



CODONICS[®]
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Safe Label System[®]

User's Manual Addendum

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Codonics, Inc.
17991 Englewood Drive
Middleburg Heights, OH 44130 USA
440.243.1198 Phone
440.243.1334 Fax
Email info@codonics.com
www.codonics.com

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European Authorized Representative:



AR Experts BV
Boeingavenue 209
1119 PD Schiphol-Rijk
The Netherlands
www.ar-experts.eu
SRN: NL-AR-000023989

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Release Notes

Summary

This section provides information about new features and product improvements added since release of the Safe Label System 500i (SLS) Point of Care Station (PCS) User's Manual version 1.3.0 and up to version 1.8.0.

WARNING: The use of label colors is intended only as an aid in the identification of drug groups and does not absolve the user from the duty of reading the label and correctly identifying the drug prior to use.

Version 1.4.0 SLS 500i

New Features

- ◆ **SLS PCS now supports 80 x 30 mm labels. These labels are typically used for larger syringes (20 mL or larger).** Refer to the AT User Manual Addendum (905-081-001) for instructions on how to set the templates in the AT.

NOTE: Make sure that the label template pack that is deployed to SLS PCS is the same as the labels installed. If a small label (48 x 17 mm) template pack is deployed to SLS PCS and large labels (80 x 30 mm) are installed, then the printed area on the label will be small.

- ◆ **SLS PCS now supports 48 x 17 mm labels. These labels are typically used for smaller syringes (10 mL or less).** The templates are set in the AT. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to set the templates in the AT.

NOTE: Make sure that the label template pack that is deployed to SLS PCS is the same as the labels installed. If a large label (80 x 30 mm) template pack is deployed to SLS PCS and small labels (48 x 17 mm) are installed, then SLS PCS will print outside the small label and ink will be sprayed inside the device.

- ◆ **SLS PCS now supports Administer Mode.** When using SLS PCS to scan the syringe barcode prior to administering a syringe, SLS PCS will announce and display the drug name and concentration as an additional check. A feature key is required to enable this feature. Contact your Codonics Sales Representative to purchase the key. Refer to "Administer Mode" on page 8 for complete instructions.

- ◆ **SLS PCS now has the ability to select or enter Total Dose (TD) and Total Volume (TV) for a syringe.** The TD and TV as well as the equivalent concentration will be displayed on the user interface and print on the label. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to configure and setup TD/TV in the AT for SLS to use. Refer to "Total Dose/Total Volume" on page 10 for instructions on how to use TD/TV on SLS.
- ◆ **SLS PCS now supports a wired hand scanner.** The recommended hand scanner is the Motorola DS4208-HC. The scanner will perform the same operations (e.g., barcode scan, post-print confirmation, administer mode) as the internal scanner. A feature key is required to enable this feature. Contact your Codonics Sales Representative to purchase the key. Refer to "Wired Hand Scanner" on page 18 for complete instructions.

WARNING: For safety purposes, the use of an extended USB wired cable is not recommended.

Product Improvements

- ◆ **Software updates can now be automatically deployed from the Administration Tool (AT) to SLS PCS when it is enabled on the network.** Refer to the AT User Manual Addendum (905-081-001) for instructions on how to automatically deploy software updates to SLS PCS. A user can still use the software installation drive and manually update SLS PCS.
- ◆ **Users can be removed from SLS PCS.** If an existing user needs to be removed from SLS PCS or a user needs to change their User ID or PIN, contact Codonics Technical Support for instructions on how to perform this procedure.
- ◆ **The amount of blank labels discharged at startup was reduced from five labels to two or three.** During a proper shutdown of SLS PCS through the user interface, media is now rolled back so that upon startup of SLS PCS the next time, fewer labels are discharged.
- ◆ **Additional barcode symbology options are now enabled and supported on SLS PCS.** These are Code 128 barcodes with GS1-128, Code 39 and Code 32, EAN-13.
- ◆ **A new Codonics screen saver is provided.** After 60 minutes of no users being logged in, a Codonics screen saver is enabled when the user is logged out. The scanner will not register scans or clear the screen saver. A user will need to touch SLS PCS screen to clear the screen saver. Previously, the screen saver was a black screen.

NOTE: The Space Pump requires revision "J" or higher software in order to be compatible with SLS labels.

- ◆ **The scanner and cutter firmware (i.e., PIC) version is now reported on SLS PCS user interface.** The information can be found in the System tab of the System Information screen.
- ◆ **When installing software, SLS PCS now automatically loads the latest printer and scanner firmware.**
- ◆ **A warning is now shown if an unsafe (e.g., not shut down from SLS PCS user interface) is detected.** The warning provided is Warning Code 86, The SLS has recovered from an unexpected shutdown. Use the power icon on the touchscreen for proper shutdown. Powering down from SLS PCS user interface ensures that the SmartDrive is properly backed up and the remainder of the system is properly shutdown.

Version 1.5.0 SLS 500i

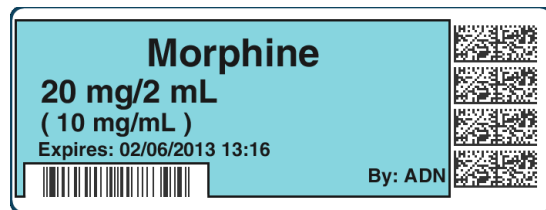
New Features

- ◆ **SLS PCS now supports Fast Print mode.** The default setting for all units with 1.5.0 installed is Fast Print: On. The setting can be adjusted in the Utilities screen by pressing the Fast Print mode button to Off.

NOTE: There is some potential in Fast Print mode for streak(s) or white lines in the printed label due to a clogged nozzle. If the quality deteriorates to an unacceptable level you can try purging the ink cartridge by selecting Clean Nozzles in the Utilities screen, changing out the ink cartridge, or changing the print mode to Fast Print: Off.

- ◆ **SLS PCS now supports integration with B.Braun Space Pump.** B.Braun compatible barcodes can be included on printed SLS syringe labels and then used to transfer data (i.e., drug name, concentration value, and concentration units) to a B.Braun Space Pump. A feature key is required to enable this feature. Contact your Codonics Sales Representative to purchase the key. Refer to Codonics B.Braun Technical Brief (901-265-001) for complete instructions.

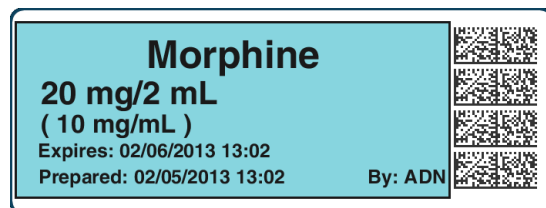
- ◆ **In addition to the traditional label, SLS PCS now supports labels with an Auxiliary 1-D barcode or labels with a Patient Write-In area on the Standard 22x60mm label (STD-2-v02).** Refer to the AT User Manual Addendum (905-081-001) for instructions on how to configure Auxiliary Barcodes in the AT. Refer to "Auxiliary Barcodes" on page 22 for use of Auxiliary Barcodes on SLS PCS. The functionality now prints the following labels depending on which option is selected in the AT: a 1-D barcode on the standard label that provides compatibility with legacy BCMA (e.g., MediTech, Epic) and AIMS (e.g., McKesson, DocuSys, GE) systems that read NDC codes.



Alternatively, in the AT you can select to have a blank area print on the label to write-in information such as patient name.



Or, configure the use of a traditional label format.



- ◆ **SLS PCS now supports Named Devices.** The network interface(s) on SLS PCS can be assigned dynamic IP addresses by the hospital network. Because the IP address of SLS PCS can change over time, providing a static device name will make it easier to configure the AT and Email Server to communicate with individual units. Each SLS PCS system includes a pre-defined device name that is unique to the Ethernet or Wireless interface on that device. The pre-defined device name(s) are associated with the SmartDrive to allow the device name(s) to remain the same when SLS PCS is swapped and the SmartDrive is transferred to the new SLS PCS. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to configure Named Devices in the AT.

NOTE: The pre-defined device names conform to a uniform naming structure:

SLS-PPP-LLLLL-N

Where:

"SLS" is a static string

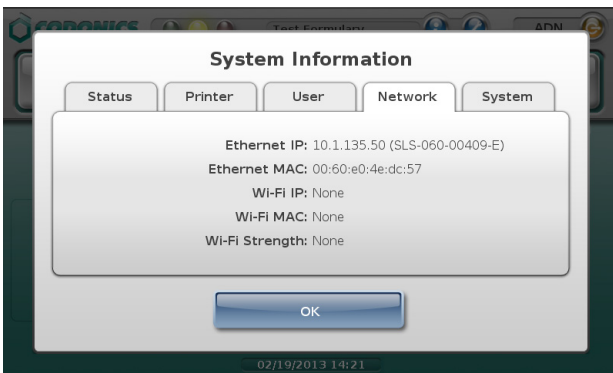
PPP = Codonics 500i product code (i.e., 060)

LLLLL = SmartDrive license code

N = "E" for Ethernet, "W" for WiFi

Example: SLS-060-12345-W

NOTE: The Network tab of the SLS PCS information screen provides users the ability to view the pre-defined device name.

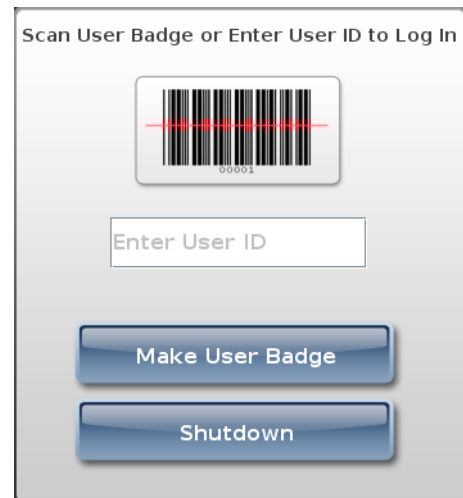


NOTE: Named Devices is enabled by default in the AT Configuration tab but can be disabled by unchecking the box.

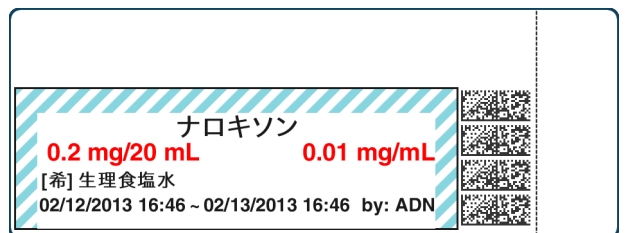
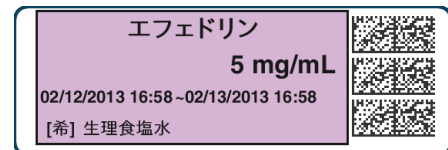
- ◆ **SLS PCS now supports variable length container IDs in Other Mode.** SLS PCS supports scanning and reading of variable-length Container IDs. For example, SLS PCS will now scan a drug container that uses a Data Matrix barcode with a 10-digit Container ID and a different container that uses an EAN-13 barcode with a 13-digit Container ID. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to configure variable length Containers IDs in the AT.

Product Improvements

- ◆ **You can now shut down from the Login screen.** Users no longer need to login to SLS PCS to shut down the device.



- ◆ **A new Japanese small and large label version provides a "Use" date range (e.g., 02/12/2013 16:58 ~ 02/13/2013 16:58) when printed.** The label template packs JP-S1-v02 and JP-L1-v02 can be selected in the AT.



- ◆ **Older localization packs (i.e., 1.4.0 or newer) can now be used with newer software releases on SLS and AT.** For example, JP-1.4.0 will now work with 1.5.0 software. If words or WAV files are not translated into the local language, they will default to English.
- ◆ **The default sound level is now set to 75%.** Previously the level was set to 100%. The sound level is able to be adjusted in the Utilities menu.
- ◆ **SLS PCS start-up and shut down was sped up.**
- ◆ **The swap process was simplified.** A user is now able to remove the SmartDrive from a non-functioning SLS PCS and place it directly into a new SLS PCS, power it up and have a functioning SLS PCS without having to perform any additional steps.
- ◆ **Changing dilution status after assigning TD/TV dilutions now warns users of invalid entries.** For example, set the Dilution Status to Dilution Allowed. Then set Preparation Method to TD/TV, and assign a few values some of which are dilutions. After setting the TD/TV values, change Dilution Status to Not Allowed and the AT now warns the user that some of the TD/TV values are dilutions and are no longer valid.
- ◆ **SLS PCS user interface now lets the user know why the system is Out of Service.** The message on the dashboard will be Out of Service, and the long message in the system information screen will include a description of the problem and suggested corrections.
- ◆ **Drug selection is now tracked in the SLS PCS tracking database.** There is now a tracking entry made tying a barcode scan to a specific selected drug before printing. When a barcode is scanned that matches or maps to multiple drugs, the options and selection are tracked.
- ◆ **A message is now displayed on the user interface dashboard when the ink carriage is in the install position.** There was a dialogue message that previously was provided but now a short dashboard message is also provided.

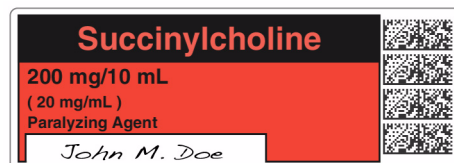
Version 1.6.0 SLS 500i

New Features

- ◆ **SLS PCS now supports Batch Mode.** Users can now automatically print multiple copies of the same label. The label can include a defined lot number and an additional initial area for use cases where one person prepares the

label and another person prepares the syringe (for example in pharmacy). A feature key is required to enable this feature. Contact your Codonics Sales Representative to purchase the key. Refer to “Batch Mode” on page 23 for complete instructions.

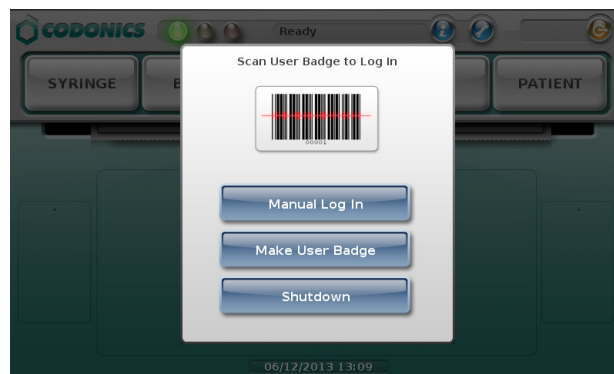
- ◆ **SLS PCS now supports an additional label, RBX-1-v01, for overlabeling in specific applications (e.g., Intelligent Hospital System (IHS) RIVA robot, Baxter, Health Robotics).** The label (sample below) is only supported in English. Contact your Codonics Sales Representative for further information.



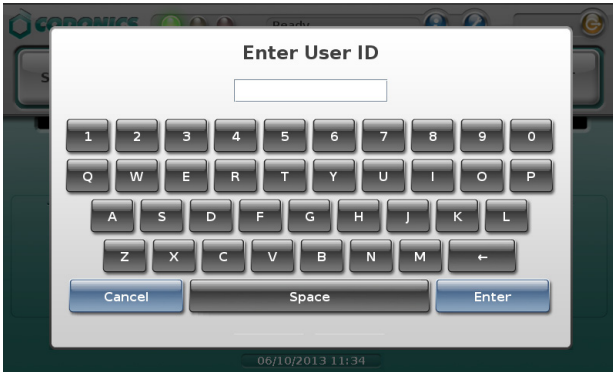
WARNING: For RBX-1-v01, users should not rely on the expiration date embedded in the SLS PCS label 2D barcode. The expiration date/time on the original label already affixed to the syringe should be used. This is because the time that the SLS PCS label was prepared will be different than when the syringe was actually filled/prepared. Users should either leave the expiration time blank or set it to 0 in the AT.

Product Improvements

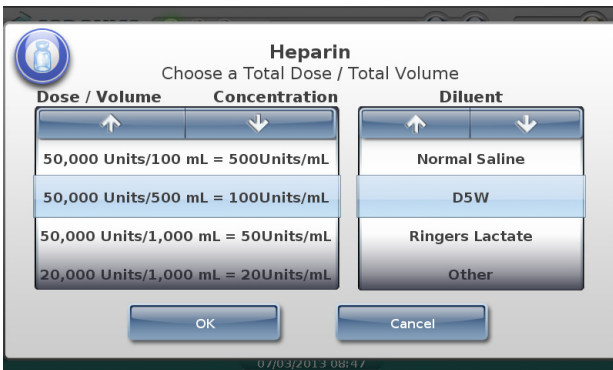
- ◆ **The SLS PCS has an updated login screen.** The Enter User ID was changed to a button instead of the white box.



After clicking on the Manual Log In, an updated keyboard is displayed to manually enter the User ID.



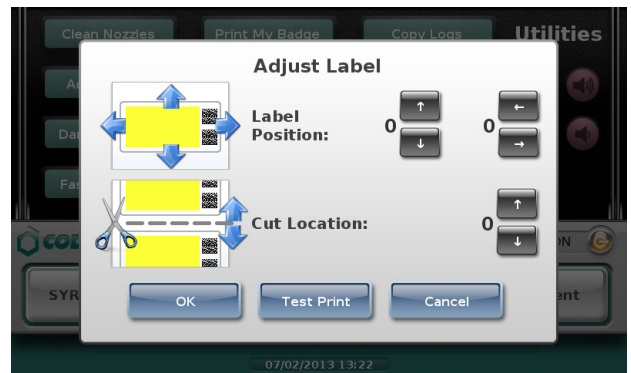
- ◆ The **Make User Badge** button can be disabled from the AT. If this configuration is selected, when a user selects the Make User Badge button, a dialog message will alert the user to contact the system administrator and a badge will not be able to be made.
- ◆ The auto-logout was extended to a maximum of 8 hours (28,800 seconds).
- ◆ The time for printing to cutting a label was reduced.
- ◆ The maximum expiration time for a drug was increased from 28 days (672 hours) to 1 year (8760 hours).
- ◆ An improved sort order for Total Dose/Total Volume values was implemented on SLS PCS TD/TV selection screen. The sort order is now as follows: TD values are descending (e.g., 10-->2) and TV values for a given TD value are ascending (e.g., 2-->10).



- ◆ The **end of roll behavior was improved**. Now at the end of a roll, the SLS PCS will print the last label, wait 10 seconds, cut the last printed label, and then automatically rewind the remaining liner. A user will then have to open up the back of the SLS PCS, remove the media core, and load a new roll of media.

WARNING: The SLS PCS waits 10 seconds before it will cut the last label at the end of roll. If you open up the cover before the last label (or strip of labels in Batch Mode) is cut and press the Unload button, then the SLS PCS will not cut the labels; it will just rewind the roll. If the label(s) hasn't cut, there is a risk as the roll rewinds that a label could peel off and become stuck inside the SLS PCS. You should make sure the last label(s) has cut before opening the front cover to replace the media.

- ◆ The ability to print a test print from the **Adjust Label** in the **Utilities** screen was added. This now allows a user to see if their label position changes have moved the printed label how much and where they want it to be located on the label media.



Version 1.7.0 SLS 500i

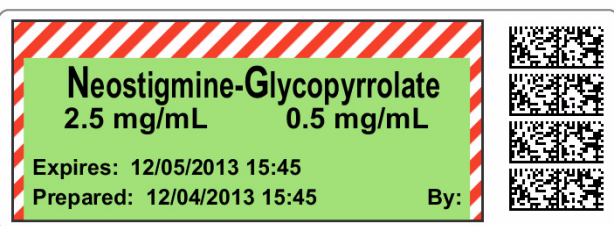
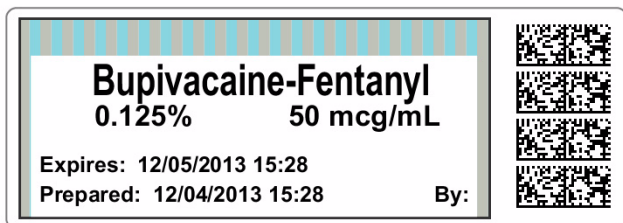
New Features

- ◆ SLS PCS is now integrated with Plexus Information System's Pharmacy Touch™ (Pharmacy management system and Capsa medication distribution cart application) and Anesthesia Touch™ Ultimate AIMS for use of Common Login and Common Scan. The system provides capability to login/logout of Anesthesia Touch™ Ultimate AIMS which will automatically login/logout of SLS PCS. Moreover, using SLS PCS to scan a container's barcode once removed from the cart will automatically pass the information to the cart for inventory control and, at the same time, initiate printing of a syringe label on SLS PCS. Lastly, scanning the syringe label barcode on SLS PCS using Administer Mode will pass the syringe label information to the Anesthesia Touch™ Ultimate AIMS. Contact your Codonics or Plexus Sales Representative for further information.

- ◆ SLS PCS supports an additional drug classification label for Beta Blocker drugs such as Labetalol. A sample is below. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to include in your formulary.



- ◆ SLS PCS supports additional label template packs for small (ME-S1), standard (ME-1), and large labels (ME-L1). There are two new combination drug labels included. They are a Local Anesthetic with Narcotic combination drug and a Relaxant Antagonist with Anticholinergic Agent combination drug. A sample of each is provided below. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to include in your formulary.



- ◆ SLS PCS supports China label template packs for small (ZH-S1), standard (ZH-1), and large labels (ZH-L1). A sample is provided below. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to include in your formulary.



- ◆ SLS PCS supports a Japan label template pack for standard (JP-1) labels. A sample is provided below. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to include in your formulary.

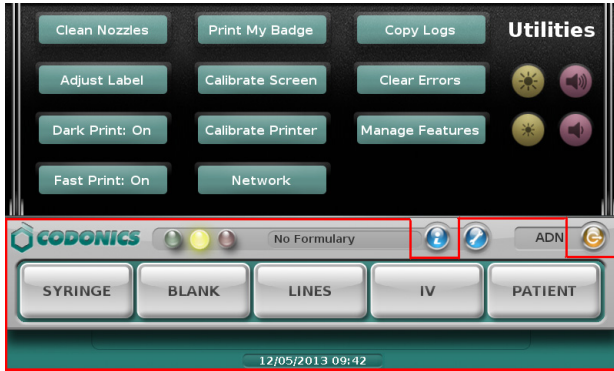


- ◆ Feature keys can be installed onto SLS PCSs over the network via the AT - Device Manager (AT-DM). Refer to the AT User Manual Addendum (905-081-001) for instructions.

Product Improvements

- ◆ SLS PCS supports improved Japan label template packs for small (JP-S1-v4) and large (JP-L1-v4) labels. The year is not included in the date range so only month and date are printed on a label. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to include in your formulary.
- ◆ SLS PCS now automatically displays a Total Dose/Total Volume (TD/TV) drug in cases where the drug is not diluted but Other is an option in the formulary. Previously, for example, a scrolling wheel with both 5 mg/10 mL and Other would display (with None for diluents), and a user would have to select 5 mg/10mL if they didn't want Other. Now, if the formulary has TD/TV options of 5 mg/10 mL and Other - Diluted but a user doesn't select the Dilute switch on SLS PCS, when they scan the vial, the drug label (no scrolling wheel) will automatically display on the screen with 5 mg/10 mL as the TD/TV and ready to print.
- ◆ The SLS PCS startup time was improved.

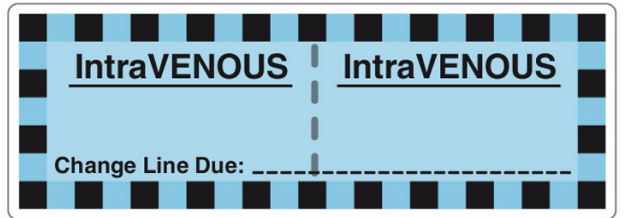
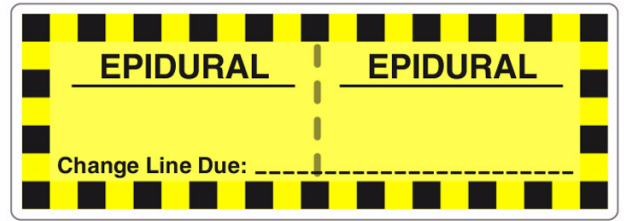
- ◆ **Additional means were provided to exit the Utilities screen.** Touching the SLS dashboard (e.g., Codonics logo, System Status area) or any of the Label Type buttons (i.e., Syringe, Blank, Lines, IV, Patient) when the Utilities screen is opened now also exits the Utilities screen. Pressing the wrench icon still exits the Utilities screen when opened. The area within the outlined border in the picture below shows the enhanced exit area.



Version 1.8.0 SLS 500i

New Features

- ◆ **SLS PCS now provides communication of Drug Not Found (DNF) events to the AT Device Manager.** With this DNF information, the AT user can update the existing formulary and distribute a new formulary package to all SLS PCSs so that other PCS users do not also experience a DNF issue for the same drug. Refer to the AT User Manual Addendum (905-081-001) for complete instructions.
- ◆ **SLS PCS now provides communication of Verification events to the AT Device Manager.** With this verification information, the AT user can update the existing formulary and distribute a new formulary package to all SLS PCSs so that other PCS users do not also have to verify the same drug that had been verified on a different SLS PCS. Refer to the AT User Manual Addendum (905-081-001) for complete instructions.
- ◆ **SLS PCS supports the Australian standard for line labels.** A sample of the labels is provided below. Refer to the AT User Manual Addendum (905-081-001) for instructions on how to include in your formulary.



Product Improvements

- ◆ **When dilution is required for a drug (e.g., a drug such as Cefazolin that requires reconstitution), SLS now announces Dilution Required before the drug name and concentration are announced.**
- ◆ **Verification of a drug on SLS PCS will now display the tallman lettering if available.** For example, Is this fentaNYL 50 mcg/mL? If tallman is not available, the drug name will be displayed. For example, Is this Propofol 10 mg/mL?
- ◆ **SLS PCS can now be configured to prevent muting of audible announcements.** The minimum volume is set in the AT. Refer to the AT User Manual Addendum (905-081-001) for instructions on including it in your configuration.
- ◆ **There is now capability to disable the service account.** SLS PCS is shipped with the Service key installed so that the service account is enabled. To enhance security, you can delete the key by pressing the Utilities screen, pressing Manage Features and deleting the Service key so that the service account cannot be accessed.
- ◆ **To enhance security, the SLS Admin account can be deleted for existing Admin accounts.** The preloaded Admin user (i.e., User 1111, PIN 1234) is still included with SLS PCS. Once upgraded to 1.8.0, you can now delete existing Admin users via the service account. Contact Codonics Technical Support for help.

Administer Mode

Overview

Version 1.4.0 and newer software includes support for Administer Mode with the Codonics Safe Label System (SLS) Point of Care Station (PCS).

This section explains how to use Administer Mode with SLS PCS.

An additional safety check, Administer Mode allows a SLS PCS user to scan the barcode of a syringe label that has been applied to a syringe prior to administering a drug to:

- ◆ Confirm the drug indicated on the syringe label with an audible announcement and a visual display of the drug name and concentration on the touch screen.
- ◆ Determine whether the drug in the syringe has passed its expiration date.

NOTE: Administer Mode requires a feature key on SLS PCS. Contact your Codonics Sales Representative to obtain the proper key.

Using Administer Mode

1. Log in to SLS PCS.
2. Scan the syringe label barcode by aligning the barcode with the barcode scanner located below the touch screen.



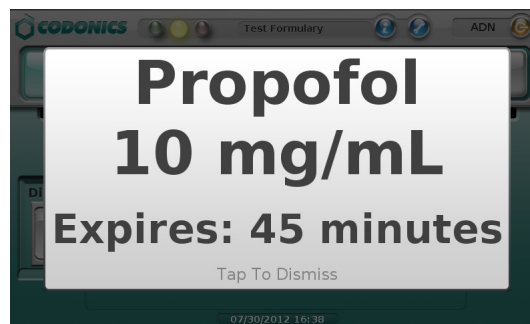
NOTE: Place the syringe below the scanner so that the red cross-hair lines up on the barcode. Placing the syringe closer to the cover, almost resting it on the cover, instead of placing it closer to the scanner, will also provide better results.

The drug information or other status from the scan is displayed and spoken.

The following topics describe the possible responses from SLS PCS.

Drug Is Found in the Formulary, Has Not Expired

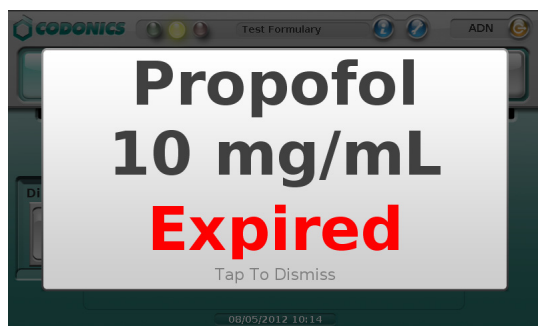
If the drug is found in the SLS formulary and it has not expired, SLS PCS announces the drug name and concentration. Both are also displayed on the touch screen with the amount of time remaining before the drug will expire.



The message will stop displaying in a few seconds, or you can tap the message to dismiss it.

Drug Is Found in the Formulary, Has Expired

If the drug is found in the SLS formulary but its expiration date has passed, SLS PCS announces that the drug is expired and then announces the drug name and concentration. This information is also displayed on the touch screen.

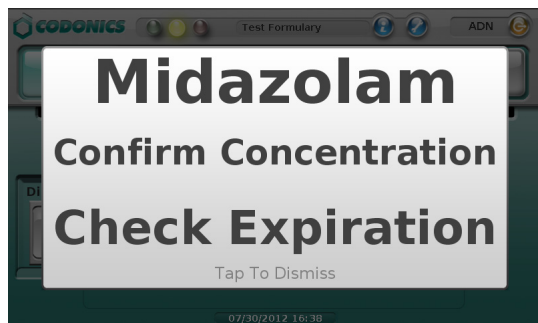


The message will stop displaying in a few seconds, or you can tap the message to dismiss it.

Drug Is Found in the Formulary, Requires Concentration Confirmation

If the drug is found in the SLS formulary but requires that the concentration must be confirmed, SLS PCS announces the drug name and that the concentration has to be confirmed. This information is also displayed on the touch screen.

This occurs if a unique concentration (for example, Other) is used for the drug or a WAV file is not available.



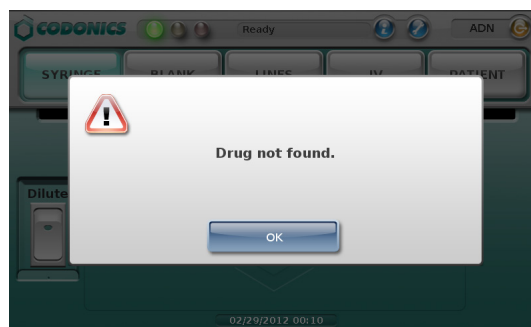
NOTE: If **0** was entered in the Expiration field in the formulary information for the drug, then a “Check Expiration” message is also included in the prompt.

The message will stop displaying in a few seconds, or you can tap the message to dismiss it.

Drug Is Not Found in the Formulary

If the drug is not found in the SLS formulary, a “Drug not found” message is displayed on the touch screen.

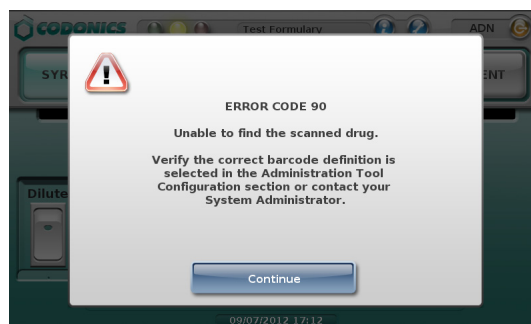
CAUTION: Not finding the drug in the formulary is a serious issue. It means that the formulary is different than the one that was used to create the syringe label. An SLS Administrator should be consulted immediately to review the logs and correct the formulary.



Tap the OK button to dismiss the message.

Unknown Error Occurs

If an unknown error occurs during Administer Mode, an error message is displayed on the touch screen.



Tap the Continue button to dismiss the message, and contact your SLS Administrator.

Total Dose/Total Volume

Overview

Version 1.4.0 and newer software includes support for Total Dose/Total Volume (TD/TV) with the Codonics Safe Label System (SLS) Point of Care Station (PCS).

This section explains:

- ◆ How SLS PCS users can select TD/TV entries on SLS PCS to provide printed syringe labels with TD/TV information

SLS Drug Preparation Methods

There are two preparation methods for managing how drugs are labeled: Normal Dilution and TD/TV.

The Normal Dilution method is commonly used in OR environments where the amount and frequency of drug administration can vary. Since the total dose being administered might not be known ahead of time, the primary information required on the syringe label is the drug name and prepared concentration.

TD/TV is commonly used when an order or prescription for a drug is issued and the drug is prepared according to the instructions in the order. TD/TV is also used in applications involving infusion pumps. Drugs prepared in this manner include the drug name, the total dose to be administered, and the total volume of the drug and diluent in the final preparation. SLS PCS also includes the equivalent concentration of the preparation on the label for regulatory compliance.

SLS allows multiple TD/TV preparations to be associated with each drug. The preparations are set up using the AT and included as part of the SLS formulary. When a drug container is scanned on SLS PCS, the user can select from the TD/TV preparations associated with that drug.

Notes About the TD/TV Preparation Method

Note the following about the TD/TV preparation method:

- ◆ The TD/TV information will be printed on labels that support it [for example, 30 x 80-mm Japan labels (JP-L1_vxx)] and shown on any applicable previews.

However, if the selected drug classification template does not support TD/TV information, the TD/TV dialog boxes described in this Technical Brief will still appear on SLS PCS, but the label will not have any TD/TV information printed on it.

- ◆ TD/TV information is not encoded in the syringe barcode.
- ◆ The TD/TV function is only supported for single drugs in the formulary. It is not supported for combination drugs.
- ◆ Administer Mode will only announce the drug name and equivalent concentration, but not the TD/TV values.

On SLS PCS— Entering TD/TV Values for a Syringe Label

For drugs in the formulary whose preparation method was specified as TD/TV, you will automatically be prompted to enter the TD/TV values when printing a syringe label.

1. Before scanning the drug container barcode, if the intent is to dilute the drug, set the Dilute switch to on.

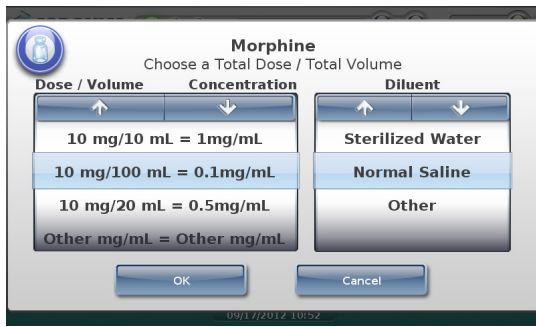


Dilute switch on position

2. Scan the drug container barcode.

NOTE: The drug will follow the verification steps, as described in the SLS User's Manual.

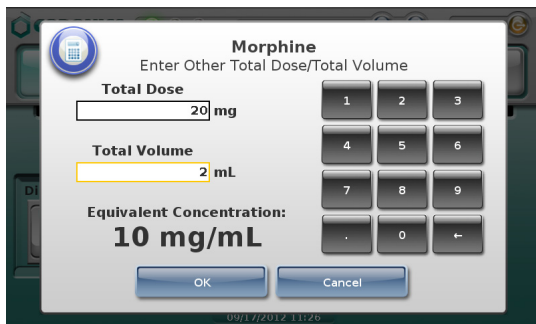
After the drug is identified, the prompt for the TD/TV entries displays.



3. Press and/or drag the Dose/Volume list until the appropriate TD/TV entry and equivalent concentration is selected (that is, it is displayed under the blue highlighted bars).
4. Press and/or drag the Diluent list until the appropriate diluent is selected.
 - ◆ If the dilution status for the drug is Not Allowed, the only option in the Diluent list will be None.
 - ◆ If the dilution status for the drug is Allowed, a None option is included at the bottom of the Diluent list.
 - ◆ If the dilution status for the drug is Required, a None option is not included in the Diluent list.
5. To save your selections, press the OK button.

If you did not select an Other TD/TV option, then continue in the label printing workflow, as described in the SLS User's Manual.

If you selected an Other TD/TV option, you are prompted to enter the dose and volume values.



6. Enter the TD/TV values in the Total Dose and Total Volume fields.

As you enter the values, the system computes the equivalent concentration and displays it in the Equivalent Concentration field.

7. To save the value entries, click the OK button.

You can continue in the label printing workflow, as described in the SLS User's Manual.

Examples of TD/TV Prompt Behavior

The following examples show the TD/TV prompt behavior on SLS PCS during the label printing procedure. The examples are based on the drug's Dilution setting and TD/TV entries, as specified in the AT.

These are examples only; they do not represent an actual drug situation. The examples are intended to represent how the TD/TV works and its behavior in the AT and SLS PCS.

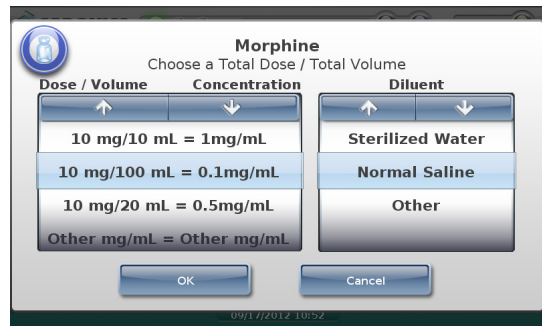
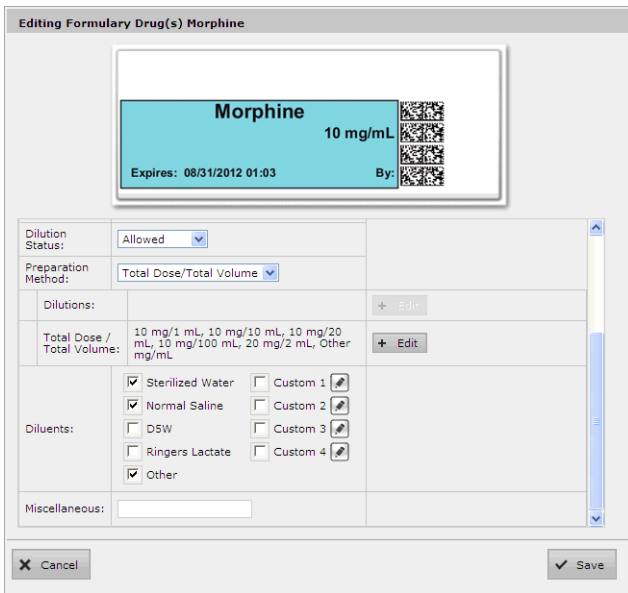
NOTE: If the TD/TV equivalent concentration is within 1% of the original container concentration, the system considers the TD/TV to be equivalent to the original concentration. Otherwise, the system considers the TD/TV to be a dilution. For example, if the original container concentration is 0.3 g but the TD/TV entry is 0.333, then they are considered different and 0.333 is considered a dilution. A warning will be displayed for the relevant AT and SLS PCS use cases.

Example 1

For this example:

- ◆ The drug is Morphine.
- ◆ The Always Show TD/TV configuration option on the Safety tab of the AT's Configuration Manager section was selected.
- ◆ The original drug container concentration is 10 mg/mL.
- ◆ The dilution status is set to Allowed.
- ◆ The available diluents are Normal Saline, Sterile Water, and Other.
- ◆ The TD/TV entries include multiples of the original container concentration and dilutions of the original concentration:
 - ◆ 10 mg/1 mL
 - ◆ 10 mg/10 mL
 - ◆ 10 mg/20 mL
 - ◆ 10 mg/100 mL
 - ◆ 20 mg/2 mL
 - ◆ Other mg/mL

The formulary settings for this drug on the Editing Formulary Drug(s) dialog box in the AT are shown below.



Only TD/TV entries that are dilutions of 10 mg/mL are displayed and the diluents are displayed.

Example 2

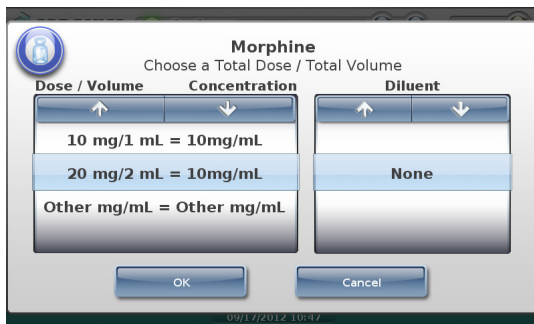
For this example:

- ◆ The drug is Heparin.
- ◆ The Always Show TD/TV configuration option on the Safety tab of the AT's Configuration Manager section was selected.
- ◆ The original drug container concentration is 10,000 Units/mL.
- ◆ The dilution status is set to Not Allowed.
- ◆ There are no available diluents.
- ◆ The TD/TV entries include multiples of the original concentration, dilutions of the original concentration, and an Other entry:
 - ◆ 10,000 Units/1 mL
 - ◆ 10,000 Units/2 mL
 - ◆ 20,000 Units/2 mL
 - ◆ 20,000 Units/4 mL
 - ◆ 40,000 Units/4 mL
 - ◆ Other Units/mL

The initial formulary settings for this drug on the Editing Formulary Drug(s) dialog box in the AT are shown below.

On SLS PCS:

- ◆ If the Dilute switch is set to **Off**, the TD/TV prompt will display as follows:



No diluted TD/TV entries or diluents will be shown because the Dilute switch is set to off. Only TD/TV entries with concentrations that are equivalent to the original concentration (for example, 10 mg/mL) are displayed and no diluents are displayed.

- ◆ If the Dilute switch is set to **On**, the TD/TV prompt will display as follows:

However, because dilutions are not allowed, the following prompt would be displayed after selecting TD/TV entries that represent dilutions of the original container concentration:

If dilutions are not intended to be included, the entries listed in the Warning message should be removed. If dilutions are intended to be included, then the Dilution Status should be changed to Allowed.

The following example shows the dilution entries removed to resolve the problem.

If no changes were made to the original TD/TV entries or dilution status, on SLS PCS:

- ◆ If the Dilute switch is set to Off, the TD/TV prompt will display as follows:

No dilution values of 10,000 Units/mL will be shown. Only TD/TV entries that are equivalent to the original container concentration of 10,000 Units/mL are displayed (for example, 20,000 Units/2 mL), and no diluents are displayed.

- ◆ If the Dilute switch is set to **On**, the following prompt that indicates that dilutions are not allowed is displayed:



Example 3

If the Warning shown in example 2 is ignored and a TD/TV entry is a dilution but the Dilution setting is **Not Allowed**, then the SLS PCS user will be able to choose a dilution but no diluents will be displayed. You should be aware that this configuration overrides the intention of not allowing dilutions.

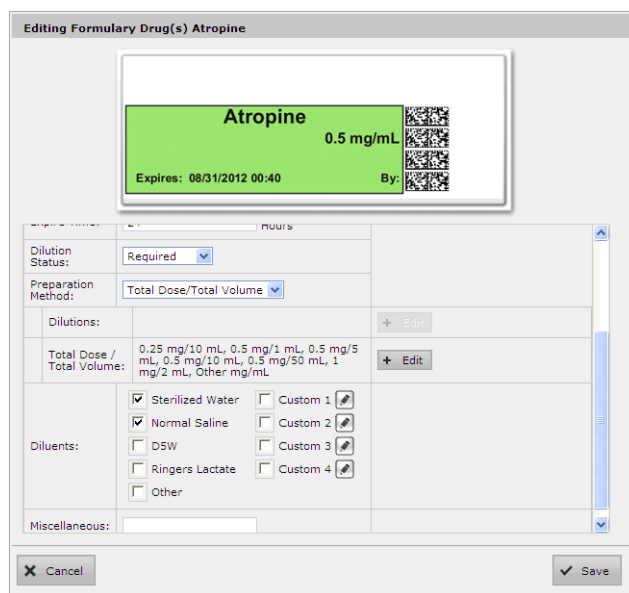
Example 4

For this example:

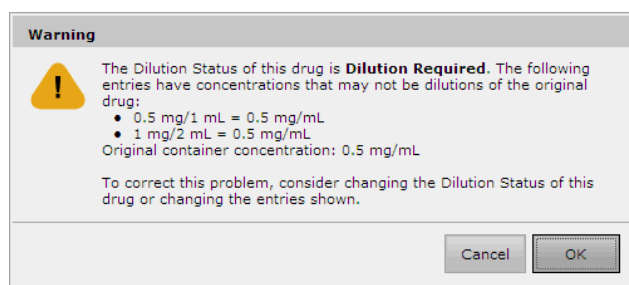
- ◆ The drug is Atropine.
- ◆ The Always Show TD/TV configuration option on the Safety tab of the AT's Configuration Manager section was selected.
- ◆ The original drug container concentration is 0.5 mg/mL.
- ◆ The dilution status is set to Required.
- ◆ The available diluents are Normal Saline and Sterile Water.
- ◆ The TD/TV entries include multiples of the original container concentration, dilutions of the original concentration, and an Other entry:
 - ◆ 0.25 mg/10 mL
 - ◆ 0.5 mg/1 mL
 - ◆ 0.5 mg/5 mL
 - ◆ 0.5 mg/10 mL

- ◆ 0.5 mg/50 mL
- ◆ 1 mg/2 mL
- ◆ Other mg/mL

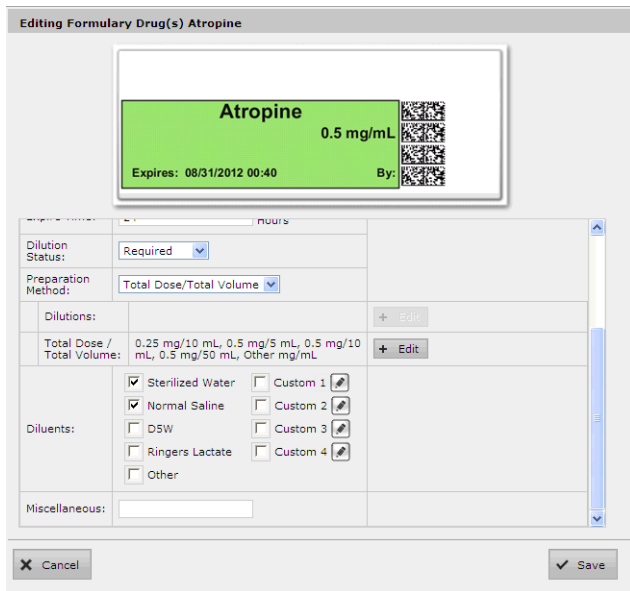
The initial formulary settings for this drug on the Editing Formulary Drug(s) dialog box in the AT are shown below.



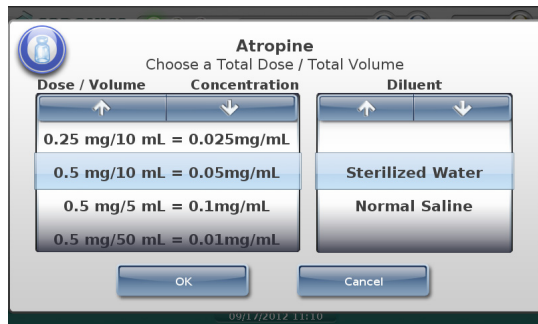
However, because dilutions are required, the following prompt would be displayed after selecting TD/TV entries that are equivalent to the original container concentration:



To correct this condition, the values listed in the Warning message should be removed, so that the final settings are as shown below.



Based on the final settings shown above, on SLS PCS the following TD/TV prompt displays regardless of whether the Dilute switch is set to Off or On:



Only TD/TV entries that are dilutions are displayed, and the diluents are displayed.

Example 5

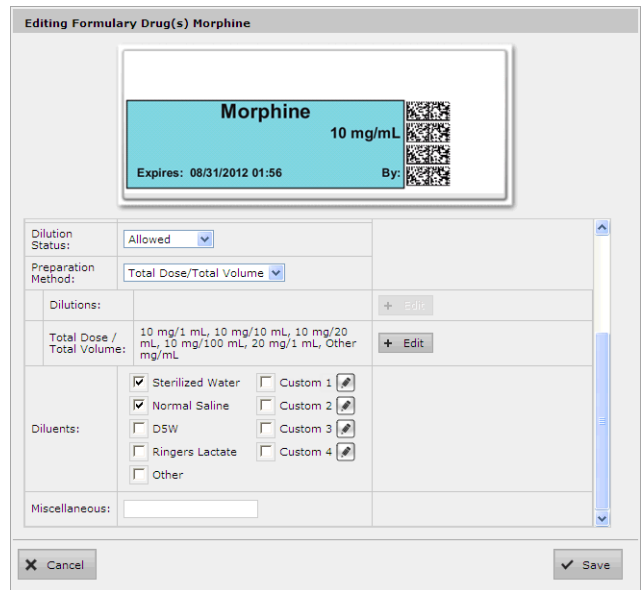
For this example:

- ◆ The drug is Morphine.
- ◆ The Always Show TD/TV configuration option on the Safety tab of the AT's Configuration Manager section was selected.
- ◆ The original drug container concentration is 10 mg/mL.
- ◆ The dilution status is set to Allowed.
- ◆ The available diluents are Normal Saline and Sterile Water.

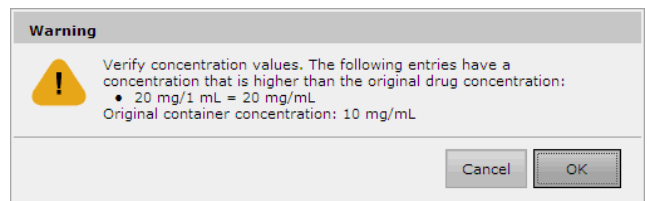
◆ The TD/TV entries include multiples of the original container concentration, a concentration that is higher than the original concentration, dilutions of the original concentration, and an Other entry:

- ◆ 10 mg/1 mL
- ◆ 10 mg/10 mL
- ◆ 10 mg/20 mL
- ◆ 10 mg/100 mL
- ◆ 20 mg/1 mL
- ◆ Other mg/mL

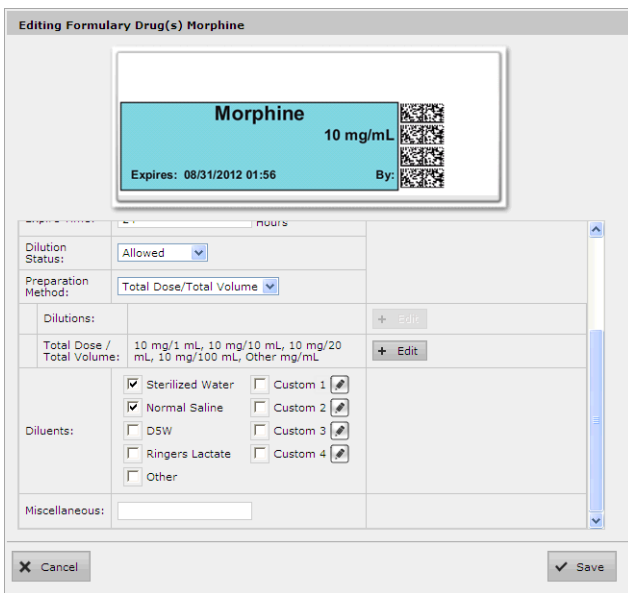
The initial formulary settings for this drug on the Editing Formulary Drug(s) dialog box in the AT are shown below.



However, because the 20 mg/1 mL entry has a concentration that is higher than the original container concentration, the following prompt would be displayed after selecting the TD/TV entries:

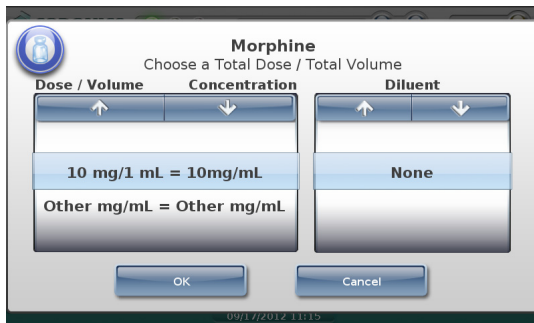


To correct this condition, the higher concentration entry listed in the Warning message should be removed, so that the final settings are as shown below.



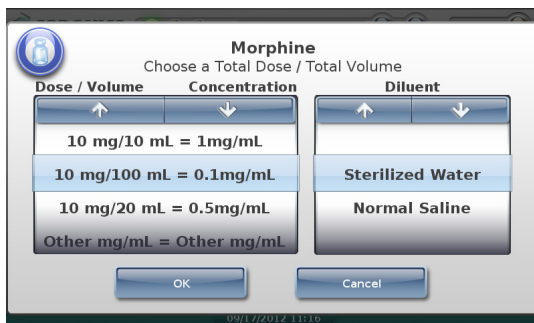
On SLS PCS:

- ◆ If the Dilute switch is set to **Off**, the TD/TV prompt will display as follows:



Only TD/TV entries whose concentration is equivalent to the original container concentration are displayed, and no diluents are displayed.

- ◆ If the Dilute switch is set to **On**, the following prompt that indicates that dilutions are allowed is displayed:



Example 6

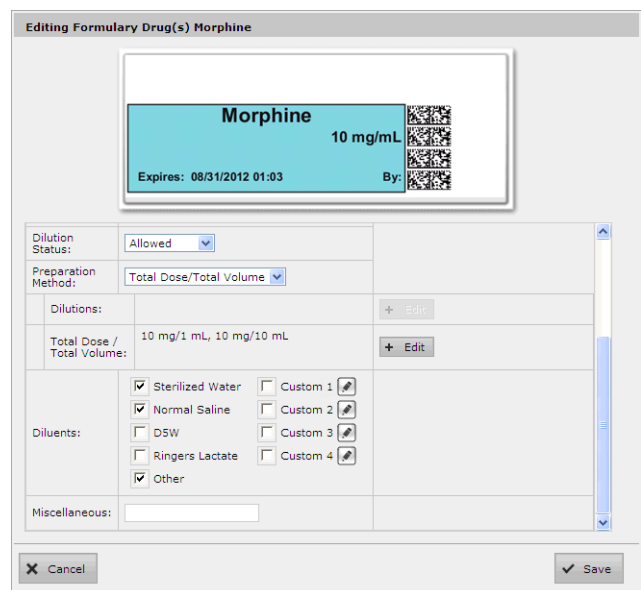
For this example:

- ◆ The drug is Morphine.
- ◆ The Always Show TD/TV configuration option on the Safety tab of the AT's Configuration Manager section was **not** selected.

NOTE: The Always Show TD/TV configuration option applies to all drugs in the formulary.

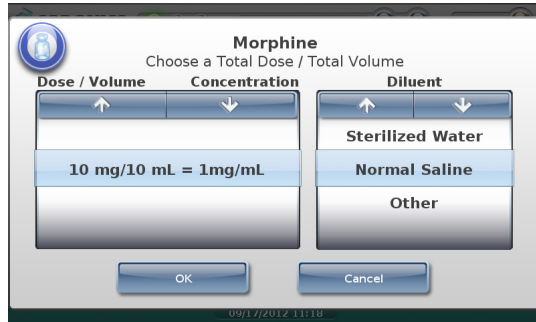
- ◆ The original drug container concentration is 10 mg/mL.
- ◆ The dilution status is set to Allowed.
- ◆ The available diluents are Normal Saline, Sterile Water, and Other.
- ◆ The TD/TV entries include a concentration that is equivalent to the original container concentration and a dilution:
 - ◆ 10 mg/1 mL
 - ◆ 10 mg/10 mL

The formulary settings for this drug on the Editing Formulary Drug(s) dialog box in the AT are shown in the screen at the top of the next column.



On SLS PCS:

- ◆ If the Dilute switch is set to **Off**, the TD/TV entry whose concentration is equivalent to the original container concentration will be automatically selected because it is the only non-diluted concentration defined for the drug. A TD/TV prompt is not displayed.
- ◆ If the Dilute switch is set to **On**, the TD/TV prompt will display as follows:



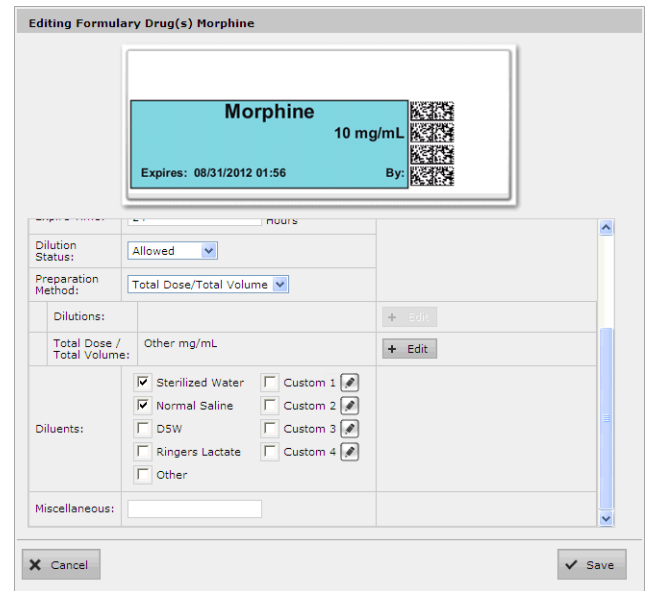
The prompt is displayed because, even though there is only one dilution value, multiple diluents have been selected for the drug. If only one diluent had been selected, then the dilution and diluent would have been automatically selected by the system and no prompt would have been displayed.

Example 7

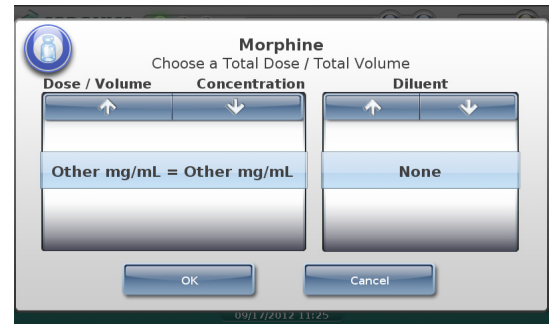
For this example:

- ◆ The drug is Morphine.
- ◆ The Always Show TD/TV configuration option on the Safety tab of the AT's Configuration Manager section was selected.
- ◆ The original drug container concentration is 10 mg/mL.
- ◆ The dilution status is set to Allowed.
- ◆ The available diluents are Normal Saline and Sterile Water.
- ◆ The only TD/TV entry is Other mg/mL.

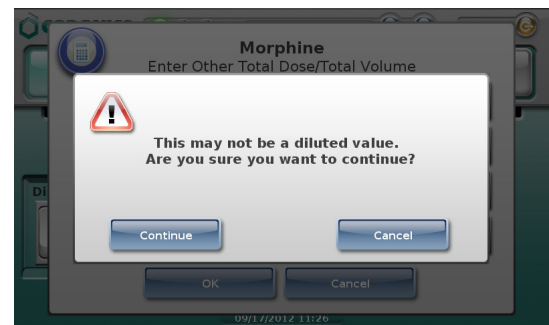
The formulary settings for this drug on the Editing Formulary Drug(s) dialog box in the AT are shown below.



On SLS PCS, if the Dilute switch is set to **Off**, only the Other entry will be displayed in the TD/TV prompt:



If the Dilute switch is set to **On** and the user selects a TD/TV entry whose concentration is equivalent to the original container concentration (for example, 20 mg/2 mL), the system will display the following message to indicate that the entered TD/TV might not be a dilution:



Wired Hand Scanner

Overview

Version 1.4.0 and newer software includes support for using a Motorola DS4208-HC barcode scanner as a wired hand scanner for scanning labels on containers that are large or not easily scanned (for example, IV bags) by the Codonics Safe Label System (SLS) Point of Care Station (PCS).

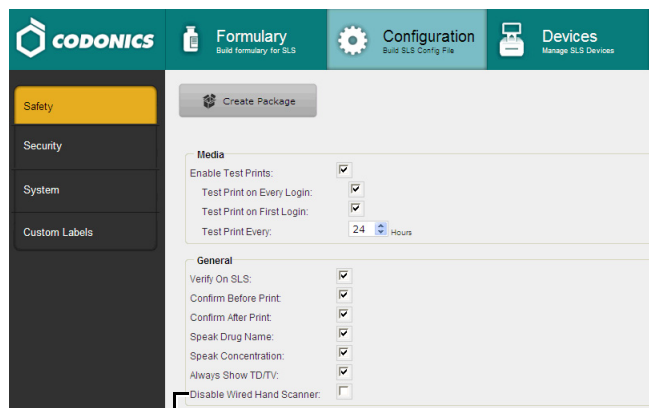
When using the wired hand scanner with SLS PCS, the scanner must be in SNAPI mode (SNAPI is the scanner's communication interface). By default, the scanner is shipped in SNAPI mode.

NOTE: The use of the wired hand scanner requires a feature key on SLS PCS. Contact your Codonics Sales Representative to obtain the proper key.

NOTE: It is recommended that you purchase the DS4208-HC scanner from Codonics. A standard DS4208-HC scanner will not provide the same performance as a DS4208-HC scanner from Codonics, which includes custom firmware.

Enabling the Use of a Wired Hand Scanner in the SLS Configuration Package

To enable the use of a wired hand scanner with SLS PCS, the Disable Wired Hand Scanner option on the Safety tab of the Administration Tool's Configuration Manager section must be deselected in the SLS configuration package, as shown in the following figure.



Disable Wired Hand Scanner option

Connecting the Wired Hand Scanner to SLS PCS

WARNING: The use of the wired hand scanner with SLS PCS can create a tipping hazard. Secure SLS PCS using the VESA mount points on the bottom of SLS PCS.

NOTE: It is recommended that you connect the wired hand scanner to SLS PCS prior to starting up or logging into SLS PCS.

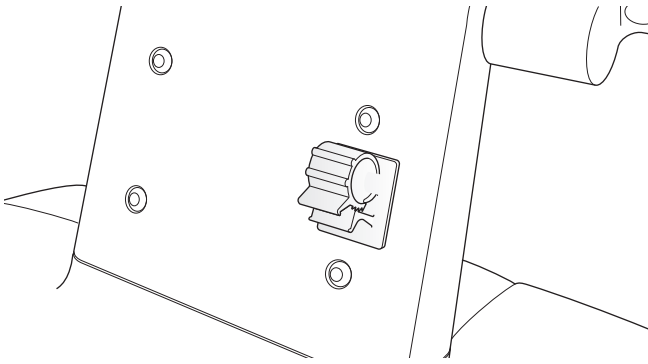
Included with the DS4208-HC barcode scanner are the following components:

- ◆ **A wired hand scanner USB cable.** This cable includes an RJ-45 connector that connects to the scanner and a standard USB connector that connects to the USB extension cable.
- ◆ **A USB extension cable.** This cable provides a safe disconnect to reduce the risk of damage to SLS PCS when the wired hand scanner USB cable is pulled tight. The cable has an angled male connector for connection to the touch screen USB port 1 and a female connector for accepting the wired hand scanner USB cable connector. A tie wrap is attached to the cable near the female connector to ensure that the cable cannot slide in the cable clip.
- ◆ **A cable clip.** This clip is used to secure the USB extension cable to the back of the display stalk.

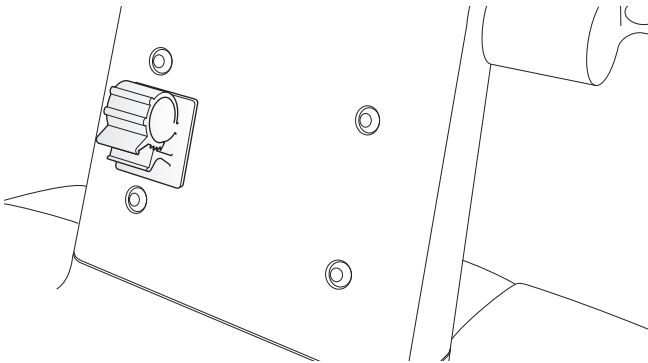
To connect the wired hand scanner to SLS PCS:

1. Make sure that SLS PCS is powered off.
2. Clean and disinfect the wired hand scanner. Refer to "Cleaning and Disinfecting the Wired Hand Scanner" on page 21.
3. Clean the back of the display stalk and let it dry.
4. Attach the cable clip to the back of the display stalk.

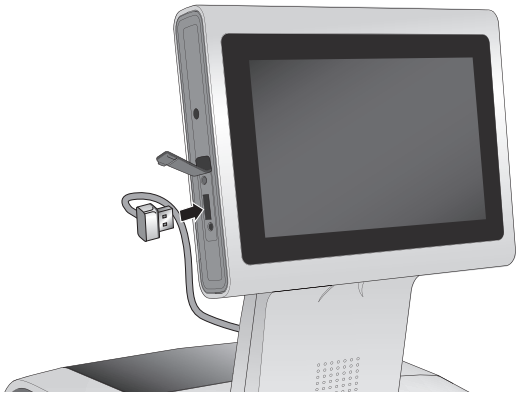
If the SLS PCS shelf is on the **right side of the medical cart**, attach the cable clip between the two screws on the right side of the display stalk, as shown in the following figure.



If the SLS PCS shelf is on the **left side of the medical cart**, attach the cable clip between the two screws on the left side of the display stalk, as shown in the following figure.



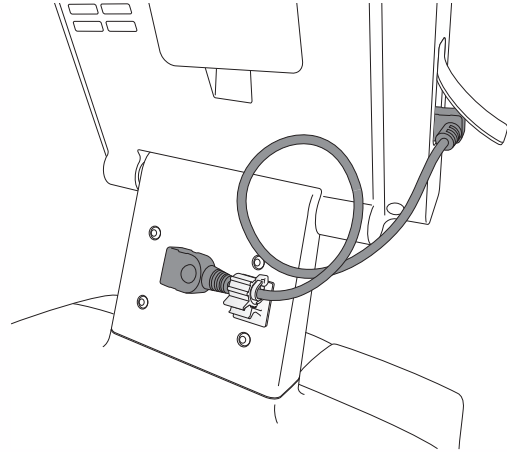
5. Insert the USB extension cable's angled connector into the touch screen USB port 1, as shown in the following figure.



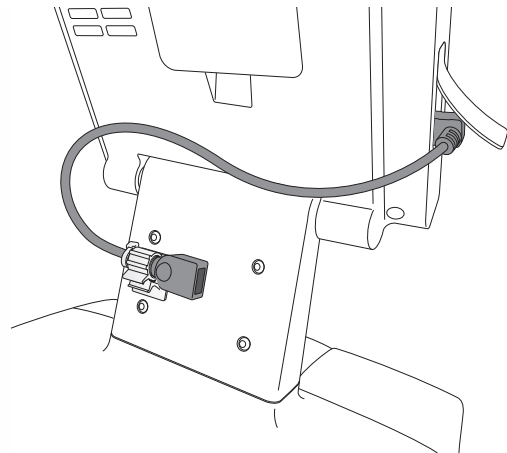
6. Attach the USB extension cable to the clip:
 - a. Depending on which side of the medical cart the SLS PCS shelf is, loop the cable as shown in the figures in the next column.
 - b. Pull up on the top tab of the cable clip.

- c. Insert the cable into the clip.
- d. Pull down on the bottom tab and push down on the top tab until you hear the top tab click into the bottom tab. Continue pushing the top tab until the cable is snug in the cable clip.

The following two figures show the USB extension cable attached for both orientations of the SLS PCS shelf.



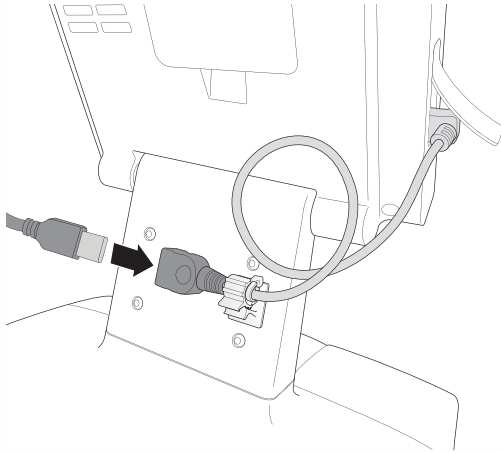
USB Extension Cable Attached with SLS PCS Shelf on Right Side of Medical Cart



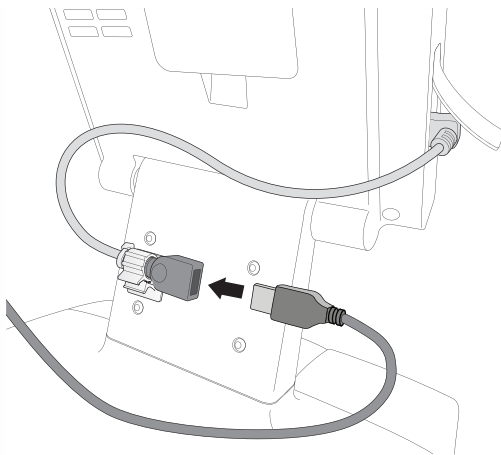
USB Extension Cable Attached with SLS PCS Shelf on Left Side of Medical Cart

7. Connect the RJ-45 connector of the wired hand scanner USB cable to the wired hand scanner:
 - a. Push the RJ-45 connector into the wired hand scanner RJ-45 port until you hear it click.

- b. Gently pull the wired hand scanner USB cable to make sure that the RJ-45 connector is securely connected.
8. Connect the USB connector of the wired hand scanner USB cable to the USB extension cable female connector, as shown in the following two figures.

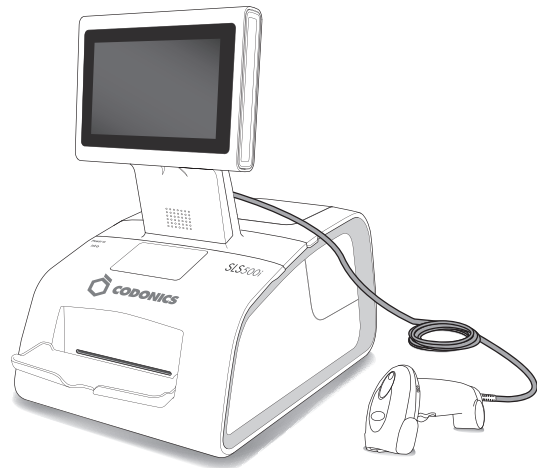


Inserting Wired Hand Scanner USB Cable with SLS PCS Shelf on Right Side of Medical Cart



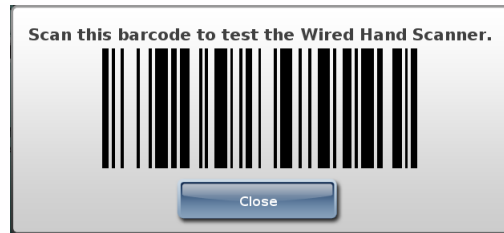
Inserting Wired Hand Scanner USB Cable with SLS PCS Shelf on Left Side of Medical Cart

An example of the connected wired hand scanner is shown in the following figure.



Testing the Wired Hand Scanner Communication with SLS PCS

After connecting the wired hand scanner and starting SLS PCS, the following prompt displays:



Scan the barcode displayed in the prompt.

This will confirm that the wired hand scanner is communicating with SLS PCS.

Configuring the DS4208-HC Scanner for SLS PCS

By default, the DS4208-HC scanner is configured to work with SLS PCS. If you ever need to reconfigure the DS4208-HC scanner to work with SLS PCS, scan the 2D barcode below.



After successfully scanning this barcode, you will hear an audible beep and then an audible sound that indicates that the DS4208-HC scanner is restarting.

Cleaning and Disinfecting the Wired Hand Scanner

Following are the cleaning and disinfecting instructions for the wired hand scanner in environments that require daily or more frequent cleaning to prevent the spread of germs.

To avoid long-term damage to the wired hand scanner, it is recommended that you disinfect it only when necessary as determined by your hospital's policy.

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.

Daily Cleaning and Disinfecting Instructions

WARNING: Always disconnect the wired hand scanner or power off SLS PCS before cleaning it. An electrical shock could occur if SLS PCS is powered on and liquid is spilled into the wired hand scanner or SLS PCS.

1. Dampen a soft cloth with one of the approved cleaning or disinfecting agents listed in the SLS User's Manual or use pre-moistened wipes.
2. Gently wipe all surfaces, including the front, back, sides, top, and bottom of the wired hand scanner.

CAUTION: Never apply liquid directly to the wired hand scanner. Be careful not to let liquid pool around the scanner window, trigger, cable connector, or any other area on the wired hand scanner.

3. Clean the trigger and in between the trigger and the housing. Use a cotton-tipped applicator to reach tight or inaccessible areas.
4. Immediately dry the scanner window after cleaning it with a soft non-abrasive cloth to prevent streaking.

5. Allow the wired hand scanner to air dry before using it.

NOTE: If the temperature is low and the humidity is high, longer drying time is required. Warm temperatures and low humidity require less drying

Monthly Deep Cleaning and Disinfecting Instructions

Maintain the wired hand scanner in good working order with a regular comprehensive cleaning routine to remove the natural build-up of dirt that occurs with everyday use on connectors, scanner window, and housing surfaces.

- ◆ **Housing surfaces:** Follow the instructions in "Daily Cleaning and Disinfecting Instructions" in the previous column to perform a general cleaning of the housing surfaces.
- ◆ **Scanner window:** Wipe the scanner window with a lens tissue or other material suitable for cleaning optical material such as eyeglasses.
- ◆ **RJ-45 port:**
 - a. Dip the cotton portion of a cotton-tipped applicator in isopropyl alcohol.
 - b. Rub the cotton portion of the cotton-tipped applicator back-and-forth across the RJ-45 port. Do not leave any cotton residue on the port.
 - c. Repeat steps a and b at least three times.
 - d. Use the cotton-tipped applicator dipped in isopropyl alcohol to remove any grease and dirt near the connector area.
 - e. Use a dry cotton-tipped applicator (that is, with **no** isopropyl alcohol applied) to dry the RJ-45 port and the connector area.

Allow the wired hand scanner to air dry before using it.

NOTE: If the temperature is low and the humidity is high, longer drying time is required. Warm temperatures and low humidity require less drying

Auxiliary Barcodes

Overview

Version 1.5.0 and newer software includes support for Auxiliary Barcodes on standard size labels with the Codonics Safe Label System (SLS) Point of Care Station (PCS).

Auxiliary barcodes can be included on printed standard size syringe labels to encode the Container ID number of the original drug container.

Auxiliary barcodes can contain:

- ◆ A 10-digit Container ID when the SLS Master Drug Database (MDD) mode is set to US NDC.
- ◆ A 10- or 13-digit Container ID when the SLS MDD mode is set to Other.

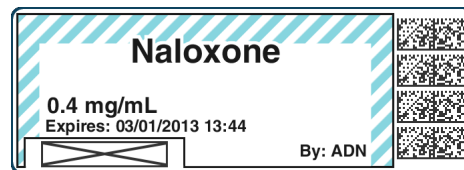
Only the original Container ID of the drug container will be encoded in the auxiliary barcode.

Currently, only 1D barcodes are supported for auxiliary barcodes.

WARNING: Scanning the auxiliary barcode in Administer Mode or when the SLS PCS main screen is displayed will create another label. If creating this label was unintended, either cancel the label's printing at the pre-print confirmation screen or discard the label.

Printing a Placeholder Graphic for a Non-Compliant Container ID

If SLS PCS detects that a drug's Container ID is not compliant with the 10-digit or 13-digit limit, it will print a label with a special "X" graphic, as shown in the example below.



For example, the last digit of a 13-digit Container ID must be a check digit for the rest of the Container ID. If it is not, then the Container ID will be non-compliant.

SLS PCS will not display any error or warning messages when non-compliant Container IDs are encountered. The placeholder graphic will act as the only indicator to the user that the drug Container ID is not compatible with the auxiliary barcode.

Batch Mode

Overview

Version 1.6.0 and newer software includes support for Batch Mode with the Codonics Safe Label System (SLS) Point of Care Station (PCS).

Batch Mode allows a Safe Label System 500i (SLS) Point of Care Station (PCS) user to automatically print multiple copies of the same label. The label can include a user defined lot number and a larger initial area for use cases where two sets of initials are required on the label. This may occur because a different person prepared the label than prepared the syringe or in a case when a second check for safety is required (for example in pharmacy).



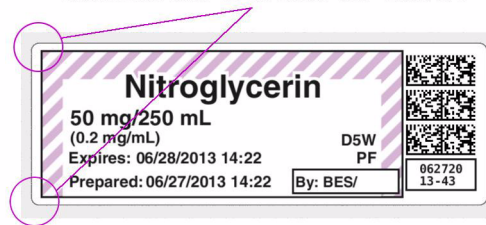
NOTE: Batch Mode requires a feature key on SLS PCS. Contact your Codonics Sales Representative to obtain the proper key.

WARNING: The safest means to label a syringe (or any container of medication) using SLS PCS is to scan a vial or ampoule, draw up the drug as the label is being printed, and then immediately label the syringe before setting it down. Batch Mode introduces the risk of a mislabeled syringe since more than one label from a single vial/ampoule scan is being created, changing the one-to-one relationship (e.g. one vial and one syringe with a single label). For example, if there is more than one filled syringe without a label, there is a potential for a syringe to be mislabeled. Or if there are more labels than there are filled syringes, there is a potential for a rogue label to be placed on the wrong syringe. Be sure to visually confirm the label you are applying is the correct one for the syringe being labeled.

NOTE: When starting to print, first make sure that the media is fed into SLS PCS properly. If the media is not fed in straight, it can cause the printed information (e.g., border, barcode) on the label to be printed onto the liner or into the perforation on large labels.

NOTE: To prevent label information from printing onto the liner, make sure you center the label contents on the label. Once media is fed into SLS PCS, the media can take about 10-20 labels to stabilize location. Once this occurs, then you should center the location by using the Adjust Label controls in the Utilities panel of SLS PCS.

Make sure printed area is centered inside of label

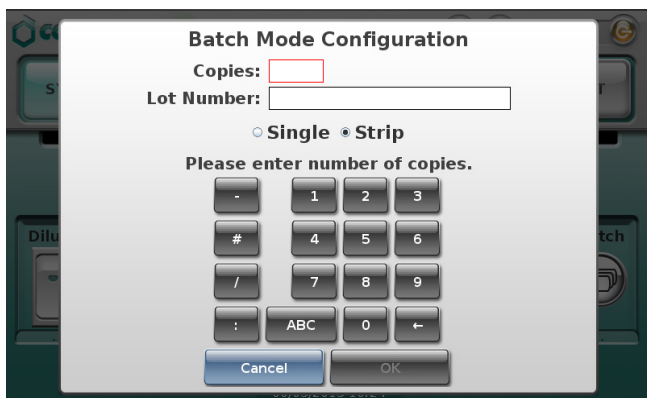


Using Batch Mode

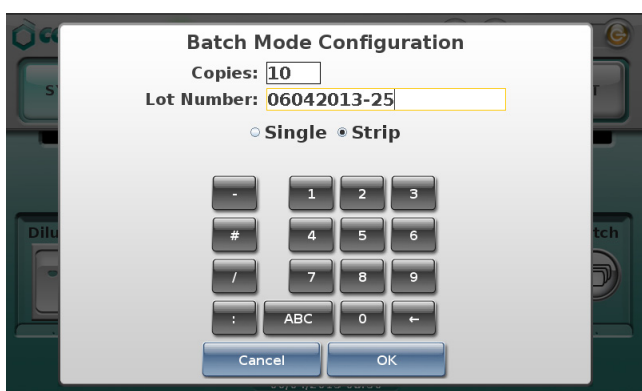
1. Log in to SLS PCS.
2. If you are making a batch of labels, touch the Batch icon.



The Batch Mode Configuration screen will open.



3. Enter the number of Copies of the label required and if applicable enter a Lot Number.



NOTE: Up to 999 copies can be printed in one batch job. Up to 18 alphanumeric characters can be used for a lot number.

NOTE: If a lot number is entered, the bottom barcode will be replaced with the human readable lot number. If a lot number is not entered, then the bottom barcode on the syringe label will print normally with a barcode. See an example of a label with the lot number in Step 8.

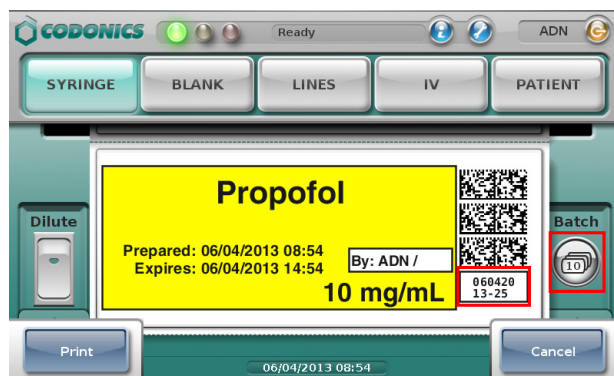
NOTE: If a lot number is entered that was previously used, an alert will be displayed on the SLS PCS display letting you know that it was already used.

NOTE: The Copies and Lot Number will not persist from batch job to batch job. This means they will be blank and a value will need to be entered for each job when Batch Mode is selected. The selection of Single or Strip will persist from batch job to batch job. This means you will need to change the entry if you want the labels to be provided differently from one job to the next.

4. Select whether you want Single labels (i.e. cut in between each copy of the label) or a Strip of labels (i.e. all the copies of the labels are placed on a single liner).

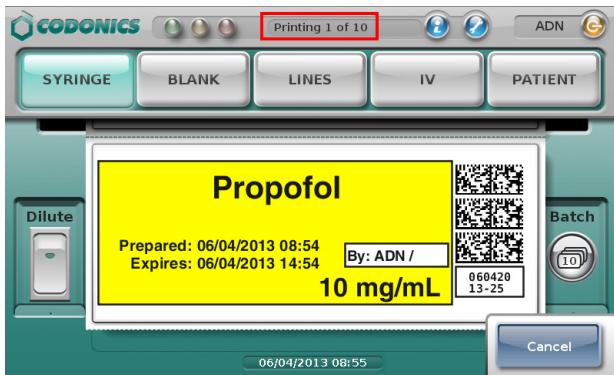
NOTE: If Strip is chosen, you will be asked at the end of the batch to cut the liner and SLS PCS will then automatically cut the liner.

5. Select OK and you will be returned to the Main SLS PCS user interface.
6. Scan the container barcode the same as if you were printing a single label.
7. The label will be displayed, the number of copies will be displayed in the Batch icon, and the lot number, if entered, will be in the bottom barcode area.



8. Once the print is started, the number of labels printed out of the job is displayed at the top of the SLS PCS user interface.

NOTE: During the printing of the batch job, you can select Cancel from the SLS PCS user interface, and the job will be stopped once the current label is finished printing.



- When the batch is completed, if Strip had been selected on the Batch Mode Configuration screen, a dialog box will be shown summarizing the job and asking if you would like to cut the strip. Select OK. SLS PCS will automatically cut the liner.



WARNING: Do not pull the strip of labels or try to tear the strip of labels. This can cause jamming and/or damage to the SLS PCS.

WARNING: Handling of long strips of labels increases the chance of a paper cut.

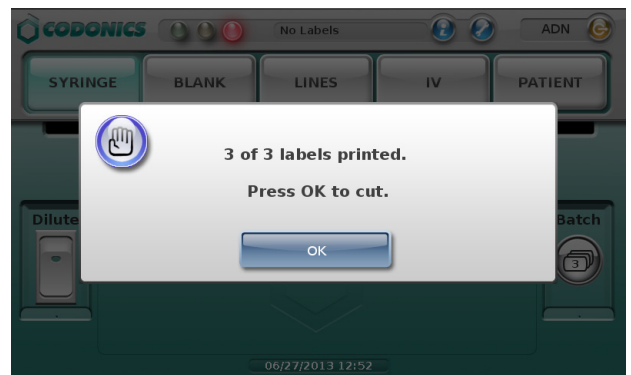
NOTE: If SLS PCS is configured for Post Print Confirmation, you will be shown the Post Print Confirmation screen after the batch is complete and will only need to scan the last label.

- Once the batch is complete, the main SLS PCS user interface will return and you can use the SLS PCS again for either a single container/single scan or in another batch job.

WARNING: If Batch Mode is used for printing a single color label (e.g., yellow for Propofol), an ink cartridge will be considered unusable if the single color is empty; even if there is a predominant amount of the two other colors (e.g., Cyan or Magenta) remaining in the cartridge. This is to make sure that all potential colors (e.g., green) can be produced with the cartridge.

End of Roll

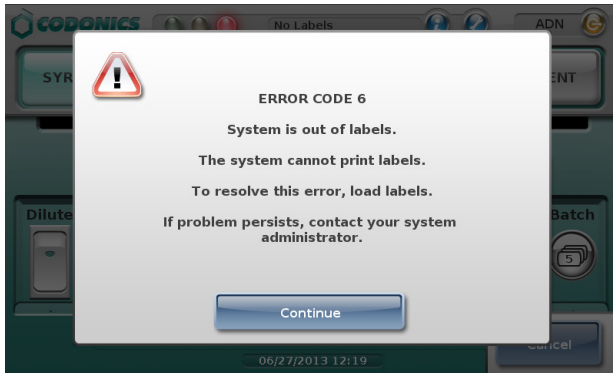
When SLS PCS reaches the end of roll using strip cut printing in Batch Mode, a dialog screen will indicate the job is complete and ask you to cut the labels.



If the job is not complete, a dialog screen will indicate how many labels have printed, and will ask you to cut the labels and to load media.



Once you select OK, SLS PCS will cut the labels and automatically rewind the media. A dialog message will appear.



At that time, open up the back of SLS PCS, remove the media core, and load a new roll of media. If the batch job is not complete, SLS PCS will then complete the batch.

If you print in Batch Mode using single cuts, when the last available label prints, SLS PCS will cut the last label and then

automatically rewind the media. A dialog message will appear indicating the system is out of labels and to load a new roll of labels. If the batch job was not completed, once a new roll of media is loaded, the job will complete.

Screen Saver and Auto-Logout

When a batch job is printing, the screen saver will not activate nor will you be automatically logged out in the following cases, even when the system is waiting at the OK to cut dialog box: any time cutting a strip of labels or at the end of a roll (either printing a strip of labels or a single print).

Issues

- ◆ **Position of the SLS PCS can affect printing.** If SLS PCS is rotated toward its right side, the hanging strip of labels can cause strain on the printing, and thus cause labels to be vertically misaligned and ink to be printed on the liner instead of the label. If SLS PCS is placed flush with an edge of a surface, like the edge of the desk/table which it is on, then the printed strip of labels will descend off the edge and not cause an issue with printing.