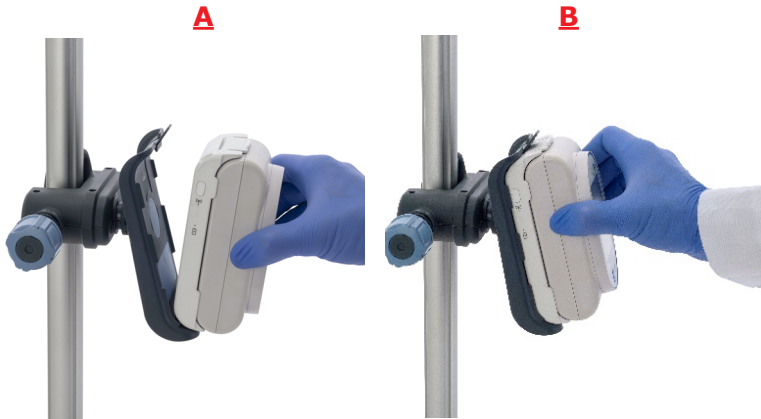


Figure 2.22. Attaching Sapphire Connect to Mini Cradle



> To disconnect 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

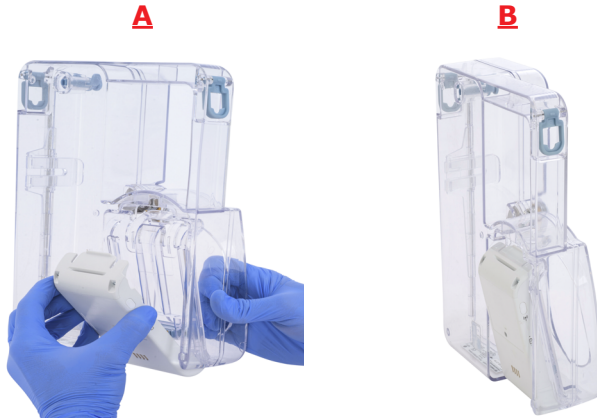


Lockbox

Sapphire Connect can be use with the PCA Lockbox 250mL.

1. Attach Sapphire Connect to the back of the lockbox (Figure 2.24)

Figure 2.24. Attaching Sapphire Connect to Lockbox



2. If using with a mini cradle, attach the entire unit via Sapphire Connect.
For more information about using the lockbox, see PCA Lockboxes on page 44.

> To remove Sapphire Connect from the Lockbox:

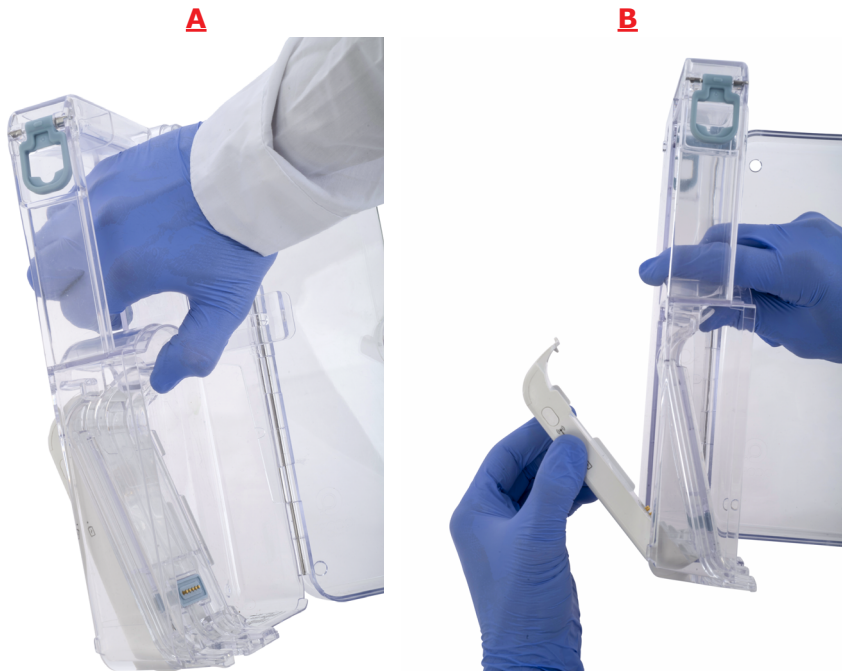
1. Unlock the Lockbox.

Figure 2.25. Opening the Lockbox



2. Hold Sapphire Connect and the Lockbox securely.
3. 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



> To remove Lockbox with Sapphire Connect from a Mini-Cradle:

1. Hold the locked Lockbox securely.
2. To release the Lockbox, press the top hook of the Mini-Cradle (Figure 2.27).

Figure 2.27.
Cradle

Removing Sapphire Connect & Lockbox from Mini



The Lockbox can be carried using the carry handle or the optional shoulder strap. The shoulder strap can be used with a pouch for storing the power supply when it is not plugged in.

Demand Bolus Handle (Blue Buttoned)

Sapphire Connect can be use 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/PIEB Bolus Handle on page 53.




Figure 2.28. 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

Communication Issues

<u>Color</u>	<u>Status</u>	<u>Meaning</u>	<u>Action</u>
<u>Blue</u> 	<u>Steady</u>	<u>Sapphire Connect is ON. This is the normal default status when using Sapphire Connect, indicating that communication is working.</u>	<u>None required.</u>
	<u>Blinking</u>	<u>Self-test is being performed. This happens when Sapphire Connect is turned ON, and lasts up to 1 minute.</u>	<u>None required.</u>
<u>Green</u> 	<u>Steady</u>	<u>Self-test was successful and communication is ready.</u>	<u>None required. The status should change to steady blue after 20 seconds.</u>
<u>Red</u> 	<u>Steady</u>	<u>Self-test failed. The Sapphire Connect unit cannot be used.</u>	<u>Contact your IT department or local representative to have the unit replaced.</u>
	<u>Blinking</u>	<u>Self-test was successful, but no cellular connection was found. This could be due to poor cellular reception or network problems.</u>	<u>Move to another location to find better reception. Try again later in case the problem was caused by the cellular network.</u>

Charging Issues

Symptom	Action
Charging LED is off when the Sapphire Connect power supply is plugged in.	Try charging another Sapphire Connect unit: <ul style="list-style-type: none">• If the second unit doesn't charge, replace the power supply.• If the second unit charges, the first unit is damaged. Contact your local representative to replace the faulty Sapphire Connect unit.

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 90%	15% to 95% (15% to 90% at transient state)
Ambient Pressure (kPa)	50 kPa to 106 kPa	70 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 every 12 months.

Technical Specifications

Parameter	Description
<u>Dimensions</u>	<u>(H x W x D) 146.5 x 78.6 x 16mm</u> <u>(5.77 x 3.09 x 0.63 in)</u>
<u>Weight</u>	<u>170g (6.3 oz) with battery</u>
<u>Connectivity</u>	<u>Cellular, Cat M1, NB-IoT and 2G</u> <u>BLE (not operable)</u>
<u>Encryption Mode</u>	<u>AES128 + CBCIV with pre-shared key</u>
<u>Digital Privacy</u>	<u>Includes a 'do not track me' and a cellular</u> <u>communication disable function</u>
<u>Power Inputs</u>	<u>USB-C; can also be charged using Sapphire mini</u> <u>cradle with splitter or IPS</u>
<u>Battery Type</u>	<u>Rechargeable Lithium-Ion battery (1 cell)</u>
<u>Battery Capacity</u>	<u>850mAh</u>
<u>Battery Output</u>	<u>3.7V (nominal)</u>
<u>Battery Life</u>	<u>Charging 500 cycles at nominal conditions, 23°C</u> <u>(74°F)</u>

Parameter	Description
<u>Operating on Battery</u>	48 hours without being connected to an external power source under the following conditions: <ul style="list-style-type: none"> • <u>300 data transactions at maximum signal strength</u> • <u>Room temperature</u>
<u>Communications with Pump</u>	<u>RS-232 Serial communication</u>
<u>Indicator LEDs</u>	<u>Power, charging, and communication</u>
<u>IPX Rating</u>	<u>IP24</u>
<u>SIM Type</u>	<u>Nano-SIM (Universal)</u>
<u>Geolocation</u>	<u>GPS</u>
<u>Data Storage Memory</u>	<u>32 MB</u>
<u>Service Life</u>	<u>1 year from date of manufacture</u>

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 no 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.

CAN ICES-003 (B)

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

Cet appareil numérique de classe B est conforme à la norme canadienne 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.

ISED Warning

Eitan Medical Ltd. n'approuve aucune modification apportée à l'appareil par l'utilisateur, quelle qu'en soit la nature. Tout changement ou modification peuvent annuler le droit d'utilisation de l'appareil par l'utilisateur.

Interference statement (if it is not placed in the device)

This device complies with Part 15 of the FCC Rules and Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:

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

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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.

Le présent appareil est conforme à l'exposition aux radiations FCC / ISED définies pour un environnement non contrôlé et répond aux directives d'exposition de la fréquence de la FCC radiofréquence (RF) et RSS-102 de la fréquence radio (RF) ISED règles d'exposition. L'émetteur ne doit pas être colocalisé ni fonctionner conjointement avec à autre antenne ou autre émetteur.

Portable Device RF Exposure Statement

RF Exposure - This device has been tested for compliance with FCC RF exposure limits in a portable configuration. At least 5 mm of separation distance between the Raptor device and the user's body must be maintained at all times. This device must not be used with any other antenna or transmitter that has not been approved to operate in conjunction with this device.

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-SAPPHIRE

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.

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.

Informations concernant l'exposition aux fréquences radio (RF)

La puissance de sortie émise par l'appareil de sans fil est inférieure à la limite d'exposition aux fréquences radio d'Industry Canada (IC). Utilisez l'appareil de sans fil de façon à minimiser les contacts humains lors du fonctionnement normal. Ce dispositif a été évalué pour et démontré conforme à la Taux IC d'absorption spécifique ("SAR") des limites lorsqu'il est utilisé dans des conditions d'exposition portatifs.

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 yellow light).

For more information regarding charging the battery, refer to [Charging the Battery](#) on page 296.

> 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 via 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 yellow 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

> **To charge the battery:**

1. Attach Sapphire Connect to the pump (for more information on how to use the Sapphire Connect (Version 1.0) on page 54).
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 yellow light (Figure 2.29B).
4. On the front of the pump, verify that the Charge LED status indicator is ON – blinking yellow light (Figure 2.29A).



When charging the Sapphire pump via the pump's power socket, the Sapphire Connect is not charged.

Figure 2.29. Charging Sapphire Pump via Sapphire Connect



> **To disconnect the AC Power Cord from the IPS:**

Unplug the USB-C power cord from the Sapphire Connect.

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)
<ul style="list-style-type: none">• 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 [231](#).

Getting Ready to Use the EBP

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

Figure 2.30. 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 2.30, #3).

Figure 2.31. 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 2.32, #A1) to its slot in the EBP, and press the latch (Figure 2.30, #3) downwards until it clicks.

Figure 2.32. 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 2.30, #4).

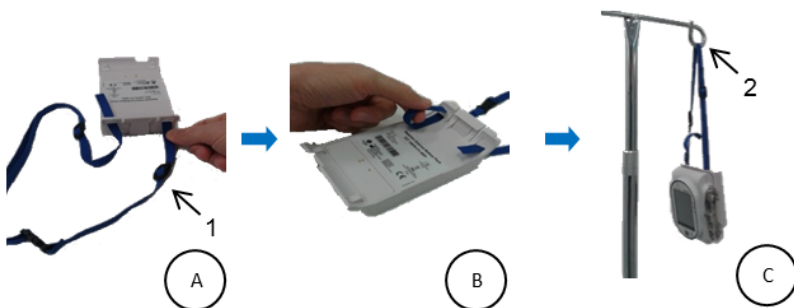
> To strap the EBP:



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 2.30, #4). Make sure that both buckles (Figure 2.33, #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 2.30, #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 2.33, #C2). For attaching instructions, refer to the next section.

Figure 2.33. 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 2.30, #1) at the bottom of the EBP, and then push it to click into the large hook (Figure 2.30, #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 2.30, #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 2.30, #2), until the pump is released from grip. Make sure not to pull the suspension hooks (Figure 2.30, #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.
-



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

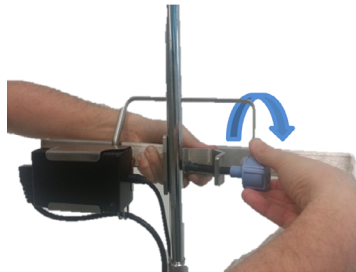


It is recommended to first attach the Mounting System to the IV pole before attaching the mini cradles to the Mounting System

> 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 2.34).

Figure 2.34. Mounting System on IV Pole



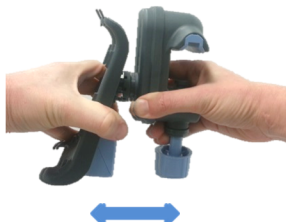


To prevent detaching from the IV pole, the Mounting System can be locked to the pole by removing the knob cap or knob key from the clamp knob.

> **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 2.35. Attaching Mini Cradle to Mounting System



Place the mini cradles according to the markings on the Mounting System, between the designated lines ([Figure 2.37](#)).

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 2.36](#) Item A). Align the cradle and tighten the knob by rotating it ([Figure 2.36](#) Item B).