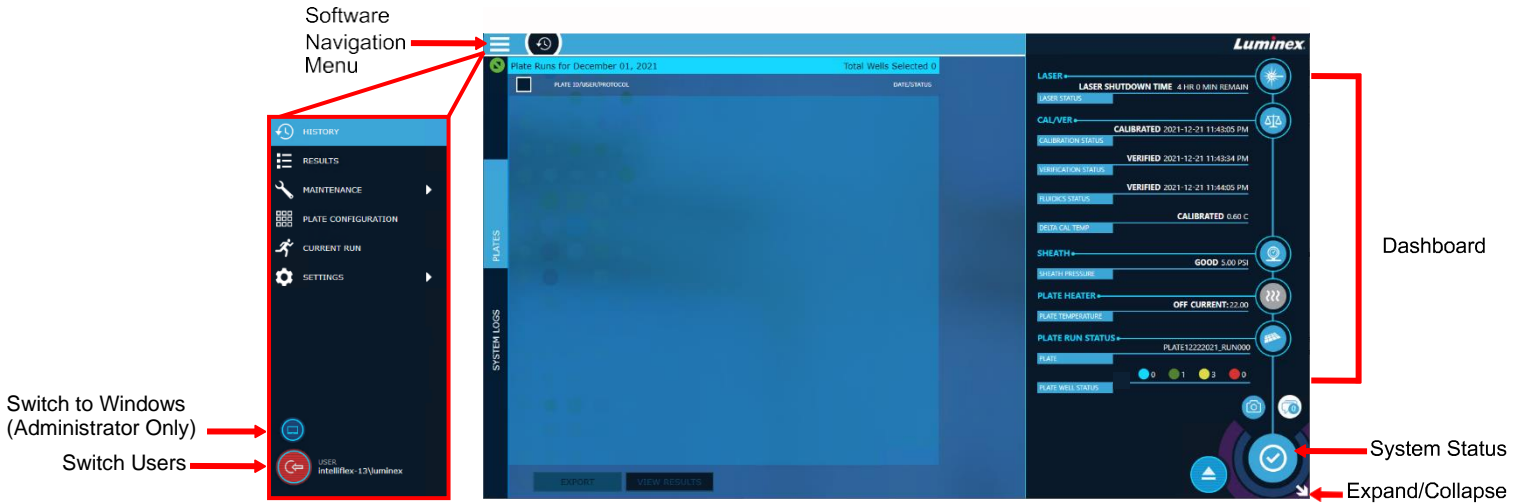


Figure 21: Dashboard

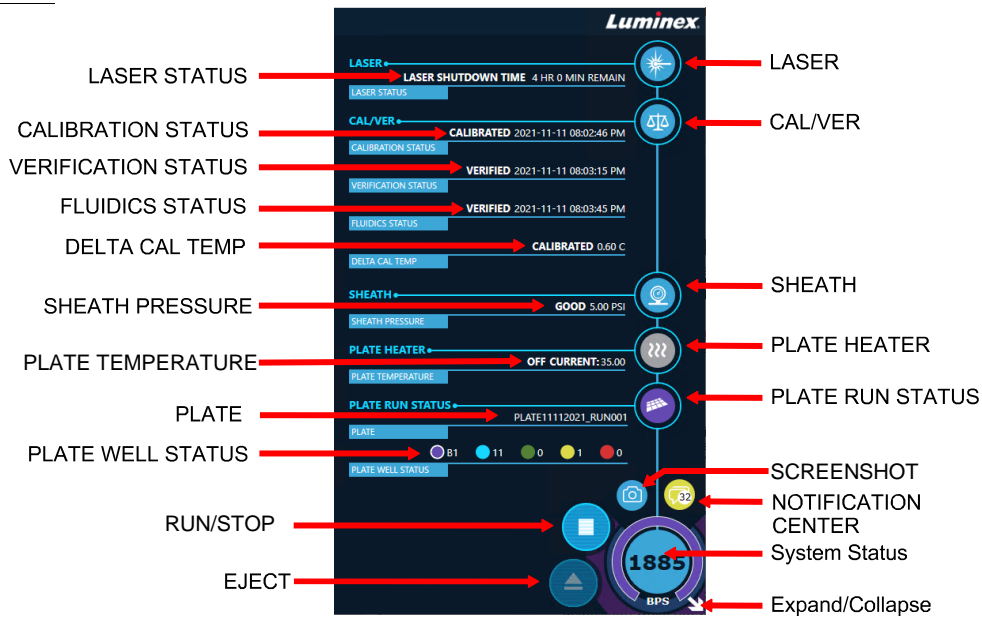





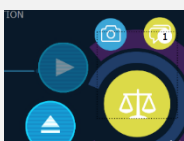
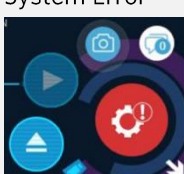




Table 1. Dashboard Elements

LASER button	<p>Turns the laser on and is an indicator for the laser status. If the laser timer is running, selecting LASER will reset it to 4 hours. If the timer has expired, selecting LASER will start the laser warmup process.</p> <ul style="list-style-type: none"> • Blue: Laser is on and ready • Orange: Laser is warming up • Gray: Laser is off
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LASER STATUS	Indicates the laser's current status. When the instrument is turned on, this will display a countdown the time to warm up. If the laser is on and warmed, the LASER SHUTDOWN TIME displays the remaining time before the lasers shut off.
CAL/VER button	Displays the MAINTENANCE > CAL/VER page and is an indicator for the calibration and performance verification status. <ul style="list-style-type: none"> • Blue: System has passed calibration and performance verification • Yellow: Warning present and calibration or performance verification has expired • Red: Error present and system has failed calibration or performance verification
CALIBRATION STATUS	Indicates the current calibration status and when the system was last calibrated.
VERIFICATION STATUS	Indicates the current verification status and when the system was last verified.
FLUIDICS STATUS	Indicates the current fluidics status and when the system was last verified.
DELTA CAL TEMP	Displays the difference in internal system temperature between the current reading and the calibrated system temperature, in degrees Celsius. Any difference greater than +/- 5°C requires recalibration.
SHEATH button	Pressing the SHEATH button will navigate to the MAINTENANCE > ROUTINES page and is also an indicator for the sheath pressure status. <ul style="list-style-type: none"> • Blue: Sheath pressure is good • Yellow: Warning present • Red: Error present; sheath fluid may be empty
SHEATH PRESSURE	Displays the status and sheath pressure in PSI.
PLATE HEATER button	Displays the SET HEATER dialog box to turn the plate heater on or off and set the plate temperature in degrees Celsius. The button is also an indicator for the plate heater status. <ul style="list-style-type: none"> • Blue: Plate heater is on and ready • Orange: Plate heater is warming up • Gray: Plate heater is off
PLATE TEMPERATURE	Displays if the plate heater is on or off, and if it's on, displays the current temperature of the plate heating block in degrees Celsius.
PLATE RUN STATUS button	Displays the CURRENT RUN page and is an indicator for the plate run status. <ul style="list-style-type: none"> • Blue: No plate is currently running • Green: Plate run status is good • Yellow: Warning present • Red: Failure or error present • Purple: Acquisition in progress
PLATE	Displays the current plate name of the run.

<p>PLATE WELL STATUS</p>	<p>Displays the current location of the well being analyzed when a plate is running, and the number of wells in progress, successfully completed, or completed with a warning or an error with color indicators.</p> <ul style="list-style-type: none"> • Purple with white border: Location of well currently being acquired • Blue: Number of pending wells to be acquired • Green: Number of successfully acquired wells • Yellow: Number of wells with a warning present • Red: Number of wells with a failure or error present
<p>System Status button</p>	<p>Displays the Dashboard and shows the current run status including the current bead count of the running acquisition. Also displays the current system status when idle.</p> <ul style="list-style-type: none"> • System calibrated, lasers on and warmed up, system fully ready  • Operation in process (ex: self test, plate extend/retract)  • Lasers off  • Lasers warming up  • Heater warming up  • Calibration Overdue  • System Error 

NOTIFICATION CENTER button	Displays the number of unread system messages, is an indicator for the status of the messages, and when selected, opens the NOTIFICATION CENTER. The message status can be cleared from the NOTIFICATION CENTER by selecting READ ALL but they will remain in the ALL section. Users can choose to clear all of the message history by selecting CLEAR HISTORY . <ul style="list-style-type: none"> • White: Unread notification present • Red: Unread notification for an error present
Expand/Collapse button	Expands to display the System Status or collapses the System Status and Dashboard displays.
EJECT button	Ejects the plate. Once the plate is ejected, the EJECT button changes to RETRACT. Retract retracts the plate, and the RETRACT button changes back to EJECT.
RUN/STOP button	 Runs the plate.  Stops the system as soon as possible. The system will stop at the next interruptible step in its process (approx. 5 minutes).
SCREENSHOT button	Takes a screen capture when selected and saves image to the previously configured folder in Settings.




Warm up the Laser

Warm up the lasers to prepare the optics prior to sample acquisition. The system automatically begins warming up when you turn power on; however, warm up the lasers if the system is idle for 4 hours or longer.

The system allows the user to perform some actions without warmed lasers. An Operator account requires a Lab Lead or Admin to approve the action by entering their credentials into the approval prompt. The override will be logged in the system log. Failure to properly warm up the lasers will affect assay results and system performance.

NOTE: Authorized users can grant permission to perform a run before the lasers are warmed up. The system records that the acquisition was performed prior to the warmup.

If the instrument has been idle for 4 hours or longer, warm up the laser.

1. Select the white **Expand** arrow  in the lower right-hand corner of the screen to open the **System Status**.
2. Select the **System Status** circle  to fully expand the **Dashboard**.
3. Select **LASER**  in the **Dashboard** to start the laser warmup.

NOTE: If the lasers are warmed up, select LASER to reset the countdown timer to 4 hours.

NOTE: The laser warmup takes approximately 30 minutes. Once successfully warmed up, the laser will show a timeout countdown.

NOTE: To minimize the Dashboard, select the white Collapse arrow in the lower right-hand corner of the screen.

Calibrate the Sample Probe Height

Calibrate the sample probe height for new plate types, before system maintenance, after removing the sample probe from the system, or as part of troubleshooting. Calibrate the sample probe height to ensure that the sample probe drops far enough in the well to acquire the sample without affecting or penetrating the bottom of the plate.




NOTE: Due to the liquid sensing capabilities of the sample probe, ensure there is no liquid in the wells or reservoirs before calibrating the sample probe height. Failure to do so will result in the system interpreting the liquid level as the bottom of the plate.

NOTE: Sample probe calibrations are saved separately for each of the three sections: PLATES, RESERVOIRS, and OFF-PLATE STRIPS. Ensure all three are calibrated.



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.

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

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > PROBE HEIGHT**.
2. Select **NEW** to create a new plate or choose a saved plate from the **SAVED PLATES** drop-down menu.
NOTE: If a saved plate is chosen, the results of the new calibration will override the previous calibration.
NOTE: To save an existing plate with a different name, select **SAVE AS**, enter the name of the plate, and select OK.
3. If **NEW** was selected, select either a 96-well or 384-well plate by toggling to the  or  well plate option.
4. Select the **DESCRIPTION** field and enter a description.
5. Based on the type of plate you are using, place an alignment disk or an alignment sphere in the well indicated in the software, if needed. For a 96 well plate, use well A6. For a 384 well plate, use well A12.

NOTE: The location used for probe height adjustment cannot be changed.

- 96-well or 384-well Hard Bottom Plate or 96-well Conical (V-Bottom) Plate - No disk is required.
- 96-well Filter or Mylar Bottom Plate - Place one 5.08 mm alignment disk into the well.
- 384-well Filter or Mylar Bottom Plate - Place one alignment sphere into the well.



NOTE: The sample probe can pierce soft-bottom plates or can halt before reaching the bottom of steeply-sloped wells.


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

NOTE: Verify the plate is not warped. Warped plates can lead to incorrect sample probe height calibration.

NOTE: Alignment disks and spheres are included in the Sample Probe Height Adjustment Kit (CN-0263-01) shipped with the instrument.

NOTE: In rare cases but modification may be required when calibrating the sample probe height to ensure optimal performance on different plate types.

6. Select  in the lower right-hand corner of the screen to eject the plate carrier.
NOTE: If the Dashboard is fully expanded, select the System Status circle  once to minimize its configuration. To minimize the Dashboard, select the white Collapse arrow.
7. Place the off-plate reagent block on the plate carrier. Place the plate on the plate holder with A1 in the top left corner.
8. Place one strip well (provided with the Calibration and Performance Verification kit) in the middle row of the off-plate reagent block.

9. Verify no liquid is in the designated plate, strip well, or off-plate reagent block.
10. Select  to retract the plate carrier.
11. Select **AUTO CALIBRATE** in the **PLATES**, **RESERVOIRS**, and **OFF-PLATE STRIPS** sections. The sample probe automatically adjusts itself and saves the reading of each calibration.

NOTE: After selecting AUTO CALIBRATE, wait until the system finishes automatically calibrating the sample probe height before selecting AUTO CALIBRATE in another section. The AUTO CALIBRATE buttons will be grayed out when the task is still in process.


NOTE: The sample probe height is automatically set to 1 mm. The sample probe automatically adjusts this distance from the bottom of the plate, or alignment disks or spheres. The distance from the bottom may be manually adjusted for specific plate types by increasing or decreasing the offset value using the arrows next the DISTANCE FROM BOTTOM field.

NOTE: The Absolute Probe Height of each section displays the number of motor steps the probe moves down from its highest point.

NOTE: To delete a plate, select the plate you want to delete from the Saved Plates drop-down menu and select DELETE from the PLATES section.

Import Calibration or Performance Verification Kits

Before calibrating or verifying the instrument, it's necessary to import a set of target values which are unique to each lot of each reagent. Import lot-specific target values by scanning a barcode which is included with each reagent kit.

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > CAL/VER**.
2. If not already selected, select the **RUN CAL/VER** tab on the left navigation bar.
3. Select **IMPORT KIT** from the top of the screen.
4. Select **SCAN**.
5. Scan the barcode on the Calibration or Performance Verification Kit Target Value Card (provided with the kit) using the integrated barcode reader. A successful scan results in the kit lot number and expiration date displaying in the **SCAN NOW** field..

NOTE: The integrated barcode reader is located below the touchscreen, to the right of the sliding front door. The scanner times out after a period of time if a readable file is not detected. If this occurs, close the dialog box and select IMPORT KIT and SCAN again.

NOTE: Find replacement barcodes for the Calibration or Performance Verification Kits at www.luminexcorp.com/intelliflex. Print or use a mobile phone screen to scan the replacement barcodes.

NOTE: If the integrated barcode reader is not functioning properly, contact *Luminex Technical Support*

6. Select **ADD**. A message displays stating the kit lot imported successfully.
NOTE: A warning message may appear if the lots were previously imported.
7. If necessary, scan another barcode and select **ADD**.
8. Select **CLOSE**.

NOTE: If CLOSE is not selected, the dialog box will close automatically and the kit will be automatically saved.

NOTE: The lot information will update in the CALIBRATION, PERFORMANCE, or FLUIDICS drop-down menus.

Calibrate the System


Calibration is important to ensure the optical system functions effectively. Calibrating the xMAP INTELLIFLEX System normalizes the settings for the classification channels (CL1, CL2, and CL3), the doublet discriminator (DD), and the reporter channels (RP1 and RP2). Use the xMAP INTELLIFLEX Calibration Kit to calibrate the system. Following calibration, use the xMAP INTELLIFLEX Performance Verification Kit to check all of the optical channels in the system for correct calibration. Be sure to verify every time you calibrate. If there is a problem with optical alignment or fluidics, the xMAP INTELLIFLEX System may pass calibration but fail performance verification.

Track the system calibration and verification results through MAINTENANCE > CAL/VER > HISTORY. Target value information for calibration and verification microspheres is available on the Calibration or Performance Verification Kit Target Value Card that comes with the kit and on the Luminex website at www.luminexcorp.com.

Calibrate the system at least once a week. The INTELLIFLEX System will notify you when it is time to recalibrate and the Dashboard displays the current calibration status. In addition, recalibrate the system if any of the following occur:

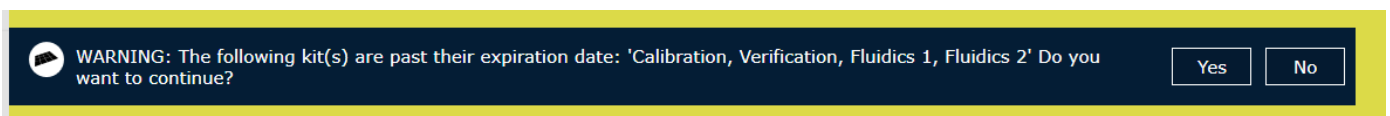
- The delta calibration temperature exceeds +/- 5°C.
- The instrument is moved.
- You experience sample acquisition problems.
- The instrument undergoes hardware maintenance, such as replacement of a part.

Verifier xMAP® microspheres are used to verify the calibration and optical integrity for the system. Do not dilute calibrators or verifiers.

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > CAL/VER**.
2. If not already selected, select **RUN CAL/VER** on the left navigation bar.
3. Activate the lot by choosing it from the **CALIBRATION, PERFORMANCE, and FLUIDICS** drop-down menus. Choose the correct reagent lot numbers for your calibration and performance verification kits.
NOTE: The lot number in the drop-down menu will match the lot number on the reagent bottle.
4. Select the **RUN** check boxes for **CALIBRATION, PERFORMANCE, and FLUIDICS**.




NOTE: After calibration, always perform verification. Fluidics can be run as part of the calibration and performance verification procedures or as a standalone procedure.

NOTE: If any of the lots are expired, the system will still allow you to run the expired lots but will prompt you to confirm and note the lot expiration in the system log.



NOTE: Expired lots are also indicated in the dashboard.



5. Select  to eject the plate carrier.
6. Place one clean strip well in the top row of the off-plate reagent block. **NOTE:** The plate layout in the software indicates reagent locations.
7. Gently vortex all calibration and performance verification kit reagents for 10 seconds each to ensure homogeneity. Do not dilute the reagents.
8. Fill the appropriate reservoirs 3/4 full of deionized water (DI water) and 3/4 full of 70% isopropanol or 70% ethanol.
NOTE: The plate layout in the software indicates reagent locations.
9. Completely invert the bottle and add six complete drops per well of each calibration reagent (IFXCAL-10) and performance verification reagent (IFXVER-10, FLUID1-05, and FLUID2-05) to the stripwell.
NOTE: The plate layout in the software indicates reagent locations.
NOTE: Luminex recommends checking the label on the bottles to ensure you are dispensing the correct reagents.
10. Select  to retract the plate carrier.
11. Select  to run.

NOTE: If you request to run calibration before the lasers are warmed up, the instrument will wait until the lasers are ready before calibrating the system.





NOTE: Calibration and verification commonly fail when vials are not mixed thoroughly, reagents are in the wrong well locations, or the wrong kit lot values are selected.

Verify the System

The xMAP INTELLIFLEX® Performance Verification Kit includes reagents to verify the calibration and optical integrity for the xMAP INTELLIFLEX System, as well as reagents to verify the fluidics channels using observations of pressure, flow rate, and well-to-well carryover. Verification uses system verifiers to ensure that the instrument is functioning properly with the current calibration settings.

Luminex recommends running performance verification daily. The xMAP INTELLIFLEX Performance Verification kit provides sufficient reagents to run Fluidics1 and Fluidics2 reagents with every verification. You may choose to run fluidics as a part of verification, or you may run fluidics at another frequency you define. Refer to your assay kit instructions for additional verification frequency requirements.


The Dashboard displays the current verification and fluidics status.

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > CAL/VER**.
2. If not already selected, select **RUN CAL/VER** tab on the left navigation bar.
3. Activate the lot by choosing it from the **PERFORMANCE VERIFICATION** and **FLUIDICS VERIFICATION** drop-down menu. Choose the correct lot numbers for your performance verification kit.
4. **NOTE:** The lot number in the drop-down menu will match the lot number on the reagent bottle.
5. Select the **RUN** check boxes for **PERFORMANCE VERIFICATION** and **FLUIDICS VERIFICATION**. If additional check boxes are selected from a previous run, clear them.
NOTE: Run fluidics as part of the performance verification procedure or as a standalone procedure.
6. Select  to eject the plate carrier.
7. Place one clean strip well in the top row of the off-plate reagent block. **NOTE:** The plate layout in the software indicates reagent locations.
8. Gently vortex all performance verification reagents for 10 seconds each to ensure homogeneity. Do not dilute the reagents.
9. Fill the appropriate reservoirs 3/4 full of deionized water (DI water) and 3/4 full of 70% isopropanol or 70% ethanol.
NOTE: The plate layout in the software indicates reagent locations.
10. Completely invert the bottle and add six complete drops per well of each performance verification reagent (IFXVER-10, FLUID1-05, and FLUID2-05) to the stripwell.
NOTE: The plate layout in the software indicates reagent locations.
NOTE: Luminex recommends checking the label on the bottles to ensure you are dispensing the correct reagents.
11. Select  to retract the plate carrier.
12. Select  to run.

View and Export Calibration or Performance Verification History

The xMAP INTELLIFLEX® System allows you to create a report of your system's calibration, verification, and fluidics history. Each report is a multi-page Excel® file with summary and detail pages, and includes lot numbers, timestamps, and run information. Luminex Technical Support uses this information to aid in troubleshooting failures but the information may also be used for your site's internal QC purposes.

To view a calibration, performance verification, or fluidics verification history report

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > CAL/VER**.
2. If not already selected, select **HISTORY** on the left navigation bar.
3. Select **CALIBRATION**, **PERFORMANCE VERIFICATION**, or **FLUIDICS VERIFICATION** on the top of the screen to view the history.

To export a calibration, performance verification, or fluidics verification history report:

1. Select **CALIBRATION**, **PERFORMANCE VERIFICATION**, or **FLUIDICS VERIFICATION** on the top of the screen, if it is not already selected.
2. Select the **DATE RANGE** radio button to filter the results or select **ALL** to view all of the results.
3. If a date range was selected, select the Calendar icon in the **FROM** field, select a date and time, and select **CLOSE**.
4. If a date range was selected, select the Calendar icon in the **TO** field, select a date and time, and select **CLOSE**. The system will not prevent you from entering a **FROM** date that is later than the **TO** date. The system will show no results when the range is entered incorrectly. Ensure the earlier date is entered in the **FROM** field and the later date is entered into the **TO** field.
5. Select the check box(es) for the data to export.
6. Select **EXPORT**.
7. Choose the location where you want to save the report.
8. Edit the File name, if necessary.
9. Select **Save**. A message displays stating whether the selected result(s) was successfully exported or not.

Chapter 5: Configuring and Running the Assay

The xMAP INTELLIFLEX® software has multiple workflows to quickly and easily set up an assay plate. Define three parameters before running an assay—layout, panel, and acquisition settings—either by configuring the instrument or by creating an importable file. Each of these parameters are independent, can be used in any combination, and can be saved individually for future repeated use. Additionally, a combination of parameters can be saved together as a protocol for future, repeated use, or as a one-time use plate.

NOTE: Some roles will not have permissions for all activities.

Software Navigation

The xMAP INTELLIFLEX® System allows for a flexible workflow. You can define, edit, and save independent layouts, panels, and acquisition settings that can be used across experiments.

Table 2. Assay Parameter Definitions

Layout	Designates wells as unknowns, standards, controls, or backgrounds, and replicates.
Panel	Defines the bead regions to analyze, their minimum counts, and target(s) names.
Acquisition Settings	Defines parameters for acquisition, such as bead type, uptake volume, plate heater temperature, and DD gating.
Protocol	Defines the combination of the layout, panel, and acquisition settings used as a template for repeated use.
Plate	Defines the combination of the layout (optional), panel, acquisition settings, and sample ID assignments (optional) for an experiment.

Figure 22: Plate Configuration

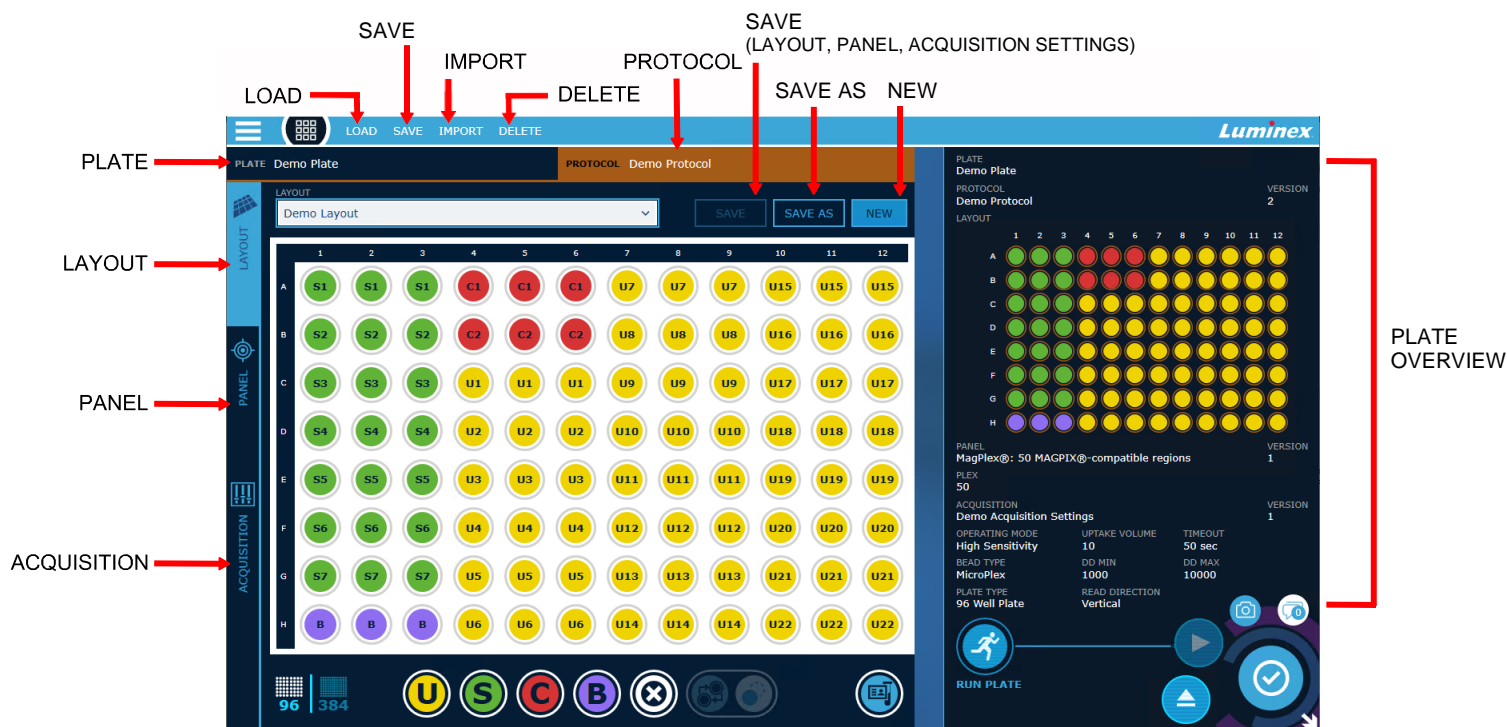


Table 3. Plate Configuration Screen Elements

LOAD	Displays PLATE and PROTOCOL menu items to load a previously saved plate or protocol.
SAVE	Displays PLATE and PROTOCOL menu items to save the defined layout, panel, and acquisition settings as a plate in a single experiment, or reuse as a protocol. NOTE: Saving is not required to run a plate. The save feature is useful when defining multiple plates in advance to recall and run at a future time.
IMPORT	Displays the Import dialog box to import a layout or panel from a .csv file.
DELETE	Allows saved layouts, panels, acquisition settings, protocols, and plates to be deleted.
PLATE	Displays the plate name if the plate was saved. If you modify any of the parameters after saving the plate, an asterisk will appear after the plate name. Save the plate again to remove the asterisk. If you do not define a plate name, then the system automatically assigns a generic plate name when the plate is run (PLATE MMDDYYYY RUNXXX).
PROTOCOL	Displays the protocol name (if applicable). If you modify any of the parameters after saving or loading the protocol, an asterisk will appear after the protocol name. Save the protocol again to remove the asterisk.




LAYOUT	Displays the PLATE CONFIGURATION > LAYOUT page to define well assignments.
PANEL	Displays the PLATE CONFIGURATION > PANEL page to define bead regions to be analyzed.
ACQUISITION	Displays the PLATE CONFIGURATION > ACQUISITION page to define acquisition settings, such as bead type, uptake volume, plate heater temperature, and DD gating.
SAVE (on Layout, Panel, Acquisition settings page)	Saves a new object or saves over the selected object.
SAVE AS (on Layout, Panel, Acquisition settings page)	Saves selections as a new object.
NEW (on Layout and Panel page)	Clears current selections on the page.
PLATE OVERVIEW	Provides an overview of the current plate selections, including associated Layouts, Panels, Acquisition Settings, Plates, Protocols, and their version numbers.

Define the Assay Parameters

Define the Layout




The xMAP INTELLIFLEX® System allows you to define, import, save, and reuse common layouts. Saving a layout is not required to run a plate.

To define and save a layout within the software:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. If not already selected, select **LAYOUT** on the left navigation bar.
3. Select **NEW**.
4. Select either a 96-well or 384-well plate by toggling to the  or  well plate option at the bottom of the screen.
NOTE: Changing the plate from a 96-well or 384 well will remove any previously selected My Plates in the Acquisition page. Select the appropriate My Plate on the acquisition page after toggling plate types.
5. Define the well locations for unknowns, standards, controls, and backgrounds.
 - a. Select and drag to highlight a series of wells, select a column or row header to highlight the entire column or row, select and highlight different wells, or select the top-left corner of the grid to highlight all wells.
 - b. Select a command below to add the well assignment to the highlighted wells.
 - Unknown (U): Yellow
 - Standard (S): Green
 - Control (C): Red
 - Background (B): Purple

NOTE: Select the X to delete a well assignment.

NOTE: xMAP INTELLIFLEX does not perform any calculations based on Dilution, Standard, or Control, but does provide Net and other statistics based on Background designations.

- c. To copy replicate wells:
 - NOTE:** Add sample information prior to copying replicate samples if you are including Sample ID or Dilution information in your plate.
 - i. Select the defined well(s), and then select  to copy the well assignment(s). A dashed blue circle displays around the selected well(s).
 - ii. Select the well(s) to paste the copied well assignment(s). A preview of the paste location(s) displays.
 - NOTE:** Continue to select well locations on the layout to preview additional paste locations until the locations are accepted and pasted.
 - NOTE:** Select a preview of a paste location to remove it from the layout.
 - iii. Select  to accept and paste the replicate well(s).
- 6. Select  to add sample information (optional).
 - NOTE:** A layout does not save sample information. If you are not running the plate immediately, save the plate to retain the sample assignments.
 - a. Select the **SAMPLE ID** field and enter the sample ID for the well(s).
 - b. Select the **DILUTION** field and enter the dilution for the well(s). Or select the up and down arrows to adjust the dilution. User-entered designations for Dilution, well type, and Standards display in the results. The system does not perform any calculations based on Dilution, Standard, or Control, but does provide Net and other statistics based on Background designations.
 - NOTE:** xMAP INTELLIFLEX Software does not perform any calculations based on Dilution values. Dilution information displays in the output file for downstream analysis.
 - c. Select **CLOSE**.
- 7. Select **SAVE AS**.
 - NOTE:** Save layouts for reuse across assays or proceed to other steps without saving.
- 8. Enter the **LAYOUT NAME**.
- 9. Select **OK**. A message displays stating the layout saved successfully.

Import the Layout

The xMAP INTELLIFLEX® System imports a layout from a spreadsheet file (.csv) via a USB or a defined network location. The imported layout files may be created in Notepad or another application. Create a file to import by using the headings in [Table 4. Importable Layout Spreadsheet Description](#).

The heading columns in the spreadsheet go across horizontally (for example, start with "Location" followed by "Plate Type" followed by "Type," "Description," then "Dilution"). Only the required headings must be included in the file.

NOTE: Luminex recommends avoiding the use of any confidential information in the spreadsheet fields.

NOTE: When creating a CSV file from another program like Excel®, ensure extra lines or commas are not present at the end of the file.

NOTE: xMAP INTELLIFLEX Software supports importing of Greek letters.

Table 4. Importable Layout Spreadsheet Description

Heading	Required	Function	Acceptable Entries
Location	Required	Assigns the location of the well on the plate to be analyzed.	Alphanumeric Example: A2, G12

Heading	Required	Function	Acceptable Entries
Plate Type	Optional	Assigns the type of plate to be analyzed.	<ul style="list-style-type: none"> • "Plate96Well" for 96-well plates • "Plate384Well" for 384-well plates <p>NOTE: If this column is used, it must be filled out for every entry. If this column is not used, the software will select the plate type based on the specified Locations.</p>
Type	Required	Assigns the well as an unknown, standard, control, or background.	<p>Alpha, Alphanumeric, or entire words Example:</p> <ul style="list-style-type: none"> • "U," "Unknown," or U1, U2, U3 • "S," "Standard," or S1, S2, S3 • "C," "Control," or C1, C2, C3 • "B," "Background" <p>NOTE: Wells with the same alphanumeric ID (for example, "U1") will be replicates and must have the same sample description if description is included.</p>
Description	Optional	Assigns the Sample ID for Unknown samples.	<p>Alpha and/or numeric</p> <p>Example: Sample identifier 1</p> <p>NOTE: Any replicate sample (as identified by Type), must have an identical Sample ID.</p>
Dilution	Optional	Assigns the Dilution for Unknown samples. NOTE: xMAP INTELLIFLEX Software does not perform any calculations based on Dilution values.	<p>Number greater than 1 with up to 2 decimal points.</p> <p>Example: 1.00, 2.50, 5.00, 7.50, 10.00, 100.00</p>

Figure 23: Example Layout with all headers shown in Excel format

	A	B	C	D	E
1	Location	Plate Type	Type	Description	Dilution
2	A1	Plate96Well	Standard		
3	B1	Plate96Well	Standard		
4	C1	Plate96Well	Standard		
5	D1	Plate96Well	Standard		
6	E1	Plate96Well	Standard		
7	F1	Plate96Well	Standard		
8	G1	Plate96Well	B		
9	H1	Plate96Well	C1		
10	A2	Plate96Well	U1	Sample 1	2
11	B2	Plate96Well	U2	Sample 2	2
12	C2	Plate96Well	U3	Sample 3	2
13	D2	Plate96Well	U4	Sample 4	2
14	E2	Plate96Well	U5	Sample 5	2
15	F2	Plate96Well	U6	Sample 6	2
16	G2	Plate96Well	B		
17	H2	Plate96Well	C2		
18	A3	Plate96Well	U1	Sample 1	2
19	B3	Plate96Well	U2	Sample 2	2
20	C3	Plate96Well	U3	Sample 3	2
21	D3	Plate96Well	U4	Sample 4	2
22	E3	Plate96Well	U5	Sample 5	2
23	F3	Plate96Well	U6	Sample 6	2

Figure 24: Example Layout with all headers shown in Notepad format

```

File Edit Format View Help
Location,Plate Type,Type,Description,Dilution
A1,Plate96Well,Standard,,
B1,Plate96Well,Standard,,
C1,Plate96Well,Standard,,
D1,Plate96Well,Standard,,
E1,Plate96Well,Standard,,
F1,Plate96Well,Standard,,
G1,Plate96Well,B,,
H1,Plate96Well,C1,,
A2,Plate96Well,U1,Sample 1,2
B2,Plate96Well,U2,Sample 2,2
C2,Plate96Well,U3,Sample 3,2
D2,Plate96Well,U4,Sample 4,2
E2,Plate96Well,U5,Sample 5,2
F2,Plate96Well,U6,Sample 6,2
G2,Plate96Well,B,,
H2,Plate96Well,C2,,
A3,Plate96Well,U1,Sample 1,2
B3,Plate96Well,U2,Sample 2,2
C3,Plate96Well,U3,Sample 3,2
D3,Plate96Well,U4,Sample 4,2
E3,Plate96Well,U5,Sample 5,2
F3,Plate96Well,U6,Sample 6,2
    
```


Figure 25: Example Layout with only required headers show in Excel format

	A	B	
1	Location	Type	
2	A1	Standard	
3	B1	Standard	
4	C1	Standard	
5	D1	Standard	
6	E1	Standard	
7	F1	Standard	
8	G1	B	
9	H1	C1	
10	A2	U1	
11	B2	U2	
12	C2	U3	
13	D2	U4	
14	E2	U5	
15	F2	U6	
16	G2	B	
17	H2	C2	
18	A3	U1	
19	B3	U2	
20	C3	U3	
21	D3	U4	
22	E3	U5	
23	F3	U6	

Figure 26: Example Layout with only required headers shown in Notepad format


```
File Edit Format View Help
|Location,Type
A1,Standard
B1,Standard
C1,Standard
D1,Standard
E1,Standard
F1,Standard
G1,B
H1,C1
A2,U1
B2,U2
C2,U3
D2,U4
E2,U5
F2,U6
G2,B
H2,C2
A3,U1
B3,U2
C3,U3
D3,U4
E3,U5
F3,U6
```

To import the layout:


1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. If not already selected, select **LAYOUT** on the left navigation bar.
3. Select **IMPORT** from the top of the screen.
4. If content is present on the Layout page, a message displays stating the sample details will be cleared. Select **Yes** to continue importing the layout, or select **No** to cancel.
NOTE: The import file replaces any previous content on the Layout page, including sample IDs.
5. In the Import dialog box, navigate to and choose the spreadsheet file (.csv) to import, then select **Open**. A message displays stating the layout imported successfully.
NOTE: Confirm the file imported correctly by reviewing the layout on the Layout page or Plate Overview pane and by viewing the sample identifiers on the Layout page.
6. Optionally, select **SAVE AS** to save the imported layout, if necessary.
 - a. Enter the **LAYOUT NAME**.
 - b. Select **OK**. A message displays stating the layout saved successfully and can be reused.

Edit the Layout

Editing the layout allows you to modify the well assignments for a previously defined layout. Once modified, you can save the layout with the same name, which overrides the previous settings, or you can save as a new layout with a different name.

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select the **LAYOUT** tab on the left navigation bar, if it is not already selected.
3. Choose a saved layout from the **LAYOUT** drop-down menu. The plate is populated with the wells to be acquired.
4. Edit the well assignments, as needed.
5. Optionally, select **SAVE** to override the previous well assignments, or select **SAVE AS** to save the layout with a different name.
NOTE: Saving is not required to immediately run an assay plate with the modified layout.
NOTE: **SAVE** is active when changes are made to the current layout.
NOTE: Changes to the layout will not affect previously saved plates or protocols associated with the original layout.
6. If **SAVE AS** was selected, enter the **LAYOUT NAME**.
7. Select **OK**. A message displays stating the layout was saved successfully.


Delete the Layout

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **DELETE** from the top of the screen.
3. Select the **PlateLayout** check box(es) for the layout(s) you want to delete.
4. Select **DELETE**.
5. Select **CLOSE**.

Define the Panel

The xMAP INTELLIFLEX® System allows you to define, import, save, and reuse common panels. Saving a panel is not required to run a plate. The software is pre-loaded with panels that match sets of bead regions compatible with other xMAP instruments.



To define and save a panel:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **PANEL** on the left navigation bar, if it is not already selected.
3. Select **NEW**.
4. Optionally, choose the normalization region from the **NORMALIZATION REGION** drop-down menu.
NOTE: MFI values generated from the region designated as the **NORMALIZATION REGION** are used to calculate

- the Net Normalized Median and the Net Normalized Average Median statistics for all of the regions read in the run.
5. Select the **REGION** field and enter the bead region number.
 6. Select the **ANALYTE-1** or the **ANALYTE-2** (xMAP INTELLIFLEX DR-SE Instrument only) field and enter the analyte ID.
 7. To add a second analyte (xMAP INTELLIFLEX DR-SE Instrument only), select the other analyte field for the region and enter the analyte ID (optional).

NOTE: Dual reporter regions must have unique names for each analyte.

NOTE: If the xMAP INTELLIFLEX® Dual Reporter operating mode is not selected in the acquisition settings, the system will not collect data for the second reporter (INTELLIFLEX DR-SE Instrument only).
 8. Select the **MIN BEADS** field and enter the minimum bead count per well.

NOTE: Select  to add a row or select  to delete a row, if necessary.

NOTE: The xMAP INTELLIFLEX System will stop the acquisition of each well when all regions have reached the designated minimum bead count, when the timeout has been reached, or when the system runs out of sample, whichever comes first.
 9. Optionally, select **SAVE AS**.

NOTE: If your role is Operator, an authorization dialog box will appear. A user with the Lab Lead or Administrator role is required to enter their username and password to authorize saving the panel.

NOTE: A plate can be run without saving the panel.
 10. Enter the **PANEL NAME**.
 11. Select **OK**. A message displays stating the panel was saved successfully.

Import the Panel

The xMAP INTELLIFLEX® System allows a panel to be imported from a spreadsheet file (.csv) via a USB or a defined network location. The files may be created in Notepad or another application such as Excel®. Create a file for importing by using the following headings in the spreadsheet as follows.

NOTE: The heading columns in the spreadsheet *must* be included and formatted in the same order as presented below. Start with "Region" and go across horizontally (for example, "Analyte-1" shall be next, followed by "Analyte-2," then "Minimum Bead Count").

NOTE: xMAP INTELLIFLEX software supports the import of Greek letters

NOTE: When creating a CSV from another program like Excel, ensure extra lines or commas are not present at the end of the file.

Table 5. Import Panel Spreadsheet Description

Heading	Function	Acceptable Entries	Examples
Region	Assigns the Bead Region.	Integers, 1-500	55, 56, 57
Analyte-1	Assigns the Analyte Name for RP1.	Text	IL-6 Free
Analyte-2	Assigns the Analyte Name for RP2.	(Optional field) Text NOTE: Do not use identical Analyte Names for RP1 and RP2	IL-6 Bound
Minimum Bead Count	Assigns the Minimum Bead Count for each region.	(Optional field) Integers	100

Heading	Function	Acceptable Entries	Examples
		NOTE: If not provided for a region or all regions, the system assigns a default value of 100.	


Figure 27: Example Panel in Excel® format

	A	B	C	D	E
1	Region	Analyte-1	Analyte-2	Minimum Bead Count	
2	54	IL-4	IL-12	100	
3	55	IL-6	IL-13	120	
4	56	IL-8	IL-15	110	
5					

Figure 28: Example Panel in Notepad format

```
File Edit Format View Help
Region,Analyte-1,Analyte-2,Minimum Bead Count
54,IL-4,IL-12,100
55,IL-6,IL-13,120
56,IL-8,IL-15,110
```

To import the panel:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **PANEL** on the left navigation bar, if it is not already selected.
3. Select **IMPORT** from the top of the screen.


NOTE: If content is present on the layout page, a message displays stating the sample details will be cleared when you load a plate. Select Yes to continue importing the panel or select No to cancel. Content on the Layout page is only cleared if you import a layout file.

NOTE: Any previous content on the Panel page will be replaced with the information from the imported panel file.
4. In the Import dialog box, navigate to and choose the file (.csv) to import, then click **Open**. A message displays stating the panel imported successfully.
5. Optionally, select **SAVE AS** to save the imported panel, if necessary.
 - a. Enter the **PANEL NAME**.
 - b. Select **OK**. A message displays stating the panel saved successfully.

NOTE: If your role is Operator, an authorization dialog will appear. A user with the Lab Lead or Administrator role is required to enter their username and password to authorize the creation of a panel.

Edit the Panel

Editing the panel allows you to modify the bead regions and analytes for a previously defined panel. Once modified, you can save the panel with the same name, which overrides the previous settings, or you can save as a new panel with a different name.

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **PANEL** on the left navigation bar, if it is not already selected.
3. Choose a saved panel from the **PANEL** drop-down menu. The analyte list changes to show the analytes used in the chosen panel.
4. Edit the panel, as needed.
5. Select **SAVE** to override the previous panel settings, or select **SAVE AS** to save the panel with a different name.

NOTE: When saving over a previous panel, the xMAP INTELLIFLEX® will assign a new version number to the panel. This can be viewed in the Plate Overview pane. Only the newest version of a panel will be available for selection when creating a new plate.


NOTE: Saving is not required to immediately run an assay plate with the modified panel.

NOTE: SAVE is active when changes are made to the current panel.

NOTE: Changes to the panel will not affect previously saved plates or protocols associated with the original panel.

NOTE: If your role is Operator, an authorization dialog box will appear. A user with the Lab Lead or Administrator role is required to enter their username and password to authorize the creation or modification of a panel.
6. If **SAVE AS** was selected, enter the **PANEL NAME**.
7. Select **OK**. A message displays stating the panel saved successfully.

Delete the Panel


1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **DELETE** from the top of the screen.
3. Select the Panel check box(es) for the panel(s) you want to delete.
4. Select **DELETE**.

NOTE: If your role is Operator, an authorization dialog box will appear. A user with the Lab Lead or Administrator role is required to enter their username and password to authorize the deletion of the panel.
5. Select **CLOSE**.

Define the Acquisition Settings

The xMAP INTELLIFLEX® System allows you to define, save, and reuse common acquisition settings across different protocols. Saving the acquisition settings is not required to run a plate.

To define and save an acquisition setting:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **ACQUISITION** on the left navigation bar, if it is not already selected.
3. In the **Plate** section, choose a saved plate configuration from the **MY PLATES** drop-down menu.

NOTE: The MY PLATES drop-down menu displays the saved plates defined in MAINTENANCE > PROBE HEIGHT.
4. Specify the direction to run the plate commands by choosing **Vertical** or **Horizontal** from the **READ DIRECTION** drop-down menu. The direction also dictates how wells are added to the plate when assigning multiple unknowns, standards, and controls at one time.
5. Choose the operating mode from the **OPERATING MODE** drop-down menu.
 - **xMAP® INTELLIFLEX High Sensitivity** - This mode configures the detection hardware at an increased laser power for optimal sensitivity in the RP1 channel. This mode is expected to generate fluorescence values significantly higher than comparable acquisitions on other xMAP platforms.
 - **xMAP® INTELLIFLEX Dual Reporter** - This mode configures the detection hardware at a standard laser power and enables detection of both the RP1 and RP2 channels. The Dual Reporter mode is the only acquisition mode which enables the RP2 channel and is only available on xMAP INTELLIFLEX DR-SE instruments.

NOTE: Dual Reporter mode is required if you created a dual reporter panel.

- **Luminex® 200™** - This mode configures the detection hardware at a standard laser power and provides the user with a secondary option to select "Low PMT" or "High PMT." Each selection is intended to produce fluorescence values comparable to equivalent selection on a Luminex 200 instrument.
- **FLEXMAP 3D®** - This mode configures the detection hardware at a standard laser power and provides the user with a secondary option to select "Low PMT" or "High PMT." Each selection is intended to produce fluorescence values comparable to equivalent selection on a FLEXMAP 3D instrument.

Table 6. Operating Modes

INTELLIFLEX Operating Modes	Compatible Instrument		RP2 Enabled	Laser Power	PMT	EDR APD	MFI Value Calculation	Dynamic Range RP1 (log)	Dynamic Range RP2 (log)
	Standard	DR-SE							
High Sensitivity	Yes	Yes	No	High	Standard	Enabled	EDR Signal	≥ 5.5	N/A
Dual Reporter	No	Yes	Yes	Standard	Standard	Not Enabled	PMT Signal	≥ 4.5	≥ 4.5
LX200 Low PMT	Yes	Yes	No	Standard	Standard	Not Enabled	PMT Signal	≥ 4.5	N/A
LX200 High PMT	Yes	Yes	No	Standard	High	Not Enabled	PMT Signal	≥ 4.5	N/A
FLEXMAP 3D Low PMT	Yes	Yes	No	Standard	Standard	Not Enabled	PMT Signal x 1.7	≥ 4.5	N/A
FLEXMAP 3D High PMT	Yes	Yes	No	Standard	High	Not Enabled	PMT Signal x 1.7	≥ 4.5	N/A

6. If the **Luminex® 200™** or **FLEXMAP 3D® OPERATING MODE** was selected, choose **Low** or **High** from the **PMT MODE** drop-down menu.
7. Choose the uptake sample volume in μL from the **UPTAKE VOLUME** drop-down menu, or enter the volume by selecting the **UPTAKE VOLUME** field and entering the value.
8. Enter a timeout value by selecting the **TIMEOUT** field and entering the value. During plate acquisition, the instrument will acquire the designated uptake volume and process this volume until one of the following conditions is met:
 - All selected regions have met the minimum bead count defined in the panel,
 - All sample volume has been consumed, or
 - The timeout value defined here is reached.
9. Choose the bead type from the **BEAD TYPE** drop-down menu.
10. Choose the DD minimum gating to acquire data for single beads only from the **DD MIN** drop-down menu, or enter the DD minimum gating by selecting the **DD MIN** field and entering the value.
11. Choose the DD maximum gating to acquire data for single beads only from the **DD MAX** drop-down menu, or enter the DD maximum gating by selecting the **DD MAX** field and entering the value.

NOTE: The Doublet Discriminator (DD) APD measures side scatter and correlates to size. Select an appropriate DD MIN and MAX for your application to eliminate aggregated beads, small particulate matter, or other non-bead events from your acquisition.
12. Choose to turn the heater **ON** or **OFF** from the **XY HEATER** drop-down.
13. If the XY Heater is on, choose the temperature in $^{\circ}\text{C}$ from the **TEMPERATURE** drop-down menu, or enter the temperature by selecting the **TEMPERATURE** and entering the value.

NOTE: If the plate heater is not warmed before the start of the run, the plate heater will turn on and sample acquisition will begin when the designated temperature is reached.


NOTE: The plate heater automatically turns off after the plate is run.
14. In the **Maintenance** section, define the maintenance routines to be run, as needed. When these optional routines

are defined, the xMAP INTELLIFLEX System automatically runs the selected cleaning routine before, during, and/or after the plate is run.


- a. Select the **RUN** check box for the **RUN PRE ASSAY MAINTENANCE ROUTINE**.
 - b. Choose the command to be run prior to the sample acquisition from the **RUN PRE ASSAY MAINTENANCE ROUTINE** drop-down menu.
NOTE: Ensure the appropriate reservoirs are filled with the required reagents.
 - c. Select the **RUN** check box for the **CLEAN ROUTINE**.
 - d. Choose the command from the **CLEAN ROUTINE** drop-down menu.
 - e. Select the **REPEAT EVERY** field and enter the number of wells to repeat the clean routine for.
 - f. Select the **RUN** check box for the **RUN POST ASSAY MAINTENANCE ROUTINE**.
 - g. Choose the command to be run after the sample acquisition from the **RUN POST ASSAY MAINTENANCE ROUTINE** drop-down menu.
NOTE: Ensure the appropriate reservoirs are filled with the required reagents.
15. Optionally, select **SAVE AS**.
NOTE: If your role is Operator, an Operator account requires a Lab Lead or Administrator to approve the action by entering their credentials into the approval prompt.
NOTE: A plate can be run without saving the acquisition settings.
 16. Enter the **ACQUISITION SETTINGS NAME**
 17. Select **OK**. A message displays stating the acquisition settings saved successfully.

Edit the Acquisition Settings

Editing the acquisition settings allows you to modify how to run the plate for previously defined acquisition settings. Once modified, you can save the acquisition settings with the same name, which overrides the previous parameters, or you can save as new acquisition settings with a different name.

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **ACQUISITION** on the left side of the screen, if it is not already selected.
3. Choose a saved acquisition from the **SETTINGS** drop-down menu.
4. Edit the acquisition settings, as needed.
5. Select **SAVE** to override the previous acquisition settings, or select **SAVE AS** to save the acquisition settings with a different name.
NOTE: If your role is Operator, an Operator account requires a Lab Lead or Administrator to approve the action by entering their credentials into the approval prompt.
NOTE: Saving is not required to immediately run an assay plate with the modified acquisition settings.
NOTE: **SAVE** is active when changes are made to the current acquisition settings.
NOTE: When saving over previous acquisition settings, the xMAP INTELLIFLEX® will assign a new version number to the acquisition settings. This can be viewed in the Plate Overview pane. Only the newest version of the acquisition will be available for selection when creating a new plate.
NOTE: Changes to the acquisition settings will not affected previously saved plates or protocols associated with the original settings
6. If **SAVE AS** was selected, enter the **ACQUISITION SETTINGS NAME**.
7. Select **OK**. A message displays stating the acquisition settings saved successfully.

Delete the Acquisition Settings

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **DELETE** from the top of the screen.
3. Select the **AcquisitionSettings** check box(es) for the acquisition setting(s) you want to delete.
4. Select **DELETE**.
NOTE: If your role is Operator, an Operator account requires a Lab Lead or Administrator to approve the action by entering their credentials into the approval prompt.
5. Select **CLOSE**.

Define the Protocol

The xMAP INTELLIFLEX® System allows you to combine a layout, panel, and acquisition settings as a protocol for repeated use. Using a protocol allows you to easily set up multiple plates from the same settings. A protocol can be defined by:


- Manually defining new layout, panel, and acquisition settings.
- Loading previously saved layout, panel, and acquisition settings.

Once the parameters have been defined, the protocol can be saved as a template for reuse.

Save the Protocol

Saving a protocol will save the parameters defined for the layout, panel, and acquisition settings for repeated use.


To save the protocol for repeated use:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **SAVE > PROTOCOL** from the top of the screen.
3. Enter the **PROTOCOL NAME**.
4. Select **OK**. A message displays stating the protocol saved successfully.
NOTE: If your role is Operator, an Operator account requires a Lab Lead or Administrator to approve the action by entering their credentials into the approval prompt.

Load the Protocol


The xMAP INTELLIFLEX® System allows you to save and reuse frequently used settings using protocols.

To load a previously saved protocol:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **LOAD > PROTOCOL** from the top of the screen.
3. Select the desired protocol.
4. Select **LOAD**.

Edit the Protocol

Editing the Protocol allows you to modify the settings for a previously defined Protocol. Once modified, you can save the Protocol with the same name, which overrides the previous settings, or you can save as a new panel with a different name.

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **LOAD > PROTOCOL** from the top of the screen.
3. Select the desired protocol.
4. Select **LOAD**.
5. Edit the layout, panel, and acquisition settings, as needed.
6. Select **SAVE** to override the previous Protocol settings, or select **SAVE AS** to save the Protocol with a different name.
NOTE: When saving over an existing Protocol, INTELLIFLEX will assign a new version number to the Protocol. This can be viewed on the Plate Overview. Only the newest version of a Protocol will be available for selection when creating a new plate.
NOTE: Saving is not required to immediately run an assay plate with the modified protocol settings but if changes have been made to the loaded Protocol, the plate and associated results will not be identified as using that Protocol.
NOTE: Changes made to well assignments or sample information are not considered a change to the Protocol


when running the plate.

NOTE: Changes to the Protocol will not affect previously saved plates associated with the original Protocol.

NOTE: If your role is Operator, an authorization dialog will appear. A user with the Lab Lead or Administrator role is required to enter their username and password to authorize the creation/modification of a protocol.

7. If **SAVE AS** was selected, enter the **PROTOCOL NAME**.
8. Select **OK**. A message displays stating the protocol saved successfully.

Delete the Protocol

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **DELETE** from the top of the screen.
3. Select the Protocol check box(es) for the protocol(s) you want to delete.
4. Select **DELETE**.
NOTE: If your role is Operator, an authorization dialog box will appear. A user with the Lab Lead or Administrator role is required to enter their username and password to authorize the deletion of a protocol.
5. Select **CLOSE**.

Define the Plate

The xMAP INTELLIFLEX® System allows you to create a plate for use with an experiment. A plate can be defined by:


- Manually defining new layout, panel, and acquisition settings.
- Loading previously saved layout, panel, and acquisition settings, or importing a layout and panel.
- Loading a protocol.

If the parameters are defined, but the experiment is not ready to be analyzed, then the plate can be saved. Or if the experiment is ready, then the plate can be run. Additionally, saving a plate allows you to assign a specific name to the plate run.

Save the Plate

Saving a plate will save the parameters defined for the layout, panel, and acquisition settings for one time use and allows you to assign a name to the assay run.


To save a plate for future use:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **SAVE > PLATE** from the top of the screen.
3. Enter the **PLATE NAME**.
4. Select **OK**. A message displays stating the plate saved successfully.
NOTE: Saving a plate will also save the collection of layout, panel, acquisition settings, and sample IDs under a user plate name.


Load the Plate

A previously saved plate can be loaded to **CURRENT RUN** in preparation of running that plate. If modifications are required prior to running, a plate can be loaded to **PLATE CONFIGURATION** to change parameters prior to running the plate.

To load a previously saved plate:

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION** or **CURRENT RUN**.
NOTE: A previously saved plate can be loaded to the **PLATE CONFIGURATION** page for further editing or to **CURRENT RUN** page for acquisition.
2. Select **LOAD > PLATE** from the top of the screen.
3. Select the desired plate.
4. Select **LOAD**.

Delete the Plate

1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. Select **DELETE** from the top of the screen.
3. Select the Plate check box(es) for the plate(s) you want to delete.
4. Select **DELETE**.
5. Select **CLOSE**.




Run the Plate






The plate heater of the xMAP INTELLIFLEX® Instrument automatically turns off after the plate is run and cools passively and slowly. It may continue to be hot after the run is complete.

Running a plate can be initiated from the **PLATE CONFIGURATION** page or by loading a plate on the **CURRENT RUN** page.

NOTE: There is no option to "re-run" a plate in the xMAP INTELLIFLEX® Software.

1. To run a previously saved plate without making modifications:
NOTE: To run a partial plate, refer to **Error! Reference source not found.** section.
 - a. Select  in the upper left-hand corner of the screen and navigate to **CURRENT RUN**.
 - b. Select **LOAD > PLATE** from the top of the screen.
 - c. Select the desired plate.
 - d. Select **LOAD**.
2. To make modifications to a saved plate before running:
 - a. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
 - b. Select **LOAD > PLATE** from the top of the screen.
 - c. Select the desired plate.
 - d. Select **LOAD** and make necessary modifications.
 - e. Select **RUN PLATE** from the Plate Overview located on the right side of the screen to make the run pending. This will navigate you to the **CURRENT RUN** page.
NOTE: If the Dashboard is fully expanded and is covering the Plate Overview pane, select the System Status circle  once to minimize its configuration.
NOTE: Define the layout, panel, and acquisition settings to activate the **RUN PLATE** button.
3. Confirm the **RUN** check box is selected for all the wells intended to be run.
NOTE: If you do not want to run a particular well, clear the **RUN** check box.

4. Select **VIEW > ACQUISITION** from the top of the screen and review the acquisition settings.
5. Select **VIEW > PANEL** from the top of the screen and review the panel settings.
NOTE: Select **CLOSE** to close the view of the panel or acquisition settings.
6. Select  to eject the plate carrier.
7. Load the plate along with any bulk reagents needed for the selected cleaning routines.
8. Select  to retract the plate carrier.
9. Select  to run the plate.

NOTE: When attempting to run a plate and the instrument is not in its optimal state for results acquisitions, the following warning messages may appear depending on the specific situation. If you wish to continue, select YES on the warning:

- If lasers are not warmed up, the following message will appear “Lasers are still warming up, do you still want to run the plate ‘XXXXXXXXXXXX’? where XXXXXXXXXXXX is the name of the plate.
- If the instrument is not properly calibrated or verified, the following message will appear “The instrument is not properly Calibrated or Verified, do you still want to run the plate ‘XXXXXXXXXXXX’? where XXXXXXXXXXXX is the name of the plate.
- If the acquisition settings for the plate does not require the heater to be on and the current temperature of the heater exceeds 35°C, the following message will appear “The temperature for the heaters is above the desired range. Do you wish to continue to run plate ‘XXXXXXXXXXXX’? where XXXXXXXXXXXX is the name of the plate.



NOTE: An Operator account requires a Lab Lead or Administrator to approve the action by entering their credentials into the approval prompt.

NOTE: The system may occasionally display a sheath pressure warning between well acquisitions. This is normal and if the system can correct the pressure before the next acquisition, the warning is not a problem. If the pressure cannot be corrected, the plate will halt. In the event of a plate halt, contact *Luminex Technical Support*.

10. (Optional) Select **STOP** during the plate run to stop the plate. The instrument will finish acquiring any wells or routines that are still running. The plate will be available as a Partial Plate for restarting.
11. After all wells are complete, a message displays stating the plate run completed.

Restart Partial Plate

If a plate stops during an acquisition, the plate will be available for loading as a Partial Plate in **CURRENT RUN**. View results for any acquired wells in **RESULTS**. To restart a partial plate:

1. Select  in the upper left-hand corner of the screen and navigate to **CURRENT RUN**.
2. Select **LOAD > PLATE** from the top of the screen. A side-window will open to show the available plates.
3. Select the desired Partial Plate.
4. Select **LOAD**.
5. Confirm the **RUN** check box is selected for all of the wells intended to run.
NOTE: The **RUN** check box will be cleared by default for previously acquired wells. Select the **RUN** check box to re-acquire the wells. If you select to re-run previously run wells, the previous results will be overwritten.
6. Select  from the bottom right side of the screen to run the plate.
NOTE: The status icon changes to a working gear when a process is active. When the plate heater turns on to maintain the selected temperature, the icon will change from yellow to orange.

Chapter 6: Monitor a Run

Software Navigation

Run monitoring on the xMAP INTELLIFLEX® System concurrently shows run statistics within a data grid and a data visualization carousel. The data grid displays well information and results fields, while the data visualization carousel includes plate status displays and heat map displays with an at-a-glance view of quantitative statistics by relative color. Within the data grid, the software may hide well information fields maximizing the space available to display the well results.

When the system begins acquiring wells, the results data appears in the data grid, as each well is acquired. As additional wells are acquired, the Well Status, and heat maps or graphs displayed. Begin to populate in the data visualization carousel. The Well Status displays a blue circle for each well that has not yet been acquired, a green circle for each successfully acquired well, a purple circle for the well that's currently being read, a yellow circle for a warning, and a red circle for an error. The circles in the heat maps display as a color gradient from blue (low signal) to white (high signal), relative to the plate. The doublet discriminator displays the bead histogram with DD gates and the Classification shows the bead map and acquired beads.

Figure 29: Current Run

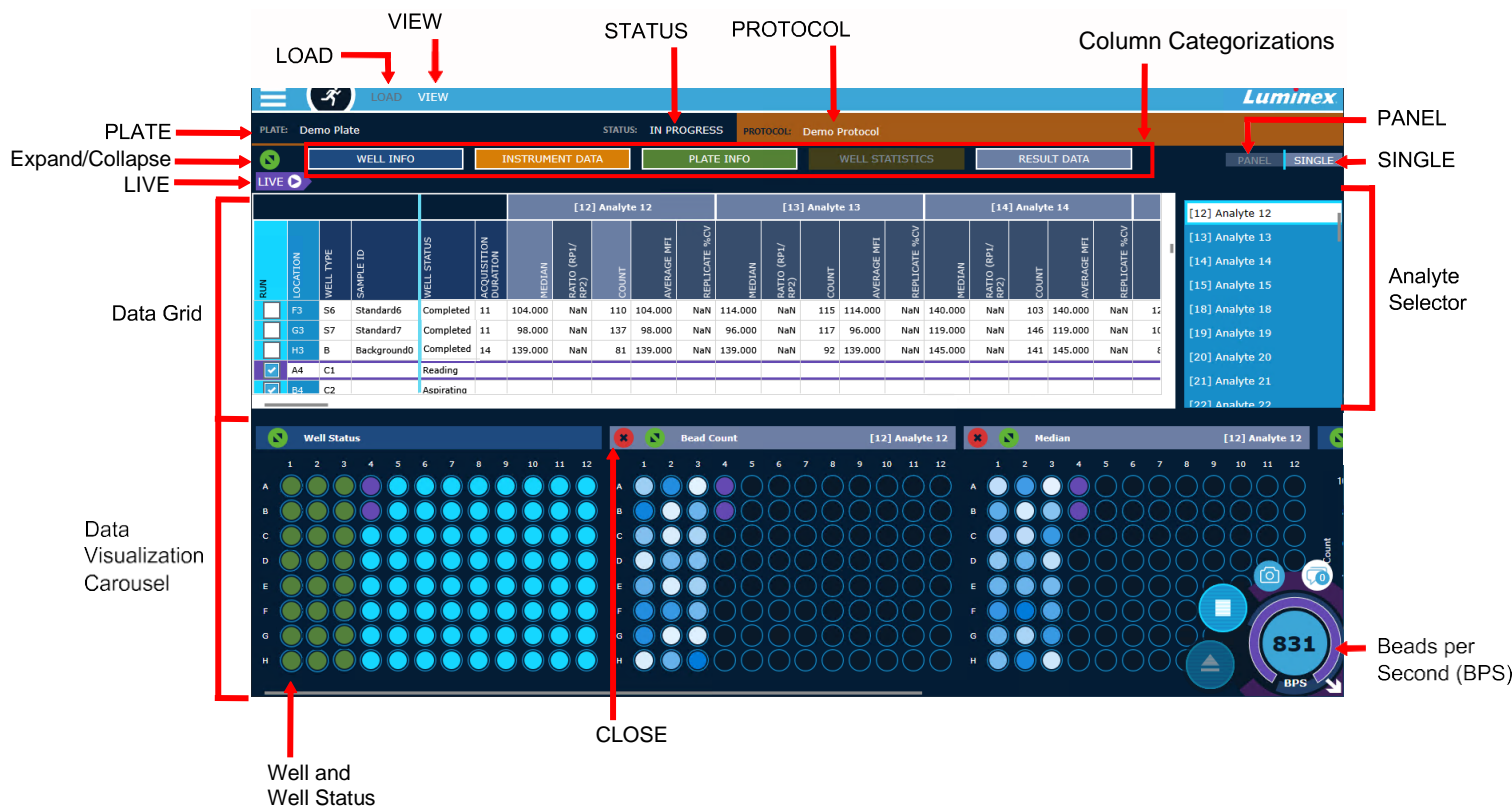


Table 7. Current Run Screen Elements

LOAD	Allows a saved, pre-configured or partial plate to be loaded for a run.
VIEW	Selecting Acquisition or Panel displays the acquisition settings or panel for the current run. Selecting Columns allows the selection of the columns that display in the data grid. For more information on available statistics, refer to Appendix A: Available Statistics per Page .
PLATE	Displays the plate name, if one was defined.
STATUS	Displays the status of the current run.
PROTOCOL	Displays the protocol name, if one was defined for the plate.
Expand/Minimize	Expand the data grid and restore the data grid to its initial state.
Column Categories	<p>The xMAP INTELLIFLEX® Software groups related data or metadata fields into Column Categories, allowing you to easily show or hide multiple columns with a single action. To hide or view information for the current run:</p> <ul style="list-style-type: none"> • Select WELL INFO to hide or view the associated columns. • Select INSTRUMENT DATA to hide or view the associated columns. • Select PLATE INFO to hide or view the associated columns. • Select WELL STATISTICS to hide or view the associated columns. • Select RESULT DATA to hide or view the associated columns.
LIVE	Return to the well that is currently being acquired.
Data Grid	Displays the well information and results. Selecting a statistic column header will display the heat map for that statistic. The columns displayed can be configured in VIEW > Columns.
Data Visualization Carousel	Displays the plate well status, heat map visualizations, and histograms.
Double Discriminator (Histogram)	Displays the DD gates and bead data in a histogram.
Classification grid (Bead Map)	Displays the active bead regions and acquired beads. Expand the view for access to options to display the entire panel, single analytes, or the slab view. Panel and single view on the Bead Map will display CL1 and CL2 information. The Slab displays CL2 and CL3 views.

PANEL	When selected, removes the heat maps (since they are analyte-specific) from the data visualization carousel and displays only the Well Status, the Doublet Discriminator histogram, and the Classification histogram.
SINGLE	When selected, returns the data visualization carousel display to the analyte-specific heat map view.
Analyte Selector	Displays the analytes for the run. When an analyte is selected, the displays in the data grid and data visualization carousel are updated based on the selected analyte.
Heat Map Visualizations	Displays a gradient of white to blue for the selected statistics. White indicates the highest value encountered and the darkest blue indicates the lowest value. The well colors will adjust during the run as new values are encountered. NOTE: When in SINGLE mode, select an grid column header to display the heat map for the data statistic.
Well	Select a well to view data for that well.
Well Status	Displays information on the well status. <ul style="list-style-type: none"> • Red: Dry well or error • Yellow: Warning • Purple: Aspirating or Reading • Green: Complete • Blue: Pending
Close	Remove a display from view in the data visualization carousel, if needed.
Beads per Second (BPS)	Displays the number of total bead events detected per second. BPS is a rolling momentary snapshot for the number of beads counted within a given amount of time. It provides an immediate assessment for the concentration of beads traveling through the cuvette.

Chapter 7: Managing Results

The xMAP INTELLIFLEX System result management tools are well-driven. In a single data grid, you can view the results of all wells acquired by the system, regardless of when they were acquired. The data grid can be filtered by plate name or by date, and results can be exported as an xPONENT®-style .csv file intended for backwards compatibility, or as a new xMAP INTELLIFLEX .csv file format or as a new system .XLS file format, compatible with common spreadsheet applications. When exporting as an xMAP INTELLIFLEX report type, you can include or exclude specific statistics and select data from wells spanning multiple plates.

Software Navigation

Figure 30: Results

The screenshot shows the 'Results' screen in the xMAP INTELLIFLEX software. At the top, there is a navigation bar with three buttons: 'ARCHIVE', 'EXPORT', and 'VIEW'. Below this is a tabbed interface with five tabs: 'INSTRUMENT DATA', 'PLATE INFO', 'WELL INFO', 'WELL STATISTICS', and 'RESULT DATA'. The 'WELL INFO' tab is currently selected. The main area displays a data grid with the following columns: MODEL NAME, SERIAL NUMBER, CALIBRATION STATE, VERIFICATION STATE, FLUIDICS VER. STATE, WELL LOCATION, WELL TYPE, WELL STATUS, SAMPLE ID, BEAD TYPE, OPERATING MODE, TOTAL ACTIVE EVENTS, TOTAL GATED EVENTS, ANALYTE NAME, MEDIAN, and BACKGROUND. The grid contains 15 rows of data for various wells. Red arrows point from labels above to the corresponding UI elements: ARCHIVE, EXPORT, VIEW, WELL INFO, WELL STATISTICS, and RESULTS DATA.


Table 8. Results Screen Elements

ARCHIVE	Displays the plate runs that can be archived. This is only available to Administrator users.
---------	--

EXPORT	Displays the RESULTS and SETTINGS menu items to allow the export of and the data statistics to include in the exported file. Results can be exported to either an INTELLIFLEX format in a CSV or MS Excel file or an xPONENT format in a CSV file. For more information on available statistics, refer to Appendix A: Available Statistics per Page.
VIEW	Displays the COLUMNS and FILTER menu items to allow the selection of data for display in the data grid and the selection of parameters to filter the results in the data grid. For more information on available statistics, refer to Appendix A: Available Statistics per Page.
INSTRUMENT DATA	Displays or hides the INSTRUMENT DATA columns when toggled.
PLATE INFO	Displays or hides the PLATE INFO columns when toggled.
WELL INFO	Displays or hides the WELL INFO columns when toggled.
WELL STATISTICS	Displays or hides the WELL STATISTICS columns when toggled.
RESULT DATA	Displays or hides the RESULT DATA columns when toggled.

View Completed Run


A completed run can be viewed through the **RESULTS** page or the **HISTORY** page. The **RESULTS** page displays previously acquired data, provides tools to choose specific data points to view, and allows a chosen subset of data to be exported in a variety of formats. The **HISTORY** page provides an alternative view to easily find and export a single plate. To view a previous run:

1. Select  in the upper left-hand corner of the screen and navigate to **RESULTS** or **HISTORY**.
2. If **HISTORY** was selected:
 - a. Select the **DATE** or **DATE RANGE** to display plates.
NOTE: If the calendar does not display, select the green circle from the top left of the screen to expand the calendar.
 - b. Select the **PLATES** tab, if it's not already selected.
 - c. Select the check box for the plate run to view.
 - d. Select **VIEW RESULTS**. The **RESULTS** page displays. Select **EXPORT** to export the results to xMAP INTELLIFLEX CSV or Excel, or xPONENT CSV.
NOTE: Statistics exported in the INTELLIFLEX reports are customized on the Results page.
NOTE: See Select Results Data Options for more information on reviewing data on the Results page.

Select Results Data Options

The **RESULTS** page allows you to change what fields are visible on screen, as well as change the fields that will be included in the exported results.

For more information on available statistics, refer to Appendix A: Available Statistics per Page.

1. Select  in the upper left-hand corner of the screen and navigate to **RESULTS**.
2. Select **VIEW > COLUMNS** to edit the results display settings.
 - a. Select the check boxes for the fields you want to include.
 - b. Select **APPLY** to apply the changes, or select **CLOSE** if no changes were made.
3. Select **VIEW > FILTER** to filter the results displayed.
 - a. To filter the results for a specific plate, select the **SEARCH BY PLATE NAME** field and enter a plate name.
 - b. Select the **DATE** radio button, or a pre-programmed time filter, to filter the results for a specified date range.
 - c. Select **APPLY** to apply the changes, or select **CLOSE** if no changes were made.
4. Select **EXPORT > SETTINGS** to edit the statistics exported in the xMAP INTELLIFLEX® report.
 - a. **NOTE:** Statistics exported in the INTELLIFLEX reports are customized on the Results page. Select the check boxes for the data points you want to include in the exported xMAP INTELLIFLEX files.
NOTE: The exported content for the xPONENT report type is not customizable.
 - b. Select **APPLY** to apply the changes, or select **CLOSE** if no changes were made.

Export to CSV or Excel®

Results can be exported to a .csv or Excel® file. There are three different report types supported by the xMAP INTELLIFLEX® System:


- xMAP INTELLIFLEX CSV
- xMAP INTELLIFLEX Excel
- xPONENT

The xMAP INTELLIFLEX CSV report type export will include the filtered results and the specific statistics selected on the RESULTS page. In the spreadsheet, each well is a row and each statistic is a column, similar to the RESULTS page view on the xMAP INTELLIFLEX System. The xPONENT report type is similar to the classic xPONENT® file format and is intended to be backwards compatible.

The xMAP INTELLIFLEX Excel report type is the same result information that is included in the xMAP INTELLIFLEX CSV report type but in a native Excel format. In addition to sample data, this file contains relevant plate information such as calibration, verification, fluidics information, system logs, and history on plate parameters (Plate, Protocol, Layout, Acquisition, and Panel).


Results can be exported from the HISTORY page or RESULTS page. The HISTORY page provides an view to easily find and export a single plate. The RESULTS page displays provides tools to choose specific data points to export, and allows a chosen subset of data to be exported in a variety of formats. Exporting from the RESULTS page allows you to combine multiple plates into a single report.

To export to a .csv file from the History page:

1. Select  in the upper left-hand corner of the screen and navigate to **HISTORY**.
2. Use the toggle to select either **SINGLE DATE** or **DATE RANGE** and use the calendar to make your selection.
NOTE: To visually see dates with run data, check the PLATES RUN box to display an orange dot on the calendar.
3. If not already selected, select **PLATES** on the middle navigation bar.
4. Select the check box for the plate run to export.
5. Select **EXPORT** at the bottom of the page.
6. Navigate to the desired location for the report.
NOTE: The .csv file can also be exported to a USB or network drive. Documents related to IT administration of the system, including guidance on changing the administrator password, configuring networking, and general IT and security best-practices, are available upon request from *Luminex Technical Support*. Please contact support@luminexcorp.com for more information.
7. Edit the **File Name**, if necessary, by selecting the field and updating the value.

8. Select **INTELLIFLEX** or **xPONENT** from the **Report Type** drop down menu.
9. If the **INTELLIFLEX** report type was selected, select **Excel File** or **CSV File**.
NOTE: Statistics exported in the INTELLIFLEX reports are customized on the Results page.
10. Select **OK**. A message displays stating the export results completed successfully.


To export a .csv file from the Results page:

1. Select  in the upper left-hand corner of the screen and navigate to **RESULTS**.
NOTE: To edit the statistics exported in the INTELLIFLEX report, select **EXPORT > SETTINGS** and select the check boxes for the settings you want to include. Select **APPLY** to apply the changes.
2. Select **EXPORT > RESULTS**.
NOTE: To filter results, select **VIEW > FILTER** to select a date range or enter a plate name. Select **APPLY**.
3. Select **EXPORT**.
4. Choose the location you want to save the report.
NOTE: The results file can be exported to a USB or network drive. Documents related to IT administration of the system, including guidance on changing the administrator password, configuring networking, and general IT and security best practices, are available upon request from *Luminex Technical Support*. Please contact support@luminexcorp.com for more information.
5. Edit the **File Name**, if necessary, by selecting the field and updating the value.
6. Choose the report type from the **Report Type** drop-down menu.
NOTE: A single xMAP INTELLIFLEX report will include data acquired from all filtered wells. An xPONENT report will include data acquired from all filtered wells that have the same panel and acquisition settings in a single report. If the panel and acquisition settings of the filtered wells are not the same, multiple xPONENT reports will be generated.
7. Select **OK**. A message displays stating the export results completed successfully.

Archive Results

NOTE: Archiving results is applicable to Administrator roles only.

Archiving data exports an xMAP INTELLIFLEX® CSV file that includes all of the sample statistics. The data will be removed from the local drive and software and cannot be reimported into the xMAP INTELLIFLEX software. Archiving prevents storing large amounts of data on the instrument that may impact software functionality.

1. Select  in the upper left-hand corner of the screen and navigate to **RESULTS**.
2. Select **VIEW > FILTER** to select a date range. Select **APPLY**.
3. Select **ARCHIVE** from the top menu.
4. Toggle the radio button to **FILTER ON** to apply the filter options selected previously or move the radio button to **ALL**.
5. Select the checkbox for the plate you want to archive and select **ARCHIVE** from the bottom middle of the screen.
6. A warning message will appear indicating that results will be archived to the configured archive directory and removed from the system. Select **Yes** to proceed with archiving the results.
NOTE: The archive directory is set in **Settings > Configuration**.

Chapter 8: Maintaining the System

To ensure accurate test results, properly clean and maintain the xMAP INTELLIFLEX® System. Read and follow all instructions in this chapter. To facilitate your maintenance process, print out and use the *Maintenance Log*.

Only use xMAP Sheath Fluid PLUS.



Use of non-Luminex approved sheath fluid shall constitute “Improper Use” and can void the warranty provided by Luminex and/or its authorized partner.

When analyzing potentially infectious biological samples on the INTELLIFLEX System, follow standard laboratory safety practices. These safety precautions shall also be taken when cleaning or maintaining the instrument.

General Maintenance Precautions

Observe the following general maintenance precautions.



Train personnel who use, maintain, or clean the instrument in standard laboratory safety practices and 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 (PPE), and use ventilation devices.

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

Refer to the applicable safety data sheet (SDS) regarding safe handling practices for any spills.

Software Navigation

The MAINTENANCE > ROUTINES page allows you to run pre-programmed maintenance commands and routines.

Figure 31: Routines

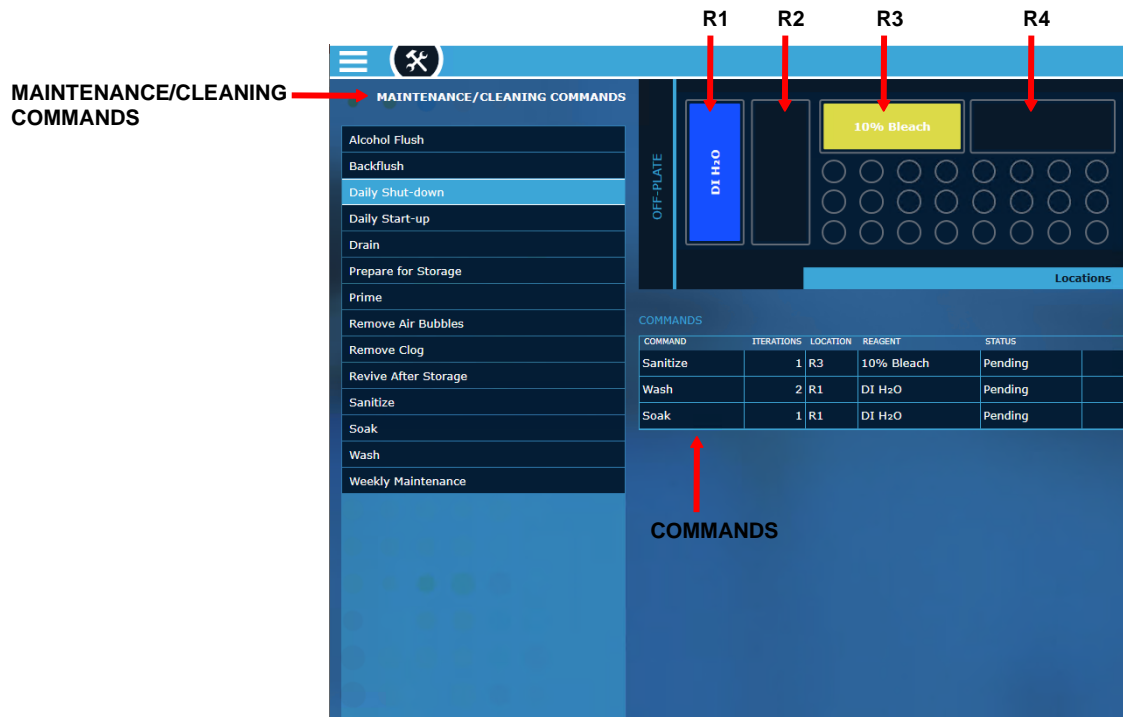


Table 9. Routines Screen Elements

<p>MAINTENANCE/CLEANING COMMANDS</p>	<p>Displays the available commands and routines.</p>
<p>COMMANDS</p>	<p>Displays the details of the selected command or routine with the commands, number of iterations, reservoir locations, required reagents, and the status.</p>

Maintenance Commands and Routines

Table 10. Maintenance Commands





Wash	Sends deionized water (DI water) through the fluidic lines in the system. It pulls the fluid from a reservoir and runs it completely through the system to the waste fluid container. The system uses at least 200µL of DI water. The Wash command takes less than a minute to complete.
Alcohol Flush	Removes air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The system uses at least 400µL of reagent. The alcohol flush takes about 5 minutes.
Soak	Perform the soak function at the end of each day. The system uses at least 250 µL of DI water. Prevents salt crystals from forming in the probe due to air exposure. Soaking the probe replaces xMAP® Sheath Fluid PLUS in the probe with water. The Soak command takes less than a minute to complete.
Sanitize	Performs a similar function as the alcohol flush command, but uses 10% bleach with no additives or sodium hydroxide (0.1N NaOH) to decontaminate sample lines and the cuvette after biohazard contact. NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background
Prime	Removes air bubbles from the system's fluidic pathways by drawing Sheath Fluid PLUS from the Sheath Fluid PLUS container. You do not need to supply solution in a plate. The system uses at least 500µL of Sheath Fluid PLUS. The Prime command takes less than a minute to complete.
Drain	Helps remove debris from the bottom of the cuvette during troubleshooting. You do not need to supply solution. Draining takes approximately 2 minutes and shall be followed by an alcohol flush with 70% isopropanol or 70% ethanol. NOTE: Ensure the reservoir indicated in plate layout of the software is empty.
Backflush	Removes obstructions from the fluidics pathways by drawing Sheath Fluid PLUS from the Sheath Fluid PLUS container. The system uses at least 1000µL of Sheath Fluid PLUS. The Backflush command takes approximately 1 minute to complete.

Table 11. Maintenance Routines

Daily Start-up	Prepares system fluidics. Luminex recommends to run the routine at the beginning of each day before performance verification or acquiring data. The routine is comprised of 1 Prime, 1 Alcohol Flush, and 2 Wash commands. It takes approximately 7 minutes to complete.
Daily Shut-down	Prepares and cleans the system for daily shut down. Luminex recommends to run the routine at the end of each day to prevent clogs and crystallization of salt in the fluidics lines. The routine is comprised of 1 Sanitize, 1 Wash, and 2 Soak commands. It takes approximately 7 minute to complete.
Prepare for Storage	Prepares and cleans the system for storage. Luminex recommends to run the routine when the system will be idle for more than a week. The routine is comprised of 1 Sanitize, 4 Washes, 1 Water Flush, and 1 Wash command. It takes approximately 14 minutes to complete.
Revive After Storage	Prepares system fluidics after storage. Luminex recommends to run the routine when the system runs for the first time and when the system has been idle for more than a week. The routine is comprised of 2 Backflushes, 3 Drains, 2 Alcohol Flushes, 1 Backflush, and 3 Wash commands. It takes approximately 20 minutes to complete.

Remove Air Bubbles	Removes air bubbles in the system. Luminex recommends to run the routine when there are indications of air in the system, such as visible pockets of air within the clear tubing lines of the sheath filter, within the clear tubing lines connected to the syringe pumps, or within the waste tubing line connected to the waste container. The routine is comprised of 2 Backflushes, 3 Drains, 2 Primes, 2 Alcohol Flushes, 1 Backflush, and 3 Wash commands. It takes approximately 20 minutes to complete.
Remove Clog	Removes clogs in the system. Luminex recommends to run the routine when there are indications of clogs, including slower acquisition rates and slower acquisition of data. The routine is comprised of 2 Backflushes, 1 Wash, 1 Backflush, 3 Drains, 2 Sanitize commands, and 3 Wash commands. It takes approximately 20 minutes to complete.
Weekly Maintenance	Prepares system fluidics in supplement to the Daily Start-up or Daily Shut-down routines. Luminex recommends to run the routine weekly to keep the fluidics optimally clean. The routine is comprised of 2 Backflushes, 2 Drains, 2 Alcohol Flushes, 1 Backflush, and 3 Wash Commands. It takes approximately 20 minutes to complete.

Run a Maintenance Routine

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > ROUTINES**.
2. Select a routine from the **MAINTENANCE/CLEANING COMMANDS**.
3. Select  to eject the plate carrier.
4. Fill the reservoir(s) indicated in the plate layout of the software 3/4 full of the appropriate reagents.
5. Select  to retract the plate carrier.
6. Select  to run. A message displays stating the maintenance routine completed successfully.

Maintain Instrument Fluids

Replace the xMAP® Sheath Fluid PLUS

Periodically monitor fluid levels. Replace the empty xMAP® Sheath Fluid PLUS container as needed. If the xMAP INTELLIFLEX System operates with an empty Sheath Fluid PLUS container, the lack of Sheath Fluid PLUS will interrupt a sample and prevent further samples from being collected. Additionally, if the Sheath Fluid PLUS high reservoir is over-filled, the xMAP INTELLIFLEX System will provide a notification and will not allow a run to start. The user should contact *Luminex Technical Support*.



Only use Sheath Fluid PLUS. Use of non-Luminex approved sheath fluid shall constitute "Improper Use" and can void the warranty provided by Luminex and/or its authorized partner.

To replace the Sheath Fluid PLUS container:

1. Unscrew the cap and remove the Sheath Fluid PLUS intake line.
2. Remove the empty Sheath Fluid PLUS container. The empty Sheath Fluid PLUS container can be used as the new waste fluid container.
3. Replace with a new Sheath Fluid PLUS container.
4. Replace the Sheath Fluid PLUS intake line and screw in the cap. Do not touch the filter on the Sheath Fluid PLUS intake line. Ensure the filter is near the bottom of the container.

Empty the Waste Fluid Container

To empty the waste fluid container:

1. Remove the waste line from the waste fluid container.
2. Discard the waste from the waste fluid container in accordance with lab protocols.
3. Attach the waste line to the new empty waste fluid container and ensure the waste fluid container is properly vented.



Do not place the waste fluid container on top of the instrument. Do not move the waste line vertically while the xMAP INTELLIFLEX® System is running.

Contact Luminex before relocating the waste fluid container or rerouting the waste line. Only move the line temporarily for cleaning and maintenance.

Maintain Instrument Hardware

Remove and Replace the Front Cover

The front cover of the xMAP INTELLIFLEX® Instrument may need to be removed and replaced in order to perform certain maintenance procedures.



Keep hands and fingers away from the syringe pumps and sample probe during operation. Observe all warnings and cautions. Keep the access door closed and the front cover of the instrument on during normal operations.

Remove the Front Cover

1. Grab onto each side of the front cover with one hand on each side.
2. With one fluid motion, pull the front cover directly towards you (the front cover will come off with little force).

Replace the Front Cover





1. Align the front cover ball studs to the openings on the chassis.
2. Push the front cover into place (you will feel the front cover lock into place).

Daily Maintenance

In addition to Performance Verification, the following daily maintenance tasks for the xMAP INTELLIFLEX® System can be performed using available software commands.

Run the Daily Start-up Routine





NOTE: Daily Start up is automatically performed when running the Calibration, Performance Verification or Fluidics routines.

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > ROUTINES**.
2. Select Daily Start-up from the **MAINTENANCE/CLEANING COMMANDS**.
3. Select  to eject the plate carrier.
4. Fill the reservoir indicated in the plate layout of the software 3/4 full of 70% isopropanol or 70% ethanol.
5. Fill the reservoir indicated in the plate layout of the software 3/4 full of deionized water (DI water).
6. Select  to retract the plate carrier.
7. Select  to run. A message displays stating the maintenance routine completed successfully.

Run the Daily Shut-down Routine

System shutdown is a standardized procedure in the xMAP INTELLIFLEX® Software.

Run the **Daily Shut-down** routine to prevent clogs and crystallization of salt in the fluidics lines. Clogs and crystallization of salt in the sample probe can cause problems with calibration, verification, and data acquisition; they can also cause sample splashing. Perform the Daily Shut Down Routine to prevent system failures.

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > ROUTINES**.
2. Select **Daily Shut-down** from the **MAINTENANCE/CLEANING COMMANDS**.
3. Select  to eject the plate carrier.
4. Fill the reservoir indicated in the plate layout of the software 3/4 full of 10% bleach with no additives.
NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.
5. Fill the reservoir indicated in the plate layout of the software 3/4 full of deionized water (DI water).
6. Select  to retract the plate carrier.
7. Select  to run. A message displays stating the maintenance routine completed successfully.

Power off the System



Luminex does not recommend shutting down the xMAP INTELLIFLEX® System while a run is in progress. Doing so may cause loss of data.

NOTE: If the Daily Shut-down routine has not been run on the MAINTENANCE > ROUTINES page, run this routine before shutting down the system.

1. Remove the plate and any bulk reagents from the instrument.
2. Push the soft power button located on the right side of the instrument (do not press and hold the soft power button).

NOTE: If a normal system shutdown is selected while an existing routine is running, the system will complete the routine prior to shutting down.

NOTE: Pressing and holding the soft power button will force the instrument to shut down. Only press and hold the soft power button in the event that the soft shutdown is not responding.

3. Select **Yes** to confirm the shutdown.

NOTE: As needed, Perform a hard power shutdown by turning off the hard power switch located on the back of the instrument and unplug the instrument. A hard power shutdown and unplugging the system may be required during troubleshooting or maintenance.

4. Perform a hard power shutdown by turning off the hard power switch located on the back of the instrument and unplug the instrument.

Weekly Maintenance

Some of the weekly maintenance tasks for the xMAP INTELLIFLEX® System can be performed using available software commands. In addition to calibrating the system, weekly maintenance includes using the software to perform a weekly maintenance routine, removing clogs, cleaning the sample probe, and visually inspecting the system.

Perform a Visual Inspection

Inspect the xMAP INTELLIFLEX® System weekly. Make sure the instrument is idle, so there are no moving parts. Remove the front cover.

- Visually inspect for leaks, corrosion, and other signs of improper function.
- Check all visible tubing connections.

Clean the Sample Probe



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. The system must not be performing any operations while you carry out this maintenance procedure.




Keep hands and fingers away from the syringe pumps and sample probe during operation. Observe all warnings and cautions. Keep the access door closed and the front cover of the instrument on during normal operations.




To clean the sample probe:

1. Turn off the xMAP INTELLIFLEX® System and unplug the power cord.
2. Remove the sample probe.
 - a. Open the sliding front access door of the INTELLIFLEX Instrument.
 - b. Unscrew the sample probe fitting on top of the sample probe completely.
 - c. Grasp the sample probe gently and push up.
 - d. Lift the sample probe out of the top of the sample probe holder.
3. Clean the sample probe using a bath sonicator or a 10 mL syringe. If you are using a bath sonicator, place the tip of the sample probe in the bath sonicator for 2 to 5 minutes of water flowing through the sample probe. If you are using a syringe, force deionized water (DI water) through the tip of the sample probe and out the large end. This dislodges any debris clogging the tip.
4. Replace the sample probe.
 - a. Place the sample probe into the sample probe holder.
 - b. Grasp the sample probe gently and pull down.
 - c. Tightly screw in the sample probe fitting on top of the sample probe.
5. Close the sliding front access door.
6. Plug in the power cord and turn on the INTELLIFLEX System.
7. Calibrate the sample probe height.

NOTE: Calibrate the sample probe height any time the sample probe is reinstalled after removal.

Run the Weekly Maintenance Routine

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > ROUTINES**.
2. Select **Weekly Maintenance** from the **MAINTENANCE/CLEANING COMMANDS**.

3. Select  to eject the plate carrier.
4. Ensure the reservoir indicated in the plate layout of the software is empty for waste.
5. Fill the reservoir indicated in the plate layout of the software 3/4 full of 70% isopropanol or 70% ethanol.
6. Fill the reservoir indicated in the plate layout of the software 3/4 full of deionized water (DI water).
7. Select  to retract the plate carrier.
8. Select  to run. A message displays stating the maintenance routine completed successfully.





Remove Clogs



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.

If you frequently use the xMAP INTELLIFLEX® System to test concentrated serum or other debris-ridden samples, Luminex recommends that you perform a clog removal weekly. Otherwise, perform this procedure as needed.

To remove clogs:

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > ROUTINES**.
2. Select Remove Clog from the **MAINTENANCE/CLEANING COMMANDS**.
3. Select  to eject the plate carrier.
4. Fill the reservoir indicated in the plate layout of the software 3/4 full of deionized water (DI water).
5. Ensure the reservoir indicated in the plate layout of the software is empty for waste.
6. Fill the reservoir indicated in the plate layout of the software 3/4 full of sodium hydroxide (0.1N NaOH).
7. Select  to retract the plate carrier.
8. Select  to run. A message displays stating the maintenance routine completed successfully.

Monthly Maintenance

Clean the Exterior Surfaces

1. Turn off the xMAP INTELLIFLEX® System and unplug the power cord.
2. Clean all exterior surfaces with a mild detergent, followed by 10% bleach with no additives, followed by deionized water (DI water).
NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.



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

3. Plug in the power cord and turn on the xMAP INTELLIFLEX System.

Semi-Annual Maintenance

Replace the HEPA Filter

The HEPA filter is the round filter located on the top right of the fluidics module. Tubing from the interior of the fluidics module is attached to the stem in the center back of the filter.

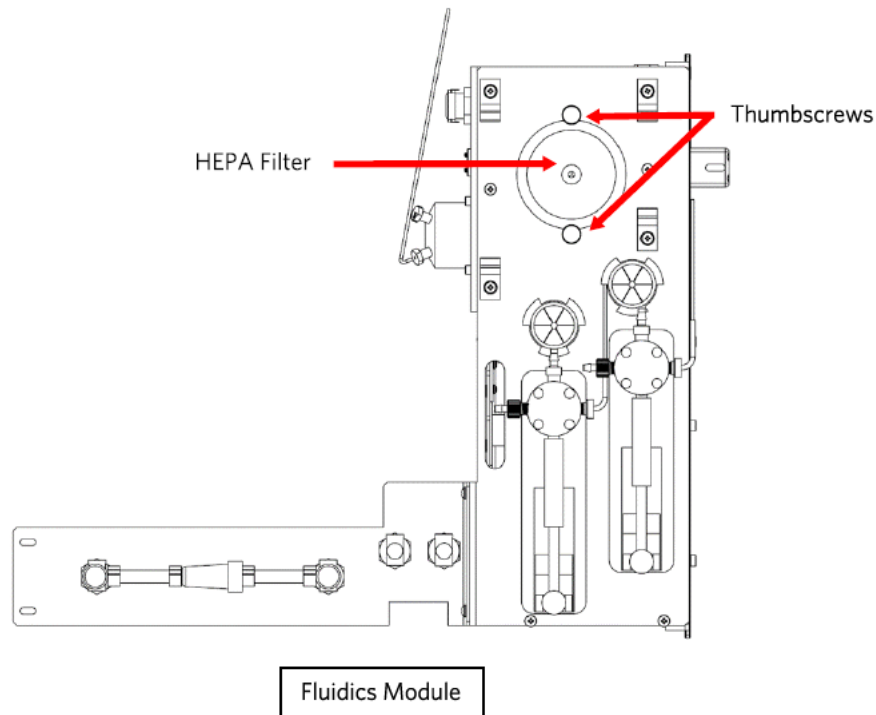
To replace the HEPA filter:

1. Turn off the xMAP INTELLIFLEX® System and unplug the power cord.
2. Remove the front cover and locate the HEPA filter on the front panel of the fluidics module.
3. Remove the two black thumbscrews that secure the HEPA filter to the panel.
4. Grasp the tubing and pull the HEPA filter 3 to 4 inches from the panel.
5. Securely hold the tubing with one hand and remove the HEPA filter with the other hand.



Do not allow the tubing to fall inside the system.

6. Connect a new HEPA filter to the tubing and position the filter.
7. Replace and tighten the two black thumbscrews that secure the HEPA filter to the panel.
NOTE: Avoid pinching the sample lines between the HEPA filter and the panel.
8. Replace the front cover.
9. Plug in the power cord and turn on the xMAP INTELLIFLEX System.



Replace the Syringes

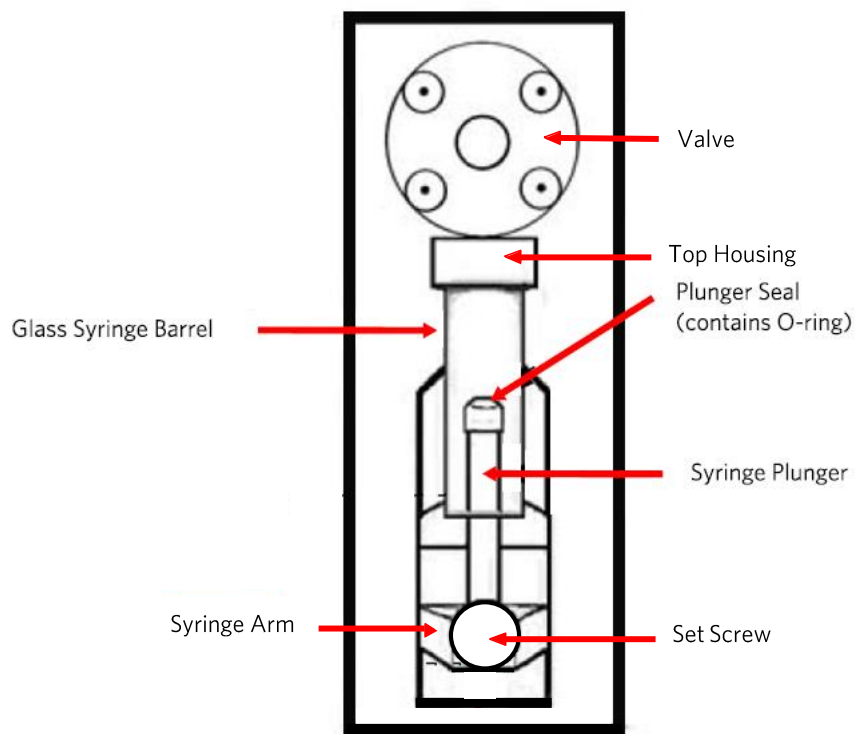
To replace each syringe:

1. Turn off the xMAP INTELLIFLEX® System and unplug the power cord.



The syringe arm does NOT deactivate when replacing the syringe; unplugging is necessary to avoid injury.

2. Remove the front cover.
3. Locate the syringe (glass cylinder with a metal rod plunger).
4. Loosen the set screw on the syringe arm (at the bottom of the syringe) and push the syringe arm down.
NOTE: The syringe arm is tight. Be prepared to use some force to move it.
5. Unscrew the syringe from valve by turning the top housing. Remove the syringe and discard in accordance with lab policies.
6. Screw the top housing of the new syringe back into the valve.
7. Return the syringe arm to its original position. The bottom of the plunger fits into the indentation in the syringe arm.
8. Hand-tighten the set screw on the syringe arm.
9. Plug in the power cord and turn on the xMAP INTELLIFLEX System.
10. Run two **Prime** commands, watching for any leaks in the syringe area.
NOTE: For information on running a maintenance command, see [Run a Maintenance Routine](#).
11. Replace the front cover.



Replace the Sheath-In Tubing

1. Turn off the xMAP INTELLIFLEX® System and unplug the power cord.
2. Disconnect the sheath-in tubing (blue connector) from the external tubing coming out from underneath the instrument by pushing down on the metal clamps at the quick-disconnect point. Unscrew the cap from the top of the xMAP® Sheath Fluid PLUS container. Pull out the remaining tubing with the filter and discard in accordance with lab protocols.
3. Insert the new cap tubing with filter into the xMAP® Sheath Fluid PLUS container and tighten the cap.
4. Connect the new sheath-in tubing to the external tubing coming out from underneath the instrument.
NOTE: A click/snap is heard when the tubing is properly connected.
5. Plug in the power cord and turn on the xMAP INTELLIFLEX System.
6. Run two **Prime** commands.

Annual Maintenance

Contact Technical Support to schedule your 12 month preventative maintenance, which includes changing/cleaning the filters by a Luminex Field Service Engineer (FSE).

As Needed Maintenance

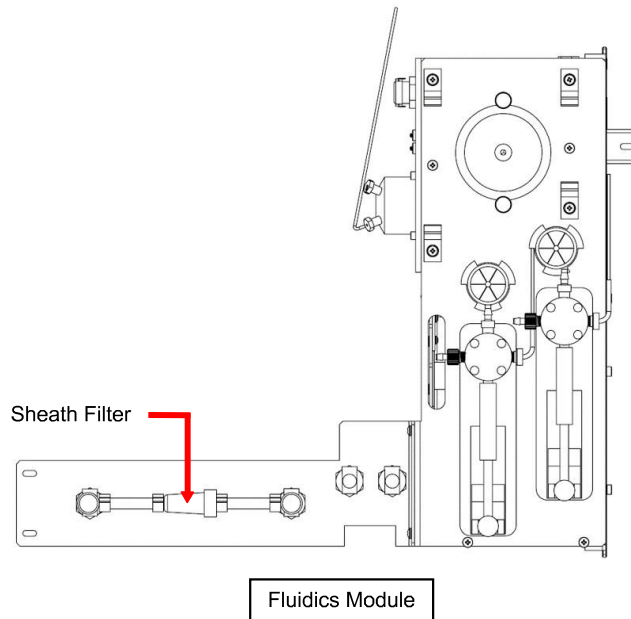
Replace the Sheath Filter

Based on guidance from *Luminex Technical Support*, you may need to replace the sheath filter outside of the Annual Maintenance performed by a Field Service Engineer (FSE).

To replace the sheath filter:

1. Turn off the xMAP INTELLIFLEX® System and unplug the power cord.

2. Remove the front cover of the INTELLIFLEX Instrument and locate the sheath filter on the front of the fluidics module.
3. Disconnect the sheath filter by pushing down on the metal clamps at each quick-disconnect point.
4. Connect the new sheath filter, matching up the color-coded fittings.
5. Replace the front cover.
6. Plug in the power cord and turn on the INTELLIFLEX System.
7. Run two **Prime** commands.



Maintenance Log

Reproduce the following form as necessary and use them to record maintenance information.

MONTH: _____ YEAR: _____

xMAP INTELLIFLEX® Maintenance Log

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Day of the Month																															
Daily																															
Warm up laser																															
Run daily start-up																															
Verify the system																															
Check fluid levels																															
Run daily shut-down																															
Weekly																															
Perform visual inspection																															
Calibrate the system																															
Clean sample probe																															
Run clog removal																															
Run weekly maintenance																															
Monthly																															
Clean exterior surfaces																															
Semi-Annual Maintenance																															
Replace HEPA filter	Yes		No																												
Replace syringes	Yes		No																												
Replace sheath-in tubing	Yes		No																												

As Needed Maintenance

Replace sheath filter Yes No If Yes, Date: _____

Replace sheath filter Yes No If Yes, Date: _____

Chapter 9: Troubleshooting

Troubleshooting procedures help users isolate, identify, and remedy problems with the system.

Software Navigation

From the **SETTINGS > SUPPORT ZIP** page, you can generate and export a support package.

Figure 32: **SETTINGS > SUPPORT ZIP**

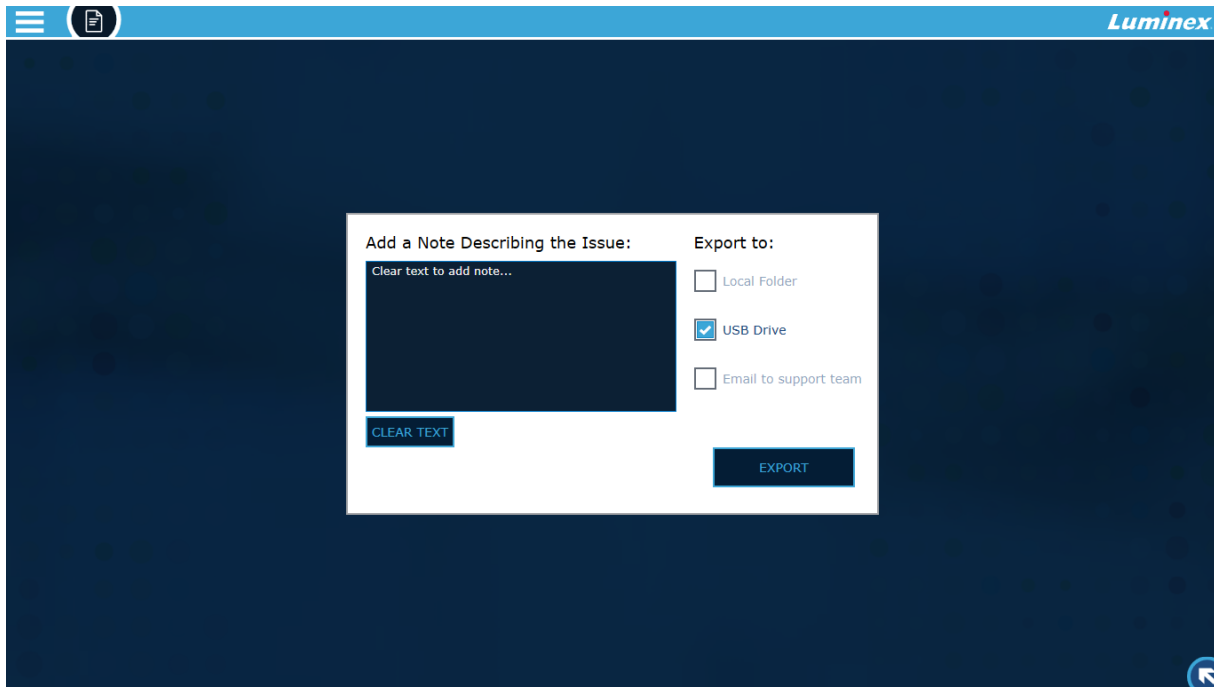
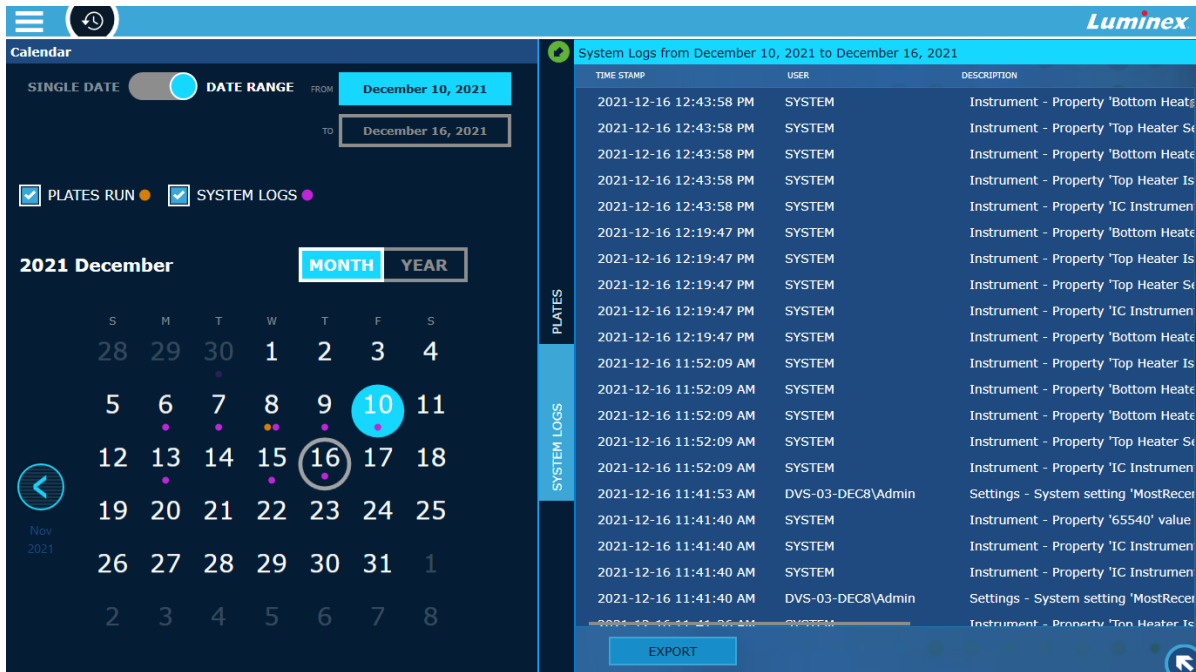



Figure 33: HISTORY




Export Support Package

The SUPPORT ZIP page creates a support package you can save locally, to a USB, or email to *Luminex Technical Support*.

1. Insert a USB into the USB port on the front of the instrument, if necessary.
2. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > SUPPORT ZIP**.
3. Select **CLEAR TEXT** and then enter a detailed description of the problem you are experiencing.
4. Select the Local folder, USB Drive, or Email to support team check boxes to specify how you want to export the support package.
5. Select **EXPORT**.
6. Review the location of the exported zipped log files in the Results dialog box.
7. Select **CLOSE**.

Export Logs

1. Select  in the upper left-hand corner of the screen and navigate to **HISTORY**.
2. Select **SYSTEM LOGS**, if it is not already selected.
3. Use the toggle to select either **SINGLE DATE** or **DATE RANGE** and use the calendar to make your selection.
4. Click **EXPORT**.
5. Choose the location you want to save the file.
6. If necessary, edit the file name by selecting the field and updating the value.
7. Select **EXPORT**. A message displays stating the export completed successfully.

Calibration/Performance Verification Failures

Calibration Failure

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

Table 12. Calibration Failure

Problem	Corrective Action
Possible Calibration Microsphere Causes:	
The calibration microspheres are not fully suspended.	Vortex the calibration vials to re-suspend the microspheres.
The wrong log 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.	Verify the calibration microspheres are in the correct well.
There are not enough calibration microspheres in the well.	Add six drops of calibration microspheres to the well. For accurate drop volume, hold the vial upside down at a 90 degree angle to the plate while dispensing them.
You are using the incorrect calibration microspheres.	Use the xMAP INTELLIFLEX® 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.	Calibrate the sample probe height.
The sample probe is clogged.	Refer to topic Troubleshooting > Clogs .
The probe fitting is loose.	Tighten the probe fitting.

Problem	Corrective Action
Other Possible Causes:	
There is a partial clog in the instrument.	Refer to Troubleshooting > Clogs .
There is air in the instrument.	Calibrate 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 deionized water (DI water).
The waste line was moved during system operation, resulting in unstable flow rate.	Stabilize the waste line during instrument operation.
No events are being collected during calibration.	Check the sheath and waste fluid levels. Verify that the tubing for both containers is tightly connected to the instrument. Check that the waste bottle cap is vented.
	Check for sample probe problems.

Performance Verification Failures

Verification problems can have a variety of causes.

Table 13. Performance Verification Failures

Problem	Corrective Action
Possible Verification Microsphere Causes:	
The verification microspheres are not fully suspended.	Vortex the verification vials to re-suspend 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.	Verify the verification microspheres are in the correct well.
There are not enough verification microspheres in the well.	Add six drops of verification microspheres to the well. For accurate drop volume, hold the vial upside down at a 90 degree angle to the plate while dispensing them.

Problem	Corrective Action
You are using the incorrect verification microspheres.	Verify that you are using the xMAP INTELLIFLEX® 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 verification microspheres, one that has been protected from light during storage.
Possible Sample Probe Causes:	
The sample probe height is incorrect.	Calibrate the sample probe height.
The sample probe is clogged.	Refer to topic Troubleshooting > Clogs .
Other Possible Causes:	
Air in in the instrument.	Verify the sample probe height. Run three Prime commands, two Alcohol Flush commands, and three Wash commands with deionized water (DI water).
The waste fluid container is not properly vented.	Verify that the waste fluid container is properly vented and that the seal is not wet or soiled.
There is a problem internal to the instrument.	Review the log of calibration reports. Check for dramatic changes in temperature, sheath pressure, or voltage. If any of these are present, contact <i>Luminex Technical Support</i> .
The waste line was moved during instrument operation, resulting in an unstable flow rate.	Stabilize the waste line during instrument operation.

Instrument Errors

Power Supply Problems

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



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

Table 14. Power Supply Problems

Problem	Possible Cause	Corrective Action
The xMAP Instrument 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.
	The uninterruptible power supply (UPS) or a surge protector is faulty.	Replace the UPS or surge protector.
	The power supply is faulty.	Contact <i>Luminex Technical Support</i> .

Fluid Leaks

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

Table 15. Fluid Leaks

Problem	Possible Cause	Corrective Action
Fluid is pooled around the xMAP INTELLIFLEX® Instrument.	Fittings, fluid tubes, or components are damaged, loose, or faulty.	Turn off and disconnect the instrument to avoid electrical shock. Contact <i>Luminex Technical Support</i> .
Fluid is dripping from the sample probe.	The sample probe is clogged.	Refer to topic Troubleshooting > Clogs .
	The sample path is clogged.	Refer to topic Troubleshooting > Clogs .

Problem	Possible Cause	Corrective Action
	The internal component is faulty.	Contact <i>Luminex Technical Support</i> .
Fluid is leaking from the front of the instrument.	The syringe seal leaks.	Replace the syringe.
	The syringe valve leaks.	Hand-tighten the syringe connection (silver knob) on the syringe valve. Run a Prime command. If leaks continue, contact <i>Luminex Technical Support</i> .

Low Bead Count

Pressurization Problems

Normal air and sheath pressure readings vary between 8 psi and 13 psi while the compressor runs. If the system pressure is out of range, your sample acquisition will fail or return inadequate results.

Table 16. Pressurization Problems

Problem	Possible Cause	Corrective Action
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 containers and the system are fully connected.
	The sheath or waste fittings are cracked.	Inspect the fittings to be sure they form a tight seal. Contact <i>Luminex Technical Support</i> .
	The system has a leak.	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 <i>Luminex Technical Support</i> .

Clogs

Often, a clog somewhere in the xMAP INTELLIFLEX® System is the cause of a fluid leak, a pressurization or sample probe problem, or a problem with calibration, verification, or data acquisition. To determine if there is a clog, check that the Beads per Second (BPS) during calibration or verification is 300 bead events per second or more. If there are fewer than that, there may be a clog in the instrument. In the event you encounter a problem that is clog-related, use the following procedure.

To troubleshoot a possible clog:

1. Clean and calibrate the sample probe height.
2. Run the **Remove Clog** routine.
3. Run the **Weekly Maintenance** routine.
4. Run calibration and performance verification.

If this procedure is unsuccessful, contact *Luminex Technical Support*.

Sample Probe Problems

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

Table 17. Sample Probe Problems

Problem	Possible Cause	Corrective Action
The sample probe leaks.	The sample probe is clogged.	Clean the sample probe.
The sample arm is stuck in the up position.	Internal component is faulty.	Contact <i>Luminex Technical Support</i> .
The sample arm does not go down smoothly.	The plate is incorrectly seated.	Adjust the plate.
	The plate is warped.	Inspect the plate. Replace the plate if it is warped.
	The sample probe is bent.	Remove the sample probe from the instrument and roll it on a clean, flat surface. If a sample probe has been bent and rolled straight more than once, discard it and replace with a new sample probe. Calibrate the sample probe height.

Bead Detail Irregularities

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



- System calibrators
- System verifiers
- Assay standards
- Assay controls
- Error messages

Review calibration/verification reports routinely to detect trends.

Use verifier xMAP® microspheres (from the performance verification kit) to check the success of the system calibration

and for troubleshooting purposes. If there is a problem with your kit results, xMAP verifiers can help determine if the problem is analyzer-related. If calibration and verification are successful, contact the kit manufacturer.

Table 18. Bead Details

System	Description	Possible Problem	Solution
xMAP® and calibrator microspheres form a group in the wrong location.			
	Calibrator microspheres group together at the top of the region.	The calibrator microspheres are photobleached.	Replace the calibrator microspheres with unphotobleached calibrator microspheres. To avoid photobleaching, protect microspheres from light.
	xMAP microspheres group together at the lower right of the region.	The xMAP microspheres are photobleached.	Replace the xMAP microspheres with unphotobleached xMAP microspheres. To avoid photobleaching, protect microspheres from light.

Customer Orderable Part Numbers

Table 19. Hardware Part Numbers

Product Description	Customer Number
Sample Probe Height Adjustment Kit	CN-0263-01
Heater Block for 96-Well Microtiter Plates	CN-0224-01
Heater Block for 384-Well Microtiter Plates	CN-0223-01
Off-Plate Reagent Block	CN-0514-01
Sample Probe Needle	CN-0221-01
Syringe Cylinder with Seal, 500 uL	CN-0013-01
Preventative Maintenance (PM) Kit, 6 months	CN-0458-01
Sheath Filter with Quick Disconnect	CN-0010-01

Product Description	Customer Number
Power Cable, Country Specific	CN-PXXX-01*
Wireless Keyboard and Mouse Combo	CN-0220-01

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

Table 20. Reagent Part Numbers


Product Description	Customer Number
xMAP® Sheath Fluid PLUS, 20 L	40-50021
xMAP® Sheath Concentrate PLUS, 1 L	40-50023
xMAP INTELLIFLEX® Calibration Kit	IFX-CAL-K20
xMAP INTELLIFLEX® Performance Verification Kit	IFX-PVER-K20

Chapter 10: Administration and Settings

System Settings

View Authorizations

The AUTHORIZATIONS tab provides a read-only mechanism to see the different actions permissible to users that are a member of the xMAP INTELLIFLEX® groups. To review authorizations:

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > CONFIGURATION**.
2. Select **AUTHORIZATIONS** on the left navigation bar, if it is not already selected.



	ADMINSTRATOR	LAB LEAD	OPERATOR
MAINTENANCE			
Running a Calibration	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Running a Verification	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Running a Fluidics Verification	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Importing/Saving a Calibration Kit	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Importing/Saving a Verification Kit	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
RESULTS			
Exporting Result Data	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Changing the Column Formatting of the INTELLIFLEX Format	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Archiving Result Data	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Running a Plate	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Ignoring Laser Warm-up When Running a Plate	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Running With Temperature Out Of Range	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Running Without Valid Calibration/Verification	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Re-Running a Well	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
CREATING/MODIFYING/DELETING			
Creating/Modifying/Deleting a Protocol	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Creating/Modifying/Deleting/Importing a Panel	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Creating/Modifying/Deleting Acquisition Settings	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Creating/Modifying/Deleting/Importing a Plate Layout	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Creating/Modifying/Deleting a Plate	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
ADMIN SETTINGS			
Changing Administrator Settings	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Configure Settings


1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > CONFIGURATION**.
2. Select **GLOBAL** on the left navigation bar, if it is not already selected.
3. To change any setting, select the appropriate field and update the value. Refer to Table 21. Configuration Setting Options
4. for a description of each setting.
5. Select **APPLY** to save the updated settings.

Table 21. Configuration Setting Options

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
DATA EXPORT DIRECTORY	Indicates the location where the result data will be automatically exported. Enter the location directly in the text field or you can select BROWSE next to the field. Once the data export location has been identified, select Save in the Data Export Directory dialog. The application does not allow setting a path that contains 'C:\'	'D:\'	x	x	
ON SCREEN DECIMAL PLACES	Indicates the number of decimal places used for the result data for both the screens and output formats. The valid range is 1-5.	3 decimal digits	x	x	
EXPORT FORMAT	Indicates the format of the results for automatic exports. To update, select the drop-down menu next to the field. Select the check box for INTELLIFLEX , xPONENT , or both.	INTELLIFLEX	x	x	
INTELLIFLEX FILE TYPE	Indicates the file type of the INTELLIFLEX format for automatic exports. To update, select the drop-down menu next to field. Select the check box for CSV , EXCEL , or both.	CSV	x	x	
AUTO EXPORT RESULTS	Indicates whether the result data is automatically exported after a plate run. To enable, toggle the button to the right.	Disabled	x	x	
EXPORT DIRECTORY	Indicates the location where the system and service support logs will be exported. Enter the location directly in the text field or select BROWSE next to the field. Once the data export location has been identified, select Save in the Export Directory dialog. The application does not allow setting a path that contains 'C:\'	'D:\'	x	x	
CALIBRATION RUN EXPIRATION	Indicates after how many days a valid calibration run becomes overdue. The valid range is 1-999 day(s).	7 days	x	x	
VERIFICATION RUN EXPIRATION	Indicates after how many days a valid performance verification run becomes overdue. The valid range is 1-999 day(s).	1 day	x	x	
FLUIDICS RUN EXPIRATION	Indicates after how many days a valid fluidics verification run becomes overdue. The valid range is 1-999 day(s).	1 day	x	x	
EXPORT DIRECTORY	The location where the system and service support logs will be exported. The location can be directly entered in the text field or you can select BROWSE next to the field. Once the data export location has been identified, select Save in the Export Directory dialog. The application does not allow setting a path that contains 'C:\'	'D:\'	x	x	
SCREENSHOT DIRECTORY	The location where screenshots taken by the xMAP INTELLIFLEX application will be saved. Enter the location directly in the text field or you can select BROWSE next to the field. Once the data export location has been identified, select Save in the Screenshot Directory dialog. The application does not allow setting a path that contains 'C:\'	'D:\'	x	x	
ARCHIVE DIRECTORY	The location where the result data will be archived. The location can be directly entered in the text field or you can select BROWSE next to the field. Once the archive location has been identified, select Save in the Archive Directory dialog. The application does not allow setting a path that contains 'C:\'	'D:\'	x		
EXPORT DELIMITER	The field delimiter character for exported xPONENT and INTELLIFLEX results. Valid options are: COMMA , TAB , SEMICOLON , PIPE , BACKSLASH , FORWARD SLASH , and	COMMA	x		

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
	DASH. To update, select the drop-down menu next to field.				
EXPORT DECIMAL SEPARATOR	The decimal place separator character for exported xPONENT and INTELLIFLEX results. Valid options are: PERIOD and COMMA . To update, choose the drop-down menu next to field.	PERIOD	x		
EXPORT ENCODING	The encoding used in the data exports. Valid options are: Windows-1252, UTF-8, UTF-8+BOM . To update, choose the drop-down menu next to field.	UTF-8+BOM	x		
SMTP SERVER NAME	The Simple Mail Transfer Protocol (SMTP) server name, which used to configure the optional capability to enable sending support files directly to Luminex Technical Support via email.	<blank>	x		
PORT	The port number utilized by the optional support zip log email functionality.	<blank>	x		
USER NAME	The user name of the account utilized by the optional support zip log email functionality.	<blank>	x		
PASSWORD	The password of the account utilized by the optional support zip log email functionality.	<blank>	x		
LOCK INACTIVITY TIMEOUT	The number of seconds of inactivity after which the application starts the screen saver at the login screen. The valid range is 10-99999 seconds.	10 seconds	x		
SESSION INACTIVITY TIMEOUT	The number of seconds of inactivity after which the application starts the screen saver after a user login. The valid range is 0-1666 minutes.	10 minutes	x		
MAXIMUM SIGNED IN	The maximum number of users that can be concurrently signed in the instrument. If after a user login, the current number of active users exceeds this field, the user with the longest inactivity time will be automatically logged out from the instrument and any unsaved data for that user will be lost.	3 users	x		
AUTOMATIC WINDOWS UPDATE	Indicates whether Windows Automatic Updates are enabled. To enable, toggle the button to the right.	Disabled	x		
AUTO SIGN-IN USER NAME	The default user name for the auto login process.	<blank>	x		
AUTO SIGN-IN PASSWORD	The default password for the auto login process.	<blank>	x		
AUTO SIGN-IN DOMAIN	The default domain for the auto login process. If you have joined the computer have been joined to a domain, the domain name should be fully qualified (FQDN).	<blank>	x		
LOCKOUT DURATION	The number of minutes a locked-out account remains locked out before automatically becoming unlocked. The available range is from 0 minutes through 99999 minutes. If you set the account lockout duration to 0, the account will be locked out until an administrator explicitly unlocks it.		x		
LOCKOUT THRESHOLD	The number of failed logon attempts that causes a user account to be locked out. A locked-out account cannot be used until it is reset by an administrator or until the lockout duration for the account has expired. The available range is from 0 and 999 failed logon attempts. If set to 0, it means the account will never be locked out.	0	x		
LOCKOUT OBSERVATION	The number of minutes that must elapse after a failed logon		x		

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
WINDOW	attempt before the failed logon attempt counter is reset to 0 bad logon attempts. The available range is 1 minute to 99999 minutes. If an account lockout threshold is defined, this reset time must be less than or equal to the Account lockout duration.				
PASSWORD EXPIRATION DAYS	The number of days from the date the password was last set that must elapse for the password to be considered expired. The available range is 0 days to 90. The default value is 90.		x		


Manage Users

The xMAP INTELLIFLEX® System supports multiple user accounts that can be set up locally on the system or a network. User Management is only available to Administrator roles.


NOTE: Domain menu options are greyed out if not connected to a network.

NOTE: Documents related to IT administration of the system, including guidance on changing the administrator password, configuring networking, and general IT and security best practices, are available upon request from Luminex Technical Support. Please contact support@luminexcorp.com for more information.


Create a Local User

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT**.
2. Enter a **USER NAME**.
3. Choose a role from the **USER ROLE** drop-down menu.
4. Choose **Enabled** or **Disabled** from the **STATUS** drop-down menu.
5. Enter a new password.
6. Select **ADD**.


Modify a Local User

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT**.
2. Select a user from the right side of the screen to highlight the account.
3. In the **MODIFY USER** section on the left side of the screen, enter a new **USER NAME** if necessary.
4. Choose a new role from the **USER ROLE** drop-down, if necessary.
5. Choose **Enabled** or **Disabled** from the **STATUS** drop-down menu.
6. Select or clear the **Change Password** check box.
7. If the **Change Password** check box was selected, enter a new password.
8. Select **SAVE**.


Remove a Local User

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT**.
2. Select a user from the right side of the screen to highlight the account.
3. In the **MODIFY USER** section on the left side of the screen, select **REMOVE**.


Add a Domain User

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT>DOMAIN>ADD USER**.
2. Enter a **USER NAME**.
3. Choose a role from the **USER ROLE** drop-down menu.
4. Select **ADD**.


Add a Domain Group

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT>DOMAIN>ADD GROUP**.
2. Enter a **GROUP NAME**.
3. Choose a role from the **USER ROLE** drop-down menu.
4. Select **ADD**.

Modify a Domain Group

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT>DOMAIN>MODIFY GROUP**.
2. Choose a group from the **GROUP NAME** drop down menu.
3. Choose a new role from the **USER ROLE** drop-down menu.
4. Select **SAVE**.





Remove a Domain Group

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT>DOMAIN>MODIFY GROUP**.
2. Choose a group from the **GROUP NAME** drop down menu.
3. Select **REMOVE**.

Chapter 11: Storing the System

Store the System

To prepare the xMAP INTELLIFLEX® System for long-term storage:

1. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > ROUTINES**.
2. Select Prepare for Storage from the **MAINTENANCE/CLEANING COMMANDS**.
3. Select  to eject the plate carrier.
4. Fill the reservoir indicated in the plate layout of the software 3/4 full of 10% bleach with no additives.
NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.
5. Fill the reservoir indicated in the plate layout of the software 3/4 full of deionized water (DI water).
6. Select  to retract the plate carrier.
7. Select  to run. A message displays stating the maintenance routine was completed successfully.
8. Turn off the xMAP INTELLIFLEX® System and unplug the power cord.
9. Remove the sample probe from the instrument.
 - a. Open the sliding front access door of the INTELLIFLEX Instrument.
 - b. Unscrew the sample probe fitting on top of the sample probe completely.
 - c. Grasp the sample probe gently and push up.
 - d. Lift the sample probe out of the top of the sample probe holder.
10. Flush the sample probe with DI water from the narrow end out through the larger end.
11. Dry the interior and exterior of the sample probe.
NOTE: The interior of the sample probe may be dried by either placing the narrow end of the sample probe in a syringe filled with air and forcing air through the sample probe or by allowing the sample probe to air dry overnight.
12. Wrap the narrowest section of the sample probe with PARAFILM®.
13. Replace the sample probe in the sample arm and tightly screw in the sample probe fitting on top of the sample probe.

Prepare the System for Use After Storage







Use of non-Luminex approved sheath fluid shall constitute “Improper Use” and can void the warranty provided by Luminex and/or its authorized partner.

Handle waste disposal in accordance with accepted medical practice and applicable regulations. If spillage occurs immediately, disinfect following appropriate laboratory procedures.

To prepare the xMAP INTELLIFLEX® System for use after long-term storage:

1. Ensure sufficient xMAP Sheath Fluid PLUS is available for instrument use.
2. Remove the PARAFILM® from the end of the sample probe.

3. Turn on the INTELLIFLEX System and watch for the following indications of correct response:
 - The compressor starts. It has a low rumbling sound.
 - Air blows out of the rear fans. Place your hand behind the xMAP INTELLIFLEX Instrument to feel it.
 - The syringes inside the system initialize.
4. Select  in the upper left-hand corner of the screen and navigate to **MAINTENANCE > ROUTINES**.
5. Select Revive After Storage from the **MAINTENANCE/CLEANING COMMANDS**.
6. Select  to eject the plate carrier.
7. Ensure the reservoir indicated in the plate layout of the software is empty for waste.
8. Fill the reservoir indicated in the plate layout of the software 3/4 full of 70% isopropanol or 70% ethanol.
9. Fill the reservoir indicated in the plate layout of the software 3/4 full of deionized water (DI water).
10. Select  to retract the plate carrier.
11. Select  to run. A message displays stating the maintenance routine was completed successfully.

Chapter 12: Shipping and Decontaminating the System

If a serious problem arises with the xMAP INTELLIFLEX® System, you may need to return the system to Luminex Corporation for repairs. If *Luminex Technical Support* directs you to return the system, the Technical Support representative will provide you with all the necessary information as well as a Return Material Authorization (RMA) number.

Decontaminate the System

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



Wear appropriate personal protective equipment (PPE), including a lab coat and disposable gloves, when performing procedures. Fresh clean gloves must be worn in each area and must be changed before leaving that area. Wash your hands thoroughly after performing the test.

Take care when handling, storing, and disposing of potentially infectious materials (i.e., samples, specimens, waste fluid, etc). Suitable barrier protection against potential pathogens is recommended during all stages of use. Adherence to appropriate local biosafety and biohazard guidelines or regulations is recommended when working with potentially infectious materials that may be unknown.

Handle waste disposal in accordance with accepted medical practice and applicable regulations. If spillage occurs immediately, disinfect following appropriate laboratory procedures.

To decontaminate the xMAP INTELLIFLEX System:

1. Remove all specimens and reagents from the system.
2. Leave deionized water (DI water) in R1 and 10% bleach with no additives in R3 of the off-plate reagent block of the system.
NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.
3. Run a Sanitize command with 10% bleach with no additives, followed by two **Wash** commands with DI water.
NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.
4. Turn off the xMAP INTELLIFLEX System and unplug the power cord.
5. Clean all exterior surfaces with a mild detergent, followed by 10% bleach with no additives, then wipe down with DI water.
NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.
6. Remove the front cover of the system.
7. Clean all accessible surfaces with a mild detergent, followed by 10% bleach with no additives, then wipe down with DI water.

NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly (Diallyldimethylammonium Chloride), can lead to build-up causing high background.

Prepare the System for Shipping

Contact *Luminex Technical Support* before preparing the instrument for shipping. They will explain how to return the system according to Luminex procedures.

Drain the Reservoir

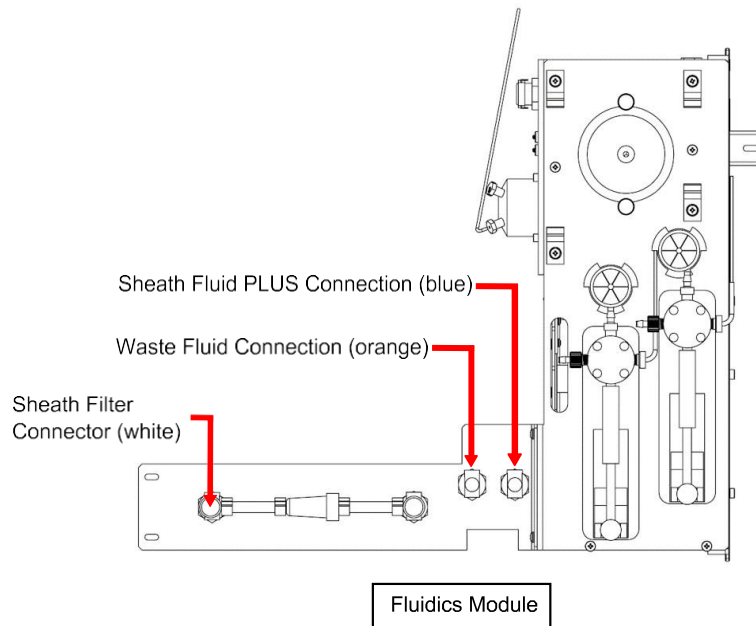


Handle waste disposal in accordance with accepted medical practice and applicable regulations. If spillage occurs immediately, disinfect following appropriate laboratory procedures

1. Power off the xMAP INTELLIFLEX® System.
2. Make sure the waste fluid container can hold at least one additional liter of fluid.
3. Remove the front cover.
4. Disconnect the xMAP Sheath Fluid PLUS tubing from the Sheath Fluid PLUS container to prevent additional Sheath Fluid PLUS from entering the reservoir.
5. Disconnect the sheath filter tubing (white connector) from its left quick disconnect point (white connection) on the fluidics module.
6. Disconnect the external waste fluid tubing (orange connector) from the white connection on the side of the instrument. This is external to the system and can be found by tracing the line from the waste container to the instrument.
7. Disconnect the Sheath Fluid PLUS tubing (blue connector) from the blue connection on the fluidics module.
8. Connect the external waste fluid tubing (orange connector) to the left quick disconnect point (white connection) of the sheath filter tubing.
9. Power on the xMAP INTELLIFLEX System. This starts the compressor, which drains the Sheath Fluid PLUS from the reservoir into the waste fluid container.
10. Power off the xMAP INTELLIFLEX System.

NOTE: To refill the reservoir, reconnect each connector to its color-matched connection and power on the instrument.

Figure 34: Sheath and Waste Fluid Connections



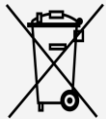
Shipment Checklist

Complete the following checklist, sign and date it, and return it with the xMAP INTELLIFLEX® System.

1. Remove all specimens from the instrument.
2. Decontaminate the instrument.
NOTE: It is the user's responsibility to decontaminate the instrument before shipment.
3. Drain the reservoir.
4. Prepare the instrument for shipping.
5. Was there an internal leak in the system? YES NO

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

Dispose of the System



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 an xMAP INTELLIFLEX® System, decontaminate the system. Next, contact *Luminex Technical Support* 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 the system outside of the European Union, contact *Luminex Technical Support*.

Appendix A: Available Statistics per Page

Table A-1. Well Information

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Well Location	Well address (e.g. A1-H12)	X	X	X
Well Type	Combination of sample type and replicate ID - U#, C#, S#, or B. # is the replicate ID.	X	X	X
Well Status	Well status. e.g. Acquired, Aspirating, Completed, Dry, Empty, Failed, Pending, Reading, Warning	X	X	X
Sample ID	User provided sample ID	X	X	X
Dilution	Dilution value entered by user (Not Applied to MFI values)	X	X	X
Protocol Name	Protocol Name used for acquisition		X	X
Protocol Version	Protocol Version used for acquisition		X	X
Panel Name	Panel Name used for acquisition		X	X
Uptake Volume	Uptake volume for acquisition. User defined in the acquisition settings.		X	X
Normalization Region	Region selected as the intra-well normalization for the panel.	X	X	X
DD Gate Low	Low DD gate setting	X	X	X
DD Gate High	High DD gate setting	X	X	X
Plate Heater Temp	Plate heater set temperature at the time of well acquisition		X	X
Bead Type	Bead Type Set in Acquisition Settings, Magplex or Microplex		X	X
Operating Mode	Instrument mode used to acquire data.		X	X
Acquisition Duration	Total time, in seconds, to reach minimum bead count for all regions (or final timeout value)	X	X	X

Table A-2. Instrument Data

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Model Name	"xMAP® INTELLIFLEX DR-SE" or "xMAP® INTELLIFLEX"		X	X
Instrument Type	"INTELLIFLEX"		X	X

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Serial Number	Instrument serial number as entered by manufacturing.		X	X
Software Version	Any applicable software/firmware version number(s)		X	X
Calibration State	Pass/fail status of most recent calibration attempt prior to the well-acquisition: "CALIBRATED", "NOT CALIBRATED", "OVERDUE", or "LOT EXPIRED"	X	X	X
Calibration Lot	Calibration reagent lot number	X	X	X
Calibration Lot Expiration	Calibration lot expiration date	X	X	X
Calibration Lot Expired	Calibration lot expiration status at the time of execution.	X	X	X
Calibration Timestamp	Date/time of completion of the most recent calibration attempt prior to the well-acquisition	X	X	X
Verification State	Pass/fail status of most recent verification attempt prior to the well-acquisition: "VERIFIED", "NOT VERIFIED", "OVERDUE", or "LOT EXPIRED"	X	X	X
Verification Lot Expired	Expiration status of the verification reagent lot at the time of execution	X	X	X
Verification Timestamp	Date/time of completion of the most recent verification attempt prior to the well-acquisition	X	X	X
Fluidics Ver State	Pass/fail status of most recent fluidics verification attempt prior to the well-acquisition: "VERIFIED", "NOT VERIFIED", "OVERDUE", or "LOT EXPIRED"	X	X	X
Fluidics Ver Timestamp	Date/time of completion of the most recent fluidics verification attempt prior to the well-acquisition	X	X	X
Fluidics 1 Ver Lot	Fluidics 1 verification lot number	X	X	X
Fluidics 1 Ver Lot Expiration	Fluidics 1 verification lot expiration date	X	X	X
Fluidics 1 Ver Lot Expired	Fluidics 1 verification lot expiration status at the time of execution	X	X	X
Fluidics 2 Ver Lot	Fluidics 2 verification lot number	X	X	X
Fluidics 2 Ver Lot Expiration	Fluidics 2 verification lot expiration date	X	X	X
Fluidics 2 Ver Lot Expired	Fluidics 2 verification expiration status at the time of execution	X	X	X

Table A-3. Plate Information

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Plate Name	Plate name		X	X
Plate Status	Status of plate. e.g. Aborted, Completed, Created, Initializing, In Progress, Partial, Pending, Stopped		X	X
Plate Start	Time/date of start of acquisition of the 1st acquisition attempt on the 1st well of the plate		X	X
Plate End	Time/date of the final acquisition (or reacquisition) of the last well of the plate		X	X
Active user	Username of the user signed in to the instrument		X	X
Authorized User	Username of the user that authorized the run		X	X
Signing User	Username of the user that signed the action (Not currently in used in software)		X	X
Plate Geometry	Type of plate designated during Plate Configuration, 96 or 384 wells		X	X
Plate Type Name	User-supplied plate type/description (e.g. '96-well filter plate')		X	X

Table A-4. Well Statistics

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Total Active Events	Total classified events in regions defined by the panel. Note: This is "Total Events" in the xPONENT export format.	X	X	X
Total Classified Events	Total classified events including out-of-panel regions	X	X	X
Total Gated Events	Total beads that passed the doublet discriminator (DD) gate	X	X	X
Total Events	Total Events detected by the instrument before being filtered by doublet discriminator (DD) gate	X	X	X
Count %CV	%CV of Count per region	X	X	X

Table A-5. Results Data

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Analyte Name	User provided Analyte Name		X	X
Region	Bead region		X	X
Median	Median of Fluorescence Intensity ("MFI")	X	X	X
Background	Average of Median signal for background wells on the same plate being exported	X	X	X

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Net Median	Median minus Background	X	X	X
Net Normalized Median	Calculated as the Net Median of each region divided by the Net Median of the normalization region (Net Normalized Median of the Normalization Region is always 1.0)	X	X	X
Ratio (RP1/RP2)	Ratio between RP1/RP2. Not available on Single reporter instrument.	X	X	X
Mean	Mean of Fluorescence Intensity	X	X	X
Trimmed Mean	Mean of the data after trimming the lowest 5% and highest 5% of the signals	X	X	X
Peak	Peak fluorescence intensity	X	X	X
Trimmed Peak	Mean of the peak of the histogram in a log-space after trimming the lowest 5% and highest 5% of the signals	X	X	X
Count	Final bead count for the analyte	X	X	X
%CV	%CV of Fluorescence Intensities	X	X	X
Trimmed %CV	%CV of the data after trimming the lowest 5% and highest 5% of the signals	X	X	X
Standard Deviation	Standard Deviation of Fluorescence Intensities	X	X	X
Trimmed Standard Deviation	Standard Deviation of the data after trimming the lowest 5% and highest 5% of the signals	X	X	X
Average MFI	Mean MFI of replicates	X	X	X
Net Average Median	Replicate Average Median minus Background	X	X	X
Net Normalized Average Median	Calculated as the average of the Net Normalized Median for all the wells in a replicate.	X	X	X
Replicate %CV	% CV of replicate well MFI values	X	X	X

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