



Pivot Insulin Delivery System Quick Start Guide



STEP 1: Open Packaging

You must complete the Pivot System Training prior to use of the Pivot System. These instructions are provided as a reference tool for Pump users. Not all safety and use information is shown. For more detailed information on the operation and use of the Pivot System, refer to the Pivot System User Guide.

- 1 Check for expiration dates and damage.
- 2 Wash your hands before starting setup.



Pump with Inserter Box



Supply Kit With Tray, Needles, and Syringes

STEP 2: Connect Pump + Cartridge

- 1 Open the Insulin Pump Starter Kit.
- 2 Open the the box containing the pump (labeled with a ①) inside the "Pump with Inserter" box, and a Tray from the Supply Kit.
- 3 A Tray consists of a Cartridge and a Patch. Remove the cartridge for this step. The patch will be used in Step 8.
- 4 Take note of the serial number inside the Pump.
- 5 Align the Cartridge notch to the Pump notch and press firmly to lock together.
- 6 **Firmly press Pump onto Cartridge** to power on Pump.



i Note: Pump will display white light and single beep to indicate power is on.



i Note: A flashing blue and green light will appear to indicate the Pump is ready to be connected with the Phone App.



STEP 3: Connect to the App

- 1 Open the Pivot™ Diabetes App.
If it is your first time in the App, follow the on-screen Glooko instructions.
- 2 Tap "Connect to Pump."
- 3 **Verify the Serial number** of the Pump on the App using the serial number located inside the Pump.
- 4 Set your Basal Schedule in the App.
Select Apply New Schedule and enter your phone passcode.
Confirm your Basal schedule on the Pump by pressing the Control Button.



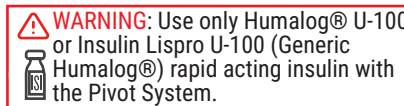
"Allow bluetooth connection"

Note: The app version represented in this image is for reference only.



STEP 4: Fill Syringe with Insulin

- 1 From the Supply Kit, take a Needle and Syringe.
WARNING: Use only Humalog® U-100 or Insulin Lispro U-100 (Generic Humalog®) rapid acting insulin with the Pivot System.
- 2 Clean the insulin vial with an alcohol wipe.
- 3 Twist the needle onto the syringe and carefully remove the needle cap.
- 4 **Draw air into the syringe** equal to the amount of insulin needed. Insert the needle into the vial and inject air.
- 5 Flip vial and fill syringe with insulin.
- 6 Remove any air in the syringe.
- 7 Gently push the plunger until you see a drop of insulin at the needle tip.



2 Clean the insulin vial with an alcohol wipe.

3 Twist the needle onto the syringe and carefully remove the needle cap.

4 **Draw air into the syringe** equal to the amount of insulin needed. Insert the needle into the vial and inject air.

5 Flip vial and fill syringe with insulin.

6 Remove any air in the syringe.

7 Gently push the plunger until you see a drop of insulin at the needle tip.

STEP 5: Fill Cartridge with Insulin

- 1 Insert the needle into the Fill Port at a 90 degree angle.
- 2 Push down on the plunger to slowly fill the Cartridge.
- 3 Check for leaks.
- 4 Check for air bubbles in the Cartridge.
If present, move the air bubble to the Fill Port and remove the air bubble with your syringe.



2 Push down on the plunger to slowly fill the Cartridge.



3 Check for leaks.

4 Check for air bubbles in the Cartridge.

If present, move the air bubble to the Fill Port and remove the air bubble with your syringe.



STEP 6: Prime the Pump

- 1 **Quick Press the Control Button 3 times** to start priming.
- 2 During priming, place the Pump upright using the underside of the Cartridge Tray by flipping the tray.
- 3 After each prime cycle, look for insulin at the end of the Exit Port. Prime again if needed.



i Note: The priming cycle may last about 4 minutes. A flashing white light and five ascending tone means a prime cycle has ended.

3 After each prime cycle, look for insulin at the end of the Exit Port. Prime again if needed.

i Note: The Pump may need multiple prime cycles if there is air remaining in the Cartridge.
Check for air and prime again within 60 seconds if no insulin is seen at the end of the pump.

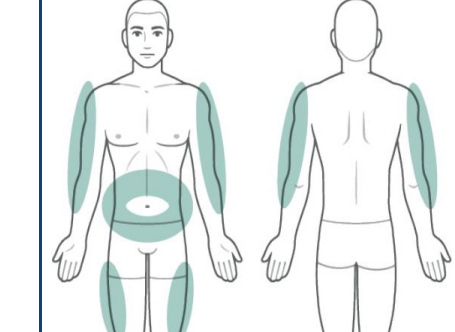
CAUTION: Do not prime your Pivot System if it is attached to your body as this could lead to moderate hypoglycemia.

STEP 7: Prepare Infusion Site

- 1 **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 water, and/or personal care products such as lotions and sunscreens can result in significantly reduced Pump lifetime. This may lead to severe hyperglycemia or Diabetic Ketoacidosis (DKA).
- 1 Wash your hands before starting setup.
- 2 Choose the appropriate site location to attach your system.
- 3 Clean the site with a 70% isopropyl alcohol wipe. Allow the site to dry.

1 Wash your hands before starting setup.

2 Choose the appropriate site location to attach your system.



i Note: The Patch must be inserted into fatty tissue on the back of the arm, abdomen, or upper thigh. Avoid the belly button. Remove excess hair as required.

3 Clean the site with a 70% isopropyl alcohol wipe. Allow the site 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.

STEP 8: Prepare the Patch

- 1 Open the Inserter Box (labeled with a ②) from the "Pump with Inserter" box.
- 2 Take the Tray used in Step 2 that you removed your Cartridge from, and align the Inserter over the Patch.
- 3 Slowly lift Inserter out of Tray.

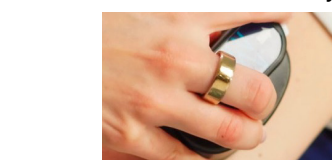


Press down to click into place.



STEP 9: Launch the Patch

- 1 Using your fingers, gently pinch or squeeze around your selected site for at least 5 seconds.
When you are ready to use the inserter, let go of the pinch.
- 2 Place the Inserter against the selected site and push the button until a "click" is heard.
Remove the inserter from your skin.
- 3 **Press down firmly** around the Patch to ensure it is attached to the skin.
- 4 **Pinch the tabs and pull upward** to remove the Clip. **Dispose** of the Clip per local guidelines.



STEP 10: Attach Pump to the Body

- 1 **Attach the Pump** to the Patch by aligning its two notches with the corresponding slots on the Patch.
- 2 Press down the rest of the Pump securely.



i Note: A solid green light and three tones indicate that Basal Delivery has begun.

Bolus Feature: How to Give a Bolus

- 1 Enter Bolus Mode:
 - Hold the Control Button
 - Wait for a **blue light** and long beep
 - Then release the button

- 2 Select the bolus amount:
 - Each quick press = 2 units of insulin**

Note: If bolus size is not correct, do nothing. A green light and three tones indicate that you have returned to Basal Delivery Mode

- 3 Pump will confirm bolus amount with beeps and blue light.

- 4 Start Delivery:
 - Hold the Control Button
 - Wait for a **blue light** and long beep
 - Then release the button.

Note: Pump will indicate bolus delivery has started with a solid blue light and three ascending tones.

Note: Maximum Bolus = 20 Units

Note: If you enter the wrong bolus amount, wait 15 seconds after confirmation and the Pump will exit Bolus Mode.

Cancel Bolus Feature: How to Cancel a Bolus in Progress

- 1 Press and hold the Control Button until you see a green light and hear a single tone (at least 6 seconds), then **immediately** release the button.



Note: A solid green light and three tones indicate that the System has returned to Basal Delivery mode.

Suspend Feature: How to Suspend Insulin Delivery

- 1 Why you may need to Suspend Delivery
 - Changing Treatment Settings
 - Shower, Swimming
 - Medical Procedures
 - Contact Sports

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

- 2 Press and hold the Control Button until you see a white light and hear a single tone (at least 7 seconds), then **immediately** release the button.

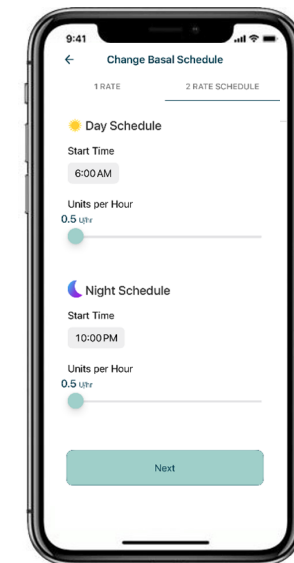
Note: You will see a blue light before the white light appears.



Note: Insulin delivery remains suspended for 30 minutes and will automatically resume after the 30-minute suspend has ended.

Change Basal Schedule: How to Change Basal Rate Settings

- 1 Suspend Delivery first
- 2 Open Pivot™ Diabetes and click Change Basal Schedule



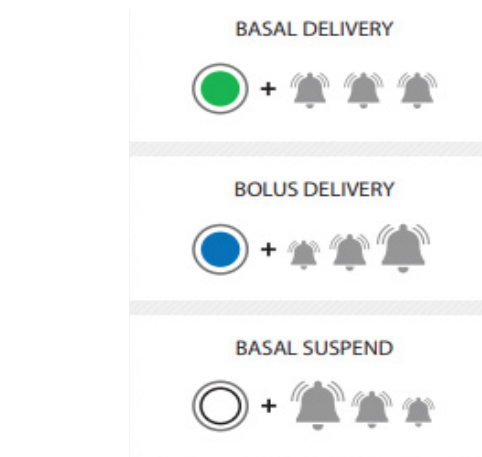
- 3 Select Apply New Schedule and enter passcode. Press Control Button on Pump to confirm schedule.



Note: Insulin delivery will automatically resume after the 30-minute suspend has ended.

Determine Pump Status

- 1 **Quick press** the Control button on the Pump. A status light and tone will appear to indicate which mode you are in.



WARNING: 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).

Important Reminder

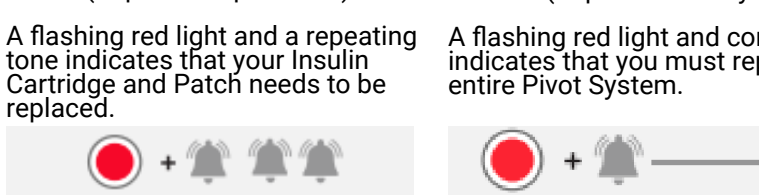
Skin products to avoid near your Pivot System:

- All insect repellents
- All deodorant sprays
- All sunscreens
- All lotions
- All perfumes

Alarms and How to Address Them

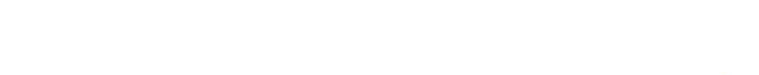
What Alarms Mean and What to Do

Delivery Alarm (Replace Disposables)
A flashing red light and a repeating tone indicates that your Insulin Cartridge and Patch needs to be replaced.



- 1 Remove Pump from Patch.

Technical Alarm (Replace Pivot System)
A flashing red light and constant tone indicates that you must replace your entire Pivot System.



- 2 Gently remove the Patch.
- 3 To unlock the Cartridge, slide the switch in the direction of the arrow. Then use the pull tab to carefully separate the Cartridge from the Pump.



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

If needed, call Customer Care for assistance if an Alarm occurs.

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 U-100 (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 devicesRefer 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 Pivot?**
 - 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 System?**
 - MRI, CT scan, X-ray, surgery, airport security
 - Swimming, showering, jacuzzi, sauna, or any 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 is the purpose of the information presented in the Pivot™ Diabetes app?**
 - All information displayed in the Pivot™ Diabetes app (besides basal schedule) is for reference only and should not be used to make treatment decisions. Consult your Healthcare Provider.
10. **What are some key safety measures for proper use of the Pivot Systems?**
 - Only install the Pivot™ Diabetes app app by Modular Medical directly from the App Store
 - Enable app updates for the Pivot™ Diabetes app app
 - Do not alter or modify components or warranty will be voided
 - Do not run Pivot™ Diabetes app app on a jailbroken mobile device

Additional Information:

The Modular Medical 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.

The Pivot System consists of an Inserter, 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 or Insulin Lispro U-100 (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 of between 2 and 20 units (in 2 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 and Insulin Lispro U-100 (Generic Humalog®).

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.

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

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