

Table of Contents

EN - English	10
Components	26
Unpacked Components	27
Front Components	27
<i>Components Inside Front Cover</i>	28
<i>Rear Components</i>	29
<i>Touch Screen Components</i>	30
<i>Wi-Fi Adapter USB Port</i>	31
Hardware Setup	32
<i>Ethernet Cable (Optional)</i>	32
<i>Wi-Fi Adapter (Optional)</i>	33
<i>Power, SmartDrive</i>	33
Startup	35
Loading Media	36
<i>Installing the Ink Cartridge</i>	37
<i>Loading Label Media</i>	38
Login	39
<i>Making a User Badge</i>	40
<i>Logging In</i>	40
Touch Screen User Interface	42
Printing a Syringe Label — Basic Use	43
Printing a Syringe Label — Advanced Operations	46
<i>Matching Container IDs</i>	46
<i>Mapped Master IDs (USA Only)</i>	47

<i>Drug Verification</i>	47
Monitoring Status.....	48
<i>Dashboard Status Information</i>	48
<i>System Information</i>	48
Maintenance.....	49
<i>Displaying the Utilities Screen</i>	49
<i>Clearing a Label Jam</i>	51
Clearing a Label Jam in the Front Media Guide	51
Clearing a Label Jam in the Rear Media Guide.....	52
Installing Update Packages.....	53
Shutdown and Power Off	55
Troubleshooting	55

Safe Label System® Drug Labeling Solution

EN - English

Documentation Notice

This document is part of the EU MDR requirements. The Codonics Safe Label System® Product is a Class I medical devices intended for use by Healthcare Professionals. Product packaging and labeling, including Graphic User Interface (GUI) for operation are offered in English and meet MDR, Annex I, Chapter III, 23.4, taking account the training and the knowledge of the potential user.

Web information, Key Specifications, Intended Use, User Manual Appendices, Quick Start Guide and Setup IFU (Instructions for use) are available in basic translation for Member State Languages. Primary IFU are available in English.

Codonics Products are Class I products intended for use by Healthcare Professionals. Products packaging and labeling, including Graphic User Interface (GUI) for operation are Offered in English and meet MDR, Annex I, Chapter III, 23.4, taking account the training and the knowledge of the potential user.

*Web information, Key Specifications, Intended Use, User manual Appendix, Quick Start Guide & Setup IFU are available in simple translation Member State Languages; primary IFU are available in English

Overview:

Codonics Safe Label System SLS 550i Point of Care Station (PCS) is the standard of care in the world's leading hospitals. An award-winning FDA Class II medical device, the system improves the safety and accuracy of medication management and labeling compliance anywhere medications are prepared. In the OR, SLS integrates with anesthesia medication carts to electronically identify the drug in hand. Visual and audible confirmation based on the NDC of the vial/ampoule provides clinicians with a real-time safety check that acts as a second set of eyes, helping to eliminate the most prevalent medication errors. On demand, SLS produces a ready-to-apply TJC-compliant label that includes a barcode that captures the NDC from the parenteral vial for integration at administration with Epic and Cerner. When used in conjunction with Codonics SLS-WAVE, this process electronically documents the patient record 'hands-free' to improve charge capture, billing accuracy and 340B compliance, creating standardization and enabling BCMA in the OR.

Safe Label System:

Integrates with existing workflows, adding TJC compliance and pharmacy oversight at every location where on-demand medications are prepared, such as the OR, ICU, PACU, patient floors and pharmacy

Provides clinicians with electronic medication safety checks while increasing productivity

Allows hospital-approved drugs, diluents, concentrations, and total dose/total volume preparations to be integrated with worldwide recognized best practices and international standards in a formulary managed by pharmacy and available at the fingertips of anyone preparing medications

Captures the exact NDC of the parenteral vial and carries it to the prepared label to provide 100% accurate documentation for charge capture and 340B accountability

Can be managed remotely including software updates and provides status feedback to specified users via the Administration Tool and Email Notifier (optional)

When used in conjunction with SLS-WAVE, the complete solution enables 'hands-free' integration with Epic and Cerner to maximize revenue, improve patient outcomes and clinician workflow by reducing manual clicks

Improve Patient Safety

Errors in preparation and selection as well as documentation inaccuracies occur for a number of reasons. Multiple distractions, poor handwriting and look-alike /sound-alike drugs greatly contribute to the potential for medication errors. SLS embraces the call to improve patient and medication safety by:

Reduces the most common drug errors made during the selection, preparation and administration of injectable and intravenous medications in the OR, including vial/ampoule swaps, mislabeling/illegible labeling, syringe swaps and expired syringes

Meets the ISMP and APSF recommendations that every anesthetizing location should have a mechanism to identify medications before drawing them up or administering them (barcode reader)

Automatically presents clinicians with visual and audible confirmations of each drug and concentration, incorporating electronic safety checks to remove the element of human error

Specifications

System: Integrated touch screen computer, 2D barcode scanner, color ink jet printer, audio feedback and network capable
(Ethernet standard, Wi-Fi optional)

Power: Universal Input: 100-240 VAC, 50/60 Hz

Dimensions: 10.43 " (26.5 cm) W, 15.67" (39.8 cm) D, 16.50 " (41.9 cm) H

Weight: 14.5 lbs. (6.6kg)

Regulatory: Full medical device compliance including Class 2 FDA and Class I MDR 2017/745/EU (CE), GMP/QSR, ISO 13485:

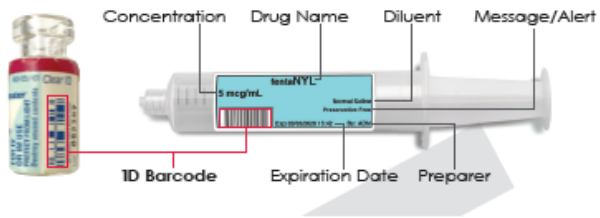
2016/NS-EN ISO 13485:2016, Electrical Safety IEC 60601-1 Ed. 3.1 and EMC/EMI: FCC Class A and IEC 60601-1-2: Ed. 4 for Professional Healthcare Facilities

Readable Barcodes: Code 128, GS1-128, Data Matrix, UPC-A, UPC-E, EAN-13, EAN-8, GS1 DataBar Family, Interleaved 2 of 5, ITF-14, Code 39, Code 32, ISBT 128, QR Code

Writable Barcodes: Data Matrix, EAN-13/UPC-A

Exact NDC matching vial to syringe

Captures NDC of parenteral vial, providing 100% accurate documentation for charge capture and the exact NDC for 340B accountability



Prints full-color labels that comply with The Joint Commission NPSG.03.04.01*, and meet the intent of ISO 26825, ASTM 4774 Standards & ASA Guidelines

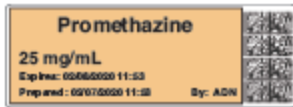
*Prints diluent and dilution if required



Shown with patient information when integrated with EMR/ADC



Shown with auxiliary barcode



60 mm x 22 mm standard size labels



Barcode for EHR/AIMS integration

SLS User Manual

Preface


Conventions Used in This Manual

Bulleted Lists

Bullets are used to display a list of nonprocedural items. For example:
 The following events trigger a synchronization of SLS data to that stored on the SmartDrive:

Automatically every 15 minutes
Formulary updates

Numbered Steps

The  icon indicates the beginning of a procedure. The steps in a procedure are numbered. For example:

- Open the front cover.
- Press the Ink button.

Notes

Notes contain additional information related to a topic or procedure. For example:

NOTE: The system will ensure that a test print is performed at least once a day.

Cautions and Warnings

Cautions alert you to actions or situations that could cause harm to equipment or data.

For example:

Warnings alert you to actions or situations that could result in personal injury. For example:

Important Information and Filenames

Bold type is used for emphasis, user interface object names, and paths or filenames.

For example:

- The Barcode Scanner scans drug container barcodes for identity and verification.
- Use the controls to correct the date and time, then press the OK button.

Purpose and Scope

Refer to this User's Manual for procedures on how to perform Safe Label System (SLS) user operations, including:

- Setting up the hardware and software
- Performing basic functions such as logging in and out, and configuring some System settings (for example, sound volume, brightness)
- Printing and confirming syringe labels
- Checking drug syringes by scanning their barcodes
- Maintaining the system
- Monitoring system status and troubleshooting common problems

Product Information

For technical assistance with SLS Point of Care Station, call Codonics Technical Support at the following number:

Phone: +1 440.243.1198

Toll Free: 800.444.1198 (USA only)

Technical Support is available 24/7/365. Technical Support is also available online via email and the Codonics web site:

Email: support@codonics.com

Web Sites: www.codonics.com

General product information can also be requested by sending email to:

Email: info@codonics.com

Please include your postal mailing address and telephone number in the email message.

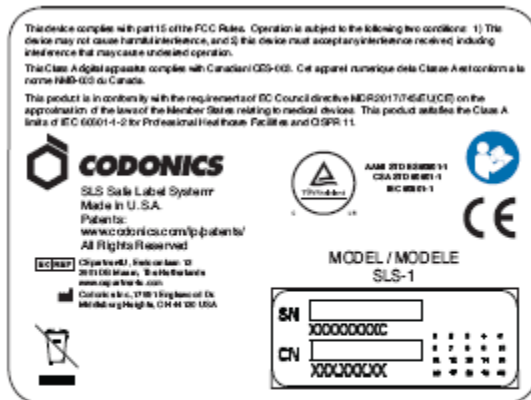
Basic product information is returned via email unless otherwise requested.

Warnings and Limitations of Use

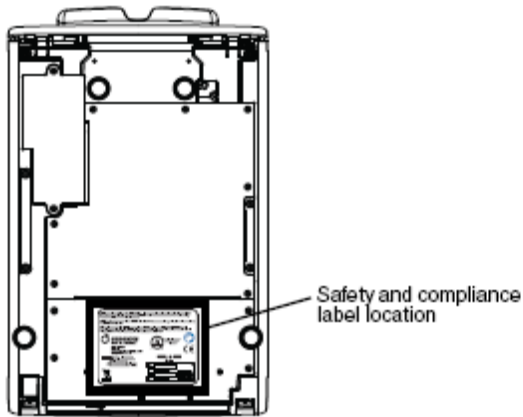
Location of Safety and Compliance Labels

Codonics is in compliance with various regulations.

The SLS PCS safety and compliance label, shown below, is located on the bottom of the device (shown on the following page).



SLS PCS safety and compliance label



SLS PCS safety and compliance label, on bottom of device

Voltage Warning

The exclamation point within a triangle is intended to alert the user to the presence of important operating and maintenance (servicing) instructions in the literature accompanying this device.



REFER SERVICING TO QUALIFIED SERVICE PERSONNEL. REMOVAL OF LABELS, COVERS, OR ENCASMENT FASTENERS MAY VOID THE WARRANTY. THIS APPARATUS MUST BE ELECTRICALLY GROUNDED. TO PREVENT FIRE OR SHOCK HAZARD, DO NOT EXPOSE THIS DEVICE TO RAIN OR MOISTURE.

EQUIPMENT IS NOT TO BE USED AS A COMPONENT OF A LIFE SUPPORT SYSTEM. Life support devices or systems are devices or systems that support or sustain life, and whose failure to perform can be reasonably expected to result in a significant injury or death to a person. A critical component is any component of a life support device or system whose failure to perform can be reasonably expected to cause the failure of the life support device or system, or to affect its safety or effectiveness.

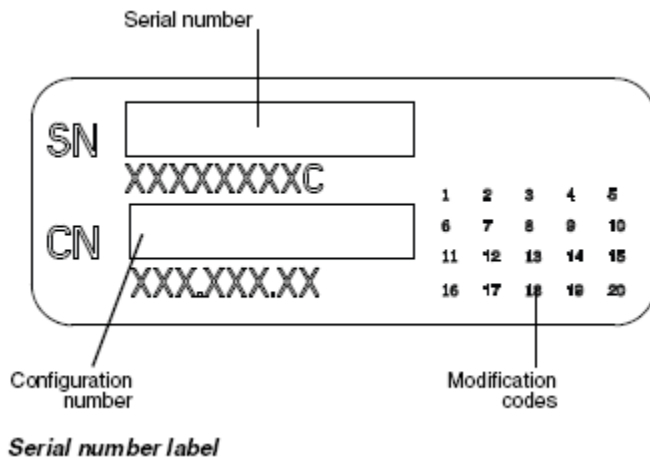
Laser Warning

WARNING This device emits CDRH/IEC Class 2 laser and IEC Class 1M light. Do not stare into beam.

Serial Number, Configuration, Date Code, and Modification Codes

The serial number label is placed onto the safety and compliance label. The serial number label includes the following information:

The serial number (SN), which uniquely identifies the unit.
The configuration number (CN), which details the build configuration.
The modifications codes, which are to the right of the CN number and are a series of 20 numbers. When any of these numbers are blocked out, that identifies a modification that was made to the unit.



Potential for Radio Frequency Interference on Device Operation

Both portable and mobile RF communications equipment can affect medical electrical equipment, including SLS PCS. SLS PCS is intended for use in the electromagnetic environment specified in the guidance and manufacturer's declaration section.

Potential for Radio and Television Interference

SLS PCS generates and uses radio frequency energy, and if not installed and used properly, that is, in strict accordance with the manufacturer's instructions, may cause interference to radio and television reception. It has been type tested and found to comply with Class A emission limits for a computing device in accordance with the specifications in Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against such interference when operating in a commercial environment. SLS PCS is not intended for use in a residential Class A environment. SLS PCS requires a medical power/ground. If your SLS does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- Reorient the receiving antenna
- Relocate SLS PCS with respect to the receiver

If necessary, you should consult Codonics Technical Support or an experienced

radio/television technician for additional suggestions. You may find the following booklet prepared by the Federal Communications Commission helpful: *How to Identify and Resolve Radio-TV Interference Problems*. This booklet is available from the U.S. Government Printing Office, Washington, D.C. 20402, Stock No. 004-000-00345-4.

This product is in conformity with the protection requirements of EC Council directive MDR 2017/745/EU(CE) on the approximation of the laws of the Member States relating to medical devices. This product satisfies the Class A limits of IEC 60601-1-2 for Professional Healthcare Facilities and CISPR 11. A declaration of conformity with the requirements of the Directive has been signed by a Codonics vice president.

Guidance Regarding Electromagnetic Emissions and Immunity

Suitable environments are as follows:

SLS550i is intended for use in hospital and clinical environments including operating rooms and the perioperative environment.

SLS550i has not been evaluated for use near HF surgical equipment. If use near HF surgical equipment is desired, the user is responsible for verifying proper operation of the SLS550i. If SLS550i does not perform correctly in this environment, move the SLS550i farther from the source of the electromagnetic disturbance.

SLS550i has not been evaluated for use in emergency medical vehicles or in residential applications.

NOTE: The radio frequency emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

As a support device, SLS550i does not provide essential performance.

WARNING Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SLS550i, its cables, or accessories. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Emissions Standards and Test Level

Test/Standard	Compliance
RF Emissions CISPR 11	Group 1. Class A
RF Emissions FCC Part 15	Class A
Conducted Emissions CISPR 11	Group 1. Class A
Harmonic Distortion IEC 61000-3-2	Class A
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies

Electromagnetic Immunity Standards and Test Levels

Test/Standard	Compliance
Electrostatic Discharge IEC 61000-4-2	+8 kV contact +2 kV, +4 kV, +8 kV, +-15 kV air
Radiated RF Immunity IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless equipment IEC 61000-4-3	Complies

Test/Standard	Compliance
Electrical Fast Transient/Burst	AC Port: ± 2 kV, 100 kHz repetition frequency
IEC 61000-4-4	SIP/SOP Ports: ± 1 kV, 100 kHz repetition frequency
Surge	Line-to-Line: ± 0.5 kV, ± 1.0 kV
IEC 61000-4-5	Line-to-Ground: ± 0.5 kV, ± 1.0 kV, ± 2.0 kV
Conducted Immunity	AC Port and SIP/SOPs:
IEC 61000-4-6	3 V, 0.15 MHz – 80 MHz 6 V, in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Magnetic Field Immunity	30 A/m, 50 Hz or 60 Hz
IEC 61000-4-8	
Voltage Dips	0% UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
IEC 61000-4-11	0% UT, 1 cycle AND 70% UT, 25/30 cycles, Single phase: at 0°
Voltage Interruptions	0% UT, 250/300 cycle
IEC 61000-4-11	

Safety Precautions

- Never connect the device’s external power supply to any outlet or power supply that has a voltage or frequency different than that specified (100 – 240 VAC, 50/60 Hz). Use only the external power supply provided with the device (Codonics part Number SLS-PS).
- When replacing the device, always power it down (refer to “Powering Off the System”) and disconnect the AC power cord prior to servicing it.
- Damage to a power cord is a fire and shock hazard. When unplugging a power cord, hold it by the plug only and remove the plug carefully.
- If a power cord or external power supply needs to be replaced, replace it only with another Codonics power cord or Codonics external power supply. Alternatively, replace it with a power cord or external power supply manufactured specifically for your power configuration.
- If the device is smoking or making unusual sounds, power off and unplug the device immediately.
- Do not insert foreign objects of any kind into the device; doing so can constitute a safety hazard and cause extensive damage.
- Do not place any liquid containers on the device. If, for some reason, liquid seeps into the device, power off the device and unplug the power cord from the source outlet. If used without taking corrective measures, the device may be damaged.
- Do not expose the device to flammable gases in concentrations high enough to cause fire or explosion.

Location Precautions

- The operating ambient temperature range of SLS PCS is 15–30°C (59–86°F), with a relative humidity of 20%–80%.

- If SLS PCS is moved quickly from an extremely cold location to a warmer one, condensation is likely to form. Do not use SLS PCS if condensation has formed.
- Wait until the condensation has evaporated. You can speed up the evaporation time by moving SLS PCS to a dryer location.
- Do not place SLS PCS in a location with high humidity or high dust. Airborne dirt particles can cause print quality problems. Avoid placing SLS PCS in locations where ventilation ducts, open doors, or frequent passers-by might expose SLS PCS and labels to high levels of debris.
- Do not locate SLS PCS in hot-springs areas where hydrogen sulfide and acidic ions are likely to be generated.
- Do not locate SLS PCS where there are oily fumes and vapors.
- Do not locate SLS PCS in direct sunlight.
- Do not locate SLS PCS near sources of high RF energy.
- Do not locate SLS PCS where it might be subject to jarring or vibrations, such as a table or desk in a high-traffic area. Jarring and vibrations can affect the print quality of labels.
- If using a VESA mount to mount the device on a wall, stand, or anesthesia supply cart, refer to the VESA Mounting Interface Standard (MIS), available at www.vesa.org, for proper location and installation information.

Cleaning Precautions

To avoid damage to the device, observe the following general precautions for cleaning the device:

- Apply the cleaner to a clean, lint-free cloth first and then clean the device.
- Liquid applied directly to the device could possibly leak inside the device and cause damage. Use extra caution when cleaning around the vents on the back of the touchscreen and speaker.
- Allow the device to completely dry before operating it again.
- Many plastic components are used in SLS PCS construction. Coat flecking and deformation is likely to occur if the device is wiped with chemical dusters, benzene, thinners, insecticides, or other solvents. Rubber and PVC materials left in contact with SLS PCS for extended periods of time will cause damage. Never use petroleum-based solutions or abrasive cleansers.
- Never use abrasive material.
- Always dilute cleaning agents according to the manufacturer's instructions, or use the lowest possible concentration.
- Do not allow the cleaning agent to remain on the device surfaces. Wipe it off immediately with a lint-free cloth moistened with water.

For cleaning instructions, refer to "Cleaning the Enclosure".

It is recommended that you disinfect the product only when necessary as determined by your hospital's policy, to avoid long-term damage to the product.

The device must be cleaned first, as described in “Cleaning the Enclosure”, before using a general disinfecting agent.

Cleaning the Enclosure

WARNING Always power off the system before cleaning. An electrical shock could occur if the system is powered on and liquid is spilled into it.

To clean the system’s enclosure, use a clean, lint-free cloth moistened with either warm water and mild soap, a diluted non-caustic detergent, or one of the following approved cleaning agents:

Ammonia: Dilution of Ammonia <3%
Alcohol: Ethanol 70%, Isopropanol 70%.

- **Over time, ink overspray might gather at the base of the device. The device uses a vacuum system to gather most of this ink on a series of saturation pads.**
- **Eventually, these pads might need to be replaced. Contact Codonics Technical Support to determine if pad replacement is necessary.**
- **If ink has gotten onto the system’s enclosure, it can be cleaned with an ammonia based window cleaner and a lint-free cloth.**
- **If scanning barcodes is inconsistent or the device is having difficulty scanning, clean the scanner’s glass window.**

Disinfecting the Enclosure

Recommended disinfecting agents include:

1 part household bleach and 5 parts water solution
A-456-N
Virex II 256
PDI Sani-Cloth®

WARNING Codonics makes no claims regarding the efficacy of the listed chemicals or methods as a means of controlling infection. Consult your hospital’s infection control officer or epidemiologist.

Disinfecting Precautions

To avoid damage to the device, observe the following general precautions for disinfecting the device:

- **Do not use Povodine, Sagrotan, or Mucocit disinfecting agents or strong solvents (for example, acetone).**
- **Do not use any disinfecting agents that corrode or damage polycarbonate.**

Media Precautions

- **Unwanted labels should be destroyed or disposed of to ensure that improper labels are not used.**
- **Only use Codonics ink cartridges and labels to ensure proper operation of the device and proper labeling of syringes. Using unapproved ink cartridges and labels could lead to unacceptable results, including poor print quality and poor label adhesion to syringes.**
- **Damage from unapproved ink or labels will void the warranty.**
- **Never refill ink cartridges, as this can result in incorrect color usage.**

Disposal Requirements

Disposal of this product and consumables shall be in accordance with all applicable laws and regulations in effect at the locality at the time of disposal. For additional information, refer Hazardous Material Information.

European Disposal Requirements

Codonics imagers and electronic accessory devices are not to be discarded or recycled; rather they are to be returned to the manufacturer. Contact Codonics directly or by the link provided for the latest information concerning:

Identification of the country-specific Importer/Distributor/Producer
Product return and treatment of our electronic products

Manufacturer: Codonics Inc.
17991 Englewood Drive
Middleburg Heights, OH 44130 USA
Phone: +1 440.243.1198
Fax: +1 440.243.1334
E-mail: WEEE@codonics.com
www.codonics.com

Codonics electronic products and accessories bearing the following symbol are subject to European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, amended by Directive 2003/108/EC. The EN 50419 symbol indicates separate collection and return required.



EN 50419 symbol

Indications for Use

Device Description

Drug preparation and administration in the perioperative environment are integral aspects of anesthesiologist's patient care responsibilities. The Codonics Safe Label System (SLS) is a simple, integrated system utilizing a barcode scanner to read and confirm drug identity from FDA NDC (National Drug Code) and other drug ID Barcodes from drug containers and automatically print labels for prepared drugs and other items in use on patients during surgical procedures. The labels are compliant with national regulations focused on improving medication safety in the perioperative environment.

The software components provide functions for scanning container barcodes; creating, reviewing, and approving the hospital-managed promotion of a formulary database; displaying on-screen and audibly confirming drug type; and printing ISO, ASTM, and TJC (The Joint Commission) content- and color-compliant labels with 1D and/or 2D barcodes. The system reads drug container barcodes and produces water resistant, color labels. The system can be integrated to function with an Anesthesia Information Management System (AIMS) workflow to provide real-time documentation of drug administration when the syringe 1D or 2D barcode is read. The system can be accessed and managed via a network (Ethernet or Wi-Fi).

Device Characteristics

The use of drug class specific pattern and color per ASTM D4774 and ISO 28625 Specifications for User Applied Drug Labels in Anesthesiology is configurable by site and dataset. *Formularies* (datasets) are uniquely named configurations that may differ in drugs, colors, dilutions, and comments to accommodate different practices within a single site or hospital (for example, pediatric versus cardiac).

Additional uses include producing labels for IVs and other artifacts used during a surgical procedure.

The Codonics SLS is generally placed in, however not limited to, the perioperative environment to identify syringes prepared for anesthesiology use during surgery.

Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

The major characteristics and functions of the family of devices include:

- **Scanning the drug container barcode directly from a vial or other type of container**
- **Decoding the manufacturer-issued barcode into the required FDA National Drug Code (NDC) or Unique Drug Identifier (UDI) number**
- **Referring the NDC/UDI number to a site-managed formulary lookup database**

- Providing audio and ISO-compliant visual “readback” of the drug name
- Providing an alert if the drug container is listed as “recalled/obsolete” in the site’s formulary
- Printing an easy-to-read, water resistant ISO 26825 compliant color label meeting The Joint Commission medication management standards and the American Society of Anesthesiologists guidelines for labeling
- Providing the basic information by which the printed label barcode can be read to document medication administration in an AIMS
- Printing labels with insertion and expiration date and time for IV lines

Device Indications for Use Statement: Prescription Use Device

The Codonics SLS PCS device and SLS software provides a simple computer-based barcode scanning and printing system to automatically verify drug identity from NDC and other drug container UDI barcodes, and to print labels for prepared drugs and other items in use on patients during surgical procedures.

The Codonics SLS PCS is generally placed in, however not limited to, the perioperative environment to identify syringes prepared for anesthesiology use during surgery. Additional uses include producing labels for IVs and other artifacts used during a surgical procedure. SLS PCS can also be used to print “non-surgical environment” color and text labels as required. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

CAUTION Federal law restricts this device to be sold for use by or on the order of a physician.

Hazardous Material Information

Materials of Construction

Codonics has set very stringent standards for evaluating products to ensure the marketing of regulatory compliant products worldwide.

We do not intentionally add, nor are we aware, that the products or packaging contain the following materials:

- Mercury, except as used in lamp applications (for example, scanning lamps, backlit LCDs).
- Cadmium, except as used as thick film inks on printed circuit boards.
- Hexavalent Chromium, except as used as thick film inks on printed circuit boards, as chromate conversion coatings on metal surfaces, and as a photoresist on glass panels of cathode ray tubes.
- Polybrominated diphenyl ethers and polybrominated biphenyls.
- Bioavailable arsenic (small amounts of arsenic used in glass, LEDs, and semiconductors are not considered to be bioavailable).

- **Bioavailable crystalline silica (small amounts of crystalline silica are used in Certain paints, coatings, and filler materials).**
- **Polychlorinated biphenyls (PCBs).**
- **Asbestos.**
- **Organic tin (not used in tin lead solder applications).**
- **Ozone-depleting substances such as chlorofluorocarbons, methyl chloroform, and carbon tetrachloride.**

Manufacturing

During manufacturing operations that produce Codonics products (including packaging), no ozone depleting substances (such as chlorofluorocarbons, methyl chloroform, and carbon tetrachloride) are used.

Specifications

System: Integrated capacitive touch screen computer, 2D barcode scanner, color ink jet printer, audio feedback, and provision for a network interface

Ink Cartridges: One color cartridge (CMY)

SmartDrive: USB flash drive for storing configuration data, formulary database, log files

Readable Barcodes: GS1 DataBar Limited (RSS Limited), GS1 DataBar Stacked (RSS-14 Stacked), GS1-128, UPC-A, Data Matrix, Code 128, Code 128 barcodes with GS1-128, Code 39, Code 32,

IFT-14, Interleaved 2 of 5, EAN-8, EAN-13

Writable Barcodes: Data Matrix

Network Interfaces: Ethernet (RJ-45), included standard

Wi-Fi (USB-2 adapter), optional, available from Codonics

Network Speeds: Ethernet, full duplex 100 Base-T only

Wi-Fi, 802.11 b/g/n (2.4 GHz) and 802.11 a/n/ac (5.0 GHz)

Network Protocols: SSH (Secure Shell) and SCP (Secure Copy)

Used to access SLS PCS from Codonics-authorized applications

Dimensions: Height: 16.5 in. (41.9 cm)

Width: 10.43 in. (26.5 cm)

Depth: 15.67 in. (39.8 cm)

Weight: 14.5 lbs (6.6 kg)

Power: Universal Input: 100-240 VAC, 50/60 Hz

Environmental: *Operating:*

Temperature: 15–30°C (59–86°F)

Humidity: 20%–80% noncondensing

Shipping and Storage:

Altitude: Sea Level to 5790 m

Temperature (Hardware): -22.2–51°C (-8–123.8°F)

Temperature (Ink Cartridge and Label Media): 1–43°C (34–110°F)

Humidity (Hardware): 5%–85% noncondensing

Humidity (Ink Cartridge and Label Media): 5%–80% noncondensing

Medical Compliance FDA cleared to market per 510(k) K101439 Class II, MDR CE (Class I),

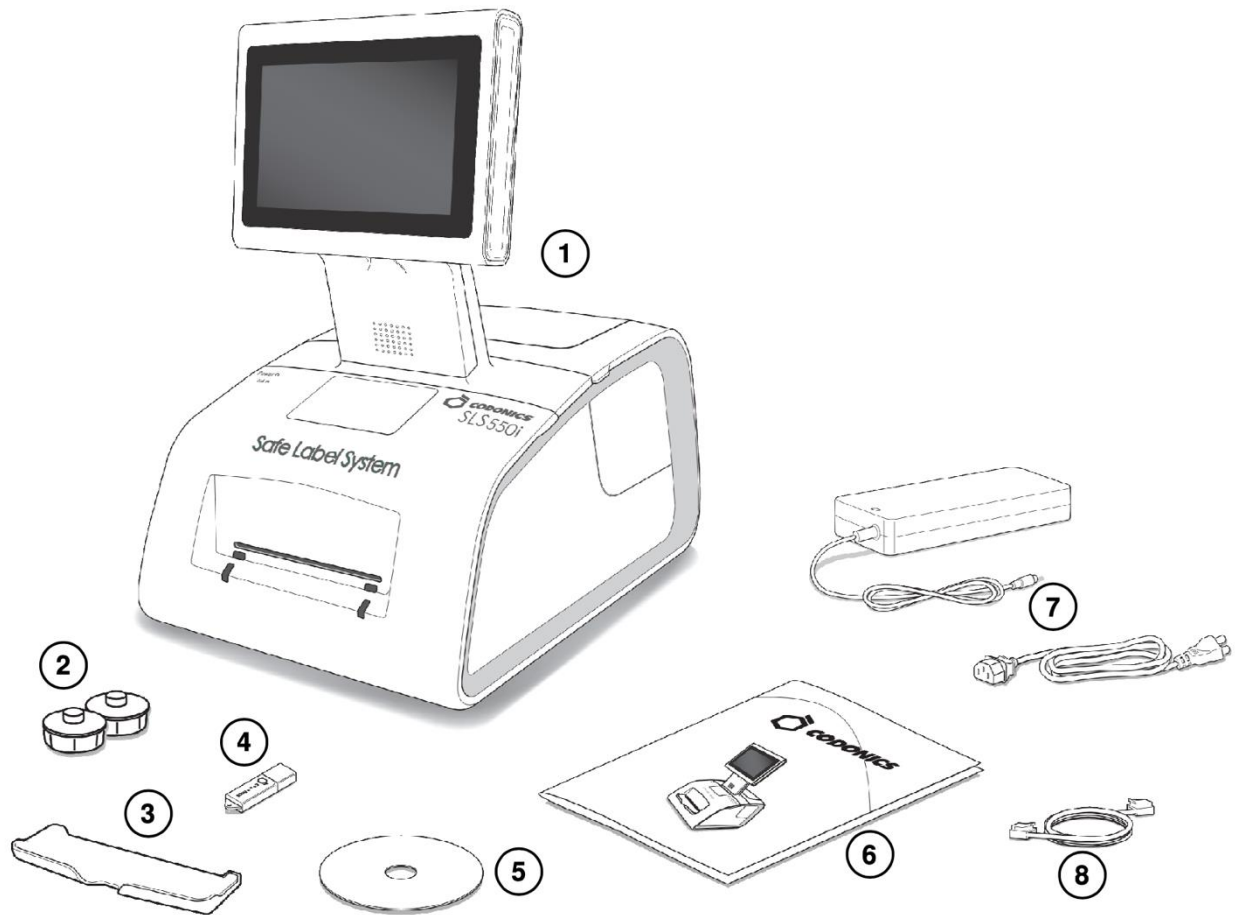
and Regulatory: GMP/QSR ISO 13485:2016, Safety IEC 60601-1 and EMC IEC 60601-1-2 for Professional Healthcare facilities

Classification: Class II equipment, Product Code BSZ, Regulation Number 868.5160

CAUTION Federal law restricts this device to be sold for use by or on the order of a physician

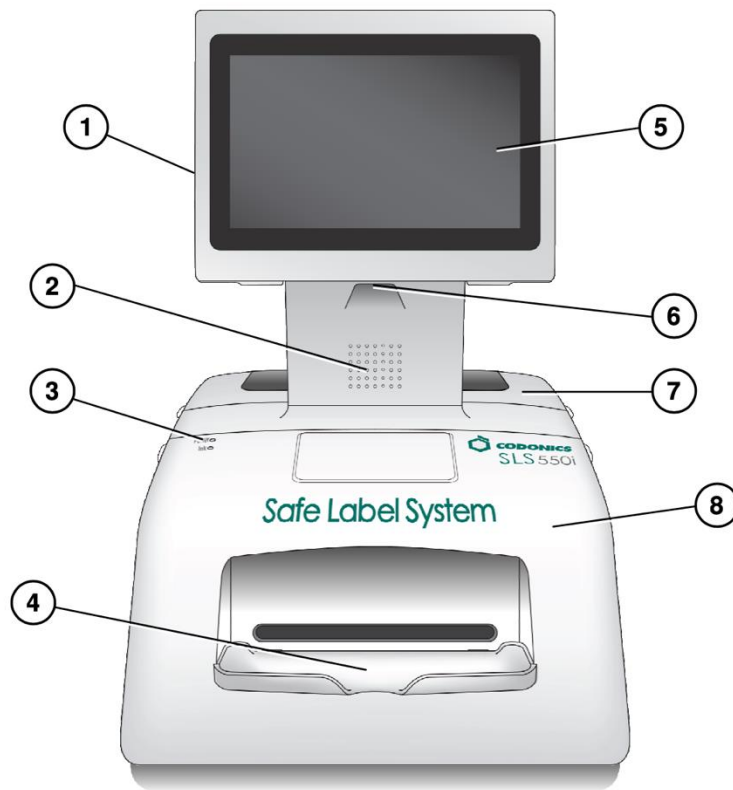
Components

Unpacked Components



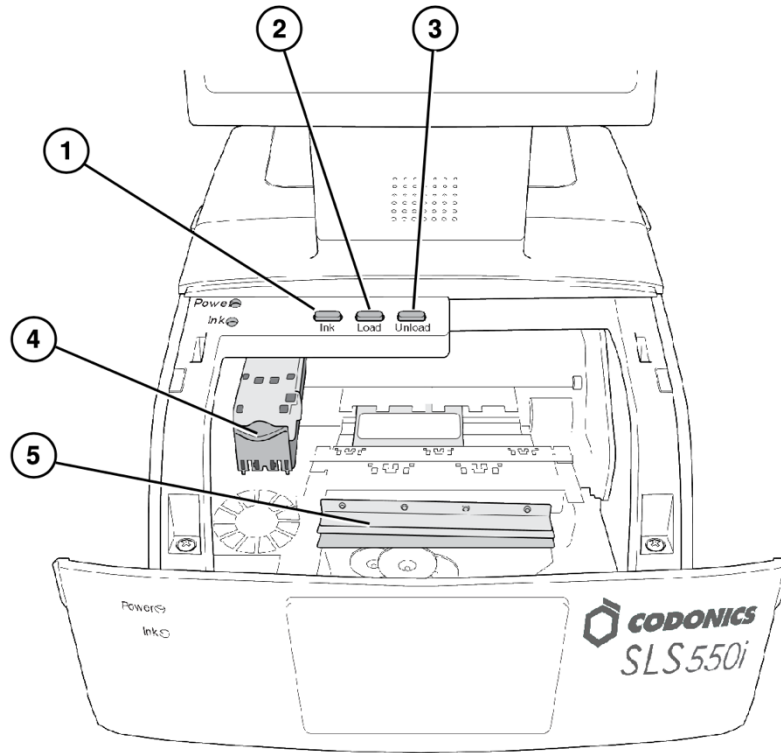
1. Safe Label System
2. Label media hubs
3. Output bin
4. SmartDrive
5. User's Manual disc
6. Reference guide and other documentation
7. External power supply and cord
8. Ethernet cable

Front Components



1. Touch screen USB port 1
2. Audio speaker
3. System power LED
4. Output bin (installed)
5. Touch screen
6. Barcode scanner
7. Rear cover
8. Front cover

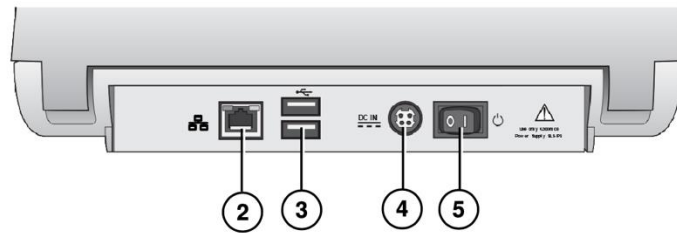
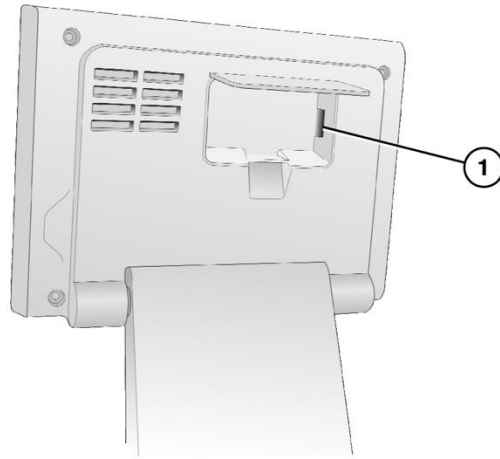
Components Inside Front Cover



- 1. Ink button
- 2. Load button
- 3. Unload button
- 4. Ink cartridge carriage
- 5. Label cutter

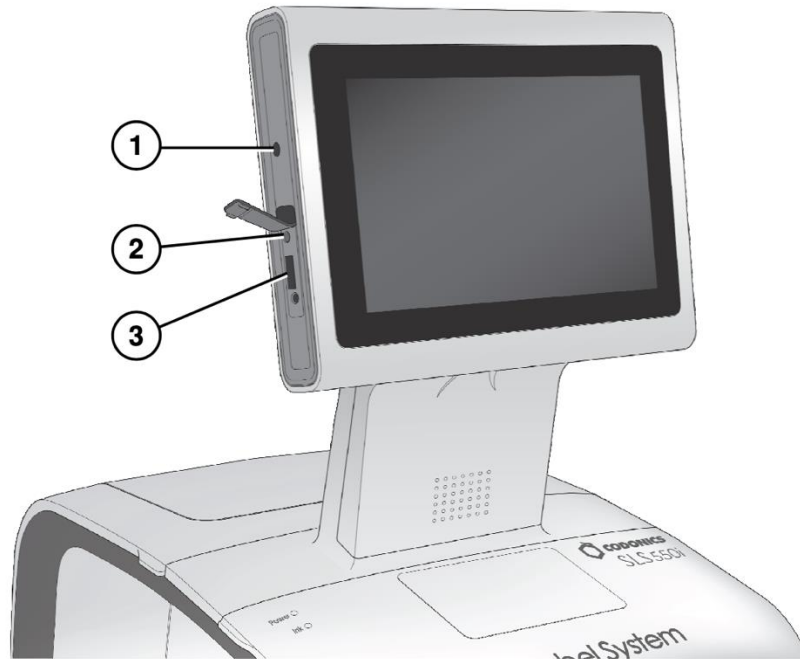
WARNING: When the front cover is open, avoid contact with the label cutter.

Rear Components



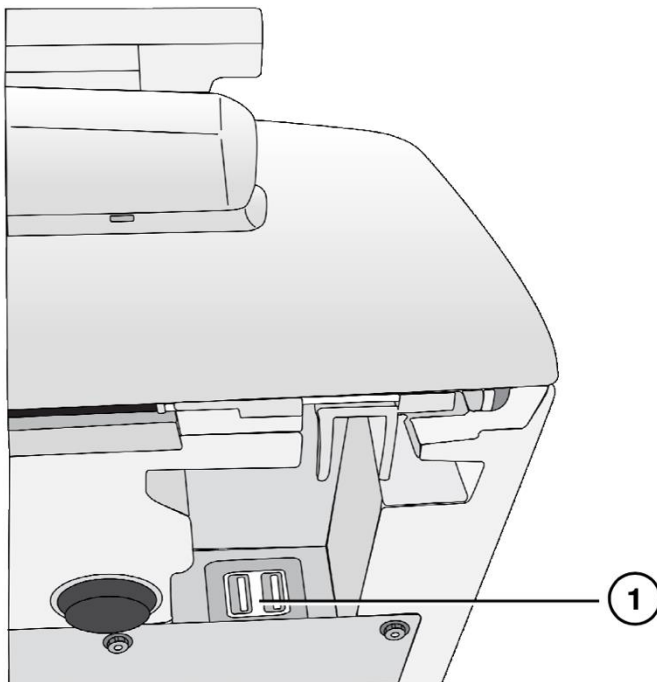
1. SmartDrive USB port 2
2. Ethernet port
3. USB ports
4. Power input port
5. Power switch

Touch Screen Components



- 1. Power LED
- 2. Reset button
- 3. USB port

Wi-Fi Adapter USB Port

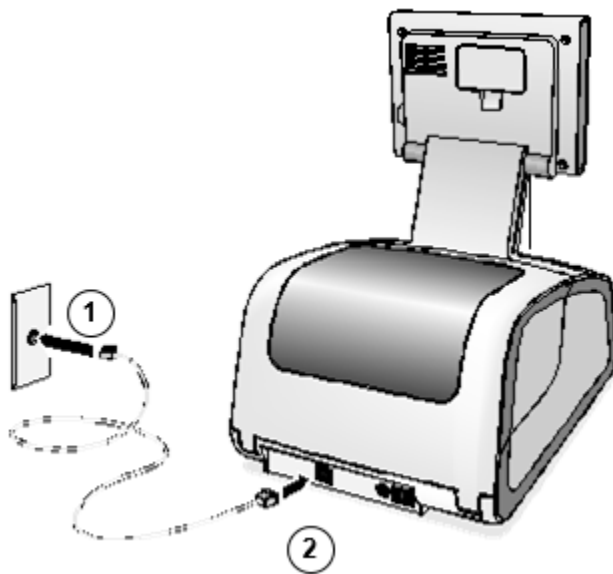


- 1. USB port for Wi-Fi adapter (bottom front right corner of the SLS)

Hardware Setup

CAUTION: Only trained users should install and configure the system.

Ethernet Cable (Optional)

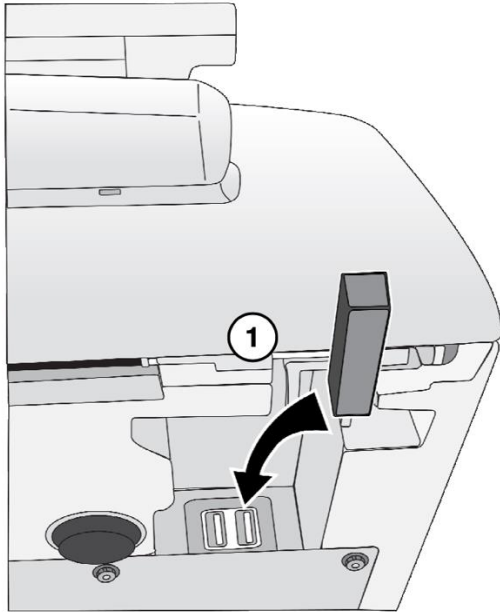


1. Connect the Ethernet cable to a hub or outlet that is connected to the network.
2. Connect the other end of the Ethernet cable to the SLS.

NOTE: For information about configuring SLS Ethernet network settings, refer to the SLS User's Manual v1.3.0.

CAUTION: The SLS supports only one network connection at a time, either Ethernet or Wi-Fi. Do not connect both an Ethernet cable and the Wi-Fi adapter at the same time.

Wi-Fi Adapter (Optional)



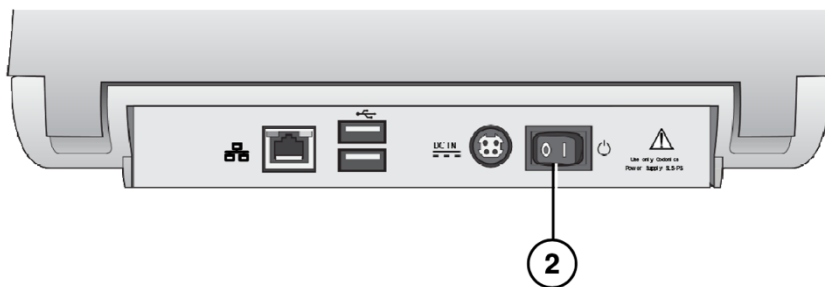
1. Insert the Wi-Fi adapter into the USB port at the bottom front right corner of the SLS.

NOTE: For information about configuring SLS Wi-Fi network settings, refer to the SLS User's Manual v1.3.0.

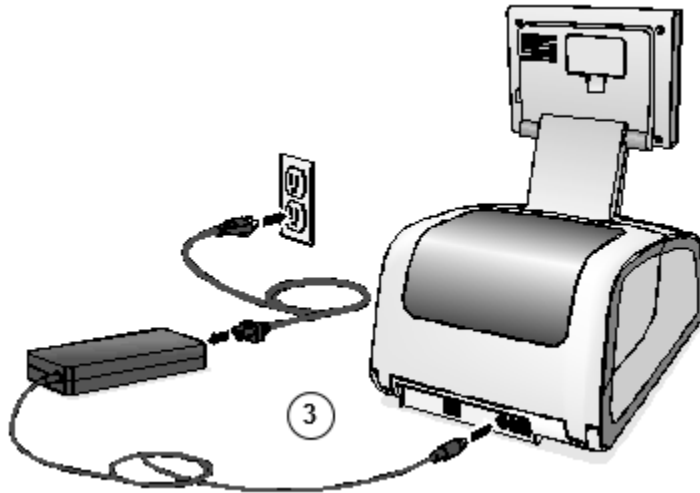
CAUTION: The SLS supports only one network connection at a time, either Ethernet or Wi-Fi. Do not connect both an Ethernet cable and the Wi-Fi adapter at the same time.

Power, SmartDrive

1. Place the SLS on a solid level surface.



2. Turn the Power switch to off.



3. Connect the external power supply.



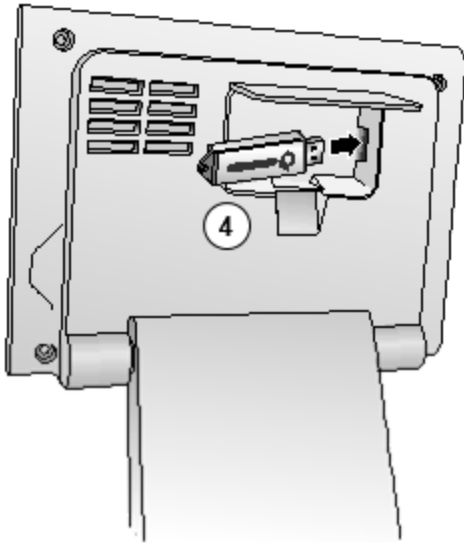
WARNING: The power cord connected to the SLS is the main disconnect for the system.



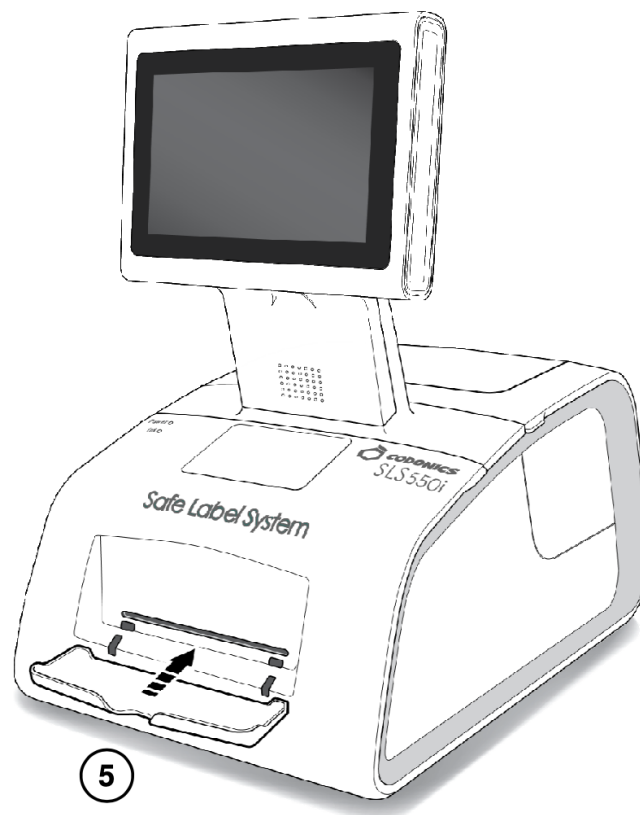
WARNING: Grounding reliability can be achieved only when the SLS is connected to a receptacle marked “Hospital Only” (that is, “Hospital Grade”).



WARNING: Do not touch a patient while also accessing SLS internal components that are under the access covers.

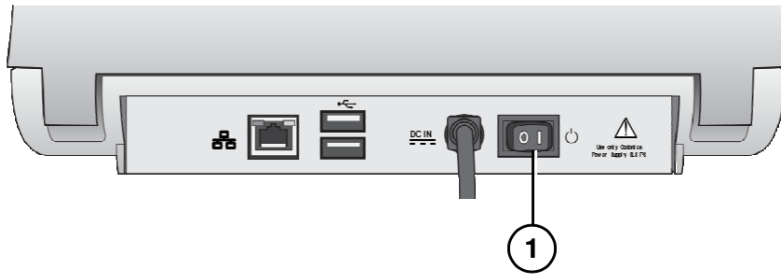


4. Insert the SmartDrive.

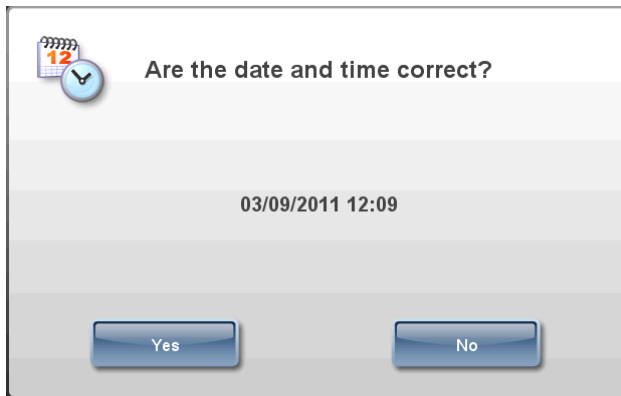


5. Insert the output bin.

Startup

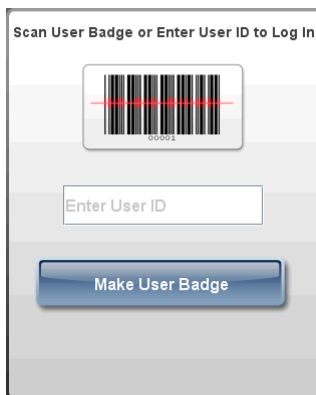


1. Turn on the Power switch.



2. Confirm or adjust the date and time.

3. The login prompt displays.



Loading Media

NOTE: Use only Codonics-supplied media.

To order media, contact Codonics Customer Service at:

Phone: +1.440.243.1198

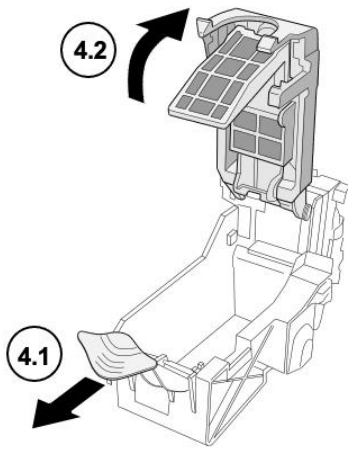
Fax: +1.440.243.1334
Toll Free: 800.444.1198 (USA only)
Web Site: www.codonics.com

Installing the Ink Cartridge

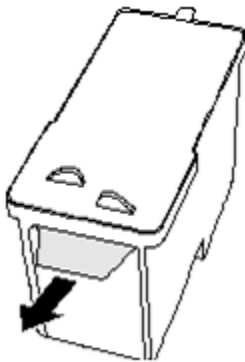
1. Open the front cover.



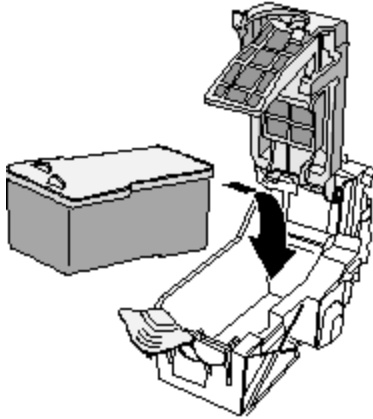
2. Press the Ink button.
3. Wait for the ink cartridge carriage to finish moving.



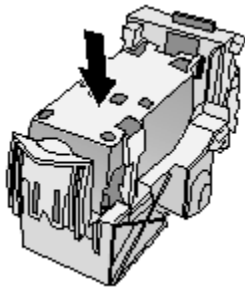
4. Open the ink cartridge carriage.



5. Remove the tape that covers the ink cartridge print head.



6. Install the ink cartridge.



7. Close the ink cartridge carriage.

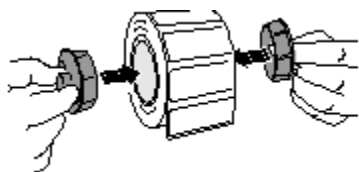


8. Press the Ink button.

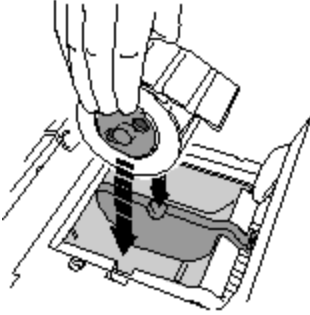
9. Close the front cover.

Loading Label Media

1. **Open the rear cover.**

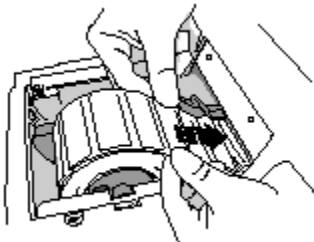


2. **Insert the label media hubs.**

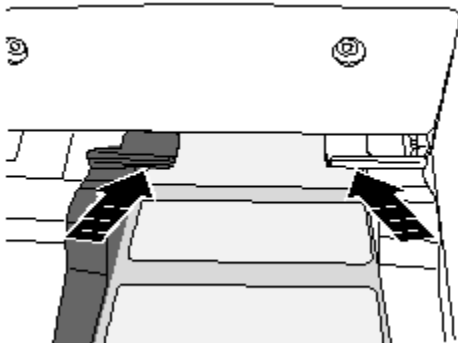


3. Place the label media and hubs in the media guides.

4. Adjust the media guides. Label media should be secure but still able to turn freely.



5. Place the label media below the media guides and into the feeder slot.



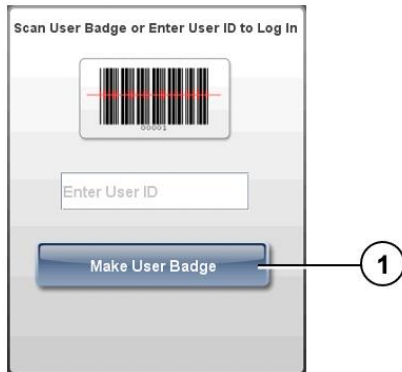
6. Feed the label media until the SLS automatically feeds it through the media path. You might need to hold the label media in place for a few seconds.

NOTE: If the SLS fails to feed the label media, open the front cover, press the Unload button, remove the media from the media path, wait until the media path rollers stop spinning, and try loading the media again.

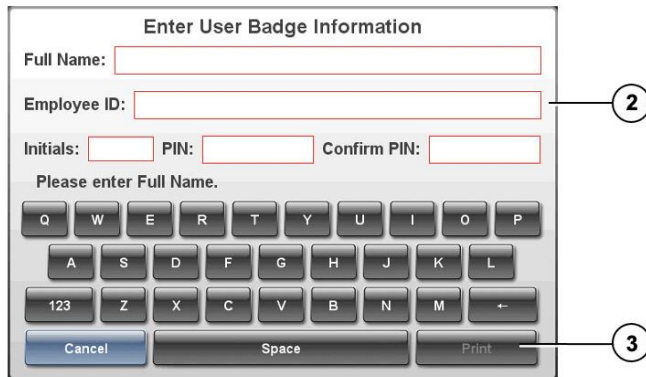
7. Close the rear cover.

Login

Making a User Badge



1. At the Login prompt, press the Make User Badge button.



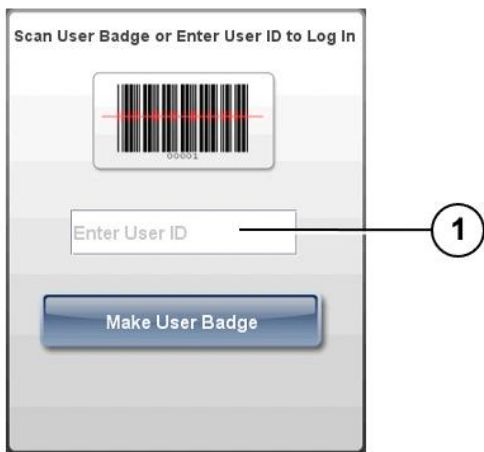
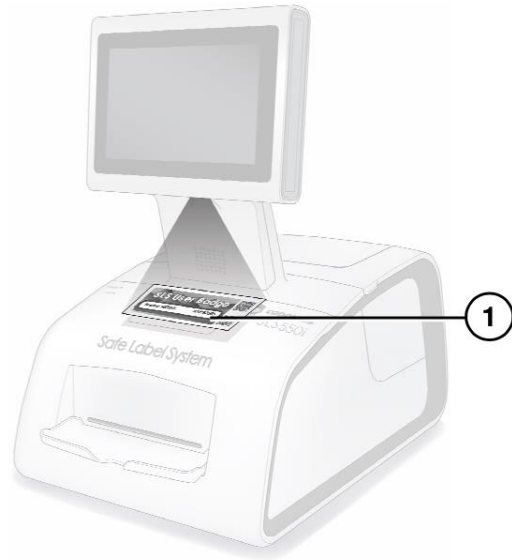
2. Enter your user information.

NOTE: The Employee ID must be unique among the SLS users.

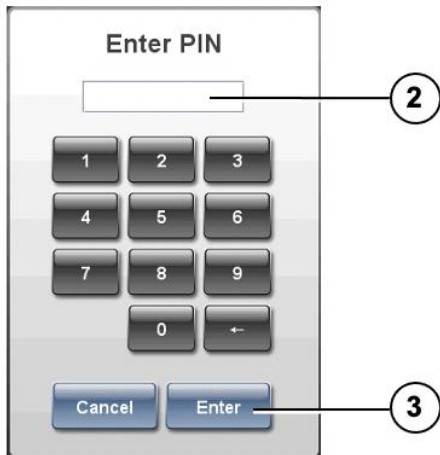
NOTE: The PIN can be up to ten digits long. If the system is not configured to require a PIN, then you will not be prompted to enter a PIN.

3. Press the Print button.

Logging In



1. At the Login prompt, scan your user badge barcode or manually enter your user ID.

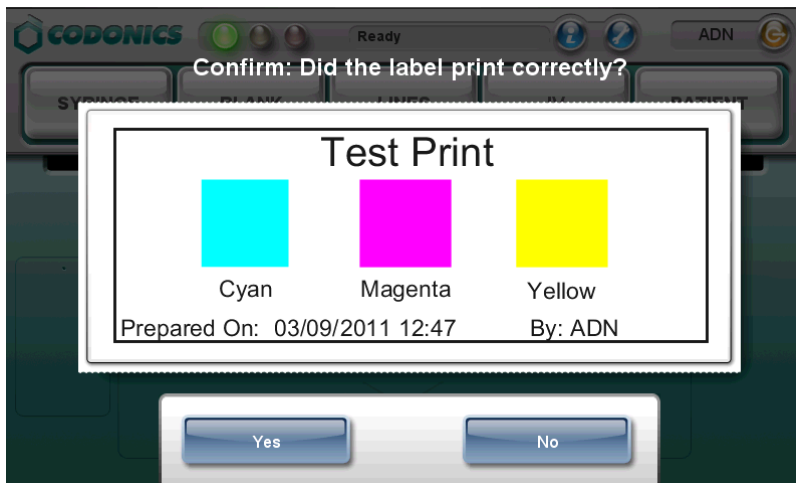


2. If the system is configured to require a PIN, enter your PIN.

NOTE: The PIN can be up to ten digits long.

3. Press the Enter button.

If a test label is printed, you are prompted to confirm that the test label printed correctly.

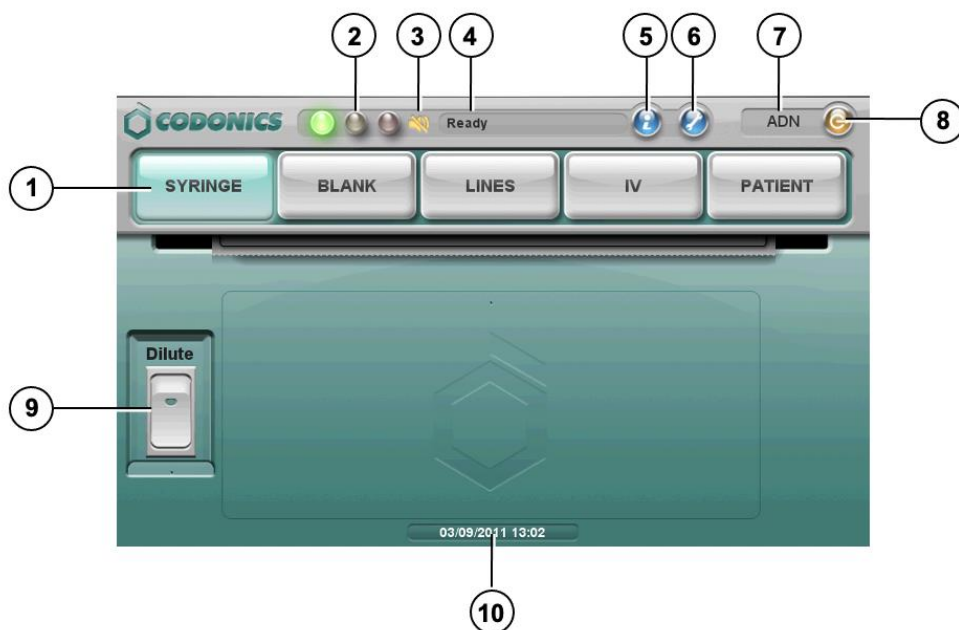


4. Inspect the test label.

5. If the test label printed correctly, press the Yes button. The system is ready for use.

If the test label did not print correctly, press the No button. Follow the on-screen instructions.

Touch Screen User Interface



1. Label type buttons
2. LED status indicators
3. Volume Muted icon
4. System status message
5. System information button
6. Utilities button
7. User initials
8. Logout button
9. Dilute switch
10. Current date and time

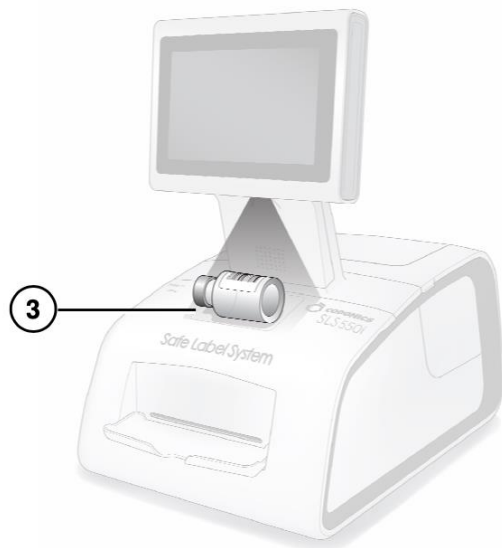
Printing a Syringe Label — Basic Use

CAUTION: The formulary used on the SLS should be one that was created by the system administrator and approved for use.

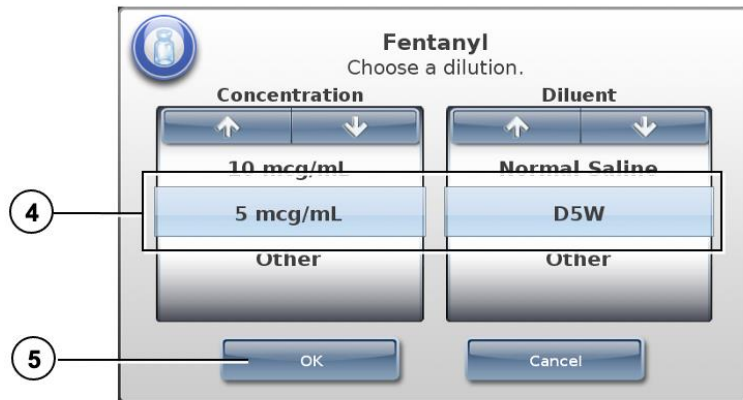


1. Press the Syringe label button.

2. To include dilution information, press the Dilute switch to turn it on.



3. Scan the drug container barcode.



4. If the Choose a Dilution prompt displays, select a concentration and diluent.

WARNING: SLS users are responsible for calculating and selecting the correct concentration and diluent.

5. Press the OK button.

If the system is configured to require confirmation before printing the label, a confirmation prompt displays.



NOTE: The label confirmation prompt is displayed for safety reasons to ensure that the correct drug information is being printed.

6. Press the Print button to confirm and print the label.

7. Retrieve the printed label from the output bin.

If the system is configured to require confirmation after printing the label, a confirmation prompt displays.



NOTE: The label confirmation prompt is displayed for safety reasons to ensure that the label has been printed correctly.

8. After reviewing the label and the screen display, perform one of the following steps:

- **Scan the barcode on the printed label. If the barcode is correct, the system indicates this and the procedure is complete.**
- **If you can see that the label did not print correctly, press the No button. Follow the on-screen instructions.**
- **If you are not able to scan the barcode, press the Unable to Scan button. Follow the on-screen instructions.**

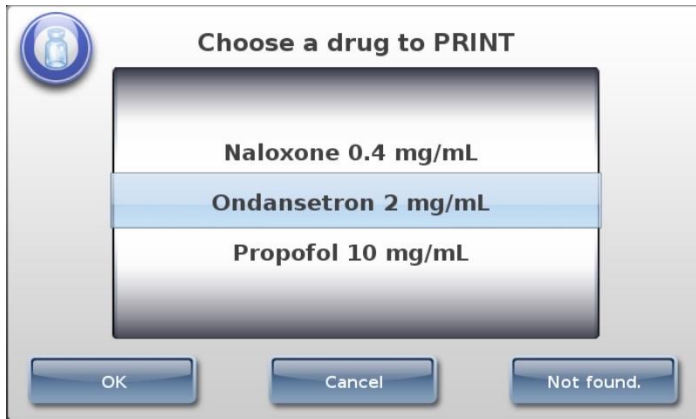
WARNING: To avoid mislabeling syringes, make sure that you immediately affix the correct label to the appropriate syringe.

WARNING: Incorrect syringe labels should be destroyed or disposed of to ensure that they are not used.

Printing a Syringe Label — Advanced Operations

Matching Container IDs

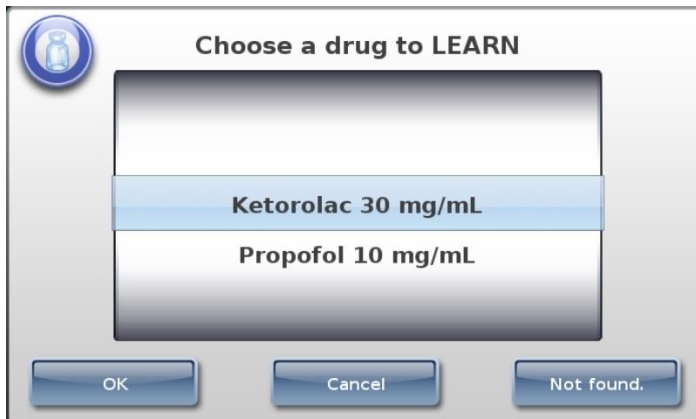
After scanning the drug container barcode, if there are multiple matching drugs with the same Container ID, they are displayed.



- If the correct drug is displayed, select it and then press the OK button.
- If the correct drug is not displayed, press the Not Found button. The procedure ends. Contact your SLS system administrator or Codonics Technical Support (+1.440.243.1198).
- To cancel the operation, press the Cancel button.

Mapped Master IDs (USA Only)

After scanning the drug container barcode, if the Container ID that was scanned can be mapped to more than one Master ID, those drugs are displayed.

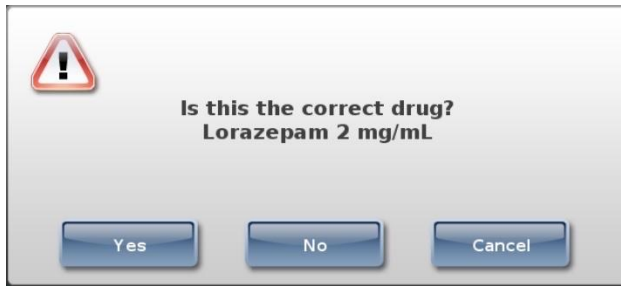


- If the correct drug is displayed, select it and then press the OK button.
- If the correct drug is not found, press the Not Found button. The procedure ends. Contact your SLS system administrator or Codonics Technical Support (+1.440.243.1198).
- To cancel the operation, press the Cancel button.

Drug Verification

If the drug has not been previously verified to ensure that the drug container information is the same as the drug information in the formulary, a verification prompt displays.

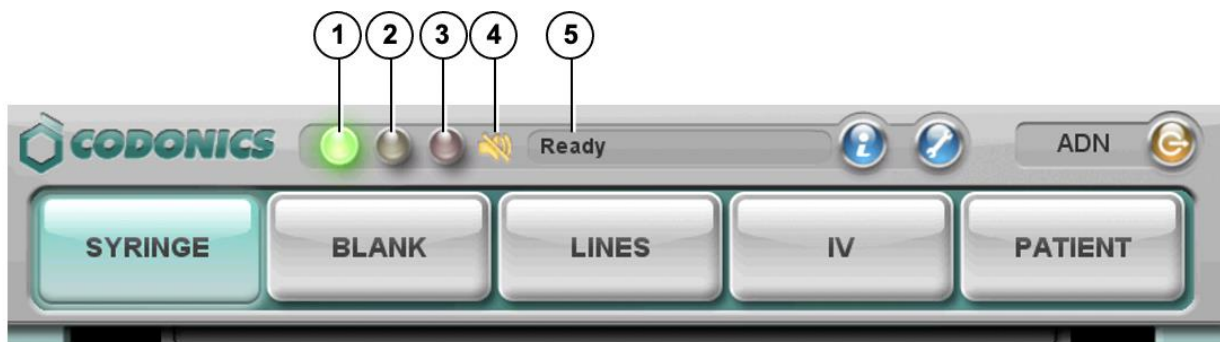
NOTE: The verification prompt only occurs once for each drug, when its container barcode is scanned for the first time.



- If the drug information is correct, press the Yes button. You are prompted again to confirm that the drug information is correct.
- If the drug information is not correct, press the No button. You are prompted again to confirm that the drug information is incorrect.
- To cancel the operation, press the Cancel button.

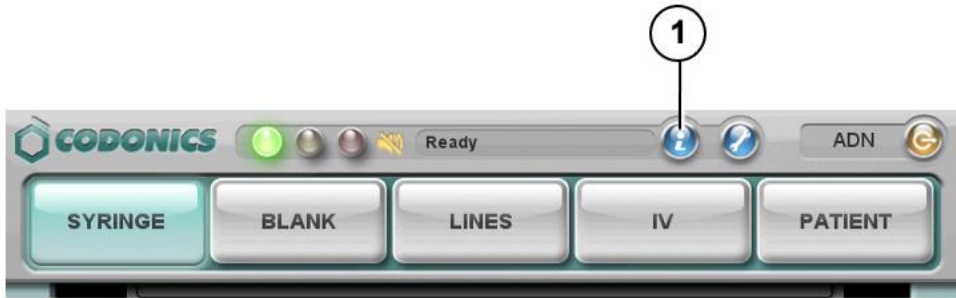
Monitoring Status

Dashboard Status Information



1. Normal: The system is ready to process or is processing a job (for example, printing).
2. Alert condition: The system can still process jobs but requires user attention (for example, low ink).
3. Critical or fault condition: The system might not be able to process jobs. The system requires immediate user attention (for example, out of label media).
4. Muted icon: Displays when the volume is muted.
5. Status messages.

System Information



1. Press the System Information icon.



2. Press the tabs to view additional information.

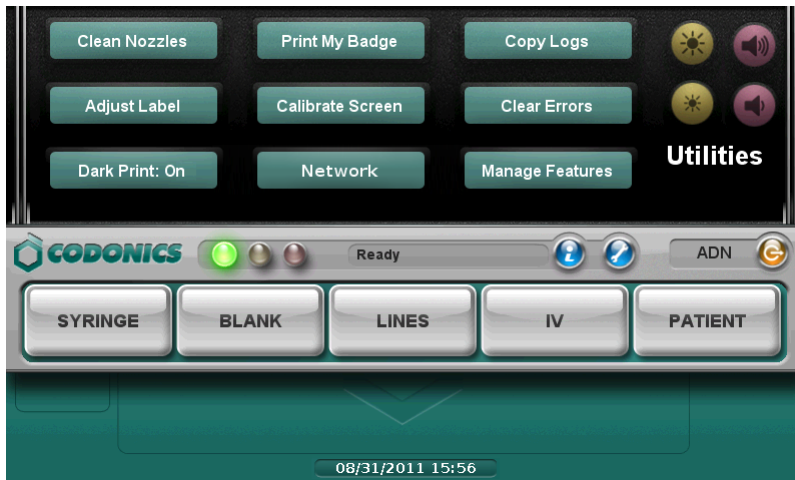
Maintenance

Displaying the Utilities Screen



1. Press the Utilities button.

The Utilities screen displays. The buttons are described in the table below.



2. To close the Utilities screen, press the Utilities button again.

Clean Nozzles

Cleans the ink cartridge nozzles

Adjust Label

Allows you to adjust the label media path to ensure that label content is properly centered on the label.

Dark Print: Off / On

Sets dark printing of black text to off or on.

Print My Badge

Prints a user badge for the user who is currently logged in.

Calibrate Screen

Calibrates the touch screen.

Network

Allows you to configure the network settings.

Copy Logs

Copies system logs to a USB flash drive that is inserted in the touch screen USB port 1.

Clear Errors

Clears system errors. This setting should only be used by system administrators after the errors are carefully reviewed.

Manage Features

Allows you to add SLS features.



Adjusts the touch screen brightness.



Adjusts the audio volume.

Clearing a Label Jam

1. Remove your gloves.
2. Open the front and rear covers.
3. Identify the location of the jammed media and use the appropriate procedure below.

Clearing a Label Jam in the Front Media Guide

1. Gently remove the label media from under the front guide by pulling up the label media near the ink carriage.

CAUTION: Avoid peeling up a label in the media path. You might have to pull the media forward through the cutter to avoid peeling a label. If a label is peeled up in the media path, do not press the adhesive side of the label against the sheet metal guides.

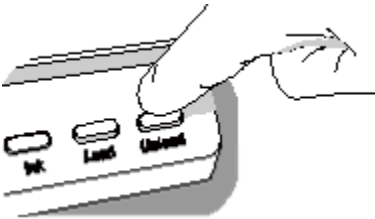
2. Use scissors to cut the liner between two labels by the ink carriage to allow you to remove the jammed label media.



If required, press the Load button to advance the label media.

NOTE: Scissors are recommended for cutting the liner so that the label media will have a straight edge. The straight edge will make loading the label media easier.

3. Gently remove the jammed portion of the label media.
4. Review the strip of labels. Make sure that you can account for all of the labels and that no labels are stuck in the front media guide. Discard the damaged label media.
5. If portions of the label media are still jammed in the media path, power off the system (refer to “Shutdown and Power Off”). Use non-metallic tweezers and carefully remove any additional label media from the media path.



6. Press the Unload button to reverse any portion of the label media that is still in the media path.
7. Inspect the label media. Use scissors to cut off any damaged labels.
8. Close the front cover, load the label media, and close the rear cover.

Clearing a Label Jam in the Rear Media Guide

1. Identify the location of the jammed media under the rear media guide.

The rear media path can be exposed by using the thumb screws to remove the rear media guide cover.

2. Use scissors to cut the liner between two labels by the ink carriage. This will reduce the number of labels being pulled back through the media path.
3. Gently remove the cut portion of the label media from the front media guide and discard it.
4. Use scissors to cut the liner between the jammed portion of the label media and the label media roll.

NOTE: Scissors are recommended for cutting the liner so that the label media will have a straight edge. The straight edge will make loading the label media easier.

5. Gently remove the jammed portion of the label media.

CAUTION: Avoid peeling up a label in the media path. If a label is peeled up in the media path, do not press the adhesive side of the label against the sheet metal guides.

6. Review the strip of labels. Make sure that you can account for all of the labels and that no labels are stuck in the rear media guide. Discard the damaged label media.

7. If portions of the label media are still jammed in the media path, power off the system (refer to “Shutdown and Power Off”). Use non-metallic tweezers and carefully remove any additional label media from the media path.



8. Press the Unload button to reverse any portion of the label media that is still in the media path.
9. Inspect the label media. Use scissors to cut off any damaged labels.
10. Close the front cover, load the label media, and close the rear cover.

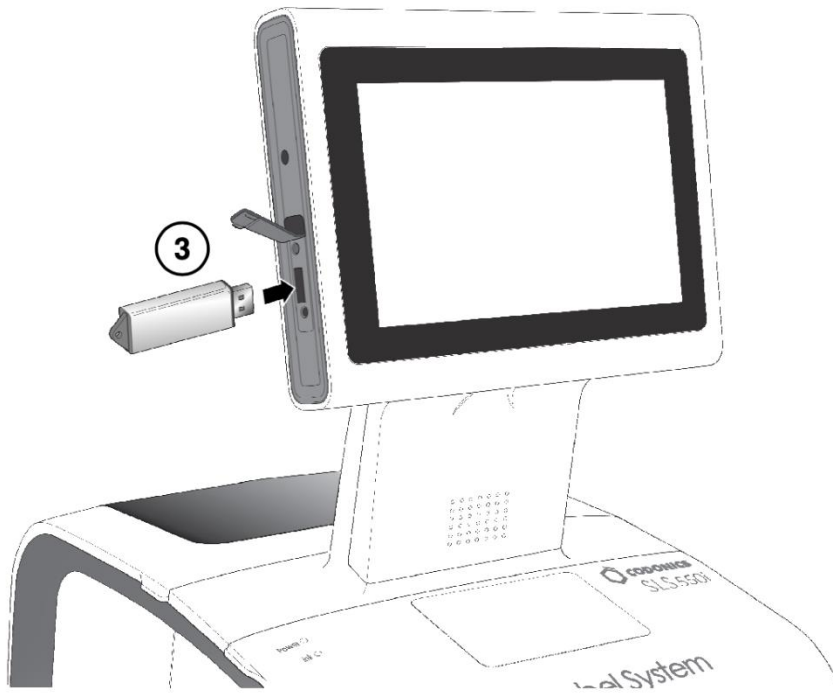
Installing Update Packages

Use this procedure to manually install formulary update packages and configuration update packages.

NOTE: Formulary and configuration update packages can also be installed remotely using the Administration Tool. For more information, refer to the *SLS Administration Tool User's Manual v1.3.0*.

CAUTION: Installing system software should only be performed as directed by Codonics Technical Support. Do not attempt to install system software without the assistance of Codonics Technical Support.

1. Log in.
2. Make sure that the SLS is not processing any print jobs or utilities.



3. Insert the USB flash drive on which the update package or software is installed.

You are prompted to confirm the installation.

4. Press the Yes button to continue.

5. When the installation files have been copied, remove the USB flash drive.

When the installation is complete, the system restarts automatically.

CAUTION: The SLS customer is responsible for ensuring that the correct formulary and configuration packages are being installed on the SLS.

CAUTION: Practice standard information technology (IT) precautions to protect data associated with the formulary (for example, securing the content of the USB flash drive on which the formulary update package is stored).

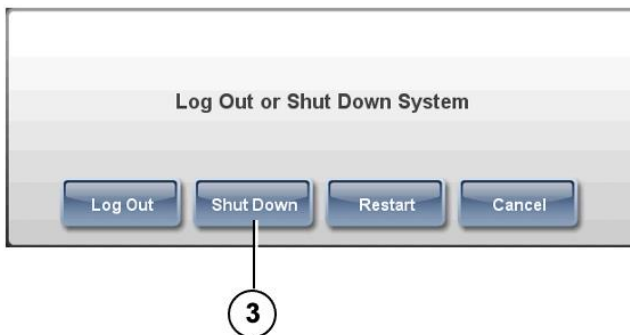
CAUTION: The SLS customer is responsible for the accuracy of the data in the formulary, including drug data that has been copied from third-party drug databases.

Shutdown and Power Off

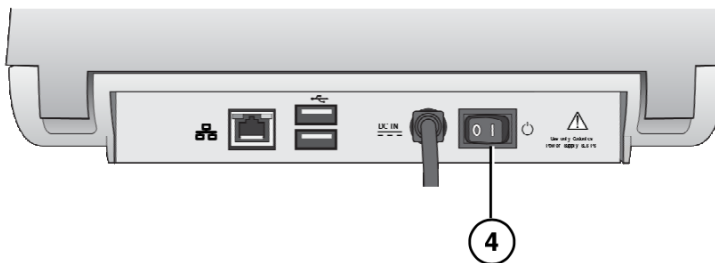
1. Make sure all print jobs have completed.



2. Press the Log Out button.



3. Press the Shut Down button.



4. When shutdown is complete, turn off the Power switch.

Troubleshooting

Problem: Startup fails.

- Check the external power supply and cables.
- Check the power switch on the rear panel.
- Verify that the SmartDrive is connected.

Problem: System will not power on.

- Replace the external power supply.

Problem: Login fails.

- Verify the user name.
- Verify the PIN.
- Verify that the user badge is correct and that its barcode quality is satisfactory.

Problem: The touch screen does not respond properly when touched.

- Run the Calibrate Screen utility.

Problem: The formulary fails to load or is invalid.

- A new formulary update package might have to be created and loaded. See your SLS system administrator.

Problem: A drug container failed verification.

- The drug might have to be added to or corrected in the formulary.
- Make sure that the barcode on the drug is of good quality.
- **CAUTION: This is a serious issue. Notify your SLS system administrator.**

Problem: A test label or syringe label did not print correctly.

- Discard the label and try again.
- If the label print quality is bad: Run the Clean Nozzles utility, Replace the ink cartridge, and Replace the label media.
- If the print is not aligned properly on the label, run the Adjust Label utility.
- If the wrong drug information is printed on the label, the drug might have to be corrected in the formulary. See your SLS system administrator.
- **CAUTION: This is a serious issue. Notify your SLS system administrator.**

Problem: The barcode scanner is not scanning.

- Make sure the barcode is correctly positioned. The red cross-hair should line up with the barcode and the container or syringe should be as close to the front cover as possible.
- Shutdown the system from the touch screen and then cycle power to the system.
- Make sure the quality of the barcode is good.
- Clean the scanner's glass window.
- The barcode symbology might not be supported. Contact Codonics Technical Support (+1 440.243.1198)

Problem: The label media is jammed.

- Clear the label jam. Refer to "Clearing a Label Jam".

Problem: The SLS will not connect to the network.

- Verify that the Ethernet cable or Wi-Fi adapter is connected.
- Verify that the SLS network settings are configured properly.

NOTE: For additional troubleshooting issues, refer to the Safe Label System User's Manual.