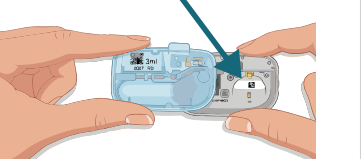
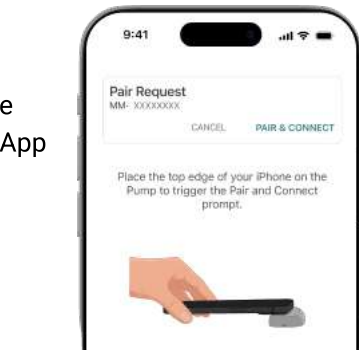
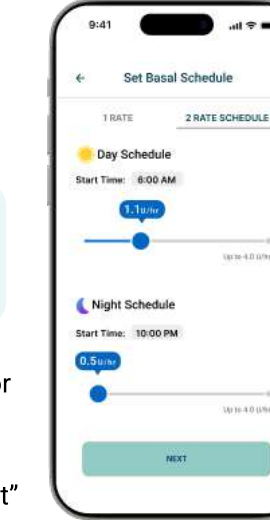
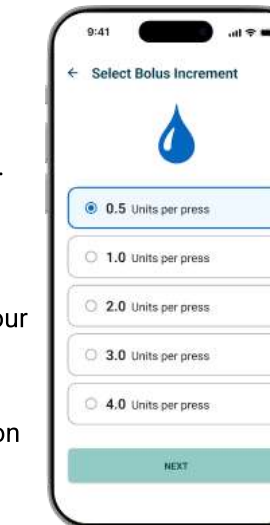
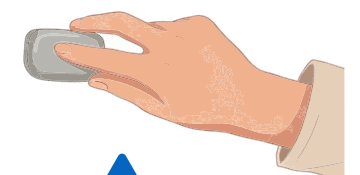
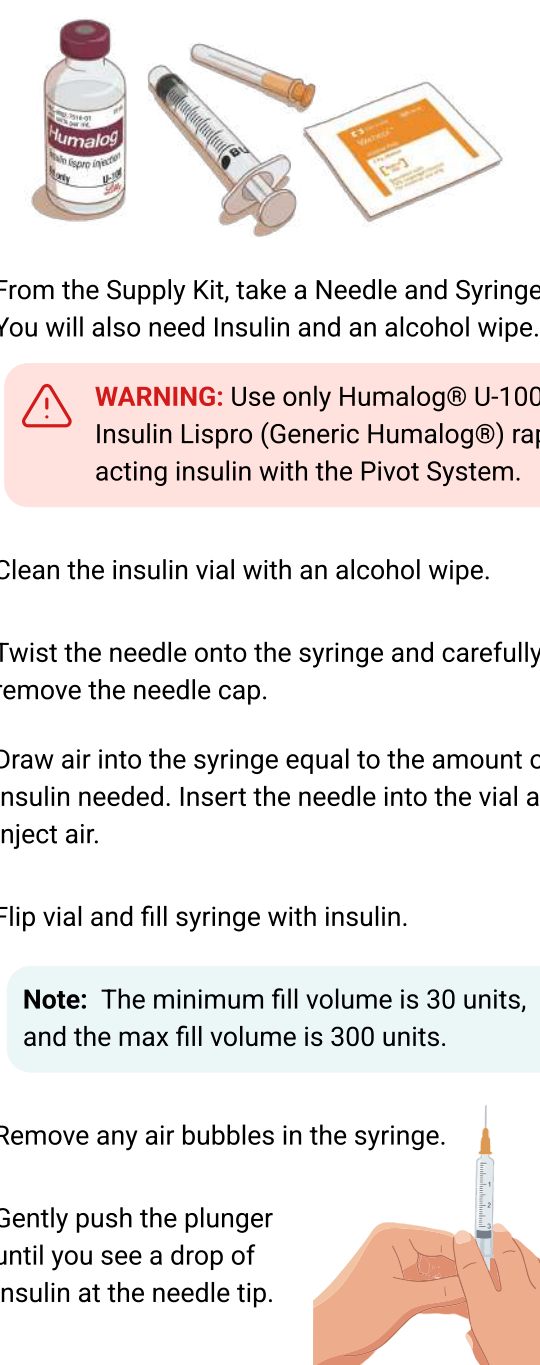
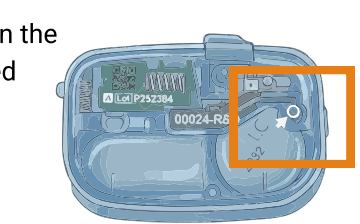
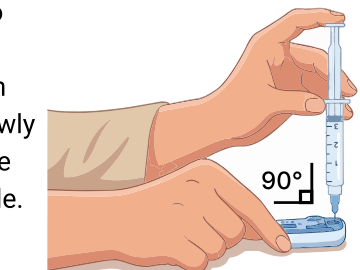
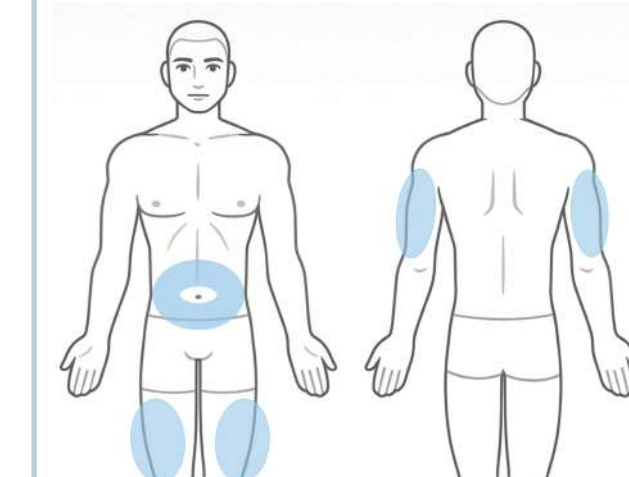
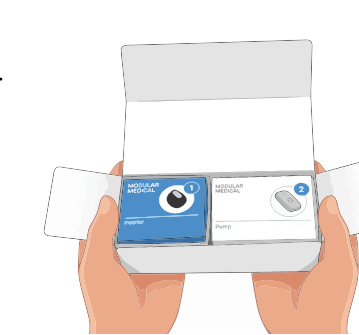
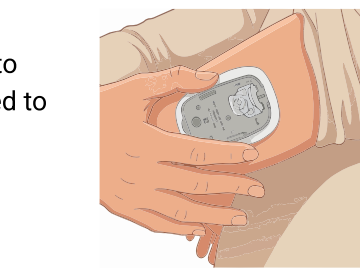
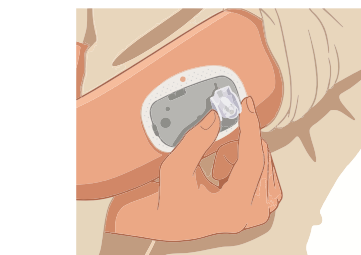
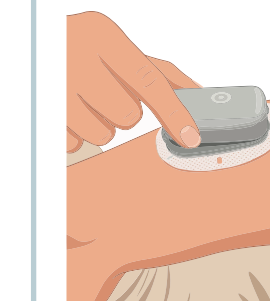


STEP 1: Open Insulin Pump Starter Kit	STEP 2: Connect Pump + Cartridge	STEP 3: Connect to the App	STEP 4: Set Treatment Settings	STEP 5: Fill Syringe with Insulin	STEP 6: Fill Cartridge with Insulin	STEP 7: Prime the Pump	STEP 8: Prepare Infusion Site	STEP 9: Prepare the Patch	STEP 10: Launch the Patch	STEP 11: Attach Pump to the Body
Welcome to Pivot™ Important: Complete Pivot System Training before using your Pivot System. This Quick Start Guide is a reference for trained users. For complete operating instructions, warnings, and safety information, refer to the Pivot System User Guide. 1.1 Before use, check for expiration dates and damage. 1.2 Wash your hands before handling or changing any setup materials. 	2.1 Open the packaging and remove the Pump and Cartridge.  2.2 Each Tray contains a Cartridge and a Patch. Take out the Cartridge and set the Patch aside in the Tray for Step 9. 2.3 Take note of the serial number inside the Pump as you will need to reference it later. 2.4 As shown, align the Cartridge battery to the round indentation inside the Pump.  Press firmly around all edges until they lock together to power on the pump. Power is on when: The pump displays a white light and plays a single beep. Pump is ready to connect to app when: A flashing blue and green light appear.	Download and install the Pivot™ Diabetes App before pairing your pump. 3.1 Open the Pivot™ Diabetes app. Note: Create an account or sign in to Glooko if needed. 3.2 Tap "Connect to Pump" Be sure to allow Bluetooth connection. 3.3 Pair the Pump to the Pivot™ Diabetes App in the manner shown below, similar to "tap to pay."  3.4 Before pairing, verify that the serial number shown in the App matches the serial number recorded in step 2.3 	The App will open to the "Set Basal Schedule" screen after pairing Pump to the App. Treatments settings are prescribed by your healthcare provider. 4.2 Pick from either a single or dual Basal rate (U/hr) and input start time for each segment and tap the "Next" button.  4.3 Select your Bolus increment: 0.5, 1.0, 2.0, 3.0, or 4.0 units per press then tap the "Next" button.  4.4 Tap "Apply Treatment Settings" and enter your phone passcode or use your Face ID. 4.5 Press the Control Button on the Pump to confirm your Treatment Settings.  Quick Press	5.1 From the Supply Kit, take a Needle and Syringe. You will also need Insulin and an alcohol wipe. WARNING: Use only Humalog® U-100 or Insulin Lispro (Generic Humalog®) rapid acting insulin with the Pivot System. 5.2 Clean the insulin vial with an alcohol wipe. 5.3 Twist the needle onto the syringe and carefully remove the needle cap. 5.4 Draw air into the syringe equal to the amount of insulin needed. Insert the needle into the vial and inject air. 5.5 Flip vial and fill syringe with insulin. Note: The minimum fill volume is 30 units, and the max fill volume is 300 units. 5.6 Remove any air bubbles in the syringe. 5.7 Gently push the plunger until you see a drop of insulin at the needle tip. 	6.1 Locate the Fill Port on the Cartridge. It is marked with a gray arrow.  6.2 Insert the needle into the fill Port at a 90° angle and push down on the plunger to slowly fill the Cartridge while keeping it at 90° angle.  6.3 Inspect the Cartridge for any signs of leaking insulin. 6.4 Look through the Cartridge reservoir window to check for air bubbles that appear as clear pockets. If present, angle the Cartridge toward the Fill Port and remove the air bubble with your syringe. 	7.1 Press the Control Button 3 times on your Pump to start priming. Note: Each prime cycle may last up to 4 minutes. 7.2 During priming, place the Pump upright using the underside of the Cartridge Tray.  7.3 During priming, the Pivot™ Diabetes App displays progress in the top status bar: "Ready to Fill and Prime" → "Priming in Progress..." → "Prime Cycle Complete" → "Pump is Ready" 7.4 The prime cycle is complete when:  - You see a flashing white light and hear 5 ascending tones on your Pump. - Your app shows "Prime Cycle Complete." 7.5 After each priming cycle, check for a drop of insulin at the Exit Port. Prime again if needed. Note: The Pump may need multiple prime cycles if there is air remaining in the Cartridge. CAUTION: Do not prime while the Pump is attached to your body. This could lead to moderate hypoglycemia.	8.1 Choose an appropriate site to attach your system. Note: The Patch must be inserted into fatty tissue on the abdomen, upper thigh, or back of arm. Avoid the belly button. Remove excess hair as required.  8.2 Clean the site with a 70% isopropyl alcohol wipe and allow to dry. CAUTION: Ensure your infusion site is clean. Failure to clean the site appropriately may lead to an infusion site infection or a delay in insulin therapy. WARNING: Avoid putting all insect repellents, deodorant sprays, lotions, sunscreens, and perfumes on or near the Pivot system. Consistent drops of the Pump and/or exposure to personal care products such as lotions and sunscreens can result in significantly reduced Pump lifetime if also exposed to water. This may lead to severe hyperglycemia or Diabetic Ketoacidosis (DKA).	9.1 Grab the Inserter from your packaging.  9.2 Take the Tray from Step 2 and align the Inserter over the Patch. Press down until it clicks into place.  9.3 Slowly lift the Inserter out of the Tray, ensuring the liner peels off cleanly. Do not touch the adhesive pad. Do not insert fingers inside the Inserter after removing the Patch from packaging. 	10.1 Gently pinch the skin around your selected site and hold for at least 5 seconds. Let go of the pinch when ready to use the inserter. 10.2 Place the Inserter against your skin and push the button until you hear a click. Remove the Inserter from your skin.  10.3 Press down firmly around the Patch to ensure it is adhered to your skin.  10.4 Pinch the tabs and pull upward to remove the Clip. Dispose of the Clip per local guidelines. 	11.1 Attach the Pump to the Patch by aligning its two notches with the corresponding slots on the Patch.  11.2 Press down firmly around the edges of the Pump until it sits flat and secure on the Patch. 11.3 Your Pivot System is now set up and delivering insulin.  Note: A solid green light and three tones indicate that Basal Delivery has begun. IMPORTANT REMINDER: Skin products to avoid near your Pivot System: • All insect repellents • All deodorant sprays • All sunscreens • All lotions • All perfumes

Plan Your Bolus Before Delivery

Before you start, read through this entire section.

Determine your desired bolus amount (in units) based on your meal and your bolus increment set in the Pivot™ Diabetes App, which can be 0.5, 1.0, 2.0, 3.0, or 4.0 units per press on the Pivot Pump.

Desired bolus amount:

__ Units

Depending on your meal

Your bolus increment:

__ Units Per Press

Find this on your app

Button presses needed:

__ Presses

Refer to the table below

HOW MANY PRESSES DO YOU NEED?

All values in units (U). The tables end at maximum presses or units for that increment.

Each Bolus Press 0.5 Units	Press	1	2	3	4	5	6	7	8	9	10 max
	Units	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0 max

Each Bolus Press 1.0 Units	Press	1	2	3	4	5	6	7	8	9	10 max
	Units	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0 max

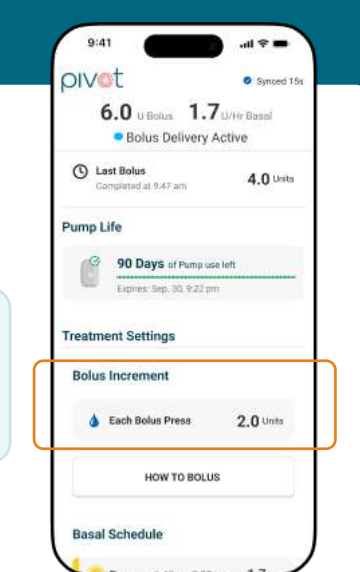
Each Bolus Press 2.0 Units	Press	1	2	3	4	5	6	7	8	9	10 max
	Units	2.0	4.0	6.0	8.0	10.0	12.0	14.0	16.0	18.0	20.0 max

Each Bolus Press 3.0 Units	Press	1	2	3	4	5	6 max
	Units	3.0	6.0	9.0	12.0	15.0	18.0 max

Each Bolus Press 4.0 Units	Press	1	2	3	4	5 max
	Units	4.0	8.0	12.0	16.0	20.0 max

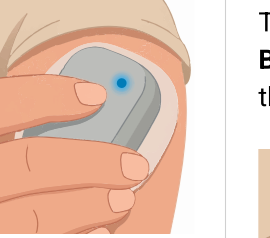
TROUBLESHOOTING FOR BOLUS DELIVERY:

- Green light came on while pressing?** You exited bolus mode. Wait 15 seconds then start again.
- Lost count or pressed too many times?** Wait 15 seconds for the pump to exit automatically and restart.
- Not sure if delivery started or concerned about the amount delivered?** In the app dashboard scroll to Pump Activity to see recent logs that display bolus activity. If bolus is still active you can cancel it. Refer to canceling a bolus section for instructions.



How to Deliver a Bolus on Your Pump

- To enter Bolus mode, hold the Control Button on your Pump until you see a blue light and hear a single tone, then release.



Bolus Mode exits after 15 seconds of inactivity. Green light indicates you are back in Basal Mode. Restart from Step 1.

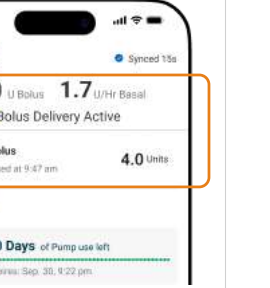
- Press the button to set your dose. Each press adds one increment (0.5, 1.0, 2.0, 3.0, or 4.0 units depending on your app setting) and is confirmed with a blue flash and beep.

Maximum presses are 10 presses or 20 Units.

- The pump plays back your dose. Perform the next step within 15 seconds.

If you are unsure of your count, or your count is wrong, do not confirm delivery. Allow the pump to return to Basal Mode and restart from Step 1.

- To confirm delivery, hold the button again until you see a blue light and long beep, then release. A solid blue light and 3 ascending tones confirm delivery has started.
- To verify that bolus delivery has started, open the Pivot™ Diabetes App Dashboard and confirm that “Bolus Delivery Active” is displayed. You can also verify bolus delivery by reviewing the Pump Activity log.



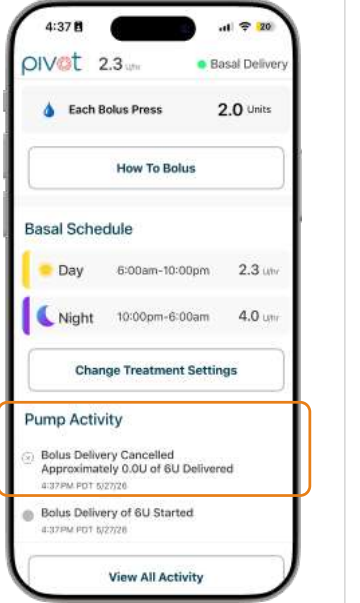
How to Cancel a Bolus in Progress

To cancel a bolus while it is active, **hold the Control Button until you see a green light** and hear a single tone, then immediately release.

A solid green light and three tones confirm cancellation and the Pump has returned to Basal Delivery.

VERIFY IF YOUR BOLUS WAS CANCELLED:

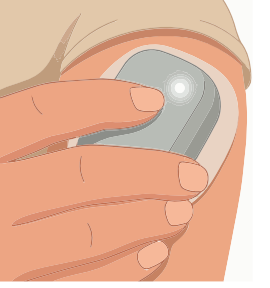
- Open your Pivot™ Diabetes App
- Navigate to the Pump Activity section
- It will display 'Bolus Delivery Cancelled' along with details.



How to Suspend Insulin Delivery

You may need to suspend insulin delivery when changing treatment settings, showering or swimming, during medical procedures, or playing contact sports.

- Press and hold the Control Button for at least 7 seconds. You will see a blue light before the white light appears. When you see the white light and hear a single tone, immediately release the button.



Note: You cannot suspend while delivering a bolus. You must cancel your bolus first.

- To verify that insulin delivery is suspended, open the Pivot™ Diabetes App Dashboard and confirm that “Insulin Delivery Suspended” is displayed at the top of the screen. You will also see delivery suspended in the "Pump Activity" log.



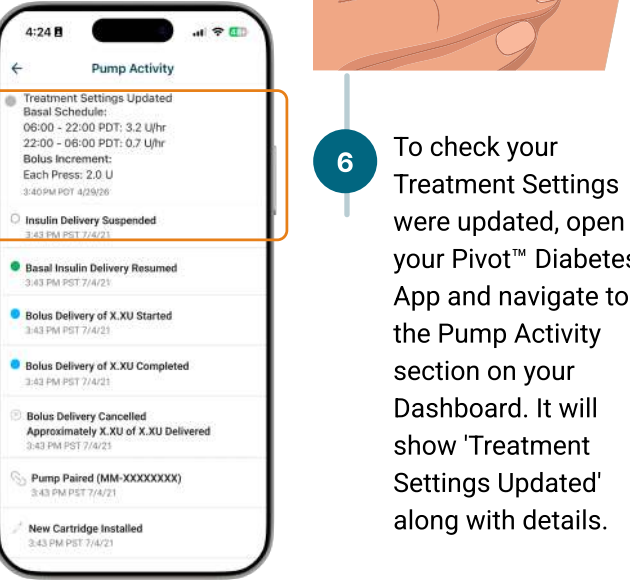
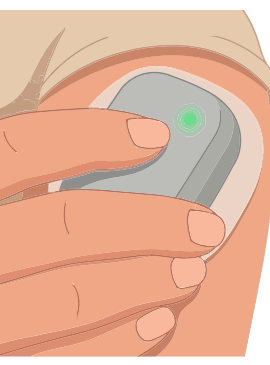
How to Resume Insulin Delivery

- To resume insulin delivery by pressing and holding the Control Button until you see a green light and hear a single tone.

Insulin delivery remains suspended for up to 2 hours and will automatically resume at the end of this period if it is not resumed manually.

How to Change Treatment Settings

- You need to suspend insulin delivery before you change treatment settings.
- On your Pivot™ Diabetes App dashboard tap the “Change Treatment Settings” button.
- Update your Basal Rate Schedule and/or Bolus increments as required.
- Select “Apply Treatment Settings” and enter passcode.
- Press Control Button on Pump to confirm your new Treatment Settings.



How to Determine Pump Status

You can check your pump status at any time by viewing the Pivot™ Diabetes App Dashboard or performing a quick press on the Control Button.

• Green Light - Basal Delivery Active



• Blue Light - Bolus Delivery Active



• White Solid Light - Insulin Delivery Suspended

• White Flashing Light - Prime Ready State



CAUTION: If the Status Check does not provide Audio and Visual feedback, the hardware may be damaged and the Pump should be replaced immediately. Failure to replace your Pump may lead to minor, moderate or severe hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA).

Alarms and How to Address Them

WHEN AN ALARM OCCURS, FOLLOW THESE STEPS:

- Open your Pivot™ Diabetes App immediately.
- The app identifies the alarm and provides step-by-step instructions to resolve it.

During an Alarm, your Pump will:

- Display a red light
- Play an alarm tone



Alarm Name and Insulin Delivery status

Steps to Resolve

Customer support number, if needed

Logged alarm info in the latest Pump Activity

UNDERSTANDING YOUR ALARM TYPE:

USE THIS INFORMATION BELOW AS A REFERENCE ONLY. ALWAYS FOLLOW THE ALARM INSTRUCTIONS IN THE PIVOT™ DIABETES APP.

- Pump Alarm: Flashing red light + constant tone. Replace your entire Pivot System.
- Cartridge Alarm: Flashing red light + repeating tone. Replace the Cartridge and Patch.
- Resumable Alarm: Flashing red light + repeating tone. Confirm steps in the app, then press and hold the Control Button until you see a green light and hear one tone, then release.

IMPORTANT INFORMATION:

- Do not ignore alarms or rely on Pump signals alone. Always use the app for guidance.
- If the Pump is detached from the Cartridge, app connectivity will be lost.

CAUTION: It is important to address an Alarm quickly. Not addressing Alarms can drain the device battery & lead to moderate hyperglycemia or DKA.

CAUTION: Always dispose of the Cartridge and Patch safely in accordance with your local disposal guidelines. The Cartridge battery poses a fire risk if not disposed of properly.

Device Removal Instructions:

TO REMOVE CARTRIDGE AND YOUR PATCH:

- Remove the Pump from the Patch.
- Gently peel the Patch away from your skin and discard.
- Slide the switch in the arrow direction and use the pull tab to separate the Cartridge from the Pump.



TO REMOVE PIVOT SYSTEM:

Remove the entire Pivot System, including the Pump, Cartridge, and Patch from your body.



Troubleshooting / FAQ

1. What things should you do prior to using Pivot?

Wash hands. Check for expiration date and damage. If expired, dispose.

2. What type of insulin can be used with Pivot?

- Humalog U-100
- Insulin Lispro (Generic Humalog®)

3. Is there anything you should avoid when choosing a site for Pivot?

- Avoid a site that is within 2 inches of the previous site or belly button.
- Avoid a site that is within 4 inches of a CGM.
- Avoid a site that is within 12 inches of other RF communication devices.
- Refer to Section 8.4 Electromagnetic Compatibility in the User Guide for more information.

4. What should you do if any of your Pivot components are dropped or if you suspect a component has been tampered with?

- Dispose of component.
- Replace with new component.

5. What products can you use to clean your Pivot System?

Mild soap and warm water. No harsh chemicals. Cartridge should remain attached during cleanings to protect internal components.

6. Are there any situations in which you should remove your Pivot?

- MRI, CT scan, X-ray, surgery, airport security.
- Swimming, showering, jacuzzi, sauna, or any other contact sports.

7. What should you do if you notice a leak from your Pump?

- Remove Pump and Patch from body and replace disposables.

8. Where should you store the device?

- In a secure location. In a cool, dry place. Away from sunlight, excessive temperature and humidity. Away from small children and pets.

9. What are some key safety measures for proper use of the Pivot System?

- Only install the Pivot™ Diabetes App by Modular Medical directly from the App Store.
- Enable app updates for the Pivot™ Diabetes App.
- Do not alter or modify components or warranty will be voided.
- Do not run Pivot™ Diabetes App on a jailbroken mobile device.

Additional Information



The Pivot Insulin Delivery System is indicated for the subcutaneous delivery of insulin at set and variable rates, for the management of diabetes mellitus in persons requiring insulin, for individuals 18 years of age and greater.

Your Pivot System consists of an Insertor, Pump, Cartridge, Patch, and the Pivot™ Diabetes App. The Pivot™ Diabetes App operates on your smartphone device and connects to the Pump via Bluetooth® connection to support basal rate programming and viewing activity information. Pivot can be filled with up to 3.0mL (300 units) of Humalog® U-100 rapid-acting insulin or Insulin Lispro (Generic Humalog®) and can be worn continuously for three days. Your Healthcare Provider will help you to manage your insulin dosing regimen and prescribe insulin. Pivot can be used by persons with diabetes to manage insulin therapy independently. Pivot is capable of delivering insulin at set and variable rates via a selectable basal rate between 0.5 – 4 units per hour (in 0.1 unit increments) and user-selected bolus doses between 0.5 and 20 Units (in 0.5, 1.0, 2.0, 3.0 & 4.0 Unit increments)

Pivot is not indicated for use in persons who do not have adequate hearing and/or vision to allow recognition of all functions of Pivot including Status and Alarms; cannot manage their diabetes independently; are unwilling to take a minimum of (4) blood glucose readings per day; require basal rates greater than 4U/hr. or less than 0.5U/hr; use insulin brands other than Humalog U-100 insulin.

Pivot is not indicated for persons who have not successfully completed training of Pivot and persons who are not capable of following the User Guide.

For additional important safety information, refer to the User Guide.

LBL-B1 v2.0

If you have any questions, please contact Modular Medical Customer Care anytime toll-free at **866-710-1200** or visit www.pivotpump.com.

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