





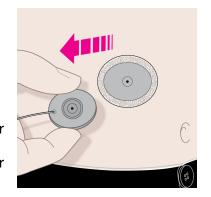


- 5. Press to silence the attention alarm.
- 6. Press to acknowledge the *Pump delivery* has stopped Attention Alarm.

Disconnect Infusion Site

 Disconnect the infusion set tubing from the catheter.

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



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



Do not remove the pump from the used cassette until after you have disconnected the infusion set tubing from your body.

Disconnecting the pump before you disconnect the infusion set tubing from your body could lead to unintended medication delivery.











Disconnect Cassette from Pump and Dispose



To avoid unintended medication delivery, disconnect from catheter before detaching the cassette from the pump.



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



2. You should hear a one beep tone coming from the pump.













3. Separate the pump from the cassette.

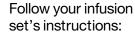


Avoid unnecessary contact with all parts on the interior of the pump exposed during the cassette changing process.



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

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

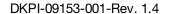


- If you also plan to change your catheter and/or infusion site.
- For proper disposal of infusion set tubing and/or catheter.















Replace Pump Battery



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



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



Before removing the remote from the charging outlet, check that the charging light on the back of the remote is green. This indicates the battery in the bay is fully charged.







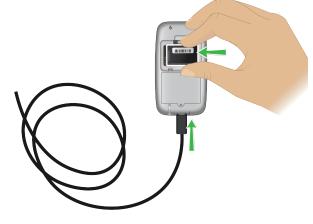






3. Open the clear cover and remove the fully charged battery from the battery bay.

Alternatively, you can obtain a fully charged battery from the battery charger.



4. Insert the depleted pump battery into the back of the remote's battery bay.

At the end of the day, remember to charge the remote with the inserted battery.

Alternatively, you can insert the depleted pump battery into the battery charger to fully charge.













- 5. Insert the battery into the pump making sure the contacts are aligned.
- 6. The pump will sound a ready tone (one beep).

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

Prepare and Fill Cassette

You can use each cassette for up to <u>three</u> days. Replace the cassette when medication runs out or after three days.



Do not use previously opened, expired or damaged disposable components. Doing so may lead to infection.



Do not connect to infusion set catheter in the body until after a newly prepared cassette is attached to the pump. Connecting the cassette to the body before attaching the pump may lead to unintended delivery.

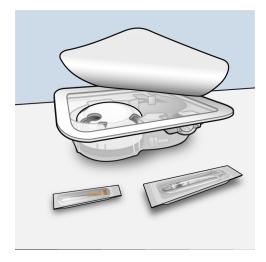




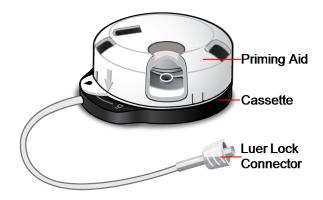
248







1. Open the disposable kit and remove the priming aid and empty cassette from the package and place the black side down on a flat surface.



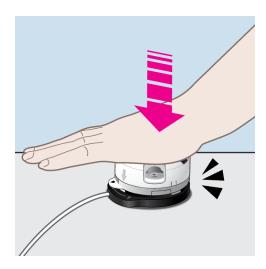
Note the important areas of the priming aid assembly.





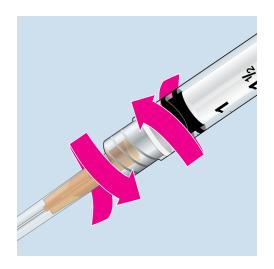






- 2. Firmly push down on the top of the priming aid with the palm of your hand until you hear a click.
- 3. Prepare your injection by removing the syringe and the needle from its packaging.

Only use the sterile, single-use, 3 mL syringe and needle to fill the cassette.



- 4. Insert the needle into the syringe *Luer Lock* and twist until finger tight.
- Wipe the top of the Remodulin vial with an alcohol wipe.
- Remove the cap from the needle.
- Pull the syringe plunger out.
- Insert the needle into the vial.





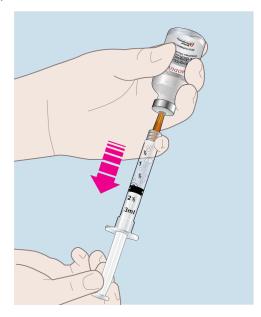
250







9. Push down on the syringe plunger to pressurize the vial.



10. While still holding the syringe, flip the vial over so the vial is on top, slowly pull down on the plunger to fill the syringe.



- 11. Fill the syringe with the amount of Remodulin (mL) that is displayed on the remote.
- 12. With the needle facing up and held vertically, tap on the syringe to remove any air bubbles.
- 13. Remove the syringe from the vial.



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





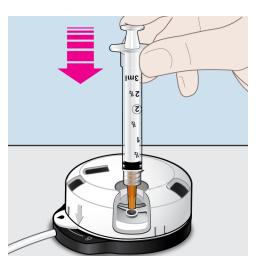








14. Insert the syringe into the hole in the priming aid and push down until you feel the needle insert into the cassette's rubber membrane.



- 15. Push down on the syringe plunger to fill the cassette with Remodulin.
- 16. When the syringe is empty, continue to push down on the plunger while removing it from the priming aid.
- 17. Dispose of the used syringe and needle in a *Sharps* container.







252







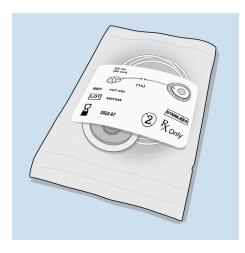
Contact your local authorities to determine the proper method of disposing the syringe and needle. Improper disposal of these items may result in injury to the operator and others from exposure to sharp or contaminated components.



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

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Connect and Prime Infusion Set



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









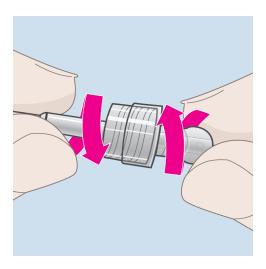








2. Open the infusion set package and remove the infusion set tubing.



3. Connect the infusion set to the cassette by twisting the Luer Lock connectors together.



Do not insert the new infusion set catheter into your body until after you have prepared the new cassette and connected it to the pump. Inserting the infusion set catheter before connecting the cassette to the pump may lead to unintended delivery.

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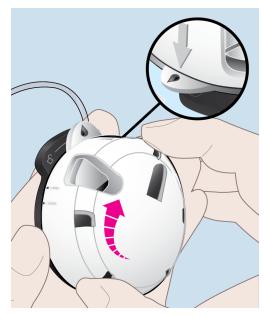






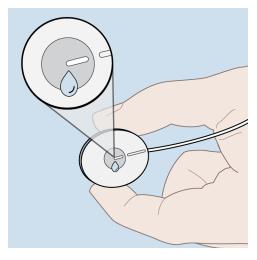






4. Holding the cassette still, rotate the priming aid clockwise until you hear a click and the arrow is aligned with the drop

symbol on the priming aid tab.



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

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



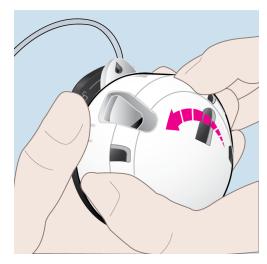




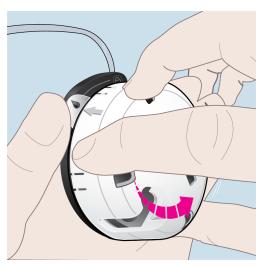




Stop Priming and Remove **Priming Aid**



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



2. Rotate counterclockwise until the tab on the priming aid becomes aligned with the Unlock symbol on the cassette.





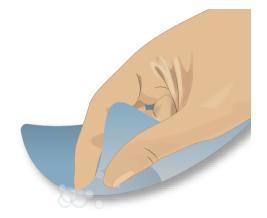








- Detach the priming aid from the cassette.
- 4. Place the cassette down on your workspace.
- 5. Wipe up medication residue that may have settled on top of the cassette during the filling process with an absorbent towel or cloth.



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















7. Dispose of the priming aid in the trash. DO NOT dispose of the newly filled cassette.

Connect Cassette to Pump



Do not connect the infusion set tubing to your catheter.

1. Before connecting the pump to the filled cassette, inspect the cassette and infusion set tubing for leaks.

If you see any leaks replace the cassette and infusion set tubing.

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





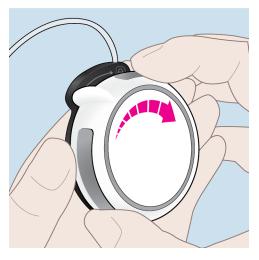
258







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



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













- 6. *Pump-bump* should align with the infusion set tubing.
- 7. You should hear a series of beeps coming from the pump followed by a final confirmation beep.



On the remote a Self Test displays.

8. Allow the Self Test on the remote to complete.



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



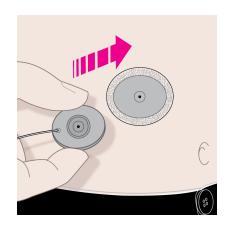


260









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

Start Delivery



- 1. To start medication delivery, press and hold the blue pump button, or on your remote, press to start delivery.
- The pump will make a four-tone sound and delivery will start.











- 3. Confirm that the remote displays a green header indicating that the pump is delivering.
- 4. Check to make sure the displayed rate matches your prescribed rate.



262

DKPI-09153-001-Rev. 1.4









Battery Charger

A hardware device used to charge the rechargeable batteries.

Cassette

A hardware component of the Remunity[™] system that holds the medication and attaches to the Pump.

Cassette Change

The process of changing the pump battery with a fully charged battery, the infusion set tubing

(sometimes the catheter), and an unfilled cassette with a filled cassette.

Catheter

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

Disposable Kit

The Disposable Kit consists of the Pharmacy-Filled Cassette attached to a Priming Aid.











Event

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

Infusion Set

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

Luer Lock

A screw connection on a syringe or infusion set tubing that creates a leak-free seal.

Prime

The process of filling the infusion set tubing with medication.

Priming Aid

A disposable hardware device used to aid in the filling and priming of the Cassette with medication.

Pump

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

Pump Battery

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

DKPI-09153-001-Rev. 1.4













Pump Bump

A protrusion on the perimeter of the pump.

Pump Dust Cover

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

R

Remodulin

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

Remote

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

S

Subcutaneous

Situated or applied under the skin

T

Tubing

Specifically the cassette or infusion set tubing.







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266





DKPI-09153-001-Rev. 1.4







INDEX

A

About 7
alarms 148
attention alarms 148
Accept 36
Access Help 36
Accessories 208
Acknowledge 36
Alarm 147
battery depleted 149
cassette depleted 150
cassette problem 153
cassette removed 151

```
occlusion 154
  pump error 158
  pump failure 159
Appendix 211, 237
Attention Alarm 147
  adjust pump 160
   basal not started 160
  delivery stopped 161
  depletes soon 162
  excessive noise 162
  low remote battery 170-171
  message timeout 163
  no communication 164
  pairing failed 166
  pairing lost 167
  pump battery low 169
```











pump idle 168
software version error 172
tech 173
walkaway 174

В

Battery
charger 69, 88, 247
Battery Bay 39
Battery Charger
status lights 47

C

268

Cancel 36

Cassette 32
connect to pump 78, 97, 258
prepare and fill 248
prepare priming aid 70, 89

Cassette Change 59
disconnect cassette from pump 66, 85, 244
patient-filled 238
supplies 61, 83, 239
with remote 60
without remote 82

Cautions 26

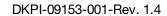
Change Rate 103

Clear Dust Cover 40, 53 Contraindications 11

Conventions 11













D

Delivery
start 81, 109, 261
start without remote 99
stop 63, 85, 107, 241
Delivery Rate
enter 57
Disposables 33

Drop Icon 74, 93, 255

DKPI-09153-001-Rev. 1.4

E

Edit 36
Emergency Contact Information 275

Essential Performance 10

F

FAQ 199 Frequently Asked Questions 199

G

GLOSSARY 263

Н

History 111
event viewer 115
previous 24 hours 114





269









pump cassette info 113 remote battery charging 112 remote battery level 112 Home Screen 38 delivery rate 38 hours remaining 38 pump battery level 38 remote battery level 38 status bar 38

270

Indications for Use 11 Infusion Set connect 73, 80, 92, 99, 253, 261 disconnect 65, 243

prime 73, 92, 253 Infusion Sets 33 Introduction 29

Luer Lock 74, 93, 250, 254

M

Main Menu 102 Maintenance 175 pump 176 remote 177 Menu functions 101













N

Next Screen 36

P

Power OFF 34 Power ON 34

Parts 208

Previous Screen 36
Priming Aid 32

dispose 75, 94, 256 remove 75, 94, 256

Pump 39

belt clip 42

DKPI-09153-001-Rev. 1.4

blue button 39
clothing clip 43
dust cover attach 41
dust cover removal 40
how to wear 41
with cassette 40
Pump Battery
charging 46
replace 68, 87, 246
status light 37
Pump Settings 36

Pump Sounds 197













R

Remote
back 37
battery charging status lights 50
charging 48
front 35
front button screen labels 36
overview 34
pairing 52
pump battery charging 48
Repeat 36
Return 145
Return to Previous Menu 102

S

Scroll Down 36
Scroll Up 36
Service 207
Set Up 45, 117
airplane mode 137
exit airplane mode 139
factory reset 140
pair to spare pump 118
paired pump 117
passcode 133
remote audio 130
screen timeout 129
system information 144











walkaway alert 127
Silence Alarm 36
Starter Kit 31
Status Bar
color indications 38
Support 207
Symbols 13
Syringe
disposal 252
fill 251
System Overview 30

T

Technical Specifications 212

Technical Support 208

Troubleshooting 175
battery charger 178
pump 189
remote 182

l

Unlock 36 USB AC Adapter 46 USB cable 46

W

Warnings 21
cassette change 25
component 21













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Emergency Contact Information

Remunity[™] Pump for Remodulin® (treprostinil) Injection

Remunity System is for prescription use only.

Clinician:

Nurse Educator:

Specialty Pharmacy:





















