Pairing Failed Attention Alarm

When the pump and remote were not able to complete the pairing process, the *Pairing Failed* Attention Alarm displays. This may be caused by wireless communication interference.

1. Press ⊠ to silence the attention alarm.

> 📝 For more information on resolving the attention alarm, press ❓.

2. Press ✓ to acknowledge the attention alarm.

3. Make sure the pump and remote are within 2 inches (50 mm) of each other and away from other electronics.

4. Use ⌄ ⌃ to highlight the pump's serial number on the remote, then press ✓ .

5. If this attention alarm is displayed again, move 0.8 m (3 ft) away from cell phones, Bluetooth devices, RFID readers, and Wi-Fi equipment and repeat *Step 1* through *Step 4*.

6. If this attention alarm is displayed persistently, contact your specialty pharmacy for technical assistance.

Pairing Lost Attention Alarm

When you have paired your pump to the spare remote, the original remote will generate a *Pairing Lost* Attention Alarm when you bring your pump back in range.

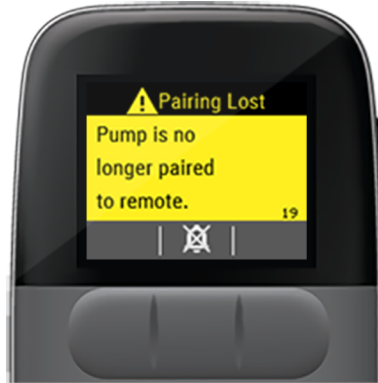1. Press ⚔ to silence the attention alarm.

2. Press ✓ to acknowledge the attention alarm.

3. Make sure the pump and remote are within 2" (50 mm) of each other and away from other electronics.

4. You will need to pair again to your original remote. *See "Pair to a Spare Pump" on page 118.*

5. If this attention alarm is displayed again, contact your specialty pharmacy for technical assistance.

Pump Idle Attention Alarm

When the pump has not been delivering medication for 15 minutes, the *Pump Idle* Attention Alarm displays.

1. Press ⊠ to silence the attention alarm.

2. Press ✅ to acknowledge the attention alarm.

3. **Press and hold the blue pump button** until you hear the *four-tone* delivering sound.

4. If the pump does not generate the *four-tone* delivering sound:

   a. Disconnect the infusion set tubing from the catheter.

   b. Disconnect the pump from the cassette.

   c. Remove and reinsert the pump battery into the pump.

   d. Listen for the confirmation beep on the pump.

   e. Connect the pump to the cassette.

   f. Wait for the self test to complete and then reconnect the infusion set tubing to the catheter.

   g. **Press and hold the blue pump button** until you hear the *four-tone* sound, or press ✅ on the remote to restart delivery.

Pump Battery Low Attention Alarm

When the pump battery will be depleted in 8 hours or when the pump battery does not have enough charge for full therapy, a *Pump Battery Low* Attention Alarm displays.

1. Press ⊠ to silence the attention alarm.

2. Press ✓ to acknowledge the attention alarm.

3. Replace the pump battery with a fully charged pump battery by performing a cassette change. *See "Cassette Change" on page 59.*

Remote Battery Low Attention Alarm

When the remote's battery needs to be charged, a *Low Battery* Attention Alarm displays along with a message that the *Remote battery is low. Charge soon*.

1. Press ⊠ to silence the attention alarm.

2. Press ✓ to acknowledge the attention alarm.

3. Use the supplied AC Adapter and USB Cable to connect the remote to a power source (e.g., wall outlet).

4. Allow the remote to fully charge.

Remote Battery Fully Charged

When the battery symbol in the top right of the remote screen is full green, the remote is fully charged.

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Request Refused Attention Alarm

When the remote sends a command to the pump and an error occurs, a *Request Refused* Attention Alarm displays.
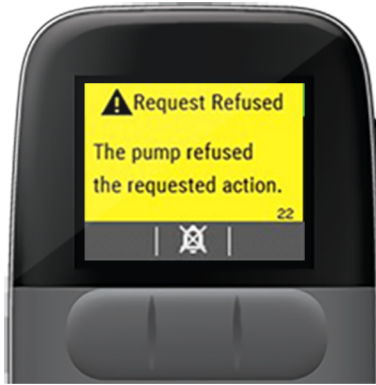
1. Press ⊠ to silence the attention alarm.

2. Press ✓ to acknowledge the attention alarm.

3. Retry the command.

Software Version Error Attention Alarm

When the pump is not able to deliver medication due to incompatible software on the pump and remote interface, a *SW Version Error* Attention Alarm with a *Pump version not compatible* message is displayed.

1. Press ⌀ to silence the attention alarm.

2. Press ✓ to acknowledge the attention alarm.

3. Gather a spare pump.

4. Pair spare pump with remote. *See "Pair to a Spare Pump" on page 118.*

5. Contact your specialty pharmacy to obtain a replacement pump.

Tech Attention Alarm

When the remote has encountered an error, the *Tech Att. Alarm* displays along with the *Error code*, *TS (Date and Time stamp)*, *SysTime*, and *SW.*

1. Press ⓧ to silence the attention alarm.

2. Use the ⌄ ⌃ to scroll through the *Tech Attention Alarm* information.

3. This alarm does not represent an emergency, but should be reported to your specialty pharmacy.

4. If this attention alarm repeats you should switch to your spare remote and request a replacement from your specialty pharmacy.

5. Press ✓ to acknowledge the *Tech Attention Alarm* message.

Walkaway Attention Alarm

When the pump previously lost communication with the remote for the user settable amount of time, the *Walkaway* Attention Alarm displays along with a *Remote stopped communicating with the pump* message.

Walkaway Attention Alarm settings are maintained when the system is powered down or loses power.

1. Press ⊠ to silence the attention alarm.

> For more information on resolving the attention alarm, press ⑦.

2. Press ☑ to acknowledge the attention alarm.

3. If the attention alarm appeared while you had your remote with you, this may have been caused by wireless communication interference. You may need to move 0.8 m (3 ft) or more from cell phones, Bluetooth devices, RFID readers, and Wi-Fi equipment to maintain communication.

Maintenance and Troubleshooting

Contact your specialty pharmacy for assistance with any of the maintenance and troubleshooting instructions.

Pump Maintenance

Dust, lint, and debris on or in the pump may have the following effects on the system:

- Decrease the water ingress protection rating.
- Interfere with the electrical connection between the pump and battery causing *Alarms* to occur.
- Cause the pump to fail start up tests.
- Interfere with the electrical connections between the remote or pump battery charger and pump battery causing the battery not to charge or to charge slowly.
- Abrade the surface of the cassette, which can lead to leaks.
- Interfere with rotating locking ring when connecting or disconnecting the cassette and pump.

Clean the pump as needed to keep the pump free of dust, lint, and debris or following exposure to dust or liquid contaminants.

1. Verify the *Dust Cover* or a *Cassette* is attached to the pump before cleaning.

2. Wet the pump assembly with *mild soap and water* and lather it up.

   Dish detergent or hand soap is acceptable.

   Do not place the pump in a dishwasher.

3. Thoroughly rinse the pump with water.

4. Thoroughly dry the pump with a dry cloth or paper towel.

   Do not rub or press on interior portions of the pump.

5. Remove the dust cover or cassette and blot the interior of the pump with dry cloth or paper towel if any moisture is visible.

Remote Maintenance

Clean the remote as needed to keep the remote free of dust, lint and debris.

- When cleaning do not submerge in water.
- Do not place the remote in the dishwasher to clean.
- Gently wipe all surfaces with a cloth or paper towel moistened with mild soap and water (dish detergent or hand soap is acceptable).
- Thoroughly dry with a dry cloth or paper towel if any moisture is present.

Troubleshooting Battery Charger

Table 8: *Battery Charger status light(s) do not turn on*
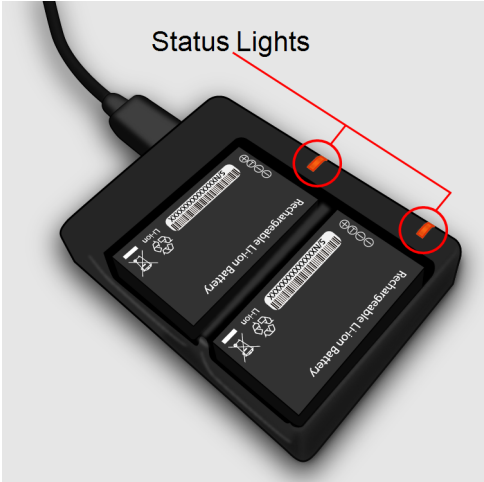
Problem	Possible Causes	Corrective Actions
Battery Charger status light(s) do not turn on (is not charging the pump battery). 	Battery Charger is not plugged into a power source.	Make sure the AC Adapter or USB Cable is plugged into the Battery Charger and connected to a power source (e.g., wall outlet).
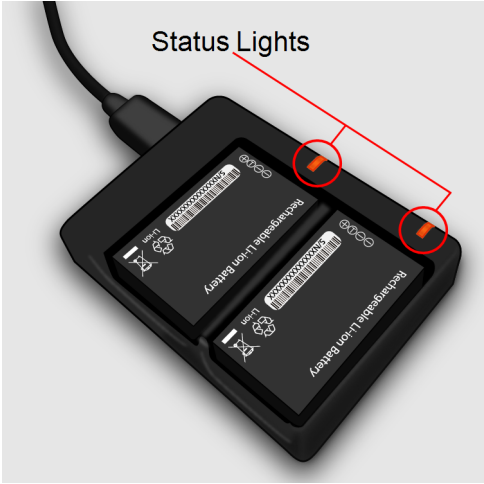
Table 8: *Battery Charger status light(s) do not turn on*

Problem	Possible Causes	Corrective Actions
	One or more components is defective: • USB Cable • AC Adapter • Battery Charger • Battery	One at a time, swap a component listed on the left with its replacement from the starter kit. If the replacement fixes the problem, contact your specialty pharmacy to replace that defective component. If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.

Table 9: *Battery Charger status light(s) turn red when a pump battery is installed*

Problem	Possible Causes	Corrective Actions
Battery Charger status light turns red when a pump battery is installed. Status Lights	Pump Battery is too hot or too cold.	Make sure the temperature of the battery, or location where you charge the battery, is between 59 °F (15 °C) and 95 °F (35 °C). Charging will start automatically when battery temperature is within that range.

Table 9: *Battery Charger status light(s) turn red when a pump battery is installed*

Problem	Possible Causes	Corrective Actions
Status Lights	Pump Battery and/or Battery Charger contacts are covered with dirt or dust.	Disconnect from power source. Then, use a dry cloth or soft bristle brush to clean the contacts.
	One or more components is defective: • Battery Charger • Pump Battery	One at a time, swap a component listed on the left with its replacement from the starter kit. If the replacement fixes the problem, contact your specialty pharmacy to replace that defective component. If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.

Troubleshooting Remote

Table 10: *Remote does not turn on*

Problem	Possible Causes	Corrective Actions
Remote does not turn on.	Remote has timed out or powered off.	Press the remote's side button to *wake up* the remote. If this does not work, press and hold the side button for about ten seconds to power on the remote (the remote will vibrate when it powers on).

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Table 10: *Remote does not turn on*

Problem	Possible Causes	Corrective Actions
	Remote is not charged.	Charge the remote using the USB Cable and AC Adapter provided in the starter kit.
	Remote is broken.	Use the spare remote provided in the starter kit. Contact your specialty pharmacy for a replacement remote.

Table 10: *Remote does not turn on*

Problem	Possible Causes	Corrective Actions
	One or more components is defective: • USB Cable • AC Adapter • Remote	One at a time, swap a component listed on the left with its replacement from the starter kit. If the replacement fixes the problem, contact your specialty pharmacy to replace that defective component. If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.

Table 11: *Pump battery does not charge when in the back of the remote*

Problem	Possible Causes	Corrective Actions
Pump battery does not charge in the back of the remote when plugged in (the status light does not turn on). 	Remote is not plugged in to a power source.	Make sure AC Adapter and USB Cable are plugged into the Remote and connected to a power source (e.g., wall outlet).
	Pump Battery and/or Battery Charger contacts are covered with dirt or dust.	Disconnect from power source. Remove the battery from the battery bay. Then, use a dry cloth or soft bristle brush to clean the contacts.

Table 11: *Pump battery does not charge when in the back of the remote*

Problem	Possible Causes	Corrective Actions
	One or more components is defective: • USB Cable • AC Adapter • Remote • Pump Battery (if in the remote's battery bay)	One at a time, swap a component listed on the left with its replacement from the starter kit. If the replacement fixes the problem, contact your specialty pharmacy to replace that defective component. If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.

Table 12: *Remote status light turns red when a Pump Battery is installed*

Problem	Possible Causes	Corrective Actions
Remote status light turns red when a Pump Battery is installed.	Pump Battery is too hot or too cold.	Make sure the temperature of the battery, or location where you charge the battery, is between 59 °F (15 °C) and 95 °F (35 °C). Charging will start automatically when battery temperature is within that range.
	Pump Battery and/or Remote contacts are covered with dirt or dust.	Disconnect from power source. Then, use a dry cloth or soft bristle brush to clean the contacts.

Table 12: *Remote status light turns red when a Pump Battery is installed*

Problem	Possible Causes	Corrective Actions
	One or more components is defective: • Remote • Pump Battery (if in the Remote's battery)	One at a time, swap a component listed on the left with its replacement from the starter kit. If the replacement fixes the problem, contact your specialty pharmacy to replace that defective component. If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.

Troubleshooting Pump

Table 13: *Cannot connect cassette to infusion set tubing*
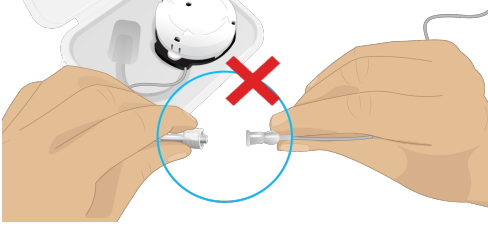
Problem	Possible Causes	Corrective Actions
Cannot connect cassette to infusion set tubing.	Damaged connector on cassette or infusion set.	If connector on cassette is damaged, discard and obtain a new cassette. If connector on infusion set is damaged, discard and obtain a new infusion set.

Table 13: *Cannot connect cassette to infusion set tubing*
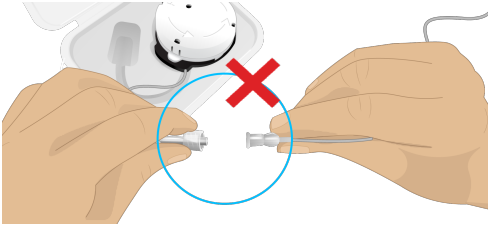
Problem	Possible Causes	Corrective Actions
Cannot connect cassette to infusion set tubing.	The infusion set is not approved for use with the cassette.	Verify you are using one of these approved infusion sets with the cassette: • Medtronic Quick-set (MMT-392, MMT-393) • Medtronic Silhouette (MMT-373) • Smiths Medical Cleo 90 (21-7230-24, 21-7220-24)

Table 14: *No fluid is visible at end of infusion set when priming*
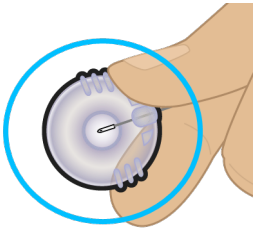
Problem	Possible Causes	Corrective Actions
No fluid is visible at end of infusion set when priming.	Priming Aid is not fully rotated.	Fully rotate the arrow on the priming aid to the lock symbol on the cassette to begin priming.
	Tubing is occluded	Inspect tubing and straighten any kinked tubing.

Table 15: *The self test passes, but the pump sounds an Attention Alarm sound when the pump button is pressed*
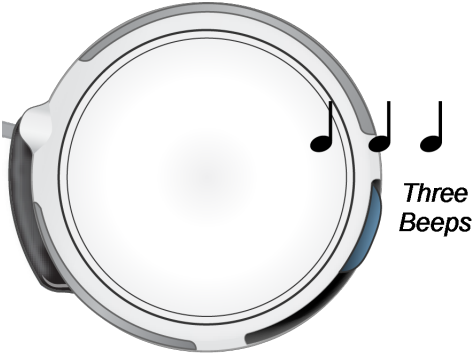
Problem	Possible Causes	Corrective Actions
The self test passes, but the pump sounds an attention alarm tone when the pump button is pressed. *Three Beeps*	Delivery rate needs to be set or updated.	Move the pump or remote within 12 inches of each other to enable wireless communication. When you reconnect to the remote, a *Basal Not Started* Attention Alarm will display. Press ⊠ and ✓. Depending upon the scenario, you may see a New Cassette? prompt. Select Yes or No accordingly. Press ✓ to start delivery again.

Table 16: *Self test does not start*

Problem	Possible Causes	Corrective Actions
Self test does not start.	Pump is not properly attached to cassette.	Make sure the pump is properly attached to the cassette.
	Remote is not paired to the correct pump.	In the remote's *Setup* menu, pair the remote to the pump you are currently using. *See "Pair to a Spare Pump" on page 118.*

Table 17: *Pump sounds an Attention Alarm signal when the pump battery is installed*
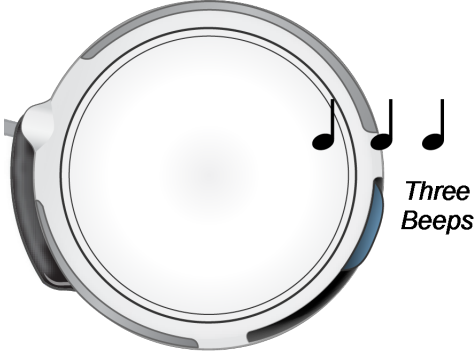
Problem	Possible Causes	Corrective Actions
Pump sounds an *Attention Alarm* tone when the pump battery is installed. *Three Beeps*	Pump battery is not fully charged. Battery is not seated properly.	Install a fully charged pump battery. Try removing and reinstalling the battery in the back of the pump.

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Table 18: *Pump sounds an Alarm signal when the pump battery is installed*

Problem	Possible Causes	Corrective Actions
Pump sounds an *Alarm* tone when the pump battery is installed. *Five Beeps, repeating (beep-beep, beep, beep-beep)*	Pump is broken.	Use the replacement pump provided in the starter kit. Contact your specialty pharmacy for a replacement pump.

Maintenance and Troubleshooting

Table 19: *Pump doesn't make a sound when pump battery is installed*

Problem	Possible Causes	Corrective Actions
Pump doesn't make a sound when pump battery is installed.	Pump battery is depleted.	Install a fully charged pump battery into pump.
	Pump is broken.	Use the replacement pump provided in the starter kit. Contact your specialty pharmacy for a replacement pump.

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Pump Sounds

Table 20: *Pump Sounds*

Sound from Pump	Status	Description
♩ *One beep*	**Ready**	Ready to progress to next step. Continue setup.
♩↻ *One repeating beep*	**Busy**	Pump is busy. Wait until pump is ready.
♫♫ Escalating *Four-tones*	**Delivering**	Pump is delivering medication. Confirm the remote displays green *Delivering* header. This tone is also an indication when exiting out of airplane mode.

Maintenance and Troubleshooting

Table 20: *Pump Sounds*

Sound from Pump	Status	Description
Three beeps Repeats every 15 seconds	**Attention Alarm**	Pump status changed. Check the remote for more information.
Three tone, Two-tone, Three-tone, Two-tone Repeats every 10 seconds	**Alarm**	Medication delivery has stopped. Check the remote for more information.

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Frequently Asked Questions (FAQ)

Below are the answers to some frequently asked questions.

> ⚠️ **The Remote, Battery Charger, and AC Adapter are NOT waterproof and should be kept clean and dry.**

Table 21: *FAQ*

FAQ	What To Do
How do I know when it's time to change my cassette?	The remote's *Home* screen displays the hours remaining until you need to change your cassette.
How often must I change the pump battery? What about the remote battery?	The remote's *Home* screen displays how much battery life remains in the pump and remote. You must change the pump battery at least every 3 days. You must charge the remote every day.

Table 21: *FAQ*

FAQ	What To Do
I have to travel, what should I bring with me to ensure I keep receiving my medication?	Keep these items on hand so that you can change a depleted cassette whenever needed and keep receiving your medication: • Spare Pump and Remote • Extra non-expired Pharmacy-Filled Cassette packages (enough for the number of days you will be traveling) in its unopened packaging. • Extra pump battery with full charge in remote battery bay. • The User Guide. • Your medication. • Your preferred Infusion Set. *See "Use only one of the following Infusion Sets" on page 33.*
What should I do with the extra tubing?	Secure tubing and pump to your body to prevent them from catching on other objects.
If I go to a concert, how will I hear my remote?	If you are in loud environments, keep the remote in a pant or shirt pocket so that you can feel it vibrate in case of an alarm or attention alarm.
I have to have an MRI procedure, can I wear my pump?	No. Avoid strong magnetic fields. Strong magnetic fields can cause a false cassette-detach alarm.

Table 21: *FAQ*

FAQ	What To Do
Can I swim with my pump?	Yes, the **pump** can tolerate immersion in fluid to depths of up to 8 ft for 30 minutes, and up to 12 feet for 3 minutes. ⚠️ The Remote, Battery Charger, and AC Adapter are NOT waterproof and should be kept clean and dry.
What should I do if I travel on an aircraft?	If requested to turn off all electronic devices during commercial flight, follow instructions to put the pump in *Airplane Mode*. *See "Airplane Mode" on page 137.* Once use of electronics is cleared, press the pump's blue button until after you hear the four-tone sound to exit airplane mode.
My remote is powered off. Does that mean I am not receiving my medication?	The pump will continue to deliver medication even when the remote is powered off.

Table 21: *FAQ*

FAQ	What To Do
What should I do when an Alarm or Attention Alarm appears on my remote?	If the remote displays an alarm or attention alarm, refer to the section on *"Alarms and Attention Alarms" on page 147.* Turn to the specific page within that section referencing the resolution to the alarm or attention alarm you see on the remote screen.
How do I stop medication delivery without my remote?	Disconnect the infusion set tubing from the infusion site.

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Table 21: *FAQ*

FAQ	What To Do
What should I do when I don't have access to my remote?	1. When the pump and remote are not in communication or the remote is *OFF*, the following functionality is still available: • A *Cassette Change* can still be performed. • The pump continues to deliver the programmed medication. • Fault detection and *Alarm* generation is still intact. 2. If your pump is sounding an audible alarm, disconnect the infusion set tubing from the infusion site and perform a *Cassette Change*. 3. If you cannot continue to use the pump to effectively treat yourself without the remote, fall back to your spare pump.

Table 21: *FAQ*

FAQ	What To Do
Why won't my remote power on?	1. If the remote does not power on, try connecting it to the AC power adapter first. 2. Make sure you press and hold the power button long enough to power *On* the remote. 3. If the remote is broken, call technical support for troubleshooting and a possible replacement.
Why won't my pump pair with the remote?	1. Make sure the pump is not attached to the cassette. 2. Make sure to **press and hold** the blue pump button for **10 seconds** even after the pump beep. After holding the pump button for ten seconds, you should hear another beep. 3. Make sure you selected the correct pump serial number.

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Table 21: *FAQ*

FAQ	What To Do
How do I change my battery without changing to a new cassette?	Ideally the pump battery change should coincide with the cassette change. To change the battery without changing the cassette, follow these steps: 1. Disconnect the infusion set tubing from the catheter. 2. Stop medication delivery on the remote. 3. Replace the pump battery. 4. Connect the cassette to the pump. 5. Connect the infusion set to the catheter. 6. Start medication delivery.
Upon removing my pump from the belt clip I pressed the *blue* button and heard a tone. Does this mean I shut the pump off?	It does not mean you shut the pump off. To determine the status of the pump *see "Pump Sounds" on page 197* You can also check the *Home* screen on your remote to see the status of medication delivery.

Table 21: *FAQ*

FAQ	What To Do
My battery charger is blinking red where I inserted the battery. What should I do?	1. Try reinserting the battery in the battery charger. 2. If the light continues to blink red, try inserting the battery into another bay. 3. If the issue persists, contact your Specialty Pharmacy.
There are different sounds that come from the pump. How do I know which one is which?	The pump will make sounds to let you know when its status has changed. Refer to *"Pump Sounds" on page 197.* for descriptions of each sound.

Service and Support

Technical Support

Discontinue use of any system component, switch to the corresponding spare if available and contact your specialty pharmacy to obtain replacement components in the event a component stops working as expected.

- In the US, contact your Specialty Pharmacy 24 hours a day/7 days a week.

Contact your specialty pharmacy for assistance with any of the following activities:

- Set up
- General use
- Maintenance
- To report unexpected operation or events
- To request replacement parts

Parts and Accessories

In the event a component stops working as expected, discontinue use and switch to a spare part (if available), and contact your specialty pharmacy to obtain a replacement.

Only use United Therapeutics Corp. specified parts.

Part Description	Part Number	Quantity
Pump	DKPI-21096-001	1
Pump Battery	DKPI-70008-001	1
Pump Battery Charger	DKPI-21072-001	1
Remote	DKPI-21088-001	1

Part Description	Part Number	Quantity
Cassette with Filling Aid (Sterile)	DKPI-11022-001	1
Dual USB AC Adapter	DKPI-40033-001	1
USB Cable 3.3 feet (1 meter)	DKPI-40034-001	1
Belt Clip	DKPI-31326-001	1
Clear Pump Dust Cover	DKPI-31219-001	1

Approved Infusion Sets

Part Description	Part Number	Quantity
Medtronic Quick-set	MMT-392, MMT-393	1
Medtronic Silhouette	MMT-373	1
Smiths Medical Cleo 90	21-7230-24, 21-7220-24	1

Service and Support

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Appendix A

Technical Specifications

The Remunity™ Pump for Remodulin® (treprostinil) Injection consists of two main components; a wearable pump and a hand held remote. These two subsystems communicate via radio.

The remote provides a means of programming/controlling the pump and viewing data logs.

The pump is designed to deliver Remodulin subcutaneously based on a programmed delivery rate, and is to be worn for up to three days at a time. The medication deliveries are made even when the pump is not in communication with the hand held remote. When the pump is not in communication with the hand held remote, fault detection and alarm generation is intact.

The pump is composed of a reusable portion and disposable portion. The reusable portion contains volume measurement hardware, pump actuation hardware, and electronics. The pump is powered by a rechargeable battery.

The disposable portion of the pump is the cassette, which includes an infusion set connector. The cassette consists of chambers for storing, pumping and measuring fluid. In addition the cassette contains valves used to control the flow of medication.

The combination of the pump and cassette chambers actively draw up to 2 µL aliquots of medication from the storage chamber in the reservoir, measure the volume of each aliquot, then deliver these aliquots into the patient. These individual measurements are used to accurately deliver medication and detect occlusions.

The pump infuses medication though a separately supplied infusion set and catheter.

The pump can be worn in several ways: It can be placed in a pocket or attached to a belt by the included belt clip accessory. There is no restriction on orientation or position of the pump relative to the infusion site.

Occlusion Detection Time:

- Rate: 16 µL/h Detection Time: 8 h
- Rate: 42 µL/h Detection Time: 8 h

The unintended *Bolus* volume following the release of an *Occlusion* is ≤40 µL (Typically <15 µL) for all delivery rates.

Under single fault conditions no more than the following medication is delivered:

- 10 µL or, if greater,
- 50% error for deliveries ≤ 8 h
- 25% error for deliveries > 8 h

The system has not been evaluated for use in *Oxygen Rich Environments* and should not be used in an area where oxygen is in use.

All parts of the Remunity™ Pump for Remodulin® (treprostinil) Injection are rated for continuous operation.

- The Remunity™ Pump for Remodulin® (treprostinil) Injection is *INTERNALLY POWERED ME EQUIPMENT*.
- When the Remunity™ Pump for Remodulin® (treprostinil) Injection remote interface is being charged it is *CLASS II* and *INTERNALLY POWERED* at all other times.

Appendix A

- The Remunity™ Pump for Remodulin® (treprostinil) Injection infusion set and catheter are *TYPE BF APPLIED PARTS*.
- The following list of components are *Applied Parts*:
    - Infusion Set
    - Catheter

The stated accuracy is valid when used with the listed infusion sets within the environmental conditions described in this User Guide.

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Environmental Protection Ratings

The pump when connected to the cassette has a rating of IP58, indicating protection from dust and continuous immersion in water. The pump can tolerate immersion to depths of up to 8 feet for 30 minutes and 12 feet for up to 3 minutes.

The remote does not have an IP rating. It should be kept dry and avoid exposing it to dust and dirt.

The pump battery charger does not have an IP rating. It should be kept dry and avoid exposing it to dust and dirt.

The AC adapters do not have an IP rating. Avoid contacting the AC adapters with dust and water.

Start-up Graph
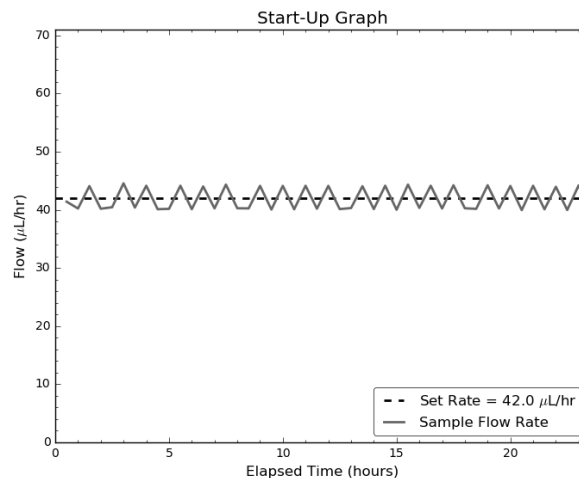
This stability curve shows the average flow rate over 30 minute periods. The measurements were taken at an intermediate basal rate of 42 µL/hr, in accordance with IEC 60601-2-24:2012, at room temperature while delivering Remodulin at a concentration of 1 mg/mL.

Trumpet Curve
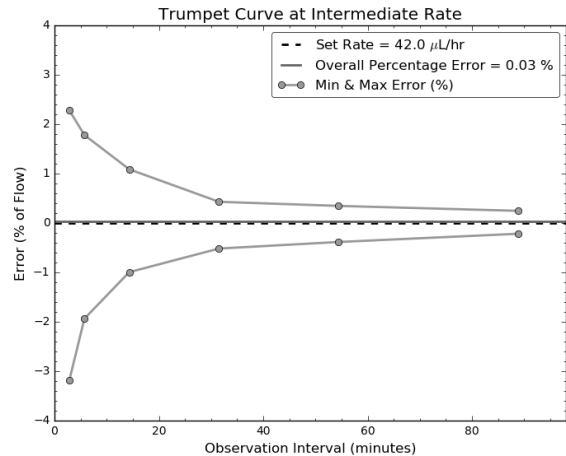
This trumpet curve shows the accuracy of the flow rate during a 4 hour and 46 minute period (100 deliveries) as a function of an averaging window. The reported percent error deviation is calculated from the overall weight increase over the full T2 time period. The data was collected at room temperature while delivering Remodulin at a concentration of 1 mg/mL. The average shot cycle, for calculations per equations 21, 23 & 24 in sub-clause 201.12.1.104 of IEC 60601-2-24: 2012, is taken as the average interval over the 100 shots in the analysis period, T2.

Table 22: *Alarm Volume Specifications*

Alarm Volume Specifications	Specification Details
The following components generate the following sound pressures when alarms are fully escalated:	
Pump	52 - 60 dBA
Remote	56 - 66 dBA

Table 23: *Pump and Cassette Specifications*

Pump and Cassette Specifications	Specification Details
Pump FCC ID	2ATGA01
Size	6 cm x 6 cm x 2 cm
Weight	50 g
Storage Environmental Range	Temperatures of -13 ℉ (-25 ℃) to 158 ℉ (70 ℃) Non-condensing humidity up to 90% Pressures of 500 hPa - 1060 hPa

Table 23: *Pump and Cassette Specifications*

Pump and Cassette Specifications	Specification Details
Operating Environmental Range	Temperatures of 41 ℉ (5 ℃) to 104 ℉ (40 ℃) Non-condensing humidity up to 90% Pressures of 700 hPa - 1060 hPa
Infusion Accuracy	6%
Maximum Infusion Pressure	< 113 kPa
Programmable Range	16 µL/h (0.016 mL) to 225 µL/h (0.225 mL), in 1µL/h (0.001 mL) increments
Pump Runtime with fully charged battery	Rate: 42 µL/h Runtime: >63.1 hours (Cassette volume limited) Rate: 225 µL/h Runtime: >11.8 hours (Cassette volume limited)
Shelf Life	Refer to the Cassette packaging to determine Cassette shelf life.
Expected Service Life	Cassette: 3 days Pump: 3 years

Table 24: *Pump Battery Specifications*

Pump Battery Specifications	Specification Details
Pump Battery Service Life	3 months
Allowable Temperature Range for Charging the Batteries	59 °F (15 °C) to 95 °F (35 °C)

Table 25: *Remote Specifications*

Remote Specifications	Specification Details
Remote Interface FCC ID	2ATGA02
Size	9.8 cm x 5.5 cm x 1.8 cm
Weight	102 g
Battery Life	The remote will typically need to be charged daily and should run all day on a charge.
Allowable Temperature Range for Charging the Batteries	59 °F (15 °C) to 95 °F (35 °C)

Table 25: *Remote Specifications*

Remote Specifications	Specification Details
Storage Environmental Range	Temperatures of -13 ℉ (-25 ℃) to 158 ℉ (70 ℃) Non-condensing humidity up to 90% Pressures of 500 hPa - 1060 hPa
Operating Environmental Range	Temperatures of 41 ℉ (5 ℃) to 104 ℉ (40 ℃) Non-condensing humidity up to 90% Pressures of 700 hPa - 1060 hPa
Expected Service Life	3 years

Table 26: *Battery Charger, AC Adapter, and USB Cable Specifications*

Battery Charger, AC Adapter, and USB Cable Specifications	Specification Details
Storage Environmental Range	Temperatures of -13 ℉ (-25 ℃) to 158 ℉ (70 ℃) Non-condensing humidity up to 90% Pressures of 500 hPa - 1060 hPa

Table 26: *Battery Charger, AC Adapter, and USB Cable Specifications*

Battery Charger, AC Adapter, and USB Cable Specifications	Specification Details
Operating Environmental Range	Temperatures of 41 ℉ (5 ℃) to 104 ℉ (40 ℃) Non-condensing humidity up to 90% Pressures of 700 hPa - 1060 hPa
Allowable Temperature Range for Charging the Batteries	59 ℉ (15 ℃) to 95 ℉ (35 ℃)
Service Life	Battery Charger: 3 years AC Adapter: 3 years USB Cable: 3 years

Table 27: *Belt Clip Specifications*

Belt Clip Specifications	Specification Details
Service Life	Belt Clip: 1 year

Remunity System Radio Specifications

Pursuant to FCC 15.21 of the FCC rules, changes not expressly approved by the party responsible for compliance might cause harmful interference and void the FCC authorization to operate this product. 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.
2. This device must accept any interference received, including interference that may cause undesired operation.

Table 28: *Remunity System Radio Specifications*

Unity System Radio Specifications	Specification Details
Transmit and Receive Frequency	2.4 - 2.5 GHz
Effective Radiated Power	< 10 mW
Modulation	Gaussian Frequency Shift Keying per IEEE 802.15.4-2006
Protocol	Bluetooth Low Energy
Effective Range (Remote to Pump)	At least 3 m
Wireless Security	AES-128 encryption with Cypher-block Chaining

Quality of Service Provisions

Interruption or corruption of communication between the Remote Interface and Pump can lead to interruptions in status updates and to making changes to therapy parameters. Momentary losses of communication will be indicated by the status bar at the top of the Remote Interface screen being gray. Interruption of communication for more than 2 hours will result in the Remote Interface declaring a *No Communication* Attention Alarm.

Common consumer electronic devices that transmit in the same frequency band used by the Remunity™ Pump for Remodulin® (treprostinil) Injection may prevent the Pump and Remote Interface from communicating. Microwave ovens, Bluetooth devices, Wi-Fi networks and 2.4 GHz cordless phones, when transmitting or receiving can cause interruption of communication between the Pump and Remote Interface. This interference, however, will not cause any incorrect data to be sent and will not cause any harm to the Remunity™ Pump for Remodulin® (treprostinil) Injection.

In each of these cases, communication problems can usually be resolved by turning off or moving away from other RF transmitting devices.

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Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Remunity™ Pump for Remodulin® (treprostinil) Injection is intended for use in the electromagnetic environment specified below. The user of the Remunity™ Pump for Remodulin® (treprostinil) Injection should ensure that it is used in such an environment.

Table 29: *Guidance and Manufacturer's Declaration - Electromagnetic Emissions*

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Remunity™ Pump for Remodulin® (treprostinil) Injection uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Remunity™ Pump for Remodulin® (treprostinil) Injection 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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-2 kV, +/-4 kV, +/-6 kV, +/-8 kV contact +/-2 kV, +/-4 kV, +/-8 kV & +/-15 kV air	+/-2 kV, +/-4 kV, +/-6 kV, +/-8 kV contact +/-2 kV, +/-4 kV, +/-8 kV & +/-15 kV air	Use in professional healthcare facility and home healthcare environments.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	20 V/m 1 MHz to 80 MHz 200 Hz 80% AM carrier 10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	Use in professional healthcare facility and home healthcare environments, excluding near high frequency surgical equipment or near MR machines. Portable communications equipment that transmit at frequencies below 80 MHz (such as Walkie-Talkies and hand held HAM radios) should be kept at least 1.0 m [3 ft 3 inches] away from the Remunity™ Pump for Remodulin® (treprostinil) Injection.

Appendix A

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier 28 V/m 430 MHz – 470 MHz 1 kHz FM carrier 9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier 28 V/m 430 MHz – 470 MHz 1 kHz FM carrier 10 V/m 704 MHz – 787 MHz 217 Hz PM carrier	Mobile RF communications equipment that transmit at frequencies below 80 MHz (such as radios in Police cars, Ambulances, Fire trucks, and vehicle mounted CB & HAM radios) should be kept at least 4.5 m [14 ft 7 inches] away from the Remunity™ Pump for Remodulin® (treprostinil) Injection. Portable and mobile RF communications equipment at frequencies above 80 MHz (such as Walkie-Talkies, hand held / vehicle mounted HAM radios, radios in Police cars, Ambulances, and Fire trucks) should be kept at least 8.9 m [30 ft] away from the Remunity™ Pump for Remodulin® (treprostinil) Injection.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier 28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier 9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier 28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier 10 V/m 5.1 GHz – 5.8 GHz	Cell phones, Wi-Fi equipment, Bluetooth devices and RFID readers should be kept at least 0.8 m [3 ft] away from the Remunity™ Pump for Remodulin® (treprostinil) Injection.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
		217 Hz PM carrier 20 V/m 2.4 GHz – 2.5 GHz 111.5 kHz PM carrier	
Conducted RF IEC 61000-4-6	3 Vrms (6 Vrms in ISM Bands) 150 kHz to 80 MHz 1 kHz 80% AM carrier	6 Vrms 150 kHz to 80 MHz 1 kHz 80% AM carrier	Use in professional healthcare facility and home healthcare environments, excluding near high frequency surgical equipment or near MR machines.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrical fast transient/burst IEC 61000-4-4	+/-2 kV 100 kHz repetition frequency	+/-2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line(s) to line(s) ± 0,5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0,5 kV, ± 1 kV line(s) to line(s) ± 0,5 kV, ± 1 kV, ± 2 kV line (s) to earth	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% U_T for 1 cycle 70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz 0% U_T for 250 cycles at 50 Hz, 300 cycles at 60 Hz	0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles 0% U_T for 1 cycle 70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz	Mains power quality should be that of a typical professional healthcare facility and home healthcare environments. If the user of the Remunity™ Pump for Remodulin® (treprostinil) Injection requires continued battery charging during power mains interruptions, it is recommended that the Remunity™ Pump for Remodulin® (treprostinil) Injection be powered from an uninterruptible power supply or a battery.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
		0% U_T for 250 cycles at 50 Hz, 300 cycles at 60 Hz	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Magnetic Fields generated by: • Metal Detectors • EAS Systems and Tag Deactivators (No Standard Applied)	N/A	300 A/m 0.1 kHz — 3.5 kHz 50 A/m 10 kHz - 60 kHz 30 A/m 50 kHz - 135 kHz	Use in professional healthcare facility and home healthcare environments, excluding near high frequency surgical equipment or near MR machines. RFID readers should be kept at least 0.3 m [1 ft] away from the Remunity™ Pump for Remodulin® (treprostinil) Injection. Hand held or walk through metal detectors may be used near the Remunity™ Pump for Remodulin® (treprostinil) Injection, but avoid prolonged exposure to them. Step through retail anti-theft detectors at a normal pace, but avoid standing in them.

Table 30: *Guidance and Manufacturer's Declaration - Electromagnetic Immunity*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance

Note: U_T is the AC mains voltage prior to application of the test level.

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Appendix B

Patient-Filled Cassette Change

The *Patient-Filled Cassette Change* is only used when instructed by your specialty pharmacy.

It is a step-by-step process for replacing the pump battery, the infusion set, and an empty cassette with a patient-filled cassette.

Follow the step-by-step procedure in the order listed to ensure a safe and efficient replacement of the battery, infusion set, and cassette when the pump and remote are in communication.

Given the drug volume required to prime the pump, the pump's calculation of the time remaining prior to cassette change may be less than expected. Be sure to check the time that you will need to replace the cassette on the Remote so that you can prepare and have your supplies available when the change is needed.

1. Before you start, wash your hands with soap and water.

Supplies Needed for Cassette Change with Remote

The following supplies should be kept on hand and are needed to facilitate a *Cassette or Pump Battery Change*.
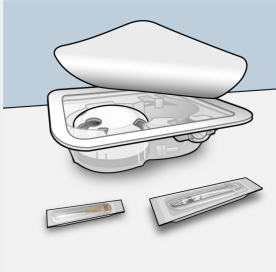
Table 31: *Components for Cassette Change*

Remote with One Fully Charged Pump Battery	Pump attached to the Used Cassette

Table 32: *Disposables for Cassette Change*

Remodulin	Non-expired Disposable Kit, Syringe and Needle	Infusion Sets
		Use only one of the following Infusion Sets • Medtronic Quick-set Infusion Set (MMT-392, MMT-393) • Medtronic Silhouette Infusion Set (MMT-373) • Smiths Medical Cleo 90 Infusion Set (21-7230-24, 21-7220-24) Always refer to your specific infusion set instructions.

Stop Delivery with Remote

⚠️ Cell phones, Bluetooth devices, RFID readers, and Wi-Fi equipment may affect the communication between the Pump and Remote or interrupt operation of the Pump. Keep the Pump and Remote at least 0.8 m [3 ft] away from these items. *See Table 28 on page 223* and *See Table 30 on page 226* for more information.

1. **Press** the **side button** to wake up the remote.

   Your delivery rate and the hours remaining on the cassette displays.

Press   1   2   3

2. Unlock 🔓 » the screen by pressing each front button from left to right.

   The *Main Menu* displays**.**

3. Press ✓ to select **Change Cassette**.

A *Delivery must be stopped before changing the cassette* message displays.

4. Press ✓ to stop medication delivery.

A *Sending request to the pump* message displays.