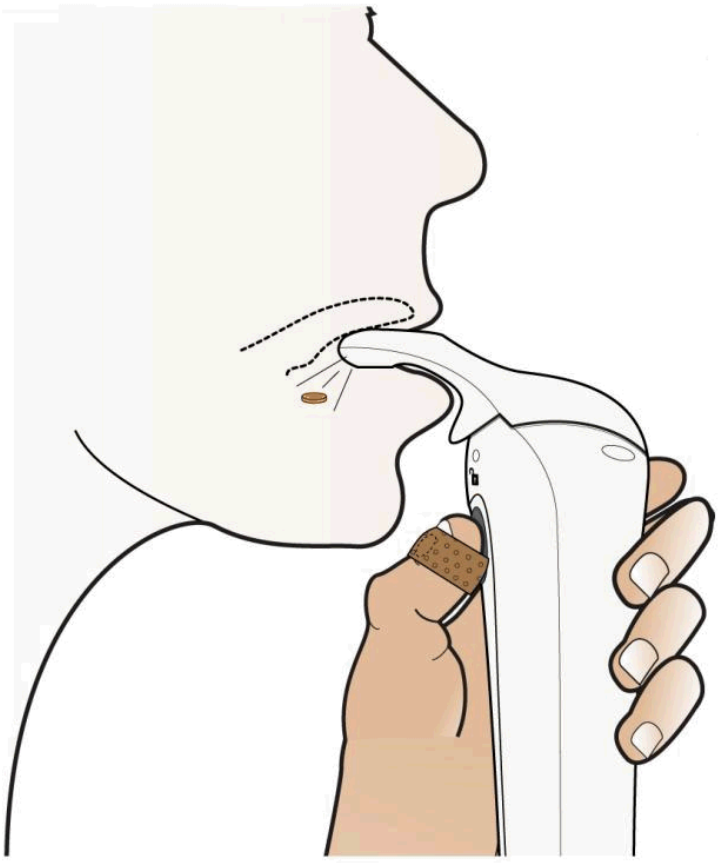
Zalviso®

(sufentanil sublingual tablet system)

Instructions for Use



1. Table of Contents

2. Explanation of Symbols

On the packaging and on the sufentanil sublingual tablet system (System) you may encounter the following symbols shown here with their meanings.

	Please consult instructions for use
	System contains a non-ionizing RF transmitter
	Do not reuse
	Keep away from MRI exposure and equipment
	Keep away from X-ray exposure and equipment
	Date of manufacture
	Manufacturer’s batch or lot code
	Class II equipment
	Type BF equipment
	Identifies switch to power on system
	System alert or alarm condition

3. Introduction and Product Features

3.1. Intended System Use

The Zalviso sufentanil sublingual tablet system (also referred to as “sufentanil sublingual tablet system” or “System”) is for the management of moderate-to-severe acute pain in adult patients in a hospital setting.

Important Safety Message! **Due to the risk of accidental exposure and/or overdose, Zalviso must only be used in acute care inpatient hospitals. The device must never be dispensed for outpatient pain management or continued after the patient is discharged from the hospital.**

3.2. About the Sufentanil Sublingual Tablet System

The sufentanil sublingual tablet system is a handheld, battery-operated, patient-controlled analgesia (PCA) System that allows patients to administer tablets to manage post-operative pain during their in-hospital stay. The tablets contain 15 mcg of sufentanil, a potent opioid and a controlled substance, so the System functions as a dispensing device as well as an electronically controlled System for dosing an opioid. Additionally, patient dosing data is captured by the System and is reviewable by the Healthcare Professional during or after patient use. The maximum amount of time permitted by a single System for patient use is 72 hours. If additional therapy is required past 72 hours, a new System has to be set up for the patient. *Refer to Section 15, Replacing the System, and Section 16, Notifications, Alerts, Alarms and Errors, for details on the System’s 72 hour limit.*

The Healthcare Professional should set up the System for each new patient. The setup process includes:

- Powering on the System
- Installing a new Cartridge into the Dispenser
- Attaching the Dispenser to the Controller
- Priming the System
- Attaching the Patient ID Thumb Tag to the patient’s thumbnail
- Attaching the Security Tether to a stationary object and then to the bottom of the Controller
- Training the patient on how to take a dose and when the dose is in lockout (unavailable) through the Patient Training Screens and demonstration
- Provide the patient with the Patient Reference Sheet to supplement patient training
- Storing the System in the Holster which is attached to the patient’s bedrail

- Following the initial setup and during patient use, the Healthcare Professional may need to perform additional tasks such as:
    - Replacing the Patient ID Thumb Tag
    - Changing a Cartridge (up to 3 Cartridges can be used in 72 hours)
    - Cleaning the System
    - Reviewing the Basic Dose History and Detailed History
    - Unlocking the Tether to adjust the Location of the System
    - Resetting the Shift Total
    - Addressing Alarms, Alerts and Notifications
    - Replacing the System
- After patient use:
    - The System should be discontinued and components handled according to instructions provided in subsequent sections of this document.

3.3. Operating Features and Definitions

The following are important System features and definitions.

Lockout – The time period when the System is not available for dosing by the patient. This period has been factory programmed to 20 minutes. The patient will not be able to dose until 20 minutes have elapsed since the last dose. *Refer to Section 7, Patient Use, for more information regarding lockout.*

Authorized Access Card (AAC) or Access Card – The System requires the Healthcare Professional to present an AAC to access the System. The AAC is a Radio Frequency Identification (RFID)-embedded card that communicates with the System and may be stored in a medication inventory management system or according to Institution procedures. *Refer to Section 4, System Components, for more information on the AAC.*

Adhesive Thumb Tag with RFID (Patient ID Thumb Tag) – The patient requires a Patient ID Thumb Tag (also referred to as Thumb Tag) to access the System and dose themselves with medication. This Thumb Tag is an RFID-embedded adhesive band that communicates with the System and is secured to the patient's thumb during initiation of therapy. The Patient ID Thumb Tag must be placed on the thumb that the patient will use for pressing the dose button. *Refer to Sections 4, 5, 6, 7 and 8 for more information on the Patient ID Thumb Tag.*

Priming Cap – Each Cartridge contains a green plastic Priming Cap that must be ejected (primed) from the Cartridge through the System before a patient can use the System. This action enables diagnostics within the System to ensure that it is performing normally before patient use. *Refer to Section 5, How to Set Up the System for a New Patient, for more information on the Priming Cap.*

The System will recognize the Drug Cartridge contents and display:

- Drug name
- Dosage strength
- Number of tablets present

Patient Training Screens *(Section 6)* – During new patient setup, the System displays a brief set of training screens that provide cues to the Healthcare Professional to train the patient on certain features of the System. This includes an interactive demonstration of the Green "Dose Available" and Blue "No Dose Available" (System in lockout) indicator lights. These screens also allow the demonstration of the flashing green light indicator within the 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. The screens also provide the Healthcare Professional cues to train the patient to remove the Cap before dosing, to hold the System upright during dosing, and to place the System in the Holster after use. *Refer to Section 7, Patient Use, for more information.*

Discontinuing Therapy – After the patient is done receiving their therapy, the System is discontinued according to instructions in *Section 14, Discontinuation of Therapy and Disposition of Used Components.*

Cartridge Access and Changing – During patient use, the Cartridge containing the medication is locked in the System. When medication is running low, the System will issue notifications through light indicators and tones. The Healthcare Professional can access the System with the AAC and select options for replacing the Cartridge. *Refer to Section 9, Changing a Cartridge, for more information on changing the Cartridge.*

Dispenser Removal – During patient use, there may be a need to remove the Dispenser and replace it with a new one. To do this, the Healthcare Professional can access the System with the AAC and select the option for replacing the Cartridge (*see Section 9, Changing a Cartridge*). Replacing the Dispenser must be accompanied by replacing the Cartridge with a new Cartridge. If the same Cartridge is used with the new Dispenser, the System will alert the Healthcare Professional that a used Cartridge is detected. This will cue the Healthcare Professional to retrieve a new Cartridge for patient use.

Replacing a Patient ID Thumb Tag – If the Patient ID Thumb Tag either ceases to operate or becomes lost or otherwise rendered unusable, the Healthcare Professional can access the System with the AAC and select the option to replace Thumb Tag. *Refer to Section 8, Replacing the Patient ID Thumb Tag, for more information.*

Resetting Shift Total – The Healthcare Professional can reset the Shift Total by accessing the System with the AAC and selecting the option for Shift Reset. *Refer to Section 12, Resetting Shift Total, for more information on the Shift Total reset function.*

Removing the Security Tether – If the System needs to be moved from the patient's bedside, it needs to be un-tethered and then re-tethered securely to an object (e.g., chair, wheelchair, gurney, walker). To do this, the Healthcare Professional can access the System with the AAC and select the option for Tether Unlock. *Refer to Section 10, Tether Unlock, for more information on securing the Tether.*

Reviewing current patient detailed use history –The detailed history contains the event log of the current patient's System which can be accessed by the Healthcare Professional by accessing the System with the AAC and selecting Detailed History from the menu. This history will provide a chronological sequence of all events that occurred within the System since initiation of therapy. *Refer to Section 11, Basic Dose History and Detailed History, for more information on the detailed history.*

Silencing Alerts/Alarms – Alerts may be temporarily silenced by the Healthcare Professional. Alarms may only be silenced by Discontinuing the System. *Refer to Section 16, Notifications, Alerts, Alarms and Errors, for more information on how to silence an Alert and address Alarms and Errors.*

Biomedical Technician Utility features – When the System is not in patient use, the System Controller has biomedical technician utility features accessible by the biomedical technician when a Technician Access Badge (TAB) is presented to the Controller. The TAB is a Radio Frequency Identification (RFID)-embedded card that communicates with the System Controller and may be stored in Biomedical or according to Institution procedures. *Refer to Section 25, Biomedical Technician Utility Menu, for more information on the biomedical technician utility features.*

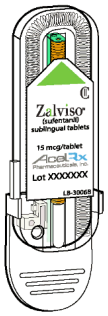
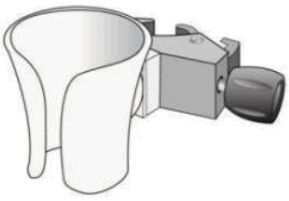
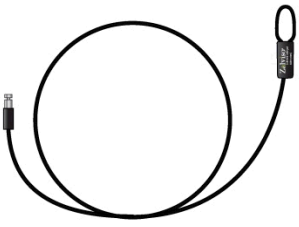
3.4. Warnings and Cautions

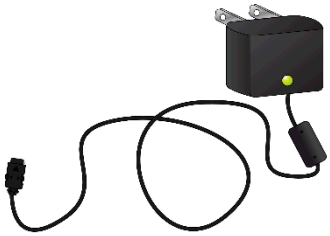
Warning: Operation is Limited to Trained Operators	The sufentanil sublingual tablet system operation is strictly limited to patients and Healthcare Professionals trained in the use of the System.
Warning: Disposal	When discarding disposable sufentanil sublingual tablet system components, adhere to local, state, federal and/or other governing regulation.
Warning: System components are not serviceable.	Tampering with, modification to, or opening of the System or its components may lead to hazardous conditions and will void manufacturer's warranty.
Warning: Increased electromagnetic emissions or decrease electromagnetic immunity.	Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Warning: Proximity to portable RF communications equipment	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the sufentanil sublingual tablet system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Caution: Be Cautious Near MRI and X-ray Equipment	Keep the sufentanil sublingual tablet system away from MRI and X-ray equipment.
Caution: Be Cautious of Electrostatic Discharge	To avoid electrostatic discharge, do not use the System in a very dry environment, especially one in which synthetic materials are present.

	**Caution:** Be Cautious of Condensation	Sudden changes in temperatures can cause condensation to form in or on the Controller. If this has occurred, do not turn on the Controller. Allow the Controller to return slowly to room temperature. Never keep the Controller or System in a room that is likely to harbor condensation (e.g. a bathroom).
	**Caution:** Do Not Improperly Clean System	Only follow cleaning procedures stated in *Section 13, Cleaning During Patient Use*, and *Section 17, Reprocessing Instructions*, in this manual. Use only specified cleaning agents.
	**Caution:** Do Not Disassemble Controller	There are no serviceable parts. Do not tamper with or open the System Controller's case.
	**Caution:** Never Immerse the Controller in Water or Other Liquids	The System is not waterproof.
	**Caution:** Never Autoclave	Never sterilize the Controller in a steam autoclave or gas sterilizer. Using autoclave or gas sterilization can seriously damage the Controller and void the warranty.

4. System Components

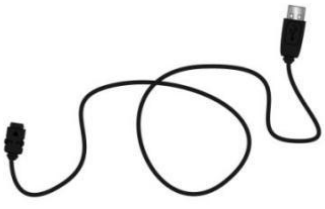
The sufentanil sublingual tablet system is comprised of the following components as shown below. Refer to the following sections for details of each component.

		
Controller (Section 4.1)	Dispenser (Section 4.2)	Cap (Section 4.3)
		
Drug Cartridge (Section 4.4)	Patient ID Thumb Tag (Section 4.5)	Authorized Access Card (AAC) (Section 4.6)
		
Holster (Section 4.7)	Security Tether (Section 4.8)	Cleaning Plug (Section 4.9)



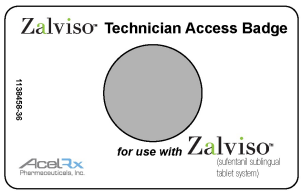
Charger

(Section 4.10)



Data Cable

(Section 4.10)



Technician Access Badge

(Section 25)

Cartridge Label RFID Reader

(Section 4.11)

The following System components are re-usable:

1. Controller
2. Holster
3. Security Tether
4. Authorized Access Card
5. Technician Access Badge
6. Charger
7. Data Cable
8. Cleaning Plug

The following System components are for single-patient use and disposable:

1. Dispenser and Cap
2. Drug Cartridge
3. Patient ID Thumb Tag

The following component is provided as an optional accessory for use in the hospital pharmacy (following patient use) and is re-usable:

1. Cartridge Label RFID Reader

4.1. Controller

The reusable Controller contains the rechargeable battery, drive mechanism for the System, and all the electronic control elements needed to track and control dosing of the tablets.

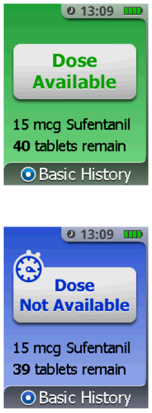
Front View of Controller

- The Controller is locked to the Dispenser and Tether while in use.
- The Controller should be appropriately cleaned and reprocessed according to the instructions in *Section 17, Reprocessing Instructions*.
- The front side of the Controller, comprising five buttons and the display screen that the Healthcare Professional will interact with while setting up and using the System, is shown below:

Power Button - Press and hold the **Power** Button for a few seconds until the Controller turns on.

If the Controller is powered on and not setup for patient use, press and hold the Power Button for a few seconds to power off the Controller. During power down, a power down audible tone is generated followed by the display and indicators turning off.

If the System is in use, the power button alone cannot be used to power off the System. Turning the System off is accomplished by accessing the System Menu and selecting "Discontinue". Follow the displayed instructions to Discontinue and power off the System.



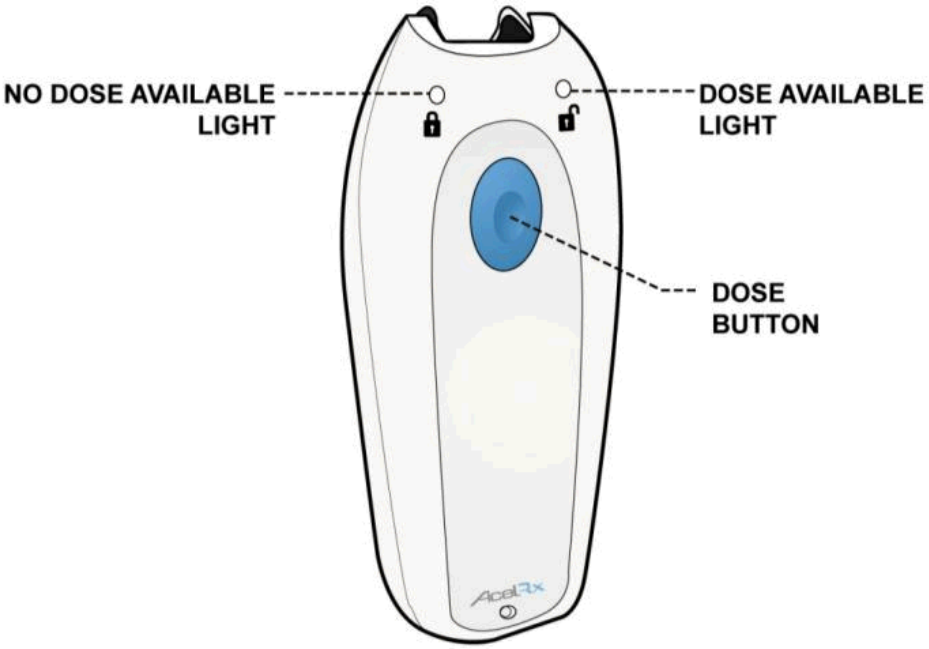
Display Screen - The Controller screen will display the current status (e.g., **Dose Available**, **Dose Not Available** and number of tablets remaining) and allow a Healthcare Professional access to the System Menu. The display has a screen timeout if there is no activity after 30 seconds. Press the **Enter/Select** or **Menu** button to wake up the System's screen and resume viewing the screen content.

Left/Right Buttons - Use the Left and Right Buttons, located below the display screen, to scroll through screen content as indicated on the screen.

Enter/Select Button - This is the blue circular button located in the center below the **Left/Right** Buttons. Use this button to select an item in the Menu. This button can also be used to access the basic dosing history that is available at any time during patient use, which does not require the Authorized Access Card. Pressing the **Enter/Select** button will also wake up the System's screen.

Menu Button - Press this button to access the System Menu. You will be prompted to scan your Authorized Access Card in order to access this menu. Pressing the **Menu** button will also wake up the System's screen.

- The back of the Controller has three main features that the patient will use on a regular basis:



Back View of Controller with Dose Button and Dose Indicators

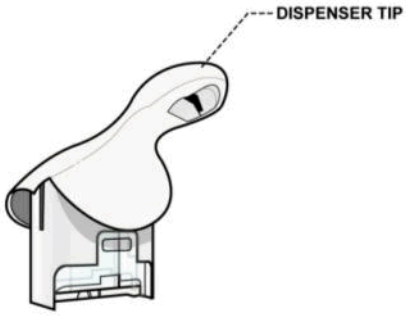
	**No Dose Available Indicator (Upper Left Side)** - A blue light will illuminate above the lock icon to indicate that the System is in lockout and a patient cannot receive a dose.
	**Dose Available Indicator (Upper Right Side)** - A green light will illuminate above the unlock icon to indicate that a dose is available for the patient.
 	**Blue Dose Button (Center)** - Healthcare Professionals will touch the Authorized Access Card to this area to access the Menu and activate functions of the System. Patients will touch their Patient ID Thumb Tag on the Blue Dose Button when the System is available for dosing. This causes the green light indicator within the Dose Button to flash indicating to the patient that the System is ready to dose and will dispense a tablet if the button is pressed. Upon actuation of the Dose Button, a tablet is dispensed to the patient.

Refer to the New Patient Setup instructions in Section 5, How to Set Up the System for a New Patient, for more details on using the Controller.

4.2. Dispenser

The single-use Dispenser has a specially designed tip to facilitate the sublingual placement of tablets.

- The Cartridge is placed inside the Dispenser and then the Dispenser is attached to the Controller.
- The patient should always place the Dispenser tip under their tongue when dispensing a tablet.
- The Dispenser should be cleaned as needed during patient use. *Refer to instructions in Section 7, Patient Use.*
- The Dispenser should be disposed of at the end of a patient's use according to institutional procedures for Biohazards.
- Never re-use a Dispenser for another patient.



DISPENSER

Refer to Section 5, How to Set Up the System for a New Patient, for more details on assembling the Cartridge, Dispenser, and Controller.

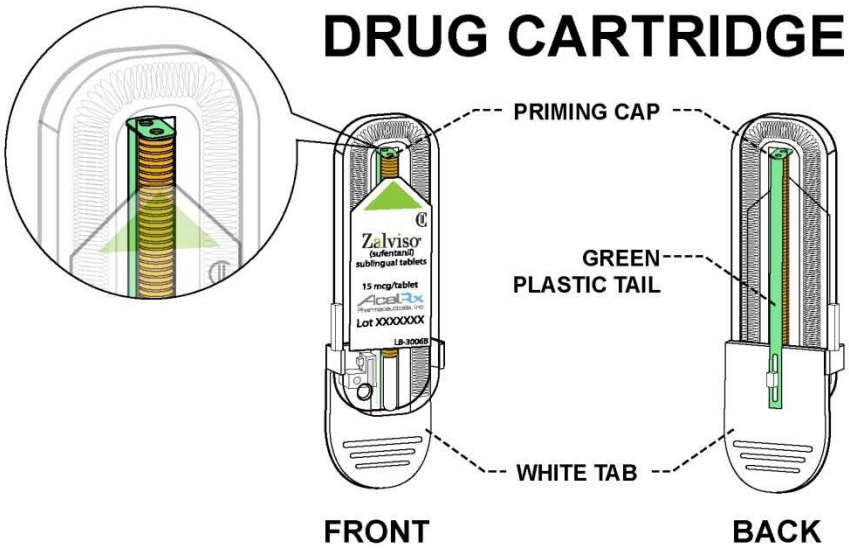
4.3. Cap

The Cap protects and covers the tip of the Dispenser and should always be placed over the tip when the System is not being used by the patient for dosing. Additionally, the Healthcare Professional should ensure the Cap is in place during setup and other Healthcare Professional handling of the System.

- The Cap may be cleaned during patient use. *Refer to instructions in Section 7, Patient Use.*
- The Cap should be disposed of at the discontinuation of therapy according to institutional procedures for Biohazards.
- Never re-use the Cap for another patient.

Refer to Section 5, How to Set Up the System for a New Patient, for more details on using the Cap.

4.4. Drug Cartridge



Each new Cartridge is intended for single-patient use and contains forty 15 mcg tablets and 1 green plastic Priming Cap.

- The Cartridge has a white tab and green plastic tail that need to be removed before the Cartridge is inserted into the Dispenser.
- The green Priming Cap will be ejected by the System during the setup process.
- Never attempt to re-use a Cartridge, either for the same patient or another patient (the System will not allow it).
- Never re-use remaining tablets from a used Cartridge for another patient.
- Always dispose of used Cartridges according to institutional procedures pertaining to Controlled Substance opioids.

Refer to Section 5, How to Set Up the System for a New Patient, for more details on preparing a new Cartridge, inserting the Cartridge into the Dispenser, and priming the System.

4.5. Patient Identification (ID) Thumb Tag

The Patient ID Thumb Tag allows secure access by the patient to the System. The Patient ID Thumb Tag contains Radio Frequency Identification (RFID) and acts as a single-patient identification key to limit the use of the System to only the patient.

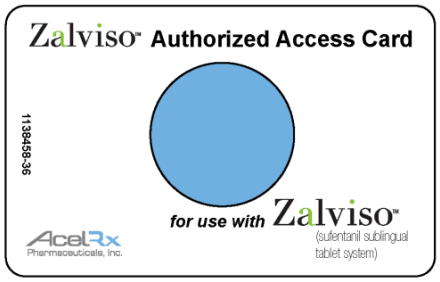
About the Patient ID Thumb Tag:

- Must be worn by the patient as it is needed to identify the patient to the System to permit dosing.
- Should only be placed on the patient's thumb and the center of the Patient ID Thumb Tag should be placed over the thumbnail.
- Should be placed onto the patient's thumb on the hand that is most accessible for System use.
- Should not be exposed to X-rays, MRIs, or other strong electromagnetic fields.
- Should be disposed of at the discontinuation of therapy according to institutional procedures.

Refer to Section 5, How to Set Up the System for a New Patient, for more details on attaching the Patient ID Thumb Tag and Section 8, Replacing the Patient ID Thumb Tag, for replacing or re-attaching the Patient ID Thumb Tag.

4.6. Authorized Access Card

The Authorized Access Card (AAC) allows the Healthcare Professional access to set up and manage the System.

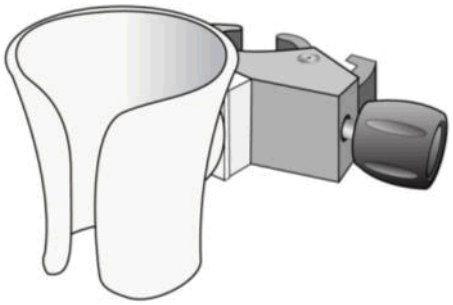


- The Healthcare Professional will use this card to gain access to the System to operate and manage it.
- The System prompts the Healthcare Professional to touch the blue circle of the AAC to the Blue Dose Button located on the back of the Controller.
- The AAC should not be exposed to X-rays, MRI, or other strong electromagnetic fields.

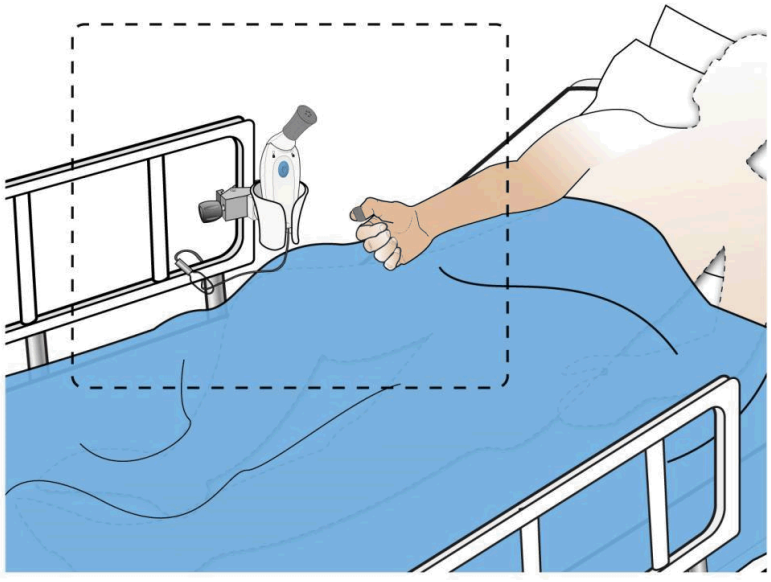
Refer to the New Patient Setup instructions in Section 5, How to Set Up the System for a New Patient, for more details on when and how to use the Authorized Access Card.

4.7. Holster

A Holster is provided for the System to be stored in when it is not in use by the patient.

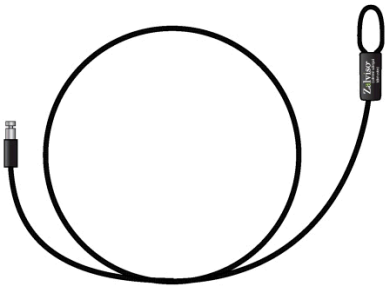


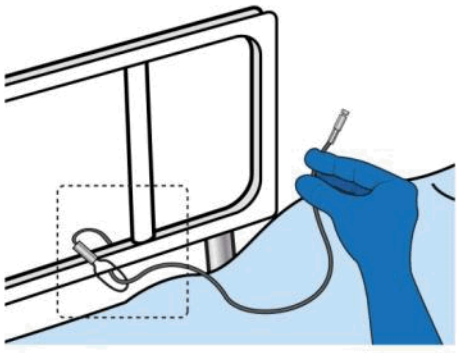
- The Holster is composed of a holder and a clamp.
- Rotate the knob on the clamp to tighten or loosen the holder to the patient's bedrail. The clamp can be rotated to assist with positioning.
- The Holster should be clamped to the patient's bedside within easy access to the patient's hand with the Patient ID Thumb Tag. *Refer to Section 5, How to Set Up the System for a New Patient.*
- When patient is not in bed and the System is moved with the patient, the Holster should be attached to an object near the patient (e.g., chair, table, walker, wheelchair or gurney) so that the System is within easy reach. The Holster should always be used to prevent inadvertent dispensing of tablets by the patient when not dosing.
- The Holster should be appropriately cleaned and reprocessed according to the instructions in Section 17, Reprocessing Instructions.



Refer to the New Patient Setup instructions in Section 5, How to Set Up the System for a New Patient, for more details on attaching the Holster.

4.8. Security Tether



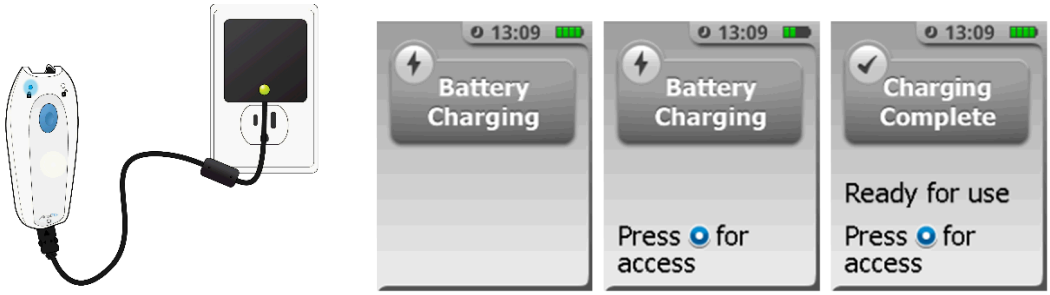


The reusable Tether is a cable assembly that will secure the System to the patient's bedside to prevent theft. One end should be attached (by creating a secure loop) to the patient's bedrail (as illustrated above) and the other end should then be placed into the bottom of the Controller. When patient is not in bed, the Tether should be attached securely to an object near the patient (e.g., chair, wheelchair, walker or gurney). The Tether should be reprocessed. *Refer to the New Patient Setup instructions in Section 5, How to Set Up the System for a New Patient, for more details on securing the Tether. Also refer to instructions in Section 17, Reprocessing Instructions.*

4.9. Cleaning Plug

The reusable Cleaning Plug is provided to cover the Controller's Charging/Data connector when the Controller is reprocessed. *Refer to Section 17, Reprocessing Instructions, where the Cleaning Plug is utilized during reprocessing of the Controller then the Cleaning Plug is reprocessed after use.*

4.10. Charger and Data Cable



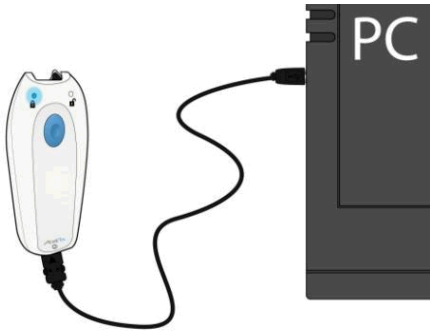
A Charger is provided to charge the Controller.

- The Controller must be charged for at least 8 hours or until the “Charging Complete” message is displayed on the screen.
- While the Controller is being charged the blue No Dose Available Light flashes to indicate status and the “Battery Charging” message is displayed on the screen.
- At the completion of charging, the blue light stops flashing and the display screen shows a “Charging Completed” message.

Refer to Section 18, Recharging the Controller, for more details about charging the Controller.

WARNING

Warning: Use only the Charger specified for the Controller. Use of any other power supply adapter may damage the Controller or cause personal injury.



A Data Cable is provided to transfer Patient Use data from the Controller to a computer. *Refer to Section 19, Transferring Patient Use Data, for details.*

4.11. Cartridge Label RFID Reader

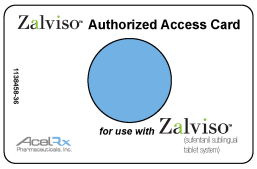
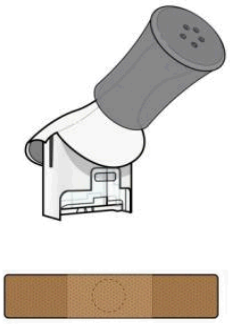
A Cartridge Label RFID Reader is available for use in the hospital pharmacy to assist with the auditing of used Drug Cartridges. The Reader enables the user to read the Cartridge RFID Label which indicates the remaining tablet count recorded by the System when the Cartridge was removed from the System. *Refer to Section 24, Use of Cartridge Label RFID Reader, for details on use of the Cartridge Label RFID Reader.*

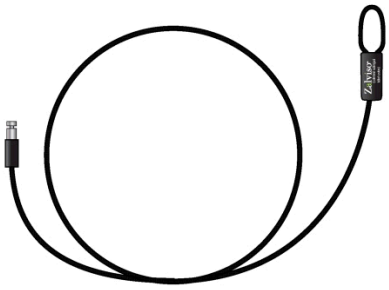
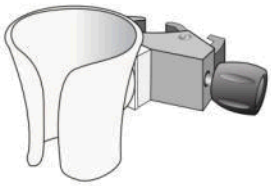
5. How to Set Up the System for a New Patient

To set up the sufentanil sublingual tablet system for a new patient, please follow the steps below:

STEP 1 **Gather Components**

1. Obtain the components listed below.
2. Inspect individual packages for damage.
3. **DO NOT** remove Cartridges from pouches until ready for use.
4. Make sure the components are all new or cleaned according to the recommended procedure.

<table>
<tr><td>  </td><td> 
</td></tr>
<tr><td>Controller</td><td>Authorized Access Card (AAC)</td></tr>
<tr><td> 
</td><td>  </td></tr>
<tr><td colspan="2">Dispenser Kit Contains:
Dispenser with Cap and Patient ID Thumb Tag and Patient Reference Sheet</td></tr>
</table>

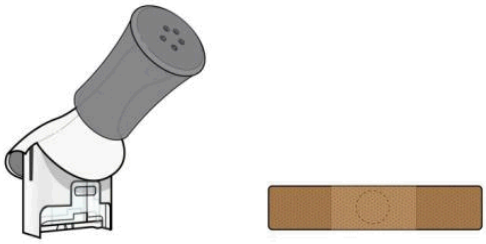
	
Patient ID Thumb Tag	**Zalviso Pouched Drug Cartridge**
	
Security Tether	**Holster**

Once all the components have been gathered, unpack all the components from their packaging and inspect for any damage. If damage is noted, replace with a newly inspected component.

If setting up more than one System at the same time, avoid set up of the Systems in close proximity (i.e. within 4 to 5 feet) to each other.

STEP 2 **Prepare Device**

Remove the Controller from its storage bag. Remove the Dispenser with Cap and Patient ID Thumb Tag from its box and individual packaging. Ensure that the Cap stays on the Dispenser tip during handling. Do not touch the tip of the Dispenser during handling to avoid contamination.



Remove the Dispenser with Cap and Patient ID Thumb Tag from the Dispenser Kit and individual packaging. Ensure that the Cap stays on the Dispenser tip during handling. Do not touch the tip of the Dispenser during handling to avoid contamination.

STEP 3 **Power-On Device**

Turn on the Controller by pressing and holding the Power button for approximately 3 to 5 seconds until the System turns on. The AcelRx screen will appear (see screen display below) and walk you through the setup process.

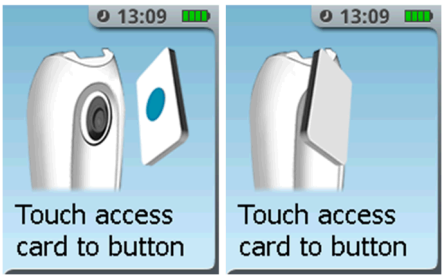
Ensure that the Controller's battery is fully charged.

If the Controller generates 3 audible beeps and then powers off, this indicates the Controller has failed the Power-On Self-Test, and should not be used. Return the Controller to Biomedical Engineering to perform diagnostics.

NOTE

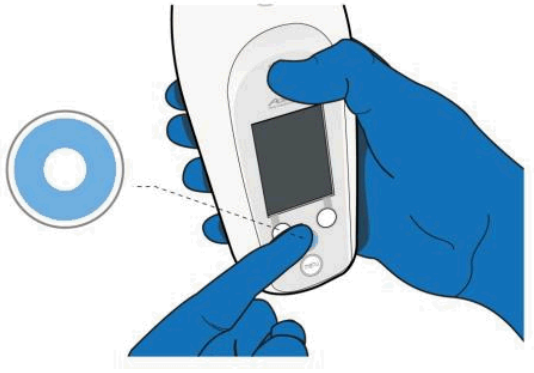
During System use, if the System doesn't receive any inputs (button presses or movement), the screen will turn off after 30 seconds. To wake the screen, press the **Enter/Select** Button or the **Menu** Button.

STEP 4 **Touch Authorized Access Card**



The screen will prompt you to touch the blue circle of the Authorized Access Card to the **Blue Dose** Button on the **BACK** of the Controller. The System will announce a tone to confirm that the System has successfully read the card.

STEP 5 Select ‘Setup for New Patient’ Function

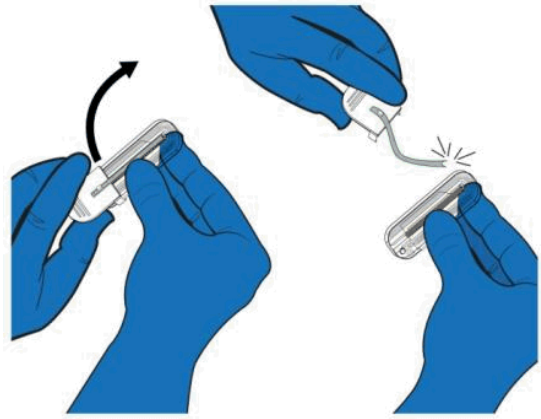


The System Menu will be displayed on the Controller screen on the front of the Controller. Select the **Setup for New Patient** function by pressing the **Enter/Select** Button. If Setup for New Patient is not highlighted then use the **Left/Right** buttons to scroll to this function.

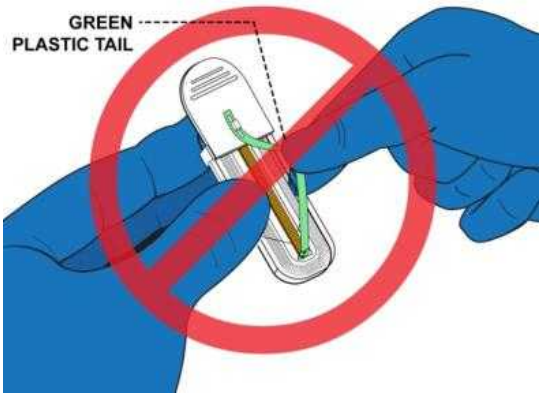
STEP 6 Prepare Drug Cartridge

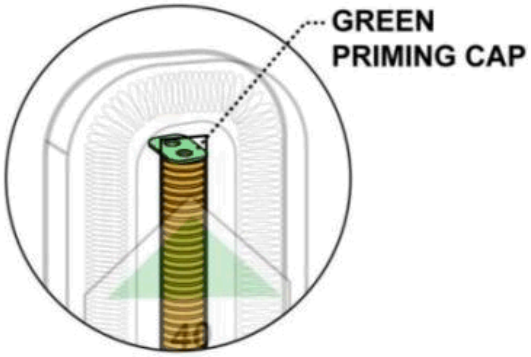
Obtain a new Drug Cartridge and prepare it for use as prompted by the screens. Remove the Drug Cartridge from its pouch.

NOTE: Only a new Drug Cartridge can be used or the System will display an error or notification. Do not remove Cartridge from the pouch until you are ready to use.



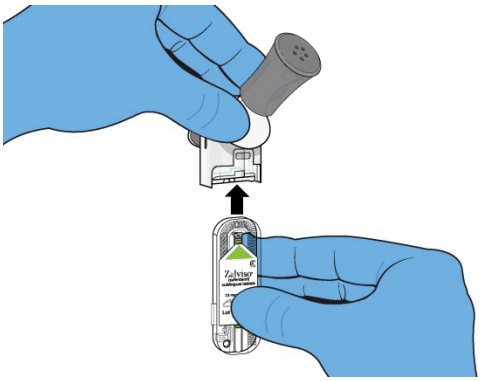
Grasp the white tab and pull up and away from the clear Cartridge body. **DO NOT GRASP THE GREEN TAIL.** Pull the white tab attached to the green plastic tail (do not twist), ensuring that the entire white tab and green tail are disconnected and removed from the Cartridge as shown below. This will leave a small green Priming Cap inside the top of the Cartridge that will be ejected by the System before patient use. The white tab and tail can be discarded.

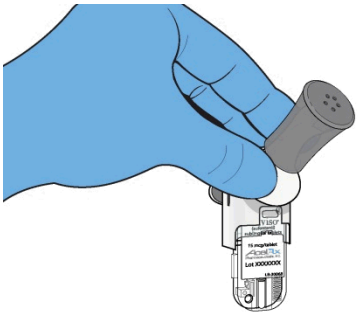




Confirm this step on the Screen by pressing the **Enter/Select** Button.

STEP 7 Insert Cartridge

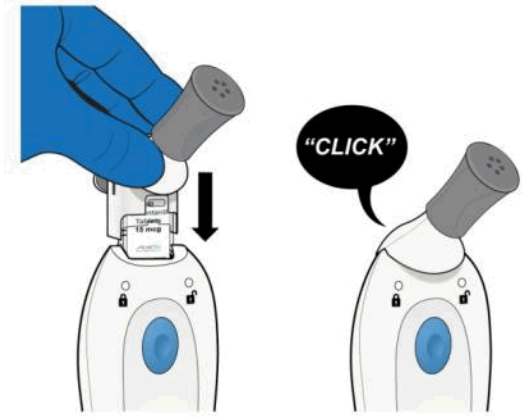




Insert the Cartridge into the bottom of the Dispenser (green arrow on Cartridge label points up).

Confirm this step on the screen by pressing the **Enter/Select** Button on the Controller.

STEP 8 **Connect Dispenser**

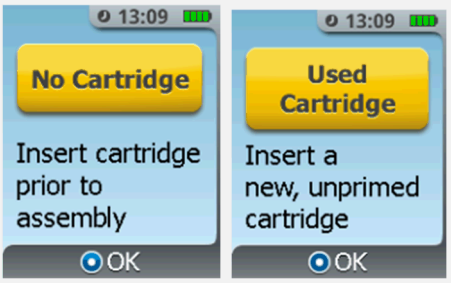


Snap the Dispenser (with Cartridge attached) onto the Controller.

INFO

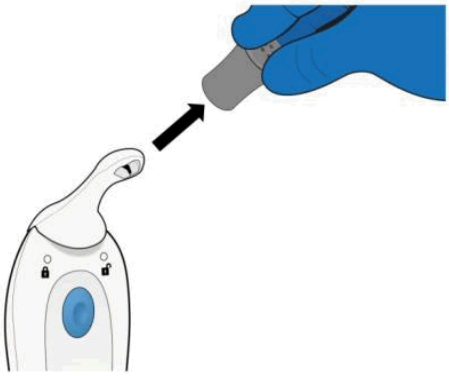
Did you receive a "No Cartridge" or "Used Cartridge" notification message?

If you received a "No Cartridge" message, the System was assembled without a Cartridge. If you received a "Used Cartridge" message, the Cartridge that was inserted was either previously used or may have been tampered with.

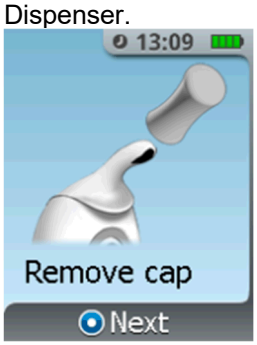


Refer to Section 16, Notifications, Alerts, Alarms and Errors, for further guidance on these notifications.

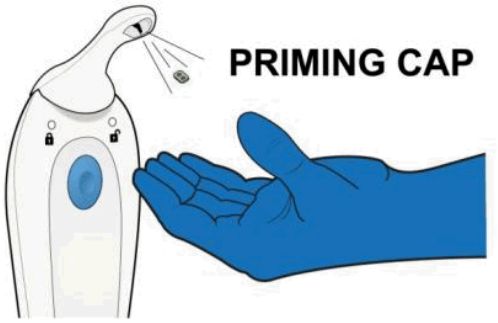
STEP 9 Remove Cap



Remove the gray protective Cap from the Dispenser.



STEP 10 Eject Priming Cap



Orient the System so that it is upright, and hold your hand directly below the Dispenser tip then press the **Enter/Select** Button to eject the green Priming Cap. *Note: Priming Cap is very small so attempt to dispense into your hand.*

The System will then eject the Priming Cap out of the Dispenser.

Select **YES** if you saw the green Priming Cap eject. If you did not see the green Priming Cap eject, examine the Dispenser Tip and the surrounding area. If you find the green Priming Cap in the Dispenser Tip remove it and select **YES**. If you find it in the surrounding area select **YES**.

Select **NO** (**Right Button**) if the green Priming Cap failed to eject and then follow the screen instructions to exit setup and discontinue the System. The next screen "Prime Failed Screen", as shown below, will instruct you to discontinue the System. Start over with a new Controller, Dispenser and Cartridge.

WARNING

The Priming Cap is not for patient use and should be discarded.

Did you hear a negative tone and receive the "Dispenser loose, press down" message?

When the "Dispenser loose, press down" screen is displayed, the System has detected the Dispenser may not be fully seated in the Controller. Press down on the Dispenser. Confirm the Dispenser is fully seated in the Controller then press the **Enter/Select** Button to retry ejecting the Priming Cap. A total of 3 attempts to eject the Priming Cap is allowed. After the 3rd attempt, the System will proceed with a prime failure and the "Error - System Cannot Be Used" screen will be displayed.