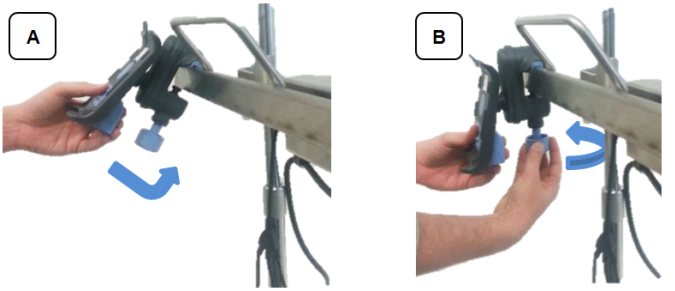
Figure 2.36. Placing Mini Cradle on Mounting System



4. Plug a DC output connector to the mini cradle splitter.
5. Fasten the DC output cables to the clips located on the bottom of the Mounting System.
6. Plug the AC input cord to the power outlet. Verify that the Mounting System power supply LED is ON.

Figure 2.37. Fully Assembled Mounting System

> To transport the Mounting System, detach it from the IV pole:

1. Unplug the AC input cord from the power outlet.
2. Firmly hold the Mounting System and rotate the clamp knob counter-clockwise, until the Mounting System is loose.
3. To carry the Mounting System always use the dedicated carry handle.

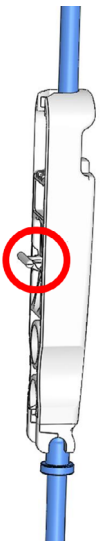
	Always contact a certified technician in cases of Mounting System electrical and mechanical malfunctions. When removing the Mounting System from the IV pole, avoid applying pressure on the power cable, connectors or cradles.

Administration Sets

The Sapphire pump should be used with a Sapphire dedicated administration set, which includes the Sapphire administration cassette. Alternatively, administration sets from different manufacturers that are regulatory cleared and labeled for use with the Sapphire infusion system, can be used as well. The list of regulatory cleared sets needs to be obtained from the official manufacturer's publication such as manufacturer's website, catalog or any other formally published document.

This cassette includes a normally closed valve (three-state Anti-Free-Flow Valve) that provides automatic anti-free-flow protection. Opening the valve allows manual priming as well as transition of infusion to gravity induced.

Figure 2.38. Sapphire Administration Cassette and AFFV



Only administration sets that include a roller clamp and do not include pressure activated valves (PAV) can be used by gravity. For more information, refer to the Directions for Use of each set.

For more information about priming the administration set and inserting it into the pump, refer to Priming Manually on page 116 and Inserting the Administration Cassette on page 111.

Sapphire Approved Administration Sets

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This section provides a list of administration sets approved by Eitan Medical Ltd. to be used with the Sapphire pump.

	Use Sapphire standard administration sets listed here or in Eitan Medical's approved list of products: https://eitanmedical.com/ Alternatively, administration sets from different manufacturers that are regulatory cleared and labeled for use with the Sapphire infusion system, can be used as well. The list of regulatory cleared sets needs to be obtained from the official manufacturer's publication such as manufacturer's website, catalog or any other formally published document. Using anything other than administration sets regulatory cleared and labeled for use with Sapphire infusion system, may result in operation that is not within the constraints and parameters of the device.

Other products available from Eitan Medical Ltd. are listed in the Eitan Medical Official Product List, at https://eitanmedical.com/

Chapter 3: Fundamental Concepts and Operations

The following sections explain the structure and function of the Main Display and the toolbar, provide an overview of the delivery modes, and describe special features that can be enabled and disabled, according to user requirements:

Working with the Main Display

The Main Display is a touch screen that serves as a work area for programming infusion parameters, and choosing from lists of possible selections. While an infusion is running, selected infusion parameters and other relevant information (such as time left until completion of the infusion) appear on the Main Display.

The following sections describe how to use the keypads, and provide an overview of the main function keys and icons that appear on the Main Display.

Using the Keypad

Numeric keypad

The keypad is used for entering digits, to specify parameters for volumes, rates and times, and typing drugs names when searching the Drug Library. As you press the relevant digits, they are displayed in the frame at the top of the Main Display, replacing the name of the parameter. Pressing **Clr**, at the lower left corner of the keypad, clears all entered digits and lets you re-enter the value.

The acceptable range of a given parameter is displayed in the upper right corner of the Main Display. When you enter a value that is outside of a permitted range, the range values stay red, and the **OK** function key is disabled. The values of a range are dynamic, and change according to other parameters that have already been programmed.

When entering time, the pump allows you to enter minutes up to the value of **59**. Infusion time of over 59 minutes must be expressed in hours and minutes. For example, 90 minutes must be entered as **1:30** (h:min).

Alphanumeric keypad

In some instances, for example, defining a new PreSet program, or entering a drug name, the keypad displays letters and symbols in addition to numbers.

The Alphanumeric keypad displays uppercase letters with numbers, and lowercase letters with symbols. Uppercase letters and numbers are the default state. Switch the default keypad from uppercase and numbers to lowercase and symbols by pressing the 'abc sym' key on the toolbar and back to default by pressing 'ABC 123' key.

Overview of Toolbar Function Keys

The function keys are located in the toolbar, and enable user actions. The function keys that appear vary according to the screen or program that is currently selected. Function keys enabling basic actions are described in the following table.

Name of Key	Action	Notes
OK	Confirms a selection or an entered parameter	If the selection involves parameters that are out of the permitted range, the **OK** key is disabled.
Prime	Initiates priming	Appears in the Attention screen, after the Prime function has been selected.
Mute/Unmute	Silences/unsilences the speaker	Appears when any alarm is triggered. The speaker unmutes automatically after 2 minutes.
Back	Displays the previous screen	
Exit	Returns to either the Start Up screen, or to the screen displaying current infusion parameters	In situations when the **Back** key and the **Exit** key will take users to the same screen, only the **Exit** key is displayed.

The following function keys are available from the Running screen:

Name of Key	Action	Notes
Lock	Locks the screen or the pump	For more information, refer to Locking the Screen on page 220 and Activating Patient Lockout on page 221.
Press to Unlock screen	Unlocks the screen	
Press to Unlock Patient	Unlocks the pump	Unlocking the screen requires a password.

Name of Key	Action	Notes
Request Pause/ Pause Bolus	Pauses an infusion or a bolus	For more information, refer to Pausing Infusions on page 218.
Request Continue/ Continue Bolus	Resumes a paused infusion or a bolus	
View/Edit	Displays a list of infusion parameters to be viewed or edited	
Bolus	Delivers a bolus during continuous, PCA and PCEA modes	

Overview of Icons

Icons that frequently appear on the Indicators Bar and the Main Display are described in the following table. In addition, some alarms appear with their own icons.

Icon	Meaning	Notes
>	Indicates that the parameter immediately adjacent to the icon can be viewed and updated directly from the Main Display.	To initiate the update, touch the box in which the icon appears.
	Rate of the infusion.	
	Volume to be infused.	

Icon	Meaning	Notes
	Time remaining until the end of the infusion.	
	Indicates that an infusion is currently running.	
	Indicates status of battery charge.	For more information, refer to Battery Care Information on page 293.
	Indicates that the current infusion is above the upper soft limit range in at least one parameter.	For more information, refer to Soft Limit on page 267.
	Indicates that the current infusion is below the lower soft limit range in at least one parameter.	For more information, refer to Soft Limit on page 267.
	Indicates that the current infusion is exceeding both upper and lower soft limit ranges.	When more than one parameter is limited by the Drug Library – one of the parameters is programmed above the upper soft limit, and another parameter is programmed below the lower soft limit. For more information, refer to Soft Limit on page 267.
	Indicates that the EBP is connected to the pump.	For more information, refer to External Battery Pack on page 78.

Icon	Meaning	Notes
	Updating data.	May appear when transitioning between lines.
	Pump connected to PC.	Indicates that the pump is connected to the PC.
	Air detection is disabled.	No Air in Line alarm is triggered when the pump air detection is disabled (OFF). A technician authorization code is required to enable or disable air detection (this can only be set manually on the pump and not by the DLE). If air detection is disabled (OFF), use a set with an air-eliminating filter to prevent injury. Always ensure that the administration set is primed before starting an infusion.
	Pump connected to Sapphire Connect.	Indicates that the pump is connected to Sapphire Connect, and that the pump data is being monitored.

Selecting Delivery Mode

The Sapphire pump is a multi-platform device that has the ability to operate in several different delivery modes.

> The delivery modes availability can be set by a technician

Possible delivery modes include:

Mode	Description/Notes
Continuous	Delivers an infusion at a constant, programmed rate. This mode includes the option to add a Secondary (Piggyback) line.
Intermittent	Delivers infusions at intermittent programmed intervals.
TPN (Total Parenteral Nutrition)	Delivers an infusion at a constant rate, with optional tapering at the beginning and end of the infusion.
PCA (Patient Controlled Analgesia)	Delivers PCA boluses, either alone or in addition to a basal programmed rate.
Multi-step	Delivers the infusion in a set of 1 and up to 25 steps.
Epidural	**PCEA (Patient Controlled Epidural Analgesia):** Delivers epidural boluses, either alone or in addition to a basal programmed rate. **Intermittent Epidural:** Delivers epidural infusions at intermittent pre-set intervals, with the option to add PCEA (refer to PIEB under Epidural Mode Options Menu **on page** 245).

> The Epidural (PCEA and Epidural Intermittent) modes do not deliver IV infusions. They deliver epidural infusions, using a special catheter and all the required clinical procedures.

Each delivery mode features its own unique options. The current mode is displayed at the right side of the Indicators Bar on some of the screens. On screens that are not mode related, such as **Delivery mode** selections screen below, the name "Sapphire" is displayed instead.

Figure 3.1. Indicators Bar: Delivery Mode

Changing the delivery mode is done using the Options menu. An authorization code of High is required to modify the delivery mode. For more information about how to change the delivery mode, refer to Setting Delivery Mode on page 225.

Enabling Special Features

Depending on the needs of a specific clinical care area or institution, the Sapphire pump can be enabled to perform special functions. An authorization code is required to enable/disable these functions.

Local configuration made after the Drug Library is loaded, will be valid until the user selects a CCA or turns the pump Off.
When Resuming an infusion after pump shutdown, local configurations will remain until the end of the current infusion. For more information about Drug Library, refer to Chapter 9: Drug Library on page 260.
When no Drug Library is loaded, all local changes made to any configuration will remain valid until reconfigured or until the pump is set to factory defaults.

The following features can be enabled/disabled by users who have an authorization code of High:

Feature	Delivery Mode(s)	Description/Notes
Allow delayed start	All	Enables users to start an infusion at a later time. The user may either define a specific delay period or set the pump to Standby. For more information, refer to Using the Set Delay Feature on page 253.
Allow PreProgram	All	Allows users to start an infusion using predefined infusion parameters. When this option is enabled, the PreSet Programs button appears on the pump Start Up screen. For more information, refer to Creating and Editing PreSet Programs on page 250.

Feature	Delivery Mode(s)	Description/Notes
Repeat last infusion	All	Allows the users to start infusions using the same infusion parameters for the same patient. When this option is enabled, the Repeat Last Infusion button appears on the pump Start Up screen. For more information, refer to Repeating Last Infusion on page 214.
Limit Period	PCA Epidural (PCEA and Epidural Intermittent)	Specifies the time period to which the dose limit type is applied (during the selected time, the delivered boluses will be limited by either maximum number, or by maximum volume).
Prime Reminder	All	Enables a reminder for the user to prime the administration set before starting an infusion. For more information, refer to Automatic Priming Using the Pump on page 114
Allow loading dose	PCA PCEA (Epidural)	Enables starting a PCA or PCEA infusion with a programmed initial clinician dose (bolus). For more information about enabling the feature, refer to PCA Options Menu on page 244 or Epidural Mode Options Menu on page 245.
Password request	Epidural (PCEA and Epidural Intermittent)	A safety feature that requires password entry to make changes to important parameters. For more information about enabling the feature, refer to Epidural Mode Options Menu on page 245.
Advanced Bolus	Continuous	Allows users to program a bolus by entering rate, amount and time. For more information, refer to Administering a Bolus on page 137.

Feature	Delivery Mode(s)	Description/Notes
Bolus Reminder	PCA Epidural (PCEA and Epidural intermittent)	Enables a reminder for the user to connect the bolus handle before starting a PCA, or PCEA or PIEB infusion that includes patient boluses. The reminder (i) instructs to connect the bolus handle directly to the pump (ii) Checks functionality – bolus press is recognized by the pump. For more information, refer to Bolus Reminder on page 232.
Auto P. Lockout	All	A safety feature that enables automatic locking of the screen. A password is required to unlock the screen in order to make changes to the infusion parameters or to start a new infusion. Activated first during a running infusion, and automatically re-activated throughout the infusion. For more information about enabling the feature, refer to Configuring General Settings on page 230. For more information about using the feature, refer to Activating Patient Lockout on page 221.
Screen Saver	All	Provides a distant view of the main parameters during a running infusion. Activated 30 seconds after the infusion starts.

A Technician authorization code is required to enable/disable the following additional features:

Feature	Delivery Mode(s)	Description/Notes
Delivery modes	All	Determines the available delivery modes. Each mode can be turned Off separately.
New Patient	All	Allows users to associate an infusion with a patient, and reset the Accumulated VI (accumulated volume infused).

Feature	Delivery Mode(s)	Description/Notes
Set Secondary (Piggyback)	Continuous	Allows users to program a Secondary infusion. For more information about programming a Secondary infusion, refer to Adding a Secondary Line on page 142.
Allow Bolus	Continuous	Allows users to program a bolus during a Continuous infusion. When this feature is enabled, the Bolus button appears in the toolbar during the running infusion. For more information about administering a bolus, refer to Administering a Bolus on page 137.
Bolus Rate	Continuous	Specifies the rate of delivery of a fast dose, for rapid volume infusion.
Sec. Bolus Rate	Continuous	Specifies the rate of delivery of a fast dose for a Secondary (Piggyback) infusion.
Occ. Auto-restart	All	Enables the pump to automatically restart an infusion, up to 5 times an hour, if a downstream occlusion was detected and cleared within 40 seconds.
Calculate Concentration	All Excluding TPN	Determines if the user enters final concentration or Drug Amount and Diluent Volume.
mL/h Only	All Excluding TPN	Allows users to use units other than mL/h. If this option is enabled, programming will automatically default to mL/h. This feature is available in the absence of a Drug Library on the pump.
Med. Titration	All	Allows users with medium authorization level to change rate during a running infusion.
Air Detection	All Excluding Epidural	Determines whether the pump air detection is disabled (OFF) or enabled (ON) during infusion. This feature should be used when meeting the clinical practice and guidelines, and coupled with an alternative method of eliminating air. When air detection is disabled (OFF), the user is prompted to use the set with an air-eliminating filter.

Setting KVO Rate

Allows users to set the default rate of fluid that is delivered when the infusion program is completed. The permitted range for the KVO rate parameter is 0-20 mL/h (for all delivery modes).

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Chapter 4: Getting Started

The following sections explain the sequence of actions necessary to prepare the pump and the administration set for an infusion:

Typical Workflow

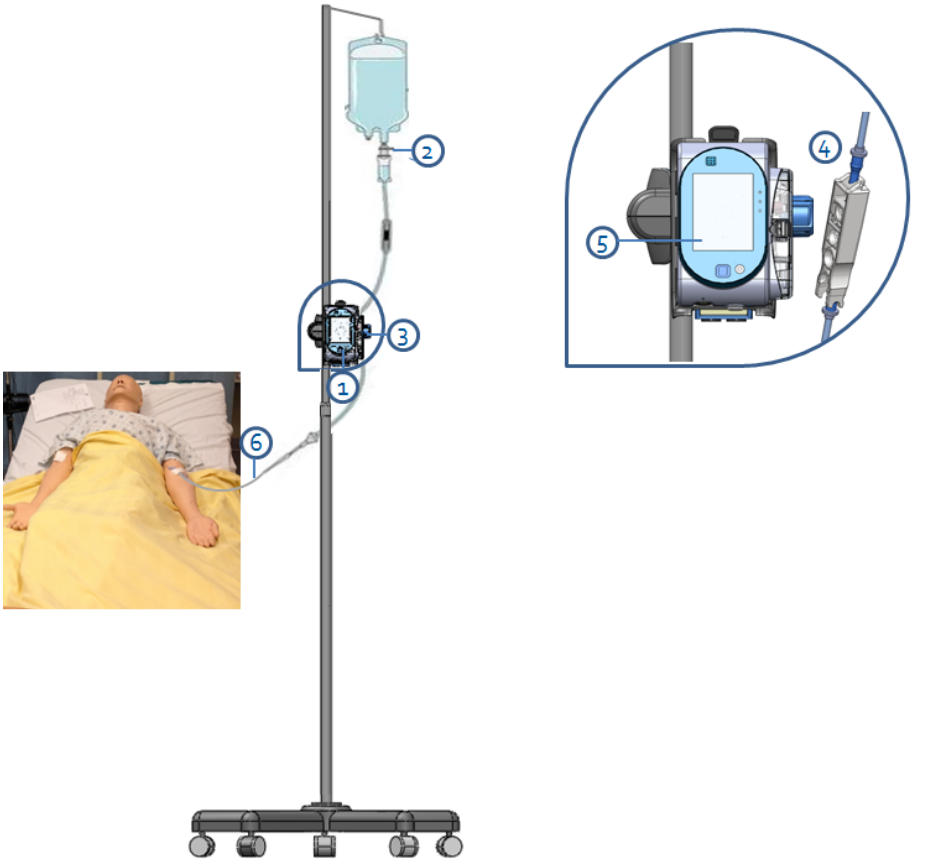
The recommended workflow for preparing the pump and administration set for an infusion comprises the following steps:

1. Turn the pump On.
2. Connect the infusion container to the administration set.
3. Open the safety door.
4. Insert the cassette.
5. Prime the administration set using the pump.*
6. Connect the administration set to the patient. When using an administration set with a filter, place the filter under the patient's IV infusion site.

* It is recommended to prime the administration set using the pump. It is possible to prime the administration set manually. For more information, refer to Priming Manually on page 116.

The workflow sequence is illustrated in the following figure:

Figure 4.1. Recommended Workflow



Turning the Pump On

The pump is turned On by pressing the **On/Off** hard key, at the lower right corner of the pump.

When a Drug Library is loaded, a message is displayed asking to accept or change the current CCA. For more information about CCA, refer to Clinical Care Area (CCA) on page 261.

⚠	While the pump turns On, a system check is performed. If you do not hear a sound from the speaker, or if items on the screen do not display properly, do not use the pump.
ℹ	If a message regarding resuming previous infusion appears upon turning the pump On, refer to Resuming Infusions After Pump Shutdown on page 217.

Turning the Pump Off

Pressing the **On/Off** hard key for 5 consecutive seconds turns the pump Off. Alternatively, press the **On/Off** hard key, and then, from the Attention screen, press **Off**.

For more information about turning the pump Off during an infusion, refer to Aborting Infusions on page 219.

The pump enables resuming an infusion after pump shut down. For more information, refer to Resuming Infusions After Pump Shutdown on page 217.

Connecting the Infusion Container to the Administration Set

This section explains how to connect the infusion container to the administration set.

> Before setting up the infusion, verify that the container, administration set and administration set package are undamaged.

> To connect the container to the administration set:

1. Open the sterilized administration set package.
2. Close the clamps and the AFFV to block the administration set. Ensure that the clamp is located at least 20 cm (8 in) from the pump (when possible).
3. Spike the administration set into the container.

> Verify that the arrow on the administration cassette is pointing toward the same direction of the fluid flow (down).

Connecting the Infusion Container: Safety Warnings

- Make sure there is no leakage from the container, and that the spike is firmly attached to the container.
- Verify that the set components are positioned correctly. The arrows on the administration cassette and the filter must point toward the direction of the flow (from the container to the patient).
- When using a filter, maintain the filter level below the vascular access site.

Opening the Safety Door

Opening the safety door involves pressing it down while simultaneously pulling the safety door open.

> To open the safety door:

1. Using your thumb, press the door outwards.

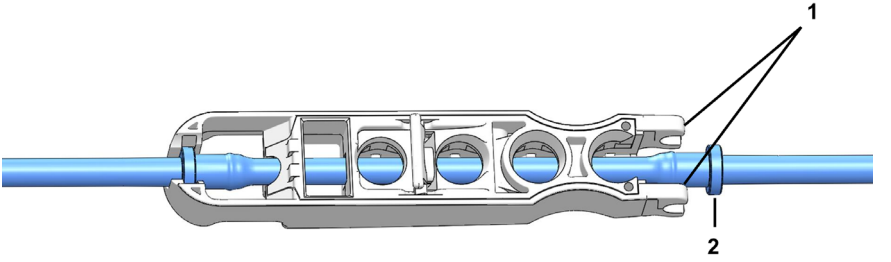
If gray latch is present, press the latch itself outwards.

2. While maintaining pressure, swing the safety door outwards.

Inserting the Administration Cassette

Inserting the administration cassette into the pump involves positioning the cassette in the proper direction, and ensuring that all portions of the cassette including the flange, are secured inside the administration cassette's housing. In Figure 4.2, the flange is represented by #2, and the saddle is represented by #1.

Figure 4.2. Administration Cassette

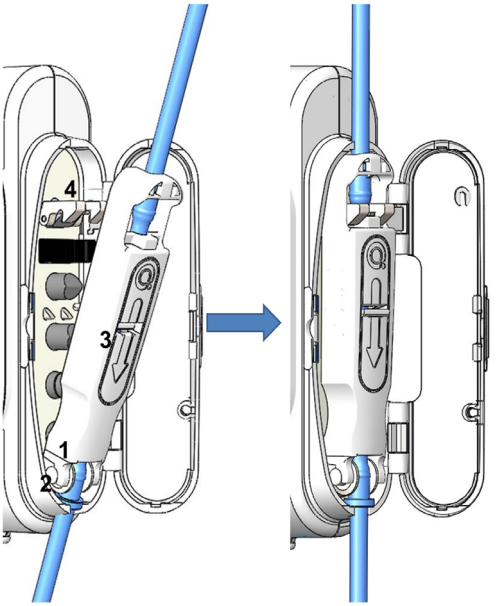


It is recommended to make sure that the pump is turned On, and to verify that all clamps on the administration set are closed before inserting the administration cassette.

> To insert the Sapphire administration cassette:

1. Open the safety door (Opening the Safety Door on page 110). Then, insert the administration cassette at an angle, by placing the saddle (Figure 4.3, #1) on the round metal anchor (#2) in the cassette's housing. Make sure that the arrow on the cassette (#3) is pointing toward the bottom of the pump, and the bottom flange is inside the cassette housing.

Figure 4.3. Insertion of Cassette



2. Clip the upper end of the administration cassette into the metal lock (Figure 4.3, #4).
3. Close the safety door over the administration cassette. Ensure that the safety door clicks upon closure.

Removing the Administration Cassette

When the infusion is complete, close the clamps, disconnect the administration set from the patient, and disconnect the administration cassette.

In case of emergency, you can stop pump operation by opening the safety door, closing the clamps, removing the administration cassette from the pump and disconnecting the administration set from the patient.

The following procedure describes how to remove the cassette from the pump.

Although the AFFV offers automatic free flow protection, a small amount of fluid (up to 0.09 mL) may be expelled when the administration cassette is detached. In order to ensure full protection, disconnect the patient from the administration set before detaching the cassette from the pump.

> To remove the Sapphire administration cassette:

1. Close all clamps on the administration set.
2. Disconnect the patient from the administration set.
3. Open the safety door (Opening the Safety Door on page 110).
4. Loosen the cassette by raising the metal lock that secures it to the pump (#4 in Figure 4.3).
5. Pull out the cassette, and close the safety door.

Automatic Priming Using the Pump

Before commencing infusion setup, the administration set needs to be primed. Priming expels all the air from the administration set, and fills it with the infusion liquid. A fully primed administration set is a set filled with infusion liquid (from which all the air was removed).

It is recommended to prime the administration set using the pump.

Priming with the pump can be initiated from the following screens:

- Start Up
- Start
- Paused (infusion or bolus)
- Air in Line Alarm

Before using the pump for priming, ensure that:

- The administration set clamp is open.
- The safety door is closed.

The Sapphire administration cassette is properly connected to the pump.

	Before priming, verify that the administration set is disconnected from the patient.

	When the Prime Reminder is enabled and the set has not yet been primed using the pump, a Prime Reminder will be displayed, enabling the user to press **Prime** in order to start priming or to press **Start** in order to proceed with the infusion (refer to Configuring General Settings, page 231).

To prime the administration using the pump

1. Position the pump in an upright position using one of the following methods:
   - Attach the pump to the cradle base.
   - Attach the pump to an IV pole using the mini cradle.
2. From the toolbar of the Start Up, Start, Air in Line Alarm, or Paused screen, press **Prime**.
3. **Verify that the administration set is disconnected from the patient.** Then, from the Attention screen, press **Prime**. Priming begins.

   While the pump is priming, a progress circle appears on the screen, with a time countdown displayed. The default priming time is 2 minutes.
   When using administration sets that contain less than 20 mL, shorter priming times can be set. For more information, refer to Set prime volume on page 231.

	During priming with the pump, the Air in line alarm is disabled. When priming, check that all clamps are opened and that there is no occlusion. Ensure that liquid, not air, enters the administration set during priming.

The pump automatically indicates when priming is finished.

If priming is completed before the default priming time has elapsed, automatic priming can be discontinued.

> To discontinue priming:

1. From the toolbar, press **Finish Prime**. Alternatively, at the bottom of the pump, press the **Stop** hard key.
2. From the toolbar, press **OK**

Priming Manually

The Sapphire administration set can also be used as a gravity set, and the Anti-Free-Flow Valve (AFFV) can be used manually.
Before commencing infusion setup, the administration set needs to be primed. Priming expels all the air from the administration set, and fills it with the infusion liquid. A fully primed set is a set filled with infusion liquid (from which all the air was removed).

	The following procedure explains how to prime the administration set manually, using gravity. However, it is recommended to prime the administration set using the pump. For more information, refer to Automatic Priming Using the Pump on page 114.

	A set with a Pressure Activated Valve (PAV) can not be primed manually. For more information, refer to the Direction for Use for each set.

> To prime the administration set manually:

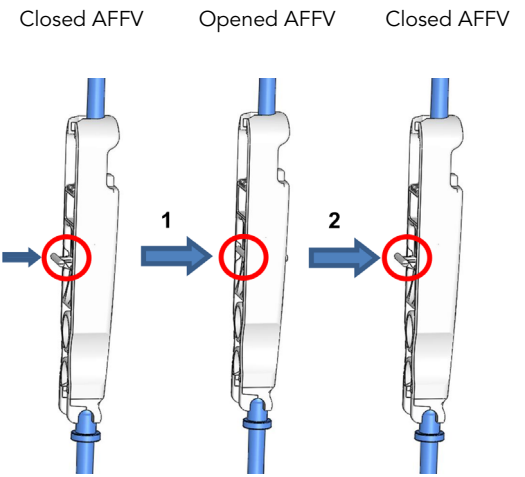
1. Open all the clamps on the administration set.
2. To allow free flow, open the AFFV by pushing it in and down, towards the center of the Sapphire administration cassette (#1 in Figure 4.4).

3. Fill the entire administration set with fluid, so that the fluid displaces all air in the administration set.

	When priming a set with a filter; the filter must remain lower than the patient line.

4. To block free flow, close the AFFV by pushing it up and away from the center of the cassette (#2 in Figure 4.4).

Figure 4.4. Opening and Closing the AFFV



	Although the AFFV offers automatic free flow protection, a small amount of fluid (up to 0.12 mL) may be expelled when the administration cassette is attached. In order to ensure full protection, insert the administration cassette to the pump housing before connecting the set to the patient.

To use as a gravity set, fix the AFFV in an open position as described in step 2 in To prime the administration set manually on page 116. Only administration sets that include a roller clamp and do not include pressure activated valves (PAV) can be used by gravity. For more information, refer to the Administration set's DFU.

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Chapter 5: Using the Delivery Modes

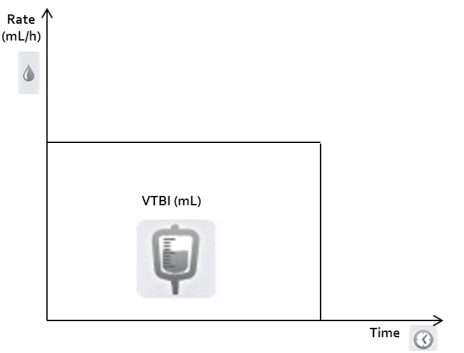
The following sections explain how to operate the pump in the different delivery modes. After setting up the pump and the infusion, always check the battery status to ensure it is sufficient for the desired infusion program.

Continuous Mode

The following sections will be reviewed:

In this mode, the pump infuses fluid at a constant, programmed rate.

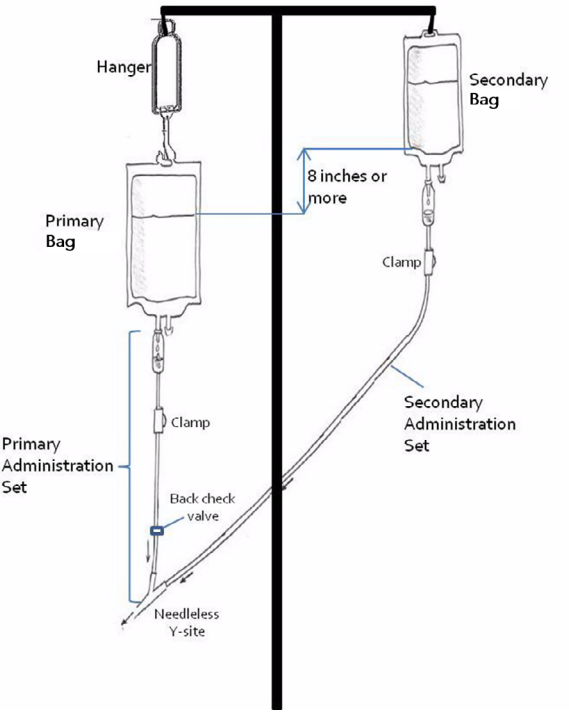
Figure 5.1. Continuous Flow Profile



The Sapphire pump can also be configured to support Secondary (Piggyback) infusions. The Secondary option is used when two medications are administered from two different bags; The user may either alternate between the bags or administer them sequentially.

	To use the Secondary option, the option must be enabled (requires Technician authorization code).

Figure 5.2. Secondary Infusion Setup



When the Secondary option is enabled, you can set Secondary infusion parameters:

- Immediately after programming the Primary infusion (Starting a Continuous Infusion Using the Secondary Function on page 129).
  OR
- While a Primary infusion is already running (Adding a Secondary Line on page 142).

Piggyback Option: Safety Warnings

When working with Secondary infusions, adhere to the following instructions and guidelines:

- Use only Sapphire administration sets designed for Piggyback infusions. (For more information, refer to Sapphire Approved Administration Sets on page 91.)
- Hang the Secondary solution container at least 8 inches above the Primary solution fluid level.
- Use the drip chamber on the set to verify that the correct line is delivering and the other line is idle.
- After the Secondary infusion is complete, clamp the Secondary administration set.

Infusion Parameters: Continuous Mode

The following infusion parameters are relevant for a Continuous infusion. When programming the infusion, it is necessary to specify two of the parameters. The third parameter is then automatically calculated by the pump.

Parameter	Description/Notes
Rate	The speed at which the fluid is infused. Rate values can range from 0.1 to 999 mL/h. **Note:** When selecting units that are not from the mL/h family, the word **Rate** is replaced with **Dose Rate**.
VTBI	The total amount of fluid to be infused. VTBI values can range from 0.1 to 9999 mL. The remaining VTBI is displayed on the screen as the infusion progresses.
Time	The period of time over which the fluid is infused. The range for the Time value varies according to the VTBI and Rate. The upper limit of the Time value is 99 hours and 59 minutes.

Starting a Continuous Infusion

The following procedure explains how to program the pump to start a new Continuous infusion.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new Continuous infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in Continuous mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the Start Up screen, select **New Infusion**.
3. If a warning that air detection is set to Off appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. If the Dosing method screen appears, select the appropriate option:
   - **mL:** Continue to Step 8.
   - **Dose calculation:** Continue to Step 5.

   Weight based units are available for both Dosing methods

   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

> To display additional concentration units press **Next**.

6. According to the pump configuration one of the following screens will appear:
   - **Concentration**: From the Concentration screen, using the keypad, enter the Concentration → **OK**; then, continue to Step 8.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**; then, continue to Step 7.
7. From the Attention screen, confirm the concentration and press **OK**.

   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen, using the keypad, enter the Patient Weight → **OK**.
10. From the Dose Rate units screen, select the appropriate dose rate units.
11. From the Edit screen, program 2 of the following 3 parameters, by selecting the relevant rows:
    - **Rate:** Using the keypad, enter the value → **OK**.
    - **VTBI:** Using the keypad, enter the value → **OK**.

- **Time:** Using the keypad, enter the value → **OK**.

The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.

	If the calculated rate is beyond the pump resolution (0.1 mL/h increments), the pump decreases the rate by 0.1 mL/h during the infusion to achieve accurate delivery of the volume in the specified time. The rate reduction is always 0.1 mL/h, and is presented on the Running screen (when selecting dose calculation, the equivalent change to 0.1 mL/h applies).

12. Review the parameters displayed on the Confirm screen.

	Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

	If the pump is configured to support Secondary infusions, Secondary infusion parameters can be programmed at this point. For detailed instructions, go to Step 3 on page 129 (To begin a new Continuous infusion using the Secondary option without Drug Library).

13. Make sure that the clamps on the administration set are open; then, press **Start**.

    The Running screen is displayed, and the infusion begins.

Throughout the infusion, the following information is displayed on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.

- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused during the current infusion. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the current infusion.

To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit** → **View system** → **Infusion values**.

> To begin a new Continuous infusion with a Drug Library:

1. From the Indicators Bar, verify that the pump is in Continuous mode.

For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98

2. From the Start Up screen, select **New Infusion**.
3. If a warning that air detection is set to Off appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. From the Drug Name screen:
   - Using the keypad, enter the drug name; then, press **Find** and proceed to Step 5.

The **Find** key can be used to display all available drugs without entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:

'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm choosing General, and press **OK**.
Proceed to Step 4 on page 124 (To begin a new Continuous infusion without Drug Library) and continue programming from there.

5. From the Drug List screen, select the row of the relevant drug.

To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 124 (To begin a new Continuous infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 8 on page 124 (To begin a new Continuous infusion without Drug Library), and continue programming from there.
   - **Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

     From the Attention screen, confirm the concentration and press **OK**.

     Proceed to Step 8 on page 124 (To begin a new Continuous infusion without Drug Library), and continue programming from there.

- **Full concentration**:

  Proceed to Step 8 on page 124 (To begin a new Continuous infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 11 on page 124 (To begin a new Continuous infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

Starting a Continuous Infusion Using the Secondary Function

The following procedure explains how to program a Continuous infusion using both Primary and Secondary lines.

> To begin a new Continuous infusion using the Secondary option without Drug Library:

1. Verify that the pump is in Continuous mode, and then enter parameters for the Primary infusion (Step 2 on page 124 through Step 11 on page 124 in To begin a new Continuous infusion without Drug Library).

> If the calculated rate is beyond the pump resolution (0.1 mL/h increments), the pump decreases the rate by 0.1mL/h during the infusion, in order to achieve accurate delivery of the volume in the specified time. The rate reduction is always of 0.1mL/h and is presented on the running screen (when selecting dose calculation, the equivalent change to 0.1mL/h applies).

2. Review the parameters displayed on the Confirm screen.

> Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

3. From the Start screen, select **Set Secondary**.
4. If the Dosing method screen appears, select the appropriate option:
   - **mL:** Continue to Step 8.
   - **Dose calculation:** Continue to Step 5.

   Weight based units are available for both Dosing methods.

   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

> To display additional concentration units press **Next**.

6. According to pump configuration one of the following screens will appear:
   - **Concentration**: From the Concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 8.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 7.
7. From the Attention screen, confirm the Concentration and press **OK**.

   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen:

   If the patient weight was entered during the primary line programming, continue to Step 10.
   If the patient weight was not entered during the primary line programming, using the keypad, enter the Patient Weight → **OK**.
10. From the **Dose Rate units** screen, select the appropriate dose rate units.
11. Program 2 of the following 3 parameters, by selecting the relevant boxes:
    - **Rate (Secondary):** Using the keypad, enter the value → **OK**.
    - **VTBI (Secondary):** Using the keypad, enter the value → **OK**.
    - **Time (Secondary):** Using the keypad, enter the value → **OK**.

    The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.
12. Review the parameters displayed on the Confirm screen.

Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

13. From the Start screen, select one of the following:
    - **Start secondary:** The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins. When the Secondary infusion is complete, the pump automatically continues with the Primary infusion.
    - **Start primary:** The Attention screen appears. After closing the clamp on the Secondary administration set, make sure that the clamps on the primary administration set are open; then, press **OK**. The Primary screen appears, and the Primary infusion begins.

Throughout the infusion, the Indicators Bar displays information regarding the current infusion (Primary, Secondary or the name of the drug infused). After the secondary infusion is completed, the pump automatically switches to the primary line, and beeps to notify the user. The following information is displayed on the Primary/Secondary screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left (in the current infusion) to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume that has been infused during the current infusion (including KVO if applied during a delayed start period) / the VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.

- **Time left:** Time remaining until the end of the current infusion.

	You can switch between the two infusions at any time. For more information, refer to Switching between Primary and Secondary Infusions on page 146.

	To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.

> To begin a new Continuous infusion using the Secondary option with a Drug Library:

1. Verify that the pump is in Continuous mode, and then enter parameters for the Primary infusion (To begin a new Continuous infusion with a Drug Library Step 2 on page 126 to Step 6 on page 127).

	If the calculated rate is beyond the pump resolution (0.1 mL/h increments), the pump decreases the rate by 0.1mL/h during the infusion in order to achieve accurate delivery of the volume in the specified time. the rate reduction is always of 0.1mL/h and presented on the running screen (when selecting dose calculation, the equivalent change to 0.1mL/h applies).

2. Review the parameters displayed on the Confirm screen.

	Verify that the parameters reflect the correct treatment according to the prescription.

   Then, press **OK**.
3. From the Start screen, select **Set Secondary**.
4. From the Drug Name screen:

- Using the keypad, enter the drug name, then press **Find** and proceed to Step 5.

The **Find** key can be used to display all available drugs without entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:

'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm choosing General and press **OK**.
Proceed to Step 4 on page 129 (To begin a new Continuous infusion using the Secondary option without Drug Library) and continue programming from there.

5. From the Drug List screen, select the row of the relevant drug.

To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 130 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 8 on page 130 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.
   - **Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

From the Attention screen, confirm the concentration and press **OK**.

Proceed to Step 8 on page 130 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.

- **Full concentration**:

  Proceed to Step 8 on page 130 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 11 on page 130 (To begin a new Continuous infusion using the Secondary option without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

Continuous Mode: Mid-infusion Actions

The following actions can be performed during Continuous infusions:

Updating Infusion Parameters

Infusion parameters can be modified by using the **View/Edit** function key. In addition, you can modify the rate, VTBI, and time left directly from the Running**,** Primary or Secondary screen.

> To update current parameters directly from the screen:

1. On the Main Display, select the relevant parameter (**Rate**, **VTBI** or **Time left**).
2. Using the keypad, enter the new value of the parameter → **OK**.
3. To confirm and save changes, press **OK**.
   To return to the original infusion screen without saving changes, press **Back**.

> To update parameters using the View/Edit function key:

1. From the toolbar, press **View/Edit**.
2. Select the box of the parameter to be updated.
3. Using the keypad, enter the new value of the parameter → **OK**.
4. To update other parameters, repeat Steps 2-3.

   In addition to parameter changes, the following actions are also available:

- **Clear Accum. VI:** Resets the total volume infused via all infusions associated with the current patient to 0 mL. For more information, refer to Clearing Accumulated VI on page 259.
- **View system:** Displays various system and pump parameters. (Refer to View Menu on page 237.)
- **Edit Primary/Secondary Line:** Allows you to update infusion parameters of the infusion that is not currently running. The pump will prompt you to pause the infusion while updating these parameters.

5. To confirm and save changes, press **OK**.

   To return to the original infusion screen without saving changes, press **Back**. Then, from the Attention screen, press **OK**.

If the dose rate is beyond the pump resolution of 0.1 mL/h increments, the pump will increase or decrease the rate by up to 0.05 mL/h. This flow rate (mL/h) is presented on the Running screen during infusion.

Administering a Bolus

The Bolus feature enables administration of a fast dose, when rapid volume infusion in the Continuous mode is necessary.

Bolus delivery allows infusion at high rates. Only certified medical personnel should use this feature.

> To deliver a bolus:

1. From the toolbar of the Running, Primary or Secondary screen, press **Bolus**.

For the **Bolus** button to appear on a Continuous running infusion, the pump needs to be configured to the Allow Bolus setting. The Allow Bolus setting can be modified by Technicians only. For more information, refer to the Service Manual. If a Drug Library is installed on the pump, the Bolus button will appear only if the option was enabled for a specific drug, or an entire CCA.

2. If the Patient Weight screen appears, using the keypad, enter the Patient Weight → **OK.**
3. According to configuration, one of the following screens will appear:
   - **Edit**:
     - **Amnt (Bolus)**: Using the keypad, enter the Bolus Amount → **OK** (the acceptable range varies, according to the current VTBI).

Trying to enter one of the unavailable (grayed out) boxes, triggers a message requesting to enter the Bolus amount first.

Enter one of the following parameters, by selecting the relevant box:

- **Rate (Bolus)**: Using the keypad, enter the Bolus Rate → **OK**.
- **Time (Bolus)**: Using the keypad, enter the Bolus Time → **OK**.

The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.

Continue to Step 4.

- **Bolus Amount:** Using the keypad, enter the Bolus Amount → **OK** (the acceptable range varies according to the current VTBI). Then, continue to Step 5.

	When trying to exit programming before its completion, a message is displayed stating that the data entered has not been saved.

	Bolus units used may differ from the units used by the infusion, due to their pre-configuration in the Drug Library.

	When the bolus is programmed by amount only, the default bolus rate is 125 mL/h. This default can be modified using a Technician authorization code. When the infusion rate is higher than 125 mL/h, the bolus rate will be 1 mL/h faster than the infusion rate. During a bolus, some of the parameters can be updated from the Bolus delivery screen. For more information, refer to Updating Bolus Infusion Parameters on page 140.

4. Review the parameters displayed on the Confirm screen.

	Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

5. To start the bolus, from the Attention screen, press **OK**.

The Bolus delivery screen is displayed, and the bolus begins.

Throughout the bolus, the following information is displayed on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Bolus Rate:** Current infusion rate.
- **Bolus VTBI:** Total bolus amount left to be infused. As the bolus progresses, this value decreases.
- **Bolus VI / Total:** Total bolus amount that has been infused during the current infusion / the total bolus amount programmed. As the infusion progresses, the Bolus VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the bolus.

When the bolus is complete, a message appears on the Main Display.

Mid-bolus Actions

The following actions can be performed during bolus delivery:

Updating Bolus Infusion Parameters

Bolus infusion parameters are updated directly from the Bolus delivery screen.

> To update parameters from the Bolus delivery screen:

1. On the Main Display, select the relevant frame (Bolus Rate, Bolus VTBI or Time Left).

> The Time Left parameter is not configurable, when the bolus was programmed by amount only.

2. Using the keypad, enter the new Rate, VTBI or Time left → **OK**.
3. From the Attention screen, press **OK**.
   Updated parameters are displayed.

Pausing a Bolus

When necessary, you can temporarily stop the bolus.

> To pause a bolus:

- From the toolbar of the bolus delivery screen, press **Pause Bolus**. Then, from the Attention screen, press **OK**.
  Alternatively, press the **Stop** hard key.
  All volume delivery stops.

> To resume a paused bolus:

1. From the toolbar of the bolus delivery screen, press **Continue Bolus**.
2. From the Attention screen, press **OK**.

Aborting a Bolus

The following procedures involve pausing and then permanently quitting the bolus, with the option to quit the entire infusion.

> To abort a bolus and quit all infusions:

1. Press the **Stop** hard key. Alternatively, press the **Pause Bolus**, then press **OK**. The bolus is paused.
2. From the toolbar, press **Quit Bolus**.
3. From the toolbar of the Paused screen, press **Quit**.
4. From the Attention screen, press **Quit infusion**.

Resuming infusion after quitting will not be possible.

> To abort a bolus and continue the infusion (Secondary option not in use):

1. Press the **Stop** hard key. Alternatively, press the **Pause Bolus**, then press **OK**. The bolus is paused.
2. From the toolbar, press **Quit Bolus**.
3. From the toolbar of the Paused screen, press **Request Continue**.
4. From the Attention screen, press **OK**.

> To abort a bolus and continue the infusion (Secondary option in use):

1. Press the **Stop** hard key. Alternatively, press the **Pause Bolus**, then press **OK**. The bolus is paused.
2. From the toolbar, press **Quit Bolus**.
3. From the toolbar of the Paused screen, press **Switch or Continue**.
4. From the Start screen, press **Primary** or **Secondary**.
5. From the Attention screen, press **OK**.

Adding a Secondary Line

The following procedure explains how to add a Secondary line while a Primary infusion is already running.

If you have already programmed the Secondary infusion, and want to start it, refer to Switching between Primary and Secondary Infusions on page 146.

Before programming a Secondary infusion, verify that the administration set you are using is appropriate for Secondary (Piggyback) infusions. For more information, refer to Sapphire Approved Administration Sets on page 91.

> To add a Secondary line while a Primary line is running, without Drug Library:

1. From the toolbar, press **View/Edit**.
2. Select **Add Sec. Line**.
3. If the Dosing method screen appears, select the appropriate option:
   - **mL:** Continue to Step 7.
   - **Dose calculation:** Continue to Step 4.

   Weight based units are available for both Dosing methods.

   Otherwise, continue to Step 10.
4. From the Concentration units screen, select the appropriate drug units.

To display additional concentration units press **Next**.

5. According to pump configuration one of the following screens will appear:
   - **Concentration**: From the Concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 7.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 6.
6. From the Attention screen, confirm the concentration and press **OK**.
   If the selected drug unit is Million Units, continue to Step 9.

7. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 8.
   - **No**: Continue to Step 9.
8. From the Patient Weight screen:

   If the patient weight was entered during the primary line programming, continue to Step 9.
   If the patient weight was not entered during the primary line programming, using the keypad, enter the Patient Weight → **OK**.
9. From the Dose Rate units screen, select the appropriate dose rate units.
10. Program 2 of the following 3 parameters, by selecting the relevant boxes:
    - **Rate (Secondary):** Using the keypad, enter the value → **OK**.
    - **VTBI (Secondary):** Using the keypad, enter the value → **OK**.
    - **Time (Secondary):** Using the keypad, enter the value → **OK**.

    The third (unprogrammed) parameter is then automatically calculated by the pump and displayed in the relevant box.

If the calculated rate is beyond the pump resolution (0.1 mL/h increments), the pump decreases the rate by 0.1mL/h during the infusion in order to achieve accurate delivery of the volume in the specified time. the rate reduction is always of 0.1mL/h and presented on the running screen (when selecting dose calculation, the equivalent change to 0.1mL/h applies).

11. Review the parameters displayed on the Confirm screen.

Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

12. From the Start screen, select one of the following:
    - **Start secondary:** The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins. When the Secondary infusion is complete, the pump automatically continues with the Primary infusion.
    - **Continue primary:** The Primary screen appears, and the Primary infusion begins.
      For more information about switching from one infusion to the other, refer to Switching between Primary and Secondary Infusions on page 146.

> To add a Secondary line while a Primary line is running, with a Drug Library:

1. From the toolbar, press **View/Edit**.
2. Select **Add Sec. Line**.
3. From the Drug Name screen:
    - Using the keypad, enter the drug name, then press **Find** and proceed to Step 4.

The **Find** key can be used to display all available drugs when not entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

    - When the required drug is not found in the Drug Library, press the **Choose General** key on the toolbar:

'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm choosing General and press **OK**.
Proceed to Step 3 on page 142 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

4. From the Drug List screen, select the row of the relevant drug.

To display additional drugs press **Next**.

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 7 on page 143 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 7 on page 143 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
   - **Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen/s of the missing value/s will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

     From the Attention screen, confirm the concentration and press **OK**.

     Proceed to Step 7 on page 143 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.
   - **Full concentration**:

     Proceed to Step 7 on page 143 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

   If a list of available drug profiles does not appear, continue to Step 7 on page 143 (To add a Secondary line while a Primary line is running, without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

Switching between Primary and Secondary Infusions

Switching between infusions involves pausing the infusion that is currently running, and then starting or continuing the other infusion.

> To switch from the Primary to the Secondary infusion:

1. Pause the Primary infusion:
   From the toolbar of the Primary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
   Alternatively, press the **Stop** hard key.
2. From the toolbar of the Primary screen, select **Switch or Continue**.
3. From the Start screen, select **Start secondary**.
   The Attention screen appears. After verifying that the clamps on the Secondary administration set are open, press **OK**. The Secondary screen appears, and the Secondary infusion begins.

> To switch from the Secondary to the Primary infusion:

1. Pause the Secondary infusion:
   From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
   Alternatively, press the **Stop** hard key.
2. From the toolbar of the Secondary screen, select **Switch or Continue**.
3. From the Start screen, select **Continue primary (or Start primary)**.
   The Attention screen appears. After verifying that the clamps on the Secondary administration set are closed, and that the clamps on the primary set are open, press **OK**. The Primary screen appears, and the Primary infusion begins.

Replacing the Current Secondary Line

During a running secondary infusion, the secondary line can be replaced by using one of the following methods:

Deleting the Current Secondary Line and Moving to the Primary Infusion

The following procedure explains how to delete the running secondary line and move to the primary infusion.

> To delete the secondary line and move to the primary infusion:

1. Pause the Secondary infusion:
   From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
   Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Delete and move to primary**.
5. The Attention screen appears. After verifying that the clamps on the Secondary administration set are closed, and that the clamps on the primary set are open, press **OK**. This will delete the current programmed secondary line.
   The paused Primary screen appears.
6. From the toolbar of the paused Primary screen, select **Request Continue**.
   Then, from the Attention screen, press **OK**.

If you want to program a new Secondary line, refer to Adding a Secondary Line on page 142.

Replacing the Current Secondary Line with a New Secondary Line

The following procedure explains how to replace the current secondary line with a different secondary infusion.

Before programming a Secondary infusion, verify that the administration set you are using is appropriate for Secondary (Piggyback) infusions. For more information, refer to Sapphire Approved Administration Sets on page 91.

> To replace the running secondary line with a different secondary line without Drug Library:

1. Pause the Secondary infusion:
   From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
   Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Replace secondary**.
5. From the Attention screen press **OK** to delete the current secondary line and to program a different secondary infusion.
6. Proceed to Step 3 on page 142 (To add a Secondary line while a Primary line is running, without Drug Library).

> To replace the running secondary line with a different secondary line with Drug Library:

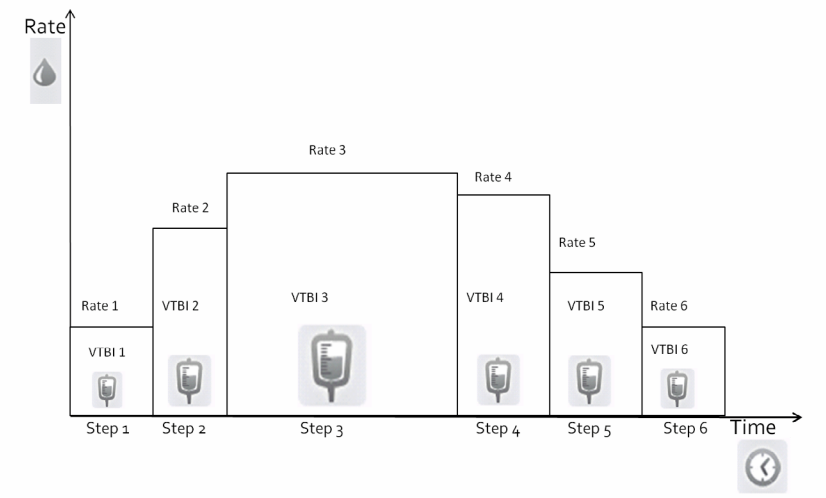
1. Pause the Secondary infusion:
   From the toolbar of the Secondary screen, press **Request Pause**. Then, from the Attention screen, press **OK**.
   Alternatively, press the **Stop** hard key.
2. From the toolbar of the paused screen, press **View/Edit**.
3. On the View/Edit screen, select **Delete/Replace Sec. Line**.
4. On the Delete/Replace screen, select **Replace secondary**.
5. From the Attention screen press **OK** to delete the current secondary line and to program a different secondary infusion.
6. Proceed to Step 3 on page 144 (To add a Secondary line while a Primary line is running, with a Drug Library).

Multi-step Mode

The following sections will be reviewed:

This mode allows the pump to deliver a series of up to 25 consecutive infusion Steps from the same infusion container. Each Step is delivered as a Continuous infusion, at its own pre-programmed parameters. Although the infusion rates of each Step can differ, the rate within a single Step does not vary (constant, continuous infusion).

Figure 5.3. Multi-step Flow Profile



Infusion Parameters: Multi-step Mode

When programming a Multi-step infusion, the number of Steps must be specified. Infusion parameters relevant to each Step are listed in the following table. During programming, it is necessary to specify two of the three parameters. The remaining parameter is then automatically calculated by the pump.

Parameter	Description/Notes
Rate	The speed at which the fluid is infused. Rate values can range from 0.1 to 999 mL/h. **Note:** When selecting units that are not from the mL/h family, the word **Rate** is replaced with **Dose Rate**.
VTBI	The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL.
Time	The period of time over which the fluid is infused. The acceptable range for time values vary according to the VTBI. The maximum Step time is 24 hours.

Starting a Multi-step Infusion

The following procedure explains how to program the pump to start a new Multi-step infusion.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new Multi-step infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in Multi-step mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the Start Up screen, select **New Infusion**.

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. If the Dosing method screen appears, select the appropriate option:
   - **mL:** Continue to Step 8.
   - **Dose calculation:** Continue to Step 5.

   Weight based units are available for both Dosing methods.

   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

> To display additional concentration units press **Next**.

6. According to pump configuration one of the following screens will appear:
   - **Concentration**: From the Concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 8.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 7.
7. From the Attention screen, confirm the concentration and press **OK**.

   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen, using the keypad, enter the Patient Weight → **OK**.
10. From the Dose Rate units screen, select the appropriate dose rate units.
11. Using the keypad, enter the number of Steps required for the infusion, and then press **OK**.
12. For the first Step, program 2 of the following 3 parameters, by selecting the relevant boxes (the digit refers to the number of the Step):
    - **Rate 1:** Using the keypad, enter the value → **OK**.

- **VTBI 1:** Using the keypad, enter the value → **OK**.
- **Time 1:** Using the keypad, enter the value → **OK**.

The unprogrammed parameter is then automatically calculated by the pump, and displayed in the relevant box.

13. After reviewing the infusion parameters for the current Step (as displayed on the Indicators Bar), press **OK** to proceed and program the next Step.
14. To program parameters for the remaining Steps of the infusion, repeat Step 12 through Step 13 of this procedure.

    After the final Step is programmed, the Confirm screen appears, displaying the following parameters:
    - **Total VTBI:** Amount of fluid to be delivered during the entire infusion.
    - **Total time:** Time period of the entire infusion.
    - **Number of steps:** Number of Steps making up the total infusion.
    - **Review Steps details:** Selecting this option displays the parameters of all programmed Steps, screen by screen (with each step displayed in its own screen).
15. Review the parameters displayed on the Confirm screen.

Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

16. Make sure that the clamps on the administration set are open; then, press **Start**.

    The Running screen is displayed, and the infusion begins.

Throughout the infusion, the current Step number is displayed on the Indicators Bar (e.g., Running 1/6) and next to parameter on main display (Rate 1,VTBI 1 and Time 1). The transition between steps is accompanied by a beep. In addition, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, instead of the step number, when working with a Drug Library.

- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View System menu and in the Running screen.
- **VTBI:** Total volume left to be infused during the current Step.
- **VI / Total:** Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the total VTBI (for the entire infusion). As the infusion progresses, the VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the entire infusion.
- **Step Time:** Time remaining until the end of the current Step.

To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**.
For more information, refer to Viewing System Parameters on page 238.

> To begin a new Multi-step infusion with a Drug Library:

1. From the Indicators Bar, verify that the pump is in Multi-step delivery mode.

For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the Start Up screen, select **New Infusion**.
3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. From the Drug Name screen:

- Using the keypad, enter the drug name, then press **Find** and proceed to Step 5.

The **Find** key can be used to display all available drugs when not entering any characters (letters, numbers or symbols), or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:

'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm Choosing General, and press **OK**.
Proceed to Step 4 on page 152 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

5. From the Drug List screen, select the row of the relevant drug.

To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 152 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g., 10 mL): proceed to Step 8 on page 152 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.
   - **Partial concentration**: the Drug Amount and/or Diluent Volume are/is missing. The screen for the missing value will appear:
     - From the Drug Amount screen, using the keypad, enter the Drug Amount → **OK**.
     - From the Diluent Volume screen, using the keypad, enter the Diluent Volume → **OK**.

   From the Attention screen, confirm the concentration and press **OK**.

Proceed to Step 8 on page 152 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

- **Full concentration**:

  Proceed to Step 8 on page 152 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 8 on page 152 (To begin a new Multi-step infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

Multi-step Mode: Mid-infusion Actions

The following actions can be performed during Multi-step infusions:

Updating Step Parameters

Infusion parameters for the current Step can be modified directly from the Running screen. In addition, infusion parameters for the current Step and the following Step can be updated by using the **View/Edit** function key.

	Parameters for only the current Step and the Step immediately following it can be modified.

	If the step being updated ends before the change is made or confirmed, the change will not be made and an Attention screen will appear.

> To update current Step parameters from the Running screen:

1. Select the frame of the parameter that you want to update (Rate, VTBI or Step Time).
2. Using the keypad, enter the new rate, VTBI (during the Step), or time remaining until the end of the Step → **OK**.
3. To confirm and save changes, press **OK**.
   To return to the original infusion screen without saving changes, press **Back**.

> To update parameters of the current or next Step using the View/Edit function key:

1. From the toolbar, press **View/Edit**.
2. Select the box of the relevant parameter.
3. Using the keypad, enter the new value of the parameter → **OK**.
4. To update other parameters, repeat Steps 2-3.

   In addition to parameter changes, the following actions are also available:
   - **Clear Accum. VI:** Resets the total volume infused via all infusions associated with the current patient to 0 mL. For more information, refer to Clearing Accumulated VI on page 259.
   - **Next step:** Allows you to update infusion parameters of the Step following the current Step. (This box appears only if there is a Step following the current Step.)
   - **View system:** Displays various system and pump parameters.
5. To confirm and save changes, press **OK**.

   To return to the Running screen without saving changes, press **Back**. Then, from the Attention screen, press **OK**.

If the dose rate is beyond the pump resolution of 0.1 mL/h increments, the pump will increase or decrease the rate by up to 0.05 mL/h. This flow rate (mL/h) is presented on the Running screen during infusion.

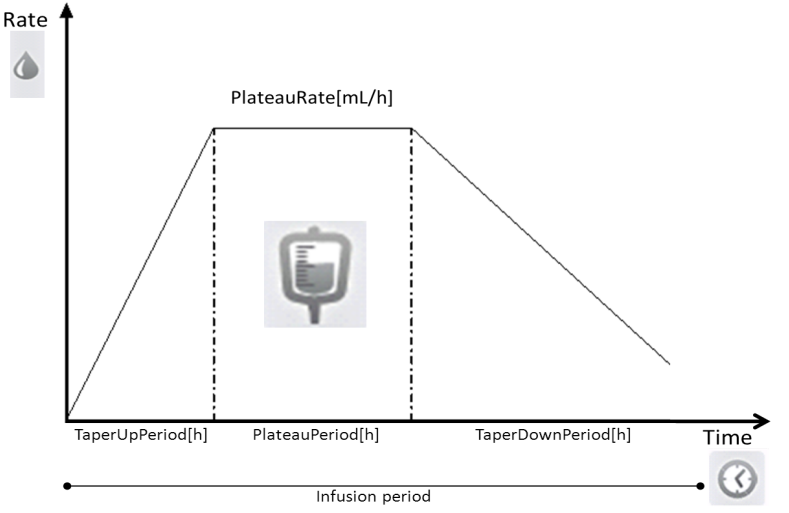
Total Parenteral Nutrition (TPN) Mode

The following sections will be reviewed:

Total Parenteral Nutrition, also known as Parenteral Nutrition or hyperalimentation, is used for patients who are unable to obtain adequate nutrients by oral or enteral routes. TPN solutions supply basic nutrients, including fluids, proteins, carbohydrates, electrolytes, fatty acids, vitamins, minerals, and trace elements directly to the patient's blood stream, bypassing the GI tract.

The TPN delivery mode permits high volume delivery of solutions, with optional tapering (ramping). When tapering is used, delivery rate is gradually increased/decreased (tapered-up/tapered-down) at the beginning and end of the infusion profile.

Figure 5.4. TPN Flow Profile



When not using tapers, the TPN infusion starts and ends at the Plateau Rate. In such cases, the Continuous delivery mode can be applied and is recommended.

Infusion Parameters: TPN Mode

The infusion parameters that need to be set for a TPN infusion are listed in the following table. Based on the values that are programmed, the pump automatically calculates the rate (and the gradual increase and decrease) necessary to deliver the infusion.

Parameter	Description/Notes
VTBI	The total amount of fluid to be infused. VTBI values can range from 0.1 to 9999 mL (with a tolerance of 0.2 mL). The remaining VTBI is displayed on the screen as the infusion progresses. The pump calculates the Plateau Rate based on the VTBI, the infusion period, and the taper values.
Taper Up	The length of time over which the rate increases to the Plateau Rate. The Taper Up and Down period can be set to 0 minutes, or range from 10 minutes to 3 hours, for each Taper.
Taper Down	The length of time over which the rate decreases to the KVO rate (from the Plateau Rate). The Taper Up and Down period can be set to 0 minutes, or range from 10 minutes to 3 hours, for each Taper.
Infusion Period	The total time duration for delivering the VTBI (including tapers and plateau period). The maximum Infusion Period is 96 hours. The minimum Infusion Period is determined by the sum of the taper periods plus 10 minutes (minimal Infusion Period between tapers).

TPN Mode: Safety Warnings

When working in TPN mode, adhere to the following safety precautions and procedures:

- Use only parenteral feeding solutions prescribed by the responsible doctor, registered dietician, nurse or other licensed medical practitioner.
- Check that the correct dosage has been programmed. While a TPN infusion is running or paused, infusion parameters cannot be changed.

- Prior to administration, verify the identity of the patient by using at least two identifiers, as well as the parenteral nutrition container label.
- The Air in Line detector working range when delivering fatty acids is 2%-20% lipids.

Starting a TPN Infusion

The following procedure explains how to program the pump to start a new TPN infusion.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new TPN infusion:

1. From the Indicators Bar, verify that the pump is in TPN mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the **Start Up** screen, select **New Infusion**.
3. If a warning that air detection is set to Off appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. Using the keypad, enter the **VTBI** value → **OK**.
5. Specify whether you want to use tapers: Select **Yes** or **No**.

   If you select **No**, proceed to Step 7.
6. Specify tapers:
   a. On the Taper Up screen, use the keypad to enter the Taper Up time → **OK**. The Taper Up time can be set to 0.
   b. On the Taper Down screen, use the keypad to enter the Taper Down time → **OK**. The Taper Down time can be set to 0.

7. Using the keypad, enter the infusion period → **OK**.
8. Review the parameters displayed on the Confirm screen.

Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

9. To begin the infusion, make sure that the clamps on the administration set are open; then, press **Start**. The infusion begins.

Throughout the infusion, the following information appears on the Main Display:

- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume delivered in the current infusion(including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Time left:** Time remaining until the end of the infusion.

All the parameters of the current infusion can be viewed from **View system → Infusion Values**.

TPN Mode: Mid-infusion Actions

The following actions can be performed during TPN infusions:

In TPN mode, infusion parameters cannot be updated using the **View/Edit** function key. To modify the parameters, you need to quit the infusion, and reprogram a new infusion.

The **View/Edit** function key can be used to perform the following actions only:

- **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
- **View system:** Displays various system and pump parameters. (Refer to View Menu on page 237.)

Pausing Infusions

The Pause function allows you to temporarily stop an infusion. Infusions can be paused using either the **Request Pause** function key, or, in an emergency, the **Stop** hard key. A message stating that the infusion is paused appears 30 seconds after pausing the infusion (audible and visual).

	Pressing the **Stop** hard key stops the infusion immediately, bypassing the need for confirmation of the Pause action. In an emergency, it is recommended to pause the infusion using the **Stop** hard key. In routine situations, using the **Request Pause** function key is recommended.

	During the plateau rate of a TPN infusion, the **Request Pause** function key is replaced with the **Taper down** key. Pausing the infusion remains available using the Taper down key (for more information, refer to Immediate Taper Down on page 165).

> To pause an infusion during the plateau rate using the Taper Down function key:

1. From the toolbar, press **Taper Down**.

> If the pump is set to a Low authorization level, with no Taper Down period programmed, the **Request Pause** key will be available, without the option to **Taper Down**.

2. From the Pause Options screen, select **Pause Infusion**; then, press **OK**.
3. The infusion is paused.

> If you do not press **OK** within 30 seconds, the infusion is not paused, and the Running screen reappears.

> To pause an infusion during taper using the Request Pause function key:

1. From the toolbar, press **Request Pause**.
2. From the toolbar of the Attention screen, press **OK**.
3. The infusion is paused.

   If the pump is set to the Low authorization level, with no Taper Down period programmed, the Request Pause key will be available, without the option to Taper down.

> If you do not press **OK** within 30 seconds, the infusion is not paused, and the Running screen reappears.

> To resume a paused infusion:

1. From the toolbar, press **Request Continue.**
2. From the toolbar of the Attention screen, press **OK**.

Immediate Taper Down

Immediate Taper Down can be used to end the infusion prematurely, utilizing taper down, to slow the infusion rate gradually before stopping. The option is available during the infusion's plateau period, provided there are more than 10 minutes before the infusion is complete. The taper down period is set to the time programmed originally for the infusion, and it can be modified when the pump is set to a Medium or higher authorization level.

Immediate Taper Down is available only in the following conditions:

- The pump is running.
- The pump is delivering at the plateau rate.
- The time left for the infusion is greater than 10 minutes.
- The pump is set to Medium or higher authorization level, in case no Taper period is programmed.

> To immediately Taper Down an infusion:

1. From the toolbar, press **Taper Down**.
2. From the Taper Down screen select **Immediate Taper Down**.

	If the pump is set to Low authorization level, the user will be prompted to acknowledge the preprogrammed Taper Down time value (skip step 3) without the ability to change it.

	When using the immediate Taper option, the original values programmed for the infusion will be presented in the Infusion Values menu.

3. From the Immediate Taper Down screen, accept the preprogrammed time settings, or enter the Taper Down time using the keypad → **OK**.

	Entering 00:00 hh:mm to Taper Down time frame will stop the infusion without tapering.

4. From the Attention screen, press **OK** to begin the Taper Down.

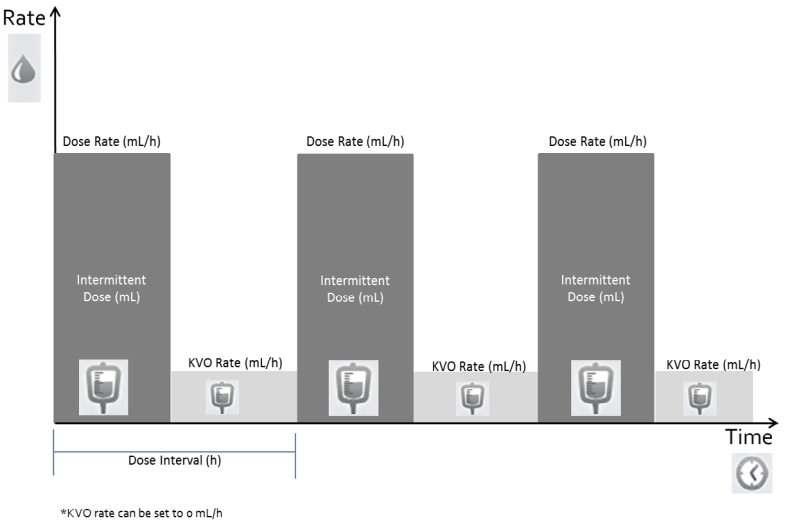
   The Taper Down running screen appears.

Intermittent Mode

The following sections will be reviewed:

This mode enables you to program a dose time and volume infusion to be repeated at regular intervals or cycles. The Dose Interval is the time frequency at which the dose is delivered. A KVO rate can be programmed to run between intermittent dose.

Figure 5.5. Intermittent Flow Profile



Infusion Parameters: Intermittent Mode

The following infusion parameters need to be set for an Intermittent infusion:

Parameter	Description/Notes
VTBI	The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL.
Intermittent Dose	The amount of each Intermittent Dose. Values can range from 0.1 to 999 mL.
Dose Time	The period of time over which the intermittent dose is delivered. Values can range from 00:01 to 96:00 hh:mm.
Dose Interval	The frequency of intermittent dose delivery (Intermittent Dose + KVO). Intermittent doses can be given as frequently as 5 minutes apart. Therefore, the minimum programmable Dose Interval is the Dose time plus 5 minutes. This rule applies even when the KVO rate is set to 0.
KVO (Keep Vein Open)	The rate of fluids delivered between doses, to prevent clotting in the infusion cannula. The KVO rate can be set from 0 to 20 mL/h.

Starting an Intermittent Infusion

The following procedure explains how to program the pump to start a new Intermittent infusion.

If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new Intermittent infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in Intermittent mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the **Start Up** screen, select **New Infusion**.
3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. If **Dosing method** screen appears, select the appropriate option:
   - **mL:** Continue to Step 8.
   - **Dose calculation:** Continue to Step 5.

   Weight based units are available for both Dosing methods

   Otherwise, continue to Step 11.
5. From the **Concentration units** screen, select the appropriate drug units.

> To display additional concentration units press **Next**.

6. According to pump configuration one of the following screens will appear:
   - **Concentration**: From concentration screen, using the keypad, enter the **Concentration** → **OK**. Then, continue to Step 8.
   - **Drug amount**: Using the keypad, enter the **Drug Amount** → **OK**. Then, using the keypad, enter the **Diluent Volume** → **OK**. Then, continue to Step 7.
7. From the Attention screen, confirm the concentration and press **OK**.

   If the selected drug unit is Million Units, continue to Step 10.
8. If the **Patient Weight** screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.

9. From the **Patient Weight** screen, using the keypad, enter the patient weight → **OK**.
10. From the **Dose Rate units** screen, select the appropriate dose rate units.
11. Using the keypad, enter the **VTBI** value → **OK**.
12. Using the keypad, enter the **Intermittent Dose** → **OK**.
13. Using the keypad, enter the **Dose Time** → **OK**.
14. Using the keypad, enter the **Dose Interval** → **OK**.
15. Using the keypad, enter the **KVO** rate → **OK**.

    The KVO rate may be set to zero.
16. Review the parameters displayed on the Confirm screen.

Verify that the parameters reflect the correct treatment according to the prescription.

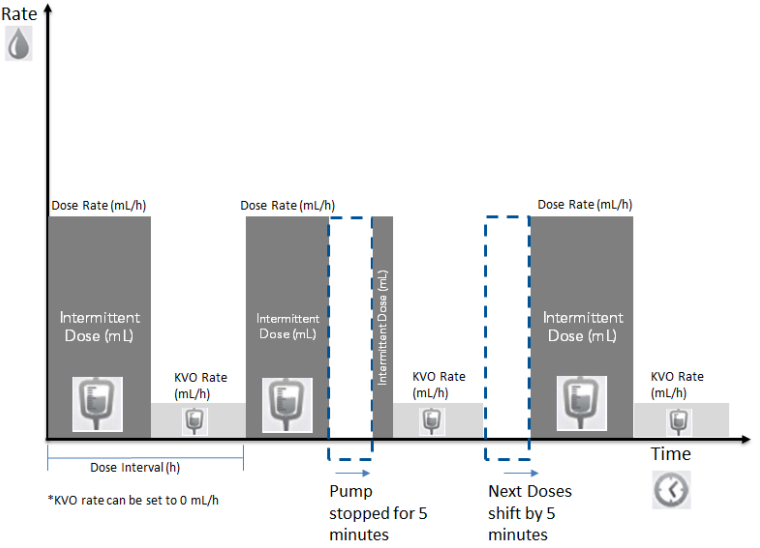
    Then, press **OK**.
17. To begin the infusion, make sure that the clamps on the administration set are open; then, press **Start**.

    The Intermittent Dose screen is displayed, and the infusion begins with the first dose.

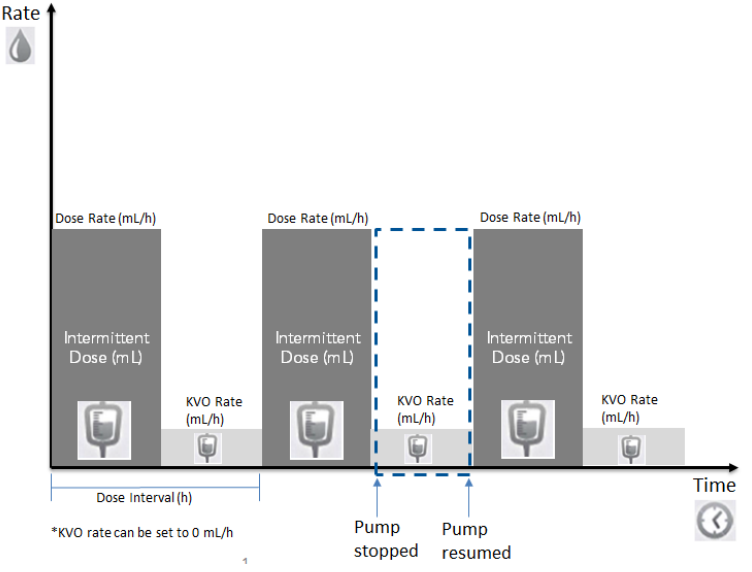
Throughout the infusion, the infusion phase (Intermittent Dose or KVO) is displayed on the Indicators Bar. In addition, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused. As the infusion progresses, this value decreases.

- **VI / Total:** Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Time to Dose:** Time remaining before the next dose starts (until the end of the current interval; Dose time left + KVO time).
  - **Pause During Dose**
    When the infusion is paused during Dose, the time to the next Intermittent Dose (Time to Dose) is paused and not displayed.



- **Pause During KVO**
  The pump can be switched off or paused between intermittent doses without impacting the dose schedule. The time to dose will be displayed, and the pump will also alert when dose schedule is due and infusion not started, reminding the user to resume the infusion.
  When the infusion is paused during KVO, the time to the next Intermittent Dose (Time to Dose) is displayed, and continues to count down.



- **Time left:** Time remaining until the end of the entire infusion.

To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**.
For more information, refer to Viewing System Parameters on page 238.

> To begin a new Intermittent infusion with a Drug Library:

1. From the Indicators Bar, verify that the pump is in Intermittent mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the **Start Up** screen, select **New Infusion**.
3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. From the **Drug Name** screen:
   - Using the keypad, enter the drug name, then press **Find** and proceed to Step 5.

> The **Find** key can be used to display all available drugs when not entering any characters (letters, numbers or symbols) or filter drug names according to the characters entered.

   - When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:

> 'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

   From the Attention screen, confirm Choosing General and press **OK**.
   Proceed to Step 4 on page 168 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
5. From the **Drug List** screen, select the row of the relevant drug.

> To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the Appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 168 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g. 10 mL): proceed to Step 8 on page 168 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
   - **Partial concentration**: the Drug Amount or Diluent Volume is missing. A screen for the missing value will appear:
     - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
     - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

     From the Attention screen, confirm the concentration and press **OK**.

     Proceed to Step 8 on page 168 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.
   - **Full concentration**:
     Proceed to Step 8 on page 168 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.

   If a list of available drug profiles does not appear, continue to Step 8 on page 168 (To begin a new Intermittent infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

Intermittent Mode: Mid-infusion Actions

The following actions can be performed during Intermittent infusions:

Updating Infusion Parameters

Infusion parameters can be modified by using the **View/Edit** function key. In addition, the VTBI for the current phase (Intermittent Dose or KVO) can be modified directly from the Main Display.

> To update parameters of the current phase from the Main Display:

1. On the Main Display, select the **VTBI** relevant frame.
2. Using the keypad, enter the new VTBI → **OK**.
3. Review the parameter displayed on the Attention screen → **OK**.

   To return to the original infusion screen without saving changes, press **Back**. Then, from the VTBI screen, press **Back**

> To update parameters using the View/Edit function key:

1. From the toolbar, press **View/Edit**.
2. Select the box of the parameter to be modified.
3. Using the keypad, enter the new value of the parameter → **OK**.

When changing Intermittent Dose or Dose Time, you will be prompted to enter the Dose interval.

4. To update additional parameters, repeat Steps 2-3.

   In addition to parameter changes, the following actions are also available:
   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 237.)

5. To confirm and save changes, press **OK**.

   To return to the original infusion screen without saving changes, press **Back**. Then, from the Attention screen, press **OK**.

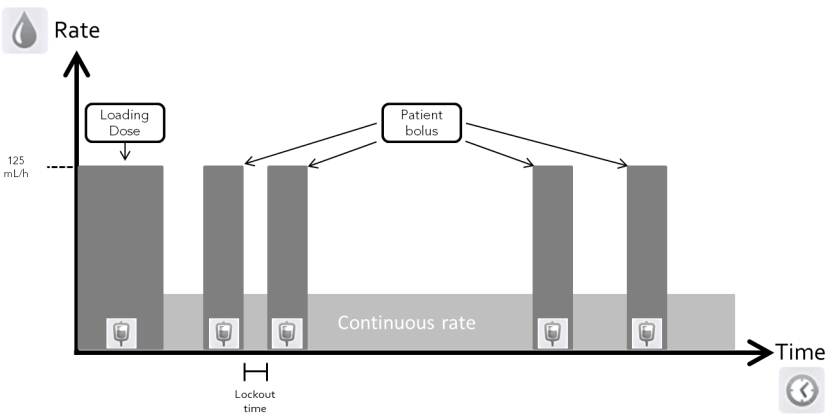
Patient Controlled Analgesia (PCA) Mode

The following sections will be reviewed:

The Patient Controlled Analgesia (PCA) mode allows the pump to deliver medication through the intravascular, subcutaneous, or perineural routes continuously, and or with boluses activated by the patient using the bolus handle or the on-screen key. Additional boluses can be administered by a clinician, using the appropriate authorization code. The administration route and infusion parameters are determined by the clinician, based on the needs of the patient.

For more information about the bolus handle, refer to PCA/PCEA/PIEB Bolus Handle on page 53.

Figure 5.6. PCA Flow Profile



Infusion Parameters: PCA Mode

The following infusion parameters need to be set for a PCA infusion:

Parameter	Description/Notes
Continuous Rate	The rate of the basal infusion. Continuous Rate values can range from 0.1 to 99.9 mL/h, or be equal to zero (Bolus Only infusion).
VTBI	The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL.
Demand Bolus	The amount of fluid infused in a single bolus. Demand bolus values can range from 0.1 to 30 mL, or be equal to zero (Continuous Only infusion).
Bolus Lockout	The minimum time that must pass between the end of one bolus to the start of the next bolus. After a bolus delivery ends, the next bolus becomes available following the lockout time.
Dose Limit	The option to choose if patient boluses are limited by number or by volume. When choosing No Limits, the patient boluses are set to the maximum allowed volume, according to the other parameters defined for the infusion, including lockout time and demand bolus.

Parameter	Description/Notes
Boluses per 1h (or 4hrs) OR Total dose per 1h (or 4 hrs)	The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (Auser with High authorization codes can set the 1 hour or 4 hours parameters.) The Total dose limit takes into account medication delivered via: Continuous rate Yes Demand Bolus Yes Loading Dose Yes Clinician bolus Yes All doses, including boluses given by clinician, are taken into account. When the Total dose limit is reached, the patient is locked out from activating additional boluses.
Loading Dose	An optional feature that begins the infusion with a clinician bolus. Loading dose values range from 0.1 to 30 mL. To use this feature, it must be enabled. For more information, refer to PCA Options Menu on page 244.

Starting a PCA Infusion

The following procedure explains how to program the pump to start a new PCA infusion.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new PCA infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in PCA mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the Start Up screen, select **New Infusion**.

3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. If the Dosing method screen appears, select the appropriate option:
   - **mL:** Continue to Step 8.
   - **Dose calculation:** Continue to Step 5.

   Weight based units are available for both Dosing methods.
   Otherwise, continue to Step 11.
5. From the Concentration units screen, select the appropriate drug units.

> To display additional concentration units press **Next**.

6. According to pump configuration one of the following screens will appear:
   - **Concentration**: From concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 8.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 7.
7. From the Attention screen, confirm the concentration and press **OK**.
   If the selected drug unit is Million Units, continue to Step 10.
8. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 9.
   - **No**: Continue to Step 10.
9. From the Patient Weight screen, using the keypad, enter the patient weight → **OK**
10. From the Dose Rate units screen, select the appropriate dose rate units.
11. Using the keypad, enter the VTBI value → **OK**.
12. Using the keypad, enter the Continuous Rate value → **OK**.
    The Continuous Rate can be set to zero.
13. Using the keypad, enter the value for the Demand Bolus → **OK**.
14. Using the keypad, enter the value for the Bolus Lockout → **OK**.

15. From the Dose Limit Type screen, specify whether the boluses available for the patient should be limited:
    - **Yes**: Continue to Step 16.
    - **No**: Continue to Step 17.

> Choosing **No** on the Dose limit screen will set patient boluses to the maximum allowed, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus.

16. From the Dose Limit Type screen, select the type of limit to apply for the infusion, and proceed to the directed step:
    - **Number of Boluses**: Using the keypad, enter the maximum number of boluses that will be available for the patient within a one or four-hour period →**OK**. Continue to Step 17.
    - **Total Dose**: Using the keypad, enter the maximum amount of medication that may be delivered within a one or four-hour period →**OK**. Continue to Step 17.
17. If Add Loading Dose screen appears, specify whether to program a loading dose:
    - **Yes:** Using the keypad, enter the value for the Loading Dose → **OK**.
    - **No:** Proceed to Step 18.

    Otherwise, continue to Step 18.
18. Review the parameters displayed on the Confirm screen.

> Verify that the parameters reflect the correct treatment according to the prescription.

    Then, press **OK**.
19. To begin the infusion, make sure that the clamps on the administration set are open; then, press **Start**.

    The Running screen appears, and the infusion begins.

Throughout the infusion, the infusion phase (Loading Dose, Running, Bolus Delivery, or Clinician Bolus) is displayed on the Indicators Bar.
In addition, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h; both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Lockout time:** Time remaining until the next bolus is available. After the lockout time elapses, this parameter changes to Bolus available (when a bolus is being given – loading dose, clinician bolus or patient bolus – this parameter does not appear).
- **Time left:** The maximum time remaining until the end of the entire infusion. If boluses are given, this time will be shortened.

To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**.
For more information, refer to Viewing System Parameters on page 238.

> To begin a new PCA infusion with a Drug Library:

1. From the Indicators Bar, verify that the pump is in PCA mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the **Start Up** screen, select **New Infusion**.
3. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
4. From the **Drug Name** screen:
   - Using the keypad, enter the drug name, then press **Find** and proceed to Step 5.

> The **Find** key can be used to display all available drugs without entering any characters (letters, numbers or symbols) or filter drug names according to the characters entered.

   - When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:

> 'Choose General' will bypass drug specific limits, the infusion will be programmed outside of the safe Drug Library environment.

   From the Attention screen, confirm Choosing General and press **OK**.
   Proceed to Step 4 on page 179 (To begin a new PCA infusion without Drug Library), and continue programming from there.
5. From the **Drug List** screen, select the row of the relevant drug.

> To display additional drugs press **Next**.

6. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 8 on page 179 (To begin a new PCA infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g. 10 mL): proceed to Step 8 on page 179 (To begin a new PCA infusion without Drug Library), and continue programming from there.
   - **Partial concentration**: the Drug Amount or Diluent Volume is missing. A screen for the missing value will appear:
     - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
     - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

     From the Attention screen, confirm the concentration and press **OK**.

     Proceed to Step 8 on page 179 (To begin a new PCA infusion without Drug Library), and continue programming from there.
   - **Full concentration**:

     Proceed to Step 8 on page 179 (To begin a new PCA infusion without Drug Library), and continue programming from there.

   If a list of available drug profiles does not appear, continue to Step 8 on page 179 (To begin a new PCA infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

PCA Mode: Mid-infusion Actions

The following actions can be performed during PCA infusions:

Updating Infusion Parameters

In PCA mode, the infusion must be paused before parameters can be updated. After the infusion is paused, infusion parameters can be modified by using the **View/Edit** function key. In addition, the Continuous Rate and VTBI for the current infusion phase can be updated directly from the Main Display. (During a bolus delivery, no parameter can be changed.)

> To update parameters for the current phase (Basal/Bolus) from the Main Display:

1. Pause the infusion (Pausing Infusions on page 218).
2. On the Main Display, select the relevant frame (**Continuous Rate** or **VTBI)**.
3. Using the keypad, enter the new Continuous Rate or VTBI → **OK**.
4. To confirm and save changes, press **OK**.
   To return to the Paused screen without saving changes, press **Back.** From the Continuous Rate of VTBI screen, press **Back**. Then, from the Attention screen, press **OK**.

> To update parameters using the View/Edit function key:

1. Pause the infusion (Pausing Infusions on page 218).
2. From the toolbar, press **View/Edit**.
3. Select the box of the parameter to be modified.

4. Using the keypad, enter the new value of the parameter → **OK**.

When modifying demand bolus limitations (volume or lockout time), the pump will prompt the user to confirm or adjust the other bolus limitations.

5. To update additional parameters, repeat Steps 3-4.

   In addition to parameter changes, the following functions are also available:
   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 237.)
   - **Delivery history:** Displays a summary of medication delivery events. For more information, refer to Viewing Delivery History on page 242.

6. To confirm and save changes, press **OK**.

   To return to the Paused screen without saving changes, press **Back**. Then, from the Attention screen, press **OK**.

Administering a Clinician Bolus

During PCEA or PIEB infusions, a bolus of any amount (within the predefined range) can be delivered by clinicians who have a High authorization level code. A Clinician Bolus can be given only while the infusion is running. The lockout time is reset after delivering a clinician bolus.

> To administer a clinician bolus:

1. From the toolbar of the Running screen, press **View/Edit**.
2. Select **Clinician bolus**.
3. Using the keypad, enter the appropriate password → **OK**.
4. On the Clinician bolus screen, using the keypad, enter the bolus amount → **OK**.
5. To start the bolus, from the Attention screen, press **OK**.

   The Clinician bolus screen appears, and the bolus begins.

The default clinician bolus infusion rate is 125 mL/h. This default can be modified using a Technician authorization code.

Epidural Mode

This mode enables the pump to deliver epidural infusions. Epidural administration is limited to short term infusions (up to 96 hours), using indwelling catheters specifically identified for epidural drug delivery.

In Epidural delivery mode, the pump can operate in either of the following sub-modes:

- **PCEA (Patient Controlled Epidural Analgesia):** Delivers epidural boluses, either alone or in addition to a basal preset rate. Alternatively, only a basal infusion (without boluses) can be programmed.
- **Intermittent Epidural:** Delivers epidural infusions at intermittent programmed intervals. The Epidural Intermittent mode also enables the addition of PCEA, in order to allow patient boluses throughout the infusion (PIEB).

The features of the Epidural mode are designed to accommodate the special requirements of an epidural infusion, such as lower VTBI, lower infusion rate, and higher backpressure. In Epidural intermittent mode and in PCEA mode, bolus rate can be configured to 125 mL/h or 200 mL/h before starting infusion (for more information, refer to Epidural Mode Options Menu on page 245).

Epidural Mode: Safety Warnings

When working with epidural infusions, adhere to the following safety procedures, guidelines and reminders:

- Before programming, always verify that the pump is in Epidural delivery mode.
- To prevent infusion of drugs not intended/labeled for epidural use, do not use administration sets with injection ports during epidural delivery.
- Use only yellow-marked administration sets for epidural infusions.
- Epidural administration of drugs other than those intended/labeled for epidural use could result in serious injury to the patient.
- Do not infuse non-epidural drugs in Epidural Delivery mode.
- Epidural drugs must be infused in Epidural Delivery mode.

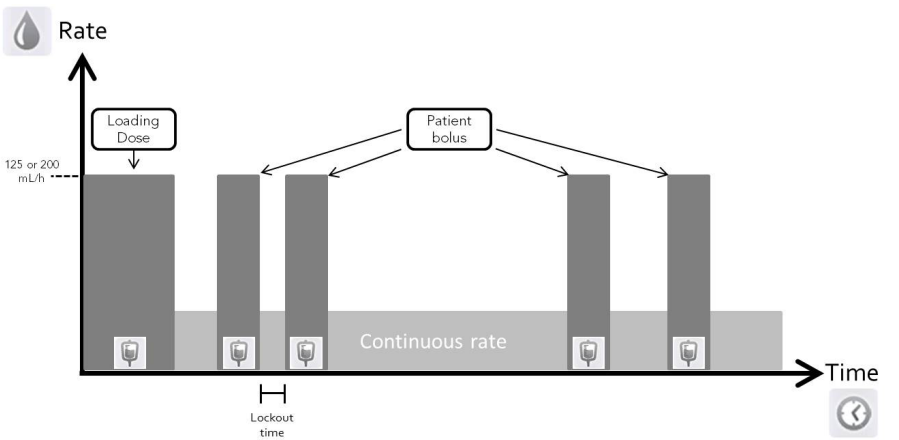
Patient Controlled Epidural Analgesia (PCEA) Mode

The following sections will be reviewed:

The PCEA mode allows the pump to deliver medication at a continuous rate (optional) and limited boluses activated by the patient (via screen key or bolus handle). Additional boluses can be provided by a clinician, using the appropriate authorization code.

For more information about the bolus handle, refer to PCA/PCEA/PIEB Bolus Handle on page 53.

Figure 5.7. PCEA Flow Profile



Infusion Parameters: PCEA Mode

The following infusion parameters need to be set for a PCEA infusion:

Parameter	Description/Notes
Continuous Rate	The speed at which the fluid is infused. Continuous Rate values can range from 0.1 to 25 mL/h, or be equal to zero (Bolus Only infusion).
VTBI	The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL.
Demand Bolus	The amount of fluid infused in a single bolus. Demand bolus values can range from 0.1 to 30 mL, or be equal to zero (Continuous Only infusion).
Bolus Lockout	The minimum time that must pass between the end of one bolus to the start of the next patient bolus. After a bolus delivery ends, the next patient bolus becomes available following the lockout time.
Dose Limit	The option to choose if patient boluses are limited by number or volume. When choosing No Limits, the patient boluses are set to the maximum allowed volume, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus.

Parameter	Description/Notes
Boluses per 1 h (or 4 hrs) OR Total dose per 1 h (or 4 hrs)	The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (Auser with High authorization codes can set the 1 hour or 4 hours parameters.) The Total dose limit takes into account medication delivered via: Continuous rate Yes Demand Bolus Yes Boluses given by a clinician, are not taken into account for the Total dose limit: Loading Dose No Clinician bolus No When the Total dose limit is reached, the patient is locked out from activating additional boluses.
Loading Dose	An optional feature that begins the infusion with a clinician bolus. Loading dose values range from 0.1 to 30 mL. To use this feature, it must be enabled. For more information, refer to Epidural Mode Options Menu on page 245.

The bolus rate applies to all boluses delivered during the infusion, and is configured before programming starts. It can be set to 125 mL/h or 200 mL/h (for more information, refer to Epidural Mode Options Menu on page 245).

Starting a PCEA Infusion

The following procedure explains how to program the pump to start a new PCEA infusion.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new PCEA infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in Epidural mode.

   > For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the Start Up screen, select **New Infusion**.
3. If **Dosing method** screen appears, select the appropriate option:
   - **mL:** Continue to Step 7.
   - **Dose calculation:** Continue to Step 4.

   Weight based units are available for both Dosing methods.
   Otherwise, continue to Step 10.
4. From the **Concentration units** screen, select the appropriate drug units.

   > To display additional concentration units press **Next**.

5. According to pump configuration one of the following screens will appear:
   - **Concentration**: From concentration screen, using the keypad, enter the **Concentration** → **OK**. Then, continue to Step 7.
   - **Drug amount**: Using the keypad, enter the **Drug Amount** → **OK**. Then, using the keypad, enter the **Diluent Volume** → **OK**. Then, continue to Step 6.
6. From the Attention screen, confirm the concentration and press **OK**.

If the selected drug unit is Million Units, continue to Step 9.

7. If the **Patient Weight** screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 8.
   - **No**: Continue to Step 9.
8. If the **Patient Weight** screen appears, using the keypad, enter the patient weight → **OK**.
9. From the **Dose Rate units** screen, select the appropriate dose rate units.
10. Using the keypad, enter the **VTBI** value → **OK**.
11. Using the keypad, enter the **Continuous Rate** value → **OK**.

    The Continuous Rate can be set to zero.
12. Using the keypad, enter the value for the Demand Bolus → **OK**.
13. Using the keypad, enter the value for the Bolus Lockout → **OK**.
14. From the Dose Limit Type screen, specify whether the infusion is according to dose limits:
    - **Yes**: Continue to Step 15.
    - **No**: Continue to Step 16.

Choosing **No** on the Dose limit screen will set patient boluses to the maximum allowed, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus.

15. From the Dose Limit Type screen, select the appropriate Dose Limit type, and proceed to the directed step:
    - **Number of Boluses**: Using the keypad, enter the maximum number of boluses that will be available for the patient within a one or four-hour period →**OK**. Continue to Step 16.
    - **Total Dose**: Using the keypad, enter the maximum amount of medication that may be delivered within a one or four-hour period →**OK**. Continue to Step 16.

16. If **Add Loading Dose** screen appears, specify whether to program a loading dose:
    - **Yes:** Using the keypad, enter the value for the Loading Dose → **OK**.
    - **No:** Proceed to Step 17.

    Otherwise, continue to Step 17.
17. Review the parameters displayed on the Confirm screen.

    Verify that the parameters reflect the correct treatment according to the prescription.

    Then, press **OK**.
18. To begin the infusion, make sure that the clamps on the administration set are open, then, press **Start**.

    The Running screen appears, and the infusion begins.

Throughout the infusion, the current infusion phase (Loading Dose, Running, Bolus Delivery or Clinician Bolus) is displayed on the Indicators Bar.
In addition, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View System menu and in the Running screen.
- **VTBI:** Total volume left to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume that has been infused during the current infusion (including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.

- **Lockout time:** Time remaining until the next bolus is available. After the lockout time elapses, this parameter changes to **Bolus available**.

> When a bolus is being given (loading dose, clinician bolus or patient bolus), this parameter does not appear.

- **Time left:** The maximum time remaining until the end of the entire infusion. If boluses are given, this time will be shortened.

> To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/Edit** → **View system** → **Infusion values**.
> For more information, refer to Viewing System Parameters on page 238.

> To begin a new PCEA infusion with a Drug Library:

1. From the Indicators Bar, verify that the pump is in Epidural mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the **Start Up** screen, select **New Infusion**.
3. From the **Drug Name** screen:
   - Using the keypad, enter the drug name, then press **Find** and proceed to Step 4.

> The **Find** key can be used to display all available drugs without entering any characters (letters, numbers or symbols) or filter drug names according to the characters entered.

- When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:

	'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

From the Attention screen, confirm Choosing General and press **OK**.
Proceed to Step 3 on page 191 (To begin a new PCEA infusion without Drug Library), and continue programming from there.

4. From the **Drug List** screen, select the row of the relevant drug.

	To display additional drugs press **Next**.

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:
   - **No concentration**: proceed to Step 7 on page 192 (To begin a new PCEA infusion without Drug Library), and continue programming from there.
   - **Diluent only** (e.g. 10 mL): proceed to Step 7 on page 192 (To begin a new PCEA infusion without Drug Library), and continue programming from there.
   - **Partial concentration**: the Drug Amount or Diluent Volume is missing. A screen for the missing value will appear:
     - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
     - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

     From the Attention screen, confirm the concentration and press **OK**.

     Proceed to Step 7 on page 192 (To begin a new PCEA infusion without Drug Library), and continue programming from there
   - **Full concentration**:

     Proceed to Step 7 on page 192 (To begin a new PCEA infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 7 on page 192 (To begin a new PCEA infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

PCEA Mode: Mid-infusion Actions

The following actions can be performed during PCEA infusions:

Updating Infusion Parameters

In PCEA mode, the infusion must be paused before any parameter can be updated. Once the infusion is paused, infusion parameters can be modified by using the **View/Edit** function key. In addition, the continuous rate and VTBI for the current infusion phase can be modified directly from the Main Display. (During a bolus delivery, no parameters can be changed.)

> To update parameters for the current phase (Basal/Bolus) from the Main Display:

1. Pause the infusion (Pausing Infusions on page 218).
2. On the Main Display, select the relevant frame (**Continuous Rate** or **VTBI)**.
3. Using the keypad, enter the new Continuous Rate or VTBI → **OK**.
4. To confirm and save changes, press **OK**.
   To return to the Paused screen without saving changes, press **Back**. From the Continuous Rate of VTBI screen, press **Back**. Then, from the Attention screen, press **OK**.

> To update parameters using the View/Edit function key:

1. Pause the infusion (Pausing Infusions on page 218).
2. From the toolbar, press **View/Edit**.
3. Select the box of the parameter to be modified.
4. Using the keypad, enter the new value of the parameter → **OK**.

> When modifying demand bolus limitations (volume or lockout time), the pump will prompt you to confirm or adjust the other bolus limitations.

5. To update additional parameters, repeat Steps 3-4.

   In addition to parameter changes, the following functions are also available:
   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 237.)
   - **Delivery history:** Displays a summary of medication delivery events. For more information, refer to Viewing Delivery History on page 242.
6. To confirm and save changes, press **OK**.

   To return to the Paused screen without saving changes, press **Back**. Then, from the Attention screen, press **OK**.

Administering a Clinician Bolus

A bolus of any amount (within the predefined safe range) can be delivered by clinicians who have High authorization level code. A clinician bolus can be given only while the infusion is running. The lockout time is reset after delivering a clinician bolus.

> To administer a clinician bolus:

1. From the toolbar of the Running screen, press **View/Edit**.
2. Select **Clinician bolus**.
3. Using the keypad, enter the appropriate password → **OK**.
4. Using the keypad, enter the bolus amount → **OK**.
5. To start the bolus, from the Attention screen, press **OK**.

   The Clinician bolus screen appears, and the bolus begins.

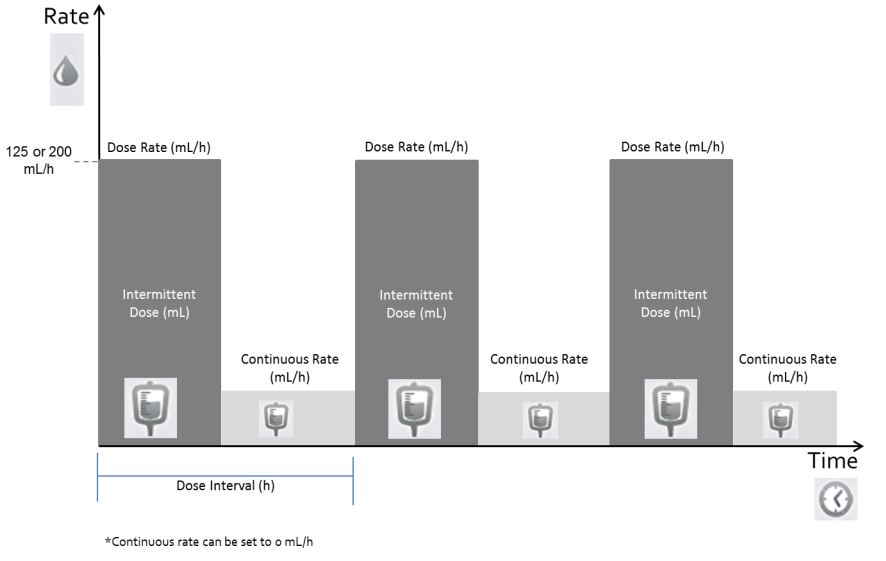
The rate of all boluses during PCEA is defined prior to programming the infusion. It can be set to 125 mL/h or 200 mL/h (for more information, refer to Epidural Mode Options Menu on page 245)

Epidural Intermittent Mode

The following sections will be reviewed:

This mode enables you to program epidural doses (boluses) that are given at a rate of 125 mL/h or 200 mL/h, and are repeated at regular intervals or cycles. The dose interval is the frequency at which the intermittent dose is delivered. A continuous rate can be programmed to run between intermittent doses.

Figure 5.8. Epidural Intermittent Flow Profile

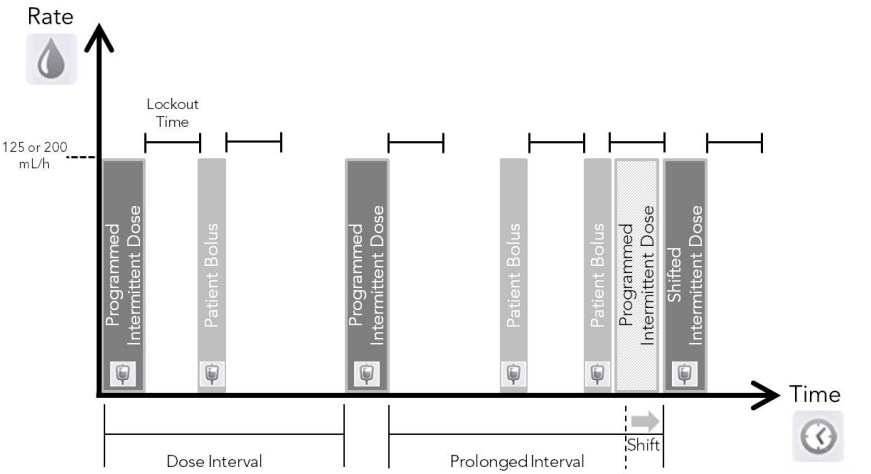


The Sapphire pump can also be configured to support PIEB (Programmed Intermittent Epidural Boluses). When enabled, the option to add PCEA is available on the Start screen. Note that in any case, an Epidural Intermittent infusion will start with an intermittent dose.

The patient will be able to activate a Patient Bolus between intermittent doses, except during the Lockout Time period immediately after an intermittent dose, or any other bolus. If the time remaining from the Patient Bolus to the next scheduled intermittent dose is shorter than the Lockout Time, the next intermittent dose will be delayed to accommodate the Lockout Time.

Unlike the Patient Bolus, the clinician will be able to administer a Clinician Bolus within the Lockout Time immediately after the intermittent dose.

Figure 5.9. Epidural Intermittent with PCEA Flow Profile



To use the PIEB option, the option must be enabled (requires high authorization code). Refer to Epidural Mode Options Menu on page 245.

For more information about the bolus handle, refer to PCA/PCEA/ PIEB Bolus Handle on page 53.

When the PIEB option is enabled, you can set PCEA infusion parameters immediately after programming the Epidural Intermittent infusion (Starting a PIEB Infusion on page 208).

Infusion Parameters: Epidural Intermittent Mode

The following infusion parameters need to be set for an Epidural Intermittent infusion:

Parameter	Description/Notes
VTBI	The total amount of fluid to be infused. The remaining VTBI is displayed on the screen as the infusion progresses. VTBI values can range from 0.1 to 9999 mL.
Intermittent Dose	The amount of each intermittent dose. Values can range from 0.1 to 30 mL.
Dose Interval	The frequency of intermittent dose delivery (Intermittent Dose + Continuous Rate). Intermittent doses can be given as frequently as 5 minutes apart. Therefore, the minimum programmable Dose Interval is the Intermittent Dose time plus 5 minutes. This rule applies even when the continuous rate is set to 0.
Continuous Rate	The rate of fluids delivered between doses, to prevent clotting in the epidural catheter. The Continuous Rate can be set from 0 to 25 mL/h (the range varies according to the Intermittent Dose volume and the Dose Interval entered).
Demand Bolus*	The amount of fluid infused in a single bolus. Demand Bolus values can range from 0.1 to 30 mL.
Bolus Lockout*	The minimum time that must pass between the end of one Demand Bolus to the start of the next Demand Bolus. After a bolus delivery ends, the next Demand Bolus becomes available following the lockout time.

Parameter	Description/Notes
Boluses per 1 h (or 4 hrs) OR Total dose per 1 h (or 4 hrs)*	The maximum number of boluses OR the maximum dose that can be delivered during a 1 hour (or 4 hours) period. (A user with High authorization codes can set the 1 hour or 4 hours parameters.) The Total dose limit takes into account medication delivered via: Continuous rate Yes Intermittent dose Yes Demand Bolus Yes Boluses given by a clinician, are not taken into account for the Total dose limit: Clinician bolus No When the Total dose limit is reached, the patient is locked out from activating additional boluses.

* Applicable only when programming Epidural Intermittent with PCEA.

The bolus rate applies to all boluses delivered during the infusion. The bolus rate can be configured to 125mL/ or 200mL/h before programming the infusion (for more information, refer to Epidural Mode Options Menu on page 245).

Starting an Epidural Intermittent Infusion

The following procedure explains how to program the pump to start a new Epidural Intermittent infusion.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new Epidural Intermittent infusion without Drug Library:

1. From the Indicators Bar, verify that the pump is in Epidural mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the Start Up screen, select **New Infusion**.
3. If **Dosing method** screen appears, select the appropriate option:
   - **mL:** Continue to Step 7.
   - **Dose calculation:** Continue to Step 4.

   Weight based units are available for both Dosing methods.
   Otherwise, continue to Step 10.
4. From the **Concentration units** screen, select the appropriate drug units.

> To display additional concentration units press **Next**.

5. According to pump configuration one of the following screens will appear:
   - **Concentration**: From concentration screen, using the keypad, enter the Concentration → **OK**. Then, continue to Step 7.
   - **Drug amount**: Using the keypad, enter the Drug Amount → **OK**. Then, using the keypad, enter the Diluent Volume → **OK**. Then, continue to Step 6.
6. From the Attention screen, confirm the concentration and press **OK**.

   If the selected drug unit is Million Units, continue to Step 9.

7. If the Patient Weight screen appears, specify whether the infusion is weight based:
   - **Yes**: Continue to Step 8.
   - **No**: Continue to Step 9.
8. From the Patient Weight screen, using the keypad, enter the patient weight → **OK**.
9. From the Dose Rate units screen, select the appropriate dose rate units.
10. Using the keypad, enter the VTBI value → **OK**.
11. Using the keypad, enter the Intermittent Dose → **OK**.
12. Using the keypad, enter the Dose Interval → **OK**.
13. Using the keypad, enter the Continuous rate → **OK**.

    The Continuous rate may be set to zero.
14. Review the parameters displayed on the Confirm screen.

Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

If the pump is configured to support PIEB option, PCEA infusion parameters can be programmed at this point. For detailed instructions, go to To begin a new PIEB Infusion without Drug Library (Step 3 on page 208).

15. To begin the infusion, make sure that the clamps on the administration set are open, and press **Start**.

    The Intermittent Dose screen is displayed, and the infusion begins with the first dose.

Throughout the infusion, the infusion phase (Intermittent Dose or Continuous Rate) is displayed on the Indicators Bar. In addition, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View System menu, and in the Running screen.
- **VTBI:** Total volume left to be infused. As the infusion progresses, this value decreases.
- **VI / Total:** Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Time Left:** Time remaining until the end of the current infusion. This parameter remains constant throughout the Standby period.
- **Time to Dose:** Time remaining until the beginning of the next Intermittent Dose. .

When the infusion is paused (Intermittent Dose or Continuous Rate), the time to next Intermittent Dose is paused and not displayed.

To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit → View system → Infusion values**.

> To begin a new Epidural Intermittent infusion with a Drug Library:

1. From the Indicators Bar, verify that the pump is in Epidural mode.

> For more information about changing delivery modes, refer to Selecting Delivery Mode on page 98.

2. From the **Start Up** screen, select **New Infusion**.
3. From the **Drug Name** screen,
   - Using the keypad, enter the drug name, then press **Find** and proceed to Step 4.

> The **Find** key can be used to display all available drugs without entering any characters (letters, numbers or symbols) or filter drug names according to the characters entered.

   - When the required drug is not found in the Drug Library, press **Choose General** key on the toolbar:

> 'Choose General' will bypass specific drug limits, and the infusion will be programmed without Drug Library limits.

   From the Attention screen, confirm Choosing General and press **OK**.
   Proceed to Step 3 on page 203 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
4. From the **Drug List** screen, select the row of the relevant drug.

> To display additional drugs press **Next**.

5. If a list of available drug profiles appears, select the appropriate drug profile and proceed according to the step directed to:

- **No concentration**: proceed to Step 7 on page 204 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
- **Diluent only** (e.g. 10 mL): proceed to Step 7 on page 204 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
- **Partial concentration**: the Drug Amount or Diluent Volume is missing. A screen for the missing value will appear:
  - From the **Drug Amount** screen, using the keypad, enter the Drug Amount → **OK**.
  - From the **Diluent Volume** screen, using the keypad, enter the Diluent Volume → **OK**.

  From the Attention screen, confirm the concentration and press **OK**.

  Proceed to Step 7 on page 204 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.
- **Full concentration**:

  Proceed to Step 7 on page 204 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.

If a list of available drug profiles does not appear, continue to Step 10 on page 204 (To begin a new Epidural Intermittent infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

Starting a PIEB Infusion

The following procedure explains how to program an Epidural Intermittent with PCEA.

> If relevant, you may skip programming by using the Repeat Last Infusion or PreSet programs procedures to begin the infusion. For more information, refer to Starting New Infusions: Shortcuts on page 214.

> To begin a new PIEB Infusion without Drug Library:

1. Verify that the pump is in Epidural Intermittent mode, and then program the Epidural Intermittent infusion (Step 2 on page 203 through Step 13 on page 204 in To begin a new Epidural Intermittent infusion without Drug Library).
2. Review the parameters displayed on the Confirm screen.

   Then, press **OK**.
3. From the Start screen, select **Add PCEA**.
4. Using the keypad, enter the value for the Demand Bolus → **OK**.
5. Using the keypad, enter the value for the Bolus Lockout → **OK**.
6. From the Dose Limit Type screen, specify whether or not the patient boluses should be limited:
   - **Yes**: Continue to Step 7.
   - **No**: Continue to Step 8.

> Choosing **No** on the Dose limit screen will set patient boluses to the maximum allowed, according to the other parameters defined for the infusion, including Lockout Time and Demand Bolus.

7. From the Dose Limit Type screen, select the appropriate Dose Limit type, and proceed to the directed step:
   - **Number of Boluses**: Using the keypad, enter the maximum number of boluses that will be available for the patient within a one or four-hour period → **OK**. Continue to Step 8.

- **Total Dose**: Using the keypad, enter the maximum amount of medication that may be delivered within a one or four-hour period → **OK**. Continue to Step 8.

8. Review the parameters displayed on the Confirm screen.

   Then, press **OK**.

Verify that the parameters reflect the correct treatment according to the prescription.

9. To begin the infusion, make sure that the clamps on the administration set are open, and press **Start**.

   The Running screen appears, and the infusion begins.

Throughout the infusion, the infusion phase (Intermittent dose, continuous rate or bolus) is displayed on the Indicators Bar. In addition, the following information appears on the Main Display:

- **Drug Name**: The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Drug Concentration**: Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate**: Current infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI**: Total volume left to be infused. As the infusion progresses, this value decreases.
- **VI / Total**: Total volume delivered in the current infusion (including KVO if applied during a delayed start period) / the total VTBI value programmed. As the infusion progresses, the VI increases, and the Total remains constant.
- **Lockout time:** Time remaining until the next bolus is available. After the lockout time elapses, this parameter changes to Bolus available.

- **Time to Dose**: Time remaining before the next dose starts (until the end of the interval time: Dose Time left + Continuous Rate time).

	When the infusion is paused (Intermittent Dose or Continuous Rate), the time to the next Intermittent Dose is paused and not displayed.

	To view all programmed parameters of the current infusion, including the rate in mL/h, from the Running screen, press **View/ Edit** → **View system** → **Infusion values**.

> To begin a new PIEB Infusion with a Drug Library:

1. Verify that the pump is in Epidural Intermittent mode, and then program the Epidural Intermittent infusion (Step 2 on page 206 through Step 5 on page 206 in To begin a new Epidural Intermittent infusion with a Drug Library).
2. Review the parameters displayed on the Confirm screen.

	Verify that the parameters reflect the correct treatment according to the prescription.

   Then, press **OK**.
3. From the Start screen, select **Add PCEA**.

Proceed to Step 4 on page 208 (To begin a new PIEB Infusion without Drug Library), and continue programming from there.

For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.

Epidural Intermittent Mode: Mid-infusion Actions

The following actions can be performed during Epidural Intermittent infusions:

Updating Infusion Parameters

In the Epidural Intermittent mode, the infusion must be paused before any parameter can be updated. Once the infusion is paused, any infusion parameter can be modified, by using the **View/Edit** function key. In addition, the rate (Continuous Rate or Dose Rate) and VTBI for the Intermittent Dose phase can be modified directly from the Main Display (during a bolus delivery, no parameter can be changed).

> To update parameters for the current phase (intermittent dose/Continuous rate) the Main Display:

1. Pause the infusion (Pausing Infusions on page 218).
2. On the Main Display, select the relevant frame (Dose rate, Continuous rate or VTBI).
3. Using the keypad, enter the new Dose rate, Continuous rate or VTBI → **OK**.
4. To confirm and save changes, press **OK**.

   To return to the Paused screen without saving changes, press **Back**. From the Dose rate, Continuous rate or VTBI screen, press **Back**. Then, from the Attention screen, press **OK**.

> To update parameters using the View/Edit function key:

1. Pause the infusion (Pausing Infusions on page 218).
2. From the toolbar, press **View/Edit**.

3. Select the box of the parameter to be modified.
4. Using the keypad, enter the new value of the parameter → **OK**.

	When changing the Intermittent Dose or Dose Rate, you will be prompted to confirm or adjust the dose interval.

	When modifying demand bolus limitations (volume or lockout) the pump will prompt you to confirm or adjust the other bolus limitations.

5. To update additional parameters, repeat Step 3 through Step 4.

   In addition to parameter changes, the following functions are also available:
   - **Clear Accum. VI:** Resets the total volume infused for all infusions associated with a patient to 0 mL.
   - **View system:** Displays various system and pump parameters. (Refer to View Menu on page 237.)
   - **Delivery History:** Displays a summary of medication delivery events. For more information, refer to Viewing Delivery History on page 242. Applies only when Epidural Intermittent with PCEA infusion was programmed.
6. To confirm and save changes, press **OK**.

   To return to the Paused screen without saving changes, press **Back**. Then, from the Attention screen, press **OK**.

Administering a Clinician Bolus

A bolus of any amount (within the predefined range) can be delivered by clinicians who have High authorization level code. A clinician bolus can be given only while the infusion is running. The lockout time is reset after delivering a clinician bolus. Clinician bolus is applicable only when programming Epidural Intermittent with PCEA.

> To administer a clinician bolus:

1. From the toolbar of the Running screen, press **View/Edit**.
2. Select **Clinician bolus**.
3. Using the keypad, enter the appropriate password → **OK**.
4. Using the keypad, enter the bolus amount → **OK**.
5. To start the bolus, from the Attention screen, press **OK**.

   The Clinician bolus screen appears, and the bolus begins.

The RATE of the Clinician Bolus, as all other boluses in PCEA mode, is defined prior to programming the infusion. It can be set to 125 mL/h or 200 mL/h (for more information, refer to Epidural Mode Options Menu on page 245).

Chapter 6: Basic Infusion Operations

The following sections explain procedures and actions that are commonly performed in all delivery modes to start and manage infusions:

Starting New Infusions: Shortcuts

The following shortcut operations allow you to begin an infusion without the need to enter required parameters:

Repeating Last Infusion

Repeat Last Infusion is a quick method to continue the infusion with a new IV bag, after the first one has been emptied or discontinued (the same infusion parameters used for the same patient). The pump automatically saves all the parameters programmed, excluding secondary line, for the last infusion performed in that delivery mode. If a parameter is updated while an infusion is running, the updated parameter is saved. The Last Infusion settings are saved even if the last infusion was not completed or the pump has been turned Off.

When using the Repeat Last Infusion option, the Delivery History, Accumulated VI parameter and the remaining Lockout Time are not cleared; instead, they continue counting from the previous infusion. For more information about Accumulated VI, and Delivery History, refer to Using the New Patient Feature on page 257.

Information about Secondary (Piggyback) infusions is not saved. This option is not relevant to Secondary infusions.

Repeat Last Infusion is not available (grayed out) when the pump settings differ from those used for the previous infusion. These include: CCA, regional settings, and PCA/PCEA infusion type.

Repeat Last Infusion does not include a loading dose, even if one was programmed for the original infusion. If required, a clinician bolus can be given when the infusion starts. For more information refer to Administering a Clinician Bolus on page 186.

> To repeat the last infusion:

1. From the Start Up screen, select **Repeat Last Infusion**.
2. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
3. Review the parameters displayed on the Confirm screen.

   Verify that the parameters reflect the correct treatment according to the prescription.

   Then, press **OK**.
4. To begin the infusion, make sure that the clamps on the administration set are open, and press **Start**.

   The Running screen appears, and the infusion begins.

Using a PreSet Program

The PreSet Programs function allows you to select an infusion with predefined parameters. Each delivery mode can support up to 25 PreSet programs. PreSet programs are available only in the delivery mode in which they were saved.

> For the PreSet Programs option to appear on the Start Up screen, the PreSet programs need to be enabled on the pump. For more information, refer to Configuring General Settings on page 230.

> To start an infusion using the PreSet Programs function:

1. From the Start Up screen, select **PreSet Programs**.

> If no PreSet program was saved in the current delivery mode, a blank screen appears.
> For more information about adding or modifying a program, refer to Creating and Editing PreSet Programs on page 250.

2. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.
3. Select the row of the desired program.

> To display additional programs, press **Next**.

4. Review the parameters that are displayed.

> Verify that the parameters reflect the correct treatment according to the prescription.

   Then, press **OK**.
5. To begin the infusion, make sure that the clamps on the administration set are open, and press **Start**.

   The Running screen appears, and the infusion begins.

Resuming Infusions After Pump Shutdown

When the pump is turned Off during an active infusion (running or paused), the option to resume the previous infusion will be displayed after the pump is turned On. This option is applicable for all delivery modes, excluding TPN.

> To resume the infusion:

1. In the Attention screen, press **OK**.
2. If a warning that the air detection is disabled (OFF) appears, ensure that a set with an air-eliminating filter is used, and press **OK**.

   The Paused infusion screen appears,
3. Press **Request continue** to resume the infusion.
4. On the Attention screen, press **OK** to confirm.
5. The Running screen appears.

	The option to resume will not be available if the pump was shut down due to an error alarm, or if the user quit the infusion.

	When a Drug Library is loaded, Resume Infusion after pump shutdown will keep local configurations changes until the end of the treatment.

> To abort the previous infusion:

- On the Attention screen, press **Exit**. The Start Up screen appears.

	When a Drug Library is loaded on the pump, the Clinical Care Area screen appears. The user can either accept or change the current CCA. For more information, refer to Clinical Care Area (CCA) on page 261.

Mid-infusion Actions

The following sections describe procedures that are commonly performed during an infusion:

Pausing Infusions

The Pause function allows you to temporarily stop an infusion. Infusions can be paused using either the **Request Pause** function key, or, in an emergency, the **Stop** hard key. A message stating that the infusion has been paused appears 30 seconds after pausing the infusion (audible and visual).

	Pressing the **Stop** hard key stops the infusion immediately, bypassing the need for confirmation of the Pause action. In an emergency, it is recommended to pause the infusion using the **Stop** hard key. In routine situations, using the **Request Pause** function key is recommended.

	Turning the pump Off after pausing the infusion allows the user to resume this infusion after turning the pump back on.

> To pause an infusion using the Stop hard key:

- At the bottom of the pump, press **Stop**. The infusion is paused.

	When the Patient Lockout or Lock Screen features are activated, it is necessary to confirm pausing from the Attention screen, by pressing **OK**.

> To pause an infusion using the Request Pause function key:

1. From the toolbar, press **Request Pause**.
2. From the toolbar of the Attention screen, press **OK**.
3. The infusion is paused.

> If you do not press **OK** within 30 seconds, the infusion is not paused, and the Running screen reappears.

> To resume a paused infusion:

1. From the toolbar, press **Request Continue.**
2. From the toolbar of the Attention screen, press **OK**.

Aborting Infusions

Aborting an infusion is performed using one of the following methods:

- **Pausing and then quitting the infusion:** Returns the pump to the Start Up screen. Resuming the infusion after quitting is impossible.
- **Turning off the pump:** Turns the pump Off mid-infusion, using the **On/Off** hard key.

When the pump is turned Off mid-infusion, the infusion parameters are saved. When the pump is turned back On, the user is prompted to indicate whether or not to continue the stopped infusion.

> In an emergency situation, it is recommended to press and hold the **ON/OFF** hard key for 5 consecutive seconds. This turns the pump Off, bypassing the need to confirm the action.

> To pause and then quit an infusion:

1. At the bottom of the pump, press the **Stop** hard key.
2. From the toolbar, press **Quit**.

3. From the toolbar of the Attention screen, press **Quit Infusion**.

	Resuming infusion after quitting will not be possible.

	When a Drug Library is loaded on the pump, the Clinical Care Area screen appears. The user can either accept or change the current CCA. For more information, refer to Clinical Care Area (CCA) on page 261.

> To turn Off the pump:

1. At the bottom of the pump, press the **ON/OFF** hard key.
2. From the toolbar, press **Off**.

   Pressing and holding the **ON/OFF** hard key for 5 consecutive seconds turns the pump Off (bypassing the need for confirmation).

	In case of emergency, when Patient Lockout or Lock Screen is activated (Activating Patient Lockout on page 221), the user must press and hold **ON/OFF** for 5 seconds to turn the pump Off, or unlock the pump before turning it Off.

Locking the Screen

Locking the display screen prevents inadvertent and unintentional changes to settings, by disabling the functionality of the touch screen. For safety, it is recommended to lock the screen while an infusion is running.

> To lock the screen:

1. From the toolbar of the Running screen, press **Lock**.
2. On the Lock options screen, select **Lock Screen**.

   The **>** icons on the Main Display and the toolbar function keys disappear. Only the **Press to Unlock Screen** function key appears on the toolbar.

> To unlock the screen:

1. From the toolbar, press **Press to Unlock Screen**.
2. From the toolbar of the Attention screen, press **OK**.

Activating Patient Lockout

The Patient Lockout feature prevents unauthorized personnel from modifying pump and infusion settings. In this state, only limited features are available. A password is required to unlock the pump.

During Patient Lockout or screen lock, the **Request Pause** function key is not available. Pause the infusion by pressing the **Stop** hard key. (Refer to To pause an infusion using the Stop hard key on page 218.)
To turn the pump Off, press and hold the **ON/OFF** hard key for 5 consecutive seconds.

> To activate Patient Lockout:

1. From the toolbar of the Running screen, press **Lock**.
2. On the Lock options screen, select **Patient lockout**.

> To release Patient Lockout:

1. From the toolbar, press **Press to Unlock Patient**.
2. Using the keypad, enter the relevant password and press **OK**.

Ending Infusion

When the infusion is complete (entire programmed VTBI delivered), the pump automatically activates the KVO (the default or the infusion rate, the lower of the two) and displays the infusion summary:

- VI - volume infused (VI for the current completed infusion. If the Accumulated VI has been cleared during this infusion, VI presents the volume infused from that time on).

- Rate – the rate at which the infusion was delivered
- Total time – the total time of the infusion

	The default KVO can be set by an authorized technician.

	When the remaining VTBI is 0.1 mL or less, the time left displayed on the screen may deviate up to a few minutes from the actual time remaining.

> To proceed with the KVO and view the KVO screen:

- From the toolbar of the Message screen, press **OK**.

> To discontinue the KVO:

1. From the toolbar of the Message screen, press **OK**.
2. From the toolbar of the KVO screen, press **Quit**.

	When a Drug Library is loaded and CCA was changed during the previous running infusion, an Attention screen appears, asking to confirm the new CCA. For more information, refer to Clinical Care Area (CCA) on page 261.

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Chapter 7: Options Menu: Configuring, Viewing and Testing

The following sections describe configuring settings, testing elements, and viewing system data using the Options menu:

Main Options: Overview

The Options screen provides access to configurable pump settings, testing modes, and system data. The screen is displayed by pressing the **Options** function key, on the toolbar of the Start Up screen.

The Options screen allows access to all configurations and settings of the Sapphire pump (as opposed to settings relevant to a specific infusion). The screen also provides access to testing components and viewing pump (as opposed to infusion) parameters (e.g., System parameters, Event logs, and Delivery History).

The Options function key is not available during an infusion. Some of the configuration and information accessed from the Options menu is also accessible during infusion via the View/Edit menu.

Setting Delivery Mode

The Sapphire pump is a multi-platform device that has the ability to operate in several different modes. Each delivery mode features its own unique options. The current mode is displayed at the right side of the Indicators Bar.

Setting the delivery mode is done using the Options menu. An authorization code of High or Technician is required to modify the delivery mode.

> When you change the delivery mode, the pump reverts to the default values for the newly selected mode.

> To change the delivery mode:

1. From the toolbar, press **Options**.
2. From the Options screen, select **Delivery mode**.
3. Using the keypad, enter the required password, and then press **OK**.
4. Select the relevant delivery mode.

> To access the PCEA or Intermittent Epidural delivery modes, select **Epidural**. Then select the relevant Epidural delivery mode.

The Start Up screen of the selected mode appears.

Managing Configuration Settings

The following sections describe how to view and update pump configuration settings:

When a drug library is loaded to the pump, local configurations made on the pump remain valid until the user selects a CCA or turns the pump Off. For more information refer to Chapter 9: Drug Library on page 260.

Managing Alarm Settings

The Alarms menu allows you to view and modify alarm-related options. Only users with authorization levels of High or Technician have access to this menu.

> To access the Alarms menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration → Alarms**.

Option	Descriptions/Notes	To Modify Parameter (from the Alarms screen)
Occlusion units	The format of occlusion units (**BAR**, **PSI** or **mmHg**).	Select **Occlusion units**. Then, select **BAR**, **PSI** or **mmHg**.

Option	Descriptions/Notes	To Modify Parameter (from the Alarms screen)
Occlusion pressure	The minimum downstream pressure that triggers an Occlusion alarm. Acceptable ranges are 5.8 to 17.4 PSI, 0.4 to 1.2 BAR or 300 to 900 mmHg. An alarm sounds when the downstream pressure reaches the set value ± the sensor sensitivity level.	Select **Occlusion pressure**. Then, using the keypad, enter the desired value → **OK**.
Pump unattended	The number of consecutive minutes of no interaction with the pump after which a Pump Unattended alarm is triggered. Options are **2**, **5** or **10** minutes. **Note:** A Pump Unattended alarm is not triggered when the pump is in Delayed start or Standby.	Select **Pump unattended**. Then, select **2 min, 5 min** or **10 min**.
Infusion near end	The number of minutes before completion of an infusion at which an Infusion Near End alarm is generated.	Select **Infusion near end**. Then, select **1 min**, **3 min**, **5 min**, **10 min** or **Off**.
Alarm volume	Sets the speaker volume for the auditory alarm signal. Options are **Maximum** or **Minimum**. **Maximum:** Errors and alarms sound level is 68 dB, Messages sound level is 59 dB. **Minimum:** Errors and alarms sound level is 65 dB, Messages sound level is 45 dB.For more information about messages and alarms, refer to Chapter 10: Alarms and Troubleshooting on page 270.	Select **Alarm volume**. Then, select **Maximum** or **Minimum**.

An Occlusion Auto-restart option exists and is available for configuration by authorized technicians only. This option allows the pump to restart the infusion automatically provided the occlusion was cleared.
If the occlusion is not cleared within 40 seconds, or the user chooses to exit the process, the downstream occlusion alarm is activated (appears within a few seconds). An Occlusion Auto-restart can occur up to 5 times in one hour.

Configuring Audio Settings

The Audio settings menu allows you to view and modify audio-related pump settings. Only users with authorization levels of High or Technician have access to this menu.

> To access the Audio settings menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration → Audio settings**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Keys volume	Sets the speaker volume for the auditory signal generated when users select functions and press keys on the pump.	Select **Keys volume**. Then, select **Low**, **High** or **Off**.
Alarm volume	Sets the speaker volume for the auditory alarm signal. Options are **Maximum** or **Minimum**. **Maximum:** Errors and alarms sound level is 68 dB, Messages sound level is 59 dB. **Minimum:** Errors and alarms sound level is 65 dB, Messages sound level is 45 dB. For more information about messages and alarms, refer to Chapter 10: Alarms and Troubleshooting on page 270.	Select **Alarm volume**. Then, select **Maximum** or **Minimum**.
Bolus Handle	Sets the Bolus auditory signal, generated when the bolus handle is pressed. When the option is set to Always On, an auditory signal is generated each time the bolus handle is pressed. When set to When Bolusing, an auditory signal is generated, when the bolus handle is pressed and bolus is available.	Select **Bolus Handle**. Then, select **Always On** or **When Bolusing**.

Configuring General Settings

The General settings menu allows you to view basic pump settings, and modify them according to clinical requirements. Only users with authorization levels of High or Technician have access to this menu.

> To access the General settings menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration → General settings**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Current CCA	Used to select the CCA to which the pump should be set. Appears only when Drug Library is loaded. For more information, refer to Clinical Care Area (CCA) on page 261.	Select **Current CCA**. Choose the appropriate CCA; then, from the Attention screen press **OK**.
Start Up config.	Set the configuration of the Start Up screen. For more information, refer to Start Up Configuration Menu on page 234.	Refer to Start Up Configuration Menu on page 234.
Authorization level	Sets the authorization lock level of the pump. For more information, refer to Managing Authorization Levels on page 246.	Select **Authorization level**. Then, enter a password and select **Low**, **Medium**, **High** or **Tech**.
Allow delayed start	Enables users to start an infusion at a later time. The user may either define a specific delay period, or set the pump to Standby. For more information, refer to Using the Set Delay Feature on page 253.	Select the **Allow delayed start** row, to toggle the option between **On** and **Off**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Allow PreProgram	Enables/disables starting infusions using predefined infusion parameters. When the option is enabled, the PreSet Programs frame appears on the Start screen. For more information, refer to Creating and Editing PreSet Programs on page 250.	Select the **Allow PreProgram** row, to toggle the option between **On** and **Off**.
Set prime volume	The amount of fluid used to prime the administration set when automatic priming is performed. The acceptable range is 2 to 25 mL.	Select **Set prime volume**. Then, using the keypad, enter the desired value → **OK**.
Backlight	Allows the user to set the degree of screen brightness for a running infusion. Backlight can also be modified during a running infusion. The Off and Partial options of this feature save power and promote longer battery life.	Select **Backlight**. Then, select **On**, **Off** or **Partial**.
Prime Reminder	Enables a reminder for the user to prime the administration set before starting an infusion. For more information, refer to Automatic Priming Using the Pump on page 114.	Select the **Prime Reminder** row, to toggle the option between **On** and **Off**.
Advanced Bolus	Allows users to program a bolus by entering rate, amount and time. When this option is disabled, the bolus is programmed by amount only, and the rate is the default bolus rate. The option is available only when Allow Bolus is enabled (by a Technician authorization code). Applicable only for the Continuous delivery mode. For more information, refer to Administering a Bolus on page 137.	Select the **Advanced Bolus** row, to toggle the option between **On** and **Off**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Bolus Reminder	Enables a reminder for the user to connect the bolus handle before starting a PCA, PCEA or PIEB infusion that includes patient boluses. The reminder: • Instructs to connect the bolus handle directly to the pump. • Checks functionality – bolus press is recognized by the pump.	Select the **Bolus Reminder** row, to toggle the option between **On** and **Off**.
Auto P. lockout	Enables/disables Patient Lockout, a safety feature that requires password entry to make any parameter changes. When the option is enabled, Patient Lockout is activated automatically as the infusion begins (Activating Patient Lockout on page 221).	Select the **Auto P. Lockout** row, to toggle the option between **On** and **Off**.

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Screen Saver	Enables/disables a far-view display of the main infusion parameters during a running infusion. These include drug information, delivery mode (color indication), infusion rate, and the phase (dose, continuous rate etc.). The screen saver appears 30 seconds after the infusion program has started, and the pump has not been touched. The screen saver will not appear in the following cases: Delayed start, end of infusion KVO, or during a Bolus delivery. The screen saver will disappear in the following cases: • Alarm – screen will revert to the alarm screen • Touching the screen – screen will revert to the Running screen • Infusion is paused – screen will revert to the Paused screen.	Select the **Screen Saver** row, to toggle the option between **On** and **Off**.

Start Up Configuration Menu

> To access the Start Up Configuration menu:

From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration → General settings → Start Up Config**

Option	Descriptions/Notes	To Modify Parameter (from the General settings screen)
Repeat last infusion	Allows the user to start infusions, using the same infusion parameters for the same patient. When the option is enabled, the Repeat Last Infusion button appears on the pump Start screen. For more information, refer to Repeating Last Infusion on page 214.	Select the **Repeat Last Infusion** row, to toggle the option between **On** and **Off**.
PreProgram	Allows the user to start an infusion using predefined infusion parameters. When the option is enabled, the PreSet Programs button appears on the pump Start Up screen. For more information, refer to Creating and Editing PreSet Programs on page 250.	Select the **PreProgram** row, to toggle the option between **On** and **Off**.

Defining Regional Parameters

The Regional menu controls date, time, language and US format settings. Only users with authorization levels of High or Technician have access to this menu.

> To access the Regional menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration → Regional**.

The following procedures explain how to configure settings from the Regional menu.

> To set the date:

1. Select the **Date** frame.
2. Using the keyboard, enter values (2 digits each) for the day, month, and year. (When US format is set, the order is month, day, and year.)
3. To confirm the new settings, press **OK**.

> To set the time:

1. Select the **Time** frame.
2. Using the keyboard, enter values (2 digits each) for the hour and the minute.
3. If necessary, switch the time units from AM to PM or vice versa, by pressing the **AM/PM** function key. (This step is relevant only when U.S. format is set.)
4. To confirm the new settings, press **OK**.

> To set the language:

1. Select the **Language** frame.
2. Select the desired language.

In some pumps, only the default language is listed.

3. To confirm the new settings, press **OK**.

> To set the US format:

1. Select the **US format** frame.
2. Toggle the settings between **On** and **Off**
3. To confirm the new settings, press **OK**.

The date will appear in month/day/year format and time will appear 12 hour format (am/pm) when this setting is toggled On.

Testing System Function

The Test system menu allows you to test basic system functionalities. Only users with authorization levels of High or Technician have access to this menu.

> To access the Test system menu:

- From the toolbar of the Start Up screen, select **Options**. Then, select **Pump configuration → Test system**.

Option	Descriptions/Notes
Speaker high	• **On:** High volume auditory signal sounds. • **Off:** No auditory signal.
Speaker low	• **On:** Low volume auditory signal sounds. • **Off:** No auditory signal.
Alarm LED	• **On:** The red (Alarm) LED is lit. • **Off:** The red (Alarm) LED is not lit.
Charge LED	• **On:** The yellow (Charge) LED is lit. • **Off:** The yellow (Charge) LED is not lit.
Running LED	• **On:** The green (Run) LED is lit. • **Off:** The green (Run) LED is not lit.
Door sensor	• **Closed:** The safety door is closed. • **Opened:** The safety door is open.
Bolus handle	• **Released:** The handle is not pressed. • **Pressed:** The handle is pressed.

View Menu

The View menu provides access to current pump settings and lists of events that are audited by the system. The main categories are:

Category	Description/Notes
View system	Provides a view of the current system settings, and allows updating selected settings. For more information, refer to Viewing System Parameters on page 238.
Event log	Provides a view of the events recorded by the system; such as authorization level change, programming infusion parameters, activated alarms etc. For more information, refer to Viewing the Event Log on page 241.
Delivery History (PCA, PCEA and Epidural Intermittent delivery modes only)	Provides a view of the boluses and the total amount of medication delivered during PCA, PCEA or PIEB infusion. The Delivery History is associated with a patient. For more information, refer to Viewing Delivery History on page 242.

> To access the View menu from the Start Up screen:

1. From the toolbar of the Start Up screen, select **Options**.
2. On the Options screen, select **View**.

> To access the View system screen from the Running screen:

1. From the toolbar of the Running screen, select **View/Edit**.
2. From the toolbar of the View/Edit screen, select **View system**.

Viewing System Parameters

The View system screen allows you to view current system settings and infusion parameters, and update selected settings. You can navigate through the pages of settings, by pressing the **Next** and the **Back** function keys.

The following settings appear in all delivery modes:

Setting	Description/Notes
Infusion Values	Displays all the programmed parameters of the current infusion, including rate in mL/h. Applicable only on an active infusion, or during Standby. Pressing **>** displays the parameters.
Alarm volume	The volume of the auditory alarm signal (**Maximum** or **Minimum**). The setting can be modified by pressing **>**, and then selecting a setting.
Occlusion	The level of downstream pressure that triggers an occlusion alarm. For more information, refer to Managing Alarm Settings on page 226. The setting can be modified by pressing **>**, entering a value using the keypad, and then pressing **OK**.
Authorization	Current authorization lock level. For more information, refer to Managing Authorization Levels on page 246. The setting can be modified by pressing **>**, selecting a setting, and then pressing **OK.** Password entry is required to change the authorization.
Current CCA	The current CCA, as pre-selected by the user, and used for the current infusion. Appears only when Drug Library is loaded. For more information, refer to Clinical Care Area (CCA) on page 261.
Next CCA	The next CCA appears only when the Drug Library is loaded, and the user changed the CCA during an infusion. **Note:** The next CCA will apply only after the infusion has ended. Applicable only during an active infusion, or during Standby. For more information refer to Clinical Care Area (CCA) on page 261.

Setting	Description/Notes
Backlight	Current backlight settings. For more information refer to Configuring General Settings on page 230. The setting can be modified by pressing **>**; then selecting **On**, **Partial** or **Off**.
Accumulated VI	The cumulative volume infused (mL). The Accumulated VI can be cleared by pressing **>**. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 258.
Accum. Prim. VI	The cumulative volume infused (mL) via the primary infusions. Appears in the View System menu only in the Continuous Delivery mode. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 258.
Accum. Sec. VI	The cumulative volume infused (mL) via the secondary infusions. Appears in the View System menu only in the Continuous Delivery mode. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 258.
VI cleared date VI cleared time	The date and time in which the Accumulated VI was last cleared. For more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 258.
Delivery mode	Current delivery mode.
Single Air detector Accumulated Air detector Accumulated Threshold	These settings are associated with the amount of air that triggers an Air in Line alarm, when the air detection is enabled (ON). These settings can be modified by Technicians only. For more information, refer to the Service Manual. **Note**: While a non-epidural infusion is running at a rate of 4 mL/h or lower, the Single air detector switches automatically On.
Air detection	This setting indicates that air detection has been disabled (OFF) – it is displayed instead of the single and accumulated air settings mentioned above.
Date Time	Current date and time. For more information, refer to Defining Regional Parameters on page 234.
Software version	The software version loaded on the pump.

Setting	Description/Notes
Drug Library name	The Drug Library name appears only if the pump is loaded with a Drug Library. For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.
Drug Library published date	The Drug Library published date appears only if the pump is loaded with a Drug Library. For more information about the Drug Library, refer to Chapter 9: Drug Library on page 260.
Serial number	Serial number of the pump.
Next Certification	Date that the pump is due for the next Certification. For more information refer to the Service Manual.
Set Prime Volume	The amount of fluid used to prime the administration set, when automatic priming is performed. The acceptable range is 2 to 25 mL.
Battery status	The approximate percentage of current battery charge. Possible values are **100%**, **75%**, **50%**, **25%**, and **Low Batt**.
KVO	The default KVO rate set for the current delivery mode. The parameter is not relevant to Intermittent or Epidural Intermittent mode (in which the KVO is equal to the KVO/continuous rate programmed for the infusion).
Bolus rate	The default bolus rate set for the current delivery mode. The parameter is not relevant to the Intermittent, TPN or Multi-step modes. In continuous mode, when the Advanced Bolus option is set to On, the bolus Amount, Rate and Time can be programmed by the user, and the bolus rate will not be displayed on the View System menu. Default bolus rate can be modified by Technicians only. For more information, refer to the Service Manual.
Secondary bolus rate	The default secondary bolus rate. This parameter is relevant only for the Continuous Delivery mode. When the Advanced Bolus option is set to On, the bolus Amount, Rate and Time can be programmed by the user, and the secondary bolus rate will not be displayed on the View System menu. Default bolus rate can be modified by Technicians only. For more information, refer to the Service Manual.

Viewing the Event Log

The Event log screen allows you to view a record of all events audited by the system. You can view a list of all events or only the events that occurred on a specific day.

> To view events that occurred on a specific day:

1. From the Options menu, select **View**.
2. On the View screen, select **Event log**.
3. On the Event log screen, select **By date**.
4. Using the keypad, enter values for the day (2 digits), the month (2 digits), and the year (2 digits). (When U.S. format is set, the order is month, day, and year.)

> To navigate directly to a component of the date (e.g., day), press the component.

5. On the toolbar, press **OK**.

   A list of events is displayed.

> If no events occurred on the selected day, a blank screen is displayed.

> To view all events:

1. From the Options menu, select **View**.
2. On the View screen, select **Event log**.
3. On the Event log screen, select **All events**.

   A list of events is displayed.

The Event log is sorted according to time, with the most recent event listed first. Each event is assigned a specific code. (For example, the code for the Pump Unattended alarm is 18.) The code appears in the Event log next to the time of the event.

When the row of an event is selected, the Event details frame displays the complete timestamp of the event (date and exact time), and a brief description of the event.
When the pump is turned Off, or a power failure occurs, the pump shut-down is registered as an event (with a time stamp), and the event log is saved.
When the number of events in the Event Log exceeds the maximum capacity, the earlier half of the event log will be cleared, in order to allow logging of new events.

Viewing Delivery History

This screen, which appears only in PCA, PCEA and PIEB delivery modes, provides a summary of all bolus-related events that occurred during a specified time frame, and the total amount of medication delivered throughout the treatment.

To access the Delivery History during PCA, PCEA, or PIEB infusion: From the tool bar select **View/Edit**; then, select **Edit PCEA** → **Delivery History**. When the pump is locked, the Delivery History can be accessed from the toolbar without unlocking the pump.

Delivery history information includes:

Name of Value	Description/Notes
Total Dose given	The total amount of drug delivered to the patient during a treatment through Boluses, Loading dose, Continuous rate, KVO if applied and Intermittent doses. When using Repeat Last Infusion, this value accumulates from the previous infusion/s.
Bolus History period	The number of hours over which the displayed boluses occurred. The default history period is 1 hour, and it can be set from 1 hour up to the number of hours that the infusion has been running. The setting can be modified by pressing **>**, entering a value using the keypad, and then pressing **OK**.

Name of Value	Description/Notes
Patient bolus given/attempts	Total number of patient boluses delivered to the patient/ number of times that the patient requested a bolus (by pushing the button on the Bolus Handle, or by pressing the **Bolus** function key).
Patient Bolus given	Total amount of infusion (in mL, mg, mcg, mUnits, million Units, gram, nanogram, mmol, or mEq) given via demand boluses.
Clinician Bolus given	Total amount of infusion (in mL, mg, mcg, mUnits, million Units, gram, nanogram, mmol, or mEq) given via boluses administered by clinicians, including loading dose.
Total Bolus given	Total amount of infusion given to the patient via boluses (loading dose, clinician, patient) or intermittent doses (PIEB).
Intermittent Doses given	Total amount of intermittent doses (in mL, mg, mcg, mUnits, million Units, gram, nanogram, mmol, or mEq). Appears only when Epidural Intermittent with PCEA is programmed.
Intermittent doses Given/ Total	Total number of Intermittent doses actually given/number of Intermittent doses programmed to be administered. Appears only when Epidural Intermittent with PCEA is programmed.

When using the **Repeat Last Infusion** option (for the same patient), the Delivery History, the accumulated VI, and the lockout time are not cleared; they continue counting from the previous infusion.

Using Special Mode Options

The following sections describe options that are available only in PCA and Epidural delivery modes:

PCA Options Menu

The PCA options screen is accessed from the main Options menu, when the pump is in PCA delivery mode. It enables you to view and update the following parameters:

Parameter	Description/Notes
Bolus rate	The rate at which a bolus (Patient bolus, Clinician bolus and Loading dose) is delivered. The bolus rate can be set from 1 and up to 600 mL/h; the default is 125 mL/h.
Allow loading dose	Enables the user to program a loading dose (starting the infusion with a clinician bolus). Select the row to toggle the option between **On** and **Off**.
Infusion type	Defines the PCA infusion type that is available for the user: • Continuous only – includes only a continuous rate without boluses (if enabled, a loading dose can be programmed) • Bolus only – includes only patient boluses and no continuous rate (clinician and loading dose can be given) • Continuous with Bolus – allows the user to program both continuous and patient boluses (either one of which is optional)
Limit Period	Specifies the time period to which the dose limit type is applied (during the selected time, the delivered boluses will be limited by either maximum number, or by maximum volume).

> To change the bolus rate from the PCA options screen::

1. Select the Bolus rate row.
2. Using the keypad, enter the value for the new bolus rate → **OK**.

3. To save the change in the system, press **OK**.

Epidural Mode Options Menu

The PCEA options and Epi Int options screens are accessed by pressing the **Options** function key when the pump is in PCEA or Epidural Intermittent delivery modes, respectively. These screens enable you to view and update the following parameters:

Parameter	Description/Notes
Bolus rate (PCEA mode only)	The rate at which a bolus (Patient bolus, Clinician bolus and Loading dose) is delivered. The bolus rate can be set from 1 and up to 600 mL/h; the default rate is 125 mL/h.
Password request	Enables a safety feature that requires a high authorization level password entry for programming and editing actions.
Allow loading dose (PCEA mode only)	Enables the user to program a loading dose (starting the infusion with a clinician bolus). Select the row to toggle the option between **On** and **Off**.
Infusion type (PCEA mode only)	Defines the PCEA infusion type that is available for the user: • Continuous only – includes only a continuous rate without boluses (if enabled, a loading dose can be programmed) • Bolus only – includes only patient boluses and no continuous rate (clinician and loading dose can be given) • Continuous with Bolus – allows the user to program both continuous and patient boluses (either one of which is optional)
Dose rate (Epi. Int mode only)	The rate at which an Intermittent dose is delivered. Options are 125 or 200 mL/h; the default rate is 125 mL/h.
Limit Period	Specifies the time period to which the dose limit type is applied (during the selected time, the delivered boluses are limited by either maximum number, or by maximum volume).
PIEB (Epi. Int mode only)	Enables the user to program a PIEB infusion.

Chapter 8: Using Advanced Features

This chapter explains how to work with less frequently used pump features. The following options are generally reserved for more advanced pump users:

Managing Authorization Levels

To help ensure patient safety, the Sapphire pump can be set to one of four authorization levels. Authorization levels control access to the programming options available in the pump. Each level allows users to access a different set of pump actions and programming options.

Authorization levels are modular. Therefore, users with a given authorization level can access actions available to their level, plus all actions available to users with lower authorization levels. The levels are:

- **Low:** All programming options are disabled, and no settings can be changed.
- **Medium:** Basic programming options, such as using shortcuts to start infusions, are enabled.
- **High:** All tasks and configuration settings are enabled, except for options limited to technician use.
- **Technician:** All settings are enabled. This level is restricted to technicians and developers only.

Passwords are defined by technician or loaded with the Drug Library.

Specific actions allowed in each of the authorization levels are listed in the following table.

Authorization Level	Allowed Actions
Low	Stop the pump, and then continue the infusion
	Power the pump On and Off
	Administer patient bolus
	Use the View menu
	Activate immediate taper-down during TPN infusion, using the taper-down period defined by the clinician
Medium	Stop the pump, and then continue the infusion
	Start infusions using the PreSet Programs feature
	Start infusions using the Repeat Last Infusion feature
	Priming with the pump
	Edit Rate during running infusion (the option must be enabled prior to the infusion by an authorized Technician)
	View bolus rate (PCA options)
	Activate immediate taper-down during TPN infusion, and set the time for it
High	Start infusions using the New Infusion feature
	View/Edit parameters
	Use the Pump Configuration menu
	Create/Edit PreSet programs (requires a unique password)
	Use of all PCA, PCEA and PIEB options
	Changing delivery mode (requires password re-entry)
	Clinician bolus
Technician	All

When the pump is turned Off, the authorization lock level setting is saved. Therefore, the lock level set most recently is maintained when the pump is turned back On.

If the pump is turned Off in Technician mode, the pump turns back On in a Low authorization level.

The current authorization lock level can be viewed via the Options menu. When an infusion is running, the lock level can be accessed via the Running screen.

> To view the current authorization lock level from the Options menu:

- From the Options menu, select **View** → **View system**.
  The Authorization parameter is displayed.

> To view the current authorization lock level via the Running screen:

1. From the toolbar of the Running screen, press **View/Edit**.
2. From the View/Edit screen, select **View system**.
   The Authorization parameter is displayed.

Setting Authorization Lock Levels

Users with an authorization level of High can reset the authorization lock level of the pump.

> To change authorization level from a lock level of High:

1. From the Options menu, select **Pump configuration** → **General settings**.
2. Select **Authorization level**. Then, using the keypad, enter the High level password → **OK**.

Because only High and Tech authorization levels can change the authorization level on the pump, a high or technician password is required to access this setting. Entering a Medium or Low level password generates an error message.

The authorization level matching the entered password, as well as all levels below it, are listed on the Main Display.

3. Select the authorization level at which you want to lock the pump. Then, from the Attention screen, press **OK**.
4. To exit the Options menu, press **OK**.

> To change authorization level from a lock level of Medium or Low:

1. From the Options menu, select **Pump configuration**.
2. On the Password screen, using the keypad, enter the High level authorization password. Then, from the toolbar, press **OK**.
3. To exit the Options menu, press **Exit**.

Do not disclose the passwords of authorization levels Medium, High or Technician to patients, home users or any other unauthorized user.

Password Re-entry

The Sapphire pump is designed to prevent inadvertent parameter changes, or actions other than those permitted by the currently set authorization level. As a safety measure, the pump will prompt the user to re-enter the High level password before performing the following actions:

- Changing delivery modes
- Changing authorization levels

Entering a High level authorization password allows access to these actions, even if the pump is set at a Medium or Low authorization lockout level.

A password entry is also required to unlock the screen when the Auto Patient Lockout feature is enabled. The authorization level of the password entered sets the authorization lockout level of the pump.

Creating and Editing PreSet Programs

The PreSet Programs feature allows users to start infusions using predefined infusion parameters, thus eliminating the need for programming. Each delivery mode can support its own set (of up to 25) predefined infusion programs. Only the infusion programs set for the currently selected delivery mode are displayed (a preset program is available for use and edit only when the pump is set to the delivery mode in which the program was saved).

> For the PreSet Programs function to appear in the Start Up screen, the pump needs to be configured to the PreProgram setting. For more information, refer to Start Up Configuration Menu on page 234.

The following procedures explain how to create, edit and delete preset programs.

> Creating and Editing preset programs can be done only by High and Technician authorization levels, and in addition require a unique password.

A PreSet program will be available for creating, using and editing only when the program settings are consistent with the current pump settings, and drug availability in the current CCA (for example, when creating a PCA PreSet program while the pump is set to Continuous + Bolus infusion type, this program can be used only when the pump is configured to Continuous + Bolus and not when the pump is configured to Continuous only or Bolus only).

> Exception: a PreSet program created with Drug amount and Diluent volume, will be available for creating, using and editing, regardless of Calculate concentration setting.

> To create a new preset program:

1. From the Indicators Bar, verify that the pump is in the desired delivery mode.
2. From the Start Up screen, select **PreSet Programs**.
3. From the toolbar, press **Create New**.
4. Using the keypad, enter the appropriate password; then, press **OK**.

5. Using the keypad, enter a relevant name for the new program.
   - To enter the second character that appears on a key, press the key twice. (Press 3 times to enter the third character, etc.)
   - To enter a space, press the **0** (zero) key once.
   - To clear the most recently entered character, press the backspace key (left arrow key at the lower right corner of the keypad).
   - To clear all entered characters, press **Clr**.

   After entering the name, press **OK**.
6. Set the relevant infusion parameters. Refer to the following table for more information about setting parameters in each mode.

Delivery Mode	Refer to:
Continuous	Starting a Continuous Infusion on page 123
Intermittent	Starting an Intermittent Infusion on page 167
TPN	Starting a TPN Infusion on page 161
Multi-step	Starting a Multi-step Infusion on page 151
PCA	Starting a PCA Infusion on page 178
Epidural	Starting a PCEA Infusion on page 191, Starting an Epidural Intermittent Infusion on page 203, or Starting a PIEB Infusion on page 208

7. Review the parameters displayed on the screen.

   

   Verify that the parameters reflect the correct treatment according to the prescription.

   Then, press **OK**. The program is saved.
8. To return to the PreSet programs screen, press **OK**.

> To edit a preset program:

1. From the Indicators Bar, verify that the pump is in the desired delivery mode.
2. From the Start Up screen, select **PreSet Programs**.

3. From the toolbar of the PreSet Programs screen, press **Edit**.
4. Using the keypad, enter the appropriate password; then, press **OK**.
5. From the list, select the program that you want to update.
6. Select the box of the parameter that you want to change. Using the keypad, enter the new parameter, and then press **OK**.

If relevant, the pump will prompt you to confirm or update other parameters that may need to be modified, based on the change made. The name of the program, drug name, drug concentration and patient weight cannot be modified.

7. Repeat Step 6 , until all relevant parameters are updated as required.
8. Review the parameters displayed on the screen.

Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**. The program is saved.

> To delete a preset program:

1. From the Indicators Bar, verify that the pump is in the desired delivery mode.
2. From the Start Up screen, select **PreSet Programs**.
3. From the toolbar of the PreSet Programs screen, press **Edit**.
4. Using the keypad, enter the appropriate password; then, press **OK**.
5. From the list, select the program that you want to delete.
6. From the toolbar, press **Delete**.
7. From the toolbar of the Attention screen, press **OK**.

   The program is deleted.

Using the Set Delay Feature

The Set Delay feature allows users to program an infusion in advance. When the option is enabled, the Set Delay option appears on the Start screen. The users can then choose to set the infusion to Standby for an unlimited time period, or to set the infusion for a defined Delayed Period, after which one of the following occurs:

- If the KVO was used during the delay period, the pump starts the infusion automatically.
- If the KVO was not used during the delay period, the alarm for the clinician sounds to start the infusion.

For the Set Delay option to appear on the Start screen, the pump needs to be configured with the **Allow delayed start** setting enabled. For more information, refer to Configuring General Settings on page 230.

> To program an infusion using the Standby option:

1. Set the relevant infusion parameters. Refer to the following table for more information about setting parameters in each mode.

Delivery Mode	Refer to:
Continuous	Starting a Continuous Infusion on page 123
Intermittent	Starting an Intermittent Infusion on page 167
TPN	Starting a TPN Infusion on page 161
Multi-step	Starting a Multi-step Infusion on page 151
PCA	Starting a PCA Infusion on page 178
Epidural	Starting a PCEA Infusion on page 191 or Starting an Epidural Intermittent Infusion on page 203

2. From the Start screen, select **Set Delay**.
3. From the Delayed Start screen, select **Standby**.
4. The Standby screen is displayed.

Throughout the Standby period, the following information appears on the screen:

- **Drug Name:** The name of the selected drug. Displayed on the indicators bar, when working with a Drug Library.
- **Concentration:** Drug concentration as entered by the user (Final concentration or Drug Amount / Diluent Volume). Displayed when applicable.
- **Rate:** Programmed infusion rate. For all dose units other than mL/h, the calculated rate will be displayed in mL/h, both in the View system menu and in the Running screen.
- **VTBI:** Total volume left to be infused. This parameter remains constant throughout the Standby period.
- **VI / Total:** Total volume that has been infused in the current infusion / the VTBI value programmed. These parameters remain constant throughout the Standby period.
- **Time left:** Time remaining until the end of the current infusion. This parameter remains constant throughout the Standby period.

During Standby, Pump unattended message will not be active.

To view all of the current infusion programmed parameters, from the Standby screen, press **View/Edit → View system → Infusion Values**.

When in Standby, the pump can be turned Off without losing the infusion parameters. To resume infusion, refer to Resuming Infusions After Pump Shutdown on page 217.

To abort Standby and the infusion, from the toolbar, press **End Standby**; then, from the Confirm screen, press **Exit**. The Start Up screen will appear.

> To start an infusion from the Standby state:

1. Press **End Standby**.
2. Review the parameters displayed on the Confirm screen.

Verify that the parameters reflect the correct treatment according to the prescription.

Then, press **OK**.

3. Make sure that the clamps on the administration set are open; then, press **Start**. The Running screen is displayed, and the infusion begins.

> To program an infusion using the Delay Period option:

1. Set the relevant infusion parameters. Refer to the following table for more information about setting parameters in each mode.

Delivery Mode	Refer to:
Continuous	Starting a Continuous Infusion on page 123
Intermittent	Starting an Intermittent Infusion on page 167
TPN	Starting a TPN Infusion on page 161
Multi-step	Starting a Multi-step Infusion on page 151
PCA	Starting a PCA Infusion on page 178
Epidural	Starting a PCEA Infusion on page 191 or Starting an Epidural Intermittent Infusion on page 203

2. From the Start screen, select **Set Delay**.
3. From the Delayed Start screen, select **Delay Period**.
4. Using the keypad, enter the desired delay period (h:min); then, press **OK**.

5. Specify whether or not to run the infusion in a KVO, during the delay period:

If KVO rate is pre-configured to 0 mL/h for the delivery mode, from the Start screen, select **Start with Delay**. (Refer to **Do not use KVO:** below)

- **Use KVO:**
  Press **Yes** → **Start with Delay**. The infusion begins with a KVO rate. When the delay period is over, the programmed infusion begins immediately.

Pressing **Start** during the delay period begins the infusion immediately (overriding the delay period).

- **Do not use KVO:**
  Press **No** → **Start with Delay**.
  On the Delayed Start screen, the words No KVO appear in the Rate frame, and a time countdown for the delay period is displayed in the Time frame.

To override the delay period, from the toolbar, press **Skip delay**. Then, from the Start screen, press **Start**.

When the delay period is over, a message (level 3, low priority alarm) is triggered.

6. To begin the infusion, verify that the clamps on the administration set are open, and press **OK**; then, press **Start**.

When a KVO rate is not used during the delay period, the infusion does not begin automatically when the delay period is over. You need to begin the infusion manually, by pressing **Start**.

Using the New Patient Feature

The Sapphire pump allows you to associate infusions to a specific patient. When the New Patient feature is enabled, and either a New Infusion or a PreSet program is selected, the pump prompts you to indicate whether the infusion to be programmed is for a new patient or not. When selecting Repeat Last Infusion, the New Patient screen does not appear, and the pump indicates that the infusion to be repeated will be used for the last patient selected.

The New Patient feature can be enabled/disabled by technicians only.

When a New Patient is selected, entries associated with the patient can be tracked in the Event Log (Viewing the Event Log on page 241). In addition, when Repeat Last Infusion is used, the pump calculates the accumulated volume infused (Accumulated VI) for all infusions associated with the patient, and the Delivery History. When a new patient is selected, the Accumulated VI and Delivery History are automatically cleared (for more information, refer to Monitoring the Accumulated Volume Infused (Shift's Total) on page 258). The current accumulated Delivery history can be viewed via the Options menu. When an infusion is running, the Delivery history can be accessed via the View/Edit soft key in the toolbar (for more information, refer to Viewing Delivery History on page 242).

> To select a New Patient:

1. From the Start Up screen, select **New Infusion** or **PreSet Programs**.
2. On the New Patient screen, select **Yes**.

Monitoring the Accumulated Volume Infused (Shift's Total)

The Sapphire pump calculates the Accumulated Volume Infused (Accumulated VI) for all infusions associated with a specific patient.

The accumulated VI includes the volume infused to a specific patient via infusions (including primary, secondary etc.), Boluses and KVO (if applied during delayed Start or post infusion). This allows the clinical staff to monitor the total volume infused to a specific patient. The Accumulated VI can be cleared during infusion or before starting another infusion (for more information, refer to Clearing Accumulated VI on page 259). The date and time in which the Accumulated VI was cleared is also captured.

The Sapphire pump also provides the volume infused in the current running infusion (VI), including KVO if applied, during a delayed start period. This VI is presented on the running screen as well as in the message given at the end of the infusion. Clearing the Accumulated VI automatically clears the VI.

Viewing Accumulated VI

The Accumulated VI value can be viewed before programming an infusion via the Options menu, or during a running infusion via the View/Edit and View System menus.

> To view the current Accumulated VI value from the Options menu:

1. From the **Options** menu, select **View → View system**.
2. From the toolbar of the View system screen, press **Next** until the Accumulated VI parameter is displayed.

> To view the current Accumulated VI value during infusion via the View/Edit menu:

1. From the toolbar of the Running screen, press **View/Edit**.

The Accumulated VI value is presented in the Clear Accum. VI box.

> To view the current Accumulated VI value during infusion via the View System menu:

1. From the toolbar of the Running screen, press **View/Edit**.
2. From the View/Edit screen, select **View system**.

3. From the toolbar of the View system screen, press **Next** until the Accumulated VI parameter is displayed.

In addition to the Accumulated VI value, when using the Continuous delivery mode, the View System screen also presents the Accumulated Volume Infused via the primary line (Accum. Prim. VI) and the Accumulated Volume Infused via the secondary line (Accu. Sec. VI). The View system function captures the date and time in which the accumulated VI was last cleared.

Clearing Accumulated VI

The Accumulated VI value is cleared in the following cases:

- The pump clears the Accumulated VI automatically
  - If the New Patient feature is disabled – Each time a New Infusion or a PreSet Programs is confirmed (**Note:** Repeating the last infusion won't clear the Accumulated VI).
  - If the New Patient feature is enabled – Each time a new patient is identified (**Note:** Repeat Last Infusion is intended for the same patient; this means that a new patient can't be identified when using the Repeat Last Infusion shortcut).
- The user clears the Accumulated VI
  - During infusion via the View/Edit screen.This will reset the total volume infused for all infusions associated with a specific patient to 0 mL.

The date and time in which the accumulated VI was cleared is captured and can be viewed in the View System menu.

> To clear the Accumulated VI value during infusion:

1. From the toolbar of the Running screen, press **View/Edit**.
2. From the View/Edit screen, press **Clear Accum. VI**.
3. From the Clear Accum. VI screen, press **Yes** to clear the Accumulated VI.

Chapter 9: Drug Library

The following sections explain about the Drug Library unique features, and describe how to operate the pump in the different delivery modes using the Drug Library:

Overview

The Drug Library contains information about customized groups of drugs and Clinical Care Areas (CCA) that were approved and saved by qualified and authorized local hospital personnel, using the Eitan Medical Drug Library Editor.

The Drug Library is identified by a Drug Library name and publish date, both displayed on the View system menu. The Drug Library name is also displayed on the Sapphire when the pump turns On.

The Drug Library functions as an error-reduction tool, thus enabling safer practice.

The Drug Library displays for each drug its available concentrations and allowed range (hard limits) of various infusion parameters, such as continuous rate and bolus amount. In addition, it contains the recommended range (soft limits) of these infusion parameters.

The information about customized groups of drugs may be specific to a CCA, or may apply to an entire institution.

The limits set in the Drug Library create a guiding range, thus reducing infusion errors. The pump alerts users when the programmed values exceed the recommended range (soft limits), and prohibits programming of values that exceed the allowed range (hard limits).

The complete detailed information about the Drug Library is available in the Drug Library Editor Software. For more information refer to Drug Library Editor user manual.

Clinical Care Area (CCA)

The Drug Library accommodates of up to 40 CCAs, and up to 8,500 unique drug profiles. Each CCA can accommodate up to 1000 drug profiles, and each unique drug profile can be assigned to more than one CCA, i.e. up to a total of 40,000 medications. The CCA unique configuration is set by the Drug Library. Local configuration made when a Drug Library is loaded remains valid until the user selects a CCA or turns the pump Off.

	CCA settings do not include TPN specific settings; TPN hard limits and KVO can be set locally by a technician only.

	When Resuming an infusion after pump shutdown, local configurations will remain until the end of the current infusion.

Changing a CCA

CCA selection is available in the following cases:

- When the pump is turned On
- When the pump is idle, from the General Settings menu
- During a running infusion (the selected CCA will apply after the infusion has completed)

The name of the selected CCA is displayed on the Indicators Bar above the screen title.

Selecting a CCA when pump is turned On

When a Drug Library is loaded, a message is displayed, asking to accept or change the current CCA.

> To accept or change a CCA:

1. Turn the pump On.
2. From the Clinical Care Area screen select whether to **Accept** or **Change** the current clinical care area:

- To accept the current CCA, press **Accept**.
  The Start Up screen appears.
- To change the current CCA, press **Change**.
  a. From the Choose CCA screen, select the relevant CCA.

To display additional CCAs press **Next**.

  b. From the Attention screen, press **OK**.

In case the current delivery mode is unavailable in the selected CCA, the pump will prompt the user to change the delivery mode.

  The Start Up screen appears.

CCA selection should be selected according to local facility procedures.

If a message regarding resuming previous infusion appears upon turning the pump On, refer to Resuming Infusions After Pump Shutdown on page 217.

Selecting a CCA from the General Settings

> To change the current CCA:

1. From the toolbar of the Start Up screen, press **Options**; then, select **Pump** → **configuration** → **General Settings**.
2. Select the **Current CCA** row.
3. From the Choose CCA screen, press the row of the relevant CCA.

To display additional CCAs press **Next**.

4. To confirm the selected CCA, press **OK**.

The Start Up screen appears.

	Selecting a CCA should be conducted according to local facility procedures.

	The Repeat Last Infusion option will be unavailable (grayed out) after the CCA is changed.

Changing a CCA during a running infusion

	When changing the CCA during a running infusion, the CCA will change only after the infusion has completed. The selected CCA name will appear in the indicators bar, two arrows on either side.

> To change a CCA during a running infusion:

1. From the Running screen press **View/Edit**.
2. From the View/Edit screen, select **View system**.
3. Select the **Current CCA** row.
4. From the Choose CCA screen, select the row of the relevant CCA.

	To display additional CCAs press **Next**.

5. From the Attention screen, confirm the selected CCA, and press **OK**.

The View/Edit screen is displayed.

To view or change the Next CCA:

- From the View/Edit screen, press **View System**.
- Press **Next CCA**.
- Select CCA from list.
  Note: To display additional CCAs press **Next**.
- From the Attention screen, press **OK**.

The Repeat Last Infusion option will be unavailable (grayed out) after the CCA is changed.

6. To return to the running infusion, press **OK**.

Programming a New Infusion with the Drug Library

When the Sapphire pump is loaded with a Drug Library, the programming flow includes additional related steps: Drug name entry, Drug list and Drug profile. Following the drug profile selection, the user is required to enter the infusion parameters according to the delivery mode.

Drug Name

After starting a **New Infusion**, the pump displays the Drug name screen.
From the Drug name screen, using the keypad, the user enters the drug name then presses **Find***.

Drug name search is not sensitive to uppercase or lowercase letters.

When the required drug is not found in the Drug Library, the user can program an infusion without a defined drug by using the **Choose General** key on the toolbar.

'Choose General' will bypass the specific drug profile limits, and the infusion will be programmed under the CCA limitations only.

Drugs List

The filtered drugs are displayed in the Drugs List screen.
The Drugs List screen displays only drugs that are available in the current CCA and delivery mode. When there are more than 4 available drugs, use the **Next** key to display additional drugs.

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* The **Find** key can be used to display all available drugs when no characters have been entered (letters, numbers or symbols), or to filter drug names according to the characters entered. The number of matching drugs found is displayed at the top right corner of the main display.

Drug Profiles

The pump displays the available profiles for the selected drug. The drug profile includes concentration and defines hard limits and soft limits. Each available drug is defined by the CCA and the delivery mode to which it was assigned; a drug profile may be available in more than one delivery mode.

Each drug profile is defined by one of the following types:

1. **No concentration**: The drug concentration or diluent volume are not needed. Available drug units are: mL/h, mL/min, mL/kg/h and mL/kg/min.
2. **Diluent only**: Solutions where medication amount is not required (e.g., 100 mL). Available drug units are: mL/h, mL/min, mL/kg/h and mL/kg/min.
3. **Partial concentration**:
   - **Without Drug Amount** Only Diluent Volume is defined. The user will be asked to enter Drug Amount (e.g., __ mg/100 mL).
   - **Without Diluent Volume** Only the Drug Amount is defined. The user will be asked to enter Diluent Volume (e.g., 10 mg/__ mL).
4. **Full concentration**: Both Drug Amount and Diluent Volume are defined.

For more information about programming a new infusion with Drug Library, according to the chosen delivery mode, refer to:

To begin a new Continuous infusion with a Drug Library on page 126
To begin a new Multi-step infusion with a Drug Library on page 154
To begin a new Intermittent infusion with a Drug Library on page 172
To begin a new PCA infusion with a Drug Library on page 182
To begin a new PCEA infusion with a Drug Library on page 194
To begin a new Epidural Intermittent infusion with a Drug Library on page 206

Soft Limit

The limits set in the Drug Library create a guiding range, thus reducing infusion errors. When programming values that exceed the recommended range (soft limits), an Attention screen is displayed, showing the applicable soft limit icon, with the details of the exceeded parameter. The user can either:

- Acknowledge the message and continue with the entered value.
- Go back and enter a new value instead of the entered value.

Figure 9.1. Soft Limit Icon

Current infusion is above upper soft limit

Current infusion is below lower soft limit

Current infusion is exceeding both upper and lower soft limits of various parameter

> To acknowledge the message and continue with the entered value:

From the Attention screen, press **OK** and continue programming.

When a soft limit has been exceeded, an applicable Soft Limits icon will be shown on the Sapphire pump indicators bar during infusion.

> To enter a new value instead of the entered value:

From the Attention screen, press **Back**.

Then, using the keypad, enter a new value and press **OK**.

Soft limits Attention screen and icon are applicable only when soft limits are defined in the Drug Library.

Update a New Drug Library Version

Following a Drug Library update, when the pump is turned On, the user is prompted to specify whether or not to update the Drug Library with the new available version. This feature is available only on Sapphire pumps with Wi-Fi capabilities.

Updating Drug Library should be conducted according to local facility procedures.
Updating a new Drug Library version may take a few minutes, during which the pump is inactive.

> To update a new Drug Library version:

From the Update screen, press **Yes**. The pump will start updating the Drug Library. At the end of the process the pump will restart and the user will be prompted to specify the CCA;

- If the last active CCA is available in the new Drug Library, the Clinical Care Area screen will appear. Press **Accept** and the Start Up screen will appear.
- If the last active CCA is not available in the new Drug Library, the Choose CCA screen will appear.

  a. Select the relevant CCA.

  b. To confirm the changed CCA, press **OK**.

  The Start Up screen will appear.

If the user chooses not to update the Drug Library upon pump turn on, the Update screen will be prompted the next time the pump is turned on.

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Chapter 10: Alarms and Troubleshooting

The following sections describe the different types of alarms and messages that can be generated by the pump, and explain how to troubleshoot common programming issues:

Alarms Overview

The Sapphire pump generates three different types of alarms. The alarm types are categorized according to the urgency of the needed response ("Immediate response" or "Awareness needed"). In all alarm types, instructions about how to proceed (and, if relevant, to solve the problem) are displayed on the touch screen.

Alarm Type	Effect on Infusion
Error – Level 1, high priority alarm	Immediate response required. Pump will shut down after 3 minutes.
Alarm – Level 2, high priority alarm	Immediate response required. Infusion stops, but may be resumed.
Message – Level 3, low priority alarm	User Awareness is required. Infusion is not interrupted.

The following sections provide details about each alarm type. Alarms related to battery problems can be prevented by adhering to the recommended guidelines for battery care (Battery Care Information on page 293).

Error – Level 1, High Priority Alarms

This type of alarm requires Immediate user attention.
When initiated, an auditory alarm sounds, the alarm LED blinks, and the recommended action is displayed on the screen. If the pump is running when the alarm occurs, the infusion stops immediately, and the pump automatically shuts down within 3 minutes. The infusion cannot be resumed.
Exception: 'Battery depleted' alarm (placed in this category because it will lead to pump shutdown within 3 minutes) can be resolved and dismissed (infusion can continue) by connecting a power supply to the pump.

The following soft keys are available during an error alarm:

- **Mute:** Silences the auditory signal (pause audio).
- **Shutdown:** Turns Off the pump immediately.

When a Battery Depleted alarm occurs, connect the pump to an AC power supply. When an error alarm is triggered, please contact an authorized technician.

Alarm Title	Screen Header	Displayed Text
Battery Depleted	Error	Pump will automatically shut down in 3 minutes. Please connect pump to power.
Internal Error	Error	Pump will automatically shut down in 3 minutes. Please contact an authorized technician.

Alarm – Level 2,High Priority Alarms

This alarm type requires immediate user response.

When triggered, an auditory alarm sounds, the alarm LED blinks, and the condition that triggered the alarm (and recommended actions, if relevant) is displayed on the screen.

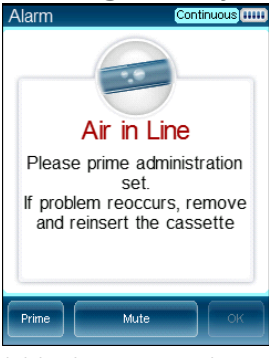
If the alarm occurs during an infusion, the infusion automatically stops. However, you may continue the infusion after the problem has been resolved. Instructions for resolution of the problem are displayed on the touch screen.

To silence the audio signal of an alarm, press the **Mute** soft key. This silences the alarm auditory signal for 2 minutes. If the issue has not been cleared after 2 minutes, the alarm auditory signal will be resumed.

Exception: 'Battery Near Depletion' alarm (placed in this category because it is considered a high priority alarm, although it does not lead to infusion automatic stop) can be resolved and dismissed by connecting a power supply to the pump.

	Resolving these alarms will lead to the Paused Infusion screen. If the alarm occurs while programming a mid-infusion action, the programming process needs to be re-initiated.

Figure 10.1. Alarm – Level 2, High Priority Alarm Screen



The following soft keys are available during a Level 2, High priority alarm:

- **Mute:** Silences the auditory signal for 2 minutes (pause audio).

- **Unmute:** Returns the auditory signal.
- **OK:** Displays the Paused screen. The infusion may then be resumed after the problem is resolved. This soft key is enabled after **Mute** is pressed.
- **Prime:** Enables automatic priming. This key appears only during an Air in Line alarm.

Alarm Title	Screen Header	Displayed Text
Infusion Complete	Alarm	VI: xxx mL Rate: xxx.x mL/h Total Time: xx:xx:xx h:min:sec
Air in Line	Alarm	Accumulated air in line is over the limit. Please prime administration set. If problem reoccurs, remove and reinsert the cassette. Please prime administration set. If problem reoccurs, remove and reinsert the cassette. Possible excessive environmental light. Please reduce exposure and check if priming is required.
Potential Air in Line	Alarm	Press OK to test for air.
Cassette Misplaced	Alarm	The administration cassette is not loaded or misplaced. Please reload the cassette. Reinsert cassette. Verify both flanges inside safety door. If problem persists contact technician. Remove the administration cassette, verify cassette chamber is clean, and correctly reinsert it. If alarm reoccurs please contact authorized technician.
Check for Occlusion	Alarm	Please verify clamps are open and set is not occluded.
Downstream Occlusion	Alarm	To clear occlusions verify: 1. Clamps are open; 2. Administration cassette is properly positioned; 3. Line is not kinked; 4. No occlusion at the output connection. If all occlusions were cleared press OK to continue.

Alarm Title	Screen Header	Displayed Text
Flow Error	Alarm	1. Remove and reinsert administration cassette; 2. Connect pump to a power supply. If alarm reoccurs contact authorized technician.
Occlusion	Alarm	To clear occlusions verify: 1. Clamps are open; 2. Administration cassette is properly positioned; 3. Line is not kinked; 4. No occlusion at the input and output connections. If all occlusions were cleared press OK to continue.
Upstream Occlusion	Alarm	To clear occlusions verify: 1. Clamps are open; 2. Administration cassette is properly positioned; 3. Line is not kinked; 4. No occlusion at the output connection. If all occlusions were cleared press OK to continue.
Insufficient Battery	Alarm	Low battery voltage for current rate. Please connect pump to power supply.
Battery Near Depletion	Alarm	Less than 10 minutes to Battery Depletion. Connect pump to power supply.*

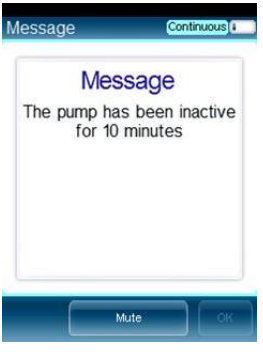
* If the alarm condition still exists after pressing **OK**, the message will be prompted again after 3 minutes (paused alarm).

Messages – Level 3, Low Priority Alarms

A Message is an alarm that requires user awareness as soon as possible. When triggered, an auditory alarm sounds, the alarm LED is steady on, and the condition that triggered the alarm (and recommended actions, if relevant) is displayed on the touch screen.

To silence the alarm's auditory signal, press the **Mute** soft key. This silences the alarm auditory signal for 2 minutes. If the issue has not been cleared after 2 minutes, the auditory signal will be resumed.

Figure 10.2. Sample Message Screen



If a message is displayed during infusion, the infusion continues, and the system continues to operate. The following soft keys are available:

- **Mute:** Silences the auditory signal for 2 minutes (pause audio).
- **Unmute:** Returns the auditory signal.
- **OK:** Confirms the message, and returns the display to the previous screen. If the infusion is complete, the pump returns to the Start Up screen. This soft key is enabled after **Mute** is pressed.

  The Message (Level 3- low priority alarm) display includes the following fields:

Alarm Title	Screen Header	Displayed Text
Low Battery	Message	30 minutes left to battery depletion. Connect pump to power supply*.
Battery Reminder	Message	End of battery life. Please contact authorized technician to replace battery.
Battery life expires in 2 weeks	Message	Battery life will expire in 2 weeks, Please contact authorized technician.
Check Battery Charge	Message	The battery could not be fully charged, Please check power supply.
Pump failed annual certification	Message	Pump failed annual certification. Please return to service.
Battery life expires in 2 days	Message	Battery life will expire in 2 days. Please contact authorized technician. The battery could not be fully charged - please check power supply.
Door Open	Message	Door open. Check administration cassette position and close the safety door*.
Infusion Near End	Message	Infusion near end.
Pump Inactive	Message	The pump has been inactive for <xx> minutes.
System Temperature out of range	Message	System temperature is out of range. If the alarm reoccurs please contact authorized technician*.
Key Stuck	Message	Key Stuck. Please release the key.
Delayed Start Over	Message	Delayed period is over.

* If the alarm condition still exists after pressing **OK**, the message will be prompted again after 2 minutes (paused alarm).

Troubleshooting

The following table lists some common programming issues, and explains how to solve them.

Problem	Probable Cause	Solution
Programming cannot be completed. The **OK** function key is disabled, and the parameter range is in red font.	The parameter entered is outside of the safety range calculated by the pump.	Verify the prescription, and obtain a new one if necessary. Enter infusion parameters within the permitted ranges.
The Set Delay option does not appear on the Start screen.	The option is not enabled.	Enable the Allow delayed start setting (Configuring General Settings on page 230). High Authorization level is required.
The PreSet Programs option does not appear on the Start Up screen in any mode.	The option is not enabled.	Enable the Allow PreProgram setting (Configuring General Settings on page 230). High Authorization level is required.
The Repeat last infusion option does not appear on the Start Up screen in any mode.	The option is not enabled.	Enable Repeat Last infusion setting (Start Up Configuration Menu on page 234). High Authorization level is required.
Loading dose cannot be programmed in PCA or PCEA mode.	The option is not enabled.	Enable the Allow loading dose setting (PCA Options Menu on page 244 or Epidural Mode Options Menu on page 245). Authorization level of High is required.
Pump becomes locked whenever an infusion starts.	The Auto Patient Lockout feature is enabled.	Disable the Auto P. Lockout option (Configuring General Settings, page 232). High Authorization level is required.

Problem	Probable Cause	Solution
A password needs to be entered to change any parameter in Epidural mode.	The Password Request feature is enabled.	Disable the **Password request** setting (Epidural Mode Options Menu on page 245). Authorization level of High is required.
~~Grey~~gray-buttoned bolus handle is not responding.	• The gray-buttoned bolus handle has become disconnected from the pump~~, or t~~ • The ~~grey~~gray-buttoned bolus handle is connected to the mini cradle together with a communication cable, or with Sapphire Connect.	• Reconnect the bolus handle to the pump. • Disconnect the communication cable from the mini cradle, or the Sapphire Connect from the Sapphire pump.
Blue-buttoned bolus handle is not responding.	The handle has become disconnected from the pump, or the blue-buttoned bolus handle is being used, and is connected to the mini cradle instead of to the pump.	Reconnect the bolus handle to the pump.
The Bolus button does not appear in the toolbar during a Continuous infusion.	The Allow Bolus feature is not enabled.	• Enable the Allow Bolus setting. Technician Authorization level is required. For more information refer to the Service Manual. • The drug profile in the Drug Library was not configured to support a bolus.
Communication error while pressing the bolus handle button.	The Bolus handle button was pressed during pump start up.	Disconnect the bolus handle from the pump, turn the pump off, and reconnect the bolus handle after turning the pump On.

Problem	Probable Cause	Solution
Pump is not charging.	• The power supply has become disconnected from the mini cradle, or with Sapphire Connect. • The power supply was connected to the pump during pump turn-off. • The power supply is not working.	• Verify that the power supply is connected to the mini cradle splitter, or to the Sapphire Connect USB-C port. • Disconnect and reconnect the power supply to the pump. • If the power supply is not functioning properly, replace it.
Recurring Air in Line alarms.	Treatment is near end, or the air detection settings are too sensitive.	Close clamps, remove administration cassette from pump and prime (flush) the set manually. If the issue is not resolved, replace the administration set. If the issue is still not resolved, have a technician review and adjust the air detection settings.
Recurring Occlusion alarms.	The occlusion issue has not been properly resolved.	• Close clamps, remove administration cassette from pump, disconnect patient and prime (flush) the set manually. • Replace the administration set. • Change the infusion site.
Occlusion alarm is triggered immediately after the infusion or bolus starts, or rate is increased.	The backpressure caused by the catheter used for the treatment, at the programmed rate, is too high.	Reduce the backpressure by either replacing the catheter or by decreasing the infusion rate.

Problem	Probable Cause	Solution
Screen saver does not appear.	• Screen saver option was not enabled. • Pump is not in an applicable state.	• Enable the Screen Saver option (refer to Configuring General Settings on page 230) • The screen saver will not appear if the pump is in one of the following states: Paused, Delayed Infusion, end of treatment KVO, during alarm, when screen is touched, when key is pressed, or during a Bolus delivery
The pump pauses when programming a secondary.	The pump is not connected to an AC outlet, and currently the battery power is insufficient to support both the primary line rate and the secondary line programming.	Connect the pump to an AC outlet, and select to continue the primary or start the secondary.
Fast depletion of AA batteries.	Power Supply is connected to the Pump, and not to electricity, while EBP is attached to the pump.	Disconnect power supply from the Pump.
Pump doesn't turn on when attached to the EBP.	Internal battery is below the required voltage level for the pump to turn on.	• If stable power supply is available, connect the power supply to the pump. • Contact an authorized technician to replace the internal battery.

Problem	Probable Cause	Solution
Pump does not show indications of connection when attached to the EBP.	• EBP was not properly attached. • AA batteries were misplaced in compartment. • AA batteries are depleted.	• Detach the EBP and re-attach it exactly as instructed. • Detach the EBP, make sure the AA batteries inserted properly and re-attach it exactly as instructed. • Detach the EBP and replace the AA batteries with fresh AA batteries and re-attach it exactly as instructed.
Pump does not show indications of connection when attached to Sapphire Connect.	• Sapphire Connect was not properly attached. • The electrical connectors are not clean.	• Detach the Sapphire Connect and re-attach it exactly as instructed (refer to Removing Sapphire Connect on page 60 and Connecting to the Pump on page 58). • Clean the Sapphire Connect electrical components (refer to Cleaning Sapphire Connect and Electric Connectors of Sapphire Accessories on page 287) and the pump P to C connectors (refer to Guidelines for cleaning/disinfecting specific pump components on page 286)

Chapter 11: Maintenance and Storage

The following sections describe the proper cleaning, preventive maintenance, and storage procedures for the pump and the battery:

Cleaning and Disinfecting the Pump

Between use on different patients, the Sapphire pump and all of its components need to be first thoroughly cleaned, and then disinfected, per hospital/medical provider protocol for multiple patient use.

Cleaning and disinfecting the pump involves wiping it with Dispatch® (Caltech) ready-to-use towels.

For cleaning – 1-minute waiting time.
For disinfecting – 15-minute waiting time.

Additional Cleaning and Disinfection Agents:

- Virex® II 256
- Virox® AHP 5 RTU, Diversey
- Klor De™ (Chlorine tablets)
- 70% Isopropyl alcohol

Cleaning and Disinfection: Safety Precautions

Before and during cleaning, adhere to the following safety guidelines and recommendations:

- Only people who are trained in the maintenance of this type of medical device should clean the infusion pump
- Before cleaning/disinfecting the pump, verify that:
  - The pump is disconnected from the patient.
  - The pump is disconnected from all connections, sets, and accessories.
  - The pump is turned Off.
- While cleaning/disinfecting the pump, do not allow fluid to enter the pump housing, speaker holes or battery chamber.
- Do not steam autoclave, ethylene oxide sterilize or immerse any part of the pump in fluid.
- Do not use spray or aerosol cleaners.
- Dispose of all cleaning/disinfectant materials per laws and regulations for infectious waste disposal.
- Do not clean or disinfect the pump using liquid household Bleach.

Before using materials other than the products listed above for cleaning and disinfecting the Sapphire Infusion pump, make sure they are listed in Eitan Medical's official approved list of materials (published at www.eitanmedical.com).

The pump must be completely dried out before connecting it to a power supply.

Cleaning and Disinfection Procedure

Cleaning/Disinfecting Solution	Manufacturer
Dispatch® (Caltech) ready-to-use towels	Caltech
Virex® II 256	Diversey
Virox® AHP 5 RTU	Diversey
Klor DeTM (Chlorine tablets)	Concept
70% Isopropyl alcohol	Veltek Associates, Inc.

Cleaning Procedure

The following procedure explains how to thoroughly clean the pump using the approved agents (listed above):

> To clean the pump:

1. Turn the pump Off and unplug the power cord from the Sapphire pump power socket.
2. Use the appropriate dilution ratio per the manufacturer's instructions.
3. When the solution is ready, apply the solution on a cloth or sponge, then squeeze so it won't drip.
4. Wipe the exterior planes areas in back and forth motions, vertically and horizontally (mainly on the pump housing).
5. The wiping should be applied with normal force, few times on the same locations (at least twice) verifying complete coverage of the areas to be thoroughly cleaned.
6. Guidelines for cleaning specific pump components are listed in the table below.
7. After the thorough cleaning process is completed, the pump should be dried out for 10 minutes.
8. Wipe the pump with a clean dry cloth.

9. Inspect the device for any visible soil after the cleaning steps (but before the disinfection steps) to ensure that the device is cleaned between uses prior to disinfection. If the device has remaining visible soil following cleaning, repeat the cleaning steps (1 through 8 above).

The pump must be completely dried out before connecting it to a power supply.

Disinfecting Procedure

The following procedure explains how to disinfect the pump using the approved agents (listed in Cleaning and Disinfection Procedure on page 284):

> To disinfect the pump:

1. Perform steps 1-6 specified in the cleaning process above.
2. Replace the cloth or sponge with a new one and repeat steps 3-5 (specified in the cleaning process above) five more times (a total of six cycles). Each area should be cleaned for at least five seconds.
3. After the disinfection process is completed, the pump should be dried out for 15 minutes.
4. Wipe the pump with a clean dry cloth.

The pump must be completely dried out before connecting it to a power supply.

Guidelines for cleaning/disinfecting specific pump components

Guidelines for cleaning/disinfecting specific pump components are listed in the following table:

Component	Cleaning Recommendations
LCD Screen	Wipe thoroughly with a squeezed sponge. Avoid scratching the LCD panel. Ensure that no fluid enters the speaker holes at the top of the panel.
Sensor Fingers	Thoroughly clean the finger tip of the sensor using only a damp cloth or sponge.
• Internal White Panel • Bubble Detector (on the internal white panel) • Anchor (on the internal white panel) • Locking tooth (on the internal white panel) • P to C connector, Power communication connector	This part should be kept free from foreign materials and dirt. If necessary, use foam swab moistened with the detergent solution thoroughly to clean the connector, particularly around the 4 fingers roots by applying normal finger force, assuring that the swab reaches all areas, at least twice. **Note**: Swabbing should be applied in vertical or horizontal movement, where possible, while less accessible areas should be swabbed in a circular motion (at least 3 bi-directional rotations clockwise-counterclockwise).

Reprocessing the pump when used by a single patient multiple times

When the Sapphire pump is used by a single patient for multiple times, the pump and all of its components need to be cleaned first, and then disinfected using 70% Isopropyl alcohol.

The user is required to clean and disinfect the pump in the following conditions (the earlier of the three):

- Every time there is visibly soiled.
- Once a week.

- After storage at the patient's home; even if not used.

Cleaning and disinfection instructions are identical to Cleaning and Disinfection Procedure on page 284.

Cleaning Sapphire Connect and Electric Connectors of Sapphire Accessories

Before cleaning/disinfecting the Sapphire Connect, verify that it is OFF and disconnected from the power supply.

Cleaning Sapphire Connect and the electrical connectors of all accessories is restricted to the use of 70% Isopropyl alcohol (IPA) ONLY.
Between use on different patients, the Sapphire Connect and accessories need to be first thoroughly cleaned, and then disinfected, per hospital/medical provider protocol for multiple patient use.

> To clean the Sapphire Connect and accessories:

1. Place the Sapphire Connect or the accessory on a clean and stable surface.
2. Apply IPA 70% lightly to a cloth or sponge.
3. Squeeze the cloth / sponge before cleaning, so that it would not drip on the accessory to be cleaned.
4. Wipe the exterior planes areas in back and forth motions, vertically and horizontally (mainly on the pump housing).
5. The wiping should be applied with normal force, a few times on the same locations (at least twice), verifying complete coverage of the areas to be thoroughly cleaned.
6. For hard-to-reach areas and electrical connectors, swab in a rotational manner for at least 3 bi-directional rotations (clockwise-counterclockwise)*.

* Be careful not to apply excessive pressure on the connector during swabbing

Figure 11.1. Cleaning Electric Connectors

7. Take caution and avoid dripping the reagent into the pins or pores of the electrical connector.
8. Allow the IPA to air dry for at least 3 minutes before connecting to power.

The user is required to clean and disinfect the Sapphire Connect in the following conditions (the earlier of the three):

- Every time it is visibly not clean.
- Once a week.
- After storage at the patient's home – even if not used.

> **To disinfect the Sapphire Connect and accessories :**

1. To disinfect the Sapphire Connect or accessory, replace cloth or sponge and repeat steps 2-6 in the cleaning process above five more times (a total of six cycles). Each area should be cleaned for at least five seconds.
2. After the disinfection process is complete, the Sapphire Connect or accessory should be dried out for 15 minutes.

The Sapphire Connect must be completely dried out before connecting it to a power supply, pump or any other accessories.

Preventive Maintenance

The following sections describe:

Routine Inspection and Maintenance Tasks

The following sections provide guidelines about inspecting and caring for the pump before and after use.

	Take care not to drop the pump. If the pump is dropped or appears to be damaged, cracked or dented, return it to your local representative for inspection.

Preliminary Inspection

Before using the Sapphire pump and its accessories, check the pump for signs of any mechanical damage.

	Do not use the pump if you identify anything which may indicate impaired functioning of the system. In such a case, contact the facility biomedical engineer or a Eitan Medical approved service technician.

Post-use Procedures

The following equipment checks should be performed following each use of the pump, and as required:

Pump Component	Action
Pump housing	Check for cracks and dents.
Power cord	Verify that the power cord is undamaged. Check the entire length of the cord, and the plug.

Alarm Testing

It is recommended to perform manual testing of the following alarms at least once a year. Alarm testing can be conducted as part of the yearly certification. For the Sapphire Epidural pump manual alarm testing, refer to the testing protocols available for authorized technicians (for more information refer to the Service Manual).

Before testing the alarms, make sure to disconnect the set from the patient.

Name of Test	Procedure
Air in Line Alarm	Connect a new Sapphire administration set to the pump without connecting it to the infusion container. Start an infusion at a rate of 100 mL/h. An Air in Line alarm should occur. **Note**: To test the Air in Line alarm, ensure that air detection is enabled (ON) in the Technician options. If air detection has been disabled (OFF), the icon is displayed, and a warning message stating that air detection has been disabled (OFF) appears when programming an infusion. The Air in Line alarm will not be triggered.
Occlusion Alarm	Start an infusion at a rate of 600 mL/h over 5 minutes. While the pump is running, close the upstream clamp. An Upstream Occlusion alarm should occur. Test the Downstream Occlusion alarm by repeating the above test, but closing the clamp or pinching the tubing downstream while the pump is running.

If an alarm is not generated, contact your local representative or authorized technician.

The operator should stand 1 meter from the pump, and verify that he/she can hear and see the alarm.

For more information about the Air in Line and Occlusion alarms, refer to Alarm – Level 2,High Priority Alarms on page 272.

Certification

To ensure proper fluid delivery, the pump should be checked by an authorized service provider at least once a year, to perform yearly certification. For more information on yearly maintenance procedures to be performed by technicians or certified service providers, refer to the Sapphire Infusion Pump Service Manual.

Battery Care Information

The Sapphire pump can operate on battery power, enabling operation of the pump during an electrical power failure, during patient transport or during ambulatory care. When working on battery power (disconnected from the main power supply) the battery charge level icon, at the upper right corner of the Indicators Bar, indicates remaining battery capacity. Check the status of the battery charge level icon regularly:

Number of Bars in Icon	Approximate Remaining Battery Capacity
5	100%
4	75%
3	50%
2	25%
1	Low

You can also check the status of the battery using the **Options** menu. For more information, refer to Viewing System Parameters on page 238.

Battery operation time is dependent upon the condition of the battery, which varies according to temperature conditions, and the extent of prior use of the battery.
For optimal performance, use the device (with battery) at Room Temperature (25°C).
An alarm is triggered when there are 30 minutes left until battery depletion, and again when there are 10 minutes left. This time may depend on the delivery rate, the frequency of pressing keys, and whether the backlight is On. When the Battery Depletion alarm sounds or following long periods of storage, connect the pump to the power supply.
Notification messages begin appearing on the Main Display of the pump 2 weeks before battery life expiration. When the battery life expires, the pump allows you to finish the current infusion and then turns Off. Make sure to test the batteries at least once a year, and replace the batteries every 2 years or every 500 charging cycles, whichever comes first.

Battery Classification

The UL 1642 Standard for Lithium batteries classifies the Lithium-Ion battery used in the Sapphire pump as follows:

- Secondary battery (rechargeable)
- Technician replaceable

Battery Safety Information

When working with the battery, adhere to the safety precautions and recommendations listed below.

Battery Safety Guidelines

- Ensure that only Eitan Medical's rechargeable Lithium Ion (Li-Ion) battery is used.
- In case of rust, bad odor, overheating, and/or other irregularities when using the battery pack for the first time, return it to your local representative.
- Avoid any contact with water. Do not immerse the battery pack in water.
- Do not open the battery casing.
- Store batteries in a closed carton.
- Short term storage temperature should be below 35°C (95°F).
- Avoid battery exposure to direct sunlight.

Long Term Battery Storage

When you store batteries for extended periods of time, ensure the following conditions:

- Well-ventilated facility, free of a corrosive gas atmosphere
- Low humidity environment (recommended up to 50% RH)
- Storage temperature should be between -20°C (-4°F) to +35°C (+95°F). The recommended temperature is 23° ±3°C (73° ±5°F).

Storage at low temperatures may affect initial battery performance. Storage at high temperatures may degrade battery performance.

Charging the Battery

Before initial use of the Sapphire pump, the battery must be charged for at least 6 hours. The battery must also be charged if it has been disconnected from the pump unit for more than 6 months. While the pump is in storage, recharge the battery at least every 12 months.
The pump can operate while it is being charged.

	When using the pump while connected to the power supply, ensure that the pump is attached securely to the power supply, the mini cradle is attached securely to an IV pole, and the power cord is secure, to prevent entanglements that might cause strangulation.

To preserve battery life, connect the pump to the main power supply using the power supply whenever possible.

	While connected to a power supply and charging, the Charge (yellow) LED blinks, and stops blinking when the battery is fully charged. If the pump is turned Off, the company logo appears on the screen while the pump is charging.

	Before charging the battery, ensure that the device is completely dry. Failure to do so may compromise patient safety.

> To charge the battery:

1. Plug the Sapphire dedicated power supply cord into the main power supply.
2. With the white arrows or red dot facing up, plug the power cord into the Sapphire pump power socket or into the splitter connector.
3. On the front of the pump, verify that the Charge LED status indicator is On (blinking yellow light).

Battery Maintenance

To promote maximum battery life, the following procedures should be performed at regular intervals.

Frequency	Action
Following each use of the pump	Check the status of battery charge, and recharge as necessary.
Every 2 years or every 500 charging cycles	Replace batteries.

Transport and Storage

The pump should always be transported in a protective case internally padded with cushioning material. It is best to use the original packaging. During handling and transport, protect the pump and the case from water, excessive humidity, and heat sources.

To safeguard the pump against prolonged exposure to dust and moisture, the pump must be stored in a clean and dry environment. It is recommended that the pump remain plugged in during storage, in order to maintain the battery at full charge. If the pump is disconnected from the power supply, or is in storage without being connected to power for several months, check the battery level, and recharge the battery before using the pump (Charging the Battery on page 296).

For any storage period, make sure that the Sapphire administration cassette is disconnected from the pump, and that the safety door over the pump mechanism is closed. Specific recommendations for long term storage conditions are listed in the following table.

Condition	Parameters
Temperature	-40°C (-40°F) to +70°C (+158°F)
Relative humidity	15% RH to 95% RH
Atmospheric pressure	50 kPa to 106 kPa (500 hPa to 1060 hPa)

Chapter 12: Technical Specifications

The following sections present technical specifications for the pump and its components:

Pump Accuracy

The following graphs and curves were derived from the pump accuracy testing procedures described in the IEC60601-2-24 standard. Testing was performed under normal conditions at room temperature (25°C, 72°F).

Normal conditions to ensure optimal accuracy of ±2.5%:

- Fluid level should be 50 cm above the pump
- No back pressure due to catheter size or difference in height of pump and infusion site
- Room temperature (25°C; 30-60% RH)
- Barometric pressure of sea level altitude (101kPa)
- IV medication with water like fluid characteristics

A tiered flow rate accuracy information is presented below with practical information of the pump accuracy under nominal and boundary conditions according to the pump specifications:

Tiered Flow Rate Accuracy Specifications

Accuracy behavior in a wide range of practical use cases.

Impact of Treatment-Related Parameters on Flow Rate Accuracy at Normal Environmental Conditions

	Ranges		
	Low	Nominal	High
Rates (mL/h)*	0.1	0.1 up to 999	999
Accuracy	±2.5% for all three ranges		

* Testing is reported only for the 2nd and 96th hours

Boluses	Rate: 10 mL/h Volume: 0.1mL	Rate:125mL/h Volume: 1mL	Rate: 600mL/h Volume: 20mL	Rate: 999mL/h Volume: 30 mL
Accuracy	±2.5% for all three ranges			

Impact of External/Environmental Parameters on Flow Rate Accuracy

Temperature (°C)*	5-15	15-30	30-40
Accuracy	Up to -3.6%	±2.5%	Up to +3.5%
Altitude (Ft)†	-978 (Dead Sea) up to sea level	Sea level to 3600	3600 - 10,000 (e.g., some cities in Colorado state)
Accuracy	Within 2.5% for all three ranges		
Backpressure (bar)	-0.133 up to 0 (requires combination of extreme parameters, e.g., patient is more than 1.5m below the pump while using a narrow catheter)	0-0.2	0.2-0.5‡
Accuracy	±2.5%	±2.5%	±5%
Head Height (m)	-0.5	-0.5 up to +0.5	0.5
Accuracy	±2.5% for all three ranges**		

* Testing was only performed at 600 mL/h.

† Testing was only performed at 25 mL/h.

‡ Higher backpressures (e.g. from use of thin catheters, backcheck valves, filters) will result in additional deviations: every increase of 0.05 bar will result in deviation of -3% in accuracy.

** When using accessories (e.g., PCA Lockboxes, Homecare Large Backpack and External Battery) where the container height deviates more than 50cm above or below the pump, there may be deviations in pump accuracy. A head height change (change in the fluid level above or below the pump) of ±25cm above the stated values may result in deviation in accuracy of ±1%.

Impact of Viscosity

The table below shows the flow rates required to maintain the delivery accuracy at a worst case viscosity of 10.8cP.

	Flow Rate (mL/h)				
	25	125	300	600	999
Average	-1.13%	-3.47%	-3.10%	-5.43%	-11.49%
STDev	0.82%	1.12%	2.48%	1.98%	0.32%

Start-up and Trumpet Graphs

The start-up graphs represent startup flow versus operating time for the first two hours from the start of the infusion. They exhibit the stability of delivery due to mechanical compliance and provide a visual representation of uniformity. Start-up graphs were performed according to the IEC 60601-2-24 standard.

In the Sapphire pump, as in all infusion systems, the action of the pumping mechanism and variations or external factors may cause fluctuations in rate accuracy. Conditions that can cause flow fluctuations include:

- Position of the infusion container
- Fluid density
- Positive and negative pressure
- Environmental temperature
- Operation of the pump beyond the recommended operating limits

Trumpet curves are named for their characteristic /shape, and are developed in accordance with IEC 60601-2-24. They display the percent flow rate deviation from the programmed rate over time. The horizontal axis represents the observation time intervals.

Over long observation windows, short-term fluctuation has little effect on accuracy, as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have a greater effect, as represented by the "mouth" of the trumpet.

Figure 12.1. Delivery Startup Graph, First 2 Hours of Test Period, 1 mL/h

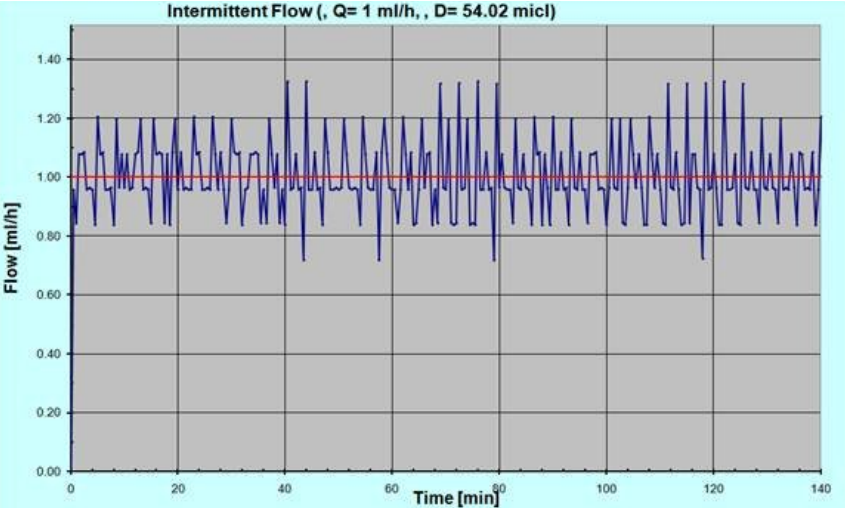


Figure 12.2. Trumpet Graph, Second Hour of Delivery, 1 mL/h

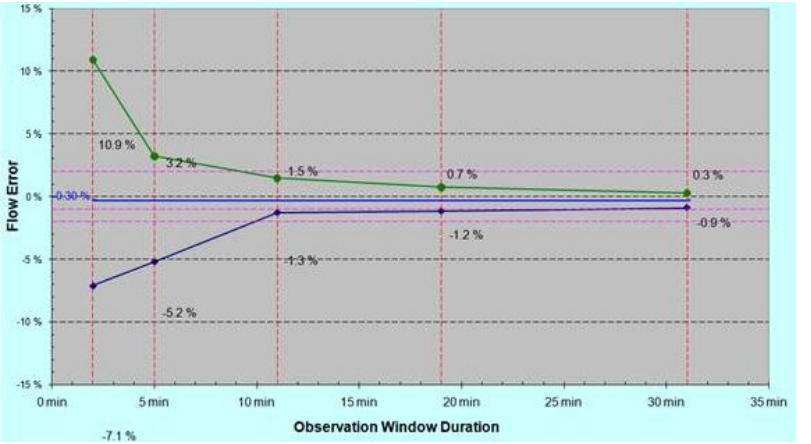


Figure 12.3. Trumpet Graph, 24th (Last) Hour of Delivery, 1 mL/h

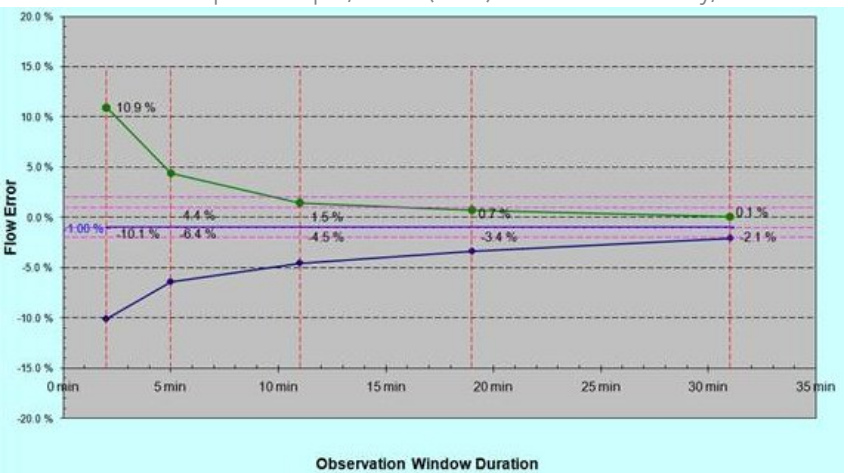


Figure 12.4. Delivery Startup Graph, First 2 Hours of Test Period, 25 mL/h

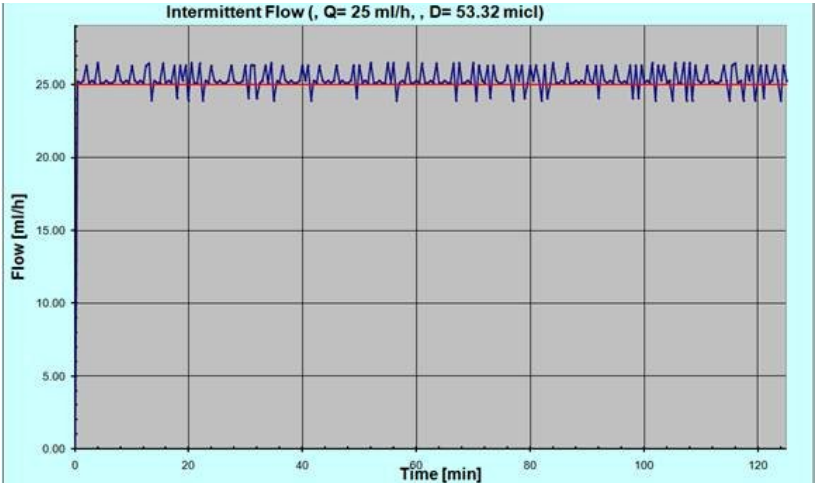


Figure 12.5. Trumpet Graph, Second Hour of Delivery, 25 mL/h

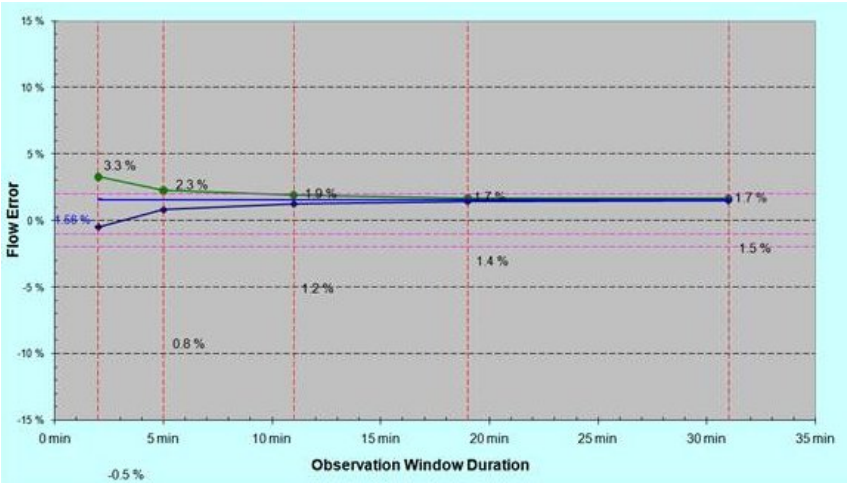
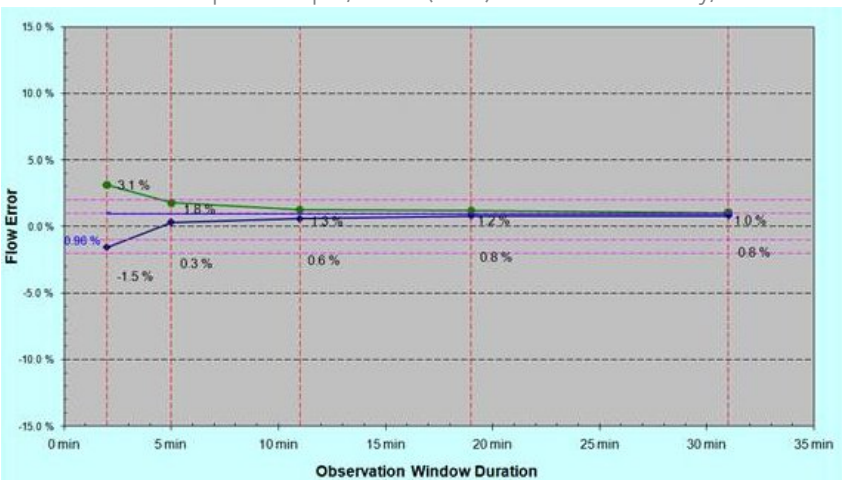


Figure 12.6. Trumpet Graph, 24th (Last) Hour of Delivery, 25 mL/h



Pump Specifications

The following table lists and describes pump specifications.

Parameter	Description
Dimensions	143 x 96 x 49 mm (5.63 x 3.78 x 1.93 in.) (H x W x D)
Weight (excluding batteries)	418 g (14.7 oz.)
Pumping mechanism	Single channel volumetric, with integral pressure sensor
Infusion delivery modes	Continuous (with and without a Secondary line), PCA, Intermittent, Multi-step, TPN, Epidural (PCEA, Epidural Intermittent)
KVO rate	Up to 20 mL/h in increments of 0.1 mL/h
Accuracy	±2.5% (Subject to external conditions such as tubing, pressure, container position relative to the pump, barometric pressure, humidity and temperature)
Defibrillation proof - recovery time	Max 1 sec
Flow rate	0.1 - 99.9 mL/h in increments of 0.1 mL/h 100 - 999 mL/h in increments of 1 mL/h
Volume (VTBI)	0.1 - 9999 mL in increments of 0.1 mL
Infusion device	Volumetric, peristaltic
External power supply	100 - 240V 50-60 Hz, 0.6A
Battery	• Rechargeable Li-Ion battery 7.4V, 1960 mA/h • 24 hrs @ 125 mL/h (with a fully charged battery, and backlight Off)* • Recharge time: up to 6 hrs (when pump is not in operation)
Adaptor	AC Adaptor 10 VDC/2.0A
~~Fuse rating~~	~~T1.6A, 250V~~
Downstream occlusion	Up to 17.4 PSI (1.2 bar or 900 mmHg)

Parameter	Description
Operating temperature	+5° (41°F) to 40°C (104°F)
Alarms	Refer to full list of alarms in Chapter 10: Alarms and Troubleshooting on page 270.
Prime	Manual or automatic priming (600 mL/h, or from air in line alarm 900 mL/h)
Sensors	• **Air in line sensor:** Detects both single and accumulated bubbles sized 0.02-0.5 mL. The desired size range of each option can be selected by the technician. • Upstream/Downstream occlusion sensor • Door open sensor • Temperature sensor

* The specification of 24 hours @ 125 mL/h was tested at an ambient temperature, with a medication/fluid with viscosity of 1cP (water like). Test results support operational time of at least 24 hours (based on 90% reliability and 95% confidence level). The impact of worst-case (i) Rate, (ii) Temperature and (iii) viscosity parameters on battery operational time were evaluated separately:

- At Rate of 800 mL/h – operational time will decrease to 18 hours
- At Temperature of 5°C – no reduction below 24 hours will occur
- At Viscosity of 10.8 Cp – no reduction below 24 hours will occur

Average Bolus Volume After Occlusion

The following table presents the average time to a downstream occlusion alarm, and the bolus volume after occlusion, at a rate of 25 mL/h.

Parameter	Pressure	
	0.4 bar	**1.2 bar**
Average bolus volume following downstream occlusion	0.135 mL	0.75 mL*
Average time to downstream occlusion alarm	38 sec	3 min

* Under single fault condition

The following table presents the average time to a downstream occlusion alarm at a rate of 0.1 mL/h.

Parameter	Pressure	
	0.4 bar	**1.2 bar**
Average time to downstream occlusion alarm	2:30 hours	12:30 hours

In case of an occlusion (upstream or downstream), clear the occlusion by disconnecting the set from the patient and priming the administration set. When priming manually, close clamps and disconnect the patient from the administration set prior to detaching the administration cassette from the pump.

Environmental Specifications

The pump should be operated within the temperature and humidity ranges specified below. To avoid damage to the pump or battery, do not store the pump or the administration set outside these temperature and humidity ranges. Do not store the pump for prolonged periods with the battery installed.

Operating Conditions

Adhere to the following operating conditions:

Condition	Details/Range
Operating mode	Long term infusion usage
Humidity	15% to 95% (15% to 90% at transient state)
Temperature	+5°C to 40°C (41°F to 104°F) (-20°C to +50°C at transient state)
Atmospheric pressure	70 kpa to 106 kpa

Environmental Conditions for Transport and Storage

When transporting or storing the pump, adhere to the following conditions:

Condition	Details/Range
Atmospheric pressure	50 kPa to 106 kPa (500 hPa to 1060 hPa)
Relative humidity	15% to 95%
Temperature	-40°C to +70°C (-40°F to 158°F)

Do not disassemble the portion of the Sapphire pump that houses the pump mechanism and the electronics. This should be done by authorized personnel only; Eitan Medical Ltd. will not be obligated to provide technical service in such a case.

When storing batteries separately from the pump, maintain the following storage temperature ranges:

Type of Storage	Temperature Range
Short term	<40°C (<95°F)
Long term	-20°C (-4°F) to +35°C (+95°F) Recommended: 23° ±3°C (73° ±5°F)

Storage at low temperatures may affect initial battery performance.
Storage at high temperatures may degrade battery performance.

The following list provides guidelines about environmental conditions and situations to be avoided when working with or storing the pump:

- Avoid locations where there is inadequate ventilation.
- Avoid locations where sudden impact or vibration may occur.
- Avoid damp locations, or locations where moisture level may increase considerably.
- Avoid locations with large temperature fluctuations.
- Avoid locations exposed to direct sunlight.
- Avoid locations near an electrical heating apparatus.
- Avoid locations exposed to chemicals or explosive gases.

Electromagnetic Compatibility Statement

The following sections provide information about testing of and recommendations for:

Electromagnetic Emission

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF emission CISPR 11	Group 1	The pump uses RF energy for its internal function only. Therefore, RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emission CISPR 11	Class B	The pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 610003-3-2	Class B	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure 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	±6 kV contact ±8 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	±1 kV at 110 & 230 VAC	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	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the pump requires continued operation during power mains interruptions, it is recommended that the pump be powered from an uninterruptible power supply or a battery.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

* The pump was tested to the EMC requirements of **IEC 60601-1-2 / EN60601-1-2 (fourth edition)** and **IEC 60601-2-24 (second edition)**.

Electromagnetic Immunity for Life-supporting Equipment and Systems

The pump is intended for use in the electromagnetic environment specified below. The customer or the user of the pump should ensure that it is used in such an environment.
Portable and mobile RF communications equipment should be used no closer to any part of the pump, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the  symbol.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance*
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 10 Vrms 150 kHz to 80 MHz	3 Vrms 3 Vrms †	Recommended separation distance (RSD) $d = 1.2\sqrt{p}$ RSD $d = 4\sqrt{p}$

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance*
		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 meters (m).	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	10 V/m 80 MHz – 2.5 GHz 80% AM, 2 Hz 80 MHz – 2.5 GHz 80% AM, 1 KHz	Recommended separation distances: • 80 MHz to 800 MHz: $d = 4\sqrt{p}$ • 800 MHz to 2.5 GHz: $d = 7.7\sqrt{p}$ At 80 MHz and 800 MHz, the higher frequency range applies.

* These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

† The pump was tested to the EMC requirements of **IEC 60601-1-2 / EN60601-1-2 (fourth edition)** and **IEC 60601-2-24 (second edition)**.

Notes

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
2. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
   For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

3. 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 Sapphire pump is used exceeds the applicable RF compliance level above, the pump should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the pump.
4. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances from Mobile RF Communication Equipment

The pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer/pump user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the pump, according to the maximum output power of the communications equipment.

The following table provides recommended separation distances between portable and mobile RF communication equipment and the pump (for life-supporting equipment and systems).

For transmitters rated at a maximum output power not listed in the table, the recommended separation distance *d* in meters (m) can be determined 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.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)			
	150 kHz to 80 MHz outside ISM bands	**150 kHz to 80 MHz in ISM bands**	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1.2\sqrt{p}$	$d = 4\sqrt{p}$	$d = 1.2\sqrt{p}$	$d = 2.3\sqrt{p}$
0.01	0.12	0.40	0.12	0.23
0.1	0.38	1.3	0.38	0.72
1	1.2	4.00	1.2	2.3
10	3.8	13	3.8	7.27
100	12	4.00	12	23

Notes

1. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
2. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
3. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
4. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz.
   This decreases the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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Chapter 13: Limited Warranty

Eitan Medical Ltd. (the "Manufacturer") warrants to the buyer who purchased the Sapphire directly from the manufacturer (Initial Buyer) that the Sapphire Infusion Pump ("Sapphire"), not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this User Manual, for a period of two year from the actual date of sale to the Initial Buyer. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, (such as the Yearly Certification Kit), and specifically excludes batteries, administration sets, extension sets or any other accessory items or equipment used with the Sapphire.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a nominal charge for postage and handling) any defective Sapphire provided a claim is made during such two year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty: This Warranty extends only to the Initial Buyer of the Sapphire.

Warranty Performance Procedure: Notice of the claimed defect must be made by Initial Buyer in writing to the Manufacturer as follows:

Eitan Medical Ltd., 29 Yad Haruzim St., P.O. Box 8639, Netanya, 4250529, Israel. Initial Buyer should send mail to support@eitanmedical.com or contact the account manager. Notice to the Manufacturer must include date of purchase, serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE SAPPHIRE. If authorized, the Sapphire must be properly and carefully cleaned, packaged and returned to the Manufacturer. Any loss or damage during shipment is at the risk of the sender.

B. Conditions of Warranty: The warranty is void if the Sapphire has been 1) repaired by someone other than the Manufacturer or its authorized agent 2) altered so its stability or reliability is affected 3) misused or 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the User Manual or use with non-approved accessories. Removal or damage to the Sapphire's serial number will invalidate this warranty.

C. Limitations and Exclusions: Repair or replacement of the Sapphire or any component part therefore is the EXCLUSIVE remedy offered by Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.

2. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE SAPPHIRE FOR ANY PARTICULAR PURPOSE.

3. The Sapphire can only be used under the instruction of medical personnel whose skill and judgment determine the suitability of the Sapphire for any particular medical treatment.

4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the Sapphire for any particular medical treatment or for any medical complications resulting from the use of the Sapphire. The Manufacturer shall not be responsible for any incidental damage or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the Sapphire.

Service Information

While under Eitan Medical warranty, the Sapphire pump must not be opened by unauthorized personnel.
Use only an authorized Eitan Medical service provider for service and repair. In the event that your pump needs to be returned for service, contact your local representative, or obtain a Return Authorization by filling an inquire form through the Eitan Medical website. The pump must be packed in a suitable container that will provide adequate protection during shipment. To ensure prompt return, a Eitan Medical authorized service representative must be notified before shipping any pump for repair. When calling for service, please be prepared to provide the serial number of the pump and software version details. A brief written description of the problem should be attached to the pump when it is returned for service.
Eitan Medical Ltd. will not be responsible for unauthorized returns or for pumps damaged in shipment due to improper packing. The Sapphire pump service life is 7 years from the date of manufacture.

Technical Support Contacts

For technical assistance, contact your local representative, or contact Eitan Medical by filling an inquire form through the Eitan Medical website https://eitanmedical.com/.

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