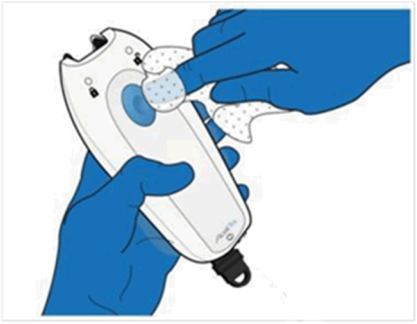
STEP 4 Disconnect and Clean Controller



1. Squeeze the side release latches on the end of the Charger to unlock and remove the end of the Charger from the bottom of the Controller.
2. Power off the Controller by pressing the **Power Button**.
3. Wipe the Controller with alcohol wipes and allow to dry.
4. Place the Controller in a clean storage bag.
5. Disconnect the Charger from the AC power outlet.

19. Transferring Patient Use Data

The Data Cable is available for transferring data from the Controller to other electronic media, if desired. To conduct downloading of the patient use data, which may be performed after a System Discontinuation for each patient, the Healthcare Professional can access the "Transfer Data" feature via an AAC or TAB.

NOTE

No patient identification information is recorded in the Controller data. Patient's usage history is recorded in the Controller data by date and time of use by the patient.

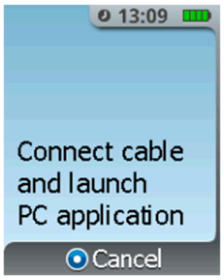
STEP 1 **Access Transfer Data Screen**

System Menu (AAC)

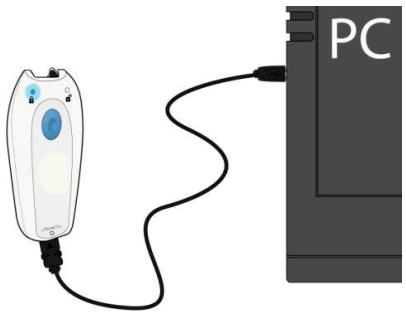
Utility Menu (TAB)

1. The Healthcare Professional must turn the System on by holding down the **Power Button** for 3 to 4 seconds.
2. The first screen they will see will ask them to touch the AAC or TAB to the **Blue Dose Button**. This action will present the System Menu or Utility Menu options.
3. Scroll to the **Transfer Data** option then select it by pressing the **Enter/Select** Button.

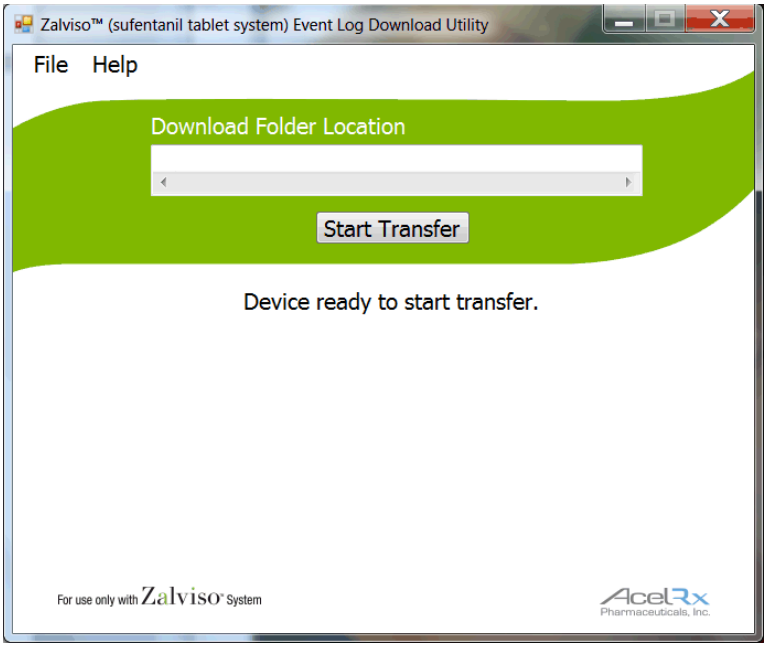
STEP 2 **Connect Cable**



1. Follow the instructions on-screen.
2. Connect the custom Data Cable to the Controller's Charging/Data connector and Computer's USB port (the Computer must be running Windows 7 operating system). Ensure the Data Cable's connector snaps into the Controller's Charging/Data Port connector.

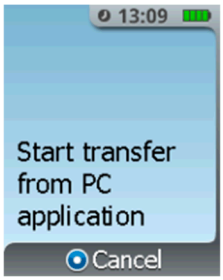


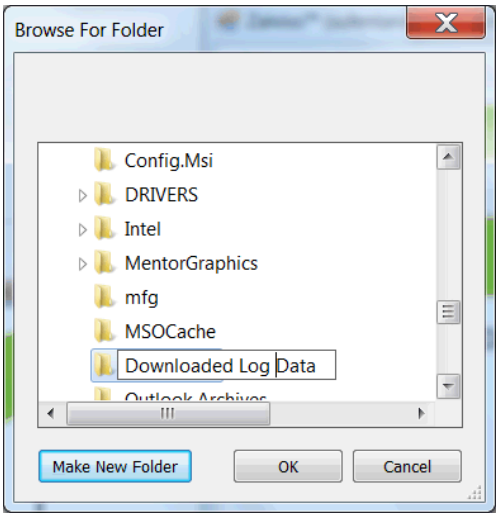
STEP 3 Launch PC Application



1. To start or launch the PC application software that transfers the patient use data from the sufentanil sublingual tablet system, double click on the “Zalviso™ (sufentanil tablet system) Event Log Download Utility” icon on the desktop (present after software installation). If the Windows Open File - Security Warning window is displayed, select “Run”.
2. A similar Download Utility application window should be displayed, as shown above.

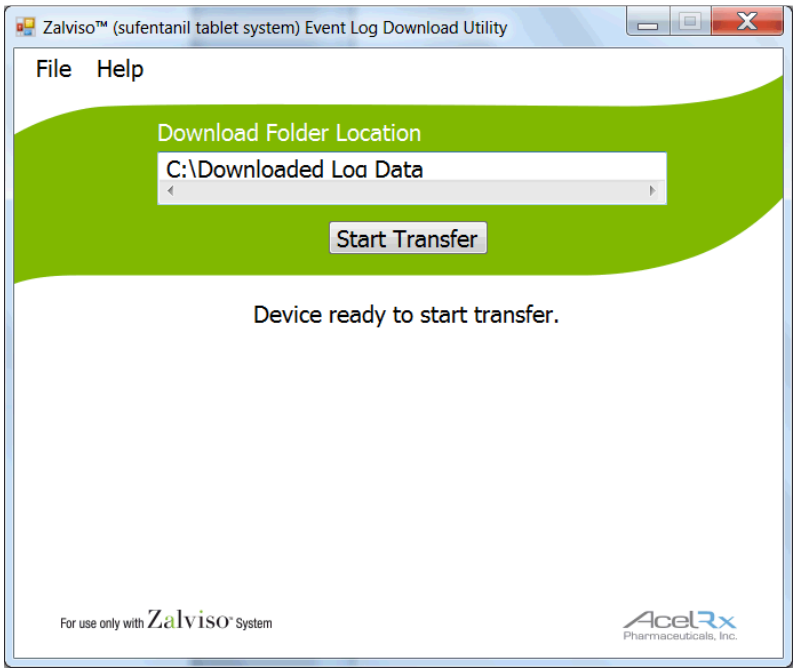
STEP 4 Make New Folder or Select Folder on PC





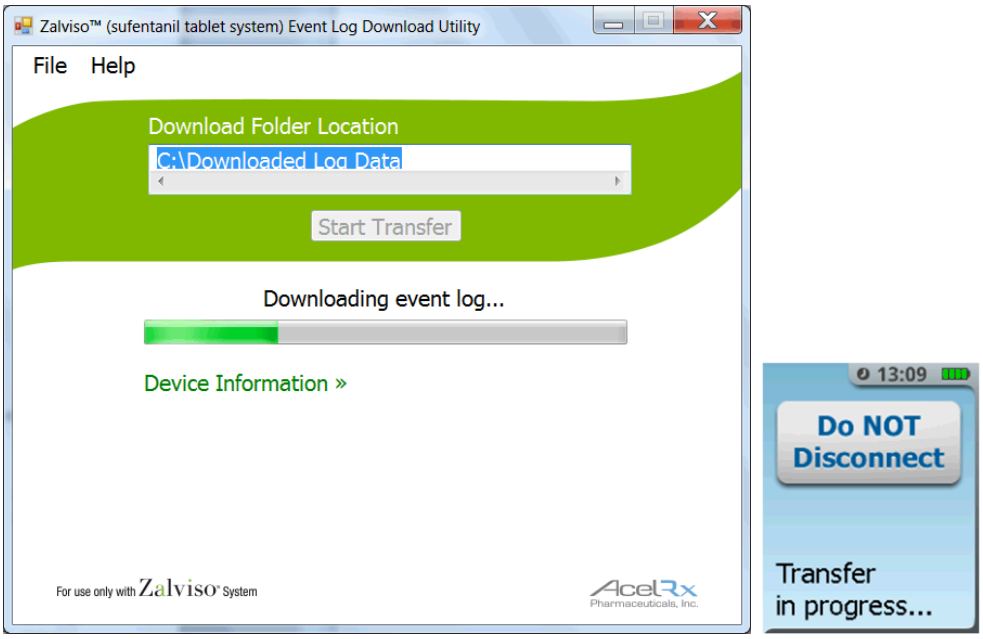
1. The System should display **Device ready to start transfer**
2. Using the PC mouse, click on the PC application's **Download Folder Location** field to activate the "Browse For Folder" window to display, as shown at left. Make New Folder according to the institution's procedure or select a folder on the PC to transfer the Patient Use Data file to. Then click on **OK** tablet.

STEP 5 Start Transfer on PC



The PC application's Download Folder field should display the folder path selected, as shown below. Using the PC mouse, click on the PC application's **Start Transfer** button.

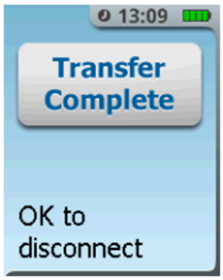
STEP 6 Await Transfer

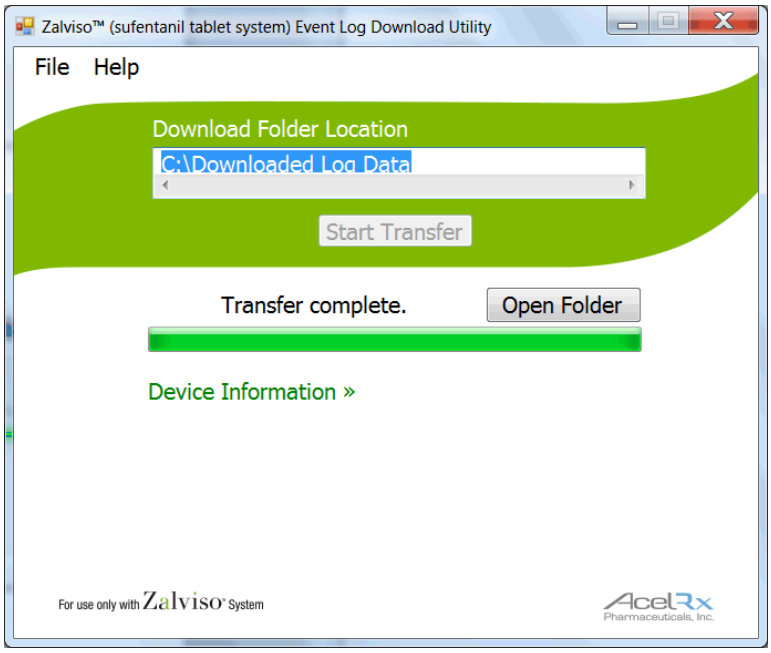


The System will display **Do NOT Disconnect, Transfer in progress…..**

DO NOT disconnect the System during the data transfer. The PC application will display **Downloading event log…** and the download status by updating the green status bar.

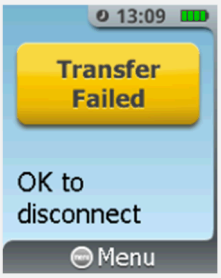
STEP 7 Confirm Transfer Complete





1. The System will display **Transfer Complete** once the Patient Use Data is successfully downloaded.
2. Disconnect the Data Cable (by squeezing on the sides) from the Controller.
3. The PC application should display a **Transfer complete** and 100% green status bar once the Patient Use Data is downloaded successfully. Click on the red "X" on the upper right-hand corner of the PC application window to close the application.

Did you receive a Transfer Failed error message?



If any error occurs at this point, follow the on screen instructions to disconnect the Data Cable and try again. Ensure the Data Cable's connector snaps into the Controller's Charging/Data Port.

If this error continues to occur, replace the Data Cable and try again. If the error continues after replacing the Data Cable, contact the biomedical technician or contact the manufacturer to arrange for the return of the Controller.

20. Reviewing Former Patient Data

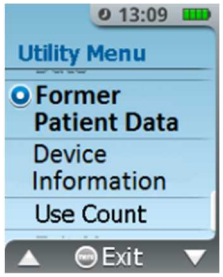
Former patient data can only be accessed using an AAC or TAB before the System has been setup for the next planned patient. It must be selected from the display screen immediately after powering on. Former patient data cannot be accessed while in patient use mode. The System will retain use history for five patients. The System memory follows the “first in first out” principle for memory allocation, meaning that the first patient’s data is erased as the sixth patient starts to use the System.

NOTE

No patient identification information is recorded in the Controller data. Patient’s usage history is recorded in the Controller data by date and time of use by the patient.

STEP 1 Access Former Patient Data Screen

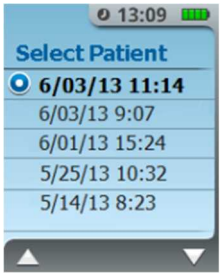
System Menu (AAC)



Utility Menu (TAB)

To view a former patient’s data, select the patient by their date and time of first dose. Scroll up or down using the **Left** or **Right** button, then pressing the **Enter/Select** button to select the patient. Press the **menu** button to return to the previous menu.

STEP 2 View Patient Data Screen



The patient’s first dose date and time is displayed in the header (e.g. 6/03/2013 11:14, shown in display below). The first display of the patient data initially summarizes the total quantity of tablets and cumulative doses for the selected patient below the header (e.g. 21 Tablets, 315 mcg taken, shown in display below).

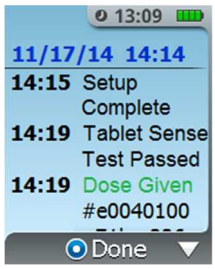
This summary is not displayed after scrolling up or down. However, the summary can be displayed again by pressing the **Enter/Select** button to exit, and then reselect the former patient from the Select Patient menu.

STEP 3 Browse Patient Data

The former patient's data history is viewed by scrolling up or down using the **Left** or **Right** button, respectively.

The former patient's data displays an event time stamp and a description of the event. A summary of events displayed:

- Priming Cap Dispensed
- Cartridge unique ID number
- Setup Complete
- New Pat ID: Patient ID Thumb Tag unique ID scanned at setup or at Change Thumb Tag
- Battery Level: battery level capacity percentage remaining and battery voltage in millivolts (mV)
- Tablet Sense Test Passed (or Failed)
- Doses Given: Displayed in green colored text when a dose is dispensed followed by Patient Thumb Tag ID number in black colored text
- Request in Lockout: Displayed in blue colored text when a dose was requested during the lockout period



Summary of events (continued):

- AAC Access followed by its unique card ID number
- Tether Locked/Unlocked
- Dispenser Unlatched/Removed
- Changed Cartridge: Displayed as Cartridge Changed followed by its unique ID number
- Shift Reset followed by shift's total tablets
- Training Screens Used: Patient training demo selected
- Error and error code: Displayed in red text as Error or Assert and corresponding error code or assert error information
- Power Down and Power Up
- Tablets Disp: Total quantity of tablets dispensed by patient when System is discontinued
- Discontinue

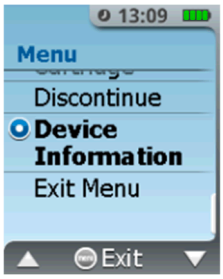
1. If the Controller goes to sleep when at viewing Former Patient Data, wake up the Controller by pressing the menu button and access using the AAC to return the Former Patient Data screen.

2. Press the **Enter/Select** button to return to the Former Patient data select menu.

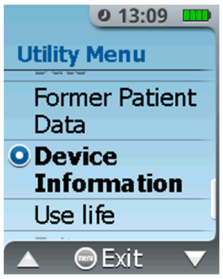
21. Device Information Screen

In the event that it is necessary for the Healthcare Professional to retrieve the sufentanil sublingual tablet system's software version or the Controller Serial number, it can be accomplished by accessing the System Menu and selecting the "Device Information". When the System is not in patient use, the biomedical technician can access the Utility Menu using the Technician Access Badge (TAB) and select "Device Information".

STEP 1 Access Device Information



System Menu (AAC)



Utility menu (TAB)

1. Access the System Menu via the AAC or access the Utility Menu via the TAB.
2. The first screen they will see will ask them to touch their AAC or TAB to the **Blue Dose Button**. This action will present the Menu options.
3. Scroll to the **Device Information** option in the System Menu or Utility Menu then select it by pressing the **Enter/Select** Button.

STEP 2 View Device Information

The sufentanil sublingual tablet system's software version and the Controller serial number are displayed.

22. Troubleshooting

WARNING

System components are not serviceable. Tampering, modifying or opening of the System or its components may lead to hazardous conditions.

DO NOT attempt to service the Controller. Opening a System component to attempt troubleshooting or repair will void the manufacturer's warranty.

NOTE

If any problems are encountered or questions arise during troubleshooting, please call: 1-855-ZALVISO (1-855-925-8476) for assistance. *Refer to Section 16 for more information related to System Notifications, Alerts/Errors and Alarms.*

NOTE

If the Controller displays a message "Error System Cannot Be Used", along with a 3 or 4 digit error cod , please call: 1-855-ZALVISO (1-855-925-8476) for assistance. Depending on the error code and other system details provided to the Call Center, the Controller may be acceptable to return to service after reprocessing/recharging, or may need to be returned to the manufacturer.

22.1. Patient Cannot Dose, but System Appears Normal

- Check to see that the green light is illuminated indicating that dosing is available.
- Check basic Dose History screen to see if patient has been receiving doses. *Refer to Section 11, Basic Dose History and Detailed History.*
- Check to see that the patient is dosing in an upright orientation. *Refer to Section 7, Patient Use.*
- While the System's dose available green light is illuminated and the System is in an upright orientation, have the patient place his thumb with the Thumb Tag on the Dose Button and observe if Dose Button light flashes. *Refer to Section 7, Patient Use.*
- If the patient's System orientation during the dose attempt is appropriate and the Dose Button does not flash green, replace the Patient ID Thumb Tag. *Refer to Section 8, Replacing the Patient ID Thumb Tag).*
    - If replacing the patient's Thumb Tag still does not result in the System permitting the patient to dose, Discontinue the System and set the patient up with a replacement System.

22.2. Patient Cannot Dose, System Appears Unresponsive

- Press **Enter/Select** button to see if screen will wake-up.
- Check to see that the green or blue dosing indicator light is illuminated indicating that the System is on.
- If the System does not wake-up, or a dose light is not on, remove the System from the patient, and set up the patient with a replacement System.

22.3. Cartridge is not Recognized during Setup or Replacing Cartridge (Receive “No Cartridge” Notification)

- Ensure that a Cartridge has indeed been inserted by removing the Dispenser.
- Re-insert Dispenser with Cartridge loaded.
- If the same notification appears, remove Dispenser and replace the Cartridge with a new one.

22.4. Authorized Access Card (AAC) or Technician Access Badge (TAB) is not Recognized by System

- Ensure that the Display is requesting to “Touch access card” for menu.
- Ensure that the AAC or TAB access card is being touched to the large Blue Dose Button on the back of the Controller and that roughly the middle of the access card is over the Dose Button.
- If the System still doesn’t recognize the AAC or TAB, retry with a different AAC or TAB and set malfunctioning AAC or TAB aside.

NOTE

If any error or problem results in the System, AAC or TAB being replaced, please notify the biomedical technician.

22.5. During Change Cartridge or Initial Set Up, the Priming Cap is not observed as being ejected from the System

1. 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**.
2. If you find it in the surrounding area select **YES**.
3. 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.
4. Start over with a new Controller, Dispenser and Cartridge.

WARNING

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

22.6. System Does Not Power On

- Check that the Controller is charged. *Refer to Section 18, Recharging the Controller.*
- Press and hold the Controller's **Power Button** for at least 5 seconds until the power on tone and display turns on.
- If the Controller powers on, then powers off and is followed by 3 audible beeps and the Controller powers down, this indicates the Controller has failed Power-On Self-Test. If this occurs, notify the biomedical technician.

22.7. System screen is on but System appears unresponsive

- Check to see if pressing the Menu button causes the Display to request to "Touch access card" for menu.

- If the System is unresponsive to accessing the Menu, contact Biomedical Engineering to arrange for removal of the System from the patient's room.
- Place the System away from the patient until it is removed.

22.8. Controller cannot be powered off when not in Patient Use

- If the Controller is displaying the **Touch access card screen** or upon waking up, displays the **Touch access card** screen, scan the AAC to display the System menu.
- Press and hold the **Power Button** for about 5 seconds until the Controller powers off.
- If the Controller is unresponsive to accessing the System menu or does not power off after pressing the **Power Button** for 5 seconds, contact Biomedical Engineering for removal.

22.9. Dispenser cannot be removed after System is Discontinued

- Power on the Controller by pressing on the **Power Button** for about 5 seconds.
- A System Error should be displayed. Proceed to System Discontinue.
- Retry removing the Dispenser.
- If Dispenser cannot be removed, contact Biomedical Engineering for removal.

22.10. Controller powers on then powers off

- If during Controller power on, 3 audible beeps are generated then the Controller powers off, this indicates the Controller has failed the Power-On Self-Test.
- Contact Biomedical Engineering for removal of the Controller.

23. General Information

23.1. System Information

Manufacturing and System Use

Manufacturer: AcelRx Pharmaceuticals
Address: 351 Galveston Drive, Redwood City, California USA 94063
Phone: 855-ZALVISO (855-925-8476)

Model: Zalviso Sufentanil Sublingual Tablet System
Classification: Class II equipment, Type BF applied part
Operating Conditions: 15°C to 40°C, 20% to 75% relative humidity

System Use Period: Once set up for patient use, each System can be used for a maximum of 72 hours per patient. System notifications are generated when the 72-hour limit is approaching and when 72-hour limit is reached *(refer to Section 16, Notifications, Alerts, Alarms and Errors).* If additional therapy is required past 72 hours, a new System has to be set up for the patient.

System Use Life: Each Controller has a minimum use life of 30,000 doses.

Certifications

- The Zalviso sufentanil sublingual tablet system complies with the applicable requirements of IEC 60601-1: 2012 and its applicable collateral standards
- The Zalviso sufentanil sublingual tablet system complies with the applicable requirements of FCC Part 15 subpart C (15.225)
-

System Power Source

- Rechargeable Li-Ion battery, 3.6Vdc, 0.5A peak, 2900mAh
- Not serviceable

Charger:

- Input: 100-240VAC, 50-60Hz, single phase, nominal input current 0.15Amps @ max load
- Output: 5V DC ± 5%, 0.6A
- Approved for Medical application. Charger is compliant to the applicable requirements of IEC 60601-1, ES 60601-1 and EN 60601-1
- Charger's Cord length: 1.8m (72 inches)

Interfaces:

- Display: 1.8-inch LCD, 176 x 220, TFT, color, white backlight
- Indicators: Green and blue indicators, Dose Available and No Dose Available indicators, respectively
- Data port: RS-232 (transmit and receive only)
- Audio notification tones, alerts and high priority alarm: Internal audio speaker
- RFID and RFID tags: 13.56 MHz, ISO 15693

Alarm:

- One high priority alarm, refer to section 16.3
- Sound pressure level (SPL) range at the operator's position (0.3m (1-foot)): 50dB(A) to 60dB(A)

Radiated Emissions Information

- Operating Frequency: single frequency, 13.56MHz
- Number of Channels: One
- Type of Modulation: OOK modulation
- Field strength: 36.9 dB(uV/m) at 30 meters
- Antenna Type: Multi-turn electrical small loop

Electromagnetic Compatibility

Table 1 – Guidance and Manufacturer's Declaration – Electromagnetic Emissions
All ME Equipment and ME Systems

Guidance and manufacturer's declaration – electromagnetic emissions		
The Zalviso sufentanil sublingual tablet system is intended for use in the electromagnetic environment specified below. The customer or the user of the Zalviso sufentanil sublingual tablet system should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Zalviso sufentanil sublingual tablet system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Zalviso sufentanil sublingual tablet system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions	Complies	

Table 2 – Guidance and Manufacturer's Declaration – Electromagnetic Immunity
All ME Equipment and ME Systems

Guidance and manufacturer's declaration – electromagnetic immunity			
The Zalviso sufentanil sublingual tablet system is intended for use in the electromagnetic environment specified below. The customer or the user of the Zalviso sufentanil sublingual tablet system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods At 0°	Voltage Dips 30% reduction, 25/30 periods At 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Zalviso sufentanil sublingual tablet system requires continued operation during power mains interruptions, it is recommended that the Zalviso sufentanil sublingual tablet system be powered from an uninterruptible power supply or a battery.
	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Voltage Dips > 95% reduction, 0.5 period At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	Voltage Dips > 95% reduction, 1 period At 0°	Voltage Dips > 95% reduction, 1 period At 0°	
	Voltage Interruptions > 95% reduction, 250/300 periods	Voltage Interruptions > 95% reduction, 250/300 periods	
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

	Caution: Be Cautious Near MRI and X-ray Equipment	Keep the Zalviso sufentanil sublingual tablet system away from MRI and X-ray equipment. Strong magnetic fields (those beyond the levels tested) may cause the device to operate improperly.

Table 3 – Guidance and Manufacturer's Declaration – Electromagnetic Immunity
ME Equipment and ME Systems that are NOT Life-supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The Zalviso sufentanil sublingual tablet system is intended for use in the electromagnetic environment specified below. The customer or the user of the Zalviso sufentanil sublingual tablet system should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz (6 Vrms in ISM radio Bands within 150kHz – 80MHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Zalviso sufentanil sublingual tablet system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Zalviso sufentanil sublingual tablet system is used exceeds the applicable RF compliance level above, the Zalviso sufentanil sublingual tablet system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Zalviso sufentanil sublingual tablet system. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4 – Recommended Separation Distances between portable and mobile RF Communications equipment and the Zalviso sufentanil sublingual tablet system

ME Equipment and ME Systems that are NOT Life-supporting

Recommended separation distances between portable and mobile RF communications equipment and the Zalviso sufentanil sublingual tablet system			
The Zalviso sufentanil sublingual tablet system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Zalviso sufentanil sublingual tablet system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zalviso sufentanil sublingual tablet system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 5 – Immunity to RF Wireless Communications Equipment

Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band [a] (MHz)**	**Service [a]**	**Modulation [b]**	**Maximum Power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

FCC Compliance Statements

This device is certified under FCC ID: 2AA4P-ARX2006

Part 15.19

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Part 15.105

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

Part 15.21

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

23.2. Inspect Packaging and Components

Make sure to inspect the packaging and components as follows:

- Inspect all shipping packages and individual packages for damage.
- Remove the primary packages from the shipping boxes. **DO NOT** remove components from their primary boxes or primary plastic bags until ready for use.

WARNING

DO NOT remove Cartridges from pouches until ready for use.

23.3. Storage and Handling

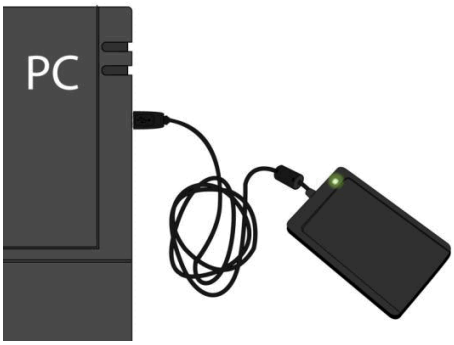
- All components should be stored at room temperature in a secure location per institutional guidelines.
- Access should be limited to authorized users.
- Drug Cartridges contain a Controlled Substance (CII Opioid) and should be stored in an appropriate secure location at controlled room temperature (15 - 30°C).

24. Use of Cartridge Label RFID Reader

The Cartridge Label RFID Reader enables the Healthcare Professional to read and display the number of remaining tablets in used Cartridges, as electronically recorded on the Cartridge RFID Label. If necessary, the Cartridge Label RFID Reader can also be used to display the Cartridge's detailed information, such as drug name, dosage strength and Drug Cartridge's unique RFID number. To read the RFID information on the Cartridge Label, refer to the instructions in this section.

To use the Cartridge Label RFID Reader to display the "tablets remaining" recorded on the Cartridge RFID Label:

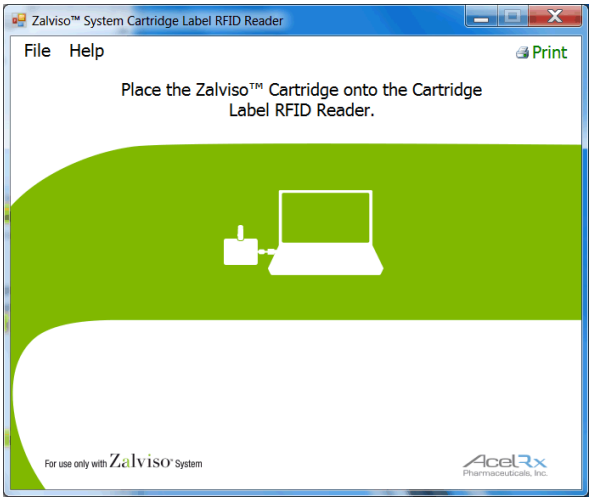
STEP 1 Connect to PC



1. Connect the Cartridge Label RFID Reader to a computer's (PC) USB port. The RFID Reader's indicator should illuminate indicating power and connection to the USB port.

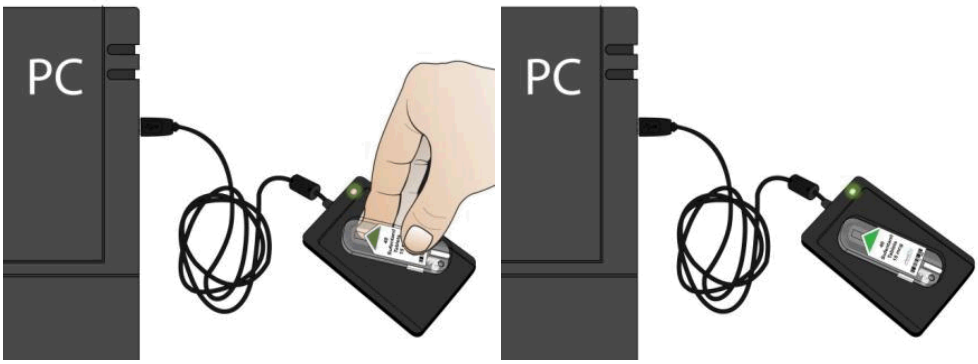
2. If not already completed, install the Cartridge Label RFID Reader application software that was provided with the Cartridge Label RFID Reader.

STEP 2 Launch PC Software



1. Execute the Cartridge Label RFID Reader application software.
2. The following screen appears on the computer screen, with "Place the Zalviso™ Cartridge onto the Cartridge RFID Reader".

STEP 3 Introduce Drug Cartridge to RFID Reader



- Place the used Drug Cartridge onto the Cartridge Label RFID Reader.

STEP 4 View “Tablets Remaining” as recorded on Cartridge Label RFID

1. The number of tablets remaining, as recorded on the Cartridge RFID Label, is displayed on the Cartridge Label RFID Reader application. The sample screen above displays the RFID scan status from a detected Cartridge RFID Label and indicates 14 tablets remaining read from the Cartridge RFID Label.

2. If desired, print the information presented on the Cartridge Label RFID Reader

application screen by clicking the “Print” button located on the upper right of the application screen.

WARNING

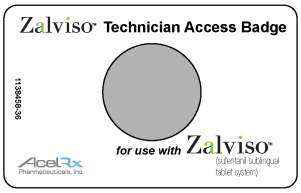
If it appears that the “tablets remaining” as recorded on the Cartridge Label RFID is <u>different</u> than the number of tablets ACTUALLY REMAINING in the Cartridge, diversion may have occurred. ***See Section 14.2 for manual tablet accounting & reconciliation.***

25. Biomedical Technician Utility Menu

When not in patient use, the biomedical technician can use a Technician Access Badge (TAB) to access the Controller's utility features consisting of:

- Diagnostics *(Refer to Section 26)*
- Transfer Data *(refer to Section 19)*
- Power Down *(Refer to Section 27)*
- Set Time and Date *(Refer to Section 28)*
- Former Patient Data *(Refer to Section 20)*
- Device Information *(Refer to Section 21)*
- Use Life *(Refer to Section 29)*

The utility menu is accessible by the biomedical technician with the use of a Technician Access Badge (TAB).



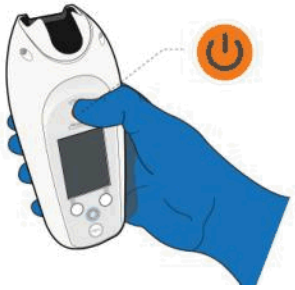
- The user will use the TAB to gain access to the System Controller's technician utility menu.
- The System Controller prompts the user to touch the gray circle of the TAB access card to the blue Dose Button located on the back of the Controller.
- The TAB does not allow the user to setup the System for its intended use.
- When the System is in patient use, menu access via the TAB is not allowed by the System.
- The TAB should not be exposed to X-rays, MRI, or other strong electromagnetic fields.

NOTE

If any problems are encountered or questions arise during use of the Biomedical Technician Utility Menu, diagnostics or troubleshooting, or if an Error has occurred, please call: 1-855-ZALVISO (1-855-925-8476) for assistance.

25.1. Accessing the Technician Utility Menu

STEP 1 Power-On Device



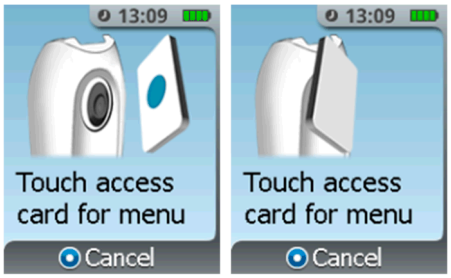
Turn on the Controller by pressing and holding the Power button for approximately 3 to 5 seconds until the System turns on. The AcelRx startup screen will appear. Ensure that the Controller's battery is fully charged. *Refer to Section 18, Recharging the Controller.*

If the AcelRx startup screen is not displayed and is followed by a 3 audible beeps or if the Controller powers off after the AcelRx startup screen appears, then followed by the display turning off and followed by a 3 audible beeps, this indicates the Controller has failed Power-On Self-Test. If Power-On Self-Test fails, proceed to the "**What To Do If a Diagnostics Test or Power-On Self-Test Fails**" section instructions described later in this section.

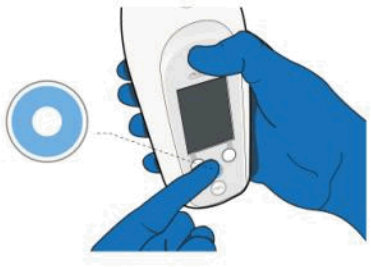
STEP 2 Touch Access Card to Controller

1. The screen will prompt you to touch the circle of the Access Card to the blue Dose Button on the **BACK** of the Controller.

2. Touch the gray circle of the TAB access card to the **Blue Dose button** on the Controller. The System will announce a tone to confirm that the System has successfully read the card.



STEP 3 **View Utility Menu**



The Utility Menu will be displayed on the Controller screen on the front of the Controller.

26. Diagnostics

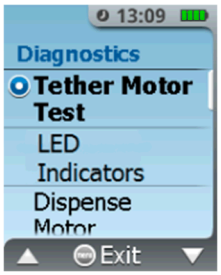
The Utility menu “Diagnostics” feature provides capabilities for the biomedical technician to check the Controller’s functions if there is an operational issue during normal System use by the nurse or patient.

26.1. Accessing the Diagnostics Screen

STEP 1 Navigate to the Diagnostics Screen

1. To access the Diagnostics menu from the Utility menu, scroll to **Diagnostics** then press the **Enter/Select** button.
2. The Diagnostics Menu will be displayed on the Controller screen on the front of the Controller.

STEP 2 View the Diagnostics Screen



The Diagnostics Menu displays a list of functional tests:

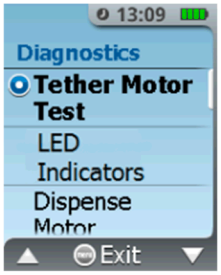
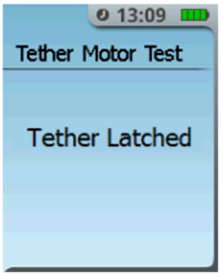
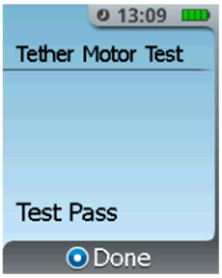
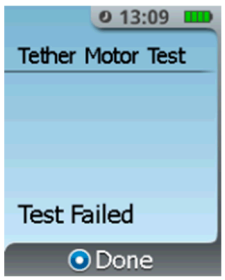
- Tether motor test
- LED indicators
- Dispense motor test
- Sound test
- RFID check
- Accelerometer test
- Buttons

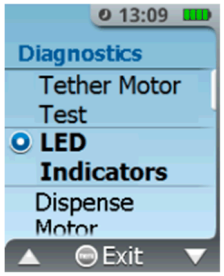
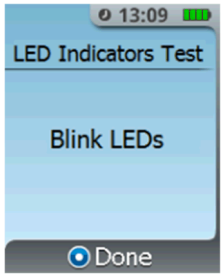
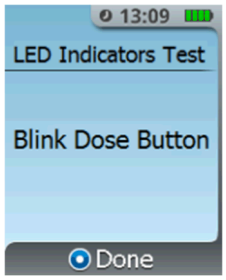
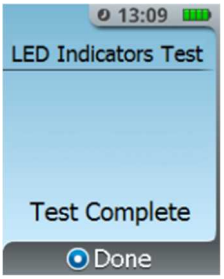
When in the Diagnostics Menu, select a functional test by using the **Left/Right** button to scroll to a functional test until highlighted in bold then press the **Enter/Select** button. To return to the Utility Menu from the Diagnostics Menu, press the **Menu** button.

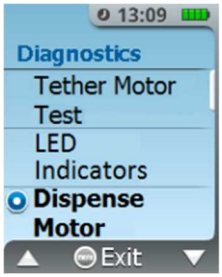
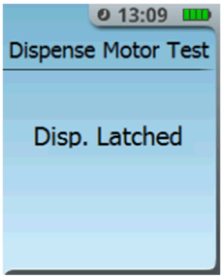
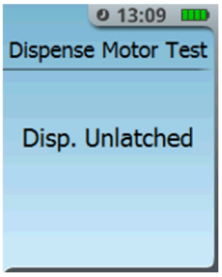
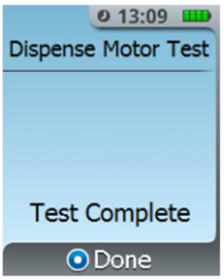
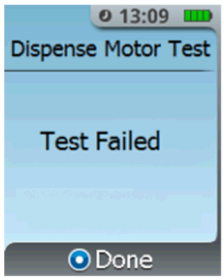
26.2. Diagnostic Test Descriptions

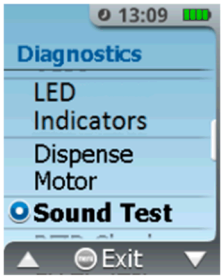
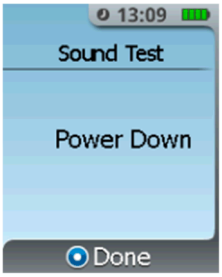
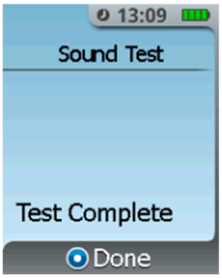
NOTE

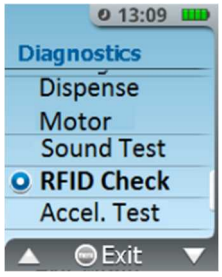
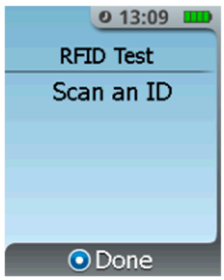
If any of the following diagnostic tests fail or do not operate as indicated please proceed to the "**What To Do If a Diagnostics Test or Power-On Self-Test Fails**" instructions described later in this section.

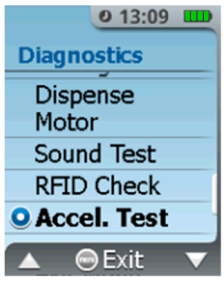
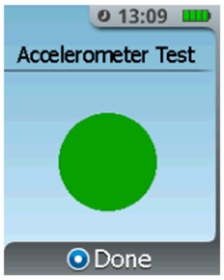
TETHER MOTOR TEST			
Diagnostic Test	***Functional Test Description***	***Technician Functional Check***	***If Functional Check Fails***
	Runs the Controller's tether motor to Tether latch position then returns to Tether unlatch position. Do not install a Tether into the Controller during the Tether motor test.  	Verify the Controller's Tether motor sound and feel as the motor runs to the Tether latch and Tether unlatch positions.  Press on the **Enter/Select** button to return to the Diagnostics Menu.	The Controller is defective if theTether Motor Test fails.  Contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

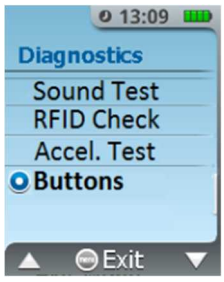
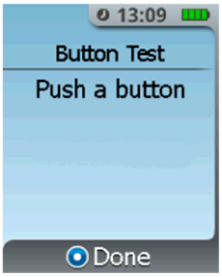
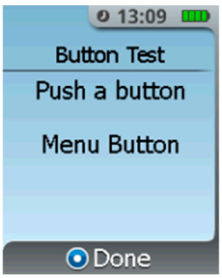
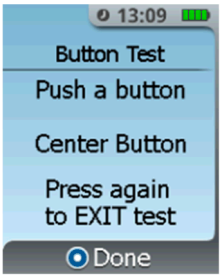
LED INDICATORS			
Diagnostic Test	***Functional Test Description***	***Technician Functional Check***	***If Functional Check Fails***
	Lights and flashes the Controller's Dose Available, No Dose Available and **Blue Dose Button** indicators in sequence.  	After pressing the **Enter/Select** button, look at the indicators on the back side of the Controller. Verify the Controller's Dose Available, No Dose Available and **Blue Dose Button** indicators light and flashes.  Press on the **Enter/Select** button to return to the Diagnostics Menu.	If the technician verifies the Controller's LED indicators do not light and flash, then the LED Indicators Test has failed. Contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

DISPENSE MOTOR TEST			
Diagnostic Test	***Functional Test Description***	***Technician Functional Check***	***If Functional Check Fails***
	Runs the Controller's dispense motor to the Dispenser latch position then returns to Dispenser unlatch position. **DO NOT** install a Dispenser into the Controller during the Dispenser motor test.  	Verify the Controller's dispense motor sound and feel as the motor runs to the Dispenser latch to Dispenser unlatch positions.  Press on the **Enter/Select** button to return to the Diagnostics Menu.	The Controller is defective if the Dispense Motor Test fails.  Contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

SOUND TEST			
Diagnostic Test	***Functional Test Description***	***Technician Functional Check***	***If Functional Check Fails***
	Generates the Controller's six audible tones in sequence. 	Verify six audible tones are generated in sequence (i.e. Power On, Power Down, Confirmation, Negative, Low Level Alert and Dose tones).  Press on the **Enter/Select** button to return to the Diagnostics Menu.	If the technician verifies the Controller does not generate all six audible tones, then the Sound Test has failed. Contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

RFID CHECK			
Diagnostic Test	***Functional Test Description***	***Technician Functional Check***	***If Functional Check Fails***
	Scans for a System secure access component such as the AAC, TAB and Patient ID Thumb Tag. When **Scan an ID** is displayed, technician places System secure access component against the Controller's **Blue Dose Button**. 	Verify the System secure access component (i.e. AAC, TAB or Patient ID Thumb Tag) is found and displayed when placed against the Controller's **Blue Dose Button**.  Press on the **Enter/Select** button to return to the Diagnostics Menu.	If the technician verifies the Controller does not detect and display the secure access component against the Controller's **Blue Dose Button** (i.e. AAC, TAB or Patient ID Thumb Tag), then the RFID Check has failed. Contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

ACCELEROMETER TEST			
Diagnostic Test	***Functional Test Description***	***Technician Functional Check***	***If Functional Check Fails***
	Checks the Controller's orientation accelerometer is functional. Accelerometer test displays an orientation circle. When the Controller is in the proper dosing position (i.e. upright) the orientation cicle should be green. When the Controller's in the improper dosing position (i.e. sideways) the orientation cicle should be blue.  	Technician starts with the Controller's orientation in the upright position and verify the orientation cicle is green. Rotate the Controller in a circular motion through various orientations and verify the orientation cicle changes from green to blue then back to green. Verifying the orientation circle color while rotating the Controller 360° in the vertical axis is one method to check the accelerometer functionality. Press on the **Enter/Select** button to return to the Diagnostics Menu.	If the technician verifies one of the following: The orientation circle does not change to green when the Controller is an upright position. When the Controller is rotated 360° in the vertical axis the orientation circle does not change color. Then the Accelerometer Test has failed. Contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

BUTTONS TEST			
Diagnostic Test	***Functional Test Description***	***Technician Functional Check***	***If Functional Check Fails***
	Checks the Controller's buttons are functional. When the **Push a button** is displayed, press one of the Controller's **Menu** button, **Power** button, **Left** button, **Right** button, **Blue Dose Button** or the **Enter/Select** (Center) button.  	While pressing the Controller's **Menu** button, **Power** button, **Left** button, **Right** button, **Blue Dose Button** or the **Enter/Select** button, verify the corresponding button name is displayed.   Press on the **Enter/Select** button to return to the Diagnostics Menu.	If the technician verifies a Controller's button is not detected when pressed, then the Buttons Test has failed. Contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

What To Do If a Diagnostics Test or Power-On Self-Test Fails

If during Controller power on, 3 audible beeps are generated then the Controller powers off, this indicates the Controller has failed the Power-On Self-Test.

If the biomedical technician verifies that a Controller repeatedly has a System Error, fails Diagnostics or fails Power-On Self-Test, contact the manufacturer to arrange the return of the Controller to the manufacturer. *Refer to Section 23, General Information, for the manufacturer's contact information.*

WARNING

System components are not serviceable. Tampering, modifying or opening of the System or its components may lead to a hazardous condition, and will void the manufacturer's warranty.

27. Power Down from Utility Menu

The Utility menu “Power Down” feature provides capabilities for the biomedical technician to power off the Controller.

Power Down

To power off the Controller from the Utility menu, scroll to **Power Down** then press the **Enter/Select** button.

The Controller’s display and indicators should turn off, and the power down tone should be audible during power down.

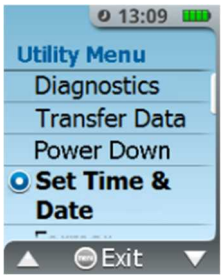
28. Set Time and Date

The Utility menu “Set Time and Date” feature provides capabilities for the biomedical technician to set the Controller’s time and date when not in normal use.

Setting the Controller’s 24-hour format time and date should be performed by the biomedical technician:

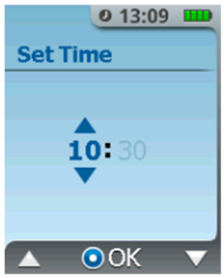
- Upon receipt of Controller from the manufacturer,
- Upon applicable annual standard and daylight time changes, or
- When Controller’s displayed time and/or date does not correspond to the institution’s time and/or date

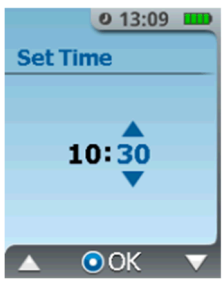
STEP 1 Navigate to Time & Date Screen



1. To set the Controller’s time and date from the Utility menu, scroll to **Set Time & Date** then press the **Enter/Select** button.

STEP 2 Set Hours & Minutes



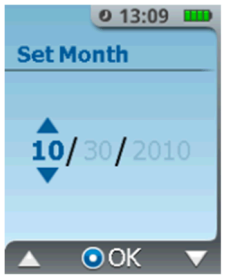


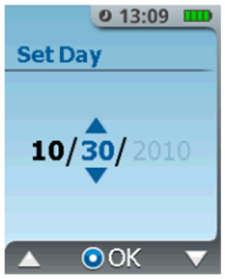
1. The Controller’s time is displayed in a 24-hour format. An example of 24-hour time format compared to 12-hour time format is shown in the table below. To set the Controller’s hour, use the right and left buttons to set the hour value. Then press the **Enter/Select** button.

12 Hour Time Format	24 hour Time Format
12:30 AM	00:30
4:14 AM	04:14
7:45 PM	19:45
11:59 PM	23:59

2. To set the Controller's minutes, use the right and left buttons to set the minute value. Then press the **Enter/Select** button.

STEP 3 Set Year, Month & Day





1. To set the Controller's year, use the right and left buttons to set the year. Then press the **Enter/Select** button.
2. To set the Controller's month, use the right and left buttons to set the month value. Then press the **Enter/Select** button.
3. To set the Controller's day, use the right and left buttons to set the day value. Then press the **Enter/Select** button.
4. Press the **Enter/Select** button to return to the Utility menu.

NOTE

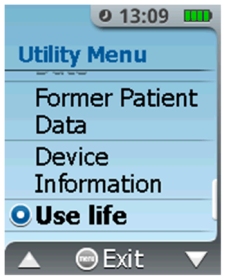
If an error was made in setting any of the values, access the Utility Menu and select **Set Time and Date** and start over.

29. Use Life

The Utility menu “Use Life” feature provides capabilities for the biomedical technician to display the cumulative dose count and total doses remaining until end of use life of the sufentanil sublingual tablet system Controller. A total count of 30,000 doses dispensed is the end of use life limit of the Controller. The Controller software will not allow the System to be set up for a new patient if the end of use life could possibly be reached during patient use, i.e., the end of use life of 30,000 doses could be reached in 3 cartridges of 40 tablets each. At the end of use life, the Controller should be disposed of according to hospital procedures for battery and electronic waste.

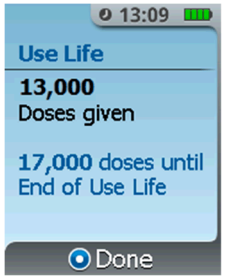
Refer to “End of Use Life Approaching” and “End of Use Life Reached” notifications in Section 16.1.

STEP 1 Navigate to Use Life Screen



To view the Use Life from the Utility menu, scroll to **Use Life** then press the **Enter/Select** button.

STEP 2 View Use Life



1. The Use Life screen displays the use life of the sufentanil sublingual tablet system. The example Use Life display indicates the sufentanil sublingual tablet system has 13,000 doses given and 17,000 doses remaining until end of use life of the Controller is reached.

2. Press the **Enter/Select** button to return to the Utility menu.

ATTACHMENT 1:

Patient Reference Sheet

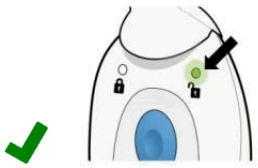
PL-1752 Rev. E

Patient Reference Sheet

Zalviso™ (sufentanil sublingual tablet system)

- Take a dose when needed for pain relief or before an activity that may increase your pain.
- For your safety, the System will make you wait at least 20 minutes between doses.
- **DO NOT** share this medication. **DO NOT** dispense tablets into your hand and take them later.
- **DO NOT** take into the shower or submerge in liquid. Call a nurse if you spill liquid on the System.

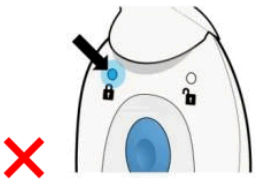
When can I take a dose?



Dose Available

(Green Light)

You may take a dose if needed.

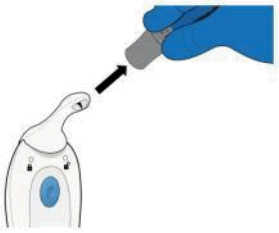


Dose Unavailable

(Blue Light)

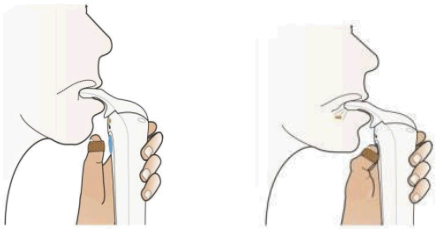
You cannot take a dose.

How do I take my dose?



Remove the Cap and hold the System in your hand that has the Patient ID Thumb Tag.

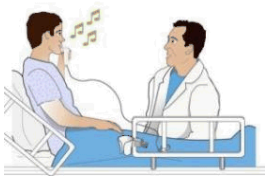
⚠ Do not touch or press the Blue Dose Button with your thumb until the Dispenser tip is under the tongue.



Keep the System relatively upright to dose.

First place the Dispenser tip UNDER your tongue and THEN press the Dose Button with your thumb.

Do not apply downward pressure on the Dispenser tip when dosing.



Keep the Dispenser tip under your tongue until you hear the dosing tone and feel the motor vibration stop.

⚠ Store the System in its Holster in between doses to minimize the chance of inadvertent dispensing of a tablet.

- **DO NOT** chew or swallow the tablet.
- **DO NOT** eat or drink and minimize talking for 10 minutes after taking a dose.
- Call the nurse if the System is continuously beeping and flashing between doses.
- Call the nurse if you have any trouble taking a dose or keeping the tablet under your tongue.
- Call the nurse if you accidentally dispense a tablet when you are not taking a dose, or if you see one or more loose tablets.

Signature Manifest

Document Number: PL-1678 **Revision:** K

Title: PL-1678 ZALVISO sufentanil sublingual tablet system - Instructions For Use

All dates and times are in Pacific Standard Time.

PL-1678 Rev J to K Zalviso IFU

Change Request

Name/Signature	Title	Date	Meaning/Reason
David Freed (DFREED)	Executive Director, Quality		
Sundaravel Ananthavel (SANANTHAVEL)	Director, Quality		
Kathy Wilson (KWILSON)	Sr. Manager, Document Control	14 Jan 2019, 12:45:26 PM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Tammy Le (TLE)	Manager, Quality		
Brandon Pe (BPE)	Manufacturing Buyer/Planner		
Anil Dasu (ADASU)	CHIEF ENGINEERING OFFICER		
Bill Callahan (BCALLAHAN)	Sr. Director Manufacturing Ops		
Casidy Domingo (CDOMINGO)	Director, Engineering		In Process
David Freed (DFREED)	Executive Director, Quality		
Kimberly Gaumer (KGAUMER)	VP Regulatory & Quality Assura		
Lana Chin (LCHIN)	Assoc Dir Regulatory Affairs		
Noel Singh (NSINGH)	Director, Supply Chain		
Sundaravel Ananthavel (SANANTHAVEL)	Director, Quality		In Process
Angie Griffin (AGRIFFIN)	Sr Director Project Management		
Majella Dooley (MDOOLEY)	SENIOR DIRECTOR REGULATORY AFF	16 Jan 2019, 11:30:11 AM	Complete
Mark Curtiss (MCURTISS)	Senior Manager, Quality	18 Jan 2019, 11:49:54 AM	Complete
Samir Shah (SSHAH)	Manager, Product Manufacturing	04 Feb 2019, 09:48:42 AM	Complete
Al Landas (ALANDAS)	Director, Elect., Software Eng	04 Feb 2019, 03:41:51 PM	Complete
Kathy Wilson (KWILSON)	Sr. Manager, Document Control	05 Feb 2019, 11:06:02 AM	Complete

ENG-MGR Approval

Name/Signature	Title	Date	Meaning/Reason
Bill Callahan (BCALLAHAN)	Sr. Director Manufacturing Ops		
Casidy Domingo (CDOMINGO)	Director, Engineering		
Noel Singh (NSINGH)	Director, Supply Chain		
Angie Griffin (AGRIFFIN)	Sr Director Project Management		
Brandon Pe (BPE)	Manufacturing Buyer/Planner		
Samir Shah (SSHAH)	Manager, Product Manufacturing		
Anil Dasu (ADASU)	CHIEF ENGINEERING OFFICER	13 Feb 2019, 12:48:19 PM	Approved

QA-MGR Approval

Name/Signature	Title	Date	Meaning/Reason

Tammy Le (TLE)	Manager, Quality		
David Freed (DFREED)	Executive Director, Quality		
Kimberly Gaumer (KGAUMER)	VP Regulatory & Quality Assura		
Sundaravel Ananthavel (SANANTHAVEL)	Director, Quality		
Mark Curtiss (MCURTISS)	Senior Manager, Quality	06 Feb 2019, 09:22:22 AM	Approved

Originator Approval

Name/Signature	Title	Date	Meaning/Reason
Al Landas (ALANDAS)	Director, Elect., Software Eng	05 Feb 2019, 11:18:23 AM	Approved

DOC-MGR Approval

Name/Signature	Title	Date	Meaning/Reason
David Freed (DFREED)	Executive Director, Quality		
Sundaravel Ananthavel (SANANTHAVEL)	Director, Quality		
Kathy Wilson (KWILSON)	Sr. Manager, Document Control	05 Feb 2019, 11:06:28 AM	Approved

REG-MGR Approval

Name/Signature	Title	Date	Meaning/Reason
Kimberly Gaumer (KGAUMER)	VP Regulatory & Quality Assura		
Lana Chin (LCHIN)	Assoc Dir Regulatory Affairs		
Majella Dooley (MDOOLEY)	SENIOR DIRECTOR REGULATORY AFF	05 Feb 2019, 08:14:20 PM	Approved

Doc Control Set Date Collaboration Step

Name/Signature	Title	Date	Meaning/Reason
David Freed (DFREED)	Executive Director, Quality		
Sundaravel Ananthavel (SANANTHAVEL)	Director, Quality		
Kathy Wilson (KWILSON)	Sr. Manager, Document Control	13 Feb 2019, 01:51:57 PM	Complete

DOC-MGR Final Approval

Name/Signature	Title	Date	Meaning/Reason
David Freed (DFREED)	Executive Director, Quality		
Sundaravel Ananthavel (SANANTHAVEL)	Director, Quality		
Kathy Wilson (KWILSON)	Sr. Manager, Document Control	13 Feb 2019, 01:52:23 PM	Approved

Notify

Name/Signature	Title	Date	Meaning/Reason
Tammy Le (TLE)	Manager, Quality	13 Feb 2019, 01:52:24 PM	Email Sent
Brandon Pe (BPE)	Manufacturing Buyer/Planner	13 Feb 2019, 01:52:24 PM	Email Sent
Samir Shah (SSHAH)	Manager, Product Manufacturing	13 Feb 2019, 01:52:24 PM	Email Sent
Anil Dasu (ADASU)	CHIEF ENGINEERING OFFICER	13 Feb 2019, 01:52:24 PM	Email Sent
Angie Fuentes (AFUENTES)	Material's Testing Logistics	13 Feb 2019, 01:52:24 PM	Email Sent
Al Landas (ALANDAS)	Director, Elect., Software Eng	13 Feb 2019, 01:52:24 PM	Email Sent
Bill Callahan (BCALLAHAN)	Sr. Director Manufacturing Ops	13 Feb 2019, 01:52:24 PM	Email Sent
Ben Yaffe (BYAFFE)	CONTRACTOR, ENGINEERING	13 Feb 2019, 01:52:24 PM	Email Sent
Casidy Domingo (CDOMINGO)	Director, Engineering	13 Feb 2019, 01:52:24 PM	Email Sent
David Freed (DFREED)	Executive Director, Quality	13 Feb 2019, 01:52:24 PM	Email Sent

Kimberly Gaumer (KGAUMER)	VP Regulatory & Quality Assura	13 Feb 2019, 01:52:24 PM	Email Sent
Kathy Wilson (KWILSON)	Sr. Manager, Document Control	13 Feb 2019, 01:52:24 PM	Email Sent
Lana Chin (LCHIN)	Assoc Dir Regulatory Affairs	13 Feb 2019, 01:52:24 PM	Email Sent
Mark Curtiss (MCURTISS)	Senior Manager, Quality	13 Feb 2019, 01:52:24 PM	Email Sent
Majella Dooley (MDOOLEY)	SENIOR DIRECTOR REGULATORY AFF	13 Feb 2019, 01:52:24 PM	Email Sent
Noel Singh (NSINGH)	Director, Supply Chain	13 Feb 2019, 01:52:24 PM	Email Sent
Sundaravel Ananthavel (SANANTHAVEL)	Director, Quality	13 Feb 2019, 01:52:24 PM	Email Sent
Angie Griffin (AGRIFFIN)	Sr Director Project Management	13 Feb 2019, 01:52:24 PM	Email Sent

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Kathy Wilson (KWILSON)	Sr. Manager, Document Control	15 Feb 2019, 03:01:12 PM	Approved