

# DreaMed Diary for MODI



## DreaMed Diary App for MODI User Guide

Exclusively for clinical investigation

# DreaMed Diary for MODI

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In the US: For in-vitro diagnostic use only



**NOTE:** This user manual is subject to periodic review, update and revision.

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MODI algorithm SW ver.: 03.01.XX



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**R<sub>x</sub>** Only



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# DreaMed Diary for MODI

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# DreaMed Diary for MODI

Table 1 – Symbols and Concepts Used in This Manual


	Manufacturer
	Manufacturing Date
	Caution: Federal law restricts this device to sale by or on the order of a physician.
 <b>WARNING</b>	<b>WARNING</b> – A warning is a statement that alerts you to the possibility of injury, death or other serious adverse reactions associated with the use or misuse of DreaMed Diary.
 <b>CAUTION</b>	<b>CAUTION</b> – A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage. The caution includes the precaution that should be taken to avoid the hazard.
 <b>IMPORTANT</b>	<b>IMPORTANT</b> – An important notice provides information or instructions essential for the correct use of DreaMed Diary. Ignoring this information may result in reduced performance, incorrect operation, or unintended outcomes.
	<b>NOTE</b> – A note provides helpful information.


## 1. Preface

The DreaMed Diary for MODI is a mobile app intended for the management of diabetes for people with type 1 and type 2 diabetes mellitus.

MODI is designed to provide comprehensive analysis of individual diabetes data based on CGM readings, i.e. glucose data, reported insulin injection data and meals information.

The User Guide provides instructions for using the DreaMed Diary app for MODI.

  
**IMPORTANT** Using MODI requires prior knowledge of diabetes management. Before starting, consult with your physician about using MODI together with the DreaMed Diary app to help manage your diabetes.

  
**IMPORTANT** Please read the entire User Guide before using the app and always follow the instructions for use. Not following these instructions may result in harm and/or lead to harmful treatment decisions.

- Using MODI and the DreaMed Diary app requires a smartphone. Make sure you are comfortable with this technology before use.
- MODI Dose Guidance and the Diary app are not monitored by your healthcare provider. Users are solely responsible for reviewing their recommendations and should consult their healthcare provider if they have concerns.

## 2. Important Safety Information

### 2.1. Indications for Use

MODI insulin dose calculator is software intended for the management of type 1 and type 2 diabetes in persons aged 18 years and older requiring long-acting insulin with or without rapid-acting insulin injections. MODI insulin dose calculator calculates a dose of basal (long-acting) insulin with or without a dose of bolus (rapid-acting for meal and correction) insulin based on glucose measurements from an iCGM (Integrated Continuous Glucose Monitor) and insulin delivery data (i.e. time of dose with or without amount of dose). MODI insulin dose calculator intended for single patient, home use and requires a prescription by a healthcare provider.

*Special conditions for Use Statement:*

- MODI is Rx - For Prescription Use Only
- MODI algorithm is not intended for use with patients treated with insulin pump, Automated Insulin Dosing (AID), intravenous (IV) insulin injections, or a combination of insulin injections and/or IV insulin and insulin pump therapy.
- MODI insulin dose calculator is not recommended for use during pregnancy. MODI has not been tested with individuals who are pregnant.

### 2.2. Contraindications for MODI Algorithm

- DreaMed Diary and MODI algorithm is not intended for use by patients who use insulin(s) other than the types indicated [below](#). Using MODI with other types of insulin may lead to potential harm.
- MODI algorithm is not intended for use with patients treated with insulin pump, Automated Insulin Dosing (AID), intravenous (IV) insulin injections, or a combination of insulin injections and/or IV insulin and insulin pump therapy.

### 2.3. Potential Harms and Residual Risks

The following are the risks associated with the use of MODI:

- Incorrect dosing of insulin (under/overdose) required for maintaining desirable blood glucose levels.
- Risks associated with severe hypoglycemia and hyperglycemia, resulted from fault in MODI algorithm, quality of the input data, and cybersecurity issues.

There are potential risks associated if the shared information is inaccurate or misleading. Potential risks may include:

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- Hyperglycemia
- Ketosis
- Diabetic Ketoacidosis (DKA)
- Mild hypoglycemia
- Severe hypoglycemia
- Obstetrics complications
- Data confidentiality
- Data availability
- Data integrity

Based on the residual risk evaluation, all risks were reduced as far as possible, to an acceptable level. The harms of these risks are similar to the common risks for diabetes patients during everyday life, using insulin.

This user guide provides information regarding the safety features incorporated into the app to help avoid the risks listed above. Be sure to follow the instructions in this manual to further reduce these risks.

## 2.4. General Information for Safe Use

This chapter outlines important safety behaviors and limitations of the DreaMed Diary App for MODI. Please read the entire user manual before using the app and always follow the instructions for use. Not following these instructions may result in harm and/or lead to harmful treatment decisions.

### Warnings and Cautions for Using MODI



#### **Pregnancy**

MODI is not designed for use during pregnancy. If you are or become pregnant, consult your healthcare provider immediately and stop using MODI Dose Guidance.



#### **Keep your information up to date**

To ensure the MODI provides accurate recommendations, always keep your personal settings current:

- Update your insulin plan whenever it changes - whether you adjust it yourself or your healthcare provider updates it.
- If your weight changes by more than 5%, update it in the app as soon as possible.



**WARNING**

### **Accurate data entry**

Ensure that all data entered into the app, including weight, insulin doses, and glucose readings, is correct and up to date. Inaccurate or outdated information may lead to inappropriate insulin recommendations which may result in harm.



**WARNING**

Log all bolus insulin doses taken 3 hours prior to using the Rapid-Insulin Dose Calculator. Missing recent doses may lead to incorrect dose recommendations.



**CAUTION**

### **Internet connection**

MODI requires a stable internet connection for proper operation. Ensure your device is connected to the internet for several hours each day to enable data syncing and receive important updates.



**CAUTION**

If at any point you are disconnected from your sensor or change your LibreView account details, contact your care team to connect it to your account.



**CAUTION**

In order to prevent potential insulin overdose, make sure that all of your bolus injections from the last three hours are logged correctly in the app. Incorrect or outdated insulin dose logging may lead to potential harm.



**IMPORTANT**

### **Traveling Across Time Zones**

MODI analyses your glucose and insulin data to optimize your insulin plan. When your local time shifts by more than 3 hours (due to travel or daylight saving changes), MODI will delay generating the next plan for a few days to let your body adjust. Frequent travel across time zones with an hour or more difference may limit MODI's ability to adjust your plan effectively. If this applies to you, consider whether using MODI fits your current lifestyle.



**IMPORTANT**

### **Compatible glucose sensors**

MODI uses the sensor (CGM) data to adjust your insulin treatment plan. Use your sensor according to the manufacturer's instructions for use.



**IMPORTANT**

### **MODI does not replace user's judgment**

The app is intended to be used as a support tool and does not replace the user's judgment in managing diabetes. Users should consult their healthcare professional in case of uncertainty about their treatment plan or if they experience unexpected changes in glucose control.



**IMPORTANT**

### **Plan updates require user approval**

MODI may recommend changes to your insulin plan, but these are never applied automatically. Always review and approve any new plan before using it.



## IMPORTANT

MODI analyses your recent data to create insulin plan recommendations for future use. If your recent weeks were not typical - such as during illness, temporary lifestyle changes, or if you plan to change your diet or exercise routine - review the new plan carefully. If you are unsure, consult your healthcare provider before applying the changes.

## General User Information and Precautions

- **MODI does not replace clinical judgement**  
MODI is designed to support your insulin treatment, but it does not replace clinical judgment or your responsibilities in managing your therapy. You are solely responsible for reviewing your recommendations and should consult your healthcare provider if you have any concerns.
- **Log all your insulin doses before injecting**  
The Rapid-Insulin Dose Calculator provides recommendations based on the information available. You are responsible for verifying and approving each dose before injection. While you are using the Rapid-Insulin Dose Calculator, make sure you have correctly logged in all bolus events in the last three hours so that active insulin is correctly calculated.
- **MODI is not monitored by your healthcare provider**  
MODI Dose Guidance and the Diary app are not monitored by your healthcare provider. Users are solely responsible for reviewing their recommendations and should consult their healthcare professional if they have concerns.
- **Date and Time settings**  
Configure your smartphone to take their date and time settings directly from the network in order to capture your events correctly.
- **Medical supervision is still required**  
MODI does not replace your healthcare provider. Please continue routine health checks and consult your provider as needed.
- **MODI is not a real-time monitoring system**  
MODI does not monitor your glucose levels in real-time and should not be used as an emergency channel. MODI retrospectively analyses your data once daily or even every few days.
- **MODI is not monitored by your healthcare provider**  
Your healthcare provider does not actively monitor your data in MODI. In case of emergency contact your healthcare provider or call 911.

## 2.5. Authorized Devices

Table 2 details the devices that are currently authorized to be used with DreaMed Diary for MODI.

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Table 2 – Authorized Devices for Use

<b>Blood Glucose Meter</b>	All meters with regulatory approval (dependent on location: EU/US/Rest of the World [ROW])	
<b>CGM</b>	Abbott	Libre 2 Plus Libre 3 Plus



**Important**

Authorized devices should be used according to manufacturer’s instructions for use.

## 2.6. Authorized Insulins

Table 3 – Approved Insulins for use

<b>Rapid Acting Analogs</b>	Admelog, Apidra, Aspart, Fiasp, Humalog U-100, Humalog U-200, Lispro U-100, Lyumjev U-100, Lyumjev U-200, Novolog, ReliOn Novolog, Novorapid
<b>Long Acting Insulin</b>	Basaglar, Degludec U-100, Degludec U-200, Glargine, Lantus, Levemir, Rezvoglar, Semglee, Soliqua, Toujeo U-300, Toujeo Max U-300, Tresiba U-100, Tresiba U-200, Xultophy, Tregludec U-100, Tregludec U-200



**Important**

Insulin should be used according to manufacturer’s instructions for use.

## 3. Introduction

### 3.1. About the DreaMed Diary App for MODI

The **DreaMed Diary App for MODI** is a mobile application designed to help people with diabetes manage their insulin treatment plan by combining standard diabetes diary functions with automated insulin dose guidance.

## DreaMed Diary for MODI

In addition to recording insulin doses, glucose values, and other relevant diabetes data, the app uses **DreaMed MODI Dose Guidance** feature to analyze patterns in glucose levels and provide optimized insulin treatment plans. These treatment plans are based solely on the data entered by the user into the app and on connected compatible devices (such as CGM).

The app's dose guidance will periodically evaluate your glycemic control, typically on a weekly basis, to recommend adjustments to the insulin treatment plan. In addition, daily assessment will identify severe hypoglycemia events and may reduce insulin doses to ensure your insulin plan is safe and aligned with your insulin needs.

The DreaMed Diary App for MODI operates as an independent tool for insulin dose guidance.



**IMPORTANT**

The app is intended to be used as a support tool and does not replace the user's judgment in managing diabetes. Users should consult their healthcare professional in case of uncertainty about their treatment plan or if they experience unexpected changes in glucose control.



**WARNING**

Log all bolus insulin doses taken 3 hours prior to using the Rapid-Insulin Dose Calculator. Missing recent doses may lead to incorrect dose recommendations.

### 3.2. Description of Intended Clinical Benefit

The key aim of diabetes management is to prevent acute complications, such as severe hypoglycemia and Diabetic Ketoacidosis (DKA), enhance overall well-being and mitigate the risk of long-term chronic complications. These goals can be achieved by optimizing the patients' glycemic control.

Results from clinical studies have demonstrated the benefits of normal or near-normal blood glucose levels and the importance of using glucose monitoring devices to achieve this<sup>1</sup>. Experts recommend that most people with diabetes should try to keep blood glucose levels as close to normal as safely possible<sup>2</sup>.

### 3.3. Intended Audience



**IMPORTANT**

Using MODI requires prior knowledge of diabetes management and confidence in using the associated technology. Before starting, consult with your physician about using MODI together with the DreaMed Diary app to help manage your diabetes.

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<sup>1</sup> ADA Position Statement. Test of glycaemia in diabetes. Diabetes Care 2003;26(Suppl.1): S106-108

<sup>2</sup> Diabetes Control and Complications Trial Research Group (DCCT): The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. New Engl J Med, 1993;329:977-86.

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- The DreaMed Diary App for MODI is intended for **adults aged 18 years and older** with diabetes who manage their own insulin treatment. It is not intended for children, adolescents, or individuals unable to independently manage their insulin therapy. The app may also be used by adult caregivers for this population.
- The app is provided under prescription from a healthcare professional (HCP). However, after the initial prescription, the HCP is not involved in reviewing or managing the data in the app. The DreaMed Diary App for MODI operates independently.

### 3.4. Connecting to Glucose Sensors

MODI requires a Libre FreeStyle Continuous Glucose Monitor (CGM) sensor (see [Authorized devices](#)) in order to monitor your glucose and provide insulin dosing changes. You will be connected by your clinical team.



CAUTION

MODI requires a stable internet connection for proper operation. Ensure your device is connected to the internet for several hours each day to enable data syncing and receive important updates.



CAUTION

If at any point you are disconnected from your sensor or change your LibreView account details, contact your care team to connect it to your account.

### 3.5. iOS or Android

The DreaMed Diary app is suited for both iPhone and Android users. Use DreaMed Diary only on phones with supported operating system per your mobile device manufacturer.

- **For iOS Devices** – Requires iOS 17 or later. Compatible with iPhone.
- **For Android Devices** – Requires device from the following brands – Samsung, LG or Google, from Android 10.0 or later. The app is compatible with most models.

## 4. First Steps

The onboarding process begins once your healthcare provider (HCP) prescribes the DreaMed Diary app for MODI. After this initial step, your HCP will not be involved in your app usage or in reviewing your data.

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## 4.1. Receiving Your Invitation

You will receive an invitation by email after your healthcare provider prescribes the DreaMed Diary App for MODI. The invitation includes a link to set up your account.

## 4.2. Setting Up Your Account

1. Open the link included in the invitation email.
2. Follow the on-screen instructions to set your personal password.

## 4.3. Downloading the App

1. Download and install the DreaMed Diary App from the Google Play Store or the Apple App Store.
2. Open the app and log in using the email address that received the invitation and the password you created.

## 4.4. Onboarding Process

The onboarding process starts automatically when you log in for the first time. Follow the on-screen prompts to complete the setup.

Once completed, the **MODI Dose Guidance** feature will become active - no additional steps are required.

### 4.4.1. Pregnancy Confirmation

- The first screen asks you to confirm that you are **not pregnant**.



#### Pregnancy

- MODI is not designed for use during pregnancy. If you are or become pregnant, consult your healthcare provider immediately and stop using MODI Dose Guidance.

### 4.4.2. Weight Entry

- Enter your current weight when prompted.
- MODI accepted weight range is 22-227 kg and 50-500lbs.
- Ensure the value is accurate, as it is used to calculate insulin dose recommendations.



Keep your weight information up to date. Update it in the app if it changes by more than 5% or whenever the app asks you to confirm it. Your weight helps Dose Guidance understand your insulin needs. Please make sure your weight is correct

## 4.4.3. Setting up Your Insulin Plan

### 1. Long-acting insulin plan (Basal plan)

- I. Select your **long-acting (basal) insulin type** from the list.
- II. Enter your daily long-acting insulin dose and the time of insulin.
- III. If you are unsure of your dose:
  - a) Consult with your healthcare professional, or
  - b) Tap "I don't know my dose" to allow DreaMed Diary to calculate an initial plan for you.



#### IMPORTANT

MODI may calculate the initial long-acting insulin dose only for users who do not use rapid-acting (bolus) insulin.

The initial dose will be set to the minimum between 10 units or 0.1 unit/Kg

### 2. Mealtime insulin (Rapid-acting / Bolus)

- I. Indicate whether you also use a mealtime (bolus) insulin.
  - This insulin is different from your long-acting insulin and is usually taken with meals.
  - MODI refers to it as **rapid-acting insulin** or **bolus insulin**.
- II. If you do not use mealtime insulin, you may proceed to review your plan.
- III. If you do use it, continue to set up your bolus plan:
  - Select your rapid-acting insulin type from the list.
  - Choose the dosing plan you use:
    - **Fixed meal** – For users who take specific insulin doses for **breakfast, lunch, and dinner**.
    - **Meal size** – For users who select a dose based on meal size (e.g., small, normal, large), which may be influenced by the meal's carbohydrate content.
  - Enter the insulin amounts according to your selected plan. If you are unsure of your dose, consult with your healthcare professional



## IMPORTANT

MODI sets and manages your insulin correction plan. The plan updates automatically by MODI and you cannot edit it.

You may view your correction plan as a sliding scale table when tapping edit from your insulin plan screen.

MODI calculates your initial correction plan, based on the following:

Correction target: 110 mg/dL

Estimated Total Daily Dose =  $0.5 * \text{weight in Kg}$

Correction Factor =  $1800 / \text{Estimated Total Daily Dose}$

MODI then creates a sliding scale correction table based on this Correction Factor and correction target.

### 3. Finalizing Your Plan

- I. Review your insulin settings and weight carefully.
- II. Confirm the plan to complete setup.



## WARNING

If your insulin plan changes - whether by your own decision or based on instructions from your healthcare provider - you must update it manually in the Diary App.

### 4. Completion

- After onboarding is complete, you can immediately begin logging your insulin doses and using the Rapid-Insulin Dose Calculator for mealtime insulin.
- MODI periodically reviews your logged data in the background and may generate insulin plan suggestions based on usage patterns and glucose trends.

## 5. Overview of Daily Use

### 5.1. What You Need to Do Each Day

The app is designed to assist you in maintaining your insulin regimen consistently and accurately.

After completing onboarding, the DreaMed Diary App for MODI supports your day-to-day diabetes management by helping you calculate insulin doses and provide you with insulin plan updates to meet your needs.

To use MODI effectively:

1. **Log every basal (long-acting) insulin injection.**
2. **Use the Rapid-Insulin Dose Calculator** to calculate and log your mealtime (rapid-acting) insulin doses.
3. **Review and approve new plan suggestions** when offered by MODI. Only once you review and confirm the new plan, will the plan be saved in your app.



**IMPORTANT**

#### **Plan updates require user approval**

- MODI may recommend changes to your insulin plan, but these are never applied automatically. Always review and approve any new plan before using it.

4. **Keep your information up to date**



**WARNING**

To ensure the MODI provides accurate recommendations, always keep your personal settings current:

- Update your insulin plan whenever it changes - whether you adjust it yourself or your healthcare provider updates it.
- If your weight changes by more than 5%, update it in the app as soon as possible.

The following sections explain how to complete each of these steps.



**IMPORTANT**

Logging your basal injections and reporting boluses using the Rapid-Insulin Dose Calculator are essential for MODI to titrate your insulin plan. Be sure to log them daily.

### 5.2. Logging Basal (Long-Acting) Insulin

To log a basal dose:

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1. Open the Diary screen.
2. Tap the Add Event button.
3. Select your long-acting insulin.
4. Enter the dose and confirm.



**NOTE:** Log all your basal insulin doses. Missing entries or wrong data entry may affect the accuracy of dose suggestions.

### 5.3. Calculating and Logging Rapid-Acting Insulin

**This section applies only to users who use rapid-acting (bolus) insulin.**

To use the Rapid-Insulin Dose Calculator:

1. On the **Diary** screen, tap the **Calculate Dose** button.
2. Enter your current glucose value as shown on your Sensor or glucometer.
3. Based on your plan type, the screen will display one of the following options:
  - **Fixed Meal plan:** You will be asked whether you are about to eat your regular meal (Yes/No).
  - **Meal Size plan:** You will be asked to select the portion size of carbohydrates you are about to eat: No Meal, Small, Normal, or Large.
4. Tap **Calculate** and view your recommended dose.
  - Edit the dose if you decide to deliver a different amount.
5. Tap **Save** to log the dose.



**WARNING**

Log all bolus insulin doses taken **3 hours prior** to using the Rapid-Insulin Dose Calculator. Missing recent doses may lead to incorrect recommendations.



**IMPORTANT**

If your insulin plan changes, update it in the app before using the Rapid-Insulin Dose Calculator.



**NOTE:** Remember to use the Rapid-Insulin Dose Calculator and log your meal doses. MODI needs this information to titrate you.

## 5.4. Reviewing and Approving Plan Updates

When a plan update is available you will be asked if you want to view your new plan, or choose **Later**.

1. Tap **“Yes”** to view the suggested changes.
2. Review the new plan and Tap **“Ok”** to apply it.
3. If you tap **Later**, a banner will appear at the top of the screen to remind you that a new insulin plan is waiting for your review. Tap the banner to view and apply the new plan.



**IMPORTANT**

MODI analyses your recent data to create insulin plan recommendations for future use. If your recent weeks were not typical - such as during illness, temporary lifestyle changes, or if you plan to change your diet or exercise routine - review the new plan carefully. If you are unsure, consult your healthcare provider before applying the changes.



**IMPORTANT**

MODI analyzes your glucose data and behavioral patterns and may suggest plan updates from time to time. These updates will never be applied automatically. You will always be asked to review and accept any recommended changes before your insulin plan is updated.



**NOTE:** Look for messages at the top of your new insulin plan. It may include important alerts and behavioral tips that will help you improve your glycemic control or even refer you to your healthcare provider.

# 6. Screens Overview

## 6.1. Navigation Bar

You can move between the main screens of the Diary App for MODI using the navigation bar at the bottom of the screen.

The navigation bar includes the following buttons:

- **Diary** – Opens the main Diary screen, where you can view and log your insulin doses, meals, and glucose readings. The Rapid-Insulin Dose Calculator is also accessed from this screen.
- **Insulin Plan** – Opens your current insulin plan, including both basal (long-acting insulin) and bolus (rapid-acting insulin) settings.
- **Settings** – Opens the settings screen, where you can update personal information, configure app preferences, and access help information.

Tap any of these buttons to switch between screens.

## 6.2. Diary Screen

The Diary screen is your home screen. It displays your insulin and meal logs in a timeline format, and it is also where MODI communicates important updates.

### Main Features:

- **Daily Log View**  
Entries are organized by day and time, showing logged insulin doses, meal details, and glucose readings.
- **Add Event Button**  
Tap this button to manually log basal insulin. You may add bolus events to log missed injections.
- **Rapid-Insulin Dose Calculator**  
For users with rapid-acting insulin plans, the Calculate Dose button opens the Rapid-Insulin Dose Calculator interface, helping you calculating your next bolus dose. See more [here](#).

## 6.3. Insulin Plan Screen

The **Insulin Plan** screen displays the insulin settings currently recommended for your treatment. These include your long-acting (basal) insulin plan and, if applicable, your rapid-acting (bolus) insulin plan.

- The **basal plan** is your long-acting insulin dose. View and inject this dose as scheduled.

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- The **bolus plan** includes the meal and correction components and is used by the **Rapid-Insulin Dose Calculator** to recommend your mealtime (rapid-acting) insulin doses.

## Main Features:

- **Basal Plan**  
Shows your selected basal insulin type, time of injection and daily dose.
- **Bolus Plan** (*for users using rapid-acting insulin*)  
Displays your selected bolus insulin type and meal plan. MODI supports two types of bolus treatment plans:
  - **Fixed Meal Plan** – insulin doses are assigned for each main meal.
  - **Meal Size Plan** – insulin doses are assigned for different portion sizes (small, normal, or large) for each meal of the day.

The meal plans divide the day into four time periods: Morning, Afternoon, Evening, and Night. The Evening and Night periods share the same settings. Each time period includes the available meal insulin doses. The night plan will always match the evening plan.

- **Edit Plan**

Tap the **Edit Plan** button to update your basal and bolus settings.

In the basal plan you may edit your insulin type, injection time and dose. For users with a bolus plan, this section includes both:

- The meal component, which can be edited
- The correction component, based on a sliding scale of glucose values

The correction plan is used by the Rapid-Insulin Dose Calculator to adjust your insulin dose when needed. It is view-only and cannot be edited.



### CAUTION

The Rapid-Insulin Dose Calculator uses both your meal plan and your defaulted correction plan to calculate recommended doses. Always ensure your editable insulin settings are up to date.



**NOTE:** When MODI suggests a new plan based on your recent data, it will appear in the Diary screen for your review and approval. Once approved, the new plan will be reflected here.

## 6.4. Settings Screen

The **Settings** screen allows you to manage your personal profile, Dose Guidance settings, Rapid-Insulin Dose Calculator preferences, and access support materials and app information. It is organized into the following sections:

### Profile

- View the name of the app user
- View and update your current weight.  
You may be prompted from time to time to confirm or update your weight.
- Log Out – Tap this option to securely sign out of your DreaMed Diary app account.



#### WARNING

Keep your weight information up to date. Update it in the app if it changes by more than 5% or whenever the app asks you to confirm it. Your weight helps Dose Guidance understand your insulin needs. Please make sure your weight is correct.

### Dose Guidance Settings

After logging in, you will go through the onboarding process, providing your weight and insulin plan. Once all your information is set, Dose Guidance will start to review your data and provide you with new insulin plans.

### General Settings

These settings are used when generating bolus dose recommendations.

- **Active Insulin Time:** Defines how long the Rapid-Insulin Dose Calculator considers previous boluses when calculating a new dose. Default 3 hours.
- **Maximum Dose Limit:** Sets an upper limit for rapid-acting insulin dose recommendations.

### About

Displays the app version and regulatory information.

### Help

Provides access to the user guide.


## 7. Notifications, Reminders and Messages

This chapter describes how the Diary app for MODI uses notifications to help you stay on track with your insulin treatment and app use. Notifications are designed to assist you in maintaining consistent logging, reviewing important updates, and confirming required information like new insulin plans.

### 7.1. Types of Notifications

The Diary app may send the following types of notifications:

- **Reminders to log insulin doses**  
You may receive a reminder to log your insulin injections if no entries have been detected for two consecutive days.
- **Plan Update notification**  
If MODI detects a need to update your insulin plan based on your recent data, you will receive a notification prompting you to review and approve the new plan.  
Open the app, review the suggested plan, and tap **OK** to activate it.
- **Reminders to wear your CGM**  
MODI may periodically check whether CGM readings are being received. If no CGM data is detected, you will receive a reminder to wear your sensor or contact your clinic team.

 **Tip:** For the best use experience, keep notifications enabled so you don't miss reminders or important plan updates.

## 8. MODI Dose Guidance

### 8.1. How MODI Auto-Titration Works

From time to time, MODI reviews your data collected since the last update to your insulin plan (manually or after MODI recommendation), using up to 21 days of glucose and insulin information if needed. If enough valid data is available, MODI will analyze your information to decide whether your basal and bolus insulin amounts should stay the same or be titrated (increased or decreased) over time.

To prepare a titration plan, MODI needs enough recent information to ensure accuracy. A titration cycle requires at least three valid days of data in the previous week. A valid day means:

- Your continuous glucose monitor (CGM) recorded at least 16 hours of CGM data per day.
- Your logged basal injection covering this day.

In addition, if you use rapid-acting insulin, MODI also requires that you use your Rapid-Insulin Dose Calculator at least three times during the last 7 days.

MODI will aim to get you to a glucose goal range of 100-130 mg/dL. This value is not configurable.

A new insulin plan may be generated every 7 days but may be delayed if recent automated or manual adjustments have been made to your plan, or if there is insufficient data available, or you travel across time zones with time difference of more than 3 hours, or when no changes were needed. This updated insulin treatment plan is designed to keep your glucose levels closer to your personal goals.

In case MODI identifies that a faster titration is required, such as a quick response to adverse hypoglycemia events in the last 3 days, a new insulin plan may be created daily.

MODI is reviewing your glucose and insulin data to look for patterns, times when your glucose tends to run high, drop too low, or stay within your target range. Using this information, and in accordance with additional data collected by the system, MODI can provide a new insulin plan from time to time.

When MODI would like to recommend changes to your therapy, it will appear in your app for you to review and activate. Changes to therapy may include:

- Changes to the insulin dosage.
- Tips or advice on how to avoid low or high glucose levels in the future.

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IMPORTANT

MODI will never change your insulin automatically. You will always be asked to review and accept any recommended changes before your insulin plan is updated.



IMPORTANT

MODI relies on accurate glucose information from your continuous glucose monitor (CGM).

Please make sure you use only approved CGM devices and follow the manufacturer's instructions for use. The accuracy of your sensor has been tested when used correctly. If the CGM is not used as directed, it may provide inaccurate readings, and MODI may then analyze data that does not fully reflect your actual glucose levels.



**NOTE:** CGM Data is pulled automatically into MODI. All data is analyzed as-is. You cannot edit, change, replace or flag out the data.

## 8.2. Inside the Algorithm: How MODI Makes Decisions

MODI uses input data to detect patterns and events for analysis. The detection process is based on the following methodologies:

1. **Filter data:** The algorithm filters out readings that could be misleading - for example, when injections were missed or when unusual behavior temporarily affected your glucose levels.
2. **Assess each day and detect patterns:** MODI compares your daily glucose results to your personal glucose target range to understand whether your insulin seems too high, too low, or appropriate. Here MODI will look for trends in your data - such as fasting and bedtime glucose levels, mealtime highs, and any low readings.



IMPORTANT

Before using MODI, read this information carefully and ensure you fully understand it, and consult your healthcare provider if you have any questions or concerns regarding using MODI.

### What MODI's recommendation may include:

1. **Changes to the Basal Plan (Long-acting Insulin)**
  - MODI uses the logged basal injection events to refine the plan based on your most recent insulin usage.
  - MODI evaluates the relationship between your bedtime and fasting glucose levels to decide whether an adjustment to your basal insulin may be needed.

### 2. Changes to the Bolus Plan (Mealtime/rapid-acting Insulin)

- MODI reviews each reported bolus dose and checks that it was taken appropriately (for example, not during a low-glucose event).
- It considers the reported insulin amount and any dose adjustments or overrides you made.
- MODI then groups all bolus doses by time of day (morning, afternoon, evening) to see whether changes are needed in the meal or correction bolus portions of your plan.

### 3. Personalized Tips and Alerts

- MODI may also share insights, tips or alerts related to your insulin delivery patterns or daily behavior to help you maintain steady glucose levels.
- All alerts and behavioral tips issued by MODI are accessible in Appendix A. This appendix contains the full list of possible alerts, along with explanations to help you understand their context and recommended actions.

## 8.3. Safety Feature and Guardrails



### IMPORTANT

The information below outlines important information regarding MODI's safety features and guardrails.

Before using MODI, read this information carefully and ensure you fully understand it, and consult your healthcare provider if you have any questions or concerns regarding using MODI.

MODI is designed with built-in safety limits, often called guardrails, to keep every insulin plan adjustment within a safe range. These limits make sure that any insulin changes stay gradual, personalized, and medically appropriate for you.

These are MODI's guardrails:

- Basal insulin:
  - Each adjustment is limited to a maximum of  $\pm 20\%$  change from your current daily basal amount. To keep basal changes extra safe, MODI also narrows the maximum allowed increase depending on your current total daily basal dose. Note that the changes might exceed this maximal percentages, as MODI rounds all doses to the nearest unit supported by your insulin pen.
  - MODI will not change your insulin type or the number of basal injections per day.

- Bolus insulin

Changes to the bolus plan are limited and depend on your glucose results after meals.

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- MODI may adjust meal or correction bolus amounts by up to  $\pm 30\%$  of your current plan value, rounded to the nearest whole number that can be injected with your pen.
- The bolus plan can include 3-4 daily periods (morning, afternoon, evening, and optional night).
- MODI does not change your insulin type or the number of injections.

All bolus injections plans are checked together with your basal plan to make sure the overall treatment remains within the safe zone:

### - Total Daily Dose

To protect you from excessive insulin dosing, MODI limits the total insulin amount that can appear in any titration plan.

- For people using basal insulin only: the total basal dose will not exceed 0.8 units per kilogram of body weight per day.
- For people using multiple daily injections (MDI): the total daily insulin dose (basal + bolus) will not exceed 2 units per kilogram per day, or below 0.1 units per kilogram per day.

Note: For all treatment types, regardless of your weight the total basal dose will not go below 4 units and will not exceed 160 units. Any meal dose will not exceed 120 units.

- When any of these limits are reached, MODI will not apply further titration changes and will notify you to contact your healthcare provider.



#### NOTES:

- Plan threshold values are not configurable.
- MODI rounds the recommended value for basal plan and sliding scale plans to the closest whole unit value.
- MODI system always uses the actual amount of insulin that was delivered (basal and bolus) for its analysis. In case there is no basal delivery data reported, the system will use the basal plan from the DreaMed Diary App. The recommended changes to the patient's plan are always calculated as a percentage of the most recent settings that were in the DreaMed Diary App.
- MODI will not recommend changes to the patient's insulin type.

## 9. Calculate Your Rapid-Insulin Doses

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### CAUTION

In order to prevent potential insulin overdose, make sure that all of your bolus injections from the last three hours are logged correctly in the app. Incorrect or outdated insulin dose logging may lead to potential harm.



### IMPORTANT

You are required to configure your smartphone to use date and time settings directly from the network, in order to capture your events correctly


- **Android:** In the **Settings** menu > **System** > **Date & Time** enable **Use network provided time and network provided time zone**.
- **iOS:** In the **Settings** menu > **General** > **Date & Time** > turn on **Set automatically**.

Tap the **Calculate Dose** button and follow the displayed instructions for calculating your bolus. Enter your glucose level and/or information about the meal you anticipate eating.

- **Fixed meal:** For users who take specific insulin doses for **breakfast, lunch, and dinner** – indicate if you are about to eat the relevant meal for the current time of the day, or calculate a correction bolus to lower your high glucose, without eating a meal.
- **Meal size:** For users who select a dose based on meal size (e.g., small, normal, large) – indicate the meal's carbohydrate content size you are about to eat, or select no meal to calculate a correction bolus to lower your high glucose, without eating a meal.

You can calculate the bolus using the bolus plan that matches the current time segment (i.e. morning, afternoon, etc.). For example, the screen below shows that the bolus will be calculated based on the Evening plan. Tap **Change** to calculate your dose using the plan of a different segment.

The Diary app does not permit you to change the hours of a plan. Therefore, for example, if you plan to eat your dinner at 4:55 pm instead of after 5:00 pm, you should change the segment to Evening plan.

Tap the help  button at the top right corner of the screen to view a quick Rapid-Insulin Dose Calculator guide.

Tap **Calculate** to generate the bolus recommendation.

A recommendation is generated for the bolus. Tap **Save** to confirm that you intend to inject the amount of insulin recommended by the Rapid-Insulin Dose Calculator and to save the event in your diary. If you need to modify the recommended amount, you can do so and then tap **Save** to confirm that you intend to inject that amount of insulin.

If your glucose is below 70mg/dl and you have not entered any meal information, a message indicating that you should eat fast-acting carbs in order to raise your blood glucose level and then recheck your blood glucose in 15 minutes is shown.

## 9.1. Rapid Insulin Dose Calculator Algorithm

### 1. How the Rapid-Insulin Dose Calculator Calculates the Bolus Dose

The Rapid-Insulin Dose Calculator adds together two main components:

- Meal Dose
  - This amount comes directly from your insulin plan and depends on your meal type or meal size.
  - The Rapid Insulin Dose Calculator uses the dose that matches the current meal period (for example, breakfast, lunch, or dinner) or the selected meal size (small, normal, or large).
- Correction Dose
  - If your glucose level is above your target, MODI calculates how much extra insulin is needed to bring your glucose back into range.
  - This correction is based on your correction plan (sliding scale): a table in your bolus plan that matches glucose levels with correction doses.
  - If your glucose level is within or below the target range, the correction dose is 0 units.

### 2. Active Insulin (AI) Adjustment

The Rapid Insulin Dose Calculator also checks how much active insulin (AI) remains from recent injections. Active insulin is the insulin still working in your body from earlier doses. To avoid stacking too much insulin, the Rapid Insulin Dose Calculator reduces the Correction Dose if active insulin is present. The adjusted correction amount depends on:

- The calculated Correction Dose, and
- The remaining active insulin level, which gradually decreases over time (based on an internal decay model<sup>3</sup>- see Figure 1 below).

If the active insulin is large enough to offset the Correction Dose need, the Correction Dose may be reduced to zero.

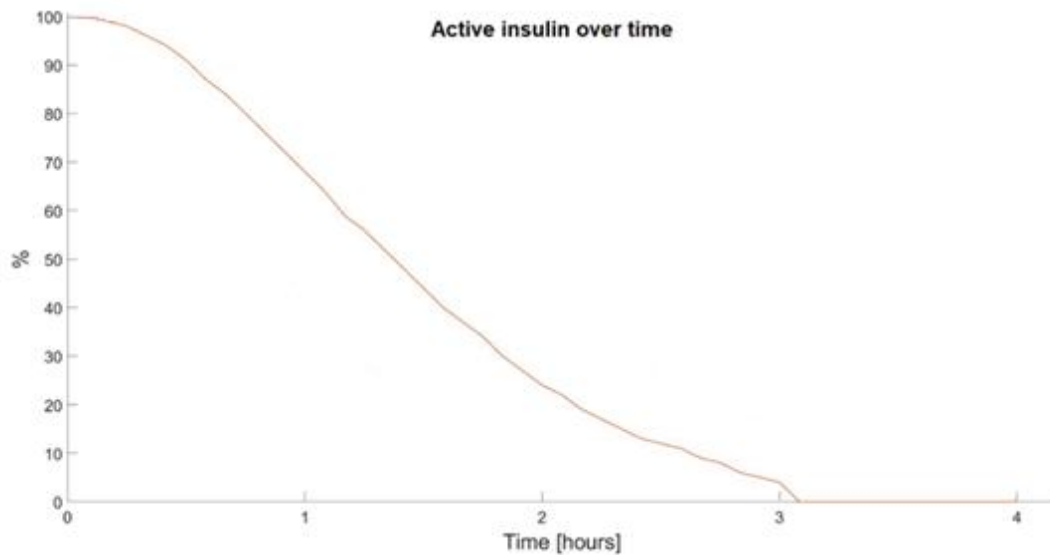
---

<sup>3</sup> Adapted from Mudaliar et al, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501

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Note: The Correction Dose is never negative.

Figure 1:



### 3. Final Calculation

After these steps, the Rapid-Insulin Dose Calculator adds together:

$$Total\ Bolus = Meal\ Dose + Correction\ Dose\ (adjusted\ for\ active\ insulin)$$

The total bolus value is then:

- Rounded down to the nearest whole insulin units.
- Checked to ensure it does not exceed your maximum allowed bolus (set in your personal settings).
- Confirmed to be at least 0 units

### 4. Example Scenarios

Scenario	Meal Dose (U)	Correction Dose (U)	Active Insulin (U)	Final Total	Notes

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Eating, glucose above target, no active insulin	4	2	0	6	Correction Dose added to meal dose.
Eating, glucose above target, some active insulin	5	2	3	5	Active insulin cancels Correction Dose.
Not eating, glucose above target, with active insulin	0	3	1	2	Correction Dose reduced for safety.
Eating, no glucose reading available, with active insulin	4	0	1	4	Regular meal dose only.

## 10. Cybersecurity



CAUTION

To help protect your personal health data and ensure proper system operation, install and use the MODI application only on mobile devices with the manufacturer's original operating system security controls enabled and only from trusted application stores (such as the Apple App Store or Google Play Store). Do not use the MODI application on a rooted or jailbroken mobile device. Protect your mobile device with a device access code, biometric authentication, or equivalent security measure.

### 10.1. Cybersecurity and Safe Use

The MODI System is designed to protect your personal health data and to operate securely as part of normal diabetes management. Security measures are built into the system to help protect data, ensure reliable operation, and reduce the risk of unauthorized access.

You can help maintain the security of the MODI System by following the guidance below.

If a user becomes aware of or suspects any cybersecurity events, they should immediately contact [support@dreamed.ai](mailto:support@dreamed.ai).

### 10.2. Using MODI Securely

- Install and use the MODI application only on mobile devices with the original operating system security features enabled.
- Download the MODI application only from trusted application stores (such as the Apple App Store or Google Play Store).
- Do not use the MODI application on a rooted or jailbroken mobile device.
- Protect your mobile device with a device access code, biometric authentication, or similar security feature.

### 10.3. Software Updates

MODI software updates are provided through official application stores and may include security improvements.

Install updates when they become available to help ensure continued secure and proper operation.

### 10.4. System Behavior and Data Protection

MODI uses secure communication and data protection measures to help keep your information confidential and reliable.

If the system detects abnormal conditions that may affect operation, MODI is designed to limit unsafe behavior and may notify the user or healthcare provider. You do not need to configure security settings to use MODI safely.

In addition, in case of significant vulnerability found by DreaMed, disclosure information will be published on the company website. In the event of a critical update, Diary App update will be enforced for all users. users are directly notified via email or phone. Following is the information disclosed:

- Overview of the identified vulnerability, its nature, potential impact, affected devices and SW versions.
- Actions taken to mitigate vulnerability, including details on software updates, patches, or other remediation measures.
- Risk assessment of vulnerability, outlining the potential risks to patient safety, data integrity, and overall device functionality if any.
- Where appropriate, instructions on how to respond upon detection of a cybersecurity vulnerability or incident will be provided.
- MODI System captures device event logs and mobile application logs. These log files are kept by the system and may be used for security event detection.

### 10.5. Support and Discontinuation of Use

Security support is provided for MODI during its supported lifetime.

If you stop using MODI, remove the application from your mobile device using standard device procedures.

If you suspect a security issue or unexpected system behavior, contact DreaMed support.

### 10.6. Additional Information

The software bill of materials (SBOM) can be provided upon request. Please contact your DreaMed Support for any additional information.

## 11. Troubleshooting and Tips

This section provides answers and guidance for common situations that may occur while using the DreaMed Diary App for MODI.

If an issue is not resolved after following these steps, users should contact their healthcare provider or DreaMed support.

### 1. I have not received a new recommendation for a while

MODI is designed to provide a new recommendation **only when it is needed** — not on a fixed schedule. If your glucose levels and insulin use appear stable, MODI may decide that no changes are currently required. This means everything is working as expected.

However, there are some cases in which MODI may **temporarily delay reviewing your plan**, such as:

- MODI does not yet have enough recent data (for example, missing CGM readings or insulin logs).
- Your CGM or phone time settings were changed, or the connection to your glucose data was temporarily interrupted.
- You recently traveled across time zones — MODI waits for your daily schedule to stabilize before reviewing your plan again (see *Traveling Across Time Zones* below).

#### What you can do:

Make sure your CGM data is being uploaded correctly and that all basal and bolus doses are logged in the app. Keep using the app and injecting insulin as usual.

Once MODI has enough consistent, reliable data, it will automatically analyze your information and provide a new recommendation if needed.

### 2. I received a new insulin plan from my healthcare provider

If your healthcare provider changes your insulin treatment, you must update the new plan manually in the DreaMed Diary App.

To do this:

1. Go to **Insulin Plan** tab and tap the **Edit** button at the top right of the screen.
2. Enter the updated basal insulin type, injection time, and daily dose.
3. Update your bolus plan if relevant — fixed doses for each meal or small/normal/large options. Keeping your plan updated ensures MODI's recommendations remain accurate and safe.

### 3. How does traveling across time zones affect MODI?

For accurate operation, your phone's date and time must be set to "Automatic (network time)". This ensures that both your phone and the MODI app update correctly when you travel.

When traveling:

- If the time zone change is up to 3 hours, MODI automatically adjusts to the new local time and continues providing new plans as usual once it has enough recent data.
- If the time zone change is greater than 3 hours, MODI temporarily pauses plan adjustments for a day to allow your daily schedule and injection times to stabilize in the new time zone. After this short adaptation period, MODI will resume providing plan updates after enough data is gathered.

During this period, you may notice that no new recommendation is provided — this is expected and will resolve automatically once MODI has enough consistent local data.



## IMPORTANT

### Traveling Across Time Zones

MODI analyses your glucose and insulin data to optimize your insulin plan. When your local time shifts by more than 3 hours (due to travel or daylight saving changes), MODI will delay generating the next plan for a few days to let your body adjust. Frequent travel across time zones with an hour or more difference may limit MODI's ability to adjust your plan effectively. If this applies to you, consider whether using MODI fits your current lifestyle.

## 4. How do I log my bolus doses?

There are two ways to record bolus doses in the DreaMed Diary App:

1. Using the Rapid-Insulin Dose Calculator (for current doses):
  - Before eating, open the Rapid-Insulin Dose Calculator, enter your current glucose level and meal information (or select meal size), and confirm the recommended dose.
  - The app automatically logs the injection and time for MODI's analysis.
  - Prefer using the Rapid-Insulin Dose Calculator to get the dose with a safe correction amount. MODI requires at least 3 Dose Calculator events to titrate.
2. Using "Add Event" (for past doses):
  - To record a bolus given earlier, tap Add Event → Bolus and enter the amount, time, and associated meal (if relevant).
  - Use this option for missed or delayed logging to maintain accurate data for MODI's analysis.

Consistent bolus logging helps MODI provide precise and personalized feedback.

## 5. Where can I find my previous recommendations

All your previous insulin plans and MODI-generated recommendations are stored in the app.

To view them, go to **Menu → Plan History**. You can share this information with your healthcare provider during clinic visits.

## 6. When should I contact my healthcare provider?

MODI may display a message advising you to consult your healthcare provider in specific cases, such as:

- Persistent low glucose even after basal insulin has been reduced to **4 units or 0.1 U/kg**.
- Ongoing high glucose despite basal reaching **0.8 U/kg** (for basal-only users) or total daily insulin reaching **2 U/kg**.
- When MODI recommends intensifying therapy beyond basal insulin (for example, adding mealtime insulin).

If you receive such a message, contact your healthcare provider for review and guidance.

## 12. Appendix A – MODI Alerts and Tips



**IMPORTANT**




The information below explains MODI’s Alerts and behavioral tips, and describes their meaning.

If you receive an alert or a behavior tip that is not clear, consult the list below.

Consult your healthcare provider if you have any questions or concerns regarding your treatment or app usage.

In some cases, MODI will display an alert along with the new plan. Please review the alert carefully and contact your healthcare provider when necessary.

*Table 4 – MODI Alerts*

#	Alert text	Description
1	 <b>WARNING</b> The app cannot lower your dose any further. Consult your healthcare provider to discuss additional treatment options.	MODI identified low glucose events, but it cannot reduce your dose any further on its own. Contact your healthcare provider to address your low glucose events.
2	 <b>CAUTION</b> You’ve reached the maximum dose allowed by the system. Consult your healthcare provider to discuss additional treatment options.	MODI reached the maximum amount of insulin it can recommend; however it may not be enough for you. Contact your healthcare provider to discuss your options further.
3	 <b>IMPORTANT</b> Your current treatment may not be enough for you. Review your treatment plan with your healthcare provider.	MODI detected that your current treatment of long-acting insulin plan may not be enough for you, and you may need to discuss it with your healthcare provider to get better glucose control.

The behavioral tips are designed to help you to optimize your insulin management by providing practical advice on following your treatment plans and using the app’s recommendations. These tips can assist you to achieve better glucose control and encourage consistent adherence to healthcare guidance.

*Table 5 – MODI Behavioral tips*

#	Behavioral tip text	Description
1	Please be sure to use your basal plan, and trust your recommended amount. If your plan changed by your healthcare provider, be sure to update it in the app.	The insulin doses in your records don’t seem to match your basal plan. Please check that your plan is updated and follow the recommended doses.

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2	Please be sure to use your basal plan, and trust your recommended amount.	Your daily basal injections don't look consistent. Inject the same amount each day as in your plan.
3	Many of your highs may be avoided. Delivering an insulin bolus for every meal and snack may help you get better outcomes.	It seems you sometimes eat without taking insulin. Remember to bolus before every meal and snack to help keep your glucose in range.
4	Many of your highs may be avoided. Remember to check your glucose level and bolus before you start eating.	It looks like your bolus is often taken after eating. Try to bolus 15 minutes before your meal to prevent high glucose events.
5	You are over treating your lows. Eat moderately when treating your lows.	It seems you're eating too much when treating a low. Try smaller amounts of fast carbs to bring your glucose up without causing a high.
6	Many of your lows may be avoided. Remember to check your glucose level and bolus before you start eating.	It looks like your bolus is often taken after eating. Try to bolus right before your meal to prevent low glucose events.
7	Be sure to deliver your basal injections at the same time every day to avoid low or high glucose events.	Your basal insulin times vary day to day. Injecting at the same time daily helps keep your glucose more stable.
8	Mealtime insulin is added to your [meal name]. Follow your New plan to achieve better glucose control.	MODI found that adding insulin for the specified meal can help improve your glucose control. Follow your updated plan for better results.
9	You took another bolus soon after the previous one, which may have caused low glucose. Be sure to wait between doses to avoid low glucose.	It looks like you gave another bolus too quickly after the last one. Wait longer before dosing again to avoid going low.
10	You took another bolus soon after a hypo event, which may have caused low glucose. Be sure to wait before bolusing after a low glucose event.	You took insulin too soon after treating a low. Give your glucose time to recover before bolusing again.
11	You took a higher bolus dose than your plan suggests, which may have caused low glucose. Be sure to follow your plan doses to avoid low glucose.	You took more insulin than your plan recommends, which likely caused your low. Stick to your plan's doses to stay safe. Try to use the app's Rapid-Insulin Dose Calculator and rely on its recommendations.

## 13. Appendix B - Glossary

Table 6 – Glossary

<b>Active insulin</b>	Amount of insulin that has been delivered and is still having an effect in lowering the blood glucose.
<b>Active insulin time</b>	The time (measured in hours) it will take until the bolus of insulin stops affecting the blood glucose. This time is used by a Rapid-Insulin Dose Calculator when calculating a bolus.
<b>Basal insulin</b>	A long acting insulin that is used to maintain a baseline amount of insulin throughout the day.
<b>Basal plan</b>	A basal (long-acting) injection that covers a full-day period.
<b>Bolus</b>	Amount of insulin that is given to treat high glucose levels and/or carbohydrate intake.
<b>Carbohydrate Ratio (CR)</b>	Indicates the ratio between an amount of carbohydrates and insulin. The ratio is used for covering carbohydrate intake.
<b>CGM / Sensor</b>	A Continuous Glucose Monitoring device, which is the sensor that continuously measures the interstitial glucose levels.
<b>Correction Factor (CF)</b>	Indicates how much one unit of insulin reduces glucose levels. This factor is used for correcting high glucose levels.
<b>DKA</b>	Diabetic Ketoacidosis, which is a life-threatening complication of diabetes mellitus.
<b>Glucose target</b>	Indicates the value toward which the glucose level is corrected. This target is used for correcting high glucose levels manually or in the Rapid-Insulin Dose Calculator.
<b>Insulin on board (IOB)</b>	Same as Active Insulin. Amount of insulin that has been delivered and is still having an effect in lowering the blood glucose.
<b>Pre meal glucose target range</b>	Indicates the desired glucose range before a meal, specifically before breakfast. This glucose target range is used in MODI's insulin plans.
<b>U-100, U-200, U-xxx</b>	Type of insulin in which every milliliter (ml) of liquid contains 100/200/xxx units of insulin.