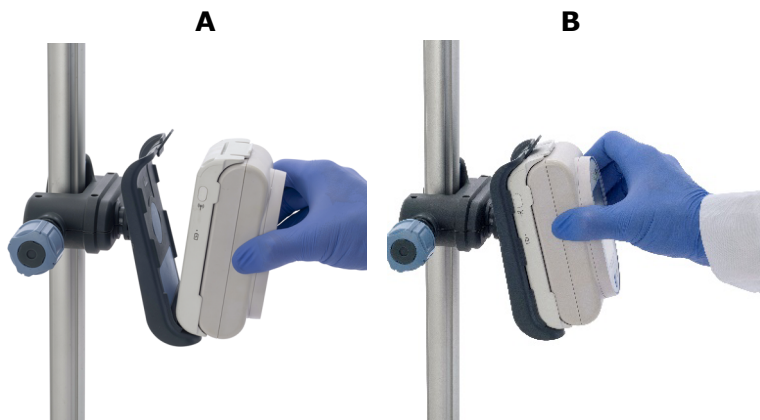


Figure 2.22. Attaching Sapphire Connect to Mini Cradle



> To remove from the mini cradle:

1. Hold the pump securely.
2. Push back on the top hook of the mini cradle until the combined pump-Sapphire Connect unit is released (Figure 2.23).

Figure 2.23. Disconnecting from Mini Cradle

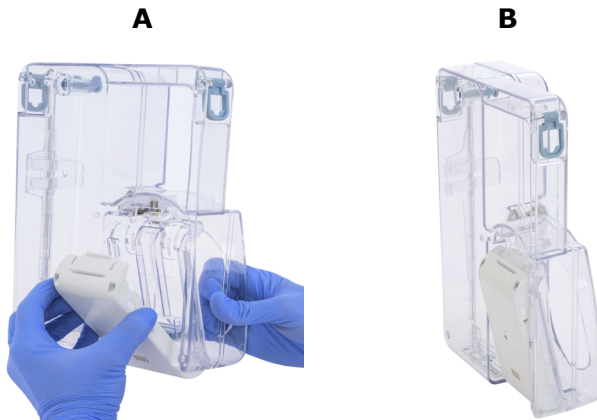


Sapphire Connect with Lockbox 250mL

Sapphire Connect can be used with the PCA Lockbox 250mL:

1. Attach Sapphire Connect to the back of the Lockbox ([Figure 2.24](#)), using the same bottom-to-top action. Make sure that the Lockbox is seated securely on both hooks of Sapphire Connect.

Figure 2.24. Attaching Sapphire Connect to Lockbox



2. If using with a mini cradle, attach the entire unit to the mini cradle via Sapphire Connect.

For more information about using the lockbox, see [PCA Lockboxes](#) on page 46.

> To remove Sapphire Connect from the Lockbox:

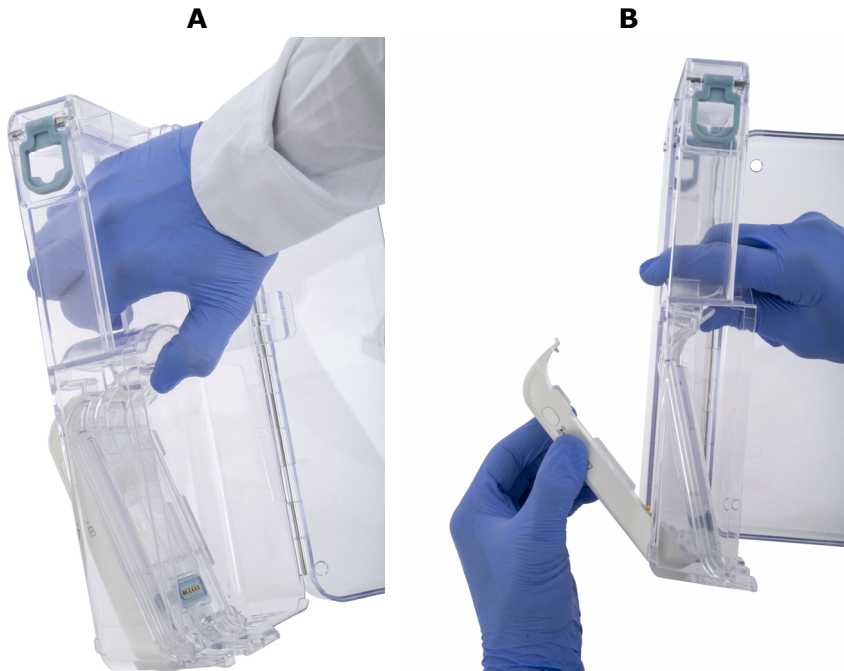
1. When using a mini cradle, remove the Lockbox from the cradle as instructed in [Removing the Lockbox from the IV pole when using Sapphire Connect](#) on page 54.
2. Unlock the Lockbox.

Figure 2.25. Opening the Lockbox



3. Hold Sapphire Connect and the Lockbox securely.
4. From the inside of the Lockbox, press the top hook up and back to release Sapphire Connect ([Figure 2.26](#)).

Figure 2.26. Releasing Sapphire Connect from Lockbox



Demand Bolus Handle (Blue Buttoned)

Sapphire Connect can be used with the blue buttoned bolus handle.

When using a bolus handle, connect the bolus handle by attaching it to the socket at the bottom of the pump. Make sure that the white arrow or red dot on the cable connector is facing up. For more information, see [PCA/PCEA Bolus Handle](#) on page 55.

Figure 2.27. Connecting Blue-Buttoned Bolus Handle



When the Sapphire pump is attached to Sapphire Connect, do not connect the pump to a gray-buttoned bolus handle.

Troubleshooting

Problem / Indication	Meaning	Probable Cause	Action
Communication LED is steady red.	Sapphire Connect has encountered an error.	• Temporary internal communication error. • Hardware error.	Reset the Sapphire Connect by pressing the on/off button for 11 seconds. Then press the on/off button again to turn on the Sapphire Connect. If the error was resolved, the Sapphire Connect should pass the self test as described in Attaching Sapphire Connect to the Pump on page 62. If the problem persists, contact your local representative, or contact Eitan Medical at www.eitanmedical.com .
Communication LED is blinking red.	Self-test was successful, but no cellular connection was found. The status should change to steady blue after 20 seconds.	Poor cellular reception or network problems.	Move to another location to find better reception. Try again later in case the problem was caused by the cellular network.

Problem / Indication	Meaning	Probable Cause	Action
Charging LED is off when the Sapphire Connect power supply is plugged in.	The Sapphire Connect is not charging.	• The USB-C connector is not properly connected. • The power supply has become disconnected from the mains power supply. • The power supply is not working. • The USB-C inlet is damaged.	• Disconnect and reconnect the power supply to the Sapphire Connect. • Verify the charger is properly connected to the mains power supply. • Try charging the Sapphire Connect unit with another power supply. • Try charging the Sapphire Connect unit with a powered mini-cradle (for more information on charging the Sapphire Connect, see page 61). If the problem persists, contact your local representative, or contact Eitan Medical at www.eitanmedical.com.
Sapphire Connect cannot be turned on.	Sapphire Connect cannot be turned on.	• If this occurs right after power-off, Sapphire Connect may be in the process of shutting down. • Sapphire Connect battery is depleted.	• After power-down, wait up to a minute and then press the On/Off button again. • Charge the Sapphire Connect battery and try again after 1 hour (for more information on charging the Sapphire Connect, see page 61). If the problem persists, contact your local representative, or contact Eitan Medical at www.eitanmedical.com.

Specifications

Environmental Conditions

Sapphire Connect shall be stored, transported, and operated under the following conditions:

Environmental Conditions			
Condition	Storage (> 72 hrs)	Transportation (< 72 hrs)*	Operating *
Temperature (°C)	-20°C to 40°C (-4°F to 104°F)	-40°C to 70°C (-40°F to 158°F)	5°C to 40°C (41°F to 104°F)
Relative Humidity (% R.H)	15% to 95%	15% to 95%	15% to 95% (15% to 90% at transient state)
Ambient Pressure (kPa)	50 kPa to 106 kPa	50 kPa to 106 kPa	70 kPa to 106 kPa

* These are the same environmental conditions as for the Sapphire infusion pump.



- Storage at low temperatures may affect initial battery performance.
- Storage at high temperatures may degrade battery performance.



Use the original packaging when transporting Sapphire Connect.



While Sapphire Connect is in storage, recharge the battery at least once every 12 months.

Technical Specifications

Parameter	Description
FCC ID	2A3JW-EM25
Dimensions	(H x W x D) 146.5 x 78.6 x 16 mm (5.77 x 3.09 x 0.63 in)
Weight	175 g (6.2 oz) with battery
Connectivity	Cellular, Cat M1 and 2G
Encryption Mode	AES128 + CBCIV with pre-shared key
Digital Privacy	Includes a 'do not track me' and a cellular communication disable function. Read Privacy policy at eitanmedical.com/privacy-policy/ .
Power Inputs	USB-C; can also be charged using Sapphire mini cradle with splitter or IPS
Battery Type	Rechargeable Lithium-Ion battery (1 cell)
Battery Capacity	900 ±50 mAh
Battery Output	3.7V (nominal)
Battery Life	Charging at least 300 cycles at nominal conditions, 23°C (74°F)
Operating on Battery	50 hours without being connected to an external power.
Communications with Pump	RS-232 Serial communication
Indicator LEDs	Power and communication, charging
IPX Rating	IP24
SIM Type	Nano-SIM (Universal)
Geolocation	GPS, Cellular

Parameter	Description
Data Storage Memory	2 MB
Firmware update	Automatic firmware updates

Communication Control	Frequency Band and Bandwidth
LTE-FDD	Cat M1:
	B1/B2/B3/B4/B5/B8/
	B12/B13/B18/B19/
	B20/B25/B26/B27/
	B28/B66/B85
GSM/EDGE	850/900/
	1800/1900 MHz
GNSS	GPS/GLONASS/
	BeiDou/Galileo/QZSS

Class B Warnings

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed in accordance with the instruction, may cause harmful interference to radio communications. However, there is nor guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

CAN ICES-003 (B)

This Class B digital apparatus complies with Canadian ICES-003.

In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception.

Modification Statements and FCC/ ISED Regulatory Notices

FCC Warning

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC Rules.

Statement according to FCC part 15.19:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Wireless notice

This device complies with FCC/ISED radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the ISED radio frequency (RF) Exposure rules. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

RF Exposure Warnings - SAR

RF Exposure Information (SAR)- FCC

This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels.

The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/eot/ea/fccid after searching on FCC ID:

2A3JW-EM25. This device has been evaluated and proven compliant with the FCC Specific Absorption Rate (SAR) limits when operated in portable exposure conditions. To ensure that RF exposure levels remain at or below the tested levels, use a belt-clip, holster, or similar accessory that maintains a minimum separation distance of 5mm between your body and the device. For body-worn operation, the device has been tested and meets the FCC RF exposure limits; the maximum SAR value is 1.6 W/kg at 0 mm.

RF Exposure Information (SAR)- IC

The radiated output power of the Wireless Device is below the Industry Canada (IC) radio frequency exposure limits. The Wireless Device should be used in such a manner such that the potential for human contact during normal operation is minimized.

This device has been evaluated for and shown compliant with the IC Specific Absorption Rate ("SAR") limits when operated in portable exposure conditions.

RF Exposure information (SAR)- CE

This device meets the EU requirements (2014/53/EU) on the limitation of exposure of the general public to electromagnetic fields by way of health protection.

The limits are part of extensive recommendations for the protection of the general public. These recommendations have been developed and checked by independent scientific organizations through regular and thorough evaluations of scientific studies. The unit of measurement for the European Council's recommended limit for mobile devices is the "Specific Absorption Rate" (SAR), and the SAR limit is 2.0 W/Kg averaged over 10 grams of body tissue. It meets the requirements of the International Commission on Non-Ionizing Radiation Protection (ICNIRP).

For next-to-body operation, this device has been tested and meets the ICNRP exposure guidelines and the European Standard EN 62311 and EN 62209-2. SAR is measured with the device directly contacted to the body while transmitting at the highest certified output power level in all frequency bands of the mobile device.

Power Supply

The pump power supply is used to charge the battery. Specifications of the power supply include:

- **Input voltage:** 100-240 VAC
- **Output voltage:** 10 VDC



To prevent entanglement, always secure the cable cord properly.



Always detach the Sapphire pump from the EBP, before connecting it to the power supply.

> To charge the battery:

1. Plug the Sapphire power supply cord into the main power supply source.
2. With the white arrows or red dot facing up, slide the power cord into the Sapphire pump power socket or into the splitter connector without rotating the connector.
3. On the front of the pump, verify that the Charge LED status indicator is On (blinking orange light).

For more information regarding charging the battery, refer to [Charging the Battery](#) on page 316.

> To disconnect the power supply from the pump:

Gently press on both sides of the power supply connector, and pull it straight out of the Sapphire pump power socket without rotating the connector.

Integrated Power Supply

The Integrated Power Supply (IPS) is a power supply that is assembled into the Mini Cradle to supply power to the pump. Specifications of the power supply include:

- Input voltage: 100-240 VAC
- Output voltage: 10 VDC

> To connect the AC Power Cord to the IPS:

1. Connect the Sapphire AC Power Cord to the IPS.
2. Connect the Cord Retainer to the IPS, using a Philips head screwdriver.



The cord retainer is an integral part of the IPS, and must be connected prior to initial use.

> To charge the battery:

1. Plug the Sapphire AC Power Cord into the main power supply source.
2. On the back of the IPS, verify that the Power LED status indicator is On (blue light).
3. Mount the pump into the mini cradle.



When using Sapphire Connect, mount the pump and the Sapphire Connect using the same bottom-to-top action.

4. On the front of the pump, verify that the Charge LED status indicator is On (blinking orange light).

> To disconnect the AC Power Cord from the IPS:

1. Unplug the Sapphire AC Power Cord from the main power supply source.
2. Disconnect the Cord Retainer from the IPS, using a Philips head screwdriver.
3. Remove the Sapphire AC Power Cord from the IPS.

USB-C Power Supply (Sapphire Connect power supply)

The Sapphire Connect power supply is used to charge both the Sapphire Connect and the Sapphire pump.

Specifications of the power supply contain the following options:

- Input voltage: 5 VDC
- Output voltage: 10 VDC



The USB-C power supply is intended for use in the home environment.

> To charge the pump's battery:

1. Attach Sapphire Connect to the pump (for more information on how to use the [Sapphire Connect \(Version 2.0\)](#) on page 56).
2. Plug the USB-C power cord into the USB-C inlet on the Sapphire Connect.
3. Verify that the Sapphire Connect charging LED is ON – blinking orange light ([Figure 2.28B](#)).
4. On the front of the pump, verify that the Charge LED status indicator is ON – blinking orange light ([Figure 2.28A](#)).



When charging the Sapphire pump via the pump's power socket, the Sapphire Connect will not charge.

Figure 2.28. Charging Sapphire Pump via Sapphire Connect



> To disconnect the USB-C Power Supply from the Sapphire Connect:

Unplug the USB-C power cord from the Sapphire Connect, by pulling the USB-C connector.

External Battery Pack

The EBP extends the pump's operation time with no need for additional charging.



Warning EBP:

- Do not use the EBP if it is difficult to insert AA batteries or to attach it to the pump.
- Do not use the EBP if the black O-Ring is missing or not attached all around the AA batteries compartment lid.
- When using the strap to hang the EBP with the pump, make sure that the pump is safely secured to the EBP.
- Hang the EBP with the pump only on an IV pole, so that there is no risk of the pump falling.



General Safety Precautions:

- Begin using the EBP before the pump shuts down due to battery depletion.
- When using the EBP with the pump, do not connect the power supply to the pump.



AA Battery Safety Guidelines:

- AA Batteries with signs of rust, bad odor, overheating, and/or other irregularities should not be used in the EBP.
- Avoid any contact of the AA batteries with water.
- Use only valid (none-expired) AA batteries in the EBP.



It is recommended to use in the EBP fresh AA alkaline batteries manufactured by the brands listed below:

- Energizer
 - Duracell
-

General information

- The duration of operation time provided by the EBP, varies according to the pump's Internal Battery power status, infusion rate, backlight settings and AA batteries power status. Operation time of the pump with the EBP is presented in the following table:

Pump Settings	Operation time duration (with fresh AA batteries of the specified brands)
• Infusion rate of 125 mL/h • Backlight set to Off • Internal Battery depleted	15-20 hours



It is recommended to turn the pump's backlight Off in order to extend its operation time. For details about configuring the backlight, refer to [Backlight](#) on page [237](#).

Getting Ready to Use the EBP

The EBP requires six 1.5 V AA batteries (not included in package).

Figure 2.29. The EBP Components



Number	Component
1	Small hooks
2	Large hook
3	Latch
4	Suspension hooks
5	EBP LED

Inserting AA Batteries into the EBP

> To insert AA batteries into the EBP:

1. Make sure that the pump is detached from the EBP.
2. Open the AA batteries compartment lid, by pushing the latch up (Figure 2.29, #3).

Figure 2.30. Opening EBP Lid



3. Place the batteries in their slots by pressing the flat end (negative pole) of each battery to the flat metal plates (marked with "-"), and then fix the other end (positive pole) in place (marked with "+").
4. After all six batteries are in place, insert the protrusion at the bottom of the lid (Figure 2.31, #A1) to its slot in the EBP, and press the latch (Figure 2.29, #3) downwards until it clicks.

Figure 2.31. Closing EBP Lid



To avoid damaging the product, open and close the batteries compartment lid only as instructed. Avoid using excessive force, as it may crack the plastic or damage the metal parts.

Strapping the EBP

If the pump needs to be hung, thread the strap supplied with the EBP through the suspension hooks (Figure 2.29, #4).

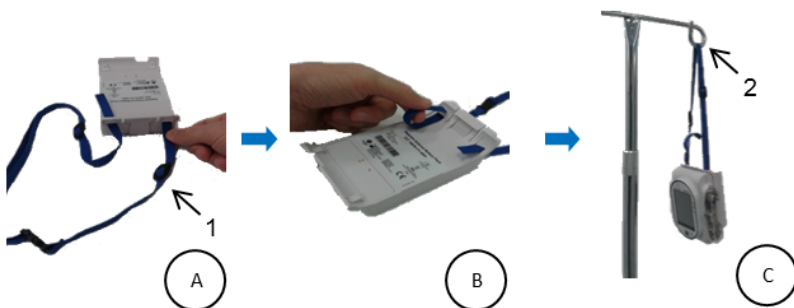
> To strap the EBP:



Thread the strap before attaching the Pump to the EBP.

1. Place the EBP with the cover facing down.
2. Thread both ends of the strap through the bottom notch of the suspension hooks (Figure 2.29, #4). Make sure that both buckles (Figure 2.32, #A1) of the strap are facing up.
3. Bend both ends of the strap to form a loop, and thread each end through the top notch of the suspension hooks (Figure 2.29, #4).
4. Thread each end through the buckle and stretch to adjust the length.
5. Attach the pump to the EBP, and hang on an IV pole (Figure 2.32, #C2). For attaching instructions, refer to the next section.

Figure 2.32. Attaching EBP Straps



Attaching the Pump to the EBP

> To attach the pump to the EBP:

1. Insert the bottom of the pump onto the two small hooks (Figure 2.29, #1) at the bottom of the EBP, and then push it to click into the large hook (Figure 2.29, #2) at the top of the EBP.
If the power supply is connected to the pump, disconnect it before attaching the EBP.
2. Check for all the indications of proper connection to the EBP:
 - a. The pump turns On.
 - b. The external battery icon appears.
 - c. The LED at the bottom of the EBP (Figure 2.29, #5) turns On.



If the LED at the bottom of the EBP doesn't light, blinks or turns off, replace the AA batteries in the EBP with new fresh AA batteries.

Detaching the Pump from the EBP

Detach the EBP when treatment ends, AA batteries are depleted or stable power supply becomes available. Detach the pump from the EBP before turning the pump Off.

> To detach the pump from the EBP:

1. Hold the pump firmly when detaching it from the EBP.
2. Detach the pump from the EBP by gently pulling the large hook (Figure 2.29, #2), until the pump is released from grip. Make sure not to pull the suspension hooks (Figure 2.29, #4), because this prevents the detachment of the pump from the EBP.
3. Check for all the indications of proper detachment:
 - a. An attention screen, indicating that the pump is operating on Internal Battery, appears.
 - b. Press **OK** to continue working with the pump.
 - c. The external battery icon disappears.
 - d. The EBP LED turns Off.



AA batteries may deplete when pump is turned off and still attached to the EBP.



If stable power supply is available, make sure to detach the Pump from the EBP before connecting the pump to a power supply.

EBP storage



It is recommended to remove the AA batteries from the EBP when not in use.

Cleaning the EBP



Clean only exterior surfaces of the EBP.

Multi-Pump Mounting System

The Mounting System is designed to facilitate the use of multiple pumps while saving valuable bed-side space and providing power consolidation. The Mounting System is designed to accommodate three mini cradles, and charge three pumps via a single power outlet, all attached to an IV pole via a single clamp. The Mounting System can also accommodate the use of a single PCA Lockbox 250mL when mounted on the right-hand mini cradle among the three.



It is recommended to use mini cradles with a splitter in order to facilitate attachment and detachment of pumps.



- Verify that the mini cradles are securely attached to the Mounting System, and that the Mounting System is securely attached to the IV pole before attaching the pumps.
 - Do not transport the Mounting System while mounted on an IV pole. Detach and carry using the handle.
 - Verify that the IV pole is not moving, tilting or wavering when mounted with a Mounting System.
 - Before using the Mounting System, make sure that the Mounting System power supply and all cords are completely dry.
 - To avoid risk of electric shock the mounting system power supply must be connected to a power outlet with protective earth.
 - Always connect the AC input cord to the Mounting System power supply, before connecting it to a power outlet.
 - Make sure that the AC input cord is fully inserted into the Mounting System power supply socket and into the power outlet.
 - Always disconnect the AC input cord from the power outlet before disconnecting it from the Mounting System power supply.
-



- Use only Sapphire dedicated AC input cord and power supply with the Mounting System.
 - To avoid entanglement of lines and cords, do not mount more than 4 Mounting Systems on a single IV pole.
 - Do not use the Mounting System power supply with Sapphire Connect.
-



It is recommended to use additional IV bag hooks (not supplied by Eitan Medical) when mounting more than two Mounting System on a single IV pole.

Setup Instructions

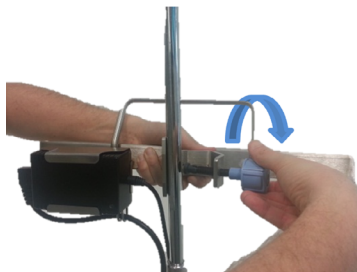


It is recommended to first attach the Mounting System to the IV pole before attaching the mini cradles to the Mounting System

> To attach the Mounting System to an IV Pole:

1. Loosen the clamp knob by rotating it counter-clockwise.
2. Firmly hold the Mounting System and place the clamp on an IV pole with the carry handle facing upwards.
3. Tighten the clamp knob by rotating it clockwise ([Figure 2.33](#)).

Figure 2.33. Mounting System on IV Pole

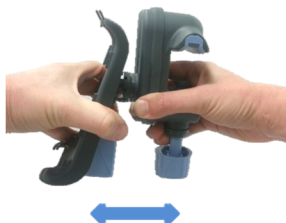


To prevent detaching from the IV pole, the Mounting System can be locked to the pole by removing the knob cap or knob key from the clamp knob.

> To attach a mini cradle to the Mounting System:

1. Rotate the mini cradle to a vertical position with the mini cradle knob pointing downward and the top hook pointing upward.

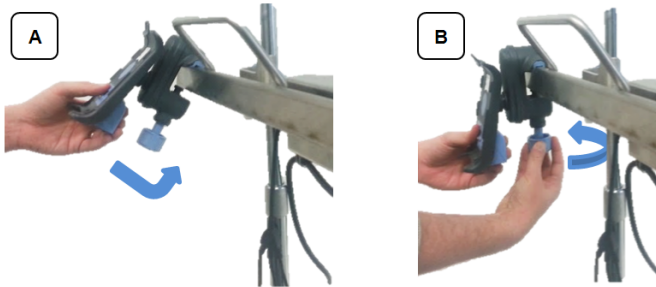
Figure 2.34. Attaching Mini Cradle to Mounting System



Place the mini cradles according to the markings on the Mounting System, between the designated lines (Figure 2.36).

2. Loosen the mini cradle knob to maximum extent by rotating it.
3. Tilt the mini cradle and place the open vice on the top of the Mounting System (Figure 2.35 Item A). Align the cradle and tighten the knob by rotating it (Figure 2.35 Item B).

Figure 2.35. 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 2.36. 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.

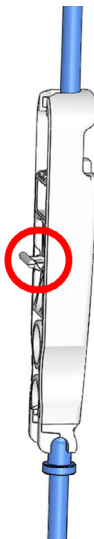
When removing the Mounting System from the IV pole, avoid applying pressure on the power cable, connectors or cradles.

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 2.37. 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 123 and [Inserting the Administration Cassette](#) on page 117.

Sapphire Approved Administration Sets

The Eitan Medical Ltd. approved list of administration sets to be used with the Sapphire pump is listed in the Eitan Medical Official Website at <https://eitanmedical.com>.



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.



All filters in Sapphire approved administration sets are air eliminating filters.

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	98
Selecting Delivery Mode	104
Enabling Special Features	106

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 227 and Activating Patient Lockout on page 228.
Press to Unlock screen	Unlocks the screen	
Press to Unlock Patient	Unlocks the pump	Unlocking the screen requires a password.

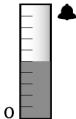
Name of Key	Action	Notes
Request Pause/ Pause Bolus	Pauses an infusion or a bolus	For more information, refer to Pausing Infusions on page 225.
Request Continue/ Continue Bolus	Resumes a paused infusion or a bolus	
View/Edit	Displays a list of infusion parameters to be viewed or edited	
Bolus	Delivers 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 313.
	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 281.
	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 281.
	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 281.
	Indicates that the EBP is connected to the pump.	For more information, refer to External Battery Pack on page 84.

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.
	Pressure display bar	Displays a bar on which the pressure alarm setting is represented by the bell on the top, the baseline downstream pressure is the bottom end represented by a "0", and the current relative downstream pressure is represented by the darker gray end of the bar.
	QR Code	A QR code icon appears on the pump startup screen tool bar. To scan the QR code, press on the icon to display a QR code containing the pump's serial number.

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:

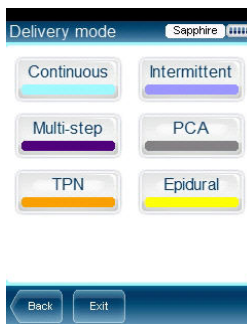
Mode	Description/Notes
Continuous	Delivers an infusion at a constant, programmed rate. This mode includes the option to add a Secondary (Piggyback) line.
Intermittent	Delivers infusions at intermittent programmed intervals.
TPN (Total Parenteral Nutrition)	Delivers an infusion at a constant rate, with 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 Add PCEA under Epidural Mode Options Menu on page 254).



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 231.

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 274. 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 or Technician:

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 265.
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 262.

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 220.
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 120
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 253 or Epidural Mode Options Menu on page 254.
Password request	All	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 254. For details on enabling the feature in all other delivery modes except Epidural , refer to Configuring General Settings on page 236
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 143.

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 Epidural intermittent with PCEA 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 238.
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 236. For more information about using the feature, refer to Activating Patient Lockout on page 228.
Screen Saver	All	Provides a distant view of the main parameters during a running infusion. Activated 30 seconds after the infusion starts.
P. Lockout Code	All	When Enabled, a password will be required when patient lockout is pressed. To modify Parameter (from the General settings screen): Select the P. Lockout Code row, to toggle the option between On and Off.

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).
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 148.
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 143.
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.

Feature	Delivery Mode(s)	Description/Notes
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	112
Connecting the Infusion Container to the Administration Set	115
Opening the Safety Door	116
Inserting the Administration Cassette	117
Automatic Priming Using the Pump	120

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 123.