If you confirm the "Error - System Cannot Be Used", follow instructions on the next screen to discontinue the System *(see Discontinuation of Therapy, Section 14)* and start over with a new Controller, Dispenser and Cartridge.

Did you receive the Prime Failed error message?
If any error occurs at this point, follow the on-screen instructions and discontinue the System *(see Discontinuation of Therapy, Section 14)* and start over with a new Controller, Dispenser and Cartridge.
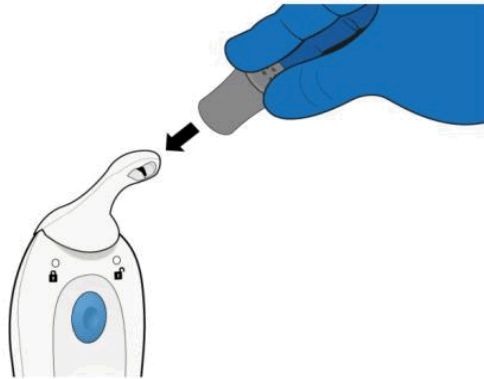
If you confirm the prime failure, follow instructions on the next screen to discontinue the System and start over with a new Controller, Dispenser and Cartridge.
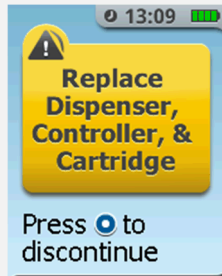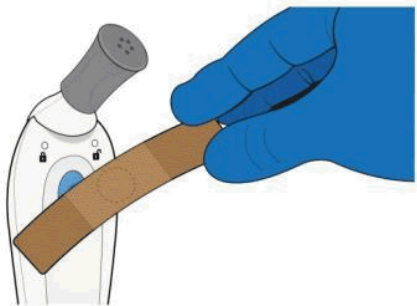
Refer to Section 16, Notifications, Alerts, Alarms and Errors, for further guidance on these notifications.
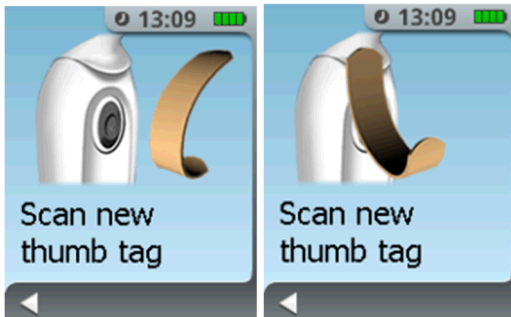
Re-Cap The System

Place the Cap back on the Dispenser before continuing.
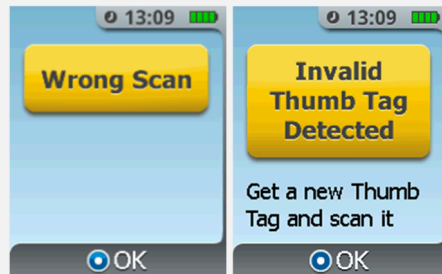
Scan Patient ID Thumb Tag

Scan the new Patient ID Thumb Tag by touching it to **Blue Dose** Button on the back side of the Controller.

(?) Did you receive the Wrong Scan or Invalid Thumb Tag Detected notification message?

If one of these notifications occurs at this point, the Patient ID Thumb Tag scanned is defective or cannot be used by the System. Obtain a new Patient ID Thumb Tag then press the **Enter/Select** button and follow the on-screen instructions to scan the new Patient ID Thumb Tag.
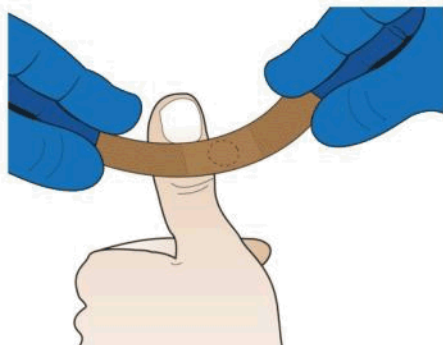

Refer to Section 16, Notifications, Alerts, Alarms and Errors, for further guidance on these notifications.
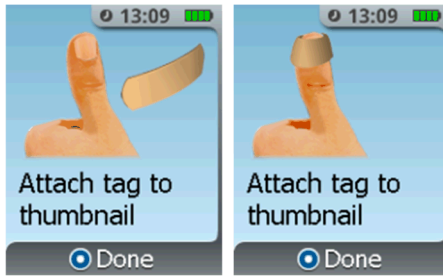
NOTE

When the Patient ID Thumb Tag is successfully scanned, you will hear an audible confirmation tone, and the System will transition to the next screen.


STEP 13   **Attach Patient ID Thumb Tag**

In preparation for the application of the Patient ID Thumb Tag, you may clean the thumb and nail with alcohol wipes and allow to dry.

Attach the Patient ID Thumb Tag to the patient's thumb. Make sure the center of the Patient ID Thumb Tag is over the patient's thumbnail.

Wrap the Thumb Tag around the thumb making sure both ends of the Thumb Tag are adhered to the thumb and not to the Patient ID Thumb Tag itself.

Confirm the Patient ID Thumb Tag is on the patient by pressing the **Enter/Select** Button on the front of the Controller.
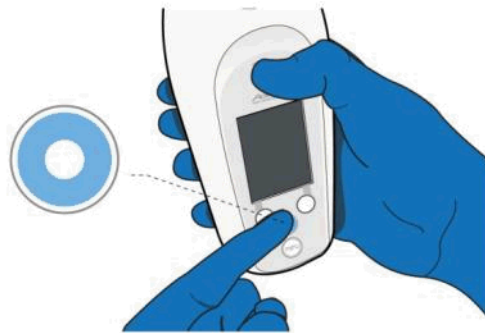
If the Patient ID Thumb Tag is dropped or is damaged while applying it onto the patient's thumb, discard it and continue to complete the setup of the System for the patient.

After setup is complete, obtain a new Patient ID Thumb Tag then follow the instructions in *Section 8, Replacing the Patient ID Thumb Tag*.

STEP 14   **Attach Holster**
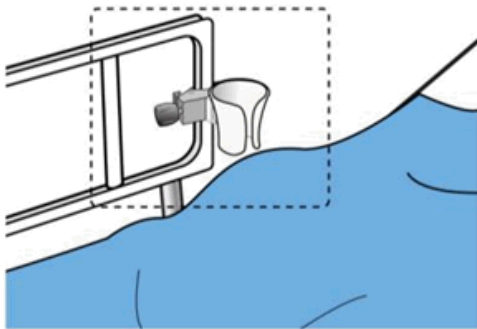
Attach the System Holster with its clamp to the patient's bedrail (recommended) or any other secure object near the patient such that the System is easily accessible to the patient.

Example Holster Mounting Position 1
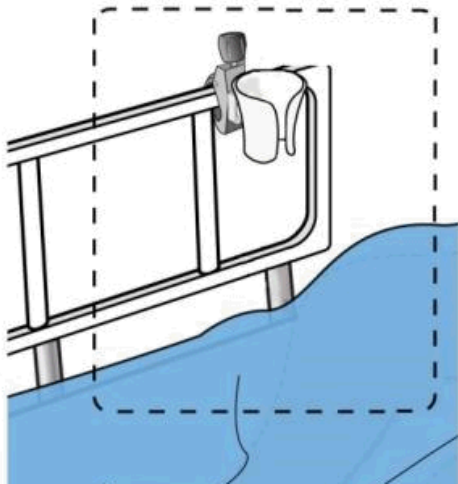
Example Holster Mounting Position 2

Attach the Security Tether securely to the patient's bedrail.

> ⚠️ **WARNING**
>
> **DO NOT** attempt to add an extension to the supplied Tether as this may result in an unsecured System or may present a strangul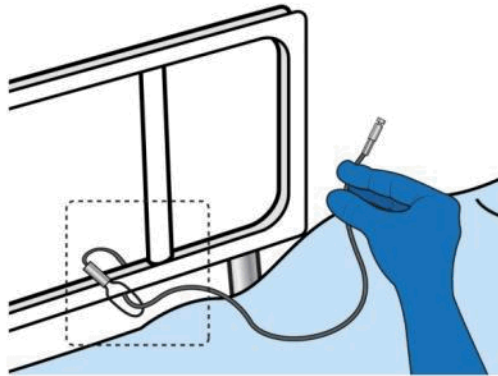ation hazard. Additionally, proper use of the Tether requires passing it through the end loop as shown above. Do not attempt to tie the Tether or use the end loop as a means to "loop" it over an object; this may result in an unsecure System.
>
> **DO NOT** attach the Tether to the patient.
>
> Ensure that the Tether does not get tangled with any equipment lines that may be near the patient, since this could interfere with patient access to therapy.

STEP 15   **Attach Tether**

Attach the other end of the Tether to the System as shown on the screen; push the end of the Tether into the Controller until it stops (a magnet will assist with pulling the Tether into the System). The System will sense the Tether and automatically move to the next sequence in the setup.

DO NOT place anything other than the Tether into the Tether port.

Proceed to Patient Training Screens
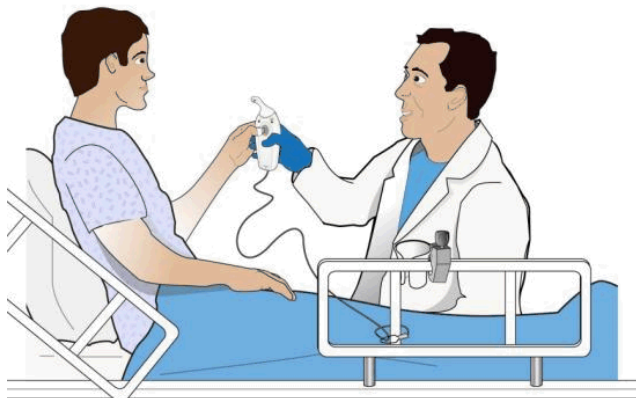
After the initial setup, the System will ask if you want to view the Patient Training Screens. These are a brief set of screens that provide cues to the Healthcare Professional to train the patient on certain System features.

It is recommended that the Healthcare Professional always educate and train patients on the content of these screens before leaving them with the System to use on their own. These screens are accessible anytime during patient use as well, by using the AAC to access the menu.

NOTE: No tablets will be dispensed during the Patient Training Screens demonstration.

There will be a flashing **DEMO** indicator in the top right hand corner of the screen throughout the use of the screens to indicate that the System is not in Patient mode.

The topics covered in these Training Screens include:

- Place the Cap on the System and store the System in the Holster during use
- How to identify when a dose is available
- Removing the protective Cap before dosing
- Holding the System upright during dosing
- Placing the Dispenser tip <u>under</u> their tongue
- An interactive demonstration of the green Dose Available and blue No Dose Available indicator lights. It also demonstrates the flashing green light indicator within the Blue Dose Button when the patient places the thumb with the Patient ID Thumb Tag near it, as well as the tones that the System provides as feedback to the patient if dosing was successful or not.

- Not chewing or swallowing the tablet. Not eating or drinking for 10 minutes after dosing. Minimize talking for 10 minutes.
- How to identify when a dose is not available
- Call the nurse if the System is continuously beeping and flashing during use
- Provide the patient with the Patient Reference Sheet to supplement patient training
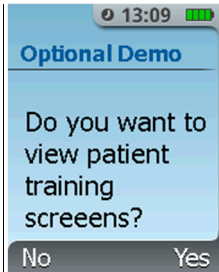
Select **YES** (**Right** Button) to continue onto the next screen to review the Patient Training Screens.

Select **NO** (**Left** Button) to skip these screens and continue to the next screen which instructs to provide the patient with the Patient Reference Sheet (Refer to Attachment 1).
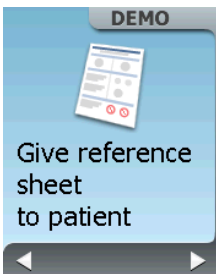
If **NO** is selected, this screen will appear. Educate the patient to refer to the Patient Reference Sheet for basic information on how to use the System.

Refer to Section 7, Patient Use for further instructions on patient use.

6. Patient Training

Patient Training Screens

The following screens are cues for the Healthcare Professional to train the patient on proper System use. The screens are not intended to be shown to the patient; rather they are prompts to the Healthcare Professional to demonstrate System features and train the patient. Some of the screens enable lights or tone demonstrations, as described below.

NOTE	No tablets will be dispensed during the Patient Training Screens demonstration. There will be a flashing **DEMO** indicator in the top right hand corner of the screen throughout the use of the screens to indicate that the System is not in Patient mode.

NOTE	In demonstration mode, if the System is left inactive for more than 30 seconds, it will go into sleep mode. To return to demo mode, use the AAC to access MENU and return to Demo Mode.
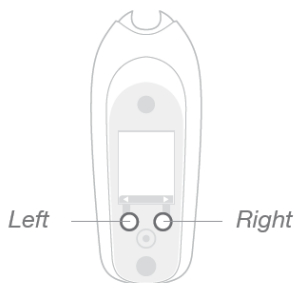
Use the **Left** and **Right** Buttons to navigate between the screens. You can repeat any Patient Training Screen as needed by pressing the Left Button. The Patient Training Screens are also accessible through the System Menu any time after the initial setup as needed.

Patient Training Screens

Cap and Store System

Remind the patient to place the Cap on the System after dosing and store the System in the Holster when not in use. When the patient is ready to use the System, remove the System from the Holster.

NOTE

It is important to remind the patient to store the System in the Holster when not in use to minimize the chance of inadvertently dispensing a tablet by accidently pressing the Dose Button. If this occurs, the patient should call the Healthcare Professional to ensure the loose tablet is found and disposed of properly.
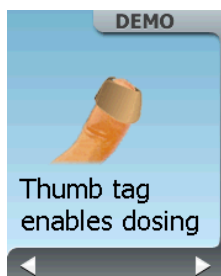
Check Dose Availability
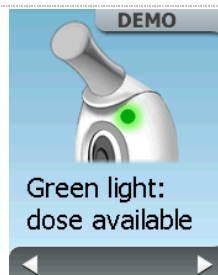
Train the patient that the green **Dose Available Light** will illuminate when a dose is available and stay illuminated until a dose is taken.

Show the patient the green light, located above the unlock icon. Inform the patient that this light indicates the System is available for the patient to take a dose.

STEP 3   **Thumb Tag Required to Dose**

Train the patient that only the thumb with the Patient ID Thumb Tag can be used to press on the **Blue Dose Button** to receive a dose of medication.

STEP 4   **Remove Cap Before Dosing**

The patient should be reminded that they must remove the Cap before dosing, otherwise the tablet will be dispensed into the Cap and the patient will not receive their dose. Should this occur accidently, the patient should call the Healthcare Professional to retrieve and properly dispose of the loose tablet in the Cap. The patient should request a new Cap if it is dropped or contaminated.

STEP 5   **Keep System Upright**
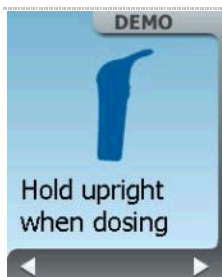
The patient should be instructed to **KEEP THE SYSTEM UPRIGHT** when dosing.

Note: System will still permit dosing if it not perfectly upright. However, the System will not permit dosing in extreme orientations (for example inverted), as the tablet may not be delivered to patient

STEP 6   **Place Dispenser Tip Under Tongue**

The patient should be reminded to first place the Dispenser Tip UNDER their tongue and THEN press the **Blue Dose Button** with their thumb. Do not apply downward pressure on the Dispenser tip when dosing.

STEP 7   **Do Not Touch Dose Button Until the Dispenser tip is under the Tongue**

The patient should be reminded not to touch or press the **Blue Dose Button** with their thumb until the dispenser tip is under the tongue.
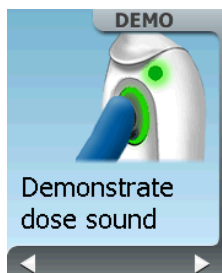
STEP 8   **Do Not Pull Down When Dosing**

The patient should be reminded not to pull down on the dispenser tip when in the mouth when dosing.

Simulate Dosing

This demonstration can be repeated multiple times as needed, the System will not dispense any tablets during this demonstration.

The patient should be reminded not to press the button until the Dispenser tip is under their tongue, and they should only remove it after they hear the dose confirmation tone, which will be heard after pressing the **Blue Dose Button***, and feel the motor vibration stop.*
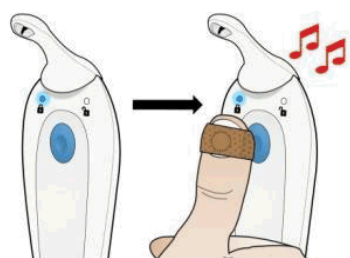
Have the patient press the **Blue Dose Button** to simulate receiving a dose so the patient can hear the tone that the System produces to confirm the dose was dispensed. Have the patient place the System in their mouth and under their tongue and press the **Blue Dose Button** to get a feel for dosing. Tell the patient that the System will not dispense any tablets during this demonstration.
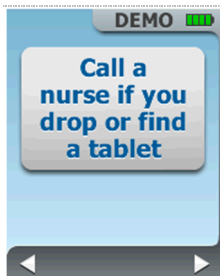
STEP 10   Do Not Chew or Swallow the Tablet, Do Not Eat or Drink for 10 min.

Educate the patient that the tablet should not be chewed or swallowed, and to not eat or drink for 10 minutes after dosing. Minimize talking for 10 minutes.

## STEP 11   Call a nurse if you drop or find a tablet

The patient should be reminded to call the nurse if they drop a tablet when dosing or if they find a tablet.

## STEP 12   Simulate Dose Lockout

Train the patient on what the System will do when in lockout and they cannot dispense a dose. The **No Dose Available Light** will be illuminated (blue) above the lock icon on the left side of the System. Train the patient that while the Dose Button can be pressed, a dose will not be dispensed.

This demonstration can be repeated multiple times as needed. Educate the patient that the blue light indicates when a dose is not
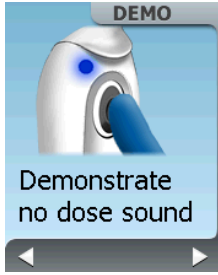
available. Have the patient press the **Blue Dose Button** on the back of the Controller to hear the "no dose" tone that the System produces to communicate that the patient cannot receive a dose and the System is in lockout.

STEP 13 **Call Nurse**
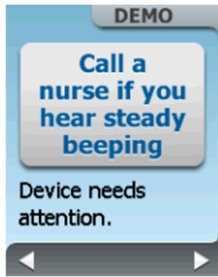
Remind the patient to call the nurse when the System is continuously beeping and flashing between doses. The System will continuously beep and flash indicators when this screen is shown.

STEP 14 **Patient Reference Sheet**
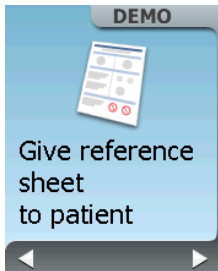
Provide the patient with the Patient Reference Sheet to supplement patient training. Educate the patient to refer to the Patient Reference Sheet for basic information on how to use the System. *Please refer to Attachment 1.*

STEP 15   **Confirm Patient Training Complete**
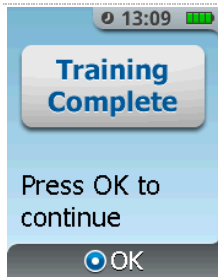
After completion of the demonstration with the patient, the System will confirm that the patient training is complete on the screen with a message **Training Complete – Press OK to continue**. Press the **Enter/Select** Button.

STEP 16   **Confirm Setup**
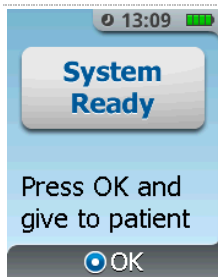
The System will confirm that the setup is complete on the screen with a message **System Ready - Press OK and give to patient**. Press the **Enter/Select** Button.

Dose Available

You will then see a green screen with the message **Dose Available**, with the drug name, dosage strength and number of tablets remaining. Hand the System to the patient and guide them through the process of taking their first dose. You should watch the patient take their first dose to ensure they understand proper System use.
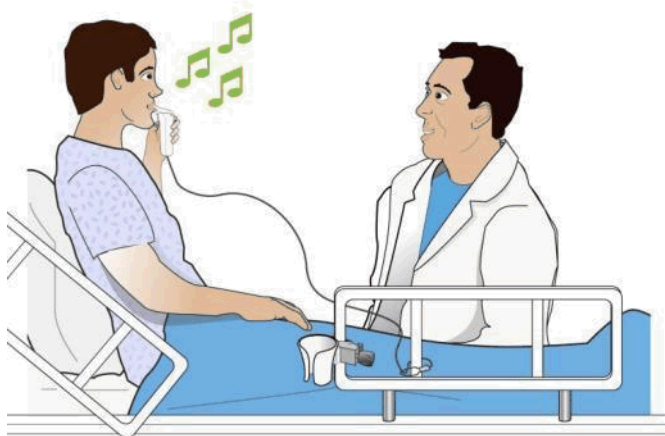
STEP 18   **Provide Additional Verbal Instructions to the Patient**

1. Use the System as needed for pain relief.
2. The System is only for the patient to use, not family or friends.
3. The System screen information is for the Healthcare Professional and should not be used by the patient to determine when to dose.
4. In the event that the System appears to be damaged, the patient should notify the Healthcare Professional. The Healthcare Professional should replace the damaged System with a new System as required.
5. The System should not be submerged in liquid, taken into shower, or placed in sink. *For instructions on cleaning the System during patient use, see Section 7, Patient Use.*


WARNING   The patient should only dose with a single tablet at the time it is dispensed by the System. The patient should never dispense tablets into their hands and take multiple tablets at a later time as this may cause serious injury or death.

Store System

Before leaving the patient's room, make sure the System is stored back in the Holster within easy reach for the patient. The System should always be stored in the Holster when not in use by the patient or the Healthcare Professional.
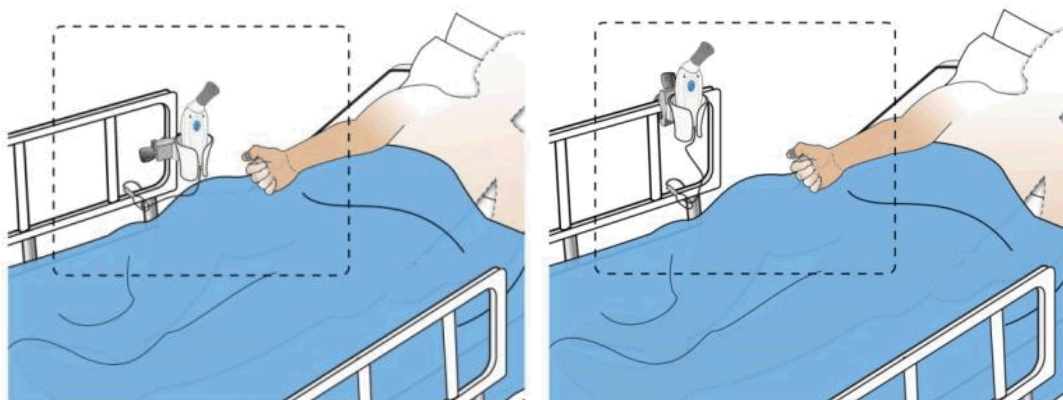
| NOTE	**Discontinuation** Once the patient is finished using the System and has completed their therapy, you will need to Discontinue the System and handle used components according to *Section 14, Discontinuation of Therapy and Disposition of Used Components*. **System Messages** *Refer to Section 7, Patient Use, for a review of tasks and System messages to be dealt with during the 72-hour use period (or Patient Use).*

7. Patient Use

While the patient is using the System the following situations and screens may be encountered:

7.1. How to Take a Dose (Dose Available)

The System has two ways to communicate that a dose is available:
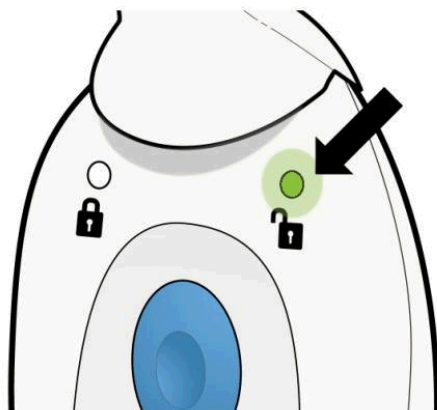
Dose Available Light	Dose Available Display
A green light will be visible on the back side of the Controller (see example above).	If the **Enter/Select** Button is pressed to wake up the screen, the front side of the Controller will display a green screen with the message **Dose Available** and list the drug name, dosage strength and number of tablets remaining. In the example above, the drug is sufentanil, dosage strength is 15 mcg and there are 40 tablets remaining.

STEP 1   **Position Device**

When the patient wants to take a dose they should:

Remove the gray Cap.

Hold the System with the same hand as the Patient ID Thumb Tag.

First place the Dispenser Tip UNDER your tongue.

The patient should then place their thumb (with Patient ID Thumb Tag) on the **Blue Dose Button**. The **Blue Dose Button** will flash green, indicating that the System has detected the valid Patient ID Thumb Tag and is ready to dose when the Patient presses the **Blue Dose Button** with the thumb..

STEP 2   **Dispense Tablet**
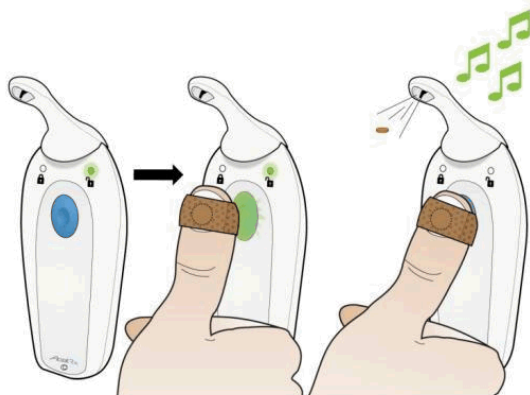
Press the **Blue Dose Button** with your thumb (with Patient ID Thumb Tag). to dispense the tablet under their tongue.
Do not apply downward pressure on the Dispenser tip when dosing.

- The patient will feel the motor vibration start.
- The System will dispense the tablet.
- The motor vibration will stop and an audible tone will communicate that the tablet was successfully dispensed.
- Once the audible tone is heard, the patient can remove the System from their mouth.
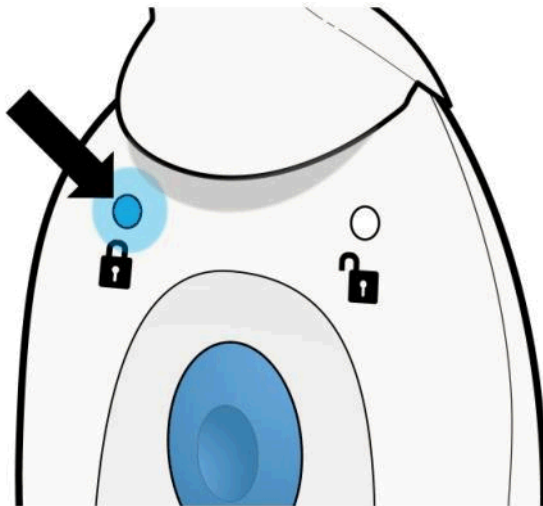
Tablet

The patient should not chew or swallow the tablet and should not eat or drink for 10 minutes. The patient should minimize talking for 10 minutes.

NOTE

STEP 3   **Administer Additional Doses (if necessary)**

A blue light will be visible on the back side of the Controller to communicate that the System is locked (for 20 minutes), after which time the patient can receive another dose if needed.

The number of tablets will update to reflect the total number remaining. In the example on the left there are now 39 tablets remaining.

Place the Cap back on the Dispenser and return to the Holster. *Refer to the next page for more information on understanding dose not available (lockout mode).*


The System's display will go to sleep (i.e. display turns off) after 30 seconds of System inactivity, but the **No Dose Available** or **Dose Available Light** will be lit. To wake up the display (i.e. turn on the display) from sleep, press the **Enter/Select** or **Menu** button.

NOTE

7.2. Understanding Dose not Available (Lockout Mode)

During the 20-minute lockout, the System has two ways to communicate that a dose is not available:
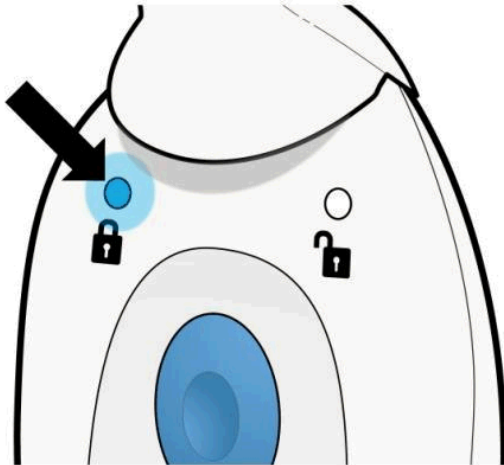
| Controller Light	On-Screen Display
A blue light will be visible on the back side of the Controller (see example above).	If the **Enter/Select** Button is pressed to wake up the screen, the front of the Controller will display a blue screen with the message **Dose Not Available** and list the drug name, dosage strength and number of tablets remaining. In the example below there are now 39 tablets remaining.

Refer to the next page for what happens if the patient presses the **Blue Dose Button** during the lockout period.

(?)

INFO

What happens if the patient presses the Blue Dose Button during the lockout period?
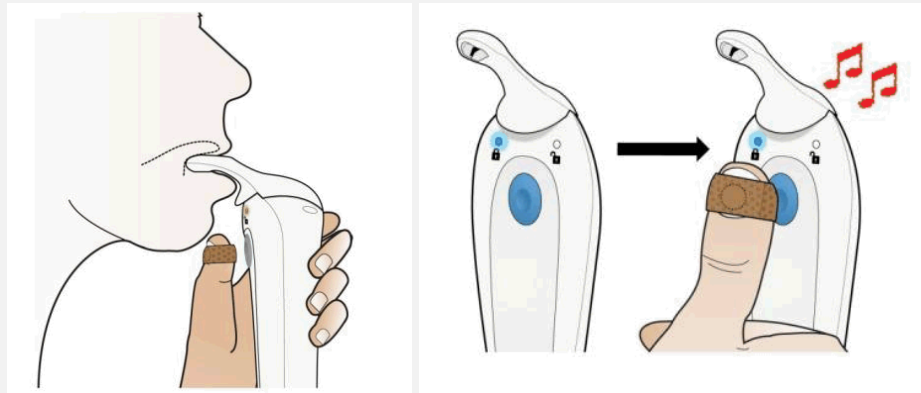
If the patient were to press the dose button during the 20-minute lockout, the System will announce a negative error tone to communicate no dose is available and the System will record the total number of requests the patient made during the lockout in the Dose History. *The total number of requests can be reviewed Section 11, Basic Dose History and Detailed History.*

7.3. Cleaning the System During Patient Use
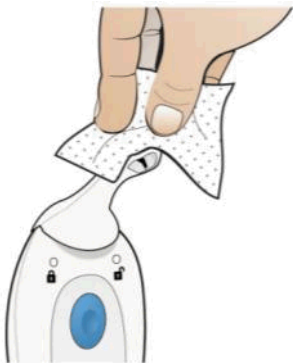
If a patient or Healthcare Professional desires to clean any part of the System during use, alcohol wipes should be used. Since the Dispenser is inserted into the patient's mouth for dosing, the patient may desire more frequent cleaning of the Dispenser than other portions of the System, possibly after each dose (though this is not required; frequency of cleaning is primarily a personal choice by the patient). Use of the Cap will protect the Dispenser tip from inadvertent contact by patient guests and Healthcare Professionals.

If for any reason the patient or Healthcare Professional notices visible contamination, clean the System as follows:

- Wipe as necessary with fresh alcohol wipes until the System appears visually clean.
- Do not saturate any part of the System. Wipes should not be excessively wet; squeeze out excessive liquid from the wipes before use.
- Let System dry before next patient use.

The Dispenser, or entire System, should be replaced if the patient or Healthcare Professional is concerned about severe contamination.
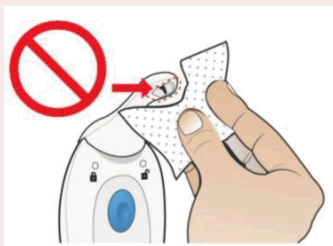
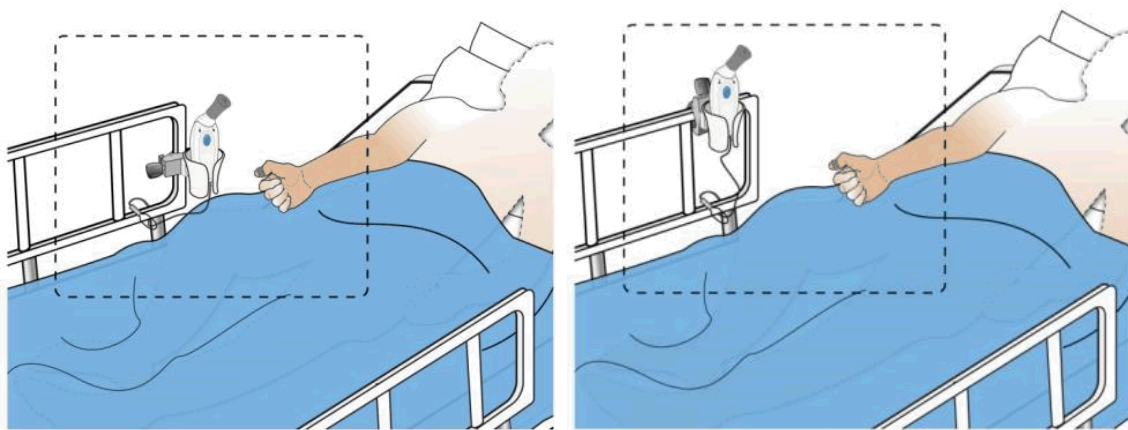| ⚠️ **WARNING**	**DO NOT** soak or immerse System in water.

⚠️ **WARNING**	**DO NOT** clean the interior portion of the tip. If interior of tip is visibly contaminated, replace the Dispenser.

7.4.   Storing the System During Patient Use

The System should be stored in the Holster between doses. Use of the Cap is recommended to avoid inadvertent contact between uses.

Holster Storage Location Examples

NOTE	It is important to remind the patient to store the System in the Holster when not in use to minimize the chance of inadvertently dispensing a tablet by accidently pressing the Dose Button. If this occurs, the patient should call the Healthcare Professional to retrieve and properly dispose of the loose tablet.

7.5.   Use of the System

|	
NOTE	Patients who do not appear to be able to appropriately use Zalviso should be switched to another form of pain management.

8. Replacing the Patient ID Thumb Tag

8.1. If the Patient ID Thumb Tag is Loose

- Secure the Patient ID Thumb Tag in place as needed by readjusting it and making sure the ends of the Patient ID Thumb Tag are adhered to the thumb and not to itself.
- If the Patient ID Thumb Tag continues to be loose, secure it in place by wrapping some medical tape around the thumb on top of the Patient ID Thumb Tag, keeping the same orientation.
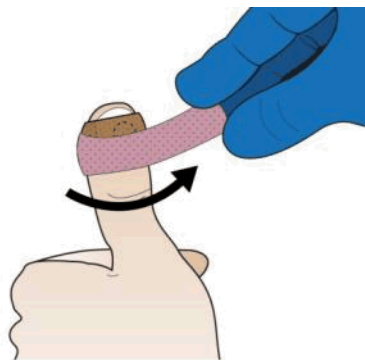
8.2. If the Patient ID Thumb Tag is Either Lost, Dropped, Defective or Becomes Non-Functional
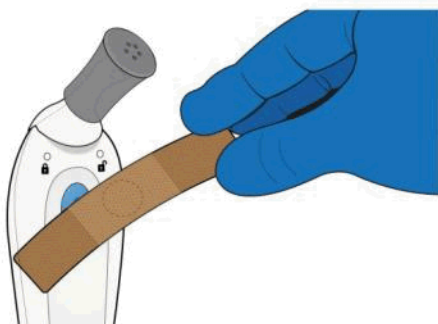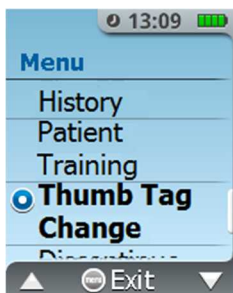

- Remove and discard used Thumb Tag as needed
- Retrieve a new Patient ID Thumb Tag and an AAC
- Press the **Menu** button to access the System Menu, scan the AAC when prompted, then scroll up or down the menu to **Thumb Tag Change**
- Select the **Thumb Tag Change** function from the menu by pressing the **Enter/Select** button.
- Follow the screen prompts and affix the new Patient ID Thumb Tag on the patient's thumb.

NOTE: When the replacement Patient ID Thumb Tag is successfully scanned, you will hear an audible confirmation tone, and the System will transition to the next screen.

Invalid Patient ID Thumb Tag Prompt
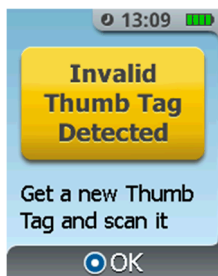
If a previously used Patient ID Thumb Tag was presented to the System during setup or Patient ID Thumb Tag change, a new Patient ID Thumb Tag is required

1. Obtain a new Patient ID Thumb Tag.
2. Press the **Enter/Select** Button.
3. Scan the new Patient ID Thumb Tag.

| **NOTE**	During System use, if the System doesn't receive any inputs (button presses or movement), the screen will turn off (sleep) after 30 seconds. To wake the screen, press the **Enter/Select** Button or the **Menu** Button. Upon the screen waking up, the System will have exited the Thumb Tag Change menu and be in Patient mode. To return to the Thumb Tag Menu, press the Menu button to access the System Menu with an AAC, then scroll up or down the menu to **Thumb Tag Change**, then select the **Thumb Tag Change** function from the menu by pressing the **Enter/Select** button.

9. Changing a Cartridge

The Cartridge may be changed if the number of tablets is depleted or if the Cartridge is empty. Follow the screen instructions for changing the Cartridge as shown in the first screen below. *Refer to Section 5, How to Set Up the System for a New Patient, for instructions on how to prepare the new Cartridge for use with the System.*

Changing a Cartridge
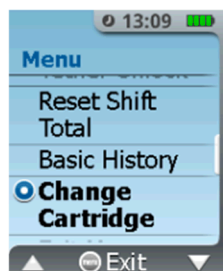
1. Retrieve a new Cartridge from the medication storage system.
2. Retrieve an AAC.
3. Press the **MENU** button, access the System Menu with the AAC, and scroll to the **Change Cartridge** function.

Note: The System does not allow the re-use of a partially used Cartridge.
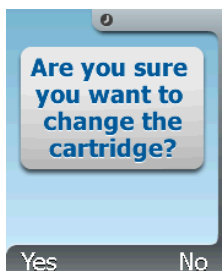
4. Select **YES** (Left button) if you are sure you want to change the Cartridge. Selecting **YES** will unlock the Dispenser to initiate changing the Cartridge. Select **NO** (Right Button) if you do not want to change the Cartridge and return to the dose status screen.
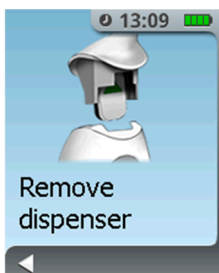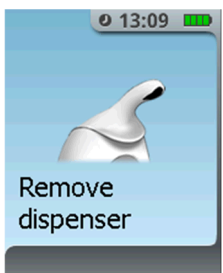

5. After **YES** is selected to change the Cartridge, remove the Dispenser by pulling up on the Dispenser. Remove and properly dispose of used Cartridge.


6. Obtain a new Drug Cartridge and prepare it for use as prompted by the screens. *Refer to Section 5, Step 6: Prepare Drug Cartridge.* Once Drug Cartridge is prepared, confirm this step on the screen by pressing the **Enter/Select** Button on the Controller.

NOTE: Only a new Drug Cartridge can be used or the System will display an error or notification.
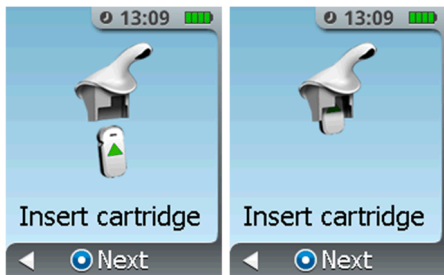
7. Insert the Cartridge into the bottom of the Dispenser (green arrow on Cartridge label points up). *Refer to Section 5, Step 7:* **Insert Cartridge**. Confirm this step on the screen by pressing the **Enter/Select** Button on the Controller.
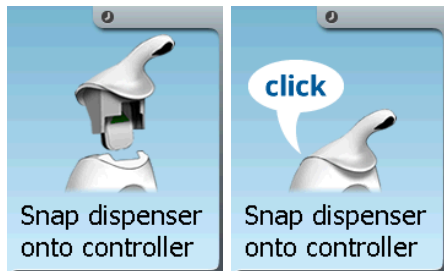

8. Snap the Dispenser (with Cartridge attached) onto the Controller. *Refer to Section 5, Step 8:* **Connect Dispenser**.

9. **Remove Cap** *(refer to Section 5, Step 9)*.
10. **Eject the Priming Cap** *(refer to Section 5, Step 10)*.
11. **Re-Cap the System** *(refer to Section 5, Step 11)*, to complete the Cartridge change.

Cartridge Empty Prompt
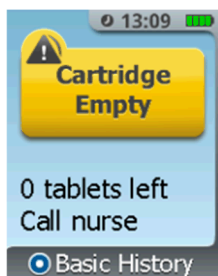
If the last tablet has been dispensed from the Cartridge, the System will show the **Cartridge Empty** screen.

Used Cartridge Prompt
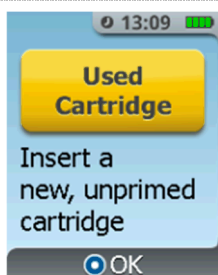
If the **Used Cartridge** screen is displayed after the Dispenser and Cartridge are snapped into the Controller, the System has detected a used or defective Cartridge. Retrieve a new Cartridge, press the **Enter/Select** button and follow the instructions to prepare and install the new Cartridge.

Basic History Prompt
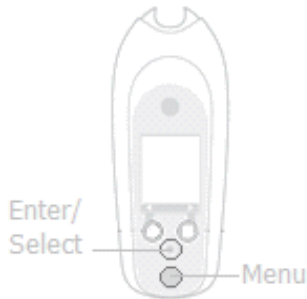
If the **Enter/Select** button is pressed instead of the **Menu** button, the display will transition to the Basic History screens. If you want to change the Cartridge press the **Menu** button to go to the Main menu and access the System with the AAC. From here you can change the Cartridge, Discontinue or perform other actions in the Menu.
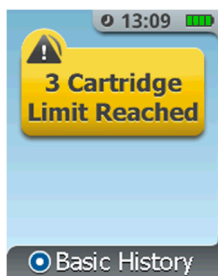
NOTE

There is a three Cartridge limit that can be used in a 72-hour period with one System. Additional Cartridge use beyond three Cartridges within 72 hours will require a new System to be set up.
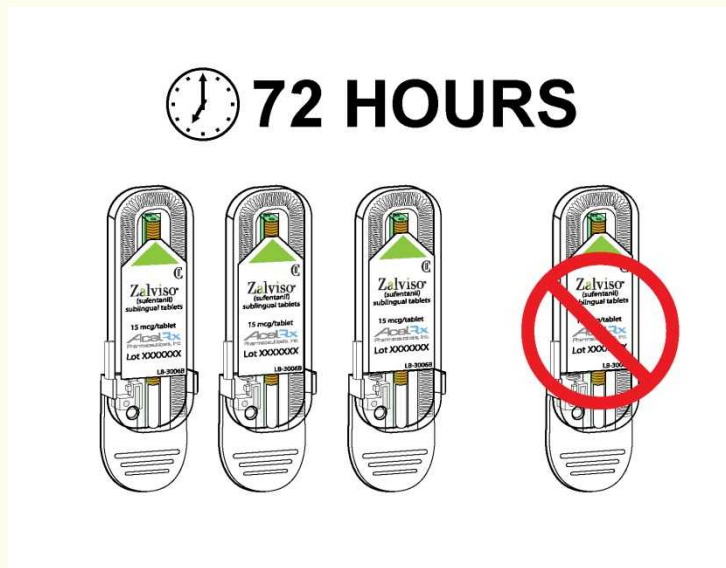
3 Cartridge Limit Reached

If the **3 Cartridge Limit Reached** screen is displayed after **Change Cartridge** is selected, the third Cartridge is in use in the System and changing the Cartridge will not be permitted. Refer to Note above.
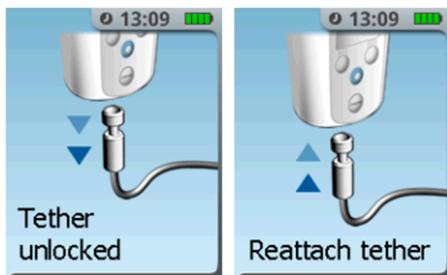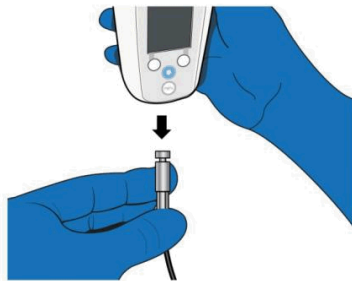
10. Tether Unlock

Access Tether Unlock Prompt

If for any reason the System needs to be repositioned during patient use, unlock the Tether from the bottom of the Controller.   Examples include moving the patient to a wheelchair, bedside chair, walker or gurney, in which case the System can be re-tethered to be in close proximity to the patient. Ensure that the Tether does not get tangled with any equipment lines that may be near the patient, since this could interfere with patient access to therapy. When the patient is being transported, ensure that the Tether does not get tangled in the wheels which may damage the System or jam the wheelchair or gurney.

Note: The Security Tether must be reattached in order to continue therapy and the System will not dispense tablets while the Tether is disconnected.

STEP 2   **Remove Tether**

1. Press the **Menu** button on the Controller.

2. Touch the Authorized Access Card to the **Blue Dose Button** on the back of the Controller to access the System Menu.

3. Highlight and select the **Tether Unlock** function by pressing the Enter/Select Button.

4. The System will release the Tether from the bottom of the Controller and display that it is unlocked. Pull down on the Tether to release it and adjust the location of the System.
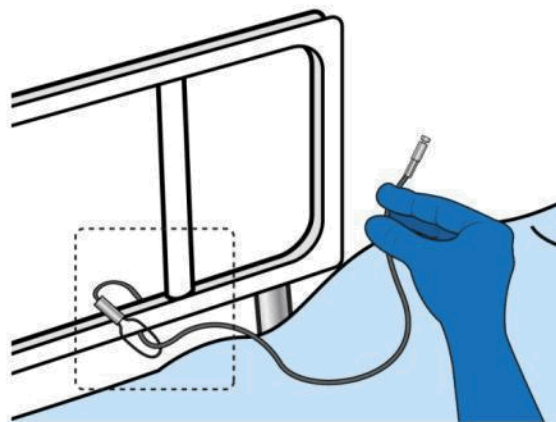
When you are ready to re-secure the Tether, first loop the Tether around the bedrail or another object such as a chair, wheelchair, walker or gurney. Reattach the Tether into the bottom of the Controller. The Controller will sense that the Tether has been inserted and lock automatically. The Holster should be attached to an object near the patient to hold the tethered System *(Refer to Section 5, Step 14).*

NOTE	If the patient is being transported, the System should be tethered to the wheelchair or gurney and the System should be placed in the attached Holster. The patient should only self-administer doses from the System when not in motion. If the patient attempts to dose while in motion, jostling may cause the tablet to miss the patient's sublingual space causing a loose tablet. Should this occur, the patient should inform the Healthcare Professional so that the loose tablet can be retrieved and disposed of properly.

11. Basic Dose History and Detailed History

11.1. Basic Dose History

The Healthcare Professional can query the System for the basic Dose History of the patient. This review can be done without the use of the Authorized Access Card. Press the **Enter/Select** Button to access the six basic Dose History screens.

STEP 1   **Current Status Screen**

When you first access the **Dose History** screen it displays the current status. Use the right arrow (press the **Right Button**) to review other details, such as the dosing totals for the last hour, dosing totals since the last shift reset, dosing totals since the System was setup, and the date/time the shift dosing total was reset.

The first screen displays the drug dosage strength, drug type and the tablets remaining in the Drug Cartridge.

STEP 2   **Last Hour Total Screen**

The next screen displays the total number of doses dispensed and total requests in lockout by the patient in the last hour.

Activity Each Hour Screen

Row 1, with Blinking Cursor indicates Current Hour, (12:10 to 13:09 in this example)
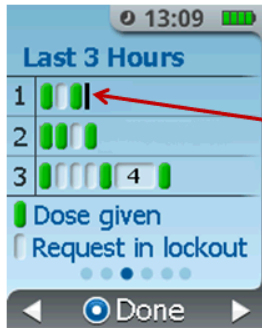
The next screen displays a graphical representation of the dosing history in the last 3 hours.

Each row represents an hour of time. The current (most recent) hour is at the top (Row 1). The blinking black "cursor" is an active indicator of the current hour. In the example at left, Row 1 at the top indicates dosing history in the current hour, or 12:10 to 13:09.

Within each row is a representation of the doses dispensed (represented by a green icon) and requests made during lock out (represented by a white icon).

NOTE	If the number of requests made during lockout exceeds 3, the graph will display as a block which contains the total number of requests during lockout for that time period (see the white block with "4" in the example above). Using the example screen above, **assuming it is 13:09 (1:09PM)**, the patient's dose history is: • Hour 1 (current hour), 12:10 – 13:09: 2 doses given, 1 request during lockout • Hour 2, 11:10 – 12:09: 3 doses given, 1 request during lockout • Hour 3, 10:10 – 11:09: 3 doses given, 7 request during lockout

NOTE	The nurse should review the dosing history to look for excessive requests during lockout and determine the cause. If a patient does not possess the cognitive ability or manual dexterity to properly use Zalviso, alternative analgesic therapy should be considered.