



REMUNITY®

User Guide



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About

The Remunity® Pump for Remodulin® (treprostinil) Injection is for single-patient use only, and the Remunity® Cassette is for single use only.

The Remunity system, which consists of a wearable infusion pump, refill cassettes, remote interface, and accessories, continually delivers Remodulin® subcutaneously (i.e., under the skin).

If you have any questions about the Remunity system, talk to your healthcare provider or specialty pharmacy representative.

This User Guide provides important safety information about the Remunity system. It is important to read and understand all instructions before using the Remunity system.

Keep this User Guide in a safe, easily accessible place for reference. We recommend keeping it in a carrying case along with your other system accessories.

You must be trained by a qualified trainer before you use the Remunity system. If you have not received training, please contact your specialty pharmacy.

The patient is identified as the Operator in this User Guide.

The following items must be understood prior to use of the Remunity system:

- The *Operator* demonstrates they know what needs to be carried with them to facilitate a cassette and/or pump battery change.
- The *Operator* is able to program the system with an appropriate delivery rate.

- The *Operator* is able to adjust the delivery rate as instructed.
 - The *Operator* understands that only Remunity cassettes may be used with the Remunity System.
 - The *Operator* understands they need to verify the proper Remodulin concentration prior to using a cassette.
 - The *Operator* is able to execute the proper procedure for changing a cassette.
 - The *Operator* is able to execute the proper procedure for resolving an alarm.
 - The *Operator* is able to fill a cassette.
 - Successful Remunity pump therapy requires sufficient physical, cognitive, visual and hearing capabilities to allow recognition and manipulation of the remote and pump. Users must have a minimum of 8 years of education to correctly interpret this User Guide.
- The *Operator* should contact local authorities about proper disposal of the durable components of the system when no longer needed. These components have electronics that contain lead and Lithium Polymer batteries.

Clinical Overview

DKPI-00061-002 was a single-center, randomized, 6-cohort, prospective study in 60 healthy adult volunteers. The objective of the study was to assess accuracy and reliability of the Remunity® Infusion System while delivering normal saline. Accuracy was assessed by weighing the Remunity Infusion System using validated methods at specific time points to compare the measured volumetric flow rate to the programmed flow rate. Remunity Infusion System reliability was assessed by reviewing device history logs, attention alarms, and alarms. Each subject in the study received subcutaneous infusions of normal saline using up to 2 Remunity Infusion System pumps concomitantly. Each pump was programmed to deliver normal saline at 16, 35, or 100 $\mu\text{L}/\text{hour}$ for up to 72 hours depending on the subject's assigned cohort.

Mean pump accuracy was assessed in 107 pumps and was -1.18% (median: -1.20%, range: -5.6% to 2.6%). Throughout the study, 77 pumps contributed 618 weight measurements taken at intervals of 6 hours or less, and 30 pumps contributed weight measurements taken after delivery of the nearly full reservoir capacity. Of the 618 intervals with pump accuracy calculations for pumps with interim time point measures, 590 intervals (95.5%) had overall pump accuracy calculations $\geq -6\%$ to $\leq 6\%$. Of the 30 pumps contributing weight measurements taken after delivery of the nearly full reservoir capacity, all 30 intervals (100%) had overall pump accuracy calculations $\geq -6\%$ to $\leq 6\%$. Pump reliability, including malfunctions and complications, was assessed in 120 pumps. Overall, 92 pumps experienced an attention alarm/alarm during infusion. Of the 92 pumps with attention alarms/alarms, 30 pumps were discontinued after experiencing the following alarms: 16 cassette depleted alarms, 10 cassette problem alarms, 3 occlusion alarms, and 1 pump failure alarm.

21% of pump samples alarmed due to early detection of reservoir depletion resulting from an addressable manufacturing defect but did not affect the overall reliability of the devices.

No action, other than acknowledgment of the attention alarm/alarm, was required for the remaining attention alarm/alarm. The pump alarmed as expected during the course of the study, and would have prompted the user to take appropriate action (e.g., restart the pump, switch to the spare pump). There were no safety concerns related to use of the Remunity Infusion System during the study.

Essential Performance

The following items are the Essential Performance of the Remunity® Pump for Remodulin® (treprostinil) Injection:

- Deliver Remodulin to the patient per specification when operating normally.
- Stop delivery to the patient in the presence of a Pump fault.
- Provide the user with audio alarms.
- Detection of occlusions in the fluid path during Remodulin delivery.
- Limit bolus volumes resulting from the clearing of an occlusion to the published levels in this document.
- Provide the operator with the ability to stop a therapy.

Indications for Use

The Remunity® Pump for Remodulin® (treprostinil) Injection (the Remunity System) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in adults (greater than 22 years old).

Contraindications

None

Conventions

This table describes typographic conventions that may be used in this document.

Table 1: Conventions

Convention	Description
Boldface type	Emphasizes heading levels, column headings, and the following literals when writing procedures: <ul style="list-style-type: none">Options and elements that appear on the remote screen.Buttons on the pump or remote.User input for procedures.

Convention	Description
<i>Italic type</i>	<ul style="list-style-type: none">Accentuates words or areas that appear on the remote screen.Terms that are listed in the glossary.Sounds from the system.
<u>Underline</u>	Emphasis of instructional details.
<i>See "Conventions" above.</i>	Provides quick and easy access to cross-referenced sections of the document. Hyperlinks to locations within the document are italicized.
Select	Used to instruct the user to choose from a list of options.
Press	Used to instruct the user to press down on a physical button.

Symbols

Table 2: Symbols



Symbol Source/ID	Symbol	Definition
21 CFR 801.15(b)	R_x Only	This symbol indicates the device is for prescription use only.
ISO 7000-1051*		This symbol indicates a medical device that is intended for one use.
ISO 7000-1135*		This symbol indicates a product should be recycled.

Table 2: Symbols





Symbol Source/ID	Symbol	Definition
ISO 7010-M002*		This symbol is used to instruct you to refer to this guide prior to using the Remunity® Pump for Remodulin® (treprostinil) Injection.
Warning / ALARM		This is the Warning safety alarm symbol. It is used to notify you of potential hazards. Obey all safety messages that follow this symbol to avoid possible injury.
Caution / ATTENTION ALARM		These are the Caution safety and attention alarm symbols. They are used to notify you of potential hazards. Obey all safety messages that follow this symbol to avoid the possibility of an alarm.
IEC 60417-5576		This is the Bell cancel symbol. It is used to indicate that an alarm condition has had its audio turned off.

Table 2: Symbols





Symbol Source/ID	Symbol	Definition
Symbol 5.1.1 of ISO 15223-1: 2012(E)*		This symbol indicates the medical device manufacturer.
Symbol 5.1.3 of ISO 15223-1: 2012(E)*		This symbol indicates the date when the medical device was manufactured.
Symbol 5.1.4 of ISO 15223-1: 2012(E)*		This symbol indicates the date after which the medical device is not to be used.
Symbol 5.1.5 of ISO 15223-1: 2012(E)*		This symbol indicates the manufacturer's lot code so that the lot can be identified.

Table 2: Symbols





Symbol Source/ID	Symbol	Definition
Symbol 5.1.6 of ISO 15223-1: 2012(E)*		This symbol indicates the manufacturer's Catalog number so that the medical device can be identified.
Symbol 5.1.7 of ISO 15223-1: 2012(E)*		This symbol indicates the manufacturer's serial number so that a specific medical device can be identified.
Symbol 5.2.4 of ISO 15223-1: 2012(E)*		This symbol indicates a medical device that has been sterilized using irradiation.
Symbol 5.3.4 of ISO 15223-1: 2012(E)*		This symbol indicates a medical device that needs to be protected from moisture.

Table 2: Symbols





Symbol Source/ID	Symbol	Definition
IEC 60417-5333*		This symbol indicates that equipment is Type BF which indicates it is electrically isolated and can safely contact a person's skin without risk of electric shock.
Figure 1 of EN 50419: 2006		This symbol indicates that equipment should not be disposed of in the trash.
RBRC Li-Ion Battery Recycling Seal		This symbol indicates that Lithium batteries should be recycled.
IEC 60417-5031*		This symbol indicates that a device requires direct current.

Table 2: Symbols


Symbol Source/ID	Symbol	Definition
'MR Unsafe' symbol, ASTM F2503-23		This symbol indicates that a device is not safe to have near an MRI.
Note: *For compliance with sub-clause 7.6.2 of IEC 60601-1: 2012.		

Table 3: Symbols for Shipping Container Markings

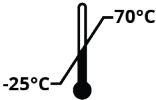
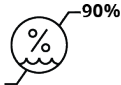
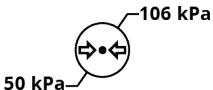
Symbol Source / ID	Symbol	Definition
Symbol 5.3.7 of ISO 15223-1:2012(E)*, with SYSTEM storage temperature limits included		This symbol indicates the storage temperature range for the Remunity System.

Table 3: Symbols for Shipping Container Markings

Symbol Source / ID	Symbol	Definition
Symbol 5.3.8 of ISO 15223-1:2012(E)*, with SYSTEM storage humidity limits included		This symbol indicates the storage humidity range for the Remunity System.
Symbol 5.3.9 of ISO 15223-1:2012(E)*, with SYSTEM storage pressure limits included		This symbol indicates the storage pressure range for the Remunity System.
Note: *For compliance with sub-clause 7.6.2 of IEC 60601-1: 2012.		

Warnings

This section provides general warnings related to the use of the Remunity System.

Additional and repeat warnings appear throughout this User Guide where appropriate.

Component Warnings

Use only the following infusion sets with the Remunity® Pump for Remodulin® (treprostinil) Injection:

- Medtronic Quick-set Infusion Set: 23 in (60 cm) - MMT-392, MMT-393
- Neria Guard: 23 in (60 cm) - 704060-5229, 704060-5226
- Medtronic Silhouette Infusion Set: 23 in (60 cm) - (MMT-373)
- Smiths Medical Cleo 90 Infusion Set: 24 in (61 cm) - (21-7230-24, 21-7220-24)

Failure to do so may affect accuracy or occlusion detection leading to harm.



Do not use disposables from previously opened or damaged sterile packaging. Using such disposables may lead to infection and subsequent harm.



Verify sterile components are not expired before use. Using expired sterile components may lead to infection and result in harm.



Do not use damaged disposable components. Using damaged disposable components may result in start-up failures, interruptions in therapy, or topical exposure to Remodulin.



Keep the pump, cassette, and tubing from contacting sharp objects that can damage the components, as this may result in delivery errors leading to harm.



Do not open or attempt to modify or repair any component of the system, as this can compromise safe operation and lead to harm.



Discontinue use of the remote and switch to your spare remote in the event the remote fails to operate as described in this User Guide. Failure to do so can lead to incorrect therapy decisions that result in harm.



To avoid a potential electrical shock hazard, any equipment connected to the system USB port must comply with either IEC 60601-1: 2012 for medical equipment or IEC-60950 for data processing equipment.



The use of cables other than those provided or specified may result in increased emission or decreased immunity of the Remunity® Pump for Remodulin® (treprostinil) Injection infusion system.



Do not use batteries and battery chargers other than those supplied as this can lead to unsafe operation resulting in harm.



Discontinue use of the pump and switch to your spare pump in the event the pump fails to operate as described in this User Guide. Failure to do so can lead to harm.



Avoid exposure of your pump to temperatures below 41 °F (5 °C) or above 104 °F (40 °C). Remodulin solutions freeze near 32 °F (0 °C) and degrades at high temperatures. If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and Remodulin cool.

Location of Use Warnings



Keep the system components, including pump batteries, away from small children. Failure to do so could result in children swallowing them which can lead to choking or damage to their digestive tract resulting in harm.



Portable and mobile RF communications equipment may affect the communication between the pump and remote or interrupt operation of the pump. If the remote indicates a loss of communication, move the pump and remote at least 12 in (30 cm) away from these items.



Do not sleep with the tubing set exposed if you have pets. Doing so can result in damage to the infusion set leading to interruption of therapy and unintended exposure to medication resulting in harm.



The Remunity® Pump for Remodulin® (treprostinil) Injection may affect nearby electrical and electronic devices, including medical devices. This interference could cause these devices to operate abnormally or stop functioning. If nearby equipment looks like it is being affected by this system, move the pump, remote, or pump battery charger away from these machines.



Do not use the system outside of the environmental conditions listed in the user guide. Doing so may cause the device to operate outside of its published accuracy which can result in harm.



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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.



Metal detectors may affect pump accuracy or trigger an alarm. Hand held or walk through metal detectors may be used near the Remunity® Pump for Remodulin® (treprostinil) Injection, but avoid prolonged exposure to them. [See Table 34 on page 233](#) for more information.



Retail anti-theft detectors may affect pump accuracy or trigger an alarm. Step through retail anti-theft detectors at a normal pace, but avoid standing in them. [See Table 34 on page 233](#) for more information.



The Remunity® Pump for Remodulin® (treprostinil) Injection is MR Unsafe. Remove the pump before entering an MRI scan room and do not bring the remote into the MRI scan room. Contact with or being in proximity to an MRI scanner can cause the pump and remote to move or lead to electric shocks and may result in severe injury.

Cassette Change Warnings



Only Remunity cassettes may be used with the Remunity® Pump for Remodulin® (treprostinil) Injection. Failure to use Remunity cassettes can lead to harm.



Damaging the portions of the pump and cassette exposed during the cassette and battery changing process can affect pumping accuracy which can lead to harm.



Delivery errors may result in adverse medical events (including serious injury) if the cassette and attached tubing are improperly primed.



Contamination to the portions of the pump and cassette exposed during the cassette and battery change process by dirt, lubricants or liquids can affect pumping accuracy which can lead to harm.



Do not connect the tubing to an installed catheter before the pump completes all self tests. Doing so may cause over delivery of medication resulting in harm.



Do not leave the cassette and infusion set connected to an inserted catheter during priming operations. Leaving the infusion set connected during priming operations can lead to the unintended delivery of medication which can lead to harm.



Do not connect the cassette to the catheter if the cassette is not connected to the pump. Connecting the cassette to the catheter without the pump connected can lead to the unintended delivery of Remodulin which can lead to harm.



Failure to prime the infusion set tubing can lead to a delay in the delivery of medication, which can lead to harm.



Avoid unnecessary contact with all parts on the interior of the pump exposed during the battery changing process.

Medication Delivery Warnings



Do not disconnect the pump from the cassette while the cassette is connected to the catheter. Disconnecting the pump from the cassette while the cassette is connected to the catheter may lead to unintended Remodulin delivery which can lead to harm.



Do not perform troubleshooting steps while the pump is connected to the catheter. Performing troubleshooting steps while the pump is connected to the catheter can lead to the unintended delivery of Remodulin which can lead to harm.

Cautions

This section provides cautions related to the use of the Remunity System.

Additional and repeat cautions appear throughout this User Guide where appropriate.



Use clean technique when filling the cassette and connecting and applying the infusion set. Failure to do so may lead to infection.



Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Use of this device without the training and supervision of a healthcare practitioner may lead to errors that result in harm.



Risk of fire and burns. Do not open, crush, heat above 140 °F (60 °C), or incinerate the pump battery or remote. Doing so can lead to fire or rapid spreading of fire resulting in harm.



This system supports flow rates between 16 $\mu\text{L/h}$ - 225 $\mu\text{L/h}$. If your flow rate is outside this range please discuss with your physician.



Replace pump batteries after three months use. Failure to replace pump batteries after three months of use may lead to Cassette Problem alarms.



Contact with insect repellents that contain DEET, skin care products, or sunscreens can damage the cassette, which may lead to leaks. This can result in loss of the IP58 rating of the pump, Cassette Problem Alarms, and/or exposure to Remodulin. Avoid getting insect repellents, skin care products, or sunscreens on the cassette. When using these products, make sure to protect the pump and cassette. If they do get on the cassette, replace the cassette by performing the steps in ["Cassette Change" on page 61](#).



Avoid operating the system in low pressure environments. Operating the system in low pressure environments may cause variation in delivery accuracy for short periods of time.

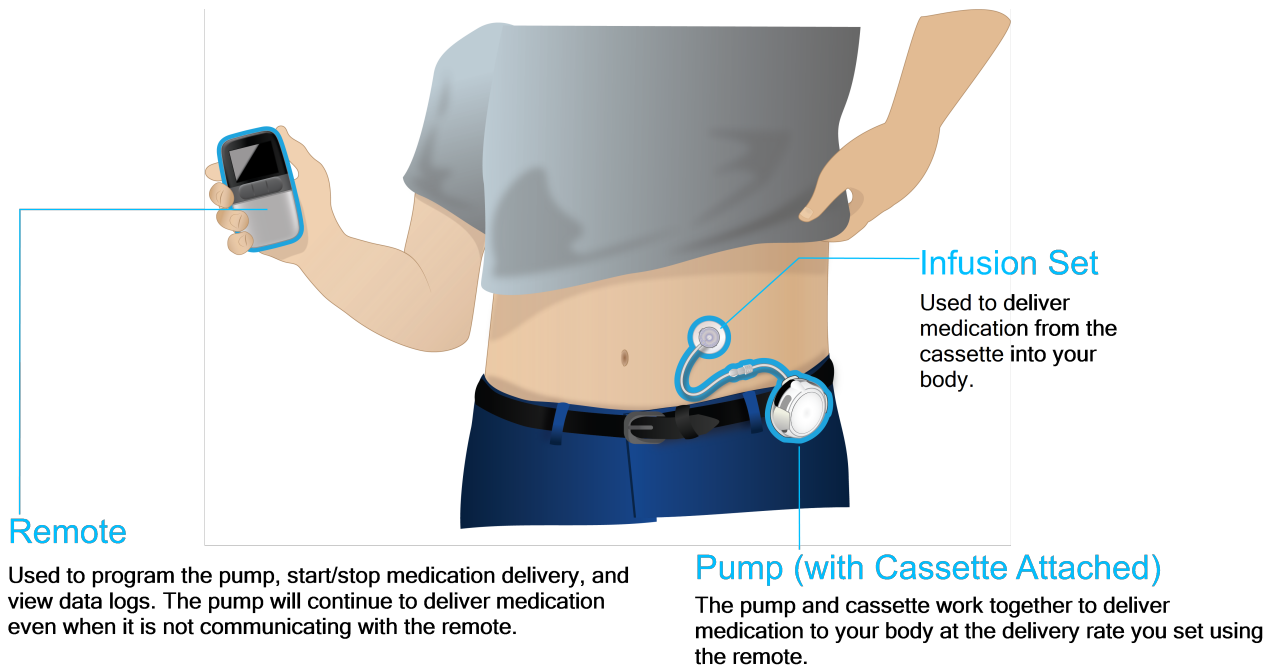
Introduction

This section introduces you to the Remunity® Pump for Remodulin® (treprostinil) Injection and provides information about:

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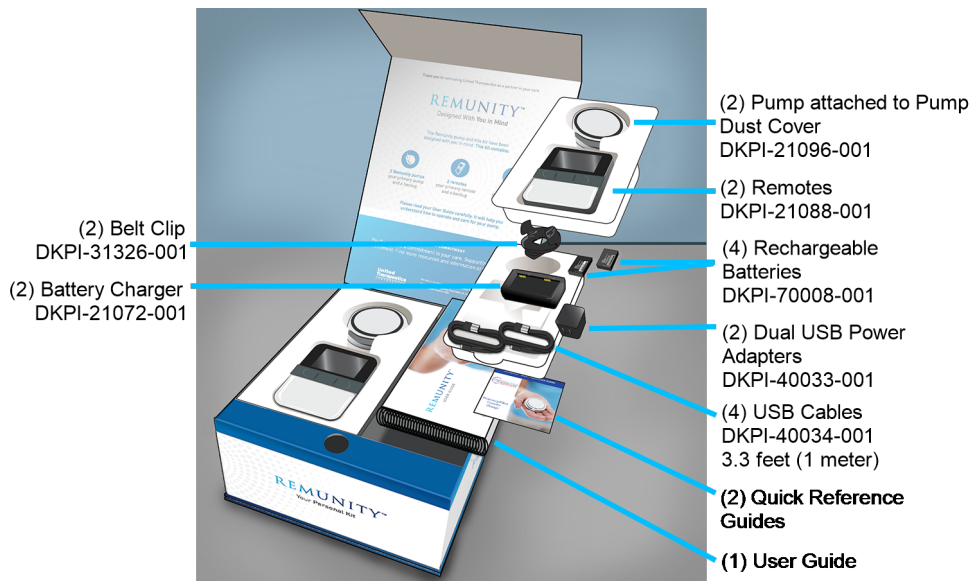
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System Overview



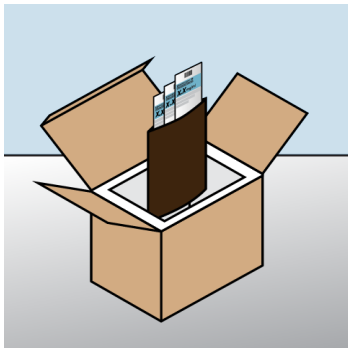
Starter Kit

When you open your pump box for the first time along with your specialty pharmacist, check that you have all the components in the box.

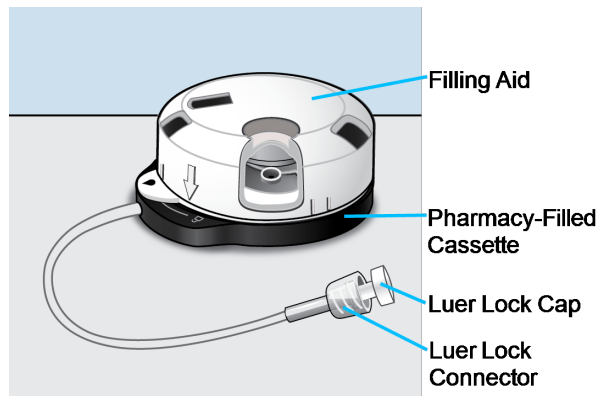


Pharmacy-Filled Cassette Package

The Remodulin pharmacy-filled cassette refill kit is supplied by your specialty pharmacy and contains multiple *Pharmacy-Filled Cassette Packages*.



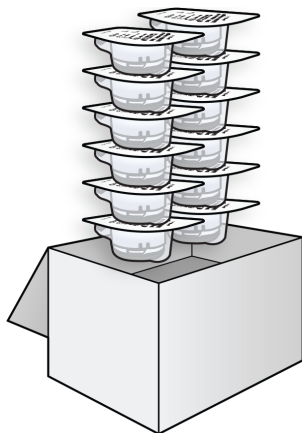
Each *Pharmacy-Filled Cassette Package* consists of a *Filling Aid* attached to a pharmacy-filled cassette. Each pharmacy-filled cassette contains enough medication for up to 72 hours.



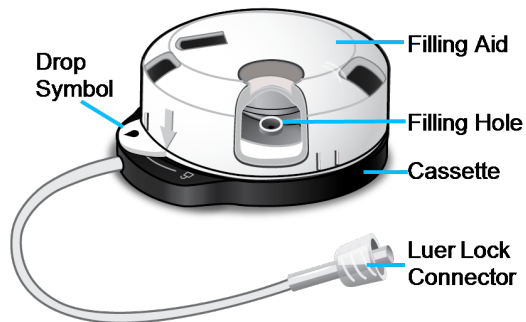
The pharmacy-filled cassette with an attached filling aid are supplied to the specialty pharmacy sterile using a gamma radiation (R) method, and filled using clean technique.

User-Filled Cassette Package

The Remodulin user-filled cassette refill kit is supplied by your specialty pharmacy and contains 12 *user-filled cassette packages*.



Each *User-Filled Cassette Package* consists of a *Filling Aid* attached to an empty cassette. Each cassette can be filled with up to 72 hours of medication.



The user-filled cassette package is supplied sterile using a gamma radiation (R) method.

Disposables

Do not use the disposables if the package has been previously opened or damaged.

Contact your specialty pharmacy to obtain the appropriate cassette packages, infusion sets, syringes and needles (user-filled only), required for use of the system:

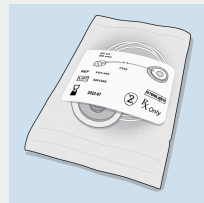
- Pharmacy-Filled Cassette Package



- User-Filled Cassette Package



Use only approved infusion sets. [See "Approved Infusion Sets" on page 215.](#)

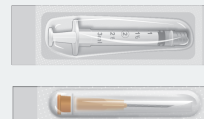


Always refer to your specific infusion set instructions.



User-Filled Only

- Use only a sterile, single-use, 3 mL syringe and 25 or 26 gauge x 5/8 inch needle with luer lock connectors.



Remote Overview

1. Press and hold the **side button** to power on the remote.

Once the remote has been powered on, the side button functions as a wake up, screen off, or back button.



Discontinue use of the remote and switch to your spare remote in the event the remote's screen is missing pixels.

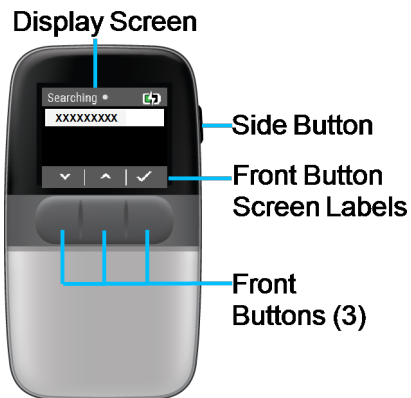
Power OFF

1. To *Power Off* the remote, press and hold the **side button** until the *Power Off* screen is displayed.

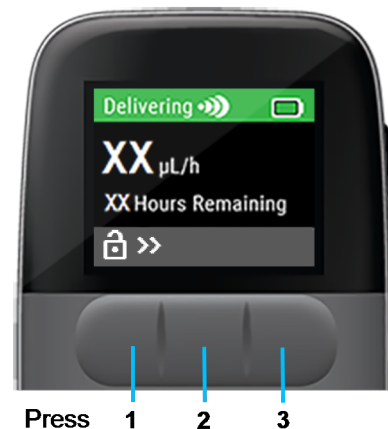


2. Press  to power off the remote.

Remote Front



The *Front Button Screen Labels* displayed on the screen are executed by pressing the coinciding **front button** below the label.









To unlock the remote press the **front buttons** in order from left to right.



Once unlocked, the remote screen will stay active for the programmed *Screen Timeout* minutes before going into sleep mode. See "*Screen Timeout*" on page 141.

Front Button Screen Labels

	Repeat a Function
	Cancel or Exit a Function
	Access Help Information
	Silence Alarm
	Edit a Value
	Acknowledge or Accept

	Scroll Up / Increase a Value
	Scroll Down / Decrease a Value
	Next Screen
	Previous Screen
	Pump Settings
	Unlock Screen

Remote Back

The remote has a battery bay on the back to store and charge a spare pump battery. This battery does not power the remote.

The *Spare Battery Status Light* on the bottom of the remote indicates the spare battery's charging status when inserted in the battery bay, the remote is powered on, and the remote is plugged in to charge.

Spare Battery Bay
(clear plastic cover not shown)



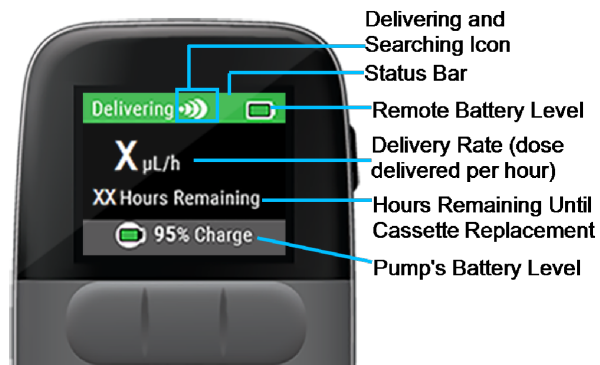
Spare Battery
Status Light

Charging Port






Color	Status
Green	Spare pump battery charging is complete
Amber	Spare pump battery is charging
Blinking Red	Charging Fault

Home Screen

The *Home Screen* displays details about your pump's medication delivery and any conditions you need to address, such as *Alarms or Attention Alarms*. See "[Alarms and Attention Alarms](#)" on [page 157](#).

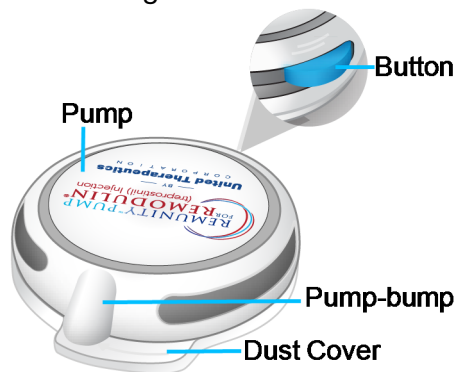


The color of the *Status Bar* indicates the remote's connection to the pump and the current delivery:

	Connected and Delivering
	Connected and NOT Delivering
	NOT Connected
	Alarm
	Attention Alarm

Pump Overview

The *Pump* connects to a *Cassette* and pumps medication under your skin at the delivery rate you set using the remote. The pump will continue to deliver medication even when it is not communicating with the remote.



The pump's blue button can be pressed to start medication delivery, exit airplane mode, and place the pump in pairing mode.

The pump is powered by a rechargeable pump battery that is inserted into the pump. Every three days you must replace the pump battery with a fully charged pump battery.



If the pump has been subjected to the extremes of specified storage temperatures, before using the pump allow it to cool off/warm up for one hour.

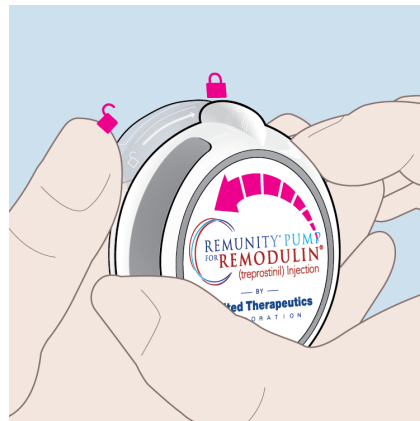
Pump with Cassette Attached



Remove the Clear Dust Cover

The pump is shipped with a *Clear Dust Cover* attached to protect the pump.

1. Remove the clear dust cover by holding the dust cover in one hand and rotating the pump counterclockwise with the other hand.



2. Separate the pump from the dust cover.

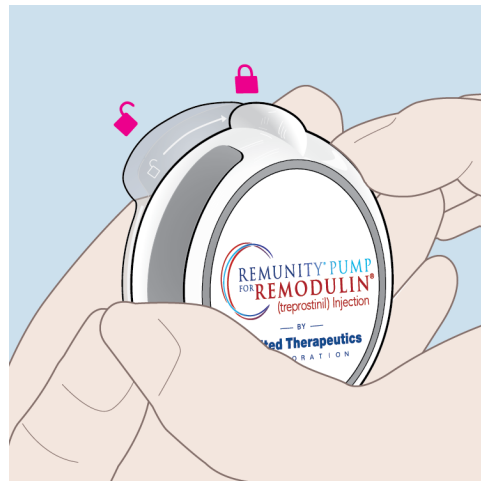
Attach the Clear Dust Cover

Whenever the pump is not being used, store the pump with the clear dust cover in place.

1. Align the *pump-bump* with the unlock symbol on the clear dust cover.



2. Holding the clear dust cover in one hand and the pump in the other, push and rotate to the lock symbol on the clear dust cover.



Pump Sounds

Table 4: Pump Sounds






Sound from Pump	Status	Description
 <i>One beep</i>	Ready	Ready to progress to next step. Continue setup.
 <i>One repeating beep</i>	Busy	Pump is busy. Wait until pump is ready.
 <i>Escalating Four-tones</i>	Delivering	Pump is delivering medication. Confirm the remote displays a green <i>Delivering</i> status bar. This tone is also an indication when exiting out of airplane mode.

Table 4: Pump Sounds

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

How to Wear Your Pump

Your *Pump* can be worn a few different ways:

- Attached to a belt with the included *Belt Clip* accessory
- Placed *in a pocket*

Make sure to secure the infusion set tubing to prevent it from catching on other objects.

Avoid strong magnetic fields, created by things like jewelry clasps, magnetic badges, and magnetic toys. Strong magnetic fields can trigger the latch detect sensor within the pump causing a false cassette detach alarm.



Belt Clip

1. The pump slides into the *Belt Clip* with the blue button facing inward.



2. Slide the belt clip onto your belt or other location on your body that will firmly support the pump.



In Your Pocket

Insert the pump into your pocket making sure the infusion set tubing is not pinched.



Set Up

Contact your specialty pharmacy for assistance with any of the set up instructions.

Charge the Pump Batteries	46
Charge the Remote and One Pump Battery	48
Pair Remote and Pump for the First Time	52
Enter Delivery Rate	57

Charge the Pump Batteries

You must charge the *Pump Batteries* before you can use the pump. A fully charged pump battery can power the pump for up to 3 days (72 hours).

Each time you replace a cassette, you should also replace the pump battery with a fully charged battery.

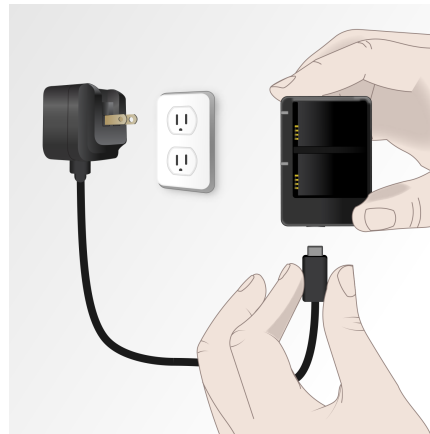
You can charge up to two pump batteries using the battery charger, and one pump battery using the remote. [See "Charge the Remote and One Pump Battery" on page 48.](#)

The pump battery charger can only be connected to the supplied AC adapter and cable for battery charging.

Charging the pump batteries using the dual USB AC adapter will take about 6 hours.

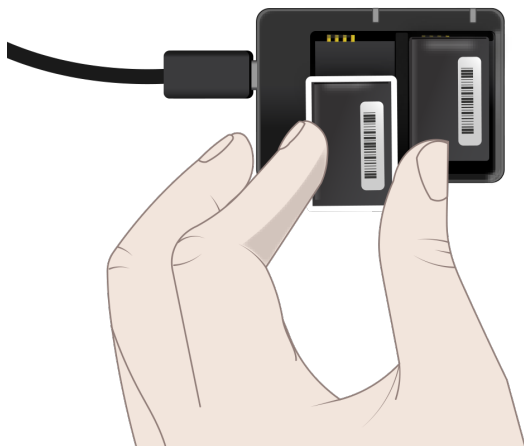
If the pump batteries have been subjected to the extremes of the specified storage temperatures, before charging or using the batteries allow them to cool off / warm up for 20 minutes.

1. Plug in one of the USB cables into the battery charger and the other end of the USB cable into the dual USB wall adapter.



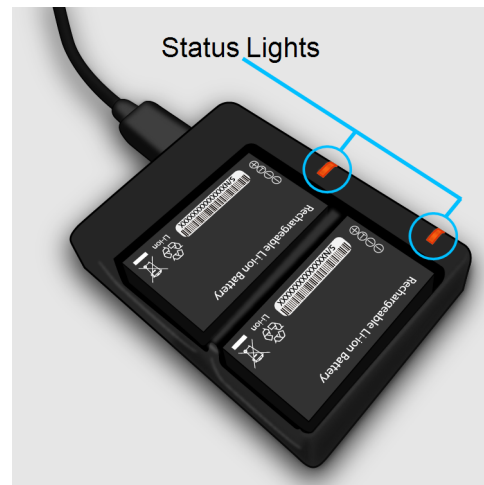
2. Plug the dual USB wall adapter into an AC power outlet.

3. Insert two rechargeable batteries into the battery charger by aligning the contacts.



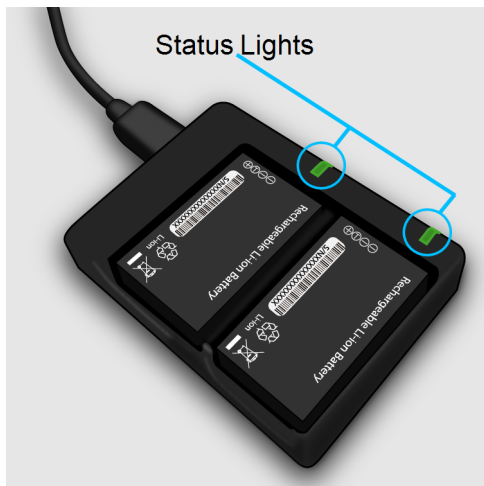
Avoid touching the electrical contacts on the battery charger when it is connected to a power source.

4. Amber battery charger status light(s) indicate the batteries are charging.



Color	Status
Green	Battery charging is complete
Amber	Battery is charging
Blinking Red	Charging Fault

5. Wait until the pump batteries are fully charged before use.



A pump battery is fully charged when the battery charger status light(s) are green.

Charge the Remote and One Pump Battery

You should charge the remote before use. The remote and pump battery in the remote will typically fully charge in 6 hours or less when connected to the supplied dual USB AC adapter.

Only the AC adapter and cable provided with the system should be used to charge the remote.

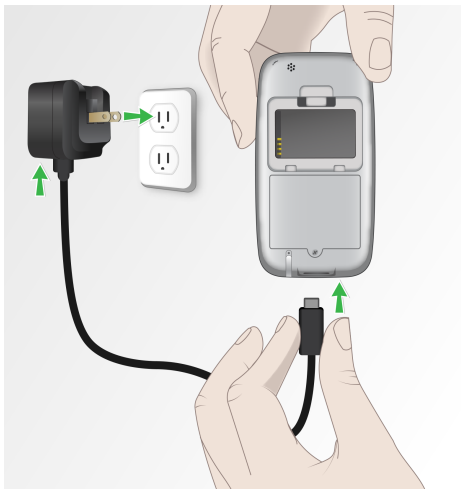
The remote will work for up to 1 day (24 hours) on a full charge. It is recommended to charge the remote daily. It is a good habit to charge the remote every evening.

The remote is charged by connecting it to the supplied dual USB AC adapter. The remote can also be used to charge a pump battery as you are charging the remote.

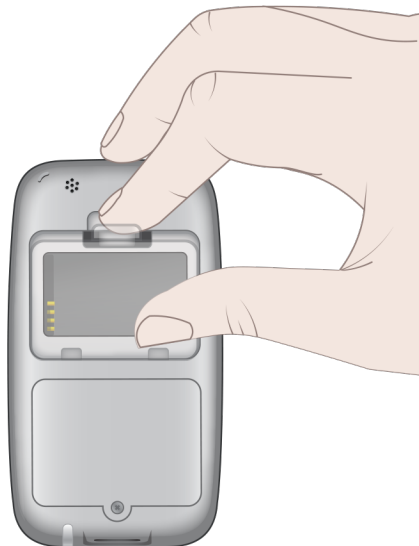
The remote is fully functional while it is charging.

If the remote has been subjected to the extremes of the specified storage temperatures, before charging or using the remote, allow the device to cool off/warm up for one hour.

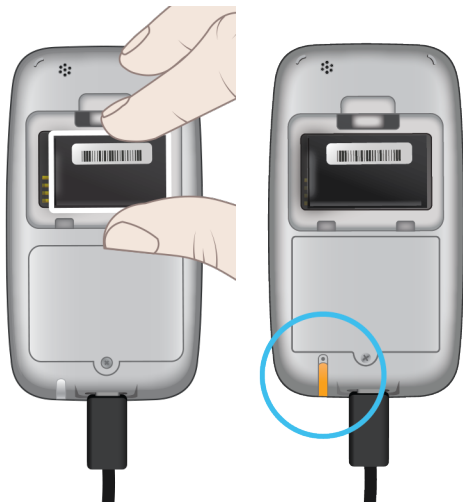
1. Plug the second USB cable into the bottom of the remote and the other end of the USB cable into the dual USB wall adapter.



2. Remove the clear cover from the remote battery bay by pushing down on the tab and pulling forward.



3. Insert a spare rechargeable pump battery into the remote battery bay on the back of the remote making sure to align the contacts.



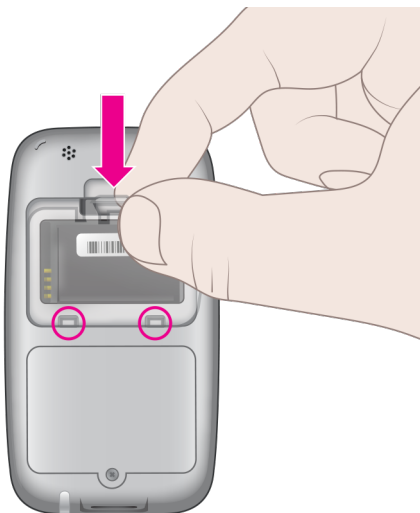
The remote battery bay will charge an inserted pump battery only when the remote is plugged in to charge. A charging spare pump battery is indicated by the amber light on the back of the remote when the remote is powered on.

Color	Status
Green	Spare pump battery charging is complete
Amber	Spare pump battery is charging
Blinking Red	Charging Fault



Avoid touching the electrical contacts in the remote battery bay when it is connected to a power source.

4. Insert the clear cover onto the remote battery bay.



5. To check the battery charge level of the remote, press the **side button** on the side of the remote.



6. Check the status bar for the charging symbol on top of the battery symbol, which indicates that the remote is charging.



7. When the battery symbol is full green in the status bar, the remote is fully charged.

Pair Remote and Pump for the First Time

Pairing the remote with the pump enables the remote to control the pump settings, including the medication delivery rate.



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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

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

The remote will search for a pump when you power on.



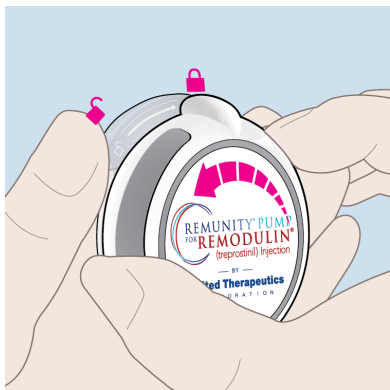
Press: **1** **2** **3**

2. Unlock the screen by pressing each front button from left to right to unlock the remote screen.



Once unlocked, the screen will stay active for 2 minutes before going into sleep mode.

The pump is shipped with a *Clear Dust Cover* attached to protect the pump.



3. Remove the clear dust cover by holding the dust cover in one hand and rotating the pump counterclockwise with the other hand.
4. Lift the dust cover off and store it with your other Remunity supplies.

5. Insert a fully charged pump battery into the pump.



The pump will be in pairing mode and sound a ready tone (one beep). If you hear a different tone, [See "Troubleshooting Pump" on page 200.](#)

6. Locate your pump serial number on the bottom of the pump.

- Place the pump and remote within 2 in (50 mm) of each other during the pairing process.

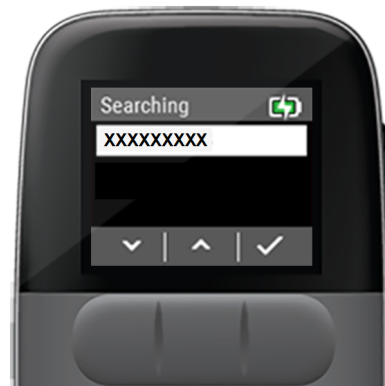





- If your pump serial number does not show up on screen after a minute, **press and hold** the pump's **blue button** for **10 seconds** to activate pairing mode. This will be confirmed by a single *Ready* beep.




After a few seconds, the pump will generate a series of beeps. Keep holding down the button until you hear the single *Ready* beep.

- Then, check the screen again for your pump serial number.



- On the remote, use   to highlight the pump's serial number and press .





11. After selecting your pump serial number you will be prompted to confirm the selected pump. Press  to confirm.



A *Pairing To...* message is displayed.

If pairing fails, [see "Pairing Failed Attention Alarm" on page 174.](#)



12. Upon successful pairing the *Paired Pump* message is displayed. Press .
13. If the remote is paired to an incorrect pump, press  and repeat the pairing instructions from [Step 6](#).

Enter Delivery Rate






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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.



Programming the incorrect delivery rate of medication will lead to errors in the dose rate of medication that can lead to harm. Programming should be performed with the direction from your healthcare provider.

The remote will prompt you to set a delivery rate (the amount of medication the pump will deliver per hour of use).

1. Use   to set your prescribed rate, then press .



The remote displays a *Fill new cassette with X.X mL, prime, and install* message.



2. Wash your hands and gather cassette change supplies.
3. If you are using a pharmacy-filled cassette, you will not need to follow the steps to fill the cassette with the amount displayed on the remote. Follow steps to "[Prepare Filling Aid](#)" on page 74.

4. If you are filling the cassette yourself, follow steps to *"Prepare and Fill Cassette" on page 98.*

Here are some important reminders to ensure continuous therapy after your first set up:

At least the following items should be kept available to facilitate a cassette or pump battery change:

- Non-expired cassette and infusion set, in their unopened packaging
- Fully charged pump battery
- Filling supplies including syringe, needle, and non-expired Remodulin for user-filled cassette

When traveling at least the following spares should be kept available:

- Fully charged remote
- Pump
- Extra fully charged pump battery
- Extra non-expired cassettes and infusion sets, in their unopened packaging

- Filling supplies including syringe, needle, and non-expired Remodulin for user-filled cassettes

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Cassette Change

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Pharmacy-Filled Cassette Change

The *Cassette Change* is a step-by-step process for replacing the pump battery, the infusion set, and an empty cassette with a 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.

Given the drug volume required to prime the cassette and infusion set, the 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.



If instructed by your physician to change the delivery rate as part of the cassette change process, the delivery rate should be changed before selecting *Change Cassette*. See "[Select Change Cassette](#)" on page 66.



The delivery rate cannot be changed during a cassette change without the remote.

Wash Hands

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



Gather Supplies

The following supplies should be kept available to complete a pharmacy-filled *Cassette Change*.

Table 5: Components for Pharmacy-Filled Cassette Change







Fully Charged Pump Battery from the Battery Charger or Remote Battery Bay	Pump attached to the Used Cassette
 OR 	

Table 6: Disposables for Cassette Change

Pharmacy-Filled Cassette Package	Infusion Sets
	<p data-bbox="519 267 1136 333">Use only approved infusion sets. <i>See "Approved Infusion Sets" on page 215.</i></p>  <div data-bbox="519 537 1498 660"><p data-bbox="750 580 1432 611">Always refer to your specific infusion set instructions.</p></div>

Select Change Cassette

If you do not have your remote, skip to "[Disconnect Infusion Site](#)" on page 68.




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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

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



Your delivery rate and the hours remaining on the cassette is displayed.



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


The *Main Menu* is displayed.



3. Press  to select *Change Cassette*.



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



4. Press  to stop medication delivery.

A *Sending request to the pump* message is displayed followed by a *Delivery Stopped* attention alarm.

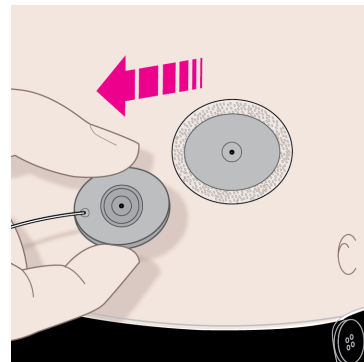


5. Press  to silence the attention alarm.
6. Press  to acknowledge the *Delivery Stopped* attention alarm.

Disconnect Infusion Site

1. Disconnect the infusion set tubing from the catheter.

Refer to the instructions provided by your infusion set's manufacturer for guidance.




You should consult with your specialty pharmacy about how often to change the catheter.

Disconnect Cassette from Pump and Dispose



To avoid unintended medication delivery, disconnect your infusion set tubing from your catheter before detaching the cassette from the pump.

1. Holding the cassette still, rotate the pump counterclockwise until the *pump-bump* is aligned with the unlock  symbol.



You should hear a *Ready* tone coming from the pump.

If you did not stop delivery with your remote, you should hear an *Alarm* tone coming from the pump.



2. Separate the pump from the cassette.



Avoid unnecessary contact with all parts on the interior of the pump exposed during the cassette changing process.

Keep dirt, lubricants and liquids away from all parts on the interior of the pump exposed during the cassette changing process.

3. Dispose of the used cassette and infusion set tubing and catheter (if removed).

Follow your infusion set's instructions:

- If you also plan to change your catheter and/or infusion site.
- For proper disposal of infusion set tubing and/or catheter.



Replace Pump Battery

Avoid unnecessary contact with all parts on the interior of the pump exposed during the battery changing process.

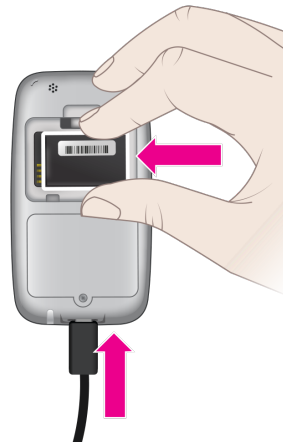
1. Turn the pump over and use the end of your finger to remove the battery from the pump.



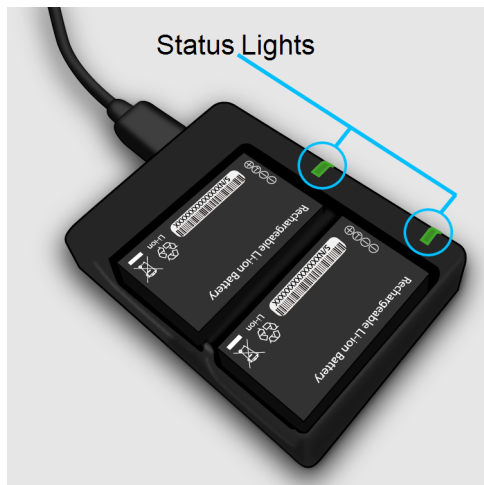
2. Insert the depleted pump battery into the battery charger or the remote battery bay.



3. If a pump battery is inserted into the remote battery bay, the battery will only charge while the remote is charging.



4. Obtain a fully charged pump battery from the battery charger or from the remote battery bay.



5. If you obtain a pump battery from the remote battery bay, make sure the spare pump battery charging light on the remote, when plugged into AC power, is green. This indicates the pump battery in the remote battery bay is fully charged.



6. Insert the fully charged pump battery into the pump making sure the contacts are aligned.



The pump will sound a *Ready* tone (one beep). Keep dirt, lubricants and liquids away from all parts on the interior of the pump exposed during the battery changing process.

Prepare Filling Aid

You can use each pharmacy-filled cassette for up to 72 hours. Replace the cassette when medication runs out or after 72 hours, whichever comes first.



Do not use disposables from previously opened or damaged sterile packaging. Using such disposables may lead to infection and subsequent harm.



Do not attach the infusion set tubing to your inserted catheter until after you have prepared the new cassette and connected it to the pump. Connecting the infusion set tubing to the catheter before connecting the cassette to the pump may lead to unintended delivery.

1. You will not need to follow the steps to fill the cassette with the amount displayed on the remote for the pharmacy-filled cassettes.

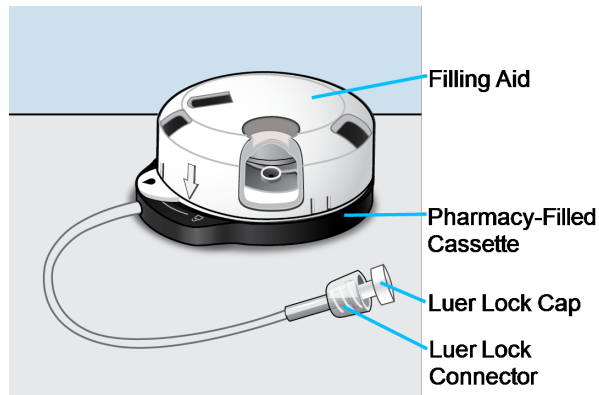
2. Open the *pharmacy-filled cassette package* and remove the plastic tray.



3. Open the plastic tray, remove the filling aid and pharmacy-filled cassette, and place it on a flat surface with the black side down.

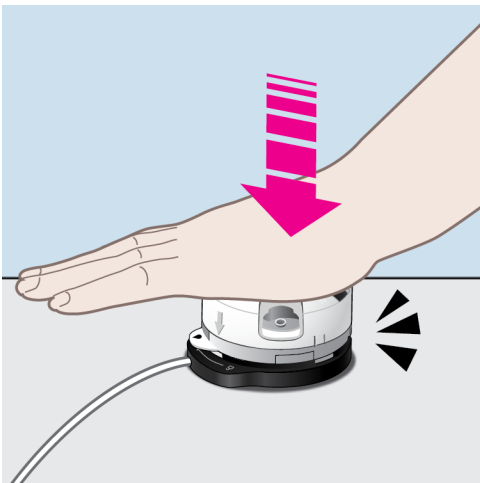


Do not use the cassette if any Remodulin is visible on the cassette or filling aid.

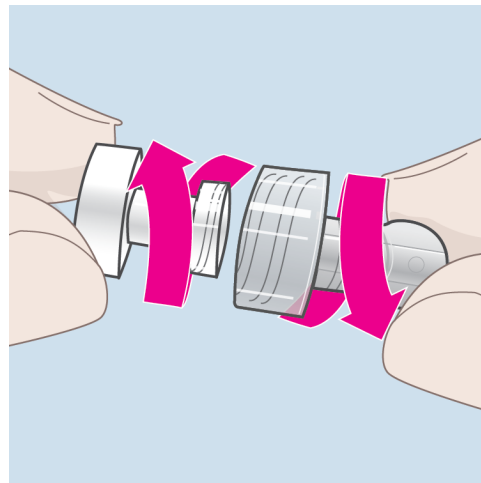


Note the important areas of the filling aid and pharmacy-filled cassette.

4. Press down on the top of the filling aid until you hear a sound or series of sounds.



5. Remove the cap from the *luer lock* connector.

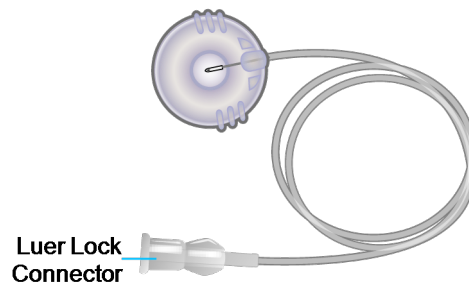


Connect and Prime Infusion Set

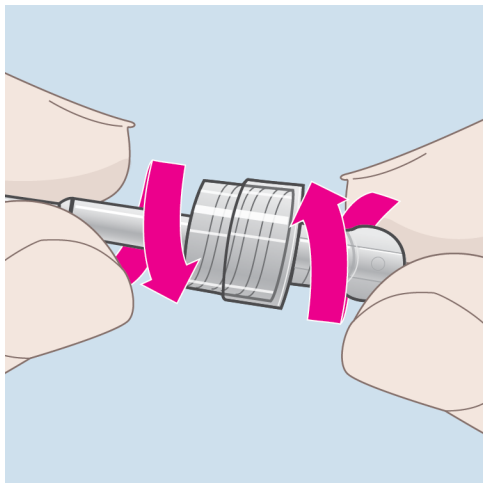
1. The infusion set tubing should be changed whenever you are performing a *cassette change*. Obtain a new infusion set package.




2. Open the infusion set package and remove the infusion set tubing.



3. Connect the infusion set to the cassette by twisting the *luer lock* connectors together.



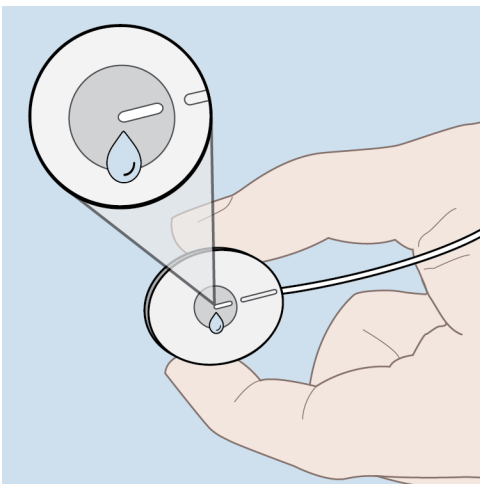
Do not attach the infusion set tubing to your inserted catheter until after you have prepared the new cassette and connected it to the pump. Connecting the infusion set tubing to the catheter before connecting the cassette to the pump may lead to unintended delivery.

4. Holding the cassette still, rotate the filling aid clockwise until you hear a sound or series of sounds and the arrow is aligned with the drop  symbol on the filling aid tab.



Do not press the filling aid and cassette together forcefully while rotating. For guidance, see ["Trouble rotating the cassette and filling aid"](#) on page 196.

5. Watch for medication drops to appear at the end of the infusion set.

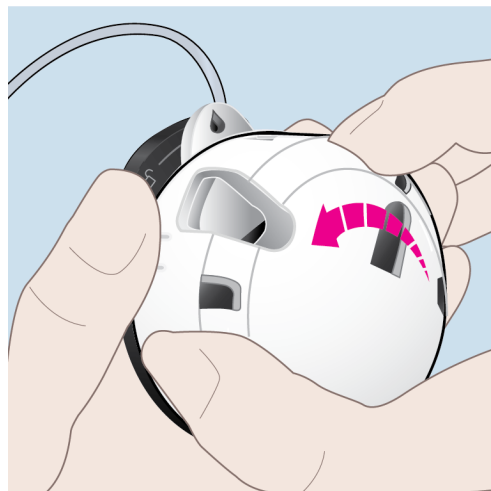


Seeing the medication drops indicates the infusion set and cassette are primed.

If the medication drops do not appear after one minute, [see "No fluid is visible at end of infusion set when priming" on page 199.](#)


Stop Priming and Remove Filling Aid

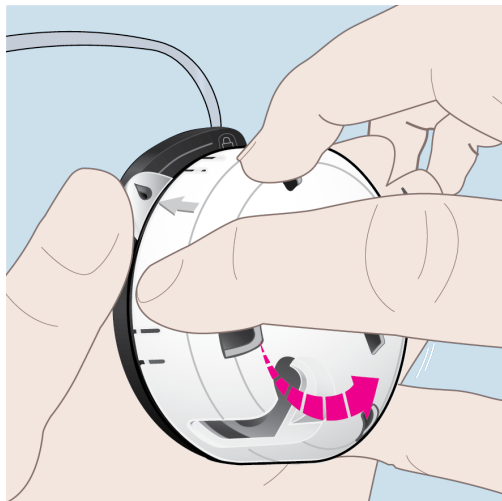
1. As soon as you see the first drops from the infusion set tubing, rotate the filling aid counterclockwise to end the priming.



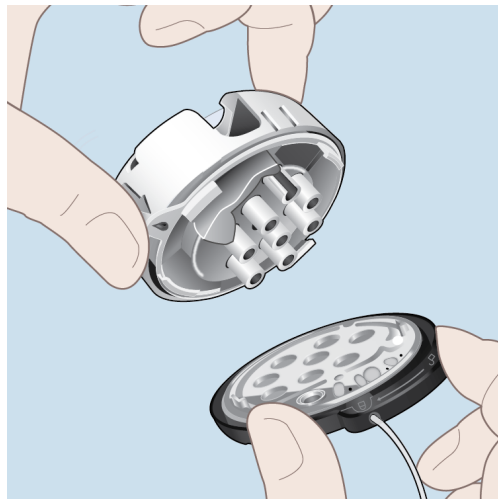


Do not press the filling aid and cassette together forcefully while rotating.

2. Rotate counterclockwise until the tab on the filling aid becomes aligned with the unlock  symbol on the cassette.

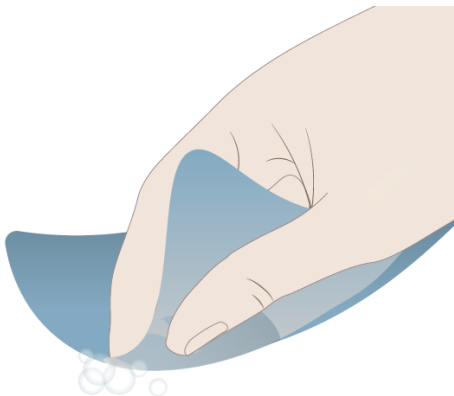


3. Detach the filling aid from the cassette.

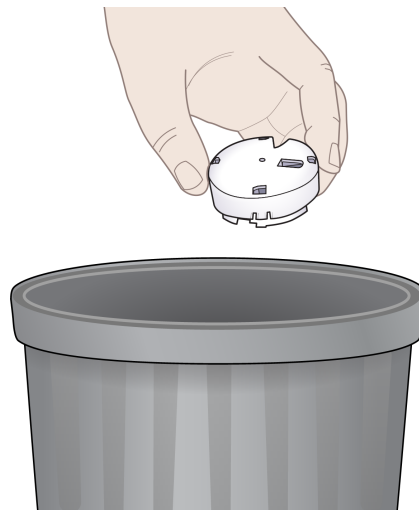


4. Place the cassette down on your workspace.

5. Wipe up any Remodulin medication residue with an absorbent towel or cloth and wash any areas that came in contact with Remodulin with soap and water.



6. Dispose of the filling aid.



Do not dispose of the newly primed cassette.


Connect Cassette to Pump

1. Before connecting the pump to the filled cassette, inspect the cassette and infusion set tubing to make sure there is no Remodulin present on any surfaces.




If there is Remodulin on the surfaces of the cassette or infusion set, replace the cassette and infusion set tubing.

2. Wipe up any medication residue with an absorbent towel or cloth and wash contacted areas with soap and water.
3. Also check to ensure the interfaces of the pump and cassette are free of dust, lint and debris.

4. Connect the filled cassette to the pump by aligning the *pump-bump* with the unlock  symbol on the cassette.



5. Push down and rotate the pump clockwise to the lock  symbol.



6. *Pump-bump* should align with the infusion set tubing.



The *Hours Remaining*, until cassette change, starts as soon as the cassette is attached to the pump.



If you have your remote, a *Self Test* is displayed.

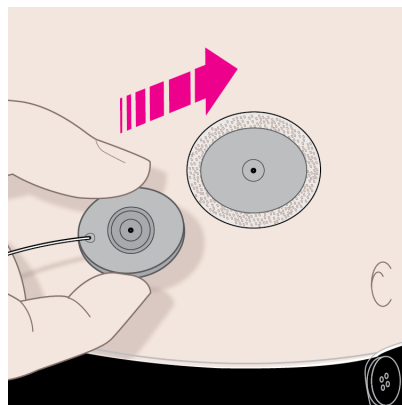


7. Listen for the *Busy* tones and one final *Ready* tone to indicate the *Self Test* has completed.



Do not connect the tubing to an installed catheter before the pump completes all self tests. Doing so may cause over delivery of medication resulting in harm.

Connect to Catheter




1. Connect the infusion set tubing from the pump to the catheter.
2. Consult with your specialty pharmacy and/or provider about how often you should change the catheter. Refer to your infusion set's instructions for steps on how to insert the infusion set's catheter into your body.

Start Delivery



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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

1. To start medication delivery, press and hold the **blue pump button**, or on your remote, press  to start delivery.



The pump will sound the *Delivering* tone and delivery will start.



If you completed the cassette change without your remote, when you reconnect with the remote, the remote will ask if you connected a new cassette. Select Yes to ensure the displayed *Hours Remaining* is accurate.

2. Confirm that the remote displays a green status bar indicating that the pump is delivering.
3. Check to make sure the displayed rate matches your prescribed rate.



User-Filled Cassette Change

The User-Filled *Cassette Change* is a step-by-step process for replacing the pump battery, the infusion set, and an empty cassette with a filled cassette.

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

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.



If instructed by your physician to change the delivery rate as part of the cassette change process, the delivery rate should be changed before selecting *Change Cassette*. See "[Select Change Cassette](#)" on page 90.



The delivery rate cannot be changed during a cassette change without the remote.

Wash Hands

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



Gather Supplies

The following supplies should be kept available to complete a user-filled *Cassette Change*.

Table 7: *Components for User-Filled Cassette Change*

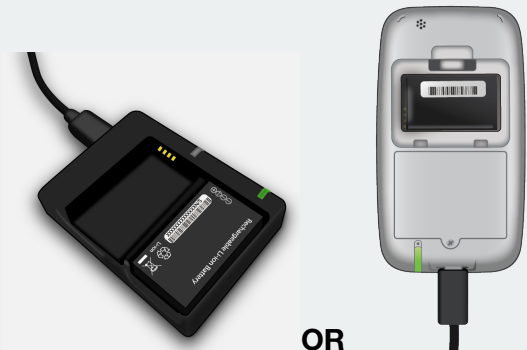


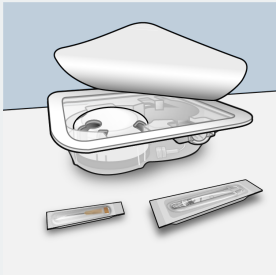


Fully Charged Pump Battery from the Battery Charger or Remote Battery Bay	Pump attached to the Used Cassette
 <p>OR</p>	

Table 8: Disposables for User-Filled Cassette Change

Remodulin	Non-expired User-Filled Cassette Package, Syringe and Needle	Infusion Sets
	 <p>Use only a sterile, single-use, 3 mL syringe and 25 or 26 gauge x 5/8 inch needle with luer lock connectors.</p>	<p>Use only approved infusion sets. <i>See "Approved Infusion Sets" on page 215.</i></p>  <div>  <p>Always refer to your specific infusion set instructions.</p> </div>

Select Change Cassette

If you do not have your remote, skip to "[Disconnect Infusion Site](#)" on page 92.




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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

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



Your delivery rate and the hours remaining on the cassette is displayed.



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


The *Main Menu* is displayed.



3. Press  to select *Change Cassette*.



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



4. Press  to stop medication delivery.

A *Sending request to the pump* message is displayed followed by a *Delivery Stopped* attention alarm.

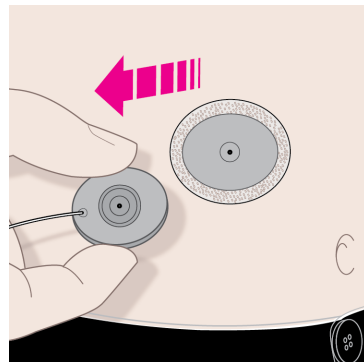


5. Press  to silence the attention alarm.
6. Press  to acknowledge the *Delivery Stopped* attention alarm.

Disconnect Infusion Site

1. Disconnect the infusion set tubing from the catheter.

Refer to the instructions provided by your infusion set's manufacturer for guidance.




You should consult with your specialty pharmacy about how often to change the catheter.

Disconnect Cassette from Pump and Dispose



To avoid unintended medication delivery, disconnect your infusion set tubing from your catheter before detaching the cassette from the pump.

1. Holding the cassette still, rotate the pump counterclockwise until the *pump-bump* is aligned with the unlock  symbol.



You should hear a *Ready* tone coming from the pump.

If you did not stop delivery with your remote, you should hear an *Alarm* tone coming from the pump.



2. Separate the pump from the cassette.



Avoid unnecessary contact with all parts on the interior of the pump exposed during the cassette changing process.

Keep dirt, lubricants and liquids away from all parts on the interior of the pump exposed during the cassette changing process.

3. Dispose of the used cassette and infusion set tubing and catheter (if removed).

Follow your infusion set's instructions:

- If you also plan to change your catheter and/or infusion site.
- For proper disposal of infusion set tubing and/or catheter.



Replace Pump Battery

Avoid unnecessary contact with all parts on the interior of the pump exposed during the battery changing process.

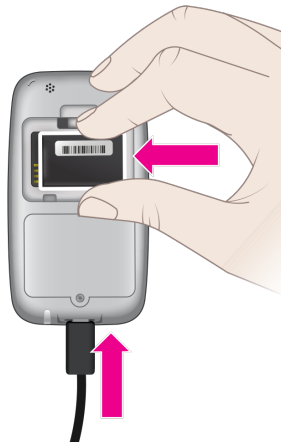
1. Turn the pump over and use the end of your finger to remove the battery from the pump.



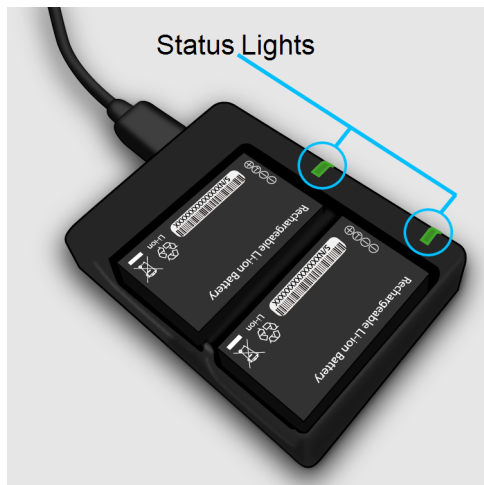
2. Insert the depleted pump battery into the battery charger or the remote battery bay.



3. If a pump battery is inserted into the remote battery bay, the battery will only charge while the remote is charging.



4. Obtain a fully charged pump battery from the battery charger or from the remote battery bay.



5. If you obtain a pump battery from the remote battery bay, make sure the spare pump battery charging light on the remote, when plugged into AC power, is green. This indicates the pump battery in the remote battery bay is fully charged.



6. Insert the fully charged pump battery into the pump making sure the contacts are aligned.



The pump will sound a *Ready* tone (one beep).

Keep dirt, lubricants and liquids away from all parts on the interior of the pump exposed during the battery changing process.

Prepare and Fill Cassette

You can use each cassette for up to 72 hours. Replace the cassette when medication runs out or after 72 hours, whichever comes first.



Do not pre-fill the cassette for future use. Pre-filling the cassette may result in a change of drug potency or reduce the purity of the Remodulin prior to use which can lead to harm.

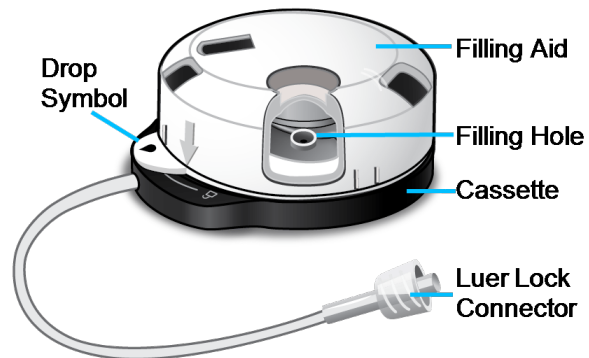
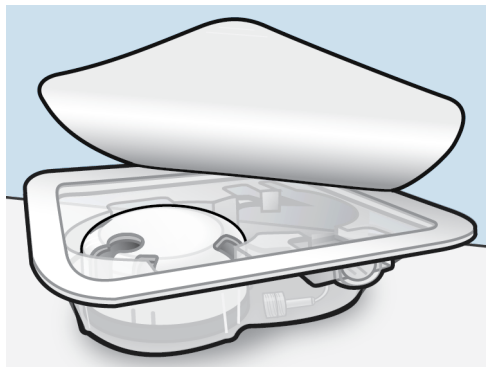


Do not use disposables from previously opened or damaged sterile packaging. Using such disposables may lead to infection and subsequent harm.

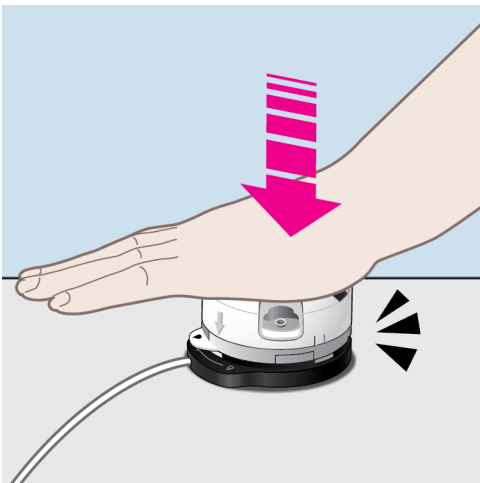


Do not attach the infusion set tubing to your inserted catheter until after you have prepared the new cassette and connected it to the pump. Connecting the infusion set tubing to the catheter before connecting the cassette to the pump may lead to unintended delivery.

1. Open the *user-filled cassette package* and remove the filling aid and empty cassette from the package and place the black side down on a flat surface.



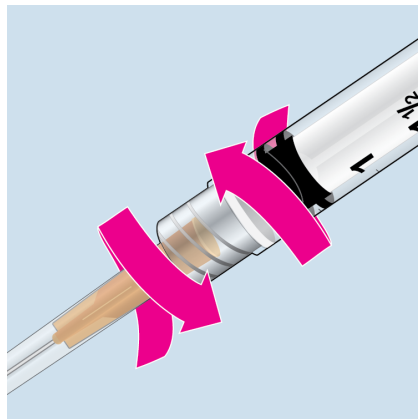
Note the important areas of the filling aid and cassette.



2. Firmly push down on the top of the filling aid with the palm of your hand until you hear a sound or series of sounds.
3. Prepare your injection by removing the syringe and the needle from its packaging.

Use only a sterile, single-use, 3 mL syringe and 25 or 26 gauge x 5/8 inch needle with *luer lock* connectors.

4. Insert the needle into the syringe *luer lock* connector and twist until finger tight.



5. Wipe the top of the Remodulin vial with an alcohol wipe.
6. Remove the cap from the needle.

7. Pull the syringe plunger out to the volume (mL) displayed on the remote.

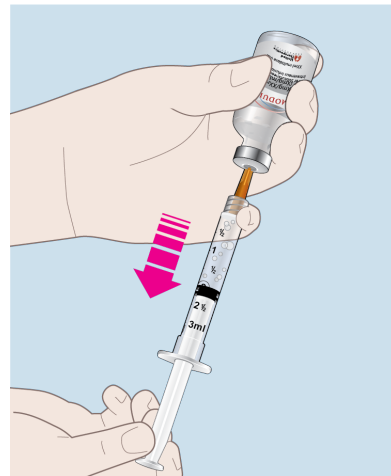


If you do not have your remote, Pull the syringe plunger out to 3 mL fill volume.

8. Insert the needle into the vial.
9. Push down on the syringe plunger to pressurize the vial.

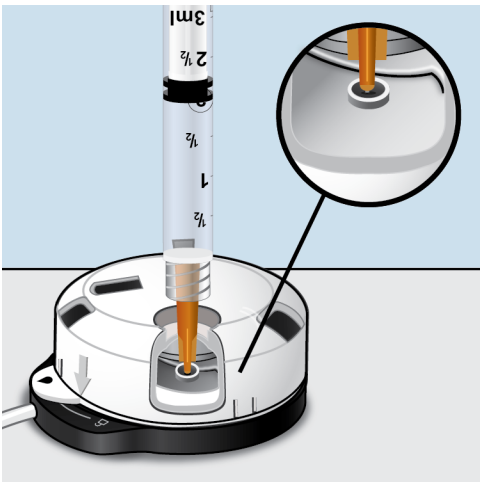
10. While still holding the syringe, flip the vial over so the vial is on top, slowly pull down on the plunger to fill the syringe with the amount of Remodulin (mL) displayed on the remote.

If you do not have your remote, fill the syringe with 3 mL of Remodulin.

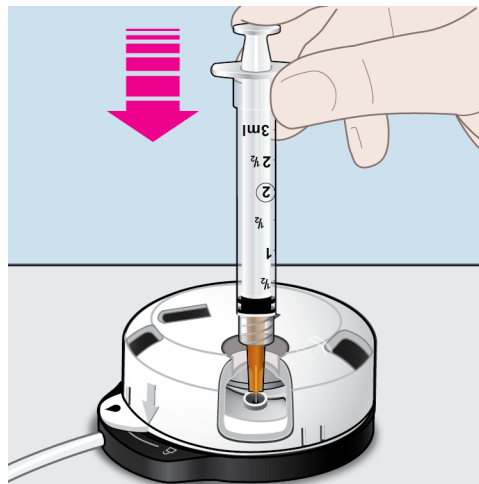


Follow the Remodulin manufacturer's instructions for use and handling.

11. With the needle facing up and held vertically, tap on the syringe to remove any air bubbles.
12. Remove the syringe from the vial.
13. Insert the syringe vertically into the hole in the filling aid and push down until you feel the needle insert into the cassette's rubber membrane.

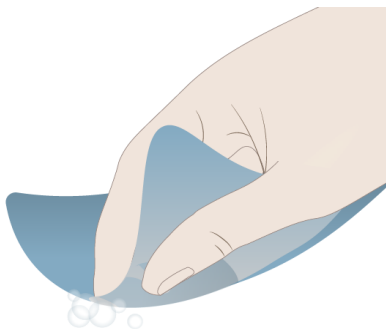


14. Push down on the syringe plunger to fill the cassette with Remodulin.



15. When the syringe is empty, continue to push down on the plunger while removing it from the filling aid.
16. Dispose of the used syringe and needle in a *Sharps* container.

Contact your local authorities to determine the proper method of disposing the syringe and needle. Improper disposal of these items may result in injury to the operator and others from exposure to sharp or contaminated components.



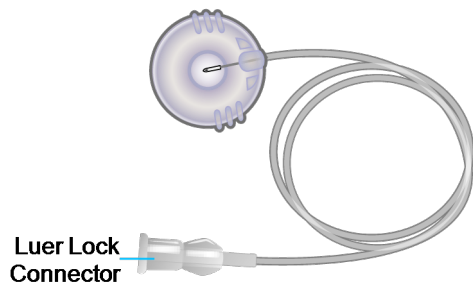
17. Wipe up any Remodulin medication residue with an absorbent towel or cloth and wash any areas that came in contact with Remodulin with soap and water.
18. Inspect the cassette to ensure there are no Remodulin drips coming from the cassette.

Connect and Prime Infusion Set

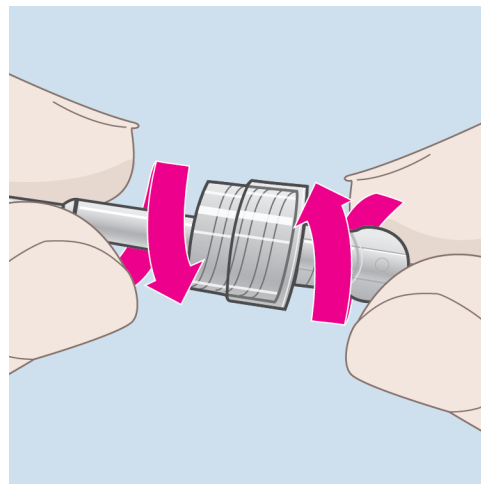
1. The infusion set tubing should be changed whenever you are performing a *cassette change*. Obtain a new infusion set package.




2. Open the infusion set package and remove the infusion set tubing.



3. Connect the infusion set to the cassette by twisting the *luer lock* connectors together.



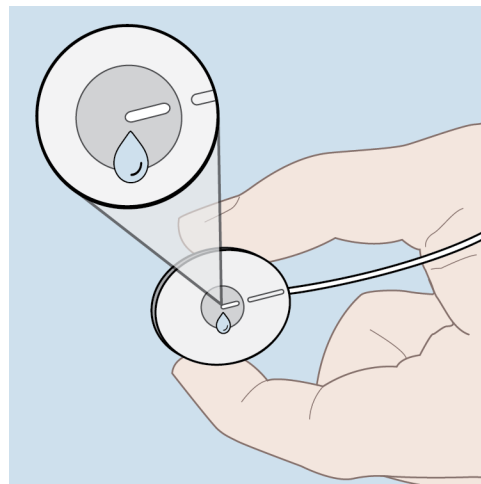
Do not attach the infusion set tubing to your inserted catheter until after you have prepared the new cassette and connected it to the pump. Connecting the infusion set tubing to the catheter before connecting the cassette to the pump may lead to unintended delivery.

4. Holding the cassette still, rotate the filling aid clockwise until you hear a sound or series of sounds and the arrow is aligned with the drop  symbol on the filling aid tab.



Do not press the filling aid and cassette together forcefully while rotating. For guidance, [see "Trouble rotating the cassette and filling aid" on page 196.](#)

5. Watch for medication drops to appear at the end of the infusion set.

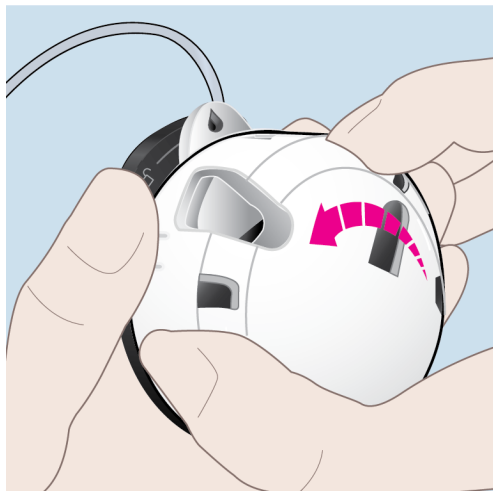


Seeing the medication drops indicates the infusion set and cassette are primed.


If the medication drops do not appear after one minute, [see "No fluid is visible at end of infusion set when priming" on page 199.](#)

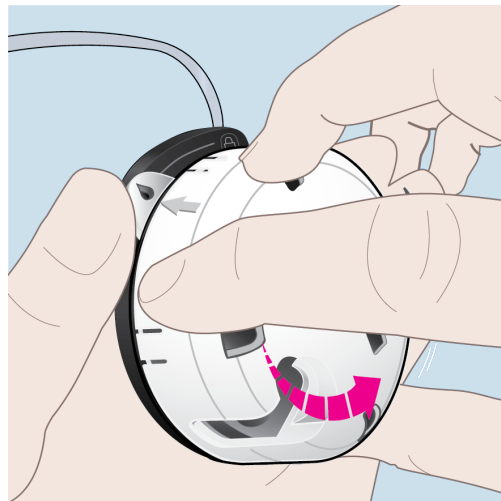
Stop Priming and Remove Filling Aid

1. As soon as you see the first drops from the infusion set tubing, rotate the filling aid counterclockwise to end the priming.

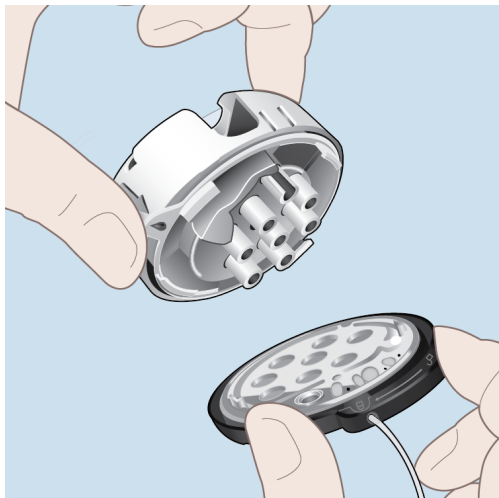


Do not press the filling aid and cassette together forcefully while rotating.

2. Rotate counterclockwise until the tab on the filling aid becomes aligned with the unlock  symbol on the cassette.

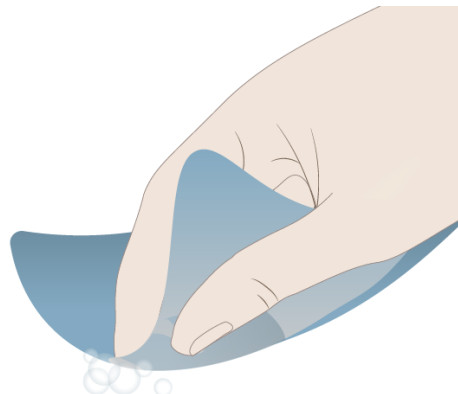


3. Detach the filling aid from the cassette.

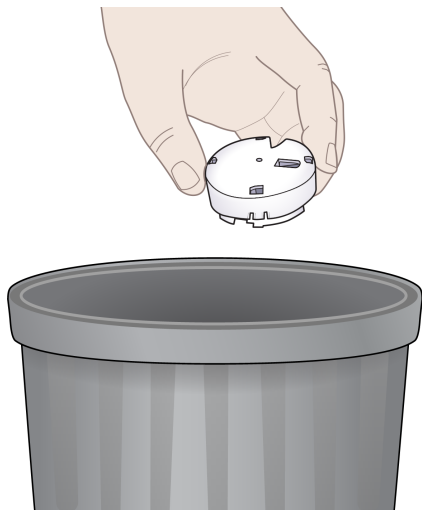


4. Place the cassette down on your workspace.

5. Wipe up any Remodulin medication residue with an absorbent towel or cloth and wash any areas that came in contact with Remodulin with soap and water.



6. Dispose of the filling aid.



Do not dispose of the newly primed cassette.


Connect Cassette to Pump

1. Before connecting the pump to the filled cassette, inspect the cassette and infusion set tubing to make sure there is no Remodulin present on any surfaces.




If there is Remodulin on the surfaces of the cassette or infusion set, replace the cassette and infusion set tubing.

2. Wipe up any medication residue with an absorbent towel or cloth and wash contacted areas with soap and water.
3. Also check to ensure the interfaces of the pump and cassette are free of dust, lint and debris.

4. Connect the filled cassette to the pump by aligning the *pump-bump* with the unlock  symbol on the cassette.



5. Push down and rotate the pump clockwise to the lock  symbol.



6. *Pump-bump* should align with the infusion set tubing.



The *Hours Remaining*, until cassette change, starts as soon as the cassette is attached to the pump.



If you have your remote, a *Self Test* is displayed.

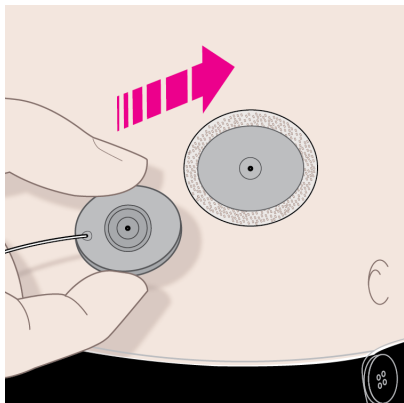


7. Listen for the *Busy* tones and one final *Ready* tone to indicate the *Self Test* has completed.



Do not connect the tubing to an installed catheter before the pump completes all self tests. Doing so may cause over delivery of medication resulting in harm.

Connect to Catheter




1. Connect the infusion set tubing from the pump to the catheter.
2. Consult with your specialty pharmacy and/or provider about how often you should change the catheter. Refer to your infusion set's instructions for steps on how to insert the infusion set's catheter into your body.

Start Delivery



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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

1. To start medication delivery, press and hold the **blue pump button**, or on your remote, press  to start delivery.



The pump will sound the *Delivering* tone and delivery will start.



If you completed the cassette change without your remote, when you reconnect with the remote, the remote will ask if you connected a new cassette. Select Yes to ensure the displayed *Hours Remaining* is accurate.

2. Confirm that the remote displays a green status bar indicating that the pump is delivering.
3. Check to make sure the displayed rate matches your prescribed rate.



Menu Functions

Contact your specialty pharmacy for assistance with any of the menu function instructions.

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Main Menu

The *Main Menu* provides access to the following features:


- Change Cassette
- Change Rate
- Stop/Start Delivery
- History
- Setup



1. Press the **side button** to display the remote's *Main Menu*.
2. Use the up and down arrows   to scroll through the list.
3. Press  to select the highlighted function.

Return to Previous Menu

During any navigation through the menu functions you can press the **side button** to return back to the previous menu screen.

Within any of the menus you can scroll down to *Return* and press .

Change Rate



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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

Use the remote to set or adjust the pump's delivery rate to match your prescribed dosage.

The remote needs to be paired and nearby the pump to change the rate.

The pump can deliver medication at rates from 16 μL (0.016 mL) to 225 μL (0.225 mL) per hour, in 1 μL (0.001 mL) increments.


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



Your delivery rate and the hours remaining on the cassette are displayed.





Press 1 2 3

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

The *Main Menu* is displayed.





3. Use the down arrow  to highlight *Change Rate*, then press .

The delivery rate is the amount of medication the pump will deliver per hour of use.



Programming the incorrect delivery rate of medication will lead to errors in the dose rate of medication that can lead to harm. Programming should be performed with the direction from your Healthcare Provider.






4. Use the up and down arrows   to change your prescribed rate.



Changing the delivery rate after a cassette change will affect the displayed *Hours Remaining*.

5. Press  to continue.



6. If the delivery rate is incorrect, press  to edit it or press  to cancel the rate change.
7. Press  to confirm the new rate.



After confirming the new delivery rate, the remote will display a *Sending request to the Pump...* message and you will hear the *Delivering* tone from the pump.

The *Estimated Depletion Time Updated To XX Hours Remaining* message is displayed.



8. Press  to return to the home screen.

The remote's home screen will appear displaying the new delivery rate and the *Hours Remaining* until the next cassette change.



The *Hours Remaining* until the next cassette change is an estimated time based on the fill volume of the cassette and the programmed delivery rate. If the delivery rate is changed after a cassette change, the displayed *Hours Remaining* may no longer be accurate.

Stop Delivery





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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

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



Your delivery rate and the hours remaining on the cassette is displayed.



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

The *Main Menu* is displayed.



3. Use the down arrow  to highlight *Stop Delivery*.



4. Press .

A *Stop Pump Delivery?* question is displayed.

5. Press  to stop medication delivery.

A *Sending request to the pump* message is displayed.



6. Press  to silence the attention alarm.
7. Press  to acknowledge the *Pump delivery has stopped* attention alarm.

Start Delivery



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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

When the pump has been stopped, the status bar changes to blue.

1. Press any **front button** to display the *main menu*.



2. Use the down arrow  to highlight *Start Delivery*.
3. Press .

A *Start Pump Delivery?* question is displayed with the last rate.



4. Press  to start medication delivery.

A *Sending request to the pump* message is displayed.

History Menu

The Remunity System stores various information about recent use of the system and is viewable anytime within the *Historical Menu*.

The system can store at least 1500 entries of the following events:

- Cassette Volume
- Delivery Start and Stopped
- Delivery Rate changes
- Alarms
- Attention Alarms
- Cassette changes
- Pump Battery changes
- Remote Powered On and Off
- Start and Finished Self Test
- The Pump delivery volume over the last 24 hours






When the logs have reached the maximum capacity, the oldest entries will be discarded.

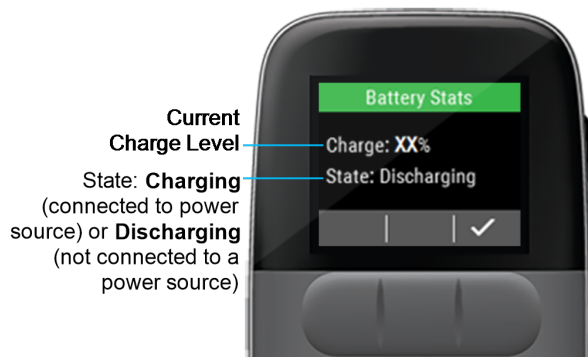
The logs are maintained when the system is powered down or loses power.


Remote Battery

The *Remote Battery* historical menu feature displays the remote's current battery charge level and charging state.

1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *History*.
4. Press .
5. The *Remote Battery* option will be highlighted, press .









6. Review the *Charge* and *State* of the remote battery and press  when finished.

Pump Cassette Info

The *Pump Cassette Info* displays the pump's remaining volume and the time until the pump is depleted.

1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *History*.
4. Press .




5. Use the down arrow  to highlight *Pump Cassette Info*.

6. Press .






The *Pump Remaining* data is displayed.



7. Review the estimated *Volume* of medication left in the cassette and the *Time* until the cassette is fully depleted.
8. Press  when finished.

Previous 24 Hours

The *Previous 24 Hours* displays the volume of medication delivered in the past 24 hours and the amount of time the pump was delivering in the last 24 hours.


1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *History*.
4. Press .
5. Use the down arrow  to highlight *Previous 24 Hours*.



6. Press .





The *Pump Last 24 Hours* data is displayed.




7. Review the *Volume* of medication delivered in the last 24 hours and the amount of *Time* the pump was delivering over the last 24 hours.
8. Press  when finished.

Event Viewer

The *Event Viewer* displays the following types of historical events along with how long ago the event occurred and any additional information:

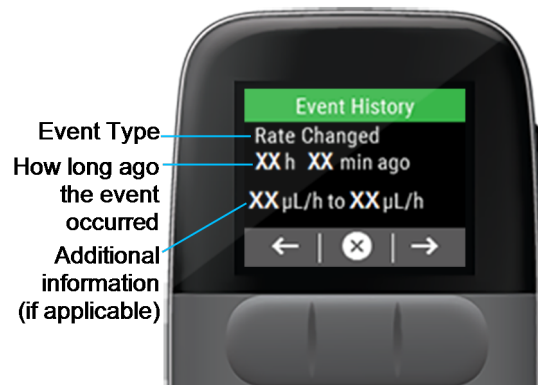
- Delivery Rate changes
 - Alarms and Attention Alarms
 - Cassette changes
 - Battery changes
 - Self Test start and finish events
 - Delivery start and stopped events
1. Press the **side button** to wake up the remote.
 2. Unlock   the screen by pressing each **front button** from left to right.
 3. Use the down arrow  to highlight *History*.
 4. Press .






5. Use the down arrow  to highlight *Event Viewer*.

6. Press .

The most recent *Event History* data is displayed.



7. Use the left and right arrows   to scroll through the list of events.

8. Press  to return to the *Historical Menu*.

Setup

The *Setup* menu is used to set your personal preferences related to the remote's settings and provides access to the following features:

- Paired Pump
- Walkaway attention alarm: ON/OFF
- Screen Timeout
- Remote Audio
- Passcode: ON/OFF
- Airplane Mode
- Factory Reset
- System Information



Paired Pump

The *Paired Pump* setting displays the pump serial number.

To view the currently paired pump serial number:

1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .
5. The *Paired Pump* menu should be highlighted, press .



The currently paired pump serial number is displayed.







6. Press  to return to the *Setup Menu*.

Pair to a Spare Pump



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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

If the pump you currently use becomes lost or damaged, you can switch to the spare pump and pair your remote to the spare pump.


1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .

The *Paired Pump* menu should be highlighted.

5. Press .

The currently paired pump serial number is displayed.



6. Press  to pair to a different pump.



The remote will display *Searching* as it locates the new pump serial number.

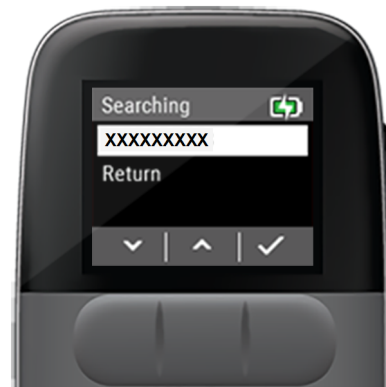





7. Place the pump and remote within 2 in (50 mm) of each other during the pairing process.
8. If your pump serial number does not show up on screen after a minute, press and hold the **blue pump button** for 10 seconds to activate pairing mode. This will be confirmed by a single *Ready* beep.




After a few seconds, the pump will generate a series of beeps. Keep holding down the button until you hear the single *Ready* beep.

9. Then, check the screen again for your pump serial number.



10. When the new pump serial number appears, use the   to highlight the new pump serial number and press .




11. Press  again to confirm pair.






A Pairing To... message is displayed.

If pairing fails, [see "Pairing Failed Attention Alarm" on page 174.](#)



12. Upon successful pairing, press  to confirm the *Paired Pump*.
- If this is the first time using a remote and pump, the remote will prompt you to set a delivery rate. Continue with [Step 13](#).
 - If you have previously used the pump or the remote, your current delivery rate is saved and you do not need to set it again. Skip to [Step 14](#).

13. Use   to set your prescribed rate, then press .

The remote displays a *Fill new cassette with X.X mL, prime, and install* message.

If you are using a pharmacy-filled cassette, you will not need to follow the steps to fill the cassette with the amount displayed on the remote.

14. Wash your hands, gather cassette change supplies, and follow the cassette change steps starting from "[Prepare Filling Aid](#)" on [page 74](#) for pharmacy-filled or "[Prepare and Fill Cassette](#)" on [page 98](#) for user-filled.

Pair to a Spare 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 3 ft (0.9 m) away from these items. [See Table 32 on page 229](#) and [See Table 34 on page 233](#) for more information.

If the remote you were using becomes lost or damaged, you can switch to the spare remote and pair your pump to the spare remote without interrupting delivery.



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

If this is the first time you are using the remote, it will search for a pump when you power on.



Press: **1** **2** **3**

2. Unlock the screen by pressing each **front button** from left to right to unlock the remote screen.



Once unlocked, screen will stay active for 2 minutes before the screen will timeout.






3. Place the pump and remote within 2 in (50 mm) of each other during the pairing process.
4. If your pump serial number does not show up on screen after a minute, press and hold the **blue pump button** for 10 seconds to activate pairing mode. This will be confirmed by a single *Ready* beep.




After a few seconds, the pump will generate a series of beeps. Keep holding down the button until you hear the single *Ready* beep.

- Then, check the screen again for your pump serial number.



- On the remote, use   to highlight the pump serial number and press .




- After selecting your pump serial number you will be prompted to confirm the selected pump. Press  to confirm.



A Pairing To... message is displayed.

If pairing fails, [see "Pairing Failed Attention Alarm" on page 174.](#)








8. Upon successful pairing the *Paired Pump* message is displayed. Press .





Walkaway Attention Alarm

To help you avoid forgetting your remote, setting this feature will let you know that you may have left your remote behind. The *Walkaway* attention alarm feature can be set to go off between 1 and 120 minutes.

Turn ON Walkaway attention alarm:

1. Press the **side button** to wake up the remote.
2. Unlock  >> the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .
5. Use the down arrow  to highlight *Walkaway Alarm:OFF*.
6. Press .



7. If needed, press the  to edit the *Walkaway* attention alarm minutes.
8. Use the up and down arrows   to select between 1 and 120 minutes.
9. Press  to accept your selection.



10. Press the **front button** under *ON* to turn on the *Walkaway* attention alarm feature.
11. Press to accept your selection.

A *Sending request to the pump* message is displayed.

Turn OFF Walkaway Attention Alarm:

1. Press the **side button** to wake up the remote.
2. Unlock the screen by pressing each **front button** from left to right.

3. Use the down arrow to highlight *Setup*.
4. Press .
5. Use the down arrow to highlight *Walkaway Alarm:ON*.
6. Press .

7. Press the **front button** under *OFF* to turn off the *Walkaway* attention alarm feature.






8. Press to accept your selection.



A *Sending request to the pump* message is displayed.



Screen Timeout

The *Screen Timeout* feature allows you to set the time before the remote's screen will sleep.

1. Press the **side button** to wake up the remote.
2. Unlock  the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .
5. Use the down arrow  to highlight *Screen Timeout*.
6. Press .

7. Use the up and down arrows   to select the time:

- One minute
- Two minutes
- Five minutes
- Ten minutes

8. Press  to accept your selection.

Any time the remote has not been used and the programmed *Screen Timeout* minutes have passed, you will need to press the **side button** to wake up the remote.






Remote Audio

The *Remote Audio* feature controls the feedback and volume options for the remote.

Feedback Options

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

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





3. Use the down arrow  to highlight *Setup*.

4. Press .




5. Use the down arrow  to highlight *Remote Audio*.

6. Press .





7. The *Feedback* option is already highlighted.
8. Press .
9. Press the up and down arrows   to select one of the three feedback options:
 - Audio and Vibration
 - Audio Only
 - Vibration Only
10. Press  to accept your selection.




Volume Options

1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .
5. Press the down arrow  to highlight *Remote Audio*.
6. Press .



7. Press the down arrow  to highlight the *Volume* option.
8. Press .







9. Press the up and down arrows   to select one of five volume levels.
10. Press  to accept your selection.



Change Rate Passcode

The *Change Rate Passcode* is *Off* by default. When turned *On* a passcode will be required to change the rate.

Turn ON Change Rate Passcode

1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .





5. Use the down arrow  to highlight *Passcode: OFF*.
6. Press .




7. Press the **front button** under *ON*.



8. Use the up and down arrows   to scroll through the first digit selection.






9. When you have the desired number press the right arrow .
10. Repeat [Step 8](#) and [Step 9](#) for the remaining three digits.
11. Confirm the passcode by repeating [Step 8](#) and [Step 9](#) to enter your new four digit passcode.






A message is displayed that the *Passcode is Enabled*.



12. Press  to return to the *Setup Menu*.

Turn OFF Change Rate Passcode


1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.

4. Press .
5. Use the down arrow  to highlight *Passcode: ON*.
6. Press .
7. Press the **front button** under *OFF*.



8. Use the up and down arrows   to enter the first digit of your current passcode.



9. When finished entering the number press the right arrow .
10. Repeat [Step 8](#) and [Step 9](#) for the remaining three digits.



A message is displayed that the *Passcode is Disabled*.





11. Press  to return to the *Setup Menu*.

Forgot My Change Rate Passcode

If you have forgotten your change rate passcode, you will need to follow the steps to factory reset your remote and pair to spare remote. See ["Factory Reset" on page 151](#).

Airplane Mode

If you are asked to turn off all electronic devices during a commercial flight, follow the steps to put the device into airplane mode.

1. Press the **side button** to wake up the remote.
2. Unlock  the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .
5. Use the down arrow  to highlight *Airplane Mode*.
6. Press .



7. Press  to enable airplane mode.

A *Sending request to the pump* message is displayed.



A Press and hold pump button to exit message is displayed.



The pump will continue to deliver medication even when the remote is in airplane mode.



When the use of electronics is cleared during a commercial flight you can exit airplane mode.

8. You will need to press and hold the **blue pump button** until after you hear the *Delivering* tone to exit airplane mode.








9. Verify the remote displays *Delivering* on the *Home* screen.



If an alarm occurs while the device is in airplane mode, the device will exit airplane mode in order to display the alarm condition.

Factory Reset

A *Factory Reset* should not be performed unless directed by your specialty pharmacist.

1. Press the **side button** to wake up the remote.
2. Unlock  >> the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .
5. Use the down arrow  to highlight *Factory Reset*.
6. Press .

You will need to select whether you want to reset the remote or the pump.

See "Remote Factory Reset" on the next page.

See "Pump Factory Reset" on page 153.

Remote Factory Reset



1. Press  to factory reset the remote.



A *Reset the Remote to defaults? Pump will be disconnected!* message is displayed.



2. Press  to confirm or  to cancel.

After confirmation, the *Remote will restart when complete* message is displayed.

The remote will display *Searching* until the pump is paired to the remote. [See "Pair to a Spare Remote" on page 135.](#)

Pump Factory Reset



1. Use the down arrow  to highlight *Pump*.
2. Press  to factory reset the pump.





A Delivery must be stopped before changing the cassette message is displayed.

3. Press  to confirm. Or  to cancel.

After confirmation, a Sending request to the pump message is displayed.



A *Delivery Stopped* attention alarm is displayed.

4. Press  to silence the attention alarm.
5. Press  to acknowledge the *Pump delivery has stopped* attention alarm.





A *Reset the Pump to defaults? Pump will be disconnected!* message is displayed.

6. Press  to confirm. Or  to cancel.

After confirmation, a *Sending request to the pump* message is displayed.










7. Press  to silence the attention alarm.
8. Press .







The remote will display *Searching* and the last connected pump serial number until the pump is paired to the remote. See "[Pair to a Spare Pump](#)" on page 130.

System Information

The *System Information* displays the *Remote*, *Radio*, *Command*, *Supervisor*, and *Pump Radio* software versions.

1. Press the **side button** to wake up the remote.
2. Unlock   the screen by pressing each **front button** from left to right.
3. Use the down arrow  to highlight *Setup*.
4. Press .
5. Use the down arrow  to highlight *System Information*.
6. Press .
7. Press  to view the software versions.

8. Use the up and down arrows   to scroll through the software versions and press  to view more information about the selected software.
9. Press  to return back to the *Software Versions* list.

Return

The *Return* selection is used to go back to the previous menu. You can also press the **side button** on the remote to return to the previous menu.

Alarms and Attention Alarms

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About Alarms and Attention Alarms

Alarms and *Attention Alarms* appear on your remote to inform you of problems you need to address.

Alarm names flash red and white in the status bar. Alarms are urgent, stop delivery, and should be addressed right away.

Attention alarm names flash yellow and black in the status bar. Attention alarms do not interrupt delivery and should be addressed as soon as possible.

If an alarm or attention alarm is not silenced within 5 minutes the system will maximize the alarm audio volume on the pump and remote. The remote will vibrate regardless of the *Remote Audio* setting.

The pump audio may be delayed for up to 10 minutes at the beginning of delivery and occasionally during therapy.



Always check the system for alarms and attention alarms when you are in an environment where you cannot hear or feel the remote or hear the pump.






If the remote is not in communication with the pump, alarms and attention alarms may not appear on the remote. The pump will still sound alarm and attention alarm tones. In order to ensure alarms and attention alarms are displayed on the remote, it should be kept within 3 ft (1 m) of the pump, preferably on the same side of your body.

Battery Depleted Alarm

When the pump battery is too low for the pump to deliver medication, a *Battery Depleted* alarm is displayed.

The status bar will flash and an alarm tone will sound.




1. Press  to silence the alarm.
2. Disconnect the infusion set tubing from your catheter.
3. Press  to acknowledge the alarm.
4. Press  to acknowledge the *Delivery Stopped* attention alarm.
5. Change the cassette and pump battery. See ["Cassette Change" on page 61.](#)



Cassette Depleted Alarm

When your cassette needs to be changed, a *Cassette Depleted* alarm is displayed.

The status bar will flash and an alarm tone will sound.

1. Press  to silence the alarm.
2. Disconnect infusion set tubing from catheter.
3. Press  to acknowledge the alarm.
4. Press  to acknowledge the *Delivery Stopped* attention alarm.
5. Change the cassette and pump battery. See ["Cassette Change" on page 61.](#)




Cassette Removed Alarm




When the pump detects that the cassette is removed without being commanded to stop delivery, a *Cassette Removed* alarm is displayed.

The status bar will flash and an alarm tone will sound.




Do not remove the pump from the used cassette until after you have disconnected the infusion set tubing from your body. Disconnecting the pump before you disconnect the infusion set tubing from your body could lead to unintended medication delivery.

1. Press  to silence the alarm.

2. Disconnect infusion set tubing from catheter.
3. Press  to acknowledge the alarm.
4. Press  to acknowledge the *Delivery Stopped* attention alarm.
5. Ensure the pump and cassette are fully disconnected.
6. Remove and reinsert the pump battery into the pump.
7. Listen for the confirmation beep on the pump.
8. Disregard the *Fill new cassette with X.X mL, prime, and install* message if you want to use your existing cassette.
 - a. Reconnect the pump to the used cassette.
 - b. Wait for the *Self Test* to complete.
 - c. Reattach the infusion set tubing to the catheter and **press and hold the blue pump button** or the  on the remote to restart delivery.






9. Select **No** to the *New Cassette?* question, then press  to start delivery.

Cassette Problem Alarm

When your cassette is broken, a *Cassette Problem* alarm is displayed.

The status bar will flash and an alarm tone will sound.



1. Press  to silence the alarm.
2. Disconnect infusion set tubing from catheter.
3. Press  to acknowledge the alarm.
4. Press  to acknowledge the *Delivery Stopped* attention alarm.
5. Change the cassette and pump battery. [See "Cassette Change" on page 61.](#)

6. If the *Cassette Problem* alarm reoccurs with a new cassette, disconnect the new cassette from the pump, switch to your spare pump, and contact your Specialty Pharmacy.

Occlusion Alarm

An *Occlusion* alarm occurs when the tubing or catheter is blocked or partially blocked from delivering your medication.


It is very important to fix an occlusion so that you do not suffer the effects of an under-dose.





The status bar will flash and an alarm tone will sound.



Do not leave the cassette and infusion set connected to an installed catheter when responding to an Occlusion Alarm. Leaving the infusion set connected during alarm resolution can lead to the unintended delivery of medication, which can lead to harm.


1. Press  to silence the alarm.
2. Disconnect infusion set tubing from catheter and check the infusion set tubing for kinks.




3. Press  to acknowledge the alarm.
4. Press  to acknowledge the *Delivery Stopped* attention alarm.
5. Disconnect the cassette from the pump.
6. If you found a kink in the infusion set tubing and corrected it you can reuse the infusion set tubing and cassette. Follow [Step a](#) through [Step h](#), otherwise skip to [Step 7](#):

- a. Disregard the message on the remote telling you to fill a new cassette with medication, prime and install. You will not need to do that since the *Occlusion* was a kink.
- b. Remove and reinsert the pump battery into the pump. You may receive a low battery attention alarm.
- c. Listen for the *Ready* beep on the pump.
- d. Reconnect the pump to the used cassette.
- e. Wait for the *Self Test* to complete.
- f. Select **No** when the *New Cassette?* question appears.



- g. Reattach the infusion set tubing to the catheter and **press and hold the blue pump button** or the  on the remote to restart delivery.
 - h. Route the infusion set tubing to avoid any sources of kinks that might have introduced the occlusion that triggered the alarm.
7. If you did not find a kink in the infusion set tubing you will need to replace the infusion set tubing as well as the cassette.
 8. Dispose of the used cassette and infusion set tubing.
 9. Obtain a new cassette package and a fully charged pump battery, then perform a cassette change. [See "Cassette Change" on page 61.](#)

10. Use the down arrow to highlight **Yes** and press  to start delivery.






11. Route the infusion set tubing to avoid any sources of kinks that might have introduced the occlusion that triggered the alarm.




Pump Error Alarm

When the pump encounters an error, a *Pump Error* alarm is displayed.

The status bar will flash and an alarm tone will sound.



1. Press  to silence the alarm.
2. Disconnect infusion set tubing from catheter.
3. Press  to acknowledge the alarm.
4. Press  to acknowledge the *Delivery Stopped* attention alarm.
5. Disconnect the cassette from the pump.
6. Remove and reinsert the pump battery into the pump.

7. Listen for the confirmation beep on the pump.
8. Disregard the *Fill new cassette with X.X mL, prime, and install* message if you want to use your existing cassette.
 - a. Reconnect the pump to the used cassette.
 - b. Wait for the *Self Test* to complete.
9. Reattach the infusion set tubing to the catheter and press and hold the blue **pump** button or select the  on the remote to restart delivery.
10. Press  to select **No** to the *New Cassette?* question.
11. Press  to start delivery.
12. If the *Pump Error* alarm occurs again, switch to your spare pump.






Pump Failure Alarm

When the pump is broken, a *Pump Failure* alarm is displayed. You will need to switch to your spare pump and may need to request a replacement from your specialty pharmacy.





The status bar will flash and an alarm tone will sound.

1. Press  to silence the alarm.
2. Disconnect infusion set tubing from catheter.
3. Press  to acknowledge the alarm.
4. Press  to acknowledge the *Delivery Stopped* attention alarm.

5. Disconnect the pump from cassette.
6. Remove the battery from the pump.
7. Gather your spare pump and insert the pump battery.
8. Listen for the confirmation beep on the pump.
9. Follow steps to *Pair* your spare pump with the remote, reconnect to the cassette, and start delivery. See ["Pair to a Spare Pump" on page 130.](#)
10. If the spare pump resolves the alarm, contact your specialty pharmacy to obtain a replacement pump for the one that failed.

Basal Not Started Attention Alarm



A *Basal Not Started* attention alarm is displayed if any of the following situations occur:

- You press and hold the pump button to start delivery when all cassette change steps have not been completed.
 - When you have put the pump into pairing mode by holding down the pump button for 10 seconds.
- Press  to silence the attention alarm.
 - Press  to acknowledge the attention alarm.



Adjust Pump Attention Alarm

When the pump is having difficulty delivering your dose an *Adjust Pump* attention alarm is displayed.

- Press  to silence the attention alarm.
- Press  to acknowledge the attention alarm.
- Move the pump closer to your infusion site.



Use only infusion sets listed within this user guide.

Delivery Stopped Attention Alarm



The *Delivery Stopped* attention alarm is displayed to ensure you are aware and reminded that delivery has been stopped.

This attention alarm occurs after every alarm and in response to the patient stopping the pump, such as during the *Cassette Change* process.

Make sure to refer to the appropriate alarm, attention alarm, or cassette change steps to resolve the delivery stopped attention alarm.





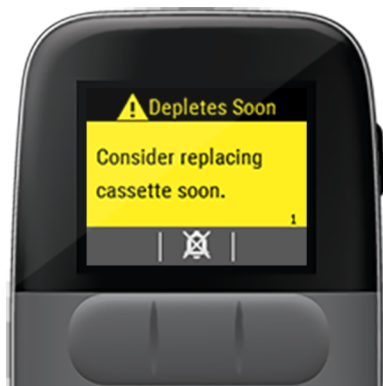
If a delivery stopped attention alarm appears outside of an alarm, attention alarm, or cassette change condition, follow these steps to restart delivery.

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 *Delivering* tone to restart delivery.
4. If the pump sounds the attention alarm, [see "The pump sounds an attention alarm tone when the pump button is pressed" on page 200.](#)

Depletes Soon Attention Alarm



When the cassette will be depleted within 2 hours, a *Depletes Soon* attention alarm is displayed.

1. Press  to silence the attention alarm.
2. Press  to acknowledge the attention alarm.
3. Prepare supplies needed for a cassette change.



Excessive Noise Attention Alarm

When your surrounding environment is excessively noisy, an *Excessive Noise* attention alarm is displayed to alert you that delivery may be impacted.

1. Press  to silence the attention alarm.
2. Press  to acknowledge the attention alarm.
3. To avoid the attention alarm from reappearing, move to a quieter area.




Message Timeout Attention Alarm


When your remote did not receive a response to the last setting change command it sent to the pump, a *Message Timeout* attention alarm is displayed. 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. Place the pump and remote within 12 inches (30 cm) of each other until communication is restored. This is indicated when the home screen's top banner is green or blue.
4. Reconfirm the last setting change to instruct the remote to send the setting change command to the pump again.
5. If this attention alarm is displayed again, move 3 ft (0.9 m) away from cell phones, Bluetooth devices, RFID readers, and Wi-Fi equipment and repeat [Step 1](#) through [Step 4](#).


No Communication Attention Alarm


When the pump and remote have not communicated with each other for 10 hours, a *No Communication* attention alarm is displayed with a *Verify pump is delivering* message. 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. Press and hold the **blue pump button** until you hear the *Delivering* tone:
 - a. If the pump makes the *Delivering* tone, place the pump and remote within 12 inches (30 cm) of each other until communication is restored. The top of the remote home screen should change to green.
 - b. If communication cannot be restored, move at least 3 ft (0.9 m) from cell phones, Bluetooth devices, RFID readers, and Wi-Fi equipment to restore communication.
 - c. If the pump does not make the *Delivering* tone, change the cassette and pump battery. See "[Cassette Change](#)" on page 61.

4. If communication cannot be restored between the pump and remote, gather your spare pump and:
 - a. Pair spare pump with remote and start delivery. *See "Pair to a Spare Pump" on page 130.*
 - b. Contact your specialty pharmacy to obtain a replacement pump.


Pairing Failed Attention Alarm

When the pump and remote were not able to complete the pairing process, the *Pairing Failed* attention alarm is displayed. 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 3 ft (0.9 m) 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 inches (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 130.](#)
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 is displayed.





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 *Delivering* tone.
4. If the pump does not generate the *Delivering* tone:
 - 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 *Ready* 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 *Delivering* tone, 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 is displayed.

1. Press  to silence the attention alarm.
2. Press  to acknowledge the attention alarm.

If the attention alarm occurs when inserting a pump battery:

1. Make sure you have inserted a fully charged pump battery.



If the attention alarm occurs with less than 8 hours remaining on the cassette:

1. Replace the pump battery at the next cassette change. See *"Cassette Change"* on page 61.

If the attention alarm occurs with more than 8 hours remaining on the cassette:



1. The pump battery should be replaced and delivery restarted with the same cassette. See *"How do I change my battery without changing to a new cassette?"* on page 210.



Remote Battery Low Attention Alarm

When the remote needs to be charged, a *Remote Battery Low* attention alarm is displayed 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.



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

Request Refused Attention Alarm

When the remote sends a command to the pump and an error occurs, a *Request Refused* attention alarm is displayed.





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 130.](#)
5. Contact your specialty pharmacy to obtain a replacement pump.




Tech Attention Alarm

When the remote has encountered an error, the *Tech Att. Alarm* is displayed 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 is displayed 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 .

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 3 ft (0.9 m) or more from cell phones, Bluetooth devices, RFID readers, and Wi-Fi equipment to maintain communication.

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Maintenance and Troubleshooting

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

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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 connection to the pump battery when charging, 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 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 with an alcohol wipe, to keep it free of dust, lint, dirt, and other debris or liquids.

- When cleaning do not submerge in water.
 - Do not place the remote in the dishwasher to clean.
1. Gently wipe all surfaces of the remote with an alcohol wipe and allow time to dry.

Troubleshooting Battery Charger

Table 9: Battery Charger status light(s) do not turn on


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

Table 9: Battery Charger status light(s) do not turn on


Problem	Possible Causes	Corrective Actions
	<p>One or more components is defective:</p> <ul style="list-style-type: none">• USB Cable• AC Adapter• Battery Charger• Battery	<p>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.</p> <p>If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.</p>

Table 10: *Battery Charger status light(s) turn red when a pump battery is installed*

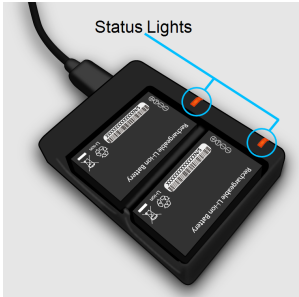
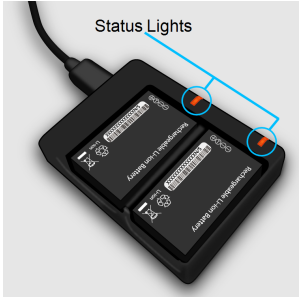
Problem	Possible Causes	Corrective Actions
<p>Battery Charger status light turns red when a pump battery is installed.</p> 	<p>Pump Battery is too hot or too cold.</p>	<p>Make sure the temperature of the battery, or location where you charge the battery, is between 59 °F (15 °C) and 95 °F (35 °C). Charging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

Table 10: Battery Charger status light(s) turn red when a pump battery is installed

Problem	Possible Causes	Corrective Actions
 <p>Status Lights</p>	<p>Pump Battery and/or Battery Charger contacts are covered with dirt or dust.</p> <p>One or more components is defective:</p> <ul style="list-style-type: none"> • Battery Charger • Pump Battery 	<p>Disconnect from power source. Then, use a dry cloth or soft bristle brush to clean the contacts.</p> <p>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.</p> <p>If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.</p>

Troubleshooting Remote

Table 11: Remote does not turn on


Problem	Possible Causes	Corrective Actions
<p>Remote does not turn on.</p> 	<p>Remote has timed out or powered off.</p>	<p>Press the remote's side button to <i>wake up</i> the remote.</p> <p>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).</p>

Table 11: 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.	<p>Use the spare remote provided in the starter kit.</p> <p>Contact your specialty pharmacy for a replacement remote.</p>
	<p>One or more components is defective:</p> <ul style="list-style-type: none"> • USB Cable • AC Adapter • Remote 	<p>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.</p> <p>If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.</p>

Table 12: Pump battery does not charge in remote battery bay


Problem	Possible Causes	Corrective Actions
<p>Pump battery does not charge in the remote battery bay when plugged in (the spare pump battery status light does not turn on).</p> 	Remote is not plugged in to a power source.	<ol style="list-style-type: none"> 1. Make sure AC Adapter and USB Cable are plugged into the remote and connected to a power source (e.g., wall outlet). 2. Power on the remote.
	Pump Battery and/or Battery Charger contacts are covered with dirt or dust.	<p>Disconnect from power source. Remove the pump battery from the remote battery bay.</p> <p>Then, use a dry cloth or soft bristle brush to clean the contacts.</p>

Table 12: Pump battery does not charge in remote battery bay


Problem	Possible Causes	Corrective Actions
	<p>One or more components is defective:</p> <ul style="list-style-type: none">• USB Cable• AC Adapter• Remote• Pump Battery (if in the remote battery bay)	<p>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.</p> <p>If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.</p>

Table 13: Spare pump battery status light turns red when a Pump Battery is installed



Problem	Possible Causes	Corrective Actions
<p>Spare pump battery status light turns red when a pump battery is installed.</p> 	<p>Pump battery is too hot or too cold.</p>	<p>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.</p>
	<p>Pump battery and/or remote contacts are covered with dirt or dust.</p>	<p>Disconnect from power source. Remove the pump battery from the remote battery bay. Then, use a dry cloth or soft bristle brush to clean the contacts.</p>

Table 13: Spare pump battery status light turns red when a Pump Battery is installed

Problem	Possible Causes	Corrective Actions
 <p>The image shows a grey medical device with a black display screen at the top. Below the screen is a rectangular battery bay. At the bottom of the device, there is a red status light, which is circled in blue. A black cable is plugged into the bottom of the device.</p>	<p>One or more components is defective:</p> <ul style="list-style-type: none"> • Remote • Pump Battery (if in the remote battery bay) 	<p>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.</p> <p>If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.</p>

Troubleshooting Cassette

Table 14: Trouble rotating the cassette and filling aid

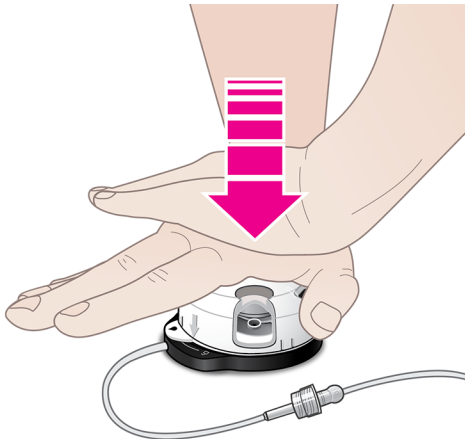
Problem	Possible Causes	Corrective Actions
Trouble rotating the filling aid arrow toward the drop symbol.	You may not have pressed down hard enough on the filling aid.	<ol style="list-style-type: none"> 1. Place the filling aid and cassette on a flat surface with the tubing pointing away from you. 2. While in a standing position, place the palm of one hand on top of the filling aid and then stack your other hand on top. 3. With straight arms, push down on the filling aid until you hear a sound or series of sounds. As this occurs, you may feel the filling aid press against the cassette. 

Table 14: Trouble rotating the cassette and filling aid

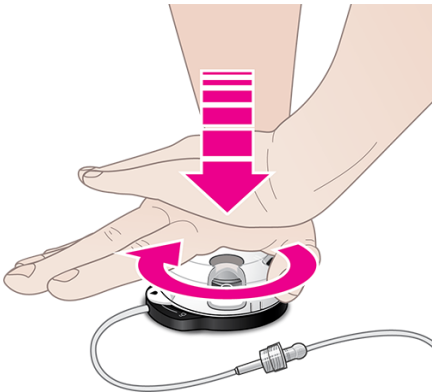
Problem	Possible Causes	Corrective Actions
Trouble rotating the filling aid arrow toward the drop symbol. (cont)	You may not have pressed down hard enough on the filling aid. (cont)	<p>4. Continue to apply pressure and <u>roll</u> the palm of your hand <u>clockwise</u> around the entire top of the filling aid 3 times.</p>  <p>If you are still having difficulty, Step 4 can be repeated.</p>

Table 15: Cannot connect cassette to infusion set tubing

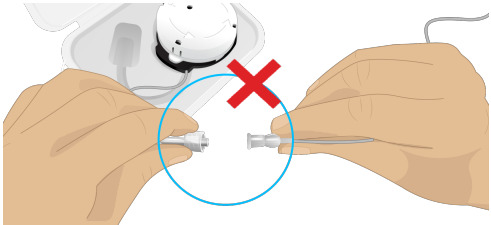
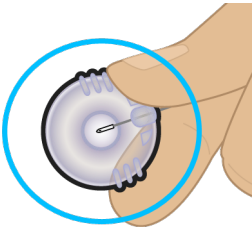
Problem	Possible Causes	Corrective Actions
<p>Cannot connect cassette to infusion set tubing.</p> 	Damaged connector on cassette or infusion set.	<p>If connector on cassette is damaged, discard and obtain a new cassette.</p> <p>If connector on infusion set is damaged, discard and obtain a new infusion set.</p>
	The infusion set is not approved for use with the cassette.	<p>Verify you are using an approved infusion set with the cassette. See "Approved Infusion Sets" on page 215.</p>

Table 16: No fluid is visible at end of infusion set when priming

Problem	Possible Causes	Corrective Actions
<p>No fluid is visible at end of infusion set when priming.</p> 	Filling Aid is not fully rotated.	Fully rotate the arrow on the filling aid to the lock symbol on the cassette to begin priming.
	Tubing is occluded	<ol style="list-style-type: none"> 1. Inspect tubing and straighten any kinked tubing. 2. Obtain a new cassette and infusion set.
	Unknown cause	<ol style="list-style-type: none"> 1. Obtain a new cassette package and restart the cassette change. See "Cassette Change" on page 61. 2. Contact your Specialty Pharmacy.
	Cassette not filled	If a user-filled cassette, follow instructions to fill the cassette.

Troubleshooting Pump

Table 17: The pump sounds an attention alarm tone when the pump button is pressed







Problem	Possible Causes	Corrective Actions
<p>The pump sounds an attention alarm tone when the pump button is pressed.</p> 	<p>All cassette change steps have not been completed, including replacing the battery and/or attaching the cassette.</p>	<ol style="list-style-type: none"> 1. Look on your remote, the <i>Basal Not Started</i> attention alarm is displayed. 2. Press  and . 3. Follow the steps displayed on the remote to complete the cassette change. See "Cassette Change" on page 61. 4. Press  to start delivery again.
	<p>Pump is being placed into pairing mode using the pump button.</p>	<p>After pairing, a <i>Basal Not Started</i> attention alarm is displayed.</p> <p>Press  and .</p>

Table 18: Self test does not start


Problem	Possible Causes	Corrective Actions
<p>Self test does not start.</p> 	<p>Pump is not properly attached to cassette.</p>	<p>Remove and reinsert the pump battery and make sure the pump is properly attached to the cassette.</p>
	<p>Remote is not paired to the correct pump.</p>	<p>In the remote's <i>Setup</i> menu, pair the remote to the pump you are currently using. See "Pair to a Spare Pump" on page 130.</p>

Table 19: Pump sounds an attention alarm tone when the pump battery is installed

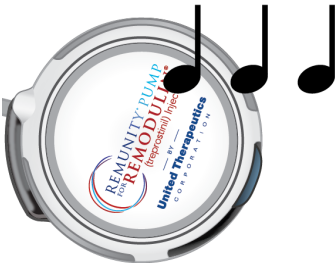
Problem	Possible Causes	Corrective Actions
<p>Pump sounds an attention alarm tone when the pump battery is installed.</p> 	<p>Pump battery is not fully charged.</p> <p>Battery is not seated properly.</p>	<p>Install a fully charged pump battery.</p> <p>Try removing and reinstalling the battery in the back of the pump.</p>

Table 20: Pump sounds an alarm tone when the pump battery is installed



Problem	Possible Causes	Corrective Actions
<p>Pump sounds an alarm tone when the pump battery is installed.</p> 	<p>Pump is broken.</p>	<p>Use the replacement pump provided in the starter kit.</p> <p>Contact your specialty pharmacy for a replacement pump.</p>

Table 21: Pump doesn't make a sound when pump battery is installed

Problem	Possible Causes	Corrective Actions
<p>Pump doesn't make a sound when pump battery is installed.</p> 	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.

Frequently Asked Questions (FAQ)

Below are the answers to some frequently asked questions.

Table 22: FAQ

FAQ	What To Do
How often must I change the pump battery? What about the remote battery?	The <i>Home</i> screen on the remote displays how much battery life remains in the pump and remote. You must insert a fully charged pump battery at least <u>every 3 days</u> . You must charge the remote <u>every day</u> .
What should I do with the extra length of 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.

Table 22: FAQ

FAQ	What To Do
<p>I have to travel, what should I bring with me to ensure I keep receiving my medication?</p>	<p>Keep these items available so that you can change a depleted cassette whenever needed and keep receiving your medication:</p> <ul style="list-style-type: none"> • Spare Pump and fully charged spare remote • Extra non-expired 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 preferred Infusion Set. See "Approved Infusion Sets" on page 215. • If using a user-filled cassette: include syringe, needle, and non-expired Remodulin.
<p>I have to have an MRI procedure, can I wear my pump?</p>	<p>No. The pump and remote are both MR unsafe and should not be brought into an MRI.</p> <p>The system is MR Unsafe. Disconnect the pump before entering an MRI scan room. Do not bring the remote or pump into an MRI scan room. Contact with, or being in proximity to, an MRI scanner can cause the pump and remote to move or lead to electric shocks and may result in severe injury.</p>

Table 22: FAQ

FAQ	What To Do
Can I get my pump wet?	<p>The pump can tolerate immersion in fluid to depths of up to 8 ft (2.4 m) for 30 minutes, and up to 12 feet (3.7 m) for 3 minutes.</p> <p>The Remote, Battery Charger, and AC Adapter are NOT waterproof and should be kept clean and dry.</p> <p>For additional information about water exposure to the infusion site, contact your healthcare provider.</p>
What should I do if I travel on an aircraft?	<p>If requested to turn off all electronic devices during commercial flight, follow instructions to put the pump in <i>Airplane Mode</i>. See "Airplane Mode" on page 149.</p> <p>Once the use of electronics is cleared, to exit airplane mode, press the blue pump button until after you hear the <i>Delivering</i> tone.</p>
My remote is powered off. Does that mean I am not receiving my medication?	<p>The pump will continue to deliver medication even when the remote is powered off.</p>

Table 22: FAQ

FAQ	What To Do
What should I do when an Alarm or Attention Alarm appears on my remote?	<p>If the remote displays an alarm or attention alarm, refer to the section on "Alarms and Attention Alarms" on page 157.</p> <p>Turn to the specific page within that section referencing the resolution to the alarm or attention alarm you see on the remote screen.</p>
How do I stop medication delivery without my remote?	Disconnect the infusion set tubing from the infusion site.
Why won't my remote power on?	<ol style="list-style-type: none"> 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 <i>On</i> the remote. 3. If the remote is broken, call technical support for troubleshooting and a possible replacement.

Table 22: FAQ

FAQ	What To Do
Why won't my pump pair with the remote?	<ol style="list-style-type: none">1. Make sure the pump is not attached to the cassette.2. Make sure to press and hold the blue pump button for <u>10 seconds</u> 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.

Table 22: FAQ

FAQ	What To Do
How do I change my battery without changing to a new cassette?	<p>Ideally the pump battery change should coincide with the cassette change. To change the battery without changing the cassette, follow these steps:</p> <ol style="list-style-type: none"> 1. Stop delivery on the remote. 2. Disconnect from the infusion site. 3. Dismiss the <i>Delivery Stopped</i> attention alarm. 4. Remove the cassette. 5. Remove the pump battery and place into a charger. 6. Insert a fully charged pump battery. 7. Reattach the cassette and wait for self-test to complete. 8. When prompted, select No on the <i>New Cassette?</i> screen. 9. Reconnect to the infusion site. 10. Start medication delivery.

Table 22: FAQ

FAQ	What To Do
<p>What should I do when I don't have access to my remote?</p>	<ol style="list-style-type: none"> 1. When the pump and remote are not in communication or the remote is <i>OFF</i>, the following functionality is still available: <ul style="list-style-type: none"> • A <i>Cassette Change</i> can still be performed. • The pump continues to deliver the programmed medication. • Fault detection and <i>Alarm</i> 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 <i>Cassette Change</i>. 3. If you cannot continue to use the pump to effectively treat yourself without the remote, use your spare pump and remote.
<p>Upon removing my pump from the belt clip I pressed the <i>blue</i> button and heard a tone. Does this mean I shut the pump off?</p>	<p>It does not mean you shut the pump off. To determine the status of the pump see "Pump Sounds" on page 41.</p> <p>You can also check the <i>Home</i> screen on your remote to see the status of medication delivery.</p>

Table 22: FAQ

FAQ	What To Do
My battery charger is blinking red where I inserted the battery. What should I do?	<ol style="list-style-type: none"> 1. Try reinserting the battery in the battery charger. 2. If the light continues to blink red, try inserting the battery into the other battery 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?	<p>The pump will make sounds to let you know when its status has changed.</p> <p>Refer to "Pump Sounds" on page 41 for descriptions of each sound.</p>

Service and Support

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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

Replacement Parts

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.

Table 23: Components

Part Description	Part Number
Pump	DKPI-21096-001
Pump Battery	DKPI-70008-001
Pump Battery Charger	DKPI-21072-001
Remote	DKPI-21088-001
Dual USB AC Adapter	DKPI-40033-001
USB Cable 3.3 feet (1 meter)	DKPI-40034-001

Table 23: Components

Part Description	Part Number
Belt Clip	DKPI-31326-001
Clear Pump Dust Cover	DKPI-31219-001

Table 24: Disposables

Part Description	Part Number
Cassette Refill Kit (12 packages)	Contact your Specialty Pharmacy

Approved Infusion Sets

Table 25: Approved Infusion Sets

Part Description	Part Number
Medtronic Quick-set: 23 in (60 cm)	MMT-392, MMT-393
Neria Guard: 23 in (60 cm)	704060-5229, 704060-5226
Medtronic Silhouette: 23 in (60 cm)	MMT-373
Smiths Medical Cleo 90: 24 in (61 cm)	21-7230-24, 21-7220-24

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Technical Specifications

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Technical Description

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 through 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.

When your pump has detected that it has under delivered by 10 μL or that the pumping chamber hasn't fully emptied for 10 successive attempts, which ever occurs first, an *Occlusion* alarm is displayed.

Occlusion Detection Time:

- Rate: 16 $\mu\text{L}/\text{h}$ Detection Time: 8 h
- Rate: 42 $\mu\text{L}/\text{h}$ Detection Time: 8 h

The unintended *Bolus* volume following the release of an *Occlusion* is $\leq 40 \mu\text{L}$ (Typically $< 15 \mu\text{L}$) 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 $\leq 8 \text{ h}$
- 25% error for deliveries $> 8 \text{ h}$

The system has not been evaluated for use in *Oxygen Rich Environments* and should not be used in an *Oxygen Rich Environment*.

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.
- 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

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



Avoid operating the system in low pressure environments. Operating the system in low pressure environments may cause variation in delivery accuracy for short periods of time.

Environmental Protection Ratings

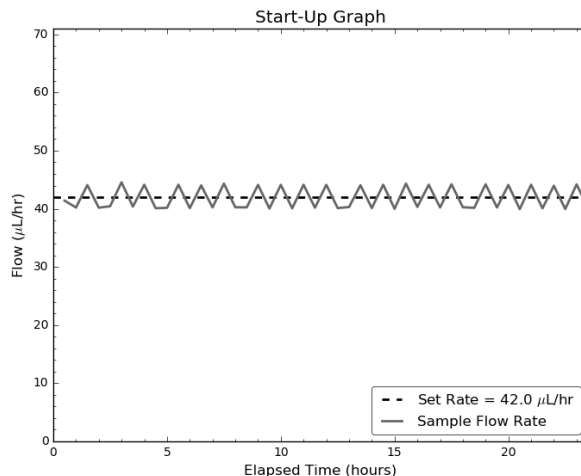
The pump when connected to the cassette has a rating of IP58, indicating protection from dust and continuous immersion in water. The pump can tolerate immersion to depths of up to 8 feet (2.4 m) for 30 minutes and 12 feet (3.7 m) for up to 3 minutes.

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.

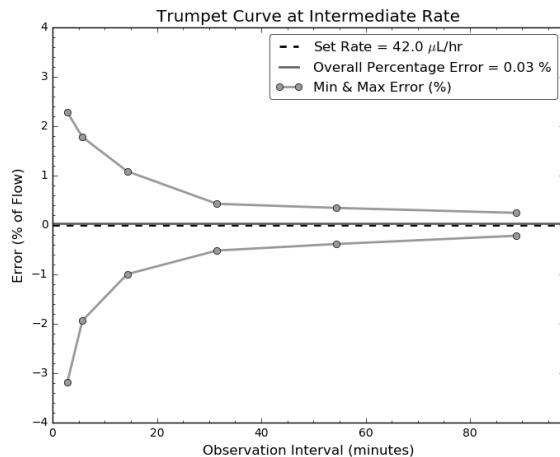
The AC adapters do not have an IP rating. Avoid contacting the AC adapters with dust and water.

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 $\mu\text{L/hr}$, 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 26: Alarm Volume Specifications

Alarm Volume Specifications	Specification Details
The following components generate the following sound pressures when alarms are fully escalated:	
Pump	50.4 - 66.5 dBA
Remote	58.0 - 67.7 dBA

Table 27: 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 °F (-25 °C) to 158 °F (70 °C) Non-condensing humidity up to 90% Pressures of 500 hPa - 1060 hPa

Table 27: Pump and Cassette Specifications

Pump and Cassette Specifications	Specification Details
Operating Environmental Range	Temperatures of 41 °F (5 °C) to 104 °F (40 °C) 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 a new 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	Empty Cassette: 2 years Refer to the Cassette packaging for expiration date.
Expected Service Life	Cassette: 3 days Pump: 3 years

Table 28: 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 29: 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 29: Remote Specifications

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

Table 30: Belt Clip Specifications

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

Table 31: Battery Charger, AC Adapter, and USB Cable Specifications

Battery Charger, AC Adapter, and USB Cable Specifications	Specification Details
Storage Environmental Range	Temperatures of -13 °F (-25 °C) to 158 °F (70 °C) Non-condensing humidity up to 90% Pressures of 500 hPa - 1060 hPa
Operating Environmental Range	Temperatures of 41 °F (5 °C) to 104 °F (40 °C) Non-condensing humidity up to 90% Pressures of 700 hPa - 1060 hPa
Allowable Temperature Range for Charging the Batteries	59 °F (15 °C) to 95 °F (35 °C)
Service Life	Battery Charger: 3 years AC Adapter: 3 years USB Cable: 3 years

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 32: 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

Quality of service for Bluetooth® Low Energy communication between the remote interface and paired pump includes the ability for the remote interface and pump to successfully transfer status, therapy commands, and alarms when in a communication range within 33 ft (10 m) during normal use.

When not in communication, the pump will deliver the last programmed therapy. Interruption or corruption of communication between the remote interface and pump leads to interruptions in status updates and the ability to make changes to therapy parameters. If communication is interrupted for more than 10 hours, a *No Communication* alert is generated.

In the absence of communication with the remote interface, alarm and attention alarm notifications will be generated by the pump. An attention alarm can be enabled by the user if communication between the remote interface and pump has been lost for a configurable amount of time. When other devices operating in the 2.4 GHz frequency range are transmitting or receiving within 4.9 ft (1.5 m), interruptions of communication may occur. This interference 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.

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 33: 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.

Table 33: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Harmonic emissions IEC 61000-3-2	Class A	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.
Voltage Fluctuations and Flicker IEC 61000-3-3	Class A	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 34: 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, +/-6 kV, +/-8 kV contact	Use in professional healthcare facility and home healthcare environments.
	+/-2 kV, +/-4 kV, +/-8 kV & +/-15 kV air	+/-2 kV, +/-4 kV, +/-8 kV & +/-15 kV air	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3		20 V/m 1 MHz to 80 MHz 200 Hz 80% AM carrier	Use in professional healthcare facility and home healthcare environments, excluding near high frequency surgical equipment or near MR machines.
	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	
	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3 cont.	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	
	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	10 V/m 704 MHz – 787 MHz 217 Hz PM carrier	
	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3 cont.	28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier	28 V/m 1700 MHz – 1990 MHz 2400 MHz – 2570 MHz 217 Hz PM carrier	Portable and mobile equipment should be used no closer to the Remunity® Pump for Remodulin® (treprostinil) Injection than 12 in (30 cm).
	9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	10 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	
		20 V/m 2.4 GHz – 2.5 GHz 111.5 kHz PM carrier	

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

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 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phase angles	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.
	0% U_T for 1 cycle	0% U_T for 1 cycle	
	70% U_T for 25 cycles at 50 Hz, 30 cycles at 60 Hz	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 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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Magnetic Fields generated by: <ul style="list-style-type: none"> • 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	<p>Use in professional healthcare facility and home healthcare environments, excluding near high frequency surgical equipment or near MR machines.</p> <p>RFID readers should be kept at least 1 ft [0.3 m] away from the Remunity® Pump for Remodulin® (treprostinil) Injection.</p> <p>Hand held or walk through metal detectors may be used near the Remunity® Pump for Remodulin® (treprostinil) Injection, but avoid prolonged exposure to them.</p> <p>Step through retail anti-theft detectors at a normal pace, but avoid standing in them.</p>

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

GLOSSARY

B

Battery Charger

A hardware device used to charge the rechargeable batteries.

C

Cassette

A hardware component of the Remunity system that holds the medication and attaches to the pump.

Cassette Change

The process of changing the pump battery with a fully charged battery, the infusion set tubing (sometimes the catheter), and a used cassette with a new cassette.

Catheter

A tubular medical device for insertion into canals, vessels, passageways, or body cavities for diagnostic or therapeutic purposes (as to permit injection or withdrawal of fluids or to keep a passage open)

E

Event

A historical entry saved within the remote. Examples of events are rate changes, cassette changes, alarms, attention alarms, and delivery start and stops.

F

Filling Aid

A disposable hardware device used to fill the cassette with medication and prime the cassette and infusion set tubing.

I

Infusion Set

The device used to connect the Remunity pump to your body. A needle is housed inside a catheter, a tiny plastic tube that is placed under the skin in the subcutaneous fat.

L

Luer Lock

A screw-type connector that connects the syringe and needle or infusion set tubing and cassette tubing

together to create a leak-free seal.

P

Pharmacy-Filled Cassette Package

The pharmacy-filled cassette package contains a pharmacy-filled cassette attached to a filling aid.

Prime

The process of filling the infusion set tubing with medication.

Pump

The main hardware component that pumps the medication into your body and wirelessly connects to the remote.

Pump-bump

A protrusion on the perimeter of the pump.

Pump Battery

The battery for the pump that can be recharged using the provided battery charger or the charging bay on the back of the remote and AC power.

Pump Dust Cover

A clear plastic cover that attaches to the bottom of the pump to protect its internal components from dust, dirt and contamination when the cassette is not attached.

R

Remodulin

For the purposes of this User Guide, an infused medication used to treat pulmonary arterial hypertension.

Remote

The remote interface or GUI device used to wirelessly program the pump.

Remote Battery Bay

The remote battery bay is located on the back of the remote for storage and charging of a spare pump battery.

S

Subcutaneous

Situated or applied under the skin

T

Tubing

Refers to the cassette or infusion set tubing.

U

User-Filled Cassette Package

The user-filled cassette package contains an empty cassette attached to a filling aid.

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Emergency Contact Information

Remunity® Pump for Remodulin® (treprostinil) Injection

Remodulin® System is for prescription use only.

Clinician:

Nurse Educator:

Specialty Pharmacy:



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