MODULAR
MEDICAL

User Guide

We are here for you.

For updates, questions, or assistance with your MODD1™ System, please contact Modular Medical Customer Care anytime.

Toll-free at 866-710-1200

Visit www.modularmedical.com

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About This User Guide

This User Guide will help you navigate your Modular Medical MODD1 Insulin Delivery System (referred to as the "MODD1 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 MODD1 System.
⚠ ***CAUTION:***	This informs you of any problems associated with the the use or misuse of the MODD1 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 MODD1 System, including injury or death.

⚠ ***WARNING:*** *Before using your MODD1 System, ensure that you have been appropriately trained on its use by a certified MODD1 System trainer. Operating the MODD1 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 MODD1 System, contact your Healthcare Provider or call Customer Care.*

TABLE OF CONTENTS

1.0 OVERVIEW

INTENDED USE: The Modular Medical MODD1 Insulin Delivery System is intended for the treatment of diabetes mellitus in persons requiring insulin.

Your MODD1 System consists of a Pump, Insulin Cartridge, Infusion Set, Adhesive Pad, and the MMI App. The MMI App operates on your smartphone device and connects to the Pump via Bluetooth® connection to support basal rate programming and viewing activity information.

The MODD1 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 MODD1 System can be used by persons with diabetes to manage insulin therapy independently.

The MODD1 System is capable of delivering insulin at set and variable rates via a selectable basal rate between 0.5 – 4 units per hour (in 0.1 unit increments) and user-selected bolus doses of between 2 and 20 units (in 2 unit increments).

1.1 INDICATIONS FOR USE

The Modular Medical MODD1 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 Modular Medical MODD1 Insulin Delivery System is compatible with Humalog® U-100 rapid acting insulin only.

Insulin Lispro (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 MODD1 System.*

1.3 CONTRAINDICATIONS FOR USE

The MODD1 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 MODD1 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 MODD1 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 0.5U/hr
8. Use with brands or concentrations of insulin other than Humalog® U-100 insulin.

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

Do not leave your MODD1 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 MODD1 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 MODD1 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 MODD1 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.

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.

WARNING: *Consistent drops of the Pump and/or exposure to personal care products such as lotions and sunscreens can result in significantly reduced Pump lifetime if also exposed to water. This may lead to severe hyperglycemia or Diabetic Ketoacidosis (DKA).*

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 MODD1 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 MODD1 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 MODD1 System itself or where the System is adhered to the skin can cause cracks in the plastic used to manufacture the Pump and Insulin Cartridge. DO NOT allow these products to come in contact with the Pump or Insulin Cartridge. ALWAYS remove your Pump before applying these products and ALWAYS wash your hands before handling your Pump or Insulin Cartridge after using such products. ALWAYS change your Insulin Cartridge if it becomes exposed to such products and immediately clean your Pump. Failure to do so may result in damage to the Pump and Insulin Cartridge and in some cases lead to moderate hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA).

1.4 Your MODD1 System

Your MODD1 Insulin Delivery System aims to simplify your diabetes management. The MODD1 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 is programmed via the MMI App using rates determined by you and your Healthcare Provider.

The figure on the next page highlights the key features of your MODD1 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 MODD1 System status. Your MODD1 System uses lights and tones to make you aware of the MODD1 System status, delivery mode, and Alarms.

You can check your MODD1 System status during use with a quick press of the Control Button.

NOTE: *The MMI App is only needed to program a new Pump, change the Basal Rate Schedule on a Pump in use.*

INFUSION SET

This component is inserted into your subcutaneous tissue and delivers insulin through a 6mm tube commonly called a cannula.

TUBING CAP

This feature connects the Insulin Cartridge to the Infusion Set.

CONTROL BUTTON

This is your primary interface with the Pump. You use it to control bolus delivery and check the status of your MODD1 System.

LED LIGHT

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

SOUND MODULE
(not pictured)

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

ADHESIVE PAD

This component secures the MODD1 System to your body.

1.5 System Components

Your MODD1 System is provided to you in two kits: the Starter Kit (or Refill Kit for later Pump replacements) and the Supply Kit. The MMI App must also be utilized to program the Pump (see Section 4.0).

The Starter Kit contains Durable Components and Accessories:

- **A Pump** *(90 day use life)*
- **An Infusion Set Inserter** *(2 year use life)* with Instructions for Use
- **Quick Start Guide**
- **User Guide** (not pictured)
- **Patient Medical Device Card** (not pictured)

PUMP

INFUSION SET INSERTER

QUICK START GUIDE

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

All accessories you need for 30 days of use

- **10 Insulin Cartridges**
- **10 Infusion Sets** with Instructions for Use
- **10 Adhesive Pads**
- **10 Syringes and Needles**

INSULIN CARTRIDGE

INFUSION SET

ADHESIVE PAD

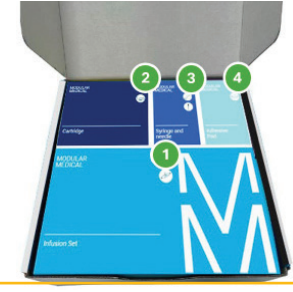
SYRINGE & NEEDLE

2.0 Setting Up Your System

Step 1: Open Packaging

1. Check for **expiration dates and damage.**
2. Open Box 1 in both the Starter Kit and Supply Kit.

SUPPLY KIT



STARTER KIT

⚠ ***CAUTION:*** *Do not use MODD1 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.*

Step 2: Prepare the Infusion Site

For this step, you will need:

- New Infusion Set
- Infusion Set Inserter
- 70% Isopropyl Alcohol Wipe (not included)

INFUSION SET

INFUSION SET INSERTER

70% ISOPROPYL ALCOHOL WIPE

Choosing where you place your infusion site is important. This will determine where you place your MODD1 System. The infusion site should be at least two inches away from your naval or previous infusion site and four inches away from a Continuous Glucose Monitor (CGM) sensor site.

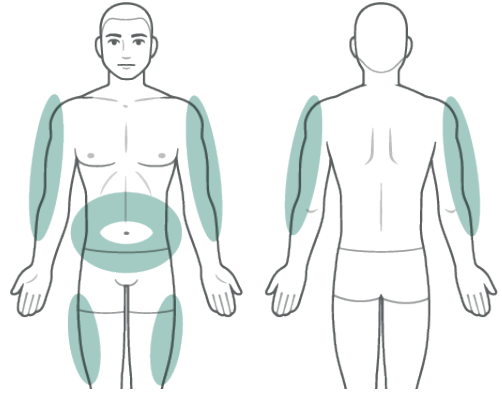
The Infusion Set must be inserted into:

- 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 MODD1 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.

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:*** *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. For more details, reference the Instructions for Use included in the Infusion Set box and Inserter Box.*

Step 3: Prepare the Infusion Set

1. Align the Infusion Set into the Inserter. **Press down to click into place before completing Step 2.**

2. Remove the paper backing.

⚠ ***WARNINGS:*** *Only use new Infusion Sets 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 Infusion Set immediately before use to prevent the risk of infection.

3 **Turn the bottom of the Inserter** until it clicks into the new position.

4 Remove the needle cover.

Step 4: Insert the Infusion Set

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

When you are ready to insert the infusion set, let go of the pinch and place the inserter against your skin. **Press the button firmly until a "click" is heard**. Remove the inserter from your skin.

2 **Press down firmly** around the Infusion Set to ensure it is attached to the skin.

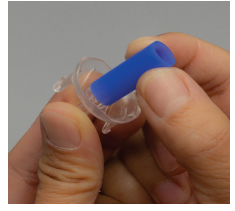
Reset the Inserter by turning the bottom back to its start position.

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

CAUTION: *Make sure to press down firmly around the Infusion Set to ensure it is adhered. Failure to do so could result in the Infusion Set falling off or cannula being removed from your tissue during use and could lead to moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).*

3 **Squeeze the tabs and pull upwards** to remove the Introducer Needle.

4 **Place the blue protective cap over the Introducer Needle** and safely dispose of after use.



WARNINGS: *Do not leave your MODD1 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.*

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

Step 5: Connect Pump and Cartridge

For this step, you will need:

- New Insulin Cartridge
- Pump

NEW INSULIN CARTRIDGE

PUMP

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

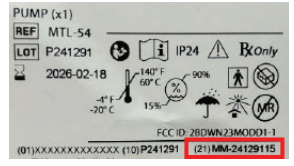
Insulin Cartridges are sterile and for single-use only. Do not attempt to reuse an Insulin Cartridge as this could lead to infection or a delay in insulin therapy.

Always inspect for damage with the Insulin 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.

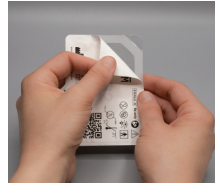
NOTE: *If this is your first time setting up your MODD1 System, you must program your Basal Rate Schedule using the MMI App. If you need to download the MMI App, you can scan the QR code in Section 4.0.*

1. Open Box 2 in the Starter Kit and Supply Kit.

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



2. **Remove the paper cover** leaving the Insulin Cartridge in its packaging and place on a flat surface.



3. Connect the Pump to the Insulin Cartridge. **Align the notch in the Pump to the blue tube on the Insulin Cartridge** and press firmly to lock together.

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 Insulin Cartridge are connected, a function check will start.

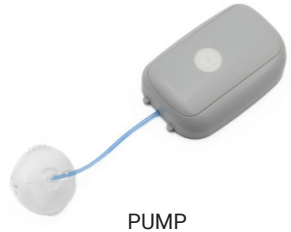
A flashing blue and green light indicates the Pump needs to be programmed with the MMI App. Proceed to Step 6 on page 23.

A flashing white light and three tones indictes the Pump is ready to be filled with insulin. Proceed to Step 7 on page 27.

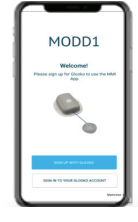
Step 6: Connect to App and Program Basal Schedule

For this step, you will need:

- An Assembled Pump
- The MMI App Installed on your Smart Phone



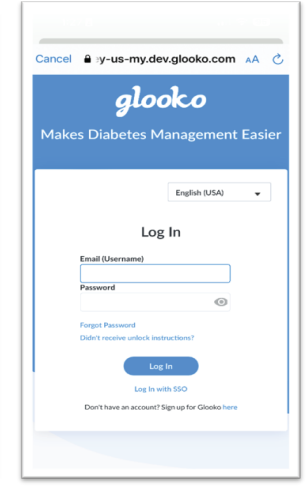
PUMP

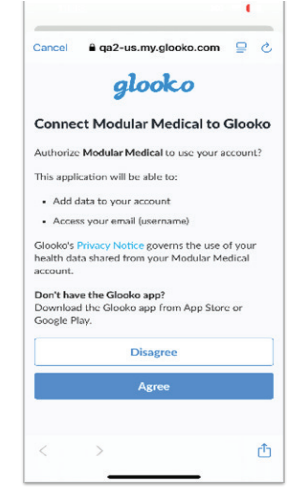


MMI APP

If you need to download the MMI App, go to the App Store. The MMI App provides an easy way to set your Basal Rate Schedule.

1 Sign Up or Log in to your Glooko Account.





2. Acknowledge the warnings, disclaimers, and terms of conditions

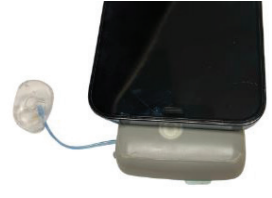
3. Acknowledge you have completed training on the MODD1 system.

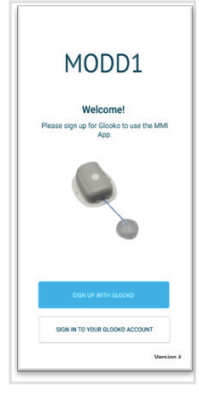
4. Press Connect to Pump on the MMI App.

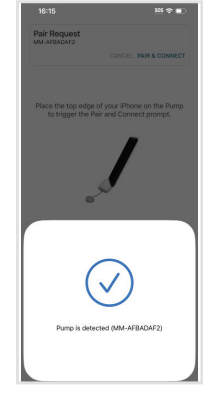
5. Place your smart device on the Pump as shown.

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

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





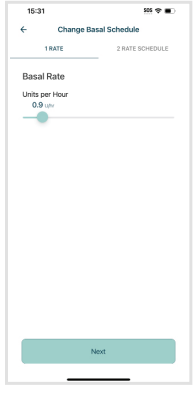


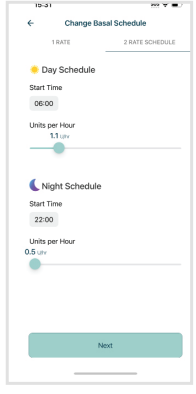
NOTE: *You must know your recommended Basal Rate Schedule before beginning programming. Your Healthcare Provider will help you determine your Basal Rate Schedule and can assist you in setting this within the MMI App.*

7 Set your Basal Rate Schedule in the app.

SINGLE RATE

One basal rate that will run continuously.





TWO-RATE

2 rates over a 24 hour period.

The day rate will end when the night rate is set to begin.

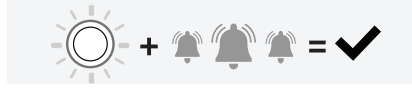
For additional information about Basal Rate Schedule, see Section 4.2.

8 Select Apply New Schedule 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 Basal Schedule.

9 A flashing white light and three tones means that your schedule is set. Now you can proceed to Step 7.



NOTE: *The MMI App will prompt you to enable user authentication if it is currently disabled.*

Step 7: 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 & SYRINGE

10 ML VIAL OF HUMALOG® U-100 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).*

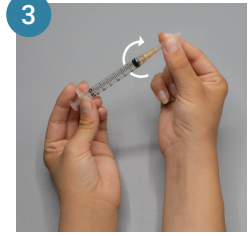
Only use Humalog® (Insulin lispro) U-100 rapid-acting insulin with the MODD1 System. Do not blend different insulins. The use of other insulin brands, concentrations of insulin, or medications can lead to moderate or severe hypoglycemia, or a toxic episode.

1 Open Box 3 in the Supply Kit.

2

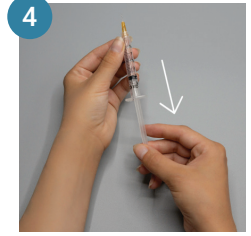
Clean the top of the insulin vial with a 70% isopropyl alcohol wipe.

3



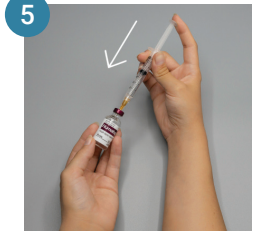
Connect needle and syringe and carefully remove the needle cap.

4



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

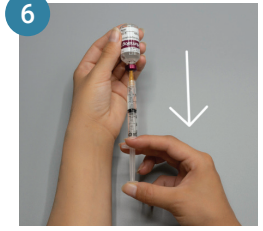
5



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*

6

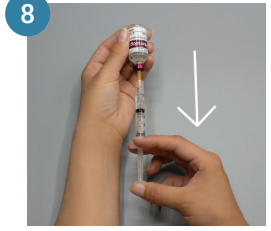


Flip the vial and the syringe, then slowly pull the plunger to fill the syringe with the amount of insulin needed for three days of Pump use.

7

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

8



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

9

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 Insulin Cartridge. Air in your MODD1 System can lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.*

Step 8: Fill the Insulin Cartridge

For this step, you will need:

- An Assembled Pump
- Syringe filled with Insulin

PUMP

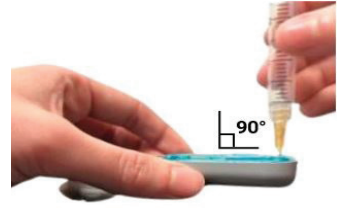
SYRINGE FILLED WITH INSULIN

⚠ **CAUTIONS:** *Check your MODD1 System for leaks regularly as leaks may lead to moderate hyperglycemia, moderate hypoglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.*

Only use the supplied Needle and Syringe for filling the Insulin 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.

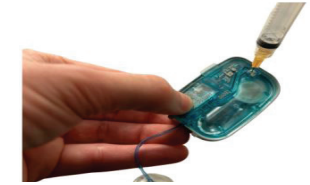
1. Locate the Fill Port on the underside of the Insulin Cartridge that is marked with a white circle.

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



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

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



4. Inspect the Insulin Cartridge and infusion tubing **for leaks.**

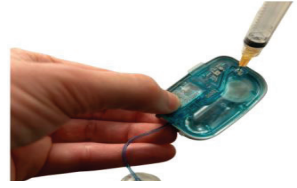
   If leaks are present, contact Customer Care. Remove and discard the Insulin Cartridge and repeat the setup procedure with a new Insulin Cartridge.

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

Check your MODD1 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 Insulin Cartridge.

6 If air bubbles are present, angle the Insulin 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 9: Prime the Infusion Tube

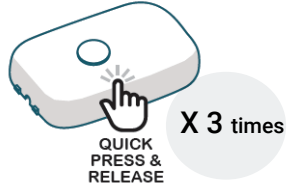
For this step, you will need:

- Filled Pump

FILLED PUMP

CAUTION: *Do not prime your MODD1 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 **Place the Pump upright** in the Insulin Cartridge tray during priming. You may look through the back of the Insulin 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 MODD1 System correctly during Priming allows the air to be removed from the Insulin Cartridge. Air in the Insulin Cartridge or infusion tubing 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 end of the Tubing Cap.** Inspect your Insulin Cartridge reservoir and infusion tubing 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.

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

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

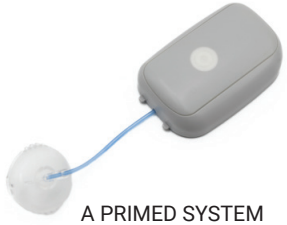
A flashing green light and a single tone indicate that Basal Delivery will automatically begin in 2 minutes.

NOTE: *If you have attempted to prime multiple times and the infusion tubing is not filled, or if visible air bubbles remain in the reservoir, you will need to replace the Insulin Cartridge with a new one.*

Step 10: Attach the Adhesive Pad and Place System

For this step, you will need:

- A Primed System
- New Adhesive Pad



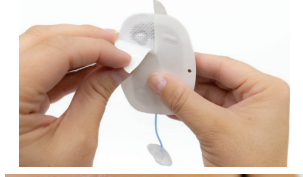
A PRIMED SYSTEM

A NEW ADHESIVE PAD

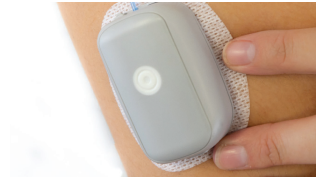
Before you begin make sure:

- The location where you want to adhere your MODD1 System is dry.
- There is enough space between the infusion site and Pump to prevent straining the infusion tubing when you adhere the System.
- To avoid placement on broken skin.

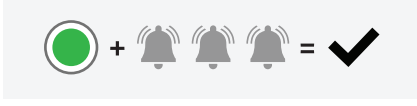
1. Open Box 4 in the Supply Kit.
2. **Connect the Pump and the Adhesive Pad** as shown.
3. **Carefully remove the paper backing** from the Adhesive Pad.
4. **Snap the Tubing Cap** onto the Infusion Set.



5 **Attach the Pump** next to the Infusion Set and press down firmly around the Adhesive Pad to ensure it is securely stuck onto your skin.



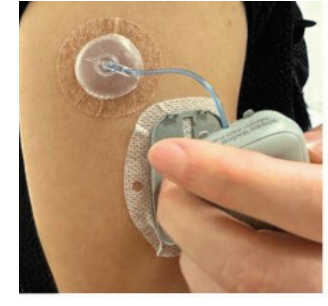
6 Basal Delivery will automatically begin when you see a solid green light and 3 tones.



⚠ ***CAUTION:*** *Remove and replace the Infusion Set and Adhesive Pad 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: *Basal Delivery will automatically begin 2 minutes after you primed your MODD1 System. A solid green light and three tones indicates that Basal Delivery has begun.*

7 **Rotate the tubing** left and right, at least one full turn in each direction, while pulling upward on the cap to ensure the Tubing Cap is fully engaged and the fluid path is opened. If needed, the Pump may be removed from the Adhesive Pad (see Section 3.6) such that the Tubing Cap can complete a full rotation.



3.0 Using the System

Your MODD1 System has three modes associated with the delivery of insulin: Basal Delivery Mode, Bolus Delivery Mode, and Basal Suspend Mode.

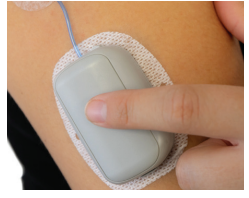
-Basal Delivery Mode Suspend is the default mode of your System and delivers a continuous flow of basal insulin. This mode automatically begins when your System has completed setup and priming.
-Bolus Delivery Mode is used to deliver a specific quantity of bolus insulin during mealtimes or to correct high blood glucose levels.
-Basal Suspend Mode is an additional mode available to temporarily pause the delivery of basal insulin.

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 increments. A single basal rate or two basal rates can be programmed in a 24-hour period. See 4.0 MMI Phone App section for more information on Basal Rate Schedule programming.*

3.1 Delivering a Bolus

1. Decide the number of insulin units you would like to deliver. **Each press equals a 2 unit increment of insulin.**
2. To enter bolus mode, **press and hold** the Control Button until you see a **blue light** and hear a single tone, then **release** the button.



Example
1 press = 2 units
5 presses = 10 units
Max Bolus: 10 presses = 20 units

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

3 Set your Bolus size by pressing the Control Button the number of times determined in Step 1.

You will see a blue light and hear a tone after each press. Tones will ascend for the first 5 button presses, then return to the first tone and ascend again for presses 6 through 10.

If you attempt to press the button more than 10 times, the request will be cancelled and your MODD1 System will return to Basal Delivery Mode.

4 The System will play back your selected bolus size with a blue light and tone for each press.

5 **If the bolus size is correct,** press and hold the Control Button until you see a blue light then release to confirm the bolus request.

The Pump will indicate Bolus delivery has started with a solid blue light and three ascending tones.

If the bolus size is not correct, do nothing. A green light and three tones indicate that you have returned to Basal Delivery Mode. You can then restart the bolus request process from Step 1.

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

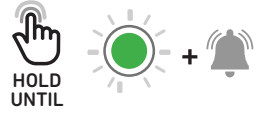
3.2 Canceling a Bolus Delivery

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 Basal Delivery

If you would like to pause your Basal insulin delivery for 30 minutes, 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.

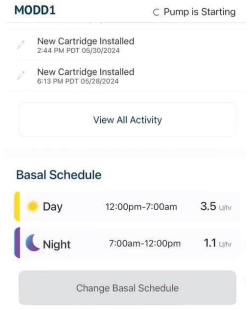
2. When you see a solid white light and hear three descending tones, that means your MODD1 System has suspended insulin delivery.

CAUTION: *Delivery remains suspended for 30 minutes. This cannot be overridden.*

NOTE: *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.*

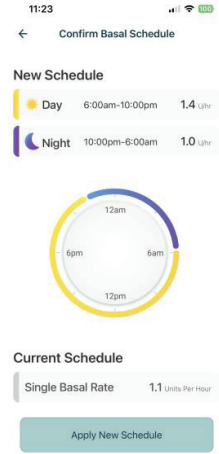
3.4 Changing the Basal Schedule

1. First, suspend insulin delivery by following the instructions in Section 3.3.
2. Open the MMI App and click Change Basal Schedule.



WARNING: *It is not possible to change the configuration of the MODD1 System while it is dispensing insulin. All changes to your Basal Rate Schedule must be done while your MODD1 System is in Basal Suspend mode or is starting up after changing the Insulin Cartridge. This prevents the risk of accidental Basal Rate Schedule changes that could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).*

3. Enter the new basal schedule. Select Apply New Schedule and provide user authentication such as Face ID or passcode.
4. Press the Control Button on the Pump to confirm the new schedule. Insulin delivery will automatically resume after the 30-minute suspend has ended.



3.5 Checking the System Status

While using your MODD1 System, you can check the MODD1 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 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 MODD1 System until you have a replacement. Contact Customer Care to order a replacement. Improper functioning of your MODD1 System could lead to moderate hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.*

BASAL DELIVERY MODE

This mode delivers insulin based on your personalized schedule. This is the default mode that starts automatically after set-up. To set your personalized Basal Rate Schedule, please use the MMI App (Section 4.0).

A green light and 3 consistent tones indicates Basal Delivery is active.

BOLUS DELIVERY MODE

This mode delivers a selected volume of insulin when needed. This is useful for managing blood glucose during mealtimes.

A blue light and 3 ascending tones indicates a bolus is in process.

BASAL SUSPEND MODE

This mode is used to pause basal insulin delivery for 30 minutes and can not be overridden.

A white light and 3 descending tones indicates there is no insulin delivered.

3.6 Detaching Your Pump

You can temporarily detach your Pump from the Adhesive Pad and the Infusion Set during a three-day use period.

Common reasons for detaching your MODD1 System include the following:

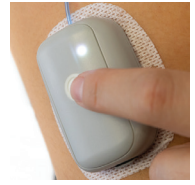
Preparing for medical procedures such as:

- MRIs
- CT scans
- X-rays
- Surgeries

Or common daily activities, like:

- Swimming
- Showering
- Contact Sports

1. First, put your Pump into Basal Suspend Mode. (See Section 3.3)
2. Disconnect the Tubing Cap by gently squeezing the sides and pulling the Tubing Cap off the Infusion Set. Leave your Infusion Set in place.
3. Disconnect your Pump by detaching the snap and pulling it away from the Adhesive Pad. Leave the Adhesive Pad in place.



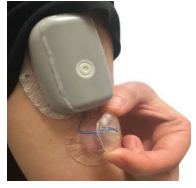
⚠ ***WARNINGS:*** *Do not leave your MODD1 System or its accessories unattended in the presence of small children or pets to prevent tampering with your device as this could lead to moderate hyperglycemia, moderate hypoglycemia, or Diabetic Ketoacidosis (DKA). Small parts also may pose an asphyxiation 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.

NOTE: *Insulin delivery will automatically resume in 30 minutes.*

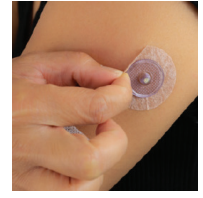
3.7 Replacing Your Infusion Set & Insulin Cartridge

Your Insulin Cartridge and Infusion Set must be replaced at the end of the three-day use period, when you receive a Delivery Alarm, or if you detect an issue.
You can detach your MODD1 System using the following steps.



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

2. Gently remove the Adhesive Pad.



3. Carefully remove your Infusion Set.

⚠ ***CAUTION:*** *Always dispose of the Insulin Cartridge, Infusion Set, and Adhesive Pad safely and in accordance with your local disposal guidelines. The battery in the Insulin Cartridge poses the risk of injury due to fire if not disposed of properly.*

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

5. Use the pull tab located on the side to carefully separate the Insulin Cartridge from the Pump.

⚠ ***CAUTION:*** *Every time you change your Insulin Cartridge, you must replace the Infusion Set 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*

3.8 Replacing Your Pump

After 90 days from when you first power on your Pump, it will provide a Technical 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 Sections 2.3 through 2.8.

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

When programming a replacement Pump with the MMI App that has already been used to program a previous Pump, you will be given the option to import the basal schedule settings (from the previous Pump) or create a new schedule.

4.0 MMI Phone Application

The MMI App is used to program your Basal Rate Schedule and to view your MODD1 System activity.

Download at the Apple® App Store®

Check the Modular Medical website for smartphone device and operating system compatibility.

WARNINGS: *If your MMI App or MODD1 System are not working correctly, please contact Customer Care. Malfunctions or failures of the MMI App or MODD1 System could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.*

Only install the MMI 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).

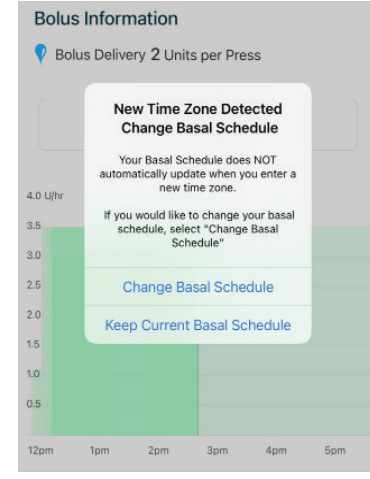
Do not run the MMI App on a jailbroken smartphone as this could create security risks and lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).

If you have concerns or questions about the MMI App, please contact Modular Medical Customer Care anytime at: 866-710-1200 or www.modularmedical.com.

The MMI App only allows you to set and view your Basal Rate Schedule. 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.

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 MMI App. Failure to do so could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, or Diabetic Ketoacidosis (DKA).*

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 MMI App. This may lead to moderate hypoglycemia, moderate hyperglycemia, or a delay in insulin therapy.*



Your Basal Rate Schedule must be programmed through the MMI App before you can use your MODD1 System. If you are using a two-rate schedule, open the MMI App to ensure the correct time zone is set up while traveling. Your Healthcare Provider will discuss your insulin delivery schedule and dosage with you.

For step-by-step instruction for setting your Basal Rate Schedule, see Section 2.0.

NOTES: *You may need to upgrade your device or the operating software to use the MMI App.*

Make sure you have automatic updates enabled on your smartphone so the MMI App gets updated automatically when new cybersecurity updates are released.

The MMI App automatically updates all activity logs 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 Basal Rate Schedule.

Mobile Connection Security

When pairing to the MMI App, your MODD1 System uses a secure Bluetooth® connection which uses dual authentication.

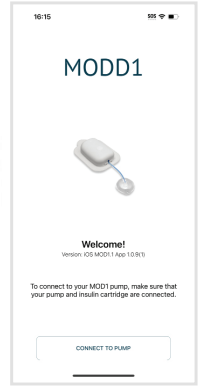
This technology uses NFC (Near-Field Communication) which allows devices to share data easily.

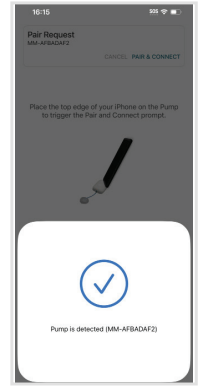
Communication between the MODD1 System and the MMI App is encrypted.

WARNING: *Make sure you keep other people from using the MMI 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 MMI App and click “Connect to Pump”.
2. Place your smartphone on top of the Pump 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 Setting Basal Schedule

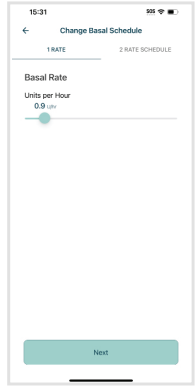
The MMI App has two options for the Basal Rate Schedule: Single Rate or Two Rate. You will use the on-screen slider to adjust the Basal Delivery Rate.

The Single Rate option will deliver insulin 24 hours per day at your chosen basal rate.

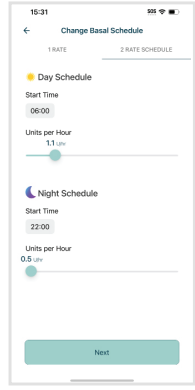
The Two Rate option will require two basal insulin delivery rates. You will choose the start time for both Day and Night. The time can be adjusted in 15 minute increments.

The Day rate will end when the Night rate is set to begin. For example, if you set your Nightime rate to begin at 8:00 PM, your Daytime rate will automatically end at 8:00 PM, and the Nightime rate will then begin.

SINGLE RATE OPTION



TWO-RATE OPTION



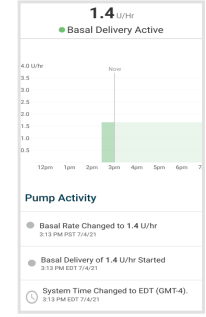
4.3 General App Interface

Pump Status Current Delivery Mode of the Pump. See Section 4.4 for a definition of all options along with the representative symbol.

Graph Displays basal rate in green and bolus in blue drops with the total quantity once the delivery is completed (or canceled). Grey regions indicate 30 minute periods of Basal Suspend. Blank areas without color indicate non-delivery periods due to the Pump being powered off or Alarms.

Activity Log Displays the last 3 activities of the Pump at a glance. See Section 4.5 for a list of all activities tracked. Press the "View All Activity" button to provide a screen with a chronological list of activity for the currently paired Pump.

Top of home screen



WARNING: *Delivery information displayed in the Activity Log is for reference only and should not be used to make treatment decisions as this could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.*

Bottom of home screen

Basal Schedule Displays the current basal rate or 2-rate schedule programmed in the connected Pump.
Press the “Change Basal Schedule” button to modify your Pump if desired during use. For more information on programming basal schedule see Section 4.2. Note that while in use, the Pump must be in Basal Suspend Mode for a basal rate change to occur.

Pump Info Displays Pump Serial Number, App Version, Pump Firmware Version, and App Unique Device Identifier (UDI).

How to Bolus Press the "How to Bolus" button to view in-app instructions on how to request a bolus.

WARNING: *Delivery information displayed on the MMI App (except for basal schedule) is for reference only and should not be used to make treatment decisions as this could lead to moderate or severe hypoglycemia, moderate or severe hyperglycemia, Diabetic Ketoacidosis (DKA), or a delay in insulin therapy.*

NOTE: *The MMI App only displays information when paired and connected with the Pump. The MMI App does not receive automatic updates from the device unless the wireless Bluetooth connection is active.*

4.4 Pump Status

Pump is Starting	**Pump is being setup: filling and priming of the System**
Basal Delivery Active	**Basal is currently being delivered**
Bolus Delivery Active	**Bolus is currently being delivered**
Basal Delivery Suspended	**Basal delivery is suspended for 30 minutes**
Syncing Pump Data	**MMI App is being updated with new Pump data**
Not Connected	**Pump is not communicating to MMI App**
Delivery Stopped	**No insulin is being delivered due to an Alarm**

4.5 Activity Log

Your MMI App will log activity for the currently paired Pump. Below is the information you may find in your Activity Log.

- New Pump Paired: A new Pump has been paired to the MMI App.
- New Insulin Cartridge Installed: The user has installed a new Insulin Cartridge to the connected Pump.
- Basal Schedule Changed: The user has changed the Basal Rate Schedule 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 Suspended: The user has suspended Basal Delivery on the connected Pump.
- Pump Delivery Alarm Detected: Delivery has stopped, the Insulin Cartridge and Infusion Set must be replaced.
- Pump Technical Alarm Detected: Delivery has stopped, the System must be replaced.

4.6 App Notifications

Your Dashboard will show important notifications regarding your MODD1 System, such as events that can affect your insulin delivery.

Use of the MMI App outside of Basal Rate Schedule programming is optional. When notifications are given on the MMI App, these are for informational purposes only. The MMI App cannot be used for resolving any notifications of the connected MODD1 System.

You will be informed of MODD1 System notifications by audio-visual signals from the Pump itself. The MMI App may assist you in recognizing the reason for the notification, however all notifications are to be dealt with by interacting with the Pump only.

Please refer to the Alarms, Section 5.0, of this User Guide for information on handling MODD1 System Alarms.

5.0 Alarms

Your MODD1 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.

DELIVERY ALARM

An issue has been detected with the disposable components of your System.
Replace your Insulin Cartridge, Infusion Set, and Adhesive Pad and rotate infusion sites.

TECHNICAL ALARM

An issue has been detected with your Pump.
Replace your entire MODD1 System.

NOTES: *If you receive an Alarm, this means that your MODD1 System has stopped delivering insulin.*
Contact Customer Care at (866) 710-1200.
To mute the Alarm tone, press the Control Button.
To turn off the Alarm you must remove power to the Pump by removing the Insulin Cartridge.

Possible Cause for Delivery Alarms

Insulin Cartridge Expired	Your Insulin Cartridge has reached 80 hours of use.
Out of Insulin	Insulin reservoir is empty.
Occlusion Detected	A blockage in the infusion tubing or Infusion Set has been detected.
Battery Empty	Battery level is depleted.
Insulin Cartridge Failure	A critical error, malfunction, or failure of your Insulin Cartridge has been detected.
Extreme Temperature	System is being used outside of the temperature limits of 41.0°F - 98.6°F (5°C - 37°C).
Extreme Altitude	System is being used outside of the altitude limits of -1,300ft - 10,000ft (1060hPa - 700hPa).

Possible Cause for Technical Alarms

Pump Failure	A critical error, malfunction, or failure of your Pump has been detected.
Expired Pump	Your Pump has reached the end of its 90 day use life.

CAUTIONS: *It is important to address an Alarm. Not addressing Alarms can lead to 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.

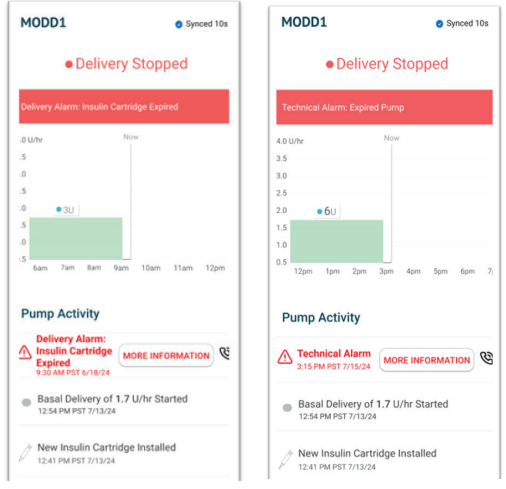
MMI App Display of Alarms

Your MODD1 System will display information about each Alarm in the MMI App when the Pump is connected to the App. The information provided will include:
- Alarm Type (Delivery or Technical Alarm)
- Alarm Name
- Date of Alarm
- Button to learn more information about the Alarm
- Call Button to Modular Medical Inc.

Note: The Pump can be connected to the MMI App while in an Alarm state.

NOTE: The Pump can be connected to the MMI App while an Alarm state is occuring.

Dashboard

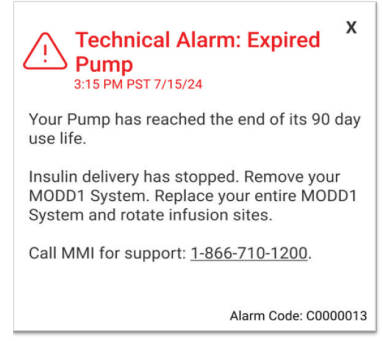


More Information about Alarms

If you select the More Information Button for the Alarm, a pop-up will appear to provide extra information about the specific alarm that occured including the Alarm Code, recommended next steps, and a phone number to call MMI support if you need help with your MODD1 System.

Note: The Pump can be connected to the MMI App while in an Alarm state.

More Information



6.0 Emergency Kit

An Emergency Kit (not provided) has the supplies you need to manage your diabetes if your MODD1 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 MODD1 System or any of its components are not working per the information provided in this User Guide, stop using your MODD1 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 Insulin Cartridges, Infusion Sets, and Adhesive Pads
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 MODD1 System stops functioning and you don't have an Emergency Kit, contact your Healthcare Provider as soon as possible.*

7.0 Care & Maintenance

Your MODD1 System does not require cleaning or maintenance.

If you would like to clean the outside of your Pump, ensure the Insulin 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 your Pump.

Your MODD1 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 Insulin 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.*

7.1 Usage Conditions

While your MODD1 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 MODD1 System will not be affected, it is possible for electronic devices to momentarily interrupt communications between the MODD1 System and the MMI App. For more information, see Section 8.4 on Electromagnetic Compatability.

Please refer to these sections for more information on usage considerations: external influences (Section 8.6), possible risks (Section 7.3), and traveling by air (Section 7.6). If you have questions regarding the use of your MODD1 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. Failure to do so can lead to moderate or severe hypoglycemia, moderate hyperglycemia, or Diabetic Ketoacidosis (DKA).*

When fitted with an Insulin 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 Support.

CAUTIONS: *Only use your MODD1 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 environemnts, 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 MODD1 System before using a sauna or jacuzzi, or while swimming, bathing, showering, or during contact sports. Your MODD1 System is only protected against minor splashing (i.e., IP24 rating). Use of the MODD1 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.

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

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

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

WARNINGS: *Do not remove the sterile Insulin Cartridge from the sealed package 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 Insulin Cartridge, inspect every part of your MODD1 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 Customer Care.

CAUTION: *Insulin Cartridges must be kept in a dry location, avoiding direct sunlight. You must store your Insulin 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 + 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 MODD1 System. Every Insulin Cartridge contains a battery that is designed to last for up to three days of use.

NOTE: *Do not attempt to replace your Insulin Cartridge battery. Doing so could lead to a delay in insulin therapy.*

7.5 Troubleshooting

If you are unable to download the MMI App, check the phone model number and Operating System version. Only specific phones and Operating Systems are approved for use with the MMI App.

If you are unable to pair your Pump to the MMI App:
* make sure the Pump is connected to an Insulin Cartridge and powered on.
* make sure the phone is not paired to another Pump - you can check connected BLE devices.
* make sure you are placing the Pump close to the Phone's NFC Antenna.

If the user cannot connect the Pump to the MMI 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 MMI App freezes while in use, close out the App and reopen it.

If the Pump disconnects from the MMI App, select "Try Again" to reconnect the device.

WARNINGS: *If you think someone has modified or tampered with your MODD1 System, replace the Pump, Insulin Cartridge, and Infusion Set. 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 basal schedule. If this did not happen intentionally, avoid pressing the button for 15 seconds until the green light stops flashing to cancel the request. This is important as an unauthorized basal schedule 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 able to be completed. 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 MODD1 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 MODD1 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 MODD1 System should not be exposed to them. Notify the Transportation Security Administration (TSA) Agent that your MODD1 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 MODD1 System is MR Unsafe.

WARNING: *The MODD1 System cannot be used inside or in proximity to an MRI machine.The device presents a projectile hazard.*

7.8 Customer Care

If your MODD1 System is not working correctly or you need technical support, assistance, or have questions about your MODD1 System, please contact Modular Medical Customer Care at 866-710-1200 or visit us online at www.modularmedical.com.

If you have a medical emergency while using your MODD1 System, seek medical attention as required.

7.9 Warranty

Modular Medical, Inc. warrants the Modular Medical MODD1 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 Insulin Cartridge, Infusion Set, and Adhesive Pad is for 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, Insulin Cartridge, Infusion Set, and Adhesive Pad have been used in accordance with the provided User Guide and will not apply if:

- The Insulin Cartridge, Infusion Set, or Adhesive Pad 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: Initiating a Return: To initiate a return, reach out to our 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 Support 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.modularmedical.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)
Weight	1.0 ounces (28 grams)
Bluetooth Low Energy (BLE)	Utilized to send information between Pump and the MMI App. The Pump transmits out information on its status, history, Alarms, and configuration to the App. The MMI App sends commands to the Pump to request this information and to set the Basal Rate Schedule.
Near Field Communication (NFC)	Utilized to ensure close proximity of MMI App to Pump, enabling the safe exchange of a BLE key.

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	2 – 20 Units (with 2 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	14.1 PSI
Bolus Volume at Release of Occlusion	0.45 Units
Residual Insulin Remaining in the Insulin 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 MODD1 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 MODD1 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 Insulin Cartridges and Insulin 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 MODD1 Pumps were tested by delivering consecutive minimum, intermediate, and maximum bolus volumes (2, 10, and 20 units). For each Bolus volume, 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 Insulin Cartridges and Insulin 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 2U Bolus Request, n=450 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	0/450 (0.0 %)	0/450 (0.0 %)	13/450 (2.9 %)	63/450 (14.0 %)	350/450 (77.8 %)	24/450 (5.3 %)	0/450 (0.0 %)	0/450 (0.0 %)	0/450 (0.0 %)	0/450 (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 2U Bolus Request, n=450 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	0/450 (0.0 %)	1/450 (0.2 %)	15/450 (3.3 %)	49/450 (10.9 %)	371/450 (82.4 %)	14/450 (3.1 %)	0/450 (0.0 %)	0/450 (0.0 %)	0/450 (0.0 %)	0/450 (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 43 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 alert until additional basal or bolus deliveries occur.*

8.4 Electromagnetic Compatability

This information provides reasonable assurance of normal operation, but does not guarantee this under all conditions. If the MODD1 System must be used in close proximity with other electrical equipment, the MODD1 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 MODD1 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 MODD1 System is a portable, body-worn device. For IEC 60601-1:2020 (Ed. 3.2) testing, Essential Performance for the MODD1 System is defined as follows:

- The MODD1 System shall not over deliver insulin.
- The MODD1 System shall not under deliver insulin.
- The MODD1 System shall detect an occlusion.

Intense electromagnetic fields may lead to a loss of Essential Performance of your MODD1 System, potentially causing complications with your therapy. If you are unsure if your MODD1 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 MODD1 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 MODD1 System is intended for use in the electromagnetic environment specified below. Always make sure that the MODD1 System is used in such an environment. The MODD1 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 MODD1 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 MODD1 System by no less than the distances calculated below:
Proximity fields from RF wireless communications equipment IEC 61000-4-3:2014	See Table 2 on the next page.	D=1.2*√P 150 kHz to 80 MHz D=1.2*√P 80 MHz to 800 MHz D=2.3*√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.

*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 MODD1 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 cannot be accurately predicted theoretically. Consider conducting an electromagnetic site survey to assess the electromagnetic environment created by fixed RF transmitters. If the fields strengths measured in the location in which the MODD1 System is to be used are greater than the applicable RF compliance level shown above, the MODD1 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 MODD1 System.

Recommended Separation Distances Between Typical Body-Worn Devices and the MODD1 Insulin Delivery System

This section provides information on the recommended separation distances between typical body-worn devices and the MODD1 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 MODD1 Pump.

used to calculate the recommended distances below.

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
Abbot Libre CGM	2dBm (1.58mW)	0.09	3.5
Medtronic Guardian Sensor 4	0.1mW	0.02	0.9
Sensonics Eversense CGM	1mW	0.07	2.8
Bluetooth Headphones	8dBm (6.3mW)	0.18	7.1

8.5 Wireless Technology Specifications

The tables below provides information regarding Bluetooth technology specifications for the MODD1 System.

Parameter	Description
Wireless Technology	Bluetooth 5.1
Wireless Function	The Bluetooth Low Energy transmitter is used to allow the user to configure basal insulin delivery schedules, and view pertinent device information via the MMI App on a compatible smartphone.
Data Transmitted	The MODD1 Pump software has two-way communication with the MMI App over Bluetooth. The MODD1 Pump software uses Bluetooth to receive commands from the MMI App. The Set Basal Schedule command is used by the MMI App to set the basal schedule on the MODD1 Pump, including basal rate and time of day that the basal rate is delivered. The MMI App receives information from the MODD1 Pump, including current status of the MODD1 Pump, logged events from the MODD1 Pump, and notification of alarms from the MODD1 Pump.

Parameter	Description
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 MODD1 System)
Intended Range	20 feet
Security Measures	The Pump only communicates with an MMI 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 MODD1 System.

Parameter	Description
Data Integrity	When the basal schedule is set, it is set correctly 100% of the time.
Data Latency or Throughput	Basal schedule is confirmed on the MMI App user interface to have been set less than 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 MODD1 System does not have signal priorities as there is a single BLE communication protocol implemented in the design.

The tables below provides information regarding NFC technology specifications for the MODD1 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 MMI App installed on a compatible smartphone.
Data Transmitted	NFC is used by the MODD1 Pump software to set up BLE with the MMI 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 MMI App.
Intended Range	Range is the effective distance for initial NFC connection when the user taps the MODD1 Pump to the mobile device running the MMI 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 MODD1 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 MODD1 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 MODD1 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 MODD1 System is intended for use in electromagnetic environments where radiated RF emissions are controlled. A minimum separation distance of 30cm between the MODD1 System and mobile RF communications equipment (transmitters) can help to prevent electromagnetic interference.

While Basic Safety and Essential Performance of the MODD1 System will not be affected, it is possible for devices commonly found in the home to interrupt communications between the Pump and the MMI App. For a description of potential external influences, see Section 8.7.

If communication between the Pump and MMI 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 an Insulin Cartridge installed in your Pump – even when you are not using your MODD1 System.
Unsupervised children or pets	May compromise internal electrical connections.	Always keep an Insulin Cartridge installed in your Pump – even when you are not using your MODD1 System.

External Influences Information	Potential Effect	Remedial Action
Sunlight	Damage to the Insulin Cartridge.	Store Insulin Cartridges away from direct sunlight in accordance with the instructions found in this User Guide.
Heat source (stove top, heater)	Physical damage to MODD1 System. Degradation of insulin.	Assure your MODD1 System is not placed near any heat source.

9.0 Label Symbols

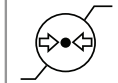
The following definitions are for symbols which you may find on your MODD1 Insulin Delivery System and/or its packaging. These symbols help to identify proper and safe use and handling of the MODD1 System.

Symbol	Meaning	Standard / Reference
LOT	Batch 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
STERILE EO	Single Sterile Barrier Using Ethylene Oxide	ISO 15223-1, Clause 5.2.3 ISO 7000-3707
	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
	Magetic Resonance (MR) Unsafe	ASTM F2503
	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
	Distributor	ISO 15223-1, Clause 5.1.9 ISO 7000-3724
	Refer to Instructions for Use	ISO 7010-M002

9.1 Glossary

Adhesive Pad - Single-use component that attaches to the users skin to secure the Pump and Insulin Cartridge Assembly.
Ascending Tones - A sequence of tones that are getting higher in pitch indicating you are in Bolus Mode.
Basal Suspend - A user selected mode that stops insulin delivery for a fixed, 30 minute period.
Bolus Increment - The 2U increment entered for every Control Button press while programming a bolus.
Cannula - The flexible soft tube (6mm length) on the Infusion Set that is inserted into the body to deliver insulin.
Contraindication - A statement that describes situations or conditions in which the MODD1 System is not to be used.
Control Button - Primary user input to control bolus delivery and check the status of the MODD1 System.
Dashboard - The main screen of your MMI App that features your current Basal Schedule, Pump Activity, and Pump information.
Delivery Alarm - Indicates that your MODD1 System has stopped insulin delivery. Requires replacement of the Insulin Cartridge, Infusion Set, and Adhesive Pad.
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 MODD1 System with its electromagnetic environment.
Emergency Kit - The necessary supplies you need to have on hand to manage your insulin therapy in case your MODD1 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.
Hypoglycemia - Low blood glucose levels.
Hyperosmolar Hyperglycemic State (HHS) - Hyperglycemia with severe dehydration in the absence of ketosis, vomiting, loss of consciousness, convulsion/seizure, and coma.
Infusion Set - Sterile, single-use, disposable component that facilitates the subcutaneous delivery of insulin.
Infusion Set Inserter - Facilitates the insertion of the Infusion Set into the body. Included in the Starter Kit. Reusable with a 2-year use life.
Insulin - The MODD1 System is indicated for use with Humalog® (Insulin lispro) U-100, rapid-acting insulin.

Insulin Cartridge - Sterile, single-use, disposable component that contains the insulin reservoir, battery, and a tubing cap that facilitates connection to the Infusion Set.
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 MODD1 System status or provide Alarm notifications.
Lipodystrophies - abnormal fat loss or distribution that cause skin bumps and scar
MMI App - The MMI App is used to configure the MODD1 System time and Basal Rate Schedule.
MODD1 System - Pump, Insulin Cartridge, and Adhesive Pad assembly and the MMI App for compatible smartphone and operating system.
Needle - Used in combination with the Syringe to fill the Insulin Cartridge reservoir with insulin. The needle is a single use accessory and is supplied in the Supply Kit.
Occlusion - A blockage within the tubing that may prevent the flow of insulin to your body.
Priming - Action taken to remove air bubbles from the Insulin Cartridge.
Pump - The Pump is the durable element of the MODD1 System that houses the System electronics and has a 90-day use life.
Quick Start Guide - An instructional guide detailing the steps to set up your MODD1 System for use. The Quick Start Guide is provided in each Starter Kit.
Supply Kit - Contains the Insulin Cartridge, Infusion Set, Adhesive Pad, and Fill Syringe and Needle (each have up to a 3-day use life).
Syringe - A sterile, single-use accessory used with a needle to fill the Insulin Cartridge. The Syringe comes in the Supply Kit.
System Status - The current state or delivery mode of your MODD1 System, checked by pressing the Control Button.
Technical Alarm - Indicates that your MODD1 System has stopped insulin delivery and your entire system must be replaced.
Temporary Removal - Removal of the MODD1 System 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.
Tubing Cap - The portion of the Insulin Cartridge that connects to the Infusion Set allowing for the subcutaneous flow of insulin.
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).

9.2 Index

Patents

The Modular Medical MODD1 Insulin Delivery System is covered by multiple patents.

Trademarks

Humalog® is a registered trademark of Eli Lilly and Company.

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.

If you have a medical emergency using your MODD1 System, seek medical attention as required.

please contact Modular Medical Customer Care at 866-710-1200 or visit us online at www.Modularmedical.com.

For updates, questions, or assistance with your MODD1 System, please contact Modular Medical Customer Care anytime.

Toll-free at 866-710-1200

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