REMUNITY™

USER GUIDE

REMUNITY™ PUMP FOR REMODULIN® (treprostinil) Injection

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Trademarks	Remodulin is a registered trademark of United Therapeutics Corp.

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About

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

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

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

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

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

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

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

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

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

- The *Operator* is able to adjust the delivery rate as instructed.
- The *Operator* understands that only Remodulin Remunity cassettes may be used with the Remunity *System*.
- The *Operator* understands they need to verify the proper Remodulin concentration prior to using a cassette.
- The *Operator* is able to execute the proper procedure for changing a cassette.
- The *Operator* is able to execute the proper procedure for resolving an alarm.
- Successful Remunity Pump therapy requires sufficient physical, cognitive, visual and hearing capabilities to allow recognition and manipulation of the Controller and Pump. Users must have a minimum of 8 years of education to correctly interpret this User Guide.

The *Operator* should contact local authorities about proper disposal of the durable components of the system when no longer needed. These components have electronics that contain lead and Lithium Polymer batteries.

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

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 ≥-6% to ≤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 ≥-6% to ≤6%. Pump reliability, including malfunctions and complications, was assessed in 120 pumps. Overall, 92 pumps experienced an attention alarm/alarm during infusion. Of the 92 pumps with attention alarms/alarms, 30 pumps were discontinued after experiencing the following alarms: 16 cassette depleted alarms, 10 cassette problem alarms, 3 occlusion alarms, and 1 pump failure alarm.

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

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

Essential Performance

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

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

Indications for Use

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

Contraindications

None

Conventions

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

Table 1: *Conventions*

Convention	Description
Boldface type	Emphasizes heading levels, column headings, and the following literals when writing procedures: • Options and elements that appear on the remote screen. • Keys and buttons on the pump or remote. • User input for procedures.

Table 1: *Conventions*

Convention	Description
Italic type	Accentuates words or phrases that appear on the remote screen.
`Courier New`	Used for identifying code samples.
Hyperlink *See "Conventions" on the previous page.*	Provides quick and easy access to cross-referenced topics. Hyperlinks to websites are highlighted in blue and may be underlined. Hyperlinks to locations within the document are italicized.
Select	Used to instruct the user to choose from a list of options.
Press	Used to instruct the user to press down on a physical button.

Symbols

Table 2: *Symbols*

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

Table 2: *Symbols*

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

Table 2: *Symbols*

Symbol Source/ID	Symbol	Definition
IEC 60417-5576		This is the Bell cancel symbol. It is used to indicate that an alarm condition has had its audio turned off.
Symbol 5.1.1 of ISO 15223-1: 2012(E)*		This symbol indicates the medical device manufacturer.
Symbol 5.1.3 of ISO 15223-1: 2012(E)*		This symbol indicates the date when the medical device was manufactured.

Table 2: *Symbols*

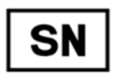
Symbol Source/ID	Symbol	Definition
Symbol 5.1.4 of ISO 15223-1: 2012(E)*		This symbol indicates the date after which the medical device is not to be used.
Symbol 5.1.5 of ISO 15223-1: 2012(E)*		This symbol indicates the manufacturer's lot code so that the lot can be identified.
Symbol 5.1.6 of ISO 15223-1: 2012(E)*		This symbol indicates the manufacturer's Catalog number so that the medical device can be identified.
Symbol 5.1.7 of ISO 15223-1: 2012(E)*		This symbol indicates the manufacturer's serial number so that a specific medical device can be identified.

Table 2: *Symbols*

Symbol Source/ID	Symbol	Definition
Symbol 5.2.4 of ISO 15223-1: 2012(E)*		This symbol indicates a medical device that has been sterilized using irradiation.
Symbol 5.3.4 of ISO 15223-1: 2012(E)*		This symbol indicates a medical device that needs to be protected from moisture.
IEC 60417-5333*		This symbol indicates that equipment is Type BF which indicates it is electrically isolated and can safely contact a person's skin without risk of electric shock.

Table 2: *Symbols*

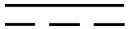
Symbol Source/ID	Symbol	Definition
Figure 1 of EN 50419: 2006		This symbol indicates that equipment should not be disposed of in the trash.
RBRC Li-Ion Battery Recycling Seal		This symbol indicates that Lithium batteries should be recycled.
IEC 60417-5031*		This symbol indicates that a device requires direct current.
'MR Unsafe' symbol, Table 1, ASTM F2503-13		This symbol indicates that a device is not safe to have near an MRI.

Table 2: *Symbols*

Symbol Source/ID	Symbol	Definition
Note: *For compliance with sub-clause 7.6.2 of IEC 60601-1: 2012.		

Table 3: *Symbols for Shipping Container Markings*

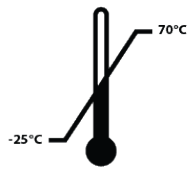
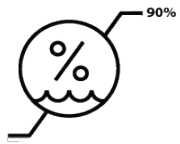
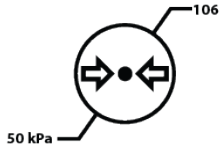
Symbol Source / ID	Symbol	Definition
Symbol 5.3.7 of ISO 15223-1:2012 (E)*, with SYSTEM storage temperature limits included		This symbol indicates the storage temperature range for the Remunity System.

Table 3: *Symbols for Shipping Container Markings*

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

Warnings

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

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

Component Warnings

DO NOT discard this User Guide. Keep it in a safe place for future reference.

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

Medtronic Quick-set Infusion Set (MMT-392, MMT-393)

Medtronic Silhouette Infusion Set (MMT-373)

Smiths Medical Cleo 90 Infusion Set (21-7230-24, 21-7220-24)

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

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

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

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

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

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

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

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

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

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

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

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

Location of Use Warnings

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

Portable and mobile RF communications equipment (such as Walkie-Talkies, hand held / vehicle mounted HAM, radios in Police cars, Ambulances, and Firetrucks) may affect the communication between the Pump and Remote or interrupt operation of the Pump. If the Remote indicates a loss of communication, move the Pump and Remote at least 8.9 m (30 ft) away from these items.

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

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

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

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

Metal detectors may affect pump accuracy or trigger an alarm. Hand held or walk through metal detectors may be used near the Remunity™ Pump for Remodulin® (treprostinil) Injection, but avoid prolonged exposure to them. *See Table 30 on page 226* for more information.

Retail anti-theft detectors may affect pump accuracy or trigger an alarm. Step through retail anti-theft detectors at a normal pace, but avoid standing in them. *See Table 30 on page 226* for more information.

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

Cassette Change Warnings

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

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

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

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

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

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

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

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

Medication Delivery Warnings

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

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

Cautions

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

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

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

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

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

This system supports flow rates between 16 µL/h - 225 µL/h. If your flow rate is outside this range please discuss with your physician.

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

Always have the following extra supplies with you if planning to be away from home, even for a short period of time:

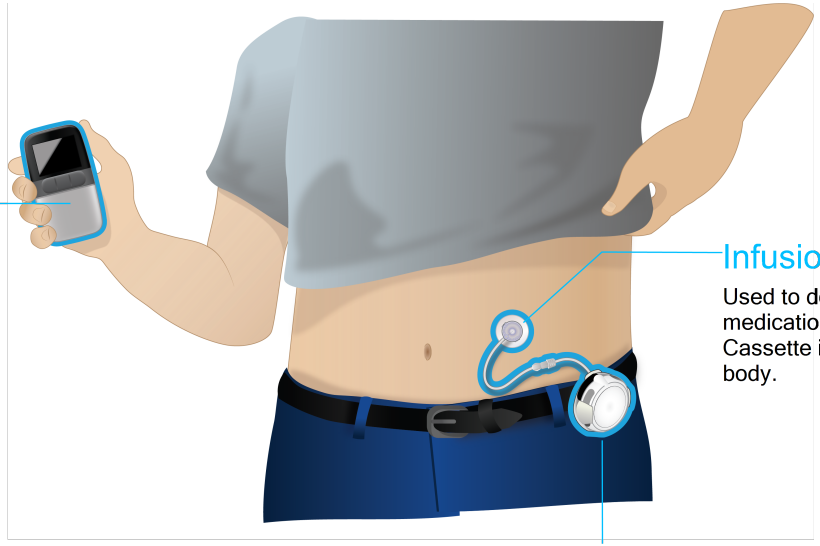
- Spare Pump and Remote
- Extra non-expired Pharmacy-Filled Cassette packages (enough for the number of days you will be traveling) in their unopened packaging.
- Extra pump battery with full charge in remote battery bay.
- This User Guide.
- Your medication.
- Your preferred Infusion Set. *See "Use only one of the following Infusion Sets" on page 33.*

Contact with oil-based lotions & sunscreens (Banana Boat® for example) and insect repellents that contain DEET can damage the exposed parts of the bottom of the cassette, which may lead to leaks. This can result in Cassette Problem Alarms and/or exposure to Remodulin. Avoid getting lotions, sunscreens, and insect repellents on the bottom of the cassette. If they do get on the bottom of the cassette, promptly clean the pump and cassette by following the cleaning instructions within *"Pump Maintenance" on page 176*.

Introduction

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

System Overview



Remote

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

Infusion Set

Used to deliver medication from the Cassette into your body.

Pump (with Cassette Attached)

The Pump and Cassette work together to deliver medication to your body at the delivery rate you set using the Remote.

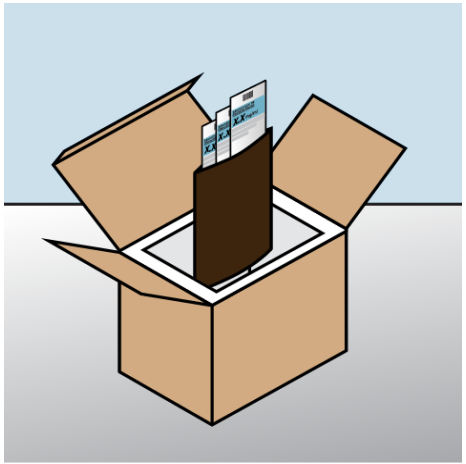
Starter Kit

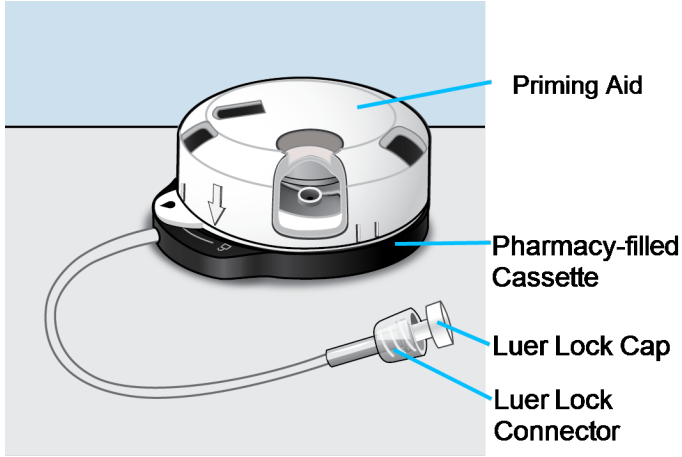
Do not use components from previously opened, expired or damaged sterile packaging. Using such components may lead to infection.

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

The Remodulin Cassette Refill Kit is supplied by your specialty pharmacy and contains multiple *Disposable Kit* packages. Each *Disposable Kit* consists of a *Priming Aid* attached to a pharmacy-filled cassette. Each pharmacy-filled cassette contains enough medication for up to 72 hours.

The pharmacy-filled cassette with an attached priming aid are supplied sterile using a gamma radiation (R) method.





Disposables

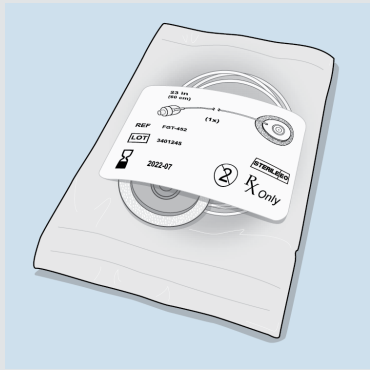
Do not use the disposables if the package has been previously opened or damaged.

Contact your specialty pharmacist to obtain the following pharmacy-filled disposable kits and infusion sets required for use of the system:

- Pharmacy-Filled Cassette Packages

Use only one of the following Infusion Sets

- Medtronic Quick-set Infusion Set (MMT-392, MMT-393)
- Medtronic Silhouette Infusion Set (MMT-373)
- Smiths Medical Cleo 90 Infusion Set (21-7230-24, 21-7220-24)



Always refer to your specific infusion set instructions.

Remote Overview

Press and hold the **Side Button** to power on the remote.

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

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

Power OFF

1. To *Power Off* the remote, **press and hold** the **Side Button** until the ***Power Off*** screen displays.

2. Press the ✓ to power off the remote.