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.Modular-Medical.com

10740 Thornmint Road
San Diego, CA 92127
United States

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 Modular Medical Insulin Delivery System trainer.*

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 a MMI App. The App operates on your smartphone device and connects to the Pump via Bluetooth® connection to support basal rate programming and 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 Professional 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 either independently or with the support of a healthcare professional.

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.

CAUTIONS:

While the MODD1 System features biocompatible materials, there is a the possibility you may experience skin irritation while using your MODD1 System.

Please refer to the Possible Risks section 7.4 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.

WARNING: *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 impact the pump's functionality.*

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

WARNING: *Do not leave your MODD1 System or its accessories unattended in the presence of small children or pets. Small parts may pose an asphyxiation or choking hazard.*

Do not modify your MODD1 System, its components, or accessories. Doing so may lead to complications with your therapy.

Only use the accessories supplied for use with the MODD1 System. The use of other accessories may case damage to the MODD1 System or complications with therapy.

Modular Medical contraindicates against using the System if you have inadequate hearing due to the importance of the audible signals provided by the Pump. Assure that you are able to hear important audio and see visual displays. Being unable to hear an alarm may prevent you from responding to a MODD1 System event that requires your immediate attention. If you are in a high-noise environment, keep an eye on your Pump, as the light signals will notify you of any issues.

It is important to check the expiry date of each component and accessory used with your MODD1 System including your insulin. Using components and accessories beyond their expiry date could lead to complications with your therapy.
Be sure to dispose of any accessories that are past their expiry date. Always adhere to your local disposal 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.

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 Professional.

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 or when changing a 2-rate Basal Schedule due to a time zone change.*

INFUSION SET

This component is inserted into your subcutaneous tissue and delivers insulin through a 6mm, 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 check the status of your MODD1 System with one quick press.

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

LED LIGHT

This provides visual 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. An iPhone App must also be utilized to program the Pump (see section 4).

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 picured)
- **Patient Medical Device Card** (not picured)

PUMP

INFUSION SET INSERTER

QUICK START GUIDE

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

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: Preparing the Infusion Site

For this step, you will need:

- New Infusion Set
- Infusion Set Inserter
- Alcohol Wipe (not included)

INFUSION SET

INFUSION SET INSERTER

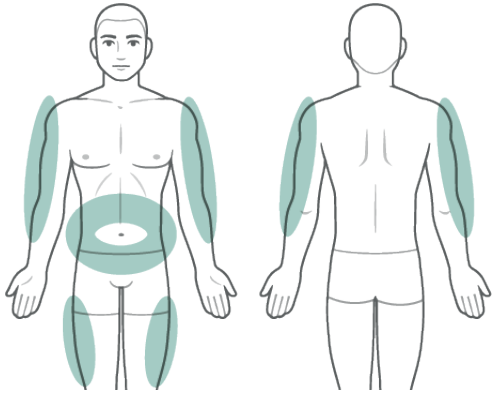
ALCOHOL WIPE

WARNING: *Avoid areas with scarring, tattoos, scars, moles, lipohypertrophy, and areas that may get bumped or constricted such as the beltline or waistline. Placing your MODD1 System incorrectly could put your health at risk.*

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 and three 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



WARNING: *Always use a new infusion site that is at least 2 inches away from previous infusion sites. Using the same infusion site repeatedly may lead to infection or lipodystrophies.*

Step 2: Inserting the Infusion Set

Before handling the Infusion Set, wash your hands with anti-bacterial soap. Then clean your infusion site with an alcohol wipe. Make sure that the area is dry.

1. Put the Infusion Set in the Inserter.

   Remove the Needle Cover and the paper backing.

2. Turn the top of the Inserter clockwise to activate.

WARNING: *Use only new Infusion Sets that are unused, unopened, and within their expiry date.*
Only unpack your Infusion Set immediately before use to prevent complications with your therapy.

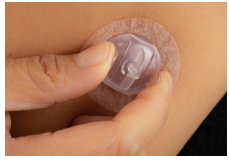
NOTES:
Ensure your infusion site is clean.

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

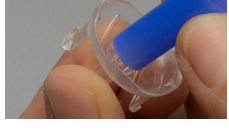
3 Place against insertion site and push the button until a “click” is heard.

4 Press down firmly around the Infusion Set to ensure it is adhered.

Squeeze the tabs and remove the introducer needle.



5 Place the blue protective cap over the Introducer needle and safely dispose of after use.



CAUTION: *Check your Infusion Set for leaks and proper placement every day. Improper placement and/or unseen damage may lead to complications with your therapy.*

WARNINGS:

Every time you change your Insulin Cartridge, you must replace the Infusion Set and use a different infusion site.

Do not leave your MODD1 System or its accessories unattended in the presence of small children or pets. Small parts may pose an asphyxiation or choking hazard.

Step 3: Power on the Pump

For this step, you will need:

- New Insulin Cartridge
- Pump

NEW INSULIN CARTRIDGE

PUMP

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.*

CAUTION: *Always inspect for damage with the Insulin Cartridge or Pump packaging before opening and on the product before use.*

WARNING: *Use only new Insulin Cartridges that are unused, unopened, and within their expiry date. Only unpack your Insulin Cartridge immediately before use to prevent complications with your therapy.*
Insulin Cartridges are sterile and for single-use only. Do not attempt to reuse an Insulin Cartridge as this could lead to infection.

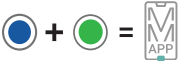
1. Remove the paper cover leaving the Insulin Cartridge in its packaging and place on a flat surface.

2. Connect the Pump to the Insulin Cartridge. Line up the notch in the Pump to the blue tube on the Insulin Cartridge and press firmly to lock together.

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

4. 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. Proceed to step 4 on page 19.

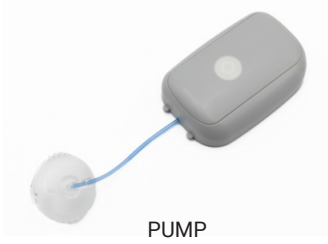


A flashing white light and three tones indictes the Pump is ready to be filled with insulin.
Proceed to Step 5 on page 21.

Step 4: Program your Basal Schedule in the App

For this step, you will need:

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



PUMP

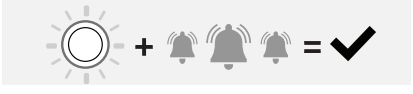
MMI APP

A flashing blue and green light indicates that you must connect your smartphone device to the MMI App.

If you need to download the MMI App, you can scan the QR code in Section 4. The MMI App provides an easy way to set your Basal Rate Schedule.

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

1. Open your MMI App and press Connect to Pump.
2. Place your smart device on the Pump.
3. Press “Pair & Connect” to confirm the pair request.
4. Set your Basal Rate Schedule.
5. A flashing green light on your Pump indicates the request was received.
6. Quickly press and release the Control Button to confirm your Basal Schedule.
7. A flashing white light and three tones means that your schedule is set. Now you can proceed to Step 5.



There are two rate options:

SINGLE RATE	TWO-RATE
One basal rate that will run continuously.	2 rates over a 24 hour period. The day rate will end when the night rate is set to begin.

Step 5: Filling the Syringe with Insulin

For this step, you will need:

- New Filling needle and syringe
- 10mL vial of Humalog® U-100 Insulin (not provided)
- Alcohol wipe (not provided)

FILLING NEEDLE & SYRINGE

10 ML VIAL OF HUMALOG® U-100 INSULIN

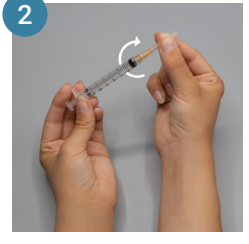
ALCOHOL WIPE

WARNINGS: *Do not reuse needles or syringes as this could contaminate your insulin and lead to an infection.*

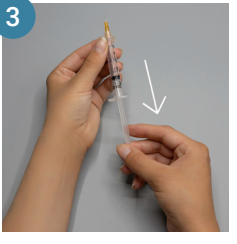
Only use Humalog® (Insulin lispro) U-100 rapid-acting insulin. Do not blend different insulins.

Ensure that your insulin is not expired and has been stored according to manufacturer's instructions. Assure it is not cloudy or discolored and the seal is free of damage. Discard insulin vial if any of these conditions apply. Always discard safely and per local guidelines.

Clean the top of the insulin vial with an alcohol wipe.



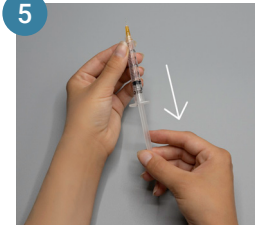
Connect needle and syringe and carefully remove the needle cap.



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

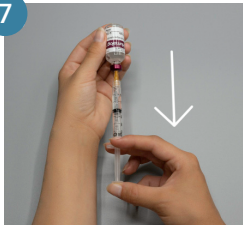
Insert the needle into the vial and gently push air into the vial.

WARNING: *Be sure to read the next steps to avoid trapping air in your MODD1System.*



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

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



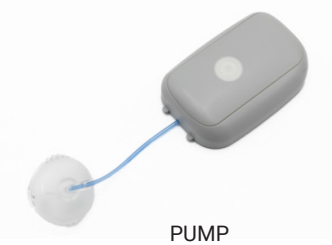
If air remains, repeat the previous step and refill the syringe as necessary. Remove the needle from the vial.

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

Step 6: Filling the Insulin Cartridge

For this step, you will need:

- An Assembled Pump
- Syringe filled with Insulin



PUMP

SYRINGE FILLED WITH INSULIN

NOTE: *Only use supplied Needle and Syringe for filling the Insulin Cartridge.*

WARNING: *Do not fill past the Insulin Cartridge maximum capacity of 3.0mL (300 units) or below the minimum of 0.8 mL (80 units). Doing so may lead to complications with your therapy.*

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

2. Carefully insert the needle into the Fill Port. Do not press down on the plunger yet.

3. Once the needle is inserted, pull the syringe plunger back to remove air from the Insulin Cartridge reservoir.

CAUTION: *The needle will not fully insert into the Insulin Cartridge. Do not force it through as this may damage the Insulin Cartridge.*

4 Remove the needle from the Fill Port. Tap the syringe barrel to force the air bubbles up to the top. Slowly press on the plunger to expel air from the syringe until you see insulin droplets at the needle tip.

5 Insert the needle back into the Fill Port and gently push to fill the Insulin Cartridge reservoir.

6 Inspect the Insulin Cartridge and infusion tubing for leaks. If leaks are present, remove and discard the Insulin Cartridge and repeat the setup procedure with a new Insulin Cartridge.

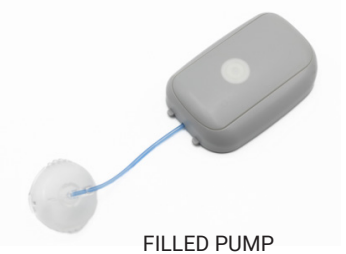
WARNING: *Never attempt to extract insulin from your Insulin Cartridge.*

NOTE: *After use, be sure to dispose of your used needle and syringe safely and in accordance to local regulations.*

Step 7: Priming the Infusion Tube

For this step, you will need:

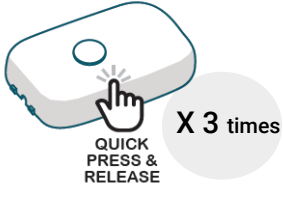
- Filled Pump



FILLED PUMP

WARNING: *Do not prime your MODD1 System if it is attached to your body; doing so could lead to a hypoglycemic event.*

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 Hold your MODD1 System as shown below to optimize priming. You may look through the back of the Cartridge to see the insulin reservoir to ensure all air bubbles are being appropriately primed out.

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

WARNING: *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 complications with your therapy.*

3 Inspect your Insulin Cartridge reservoir and infusion tubing for any air bubbles.

If air remains, press the Control Button 3 times to repeat the priming cycle. You have **60 seconds** to start another prime cycle.

Look for a drop of insulin at the end of the Tubing Cap. Priming is complete if you see a drop of insulin and no air bubbles

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

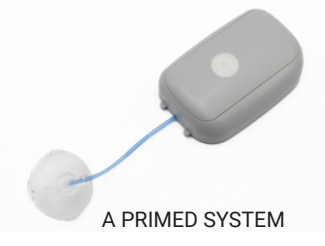
A flashing green light and a single tone indicate the Basal Delivery will automatically begin in 2 minutes.

CAUTION: *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 8: Attaching the Adhesive Pad and Placing the System to Your Body

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.
- You are rotating your infusion site to prevent irritation

1. Connect the Pump and the Adhesive Pad as shown.

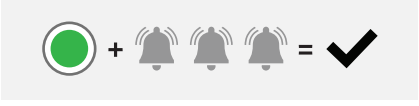
2. Carefully remove the paper backing from the Adhesive Pad.

3. Snap the Tubing Cap onto the Infusion Set.

NOTE: *Ensure the location is dry and there is enough space for the infusion tubing so that it is not pulled when you adhere the System.*

4. Press down firmly around the Adhesive Pad to ensure it is securely stuck onto your skin.

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



WARNING: *To prevent potential irritation, the Infusion Set and Adhesive Pad should be removed no later than three days after attaching.*

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.*

3.0 Using the System

Your MODD1 System has three insulin delivery settings: Basal, Bolus, and Basal Suspend. The lights and tones will indicate which of the three modes you are in.

After successfully filling and priming, your Pump will automatically transition into Basal Delivery Mode, the default delivery mode of your System.

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 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.

If the LED lights or tones are not functioning, the System should be removed and Pump replaced.

WARNING: *If the Control Button stops working at any time, stop using your MODD1 System until you have a replacement. Improper functioning of your MODD1 System could lead to complications with your 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 4.1).

A green light and 3 consistent tones indicated 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

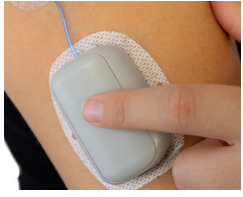
This mode is used to pause basal insulin delivery for 30 minutes and can not be overridden.

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

3.2 Delivering a Bolus

1. Decide the number of insulin units you would like to deliver.

   Press and hold the Control Button until you see a blue light and hear a single tone, then release.



Example

1 press = 2 units

5 presses = 10 units

Max Bolus: 10 presses = 20 units

NOTE: *Check blood sugar before and after a bolus*

2 Set your Bolus size by pressing the Control Button repeatedly. You will see a blue light and hear an ascending tone for each press. There are 2 unit increments per 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.

3 The System will play back your selected bolus size with a blue light and tone for each press (2 unit increment).

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.

4 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 now restart your bolus dose programming.

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

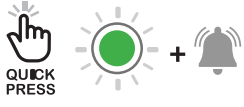
3.3 Cancelling a Bolus Delivery

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 for extended amount of time (approximately 7-10 seconds) until you see a green light and hear a single tone, then release.

   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.*

3.4 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 for an extended period (approximately 7-10 seconds) until you see a white light and hear a single tone, then release.

   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.

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

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

3.5 Detaching Your Pump

You can temporarily detach your MODD1 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:

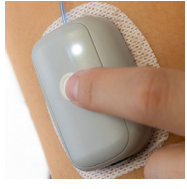
- swimming,
- shower,
- physical activity

WARNING: *Be mindful of your Pump while changing your Insulin Cartridge. Damage to the exposed electrical components may lead to complications with your therapy. Always keep an Insulin Cartridge attached to your Pump while storing.*

1. First, put your Pump into Basal Suspend Mode. (See Section 3.5)

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. Small parts may pose an asphyxiation or choking hazard.

Always store your pump in a safe and secure place when not in use to ensure it is not mishandled.

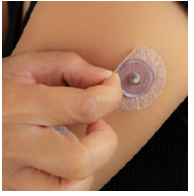
Insulin delivery will automatically resume in 30 minutes.

3.6 Replacing Your Infusion Set & Cartridge

Your Insulin Cartridge and Infusion Set must be replaced at the end of their three-day use period, when you receive a high-priority alarm, or if it's no longer functional or 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 3.5.

2. Gently remove the Adhesive Pad.



3. Carefully remove your Infusion Set.

NOTE: *Always dispose of the Insulin Cartridge, Infusion Set, and Adhesive Pad safely and in accordance with your local disposal guidelines.*

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.

WARNINGS: *To prevent damage, always keep an Insulin Cartridge attached to your Pump. Exposing the inside of your Pump for extended periods of time can lead to complications with your therapy.*

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 infection or lipodystrophies. Contact your Healthcare Professional if you have symptoms of an infection at your insulin infusion site.

3.7 Replacing Your Pump

After 90 days from when you first power on your pump it will expire and provide a High Priority Technical Alarm as identified in section 5.0.

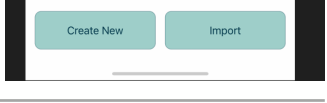
The full System must be removed as shown in section 3.5 and 3.6.

Proceed with assembling the pump as shown in section 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® or by scanning the QR code on this page.

Compatible with only the iPhone 12 Pro Max running iOS 16

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.

Do not run the MMI App on a jailbroken smartphone because of the risk of cybersecurity problems.

WARNING: *Before updating your phone OS, make sure the version is supported or you may not be able to continue using the MMI App.*

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

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, ensure the correct time zone is set up within the MMI App while traveling. Your Healthcare Professional will discuss your insulin delivery schedule and dosage.

NOTE: *The MMI App automatically updates all activity logs to match your current time on the phone but will not make any adjustments to your Pumps basal delivery. If you are using a 2-rate Basal Schedule and want to adjust your Pump to a new time zone, you must manually reprogram this through the MMI App.*

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 3.2) for more information.

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 in startup mode after changing the Insulin Cartridge.

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.

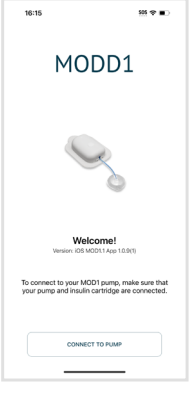
NOTE: *Make sure you keep other people from using the MMI App on your smartphone by keeping your smartphone secured and setting it to unlock with a passcode, fingerprint, face ID, or similar.*

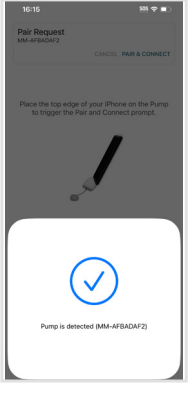
4.1 Connecting the App to the Pump

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

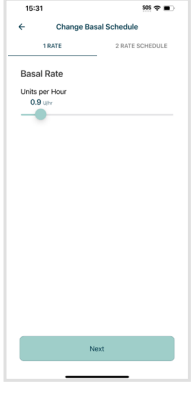
The MMI App has two options for the Basal Rate Schedule: Single Rate or Two Rate. You will use the on-screen slider to adjust the basal delivery rate.

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

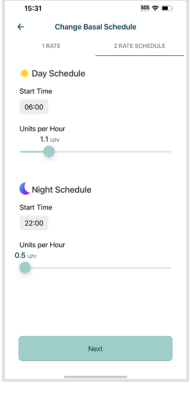
The Two Rate option will require two basal insulin delivery rates. You will choose the start time for both Day and Night. The time
can be adjusted in 15 minute increments.

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

The following 2 images show the informaton and sections on the App's main screen. You

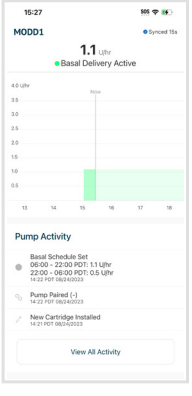
Pump Status Current Delivey State of the Pump. See Section 4.4 for a definition of all options along with the representative symbol.

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

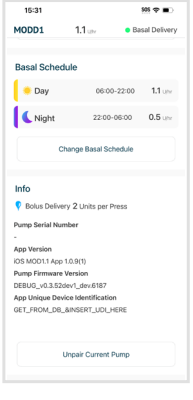
Activity Log Displays the last 3 activities of the pump at a glance. See Section 4.5 for a list of all ativities tracked.

Press the "View All Activity" button to provide a pop-up screen with a chronological list of activity for the currently paired pump.

Top of home screen



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 4.0.. Note that while in use, the pump must be in Basal Sus-

Pump Info

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

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 in setup Mode: filling and priming of the System
Basal Delivery Active	Basal delivery is currently being delivered
Bolus Delivery Active	Bolus is being delivered
Basal Delivery Suspended	Basal is suspended for 30 minutes
Syncing Pump Data	App is being updated with new Pump data
Not Connected	Pump is not communicating to MMI App
Delivery Stop	No insulin is being delivered due to a critical 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 the 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 Pump must be replaced.

WARNING: *Delivery information displayed on the MMI App (except for basal schedule) is for reference only and treatment decisions should not be made based on this information.*

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.

Users are informed of MODD1 System notifications by audio-visual signals from the Pump itself. The App may assist you in recognizing the reason for the notification, however, users are trained to deal with notifications by interacting with the Pump only.

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

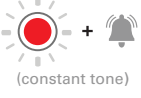
5.0 Critical Alarms

Your MODD1 System will notify you with a flashing red light and tone if there is a problem .
You may momentarily mute the audio feedback (tone) of an Alarm by quick pressing the Control Button.

DELIVERY ALARM

There is an issue with your Insulin Cartridge or Infusion Set and they must both be replaced.

TECHNICAL ALARM



Your Pump has a malfunction and must be replaced along with the Insulin Cartridge

NOTES:
If you receive an Alarm, this means that your MODD1 System has stopped delivering insulin.
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 blockage in the infusion tubing or infusion set has been detected.
Extreme Temperature	System is being used outside of the temperature limits 60.8°F-98.6°F (16°C-37°C).
Extreme Altitude	System is being used outside of the altitude limits 0-10,000ft (700-1060hPa).

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.

WARNINGS:

If your System loses power, Alarms will not sound until power is restored.
It is important to address an Alarm. Not addressing Alarms can lead to complications with your therapy.
If you receive an Alarm during bolus delivery you will not receive the full quantity.
You should check your blood sugar level.

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 professional for further advice regarding your Emergency Kit.

WARNING: *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.*
Please contact Customer Care at (866) 710-1200 to 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

NOTE: *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. Do not use alcohol, cleaners, solvents, or abrasive products to clean your Pump. 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.

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 complications with your 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.

WARNINGS: *For your safety, you should remove your Pump in certain scenarios such as during contact sports, medical procedures, X-ray exposure, or any activity which can damage your Pump. While the System is protected against minor splashing, it should not be overexposed to excessive liquid, such as while swimming, bathing, or showering. The MODD1 System cannot be used inside or in proximity to an MRI machine or X-ray scanner.*

Do not use the System in oxygen-rich environments, environments rich in flammable anesthetics, or other volatile agents.

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 Professional.

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

Condition	Appropriate Range
Operating Temperature Range	60.8° - 98.6°F (16-37°C)
Operating Humidity	15-90% non-condensing
Operating Altitude with Sea-Level to 10,000	1060 - 700 hPa (up to 10,000 feet when not in a pressurized cabin)

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: *Always keep your Pump attached to an insulin Cartridge to prevent internal damage.*
Store your Pump in a dry, clean location that is out of reach of small children and pets.
Storage of your Pump must be within the temperature and humidity ranges shown below.

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

If you lose your Pump, contact Modular Medical Customer Care at 866-710-1200 to discuss a replacement.

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

CAUTION: *Do not remove the Insulin Cartridge from the sealed package until you are ready to attach it to your Pump.*
Insulin Cartridges are supplied to you sterilized and should only be opened immediately before use.
You must store your Insulin Cartridges according to the information found on their labeling.
Insulin Cartridges must be kept in a dry location, avoiding direct sunlight.

WARNING: *Always follow the storage instructions on each components 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 complications with your therapy. If a part is damaged, please contact Customer Care.*

7.3 Possible Risks

The possible risks of insulin therapy include:

- **A possibility of experiencing hyperglycemia or Diabetic Ketoacidosis if insufficient insulin is delivered.**
- **The possibility of hypoglycemia or low blood sugar resulting from delivering too much insulin.**

There is a possibility of experiencing the following side effects while using the MODD1 System:

- In rare cases, there is the possibility of minor skin irritation around the area of the Adhesive Pad or the Infusion Set
- There is a possibility of developing lipodystrophy, a hardened tissue area caused by not sufficiently rotating your infusion site.

You can prevent lipodystrophies by placing the MODD1 System in a different body region each time.

7.4 Non-serviceable Equipment Statement

No maintenance is required for the MODD1 System . Every Cartridge contains a battery that is designed to last for up to three days of use.

CAUTION: *Do not attempt to replace your Insulin Cartridge battery. Doing so could lead to complications with your therapy.*

7.5 Troubleshooting

If you drop your Pump or if it receives impact of any kind, visually inspect to ensure it is not damaged. Perform a Status Check with a quick press of the Control Button. This will let you know the tones and lights are working correctly. See Section 3.1 for more information on status check.

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 MMI App freezes while in use, close out the App and reopen it.

If the Status Check does not provide Audio and Visual feedback, the hardware may be damaged and the pump should be replaced immediately.

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.

If you think someone has modified or tampered with your MODD1 System, replace the Pump, Insulin Cartridge, and Infusion Set.

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.

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 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.

If traveling internationally, contact Modular Medical Care Customer Care before your trip to obtain a travel loaner Pump in case your Pump malfunctions outside Modular Medical's replacement area.

7.7 MRI Safety Information

The MODD1 System is MRI Unsafe.

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

7.8 Customer Care

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

If you have a medical emergency using your MODD1 System, consult your Healthcare Professional.

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 up to six (6) months from the date of purchase and 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, 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 multiple times.*
- *The components have been altered or modified.*
- *The components are damaged from an event or accident, unrelated to defective materials or workmanship.*
- *The components are damaged by force majeure.*
- *The components are damaged from misuse, abuse, negligence.*

7.10 Returns and Exchanges Policy

At Modular Medical, we strive to ensure your satisfaction with our products. We accept most new, unopened items for refund or exchange within 60 days of the original shipment date.

Initiating a Return: To initiate a return, reach out to our Customer Care Team via email at CustomerCare@Modular-Medical.com to obtain a Return Merchandise Authorization (RMA) number. Ensure that the item is in its original packaging, undamaged, and was purchased within the last 60 days for the return to be accepted. Returns made without a RMA number will be returned to the customer, freight collect. This policy is subject to applicable law.

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

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

Defective or Faulty Products:
If you believe the products are defective or faulty, please contact us via our Customer Support line: 1-866-710-1200. Modular Medical reserves the right to modify this Return Policy. Any changes will be communicated by posting an updated version on our website.

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

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.Modular-Medical.com

8.0 Technical Information

This section provides technical specifications, including performance characteristics, options, settings and Electromagnetic Compatibility information and also has warranty and product return information.

8.1 System Specifications

The specifications meet the international standards set in IEC 60601-1.

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 App sends commands to the Pump to request this information and to set the Basal 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: 60.8°F to 98.6°F (16°C to 37 °C) Humidity: 15% to 90% RH non-condensing
Operating Atmospheric Pressure	-1,300 feet 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: 15% 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)

SPECIFICATION TYPE	SPECIFICATION DETAILS
Alarm Type	Visual and audible
Basal Delivery Rate	0.5 – 4 Units/hr
Basal Delivery Accuracy	+/- 3% (at all Basal delivery rates)
Bolus Delivery Size	2 – 20 Units with 2 unit increment
Bolus Delivery Rate	0.83 Units/min
Bolus Delivery Accuracy	+/- 3% (at all Bolus volumes)
Maximum Infusion Pressure Generated and Occlusion Alarm Threshold	14.8 PSI
Bolus Volume at Release of Occlusion	0.7 units
Residual Insulin Remaining in the Insulin Cartridge (unusable)	Less than 11 units
Maximum Audible Alarm Volume	42 dBA at 1 meter

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, 43 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 14 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 Cartridge 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=16 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]	0.60 U [0.54, 0.69]	3.06 U [2.83, 3.39]	6.00 U [5.56, 6.58]

Intermediate Basal Rate Delivery Performance (2 U/hr, n=16 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]	2.09 U [1.96, 2.24]	11.87 U [11.10, 12.98]	23.54 U [21.90, 25.86]

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]	4.11 U [3.98, 4.40]	24.09 U [22.56, 25.51]	47.74 U [44.26, 50.89]

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 [0.58, 0.69]	3.20 U [2.93, 3.40]	6.23 U [5.72, 6.65]

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 [1.97, 2.34]	12.28 U [11.16, 13.23]	24.17 U [22.04, 26.34]

Maximum Basal Rate Delivery Performance (4 U/hr, n=14 aged Pumps)

Basal Duration (Units Delivered at 4 U/hr)	1 hour (4.0 U)	6 hour (24.0 U)	12 hour (48 .0U)
Amount Delivered (Median) [min, max]	4.18 U [3.81, 4.73]	24.46 U [21.90, 26.99]	48.72 U [43.19, 53.52]

Bolus Delivery

To assess bolus delivery accuracy, 31 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 13 pumps were new and a minimum of 14 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=390 boluses, n=13 new Pumps							
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/390 (0.0 %)	0/390 (0.0 %)	81/390 (20.8 %)	272/390 (69.7 %)	37/390 (9.5 %)	0/390 (0.0 %)	0/390 (0.0 %)	0/390 (0.0 %)

	Units of Insulin Delivered After a 10U Bolus Request, n=422 boluses, n=15 new Pumps							
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/422 (0.0 %)	0/422 (0.0 %)	44/422 (10.4 %)	278/422 (65.9 %)	100/422 (23.7 %)	0/422 (0.0 %)	0/422 (0.0 %)	0/422 (0.0 %)

	Units of Insulin Delivered After a 20U Bolus Request, n=195 boluses, n=14 new Pumps							
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/195 (0.0 %)	0/195 (0.0 %)	14/195 (7.2 %)	138/195 (70.8 %)	43/195 (22.1 %)	0/195 (0.0 %)	0/195 (0.0 %)	0/195 (0.0 %)

	Units of Insulin Delivered After a 2U Bolus Request, n=420 boluses, n=14 aged Pumps							
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/420 (0.0 %)	1/420 (0.2 %)	68/420 (16.2 %)	289/420 (68.8 %)	62/420 (14.8 %)	0/420 (0.0 %)	0/420 (0.0 %)	0/420 (0.0 %)

	Units of Insulin Delivered After a 10U Bolus Request, n=431 boluses, n=15 aged Pumps							
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/431 (0.0 %)	0/431 (0.0 %)	73/431 (16.9 %)	288/431 (66.8 %)	70/431 (16.2 %)	0/431 (0.0 %)	0/431 (0.0 %)	0/431 (0.0 %)

	Units of Insulin Delivered After a 20U Bolus Request, n=197 boluses, n=14 aged Pumps							
	<25%	25-75%	75-95%	95-105%	105-125%	125-175%	175-250%	>250%
Number and Percent of Boluses within Range	0/197 (0.0 %)	0/197 (0.0 %)	25/197 (12.7 %)	132/197 (67.0 %)	40/197 (20.3 %)	0/197 (0.0 %)	0/197 (0.0 %)	0/197 (0.0 %)

8.3 Time to Occlusion Alarm

Operating Rate	Typical	Maximum
Bolus (2 Units or greater)	1 Minute 51 Seconds	2 Minutes 19 Seconds
Basal (2 Units/hr)	30 Minutes 29 Seconds	31 Minutes 31 Seconds
Basal (0.5 Units/hr)	2 Hours 0 Minutes	2 Hours 0 Minutes

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, the MODD1 System is a portable, body-worn device. For IEC 60601-1 testing, Essential Performance for the MODD1 System is defined as follows:

- The MODD1 Systrem 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 3.1) with a quick press of the Control Button. Ensure to take regular blood glucose readings. If, for any reason, your System stops delivering insulin and you do not have your Emergency Kit with you, contact your Healthcare Professional or emergency assistance immediately.

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.

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	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	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 MODD1 by no less than distances calculated below: 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.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 2 below.	

Test	Compliance Level	Electromagnetic Environment Guidance
Electromagnetic Immunity		
Rated power frequency magnetic fields IEC 61000-4-8	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	8A/m, 30kHz 65A/m, 134.2kHz 7.5A/m, 13.56 MHz	NA
*E1= 3V/m, 80 MHz to 2.7GHz		

Table 2: For transmitters specified in the table below, the recommended separation distance is 30 cm (12 inches).

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

WARNINGS:

Portable RF communicationss 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 lead to degradation of the MODD1 System and complications with your therapy.

Use of this equipment adjacent to other equipment should be avoided because this can result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The Pump may not operate correctly above 10V/m. 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., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT), Cellular 5G, and unique medical emitters, such as electrocautery, MRI, electrosurgical units, and diathermy devices, and TV broadcast 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 measure may be necessary, such as reorienting or relocating the MODD1 System.

8.5 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:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Compliance with these guidelines provides reasonable protection from harmful interference. The MODD1 System is intended for use in electromagnetic environments where radiated RF emissions are controlled. A minimum separation distance of 30 cm 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 MODD1 System and the MMI App. For a description of potential external influences see section 8.6 of this guide.

If communications between Pump and App are interrupted, move to a different area so the wireless link may be re-established. Interruptions to the wireless communications will not affect the Pump protective systems. Alarms will continue to sound as necessary. Modifications or changes that are not approved by Modular Medical may 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.*

This device 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.

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.

8.6 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
GTI N 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 Ehylene 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
	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 stopes 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 and Infusion Set.
Descending Tones - A sequence of tones that are getting lower in pitch indicating you are in Basal Suspend Mode.
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.
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.
Infusion Site - Location where insulin will be delivered to your body via the cannula of the Infusion Set.

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 Alert and Alarm notifications.
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 Apple iPhone 12 Pro Max.
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 Pump must be replaced.
Temporary Removal - Removal of the MODD1 System for a short time during activities such as bathing, contact sports, or swimming.
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 Medicall MODD1 Insulin Infusion 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, consult your Healthcare Professional.

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

toll-free at 866-710-1200.

Visit www.Modular-Medical.com

Modular Medical Inc.
10740 Thornmint Road
San Diego, CA 92127
United States
866-710-1200
www.modular-medical.com