Remunity**PRO**™

User Guide

RemunityPRO™ for REMODULIN®
(treprostinil) Injection

The RemunityPRO system is MR Unsafe. Contact your Specialty Pharmacy or healthcare provider before disconnecting the pump from your infusion site. Do not bring your 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.

Enter your Specialty Pharmacy or healthcare provider contact, detach the MR Unsafe card, and keep with you while using the system.

MR Unsafe
This person has a RemunityPRO™ Pump for Remodulin®.

Contact the Specialty Pharmacy or healthcare provider below before disconnecting the pump. The pump and remote cannot enter an MRI scan room or an MR system. Doing so may result in injury.

Manufactured For: United Therapeutics Corp.

RTP, NC USA 27709, +1 877-864-8437

Keep this card with you while using the system.

MR Unsafe
This person has a RemunityPRO™ Pump for Remodulin®.

Contact the Specialty Pharmacy or healthcare provider below before disconnecting the pump. The pump and remote cannot enter an MRI scan room or an MR system. Doing so may result in injury.

Manufactured For: United Therapeutics Corp.

RTP, NC USA 27709, +1 877-864-8437

Keep this card with you while using the system.

Emergency Contact Information

RemunityPRO is for prescription use only.	
Name:	
Phone:	
Healthcare Provider:	
Pump Trainer:	
Specialty Pharmacy:	
Notes:	

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About this User Guide

This user guide provides important safety information about the RemunityPRO™ System. It is important to read and understand all instructions before using the system.

Keep this user guide in a safe, easily accessible location along with your other system accessories.

Conventions

The following conventions are used in this user guide.

Table 1: *Conventions*

Convention	Description
Bold Text	**Bold Text** is used to emphasize buttons on the remote or pump the operator interacts with.
Italic Text	*Italic Text* is used to emphasize: • Words or phrases that appear on the remote screen. • Sounds played by the system. • Headings and table captions.

Convention	Description
See "Conventions" above.	Provides a link to cross-referenced sections within the user guide.

Terminology

Table 2: *Terminology*

Term	Description
Keypad	A tool displayed within the remote to enter alpha or numeric values.
Picker	A tool displayed within the remote to select a value. Swipe up or down on the screen to select a value.
Tap	Quickly and gently touch the screen with your fingertip.
Press	Used to instruct the operator to press down on a button.
Select	Choose from a list of options.

Symbols

The following symbols are used within this user guide, along with their description.

Table 3: *User Guide Symbols*

Symbol	Definition
	Read instructions prior to use.
	Identifies an important note about the use of the system.
	Caution - Used to notify the caregiver or patient of potential hazards. Obey all safety messages that follow this symbol to avoid minor or moderate injury.

Symbol	Definition
⚠️	Warning - Used to notify the caregiver or patient of potential hazards. Obey all safety messages that follow this symbol to avoid serious injury or death.
$((\cdot))$	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

The following symbols are displayed on your pump, remote, supplies, and packaging. These symbols provide information necessary to use the system and supplies safely.

Table 4: *Symbols*
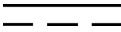
Symbol	Definition
R_X *Only*	Prescription use only
② (crossed out)	Single use only
♻	Material may be recycled
— — —	Direct Current required

Table 4: *Symbols*

Symbol	Definition
Li-ion	Recycle lithium-ion batteries
	Alarm has been silenced
	Manufacturer
	Expiration Date
LOT	Lot number

Symbol	Definition
REF	Catalog number
SN	Serial number
STERILE R	Sterilized using irradiation
	Keep dry
	Type BF Applied Part

Table 4: *Symbols*

Symbol	Definition
	Separate collection for electrical and electronic equipment waste.
	Indicates a potential hazard. Obey all safety messages that follow this symbol.
	Indicates a potential hazard. Obey all safety messages that follow this symbol.
	Alert - Obey all safety messages that follow this symbol to avoid the possibility of an alarm.
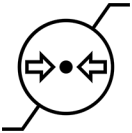
Symbol	Definition
	Alarm - Obey all safety messages that follow this symbol to avoid possible injury.
	Magnetic Resonance Unsafe – Items should not enter an MRI scanner room.

Table 5: *Symbols for Shipping Container Markings*

Symbol	Definition
	Temperature limit

Symbol	Definition
	Humidity limit
	Pressure limit
	Keep away from sunlight

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The RemunityPRO System

System Description

The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection is intended for the management of Pulmonary Arterial Hypertension. RemunityPRO is for single-patient use. The RemunityPRO cassette is for single use only.

The RemunityPRO system consists of a wearable infusion pump, a cassette that is filled with up to three days of Remodulin, a remote, and accessories for continuous subcutaneous (under the skin) delivery of Remodulin.

You must be trained by a qualified trainer before you use the RemunityPRO 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 RemunityPRO system:

- The *Operator* is able to program the system with the prescribed delivery rate.
- The *Operator* is able to adjust the delivery rate as instructed.
- The *Operator* understands that only RemunityPRO cassettes may be used with the RemunityPRO system.
- The *Operator* is able to verify the proper Remodulin concentration prior to filling a cassette.
- The *Operator* is able to execute the proper procedure for changing a cassette, including filling and priming.
- The *Operator* is able to execute the proper procedure for resolving an alarm.
- The *Operator* understands what supplies are required to facilitate a cassette and/or pump battery change.

Successful therapy requires sufficient physical, cognitive, visual and hearing capabilities to allow recognition and manipulation of the remote and pump.

If you have any questions about RemunityPRO, please contact your healthcare provider or Specialty Pharmacy representative.

Contact local authorities about proper disposal of electronic system components that contain lead and lithium ion batteries when no longer needed.

Indications for Use

The RemunityPRO™ Pump for Remodulin® (treprostinil) Injection (the RemunityPRO system) is intended for continuous subcutaneous delivery of Remodulin (treprostinil) Injection for use in patients, ages 17 and older.

Contraindications

The RemunityPRO system is not intended for operators who are unable or unwilling to:

- Maintain sufficient patient-care skills
- See a healthcare provider(s) regularly

Compatibility

Only use specified compatible infusion sets and cassettes.

RemunityPRO system components are not compatible with previous versions of the Remunity system. Components from previous versions of the Remunity system are not compatible with the RemunityPRO system.

Cassettes

The RemunityPRO system is only compatible with the RemunityPRO system *Cassette*. This cassette was found to be compatible with the RemunityPRO system for 72 hours (3 days) maximum use time for the delivery of Remodulin.

Infusion Sets

The RemunityPRO system is compatible with the following infusion sets:

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

Replace your infusion set every 48-72 hours, or per instruction from your Specialty Pharmacy or healthcare provider.

Read the manufacturer instructions prior to use.

Important Safety Information

The following includes warnings ⚠ and cautions ⚠ related to the use of the RemunityPRO system.

Warnings

Warnings provide information about specific scenarios and the possible outcomes that may occur as a result of failing to follow the provided guidance, which may lead to serious injury or death.

Reinforcement of warnings appear throughout the user guide, where applicable.

Delivery Rate

> ⚠ Programming the delivery rate incorrectly will lead to Remodulin dosage errors. The delivery rate should always be set with direction from your Specialty Pharmacy or healthcare provider.

Location of Use

> ⚠ The system may affect nearby electrical devices (such as antennas or radios), including medical ones. This could cause these devices not to work properly or stop working. Keep the pump, remote, and pump battery charger at least 12 in (30 cm) away from these devices.

> ⚠ 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 12 in (30 cm) away from these items.

Metal detectors may affect pump accuracy or trigger an alarm. Handheld or walk through metal detectors may be used near the system, but prolonged exposure to them should be avoided.

Retail anti-theft detectors may affect pump accuracy or trigger an alarm. Walk through retail anti-theft detectors at a normal pace, but avoid standing in them.

If the remote is not in communication with the pump, alarms and alerts may not appear on the remote. The pump will still play alarm and alert sounds. In order to ensure alarms and alerts are displayed on the remote, the remote and pump must be kept in communication.

Avoid exposing your RemunityPRO system to temperatures below 41 °F (5 °C) or above 104 °F (40 °C). When in cold temperatures, the pump should be worn close to the body and covered in warm clothing. When in warm temperatures, take measures to keep the pump cool.

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, which may lead to harm.

Cassette Change

Always have your backup supplies available, including your alternate pump and remote set, and all of the supplies necessary to complete a cassette change. Your backup supplies may be needed if delivery stops unexpectedly or the pump fails.

Do not connect the cassette and infusion set tubing to your infusion site while filling a cassette and priming the infusion set tubing. Connecting the infusion set tubing to your infusion site while filling a cassette and priming the infusion set tubing may lead to unintended Remodulin delivery.

Make sure to prime the infusion set tubing. Failure to prime the infusion set tubing may lead to a delay in the delivery of Remodulin or cause a delivery error.

⚠ Do not connect infusion set tubing to your infusion site before the pump completes *Self Test*. Connecting infusion set tubing to your infusion site during *Self Test* may lead to unintended Remodulin delivery which may lead to harm.

⚠ Avoid unnecessary contact with the inner surfaces of the pump or cassette while they are separated. Damaging the inner surfaces of the pump or cassette may affect pumping accuracy which may increase or decrease delivery.

⚠ Disconnect the infusion set tubing from your infusion site before removing the cassette from the pump. Unintended delivery of Remodulin may occur if the cassette is removed from the pump before disconnecting from your infusion site.

⚠ Do not connect a filled cassette and infusion set tubing to your infusion site if the filled cassette is not attached to the pump. Connecting the filled cassette and infusion set tubing to your infusion site before connecting the cassette to the pump may lead to unintended Remodulin delivery.

⚠ Only fill cassettes at the time you plan to use them. Filling a cassette before you plan to use it may result in a change to the potency or purity of the Remodulin prior to use, which can lead to harm.

⚠ If air bubbles are present in the infusion set tubing, perform a cassette change. Air bubbles in the infusion set tubing may lead to over or under delivery of Remodulin, which may lead to harm.

Occlusion Alarm

⚠ Only use cassettes and infusion sets approved for use with the RemunityPRO system. Failure to do so may affect accuracy or occlusion detection which may lead to harm.

⚠ Do not leave the cassette and infusion set tubing connected to your infusion site when investigating or resolving an *Occlusion* alarm. Leaving the infusion set tubing connected during an *Occlusion* alarm may lead to unintended delivery of Remodulin.

Batteries and Charging

Only use the provided wall power adapter and charging cables. Use of other wall power adapters or cables could damage the system or result in fire or burns.

Do not use batteries or battery chargers that were not supplied with the RemunityPRO system. Use of batteries and battery chargers that did not come with the RemunityPRO system may lead to unsafe operation which may lead to harm.

Disposables

Do not use sterile components that are past the expiration date on their package. Using expired sterile components may lead to infection.

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

Do not use disposable components from previously opened or damaged sterile packaging. Use of disposable components from previously opened or damaged sterile packaging may lead to infection.

Sharp Objects

Keep the pump, cassette, and infusion set tubing away from sharp objects. Sharp objects may damage these components which may cause delivery errors. Delivery errors may lead to harm.

Pets

Pets may damage your infusion set tubing while sleeping which may lead to an interruption of Remodulin delivery or infection. Do not sleep with your infusion set tubing exposed if pets are present.

Small Parts

Keep small parts and exposed infusion set tubing out of the reach of unsupervised children to prevent choking.

DKUT-09009-001 -1.9

Keep the batteries included with the RemunityPRO system away from children. The pump batteries are small enough to be swallowed resulting in choking or damage to their digestive tracts.

Discontinue Use

If the pump or remote fail to work as detailed in the user guide, stop using the pump and remote and switch to the alternate pump and remote set included with your system. Using the pump or remote when they are not working as detailed in the user guide may lead to harm.

Maintenance and Troubleshooting

Do not perform troubleshooting steps while the pump is connected to your infusion site. Performing troubleshooting steps while the pump is connected to your infusion site may lead to unintended delivery of Remodulin, which may lead to harm.

Do not attempt to open, modify, or repair any parts of the system. Attempting to open, modify, or repair parts of the system could lead to unsafe operation and may lead to harm.

Dirt, lubricants, or liquids may contaminate inner surfaces of the pump while it is separated from the cassette. Contamination may affect pumping accuracy, which may increase or decrease delivery.

Medical Procedures

The RemunityPRO system is MR Unsafe. Contact your Specialty Pharmacy or healthcare provider before disconnecting the pump from your infusion site. 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.

Always notify medical staff about your RemunityPRO system. If you need to stop Remodulin delivery for a medical procedure, follow guidance from your Specialty Pharmacy or healthcare provider for proper treatment.

The RemunityPRO system should not be exposed to any of the following without consulting with your Specialty Pharmacy or healthcare provider:

- X-ray
- Computed Tomography (CT) scan
- Positron Emission Tomography (PET) scan
- Diathermy Devices
- Electrocautery Devices
- Pacemaker/Automatic Implantable Cardioverter Defibrillator (AICD) placement or reprogramming
- Cardiac Catheterization
- Nuclear Stress Test
- Other exposure to radiation

Your RemunityPRO pump and remote must be left outside of the procedure room. Failure to leave your pump and remote outside of the procedure room may lead to harm.

Cautions

Cautions provide information about detailed situations and the possible result of not following the guidance which could lead to minor or moderate injury.

Reinforcement of cautions appear throughout the user guide, where applicable.

Remodulin Delivery

This system supports flow rates between 8 µl/h - 225 µl/h. If the required flow rate is outside this range please discuss with your Specialty Pharmacy or healthcare provider.

Prolonged Noise and Vibration

Prolonged noise or vibration may interfere with the pump's ability to continue delivery and trigger an alarm.

Batteries and Charging

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

⚠️ Surfaces of the pump battery charger may reach 131 °F (55 °C). Avoid contacting the pump battery charger surfaces when they are warm to the touch. Making contact with the charger while it is warm to the touch may result in burns.

⚠️ Do not use the wall power adapter if it is visibly damaged or malfunctioning. Using a damaged or malfunctioning wall power adapter can result in electrical shock.

⚠️ The use of cables other than those provided or specified may result in increased radio frequency emission or decreased radio frequency immunity of the system.

Clean Technique

⚠️ Use clean technique when filling the cassette and interacting with the infusion set. Failure to do so may lead to infection.

General

⚠️ Do not open, crush, heat above 140 °F (60 °C), or incinerate the pump battery or remote. Doing so can lead to fire, burns, and property damage.

⚠️ The volume on the remote should be louder than your surroundings so your system notifications are not missed.

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

The RemunityPRO system should not be exposed to X-ray screening used for carry-on and checked luggage. Consult with your healthcare provider or Specialty Pharmacy before you travel. It is recommended to notify the security agent that you would prefer an alternate means of screening. The RemunityPRO system has been designed to withstand common electromagnetic interference including airport metal detectors.

Skin Care Products

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 IP24 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 these products do get on the cassette, wipe them off immediately with a clean cloth.

System Overview

The RemunityPRO system consists of a pump attached to a cassette, a remote, and a compatible infusion set for continuous subcutaneous delivery of Remodulin.

Infusion Set

Used to deliver Remodulin from the cassette into your body.

Remote

Used to program the pump, start/stop Remodulin delivery, and view data logs. The pump will continue to deliver Remodulin even when it is not communicating with the remote.

Pump (with Cassette Attached)

The pump and cassette work together to deliver Remodulin to your body at the delivery rate you set using the remote.
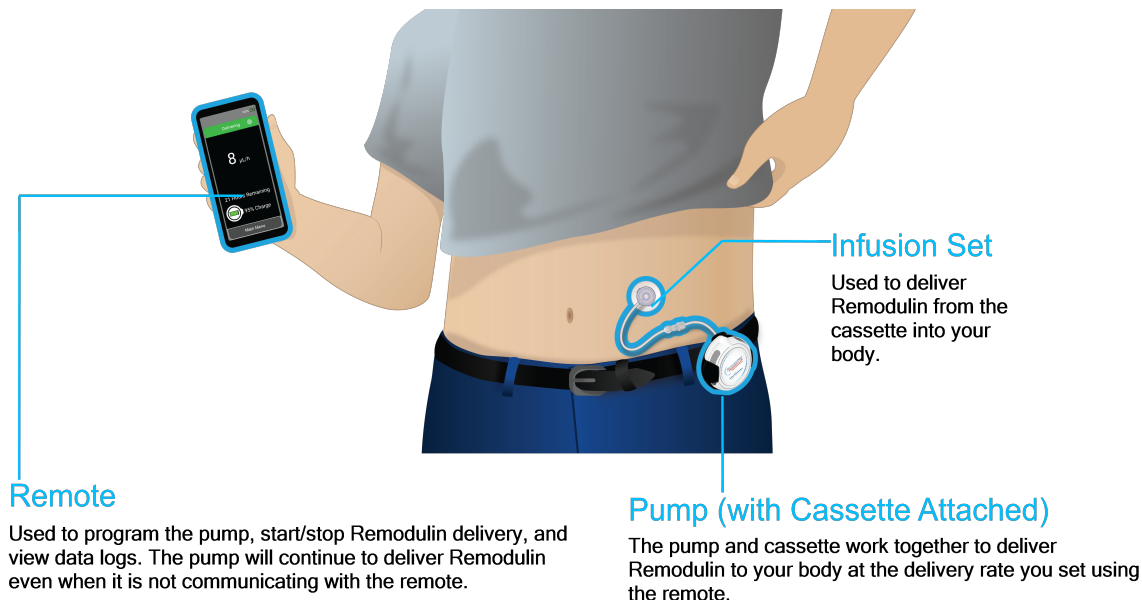
Starter Kit

The *Starter Kit* includes a primary and an alternate system with a User Guide and Cassette Change Quick Reference Guide.

Each system includes:

1. Remote and Pump (with attached pump cover) Set
2. Pump Battery Charger and Rechargeable Pump Batteries (2)
3. Pump Clip
4. Wall Power Adapter with 2 USB ports
5. USB Cables (2)

If needed, contact your Specialty Pharmacy for replacement parts.
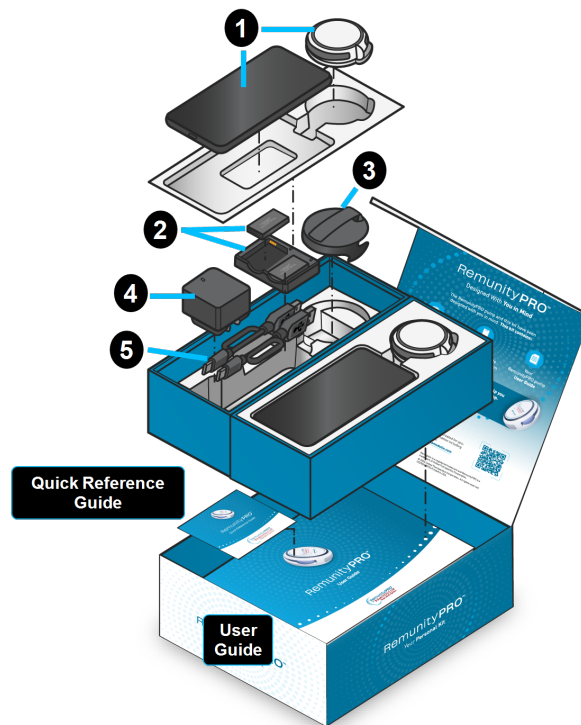
Cassettes

Cassettes are single-use and provided in individual, sterile packages. The cassette has a luer connector to attach to an approved infusion set, and a filling port to fill the cassette with Remodulin.

Luer Connector

Cassette

Filling Port
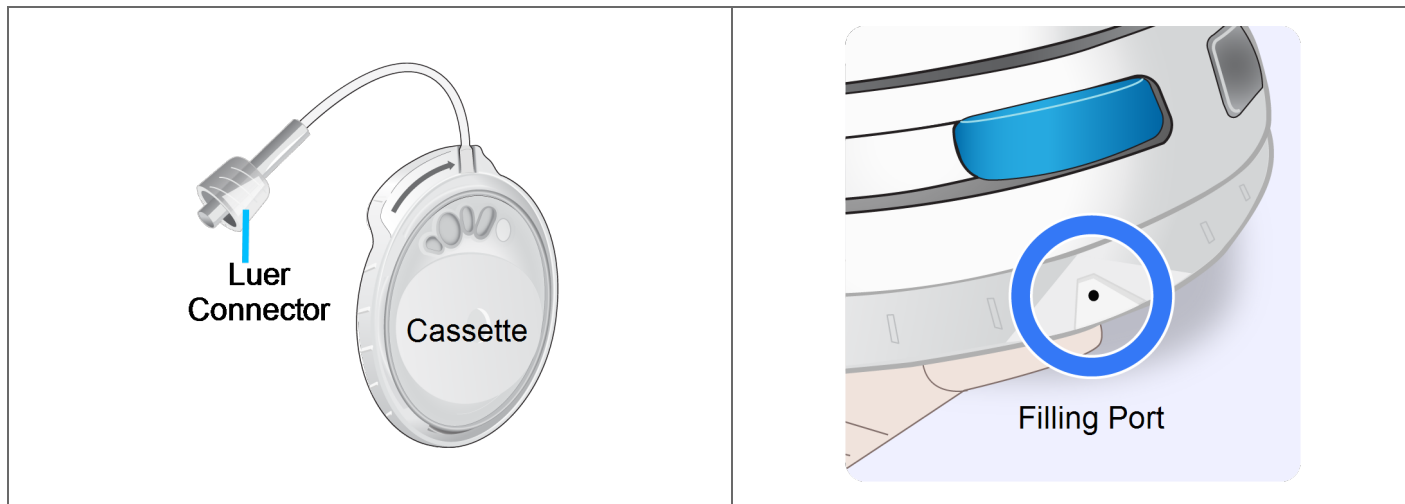
Infusion Sets and Cassette Change Supplies

Additional single-use supplies necessary to use the system include, an infusion set, which consists of infusion set tubing and cannula, as well as a needle, syringe, and alcohol wipes.

Do not use any cassette change supplies from packages that are damaged or have already been opened.

Only use cassette change supplies that have been approved for use within the system.

The following infusion sets are approved for use:

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

Always refer to the instructions provided by the infusion set manufacturer.

The following syringe and needles are approved for use for filling the cassette:

- 3 mL syringe with luer connector
- 27 gauge x 3/8 inch (0.40 mm x 10 mm) needle with luer connector

   OR
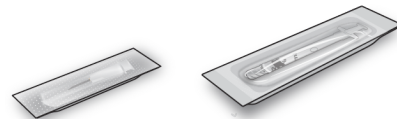
- 26 gauge x 3/8 inch (0.45 mm x 10 mm) needle with luer connector

Cassette change supplies provided with previous versions of the Remunity system are not compatible with the RemunityPRO system.

Backup Supplies

Keep these backup supplies with you at all times:

- Alternate Pump and Remote set
- Non-expired Cassette, in unopened package
- Non-expired Infusion Set, in unopened package
- Sterile Syringe and Needle
- Fully charged Pump Battery
- Battery Charger
- Wall Power Adapter
- USB Cable
- Remodulin
- Alcohol Wipes

Refer to instructions from your Specialty Pharmacy for additional backup supplies and information.

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Get to Know the System

Remote

The remote is used to program the pump, start and stop delivery, and view pump data.

To power on the remote:

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

Power On/Off

The remote screen will stay active for the programmed *Screen Timeout* before going into sleep mode. To adjust the *Screen Timeout*, *see "Screen Timeout" on page 103*.

To unlock the remote:

1. Press the **power button** to turn on the screen.

2. Touch 🔒 and slide to unlock the screen.

To power off/restart the remote:

1. Press and hold the **power button**.
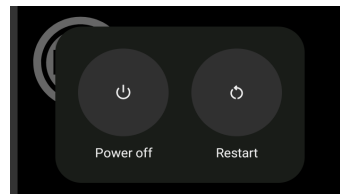
Power off   Restart

2. Tap **Power Off** or **Restart**.

Events are maintained when the RemunityPRO system is powered down or loses power.

To adjust the remote volume:

1. Press the remote volume button up or down to adjust the volume.

Volume Up

Volume Down

Ports

The remote contains the following ports:

- Charging (USB-C) – This port is used to charge the remote. Data communication through this port is disabled by the remote software configuration.
- Audio Jack – All signals through this port are disabled by the remote software configuration.
- Bluetooth LE – This port is used to securely send information between the pump and remote, such as current status and therapy settings.
- Wi-Fi – Data communication through this port is disabled by the remote software configuration.
- Cellular – Data communication through this port is disabled by the remote software configuration.

Remote Screen Icons

Icon	Description
(i)	Access Help Information
🔕	Silence Alarm or Alert
✎	Edit a Value
✓	Acknowledge or Accept
⌃	Scroll Up / Increase a Value
⌄	Scroll Down / Decrease a Value
→	Next Screen
←	Previous Screen
⚙	About - Support Menu
?	About - Software Version
🔓	Slide to Unlock

Home Screen

The *Home Screen* displays details about your pump delivery rate, remote and pump battery levels, and any conditions you need to address, such as *Alarms or Alerts*. Refer to *"Alerts" on page 121* or *"Alarms" on page 135.* It also provides access to the *Main Menu*.

1. Remote battery level (and charging indicator)
2. Status bar
3. Delivery rate in µL/h (microliters per hour)
4. Hours remaining until cassette change
5. Pump battery level
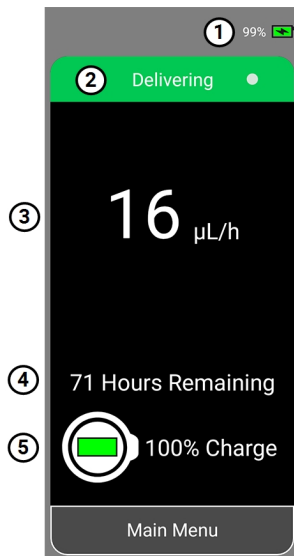
Remote Battery Level

When the remote is powered on, the remote battery level is displayed as a percentage and a color-filled icon in the top right corner of the screen. A lightning bolt is displayed within the remote battery icon to indicate when the remote is charging.

Remote Charge	Remote Charging	Status
		Between 40% and 100% charge
		Between 20% and 40% charge
		Below 20% charge

Status Bar

The color of the *Status Bar* indicates if the remote is communicating with the pump, and the pump delivery status.
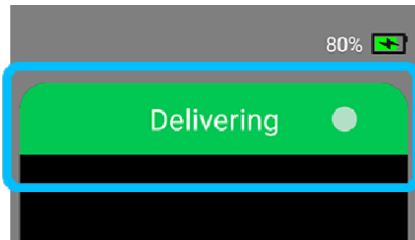
Green	Communicating and Delivering
Blue	Communicating and NOT Delivering
Gray	NOT Communicating

Delivery Rate

The system displays the Remodulin delivery rate in microliters per hour (μL/h).

The delivery rate can be set from 8 μL (0.008 mL) to 225 μL (0.225 mL) per hour, in 1 μL (0.001 mL) increments.
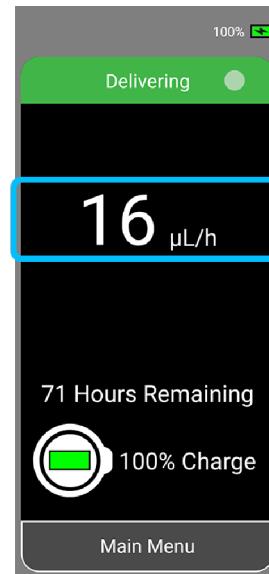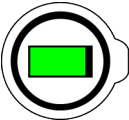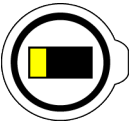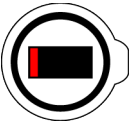
Hours Remaining

Directly under the delivery rate, the remote displays the estimated hours remaining until the cassette needs to be changed. This value counts down and displays the whole hours remaining. Take note of the remaining hours so you know when you need to complete a cassette change. The system will notify you when your cassette gets low or needs to be replaced.
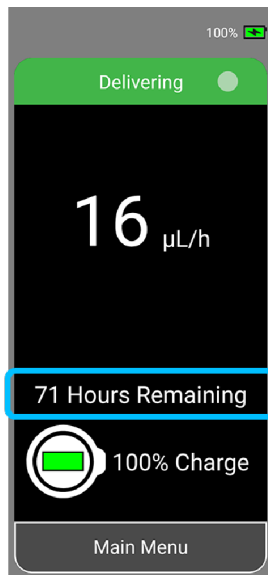
Pump Battery Level

The pump battery level is displayed as a color-filled icon and the percentage of the battery charge remaining.

Pump Battery Level	Status
	Between 40% and 100% charge
	Between 20% and 40% charge
	Below 20% charge

Pump Overview

The pump, when connected to a cassette and infusion set, delivers Remodulin under the skin at the delivery rate (µL/h) instructed by your Specialty Pharmacy or healthcare provider and set using the remote.

The pump is shipped with an attached pump cover. The pump cover should be removed and stored in a safe, easily accessible location along with this user guide and your other system accessories.

When your alternate system is not being used, store the pump with the pump cover attached.

The pump is powered by a rechargeable battery designed for use with the RemunityPRO pump. During the cassette change process the battery is removed from the pump and inserted into the pump battery charger. A fully charged battery is inserted into the pump.

Pump-Bump

The pump-bump and alignment ridge are features on the pump to help align the pump when attaching a cassette or pump cover.

Pump-Bump

Alignment Ridge
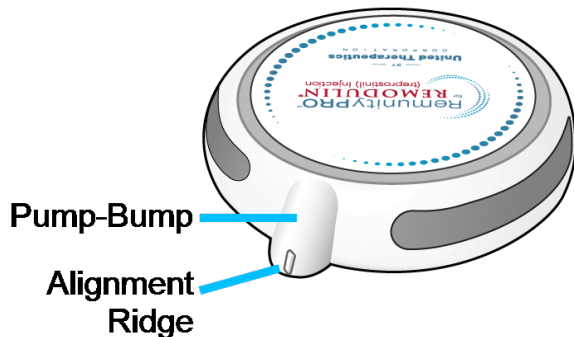
When attaching a new cassette to the pump, align the ridge on top of the pump-bump with the ridge on the cassette. When the ridges are aligned, turn the pump clockwise toward the infusion set tubing.
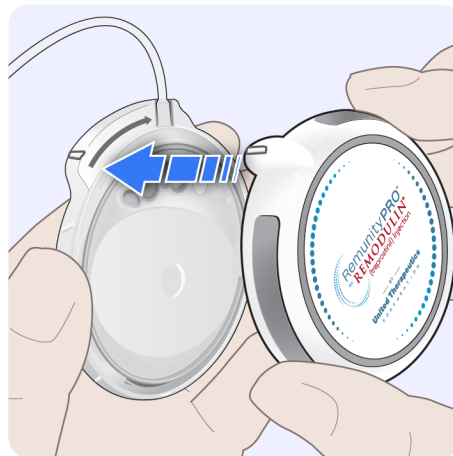
When the ridge on the pump-bump is aligned with the infusion set tubing, the cassette has been fully attached.

Pump Button
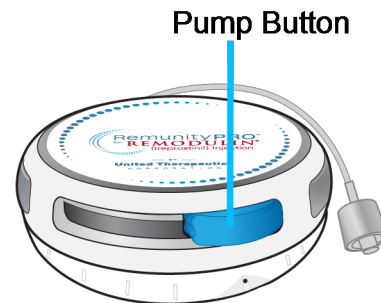
Pump Button

The *pump button* provides the ability to:

• Confirm that delivery is in progress. *See "Verify the Pump is Delivering" on page 60.*

• Place the pump in pairing mode. *See "Pair a Pump" on page 100.*

Communication between your Remote and Pump

Your RemunityPRO pump and remote communicate using Bluetooth Low Energy (LE) to send status and therapy information.

Bluetooth LE is a short-range wireless technology used for exchanging data between devices over short distances. Bluetooth Low Energy is designed for very low power operation within the 2.4 GHz band.

The RemunityPRO remote is designed to communicate only with the RemunityPRO pump that has the same numeric serial number.

> ⚠️ 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 away from these items.

> ⚠️ If the remote is not in communication with the pump, alarms and alerts may not appear on the remote. The pump will still play alarm and alert sounds. In order to ensure alarms and alerts are displayed on the remote, the remote and pump must be kept in communication.

> ⚠️ The system may affect nearby electrical devices (such as antennas or radios), including medical ones. This could cause these devices not to work properly or stop working. Keep the pump, remote, and pump battery charger at least 12 in (30 cm) away from these devices.

> 📝 The remote should be kept close to the patient at all times while using the RemunityPRO system to maintain communication between the pump and remote. If communication is lost between the pump and remote, the pump will continue to deliver Remodulin at your programmed rate and will continue to detect alarm conditions.

System Sounds

System sounds are played from the pump or remote in order to help you hear the current status of the system.

Table 6: *Sounds from the Pump*

Sounds from the Pump					
Sound	**Description**	**Sound**	**Description**	**Sound**	**Description**
Quick beep	Pump battery has been inserted into the pump.	*Busy* - One repeating beep	The pump is busy. Wait until the pump is ready to continue.	*Delivering* - Four ascending tones	The pump is delivering. The *Delivering* status is displayed on the remote status bar.
Ready - One beep	Ready to progress to next step. Continue.	*Priming* - Two repeating tones	Infusion set tubing priming is in progress.	*Delivery Stopped* - Three descending tones	Remodulin delivery has been stopped.

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Table 7: *Sounds from the Pump and Remote*

Sounds from the Pump and Remote	
Sound	**Description**
Alert - Three beeps, repeating every 15 seconds	Pump status changed. Check the alert displayed on the remote for more information.
Alarm - Three beeps, two beeps, three beeps, two beeps, repeating every 10 seconds	The pump is not delivering. Check the alarm displayed on the remote for more information.

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First Time Set Up

Contact your Specialty Pharmacy for assistance with any of the set up instructions.

> 📝 If the pump or remote have been subjected to the extremes of specified storage temperatures, allow it to cool off/warm up for one hour before use.

Charge the Pump Batteries

Before you use the RemunityPRO system for the first time, make sure you charge the pump batteries.

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

The pump batteries typically take 6 hours or less to charge.

The pump batteries should only be charged using the provided battery charger, wall power adapter, and USB charging cables.

Keep the pump batteries, pump battery charger, and wall power adapter clean and dry.

> ⚠ Do not use batteries or battery chargers that were not supplied with the RemunityPRO system. Use of batteries and battery chargers that did not come with the RemunityPRO system may lead to unsafe operation which may lead to harm.

> ⚠ Only use the provided wall power adapter and charging cables. Use of other wall power adapters or cables could damage the system or result in fire or burns.

A fully charged pump battery will power the pump for 3 days (72 hours).

1. Plug the USB cable into the wall power adapter and the battery charger.
2. Plug the wall power adapter into a wall power outlet.
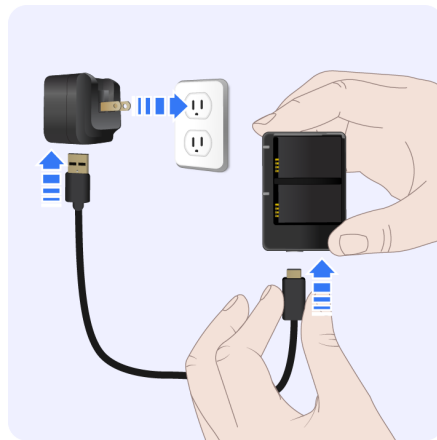
> ✎ Avoid touching the electrical contacts on the battery charger when the charger is connected to a power source.

3. Insert the pump batteries into the battery charger by aligning the contacts on the batteries with the contacts on the charger.

   When the pump batteries are charging, the status lights are orange.

When the pump batteries are fully charged, the status lights are green and are ready for use.

Color	Status
Green	Pump battery is fully charged
Orange	Pump battery is charging
Blinking Red	Charging Fault

Charge the Remote

Before you use the system for the first time, make sure you charge the remote.

If the remote has been subjected to the extremes of specified storage temperatures, allow it to cool off/warm up for 1 hour before charging.

The remote will take 6 hours or less to charge when connected to the supplied wall power adapter.

The remote should only be charged using the provided wall power adapter and USB cable.

The remote will continue to work for more than 1 day (24 hours) when fully charged, but should be charged every night.

Keep the remote and wall power adapter clean and dry.

The remote can be used, and is fully functional, while the remote is charging.

1. Plug the second USB cable into the remote and the wall power adapter.

2. Plug the wall power adapter into a wall power outlet.
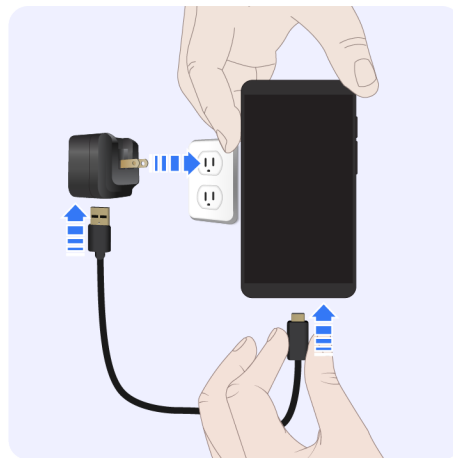
The remote battery level is displayed briefly. It is recommended to fully charge the remote before setting up your system. If needed, press the **power button** to view the remote battery level again.
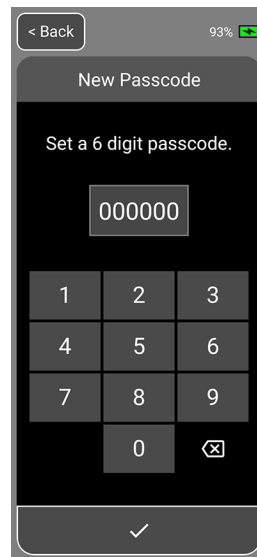
Set Passcode

A *Passcode* is required to make changes to the *Delivery Rate*.

Your passcode should not be shared with unauthorized users.

1. Tap ☑ to start setting up your passcode.

93% 🔋

Set Passcode

Passcode is required to use the pump.

✓
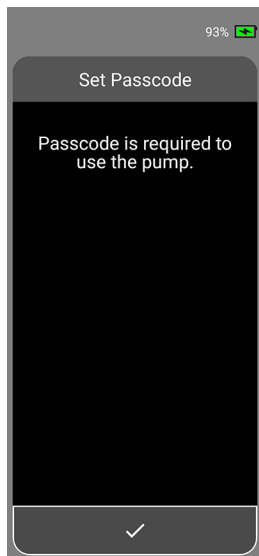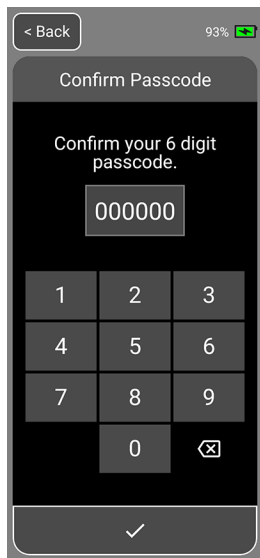
2. Using the keypad, type in your new 6-digit passcode. Make sure to choose a passcode that you will remember.

< Back   93% 🔋

New Passcode

Set a 6 digit passcode.

000000

1	2	3
4	5	6
7	8	9
	0	⌫

✓

3. Tap ☑ to accept the *New Passcode* and continue.

4. Enter your new passcode again and tap ☑ to confirm.

< Back   93% 🔋

Confirm Passcode

Confirm your 6 digit
passcode.

000000

1	2	3
4	5	6
7	8	9
	0	⌫

✓

5. Proceed to *"Pair Remote and Pump for the First Time" below*.

Pair Remote and Pump for the First Time

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

Your pump pairs to your remote similarly to how other devices pair to your smart phone, such as Bluetooth headphones.

The RemunityPRO pump is shipped with a *Pump Cover* attached.

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

2. Store the pump cover with your other RemunityPRO supplies.

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

When the battery is inserted successfully, the pump will play a *Quick* beep followed by a *Ready* beep and the remote will advance automatically.

The pump will be Bluetooth discoverable and the serial number will automatically be displayed on the *Select a Pump* screen.

The RemunityPRO remote is designed to communicate only with the RemunityPRO pump that has the same numeric serial number.

Only the pump with the matching numeric serial number will be displayed.

84%

Select a Pump

23042115D

If the pump serial number is not displayed, tap the info icon for pairing instructions.

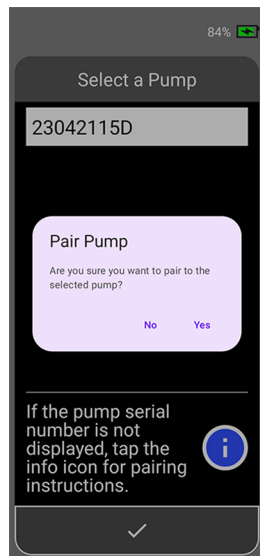Tap ⓘ for more instructions if the serial number does not display.

The pump serial number is located on the bottom of the pump. The remote serial number is located on the back of the remote.
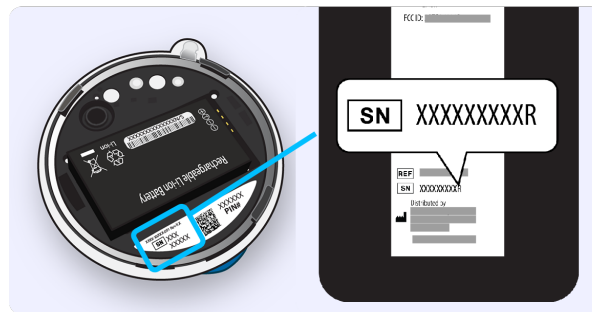
4. Make sure to place the pump and remote within 2 in (50 mm) of each other during the pairing process.
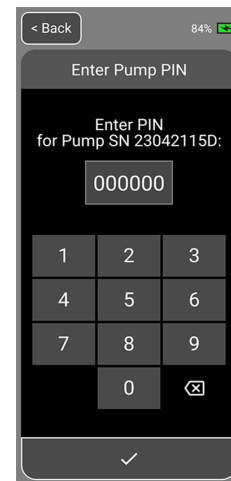
5. Tap ☑ to continue.

6. Tap **Yes** to confirm you would like to pair to the selected pump.

7. Enter the pump **PIN**.

    The pump PIN is located on the bottom of the pump.

8. Tap ✓ to continue.

    When the pump and remote have been successfully paired, the *Paired Pump* screen is displayed.

    If pairing fails, *see "Pairing Failed Alert" on page 127.*

9. Tap ✓ to continue.

Enter Delivery Rate

⚠️ Programming the delivery rate incorrectly will lead to Remodulin dosage errors. The delivery rate should always be set with direction from your Specialty Pharmacy or healthcare provider.

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

1. Use the picker by swiping up or down to select your prescribed rate, then tap ☑ to continue.
2. Tap **Yes** to confirm your delivery rate or *No* to return to edit or select a different rate.

85%

Set Delivery Rate

15

16 µL/h

17

✓
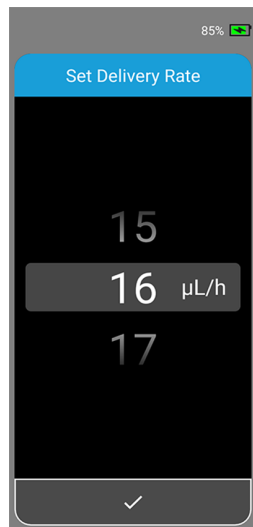
Gather your Supplies

The following supplies are needed for your first time set up:

- New Cassette
- New Syringe and Needle
- New Infusion Set
- Alcohol Wipes
- Remodulin

Disposable components should be unopened and used before the date on the packaging.

⚠️ Do not use sterile components that are past the expiration date on their package. Using expired sterile components may lead to infection.

⚠️ Do not use damaged disposable components. Using damaged disposable components may result in start-up failures, interruptions in therapy, or topical exposure to Remodulin.
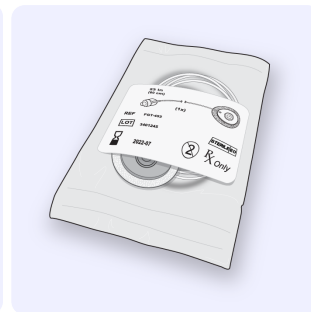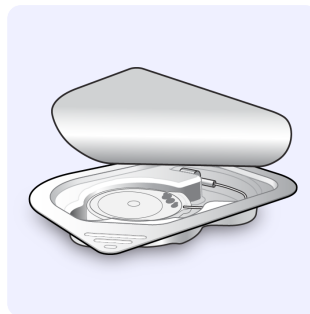
> ⚠️ Do not use disposable components from previously opened or damaged sterile packaging. Use of disposable components from previously opened or damaged sterile packaging may lead to infection.

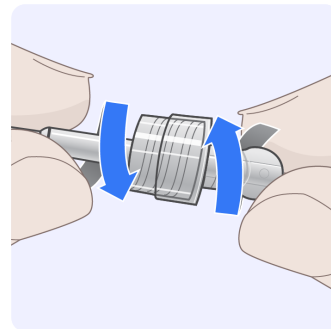# Prepare New Infusion Set Tubing and New Cassette

1. Wash your hands with soap and water.

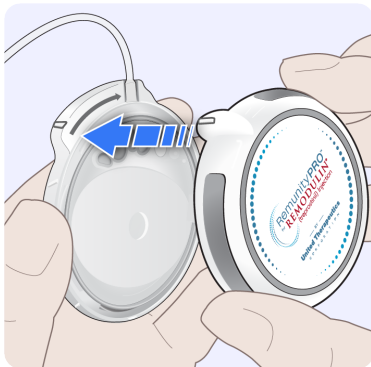2. Open and remove the new cassette and infusion set from their packaging.

3. Attach the new infusion set tubing to the new cassette by twisting the luer connectors together.

Attach New Cassette to Pump

Avoid unnecessary contact with the inside of the pump and cassette which is exposed during a cassette change.

1. Make sure the surfaces of the cassette and the pump are clean and free of fluid and debris.

2. To attach the cassette to the pump, align the ridges on the pump-bump and the top of the cassette.
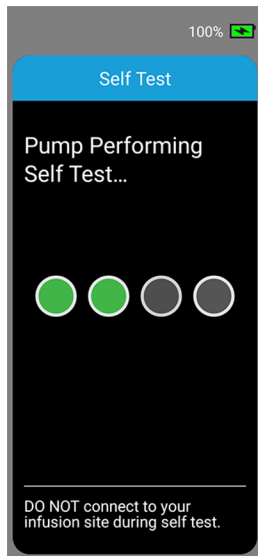

3. Push down and rotate the pump clockwise so the ridge on the pump-bump is aligned with the infusion set tubing.

A series of *busy* beeps will be played by the pump while the pump conducts a *Self Test*. The *Self Test* is displayed on the remote.

If the cassette is not properly attached, a *Remove Cassette* message is displayed. Remove and reattach the cassette to the pump to continue.

4. Wait for the *Self Test* to complete.

Self Test

Pump Performing Self Test...

DO NOT connect to your infusion site during self test.

100%

Fill the Cassette

The cassette should be filled with the amount (mL) of Remodulin displayed on your remote. This is determined based on your programmed delivery rate (µL/h).

⚠️ Only fill cassettes at the time you plan to use them. Filling a cassette before you plan to use it may result in a change of the drug potency or reduce the purity of the Remodulin prior to use which can lead to harm.
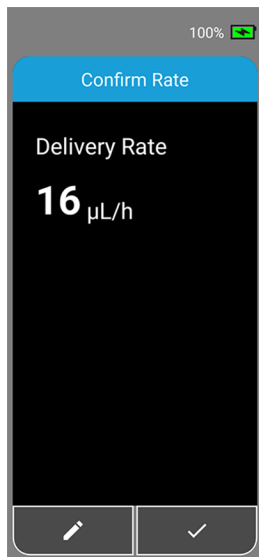
Cassette change supplies provided with previous versions of the Remunity system are not compatible with the RemunityPRO system.

1. Confirm your delivery rate matches your prescribed rate and tap ☑ to continue.
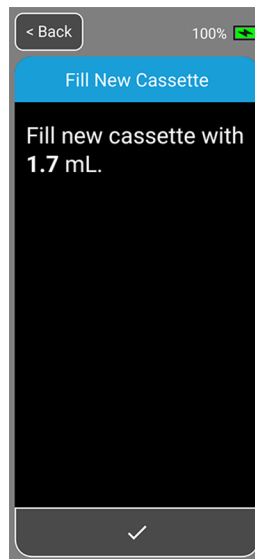
If you need to edit the *Delivery Rate:*

   a. Tap ✎.
   b. Enter your 6-digit **passcode** and tap ☑.
   c. Use the picker by swiping up or down to change the rate.
   d. Tap ☑ to select.
   e. Tap **Yes** to confirm the change to the delivery rate or *No* to edit your rate.
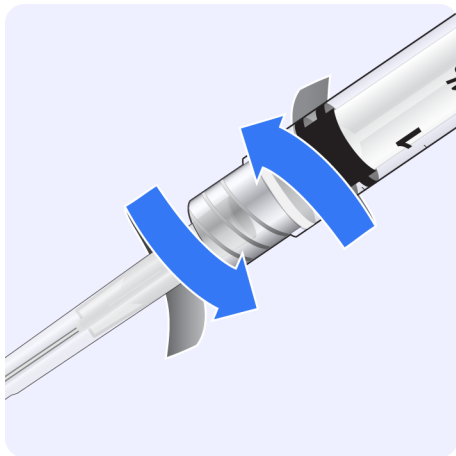
The amount of Remodulin needed to fill the new cassette is displayed.

Remain on the *Fill New Cassette* screen until after you fill the cassette.
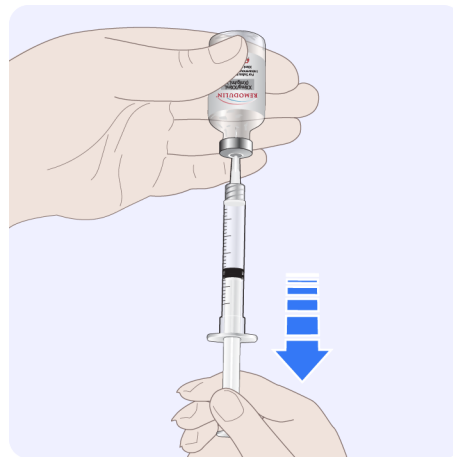
2. Clean the top of the Remodulin vial with an alcohol wipe.
3. Open a new syringe and needle.
4. Attach the needle to the syringe luer connector by twisting until finger tight.

5. Remove the cap from the needle.
6. Pull the syringe plunger out to the volume (mL) displayed on the remote.
7. Insert the needle into the vial.

8. Press down on the syringe plunger to add air to the vial.
9. While still holding pressure on the plunger, flip the vial so it is above the syringe.
10. Slowly pull down on the plunger to fill the syringe with the amount (mL) of Remodulin displayed on the remote.

11. With the needle facing up and held vertically, tap on the syringe to remove any visible air bubbles.

12. Remove the syringe from the vial.
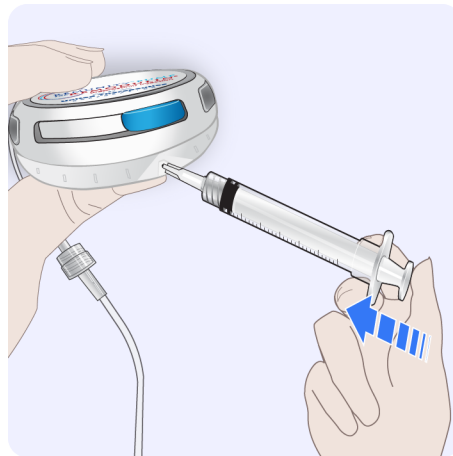
13. Insert the needle straight into the filling port on the side of the cassette. Do not force the needle.

14. Push the syringe plunger down to fill the cassette. Continue to hold the syringe plunger down while removing the needle from the cassette.
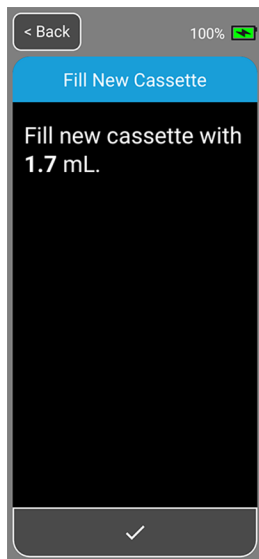
DKUT-09009-001 -1.9

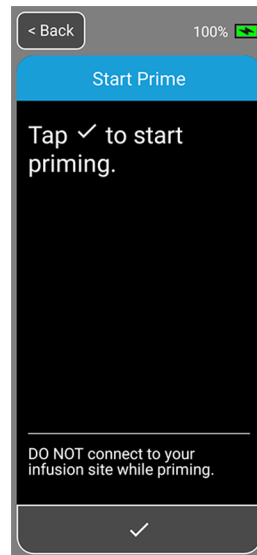15. Dispose of the used syringe and needle in a sharps container.

    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.

16. Tap ✓ to confirm the new cassette was filled with the amount of Remodulin shown on the remote.

< Back	100%
Fill New Cassette	

Fill new cassette with **1.7** mL.

✓

Prime Infusion Set Tubing

1. Tap ✓ to start priming the infusion set tubing.

< Back	100%
Start Prime	

Tap ✓ to start priming.

DO NOT connect to your infusion site while priming.

✓

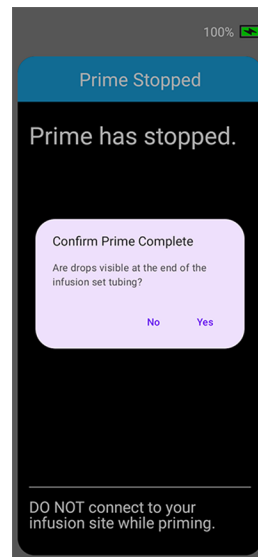A series of *Priming* sounds will be played by the pump as priming occurs.

2. Watch for drops to appear at the end of the infusion set tubing.

    Drops of Remodulin at the end of the infusion set tubing indicates the cassette and tubing are primed.

3. When drops are visible at the end of the infusion set tubing tap ☑ on the remote to stop prime.

4. Tap **Yes** to confirm priming is complete or tap *No* to start priming again.
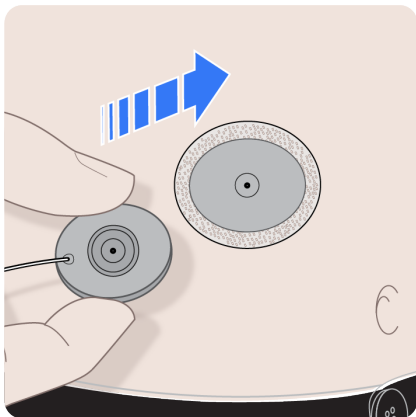
    If drops are not visible when priming is completed, *see "Drops are not visible at end of infusion set when priming." on page 155*.

5. Inspect the luer lock connection and infusion set tubing for unintended leaks. If any leaks are visible, replace the cassette and infusion set tubing.
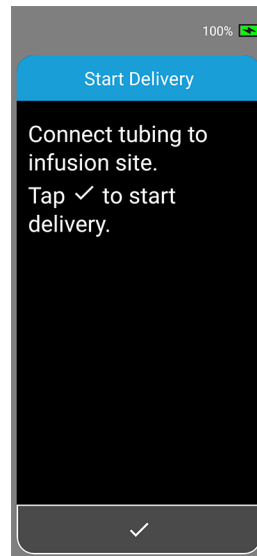
DKUT-09009-001 -1.9

Connect Tubing to Infusion Site and Start Delivery

1. Connect the primed infusion set tubing to the infusion site.

2. Route the infusion set tubing to avoid any sources of kinks that may introduce an *Occlusion* alarm.
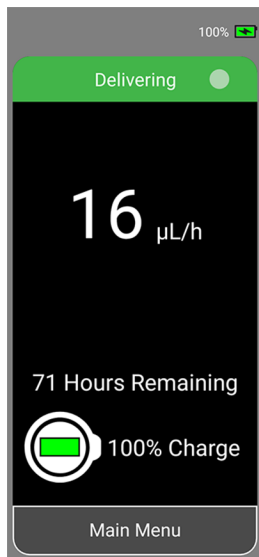
3. Tap ☑ to start delivery.

The pump will play the *Delivering* sounds.

The status bar will turn green to indicate Remodulin delivery is in progress.

4. Verify the delivery rate displayed on the home screen matches your prescribed delivery rate.

5. Wipe up any Remodulin residue with an absorbent towel or cloth and clean any areas that came into contact with Remodulin.

Verify the Pump is Delivering

The pump button is used to verify that Remodulin delivery is in progress.

Press and hold the **pump button** for 3 seconds.

If the pump plays the *Delivering* sounds, the pump is delivering Remodulin.

If the pump plays a *Ready* beep, the pump is not delivering Remodulin and operator action, such as starting delivery or completing a cassette change, is required.

How to Wear the Pump

The pump can be worn in the following ways:

- Attached to clothing with the included pump clip
- Placed in a pocket

Make sure to secure the infusion set tubing and pump to prevent them from catching on other objects.

The pump, with a cassette attached, provides protection from splashing water from any direction.

When the system is used in a loud environment the remote should be kept in a clothing pocket so the vibration of an alarm notification can be felt. Check the system for alarms and alerts if you are in an environment where you cannot feel the remote or hear the system sounds.

Avoid strong magnetic fields created by things like jewelry clasps, magnetic badges, and magnetic toys. Strong magnetic fields can trigger a false *Cassette Removed* alarm.

⚠ Keep the pump, cassette, and infusion set tubing away from sharp objects. Sharp objects may damage these components which may cause delivery errors. Delivery errors may lead to harm.
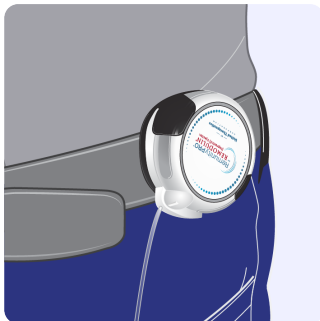
⚠ Pets may damage your infusion set tubing while sleeping which may lead to an interruption of Remodulin delivery or infection. Do not sleep with your infusion set tubing exposed if pets are present.

Pump Clip

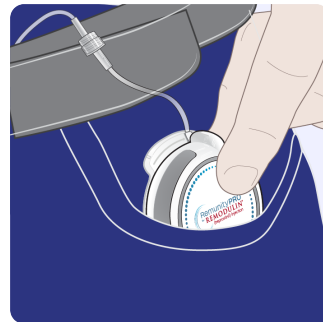1. The pump slides downward into the pump clip with the pump-bump pointing up.

2. Clip to a belt or clothing, where the pump can be firmly supported.

In a Pocket

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

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Cassette Change

Cassette Change is a step-by-step process for changing your cassette and supplies to restart delivery. A cassette change should be performed:

- Within the last 2 hours of therapy after receiving a *Cassette Low* alert.
- Before 72 hours of therapy is complete.

> Check the *Hours Remaining* on your remote so that you will be prepared and have your supplies available when the change is needed.

Gather your Supplies

The following supplies should be kept on hand and are needed for a *Cassette Change:*

- Battery Charger with a Fully Charged Pump Battery
- New Cassette
- New 3 mL Syringe and 27 gauge x 3/8 inch (0.40 mm x 10 mm) or 26 gauge x 3/8 inch (0.45 mm x 10 mm) Needle
- New Infusion Set
- Alcohol Wipes
- Remodulin

Disposable components should be unopened and used before the date on the packaging.

> Cassette change supplies provided with previous versions of the Remunity system are not compatible with the RemunityPRO system.

> Make sure the pump battery charger status light is green, indicating the pump battery is fully charged.

> ⚠️ Do not use sterile components that are past the expiration date on their package. Using expired sterile components may lead to infection.

> ⚠️ Do not use damaged disposable components. Using damaged disposable components may result in start-up failures, interruptions in therapy, or topical exposure to Remodulin.
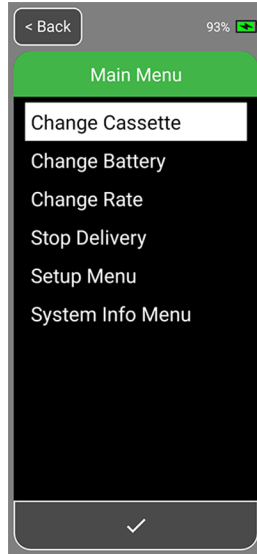
> ⚠️ Do not use disposable components from previously opened or damaged sterile packaging. Use of disposable components from previously opened or damaged sterile packaging may lead to infection.
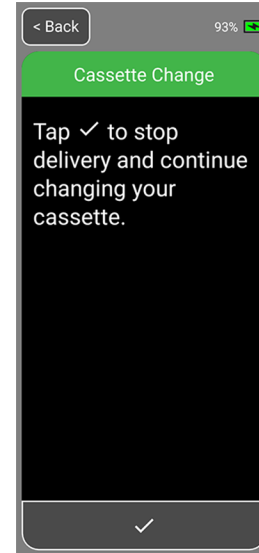
Start Cassette Change

1. Tap **Main Menu**.
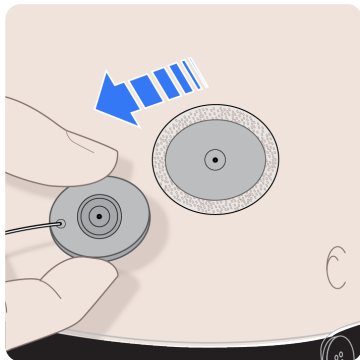
2. Tap **Change Cassette** and ☑ to select.

3. Tap ☑ to stop delivery.

The pump plays the *Delivery Stopped* sounds.

Disconnect from Infusion Site

1. Disconnect the infusion set tubing from your infusion site.

2. Tap ☑ to continue.

> ⚠️ Disconnect the infusion set tubing from your infusion site before removing the cassette from the pump. Unintended delivery of Remodulin may occur if the cassette is removed from the pump before disconnecting from your infusion site.

Remove and Dispose of Used Cassette

Avoid unnecessary contact with the inside of the pump and cassette which are exposed during a cassette change.
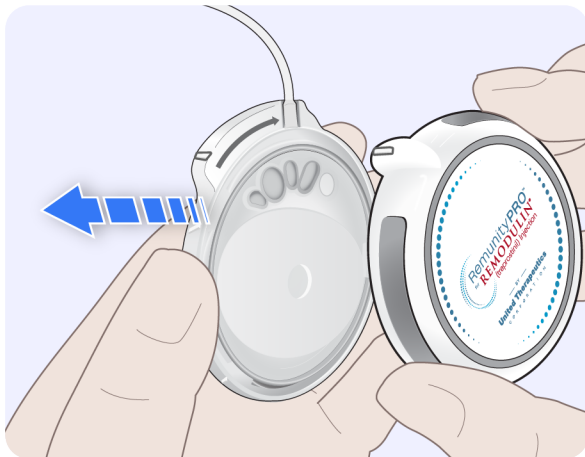
Keep dirt, lubricants, and liquids away from the inside of the pump and cassette which are exposed during a cassette change.

1. Holding the cassette still, rotate the pump counterclockwise until the ridges on the pump-bump and the top of the cassette are aligned.
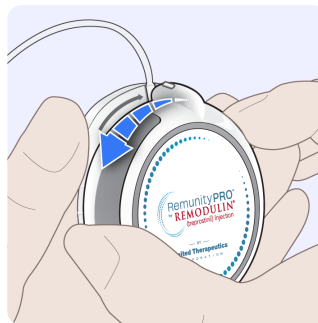
The pump will play a *Ready* beep.

2. Remove the cassette from the pump.

3. Dispose of the used cassette and infusion set tubing.

    Contact local authorities to determine the proper method for disposal of used cassettes and infusion sets.

    Improper disposal of these items may result in injury to the operator and others from exposure to sharp or contaminated components.

Replace Pump Battery

1. Remove the battery from the pump.

2. Insert the depleted battery into the battery charger.

3. Get a fully charged battery from the battery charger.

> This is indicated by a green status light on the battery charger.
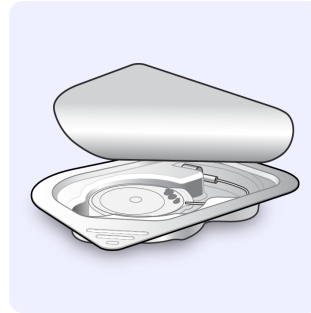

4. Insert the fully charged battery into the pump.

> When the battery is inserted successfully, the pump will play a *Quick* beep followed by a *Ready* beep and the remote will advance automatically.

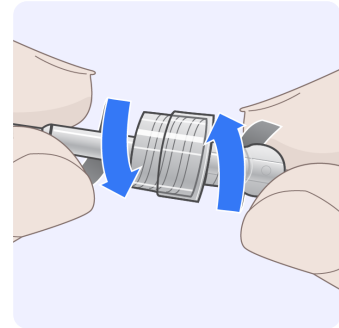# *Prepare New Infusion Set Tubing and New Cassette*

1. Wash your hands with soap and water.

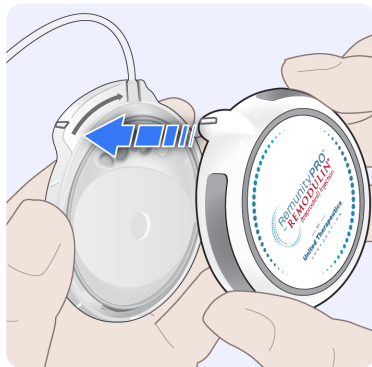2. Open and remove the new cassette and infusion set from their packaging.

3. Attach the new infusion set tubing to the new cassette by twisting the luer connectors together.

Attach New Cassette to Pump

Avoid unnecessary contact with the inside of the pump and cassette which is exposed during a cassette change.

1. Make sure the surfaces of the cassette and the pump are clean and free of fluid and debris.

2. To attach the cassette to the pump, align the ridges on the pump-bump and the top of the cassette.
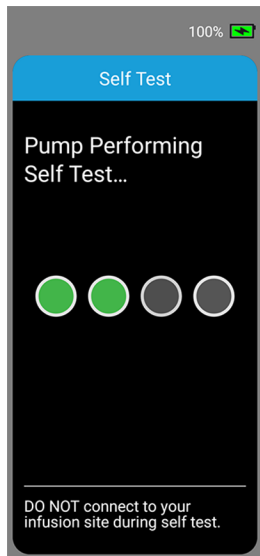

3. Push down and rotate the pump clockwise so the ridge on the pump-bump is aligned with the infusion set tubing.

A series of *busy* beeps will be played by the pump while the pump conducts a *Self Test*. The *Self Test* is displayed on the remote.

If the cassette is not properly attached, a *Remove Cassette* message is displayed. Remove and reattach the cassette to the pump to continue.

4. Wait for the *Self Test* to complete.

100% 🔋

Self Test

Pump Performing
Self Test...

⬤ ⬤ ◯ ◯

DO NOT connect to your
infusion site during self test.

Fill the Cassette

The cassette should be filled with the amount (mL) of Remodulin displayed on your remote. This is determined based on your programmed delivery rate (µL/h).

⚠ Only fill cassettes at the time you plan to use them. Filling a cassette before you plan to use it may result in a change of the drug potency or reduce the purity of the Remodulin prior to use which can lead to harm.
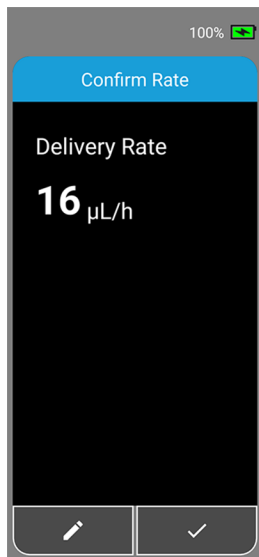
📝 Cassette change supplies provided with previous versions of the Remunity system are not compatible with the RemunityPRO system.

1. Confirm your delivery rate matches your prescribed rate and tap ✅ to continue.

If you need to edit the *Delivery Rate:*
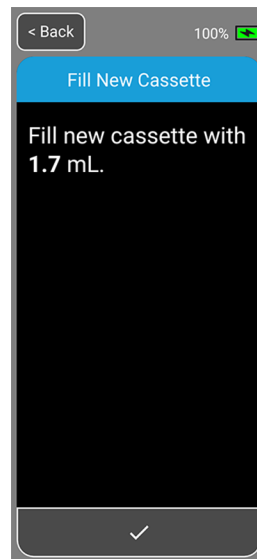
a. Tap 🖊.

b. Enter your 6-digit **passcode** and tap ✅.

c. Use the picker by swiping up or down to change the rate.

d. Tap ✅ to select.

e. Tap **Yes** to confirm the change to the delivery rate or *No* to edit your rate.
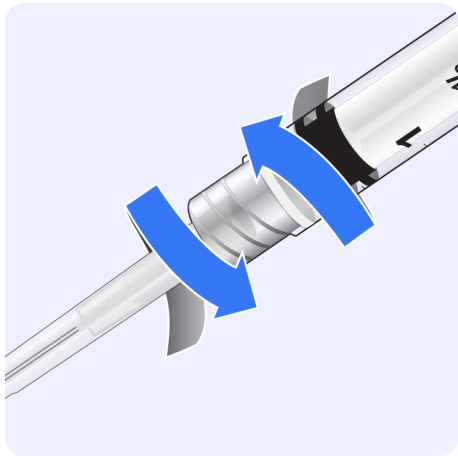
The amount of Remodulin needed to fill the new cassette is displayed.

> Remain on the *Fill New Cassette* screen until after you fill the cassette.
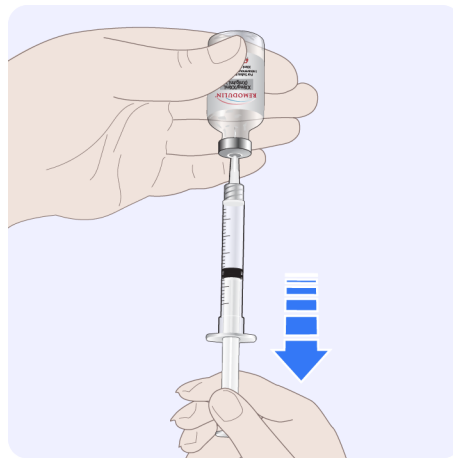
2. Clean the top of the Remodulin vial with an alcohol wipe.

3. Open a new syringe and needle.

4. Attach the needle to the syringe luer connector by twisting until finger tight.

5. Remove the cap from the needle.

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

7. Insert the needle into the vial.

8. Press down on the syringe plunger to add air to the vial.

9. While still holding pressure on the plunger, flip the vial so it is above the syringe.

10. Slowly pull down on the plunger to fill the syringe with the amount (mL) of Remodulin displayed on the remote.

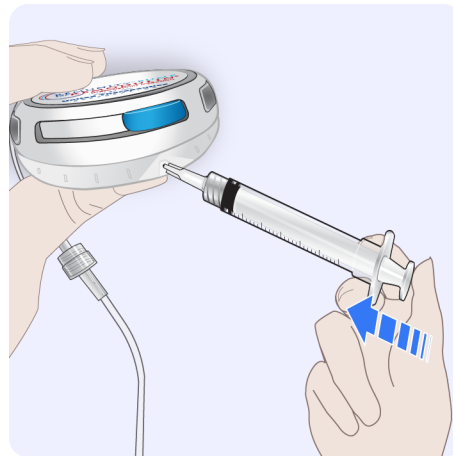11. With the needle facing up and held vertically, tap on the syringe to remove any visible air bubbles.

12. Remove the syringe from the vial.

13. Insert the needle straight into the filling port on the side of the cassette. Do not force the needle.
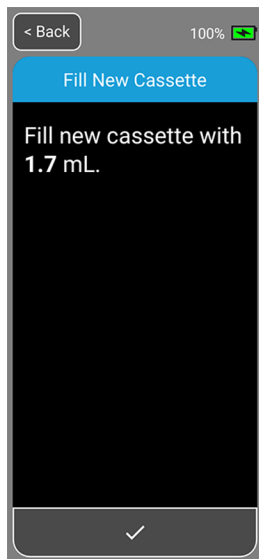

14. Push the syringe plunger down to fill the cassette. Continue to hold the syringe plunger down while removing the needle from the cassette.

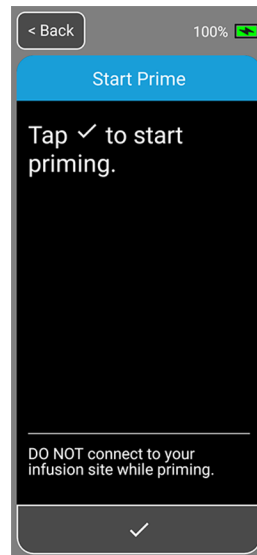15. Dispose of the used syringe and needle in a sharps container.

    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.

16. Tap ✓ to confirm the new cassette was filled with the amount of Remodulin shown on the remote.

< Back   100% 🔋

Fill New Cassette

Fill new cassette with **1.7** mL.

✓

Prime Infusion Set Tubing

1. Tap ✓ to start priming the infusion set tubing.

< Back   100% 🔋

Start Prime

Tap ✓ to start priming.

_____

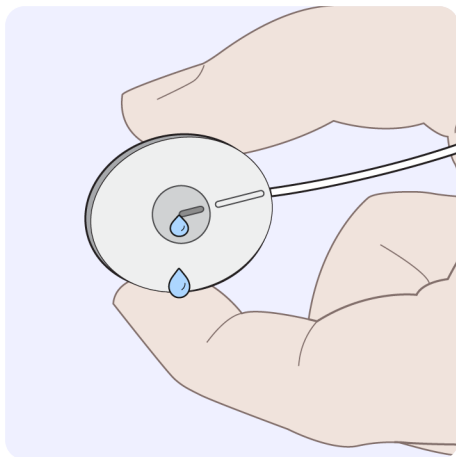DO NOT connect to your infusion site while priming.

✓

A series of *Priming* sounds will be played by the pump as priming occurs.

2. Watch for drops to appear at the end of the infusion set tubing.

   Drops of Remodulin at the end of the infusion set tubing indicates the cassette and tubing are primed.
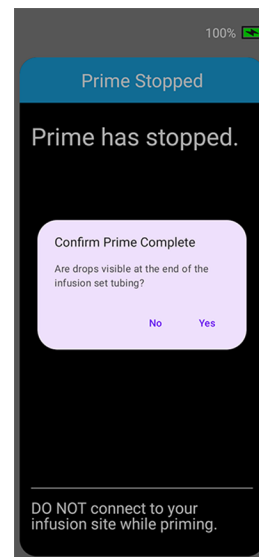
3. When drops are visible at the end of the infusion set tubing tap ☑ on the remote to stop prime.

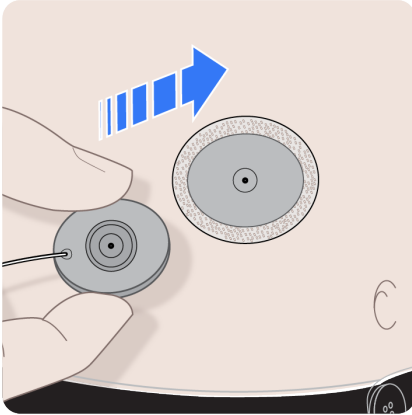4. Tap **Yes** to confirm priming is complete or tap *No* to start priming again.

   If drops are not visible when priming is completed, *see "Drops are not visible at end of infusion set when priming." on page 155*.

5. Inspect the luer lock connection and infusion set tubing for unintended leaks. If any leaks are visible, replace the cassette and infusion set tubing.
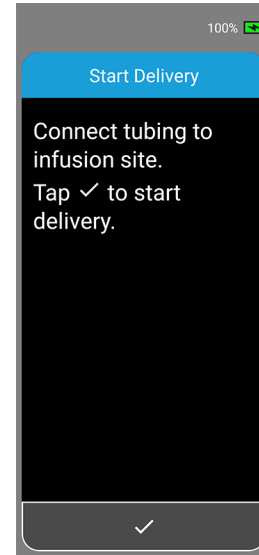
Connect Tubing to Infusion Site and Start Delivery

1. Connect the primed infusion set tubing to the infusion site.

2. Route the infusion set tubing to avoid any sources of kinks that may introduce an *Occlusion* alarm.

3. Tap ☑ to start delivery.

The pump will play the *Delivering* sounds.

The status bar will turn green to indicate
Remodulin delivery is in progress.

4. Verify the delivery rate displayed on the home
   screen matches your
   prescribed delivery rate.

5. Wipe up any Remodulin
   residue with an absorbent
   towel or cloth and clean
   any areas that came into
   contact with Remodulin.
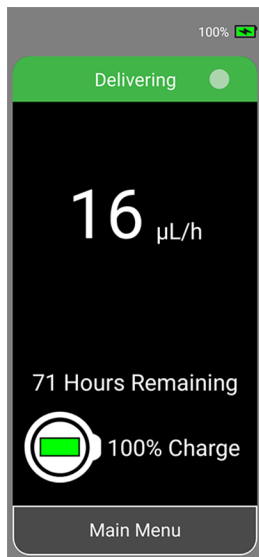
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Main Menu

Main Menu Overview

When delivery is in progress, the *Main Menu* provides access to:

- Change Cassette
- Change Battery
- Change Rate
- Stop Delivery
- Setup Menu
- System Info Menu
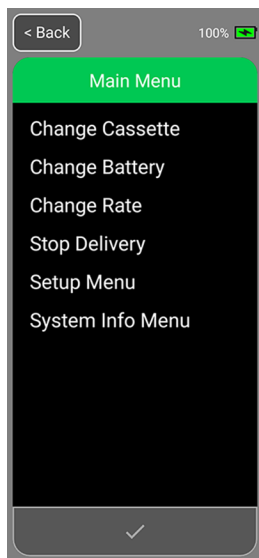
When delivery is not in progress, the *Main Menu* provides access to:

- Change Cassette
- Change Battery/Use Current Cassette
- Change Rate
- Start Delivery
- Setup Menu
- System Info Menu
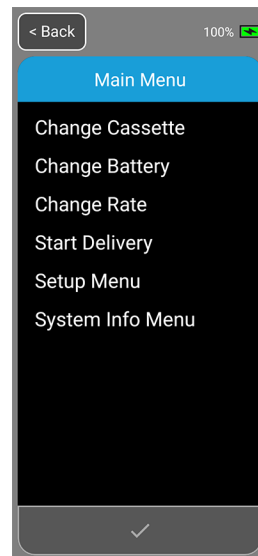
Change Cassette

Cassette Change is a step-by-step process for changing your cassette and supplies to restart delivery. A cassette change should be performed:

- Within the last 2 hours of therapy after receiving a *Cassette Low* alert.
- Before 72 hours of therapy is complete.

Change Battery

If you need to change your pump battery during an infusion and time is remaining in your therapy, a *Battery Change* can be completed to continue with the current cassette.

Gather your Supplies

The following supplies are needed for a battery change:

- Battery Charger with a fully charged pump battery

A fully charged pump battery is indicated by a green status light on the pump battery charger.

Start Battery Change

1. Tap **Main Menu**.

2. Tap **Change Battery** and ☑ to continue.

   If delivery is in progress when the battery change is started, a message is displayed to indicate that delivery must be stopped to continue.

3. Tap ☑ to confirm the request to stop delivery.

   The pump will play the *Delivery Stopped* sounds.

Disconnect from Infusion Site

1. Disconnect the infusion set tubing from your infusion site.
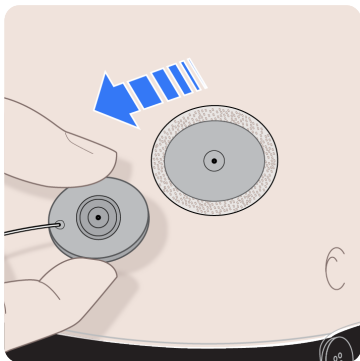
2. Tap ✅ to continue.

> ⚠️ Disconnect the infusion set tubing from your infusion site before removing the cassette from the pump. Unintended delivery of Remodulin may occur if the cassette is removed from the pump before disconnecting from your infusion site.

Remove Cassette from Pump

Avoid unnecessary contact with the inside of the pump and cassette which are exposed during a battery change.

Keep dirt, lubricants, and liquids away from the inside of the pump and cassette which are exposed during a battery change.

1. Holding the cassette still, rotate the pump counterclockwise until the ridges on the pump-bump and the top of the cassette are aligned.

   The pump will play a *Ready* beep.

2. Remove the cassette from the pump.
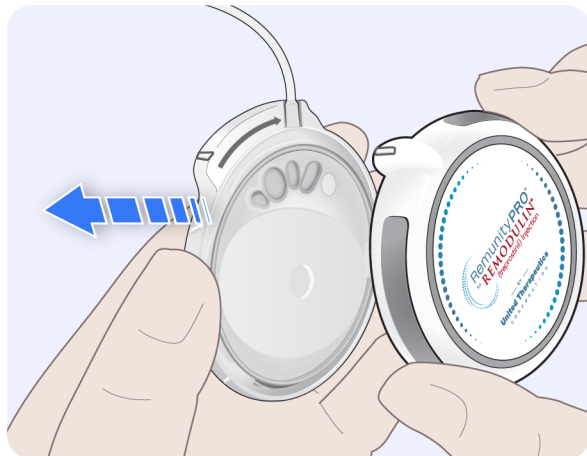
3. Place your cassette and infusion set tubing aside.

⚠️ Dirt, lubricants, or liquids may contaminate inner surfaces of the pump while it is separated from the cassette. Contamination may affect pumping accuracy, which may increase or decrease delivery.

Replace Pump Battery

1. Remove the battery from the pump.

2. Insert the depleted battery into the battery charger.

3. Get a fully charged battery from the battery charger.

This is indicated by a green status light on the battery charger.

4. Insert the fully charged battery into the pump.

When the battery is inserted successfully, the pump will play a *Quick* beep followed by a *Ready* beep and the remote will advance automatically.

Attach Current Cassette to Pump

Avoid unnecessary contact with the inside of the pump and cassette which is exposed during a battery change.

1. Make sure the surfaces of the cassette and the pump are clean and free of fluid and debris.

2. To attach the current cassette to the pump, align the ridges on the pump-bump and the top of the cassette.
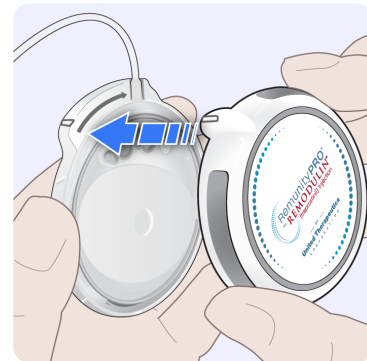
3. Push down and rotate the pump clockwise so the ridge on the pump-bump is aligned with the infusion set tubing.

A series of *Busy* beeps will be played by the pump while the pump conducts a *Self Test*. The *Self Test* is displayed on the remote.

If the cassette is not properly attached, a *Remove Cassette* message is displayed. Remove the cassette and reattach the cassette to the pump to continue.
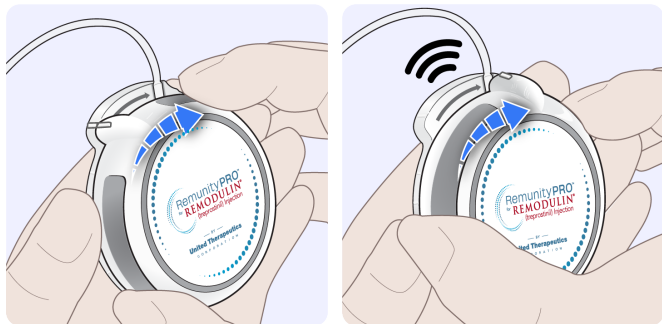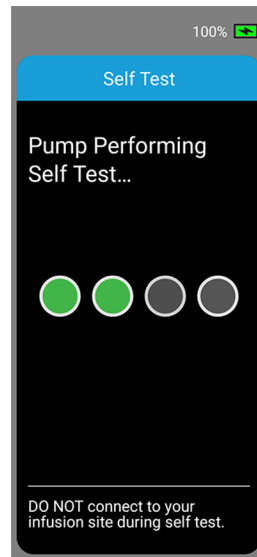
4. Wait for the *Self Test* to complete.

100%

Self Test

Pump Performing Self Test...

DO NOT connect to your infusion site during self test.

⚠️ Do not connect infusion set tubing to your infusion site before the pump completes *Self Test*. Connecting infusion set tubing to your infusion site during *Self Test* may lead to unintended delivery which may lead to harm.

5. Confirm your delivery rate matches your prescribed rate and tap ✅ to continue.

If you need to edit the *Delivery Rate:*

a. Tap ✏️.
b. Enter your 6-digit **passcode** and tap ✅.
c. Use the picker by swiping up or down to change the rate.
d. Tap ✅ to select.
e. Tap **Yes** to confirm the change to the delivery rate or *No* to edit or select a different rate.

100% 🔋

Confirm Rate

Delivery Rate

16 µL/h

✏️   ✓

Connect Tubing to Infusion Site and Start Delivery

1. Connect the primed infusion set tubing to the infusion site.

2. Route the infusion set tubing to avoid any sources of kinks that may introduce an *Occlusion* alarm.

3. Tap ☑ to start delivery.

The status bar will turn green to indicate Remodulin delivery is in progress.

4. Verify the delivery rate displayed on the home screen matches your prescribed delivery rate.

The pump will play the *Delivering* sounds.

> To ensure continuous therapy, *see "Backup Supplies" on page 25*.

Use Current Cassette

A *Use Current Cassette* option is displayed within the *Main Menu* if you tapped *Cancel* while resolving an alarm, or if the cassette has been removed from the pump and re-attached while delivery is stopped.

Use Current Cassette allows delivery to resume with the cassette that was previously in use without the need to perform a full cassette change.

1. Tap **Main Menu**.
2. Tap **Use Current Cassette** and ☑ to continue.
3. Tap ☑ to confirm you are using your current cassette.
4. Continue to *"Replace Pump Battery" on page 86*.

92
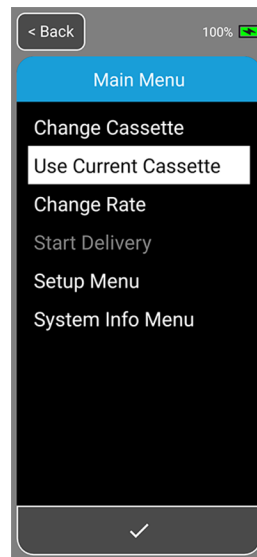
Change Rate

The pump can deliver Remodulin at rates from 8 to 225 µL/h (0.008 to 0.225 mL/h), in 1 µL/h (0.001 mL/h) increments.

Delivery rates can be changed while infusion is in progress. Changing the rate may affect the hours remaining for delivery. The pump and remote must be in communication to change the delivery rate.

⚠️ **Programming the delivery rate incorrectly will lead to Remodulin dosage errors. The delivery rate should always be set with direction from your Specialty Pharmacy or healthcare provider.**

1. Tap **Main Menu**.

2. Tap **Change Rate** and ☑ to continue.

```
< Back                    100% 🔋

          Main Menu

   Change Cassette
   Change Battery
   Change Rate
   Stop Delivery
   Setup Menu
   System Info Menu


              ✓
```
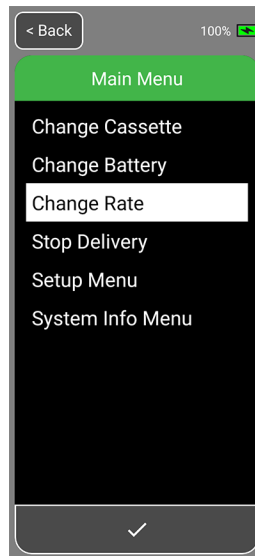
3. Enter your 6-digit **passcode** and tap ☑.

4. Use the picker by swiping up or down to change the delivery rate.

5. After the delivery rate has been changed, tap ✅ to continue.

6. Tap **Yes** to confirm your delivery rate or *No* to edit or select a different rate.

   The pump will play the *Delivering* sounds.

```
< Back                    84% 🔋

        Set Delivery Rate

              15

              16   μL/h

              17

                ✓
```
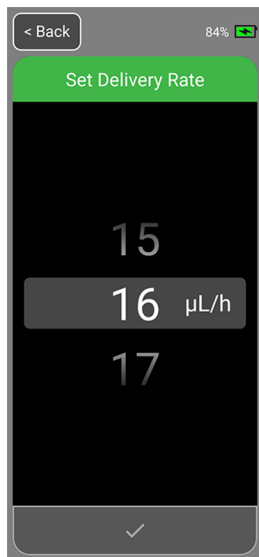
7. A *Time Remaining* message is displayed to inform you that your estimated time remaining has been updated, tap ✅ to continue.

```
                          100% 🔋

         Time Remaining

    Estimated time
    remaining updated
    to 66 Hours




                ✓
```
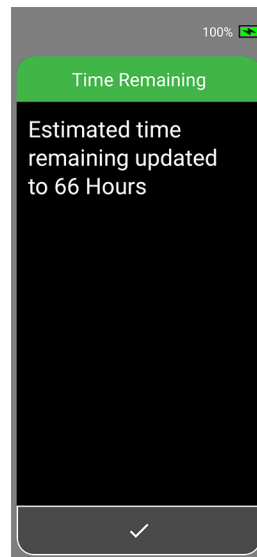
The home screen displays the updated delivery rate and the *Hours Remaining* until the next cassette change.

100% 🔋

Delivering ⬤

16 μL/h

66 Hours Remaining

🔋 100% Charge
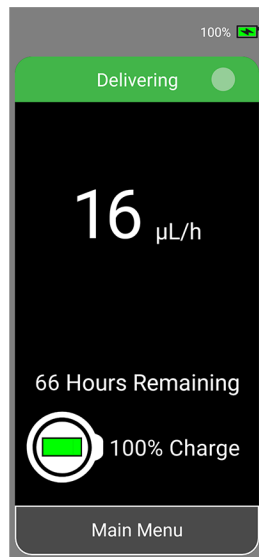
Main Menu

The *Hours Remaining* is estimated based on the cassette fill volume and programmed delivery rate.

Stop Delivery

1. Tap **Main Menu**.
2. Tap **Stop Delivery** and ✓ to continue.
3. Tap ✓ to confirm the request to stop delivery.
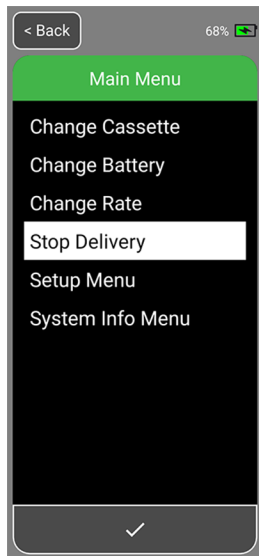
When the pump has stopped delivery:

- Pump plays the *Delivery Stopped* sound
- Status bar will turn blue and displays *Pump Stopped*.

Start Delivery

The pump and remote must be in communication to start delivery. The status bar will be blue to indicate that the remote and pump are communicating and delivery is not in progress.

1. Tap **Main Menu**.

2. Tap **Start Delivery** and ☑ to continue.
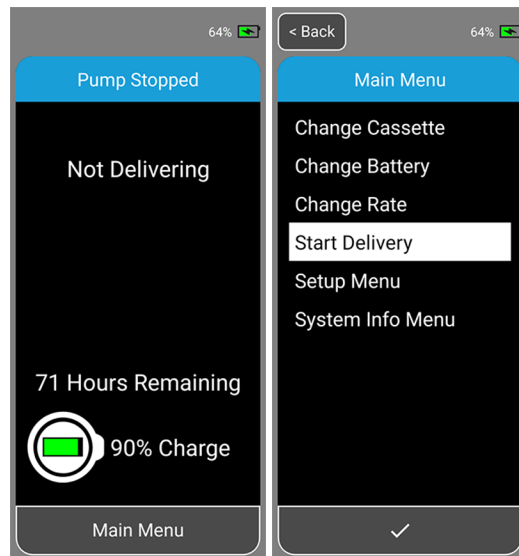
3. Confirm your delivery rate and tap ✓ to start delivery.
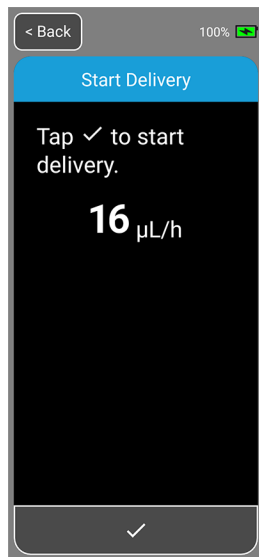
The pump will play the *Delivering* sound. The status bar will turn green to indicate Remodulin delivery is in progress.
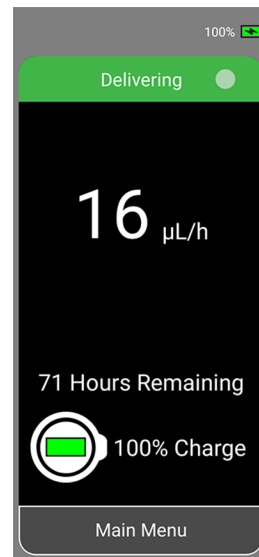
Setup Menu

The *Setup Menu* is used to set your personal preferences related to the RemunityPRO system.

1. From the *Home Screen*, tap **Main Menu**.

2. Tap **Setup Menu** and ☑ to select.
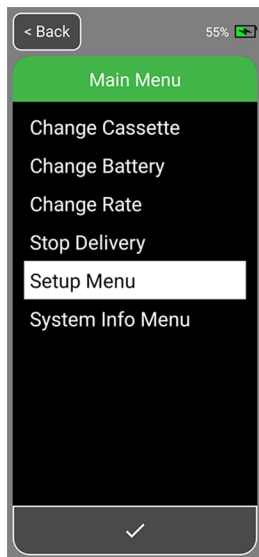
Setup Menu provides access to the following features:

- Pair a Pump
- Screen Timeout
- Screen Brightness
- Remote Audio
- Change Passcode
- Factory Reset

Pair a Pump

Pair a Pump allows the RemunityPRO remote to be paired to the RemunityPRO pump that has the same numeric serial number in the event that pairing is lost.

> ⚠️ Always have your backup supplies available, including your alternate pump and remote set, and all of the supplies necessary to complete a cassette change. Your backup supplies may be needed if delivery stops unexpectedly or the pump fails.

Remote displays: *No communication with pump.*

1. Tap **Main Menu**.

2. Tap **Setup Menu** and ☑.

3. Tap **Pair a Pump** and ☑.

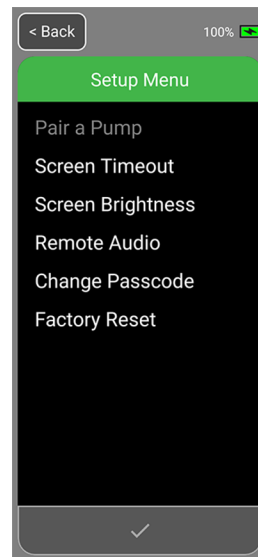   *Select a Pump* is displayed and the remote is ready to pair to the pump with the same numeric serial number.

If your pump is *Delivering*, continue to *Step 4*.

If your pump is not *Delivering*, go to *Step 7*.

4. Disconnect infusion set tubing from the infusion site.

5. Remove the cassette from the pump.

    Removing the cassette from the pump while delivery is in progress will cause a *Cassette Removed* alarm.

[Remote screen: 97% battery, Searching, No communication with pump., ⓘ, Main Menu]
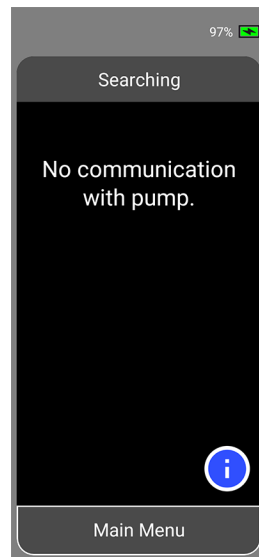
6. Remove the pump battery to silence the alarm.

7. Insert a fully charged battery into the pump.

   The pump will play a *Quick* beep followed by a single *Ready* beep.

   Wait for the *Ready* beep before advancing.

8. Place the pump and remote within 2 in (5 cm) of each other during the pairing process.

9. Press and hold the blue **pump button** for 5 seconds until an additional *Ready* beep is played.

   Only the pump with the same numeric serial number will be displayed.

   If the *Ready* beep is not played before holding the blue pump button, the pump will not enter pairing mode.

If a pump serial number is not displayed after pressing and holding the pump button, check the numeric portions of the pump and remote serial numbers are the same.
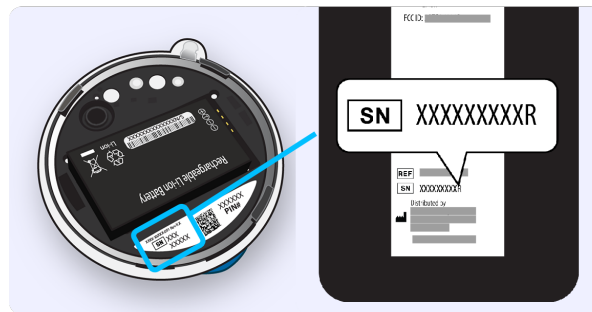
10. Tap ☑ to select the pump serial number.

11. Tap **Yes** to confirm.

12. Using the keypad, enter the pump **PIN** and ☑.

13. Upon successful pairing,

    tap ☑ to continue.

14. Continue with a new or current cassette to start delivery.

Pair a Pump

To continue with your current cassette:

1. Tap ✅ to select *Current Cassette*.
2. Tap ✅ to confirm you are using your current cassette.
3. Attach your current cassette to the pump.
4. Wait for *Self Test* to complete before continuing.
5. Confirm your delivery rate and tap ✅ to continue.
6. Connect the infusion set tubing to the infusion site.
7. Tap ✅ to start delivery.

To continue with a new cassette:

1. Tap **New Cassette** and ✅ to continue.
2. Tap ✅ to confirm you are using a new cassette.
3. Gather supplies, wash your hands, and follow cassette change steps starting from

DKUT-09009-001 -1.9

Screen Timeout

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

1. From the *Home Screen*, tap **Main Menu** at the bottom of the screen.

2. Tap **Setup Menu** and ☑ to select.

3. Tap **Screen Timeout**
   and ☑ to select.

4. Tap **-** and **+** to adjust the time:
   - One minute
   - Two minutes
   - Five minutes
   - Ten minutes

5. Tap ☑ to accept your selection.

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

Screen Brightness

The *Screen Brightness* feature allows you to change the brightness of the remote screen.

1. From the *Home Screen*, tap **Main Menu** at the bottom of the screen.

2. Tap **Setup Menu** and ☑ to select.

3. Tap **Screen Brightness** and ☑ to select.

4. Tap and slide the bar or use ⌄⌃ to adjust the remote screen brightness.

5. Tap `< Back` to return to the *Setup Menu*.

< Back	100%

Screen Brightness

70 %
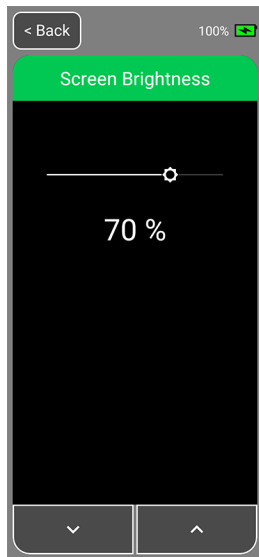
Remote Audio

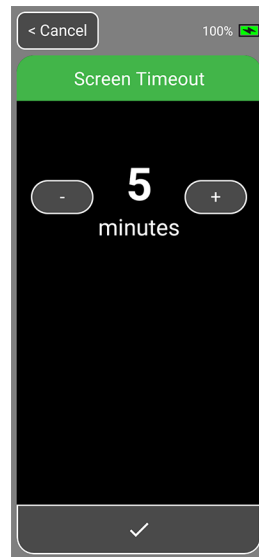The *Remote Audio* feature controls the feedback and volume options for the remote.

1. From the *Home Screen*, tap **Main Menu** at the bottom of the screen.

2. Tap **Setup Menu** and ☑ to select.

3. Tap **Remote Audio** and ☑ to select.

To change the Feedback Option:

The *Feedback* option that is currently selected is highlighted.

1. Tap ☑ to change the feedback option.

2. Use the picker by swiping up or down to select one of the three feedback options:
   - Audio Only
   - Vibration Only
   - Audio and Vibration
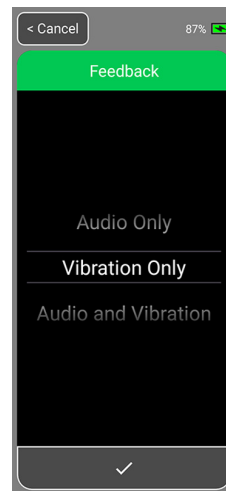
3. Tap ☑ to accept your selection.

To change the Volume Level:

1. Tap **Volume** and ☑ to select.
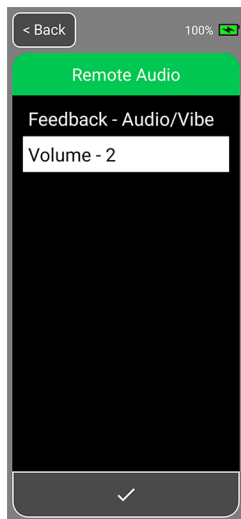
2. Tap **-** and **+** to adjust the volume level.
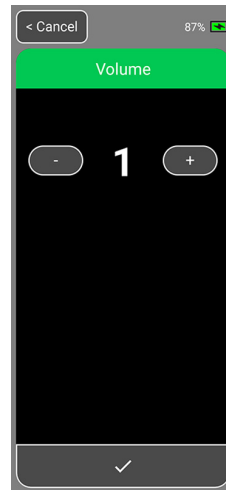
The remote will play a sound at the selected volume level as the volume level is increased or decreased.

3. Tap ☑ to accept your selection.

Change Passcode

A *Passcode* was programmed during the first time set up to provide additional security when updates to the *Delivery Rate* are needed.

> Your passcode should not be shared with unauthorized users.

To change the passcode:

1. From the *Home Screen*, tap **Main Menu** at the bottom of the screen.

2. Tap **Setup Menu** and ✓ to select.

3. Tap **Change Passcode** and ✓ to select.

4. Using the keypad, enter your current 6-digit **passcode**.
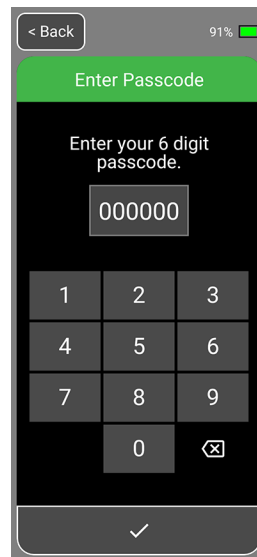
5. Tap ✓ to continue.

6. Enter your **new passcode** and tap ☑ to continue.

7. Enter your **new passcode again** and tap ☑ to confirm.

< Back	90% ▭
New Passcode	
Set a 6 digit passcode.	
000000	
1	2	3
4	5	6
7	8	9
	0	⌫
✓	

< Back	90% ▭
Confirm Passcode	
Confirm your 6 digit passcode.	
000000	
1	2	3
4	5	6
7	8	9
	0	⌫
✓	

Forgot My Passcode

If you have forgotten your *Passcode*, you will need to follow the steps to factory reset your remote. *See "Remote Factory Reset" on the facing page.*

Remote Factory Reset

A *Factory Reset* should not be performed unless directed by your Specialty Pharmacy.

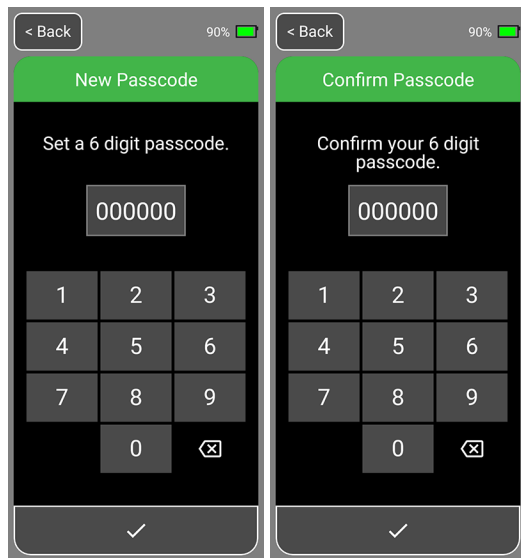1. From the *Home Screen*, tap **Main Menu** at the bottom of the screen.

2. Tap **Setup Menu** and ✓.

3. Tap **Factory Reset** and ✓.

4. Press ✓ to reset the remote to the defaults and disconnect from the pump or tap `< Back` to return to the *Setup Menu*.
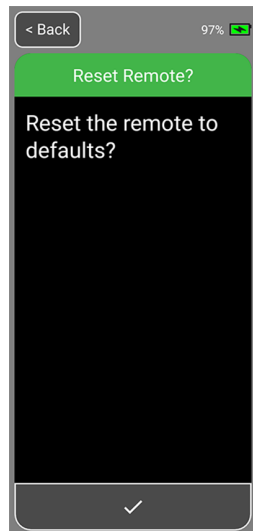
5. Tap ✓ to set a passcode.

6. Use the keypad to enter a 6-digit passcode and tap ✓.

7. Enter your passcode again and tap ✓ to confirm passcode.

   Select a Pump is displayed and the remote is ready to pair to the pump it was originally packaged with.

8. Disconnect infusion set tubing from the infusion site.

9. Remove the cassette from the pump.

   Removing the cassette from the pump while delivery is in progress will cause a *Cassette Removed* alarm.

10. Remove the pump battery to silence the alarm.

11. Insert a fully charged battery into the pump.
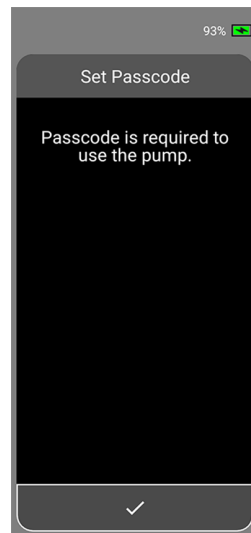
The pump will play a *Quick* beep followed by a single *Ready* beep.

Wait for the *Ready* beep before advancing.

12. Place the pump and remote within 2 in (5 cm) of each other during the pairing process.

13. Press and hold the blue **pump button** for 5 seconds until an additional *Ready* beep is played.

Only the pump with the matching numeric serial number will be displayed.

> If the *Ready* beep is not played before holding the blue pump button, the pump will not enter pairing mode.

If a pump serial number is not displayed after pressing and holding the pump button, check the numeric portions of the pump and remote serial numbers are the same.
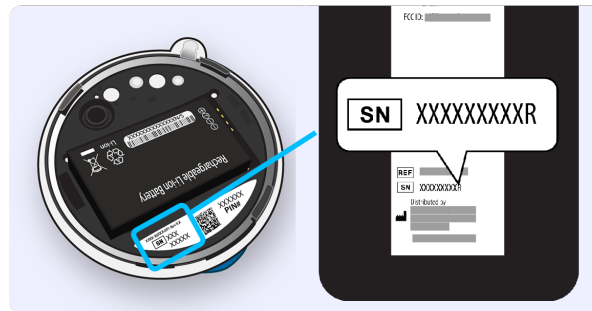
14. Tap ☑ to select the pump serial number.

15. Tap **Yes** to confirm.

16. Using the keypad, enter the pump **PIN** and tap ☑.

17. Upon successful pairing, tap ☑ to continue.

18. Continue with a new or current cassette to start delivery.

To continue with your current cassette:

1. Tap ✓ to select *Current Cassette*.
2. Tap ✓ to confirm you are using your current cassette.
3. Attach your current cassette to the pump.
4. Wait for *Self Test* to complete before continuing.
5. Confirm your delivery rate and tap ✓ to continue.
6. Connect the infusion set tubing to the infusion site.
7. Tap ✓ to start delivery.

To continue with a new cassette:

1. Tap **New Cassette** and ✓ to continue.
2. Tap ✓ to confirm you are using a new cassette.
3. Gather supplies, wash your hands, and follow cassette change steps starting from *"Prepare New Infusion Set Tubing and New Cassette" on page 70*.

System Info Menu

Information about the paired pump, current cassette, and event history is available within the *System Info Menu*.

The system stores at least four months of history. When additional history can not be stored, the oldest records are discarded.

1. From the *Home Screen*, tap **Main Menu** at the bottom of the screen.

2. Tap **System Info Menu** and ☑ to select.
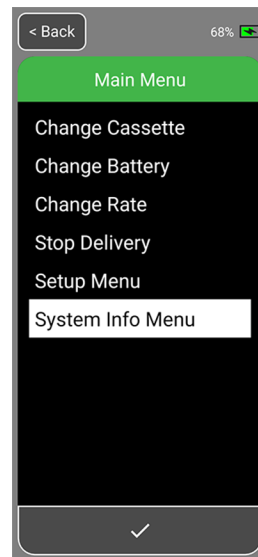
System info includes details about:

- Your paired pump
- Estimated volume remaining in the cassette
- Volume delivered over the last 24 hours
- Events including:
  - Delivery Start and Stop
  - Delivery Rate Changes
  - Alarms and Alerts
  - Cassette Change
  - Pump Self Test
  - Pump Battery Change
  - Remote Power On and Off

< Back	89%

System Info Menu

Paired Pump

Cassette Info

Previous 24 Hours

Event History

About

✓
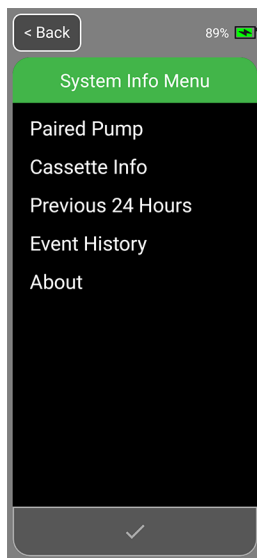
> System info is not impacted by loss of system power or by powering off the system.

Paired Pump

Paired Pump displays the serial number of the pump that is paired to the remote.

1. Tap **Main Menu**.

2. Tap **System Info Menu** and ☑ to continue.

3. Tap **Paired Pump** and ☑ to select.

< Back	90%
System Info Menu	
Paired Pump	
Cassette Info	
Previous 24 Hours	
Event History	
About	
✓	
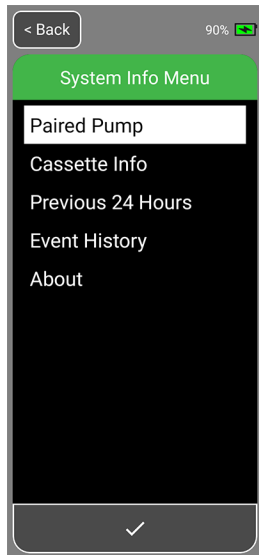
The serial number of the paired pump is displayed.

< Back	100%
Paired Pump	
You are paired to 23032037D	
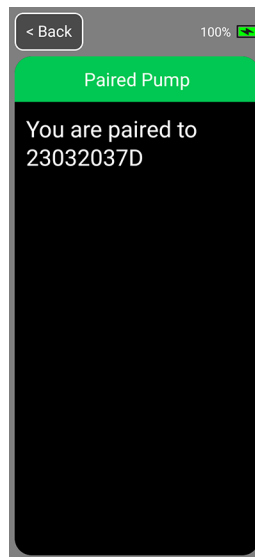
4. Tap < Back to return to the *System Info Menu.*

Cassette Info

Cassette Info displays the estimated volume remaining in the cassette.

1. Tap **Main Menu**.
2. Tap **System Info Menu** and ☑ to continue.
3. Tap **Cassette Info** and ☑ to select.

< Back	90% 🔋
System Info Menu	
Paired Pump	
Cassette Info	
Previous 24 Hours	
Event History	
About	
✓	
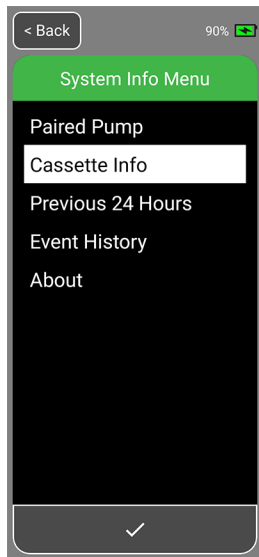
4. Review the *Estimated volume remaining in the cassette*.

< Back	97% 🔋
Cassette Info	
Estimated volume remaining in the cassette is: **784** µL	
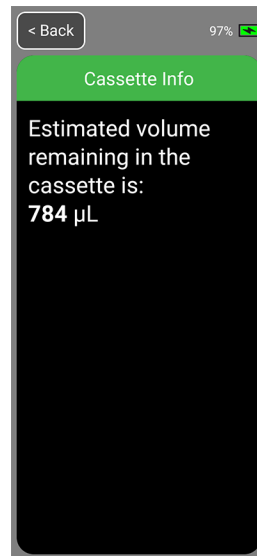
5. Tap < Back to return to the *System Info Menu*.

Previous 24 Hours

Previous 24 Hours provides information on the amount of Remodulin delivered and the amount of time delivery was in progress with this pump during the previous 24 hours.

1. Tap **Main Menu**.
2. Tap **System Info Menu** and ✓ to continue.
3. Tap **Previous 24 Hours** and ✓ to select.
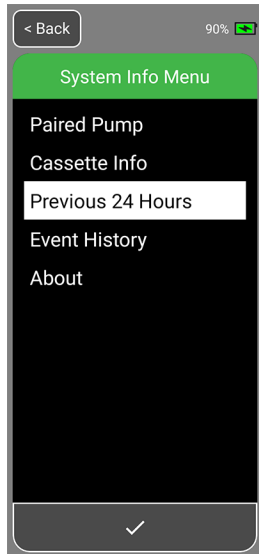
The volume of Remodulin delivered, and the amount of time delivery was in progress are displayed.

4. Tap `< Back` to return to the *System Info Menu*.

DKUT-09009-001 -1.9
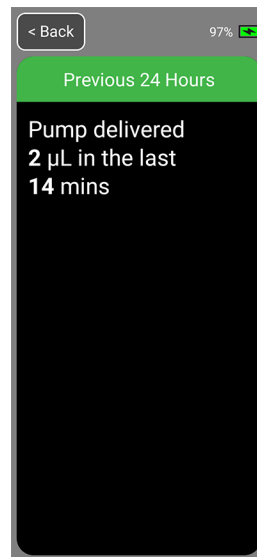
Event History

The *Event History* displays the history of events recorded by the RemunityPRO system, including a description of the event, and how long ago the event occurred.

Events are maintained when the RemunityPRO system is powered down or loses power.

1. Tap **Main Menu**.
2. Tap **System Info Menu** and ☑ to continue.
3. Tap **Event History** and ☑ to select.
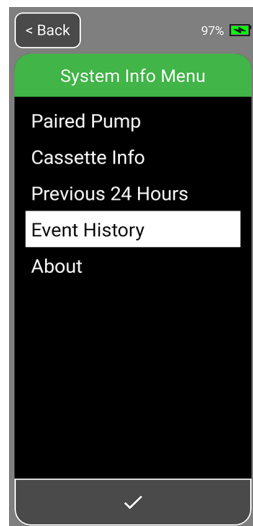
The most recent *Event History* information is displayed.

Event Type — Delivery Started
How long ago the event occurred — **45** s ago
Additional information (if applicable) — **8** µL/h

4. Tap ← → to scroll through *Event History*.
5. Tap < Back to return to *System Info Menu*.

About

About displays software version information, which may be useful if technical support is required.

1. Tap **Main Menu**.
2. Tap **System Info Menu** and ☑ to continue.
3. Tap **About** and ☑ to select.

To view the support menu:

1. Tap ⚙.
2. Tap `< Back` to return back to the previous screen.
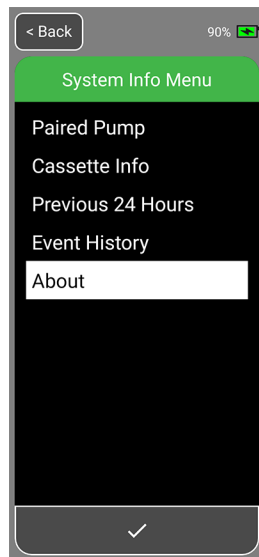
To view the Software Versions:

1. Tap ❓.
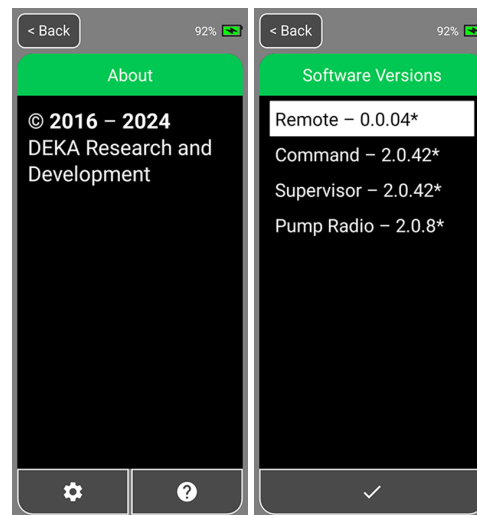
2. Tap any of the software versions and ☑ to view additional information.

3. Tap ☑ to return back to the *Software Versions* list.

About Alerts and Alarms

Alerts and *Alarms* are generated by the remote and pump to let you know the system requires your attention.

⚠️	When an alert is occurring, the name and details of the alert is displayed and the pump plays the *Alert* sounds. Alerts may occur while delivery is in progress or while delivery is stopped. An alert does not change the state of delivery. Alerts should be addressed as soon as possible to ensure continuous delivery.
🔺	When an alarm is occurring, the name and details of the alarm is displayed and the pump plays the *Alarm* sounds. Delivery is stopped and the alarm should be addressed right away.

Alarms are higher priority than alerts. In the event an alert and alarm occur at the same time, the alarm will be displayed on the remote. Alerts for the pump are always treated with higher priority than alerts for the remote.

Alerts and alarms that have not been silenced within 5 minutes will escalate to the maximum volume on the remote and the pump. The remote will also vibrate regardless of the *Remote Audio* setting.

All alarms and some alerts display an information icon ⓘ that can be tapped for more information.

If < Cancel is tapped during alarm resolution, the home screen is displayed. Upon returning to the main menu, only the available options will be displayed, which may include *Change Cassette* and *Use Current Cassette*. Some alarms, such as *Cassette Empty*, require a *Cassette Change* to be completed to proceed. For those alarms, the *Use Current Cassette* option is not available.

⚠️ Do not perform troubleshooting steps while the pump is connected to your infusion site. Performing troubleshooting steps while the pump is connected to your infusion site may lead to unintended delivery of Remodulin, which may lead to harm.

When the RemunityPRO system is used in a loud environment the remote should be kept in a clothing pocket, close to the body, so the vibration from an alert or alarm notification can be felt. Check the system for alarms and alerts if you are in an environment where you may not be able to feel or hear RemunityPRO system alert or alarm notifications.

Alerts

Adjust Pump Alert

Alert Display	Description:
  Alert Adjust Pump Move pump closer to the infusion site. **Sounds** Pump: No sound for 5 minutes. Alert upon escalation. Remote: Alert	The pump needs to be moved closer to the infusion site.
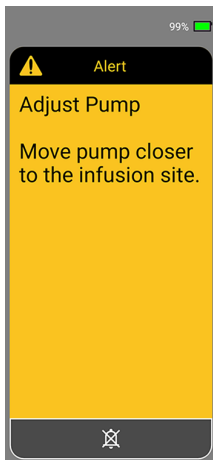
Description:

The pump needs to be moved closer to the infusion site.

What To Do:

1. Tap ⌧ to silence the alert.
2. Tap ☑ to dismiss the alert screen.
3. Move the pump closer to the infusion site.

Cassette Low Alert
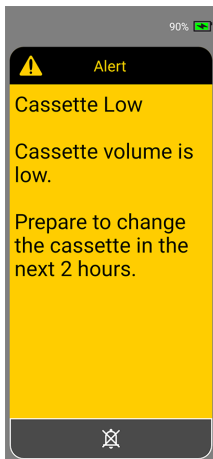
Alert Display	Description:
 90% 🔋 ⚠ **Alert** Cassette Low Cassette volume is low. Prepare to change the cassette in the next 2 hours. 🔕 **Sounds** Pump: No sound for 5 minutes. Alert upon escalation. Remote: Alert	The cassette volume is low. A cassette change should be completed within the next 2 hours. **What To Do:** 1. Tap 🔕 to silence the alert. 2. Tap ☑ to dismiss the alert screen. 3. Prepare to complete a cassette change in the next 2 hours. *See "Cassette Change" on page 63.*

Charge Remote Alert
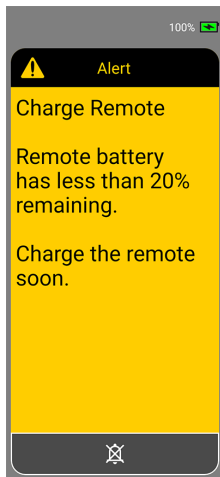
Alert Display	Description:
  Sounds Pump: No sound Remote: Alert	The remote has less than 20% remaining. The remote should be charged soon.
	What To Do: 1. Tap ⊠ to silence the alert. 2. Tap ☑ to dismiss the alert screen. 3. Use the supplied wall power adapter and USB cable to charge the remote. The remote is fully functional while charging.

Message Timeout Alert
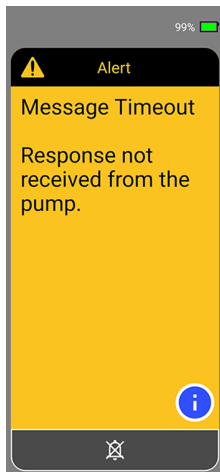
Alert Display	**Description:**
Sounds Pump: No sound Remote: Alert	The remote did not receive a response from the pump for the last message that was sent.

What To Do:

1. Tap ⊠ to silence the alert.

   For more information about the *Message Timeout* alert, tap ⓘ. Tap ‹ Back to return to the alert.

2. Tap ☑ to dismiss the alert screen.

3. Repeat the last action.

No Communication Alert
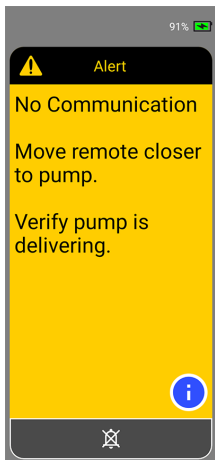
Alert Display	Description:
91% 🔋 ⚠ **Alert** No Communication Move remote closer to pump. Verify pump is delivering. ⓘ ⊠	The remote and pump have not been in communication for 10 hours.

	What To Do:
Sounds Pump: No sound Remote: Alert	1. Tap ⊠ to silence the alert. For more information about the *No Communication* alert, tap ⓘ. Tap `< Back` to return to the alert. 2. Tap ☑ to dismiss the alert screen. 3. Move the remote closer to the pump and confirm that the pump is delivering.

Pairing Failed Alert

Alert Display	Description:
	The pump and remote were not able to pair.
	This alert can occur if:
	• The pump PIN was entered incorrectly.
	• Communication with the pump was lost:
	- the pump and remote are too far away from each other
	- the pump battery was removed during pairing
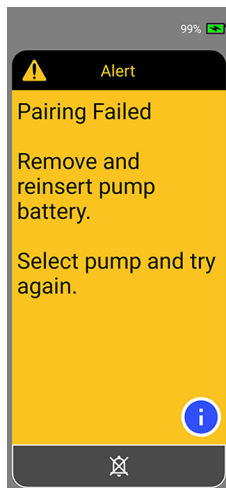
Alert Display

Sounds

Pump: No sound

Remote: Alert

Description:

The pump and remote were not able to pair.

This alert can occur if:

- The pump PIN was entered incorrectly.
- Communication with the pump was lost:
  - the pump and remote are too far away from each other
  - the pump battery was removed during pairing

What To Do:

1. Tap ⊠ to silence the alert.

   For more information about the Pairing Failed alert, tap ⓘ.
   Tap < Back to return to the alert.

2. Tap ☑ to dismiss the alert screen.

3. Follow the steps to *Pair a Pump*.

Pairing Lost Alert
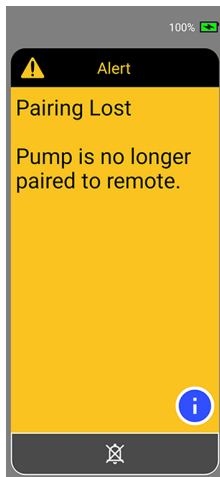
Alert Display	**Description:**
100% 🔋	The pump has been placed into pairing mode by pressing the blue pump button for 5 seconds. The remote that was paired to the pump generates a *Pairing Lost* alert when the pump is in communication range.
⚠ **Alert**	
Pairing Lost	
Pump is no longer paired to remote.	
ⓘ	
🔕	
Sounds	**What To Do:**
Pump: No sound	1. Tap 🔕 to silence the alert.
Remote: Alert	For more information about the *Pairing Lost* alert, tap ⓘ . Tap `< Back` to return to the alert.
	2. Tap ☑ to dismiss the alert screen.
	3. Follow the steps to *Pair a Pump.* *See "Pair a Pump" on page 100.*

Pump Battery Low Alert
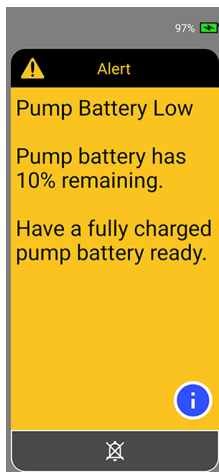
Alert Display	Description:
	The pump battery is low and has 10% power remaining.

Sounds

Pump: No sound for 5 minutes. Alert upon escalation.

Remote: Alert

What To Do:

1. Tap ⊠ to silence the alert.

   For more information about the *Pump Battery Low* alert, tap ⓘ. Tap `< Back` to return to the alert.

2. Tap ☑ to dismiss the alert screen.

3. Follow the steps to change your pump battery to continue using your current cassette, or complete a *Cassette Change*. *See "Change Battery" on page 84 or "Cassette Change" on page 63.*

Pump Idle Alert
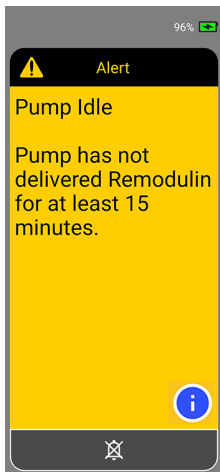
Alert Display	**Description:**
96% 🔋 ⚠️ **Alert** Pump Idle Pump has not delivered Remodulin for at least 15 minutes. ℹ️ 🔕 **Sounds** Pump: No sound for 5 minutes. Alert upon escalation. Remote: Alert	The pump has not been delivering Remodulin for at least 15 minutes. Reasons why Remodulin delivery may be stopped: • Delivery has been stopped manually. • An alarm has occurred and has not been resolved. • Cassette or battery change are in progress. **What To Do:** 1. Tap 🔕 to silence the alert. For more information about the *Pump Idle* alert, tap ℹ️ . Tap < Back to return to the alert. 2. Tap ☑️ to dismiss the alert screen.

If you are in the middle of a cassette or battery change when a pump idle alert occurs, continue with the cassette or battery change steps.

Otherwise, follow these steps to resume delivery:

1. Tap **Main Menu**.
2. Tap **Start Delivery** to highlight the menu option.
3. Tap ☑ to select *Start Delivery*.
4. Confirm the infusion set tubing is connected to the infusion site.
5. Confirm the delivery rate and tap ☑ to *Start Delivery*.

Remote Error Alert
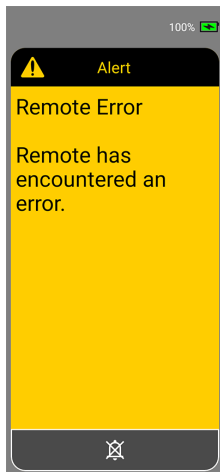
Alert Display	**Description:**
100% ⚠ **Alert** Remote Error Remote has encountered an error. 🔇	The remote has encountered an error.
Sounds Pump: No sound Remote: Alert	**What To Do:** 1. Tap 🔇 to silence the alert. 2. Tap ☑ to dismiss the alert screen. 3. Your remote will restart. 4. If the alert occurs again, switch to your alternate pump and remote set and call your Specialty Pharmacy for a replacement pump and remote.

Request Refused Alert
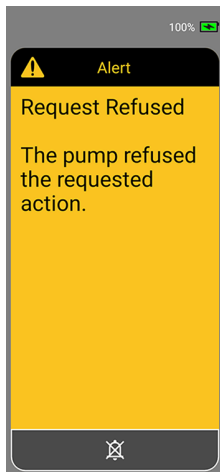
Alert Display	**Description:**
100%	The remote sent a message to the pump and an error occurred.
⚠ **Alert**	
Request Refused	
The pump refused the requested action.	
⊠	**What To Do:**
Sounds	1. Tap ⊠ to silence the alert.
Pump: No sound	2. Tap ☑ to dismiss the alert screen.
Remote: Alert	3. Repeat the last action.
	4. If the alert occurs again, switch to your alternate pump and remote set and call your Specialty Pharmacy for a replacement pump and remote.

Software Version Alert
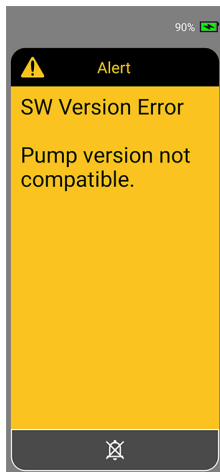
Alert Display	Description:
Alert Display 90% ⚠ **Alert** SW Version Error Pump version not compatible. ⊠ **Sounds** Pump: No sound Remote: Alert	**Description:** The pump and remote being paired are not compatible. **What To Do:** 1. Tap ⊠ to silence the alert. 2. Tap ☑ to dismiss the alert screen. 3. Contact your Specialty Pharmacy to obtain a replacement pump and remote.

Alarms

Cassette Empty Alarm

Alarm Display	Description:
Sounds Pump: No sound for 5 minutes. Alarm upon escalation. Remote: Alarm	The cassette is empty and a *Cassette Change* needs to be completed.
	What To Do: 1. Tap ⊠ to silence the alarm. 2. Disconnect the infusion set tubing from your infusion site. For more information about the *Cassette Empty* alarm, tap ⓘ. Tap `< Back` to return to the alarm. 3. Tap ☑ to dismiss the alarm screen. 4. Confirm the infusion set tubing is not connected to the infusion site and tap ☑ to continue. 5. Gather supplies and follow *Cassette Change* steps starting from *"Remove and Dispose of Used Cassette" on page 66.*

Cassette Problem Alarm

Alarm Display	Description:
Sounds Pump: No sound for 5 minutes. Alarm upon escalation. Remote: Alarm	The cassette is not working properly and needs to be replaced.

What To Do:

1. Tap ⌧ to silence the alarm.
2. Disconnect the infusion set tubing from your infusion site.

   For more information about the *Cassette Problem* alarm, tap ⓘ. Tap ‹ Back to return to the alarm.
3. Tap ☑ to dismiss the alarm screen.
4. Gather supplies and follow *Cassette Change* steps starting from *"Disconnect from Infusion Site" on page 66.*

Cassette Removed Alarm
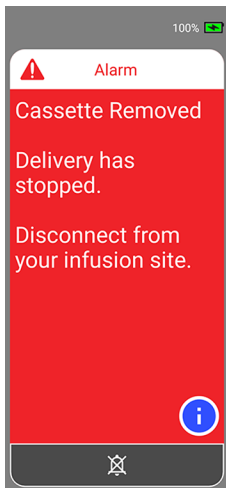
Alarm Display	**Description:**
	The cassette has been removed or partially removed from the pump while delivery is in progress.

Alarm Display (screen shows:)

100%

⚠ Alarm

Cassette Removed

Delivery has stopped.

Disconnect from your infusion site.

ⓘ

🔕

Sounds

Pump: No sound for 5 minutes. Alarm upon escalation.

Remote: Alarm

What To Do:

1. Tap 🔕 to silence the alarm.
2. Disconnect the infusion set tubing from your infusion site.
   For more information about the *Cassette Removed* alarm, tap ⓘ. Tap `< Back` to return to the alarm.
3. Tap ☑ to dismiss the alarm screen.
4. Confirm the infusion set tubing is not connected to the infusion site and tap ☑ to continue.
5. Remove the cassette from the pump.
6. Remove the pump battery.
7. Insert a battery into the pump.
   The pump will play a *Quick* beep then a *Ready* beep and the remote will advance automatically.

To continue with your current cassette:	To continue with a new cassette:
1. Tap ✅ to select *Current Cassette*. 2. Tap ✅ to confirm you are using your current cassette. 3. Attach your current cassette to the pump. 4. Wait for *Self Test* to complete before continuing. 5. Confirm your delivery rate and tap ✅ to continue. 6. Reconnect the infusion set tubing to the infusion site. 7. Tap ✅ to start delivery.	1. Tap **New Cassette** and ✅ to continue. 2. Tap ✅ to confirm you are using a new cassette. 3. Gather supplies, wash your hands, and follow cassette change steps starting from *"Prepare New Infusion Set Tubing and New Cassette" on page 70*.

Occlusion Alarm

Alarm Display	**Description:**
100%	Remodulin is blocked from being delivered due to a kink or blockage in your infusion set tubing or infusion site.

Alarm Display

⚠ Alarm

Occlusion

Delivery has stopped.

Disconnect from your infusion site.

ⓘ

🔇

Sounds

Pump: No sound for 5 minutes. Alarm upon escalation.

Remote: Alarm

Description:

Remodulin is blocked from being delivered due to a kink or blockage in your infusion set tubing or infusion site.

⚠ Do not leave the cassette and infusion set tubing connected to your infusion site when investigating or resolving an *Occlusion* alarm. Leaving the infusion set tubing connected to your infusion site during a *Occlusion* alarm may lead to unintended delivery of Remodulin.

What To Do:

1. Tap 🔇 to silence the alarm.
2. Disconnect the infusion set tubing from your infusion site.

   For more information about the *Occlusion* alarm, tap ⓘ.
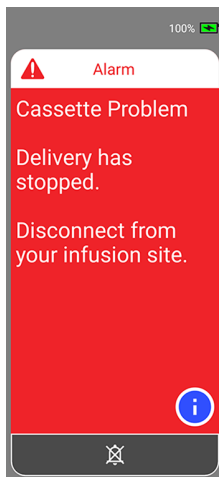   Tap `< Back` to return to the alarm.
3. Tap ☑ to dismiss the alarm screen.
4. Confirm the infusion set tubing is not connected to the infusion site and tap ☑ to continue.

5. Straighten the infusion set tubing and check for kinks.
6. Remove the cassette from the pump.
7. Remove the pump battery.
8. Insert a battery into the pump.

   The pump will play a *Quick* beep followed by a *Ready* beep and the remote will advance automatically.

9. Tap ☑ to select *Current Cassette*.
10. Tap ☑ to confirm you are using your current cassette.
11. Attach your current cassette to the pump.
12. Wait for *Self Test* to complete before continuing.
13. Confirm your delivery rate and tap ☑ to continue.
14. Reconnect the infusion set tubing to the infusion site.
15. Tap ☑ to start delivery.

If the alarm occurs again:

1. Repeat steps 1-8.
2. Tap **New Cassette** and ☑ to continue.
3. Tap ☑ to confirm you are using a new cassette.
4. Gather supplies, wash your hands, and follow cassette change steps starting from *"Prepare New Infusion Set Tubing and New Cassette" on page 70*.

If you continue to receive *Occlusion* alarms after completing all steps, contact your Specialty Pharmacy.

Pump Battery Depleted Alarm

Alarm Display	Description:
	The pump battery does not have enough charge to continue delivery.

Alarm Display
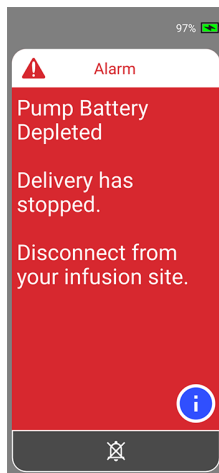
Sounds

Pump: No sound for 5 minutes. Alarm upon escalation.

Remote: Alarm

Description:

The pump battery does not have enough charge to continue delivery.

What To Do:

1. Tap ⌧ to silence the alarm.
2. Disconnect the infusion set tubing from your infusion site.
   For more information about the *Pump Battery Depleted* alarm, tap ⓘ . Tap < Back to return to the alarm.
3. Tap ☑ to dismiss the alarm screen.
4. Confirm the infusion set tubing is not connected to the infusion site and tap ☑ to continue.
5. Remove the cassette from the pump.
6. Remove the pump battery.
7. Insert a fully charged battery into the pump.
   The pump will play a *Quick* beep followed by a *Ready* beep and the remote will advance automatically.

To continue with your current cassette:	To continue with a new cassette:
1. Tap ✅ to select *Current Cassette*. 2. Tap ✅ to confirm you are using your current cassette. 3. Attach your current cassette to the pump. 4. Wait for *Self Test* to complete before continuing. 5. Confirm your delivery rate and tap ✅ to continue. 6. Reconnect the infusion set tubing to the infusion site. 7. Tap ✅ to start delivery.	1. Tap **New Cassette** and ✅ to continue. 2. Tap ✅ to confirm you are using a new cassette. 3. Gather supplies, wash your hands, and follow cassette change steps starting from *"Prepare New Infusion Set Tubing and New Cassette" on page 70*.

Pump Error Alarm
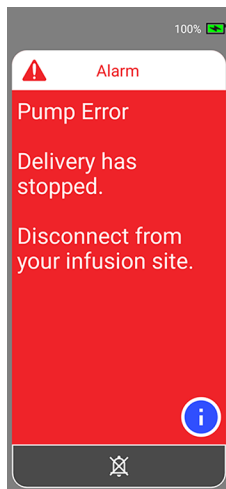
Alarm Display	Description:
Alarm Display 100% 🔋 ⚠ Alarm Pump Error Delivery has stopped. Disconnect from your infusion site. ℹ ⊠ **Sounds** Pump: No sound for 5 minutes. Alarm upon escalation. Remote: Alarm	**Description:** An error has occurred and the pump needs to be restarted.

What To Do:

1. Tap ⊠ to silence the alarm.
2. Disconnect the infusion set tubing from your infusion site.

   For more information about the *Pump Error* alarm, tap ℹ.
   Tap < Back to return to the alarm.
3. Tap ☑ to dismiss the alarm screen.
4. Confirm the infusion set tubing is not connected to the infusion site and tap ☑ to continue.
5. Remove the cassette from the pump.
6. Remove the pump battery.

7. Insert a battery into the pump.

   The pump will play a *Quick* beep followed by a *Ready* beep and the remote will advance automatically.
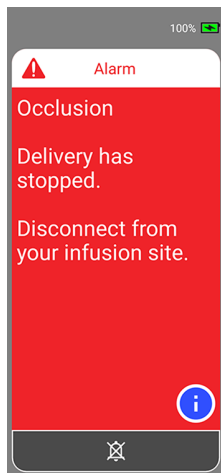
8. Tap ✅ to select *Current Cassette*.

9. Tap ✅ to confirm you are using your current cassette.

10. Attach your current cassette to the pump.

11. Wait for *Self Test* to complete before continuing.

12. Confirm your delivery rate and tap ✅ to continue.

13. Reconnect the infusion set tubing to the infusion site.

14. Tap ✅ to start delivery.

If the alarm occurs again:

1. Tap ⊠ to silence the alarm.

2. Disconnect the infusion set tubing from your infusion site.

3. Tap ✅ to dismiss the alarm screen.

4. Confirm the infusion set tubing is not connected to the infusion site and tap ✅ to continue.

5. Switch to your alternate pump and remote set and perform a cassette change to restart therapy.

6. Contact your Specialty Pharmacy to obtain a replacement pump and remote.

Pump Failure Alarm
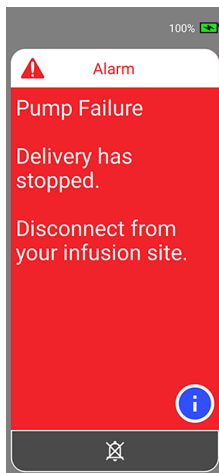
Alarm Display	Description:
Sounds Pump: No sound for 5 minutes. Alarm upon escalation. Remote: Alarm	The pump is not working as expected and Remodulin cannot be delivered.

What To Do:

1. Tap ⊠ to silence the alarm.
2. Disconnect the infusion set tubing from your infusion site.

   For more information about the *Pump Failure* alarm, tap ⓘ. Tap < Back to return to the alarm.
3. Tap ☑ to dismiss the alarm screen.
4. Confirm the infusion set tubing is not connected to the infusion site and tap ☑ to continue.
5. Switch to your alternate pump and remote set and perform a cassette change to restart therapy.
6. Contact your Specialty Pharmacy to obtain a replacement pump and remote.

Prepare to Travel

The RemunityPRO system can be used while traveling on an aircraft. Traveling with the RemunityPRO system requires some planning ahead. Be sure to order supplies before your trip so that you have enough with you while you are away from home.

Keep your backup supplies with you during trips or vacations. When you travel outside the country, or for long periods of time, be sure to take extra supplies:

- Extra non-expired cassettes, in unopened packages
- Extra non-expired infusion sets, in unopened packages
- Extra sterile syringes and needles
- Battery charger and wall power adapter
- USB cables
- Extra Remodulin
- A letter from your healthcare provider explaining the medical need for your pump and other supplies.

Airport Security

Before traveling by plane, familiarize yourself with the airport security procedures and prepare your supplies for the security process and flight. Airport security checks and screening procedures may change, so review the airport website and the TSA website for travel updates before your trip. Pack your supplies in your carry-on luggage. Do not pack your supplies in checked luggage as it could get delayed or lost.

Airport security offers the option of requesting a visual inspection of your medical supplies rather than putting them through the X-ray. You should request this before the screening process begins.

- Your medical supplies should be in a separate bag when you approach the security officer.
- To prevent contamination or damage to your supplies, you should display, handle, and repack your own supplies during the visual inspection process.
- It is not recommended to expose your pump to X-ray machines. Notify the security agent and request an alternate means of screening.

Visit the TSA contact center if you have any further questions or concerns.

> ⚠️ The RemunityPRO system should not be exposed to X-ray screening used for carry-on and checked luggage. Consult with your healthcare provider or Specialty Pharmacy before you travel. It is recommended to notify the security agent that you would prefer an alternate means of screening. The RemunityPRO system has been designed to withstand common electromagnetic interference including airport metal detectors.

Traveling with Spare Pump Batteries

 When traveling, spare pump batteries must be protected from damage to prevent a short circuit from occurring. Spare pump batteries must be placed in carry-on baggage only.

Prepare alternate pump batteries for travel using one of the following methods:

- Place batteries individually in a plastic bag or protective pouch.
- Place batteries in the provided pump battery charger.

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Troubleshooting
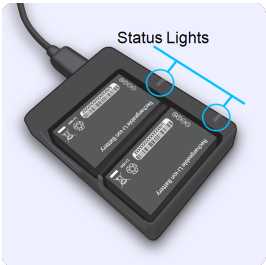
Contact your Specialty Pharmacy for assistance with any of the troubleshooting information.
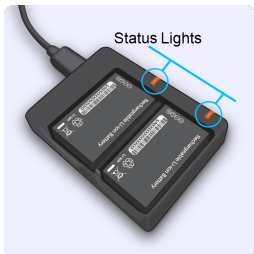
Table 9: *Battery Charger status light(s) is blinking red when a pump battery is inserted*

Problem	Possible Causes	Corrective Actions
Battery Charger status light is blinking red when a pump battery is inserted. Status Lights	Pump Battery is too hot or too cold.	Check the temperature of the location where you charge the pump battery to make sure it's between 59 °F (15 °C) and 95 °F (35 °C). Charging will start automatically when battery temperature is within the specified range.
	Pump battery or battery charger contacts are dirty.	Disconnect the battery charger from the power source. Use a dry cloth or soft bristle brush to clean the battery charger and pump battery contacts.
	One or more components of your RemunityPRO system are defective: • Battery Charger • Pump Battery	One at a time, swap a component listed on the left with its alternate from the *Starter Kit*. If the alternate fixes the problem, contact your Specialty Pharmacy to replace that defective component. If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.

Pump and Cassette

Table 10: *Cannot connect cassette to infusion set tubing*
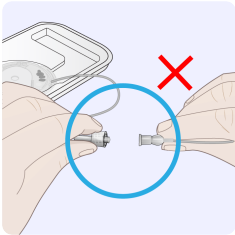
Problem	Possible Causes	Corrective Actions
Cannot connect cassette to infusion set tubing.	Damaged luer connector on the cassette or infusion set tubing.	If the luer connector on the cassette is damaged, discard the cassette and open a new cassette. If the luer connector on the infusion set tubing is damaged, discard the infusion set tubing and open a new infusion set.
	The infusion set is not approved for use with the system.	Verify you are using an approved infusion set.*See "Infusion Sets " on page 12.*

Table 11: *Drops are not visible at end of infusion set when priming*
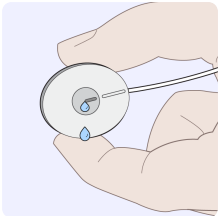
Problem	Possible Causes	Corrective Actions
Drops are not visible at end of infusion set when priming.	Cassette may not have been filled.	The *Prime Stopped* message was automatically displayed asking for confirmation if drops were visible at the end of the infusion set tubing. If this has occurred two or more times, follow these steps: 1. Remove and dispose of the cassette. 2. Remove and re-insert the pump battery. 3. Complete a cassette change with a new cassette.
	Infusion set tubing is occluded.	Inspect the infusion set tubing to make sure there are no visible kinks. Remove any kinks and continue priming.
	Unknown cause	1. Follow the steps to complete a *Cassette Change*. *See "Cassette Change" on page 63.* 2. If the problem persists, contact your Specialty Pharmacy.

Table 12: *Self Test does not start*
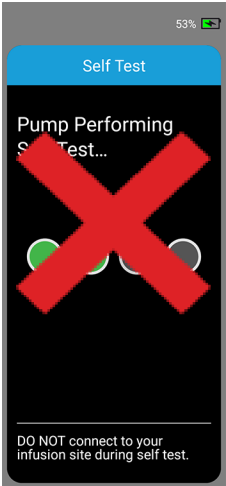
Problem	Possible Causes	Corrective Actions
Self Test does not start. 	Pump is not properly attached to cassette.	Make sure the pump is properly attached to the cassette.
	Depleted pump battery	Insert a fully charged pump battery.
	Pump battery not removed during *Cassette Change*.	Remove pump battery and insert a fully charged pump battery during cassette change.

DKUT-09009-001 -1.9

Table 13: *Self Test did not appear on remote*
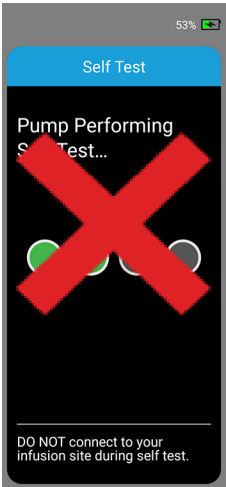
Problem	Possible Causes	Corrective Actions
Self Test did not appear on the remote but played from the pump. 	Remote is not paired to the pump.	In the remote *Setup Menu*, pair the remote to the pump currently being used. *See "Pair a Pump" on page 100.*
	Remote is not in communication with the pump.	Place the pump and remote within 2 in (5 cm) of each other until the status bar at the top of the home screen turns blue.

Table 14: *An Alert is generated when a pump battery is inserted into pump*

Problem	Possible Causes	Corrective Actions
An *Alert* is generated when the pump battery is inserted into pump.	The pump battery has 10% charge remaining.	Insert a fully charged pump battery.

Table 15: *An Alarm is generated when a pump battery is inserted into the pump*

Problem	Possible Causes	Corrective Actions
An *Alarm* is generated when a pump battery is inserted into the pump.	Pump is broken.	Use the alternate pump and remote set provided in the *Starter Kit*. Contact your Specialty Pharmacy for a replacement pump and remote.

Table 16: *No sound is generated when a pump battery is inserted into the pump.*

Problem	Possible Causes	Corrective Actions
No sound is generated when a pump battery is inserted into the pump.	Pump battery is depleted.	Install a fully charged pump battery into pump.
	Pump is broken.	Use the alternate pump and remote set provided in the *Starter Kit*. Contact your Specialty Pharmacy for a replacement pump and remote.

⚠ Only use the provided wall power adapter and charging cables. Use of other wall power adapters or cables could damage the system or result in fire or burns.

⚠ Do not use batteries or battery chargers that were not supplied with the RemunityPRO system. Use of batteries and battery chargers that did not come with the RemunityPRO system may lead to unsafe operation which may lead to harm.

⚠ The use of cables other than those provided or specified may result in increased radio frequency emission or decreased radio frequency immunity of the system.

Remote

Table 17: *Remote does not turn on*

Problem	Possible Causes	Corrective Actions
Remote does not turn on.	Remote has timed out or powered off.	Press the remote **power button** to *wake up* the remote. If this does not work, press and hold the **power button** to power on the remote. The remote screen will light up and the remote will vibrate when it powers on.
	Remote is not charged.	Charge the remote using the USB cable and wall power adapter provided. To confirm the pump is *Delivering*, press and hold the blue **pump button** for 3 seconds and verify the pump plays the *Delivering* sounds. The remote can be used, and is fully functional, while charging.

Table 17: *Remote does not turn on*

Problem	Possible Causes	Corrective Actions
Remote does not turn on.	Remote is broken.	Use the alternate pump and remote set provided in the *Starter Kit* and contact your Specialty Pharmacy for a replacement pump and remote.
	One or more components are defective: • USB Cable • Wall Power Adapter	One at a time, swap a component listed on the left with its replacement from the *Starter Kit*. If the replacement fixes the problem, contact your Specialty Pharmacy to replace that defective component. If the replacement does not fix the problem, swap back to the original component, then try replacing the next component on the list.

⚠ Only use the provided wall power adapter and charging cables. Use of other wall power adapters or cables could damage the system or result in fire or burns.

⚠ The use of cables other than those provided or specified may result in increased radio frequency emission or decreased radio frequency immunity of the system.

Pump and Remote Pairing

Table 18: *Pump serial number is not available on Select a Pump screen*

Problem	Possible Causes	Corrective Actions
Pump serial number is not available on the *Select a Pump* screen for pairing.	Pump and Remote are not from the same set.	1. If the pump has been placed in pairing mode, but does not appear on the *Select a Pump* screen, verify the serial number on the pump label matches the serial number on the remote label. A pump can only be paired to the remote with the matching serial number. 2. Verify the pump and remote have the same serial number and place the pump in pairing mode. 3. If problems with pairing continue, switch to your alternate system and contact your Specialty Pharmacy for assistance.

Frequently Asked Questions

Please refer to the table below for answers to frequently asked questions about the system.

Table 19: *Frequently Asked Questions*

Question	Answer
I have forgotten my passcode. What do I need to do?	If you have forgotten your passcode, follow the steps to factory reset the remote. *See "Remote Factory Reset" on page 109.*
How do I know when it is time to change the cassette?	The *Home Screen* displays the hours remaining until you need to change the cassette. Once the expected time has passed, the remote displays **--** *Hours Remaining*. A *Cassette Low* alert lets you know when the cassette will be depleted within the next two hours.
How often should I change the battery in the pump?	The pump battery should be replaced with a fully charged battery each time a cassette change is completed. A cassette change should be completed at least every 3 days. The *Home Screen* displays information on the pump battery status.

Table 19: *Frequently Asked Questions*

Question	Answer
I pressed the pump button by accident. Did I do anything?	Pressing the pump button by accident cannot change delivery status or shut the pump off.
Can I get the pump wet?	Yes. When attached to a cassette, the pump can be exposed to splashing water, such as showering. The pump, when attached to a cassette or pump cover, can be cleaned by following the steps for *"Clean the Pump" on page 170.* Keep the pump batteries, pump battery charger, and wall power adapter dry. Also keep the pump batteries, pump battery charger, and wall power adapter clean and away from dust and dirt.

Troubleshooting

Table 19: *Frequently Asked Questions*

Question	Answer
What should I do with the excess infusion set tubing?	Make sure to secure the infusion set tubing and pump to prevent them from catching on other objects. Route the infusion set tubing to avoid any sources of kinks that may introduce an *Occlusion* alarm. ⚠️ Keep the pump, cassette, and infusion set tubing away from sharp objects. Sharp objects may damage these components which may cause delivery errors. Delivery errors may lead to harm. ⚠️ Pets may damage your infusion set tubing while sleeping which may lead to an interruption of Remodulin delivery or infection. Do not sleep with your infusion set tubing exposed if pets are present.
Can the pump be worn during an MRI?	No. The pump and remote are both MR unsafe and should not be brought into an MRI. 🚫MR The RemunityPRO system is MR Unsafe. Contact your Specialty Pharmacy or healthcare provider before disconnecting the pump from your infusion site. 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.

Table 19: *Frequently Asked Questions*

Question	Answer
If I am in a loud environment, will I be able to hear the remote or pump?	It may be difficult to hear the remote or pump in loud environments. Make sure you keep the remote in clothing, worn close to the body, so you can feel it vibrate during an alarm or alert condition. ⚠️ The volume on the remote should be louder than your surroundings so your system notifications are not missed.
Can I get the provided remote wet?	No. The remote can not get wet. To properly clean the remote, follow the steps for *"Clean the Remote" on page 172.* 📝 Keep the remote and wall power adapter dry. Also keep the remote and wall power adapter clean and away from dust and dirt.
How often should I charge the remote?	It is best practice to charge the remote every night. The remote is fully functional while being charged. The *Home Screen* displays information on the remote battery status.

Table 19: *Frequently Asked Questions*

Question	Answer
How can I tell if Remodulin is being delivered if the remote is powered off or inaccessible?	Communication between the remote and pump is not required in order to continue Remodulin delivery. Check to make sure delivery is in progress by pressing and holding the **pump button** for 3 seconds. If delivery is in progress, the pump will play the *Delivering* sounds. If delivery is not in progress, the pump will play a *Ready* beep, indicating that the system is ready for you to take an action. Delivery will need to be started using the remote.
What should I do when I see an *Alert or Alarm* on the remote?	Follow instructions provided in *"Alerts" on page 121* or *"Alarms" on page 135.* Each alert and alarm that can be generated by the RemunityPRO system has a description, along with the steps needed for resolution.
Can I change the pump battery without changing the cassette?	Yes. However, it is recommended that a fully charged pump battery is used when completing a cassette change. If you need to change your pump battery during an active therapy, follow these steps: Follow steps to *"Change Battery" on page 84.*

Table 19: *Frequently Asked Questions*

Question	Answer
How do I stop Remodulin delivery if I do not have my remote or my remote is not working?	You should not stop delivery when you do not have your remote without consulting with your healthcare provider or Specialty Pharmacy. The remote is required to restart delivery. If you need to stop delivery without your remote: 1. Disconnect the infusion set tubing from your infusion site. 2. Remove the cassette from the pump to stop delivery. The pump will play the alarm sounds as soon as the cassette is removed from the pump. 3. Silence the alarm by removing the battery from the pump. ⚠️ Disconnect the infusion set tubing from your infusion site before removing the cassette from the pump. Unintended delivery of Remodulin may occur if the cassette is removed from the pump before disconnecting from your infusion site.

Maintenance

Contact your Specialty Pharmacy for assistance with any of the maintenance instructions.

Pump Care

It is important to keep the pump clean. Dust, lint, dirt, and other debris or liquids 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 *Self Test*.
- Interfere with the electrical connections between the pump battery charger and pump battery causing the battery not to charge or to charge slowly.
- Scrape 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

Clean the exterior of the pump as needed in order to keep it free of dust, lint, dirt, and other debris or liquids.

> Do not place the pump in a dishwasher.

1. Verify the pump cover or a cassette is attached to the pump before cleaning.

2. Clean the pump with water and a mild soap such as dish detergent or hand soap.

3. Thoroughly rinse the pump with water.
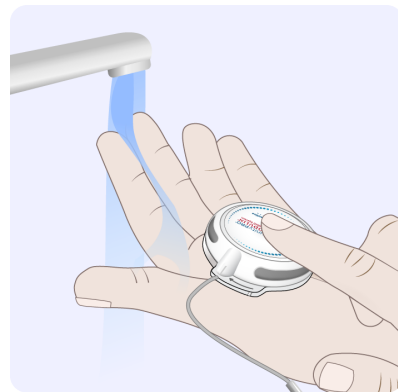
4. Thoroughly dry the pump with a dry cloth or paper towel.
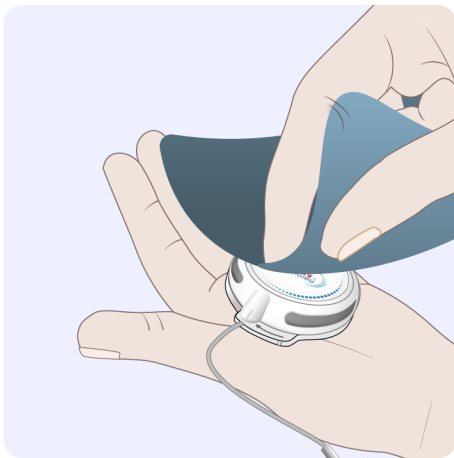
5. Remove pump cover or cassette.

6. If any moisture is visible, gently blot the interior of the pump with a dry cloth or paper towel.
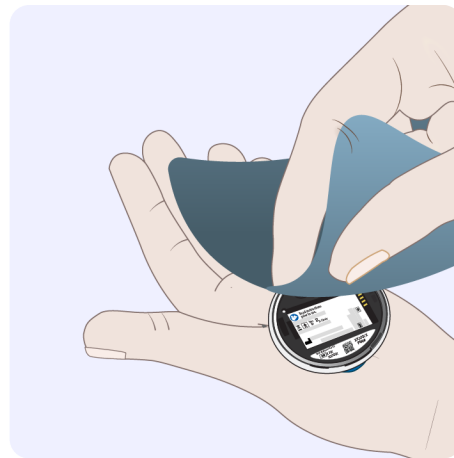
7. Make sure there is no moisture in the pump.

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

Clean the Remote

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 the remote to dry completely.

Service and Support

Technical Support

In the event the pump or remote stops working as expected, discontinue use and switch to the alternate pump and remote set. If any other part of the system (cassette, pump battery, battery charger, wall power adapter, or USB cable) stops working as expected, discontinue use and switch to the provided spare part. Contact your Specialty Pharmacy to obtain replacement parts.

- 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 and general use
- Maintenance
- To report unexpected operation or events
- To request replacement parts

If you would like a copy of the machine-readable SBOMs for the system, please reach out to **cybersec@dekaresearch.com** to make a request.

Replacement Parts

In the event a component of your RemunityPRO system 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.

Replacement Parts	Part Number
RemunityPRO Cassette Packages • Cassettes (10)	DKUT-10006-001
RemunityPRO Pump and Remote Replacement Kit • Pump kit • Remote kit	DKUT-10008-001
RemunityPRO Pump Battery Replacement Kit • Pump battery charger (1) • Rechargeable pump battery (2)	DKUT-11087-002
RemunityPRO Pump Clip Replacement Kit • Pump clip (1)	DKUT-11088-002

Approved Infusion Sets

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

Technical Description

This device has not been authorized as required by the rules of the Federal Communications Commission. This device is not, and may not be, offered for sale or lease, or sold or leased, until authorization is obtained.

The RemunityPRO system consists of a wearable pump attached to a cassette and a hand-held remote, which communicate via Bluetooth wireless radio.

The remote provides the ability to program and control the pump, and view log data relevant to therapy. The system also maintains an internal log of the following forensic evidence:

- All interactions between the pump and remote, between the user and the pump, and between the user and the remote
- Engineering information such as internal system commands and responses
- Relevant therapy data

This log is only accessible by the system manufacturer, and does not contain any protected health information.

The pump is designed to deliver Remodulin subcutaneously based on a programmed delivery rate, and is intended to be worn for up to three days at a time. Delivery of Remodulin continues uninterrupted in the event that communication is lost between the pump and remote. Additionally, while the pump and remote are not in communication, fault detection and alarm generation functions are maintained.

The pump contains volume measurement hardware, pump actuation hardware, and electronic elements. The pump is powered by a RemunityPRO system rechargeable pump battery.

The cassette includes chambers for storing, measuring, and pumping fluid, the valves to control the flow of Remodulin, and a standard luer connector for connection to an infusion set.

The attached pump and cassette actively draw up to 2 µL aliquots of fluid from the storage chamber, measures the volume of the aliquot, and delivers each aliquot to the patient. These individual measurements are used to accurately deliver Remodulin and detect occlusions.

Infusion of Remodulin is done through the use of a separately supplied infusion set (infusion set tubing and cannula).

The pump can be worn in various ways. The pump can be attached to a belt with the pump clip accessory, or placed in a pocket. There is no restriction on orientation or position of the pump relative to the infusion site.

Occlusion Detection: An *Occlusion* alarm occurs when your pump has detected that it has under delivered by 10 µL or that the pumping chamber has not fully emptied for 10 successive aliquot intervals, which ever occurs first.

Occlusion Detection Time:

- Rate: <100 µl/h Detection Time: < 8 hours
- Rate: ≥100 µl/h Detection Time: < 12 minutes

Maximum time to detect occlusion will vary based on user-selected delivery rates. Certain factors, such as the presence of air in the infusion set can delay an *Occlusion* alarm.

The unintended *Bolus* volume following the release of an occlusion is ≤8 µL for all delivery rates.

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

- 50% for deliveries ≤ 8 hours
- 25% for deliveries > 8 hours

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

All parts of the system are rated for continuous operation.

The RemunityPRO system is INTERNALLY POWERED ME EQUIPMENT.

When the remote is being charged, it is CLASS II and INTERNALLY POWERED at all other times.

The infusion set tubing and cannula are TYPE BF APPLIED PARTS.

The stated accuracy is valid when the system is used with the approved infusion sets, in the environmental conditions described in this User Guide.

Essential Performance

The following items are the essential performance of the RemunityPRO system:

- Will not over or under deliver a clinically significant amount of Remodulin without notification to the operator.
- Stop delivery to the patient in the presence of a pump fault that presents unacceptable risk.
- Provide the operator 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.

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 36 µL/hr, in accordance with IEC 60601-2-24: 2012, at room temperature while delivering Remodulin at a concentration of 1 mg/mL.
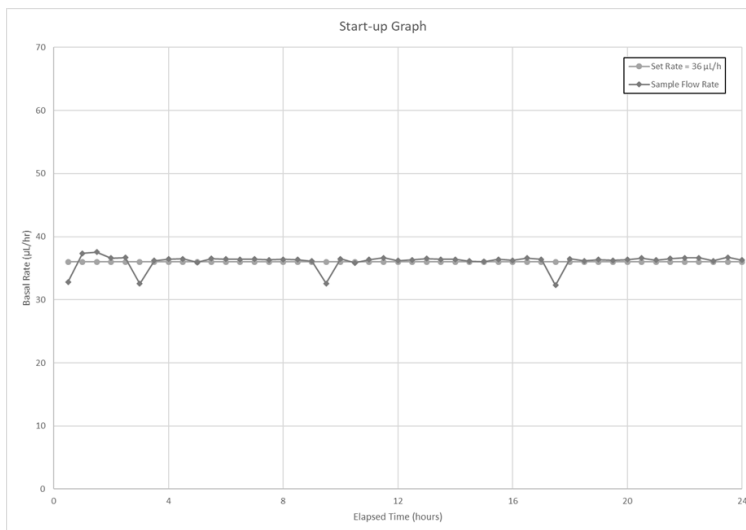
Trumpet Curve

This trumpet curve shows the accuracy of the flow rate over a 5 hour and 34 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.
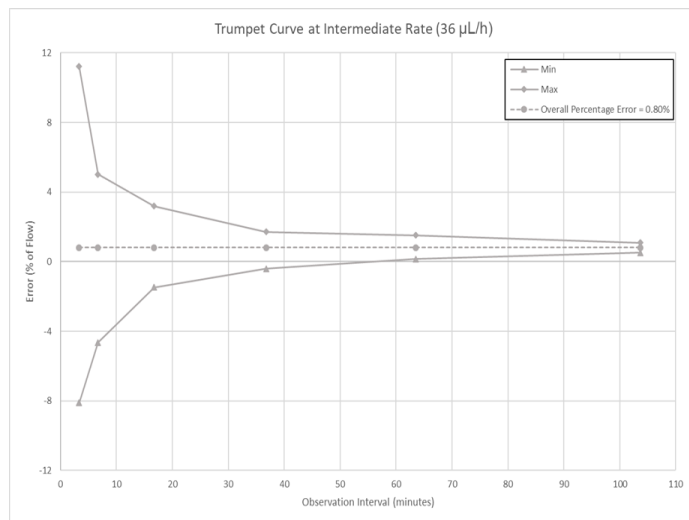
Radio Specifications

Pursuant to 47 CFR 15.21 regarding 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 20: *RemunityPRO System Radio Specifications*

Radio Specification	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)	33 ft (10 m)
Wireless Security	AES-128 encryption with Cypher-block Chaining

Table 20: *RemunityPRO System Radio Specifications*

Radio Specification	Specification Details
Data Packet Size	Up to 80 bytes
Data Packet Transmission Rate	Up to 24 packets per minute

Quality of Service Provisions

Quality of service for Bluetooth Low Energy communication between the remote and paired pump includes the ability for the remote 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 and pump leads to interruptions in status updates and the ability to make changes to therapy parameters. If communication is interrupted, the following may occur:

- A *Message Timeout* alert is generated when a response from the pump is not received by the remote within 15 seconds.
- A *Pairing Failed* alert is generated if pairing between the pump and remote is not established within 45 seconds.
- A *No Communication* alert is generated when communication has been interrupted for 10 hours.

In the absence of communication with the remote, alarm and alert notifications will be generated by the pump. 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 RemunityPRO system.

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

Table 21: *Alarm Volume Specifications*

Alarm Volume Specifications	Specification Details
The following components generate the following sound pressures when alarms are fully escalated:	
Pump	61.1 - 76.3 dBA*
Remote	75.1 - 81.7 dBA*
*Measurements are taken 1 m from the device.	

Table 22: *Pump and Cassette Specifications*

Pump and Cassette Specifications	Specification Details
Pump FCC ID	2ATGA03
Pump Size	5.9 cm x 5.5 cm x 1.7 cm
Pump Weight (when attached to a filled cassette)	50 g

Table 22: *Pump and Cassette Specifications*

Pump and Cassette Specifications	Specification Details
Pump Cool Off/Warm Up time (after being subjected to the extremes of specified storage temperature)	1 hour
Pump History Storage	≥ 2000 event entries
Ingress Protection (IP) Rating	IP24 Protection from splashing water from any direction.
Storage Environmental Range - Cassette	Temperatures of -13 ˚F (-25 ˚C) to 140 ˚F (60 ˚C) Non-condensing humidity up to 90% Pressures of 50 kPa - 106 kPa
Storage Environmental Range - Pump	Temperatures of -13 ˚F (-25 ˚C) to 158 ˚F (70 ˚C) Non-condensing humidity up to 90% Pressures of 50 kPa - 106 kPa

Table 22: *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 of 15 to 90% Pressures of 70 kPa - 106 kPa
Pump Infusion Accuracy	+/- 6%
Maximum Infusion Pressure	< 48 kPa
Prime Delivery Rate	15 µL/min
Programmable Range	8 µL/h (0.008 mL/h) to 225 µL/h (0.225 mL/h), in 1 µL/h (0.001 mL/h) increments
Pump Runtime with fully charged battery	Rate: 8 µL/h Runtime: 72 hours Rate: 36 µL/h Runtime: 72 hours Rate: 225 µL/h Runtime: > 11.8 hours (cassette volume limited)

Table 22: *Pump and Cassette Specifications*

Pump and Cassette Specifications	Specification Details
Shelf Life	Cassette: 2 years
Cassette Sterilization Method	Gamma radiation
Expected Service Life	Cassette: 3 days Pump: 3 years

Table 23: *Pump Battery Specifications*

Pump Battery Specifications	Specification Details
Storage Environmental Range	Temperatures of -4 ℉ (-20 ℃) to 113 ℉ (45 ℃) Non-condensing humidity up to 75% Pressures of 50 kPa - 106 kPa
Pump Battery Service Life	4 months
Allowable Temperature Range for Charging the Batteries	59 ℉ (15 ℃) to 95 ℉ (35 ℃)

Table 23: *Pump Battery Specifications*

Pump Battery Specifications	Specification Details
Cool Off/Warm Up time (after being subjected to the extremes of specified storage temperature)	20 minutes

Table 24: *Remote Specifications*

Remote Specifications	Specification Details
Remote FCC ID	2ATGA6008B
Size	16.2 cm x 7.4 cm x 0.9 cm
Weight	175 g
Battery Life	The remote will typically need to be charged daily and should run all day on a charge.
Cool Off/Warm Up time (after being subjected to the extremes of specified storage temperature)	1 hour

Table 24: *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 50 kPa - 106 kPa
Operating Environmental Range	Temperatures of 41 ˚F (5 ˚C) to 104 ˚F (40 ˚C) Non-condensing humidity of 15 to 90% Pressures of 70 kPa - 106 kPa
Expected Service Life	3 years

Table 25: *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 50 kPa - 106 kPa

Table 25: *Battery Charger, AC Adapter, and USB Cable Specifications*

Battery Charger, AC Adapter, and USB Cable 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 70 kPa - 106 kPa
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

Table 26: *Pump Clip Specifications*

Pump Clip Specifications	Specification Details
Service Life	1 year

DKUT-09009-001 -1.9

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 μL/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 alternate pump). There were no safety concerns related to use of the Remunity Infusion System during the study.

Emissions and Immunity Testing

The RemunityPRO™ System is intended for use in the electromagnetic environment specified below. The user of the RemunityPRO™ System should assure that it is used in such an environment.

Table 27: *Emissions Testing*

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The RemunityPRO™ System 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 RemunityPRO™ System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	The RemunityPRO™ System 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 27: *Emissions Testing*

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	The RemunityPRO™ System 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 28: *Immunity Testing*

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

Table 28: *Immunity Testing*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	10 V/m 80 MHz to 2.7 GHz 1 kHz 80% AM carrier	Use in home healthcare environments, excluding near high frequency surgical equipment or near MR machines. Portable and mobile RF communication equipment should be used no closer to any part of the RemunityPRO system, including cables, than the recommended separation distance of 12 in (30 cm).
	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	27 V/m 380 MHz – 390 MHz 18 Hz PM carrier	
	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	28 V/m 430 MHz – 470 MHz 1 kHz FM carrier	

Table 28: *Immunity Testing*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3 (cont)	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	9 V/m 704 MHz – 787 MHz 217 Hz PM carrier	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	28 V/m 800 MHz – 960 MHz 18 Hz PM carrier	

Table 28: *Immunity Testing*

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	
	9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	9 V/m 5.1 GHz – 5.8 GHz 217 Hz PM carrier	
Conducted RF IEC 61000-4-6	3 Vrms (6 Vrms in ISM Bands) 150 kHz to 80 MHz 1 kHz 80% AM carrier	6 Vrms 150 kHz to 80 MHz 1 kHz 80% AM carrier	Use in a professional healthcare facility and home healthcare environment, excluding near high frequency surgical equipment or near MR machines.

Table 28: *Immunity Testing*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrical fast transient/burst IEC 61000-4-4	+/-2 kV 100 kHz repetition frequency	+/-2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical professional healthcare facility and home healthcare environment.
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV line (s) to line(s)	± 0,5 kV, ± 1 kV line (s) to line(s)	Mains power quality should be that of a typical professional healthcare facility and home healthcare environment. Line to Earth surges not applicable for the RemunityPRO™ System per sub clause 7.3 of IEC 61000-4-5.

Table 28: *Immunity Testing*

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 or home healthcare environment. If the use of the RemunityPRO™ System requires continued battery charging during power mains interruptions, it is recommended that the RemunityPRO™ System 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	

Table 28: *Immunity Testing*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
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.
Proximity Magnetic Fields Immunity IEC 61000-4-39	30 kHz 8 A/m - Continuous Wave 134.2 kHz 65 A/m - 2.1 kHz Pulse Modulation 13.56 MHz 7.5 A/m – 50 kHz Pulse Modulation	30 kHz 8 A/m - Continuous Wave 134.2 kHz 65 A/m - 2.1 kHz Pulse Modulation 13.56 MHz 7.5 A/m – 50 kHz Pulse Modulation	Equipment that intentionally generates strong magnetic fields, such as inductive power chargers and LF and HF RFID readers, should be kept at least 6 inches (15 cm) away from components of the RemunityPRO™ System.

Table 28: *Immunity Testing*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
RFID Immunity AIM 7351731: 2021	134.2 kHz RFID fields	134.2 kHz RFID fields	AIM 7351731 testing applies to medical electrical equipment and systems. AIM 7351731 sets forth test methods/levels for the electromagnetic immunity of such equipment/systems.

Table 28: *Immunity Testing*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
RFID Immunity AIM 7351731: 2021 (cont)	13.56 MHz RFID fields 13.56 MHz RFID fields 13.56 MHz RFID fields	13.56 MHz RFID fields 13.56 MHz RFID fields 13.56 MHz RFID fields	
	433.92 MHz RFID fields	433.92 MHz RFID fields	
	860 MHz to 960 MHz RAIN RFID fields	860 MHz to 960 MHz RAIN RFID fields	
	2.4 GHz RFID fields	2.4 GHz RFID fields	
Note: U_T is the a.c. mains voltage prior to application of the test level.			

GLOSSARY

B

Battery Charger

A hardware device used to charge the pump batteries.

C

Cannula

A thin tube inserted subcutaneously to administer Remodulin.

Cassette

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

Cassette Change

Cassette Change is a step-by-step process for inserting a fully charged pump battery, attaching a new cassette and infusion set tubing, filling the cassette, and priming the infusion set tubing. The cassette should be changed when it is depleted, or after 72 hours, whichever comes first.

E

Event

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

F

Filling Port

The hole in the cassette used to fill the cassette with Remodulin.

I

Infusion Set

The device used to connect the pump to the patient. The infusion set consists of infusion set tubing and a cannula which is inserted into the subcutaneous fat.

Infusion Site

The location on your body where the cannula was inserted.

L

Luer connector

A connector, found on the end of the cassette tubing, the syringe, or infusion set tubing, that creates a leak-free seal.

P

Prime or Priming

The process of filling the infusion set tubing with Remodulin.

Pump

The hardware component that pumps Remodulin into your body and communicates with the remote.

Pump-Bump

The protrusion on the perimeter of the pump used as a reference point for proper alignment when attaching and removing the pump from the cassette or pump cover.

Pump Battery

The rechargeable battery used to power the pump.

Pump Cover

A clear plastic cover that attaches to the bottom of the pump during shipping and to protect the pump when it is not attached to a cassette or during maintenance.

R

Remodulin

An infused medication used to treat pulmonary arterial hypertension.

Remote

The remote interface that communicates with the pump via Bluetooth.

S

Sharps Container

A sharps container is a hard plastic container that is used to safely dispose of hypodermic needles and other sharp medical instruments.

Subcutaneous

Situated or applied under the skin.

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