MODULAR MEDICAL

pivot

User Guide

We are here for you.

For updates, questions, or assistance with your Pivot™ System, please contact Modular Medical Customer Care anytime.

Toll-free at 866-710-1200

Visit www.pivotpump.com

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About This User Guide

This User Guide will help you navigate your Pivot Insulin Delivery System (referred to as the "Pivot System"). It provides warnings, helpful notes, and step-by-step instructions for the safe use of the System. Federal law restricts this device to sale by or on the order of a physician. The System should only be used by people who have been prescribed this device and only for the stated intended use. This User Guide uses symbols and highlighted text to indicate important information. Important safety information is highlighted, as seen below.

NOTE:	This provides helpful information to assist with the use of your Pivot System.
⚠ ***CAUTION:***	This informs you of any problems associated with the use or misuse of the Pivot System, including malfunctions, failures, damage to the device or other property.
⚠ **WARNING:**	This informs you of important safety information associated with the use or misuse of the Pivot System, including injury or death.

⚠ **WARNING:** Before using your Pivot System, ensure that you have been appropriately trained on its use by a certified Pivot System trainer. Operating the Pivot System in the absence of training can lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA). If you have questions or need further information on how to schedule training on your Pivot System, contact your Healthcare Provider or call Modular Medical Customer Care.

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1.0 OVERVIEW

INTENDED USE: The Pivot Insulin Delivery System is intended for the treatment of diabetes mellitus in persons requiring insulin.

Your 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 treatment settings programming and viewing activity information.

The Pivot System can be filled with up to 3.0mL (300 units) of Humalog® U-100 rapid-acting insulin and can be worn continuously for three days. Your Healthcare Provider will help you to manage your insulin dosing regimen and prescribe insulin.

The Pivot System can be used by persons with diabetes to manage insulin therapy independently.

1.1 INDICATIONS FOR USE

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.

1.2 INSULIN COMPATIBILITY INFORMATION

The Pivot System is compatible with Humalog® U-100 rapid acting insulin only.

Insulin Lispro U-100 (Generic Humalog®) may be used in place of Humalog® U-100 rapid acting insulin.

CAUTION: Please refer to the Possible Risks Section 7.3 for more information on the possible side effects of using your Pivot System.

1.3 CONTRAINDICATIONS FOR USE

The Pivot System is contraindicated for:

1. Diagnosing Diabetes Mellitus
2. Use by patients who do NOT have adequate hearing and/or vision to allow recognition of all functions of the Pivot System including Status and Alarms
3. Use by patients who cannot manage their Diabetes therapy
4. Use by patients unwilling to take a minimum of four (4) blood glucose readings per day
5. Use by patients who are unable to use the Pivot System in accordance with this User Guide
6. Use by patients who are not capable of following the User Guide
7. Use by patient populations requiring basal rates greater than 4 U/hr or less than 0.5 U/hr
8. Use with brands or concentrations of insulin other than Humalog® U-100 or Insulin Lispro U-100 (Generic Humalog®)

WARNINGS: Federal law restricts this device to sale by or on the order of a physician.

Do not leave your Pivot System or its accessories unattended in the presence of small children or pets to prevent tampering with your device as this could lead to moderate hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA). Small parts also may pose an asphyxiation or choking hazard that could lead to injury or death.

Do not modify your Pivot System, its components, or accessories. Doing so will void your warranty and may lead to moderate hyperglycemia, moderate or severe hypoglycemia, or Diabetic Ketoacidosis (DKA). Only use the components and accessories supplied for use with the Pivot System. The use of other components or accessories could lead to moderate hypoglycemia, moderate or severe hyperglycemia, Diabetic Ketoacidosis (DKA), an allergic reaction, or a delay in insulin therapy.

DO NOT expose your Pump within 6 inches from common products with magnets, including cell phone cases or wireless charging cases. Exposure to magnets or products with magnets may interfere with the Pump motor. Damage to the motor can lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

It is important to check the expiration date of each component and accessory of your Pivot System. Using components and accessories beyond their expiration date could lead to infection, moderate, or severe hyperglycemia, or Diabetic Ketoacidosis (DKA). Be sure to dispose of any components or accessories that are past their expiration date in adherence with local guidelines.

WARNING: Consistent drops of the Pump, 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).

CAUTIONS: Modular Medical contraindicates against using the System if you have inadequate hearing due to the importance of the audible signals provided by the Pump. Ensure that you are able to detect audio and visual notifications. Being unable to hear an Alarm may prevent you from responding to a Pivot System event that requires your immediate attention and may lead to moderate hyperglycemia or Diabetic Ketoacidosis (DKA). If you are in a high-noise environment, keep an eye on your Pump, as the light signals will notify you of any issues.

The Pivot System is incompatible with certain common products that are used on the skin. These include bug sprays with or without DEET, perfumes, deodorant sprays, body lotions and sunscreens. Use of these products on the Pivot System itself or where the System is adhered to the skin can cause cracks in the plastic used to manufacture the Pivot components. DO NOT allow these products to come in contact with the Pump, Cartridge or Inserter. ALWAYS remove your Pump before applying these products and ALWAYS wash your hands before handling your Pump, Cartridge or Inserter after using such products. ALWAYS change your Cartridge if it becomes exposed to such products and immediately clean your Pump. Failure to do so may result in damage to the Pump, Insulin Cartridge or Inserter and in some cases lead to moderate hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA).

1.4 Your Pivot System

Your Pivot Insulin Delivery System aims to simplify your diabetes management. The Pivot System offers a user-selected Basal Rate Schedule for all-day insulin therapy, on demand Bolus dosing for correcting glucose levels, and Basal Suspend to temporarily stop insulin flow.

Your basal rate schedule and bolus increment are programmed via the Pivot™ Diabetes app using rates determined by you and your Healthcare Provider.

The figure on the next page highlights the key features of your Pivot System. It is essential to understand each feature for correct use.

Your Pump has a single button to initiate priming, control insulin delivery, and check your Pivot System status. Your Pivot System uses lights and tones to make you aware of the Pivot System status, delivery mode, and Alarms.

You can check your Pivot System status during use with a quick press of the Control Button.

NOTE: The Pivot™ Diabetes app is mandatory for programming a new Pump and for modifying the basal rate schedule and bolus increment on a Pump in use, and must be used to determine and manage appropriate responses to all alarms.

CONTROL BUTTON

This is your primary interface with the Pump. You use it to control bolus delivery and check the status of your Pivot System.

SOUND MODULE
(not pictured)

This provides auditory feedback for button inputs, status checks, and Alarms.

PATCH

This component includes a cannula that is inserted into your subcutaneous tissue to allow insulin delivery. It also includes the adhesive that secures the Pivot System to your body.

LED LIGHT

This provides visual feedback for button inputs, status checks, and Alarms.

1.5 System Components

Your Pivot System is provided to you in the Pivot Insulin Pump Starter Kit, which consists of: 2 Supply Kits and 1 Pump with Inserter Kit. The Pivot™ Diabetes app must also be utilized to program the Pump (see Section 4.0).

The Pivot Insulin Pump Starter Kit contains:

- **Pump (90 day use life)**
- **Inserter (2 year use life)**
- **Quick Start Guide**
- **User Guide (not pictured)**
- **Patient Medical Device Card (not pictured)**
- **10 Cartridges and 10 Patches (in sealed trays)**
- **10 Needles and 10 Syringes (not pictured)**

Pump

Inserter

Quick Start Guide

Tray
(Cartridge + Patch)

The Supply Kit contains the disposable components and accessories with 3 day use life:

All accessories you need for *30* days of use

- **10 Cartridges**
- **10 Patches**
- **10 Syringes and Needles**

CARTRIDGE

PATCH

SYRINGE & NEEDLE

2.0 Setting Up Your System

Step 1: Open Packaging

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

Insulin Pump Starter Kit

Supply Kit

⚠ CAUTION: Do not use Pivot System components if they have been dropped as there could be unseen damage to the device that could lead to moderate hypoglycemia, moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

Note: The "Use By" date is found on the packaging of relevant components in the following format: **YYYY-MM-DD**
For more information on symbols, please refer to the Glossary of Packaging Symbols in Section 9.0.

Step 2: Connect Pump and Cartridge

For this step, you will need:

1. New Cartridge
2. Pump

New Cartridge

Pump

WARNINGS: Only unpack your Cartridge immediately before use to prevent the risk of infection.

Cartridges are sterile and for single-use only. Do not attempt to reuse a Cartridge as this could lead to infection or a delay in insulin therapy.

Always inspect for damage with the Cartridge or Pump packaging before opening and on the product before use. Failure to do so may lead to infection, moderate hypoglycemia, moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

NOTE: If this is your first time setting up your Pivot System, you must program your Basal Rate Schedule and Bolus Increment using the Pivot™ Diabetes App, available for download in the App Store.

1. Open the White Box labeled with a (2) in the Pivot Insulin Pump Kit and open a Tray in the Supply Kit.

   Note that the Pump serial number is located on the inside of the device as shown in the photo to the right. Take note of the serial number as this will not be visible once the Cartridge is assembled.

2. **Remove the paper cover** and take the Cartridge out of the packaging and place on a flat surface.

3. Connect the Pump to the Cartridge. Align the Cartridge notch to the Pump notch and press firmly to lock together. Ensure the Cartridge is fully seated by **pressing firmly around all the edges until you hear a click.**

Pump Serial Number

Pump with Inserter Box

4 When connected successfully, you will see a white light and hear a single tone.
If you receive a red light go to the Alarm Section 5.0.

5 When the Pump and Cartridge are connected, a function check will start.

A flashing blue and green light indicates the Pump needs to be programmed with the Pivot™ Diabetes app. Proceed to Step 3.

A flashing white light and three tones indicates the Pump is ready to be filled with insulin. Proceed to Step 4.

Step 3: Connect to App and Set Treatment Settings

For this step, you will need:

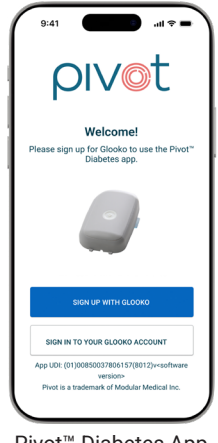
- An Assembled Pump
- The Pivot™ Diabetes app Installed on your Smartphone

Pump

The Pivot™ Diabetes app is available to download from the App Store. The Pivot™ Diabetes app provides an easy way to set your Basal Rate Schedule.

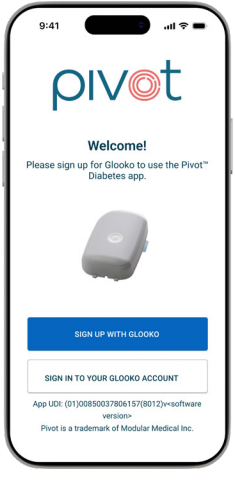
NOTES: The Pivot™ Diabetes app will work while traveling internationally, however the app must be linked to the US App Store.

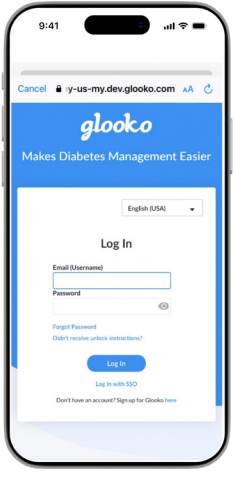
In case of BLE failure, you cannot connect or pair to the Pump.



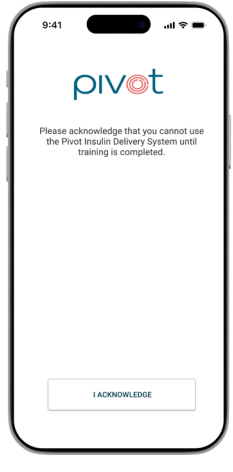
Pivot™ Diabetes App

1 Sign Up or Log in to your Glooko Account.





2 Read and accept the acknowledgements to proceed.

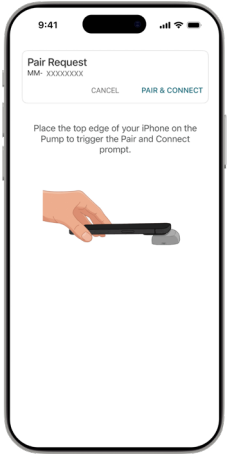


3. Press Connect to Pump on the Pivot™ Diabetes app.

4. Place your Smartphone on the Pump as shown, with the back camera facing the Control Button.

5. Press “Pair & Connect” to confirm the pair request.

   Verify the paired Serial Number shown in the App matches the serial number inside the pump.

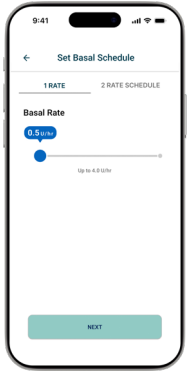


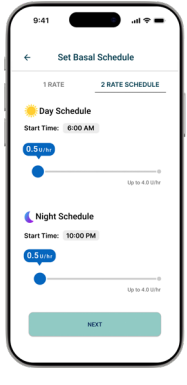
NOTE: *You must know your recommended Treatment Settings before beginning programming. Your Healthcare Provider will help you determine your Treatment Settings and can assist you in setting this within the Pivot™ Diabetes app.*

6 Set your Basal Rate Schedule in the app. The Basal Rate Schedule has two options: Single Rate or Two Rate. Use the on-screen slider to adjust the Basal Delivery Rate.

SINGLE RATE

One basal rate that will run continuously over a 24-hour period.





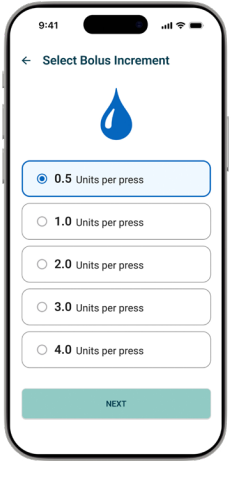
TWO-RATE

The Two Rate option requires two basal insulin delivery rates. You will choose the start time for both Day and Night rates, adjustable in 15-minute increments. The Day rate ends when the Night rate begins.

For example, if you set your Nighttime rate to begin at 8:00 PM, your Daytime rate will automatically end at 8:00 PM, and the Nighttime rate will then begin.

7 Next, set your Bolus Increment in the app.

Set your bolus increment level in 0.5, 1.0, 2.0, 3.0, and 4.0 unit increments. Each press of the Control Button on the Pump while setting up a bolus will deliver this amount of insulin. See Section 3.1 for further instructions on how to deliver a bolus.



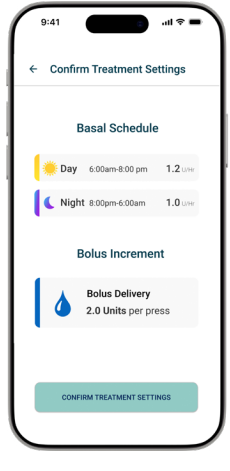
8 Select "Confirm Treatment Settings" and provide user authentication such as Face ID or passcode.

A flashing green light on your Pump indicates the request was received.

Quickly press and release the Control Button to confirm your Treatment Settings.

9 A flashing white light and three tones means that your schedule is set. Now you can proceed to Step 4.

NOTE: *The Pivot™ Diabetes app will prompt you to enable user authentication if it is currently disabled.*



Step 4: Fill the Syringe with Insulin

For this step, you will need:

- New filling needle and syringe
- 10mL vial of Humalog® U-100 Insulin (not provided)
- 70% Isopropyl Alcohol Wipe (not provided)

Filling Needle and Syringe

10 ML Vial of Humalog® Insulin

70% Isopropyl Alcohol Wipe

WARNINGS: Do not reuse needles or syringes as this could lead to an infection, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

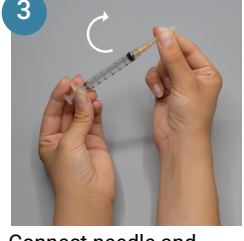
Only use Humalog® (Insulin lispro) U-100 rapid-acting insulin with the Pivot System. Do not blend different insulins. The use of other insulin brands, concentrations of insulin, or medications can lead to moderate or severe hypoglycemia, or a toxic episode.

1 From the Supply Kit, take a Needle and Syringe.

2

Clean the top of the insulin vial with a 70% isopropyl alcohol wipe.

3

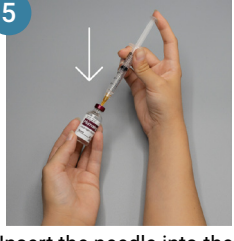


Connect needle and syringe and carefully remove the needle cap.

4

Draw air into the syringe equal to the amount of insulin needed for three days of Pump use.

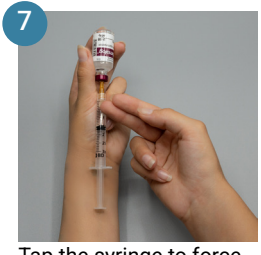
5



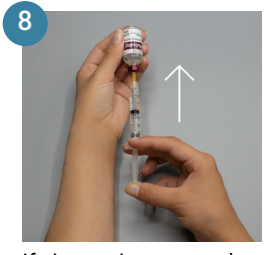
Insert the needle into the vial and gently push air into the vial.

WARNING: Make sure you clean the top of the insulin vial with an alcohol wipe before withdrawing insulin. Failure to do so could contaminate the needle and lead to an infection.

Flip the vial and the syringe, then slowly pull the plunger to fill the syringe with the amount of insulin needed for three days of Pump use.



Tap the syringe to force any air bubbles to the top. Gently push the plunger to release the air back into vial.



If air remains, repeat the previous step and refill the syringe as necessary. Remove the needle from the vial.

Gently push the plunger until a drop of insulin is seen at the needle tip.

CAUTION: Ensure that air is expelled from the syringe prior to filling the Cartridge. Air in your Pivot System can lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

Step 5: Fill the Cartridge

For this step, you will need:

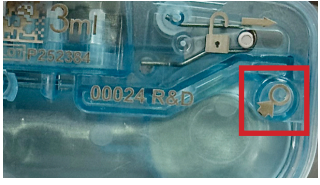
- An Assembled Pump
- Syringe filled with Insulin

Pump

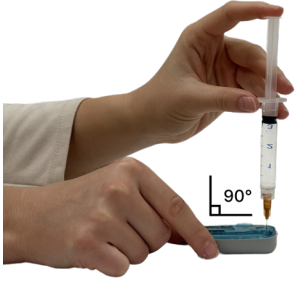
Syringe filled with Insulin

⚠ **CAUTIONS:** Only use the supplied Needle and Syringe for filling the Cartridge. The use of other Needles or Syringes could lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), an allergic reaction, or a delay in insulin therapy.

1. Locate the Fill Port on the underside of the Cartridge that is marked with a white circle.



2. Carefully insert the needle into the Fill Port **at a 90 degree angle**.



NOTE: Do not fill the Cartridge past its maximum capacity of 3.0 mL (300 units), or below its minimum of 0.3 mL (30 units).

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

4 Inspect the Cartridge **for leaks.**

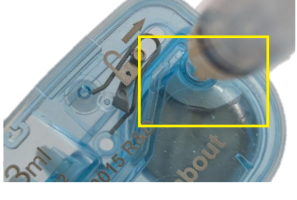
If leaks are present, contact Modular Medical Customer Care. Remove and discard the Cartridge and repeat the setup procedure with a new cartridge. If a new Cartridge is used, dispose of the unused Patch, as the sterile barrier is now breached.

CAUTIONS: Never attempt to extract insulin from a used Cartridge as this could lead to moderate hyperglycemia or Diabetic Ketoacidosis (DKA).

Check your Pivot System for leaks regularly as leaks may lead to moderate hyperglycemia, moderate hypoglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

5 Check for **air bubbles** in the Cartridge.

6 If air bubbles are present, angle the Cartridge as shown to move the air bubble to the Fill Port. Reinsert the needle into the Fill Port and draw back the plunger to remove the air bubble.



WARNING: After use, be sure to dispose of your used needle and syringe safely and in accordance with local regulations to prevent injury or infection from an accidental needle stick.

CAUTION: Do not pierce the Fill Port more than 4 times as this could cause insulin to leak and could lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

Step 6: Prime the System

For this step, you will need:

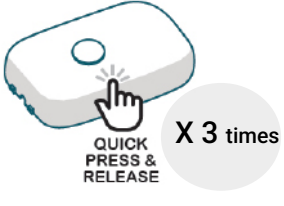
- Filled Pump

Filled Pump

NOTE: If you do not prime within 45 minutes of powering on the pump, the pump will alarm

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

1. **Press the Control Button with three quick consecutive presses** to activate Priming Mode. You will see a white light and hear a repeating tone that indicates priming is in progress.



2. **During priming, place the Pump upright**. You can use the underside of the Cartridge Tray by flipping the tray. You may look through the back of the Cartridge to see the insulin reservoir to ensure all air bubbles are being appropriately primed out.

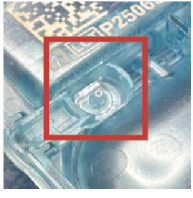
The priming cycle may last about 4 minutes.

You will see a flashing white light and hear five ascending tones that indicates the first priming cycle is complete.

CAUTION: Holding your Pivot System correctly during Priming allows the air to be removed from the Cartridge. Air in the Cartridge can lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

3 After each prime cycle, **look for a drop of insulin at the Exit Port.** Inspect your Cartridge reservoir for any air bubbles.

If air remains, press the Control Button 3 times while the white light on your System is flashing to initiate another priming cycle. You have **60 seconds** to start another prime cycle.



4 Your opportunity to prime will end after 60 seconds have passed with no additional presses of the Control Button.

A flashing green light and a single tone indicate that Basal Delivery will automatically begin in 2 minutes.

Priming is complete when you see a drop of insulin at the end of the Exit Port and no air bubbles remain.

NOTE: *If you have attempted to prime multiple times and air bubbles remain in the reservoir, you will need to replace the Cartridge with a new one.*

Step 7: Prepare the Infusion Site

For this step, you will need:

- New Patch (with Clip)
- Inserter
- 70% Isopropyl Alcohol Wipe
  (not included, not imaged)

Patch
(Inside Tray)

Inserter

Clip

Choosing where you place your patch is important.

The patch should be at least two inches away from your navel or previous infusion site and must be four inches away from a Continuous Glucose Monitor (CGM) sensor site.

The Patch must be launched into:

- Fatty tissue on the abdomen
- The upper thigh area
- The back of the arm

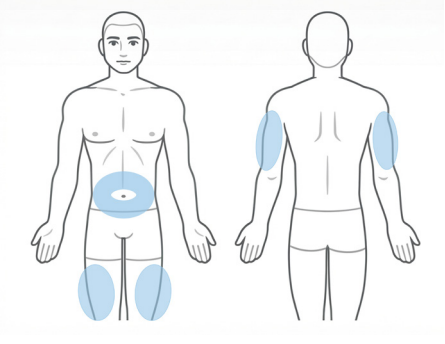
CAUTIONS: Avoid areas with scarring, tattoos, moles, lipodystrophy, and areas that may get bumped or constricted such as the beltline or waistline. Placing your Pivot System incorrectly could lead to moderate hyperglycemia, or Diabetic Ketoacidosis (DKA). Always use a new infusion site that is at least 2 inches away from the previous infusion site. Using the same infusion site repeatedly may lead to infusion site infection, lipodystrophies, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA). Contact your Healthcare Provider if you have symptoms of an infection at your infusion site.

WARNINGS: Always check your blood glucose 1-2 hours after changing your infusion site. DO NOT change your Patch right before bed. Change it at least 3 hours before going to bed to allow enough time to confirm that your Patch is delivering insulin as intended. Your Pivot Pump is designed to deliver insulin reliably, but because it uses only rapid-acting insulin, you will not have long-acting insulin in your body. To prevent Diabetic Ketoacidosis (DKA), moderate hypoglycemia, or infection, you must be prepared to inject insulin if delivery is interrupted for any reason.

1. Before setup, **wash your hands.**

2. Choose the **appropriate site location** to attach your system.

3. **Remove excess hair** as required. **Clean the site** with a 70% isopropyl alcohol wipe. Allow the site to dry.



CAUTION: Do not place the device on broken skin. Before use, 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 1) from the Pump with Inserter box.

2. Use the arrow on the label on top of the Inserter to align it over the Clip. **Once aligned, push Inserter until a click is heard.**

NOTE: Do not try to remove the Patch with your hands, use the Inserter.

3 Holding the tray with one hand, slowly lift Inserter upwards out of packaging. The lining will remove automatically throughout this process.

4 Visually inspect your tray after peeling to ensure proper detachment.

If the liner has not detached in one piece, do not attempt to insert the Patch. With the inserter facing away from you, click the white button and launch it on a hard surface to reset. Discard and grab a new tray.

WARNING: Every time you change your Cartridge, you must use a different infusion site and replace the Patch. Not doing so can lead to infection, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).

WARNINGS: Only use new Patches that are unused, unopened, and within their expiration date to avoid the potential for infection, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).
Only unpack your Patch immediately before use to reduce the risk of infection.

CAUTION: If the Clip is detached from the Patch, discard this Patch and replace with a new Patch. If Patch is not replaced this could lead to moderate hyperglycemia or Diabetic Ketoacidosis (DKA).

If you are unable to attach the Inserter to the Patch, discard this Patch and replace with a new Patch. If the Patch is not replaced it could lead to a delay in insulin therapy, moderate hyperglycemia or Diabetic Ketoacidosis (DKA).

Lift the Inserter slowly, if the Inserter detaches from the Patch when lifting the Inserter out of packaging, do not attempt to reuse that Patch this could lead to a delay in insulin therapy, moderate hyperglycemia or Diabetic Ketoacidosis (DKA).

If the Inserter is not functional, stop using your Pivot System until you have a replacement. Using an Inserter that is not functional could lead to a delay in insulin therapy, moderate hyperglycemia or Diabetic Ketoacidosis (DKA).

Step 9: Launch the Patch

1. Using your fingers, create a **wide pinch around your selected site** and gently squeeze your skin for at least 5 seconds.

2. When you are ready to insert the Patch, let go of the pinch and place the Inserter against your skin. **Press the Launch Button firmly until a "click" is heard**. Remove the Inserter from your skin.

⚠ ***CAUTION:*** Make sure to press down firmly around the Patch to ensure it is adhered. Failure to do so could result in the Patch falling off and cannula being removed from your tissue during use and could lead to moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).
Remove and replace the Patch no later than three days after attaching. Failure to do so could lead to infusion site infection, lipodystrophies, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

NOTE: Do not attempt to insert Patch if the adhesive pad is stuck onto itself.
Do not insert fingers inside Inserter after removing the Patch from packaging.
Do not point the Inserter at your face or any other part of your body where you do not intend to insert the Patch.

3 **Press down firmly** around the Patch to ensure it is attached to the skin.

4 **Pinch the tabs and pull upwards** to remove the Clip and safely dispose of after use.

WARNINGS: Do not leave your Pivot System or its accessories unattended in the presence of small children or pets to prevent tampering with your device as this could lead to moderate hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA). Small parts also may pose an asphyxiation or choking hazard that could lead to injury or death.

The Clip is sterile and for single-use only. Do not attempt to reuse or re-insert a Clip as this could cause damage to the cannula leading to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or could lead to infection.

After use, be sure to dispose of your Clip safely and in accordance with local regulations to prevent injury or infection from an accidental needle stick.

Step 10: Attach the System

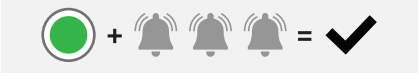
For this step, you will need:

- A Primed Pump

Primed Pump

1. **Attach the Pump** to the Patch by aligning its two notches with the corresponding slots on the Patch and pressing the rest of the Pump securely.

2. Basal Delivery will automatically begin when you see a solid green light and 3 tones.



CAUTION: Make sure the Pump is fully engaged to all slots in the Patch, as this could lead to moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

NOTE: Basal Delivery will automatically begin 2 minutes after you have primed your Pivot System. A solid green light and three tones indicates that Basal Delivery has begun.

3.0 Using the System

Your Pivot System has four modes associated with the delivery of insulin: Basal Delivery Mode, Bolus Delivery Mode, Basal Suspend Mode, and Prime Ready State.

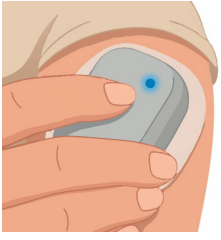
1. **Basal Delivery Mode** is the default mode of your System and delivers a continuous flow of basal insulin. This mode automatically begins when your System has completed setup and priming.
2. **Bolus Delivery Mode** is used to deliver a specific quantity of bolus insulin during mealtimes or to correct high blood glucose levels.
3. **Basal Suspend Mode** is an additional mode available to temporarily pause the delivery of basal insulin.
4. **Prime Ready State** indicates the Pump is ready to begin priming but has not yet been initiated.

Pump lights and tones indicate which of these modes your Pump is currently in. You can check the current mode of your Pump by performing a Status Check (See Section 3.5).

NOTE: Basal Delivery can be set to a rate of your choosing, between 0.5 - 4.0 units per hour, in 0.1 unit per hour increment. A single basal rate or two basal rates can be programmed in a 24-hour period. See 4.0 Pivot Phone App section for more information on Basal Rate Schedule programming. Bolus Delivery can be set in 0.5, 1.0, 2.0, 3.0, or 4.0 unit increments, with a maximum of 20 units. See Section 3.1 for bolus delivery instructions.

3.1 Delivering a Bolus

A bolus is a dose of insulin delivered on demand at mealtimes or to correct high blood glucose. You control it using the button on your Pump. Before you start, know your dose in units and your bolus increment. Your increment is set in the app and determines how much insulin each button press delivers.



BEFORE YOU START, HAVE THESE 3 THINGS READY.

1. Your Dose:

__ __ Units

depending on your meal

2. Your Increment:

__ __ Units

set in the Pivot™ Diabetes app. Check app Dashboard.

3. Button presses needed:

__ __ Presses

see table on the next page

STEPS:

1. **Know your dose and find your presses in the table.**
   Max dose is 20 units or 10 presses. Use the table to find the number of presses for your increment.

2. **Hold the control button until you see a blue light and hear a beep, then release.**
   You are now in bolus mode. A blue light and single beep confirm this.

3. **Once the blue light appears, quick press the button until you reach your dose. Each press adds one increment and gives one blue flash and beep to help you count.**
   Tones rise for presses 1 to 5, then reset and rise again for presses 6 to 10.

HOW MANY PRESSES DO YOU NEED?

0.5 U per press		1.0 U per press		2.0 U per press		3.0 U per press		4.0 U per press	
Press	Units	Press	Units	Press	Units	Press	Units	Press	Units
1	0.5	1	1.0	1	2.0	1	3.0	1	4.0
2	1.0	2	2.0	2	4.0	2	6.0	2	8.0
3	1.5	3	3.0	3	6.0	3	9.0	3	12.0
4	2.0	4	4.0	4	8.0	4	12.0	4	16.0
5	2.5	5	5.0	5	10.0	5	15.0	5	20.0
6	3.0	6	6.0	6	12.0	6	18.0		
7	3.5	7	7.0	7	140				
8	4.0	8	8.0	8	16.0				
9	4.5	9	9.0	9	18.0				
10	5.0	10	10.0	10	20.0				

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

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

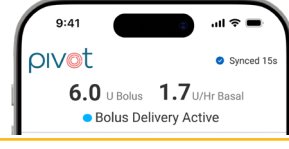
If the count is wrong, wait 15 seconds. The pump returns to basal mode automatically. Start again from step 2.

5 **To confirm, hold the button again until you see a blue light and long beep, then release.**

Delivery has started. A solid blue light and 3 ascending tones confirm this.

6 **Check the Pivot™ Diabetes app to confirm delivery.**

The dashboard will show "Bolus Delivery Active" on the top. You can also scroll down to see it logged under Pump Activity.



CAUTION: Check blood glucose levels before and after a bolus to prevent the risk of moderate hypoglycemia.

Not confirming a Bolus request could lead to moderate hyperglycemia and Diabetic Ketoacidosis (DKA).

NOTE: While a bolus is actively being delivered, you will not be able to program a second bolus delivery.

Maximum bolus is 10 button presses or 20 units, whichever comes first. If exceeded, the bolus cancels automatically and you will need to start again.

What to do if something goes wrong:

Green light came on while I was still pressing

You exited bolus mode. This happens if there was more than 15 seconds between presses or if you exceed maximum number of button presses from the table. You need to start again from step 2.

Lost count or pressed too many times?

Do not guess. Wait 15 seconds for the pump to exit bolus mode automatically, then start again from step 2 with a fresh count.

Not sure if delivery started or concerned about the amount delivered?

Open the Pivot™ Diabetes app and check the dashboard for "Bolus Delivery Active." You can also scroll to Pump Activity to see a log of recent events. If delivery is still active you can cancel it. Refer to Section 3.2 for more instructions.

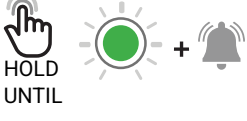
3.2 Canceling a Bolus Delivery

1. Check that you are currently in Bolus Delivery Mode by making a quick press on the Control Button.

   Look for a blue light on the Pump and listen for three ascending tones to indicate that you are currently in Bolus Delivery Mode.

2. **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.

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



NOTE: *The amount of insulin delivered before a Bolus is cancelled depends on how much time has passed since the bolus delivery began. Check your blood glucose levels.*

3.3 Suspending and Resuming Basal Delivery

You may pause your Basal insulin delivery for up to *2 hours*. You can do so by entering Basal Suspend Mode.

1. 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.

   You will observe a blue light and tone before it turns to white.

2. When you see a solid white light and hear three descending tones, that means your Pivot System has suspended insulin delivery.

3. You can resume insulin delivery at any time by repeating the long press, or delivery will automatically resume after 2 hours.

NOTE: *Delivery remains suspended for 2 hours. Basal delivery may not be suspended while the Pump is in Bolus Delivery Mode. Follow the instructions in Section 3.2 to first cancel your bolus, then you may suspend basal delivery.*

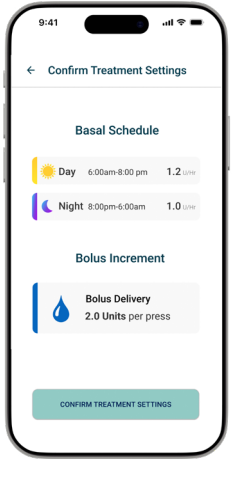
3.4 Changing Treatment Settings

1. First, suspend insulin delivery by following the instructions in Section 3.3.
2. Open the Pivot™ Diabetes app and click Change Treatment Settings.

WARNING: *It is not possible to change the configuration of the Pivot System while it is dispensing insulin. All changes to your Treatment Settings must be done while your Pivot System is in Basal Suspend mode or is starting up after changing the Cartridge. This prevents the risk of accidental Treatment Settings changes that could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).*

3 Enter the new basal schedule and/or new bolus increment. Then select Confirm Treatment Settings and provide user authentication such as Face ID or passcode.

4 Press the Control Button on the Pump to confirm the new treatment settings. Insulin delivery will automatically resume after the 2-hour suspend period ends, or you can resume it earlier by following the instructions in Section 3.3.



3.5 Checking System Status

While using your Pivot System, you can check the Pivot System status anytime with a quick press of the Control Button.
This check will show you the current Delivery Mode and also provide confirmation that the LED lights and sound signal tones are working correctly.

WARNING: If the Status Check does not provide Audio and Visual feedback, the hardware may be damaged and the Pump should be replaced immediately. Contact Modular Medical Customer Care to order a replacement. Failure to replace your Pump may lead to moderate or severe hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA).

CAUTION: If the Control Button stops working at any time, stop using your Pivot System until you have a replacement. Contact Modular Medical Customer Care to order a replacement. Improper functioning of your Pivot System could lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

BASAL DELIVERY MODE Indicated by a green light and 3 consistent tones		This mode **delivers insulin based on your personalized schedule.** This is the default mode that starts automatically after set-up. To set your Basal Rate Schedule, please use the Pivot™ Diabetes app (Section 4.0).
BOLUS DELIVERY MODE Indicated by a blue light and 3 ascending tones		This mode **delivers a selected volume of insulin** when needed. To set your personalized Bolus Increment, please use the Pivot Diabetes app (Section 4.0). This is useful for managing blood glucose during mealtimes.
BASAL SUSPEND MODE Indicated by a white light and 3 descending tones		This mode is used to **pause basal insulin delivery** for up to 2 hours. Delivery will resume automatically when the suspend period ends, or can be resumed earlier by the user.
PRIME READY STATE Indicated by a flashing white light and 3 ascending-then-descending tones		This mode indicates **the pump is ready to begin priming** but has not yet been initiated by user. Priming must be started by pressing the Control Button 3 times.

3.6 Detaching Your Pump

You can temporarily detach your Pump from the Patch during a three-day use period.

Common reasons for detaching your Pump include the following:

Preparing for medical procedures such as:

- MRIs
- CT scans
- X-rays
- Surgeries

Or common daily activities, like:

- Showering
- Swimming
- Contact Sports

⚠ **CAUTION:** Do not attach and reattach the Pump to the Patch more than 6 times during use, this could lead to moderate hyperglycemia, moderate hypoglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

1. First, put your Pump into Basal Suspend Mode. (See Section 3.3)
2. Disconnect your Pump by detaching the snap and pulling it away from the Patch. Leave the Patch in place.

WARNINGS: Do not leave your Pivot System or its accessories unattended in the presence of small children or pets to prevent tampering with your device as this could lead to moderate hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA). Small parts also may pose an asphyxiation or choking hazard that could lead to injury or death.

Always store your Pump in a safe and secure place when not in use to ensure it is not mishandled. Failure to secure your Pump could create security risks and lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, Diabetic Ketoacidosis (DKA), or catastrophic over delivery of insulin resulting in death.

After suspending insulin delivery and before it resumes, make sure to wash your hands when reconnecting the Pump to the Patch to minimize risk of infection.

CAUTION: Monitor your blood glucose levels after reattaching your pump. Failure to do so could lead to moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

NOTE: Insulin delivery will automatically resume after the 2-hour suspend has ended, or after the user resumes insulin delivery.

3.7 Replacing Your Patch & Cartridge

Your Cartridge and Patch must be replaced at the end of the three-day use period, when you receive a Cartridge Alarm or if you detect an issue. You can detach your Pivot System using the following steps.

1. First, remove the Pump as shown in the previous Section 3.6.

2. Carefully remove your Patch.

⚠ **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.

NOTE: If an issue is detected, please contact Modular Medical Customer Care before discarding supplies.

3 To remove the Cartridge from your Pump, locate the small release latch that's next to the lock icon on the underside of the Cartridge and slide it in the direction of the arrow to release.

4 Use the pull tab located on the side to carefully separate the Cartridge from the Pump. To replace Cartridge and Patch refer to Section 2.0.

NOTE: As shown in the illustration to the left, after removing a cartridge, do NOT stack it on top or underneath of the pump.

Additionally, once the latch is released, do NOT reattach the old Cartridge to the Pump. The Pump should only be attached to a new Cartridge.

CAUTION: Every time you change your Cartridge, you must replace the Patch and use a different infusion site. The new infusion site must be at least 2 inches away from the previous infusion site. Using the same infusion site repeatedly may lead to infusion site infection, lipodystrophies, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA). Contact your Healthcare Provider if you have symptoms of an infection at your insulin infusion site.

3.8 Replacing Your Pump

After 90 days from when you first power on your Pump, it will provide a Pump Expired Alarm as identified in Section 5.0.

The full System must be removed as shown in Section 3.7.

Proceed with assembling the Pump as shown in Section 2.

In some instances, your Pump might go beyond 90 days. See Section 5.2 for more information on the last Cartridge use.

NOTES: Removing the Cartridge from the Pump will disconnect power and turn off the Alarm.

When programming a replacement Pump with the Pivot™ Diabetes app that has already been used to program a previous Pump, you will be given the option to import the Treatment settings (from the previous Pump) or create a new Treatment Setting.

4.0 Pivot Phone Application

The Pivot™ Diabetes app is used to program your Treatment Settings and to view your Pivot System alarms and activity. Check www.pivotpump.com for smartphone device and operating system compatibility. **Download at the Apple App Store®.**
If you have concerns or questions about the Pivot™ Diabetes app, please contact Modular Medical Customer Care anytime at: **866-710-1200** or **www.pivotpump.com**

WARNINGS: If your Pivot™ Diabetes app or Pivot System are not working correctly, please contact Modular Medical Customer Care. Malfunctions or failures of the Pivot™ Diabetes app or Pivot System could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.
Only install the Pivot™ Diabetes app by Modular Medical, Inc. directly from the App Store to prevent security risks that could lead to moderate or severe hyperglycemia, moderate or severe hypoglycemia, or Diabetic Ketoacidosis (DKA).
Do not run the Pivot™ Diabetes app on a jailbroken smartphone as this could create security risks and lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).

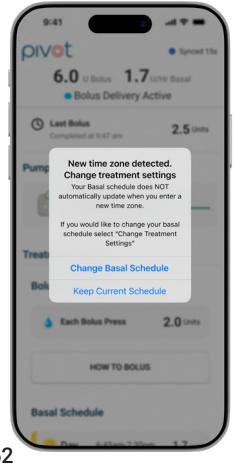
NOTE: International travel is permitted, however, the app must be linked to the US App store.

The Pivot™ Diabetes app only allows you to set and view your Treatment Settings. It does not allow you to administer bolus doses. Your bolus doses are dispensed through the Pump using the Control Button. Refer to the Bolus Delivery section (Section 3.1) for more information.

For step-by-step instructions for setting your Treatment Settings, see Section 2.0.

CAUTION: Before updating your phone's operating system (OS), make sure the version is supported or you may not be able to continue using the Pivot™ Diabetes app. This may lead to moderate hypoglycemia, moderate hyperglycemia, or a delay in insulin therapy.

NOTES: You may need to upgrade your device or the operating software to use the Pivot™ Diabetes app.
Make sure you have automatic app updates enabled on your smartphone so the Pivot™ Diabetes app gets updated automatically when new cybersecurity updates are released.



When using a Two-Rate Basal Schedule, ensure the correct time zone is selected in the Pivot™ Diabetes app before and during travel. Your Healthcare Provider will discuss your insulin delivery schedule and dosage with you.

WARNING: If you are using a Two-Rate Basal Schedule and are traveling to a different time zone, update your Basal Rate Schedule using the Pivot™ Diabetes app. Failure to do so could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).

The Pivot™ Diabetes app automatically updates all displayed times to match your current time on the phone when the app is open and connected to the Pump, but will not make any adjustments to your Pump's Treatment Settings.

Mobile Connection Security

When pairing to the Pivot™ Diabetes app, your Pivot System uses a secure Bluetooth® connection which uses dual authentication.

This technology uses NFC (Near-Field Communication) which allows devices to share data easily.

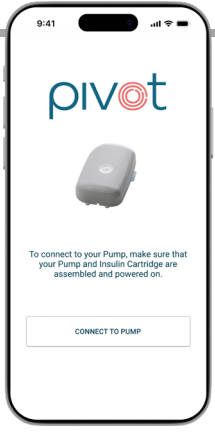
Communication between the Pivot System and the Pivot™ Diabetes app is encrypted.

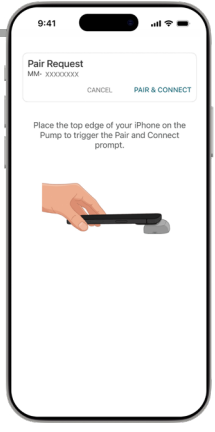
WARNING: Make sure you keep other people from using the Pivot™ Diabetes app on your smartphone by keeping your smartphone secured and setting it to unlock with a passcode, fingerprint, face ID, or similar user authentication. Failure to secure your smartphone could create security risks and lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

4.1 Connecting the App to the Pump

1. Open your Pivot™ Diabetes app and click “Connect to Pump”.

2. Place your smartphone on top of the Pump in a fashion similar to tap to pay, and press “Pair & Connect” to confirm the request.





NOTE: The phone must be placed against the Pump in the orientation shown and held there to provide the NFC connection.

4.2 General App Interface

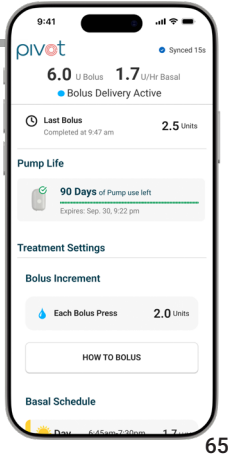
Your Pivot™ Diabetes app Dashboard displays real-time information about your Pump status, recent activity, and Treatment Settings. When your Pump detects an issue, the app will display information to help you identify and address the Alarm, however all notifications are to be dealt with by interacting with the Pump only.

Pump Status - Current Delivery Mode of the Pump. See section 4.3 for definition of all options.

Last Bolus - Displays when the last bolus was completed, and how much insulin was delivered.

Pump Life- Displays how much use is left in your Pump.

NOTE: The Pivot™ Diabetes app only displays information when paired and connected with the Pump. The Pivot™ Diabetes app does not receive automatic updates from the device unless the wireless Bluetooth connection is active.

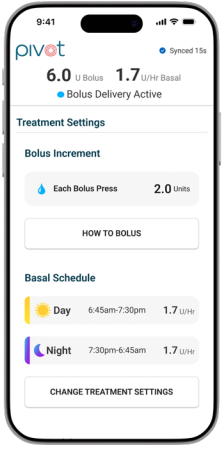


Bolus Increment - Displays your selected Bolus Increment per press.

How to Bolus Button- Displays step-by-step instructions on how to deliver a bolus.

Basal Schedule - Displays the current basal schedule programmed in the connected Pump.

Change Treatment Settings Button - Press the button to modify the basal schedule and bolus increment.
NOTE: The Pump must be suspended to change treatment settings.



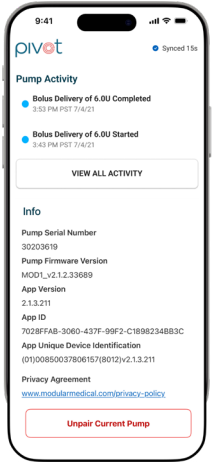
Pump Activity- Displays the last 2 activities of the Pump at a glance.

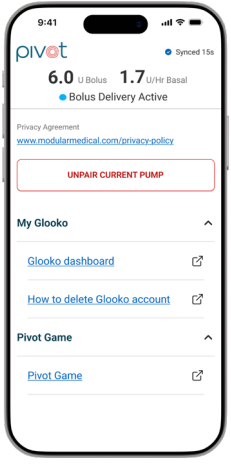
View All Activity Button - Press the button to see a chronological list of activity for the currently paired pump.

Pump Information- Displays Pump serial number, App Version, Pump Firmware version and App Unique Identifier.

Unpair Current Pump Button- Press this button to unpair from your current Pump.

My Glooko - Displays your Glooko account information. Deleting your Glooko account will permanently remove your stored activity data and you will no longer be able to use the Pivot™ Diabetes app.



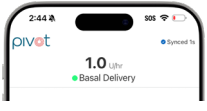


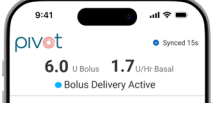
4.3 Pump Status Indicator

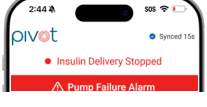
The Pivot™ Diabetes app displays the current status of your Pump at the top of the screen. This updates automatically whenever your Pump's activity changes.

During Setup and Priming:
- Loading — Pump is starting up.
- Ready to Fill and Prime — Pump is ready to be filled with insulin.
- Priming in Progress — Priming cycle is currently running.
- Prime Cycle Complete — A priming cycle has finished.
- Pump is Ready — Priming is complete and Basal Delivery will begin within 2 minutes.

During Use:
- Basal Delivery — Basal insulin is currently being delivered.
- Bolus Delivery Active — A bolus is currently being delivered.
- Insulin Delivery Suspended — Basal delivery is paused for up to 2 hours unless you resume delivery earlier.
- Insulin Delivery Stopped — Insulin delivery has stopped due to an Alarm. An Alarm banner will show the type of Alarm. Refer to Section 5.0 for instructions on how to respond.







4.4 Pump Activity

Your Pivot™ Diabetes app will log activity for the currently paired Pump. Below is the information you may find in your Pump Activity.

- Pump Paired: A new Pump has been paired to the Pivot™ Diabetes app.
- New Cartridge Installed: The user has installed a new Cartridge to the connected Pump.
- Treatment Settings Updated: The user has changed the Treatment Settings of the connected Pump.
- Bolus Delivery Completed: The connected Pump has completed delivery of a bolus.
- Bolus Delivery Canceled: The user has canceled a bolus delivery on the connected Pump.
- Basal Delivery Resumed: Basal insulin delivery has restarted after a suspend period, either manually by the user or automatically after 2 hours.
- Insulin Delivery Suspended: The user has suspended Basal Delivery on the connected Pump.
- Pump Cartridge Alarm Detected: Delivery has stopped, the Cartridge and Patch must be replaced.
- Pump Alarm Detected: Delivery has stopped, the System must be replaced.
- Insulin Delivery Resumed: The message displayed after resuming insulin delivery from a resumable alarm.

5.0 Alarms

Your Pivot System will notify you of problems using Alarms with a flashing red light and tone. You may mute the audio feedback (tone) of an Alarm for 30 minutes by quickly pressing the Control Button.

Check your Pivot™ Diabetes app for more information about the type of Alarm you have received and the steps to resolve the alarm.

Alarm on the Pump

CARTRIDGE ALARM	+ **Flashing red + repeating tone**	An issue has been detected with your Cartridge. Please replace your Cartridge, Patch, and rotate infusion sites.
PUMP ALARM	+ **Flashing red + constant tone**	An issue has been detected with your Pump. Please contact Modular Medical Customer Care and replace your entire Pivot System.

CARTRIDGE ALARM: RESUMABLE	**Flashing red + repeating tone**	The Pump has detected that it is outside of operating conditions and requires user attention. If a resumable alarm occurs, you must change conditions, then resume delivery by long-pressing the control button until you see a green light.

Cartridge and Resumable alarms look and sound the same on your Pump. The only way to tell them apart is by checking the pop-up on your Pivot™ Diabetes app.

NOTES: If you receive an Alarm, this means that your Pivot System has stopped delivering insulin. For further assistance, contact Customer Care at +1 (866) 710-1200. To mute the Alarm tone, press the Control Button on the Pump.

Possible Causes for Alarms

Pump Failure Alarm	A critical error, malfunction, or failure of your Pump has been detected.
Pump Expired Alarm	Your Pump has reached the end of its use life.
Cartridge Alarm: Occlusion	Insulin delivery is blocked at the infusion site or within the Cartridge.
Cartridge Alarm: Battery	The Cartridge battery has run out of power and must be replaced.
Cartridge Alarm	A malfunction with your Cartridge has been detected and it needs to be replaced.
Cartridge Alarm: Empty Cartridge	Insulin reservoir is empty.
Cartridge Alarm: Expired	Your Cartridge and Patch have reached their end of use and must be replaced.

Cartridge Alarm: High Temperature	System is being used outside of the temperature limits of 113°F (45°C).

Resumable alarms include the following:

Cartridge Alarm: Low Temperature	System is being used below the temperature limit of 55.4°F (13.0°C)
Cartridge Alarm: High Altitude	System is being used above the altitude limits above 10,000ft (700hPa).
Cartridge Alarm: Low Altitude	System is being used below the altitude limits below -1,300ft (1060hPa).

CAUTIONS: Alarms must be addressed promptly. Failure to respond to alarms may result in premature battery drain, which can stop insulin delivery and increase the risk of moderate hyperglycemia or diabetic ketoacidosis (DKA).

If you receive an Alarm during a bolus delivery, you will not receive the full quantity. This may lead to moderate hyperglycemia.

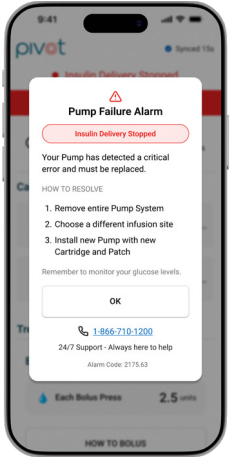
You should regularly check your blood glucose levels. Failure to do so can lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA),or a delay in insulin therapy.

Pivot™ Diabetes App Display of Alarms

When your Pump is connected to the Pivot™ Diabetes app and an Alarm occurs, a pop-up will automatically appear on your Pivot™ Diabetes app screen. The pop-up includes:

- Alarm name and insulin delivery status
- A description of the issue and step-by-step instructions on how to resolve it.
- An Alarm Code
- For Alarms that may need Customer Care assistance, a Customer Care phone number will also be displayed in the pop-up

Press OK to acknowledge the Alarm and dismiss the pop-up.



More Information on Alarms

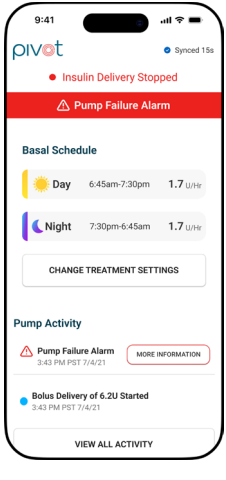
When your Pump is connected to the Pivot™ Diabetes app and an Alarm occurs, the Alarm will be displayed on your Dashboard once the pop-up is dismissed.

Alarm Banner: An Alarm banner will appear at the top of the screen showing the Alarm name and current delivery status.

Pump Activity: The Alarm will also appear in your Pump Activity. Tap "More Information" to view additional details about the Alarm.

Alarm Banner

Pump Activity



NOTE: The Pump may remain connected to the Pivot™ Diabetes app while an Alarm is occurring.

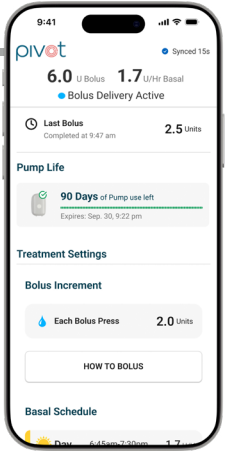
5.1 Pump Life

Your Pivot™ Diabetes app displays the remaining use life of your Pump under the Pump Life section on your Dashboard. The widget will display the number of days remaining along with the expiry date and time. As your Pump approaches the end of its 90-day use life, the widget will change to indicate the urgency:

- 90 days remaining — Full green progress bar
- 14 days remaining — Orange progress bar
- 7 days remaining — Red progress bar
- 3 days remaining — Pop up reminder
- Pump Expired — Tap "More Information" for next steps

Once your Pump reaches the end of its use life, follow the instructions in Section 3.8 to replace your Pump.

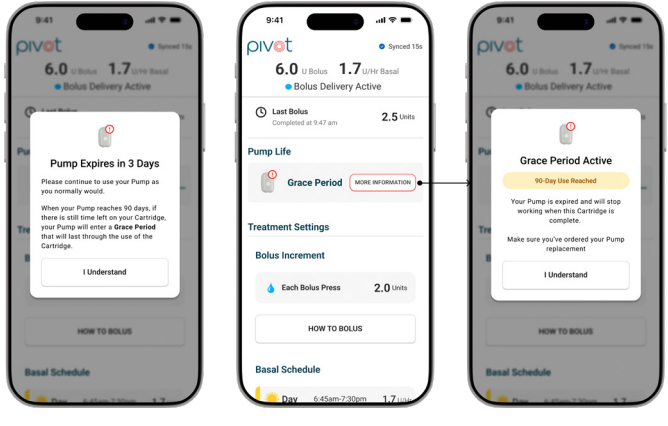
NOTE: Your Cartridge must be replaced every 3 days regardless of Pump life remaining.



5.2 Grace Period

The Grace Period extends your Pump life beyond 90 days. This occurs when a new Cartridge session is started before the Pump reaches its 90-day expiry. In this case, the Pump will continue operating until the current Cartridge session ends. You will be notified 3 days before the pump expires with a pop up message.

Once the Cartridge session ends, the Pump Expired Alarm will activate and the Pump must be replaced. Follow the instructions in Section 3.8.



6.0 Emergency Kit

An Emergency Kit (not provided) has the supplies you need to manage your diabetes if your Pivot System is not working.

Make sure that your family, friends, and coworkers have access to your Emergency Kit. They can help you use it when necessary. Please consult your Healthcare Provider for further advice regarding your Emergency Kit.

CAUTION: If your Pivot System or any of its components are not working per the information provided in this User Guide, stop using your Pivot System and revert to your Emergency Kit to prevent moderate hypoglycemia, moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy. Please contact Customer Care to report an issue and arrange for replacement product.

Your Emergency Kit should include the following:

1. Spare Cartridges and Patches
2. Rapid-acting insulin and syringes or pens
3. Infusion site preparation products
4. Blood glucose testing supplies: meter, strips, lancets, control solution
5. Fast-acting carbohydrate to treat low blood glucose
6. Glucagon emergency kit
7. Diabetic identification card

CAUTION: If your Pivot System stops functioning and you don't have an Emergency Kit, contact your Healthcare Provider as soon as possible.

7.0 Care & Maintenance

Your Pivot System does not require routine maintenance. If you would like to clean the outside of your Pump or Inserter, follow the instructions below:
- To clean the outside of your Pump, ensure the Cartridge is fully attached and use a cloth moistened with water and a mild detergent to clean, then gently dry. Never submerge your Pump in any liquid or expose it to heat in an attempt to dry it.
- To clean the outside of your Inserter, use a cloth moistened with water and mild detergent to clean, then gently dry. Never submerge your Inserter in any liquid or expose it to heat in an attempt to dry it.

Your Pivot System, including all components and accessories, should be disposed of in accordance with your local regulations.

CAUTION: Only clean the Pump with water and a mild soap. Do not use alcohol, cleaners, solvents, or abrasive products to clean the Pump as this could lead to a toxic episode or cause cracks or discoloration to the Pump housing.

NOTE: The Cartridge must remain fully attached while cleaning. Never submerge your Pump or allow water to get inside the Pump. Doing so may lead to a delay in insulin therapy and may affect your warranty.
Only clean the Inserter with water and a mild soap. Do not use alcohol, cleaners, solvents, or abrasive products to clean the Inserter as this could cause cracks or discoloration to the Inserter housing.

7.1 Usage Conditions

While your Pivot System operates in most environments, there are some limitations and factors that may affect your therapy.

While the Basic Safety and Essential Performance of your Pivot System will not be affected, it is possible for electronic devices to momentarily interrupt communications between the Pivot System and the Pivot™ Diabetes app. For more information, see Section 8.4 on Electromagnetic Compatibility.

Please refer to these sections for more information on usage considerations: external influences (Section 8.7), possible risks (Section 7.3), and traveling by air (Section 7.6). If you have questions regarding the use of your Pivot System, please contact your Healthcare Provider.

The following is a brief summary of the environmental operating conditions required for your System to function properly.

Condition	Appropriate Range
Operating Temperature Range	41.0°F - 98.6°F (5°C - 37°C)*
Operating Humidity	15-90% non-condensing
Operating Altitude	-1,300ft. to 10,000ft. (1060 hPa - 700 hPa)

*The Pump temperature equilibrates from 60.8°F to 98.6°F (16°C - 37°C) when worn on the body.

WARNINGS: Do not expose the Pump to unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy devices. Exposure to these devices can lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

When fitted with a Cartridge, newly manufactured Pumps are water resistant (IP24). Over time, the moisture protection capabilities of the Pump may be compromised by incidental bumps, drops, shock, exposure to incompatible chemicals or other unintentional events the Pump may be exposed to over time under normal use conditions. Always inspect your Pump for damage.
If there are signs of fluid entry, discontinue the use of the Pump and contact Customer Care.

CAUTIONS: Only use your Pivot System within the environmental operating conditions specified in this section. Failure to do so could lead to moderate hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

Do not use the System in oxygen-rich environments, environments rich in flammable anesthetics, or other volatile agents as this presents a risk of fire or explosion that could lead to injury.

It is important to remove your Pivot System before using a sauna or jacuzzi, or while swimming, bathing, showering, or during contact sports. Your Pivot System is only protected against minor splashing (i.e., IP24 rating). Use of the Pivot System in these scenarios could lead to moderate hyperglycemia or Diabetic Ketoacidosis (DKA).

7.2 Storage Conditions

If you need to stop using your Pump for an extended period, please follow these guidelines on proper and safe storage of your Pump.

Storage Condition of Pump and Inserter	Temperature: -4°F to 140°F (-20°C to 60°C) Humidity: 15% to 90% RH non-condensing

CAUTION: Store your Pump in a dry, clean location. Storage of your Pump must be within the temperature and humidity ranges shown above. Failure to store your Pump correctly can lead to moderate hypoglycemia, moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

Please follow these guidelines on the proper storage of your Cartridges:

WARNINGS: Do not remove the sterile Cartridge from the sealed Tray until you are ready to attach it to your Pump to prevent the risk of infection.

Always follow the storage instructions on each component's packaging. While replacing the Cartridge, inspect every part of your Pivot System to ensure there are no signs of damage. Damaged components may not work correctly and could lead to infection, moderate hypoglycemia, moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy. If a part is damaged, please contact Modular Medical Customer Care.

CAUTION: Cartridges must be kept in a dry location, avoiding direct sunlight. You must store your Cartridges according to the information found on their labeling. Failure to do so can lead to moderate hypoglycemia, moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

7.3 Possible Risks

The possible risks of insulin therapy include:

- Hypoglycemic Episode (low blood glucose)
- Other cases of low blood glucose for extended periods
- Hyperglycemia and Diabetic Ketoacidosis (DKA)
- Hyperosmolar Hyperglycemic State (HHS), or other cases of high blood glucose for extended periods
- Injury requiring medical intervention
- Injury not requiring medical intervention
- Infection leading to serious injury or death if left untreated
- Infection not leading to serious injury or death if left untreated
- Toxic Episode
- Allergic Reaction
- Lipodystrophies

NOTE: See Section 9.1 Glossary for definition of the terms used above.

7.4 Non-Serviceable Equipment Statement

No maintenance is required for the Pivot System. Every Cartridge contains a battery that is designed to last for up to 3 days of use.

NOTE: Do not attempt to replace your Cartridge battery. The Cartridge is a single-use component and must be disposed of after 3 days of use.

7.5 Troubleshooting

If you are unable to use the Pivot™ Diabetes app after installing it, check that your phone model and Operating System version are supported. Unsupported devices will display a message upon opening the app.

If you are unable to pair your Pump to the Pivot™ Diabetes app:

- Ensure the Pump is connected to a Cartridge and powered on.
- Ensure the phone is not paired to another Pump. You can check connected BLE devices to verify.
- Ensure the Pump is placed close to the phone's NFC antenna.

If you can not connect the Pump to the Pivot™ Diabetes app in the presence of other wireless devices working at 2.4GHz, move the Pump away from the 2.4GHz wireless device. If this does not resolve the issue, place the Pump closer to the smartphone.

If the Pivot™ Diabetes app freezes while in use, close out the App and reopen it.

If the Pump disconnects from the Pivot™ Diabetes app, select "Try Again" to reconnect the device.

WARNINGS: If you think someone has modified or tampered with your Pivot System, replace the Pump, Cartridge, and Patch. Not replacing your System could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).

If you unexpectedly see a flashing green light on your Pump and don't hear an audible tone, this means that the Pump has received a request to change your treatment settings. If this did not happen intentionally, do not press the Control Button for 15 seconds until the green light stops flashing. This will cancel the request. This is important as an unauthorized treatment settings change could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).

CAUTION: If the Control Button is damaged, a Status Check will not be performed. This will also impede the ability to Prime, Input a Bolus, or Suspend Basal delivery which could lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.

7.6 Traveling by Air

Pack your Pivot System supplies in your carry-on luggage. Do not pack your supplies in checked baggage, as they could get delayed or lost. Always carry an Emergency Kit while traveling. For more information on the contents of your Emergency Kit, please see Section 6.0 of this User Guide.

Do not expose your Pivot System to X-ray screening used for carry-on and checked luggage. Newer full-body scanners used in airport security screening are also a form of X-ray screening and your Pivot System should not be exposed to them. Notify the Transportation Security Administration (TSA) Agent that your Pivot System cannot be exposed to X-ray machines and request an alternate means of screening.

Visit TSA's website at www.tsa.gov if you have any questions or concerns.

You can contact TSA at TSA-ContactCenter@tsa.dhs.gov or call 1-866-289-9673.

7.7 MRI Safety Information

The Pivot System is MRI Unsafe.

WARNING: The Pivot System cannot be used inside or in proximity to an MRI machine. The device presents a projectile hazard.

7.8 Modular Medical Customer Care

If your Pivot System is not working correctly or you need technical support, assistance, or have questions about your Pivot System, please contact Modular Medical Customer Care at 866-710-1200 or visit us online at www.pivotpump.com.

If you have a medical emergency while using your Pivot System, seek medical attention as required.

7.9 Warranty

Modular Medical, Inc. warrants the Modular Medical Pivot Insulin Delivery System components against defects in materials and workmanship, under normal use, and will provide a replacement for components that qualify under the terms of this warranty. The warranty period for the Pump is ninety (90) days from the time of first power on activation. The warranty period for the Cartridge and Patch is up to three (3) days from time of use and within the expiration date printed on the labels.

This Warranty is valid only if the Pump, Cartridge, and Patch have been used in accordance with the provided User Guide and will not apply if:

- The Cartridge or Patch have been reused.
- The components have been altered or modified.
- The components are damaged from an event or accident.
- The components are damaged by force.
- The components are damaged from misuse, abuse, and negligence.

7.10 Returns and Exchanges Policy

At Modular Medical, we strive to ensure your satisfaction with our products.

Initiating a Return: To initiate a return, reach out to our Modular Medical Customer Care Team via email at Customer-Care@Modular-Medical.com to obtain a Return Merchandise Authorization (RMA) number. Returns made without an RMA number will be returned to the customer, freight collect. This policy is subject to applicable law.

Refund and Exchange Process:
Modular Medical will process your refund or exchange promptly after receiving and inspecting the returned item.

Return Address: All returns pre-authorized by Modular Medical should be sent to:

Modular Medical, Inc.
Customer Care - Returns
10740 Thornmint Road
San Diego, CA 92127

Thank you for choosing Modular Medical. Your satisfaction is our priority.

Defective or Faulty Products:

In the event you believe a product to be defective or faulty, you must first contact Modular Medical Customer Care at 1-866-710-1200. Prior written authorization from Modular Medical is required before any defective or faulty products may be returned. Upon receipt of such authorization, the product(s) must be packaged and returned in accordance with the instructions provided in the Product Return Kit supplied by Modular Medical. Subject to prior authorization, Modular Medical shall be responsible for all reasonable shipping costs, where applicable, incurred in connection with the return of the defective product(s). Modular Medical reserves the right to modify this Return Policy. Any changes will be communicated by posting an updated version on our website.

7.11 Customer Complaints

A patient, and when appropriate, a patient's representative has the right to have any concerns, complaints and grievances addressed. Sharing concerns, complaints and grievances will not compromise a patient's care, treatment or services.
If a patient has a concern, complaint, or grievance, he or she may contact Modular Medical Customer Care anytime at:

866-710-1200 or www.pivotpump.com

8.0 Technical Information

This section provides technical specifications, including performance characteristics, options, settings and Electromagnetic Compatibility information.

8.1 System Specifications

The specifications meet the international standards set in IEC 60601-1:2020 (Ed. 3.2).

SPECIFICATION TYPE	DETAILS
Classification	Class II, Infusion Pump.Internally Powered Equipment, Type BF applied part.
Size	2.3” x 1.5” x 0.6” (6.0 cm x 4.0 cm x 1.5 cm)
Cannula Insertion Depth	0.25–0.27 in (6.40–6.80 mm)
Bluetooth Low Energy (BLE)	Utilized to send information between Pump and the Pivot™ Diabetes app. The Pump transmits information on its status, history, Alarms, and configuration to the App. The Pivot™ Diabetes app sends commands to the Pump to request this information and to set the Treatment Settings.
Near Field Communication (NFC)	Utilized to ensure close proximity of Pivot™ Diabetes app to Pump, enabling the safe exchange of a BLE key.
Weight	1.0 ounces (28 grams)

SPECIFICATION TYPE	SPECIFICATION DETAILS
Operating Conditions	Temperature: 41.0°F to 98.6°F (5°C to 37 °C)* Humidity: 15% to 90% RH non-condensing
Operating Atmospheric Pressure	-1,300ft to 10,000ft (1060 hPa to 700 hPa)
Storage Condition for Single-Use Components	Temperature: 41°F to 104°F (5°C to 40°C) Humidity: 20% to 90% RH non-condensing
Storage Condition of Pump	Temperature: -4°F to 140°F (-20°C to 60°C) Humidity: 15% to 90% RH non-condensing
Dust and Moisture Protection	IP24: Protection from touch by fingers and objects greater than 12 mm and protected from water spray in any direction
Reservoir Volume	3.0 mL (300 units)
Insulin Concentration	U-100 (Humalog)

*The Pump temperature equilibrates from 60.8°F to 98.6°F (16°C - 37°C) when worn on the body.

SPECIFICATION TYPE	SPECIFICATION DETAILS
Alarm Type	Visual and audible
Basal Delivery Rate	0.5 – 4 Units/hr (with 0.1 Unit/hr increment)
Typical (Mean) Basal Delivery Accuracy at All Flow Rates	+/- 5% (tested per AAMI TIR101:2021)
Bolus Delivery Size	0.5 – 20 Units (with configurable Unit increment)
Bolus Delivery Rate	0.83 Units/min
Typical (Mean) Bolus Delivery Accuracy at All Volumes	+/- 5% (tested per AAMI TIR101:2021)*
Maximum Infusion Pressure Generated at Occlusion Alarm Threshold	24.75 PSI
Bolus Volume at Release of Occlusion	0.42 Units
Residual Insulin Remaining in the Cartridge (unusable)	Less than 11 Units
Maximum Audible Alarm Volume	42 dBA at 1 meter

*At low insulin reservoir volumes, there is potential for a clinically significant amount of insulin to either be underdelivered or overdelivered which could result in either hyperglycemia or hypoglycemia.

8.2 Performance Characteristics

The Pivot System delivers insulin in two ways: basal insulin delivery (continuous) and bolus insulin delivery. The following accuracy data was collected on both types of delivery in laboratory studies performed by Modular Medical.

Basal Delivery

To assess basal delivery accuracy, 33 Pivot Pumps were tested over minimum, intermediate, and maximum Basal Rates (0.5, 2, and 4 U/hr). For each Basal rate, a minimum of 15 Pumps were new and a minimum of 15 Pumps had been aged to simulate 90 days of regular use. For both aged and unaged Pumps, the testing included a mixture of new Cartridges and Cartridges accelerated aged to the end of its shelf life. Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy. The following tables report the typical basal performance (median) observed, along with the lowest and highest results observed for minimum, intermediate, and maximum Basal Rate settings for all Pumps tested. For all rates tested, accuracy is reported from the time basal delivery started with no warm-up period.

Minimum Basal Rate Delivery Performance (0.5 U/hr, n=15 new Pumps)

Basal Duration (Units Delivered at 0.5 U/hr)	1 hour (0.5 U)	6 hour (3.0 U)	12 hour (6.0 U)
Amount Delivered (Median) [min, max]	0.62 U [0.57, 0.65]	3.16 U [3.03, 3.26]	6.17 U [5.93, 6.39]

Intermediate Basal Rate Delivery Performance (2 U/hr, n=15 new Pumps)

Basal Duration (Units Delivered at 2 U/hr)	1 hour (2.0 U)	6 hour (12.0 U)	12 hour (24.0 U)
Amount Delivered (Median) [min, max]	2.10 U [2.02, 2.25]	12.05 U [11.53, 12.78]	24.05 U [22.88, 25.56]

Maximum Basal Rate Delivery Performance (4 U/hr, n=15 new Pumps)

Basal Duration (Units Delivered at 4 U/hr)	1 hour (4.0 U)	6 hour (24.0 U)	12 hour (48.0 U)
Amount Delivered (Median) [min, max]	4.20 U [4.05, 4.45]	24.51 U [23.47, 25.82]	48.81 U [46.53, 51.58]

Minimum Basal Rate Delivery Performance (0.5 U/hr, n=15 aged Pumps)

Basal Duration (Units Delivered at 0.5 U/hr)	1 hour (0.5 U)	6 hour (3.0 U)	12 hour (6.0 U)
Amount Delivered (Median) [min, max]	**0.63 U [0.59, 0.65]**	**3.19 U [3.03, 3.33]**	**6.22 U [5.92, 6.58]**

Intermediate Basal Rate Delivery Performance (2 U/hr, n=15 aged Pumps)

Basal Duration (Units Delivered at 2 U/hr)	1 hour (2.0 U)	6 hour (12.0 U)	12 hour (24.0 U)
Amount Delivered (Median) [min, max]	**2.17 U [2.03, 2.25]**	**12.16 U [11.32, 12.82]**	**24.14 U [22.48, 25.47]**

Maximum Basal Rate Delivery Performance (4 U/hr, n=15 aged Pumps)

Basal Duration (Units Delivered at 4 U/hr)	1 hour (4.0 U)	6 hour (24.0 U)	12 hour (48.0 U)
Amount Delivered (Median) [min, max]	**4.22 U [4.00, 4.51]**	**24.33 U [22.94, 25.85]**	**48.40 U [45.57, 51.37]**

Bolus Delivery

To assess bolus delivery accuracy, 32 Pivot Pumps were tested by delivering consecutive intermediate, and maximum bolus volumes (10, and 20 units). For intermediate and maximum bolus volumes, a minimum of 15 new Pumps and a minimum of 15 aged Pumps were used. To assess the bolus delivery accuracy of the minimum bolus dose (0.5 units), 10 new Pivot Pumps and 10 aged Pumps were used. Pump aging was performed to simulate 90 days of regular use. For both aged and unaged Pumps, the testing included a mixture of new Cartridges and Cartridges accelerated aged to the end of its shelf life.

Water was used as a substitute for insulin. The water was pumped into a container on a scale and the weight of the liquid at various time points was used to assess pumping accuracy. The following tables report the average, minimum, and maximum bolus sizes as well as the number of boluses which were observed to be within the specified range of each target bolus volume.

	Units of Insulin Delivered After a 0.5U Bolus Request, n=298 boluses, n=10 new Pumps									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/298 (0.0 %)	0/298 (0.0 %)	29/298 (9.7 %)	53/298 (17.8 %)	200/298 (67.1 %)	16/298 (5.4 %)	0/298 (0.0 %)	0/298 (0.0 %)	0/298 (0.0 %)	0/298 (0.0 %)

	Units of Insulin Delivered After a 10U Bolus Request, n=423 boluses, n=15 new Pumps									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/423 (0.0 %)	0/423 (0.0 %)	1/423 (0.2 %)	41/423 (9.7 %)	332/423 (78.5 %)	47/423 (11.1 %)	2/423 (0.5 %)	0/423 (0.0 %)	0/423 (0.0 %)	0/423 (0.0 %)

	Units of Insulin Delivered After a 20U Bolus Request, n=209 boluses, n=15 new Pumps									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/209 (0.0 %)	0/209 (0.0 %)	1/209 (0.5 %)	16/209 (7.7 %)	178/209 (85.2 %)	14/209 (6.7 %)	0/209 (0.0 %)	0/209 (0.0 %)	0/209 (0.0 %)	0/209 (0.0 %)

	Units of Insulin Delivered After a 0.5U Bolus Request, n=297 boluses, n=10 aged Pumps									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/297 (0.0%)	0/297 (0.0 %)	31/297 (10.4 %)	72/297 (24.2 %)	191/297 (64.3 %)	3/297 (1.0 %)	0/297 (0.0%)	0/297 (0.0%)	0/297 (0.0%)	0/297 (0.0%)

	Units of Insulin Delivered After a 10U Bolus Request, n=419 boluses, n=15 aged Pumps									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/419 (0.0 %)	0/419 (0.0 %)	1/419 (0.2 %)	58/419 (13.8 %)	318/419 (75.9 %)	42/419 (10.0%)	0/419 (0.0 %)	0/419 (0.0 %)	0/419 (0.0 %)	0/419 (0.0 %)

	Units of Insulin Delivered After a 20U Bolus Request, n=210 boluses, n=15 aged Pumps									
	<25%	25-75%	75-90%	90-95%	95-105%	105-110%	110-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/210 (0.0 %)	0/210 (0.0 %)	1/210 (0.5 %)	17/210 (8.1 %)	180/210 (85.7 %)	12/120 (5.7 %)	0/210 (0.0 %)	0/210 (0.0 %)	0/210 (0.0 %)	0/210 (0.0 %)

8.3 Time to Occlusion Alarm

Operating Rate	Typical	Maximum
Bolus (4 Units or greater)	4 Minutes 41 Seconds	4 Minutes 46 Seconds
Basal (2 Units/hr)	1 Hour 45 Minutes	1 Hour 45 Minutes
Basal (0.5 Units/hr)	7 Hours 0 Minutes	7 Hours 0 Minutes

NOTE: The time to detect an occlusion alarm is based upon the insulin volume not delivered. A bolus of less than 4 units might not trigger an occlusion alarm until additional basal or bolus deliveries occur.

8.4 Electromagnetic Compatibility

This information provides reasonable assurance of normal operation, but does not guarantee this under all conditions. If the Pivot System must be used in close proximity with other electrical equipment, the Pivot System should be observed in this environment to verify normal operation. Special precautions for electromagnetic compatibility must be taken when using medical electrical equipment.

The Pivot System shall be placed into service with adherence to the EMC information provided here. Using accessories not specified in this User Guide may adversely impact safety, performance, and electromagnetic compatibility, including increased emissions and/or decreased immunity.

According to the definitions provided in IEC 60601-1:2020 (Ed. 3.2), the Pivot System is a portable, body-worn device. For IEC 60601-1:2020 (Ed. 3.2) testing, Essential Performance for the Pivot System is defined as follows:

- The Pivot System shall not over deliver insulin.
- The Pivot System shall not under deliver insulin.
- The Pivot System shall detect an occlusion.

Intense electromagnetic fields may lead to a loss of Essential Performance of your Pivot System, potentially causing complications with your therapy. If you are unsure if your Pivot System is functioning correctly check the System status (Section 3.5) with a quick press of the Control Button. Ensure to take regular blood glucose readings. If, for any reason, your Pivot System stops delivering insulin and you do not have your Emergency Kit with you, contact your Healthcare Provider or seek medical attention as required.

The Pivot System is intended for use in the electromagnetic environment specified below. Always make sure that the Pivot System is used in such an environment. The Pivot System is compliant to IEC 60601-1-2:2020 (Ed. 4.1) with the limits listed below.

Test	Compliance Level	Electromagnetic Environment Guidance
Electromagnetic Emissions		
Radiated Emissions, CISPR 11	Group 1, Class B	The Pivot System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference.
Electromagnetic Immunity		
Electrostatic Discharge, ESD IEC 61000-4-2:2008	Contact: ± 8 kV Air: ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	If floors are covered with synthetic material, the relative humidity should be at least 5%.

Test	Compliance Level	Electromagnetic Environment Guidance
Electromagnetic Immunity		
Radiated Immunity IEC 61000-4-3:2014	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Except as indicated in the following Table 2, portable and mobile communications equipment should be separated from your Pivot System by no less than the distances calculated below: $D=1.2*\sqrt{P}$ 150 kHz to 80 MHz $D=1.2*\sqrt{P}$ 80 MHz to 800 MHz $D=2.3*\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum interfering transmitter power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level E1*. Interference may occur in the vicinity of equipment containing a transmitter.
Proximity fields from RF wireless communi-cations equipment IEC 61000-4-3:2014	See Table 2 on the next page.	

*E1= 10V/m, 80 MHz to 2.7GHz

Test	Compliance Level	Electromagnetic Environment Guidance
Electromagnetic Immunity		
Rated power frequency magnetic fields IEC 61000-4-8:2009	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic Fields IEC 61000-4-39:2017	8A/m, 30kHz 65A/m, 134.2kHz 7.5A/m, 13.56 MHz	N/A

Table 2: For transmitters specified in the table below, the recommended separation distance is 30 cm (12 inches) as tested by IEC 60601-1-2:2020 (Ed. 4.1).

Band (MHz)	Power Limit (V/m)	Service
380 to 390	27	TETRA 400430 to 470
430 to 470	28	GMRS 460, FRS 460800 to 960
704 to 787	9	LTE Band 13, 172400 to 2570
800 to 960	28	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5
1700 to 1990	28	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS
2400 to 2570	28	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7
5100 to 5800	9	WLAN 802.11 a/n

WARNINGS: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pivot System specified by the manufacturer. This could cause disruptions in device performance or a device malfunction, which may lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).

Do not expose the Pump to power limits greater than those indicated in this section as this could lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA). Field strengths from fixed transmitters, such as amateur radio, AM and FM radio broadcasts, base stations for radio (cellular/cordless) telephones, TV broadcast, Radio Frequency Identification (RFID) readers, electronic security systems (e.g., X-rays, metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT), and Cellular 5G can not be accurately predicted theoretically. Consider conducting an electromagnetic site survey to assess the electromagnetic environment created by fixed RF transmitters. If the field strengths measured in the location in which the Pivot System is to be used are greater than the applicable RF compliance level shown above, the Pivot System should be observed to ensure correct operation. If correct operation is not maintained, additional measures may be necessary, such as reorienting or relocating the Pivot System.

Recommended Separation Distances Between Typical Body-Worn Devices and the Pivot Insulin Delivery System

This section provides information on the recommended separation distances between typical body-worn devices and the Pivot System. The Pump is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. You can help prevent electromagnetic interference by maintaining a minimum distance between transmitting equipment and the Pump as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	150kHz to 80MHz D=1.2*√P (m)	80MHz to 800MHz D=1.2*√P (m)	800MHz to 2.7GHz D=2.3*√P (m)
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.72
1.0	1.2	1.2	2.3
10	3.7	3.7	7.2
100	12	12	23

The table below provides a list of typical body worn, Bluetooth (2.4GHz) devices and the recommended separation distance from the transmitter to the Pivot Pump.

RF Communication Equipment	Typical Output Power and Frequency (W, Hz)	Recommended Separation Distance (m)	Recommended Separation Distance (inches)
Dexcom G7 CGM	1mW	0.07	2.8
Abbott Libre CGM	2dBm (1.58mW)	0.09	3.5
Medtronic Guardian Sensor 4	0.1mW	0.02	0.9
Senseonics Eversense CGM	1mW	0.07	2.8
Bluetooth Headphones	8dBm (6.3mW)	0.18	7.1

8.5 Wireless Technology Specifications

The tables below provide information regarding Bluetooth technology specifications for the Pivot System.

Parameter	Description
Wireless Technology	Bluetooth 5.1
Wireless Function	The Bluetooth Low Energy transmitter is used to: a. Allow the user to configure basal insulin delivery schedules. b. Allows the user to set bolus increment per button press c. View pertinent device information, including information about alarms, via the Pivot™ Diabetes App on a compatible smartphone.

Parameter	Description
Data Transmitted	The Pump software has two-way communication with the Pivot™ Diabetes App over Bluetooth. The Pump software uses Bluetooth to receive commands from the app. A treatment settings command is used by the app to: a. Set the basal schedule on the Pump, including basal rate and time of day that the basal rate is delivered. b. Set the bolus increment per button press. The Pivot™ Diabetes App receives information from the Pump, including the current status of the Pump, logged events from the Pump, and information about alarms from the Pump.
Wireless Protocol	Bluetooth Low Energy (BLE); IEEE 802.15.4
RF Frequency	2400 - 2483.5 MHz; Gaussian Frequency Shift Keying (GFSK) modulation
Transfer Power	+4dBm (maximum output power for Pivot System)
Intended Range	20 feet
Security Measures	The Pump only communicates with a Pivot™ Diabetes app that it has been paired with. Communication over BLE is encrypted.

The table below provides the Quality of Service (QoS) regarding Bluetooth technology for the Pivot System.

Parameter	Description
Data Integrity	When the basal schedule and bolus increment are set, they are set correctly 100% of the time.
Data Latency or Throughput	Basal schedule and bolus increment per button press are confirmed on the App user interface to have been set <30 seconds after the user has confirmed the schedule via button press on the Pump.
Accessibility and Signal Priorities of Network	No loss of wireless connection and no loss or interruption in data communication between Pump and companion device with maximum distance of 20 feet unobstructed. The Pivot System does not have signal priorities as there is a single BLE communication protocol implemented in the design.

The tables below provide information regarding NFC technology specifications for the Pivot System.

Parameter	Description
Wireless Technology	Near Field Communication (NFC)
Wireless Function	NFC is used during initial setup to facilitate pairing of the Pump with the Pivot™ Diabetes app installed on a compatible smartphone.
Data Transmitted	NFC is used by the Pivot Pump software to set up BLE with the Pivot™ Diabetes app.
Wireless Protocol	Near Field Communication (NFC)
RF Frequency	13.56 MHz
Transfer Power	Not applicable. The Pump has a passive NFC tag which is activated by the mobile device running the Pivot™ Diabetes app.
Intended Range	Range is the effective distance for initial NFC connection when the user taps the Pivot Pump to the mobile device running the Pivot™ Diabetes app.
Security Measures	NFC is used to set up secure BLE communication.

The table below provides the Quality of Service (QoS) regarding NFC technology for the Pivot System.

Parameter	Description
Data Integrity	The passive NFC tag on the Pump sends the correct information when an acceptable RFID on a compatible smartphone activates it.
Data Latency or Throughput	Data latency or throughput of NFC does not lead to unacceptable risk, therefore QoS is not applicable for this parameter.
Accessibility and Signal Priorities of Network	As the Pivot System utilizes a passive NFC tag that is activated by an acceptable RFID, accessibility and signal priorities for NFC are not applicable.

8.6 Federal Communications Commission (FCC)

The Pivot System is assigned to the FCC ID #2BDWN23MODD1-1 and complies with Part 15 of the FCC rules.
Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.
Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC Compliance Statement
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

Compliance with these guidelines provides reasonable protection from harmful interference. Harmful interference is defined in 47 CFR §2.1 as interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the International Telecommunication Union Radio Regulations. The Pivot System is intended for use in electromagnetic environments where radiated RF emissions are controlled. A minimum separation distance of 30cm between the Pivot System and mobile RF communications equipment (transmitters) can help to prevent electromagnetic interference.

While Basic Safety and Essential Performance of the Pivot System will not be affected, it is possible for devices commonly found in the home to interrupt communications between the Pump and the Pivot™ Diabetes app. For a description of potential external influences, see Section 8.7.

If communication between the Pump and Pivot™ Diabetes App is interrupted, move to a different area so the wireless link may be re-established. Interruptions to wireless communication will not affect the Pump's protective systems. Alarms will continue to sound as necessary. Modifications or changes that are not approved by Modular Medical may void a user's authority to operate the equipment.

SAR Statement

This equipment that is intended to be operated close to the human body is tested for body-worn Specific Absorption Rate (SAR) compliance. The SAR limit set by the FCC is 1.6 W/kg when averaged over 1g of tissue. When carrying the product or using it while worn on your body, by design, the mounting of the device ensures a minimum distance of 10mm from the body to ensure the compliance with RF exposure requirements. This equipment complies with ANSI/IEEE C95.1-1999 and are tested in accordance with the measurement methods and procedures specified in OET Bulletin 65 Supplement C.

8.7 External Influences Information

External Influences Information	Potential Effect	Remedial Action
Cordless telephones, microwave ovens, wi-fi senders, broadband routers, cell phones, walkie-talkies	Loss of wireless communications (interference) between Pump and smartphone.	Move away from the source of the interference.
Dust/Lint	May compromise internal electrical connections.	Always keep a Cartridge installed in your Pump – even when you are not using your Pivot System.
Unsupervised children or pets	May compromise internal electrical connections.	Always keep a Cartridge installed in your Pump – even when you are not using your Pivot System.

External Influences Information	Potential Effect	Remedial Action
Sunlight	Damage to the Cartridge.	Store Cartridges away from direct sunlight in accordance with the instructions found in this User Guide.
Heat source (stove top, heater)	Physical damage to Pivot System. Degradation of insulin.	Assure your Pivot System is not placed near any heat source.

9.0 Label Symbols

The following symbols may appear on your Pivot Insulin Delivery System and its packaging. These symbols indicate proper and safe use and handling of the Pivot System.

Symbol	Meaning	Standard / Reference
LOT	Code	ISO 15223-1 Ref 5.1.5 ISO 7000-2492
REF	Part Number	ISO 7000-2493 ISO 15223-1 Ref 5.1.7
Rx only	Prescription Required	FDA 21CFR part 801
GTIN UDI	Unique Device Identifier	ISO 15223, Clause 5.7.10

Symbol	Meaning	Standard / Reference
STERILE R	Sterilized Using Gamma Irradiation	ISO 15223-1 Ref 5.2.4
	Single Use Only	ISO 7000-1051 ISO 15223-1 Ref 5.1.6
/EXP	Use By Date	ISO 15223-1 Ref 5.1.4 ISO 7000-2607

Symbol	Definition	Standard / Reference
	Do Not Use if Packaging is Damaged	ISO 15223-1 Ref 5.2.8
	Caution	IEC 60601-1 Table D.2 ISO 7010-W001
	Consult Instructions for Use	IEC 60601-1 Table D.2 ISO 7010-M002 Table 5
	Type BF Applied Part (Body Contacting)	IEC 60601-1 Table D.1 IEC 60417-5333 IEC 60601-1 Table D.1
	Non-Pyrogenic	ISO 15223-1 Ref 5.6.3 ISO 7000-2724

Symbol	Definition	Standard / Reference
MR	Magnetic Resonance (MR) Unsafe	ASTM F2503
MD	Medical Device	ISO 15223 – 1, Clause 5.7.7
	Keep Dry	ISO 15223-1, Clause 5.3.4
	Fragile - Handle with care	ISO 7000-0621, 2014-06-04
IP24	Dust and Moisture Protection	ISO 15223-1 Ref 5.6.3 ISO 7000-2724

Symbol	Definition	Standard / Reference
	Temperature Limit for Storage	ISO 15223-1 Ref 5.3.7
	Humidity Limit for Storage	ISO 15223-1 Ref 5.3.8
	Atmospheric Pressure Limit for Operation	ISO 15223-1 Ref 5.3.9
	Keep Away from Sunlight	ISO 15223-1, Clause 53.2 ISO 7000-0624

Symbol	Definition	Standard / Reference
	Manufacturer	ISO 15223-1 Ref 5.1.1 ISO 7000-3082
	Date of Manufacture	ISO 15223-1 Ref 5.1.3 ISO 7000-2497
	Refer to Instructions for Use	ISO 7010-M002

9.1 Glossary

Ascending Tones - A sequence of tones that are getting higher in pitch indicating you are in Bolus Mode.
Basal Rate - The continuous rate at which insulin is delivered by the Pump, measured in units per hour (U/hr).
Basal Suspend - A user-selected mode that pauses insulin delivery for up to 2 hours. Delivery resumes automatically when the suspend period ends, or can be resumed earlier by the user.
Bolus - A dose of insulin delivered on demand to manage blood glucose during mealtimes or to correct high blood glucose levels.
Bolus Increment - The amount of insulin delivered with each Control Button press during a bolus. The increment is configurable between 0.5 and 4.0 units per press.
Cannula - The flexible soft tube (6.6mm length) on the Patch that is inserted into the body to deliver insulin.
Cartridge - Sterile, 3-day, single-use, disposable component that contains the insulin reservoir, battery, and port that facilitates connection to the Patch.
Cartridge Alarm - Indicates that your Pivot System has stopped insulin delivery. Requires replacement of the Cartridge and Patch.
Clip - Sits on top of the Patch to insert the needle into the skin. Squeeze both sides of the Clip to safely remove it.
Contraindication - A statement that describes situations or conditions in which the Pivot System is not to be used.
Control Button - Primary user input to control bolus delivery and check the status of the Pivot System.

Dashboard - The main screen of your Pivot™ Diabetes app displaying your current Treatment Settings, Pump status, recent Pump Activity, and Alarm information.
Descending Tones - A sequence of tones that are getting lower in pitch indicating you are in Basal Suspend Mode.
Diabetic Ketoacidosis (DKA) - Serious complication of diabetes that occurs when the body can't produce enough insulin.
Electromagnetic Compatibility - The compatibility of the Pivot System with its electromagnetic environment.
Emergency Kit - The necessary supplies you need to have on hand to manage your insulin therapy in case your Pivot System stops working.
Glucose - The type of sugar found in the blood, and the main source of energy for cells within the body.
Hyperglycemia - High blood glucose levels.
Hyperosmolar Hyperglycemic State (HHS) - Hyperglycemia with severe dehydration in the absence of ketosis, vomiting, loss of consciousness, convulsion/seizure, and coma
Hypoglycemia - Low blood glucose levels.
Infusion Site - Location where insulin will be delivered to your body via the cannula of the Patch.
Inserter - Facilitates the insertion of the Patch into the body. Included in the Pivot Insulin Pump Kit. Reusable with a 2-year use life.
Insulin - The Pivot System is indicated for use with Humalog® (Insulin Lispro) U-100, rapid-acting insulin.
Insulin Pump - A medical device that facilitates the delivery of insulin to the body to aid in the management of diabetes.

LED Light - A visual indicator on the Pump used to notify you of Pivot System status or provide Alarm notifications.
Lipodystrophies - Abnormal fat loss or distribution that cause skin bumps and scarring.
Needle - Used in combination with the Syringe to fill the Cartridge reservoir with insulin. The needle is a single use accessory and is supplied in the Supply Kit.
Occlusion - A blockage within the fluid path that may prevent the flow of insulin to your body.
Patch - Sterile, 3-day, single-use, disposable component that adheres the Pump and Cartridge to the user's skin and facilitates the subcutaneous delivery of insulin.
Pivot™ Diabetes app - Used to configure Treatment Settings including Basal Rate Schedule and Bolus Increment, view Pump activity, and identify and address Alarms.
Pivot System - Inserter, Pump, Cartridge, and Patch and the Pivot™ Diabetes app for compatible smartphone and operating system.
Priming - Action taken to remove air bubbles from the Cartridge.
Pump - The Pump is the durable element of the Pivot System that houses the System electronics and has a 90-day use life.
Pump Alarm - Indicates that your Pivot System has stopped insulin delivery and your entire system must be replaced.
Quick Start Guide - An instructional guide detailing the steps to set up your Pivot System for use. The Quick Start Guide is provided in each Pivot Insulin Pump Kit.

Resumable Alarm - A Cartridge Alarm that occurs when the Pump detects it is outside of operating conditions. Insulin delivery can be resumed after conditions normalize by long-pressing the Control Button until a green light appears.
Resume Insulin Delivery - The action of restarting basal insulin delivery after a suspend period, either manually by the user or automatically after 2 hours.
Supply Kit - Contains the Cartridge and Patch, Fill Syringe, and Needle.
Syringe - A sterile, single-use accessory used with a needle to fill the Cartridge. The Syringe comes in the Supply Kit.
System Status - The current state or delivery mode of your Pivot System, checked by pressing the Control Button.
Temporary Removal - Removal of the Pivot Pump for a short time during activities such as bathing, contact sports, or swimming.
Toxic Episode - Condition in which there is a small amount of material in the body that requires treatment to prevent permanent damage.
Treatment Settings - The configurable parameters of your Pivot System, including your Basal Rate Schedule and Bolus Increment, programmed via the Pivot™ Diabetes app.
Type BF Applied Part - Class II, Infusion Pump. Internally powered Protection from electrical shock, remote possibility of shock.
U-100 Insulin - Rapid-acting insulin with 100 units of insulin per milliliter (mL).

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Patents

The Pivot Insulin Delivery System is covered by multiple patents.

Trademarks

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The Bluetooth® word mark and logos are registered trademarks of Bluetooth SIG, Inc.

All other third party marks are the property of their respective owner.

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If you have a medical emergency using your Pivot System, seek medical attention as required.

For updates, questions, or assistance with your Pivot System, please contact Modular Medical Customer Care anytime.

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