

Appendix: Luminex® Sheath Delivery System

Specifications

General

- Ambient temperature: 15°C to 30°C (59° to 86°F)
- Humidity: 20% to 80%, noncondensing
- Altitude: designed to operate at up to 2400m (7874 feet) above mean sea level
- Physical dimensions: 20 cm (8 inches) W x 30 cm (11.75 inches) D x 24.75 cm (9.75 inches) H
- Weight: 9 kg (20 lbs)
- UL installation category: UL Installation Category II, as defined in Annex J of UL 3101-1
- Pollution degree: UL Pollution Degree 2, as defined in Section 3.7.3.2 of UL 3101-1

Power

- Input voltage range: 100-240 VAC, 0.4 Amps, 47-63 Hz
- AC inlet fuse: 2 Amp, 250 VAC, Time lag

Intended Use

The Luminex® Sheath Delivery (Luminex SD™) system is designed for use with UL-listed Luminex 100™ or Luminex 100 IS™ analyzer systems. With the Luminex SD system, you can run samples continuously without needing to refill sheath bottles. The Luminex SD automatically draws sheath from a non pressurized bulk sheath container to constantly maintain a reservoir of pressurized sheath fluid. A single 20 liter sheath container provides enough fluid for 48 hours or more of normal operation.

Hardware

The Luminex Sheath Delivery system includes these parts:

- Luminex Sheath Delivery device
- Waste line tubing (orange fitting)
- Sheath fluid line (blue fitting)
- Air line (green fitting)
- Sheath fluid intake line (white fitting)
- Power cord
- Screwdriver



Sheath Fluid Delivery Device

Installation

- ◆ To install the Sheath Delivery system, follow these steps:
1. Start with the original Luminex sheath fluid and waste containers connected to the Luminex 100. Check that the sheath fluid container is filled to just below the air intake valve.
 2. Make sure the Luminex 100 is turned on and start the Luminex Data Collector software.
 3. Calibrate your system.
 4. From the **Analyzer** menu, select **Prime** after the pressure has stabilized. Record the air and sheath pressure, as displayed in the Luminex system monitor.

Air pressure: _____ psi.

Sheath Pressure: _____ psi.

Save this information. You will need it later in the installation procedure, and you will also need to refer to it if you use the Luminex 100 with the original sheath fluid container again.

Note: Do not place the Sheath Delivery System on top of the LX100 Analyzer.

5. At the end of the prime cycle, disconnect the sheath fluid container. Store it in a safe place. If you plan to use the Sheath Delivery system waste line, disconnect the waste container as well.
6. Place the Sheath Delivery system near the sheath fluid connection on the Luminex 100 and make the following connections:
 - Connect the sheath fluid line (blue fitting) to the **Sheath Out** connector on the front of the Sheath Delivery system.
 - Connect the air line (green fitting) to the **Air In** connector on the front of the Sheath Delivery system.
 - Connect the sheath fluid line to the sheath fluid connector on the side of the Luminex 100 (blue fitting).
 - Connect the air line to the air connector on the side of the Luminex 100 (green fitting).
 - If you are using the Sheath Delivery system waste line, connect the waste line tubing to the waste connector on the side of the Luminex 100 (orange fitting). Place the other end of the waste line into an appropriate biohazard receptacle. Cut off excess tubing and make sure the waste receptacle is level with the Luminex 100 or no more than three feet below it.

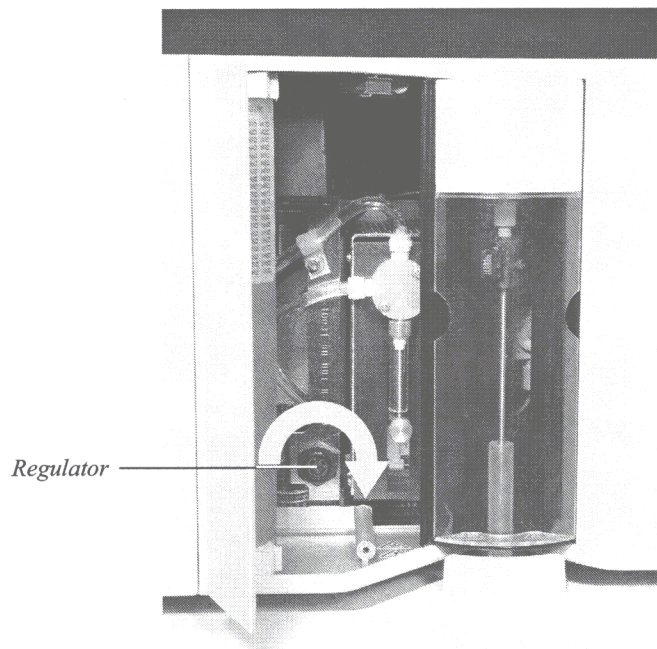
- Connect the sheath fluid intake line (white fitting) to the **Sheath In** connector on the front of the Sheath Delivery system.
- Connect the power cord to the back of the Sheath Delivery system and plug the other end into an approved outlet.

Note: Ensure that the sheath fluid box is at least three feet below the system, otherwise the Sheath Delivery System will overflow.

7. Lower the stainless steel filter end of the sheath fluid line to the bottom of a full box of sheath fluid. Secure the cap on the sheath fluid box. Place the sheath fluid container so that the cap is on the top.

8. Turn on the power to the Sheath Delivery system; the Sheath Delivery system should automatically prime itself. You hear the Sheath Delivery system pump turn on. When the SD reservoir is about 2/3 full, it will automatically stop priming.
9. Open the center access door on the Luminex 100. Use a screwdriver to turn the regulator fully clockwise. This usually takes three to six full turns.

Note: The regulator must be fully opened to work properly. It is important to make sure that you turn it as far as it will go.



10. From the **Analyzer** menu, select **Prime**. During this prime cycle, use a screwdriver to adjust the regulator on the front of the Sheath Delivery system (picture not shown). Adjust it until the sheath pressure displayed on the Luminex system monitor reads the same as the sheath pressure you recorded in step 4. The

system should stabilize at this sheath pressure. The air pressure should be the same as you recorded in step 4, within 0.1 psi.

If the Prime cycle ends before you have completed the adjustment, select **Prime** again and continue to adjust the regulator.

11. Calibrate the system again. Observe the sheath pressure displayed on the system monitor during the calibration cycle. The pressure should be within 0.1 psi of the pressure recorded in Step 4.

Using the Sheath Delivery System

Whenever you turn on the Luminex 100, you should make sure the Luminex Sheath Delivery system is also on. When not powered on, the reservoir in the Luminex Sheath Delivery system can be depleted but it will not refill. This could result in air being introduced into the Luminex 100. You can leave the Luminex Sheath Delivery system powered on at all times if you wish.

The Sheath Delivery system may be used either with the waste bottle provided with the Luminex 100 or with the waste line provided with the Sheath Delivery system. If you use the waste bottle provided with the Luminex 100, you must continue to monitor and periodically empty it.

Audible Alarm and Fault LED

The Luminex Sheath Delivery system has an audible alarm that sounds to indicate that the bulk sheath fluid container is empty. The red fault light on the front panel flashes as the alarm sounds. When this happens, insert the filtered end of the sheath intake line into a new container of sheath fluid and press the Prime button on the front of the Sheath Delivery system. If the alarm does not go off when you push prime, turn the power off and restart it. The Luminex Sheath Delivery system refills its reservoir and resumes normal operation.

The bulk sheath container may be replaced while using the Luminex 100 without interrupting operation. It is not necessary to prime the Sheath Delivery system if you do this.

Maintenance and Cleaning

Proper maintenance and cleaning of the Luminex Sheath Delivery system should be performed to preserve the instrument's longevity and reliability.

Regularly, as required. Replace the sheath fluid as required.

Weekly. Visually inspect the Luminex Sheath Delivery system and its connections for leaks. If you see a leak, turn off the power to the Luminex Sheath Delivery system and contact Luminex Corporation.

Monthly. Turn off the power to the Luminex Sheath Delivery system. Clean the exterior surfaces by wiping with mild germicidal detergent, followed by a 10% bleach solution. Use glass cleaner and a soft cloth to clean the reservoir window.

Troubleshooting

If the empty bulk sheath fluid container is not replaced and the system continues to operate, the Luminex Sheath Delivery system eventually vents pressure to prevent air from being introduced into the Luminex 100. This may interrupt a sample and prevent further samples from being collected.

Filter. If the filter attached to the sheath intake line becomes clogged from extended use, an alarm will sound even though the bulk sheath container is not empty. If this happens, contact Luminex customer service for a replacement filter.

Malfunction. If the alarm sounds even though the bulk sheath container has fluid and the sheath filter is in good condition, the system is reporting a malfunction. If this happens, please call Luminex customer support.

Draining the Sheath Delivery system reservoir. If you need to ship the Sheath Delivery system back to Luminex Corporation, drain the reservoir before you pack the system. Call customer support for further information.

Contact Information

Toll free customer assistance is available to users in the U.S. and Canada by calling 1-877-785-BEAD (2323) between the hours of 7:00 a.m. and 7:00 p.m. Central Time, Monday through Friday. Users outside of the U.S. and Canada can call us at +1 512-381-4397 between the hours of 7:00 a.m. and 7:00 p.m. Central Time, Monday through Friday. Inquiries may also be sent by email to support@luminexcorp.com.