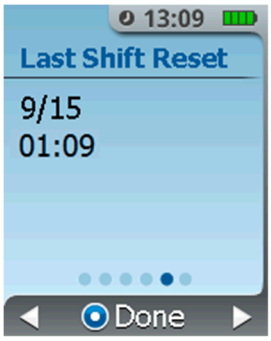
STEP 4 **Shift Total Screen**

The next screen displays the total number of doses dispensed and requests made by the patient since the last shift reset.

STEP 5 **Last Shift Reset Screen**



The next screen displays the date and time the shift dosing total was last reset.

STEP 6 **Use Total Screen**

The final screen displays the total number of doses dispensed and requests made by the patient since the therapy was initiated (since first dose). The Use Total time displayed is the elapsed time since the first tablet dosed.

11.2. Detailed History

The System stores detailed history as an event log that includes data on:

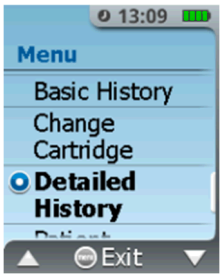
- System power on and power off
- Access using the AAC
- Patient ID Thumb Tag activation, Drug Cartridge information
- System setup
- Tether lock and unlock
- Access to patient training screens
- Quantity of successful doses, total doses delivered, patient attempted doses
- Dispenser removed
- Cartridge changes
- Shift reset
- System Discontinue
- Remaining battery capacity, battery charger connected or disconnected
- System alarm and errors

The event log is stored in the System's non-volatile memory; therefore, the event log data is maintained in the System when the System is powered off or if the System experiences an unexpected power loss. The event log cannot be deleted from the System. When the event log reaches its storage capacity, the oldest event is erased to create space for new events in a first-in-first-out process.

Detailed History Access

The Healthcare Professional uses the Authorized Access Card (AAC) to review all events that have occurred during System use.

STEP 1 Access Detailed History



1. Press the **Menu** button on the Controller.
2. Touch the AAC to the **Blue Dose Button** on the back of the Controller to access the System Menu.
3. Highlight and select the **Detailed History** function by pressing the **Enter/Select** Button.

STEP 2 **View Detailed History**

Each item displays a time stamp and a message of what event occurred at that time.

- If a dose was dispensed this is communicated as **Dose Given** in green text followed by the Patient ID Thumb Tag unique ID number.
- If a dose was requested during the lockout period this is communicated as **Requested in Lockout** in blue text.
- AAC access
- Tether Locked/Unlocked (Tether Connected)
- Cartridge changed
- Shift Reset
- Patient Training Screens Used (Demo Used)
- Shift Total and the cumulative dose values associated with that shift

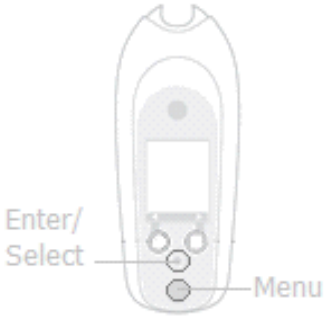
The full history is presented as a scrollable list. There is a white scroll bar on the right of the screen to indicate how much content is available before or after the current page of content being viewed. The history is presented with the most recent event on top of the list. As shown in the above example, doses dispensed are shown as “Dispensed” in green text and dose requests are displayed as “Requested” in blue text.

When you are done reviewing the history, select the **Enter/Select** Button to return to the System Menu.

12. Resetting Shift Total

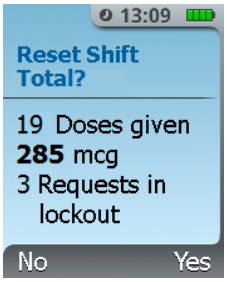
The Healthcare Professional can reset the cumulative dose count for the shift.

STEP 1 Access Reset Shift with AAC



1. Press the **Menu** button on the Controller.
2. Touch the AAC to the back of the Controller to access the System Menu.
3. Highlight and select the **Reset Shift** Total function and press the **Enter/Select** Button.

STEP 2 Press Reset Shift

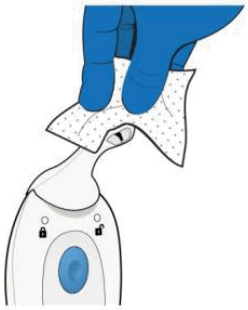


1. The screen will display the cumulative number of tablets dispensed, the cumulative dose and the total number of requests since the last total reset.
2. Select **YES** (**Right Button**) to reset the shift total. *NOTE: This function cannot be cancelled. Make sure you want to reset the shift total before selecting "Yes".*

STEP 3 Confirm Reset Shift

1. Select **NO** (**Left Button**) to return to the previous screen.
2. Once you have selected **YES**, the shift totals will display **0**.

13. Cleaning During Patient Use



The System may need to be cleaned as needed during patient use as described below.

The System including all of its components may be cleaned by the patient or Healthcare Professional as needed. When cleaning the System, only alcohol wipes should be used.

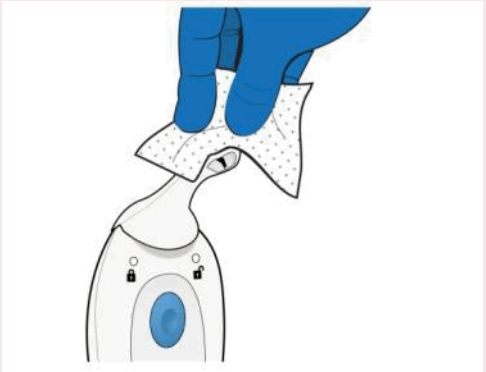
Wipe as necessary until the System appears visually clean. **DO NOT** saturate any part of the System. Wipes should not be excessively wet; squeeze out excessive liquid from the wipes before use. The System should be replaced if the patient or Healthcare Professional is concerned about severe contamination.

WARNING

DO NOT soak or immerse System in water.

WARNING

DO NOT clean the interior portion of the Dispenser tip.



14. Discontinuation of Therapy, Disposition of Used Components and Accounting of Remaining Tablets

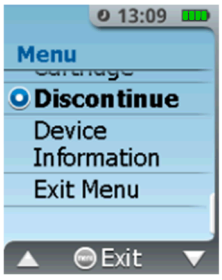
When a patient is finished using the System, the Healthcare Professional will need to Discontinue the System to shut it down and disassemble the used components for disposition. The System will retain the use history for five patients. *Refer to Section 20, Reviewing Former Patient Data, for details.*

<u>Important Safety Message!</u> Due to the risk of accidental exposure and/or overdose, Zalviso must never be dispensed for outpatient pain management or continued after the patient is discharged from the hospital. Do not send any Zalviso tablets, Cartridges, or system components home with any patient upon discharge.

14.1. Discontinuation of Therapy and Disposition of Used Components

To Discontinue, perform the following:

STEP 1 **Access 'Discontinue' Menu**



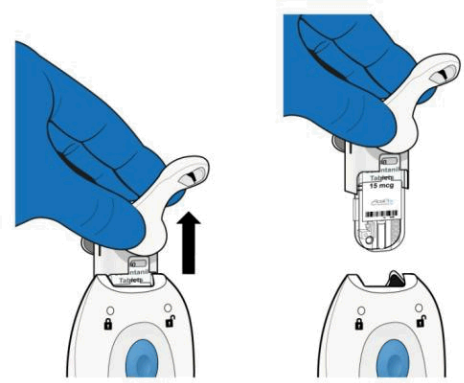
1. Press the **Menu** Button near the bottom of the Controller and the System will prompt you to touch the Authorized Access Card to the **Blue Dose Button** on the back of the Controller to access the System Menu.
2. Scroll to the Discontinue function and select it by pressing the **Enter/Select** Button.

STEP 2 Confirm 'Discontinue'

1. The screen will ask if you want to discontinue treatment.
2. **Record the number of tablets remaining** per hospital procedures, including any double signatures or witnessing by a second Healthcare Professional.
3. Press **No** (**Left Button**) to return to the previous screen.
4. Press **Yes** (**Right Button**) to acknowledge that you would like to Discontinue the System. *NOTE: You will not be able to cancel this function. Make sure you want to shut down before selecting* **Yes**.

STEP 3 Dispenser Unlocked

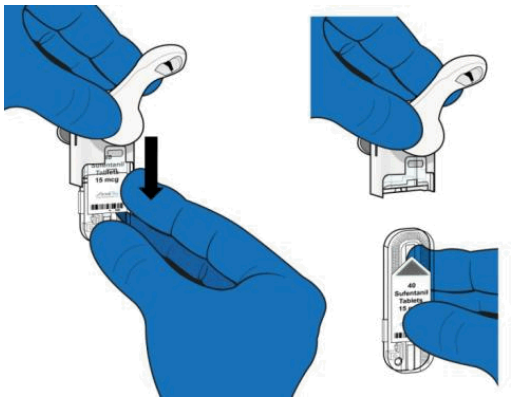
The System automatically unlocks the Dispenser and Tether. Remove the Dispenser with Cartridge from the System. Press the **Enter/Select** button to continue.



STEP 4 **Dispose of Cartridge to CII Waste**

Remove the Cartridge from the Dispenser by pulling the Cartridge down. The screen will show a reminder to dispose of the used Cartridge in CII waste.
Alternatively, the used Drug Cartridge may be returned to the hospital pharmacy for disposal.

Press the **Enter/Select** button to continue.



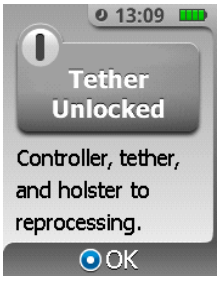
Tools to aid sufentanil tablet accountability include:

- The Controller will display the number of tablets remaining in the Cartridge at the time of System Discontinuation of therapy.
- The Cartridge Label RFID Reader (*see Section 24, Use of Cartridge RFID Label Reader*) enables the Healthcare Professional to scan and display the number of remaining tablets in used Cartridges, at the time of System Discontinuation of therapy, as electronically recorded on the Cartridge RFID Label.
- Manual counting of tablets may be performed on used Cartridges after removal from the System (*see Section 14.2, below*). This method can be used if discrepancies or diversion is suspected to have occurred.

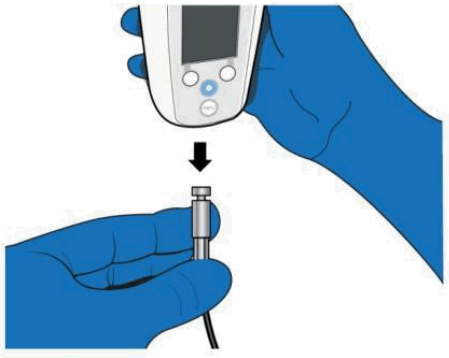
STEP 5 Dispose Dispenser to Biohazard Waste

Reminder to dispose the used Dispenser and Cap into biohazard waste according to institutional procedures. Press the **Enter/Select** button to continue.

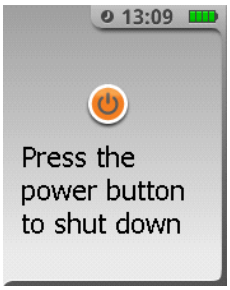
STEP 6 Remove Tether, Send Reusable Components to Reprocessing



Remove the Tether from the bottom of the Controller. Screen shows reminder to send reusable System components (i.e. Controller, Tether and Holster) to reprocessing. Press the **Enter/Select** button to continue.



STEP 7 **Power Off Device**



Press the **Power Button** briefly to shut the System down (screen turns off). Send reusable System components (Controller, Tether and Holster) to reprocessing.

WARNINGS	Never re-use the Dispenser or Cap with another patient.
	Never attempt to re-use a Cartridge, either for the same patient or another patient (the System will not allow it).
	Never remove remaining tablets from a used Cartridge to dose a patient. • Remove the used Patient ID Thumb Tag and dispose according to institutional procedures. • Reprocess the Controller, Tether and Holster for use with the next patient using the instructions described in *Section 17, Reprocessing Instructions*.

14.2. Accounting of Remaining Tablets

Since the drug tablets are a Schedule II (CII) substance, accounting of tablets is very important after Discontinuation of Therapy. There are three methods for remaining tablet accounting:

1. Electronic - Controller Display During Discontinuation of Therapy
2. Electronic - Cartridge Label RFID Reader
3. Manual – Counting Tablets While Still in Cartridge

- Method 1 can be used when the Cartridge is still contained within the Controller during discontinuation.
- Method 2 can be used with a stand-alone Cartridge.

- Method 3 can be used with a stand-alone Cartridge to count the number of tablets remaining in the Drug Cartridge and confirm the amount of tablets remaining from Methods 1 and 2 above.

METHOD 1 Electronic – System Display During Discontinuation of Therapy

During Discontinuation of Therapy (*Section 14.1*) the System displays the number of tablets remaining. In the example at left, 12 tablets are remaining. This is the primary method for accounting of remaining tablets.

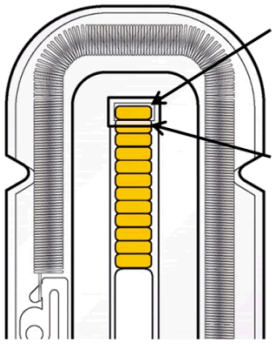
NOTE: as is typical with CII drug, it is recommended to get a witness at this point to verify and document the number of remaining tablets.

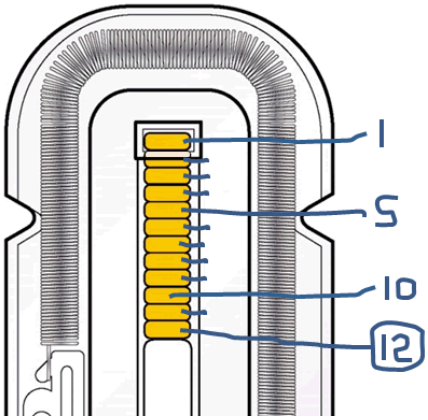
METHOD 2 Electronic – Cartridge Label RFID Reader

The Cartridge Label RFID Reader (*see Section 24, Use of Cartridge RFID Label Reader*) enables the Healthcare Professional to read and display the number of remaining tablets in used Cartridges, at the time of System Discontinuation of therapy, as electronically recorded on the Cartridge Label RFID. In the example at left, 12 tablets should be remaining in the used Cartridge.

NOTE: as is typical with CII drug, it is recommended to get a witness at this point to verify and document the number of remaining tablets.

METHOD 3 **Manual – Counting Tablets While Still In Cartridge**





All remaining tablets are visible through the clear plastic cartridge. The example shown at left has 12 tablets remaining.
To aid counting, magnification is recommended. The tablets can be magnified using reading glasses, or enlarging a photo image taken by a smartphone.

A suggested alternative method (when over 10 tablets are remaining), is to print an enlarged image of the tablets using the "zoom" feature on a photocopier. The tablets can then be counted off on the paper copy with a pen in sets of 5 to facilitate counting the tablets, as shown in the example at left. In this example, there are 12 tablets remaining.

NOTE: Regardless of the enlargement method used, be sure to count the 1st tablet as the one in the rectangular slot at the top of the cartridge; this slot is where tablets exit the dispenser during use.

NOTE: as is typical with CII drug, it is recommended to get a witness at this point to verify and document the number of remaining tablets.

15. Replacing the System

The System will need to be replaced if the 72-hour limit for the System has been reached or when a low battery condition is observed and the patient still requires therapy.

Replacement of the System may also need to be done by the Healthcare Professional in the event that the System has become non-functional or experiences an Error that precludes further use.

To replace the System:

- Follow the steps for Discontinuing the System in *Section 14, Discontinuation of Therapy and Disposition of Used Components*.
- The used System should be removed after the discontinuation process.
- Follow the instructions for setting up a new System as described in *Section 5, How to Set Up the System for a New Patient*.

To return a non-functional or System with an Error that precludes use:

The used System should be returned to biomedical engineering for reprocessing (*Section 17, Reprocessing Instructions*) and diagnostics (*Section 26, Diagnostics*).

16. Notifications, Alerts, Alarms and Errors

In addition to dosing information, the System will notify the patient and Healthcare Professional of certain situations:

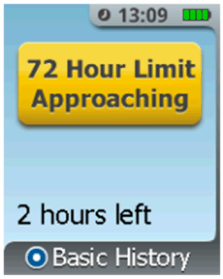
- Notifications (*Section 16.1*)
- Alerts (*Section16.2*)
- Alarms (*Section 16.3*)
- Errors (*Section16.2*)

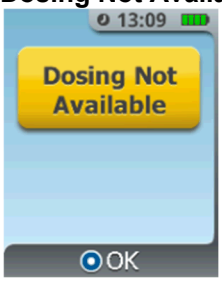
Refer to each section below for more details. *For more information, please refer to Section 26, Diagnostics, for Diagnostic test screens and errors.*

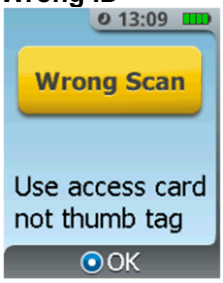
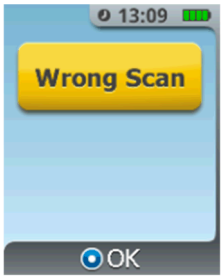
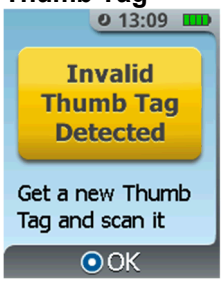
16.1. Notifications

Notifications are a visual and/or audio signal indicating operating status or a message that may require action, though there is not an unsafe condition. Notifications are indicated with a yellow screen without the "!" symbol, and are accompanied by the low level notification tone. The tone and screen will repeat based on the type of message.

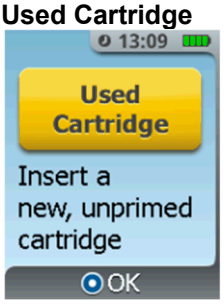
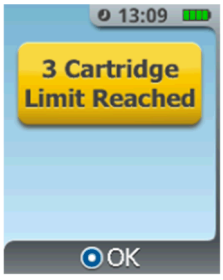
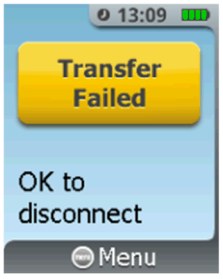
Review the types of notifications below. For each notification the meaning, example of the screen and the action(s) to take are listed.

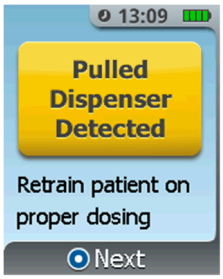
Notification Type	*Meaning*	*Action(s) to Take*
Low Battery 	If this screen appears, the battery capacity is getting low to the point where it will soon not be able to continue functioning to delivery therapy (approximately 2 hours)	If in patient use, System must be removed and sent for reprocessing and recharging. WARNING Do not connect the Charger to the sufentanil sublingual tablet system while it is being used by a patient. Battery charging is only active when the Controller is discontinued. Replace with a new System as needed. If System is being charged, continue charging until battery is completely charged.
	 Four green bars mean the battery is fully charged.	
	 Two yellow bars means the battery is running low.	Press the **Menu** Button. Scan the AAC (notification is silenced at this point).
	 One red bar means the battery is critically low and the Controller should be discontinued.	Proceed to System Menu. Proceed to Discontinue and replace with a new System if required. Reprocess and charge the Controller *(Sections 17 and 18, respectively)*.
72 Hour Limit Approaching 	The 72 hour time limit is approaching. The screen will count down starting at 2 hours, 1 hour and 30 minutes left. This message will re-appear at set intervals if the System is not discontinued.	The System must be removed from patient use before the time period has expired and replaced as needed for continued therapy. Press the Menu Button. Scan the AAC (notification is silenced at this point). Proceed to System Menu. Scroll to Discontinue and replace with a new System if required.

Notification Type	*Meaning*	*Action(s) to Take*
Low Tablet Count 	Tablet count is getting low. This screen will start notifying of this condition when there are 2 tablets remaining and will re-appear at 1 and 0 tablets remaining.	The Cartridge will need to be replaced once empty. If the 3 Cartridge limit has been reached, the System will not permit use of additional Cartridges. A new System will be required to continue therapy. Press the Menu Button. Scan the AAC (notification is silenced at this point). Proceed to System Menu. Scroll to Replace Cartridge option and follow directions. *If 3 Cartridge limit has been reached, refer to "3 Cartridge Limit Reached" notification below.*
Dosing Not Available 	The System cannot be returned to the patient for dosing. This screen appears when another condition occurred that prompted menu access, but returning to patient mode is not an option, such as 3 Cartridge limit, low battery alarm, etc.	The System must be removed from use. Press the **Enter/Select** Button to return to the System Menu. Scroll to Discontinue and replace with a new System if required.

Notification Type	*Meaning*	*Action(s) to Take*
Wrong ID  	Depending on the stage of setup, either the Patient ID Thumb Tag was scanned instead of the AAC, or the AAC was scanned instead of the Patient ID Thumb Tag.	During initial power-up, the AAC must be scanned. If this Error message is received at this point, the Patient ID Thumb Tag was scanned accidentally. Scan the AAC to correct this problem. Once in setup, on the Patient ID activation step, if the AAC was scanned accidentally this Error message will appear. Scan the Patient ID Thumb Tag to correct this problem.
Invalid Patient ID Thumb Tag 	A previously used Patient ID Thumb Tag was presented to the System during setup or Patient ID Thumb Tag change. A new Patient ID Thumb Tag is required.	1. Obtain a new Patient ID Thumb Tag. 2. Press the Enter/Select Button. 3. Scan the new Patient ID Thumb Tag.

Notification Type	*Meaning*	*Action(s) to Take*
No Cartridge 	The System was assembled without a Cartridge.	If the Healthcare Professional determines that there is no Cartridge in the Dispenser, a Cartridge should be inserted into the Dispenser. If the Healthcare Professional determines that there is a Cartridge present in the System and yet the error message shows up on the System, a new Cartridge should be retrieved and inserted into the System. 1. Press the **Enter/Select** Button. 2. Follow the screen prompts to remove the Dispenser. 3. Insert a new Cartridge, then proceed with the normal setup outlined in *Section* 5. 4. Retain the unused Cartridge for reconciliation per institutional procedures governing controlled substances. If this condition persists, notify Biomedical Engineering and set up a new System as needed.

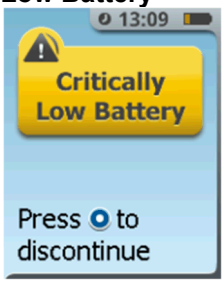
Notification Type	*Meaning*	*Action(s) to Take*
Used Cartridge 	The Cartridge that was inserted has been used or tampered with.	Remove the Cartridge from the Dispenser and replace with a new Cartridge to continue or begin therapy. 1. Press the **Enter/Select Button**. 2. Follow the screen prompts to remove the Dispenser. 1. Insert a new Cartridge, and then proceed with the normal setup outlined in *Section* 5. Retain the used Cartridge for reconciliation per institutional procedures governing CII opioids.
3-Cartridge Limit Reached 	This screen only appears if a Cartridge change is attempted while on the 3rd Cartridge or if the 3rd Cartridge is empty.	1. Press the **Menu button** to return to the System Menu. 2. Proceed to Discontinue and replace with a new System if required.
Transfer Failed 	Data transfer from the System to a computer has failed.	Repeat steps for Data Transfer. 2. Disconnect the Data Cable from the System. 3. Press the menu button to return to the System Menu. 4. Retry Transfer Data *(refer to Section 19)*. 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.

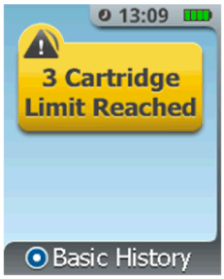
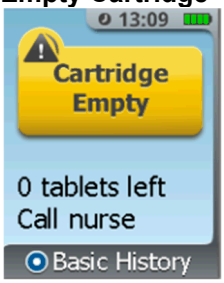
Notification Type	*Meaning*	*Action(s) to Take*
Pulled Dispenser Detected 	Patient is pulling down on Dispenser when attempting to dose.	1. Press the **Enter/Select Button**. 2. Follow the screen prompts to remind the patient not to pull down on the Dispenser when dosing and observe patient dosing. 3. Two attempts are allowed to retrain the patient on proper dosing. After the second attempt, the System will proceed to "Error – System Cannot Be Used". *(refer to Section 16.2)*
End of Use Life Approaching 	The "End of Use Life Approaching" screen is displayed only when the Controller is connected to a Charger and the cummulative dose count of the Controller exceeds 27,000 doses, or 90% of the Controller 30,000 dose use life. This alert indicates that the hospital should consider ordering a new Controller within the next several months.	1. Press the **Enter/Select Button** to continue charging the Controller.
End of Use Life Reached 	The "End of Use Life Reached" screen is displayed when the cummulative dose count exceeds 29,880 doses, or there are less than 120 doses (3 40-count cartridges) left until the 30,000 dose limit is reached. The Controller cannot be used to setup a new patient, avoiding the possibility of the end of use life occuroing during patient use (up to 3 cartridges).	1. Press the **Enter/Select Button**. 2. Follow the screen prompts to power off the Controller. 3. Get another Controller to setup a new patient. 4. Dispose of the old Controller per hospital procedures for battery and electronic waste.

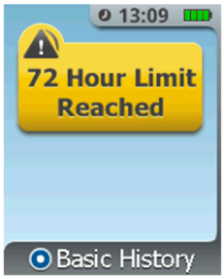
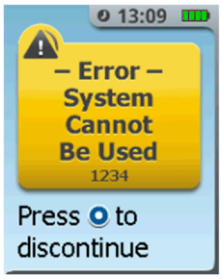
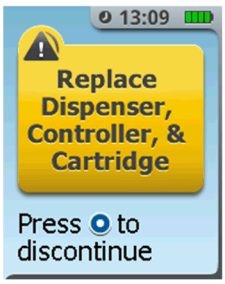
16.2. Alerts and Errors

Alerts are a visual and audio signal indicating the need for immediate action, though there is not an unsafe condition. These are represented by a yellow screen with an Alert symbol (see left) in the in the upper-left corner coupled with a repetitive audible alert tone.

System alerts are reviewed below. For each alert; the meaning, example of the screen, and the action(s) to take are listed. A System error is displayed as an alert.

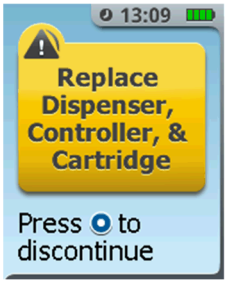
Alert Type	*Meaning*	*Action(s) to Take*
Low Battery 	If this screen appears with the "!" warning, the battery capacity is too low to continue therapy.	If in patient use, System must be removed, reprocessed and charged. If System is being charged, continue charging until battery is completely charged. WARNING Do not connect the Charger to the sufentanil sublingual tablet system while it is being used by a patient. Battery charging is only active when the Controller is discontinued. If System is being charged, continue charging until battery is completely charged 1. Press the **Enter/Select Button**. 2. Scan the AAC (Alert is silenced at this point). 3. Record the tablet count if applicable. 4. Scroll to Discontinue the System. 5. Remove both the Dispenser and Cartridge. 6. Set up a new System as needed. 7. Reprocess and charge the Controller *(Sections 17 and 18, respectively)*.

Alert Type	*Meaning*	*Action(s) to Take*
Insufficient Battery Power for Use 	During setup, the System checks to see if there is enough power for 72 hours of therapy. If the System does not have enough battery power to be used for therapy, this alert will be displayed.	The System must be replaced and charged. 1. Press the **Enter/Select** Button to exit the setup mode and proceed to the System Menu or 2. Depending on the stage of setup, press the **Enter/Select** Button and proceed to the Discontinue process. 3. Reprocess and charge the Controller *(Sections 17 and 18, respectively)*.
3 Cartridge Limit Reached 	The System is factory programmed to only allow 3 Cartridges to be used during the 72 hours of therapy with a single Controller. This alert indicates that three Cartridges have been used and no more are allowed with this System.	The System must be removed from use. 1. Press the **Menu** Button. 2. Scan the AAC (Alert is silenced at this point). 3. Press the **Right** Button below the screen to proceed to the Discontinue process or press the **Left** button to proceed to the System Menu. Going to the System Menu does not allow exit to patient dosing mode. Select Discontinue from the System Menu and proceed to discontinue the System. 4. Set up a new System as needed.
Empty Cartridge 	All 40 tablets have been dispensed from the Cartridge.	A new Cartridge must be loaded if continuation of therapy is desired. 1. Press the **Menu** Button. 2. Scan the AAC (Alert is silenced at this point). If the 3 Cartridge limit has not been reached, press the **Enter/Select** Button and proceed to setup with a new Cartridge as prompted.

Alert Type	*Meaning*	*Action(s) to Take*
72 Hour Limit Reached 	The System is designed for 72 hours of use and the 72 hour time limit has been reached.	The System must be removed from use. • Press the **Menu** Button. • Scan the AAC (Alert is silenced at this point). • Press the **Right** Button below the screen to proceed to the Discontinue process OR press the **Left** Button to proceed to the System Menu. If you proceed to the System Menu, you will not be able to exit to patient dosing mode, as further patient dosing is not permitted. Select Discontinue from the System Menu and proceed to discontinue the System. Proceed to Discontinue and replace with a new System if additional therapy is needed.
Error – System Cannot Be Used  	A System error has occurred. System Errors are accompanied by Error Codes- eg, “Error 301, Error 302” etc. In the example at left, the error code is “1234”	The System must be removed from current patient use: 1. Press the **Enter/Select** Button. 2. Scan the AAC (Alert silenced at this point). 3. Record the tablet count if applicable. 4. Press the **Enter/Select** Button to discontinue, or, if the System is unresponsive, press and hold the Power Button to power-off the System. 5. Remove both the Dispenser and Cartridge and dispose according to *Section 14*. 6. Do not reuse the Controller, Dispenser or Cartridge for a new setup. Return the Controller to Biomed for follow up with the manufacturer as described in the note below. 7. Set up a new System as needed.

NOTE

If any System error occurs, the Biomedical Engineering staff (or HCP) should call 1-855-ZALVISO to report the error. Based on the type of error and other system details, the user will be instructed to either reprocess the Controller and return it to use, or return the Controller to the manufacturer.

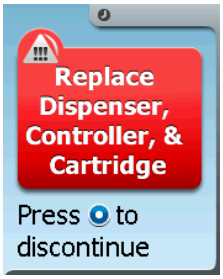
Alert Type	*Meaning*	*Action(s) to Take*
Prime Failed  	The Priming Cap failed to dispense due to functional error or tampered Cartridge.	The System must be removed from use. 1. Press the **Enter/Select** Button to continue and follow instructions on the screen to discontinue the System. Remove both the Dispenser and Cartridge and dispose according to *Section 14*. Return the Controller for reprocessing and charging. **DO NOT** reuse the Controller, Dispenser or Cartridge for a new setup. Set up a new System as needed.

16.3. Alarm

Alarms are situations where immediate action is required and a potentially unsafe condition exists. Alarms are indicated by a flashing red screen with an alarm symbol (see left) in the upper-left corner and a flashing alarm message accompanied by flashing indicator lights and a repetitive audible high-level alarm tone produced by the System which repeats until the Healthcare Professional confirms and responds to the alarm. The audio alarm cannot be silenced and will stop only when System Discontinue is completed.

The System has only one alarm condition. This high priority alarm condition will occur only when the Dispenser has been disconnected or pried from the Controller once the System has been set up. If this alarm situation were to occur during patient use, the Healthcare Professional should make an assessment as to whether intentional misuse is

suspected or if this condition was caused by an accidental dislodging of the Dispenser. If an alarm was to occur, the Healthcare Professional should press the **Enter/Select** Button and follow the on-screen instructions to Discontinue the System.

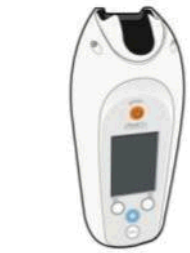
Alarm Type	*Meaning*	*Action(s) to Take*
High Priority Alarm Dispenser Disconnected  	The Dispenser has become disconnected.	Press the **Enter/Select** button to proceed to Discontinue and replace with a new System (Replace the Dispenser, Controller and Cartridge). Investigate for cause of alarm to determine if caused intentionally or accidentally. Note: The “Dispenser Disconnected” alarm screen flashes five times then the “Replace Dispenser, Controller, & Cartridge” alarm screen flashes five times at a periodic rate. The audio alarm will stop only when Discontinue is completed.

17. Reprocessing Instructions

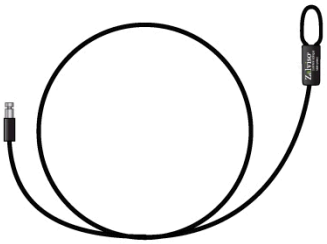
17.1. Reprocessing of Reusable Components

Reprocessing is required for the reusable, patient contacting parts of the sufentanil sublingual tablet system, which are the:

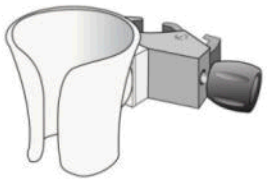
- Controller
- Security Tether (“Tether”)
- Holster



CONTROLLER



SECURITY TETHER



HOLSTER

These three reusable parts must be reprocessed before the next patient may use the System. Reprocessing greatly decreases the chance of passing on pathogens from one patient to the next.

Reprocessing the Cleaning Plug

CLEANING PLUG

The Cleaning Plug, used to protect the Charging/Data port during reprocessing of the Controller, must itself be reprocessed after use to avoid potentially transmitting contamination from one Controller to the next.

Reprocessing Instructions

Reprocessing consists of two distinct and important steps:

- **Cleaning** – cleaning prevents passing contaminants (e.g., food, human waste, bacteria) from one patient to the next. More importantly, it removes dirt and contaminants from the device so that the next step, disinfection, is effective.

- **Disinfection** – disinfection kills pathogens that may come from the patient (e.g., through touch, blood or other bodily fluids, coughing or sneezing on the device), or may come from Healthcare Professionals or visitors that may handle the device with unclean hands. Effective disinfection helps prevent the spread of disease to the next user of the System.

Cleaning and Disinfection Supplies

Sani-Cloth Plus® Germicidal Disposal Cloths

("Sani-Cloth Plus Wipes") are recommended for both cleaning and disinfecting the Controller, Tether and Holster before use by the next patient, and also for reprocessing the Cleaning Plug. Sani-Cloth Plus Wipes have been shown to effectively clean and disinfect these reusable parts. Sani-Cloth Plus Wipes are manufactured by PDI, and are available through hospital supply stores. These wipes are EPA Registered (Reg. No. 9480-6) and approved for use on hard patient-contacting surfaces in many hospitals in the US. These wipes have been proven to be effective, when the label directions are followed, in killing a broad range of bacteria and viruses typically found in hospital settings.

NOTE: *If an alternative germicidal wipe is used, the hospital must confirm that the germicidal effectiveness, per the manufacturer, is equivalent to Sani-Cloth Plus Wipes.*

WARNING

It is very important to follow the Sani-Cloth Plus Wipes' label instructions for cleaning and disinfecting, which have been incorporated into these reprocessing instructions. Especially important for disinfection of pathogens is to keep the component wet for the full recommended "Contact Time" of 5 minutes. Anything less than 5 minutes will not assure effective disinfection of the System for the next patient.

Pointed Disposable Cleaning Swabs

These should be available for cleaning and disinfecting hard to reach areas on the Controller, Tether and Holster that may accumulate dirt and debris during patient use. As described in the reprocessing instructions below, the swab may be used as a stiffener for a wipe to dig into small crevices, or may be wetted with a wipe and used alone to clean tight areas.

(An example of an effective pointed swab is Qosmedix 10222, “Point/Point Cotton Swab, Paper Handle, 3in”, manufactured and distributed by Qosina, Edgewood, NY.)

Custom Cleaning Plug

This is provided to protect the Charging/Data port on the bottom of the Controller during the cleaning step of reprocessing. The Charging/Data port has metal contacts near the opening that may be damaged by germicidal solutions, as are in Sani-Cloth Plus wipes. Only the Cleaning Plug should be used to cover the Charging/Data port during cleaning, otherwise the Controller port contacts may be damaged.

Clean Gloves

Gloves (Non-latex recommended) should be worn when reprocessing the Controller, Tether, Holster and Cleaning Plug, as recommended by the Sani-Cloth Wipe manufacturer. Gloves not only protect hospital personnel from prolonged contact with the germicidal chemicals in the wipes, but also protect the device from possible contamination from the personnel.

Cleaning Brush

A soft bristled brush (e.g., Graham Field Adult Toothbrush, Cat. No. 3395-1, available from Fisher Scientific, Cat. No. 19027438) should be used.

Pre-Treatment of the Reusable Part of the System at Point-of-Use, Prior to Reprocessing

After discontinuation of patient treatment and the System has been disassembled per the instructions, the reusable parts of the System (Controller, Tether and Holster) should be sent to the appropriate reprocessing center within the hospital. If hospital procedures allow, any part that has excessive contamination at the point-of-use (e.g., has been bled or vomited upon), should be pre-treated by cleaning at the point of use *prior* to delivery to the reprocessing area. Pre-treatment helps prevent the spread of pathogens which may be present on the device as it is conveyed to the reprocessing area. In addition, pre-treatment will help remove heavy soil from the device which may otherwise dry, possibly requiring extra effort to thoroughly clean.

If hospital procedures permit, pre-treat any heavily soiled, reusable part at point-of-use by carefully performing the cleaning as follows:

- **Pre-Treatment of Excessively Soiled Controller at Point-of-Use**
  Follow the "Cleaning the Controller" instructions below. Pre-treatment cleaning only requires gloved hands and Sani-Cloth Plus wipes. If no swabs are available to get into crevices on device, remove as much contamination as possible at point of use; swabs can be used during actual reprocessing cleaning.

WARNING

If a Cleaning Plug is not available for pre-treatment, take extra care to avoid the charging/data port and Tether hole when cleaning the Controller. See other cautions in the cleaning instructions for the Controller.

- **Pre-Treatment of Excessively Soiled Tether at Point-of-Use**
  Follow the "Cleaning the Tether" instructions below.

- **Pre-Treatment of Excessively Soiled Holster at Point-of-Use**
  Follow the "Cleaning the Holster" instructions below. NOTE: In normal use, the Holster clamp metal parts (screw, spring, etc.) are not typically soiled. If the Holster Clamp becomes excessively soiled, dispose the entire Holster in biohazard waste per hospital instructions.

After pre-treatment at point-of-use, transport components for reprocessing.

17.2. Reprocessing the Controller

WARNING

The Controller contains electronic components. Never spray or submerge the Controller – use only germicidal wipes. Avoid excessive liquid from the wipes around holes to avoid damage to internal components.

WARNING

DO NOT contact the Charging/Data port with germicidal wipes – these have been found to corrode the metal terminals after successive reprocessing. Avoid wetting the metal contacts of the Charging/Data port, or excessive fluid around the Tether hole or Charging/Data port. Electronic components are exposed and just inside the device and may be damaged by excessive moisture.

DO NOT insert a wipe, brush or swab into the Tether port; this may damage the Controller.

WARNING

Use of the Cleaning Plug is highly recommended. If a Cleaning Plug is not available, take extra care to avoid the Charging/Data port when cleaning the Controller.

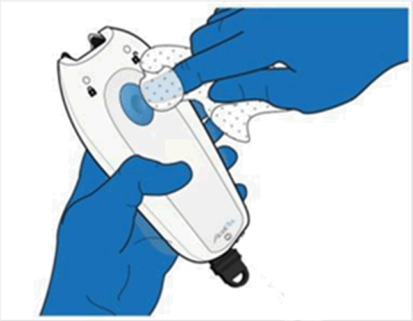
STEP 1 **Insert Cleaning Plug**

1. Put on a pair of clean gloves.
2. Insert a cleaned and disinfected Cleaning Plug into the Charging/Data port. The Cleaning Plug should snap into place, just like the charging and data cables.
3. There is no need to plug the Tether port.

NOTE

Use as many fresh wipes as necessary to reprocess the Controller.

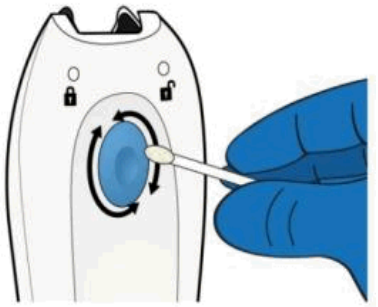
STEP 2 **Clean the Controller**



Using a fresh Sani-Cloth Plus Wipe, thoroughly clean the outside surfaces of the Controller, starting with the **Dose Button Side**. Remove all visible contamination (“soil”).

Use as many fresh wipes as necessary to clean the outside surfaces of the Controller.

STEP 3 **Clean Dose Button Area**

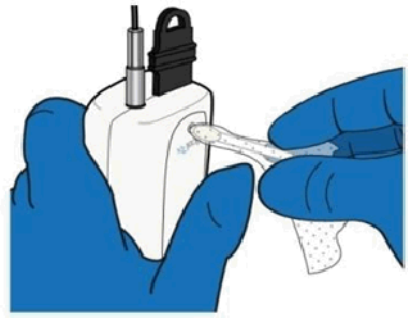


Disinfecting wipes can and should be used generously around the Dose Button since the Dose Button is mechanically sealed to the Controller cover to allow thorough cleaning. Be sure to thoroughly clean the Dose Button and the area between the shell and button. Use swabs, moistened with a Sani-Cloth Plus wipe, to get into crevice around Dose Button.

STEP 4 **Clean Indicator Lights**

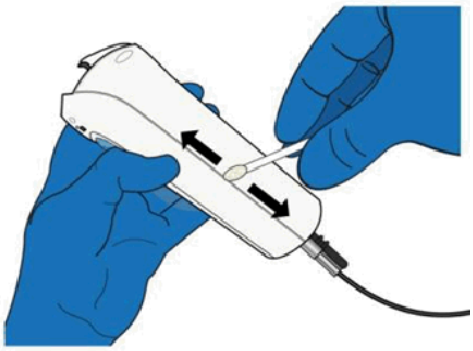
Using a Sani-Cloth Plus wipe wrapped around a swab (or a swab moistened with a wipe), clean the two lights on the Dose Button side. The black “pocket” in the top of the Controller (dotted arrow, at left) is covered by the Dispenser during use and *need not be cleaned*. However, if desired, the pocket *may* be cleaned with wipes or moistened swabs.

STEP 5 Clean Recessed Area



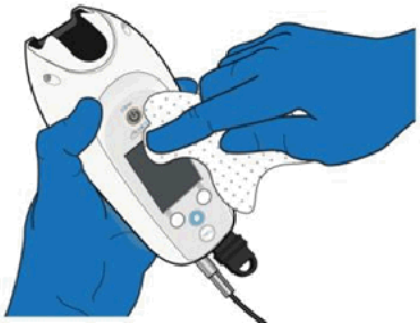
Using a Sani-Cloth Plus wipe wrapped around a swab (or a swab moistened with a wipe), clean the recessed area as noted in the figure below on the Dose Button Side of the Controller.

STEP 6 Clean Seam



Using a swab moistened with a Sani-Cloth Plus Wipe, or a wipe held tightly over a gloved fingernail, thoroughly clean the seam that runs around the Controller.

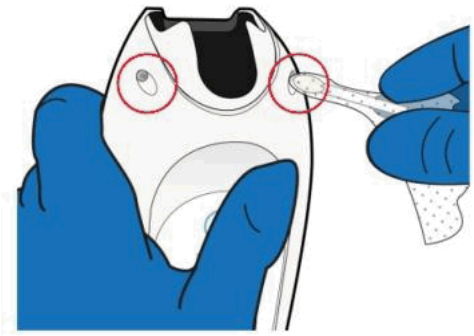
STEP 7 Clean Screen Side



Using Sani-Cloth Plus Wipes and swabs, thoroughly clean the front side (the screen side) of the Controller.

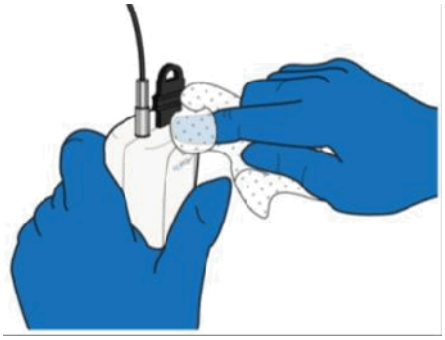
The front side of the Controller has several buttons and a display which are protected by a sealed plastic membrane. Use as many wipes and swabs as needed to thoroughly clean these areas, as well as the crevice between the Controller shell and plastic membrane. Remove all visible soil.

STEP 8 Clean Recessed Areas on Controller



Using a Sani-Cloth Plus wipe, wrapped around a swab (or a swab moistened with a wipe), clean the recessed areas as noted in the figure below on the front side of the Controller.

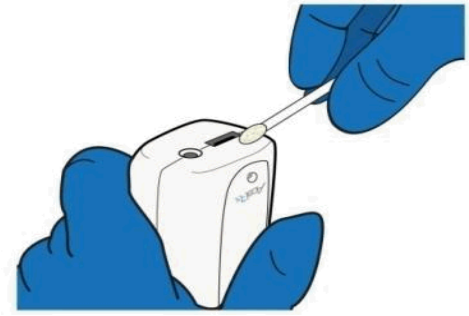
STEP 9 Clean Bottom of Controller



Thoroughly clean the bottom of the Controller, carefully cleaning around the Cleaning Plug and Tether port. **DO NOT** insert a wipe, brush or swab into the Tether port; this may damage the Controller.

After the Controller has been thoroughly cleaned (all visible soil removed), remove the Cleaning Plug by squeezing on the sides. The Cleaning Plug may now be contaminated and should be set aside for reprocessing.

STEP 10 Clean Area Under Cleaning Plug



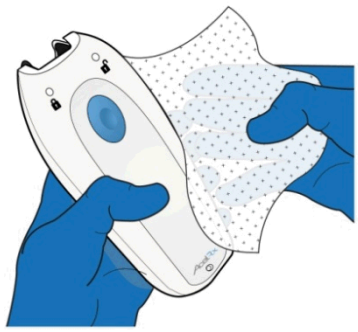
Using a swab moistened with a Sani-Cloth Plus wipe, carefully clean the Controller surface around the bottom of the Controller, avoiding the inside of the Tether port and Charging/Data Port. Thoroughly clean the areas exposed after removing the Cleaning Plug, and areas hard to reach on the outside of the Controller when the Cleaning Plug was in place.

STEP 11 Disinfect the Controller

WARNING

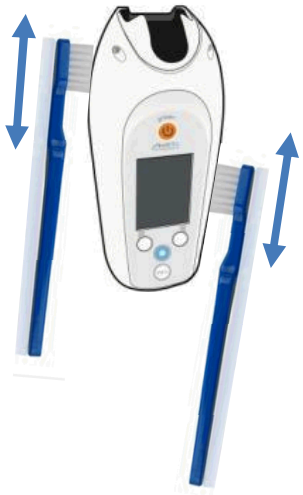
All external surfaces of the Controller, especially crevices and seams should be thoroughly wetted (**being careful to avoid wetting the Charging/Data port and Tether port**). Most surfaces will dry within 2-3 minutes, so multiple applications of fresh wipes at each location will be necessary to keep the surfaces wetted for 5 minutes.

STEP 12 Thoroughly Wet the Outside of Controller



Using a fresh Sani-Cloth Plus Wipe, thoroughly and vigorously wet the entire outside surface of the Controller. Use swabs wrapped in germicidal wipes, or swabs wetted with the wipes to thoroughly wet the crevices and screw holes on the Controller.

STEP 13 Use the Brush to Disinfect the Seams



WARNING

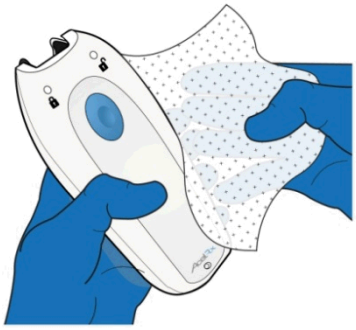
A soft bristled brush **MUST** be used on the seams of the Controller to ensure disinfection of the seams.

Use a soft bristled brush (e.g., Graham Field Adult Toothbrush, Cat. No. 3395-1, available from Fisher Scientific, Cat. No. 19027438) to disinfect the seams on the sides of the Controller.

KEEP WET
5 MINUTES

Keep the surfaces of the Controller wet for a **MINIMUM OF FIVE (5) MINUTES**, as recommended by the wipe manufacturer. The full 5 minute wetting (contact) time is important to kill resistant pathogens.

STEP 14 **(Optional) Disinfect Controller in Two Stages**



In order to keep all of the surfaces of the Controller wet for the minimum 5 minute time, the Controller may be disinfected in two stages: one with the **Dose Button** side and left side seam held generally upward and horizontal, and a second stage with the Screen side and right side held generally upward and horizontal. For each stage, the Controller surfaces, crevices and seams should be wetted for 5 minutes.

The seams and crevices of the Controller (except the Charging/Data port and Tether port) can withstand thorough wetting, therefore a Sani-Cloth Plus wipe may be "wrung" in order to allow liquid disinfectant from the wipe to pool in the recess and wick into the crevices. A soft-bristled brush should also be used in the seams and crevices to assure disinfectant penetrates sufficiently. **DO NOT** use this method around the Data/Charging Port or Tether hole.

STEP 15 **Air-dry Controller**

1. After all Controller surfaces have been kept wetted for 5 minutes, set the Controller down on a clean dry surface (previously disinfected with Sani-Cloth Plus Wipes) and allow to air dry.

2. Controller reprocessing is now complete. After confirming that the Controller is completely dry, place the reprocessed Controller into a clean storage bag.

WARNING

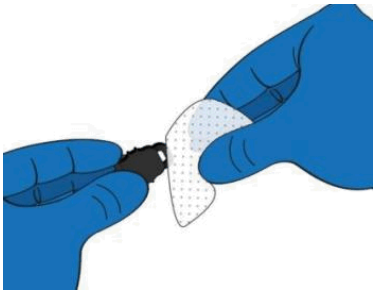
Confirm that the Controller is dry before storage. If not completely dry, condensation within the bag or container may harm internal electronic parts.

17.3. Reprocessing the Controller's Cleaning Plug

CLEANING PLUG

The Cleaning Plug may be reused to reprocess the next Controller, but should first be cleaned and disinfected, to avoid possible transfer of contamination from one Controller to the next.

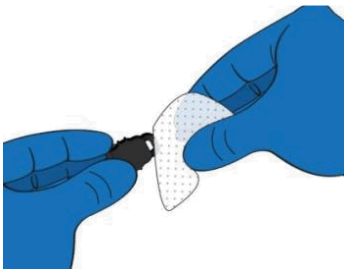
STEP 1 Clean the Cleaning Plug



1. Put on a pair of fresh gloves.
2. Using a fresh Sani-Cloth Plus Wipe, clean off the outside surface and the inside "lip", avoiding the metal contacts inside the Cleaning Plug. Use additional wipes as necessary to clean the plug

AVOIDING CLEANING METAL CONTACTS

STEP 2 **Disinfect the Plug**

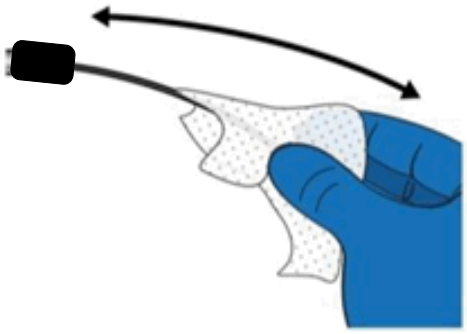


KEEP WET
5 MINUTES

1. Using a fresh Sani-Cloth Plus Wipe, thoroughly and vigorously wet the entire outside surface and inside lip of the Cleaning Plug.
2. Keep the surfaces of the Cleaning Plug wet for a **MINIMUM OF FIVE (5) MINUTES**, as recommended by the wipe manufacturer. The full 5 minute wetting (contact) time is important to kill resistant pathogens.
3. Allow Cleaning Plug to air dry on a clean dry surface. After confirming the Cleaning Plug is completely dry, store in a clean storage bag.
4. Reprocessing of the Cleaning Plug is complete.

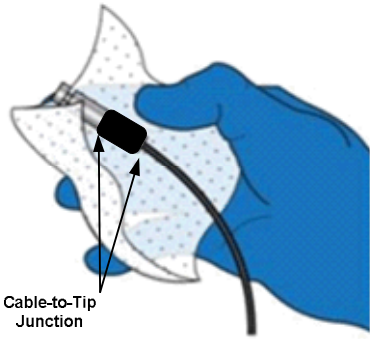
17.4. Reprocessing the Tether

STEP 1 Clean the Cable



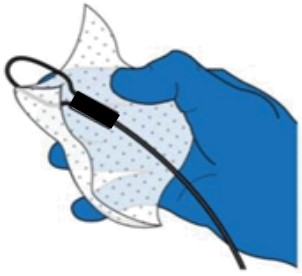
1. Put on a pair of clean gloves.
2. Using a fresh Sani-Cloth Plus Wipe, thoroughly clean the cable portion of the Tether. Use as many fresh Sani-Cloth Plus Wipes as needed to remove all soil from the cable.

STEP 2 Clean the Tip



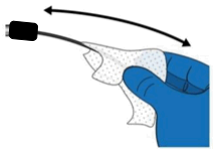
Using additional wipes, clean the Tether Tip, the metal portion shown in the figure at left. Pay special attention to crevices at the cable-to-tip junction. A wipe wrapped around a swab, or a swab wetted with a wipe may be used to thoroughly clean the tip.

STEP 3 Clean the Loop

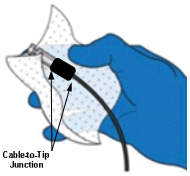


1. Using a fresh Sani-Cloth Plus Wipe clean the Tether loop. Remove all visible soil.
2. Now that the Tether has been thoroughly cleaned, it still needs to be disinfected.

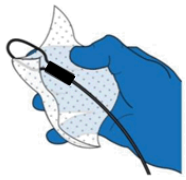
STEP 4 Disinfect the Tether



Wet the Cable,



the Tip, and



the Loop

KEEP WET
5 MINUTES

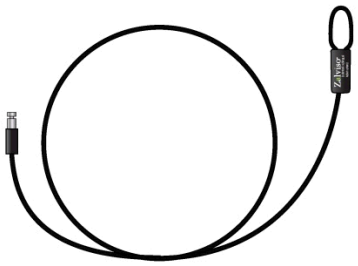
1. Using a fresh Sani-Cloth Plus Wipe, thoroughly and vigorously wet the entire outside surface of the entire Tether, including the Tether tip, Tether cable and Tether loop. Use swabs wrapped in germicidal wipes, or swabs wetted with the wipes to thoroughly wet the crevices on the Tether tip, especially the cable-to-tip junction, and the Tether loop.

2. Allow the surfaces of the entire Tether to remain wet for a **MINIMUM OF FIVE (5) MINUTES**.

3. **THE FULL 5 MINUTE WETTING TIME IS IMPORTANT TO KILL RESISTANT PATHOGENS.**

4. If parts of the Tether dry off before 5 minutes have elapsed, use additional wipes to keep surfaces of the Tether wetted for the entire 5 minutes.

STEP 5 Air Dry the Tether

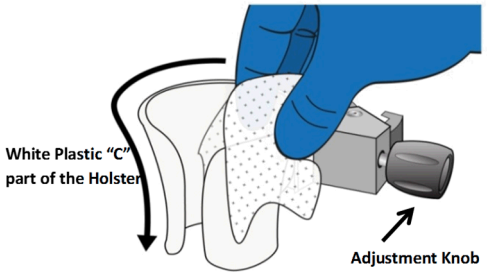


1. Set the Tether down on a clean surface (previously disinfected with Sani-Cloth Plus Wipes) and allow to air dry. Store the reprocessed Tether in a clean storage bag.

2. Tether reprocessing is now complete.

17.5. Reprocessing the Holster

STEP 1 **Clean the Holster**



1. Put on a pair of clean gloves.

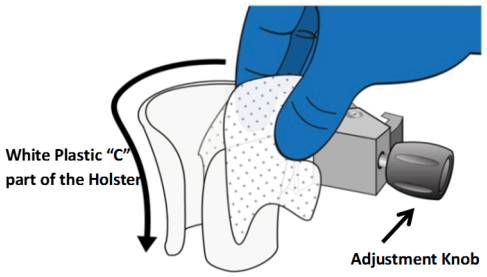
2. Using a fresh Sani-Cloth Plus Wipe, thoroughly clean the white plastic portion of the Holster. Use as many fresh Sani-Cloth Plus Wipes as needed to remove all soil from this area, both inside and outside the "C" of the Holster.

3. Use swabs wrapped in germicidal wipes, or swabs wetted with the wipes to thoroughly clean the crevices on the "C" of the Holster, especially at the bottom.

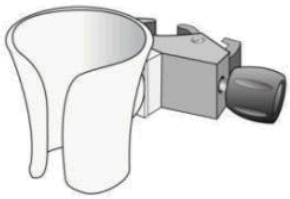
4. Using a fresh Sani-Cloth Plus Wipe, thoroughly clean the adjustment knob on the clamp.

5. Now that the Holster has been thoroughly cleaned, it still needs to be disinfected.

STEP 2 **Disinfect the Holster**



KEEP WET
5 MINUTES



1. Using a fresh Sani-Cloth Plus Wipe, thoroughly and vigorously wet all of the surfaces of the white plastic "C" part of the Holster and the Adjustment Knob on the Holster clamp. Use swabs wrapped in germicidal wipes, or swabs wetted with the wipes to thoroughly wet crevices on the surfaces of the white plastic "C" part of the Holster and the adjustment knob on the Holster clamp. Keep the surfaces of the entire Holster wet for a **MINIMUM OF FIVE (5) MINUTES.**
2. **THE FULL 5 MINUTE WETTING TIME IS IMPORTANT TO KILL RESISTANT PATHOGENS.**
3. If parts of the Holster dry off before 5 minutes have elapsed, use additional wipes to keep all surfaces wetted for the entire 5 minutes.
4. After 5 minutes have elapsed, set the Holster down on a clean surface (previously disinfected with Sani-Cloth Plus Wipes) and allow to air dry. After confirming the Holster is completely dry, store the reprocessed Holster in a clean storage bag.
5. Holster reprocessing is now complete.

18. Recharging the Controller

WARNING

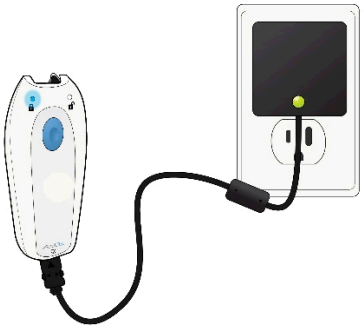
Use only the Charger specified for the Controller. Use of any other power supply adapter may damage the Controller or cause personal injury.

WARNING

Do not connect the Charger to the sufentanil sublingual tablet system while it is being used by a patient. Battery charging is only active when the Controller is discontinued.

The Controller's rechargeable battery should be charged for at least 8 hours or until the "Charging Complete" message appears on the display screen. If the Controller has been used by a patient, it should always be reprocessed according to instructions in *Section 17, Reprocessing Instructions*, before following the charging instructions below.

STEP 1 Connect Charger



1. Use the supplied Charger only or damage to the Controller may occur.
2. Connect the Charger to a 110/120V 60Hz AC power outlet. The green indicator light on the Charger should light when charging.
3. Insert the end of the Charger into the charging port on the Controller being careful not to insert it into the Tether port. The Charger has polarization keys and can only be inserted into the Controller's charging port in one orientation. The Charger should insert and lock into the Controller's charging port.

STEP 2 Charge Battery

Fully Charged

Four green bars mean the battery is fully charged.

Running Low

Two yellow bars means the battery is running low.

Fatally Low

One red bar means the battery is fatally low and the Controller should be charged.

1. While the Controller's battery is charging, the display screen will show a "Battery Charging" message and the battery icon in the upper-right corner of the screen will animate to show that it's charging. On the back of the Controller the blue No Dose light will turn on and flash as a redundant indicator that the Controller is being charged.

2. A battery icon is displayed in the upper-right corner of the Controller screen and is composed of 4 bars. The battery icon will show 4 green bars when it is full and will display one red bar when it's fatally low.

3. While charging, the Controller will turn off the display after 30-seconds of inactivity. Moving the Controller will turn on the display and show the charging status.

STEP 3 Confirm Charge Complete

When the battery is done charging the screen will display a message "Charging Complete" and 4 green bars  will display in the upper-right corner of the screen to confirm that the battery is fully charged. The blue LED on the back of the unit will stop flashing and the green LED will be illuminated.