

Luminex[®]

complexity simplified.

xMAP INTELLIFLEX[®] 2.0 User Manual

RUO

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

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Chapter 1: System and Software Introduction

Instrument Overview

xMAP INTELLIFLEX® Systems and xMAP INTELLIFLEX® DR-SE Systems are flow cytometry-based optomechanical instruments designed to analyze multiplex assays performed using Luminex proprietary xMAP® Technology. This technology utilizes polystyrene microspheres that are internally dyed with up to three different fluorophores to create 500 distinguishable spectral regions.

In these multiplex assays, target analytes bind to capture antigens that are covalently bonded to the surface of the xMAP microsphere. Fluorescently labeled reporter molecules then bind to these target analytes captured on the surface of the xMAP microsphere. The xMAP INTELLIFLEX and xMAP INTELLIFLEX DR-SE Systems integrate mechanical, fluidics, and optic systems to transport, excite, and analyze individual microspheres and associated fluorescent reporter molecules to detect the presence or absence of target analytes for each region.

The xMAP INTELLIFLEX and xMAP INTELLIFLEX DR-SE Systems are capable of measuring up to 500 analytes per sample using one classification laser and one reporter laser. The INTELLIFLEX DR-SE Systems are also capable of measuring up to two parameters per analyte using a second reporter laser. The xMAP INTELLIFLEX and xMAP INTELLIFLEX DR-SE Systems can accommodate 96-well or 384-well plates, and are designed to reduce the need for optical alignment, resulting in smaller and lighter readers compared to 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.

For more information refer to the *Additional Resources* section.

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

Fax: 512-219-5114

Email: support@luminexcorp.com.

Additional Resources

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

For documents, enter <https://www.luminexcorp.com/intelliflex/#documentation> into your browser address field. Some useful documents include:

- xMAP INTELLIFLEX System User Manual- Provides latest information, specifications, and step-by-step operating instructions for the xMAP INTELLIFLEX.
- xMAP INTELLIFLEX System Administrator Guide- Contains essential information for system administrators and IT professionals regarding operating system configuration, network drive usage, and other integration capabilities and limitations. The guide also covers IT administration topics such as changing the administrator password, configuring networking, and general IT and security best practices.
- INTELLIFLEX System Quick Guide- Contains a system maintenance log and quick guidance on daily start up activities.
- INTELLIFLEX 2.0 (RUO) Change Log- Contains details on new functionality introduced in each software release, notes when a known software issue has been resolved, and provided workarounds for known remaining bugs.
- xMAP INTELLIFLEX V2.0 FAQ- Contains commonly asked questions.
- xMAP INTELLIFLEX Compliance Matrix- 21 CFR Part 11- Explains how the xMAP INTELLIFLEX system helps users achieve compliance to 21 CFR Part 11.
- xMAP INTELLIFLEX Compliance Matrix- Annex 11- Explains how the xMAP INTELLIFLEX system helps users achieve compliance to Annex 11.
- xMAP INTELLIFLEX Automation Programmer's Reference- Contains information for developers to create interfaces with the xMAP INTELLIFLEX API.

























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*.

For video references, enter <https://www.youtube.com/@Luminexcorporation> into your browser address field. Search on the desired topic or navigate through menus.

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.		Manufacturer.
	Conformite Europeenne (EU CE Marking of Conformity).		Use-by-date.
	Alternating Current.		WEEE Symbol.
	Batch Code.		Protective earth; protective ground.
	On (Power).		Serial number.
	Off (Power).		TÜV SÜD NRTL Certification Mark.
	EPUP Symbol.		MET 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

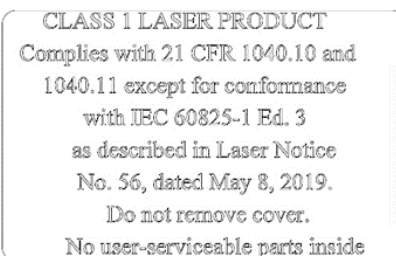
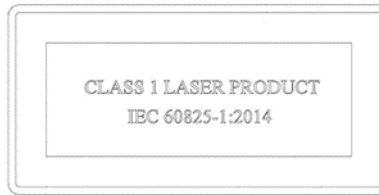


Figure 2: Laser Class Label



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

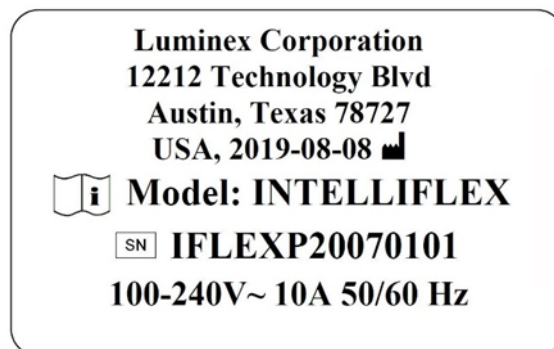
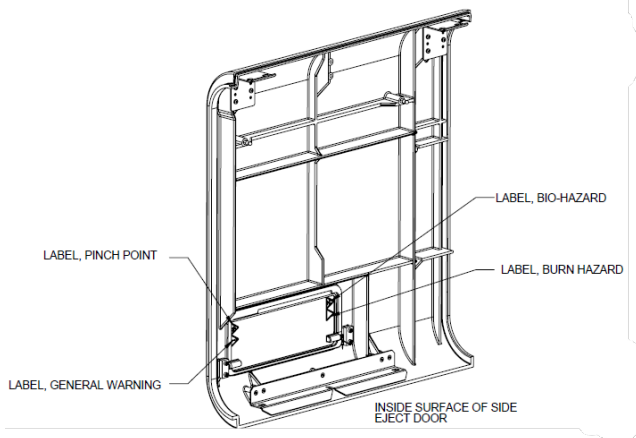
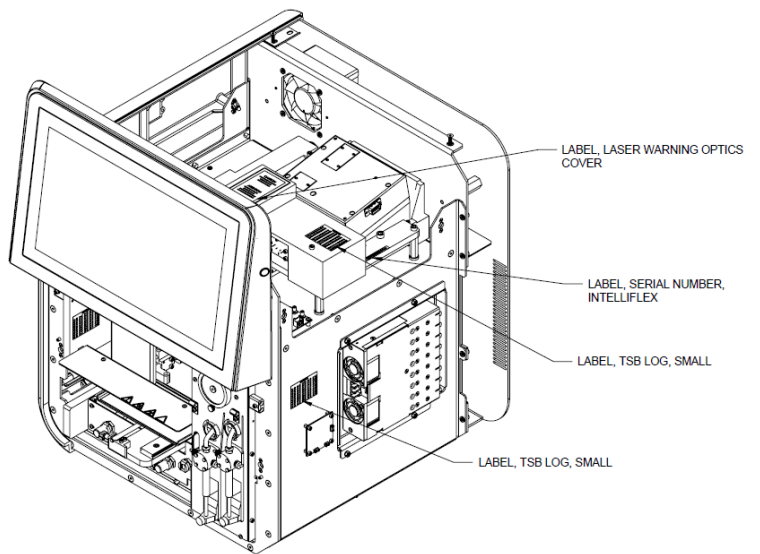
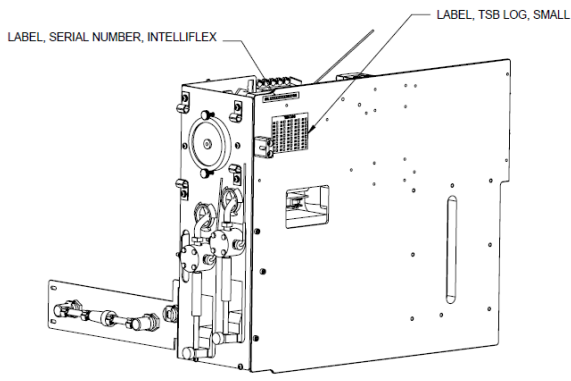
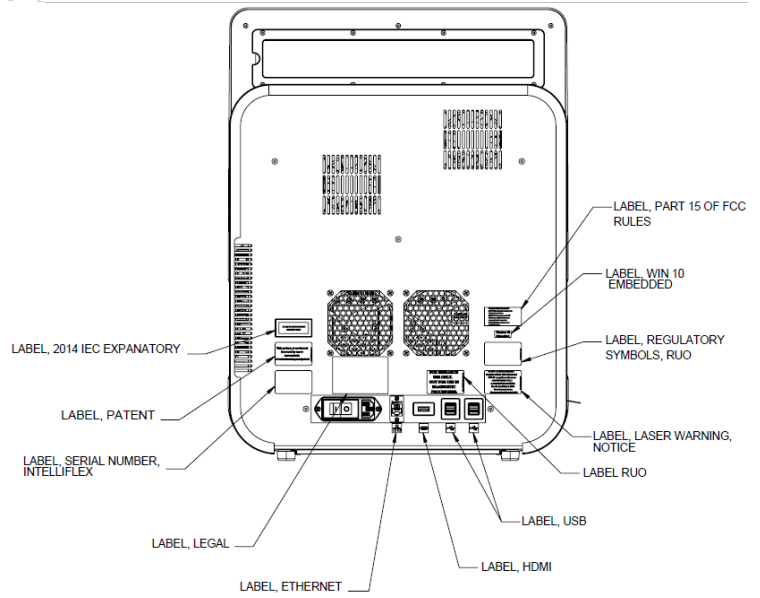
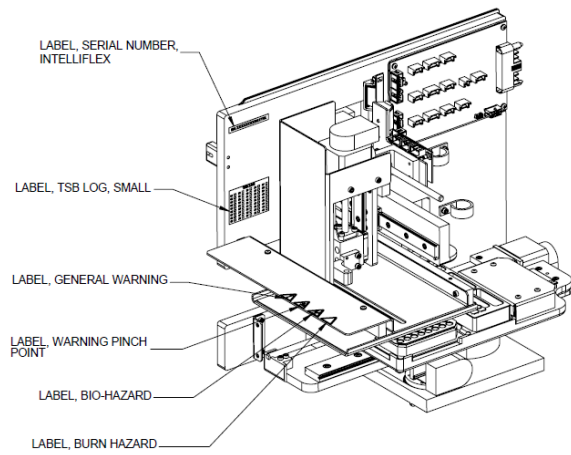


Figure 5: Label Placement Diagrams



Warnings and Precautions



Consult safety documentation where the caution symbol is marked.

When 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

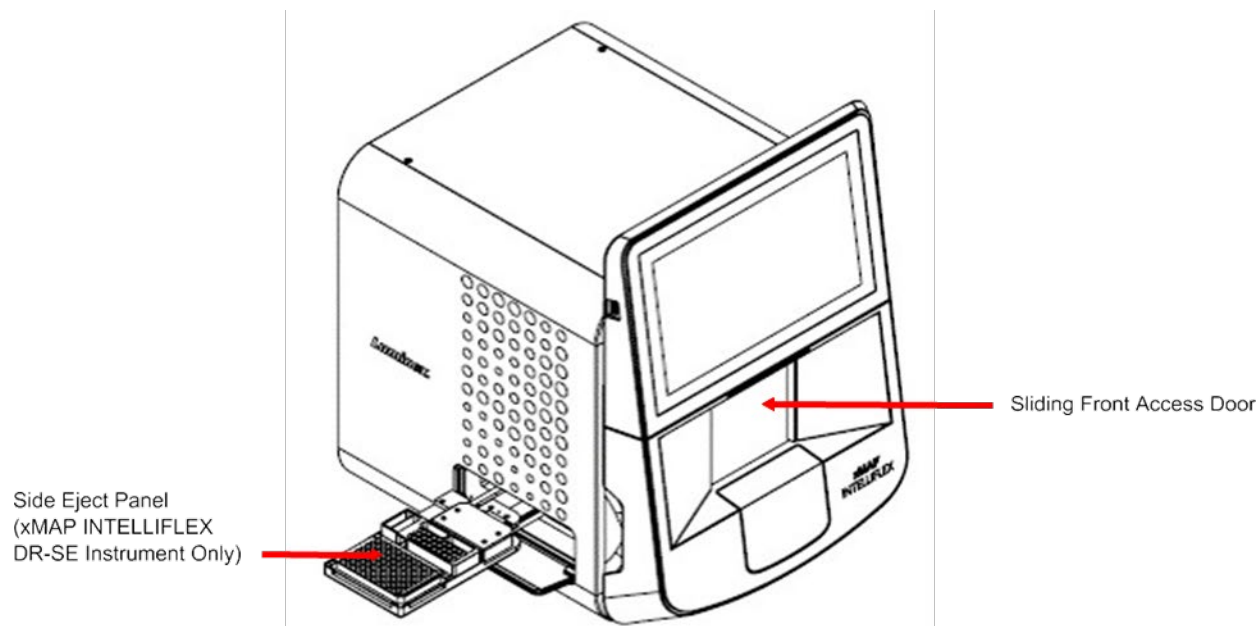


The system has parts that move during operation. Risk of personal injury is present. The moving parts present puncture, hand-crushing hazards, and pinching hazards.



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 Engineers. 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 “ <i>Safety Management No. CDC-22, Decontamination of Laboratory Sink Drains to remove Azide salts</i> ” (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 set point).
- Plate run time: 96-well plate in approximately 20 minutes; 384-well plate in approximately 75 minutes

Electronics Specifications

- USB for data transfer and connection to optional peripherals (keyboard and mouse)
- Input voltage range: 100 V~ to 120 V~, 10.0 A, 50 Hz to 60 Hz or 200 V~ to 240 V~, 5.0 A, 50 Hz to 60 Hz
- Installation category: II - As defined in IEC 61010-1:2010 AMD1:2016

Fluidics Specifications

- Cuvette: 200 µm square flow channel

- Sample injection rate: 2 μ L/second
- Sample uptake volume: 10 μ L to 200 μ L
- 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
- Liquid-sensing probe capabilities: 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 (DR-SE model only)
- 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.



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
- Sample probe height adjustment kit
- 96-well heater block
- 384-well heater block

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® and 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 (Diallyldimethyl- ammonium 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.

Figure 7: HEPA Filter

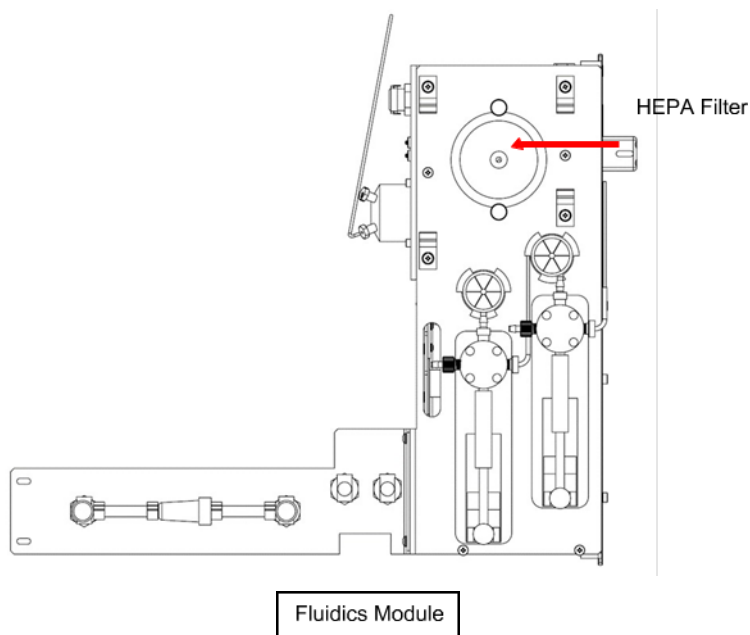


Figure 8: Front Air Intake Filter

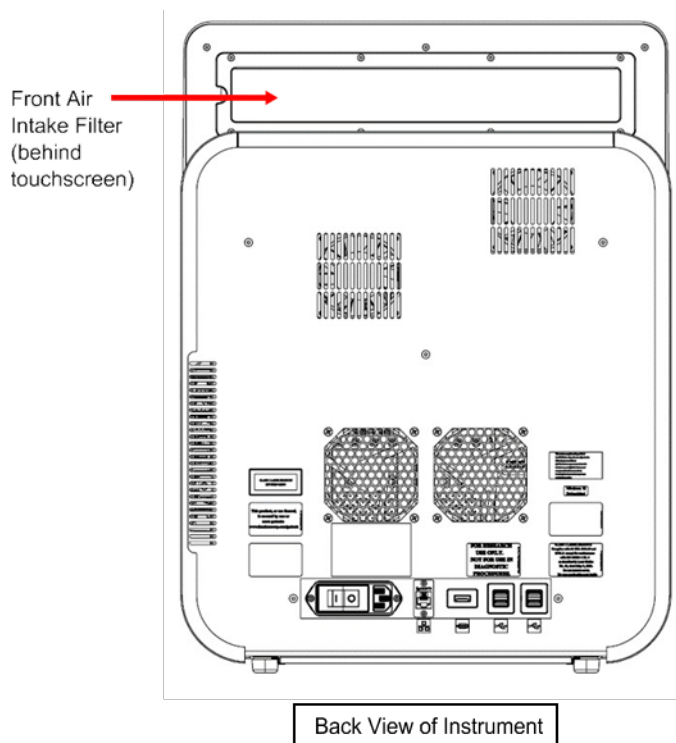
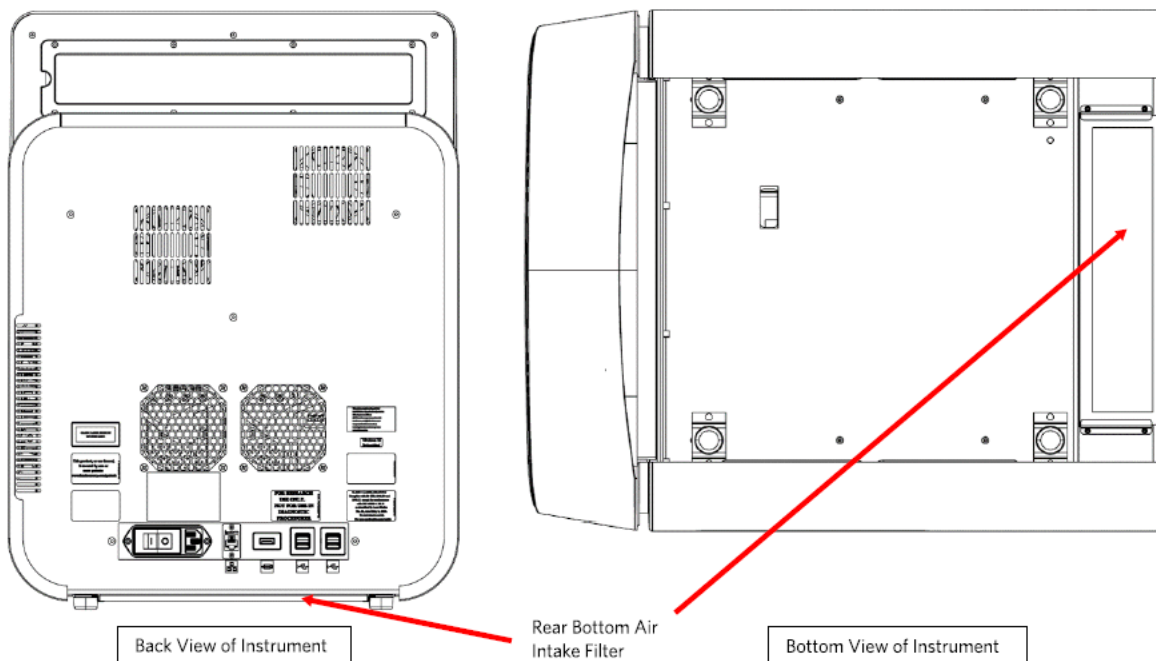


Figure 9: Rear Bottom Air Intake Filter



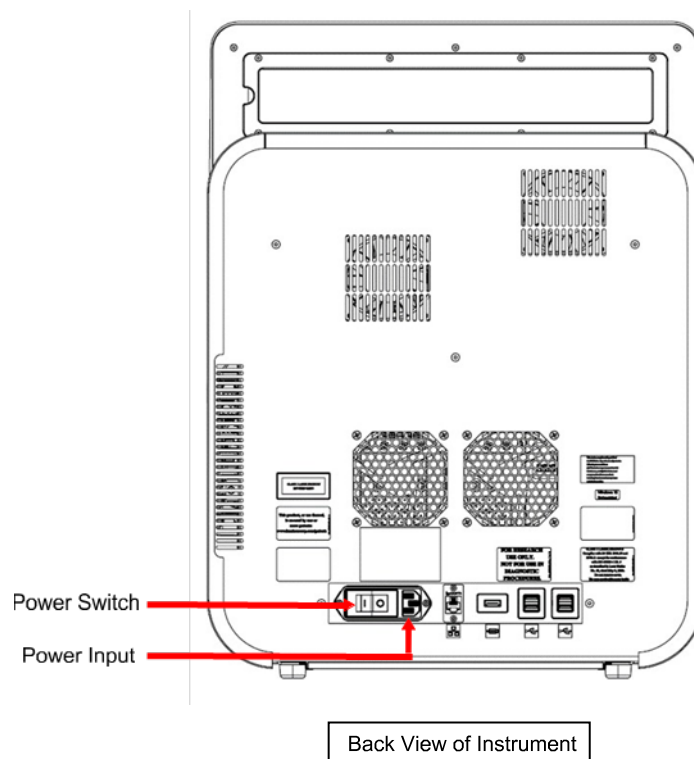
Electrical Subsystem

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



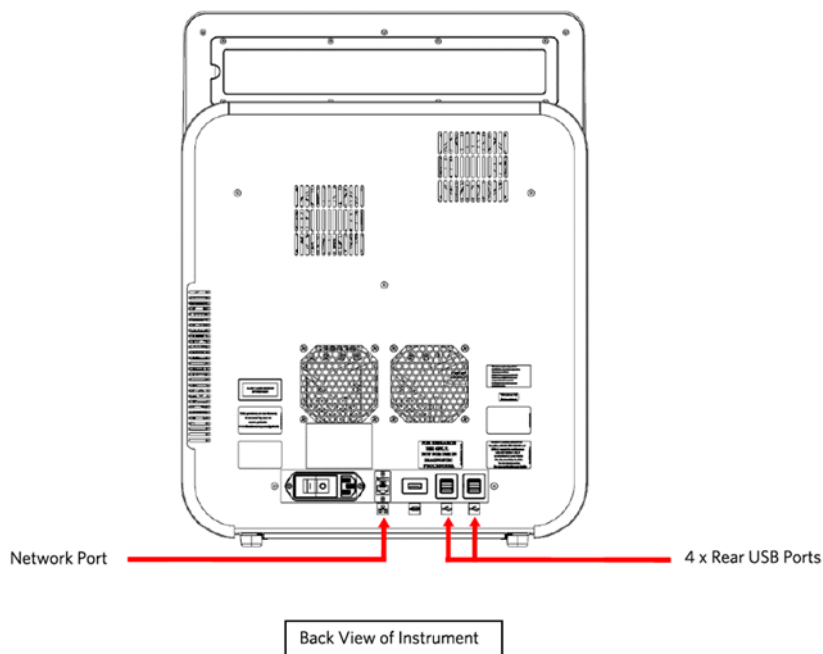
Do not obstruct the power input module as a means of disconnection. Connect only to outlets that contain protective earthing.

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.

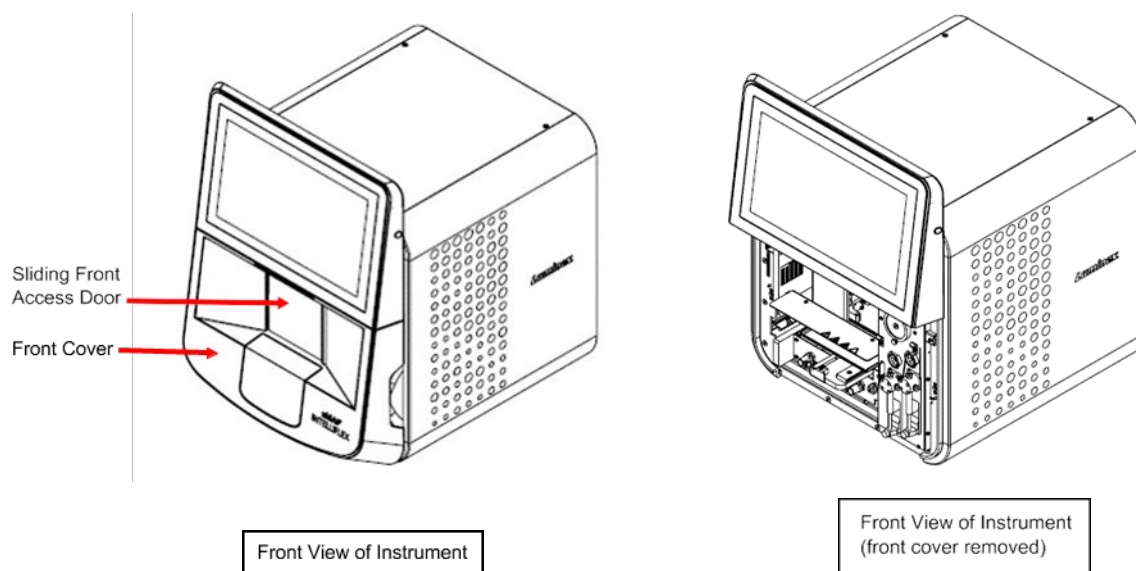
Front Cover and Access Door

The xMAP INTELLIFLEX® Instrument has a clear sliding front access door and one front cover. Sliding the access door open provides easy access to the sample probe for routine maintenance. Removing the front cover provides 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

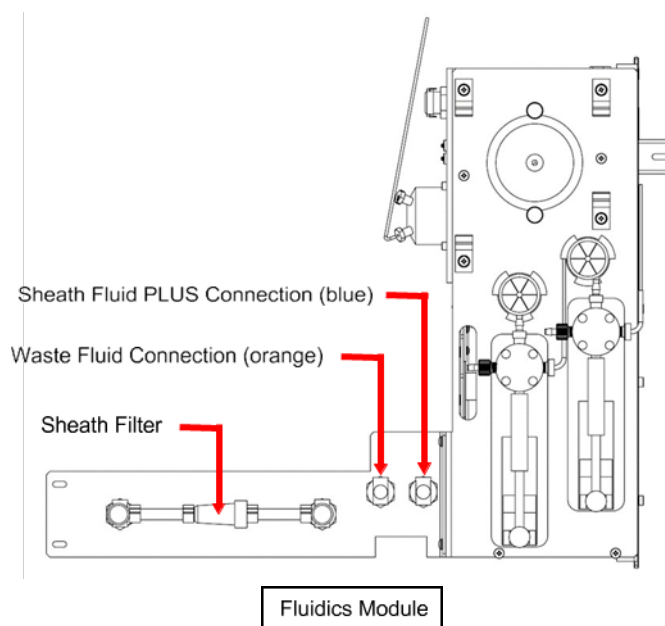


Fluidics Module

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:

Total sample volume (μL) - Sample uptake volume (μL) + 45 μL < Maximum well volume (μL)

- 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.

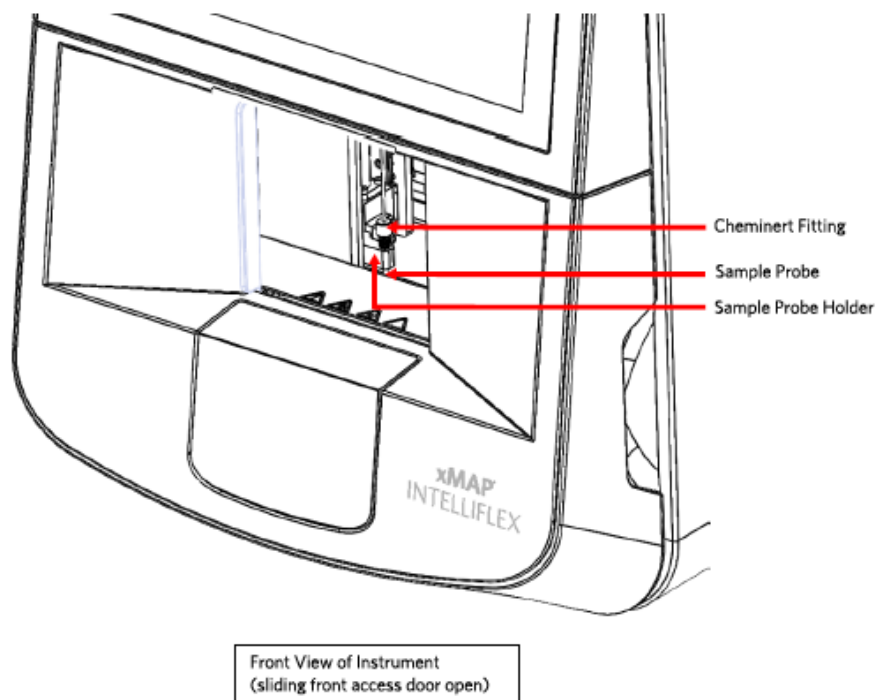
Cheminert® Fitting

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



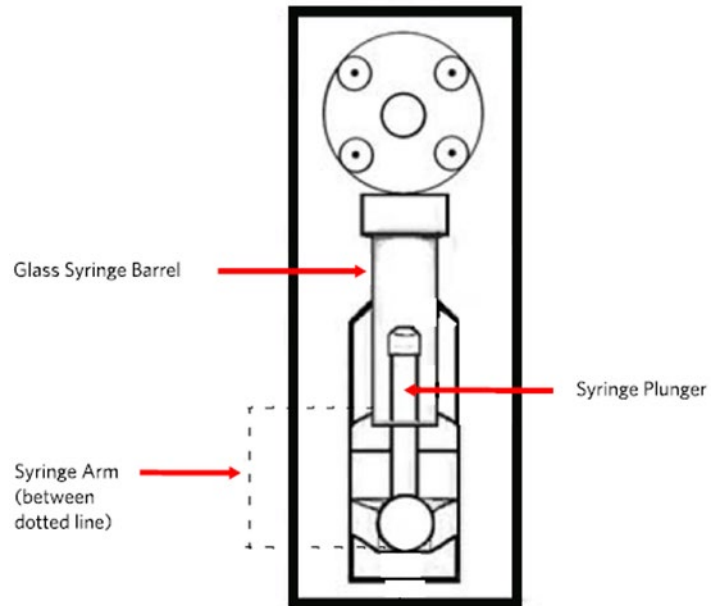
Syringe Pump

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



Avoid contact with moving parts.

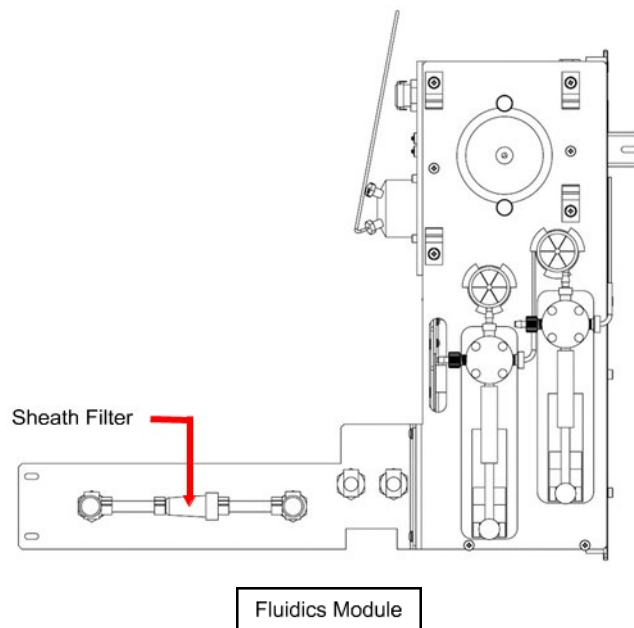
Figure 15: Syringe Pump



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.

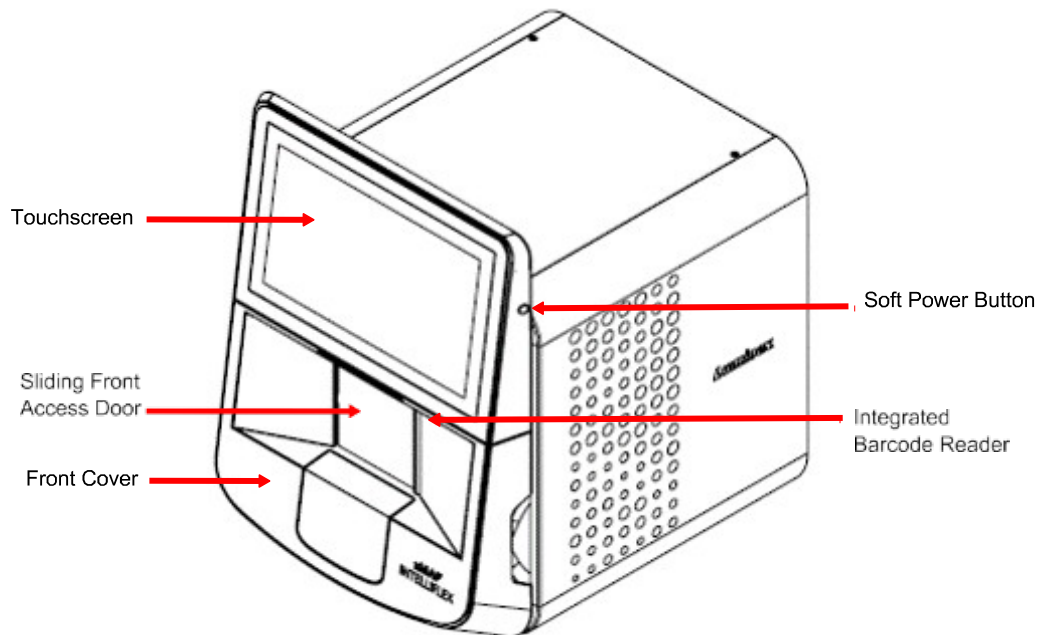
Keyboard or Mouse - Users may optionally choose to attach a different USB keyboard and/or mouse from what was provided with the xMAP INTELLIFLEX® System. Peripheral devices must be capable of functioning as a USB human interface device (HID) using standard Microsoft® Windows® drivers and must not require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



Front and Right View of Instrument

Figure 18: Front and Left Side

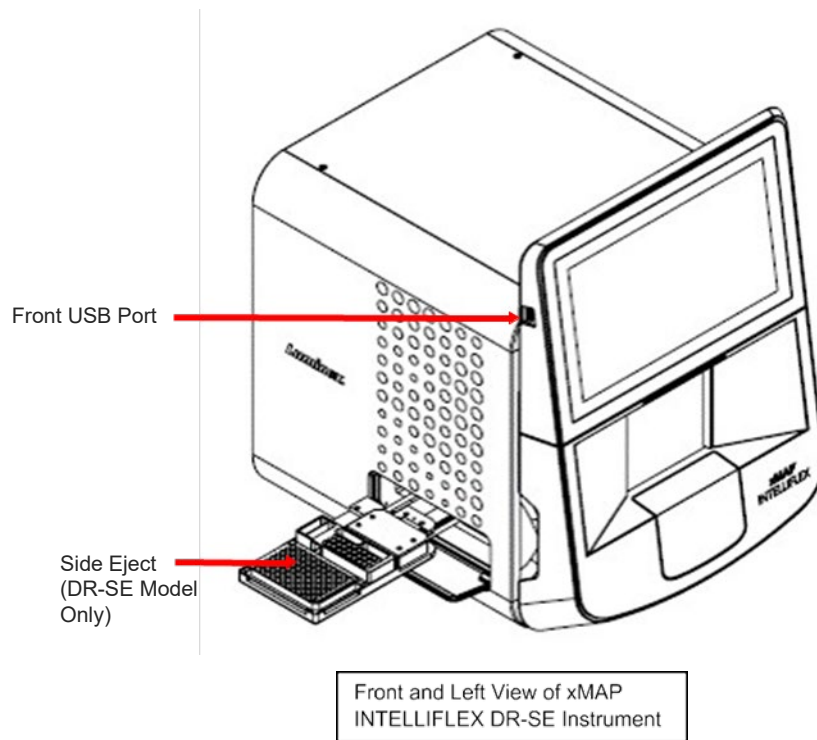
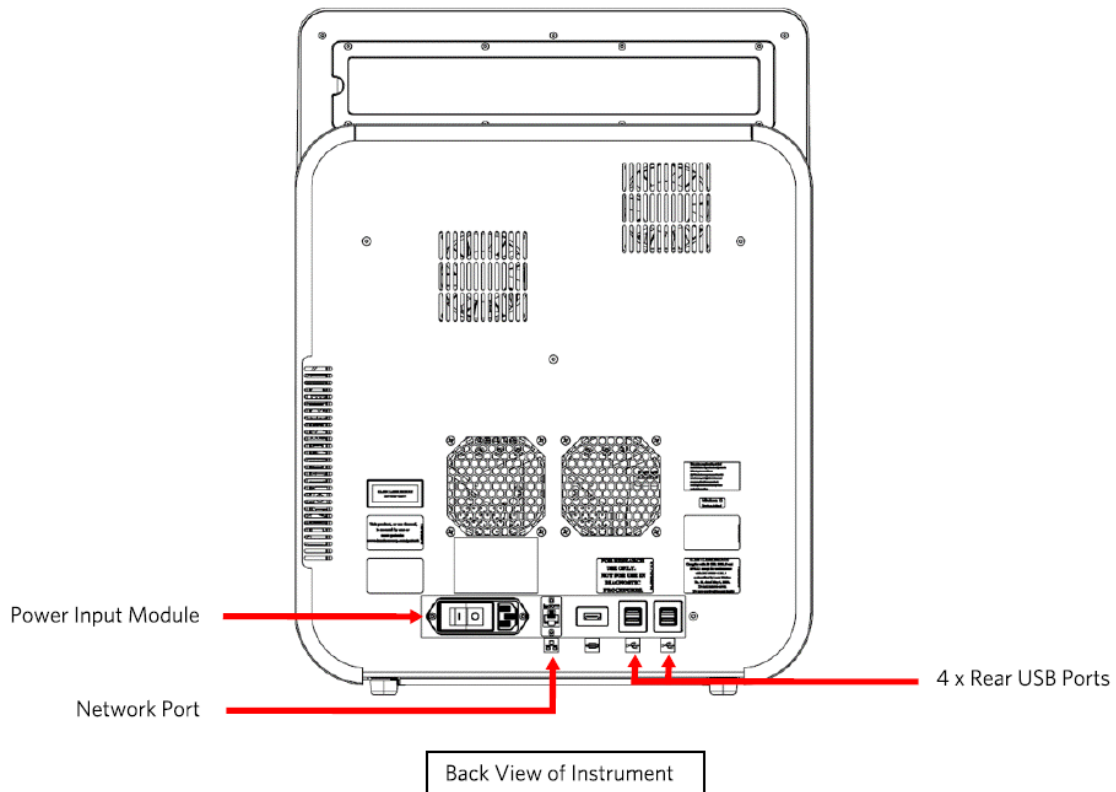


Figure 19: Back Side



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 as shown in **Figure 19**. The hard power switch controls the flow of power to the instrument. The soft power button can be used to routinely power the system on and off. 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. 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 blue light on the front of the instrument and the sound of the fan indicate that xMAP INTELLIFLEX System is on. The system takes approximately 2 minutes to complete the initialization process and self-test. During this time:

- The Status Screen will display default data (Lasers Off, Sheath Pressure 0, etc.)
- If you sign in, the application will not accept any input
- The soft power button will be disabled

When the startup process is complete, the status screen will display current system data and the application will be available for use if you are signed in.


Sign in to the Software

The xMAP INTELLIFLEX Software supports multiple users either locally or on a network. For more information on user management, refer to *Administration and Settings*

Luminex provides three default user accounts: Administrator, Lab Lead, and Operator. The default password for Lab Lead 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. Move the mouse or tap the Status screen to display the Sign in screen
2. Enter the Sign in credentials for the account displayed or select **Switch Users** to sign in as a different user.
 - a. If this is the first time you have started the software, read the End-User License Agreement (EULA), and select **Accept**

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

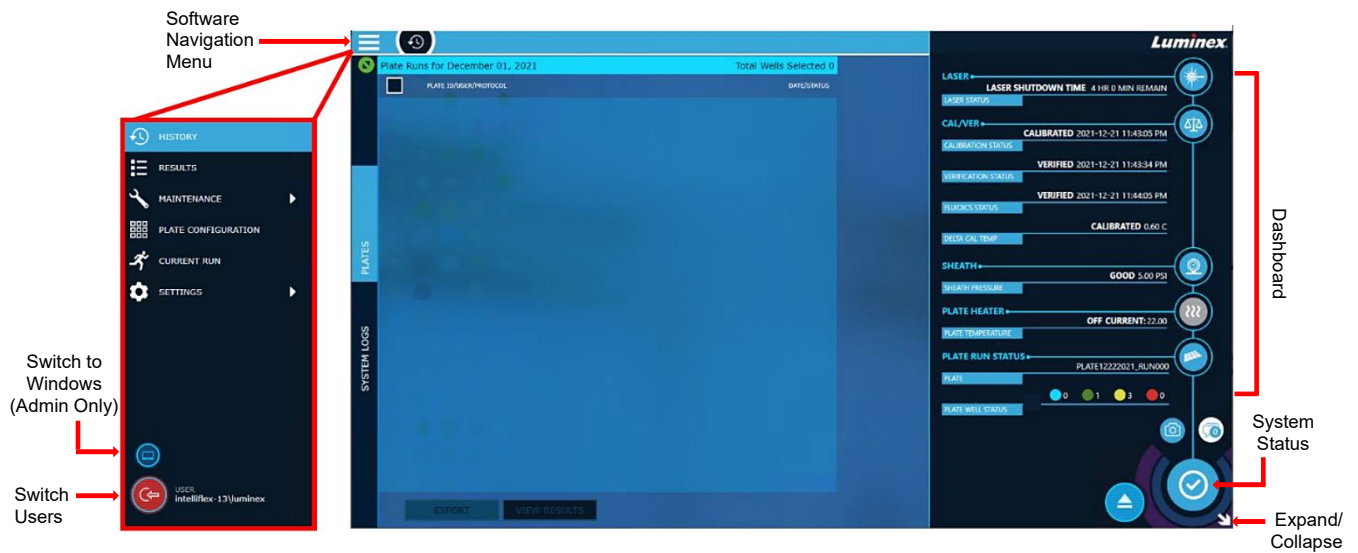


Figure 21: Dashboard

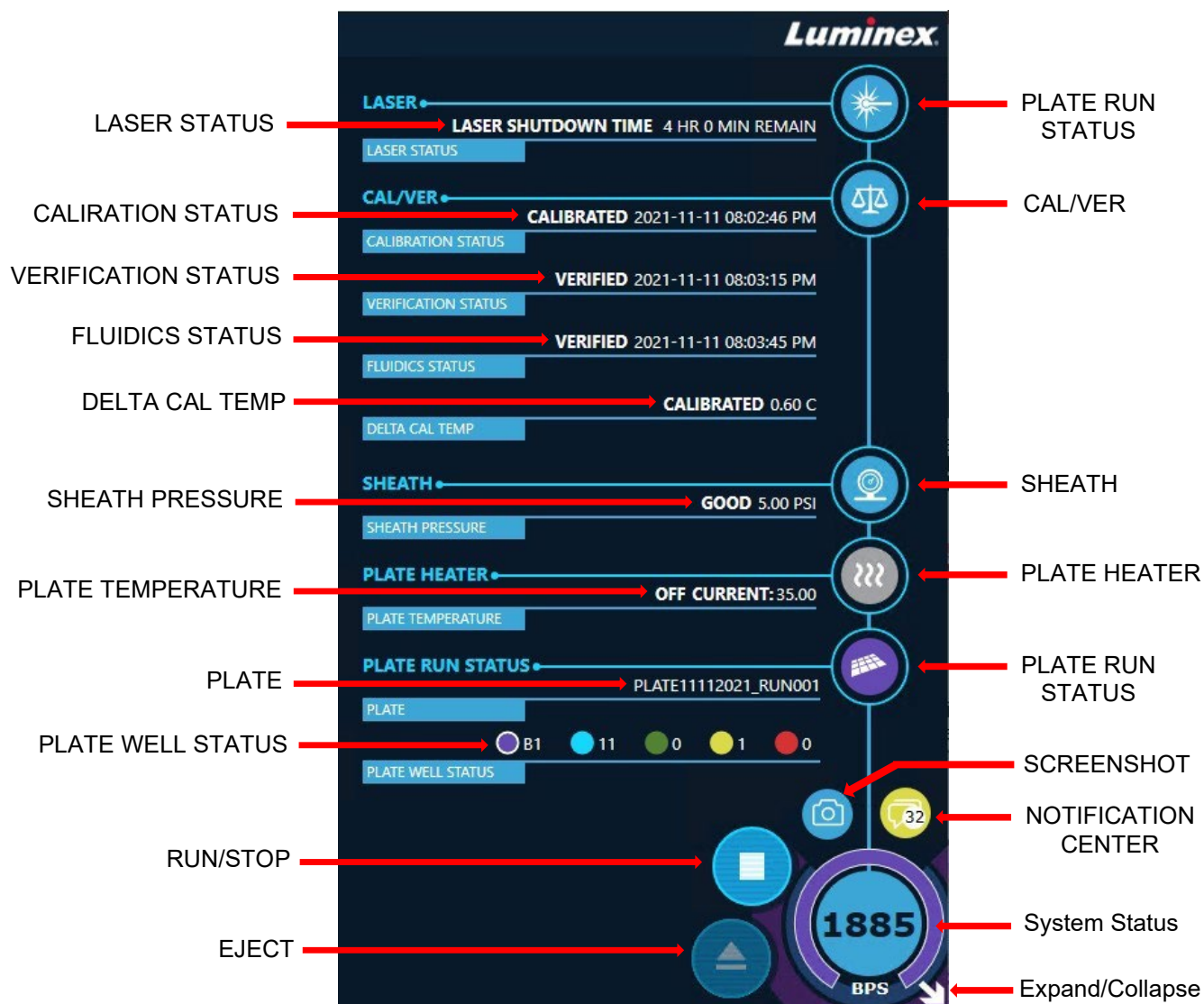


Table 1. Dashboard Elements

<p>LASER button</p>	<p>Turns the lasers on and indicates the laser status. If the laser timer is running, selecting LASER will reset the timer to 4 hours. If the timer has expired, selecting LASER will start the laser warmup process.</p> <p>The laser button changes color to indicate the laser status:</p> <ul style="list-style-type: none"> • Blue: Laser is on and ready • Orange: Laser is warming up • Gray: Laser is off
<p>LASER STATUS</p>	<p>States the current laser status. When the instrument is turned on, the WARMING time displays the time remaining until the laser is warmed up. If the laser is on and warmed, the LASER SHUTDOWN TIME displays the remaining time before the laser shuts off.</p>
<p>CAL/VER button</p>	<p>Displays the MAINTENANCE > CAL/VER page and indicates the calibration and performance verification status.</p> <p>The CAL/VER button changes color to indicate the calibration and performance verification status:</p> <ul style="list-style-type: none"> • Blue: System has passed calibration and performance verification • Yellow: Warning present and calibration or performance verification is overdue. • Red: Error present and system has failed calibration or performance verification
<p>CALIBRATION STATUS</p>	<p>States the current calibration status and when the system was last calibrated.</p>
<p>VERIFICATION STATUS</p>	<p>States the current verification status and when the system was last verified.</p>
<p>FLUIDICS STATUS</p>	<p>States the current fluidics status and when the system was last verified.</p>
<p>DELTA CAL TEMP</p>	<p>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.</p>

<p>SHEATH button</p>	<p>Displays the MAINTENANCE > ROUTINES page and indicates the sheath pressure status.</p> <p>The SHEATH button changes color to indicate the sheath pressure status:</p> <ul style="list-style-type: none"> • Blue: Sheath pressure is good • Yellow: Warning present • Red: Error present; sheath fluid may be empty <p>NOTE: Refer to <i>Troubleshooting</i> for error messages and resolutions.</p>
<p>SHEATH PRESSURE</p>	<p>States the current sheath pressure status and the sheath pressure in PSI.</p>
<p>PLATE HEATER button</p>	<p>Displays the SET HEATER dialog box to turn the plate heater on or off and set the plate temperature in degrees Celsius. The PLATE HEATER also changes color to indicate the plate heater status:</p> <ul style="list-style-type: none"> • Blue: Plate heater is on and ready • Orange: Plate heater is warming up • Gray: Plate heater is off
<p>PLATE TEMPERATURE</p>	<p>Displays whether the plate heater is on or off, and displays the current temperature of the plate heating block in degrees Celsius when the plate heater is on</p>
<p>PLATE RUN STATUS button</p>	<p>Displays the CURRENT RUN page and indicates the plate run status.</p> <p>The PLATE RUN STATUS button changes color to indicate the plate run status:</p> <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
<p>PLATE</p>	<p>Displays the plate name of the current run or indicates no plate is in progress.</p>
<p>PLATE WELL STATUS</p>	<p>Displays the location of the well being analyzed when a plate is running and the number of wells in progress, successfully completed, or completed with color indicators of warnings or errors.</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

System Status button

Displays the Dashboard and shows the current run status, including the current bead count of the running acquisition, and indicates the current system status when idle.

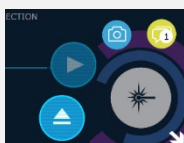
- System calibrated, lasers on and warmed up, system fully ready



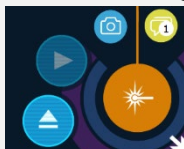
- Operation in process (ex: self test, plate extend/retract)



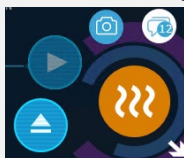
- Lasers off



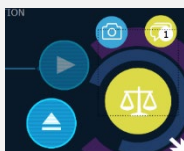
- Lasers warming up



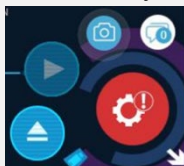
- Heater warming up








- Calibration Overdue



- Service Only – Contact *Luminex Technical Support*






<p>NOTIFICATION CENTER button</p>	<p>Displays the number of unread system messages, indicates the status of the messages, and when selected, opens the NOTIFICATION CENTER.</p> <p>Select READ ALL to clear the message notifications from the NOTIFICATION CENTER. The messages will remain in the ALL section.</p> <p>Select CLEAR HISTORY to clear the message history.</p> <p>The NOTIFICATION CENTER button changes color to indicate the status:</p> <ul style="list-style-type: none"> • White: No unread warning or error notification present • Yellow: Unread notification for a warning present • Red: Unread notification for an error present
<p>Expand/Collapse button</p>	<p>Expands the System Status display or collapses the System Status and Dashboard displays.</p>
<p>EJECT button(s)</p>	<p>Ejects the plate. Once the plate is ejected, the EJECT button  changes to the RETRACT button . The RETRACT button retracts the plate carrier. Once the plate carrier retracts, the RETRACT button changes back to the EJECT button.</p> <p>On DR-SE model instruments, a side eject button  may be displayed in addition to, or instead of, the front eject button shown.</p>
<p>RUN/STOP button</p>	<p> Runs the plate.</p> <p> Stops the system at the next interruptible step in its process (approx. 5 minutes).</p>
<p>SCREENSHOT button</p>	<p>Takes a screen capture when selected and saves image to the previously configured folder in Settings.</p>

Warm up the Lasers

Warm up the lasers to prepare the optics prior to sample acquisition. The lasers automatically begin warming up when you turn the power on; however, you will need to warmup the lasers if the system is idle for 4 hours or longer. The lasers take approximately 30 minutes to warm up.

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

To warm up the lasers:

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. Once successfully warmed up, the **LASER STATUS** displays a timeout countdown.
 - a. Select the **LASER** button to reset the countdown timer to 4 hours.
 - b. 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 to ensure proper acquisition of samples for new plate types, before system maintenance, after replacing the sample probe from the system, or as part of troubleshooting. Calibrating the sample probe height also ensures that the sample probe drops far enough into the well to acquire the sample without compromising the bottom of soft bottom plates or halting before reaching the bottom of steeply sloped wells. To prevent soft-bottom plates from being pierced by the sample probe, use the alignment disk included in the Sample Probe Height Adjustment Kit (CN-0015-01) shipped with the instrument or use the alternative method listed in the subsequent section.

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.

Sample probe height 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.

Calibrate the Sample Probe Height for a Plate Type

Load the Plate and Alignment Assistance Tool

1. Select  in the lower right-hand corner of the screen to eject the plate carrier.

- Place a plate of the desired type for probe adjustment on the plate carrier with the plate oriented so A1 is in the top left corner. Confirm that no liquid is present in the plate.





NOTE: Do not insert a plate or use an alignment tool when calibrating the sample probe height for 384-well Filter or Mylar Bottom Plates. Refer to *Alternative Probe Height Calibration for Mylar and Filter Bottom Plates*.

- Place the appropriate alignment disk in the specified well position using the following guidelines:

Plate	Plate Type	Alignment Assistance	Well Position
96-well	Hard Bottom Plate	No tool required	A6
384-well	Hard Bottom Plate	No tool required	A12
96-well	Filter or Mylar Bottom Plate	Large alignment disk	A6
384-well	Filter or Mylar Bottom Plate	Refer to <i>Alternative Probe Height Calibration for Mylar and Filter Bottom Plates</i>	



- Select  to retract the plate carrier.

Create a New Plate Type

- Select  in the upper left-hand corner of the screen to open the Software Navigation Menu, then navigate to **MAINTENANCE > PROBE HEIGHT**.
- Select **NEW** to define a new plate type.
- Optionally, enter a description in the **DESCRIPTION** field.
- Select either a 96-well or 384-well plate option in the software by toggling to the  or  well plate option.
- Press **AUTO CALIBRATE**  in the **PLATES** section. The sample probe automatically adjusts to the well and saves the probe height. A message is displayed indicated the new plate type can now be saved.
- Select **SAVE AS**, enter the name of the plate, select **SAVE** on the SAVE AS dialog. A message is displayed indicating the plate type has been saved.


The plate type is now available for selection in the MY PLATES drop-down in ACQUISITION settings under PLATE CONFIGURATION.

Update Probe Height for a Saved Plate Type

- Select  in the upper left-hand corner of the screen to open the Software Navigation Menu, then navigate to **MAINTENANCE > PROBE HEIGHT**.
- Choose a saved plate type from the **SAVED PLATES** drop-down menu.
- To save an existing plate type with a different name, select **SAVE AS**, enter the new name, then select **SAVE**.
- To update the probe height, press **AUTO CALIBRATE**  in the **PLATES** section. The sample probe automatically adjusts to the well and saves the the probe height. A message is displayed indicating the probe height has been updated and saved.

The plate type is now available for selection in the MY PLATES drop-down ACQUISITION settings under PLATE CONFIGURATION.

Delete a Saved Plate Type

1. Select  in the upper left-hand corner of the screen to open the Software Navigation Menu, then navigate to **MAINTENANCE > PROBE HEIGHT**.
2. Choose a saved plate type from the **SAVED PLATES** drop-down menu.
3. Select **DELETE** in the **PLATES** section. A message is displayed indicating the plate type was deleted.

Manually Adjust the Sample Probe Height

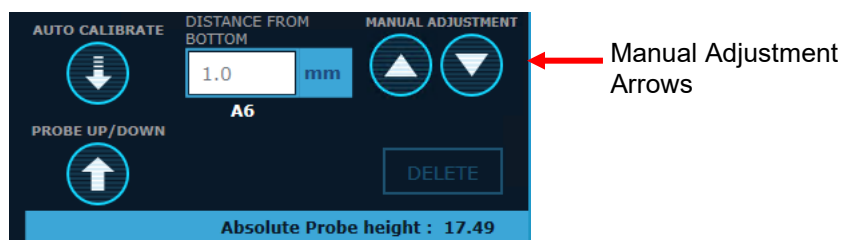
Manual adjustment may be used when calibrating the sample probe height to ensure optimal performance on different plate types.

The **DISTANCE FROM BOTTOM** defaults to one (1) mm and will adjust to this distance from the bottom of a hard bottom plate, from alignment disks, or the plate carrier when AUTO CALIBRATE is used. The **DISTANCE FROM THE BOTTOM** may be manually adjusted for specific plate types by increasing or decreasing the offset value using the arrows next to the **DISTANCE FROM BOTTOM** field illustrated in **Figure 22**. When manually adjusting the probe height, the probe is adjusted in 0.1 mm increments each time the user interfaces with the manual adjust feature.

The **DISTANCE FROM BOTTOM** is saved with the plate and will be the distance used for the **AUTO CALIBRATE** if rerun.




CAUTION: The probe physically moves when manually adjusting the height. There is potential to pierce the bottom of the plate.

Figure 22



The Absolute Probe Height of each section displays the absolute distance (in millimeters) from the probe's highest point.

Manually Adjust the Probe Height for a Saved Plate Type

1. Select  in the upper left-hand corner of the screen to open the Software Navigation Menu, then navigate to **MAINTENANCE > PROBE HEIGHT**.
2. Choose a saved plate type from the **SAVED PLATES** drop-down menu.
3. Select the **PROBE UP/DOWN** button.
4. Manually adjust the probe height by selecting the Manual Adjustment Arrows  and .
5. Select **SAVE** in the **PLATES** section. A message is displayed indicating the plate type was saved.

The plate type is now available for selection in the MY PLATES drop-down in ACQUISITION settings under PLATE CONFIGURATION.

Alternative Probe Height Calibration for Mylar and Filter Bottom Plates

To optimize the performance of 384-well Mylar or Filter bottom plates, do not install 384-well Mylar or Filter bottom plates on the plate carrier when calibrating the probe height for these plate types. Use the provided calculation, **AUTO CALIBRATE** function, and **MANUAL ADJUSTMENT** feature to calibrate the sample probe height:

1. Use the datasheet for the plate you intend to adjust the probe height to; subtract the “well depth” from the “plate height” and then add in the desired “probe clearance” from the well bottom as shown in the Example 1 or Example 2. This is the desired distance from the tray for the probe to be adjusted.

Example 1:

Plate Type: Corning 384-well plate (Catalog #3703)

Plate Height: 14.2 mm - **Well Depth:** 11.43 mm + **Probe Clearance** 1.0 = 3.77 mm (3.8 mm)

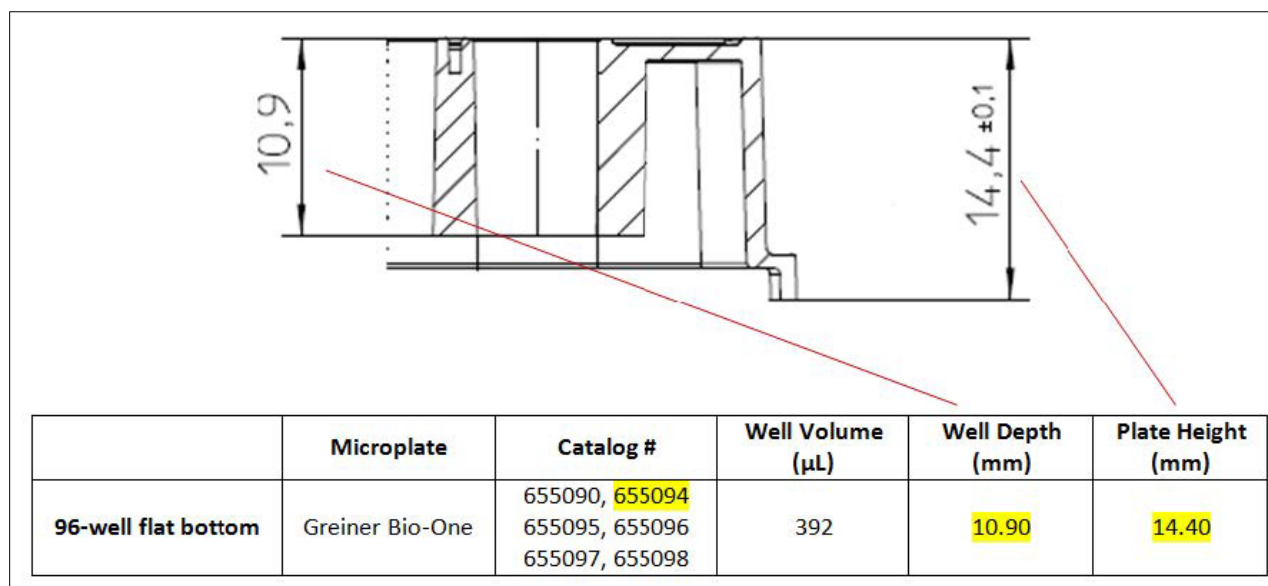
	Representative microplate (Corning Cat. #)	Well Volume (uL)	Well Depth (mm)	Well Diameter (top/bottom) (mm)	Plate Length (mm)	Plate Width (mm)	Plate Height (mm)
384 Well Microplates							
Solid black, white, and clear polystyrene plates							
384 well flat bottom	3640, 3652, 3654, 3844, 3680, 3700, 3701, 3702, 3703, 3704, 3705, 3708, 3709, 3710, 3723, 3844	112	11.43	3.63 / 2.67 (width)	127.8	85.5	14.2









NOTE: Numbers rounded to the nearest tenth of a millimeter

Example 2:

Plate Type: Greiner Bio One 96-well flat bottom plate (Catalog #655094)





Plate Height: 14.40 mm - **Well Depth:** 10.90 mm + **Probe Clearance** 1.0 = 4.50 mm



2. Confirm that a plate is not installed on the plate carrier.
 - a. If a plate is installed on the plate carrier, select  in the lower right-hand corner of the screen to eject the plate carrier.
 - b. Remove the plate.
 - c. Select  to retract the plate carrier.
3. Select  in the upper left-hand corner of the screen then navigate to **MAINTENANCE > PROBE HEIGHT**.
4. Select **NEW** to create a new plate type.
5. Optionally, enter a description in the **DESCRIPTION** field.
6. Select either a 96-well or 384-well plate option in the software by pressing  or .
7. Press **AUTO CALIBRATE**  in the **PLATES** section. The sample probe automatically adjusts to the plate carrier tray and saves the reading for the probe height.
8. Select **SAVE AS**, enter the name of the plate type, then select **SAVE**.
9. Select the **PROBE UP/DOWN** button.
10. Use the manual adjustment buttons  and  in the **PLATES** section to set the **DISTANCE FROM BOTTOM** to the value calculated in step 1.
11. Select **SAVE**. A message is displayed indicating the plate type was saved.
The plate type is now available for selection in the My Plates drop-down in Acquisition Settings under PLATE CONFIGURATION.

Calibrating Reservoir & Strip Well Probe Height

There is one probe height for the reservoirs and one for the strip wells. The probe height is automatically saved after auto calibration.

1. Select  in the lower right-hand corner of the screen to eject the plate carrier
2. Place off-plate reagent block on the plate carrier with one replacement strip well in the middle row of the off-plate reagent block. The strip well is provided with the Calibration and Performance Verification kit.
NOTE: The off-plate reagent block is keyed and can only be installed in one direction.
3. Verify no liquid is present in the strip well or reservoirs.
4. Select  to retract the plate carrier.
5. Select  in the upper left-hand corner of the screen then navigate to **MAINTENANCE > PROBE HEIGHT**.
6. Press **AUTO CALIBRATE**  in the **RESERVOIRS** section. The sample probe automatically adjusts to the reservoirs and saves the probe height. A message is displayed indicating the probe height was saved.
7. Once the system finishes calibrating the sample probe height in the **RESERVOIRS** section. Press **AUTO CALIBRATE** in the **OFF-PLATE STRIPS** section. The sample probe automatically adjusts to the wells and saves the probe height. A message is displayed indicating the probe height was saved.
8. Probe Height Calibration is now complete for Reservoirs and Strip Wells.


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 the barcode included with each reagent kit.

The integrated barcode reader is located below the touchscreen, to the right of the sliding front door. The scanner times out and the dialog closes automatically after a period of time if a readable barcode is not detected.

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

To import lot-specific target values,

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**.
 - a. If the dialog closes because scanner times out, select **IMPORT KIT > SCAN** from the top of the screen again.
5. Use the barcode reader located below the touchscreen to scan the barcode on the Calibration or Performance Verification Kit Target Value Card (provided with the kit). If the scan is successful, a message displays stating the kit lot imported successfully.

NOTE: An error message is displayed if the lots were previously imported.

 - a. The kit lot number and expiration date are displayed in the **SCAN NOW** field.
 - b. The imported kit is automatically selected in the appropriate **CALIBRATION, PERFORMANCE VERIFICATION, or FLUIDICS VERIFICATION** drop-down menu.
6. If necessary, scan another barcode.
7. Select **CLOSE**. If **CLOSE** is not selected, the dialog box closes automatically.

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 (DR-SE model only)). 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 xMAP 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. Select the reagent lot from the **CALIBRATION, PERFORMANCE VERIFICATION, and FLUIDICS VERIFICATION** drop-down menus. Choose the correct reagent lot numbers for your calibration and performance verification kits by selecting the lot number in the drop-down menu that matches the lot number on the reagent bottle.
4. Select the **RUN** check boxes for **CALIBRATION, PERFORMANCE, and FLUIDICS**.
 - a. 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. Expired lots are also indicated in the dashboard.




WARNING: The following kit(s) are past their expiration date: 'Calibration, Verification, Fluidics 1, Fluidics 2' Do you want to continue?



Yes

No

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

5. Select  to eject the plate carrier.
6. Place one clean strip well in the top row of the off-plate reagent block.
7. Gently vortex all calibration and performance verification kit reagents for approximately 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, as indicated in the plate layout displayed on the **RUN CAL/VER** tab.
9. Completely invert the reagent bottles, and add six drops per well of each calibration reagent (IFXCAL-10) and performance verification reagent (IFXVER-10, FLUID1-05, and FLUID2-05) to the strip well, as indicated in the plate layout displayed on the **RUN CAL/VER** tab.

NOTE: Check the label on the bottles to ensure you are dispensing the correct reagent.

10. Select  to retract the plate carrier.
11. Select  to run. The instrument will wait until the lasers are warmed up 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.

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. Select the reagent lot from the **PERFORMANCE VERIFICATION** and **FLUIDICS VERIFICATION** drop-down menu. Choose the correct lot numbers for your performance verification kit by selecting the lot number in the drop-down menu that matches the lot number on the reagent bottle.
4. Select the **RUN** check boxes for **PERFORMANCE VERIFICATION** and **FLUIDICS VERIFICATION**. If additional check boxes are selected from a previous run, clear them.
 - a. You can run fluidics as part of the performance verification procedure or as a standalone procedure.
5. Select  to eject the plate carrier.
6. Place one clean strip well in the top row of the off-plate reagent block.
7. Gently vortex all performance verification reagents for approximately 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, as indicated in the plate layout displayed on the **RUN CAL/VER** tab.
9. Completely invert the bottle and add six drops per well of each performance verification reagent (IFXVER-10, FLUID1-05, and FLUID2-05) to the strip well, as indicated in the plate layout displayed on the **RUN CAL/VER** tab.

NOTE: Check the label on the bottles to ensure you are dispensing the correct reagent.
10. Select  to retract the plate carrier.
11. 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. Toggle the **DATE RANGE** radio button to filter the results by a date range, or select **ALL** to view all of the results.
 - a. If a date range was selected:
 - i. , Select the Calendar icon in the **FROM** field, select a date and time, and select **CLOSE**.
 - ii. Select the Calendar icon in the **TO** field, select a date and time, and select **CLOSE**.Ensure the earlier date is entered in the **FROM** field and the later date is entered in the **TO** field. The system will not prevent you from entering a **FROM** date that is later than the **TO** date. If the range is entered incorrectly, the system will not display results.
3. Select the check box(es) for the data to export.
4. Select **EXPORT**.
5. Choose the USB or network drive location where you want to save the report.
6. Edit the File name, if necessary.
7. Select **EXPORT**. A message displays stating whether the selected result(s) was successfully exported or not.

Chapter 5: Configuring 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 analyte 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 (optional), panel, and acquisition settings used as a template for repeated use.
Plate	Defines the combination of the layout, panel, acquisition settings, and Sample ID/Description assignments (optional) for an experiment.

Figure 23: Plate Configuration

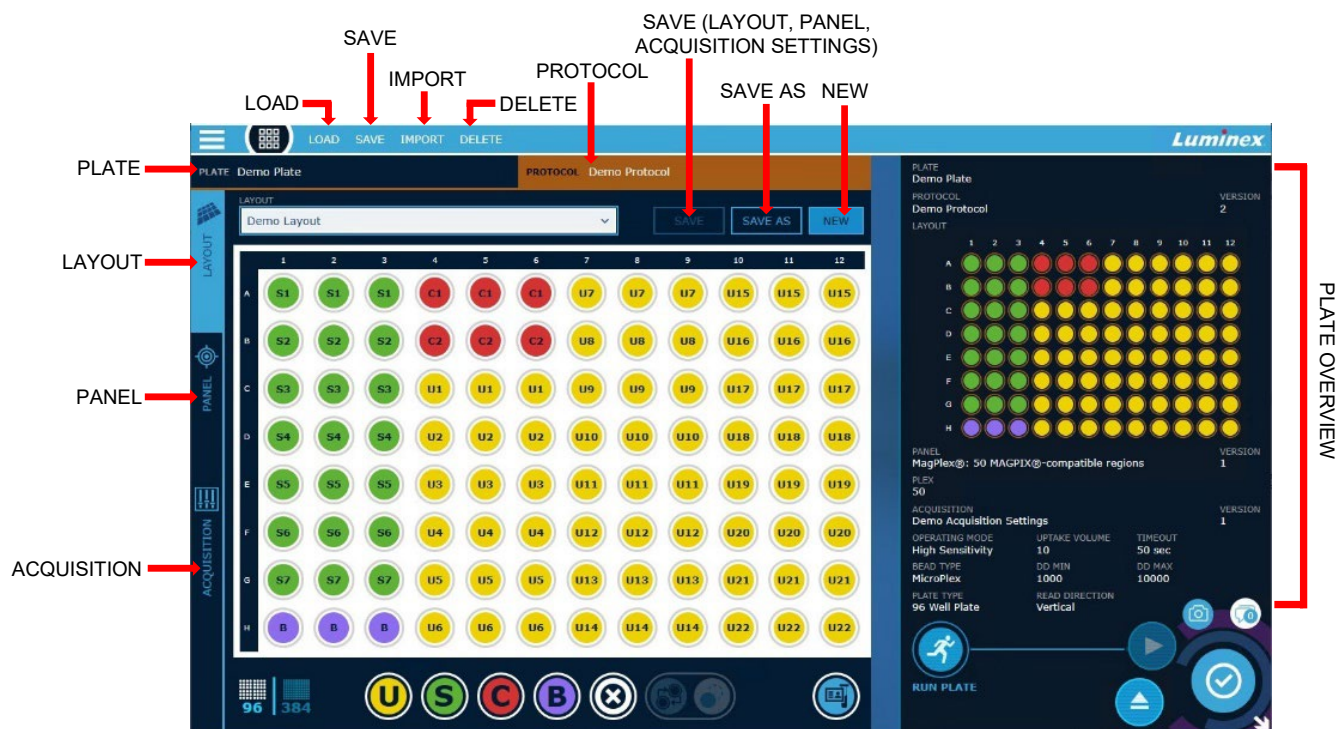


Table 3. Plate Configuration Screen Elements

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	<p>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 to indicate that the modifications have not been saved.</p> <p>NOTE: If you modify the plate parameters and do not save the modifications, the new plate parameters will not be used.</p> <p>If you do not define a plate name, the system automatically assigns a generic plate name when the plate is run (PLATE MMDDYYYY RUNXXX).</p>
PROTOCOL	<p>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 to indicate that the modifications have not been saved. Save the protocol again to keep the changes.</p> <p>NOTE: If you modify the protocol and do not save the modifications, the protocol name will not be used.</p>
LAYOUT	<p>Displays the PLATE CONFIGURATION > LAYOUT page to define well assignments.</p>
PANEL	<p>Displays the PLATE CONFIGURATION > PANEL page to define bead regions to be analyzed.</p>
ACQUISITION	<p>Displays the PLATE CONFIGURATION > ACQUISITION page to define acquisition settings, such as bead type, uptake volume, plate heater temperature, and DD gating.</p>
SAVE (on Layout, Panel, Acquisition settings page)	<p>Saves a new object or saves over the selected object.</p>
SAVE AS (on Layout, Panel, Acquisition settings page)	<p>Saves selections as a new object.</p>
NEW (on Layout and Panel page)	<p>Clears current selections on the page.</p>
PLATE OVERVIEW	<p>Provides an overview of the current plate selections, including associated Layouts, Panels, Acquisition Settings, Plates, Protocols, and their version numbers.</p>
RUN PLATE	<p>Navigates to Current Run and loads the configured plate.</p>



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. 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. You can select the well locations by encircling desired wells to highlight a series of wells, selecting a column or row header to highlight the entire column or row, selecting individual wells to highlight nonadjacent wells, or selecting 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.



The system does not perform any calculations based on Standards or Controls, but does provide Net and other statistics based on Background designations.

- Unknown (U): Yellow
- Standard (S): Green
- Control (C): Red
- Background (B): Purple

NOTE: Select **X** to delete a well assignment.

6. To copy well assignments to replicate wells,
 - a. Add sample information if you are including Sample ID/Description or Dilution information in your plate.
 - b. Select the defined well(s), and then select  to copy the well assignment(s). A dashed blue circle displays around the selected well(s).
 - i. Select the well(s) to paste the copied well assignment(s). A preview of the paste location(s) displays. Continue to select well locations on the layout to preview additional paste locations.

NOTE: Select a preview of a paste location to remove it from the layout.

- ii. Select  to accept and paste the replicate well(s).
5. 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.

6. Select the **DESCRIPTION** field and enter the Sample ID/Description for the well(s).
 - a. The software provides default values when you assign wells to the plate. You can update the default

values as necessary.

- i. All replicates of the same sample must have the same Description value.
 - ii. All background samples are considered replicates and must have the same Description value.
7. 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 and Well type display in the results.
- a. You can enter dilution values with up to seven (7) digits of precision and two (2) decimal places.
NOTE: xMAP INTELLIFLEX Software does not perform any calculations based on Dilution values. Dilution information displays in the output file for downstream analysis.
8. Select **CLOSE**.
9. Optionally, select **SAVE AS** to save the layout for reuse.
- a. Enter the **LAYOUT NAME**.
 - b. Select **SAVE**. 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*.

Only the required heading “Location” must be included in the file.

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

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
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 NOTE: Include the same entry for every well. If the Plate Type is not specified, the software will select the plate type based on the specified Locations .

Heading	Required	Function	Acceptable Entries
Type	Optional	Assigns the well as an unknown, standard, control, or background. “Unknown” is assigned by default if the Type is not specified for a Location .	Alpha, Alphanumeric, or entire words Example: <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” NOTE: Wells with the same alphanumeric ID (for example, “U1” or “B”) will be considered replicates and must have the same sample Description , if Description is included.
Layout Name	Optional	Assigns the default layout name. NOTE: Save the layout after import to use this name.	Text NOTE: Include the same entry for every well.
Description	Optional	Assigns the Sample ID/Description	Text Example: Sample identifier 1 NOTE: Any replicate samples (as identified by Type), must have the same Sample ID/Description. All “Background” samples must have the same Description.
Dilution	Optional	Assigns the Dilution for Unknown samples. NOTE: xMAP INTELLIFLEX Software does not perform any calculations based on Dilution values. Dilution values are limited to seven (7) digits of precision and two (2) decimal places.	Number greater than 1 with up to 2 decimal points. Example: 1.00, 2.50, 5.00, 7.50, 10.00, 100.00

Figure 24: Example Layout 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 25: Example Layout 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
    
```

To import the layout:


1. Select  in the upper left-hand corner of the screen and navigate to **PLATE CONFIGURATION**.
2. 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: If **Yes** is selected, the import file will replace any previous content on the Layout page, including Sample IDs/Descriptions.

5. In the Import dialog box, choose the spreadsheet file (.csv) to import, then select **Import**. A message displays stating the layout imported successfully.
6. Review the layout and the sample identifiers on the Layout page to confirm the file imported correctly.
7. Optionally, select **SAVE AS** to save the layout for reuse
 - a. Update the **LAYOUT NAME** if necessary.
 - b. Select **SAVE**. 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.
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.

6. If you selected **SAVE AS**, enter the **LAYOUT NAME**.
7. Select **SAVE**. 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 **Plate Layout** 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
3. Select **NEW** or select one of the predefined panels from the Panel drop-down menu.
4. Select the bead regions to include using the region selector. Select the range of regions to display using the numbered ranges on the left side of the region selector.
5. On DR-SE model instruments only, select the **Show Analyte 2** check box to show the analyte name field for the second reporter.

NOTE: If the xMAP INTELLIFLEX® Dual Reporter operating mode (INTELLIFLEX DR-SE Instrument only) is not selected in the acquisition settings when running a plate, the system will not collect data for the second reporter.

6. For each included region:
 - Update the Analyte name for the first reporter from the default value if necessary.
 - On DR-SE model instruments, add the second reporter analyte name if using the second reporter. Dual reporter regions must have unique names for each analyte.
 - Select the **MIN BEADS** field and enter the minimum bead count for the region.

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.

7. 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.

8. Optionally, select **SAVE AS** to save the panel for reuse. You can run a plate without saving the panel.

NOTE: Lab Lead or Administrator authorization is required to save the panel.

- a. Enter the **PANEL NAME**.
- b. Select **SAVE**. 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®. Use the headings entry formats provided in *Table 5. Import Panel Spreadsheet Description* in the spreadsheet to create a file for importing. When creating a CSV from another program like Excel, ensure extra lines or commas are not present at the end of the file.

NOTE: xMAP INTELLIFLEX software supports the import of Greek letters

Table 5. Import Panel Spreadsheet Description

Heading	Required	Function	Acceptable Entries
PanelName	Optional	Specifies the default Panel Name that will be displayed when the Panel is saved.	Text NOTE: If this column is used, every entry must include the same Panel Name .
Region	Required	Assigns the Bead Region.	Integers from 1 to 500.
Analyte-1	Required	Assigns the Analyte Name for RP1.	Text
Analyte-2	Optional	Assigns the Analyte Name for RP2 (DR-SE model only).	Text NOTE: Do not use identical Analyte Names for RP1 and RP2
Minimum Bead Count	Optional	Assigns the Minimum Bead Count for each region.	Integers NOTE: If a Minimum Bead Count is not provided for a region or regions, the system assigns a default value of 100.
Normalization	Optional	Indicates whether the Region is the normalization region.	“True” or “False” NOTE: Only one region can have a value of “True”.

Figure 26: Example Panel in Excel® format


	A	B	C	D	E
1	PanelName	Region	Analyte-1	Analyte-2	Minimum Bead Count
2	My Panel1	1	Region 1 Reporter 1 Analyte	Region 1 Reporter 2 Analyte	90
3	My Panel1	2	Region 2 Reporter 1 Analyte	Region 2 Reporter 2 Analyte	100
4	My Panel1	3	Region 3 Reporter 1 Analyte	Region 3 Reporter 2 Analyte	110
5					

Figure 27: Example Panel in Notepad format

```

TestPanelValidFormat.csv - Notepad
File Edit Format View Help
PanelName,Region,Analyte-1,Analyte-2,Minimum Bead Count
My Panel1,1,Region 1 Reporter 1 Analyte,Region 1 Reporter 2 Analyte,90
My Panel1,2,Region 2 Reporter 1 Analyte,Region 2 Reporter 2 Analyte,100
My Panel1,3,Region 3 Reporter 1 Analyte,Region 3 Reporter 2 Analyte,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.
3. Select **IMPORT** from the top of the screen.
 - a. If content is present on the layout page, a message displays stating the sample details will be cleared if 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: If **Yes** is selected, any previous content on the Panel page will be replaced with the information from the imported panel file.
4. In the Import dialog box, choose the file (.csv) to import, then select **Open**. A message displays stating the panel imported successfully.
5. Optionally, select **SAVE AS** to save the imported panel for reuse.
 - a. Update the **PANEL NAME** if necessary.
 - b. Select **SAVE**. A message displays stating the panel saved successfully.

NOTE: Lab Lead or Administrator authorization is required to save the panel.

Edit the Panel

Editing the panel allows you to modify the bead regions and analytes for a previously defined panel. Modifying the panel does not affect previously saved plates or protocols associated with the original 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.
3. Choose a saved panel from the **PANEL** drop-down menu. The analyte list updates to display 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. You can run an assay plate with the modified panel without saving the edited panel prior to the run.

NOTE: If you select **SAVE**, the xMAP INTELLIFLEX® System assigns a new version number to the panel that can be viewed in the Plate Overview pane. Previous versions are not available for use with new plates.

- a. If **SAVE AS** was selected, enter the **PANEL NAME**.
- b. Select **SAVE**. A message displays stating the panel saved successfully.

NOTE: Lab Lead or Administrator authorization is required to save the panel.

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: Lab Lead or Administrator authorization is required to delete a 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	Laser Power	PMT	EDR APD	MFI Value Calculation	Dynamic Range RP1 (log)	Dynamic Range RP2 (log)
	Standard	DR-SE	Enabled						
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

- If the **Luminex® 200™** or **FLEXMAP 3D® OPERATING MODE** was selected, choose **Low** or **High** from the **PMT MODE** drop-down menu.
- 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.
- 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.
- Choose the bead type from the **BEAD TYPE** drop-down menu.
- 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.
- 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.
 - a. If the XY Heater is on, choose the temperature in °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. The plate heater automatically turns off after the plate is run.
13. 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.
14. Optionally, select **SAVE AS**. A plate can be run without saving the acquisition settings.

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.
15. Enter the **ACQUISITION SETTINGS NAME**
16. Select **SAVE**. 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. You can run an assay plate with the modified acquisition setting without saving the edited panel prior to the run.

NOTE: Lab Lead or Administrator authorization is required to save the panel.

NOTE: When saving over previous acquisition settings, the xMAP INTELLIFLEX® assigns 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.

- a. If **SAVE AS** was selected, enter the **ACQUISITION SETTINGS NAME**.
- b. Select **SAVE**. 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 **Acquisition Settings** check box(es) for the acquisition setting(s) you want to delete.
4. Select **DELETE**.

NOTE: Lab Lead or Administrator authorization is required to save the panel.

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 **SAVE**. A message displays stating the protocol saved successfully.

NOTE: Lab Lead or Administrator authorization is required to save the panel.

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. Modifying the Protocol does not affect previously saved plates associated with the original Protocol. Changes made to well assignments

or sample information are not considered a change to the Protocol when running the plate.

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. When saving over an existing Protocol, INTELLIFLEX assign a new version number to the Protocol that you can view in the Plate Overview. Only the newest version of a Protocol is available for selection when creating a new plate.

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: 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: If you select **SAVE**, the xMAP INTELLIFLEX® System assigns a new version number to the protocol that can be viewed in the Plate Overview pane. Previous versions are not available for use with new plates.

NOTE: Lab Lead or Administrator authorization is required to save the panel.

7. If **SAVE AS** was selected, enter the **PROTOCOL NAME**.
8. Select **SAVE**. 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: Lab Lead or Administrator authorization is required to save the panel.

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, acquisition settings and sample information.
- Loading previously saved layout, panel, and acquisition settings, or importing a layout (which may include sample information) 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.

Add or Edit Well Information

1. Select  to add or edit well information (optional).
 - a. Select the **DESCRIPTION** field and enter the Sample ID/Description for the well(s).


NOTE: Any replicate sample (as identified by Type), must have an identical Sample ID/Description.
 - 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 and Well type display in the results. The system does not perform any calculations based on Standards or Controls, 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**.

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 **SAVE**. A message displays stating the plate saved successfully.

NOTE: Saving a plate will also save the collection of layout, panel, acquisition settings, and sample information under a user plate name.


Load the Plate

A previously saved 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**.
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**.

Send the Plate to Current Run

Once the plate is configured, it can be loaded in Current Run to start running.

1. Select **RUN PLATE** from the Plate Overview located on the right side of the screen to make the run pending.
2. Once the run is pending, the **CURRENT RUN** page displays.
3. If the Dashboard is fully expanded and is covering the Plate Overview pane, select the System Status circle  once to minimize its configuration.

Chapter 6: Starting and Monitoring a Run

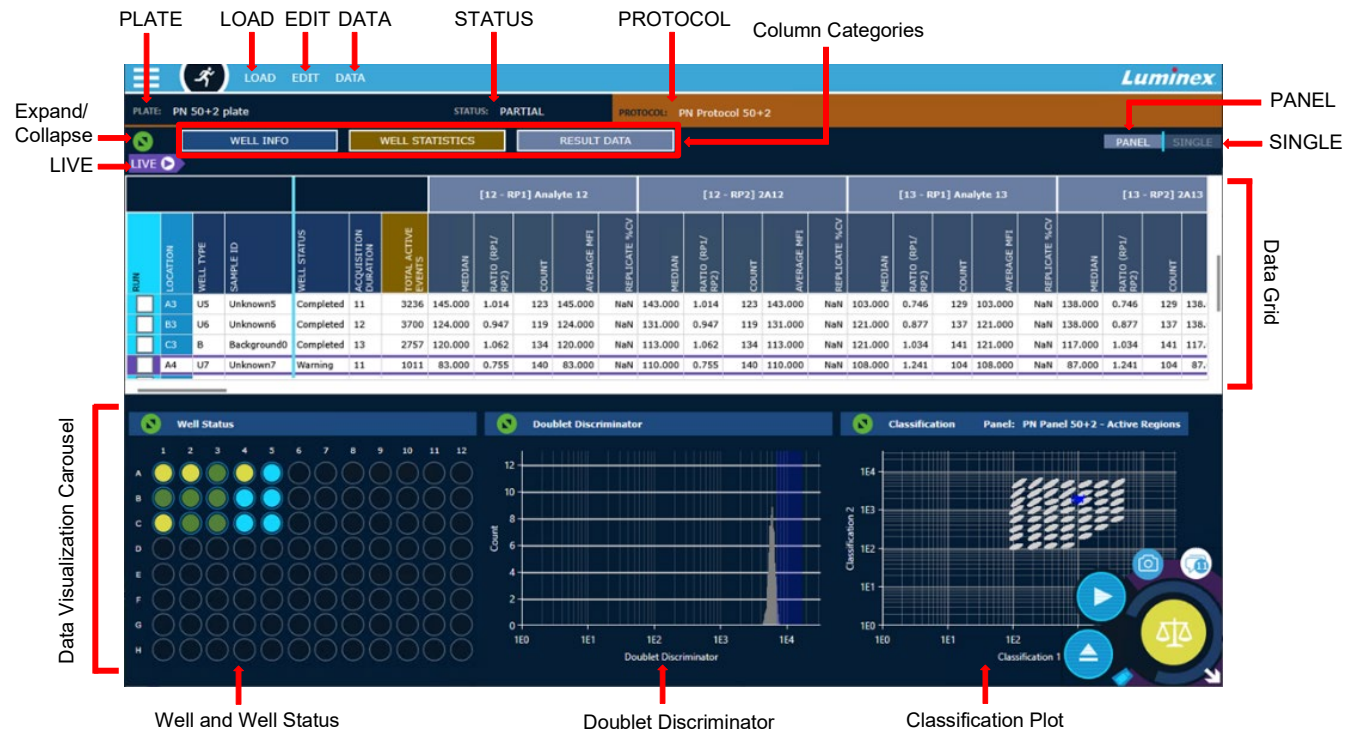
Software Navigation

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 well for each well that has not yet been acquired, a green well for each successfully acquired well, a purple well for the well that is currently being read, a yellow well for a warning, and a red well for an error. The wells 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 plot shows the bead map and acquired beads.

Editing, Starting and Monitoring a run is done in Current Run.

Figure 28: Current Run



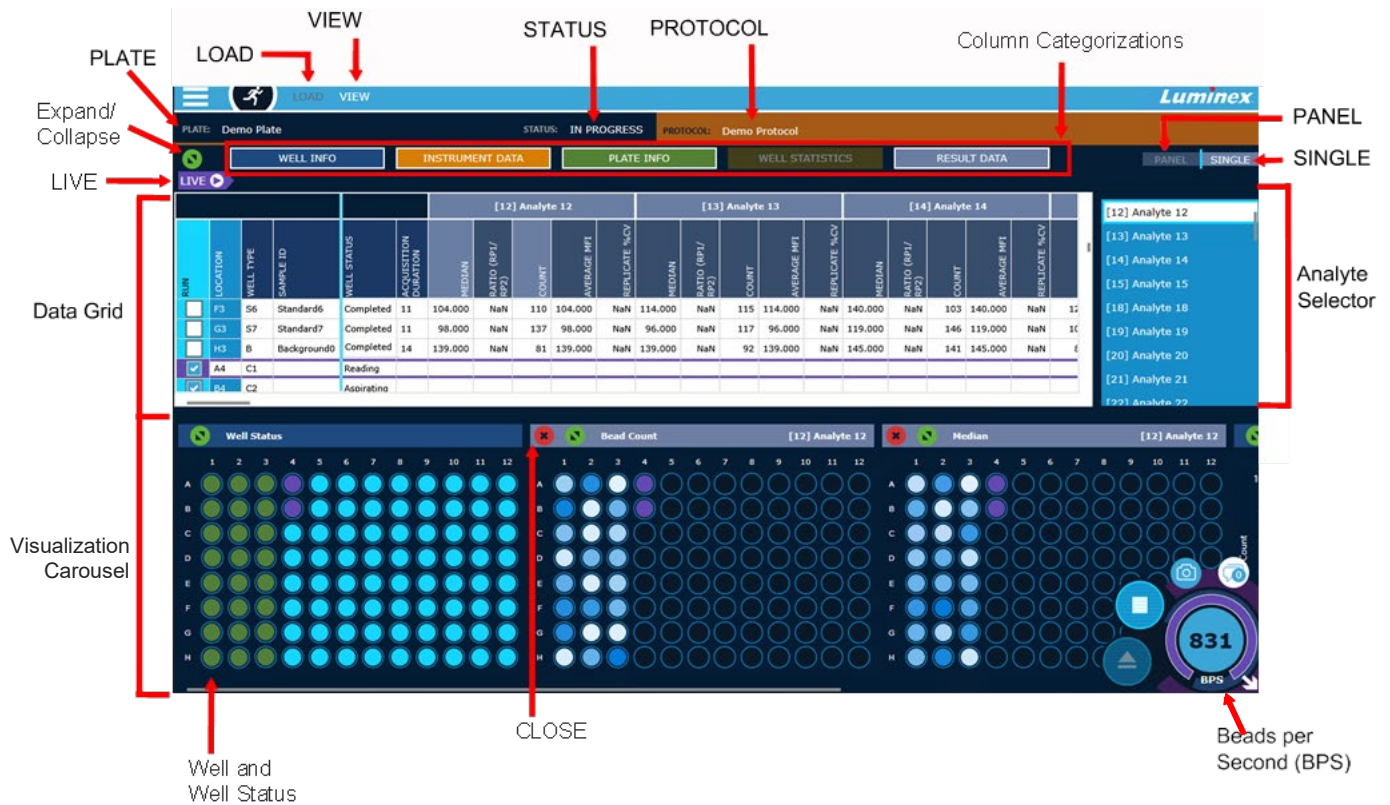


Table 7. Current Run Screen Elements

LOAD	Allows a saved, pre-configured or partial plate to be loaded for a run.
EDIT	Displays the plate editor.
DATA	Allows the selection of the columns that display in the data grid. For more information on available statistics, refer to <i>Appendix A: Available Statistics per Page</i> .
PLATE	Displays the plate name.
STATUS	Displays the status of the current run.
PROTOCOL	Displays the protocol name, if one was defined for the plate.

Expand/Collapse	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 DATA > Columns .
Data Visualization Carousel	Displays the plate well status, heat map visualizations, and histograms.
Doublet Discriminator (Histogram)	Displays the DD gates and bead count data in a histogram.
Classification plot (Dot Plot)	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 Classification plot 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 plot.
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 SINGLE is selected. 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	<p>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.</p> <p>NOTE: When in SINGLE mode, select a grid column header to display the heat map for the data statistic.</p>
Well	<p>Select a well to view data for that well.</p>
Well Status	<p>Displays information on the well status.</p> <ul style="list-style-type: none"> • Red: Dry well or error • Yellow: Warning • Purple: Aspirating or Reading • Green: Complete • Blue: Pending
Close	<p>Remove a display from view in the data visualization carousel, if needed.</p>
Beads per Second (BPS)	<p>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.</p>

Run the Plate






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

A plate can be loaded in **CURRENT RUN** by selecting **RUN PLATE** from the **PLATE CONFIGURATION** page or by selecting **LOAD > PLATE** and selecting the plate in the **CURRENT RUN** page.

Once the plate is loaded in **CURRENT RUN** you can run the plate or edit the plate prior to running.

1. To modify a plate before running:
 - a. With the plate loaded in **CURRENT RUN**, select **EDIT**. The Plate Editor page displays.
 - b. Make changes to the PLATE NAME, Panel, Acquisition settings, Layout, and Sample List. Refer to *Editing a Partial Plate* for more details.
 - c. Select **SAVE** to save the changes.
2. Optionally, select **EDIT** from the top of the screen to open the plate editor and review the plate settings.
 - a. Select **CANCEL** to close the plate editor without making changes.
3. Confirm the **RUN** check box is selected for all the wells intended to be run.

NOTE: If you do not want to acquire a particular well, clear the **RUN** check box.
4. Select  to eject the plate carrier.
5. Load the plate along with any bulk reagents needed for the selected cleaning routines.
6. Select  to retract the plate carrier.
7. Select  to run the plate.
8. If the instrument is not in its optimal state for results acquisitions, the following warning messages may appear. 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.

NOTE: Lab Lead or Administrator authorization is required to approve the action.

NOTE: The system may occasionally display a sheath pressure warning between well acquisitions. 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*.

9. (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 editing and restarting.
10. After all wells are complete, a message displays stating the plate run completed.

Editing a Partial Plate

If a plate is stopped during an acquisition, the plate will be available for editing in **CURRENT RUN**.

1. Select **EDIT**. The Plate Editor displays.
2. Make changes to the Plate name by updating the **PLATE NAME** field.
3. To edit the Panel, select the **Panel** tab.
 - a. To change the normalization region, select a new normalization region from the **NORMALIZATION REGION** drop-down.
 - b. To select a new pre-defined panel, select the panel from the **PANEL** drop-down.
 - c. To make changes to individual regions (analyte names or minimum bead counts) use the analyte table.
 - d. To add and remove bead regions, use the bead region selector.
4. To edit the Acquisition Settings, select the Acquisition tab.
 - a. Change the **Bead Type**, **DD Min** and **DD Max** values as required.
NOTE: If you need to make changes to other acquisition parameters, go to PLATE CONFIGURATION, modify the acquisition settings and start a new run.
5. To edit the **Plate Layout**, select **Layout**. Refer to Step 6 to update Sample information.
 - a. To change the sample type for a well, select the well and select the new sample type.
 - b. To create replicates of wells, delete the original well assignment, then copy and paste the original samples into the replicate wells. (Refer to *Define the Layout*.)
 - c. To delete wells that were not acquired, select the wells and select **X (Delete)**.
 - d. To add new wells for acquisition, select the empty wells, then select a sample type.
6. To edit the sample information, select **Sample List**
 - a. Select the **DESCRIPTION** field to update the Sample ID/Description for the well(s).
 - b. Select the **DILUTION** field to update the dilution for the well(s).
7. Once all necessary changes have been made on all tabs (Panel, Acquisition, Layout, Sample List), select **SAVE** to save the changes and start the reanalysis process for any previously acquired wells. The previously acquired wells will be reanalyzed using the updated settings and the un-acquired wells will be available for acquiring with the updated settings.


NOTE: The reanalysis process may take some time to finish depending on the number of wells and other configuration settings. Notification messages may be displayed during the reanalysis process. These messages are displayed in the same manner as the messages displayed during a plate run.

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 changes.


NOTE: If the original plate was run with a predefined named protocol, panel, layout or acquisition settings, the software will ask if you would like to apply the changes to the existing named configuration item. Applying changes to the existing named protocol or configuration item will affect all future plates created with that protocol or item. Changes made to the layout in Current Run apply to the current plate only and are not saved as part of the protocol.

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. If the plate is not already loaded in **CURRENT RUN**, 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 be acquired.

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-acquire previously acquired 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. If the plate heater turns on to maintain the selected temperature, the icon will change from yellow to orange.

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 xMAP INTELLIFLEX .csv file format or as a xMAP INTELLIFLEX .XLSX 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

Results

Figure 29: Results

The screenshot displays the 'Results' page of the xMAP INTELLIFLEX software. The interface features a top navigation bar with tabs for 'INSTRUMENT DATA', 'PLATE INFO', 'WELL INFO', 'WELL STATISTICS', and 'RESULT DATA'. A search bar on the right indicates 'SEARCH BY: Demo' and a date range filter is set to 'DATE TODAY FROM 2021-12-22 TO 2021-12-22'. The main data grid contains 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 data rows show various well results, including standards and analytes, with associated status and numerical values.

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	BACKGROUND
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	A1	S1	Warning	Standard1	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	2133	3301	Analyte 12	134.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	B1	S2	Warning	Standard2	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	2793	2105	Analyte 12	107.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	C1	S3	Completed	Standard3	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	1708	3290	Analyte 12	122.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	D1	S4	Completed	Standard4	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	1523	3434	Analyte 12	120.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	E1	S5	Warning	Standard5	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	3157	3642	Analyte 12	110.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	F1	S6	Warning	Standard6	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	2927	2384	Analyte 12	97.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	G1	S7	Warning	Standard7	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	1071	3132	Analyte 12	110.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	H1	B	Warning	Background0	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	1316	3787	Analyte 12	114.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	A2	S1	Warning	Standard1	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	2231	2374	Analyte 12	100.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	B2	S2	Completed	Standard2	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	3069	2568	Analyte 12	142.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	C2	S3	Completed	Standard3	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	1805	3717	Analyte 12	133.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	D2	S4	Completed	Standard4	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	1155	3040	Analyte 12	109.000	114.667
xMAP® INTELLIFLEX DR-SE	IFLEX000001	Calibrated	Verified	Verified	E2	S5	Warning	Standard5	MicroPlex	xMAP® INTELLIFLEX High Sensitivity	1928	2420	Analyte 12	111.000	114.667

Table 8. Results Screen Elements

ARCHIVE	Displays the plate runs that can be archived. This option 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 XLSX file or an xPONENT format in a CSV file. For more information on available statistics, refer to <i>Appendix A: Available Statistics per Page</i> .
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 <i>Appendix A: Available Statistics per Page</i> .
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.
DATE RANGE	Displays the results selected date range.

History

Figure 30: History

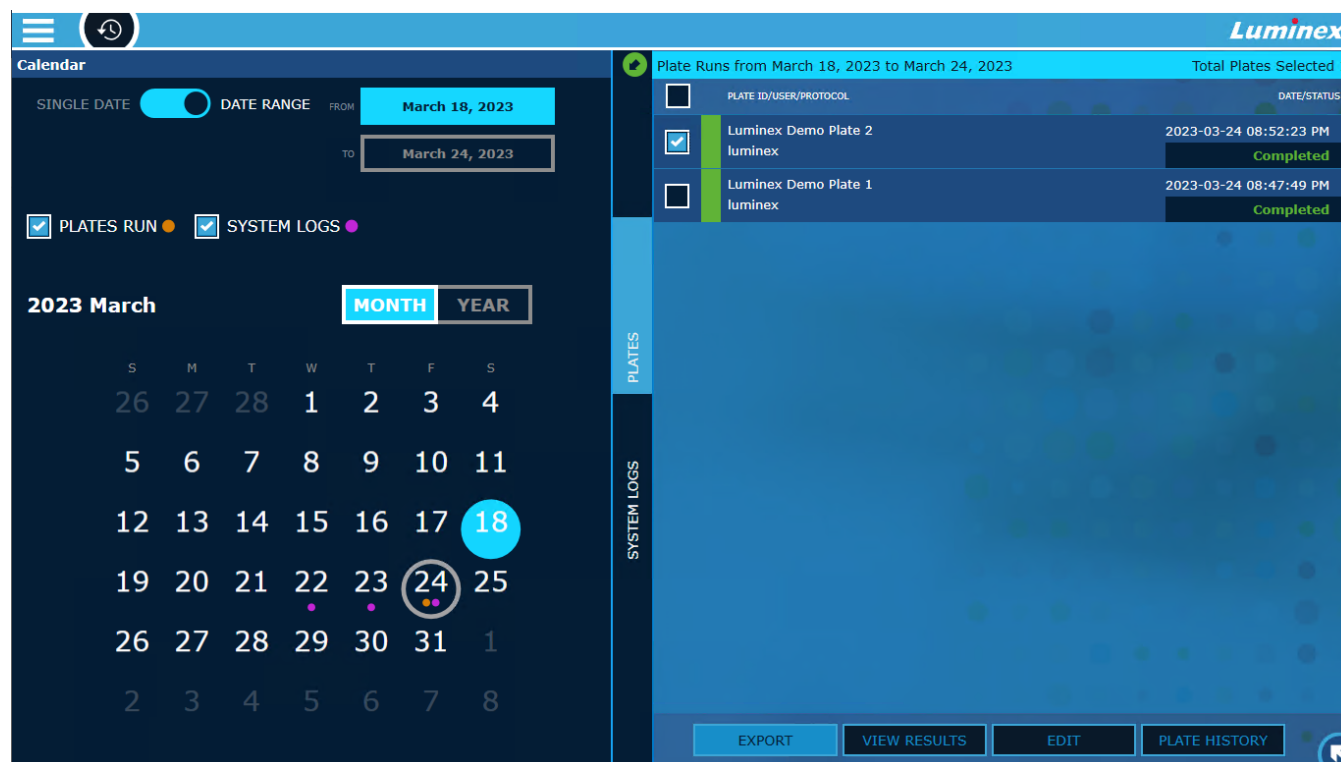


Table 9. History Screen Elements

Calendar	Displays the calendar for selecting a date range. PLATES RUN and SYSTEM LOGS indicator dots are shown under dates where plate runs or system logs are available for display.
SYSTEM LOGS	Displays the System Logs for the dates selected in the calendar. The most recent logs are shown at the top of the list.
PLATES	Displays previously run plates in the selected date range.
EXPORT	Exports results for the selected plate(s).
VIEW RESULTS	Navigates to Results and shows results filtered for the selected plate(s).


EDIT	Displays the plate editor.
PLATE HISTORY	Displays the plate history

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.

View Results in Results Page

To view completed well results in the Results Page:


1. Select  in the upper left-hand corner of the screen and navigate to **RESULTS**.

Well results are displayed based on Filter settings

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. Select the check boxes for the data points you want to include in the exported xMAP INTELLIFLEX files.

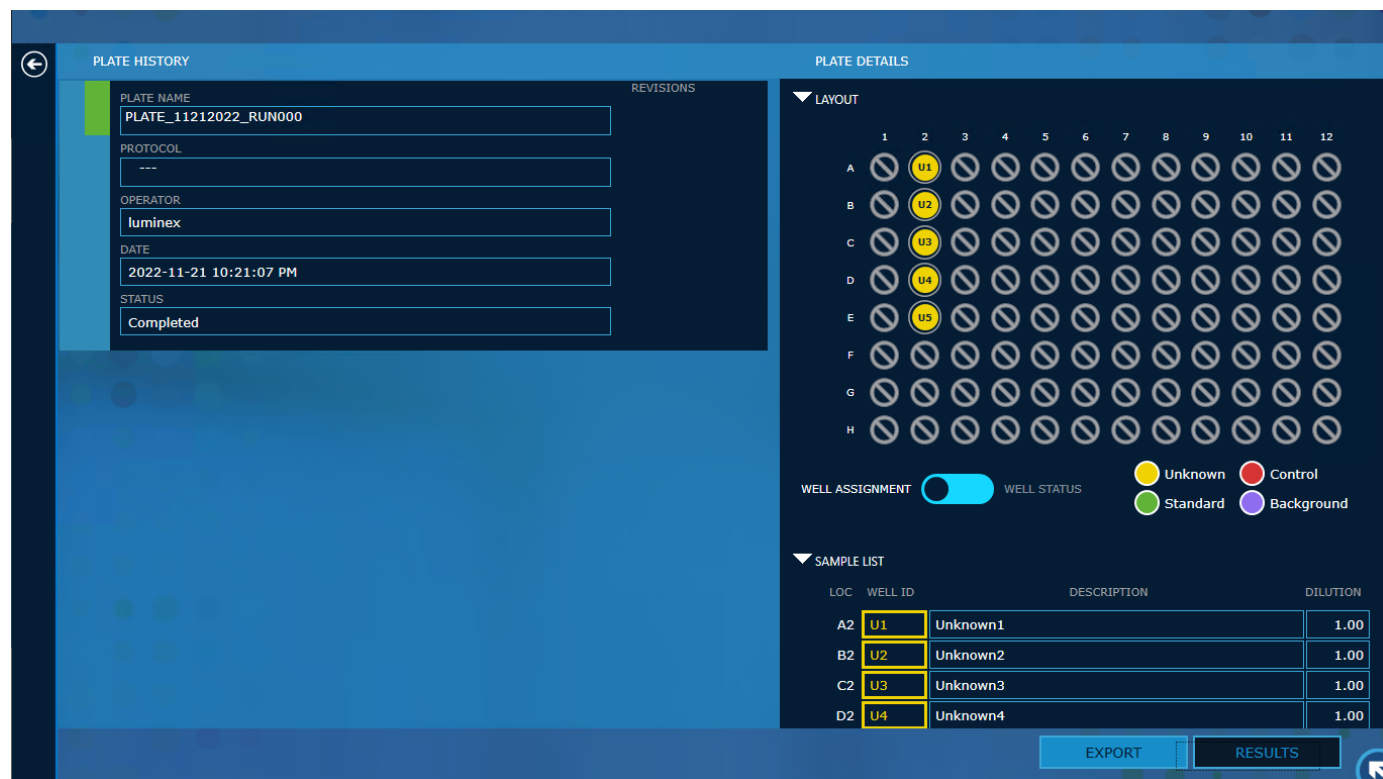
NOTE: The exported content for the xPONENT report type is not customizable, only data points exported in the INTELLIFLEX reports are customized on the Results page.
 - b. Select **APPLY** to apply the changes, or select **CLOSE** if no changes were made.

View Results in History page

To view a previous run:

1. Select  in the upper left-hand corner of the screen and navigate to **HISTORY**.
NOTE: If the calendar does not display, select the green circle from the top left of the screen to expand the calendar.
2. Use the toggle to select either **SINGLE DATE** or **DATE RANGE** and use the calendar to make your selection.
NOTE: To see dates with run data, check the **PLATES RUN** box to display an orange dot on the calendar. Select the **PLATES** tab, if it's not already selected.
3. Select the check box for the plate run(s) to view.
4. Select **VIEW RESULTS**. The results from the selected plate run(s) are displayed in the **RESULTS** page.
Note: See *View Results in Results Page* for more information on reviewing data on the Results page.

View Plate Version History



The screenshot displays the 'PLATE HISTORY' and 'PLATE DETAILS' sections of the software interface.

PLATE HISTORY:

- PLATE NAME: PLATE_11212022_RUN000
- PROTOCOL: ---
- OPERATOR: luminex
- DATE: 2022-11-21 10:21:07 PM
- STATUS: Completed

PLATE DETAILS:

LAYOUT: A 12x8 grid of wells (A-H rows, 1-12 columns). Wells A2, B2, C2, and D2 are highlighted in yellow, indicating they are 'Unknown'.

WELL ASSIGNMENT: **WELL STATUS:**

Legend:


- Yellow circle: Unknown
- Red circle: Control
- Green circle: Standard
- Purple circle: Background

SAMPLE LIST:

LOC	WELL ID	DESCRIPTION	DILUTION
A2	U1	Unknown1	1.00
B2	U2	Unknown2	1.00
C2	U3	Unknown3	1.00
D2	U4	Unknown4	1.00

Buttons: EXPORT, RESULTS

To view the version history of a plate:

1. Select  in the upper left-hand corner of the screen and navigate to **HISTORY**.
NOTE: If the calendar does not display, select the green circle from the top left of the screen to expand the calendar.
2. Use the toggle to select either **SINGLE DATE** or **DATE RANGE** and use the calendar to make your selection.
NOTE: To see dates with run data, check the **PLATES RUN** box to display an orange dot on the calendar.

3. Select the **PLATES** tab, if it's not already selected.
4. Select the check box for the appropriate plate run.
5. Select **PLATE HISTORY**. The plate version history is displayed. For each revision, the area of change is indicated along with the main properties of the plate.
6. Select a version of the plate to view details for that version.

For the selected version of the plate, a summary of all the settings used when that plate was run is shown divided into Layout, Sample List, Panel, and Acquisition. The expander controls can be used to expand or collapse each section.

To view results for that version of the plate, select **RESULTS**. Refer to *Plate Version Results* for details on viewing version result options.

To export results for the selected version of the plate, refer to *Export Plate Version Results from the History Page*.

Plate Version Results

The screenshot shows the 'EXPORT SETTINGS' and 'COLUMNS' tabs at the top. The 'WELL STATISTICS' tab is selected, displaying a table with the following data:

MODEL NAME	INSTRUMENT TYPE	SERIAL NUMBER	PLATE NAME	PLATE START	ACTIVE USER	WELL LOCATION	WELL TYPE	WELL STATUS	SAMPLE ID	PROTOCOL NAME	PROTOCOL VERSION	PANEL NAME
xMAP® INTELLIFLEX DR-SE	INTELLIFLEX	IFLEXP99001001	PLATE_11212022_RUN000	2022-11-21 10:20:15 PM	intelliflex-8\luminex	A2	U1	Warning	Unknown1		0	MagPlex®: 50 MAGP
xMAP® INTELLIFLEX DR-SE	INTELLIFLEX	IFLEXP99001001	PLATE_11212022_RUN000	2022-11-21 10:20:15 PM	intelliflex-8\luminex	B2	U2	Completed	Unknown2		0	MagPlex®: 50 MAGP
xMAP® INTELLIFLEX DR-SE	INTELLIFLEX	IFLEXP99001001	PLATE_11212022_RUN000	2022-11-21 10:20:15 PM	intelliflex-8\luminex	C2	U3	Warning	Unknown3		0	MagPlex®: 50 MAGP
xMAP® INTELLIFLEX DR-SE	INTELLIFLEX	IFLEXP99001001	PLATE_11212022_RUN000	2022-11-21 10:20:15 PM	intelliflex-8\luminex	D2	U4	Warning	Unknown4		0	MagPlex®: 50 MAGP
xMAP® INTELLIFLEX DR-SE	INTELLIFLEX	IFLEXP99001001	PLATE_11212022_RUN000	2022-11-21 10:20:15 PM	intelliflex-8\luminex	E2	U5	Completed	Unknown5		0	MagPlex®: 50 MAGP

Below the table, there are two graphs:

- Doublet Discriminator:** A scatter plot with 'Count' on the y-axis (0 to 10) and 'Doublet Discriminator' on the x-axis (1E0 to 1E4). A single data point is visible at approximately 1E4 on the x-axis.
- Classification:** A scatter plot with 'Classification 2' on the y-axis (1E0 to 1E4) and 'Classification 1' on the x-axis (1E0 to 1E4). A cluster of data points is visible in the upper right quadrant, roughly between 1E2 and 1E3 on both axes.

An 'EXPORT' button is located at the bottom right of the interface.

Table 10. Plate Version Screen Elements

Expand/Collapse	Expand the data grid or histogram and restore 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 INSTRUMENT DATA to hide or view the associated columns. • Select PLATE INFO to hide or view the associated columns. • Select WELL 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.
Data Grid	Displays the well information and results. The columns displayed can be configured in COLUMNS .
Doublet Discriminator (Histogram)	Displays the DD gates and bead count data in a histogram.
Classification Plot (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	Displays the Doublet Discriminator histogram, and the Classification Plot data for the panel.
SINGLE	Displays the Doublet Discriminator histogram, and the Classification Plot data for the selected analyte.
EXPORT	Displays the Export dialog.

After selecting **RESULTS** from the Plate Version History, the results for that version of the plate will be displayed similarly to the **RESULTS** view.

1. Select **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.
2. Select **EXPORT SETTINGS** to edit the statistics exported in the xMAP INTELLIFLEX® reports.
 - a. 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 XLSX

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

- INTELLIFLEX CSV
- INTELLIFLEX XLSX
- xPONENT CSV

The 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 INTELLIFLEX XLSX report type is the same result information that is included in the 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).

The xPONENT CSV report type is similar to the classic xPONENT® file format and is intended to be backwards compatible. The file includes a CRC value that can be used to verify the file content has not been modified after export. This CRC value is also recorded in the system log record when the file is exported.

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.

NOTE: Pending wells (wells not selected for acquisition or wells left over after run was stopped) and dry wells are included in the exported INTELLIFLEX CSV and XLSX files. Pending and dry wells are not included in the xPONENT CSV files.

Export Plate Results from the History Page:

1. Select  in the upper left-hand corner of the screen and navigate to **HISTORY**.

NOTE: If the calendar does not display, select the green circle from the top left of the screen to expand the calendar.
2. Use the toggle to select either **SINGLE DATE** or **DATE RANGE** and use the calendar to make your selection.


NOTE: To 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 USB or network drive location for the report.
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 **XLSX File** or **CSV File**.

NOTE: Statistics exported in the INTELLIFLEX reports are customized on the Results page.

10. Select **EXPORT**. A message displays stating the export results completed successfully.

Export Results from the Results Page:

1. Select  in the upper left-hand corner of the screen and navigate to **RESULTS**.
 - a. To edit the statistics exported in the INTELLIFLEX report, select **EXPORT > SETTINGS** and select the check boxes for the settings you want to include.
 - b. Select **APPLY** to apply the changes.
2. To filter results, select **VIEW > FILTER** to select a date range or enter a plate name. Select **APPLY**.
3. Select **EXPORT > RESULTS**.
4. Select **EXPORT**.
5. Navigate to the desired USB or network drive location for the report.
6. Edit the **File Name**, if necessary, by selecting the field and updating the value.
7. Choose the report type from the **Report Type** drop-down menu.
8. If the INTELLIFLEX report type was selected, select **XLSX File** or **CSV File**.

NOTE: A single xMAP INTELLIFLEX report includes data acquired from all filtered wells. An xPONENT report includes 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 are generated.

9. Select **EXPORT**. A message displays stating the export results completed successfully.

Export Plate Version Results from the History Page

1. Select  in the upper left-hand corner of the screen and navigate to **HISTORY**.

NOTE: If the calendar does not display, select the green circle from the top left of the screen to expand the calendar.

2. Select the **DATE** or **DATE RANGE** to display plates.
3. Select the **PLATES** tab, if it's not already selected.
4. Select the check box for the plate run to view the version history.
5. Select **PLATE HISTORY**. The plate version history is displayed.
6. Select a version of the plate.
7. Select **EXPORT** at the bottom of the page.
8. Navigate to the desired USB or network drive location for the report.

9. Edit the **File Name**, if necessary, by selecting the field and updating the value.
10. Select **INTELLIFLEX** or **xPONENT** from the **Report Type** drop down menu.
11. If the **INTELLIFLEX** report type was selected, select **XLSX File** or **CSV File**.


NOTE: Statistics exported in the INTELLIFLEX reports are customized on the Results page.

12. Select **EXPORT**. A message displays stating the export results completed successfully.

Archive Results

NOTE: Only Administrators can archive results.

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**.

7. Once archiving is complete, a message displays stating the archive completed successfully.

NOTE: Archiving removes all versions of the plate. If the plate was edited multiple times after acquiring data, there will be multiple deletion logs in the system log.

Chapter 8: Editing Results

The xMAP INTELLIFLEX® System history tools provide methods for users to modify previously acquired datasets. By selecting a previously acquired plate, the user can change the acquisition parameters, update the plate layout, mark the plate as completed, and then Save the plate to update the results.

Partial or completed plates can be edited using the plate editor in **HISTORY**. Partial plates can also be edited for reanalysis in **CURRENT RUN**. Refer to *Chapter 6: Starting and Monitoring a Run*.

Software Navigation


Select  in the upper left-hand corner of the screen and navigate to **HISTORY**. Refer to *Managing Results – Software Navigation – History* for details.

Figure 31: Plate Editor in HISTORY

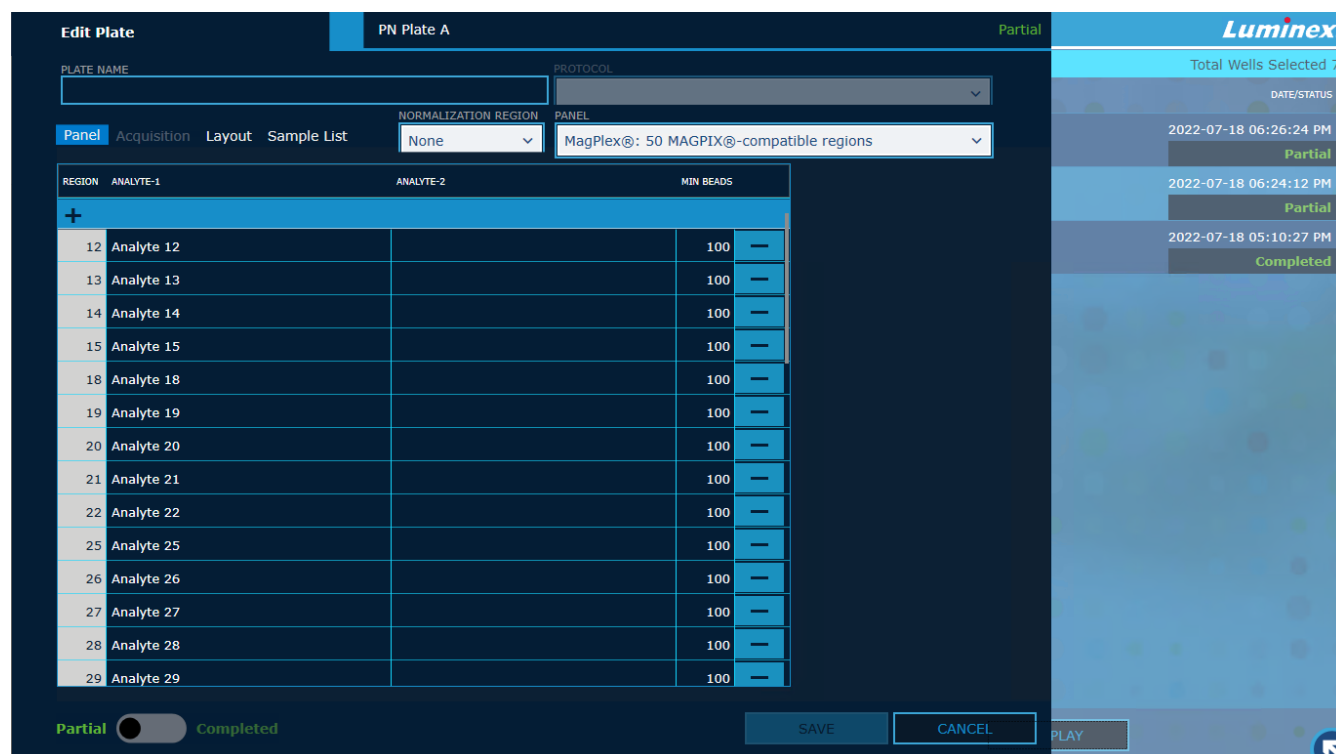


Table 11. Plate Editor Screen Elements

PLATE NAME	Displays the current plate name and can be edited to apply a new plate name.
PROTOCOL	Displays the protocol used to run the plate (if applicable).
PANEL	Displays the Panel editor. You can change the normalization region, select a new panel, or modify the existing panel.
ACQUISITION	Displays the Acquisition settings editor.
LAYOUT	Displays the Layout editor.
SAMPLE LIST	Displays the Sample List editor.
PLATE STATUS TOGGLE	Removes any pending (unacquired) wells and updates the run status to Edited-completed when Save is selected. Plates marked as completed will not appear in the load list of Plate Configuration or Current Run.
SAVE	Selecting the SAVE button starts the reanalysis process with the updated settings.

Edit the Plate for Reanalysis

Partial or completed plates can be edited using the plate editor in **HISTORY**.

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

1. Select  in the upper left-hand corner of the screen and navigate to **HISTORY**.

NOTE: If the calendar does not display, select the green circle from the top left of the screen to expand the calendar.

2. Select the **DATE** or **DATE RANGE** to display plates.
3. Select the **PLATES** tab, if it's not already selected.
4. Select the check box for the plate run to edit.
5. Select **EDIT**. The Plate Editor page displays.
6. Make changes to the Plate name by updating the **PLATE NAME** field,

7. To delete the wells that were not acquired on a Partial Plate, toggle the Plate Status radio button to COMPLETED.
8. Update the Panel, Acquisition settings, Layout, Sample list on the individual tabs (refer to the Edit the Panel, Edit the Acquisition Settings, Edit the Layout, and Edit the Sample List sections below for details).
9. Select **SAVE** to save the changes and start the reanalysis process. The plate will be reanalyzed using the updated settings.

NOTE: The reanalysis process may take some time to finish depending on the number of wells and other configuration settings. Notification messages may be displayed during the reanalysis process. These messages are displayed in the same manner as the messages displayed during a plate run.

10. Select **VIEW RESULTS** to display the updated values in **RESULTS**.

NOTE: If the original plate was run with a predefined protocol, the software will ask if you would like to apply the changes to the existing protocol. Applying changes to the existing protocol will affect all future plates created with that protocol.

Edit the Panel

1. On the Plate Editor, select **Panel**.
2. To change the normalization region, select a new normalization region from the **NORMALIZATION REGION** drop-down.
3. To select a new pre-defined panel, select the panel from the **PANEL** drop-down.
4. To make changes to individual regions (analyte names or minimum bead counts) use the analyte table.
5. To add and remove bead regions, use the bead region selector.
6. Once all necessary changes have been made on all tabs (Panel, Acquisition, Layout, Sample List), select **SAVE** to save the changes and start the reanalysis process.

Edit the Acquisition Settings

1. On the Plate Editor, select **Acquisition**.
2. Change the Bead Type, DD Min and DD Max values as required.
3. Once all necessary changes have been made on all tabs (Panel, Acquisition, Layout, Sample List), select **SAVE** to save the changes and start the reanalysis process.

Edit the Layout

1. On the Plate Editor, select **Layout**.
2. Edit the well assignments, as needed. To change the sample type for the well, select the well and select the new sample type. Refer to *Edit the Sample List* to update Sample information.
3. To create replicates of wells, delete the original well assignment, then copy and paste the original samples into the replicate wells.
4. Once all necessary changes have been made on all tabs (Panel, Acquisition, Layout, Sample List), select **SAVE** to save the changes and start the reanalysis process.

NOTE: Well assignments can be deleted while editing but all acquired wells must be assigned before saving the plate to start the reanalysis process.

Edit the Sample List

1. On the Plate Editor, select **Sample List**.
2. Update the Sample ID/Description and Dilution as needed
 - a. Select the **DESCRIPTION** field to update the Sample ID/Description for the well(s).
 - b. Select the **DILUTION** field to update the dilution for the well(s).
3. Once all necessary changes have been made on all tabs (Panel, Acquisition, Layout, Sample List), select **SAVE** to save the changes and start the reanalysis process.

Viewing Edited Results

Once the reanalysis process is complete, the edited results can be viewed in **RESULTS** with the updated result values and an updated run and well status indicating that the result is from a post-run edit. The updated statuses for wells are Edited-Completed, Edited-Warning, Edited-Failed and Edited-Dry. For plate runs, the updated statuses are Edited-Completed, Edited-Partial, Edited-Aborted, and Edited-Stopped.

Chapter 9: 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 xMAP 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 32: Routines

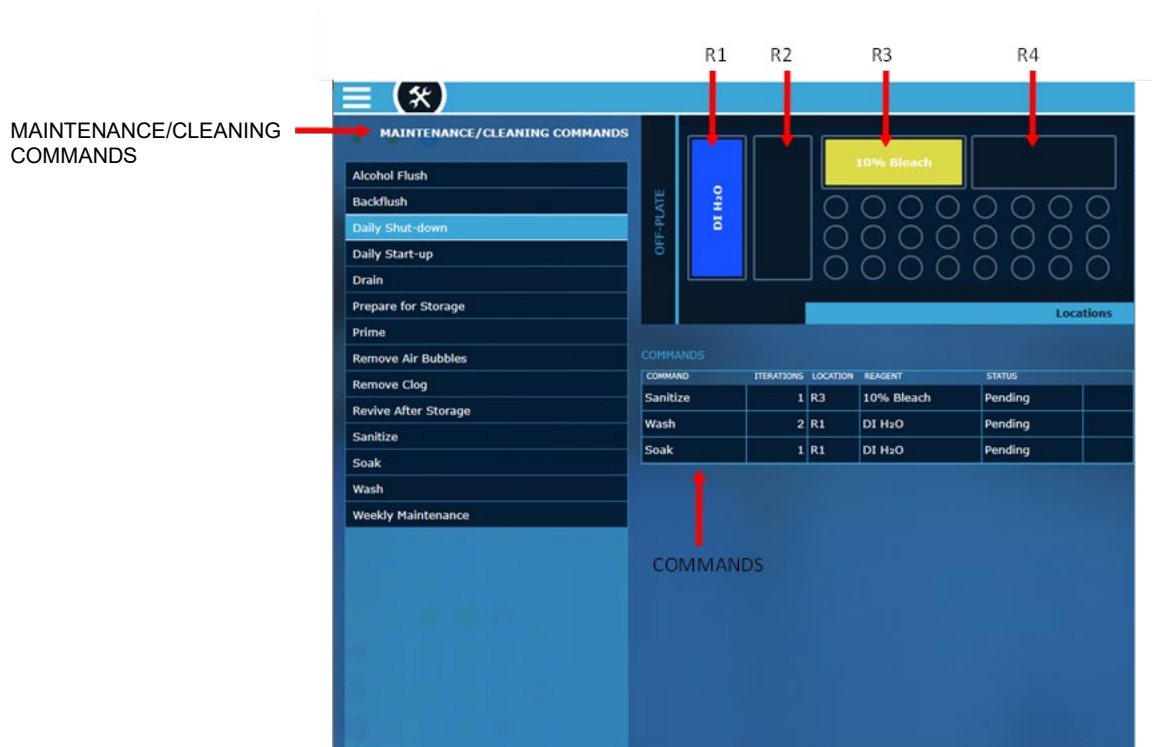


Table 12. Routines Screen Elements

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





Maintenance Commands and Routines

Table 13. Maintenance Commands and Routines

Alcohol Flush	Removes air bubbles from the sample tubing and the cuvette using 70% isopropanol or 70% ethanol. The system uses at least 400 µL of reagent. The Alcohol Flush command takes about 5 minutes.
Backflush	Removes obstructions from the fluidics pathways by drawing Sheath Fluid PLUS from the Sheath Fluid PLUS container. The system uses at least 1000 µL of Sheath Fluid PLUS. The Backflush command takes approximately 1 minute 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.
Daily Start-up	Prepares system fluidics. Luminex recommends running 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.
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.
Prepare for Storage	Prepares and cleans the system for storage. Luminex recommends running 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.
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 500 µL of Sheath Fluid PLUS. The Prime command takes less than a minute to complete.
Remove Air Bubbles	Removes air bubbles in the system. Luminex recommends running 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 running 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.
Revive After Storage	Prepares system fluidics after storage. Luminex recommends running 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.
Sanitize	<p>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.</p> <p>NOTE: 10% bleach is defined as 0.6% to 0.8% sodium hypochlorite. Additives, such as poly(diallyl dimethylammonium chloride), can lead to build-up causing high background</p>
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.
Stringent Clean	Removes severe clogs in the system. Luminex recommends to running the routine when there are indications of clogs, including slower acquisition rates and slower acquisition of data and running Remove Clog did not resolve the issue. It takes approximately 40 minutes to complete.
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 200 µL of DI water. The Wash command takes less than a minute to complete.
Weekly Maintenance	Prepares system fluidics in supplement to the Daily Start-up or Daily Shut-down routines. Luminex recommends running 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 Verification 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 (diallyl dimethyl-ammonium 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.

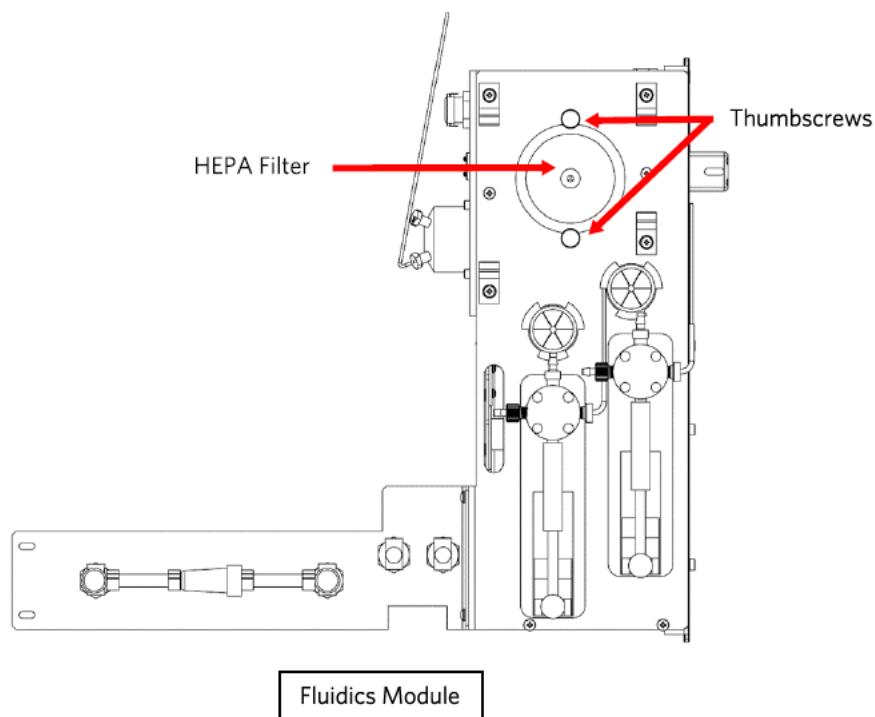


Do not allow the tubing to fall inside the system.

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

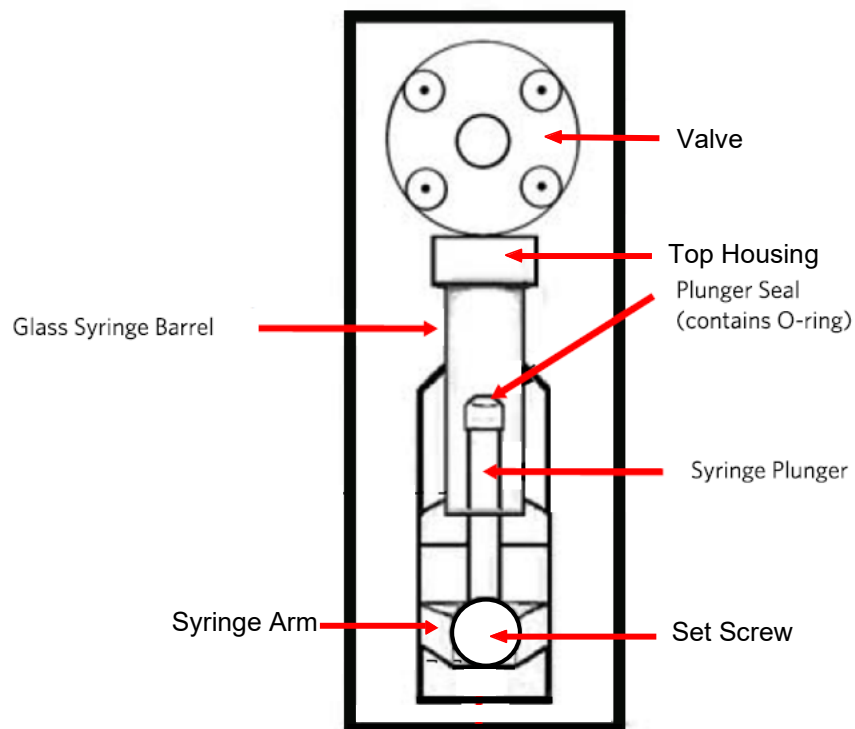
To replace each syringe:

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 Field Service Engineer.

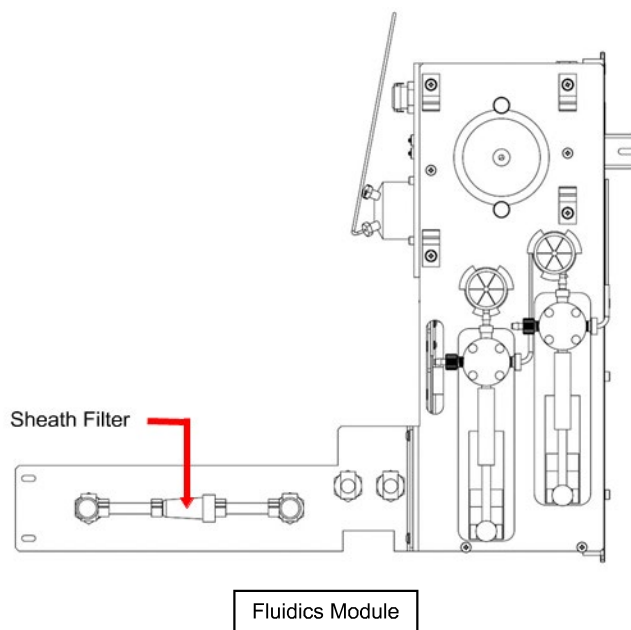
As Needed Maintenance

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.

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

Day of the Month	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				
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																																	

Replace sheath filter

Yes No If Yes, Date: _____

Replace sheath filter

Yes No If Yes, Date: _____

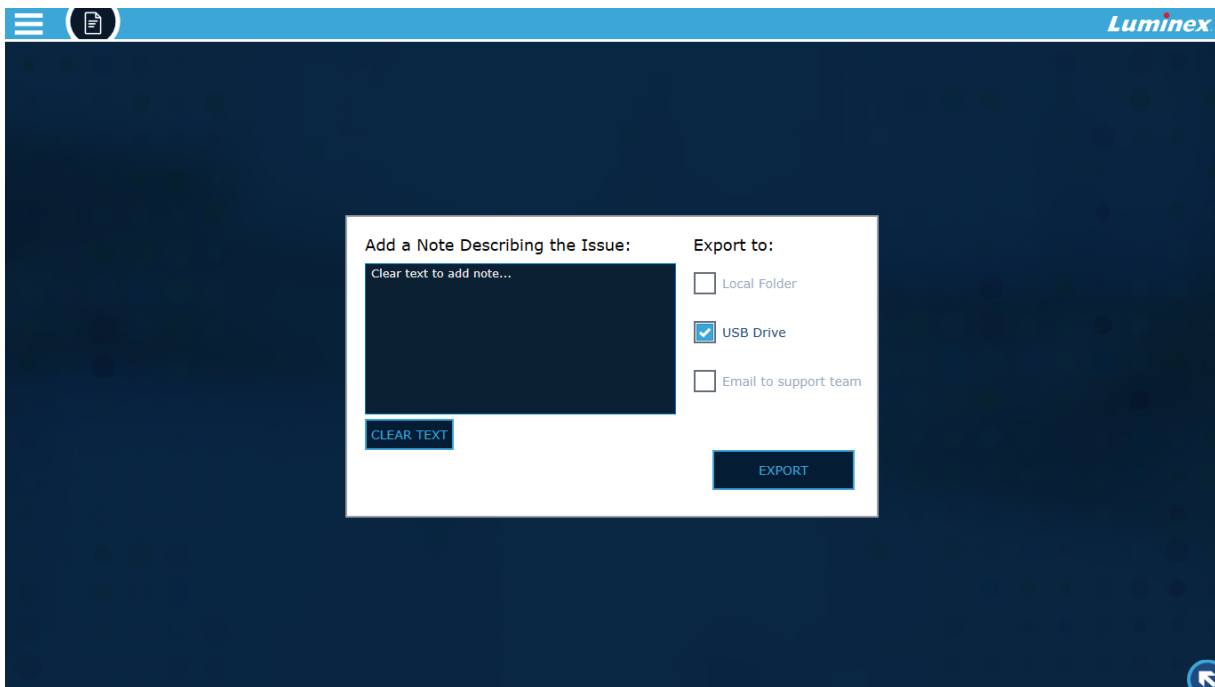
Chapter 10: Troubleshooting

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 33: SETTINGS > SUPPORT ZIP




From the **HISTORY** you can view and export the system logs.

Figure 34: HISTORY


TIME STAMP	USER	DESCRIPTION
2021-12-16 12:43:58 PM	SYSTEM	Instrument - Property 'Bottom Heate
2021-12-16 12:43:58 PM	SYSTEM	Instrument - Property 'Top Heater S
2021-12-16 12:43:58 PM	SYSTEM	Instrument - Property 'Bottom Heate
2021-12-16 12:43:58 PM	SYSTEM	Instrument - Property 'Top Heater Is
2021-12-16 12:43:58 PM	SYSTEM	Instrument - Property 'IC Instrumen
2021-12-16 12:19:47 PM	SYSTEM	Instrument - Property 'Bottom Heate
2021-12-16 12:19:47 PM	SYSTEM	Instrument - Property 'Top Heater Is
2021-12-16 12:19:47 PM	SYSTEM	Instrument - Property 'Top Heater S
2021-12-16 12:19:47 PM	SYSTEM	Instrument - Property 'IC Instrumen
2021-12-16 12:19:47 PM	SYSTEM	Instrument - Property 'Bottom Heate
2021-12-16 11:52:09 AM	SYSTEM	Instrument - Property 'Top Heater Is
2021-12-16 11:52:09 AM	SYSTEM	Instrument - Property 'Bottom Heate
2021-12-16 11:52:09 AM	SYSTEM	Instrument - Property 'Bottom Heate
2021-12-16 11:52:09 AM	SYSTEM	Instrument - Property 'Top Heater S
2021-12-16 11:52:09 AM	SYSTEM	Instrument - Property 'IC Instrumen
2021-12-16 11:41:53 AM	DVS-03-DEC8\Admin	Settings - System setting 'MostRece
2021-12-16 11:41:40 AM	SYSTEM	Instrument - Property '65540' value
2021-12-16 11:41:40 AM	SYSTEM	Instrument - Property 'IC Instrumen
2021-12-16 11:41:40 AM	SYSTEM	Instrument - Property 'IC Instrumen
2021-12-16 11:41:40 AM	DVS-03-DEC8\Admin	Settings - System setting 'MostRece
2021-12-16 11:41:40 AM	SYSTEM	Instrument - Property 'Top Heater Is

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**.


View System 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.

NOTE: Hide the Calendar by selecting  to view the system log in the full screen.

4. If new logs are recorded while you are viewing the page, a refresh bar will appear at the top of the log window. Select this bar to view the new log messages.

Export System 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 desired USB or network drive 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.

NOTE: If the date range selected with result in a file that is too big to export, the message will indicate that a shorter date range should be selected in order to export the system log report.

Calibration/Performance Verification Failures

Calibration Failure

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

Table 14. 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.

Problem	Corrective Action
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 <i>Troubleshooting > Clogs</i> .
The probe fitting is loose.	Tighten the probe fitting.
Other Possible Causes:	
There is a partial clog in the instrument.	Refer to <i>Troubleshooting > Clogs</i> .
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 15. 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.
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.

Problem	Corrective Action
The sample probe is clogged.	Refer to topic <i>Troubleshooting > Clogs</i> .
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 16. 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 Luminex Technical Support.

Fluid Leaks

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

Table 17. 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 <i>Troubleshooting > Clogs</i> .
	The sample path is clogged.	Refer to topic <i>Troubleshooting > Clogs</i> .
	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.

Problem	Possible Cause	Corrective Action
	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 18. 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 and acquisition failure.

Table 19. 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


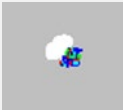
Use these tools to assist in diagnosing instrument and assay-related problems:

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

Review calibration/verification reports routinely to detect trends.

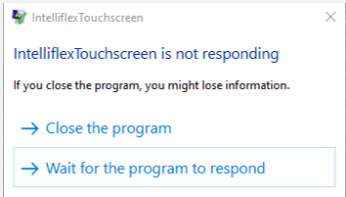
Use verifier xMAP® microspheres (from the performance verification kit) to check the success of the system calibration and for troubleshooting purposes. If there is a problem with your kit results, xMAP verifiers can help determine if the problem is analyzer-related. If calibration and verification are successful, contact the kit manufacturer.

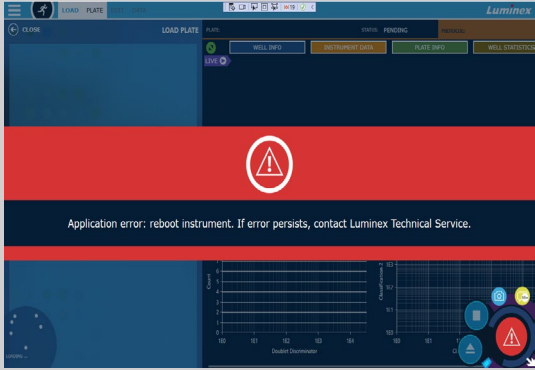
Table 20. Bead Details

Symptom	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.

Application Errors

Table 21. Application Error Problems

Problem	Possible Cause	Corrective Action
<p>The following error dialog appears on the instrument:</p> 	<p>The User Interface (UI) is busy processing more data than usual.</p>	<p>Stop any user interaction, wait for the application to recover.</p> <p>If the problem persists after stopping user interaction, reboot the instrument.</p> <p>If the problem persists, contact <i>Luminex Technical Support</i>.</p>

Problem	Possible Cause	Corrective Action
<p>The following error message appears on the instrument:</p> 	<p>The User Interface (UI) is having temporary connectivity issues with the Service layer of the application.</p> <p>The Service layer is busy processing more data than usual and therefore has not communicated back to the User Interface (UI) in a timely fashion.</p>	<p>While this message is being displayed no user interaction is possible. If this screen is only shown for a few seconds, the Instrument does not need to be restarted.</p> <p>If this screen is shown for more than a few minutes, reboot the instrument.</p> <p>If the problem persists, contact <i>Lumindex Technical Support</i>.</p>

Customer Orderable Part Numbers

Table 22 Hardware Part Numbers

Product Description	Customer Number
Sample Probe Height Adjustment Kit	CN-0015-01
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
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 *Lumindex Technical Support*.

Table 23. 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 11: Administration and Settings

System Information

The **ABOUT** page displays system model and version information, active licensed features and role of the signed in user. It also provides access to import new Licenses, perform Software Updates, view the Software License Agreement, and create a Windows Backup image.

The screenshot shows the 'System Information' page in the Luminex software interface. The page has a blue header with the Luminex logo and an 'IMPORT LICENSE' button. The main content area is white and contains the following information:

- System:** xMAP INTELLIFLEX® DR-SE
- Version:** 2.0
- Serial Number:** IFLEXP99001001
- Electronic Record Compliance:** Licensed, Expiration: 2099-09-14
- Automation:** Licensed, Expiration: 2099-09-14
- IP Address:** 10.0.0.108
- Machine Name:** intelliflex-8
- Components:**
 - Luminex INTELLIFLEX Bundle 2.0.78
 - Luminex INTELLIFLEX Instrument Control 4.255.589.0
 - Luminex INTELLIFLEX Services 2.0.93.0
 - Luminex INTELLIFLEX Touchscreen 2.0.76.0
 - Firmware Bootloader 0.1.2
 - Firmware Executable Version 2.3.4
 - Firmware Linux Kernel 1.2.3
 - Firmware SD Image 3.4.5
 - Shell N/A
- Copyright:** Copyright © Luminex Corporation 2020-2021
- User Role:** Administrator


At the bottom of the page, there are three action buttons:

- Luminex Software Update
- Luminex Software License Agreement
- Create Windows Backup Image

Create Windows Backup Image

A Windows Backup Image can be created from the **ABOUT** page or using the Command Line. For more information about creating a backup and restoring from a backup, refer to the *xMAP INTELLIFLEX System Administrator Guide*.

To access Create Windows Backup Image from the user interface:

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > ABOUT**.
2. Select **Create Windows Backup Image**.


3. Select the appropriate USB, external or network drive and the desired folder.
4. Press the **Select** button to start the backup process. A message displays indicating the backup is in progress.

Once you are notified that the backup is created, refer to *xMAP INTELLIFLEX System Administrator Guide* for information on restoring from a backup image.

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.



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 24. Configuration Setting Options*
4. Select **APPLY** to save the updated settings.

NOTE: Some settings require the instrument to be restarted before they take effect. Restart the instrument if the indicated in the notification message.

NOTE: Selecting RESET will revert to the previously saved settings.

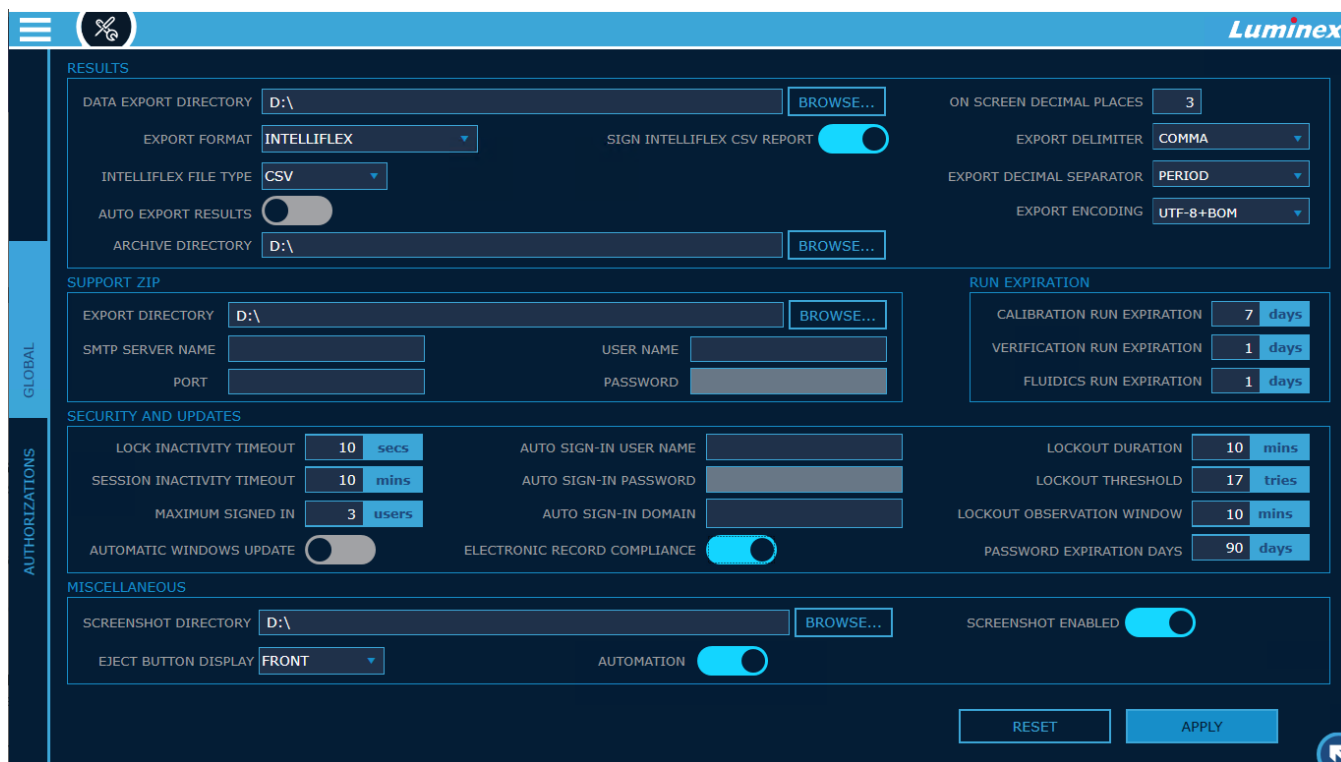


Table 24. Configuration Setting Options

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
RESULTS					
DATA EXPORT DIRECTORY	Indicates the USB or network drive 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	

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
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	
SIGN INTELLIFLEX CSV REPORT	Available when a valid Electronic Records Compliance license is installed and the feature is active. Includes a digital signature when exporting a results report in INTELLIFLEX CSV format.	Enabled	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 (complete or partial) or edit. To enable, toggle the button to the right.	Disabled	x	x	
NETWORK ACCOUNT NETWORK PASSWORD	Only shown if a network drive is entered in DATA EXPORT DIRECTORY and AUTO EXPORT RESULTS is enabled. System restart is required after updating.	<blank>	x	x	
TEST	Only shown if a network drive is entered in DATA EXPORT DIRECTORY. Enabled when a value is entered in NETWORK ACCOUNT and NETWORK PASSWORD. Tests the network credentials provided. Indicates successful if entered credentials have access to the folder set in DATA EXPORT DIRECTORY		x	x	

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
ARCHIVE DIRECTORY	The USB or network drive 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	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	x	x	
EXPORT DELIMITER	The field delimiter character for exported xPONENT and INTELLIFLEX results. Valid options are: COMMA, TAB, SEMICOLON, PIPE, BACKSLASH, FORWARD SLASH, and DASH . To update, select the drop-down menu next to field.	COMMA	x		
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	x	
SUPPORT ZIP					
EXPORT DIRECTORY	The USB location where the support zip will be exported. The USB 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.	'D:\'	x	x	

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
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 email functionality.	<blank>	x		
USER NAME	The user name of the account utilized by the optional support zip email functionality.	<blank>	x		
PASSWORD	The password of the account utilized by the optional support zip email functionality.	<blank>	x		
RUN EXPIRATION					
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	
SECURITY AND UPDATES					
LOCK INACTIVITY TIMEOUT	The number of seconds of inactivity after which the application starts the screen saver at the sign in screen. The valid range is 10-99999 seconds.	10 seconds	x		
SESSION INACTIVITY TIMEOUT	The number of minutes of inactivity after which the application starts the screen saver after a user sign in. The valid range is 0-1666 minutes.	10 minutes	x		

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
MAXIMUM SIGNED IN	The maximum number of users that can be concurrently signed in the instrument. If after a user sign in, the current number of active users exceeds this field, the user with the longest inactivity time will be automatically signed 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. System restart is required after updating.	Disabled	x		
AUTO SIGN-IN USER NAME	The default user name for the auto sign in process. System restart is required after updating.	<blank>	x		
AUTO SIGN-IN PASSWORD	The default password for the auto sign in process. System restart is required after updating.	<blank>	x		
AUTO SIGN-IN DOMAIN	The default domain for the auto sign in process. If you have joined the computer have been joined to a domain, the domain name should be fully qualified (FQDN). System restart is required after updating.	<blank>	x		
ELECTRONIC RECORD COMPLIANCE	Available when a valid Electronic Records Compliance license is installed. Enables or disables all the ERC features: <ul style="list-style-type: none"> • Electronic Signatures • Electronic signatures in System Log • Results in System Log • Digital Signatures on exported files • Inclusion of Sign in/Sign out in System Log 	Enabled when licensed	x		

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
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.	30	x		
LOCKOUT THRESHOLD	The number of failed sign in 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 sign on attempts. If set to 0, it means the account will never be locked out.	0	x		
LOCKOUT OBSERVATION WINDOW	The number of minutes that must elapse after a failed sign in attempt before the failed sign in attempt counter is reset to 0 bad sign in 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.	30	x		
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. Setting to 0 means the password will never expire.	90	x		
MISCELLANEOUS					
SCREENSHOT DIRECTORY	The USB or network drive 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	

Settings Name	Description	Default Value	User Group		
			Administrator	Lab Lead	Operator
SCREENSHOT ENABLED	Indicates whether the screenshot button is displayed in the Dashboard. To enable, toggle the button to the right.	Enabled	x	x	
EJECT BUTTON DISPLAY	Available on DR-SE model instruments only. Select SIDE from the drop-down menu to display the side eject button. Select FRONT from the drop-down menu to display the front eject button. Both buttons can be displayed at the same time.	FRONT	x	x	
AUTOMATION	Available when a valid Automation license is installed. Enables and disables access to the Automation API.	Enabled when licensed.	x	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.


Refer to the *xMAP INTELLIFLEX System Administrator Guide* for information on managing domain level user accounts.

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


Create a Local User

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT**.
NOTE: If already on USER MANAGEMENT select **REFRESH** to deselect the user.
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.
NOTE: the user will be required to change their password on sign in.
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.
NOTE: the user will be required to change their password on sign in.
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**.
4. Select **Yes** to confirm.


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 12: Electronic Records Compliance

Refer to *Configure Settings* for instructions on disabling and enabling the licensed feature. Additional information on how the software supports Electronic Records Compliance can be found in the following documents:

- *xMAP INTELLIFLEX Compliance Matrix- 21 CFR Part 11*
- *xMAP INTELLIFLEX Compliance Matrix- Annex 11*

Obtain and Install License

Get License File

The xMAP INTELLIFLEX® System imports a license file from a USB or a defined network location. The license file is provided by Luminex and is specific for a particular instrument. Contact *Luminex Technical Support* for more information.

Install License File

Once you have the license file on a USB that is inserted into the system or in a defined network location accessible to the xMAP INTELLIFLEX System, follow the steps to install the license on the system.


1. Navigate to **SETTINGS > ABOUT**.
2. Select **IMPORT LICENSE** from the top of the screen.
3. In the Import dialog box, choose the license file (.iflx) to import, then select **Import**. A message displays stating the license imported successfully and a system restart is required.
4. Restart the instrument to finish installing the license.

NOTE: The Electronic Records Compliance features are enabled by default when the license file is imported. If you wish to disable the feature, you can do so in **SETTINGS > CONFIGURATION**.

Electronic Signatures

Manage Electronic Signatures

When the Electronic Records Compliance feature is licensed and enabled, the **SIGNATURES/AUTHORIZATIONS** tab provides a mechanism to configure which actions require electronic signatures. To configure electronic signatures,

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > CONFIGURATION**.
2. Select **SIGNATURES/AUTHORIZATIONS** on the left navigation bar, if it is not already selected.
3. To enable Electronic Signatures for any action, select the checkbox. A message displays stating the setting was successfully applied. The action is recorded in the System Log.



Applying Electronic Signatures

When initiating an action that has electronic signatures active, an electronic signature dialog box will appear. The dialog box requires password authorization and a comment to sign the action. A default comment is provided that you can update with more specific information.

If your role is Operator, for actions that the Operator role is not authorized to perform, an authorized user must enter the password and comment to authorize the action and to record the electronic signature.

Viewing Electronic Signatures

Electronic signatures (including comments) are recorded in the **System Log**. To View and Export System Logs, refer to *Chapter 10: Troubleshooting View System Logs and Export System Logs*.

Electronic Signatures related to results are also available in the INTELLIFLEX XLS format results file for actions associated with the exported results.

- Electronic signatures for **Saving Plates, Protocols, Plate Layouts, Acquisition Settings** and **Panels** associated with a plate can be found in the **Plate History, Protocol History, Plate Layout History, Acquisition History** and **Panel History** tabs of the INTELLIFLEX XLSX format results file.
- Electronic signatures for Calibration and Verification runs related to a plate can be found in the **Calibration Details** and **Verification Details** tabs of the INTELLIFLEX XLSX format results file.

- Electronic signatures for running a plate or reanalyzing a plate can be found in the **Plate Run Details** tab of the INTELLIFLEX XLSX format results file.

System Log Additions for Electronic Records Compliance

When the Electronic Records Compliance feature is licensed and enabled, the **SYSTEM LOGS** will contain additional information.

System Logs

System log entries are recorded for the following actions in addition to the standard system log entries:

- Electronic Signatures
- User Sign In and Sign Out (including failed attempts)
- Failed Authentication or Electronic Signature attempts

To View and Export System Logs, refer to *Chapter 10: Troubleshooting View System Logs and Export System Logs*.

Well Results in System Logs

When the Electronic Records Compliance feature is licensed and enabled, the system log contains well results for each completed well acquisition for the exported date range. For each well, the well results include the **Plate Name**, **Sample ID**, **Well Location** and **Well Type**. For each region in the well, the well results include the **Analyte Name**, **Median**, and **Count**.

To Export System Logs, refer to *Troubleshooting Export System Logs*.

Digital Signatures on Exported Files

When the Electronic Records Compliance feature is licensed and enabled, digital signatures are applied to exported XLSX format files. A valid digital signature indicates that modifications have not been made after the information was exported from the system. The signature is viewable when the file is opened in Excel software.

Calibration and Verification Reports

Digital signatures are applied to the exported calibration, verification, and fluidics history reports. To export Calibration and Verification reports, refer to *Preparing the System – View and Export Calibration or Performance Verification History*.

System Log Report

Digital signatures are applied to the exported **System Log Report**. To export System Logs, refer to *Troubleshooting – Export System Logs*.

Result Reports

Digital signatures are applied to **Result Reports** exported in the xMAP INTELLIFLEX XLSX or CSV format. The digital signature can be turned off for the CSV format files in **SETTINGS > CONFIGURATION**.

To export the results, refer to *Managing Results – Export to CSV or XLSX*.

Verifying Digital Signatures

Opening a digitally signed XLSX format file using Excel software verifies the digital signature. Verification of the digital signature on a CSV format file is not available at this time.

Chapter 13: Automation Features

Refer to *Configure Settings* for instructions on disabling and enabling the licensed feature.

Additional information on using Automation Features can be found in *xMAP INTELLIFLEX Automation Programmer's Reference*.

Obtain and Install Automation License

Get License File

The xMAP INTELLIFLEX® System imports a license file from a USB or a defined network location. The license file is provided by Luminex and is specific for a particular instrument. Contact *Luminex Technical Support* for more information.

Install License File


Once you have the license file on a USB that is inserted into the system or in a defined network location accessible to the xMAP INTELLIFLEX System, follow the steps to install the license on the system.

1. Navigate to **SETTINGS > ABOUT**.
2. Select **IMPORT LICENSE** from the top of the screen.
3. In the Import dialog box, navigate to and choose the license file (.iflx) to import, then select **Import**. A message displays stating the license imported successfully and a system restart is required.
4. Restart the instrument to finish installing the license.

NOTE: The Automation features are enabled by default when the license file is imported. If you wish to disable the automation, you can do so in **SETTINGS > CONFIGURATION**.

Add User to Automation Role

When the Automation feature is licensed and enabled, the User Management tab provides a mechanism to configure which users can access the instrument through the automation interface. To add Automation access for a user:

1. Select  in the upper left-hand corner of the screen and navigate to **SETTINGS > USER MANAGEMENT**.
2. Select a User from the list of users.
3. Select the Enable Automation checkbox.

4. Select **SAVE**.





System Log Additions for Automation

When the Automation feature is licensed and enabled, the **SYSTEM LOGS** will contain the source IP address for requests not originating from the instrument.

Chapter 14: 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 (diallyl dimethylammonium 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 15: 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 (diallyl dimethylammonium 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 (diallyl dimethylammonium 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 (diallyl dimethylammonium 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 (diallyl dimethylammonium 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

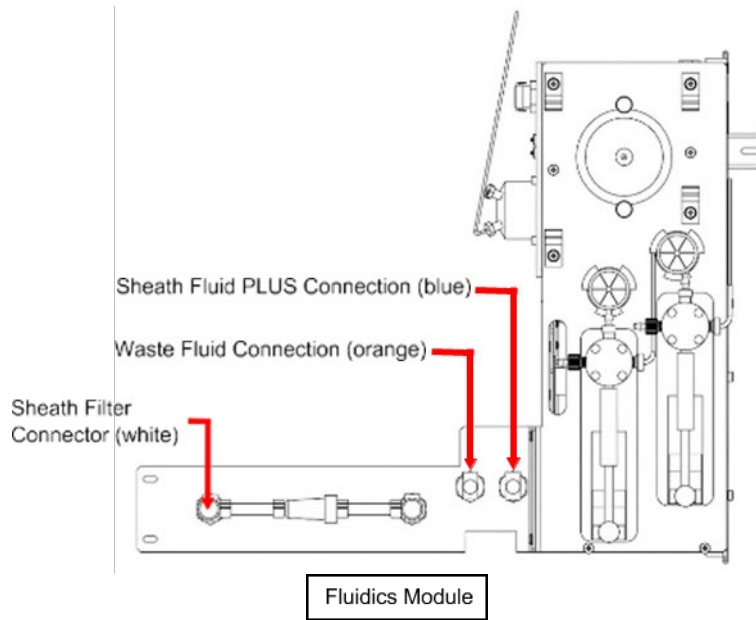


Handle waste disposal in accordance with accepted medical practice and applicable regulations. If spillage occurs immediately, disinfect following appropriate laboratory procedures

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



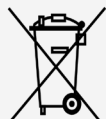
Shipment Checklist

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, Edited-Completed, Edited-Warning, Edited-Failed, Edited-Dry	X	X	X
Sample ID	User provided Sample ID/Description	X	X	X
Dilution	Dilution value entered by user (Not Applied to MFI values)	X	X	X
Protocol Name	Protocol Name used for acquisition (includes version)		X	X
Protocol Version	Protocol Version used for acquisition		X	X
Panel Name	Panel Name used for acquisition (includes version)		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

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
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) For Edited plates the value will be the reanalysis duration.	X	X	X
Well Acquisition Start	Most recent physical acquisition start time for a well		X	X
Well Acquisition End	Most recent physical acquisition end time for a well		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
Serial Number	Instrument serial number.		X	X
Software Version	Any applicable software/firmware version number(s)		X	X

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Calibration State	Calibration Status at the time the plate was run. “Calibrated” – valid calibration “Not Calibrated” – invalid calibration “Overdue” – calibration is passed valid date “Lot Expired” – calibration was run with expired reagents	X	X	X
Calibration Lot	Calibration reagent lot number	X	X	X
Calibration Lot Expiration	Calibration reagent lot expiration date	X	X	X
Calibration Lot Expired	Calibration reagent lot expiration status at the time the calibration run was performed. TRUE (expired) or FALSE (not expired)	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	Verification Status at the time the plate was run. “Verified” – valid verification “Not Verified” – invalid verification “Overdue” – verification is passed valid date “Lot Expired” – verification was run with expired reagent	X	X	X
Verification Lot	Verification reagent lot number	X	X	X
Verification Lot Expiration	Verification reagent log expiration date	X	X	X
Verification Lot Expired	Expiration status of the verification reagent lot at the time the verification run was performed. TRUE (expired) or FALSE (not expired)	X	X	X

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
Verification Timestamp	Date/time of completion of the most recent verification attempt prior to the well-acquisition	X	X	X
Fluidics Ver State	Fluidics Verification Status at the time the plate was run. “Verified” – valid verification “Not Verified” – invalid verification “Overdue” – verification is passed valid date “Lot Expired” – verification was run with expired reagent	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 reagent lot number	X	X	X
Fluidics 1 Ver Lot Expiration	Fluidics 1 verification reagent lot expiration date	X	X	X
Fluidics 1 Ver Lot Expired	Fluidics 1 verification reagent lot expiration status at the time the verification run was performed. TRUE (expired) or FALSE (not expired)	X	X	X
Fluidics 2 Ver Lot	Fluidics 2 verification reagent lot number	X	X	X
Fluidics 2 Ver Lot Expiration	Fluidics 2 verification reagent lot expiration date	X	X	X
Fluidics 2 Ver Lot Expired	Fluidics 2 verification reagent lot expiration status at the time the verification run was performed. TRUE (expired) or FALSE (not expired)	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, Edited-Completed, Edited-Partial, Edited-Aborted, Edited-Stopped, Edit-Initializing, Edit-In Progress		X	X
Plate Start	Time/date of start of acquisition of the 1st acquisition attempt on the 1st well of the plate	X	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 when the plate was run	X	X	X
Authorized User	Username of the user that authorized the run	X	X	X
Signing User	Username of the user that signed the start run action with the Electronic Records Compliance electronic signature enabled	X	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

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
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
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. (Available on DR-SE model only)	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

Name	Description	Current Run	Viewing Results	Exporting INTELLIFLEX format
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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