



Codonics Safe Label System Installation Scope Summary

Product Overview

The Codonics Safe Label System (“SLS”) is an FDA-cleared Class II medical device (510K K101439) that improves the safety and accuracy of medication preparation and labeling compliance anywhere medications are prepared. The Safe Label System consists of the following components:

1. ***The SLS Point-of-Care Stations*** (“SLS PCS”) - Are embedded devices used by anesthesia providers in operating rooms and other anesthetizing locations to label drugs that are prepared into secondary containers such as syringes and IV bags. The current shipping SLS PCS models are the SLS 550i and SLS 600i.
 - An optional Wi-Fi adapter is available from Codonics that plugs into a USB port on the bottom of the SLS PCS. The Wi-Fi adapter is enabled by a Codonics-issued Feature Key installed on the SLS PCS.
 - When the Wi-Fi adapter is enabled, both the built-in Ethernet port and Wi-Fi can be configured and used concurrently.
 - Other third-party Wi-Fi adapters are not supported.
2. ***The SLS Administration Tool*** (“SLS AT”) - Is a Windows-based application installed and run on a hospital-supplied server or computer, server (or VM) recommended. It is a required component of the Safe Label System. The SLS AT is typically accessed by the pharmacy using a web browser to maintain the drug formulary and safety configuration settings of the SLS PCS devices. It also provides devices status and alerts to the system administrator(s).
 - A barcode scanner is required for learning and verifying drug containers with the SLS AT.
 - Codonics offers a barcode scanner in the SLS AT Accessory Kit.
 - Other third-party USB barcode scanners configured as an HID device, with AIM code support and appropriate barcode symbologies enabled can be used. Hand scanners from Zebra (formerly Motorola), Honeywell, Code and Datalogic have been used successfully with the SLS AT. Codonics does not guarantee the operation of any third-party hand scanner other than the Codonics supplied scanner.
 - The SLS Email Notifier (“SLS EN”) is a Windows-based application that runs as a background service without a UI. The SLS EN is installed and runs on a hospital-supplied server or computer. It can be run on the same computer or server hosting the SLS AT. The SLS EN is an optional application that monitors the status and user events of the SLS PCS devices connected to the network and generates emails to specified users or groups with notifications that require attention.



Implementation Requirements

1. **The SLS Point-of-Care Stations** (“SLS PCS”) - Requires an electrical power port (emergency power port recommended) and a network connection (ethernet or Wi-Fi). The SLS PCS cannot be plugged into the Mira Care Station for power or network connectivity. are the SLS 550i and SLS 600i.
2. **The SLS Administration Tool** (“SLS AT”) - Requires a is a Windows-based computer or server. Most sites install the SLS AT on a VM. It is recommended that the application suite not be installed on a VM with other devices as the SLS AT and other applications have not been tested together to ensure that there are no conflicts or issues. System requirements are below:

Minimum Configuration		Recommended Configuration	
Processor	Core i7-4790K / Xeon E3-1286 v3 or faster.	Processor	Core i7-11700K / Xeon E-2336 or faster.
RAM	6 GB	RAM	8 GB
Application Disk Space	10 GB	Application Disk Space	100 GB

Note:

- For best performance, use a locally attached SSD or high-speed RAID for hosting the SLS AT data directory.
- A processor with at least four cores is recommended in hosting systems.
- When running more than one instance of the SLS AT on the same hosting system, increase the system RAM by at least 3 GB for each additional instance.
- The hardware configurations shown are sufficient for running the SLS EN (Email Notifier) on the same system hosting the SLS AT.

Remote Access

Remote access is not required by Codonics. Remote access is recommended to simplify the installation and provide a better support experience. Codonics offers SecureLink as our preferred method of remote access but will use customer specific VPNs, etc. as requested. Alternatively Codonics can use video conferencing applications (Zoom, Teams, GoToMeeting, etc.) as need for screen sharing.



Requirements for Integration with the Mira Care Station

The network interface and communication protocol on SLS PCS devices that is used by the SLS AT and SLS EN is also designed to be used by third-party devices to achieve integration with SLS PCS devices. This interface is called the SLS SNET interface. The Mira Care station supports SLS SNET integration with Codonics SLS PCS when using software version xxxx on the Mira Care Station. All currently shipping and supported Codonics software versions support the integration functionality.

When using integration between the SLS PCS and Mira Care Station when a user logs in to the Mira Care Station, the system provides Common Login functionality. With Common Login functionality the cart sends a message to the SLS PCS device logging in the user on the SLS PCS.

Network connectivity requirements for integration of SLS PCS and Mira Care Station

Common Login functionality requires near real-time communication between the paired devices. When a user enters their login credentials on the Mira Care Station they expect to immediately see the login on the SLS as well.

- To ensure this occurs Codonics and Intelligaurd have decided that the only supported configurations for integration of the devices are:
 - both devices connected to the network wirelessly and connected to each other using a direct connect cable.
 - both devices connected to the hospital network using ethernet connections.
- A hybrid system (one device connected using ethernet and one device connected wirelessly) or both devices connected wirelessly without a direct connect cable are not supported.
 - a. In real-world testing these two configurations were not reliable enough for near real-time communications due to wi-fi latency.
 - b. Systems connected in unsupported fashion demonstrated delays in login or scans as well as occasional inability to communicate. These problems were reported inconsistently within facilities and were demonstrated to be related to network usage, distance from an access point, latency, etc.

Codonics Technical Support

- The answers to many IT and implementation questions can be found in the Safe Label System IT Resource Guide available at the Codonics web site at: https://radiology.codonics.com/images/email/US_web/900-653-016.03.pdf
- Codonics Technical Support is available 24 / 7. Codonics “800 Number” is staffed from 8:30 to 5:30 Eastern, Monday through Friday and the technical support paging system is available at all other times. To contact Codonics technical support please call (800) 444-1198 or email the team at Support@Codonics.com.
- Safe Label System Installation questions or concerns may be directed to the installation team at (800) 444-1198 or via email at Installation@Codonics.com.