endo.digital

DreaMed Diary App
User Guide

DreaMed Diary IFU #PR-4630 Version 9.0

endo.digital WAS DEVELOPED BY –

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In the US: For in-vitro diagnostic use only

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Rx Only

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

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Before You Begin

Using This User Manual

This user manual is intended for people with diabetes that administer Multiple Daily Injections (MDIs) of insulin, who will be using the DreaMed Diary App to easily log and track blood glucose levels, insulin delivery and physical activity, as well as carb and meal information as part of the endo.digital Platform used by your HCP.

The DreaMed Diary app is suited for both iPhone and Android users. The app is almost identical on both types of devices. Any significant differences are described in the relevant place in this user manual.

NOTE: Some features differ slightly between iPhone and Android devices, such as date pickers. Some of the screen captures shown in this user manual are from iPhone devices and others from Android devices and therefore may appear slightly different than on your device.

This user manual contains the following chapters –

- **Chapter 1, Introduction,** page 10, introduces the DreaMed Diary app.
- **Chapter 2, Using DreaMed Diary,** page 12, describes the workflow for using the DreaMed Diary app.
- **Chapter 3, DreaMed Diary Screens,** page 32, describes the screens of the DreaMed Diary app.
- **Chapter 4, Using the Bolus Calculator,** page 57, describes the Bolus Calculator and how to use it.

Table 1 – Symbols and Concepts Used in This Manual

Symbol	What It Means
	Manufacturer
	Manufacturing Date
	For Prescription use only
	**Note –** A note provides helpful information.
 **Caution**	**Caution –** 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.
 **WARNING**	**WARNING –** 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 endo.digital.

Glossary

Table 2 – Glossary

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

User Safety

The DreaMed Diary is a mobile app intended for use by people with diabetes, in order to log, track and share blood glucose levels, insulin delivery, physical activity, as well as carbs and meal information with their healthcare provider. DreaMed Diary also enables people to communicate with their healthcare provider.

The app also enables the patient to see their insulin treatment recommendations provided by their healthcare provider. The insulin treatment plan may be generated by the endo.digital algorithm or by the healthcare provider manually.

Indications for Use

endo.digital Platform

endo.digital Platform is intended for the management of diabetes by people with diabetes and their healthcare providers in order to report, upload, log, track, share, monitor and review their data using web and mobile applications. endo.digital Platform also enables communication between people with diabetes and their healthcare providers as well as among healthcare providers

endo.digital Platform enables the healthcare provider to use endo.digital Algorithm for treatment recommendations as described below and prescribe endo.digital Bolus Calculator for patient use.

endo.digital Algorithm

endo.digital Algorithm is a decision-support software intended for assisting healthcare professionals in the management of their patients with diabetes who monitor their glucose levels using continuous glucose monitor (CGM) and/or Self-Monitoring Blood Glucose (SMBG) meter; and use any of the following insulin types as their therapy to glucose level management via subcutaneous injections or continuous sub-cutaneous insulin infusion (CSII; insulin pump) reported either manually or automatically:

- Long acting insulins (for injections only)
- Short acting insulins:
  - Rapid acting analogs (for injections and insulin pump according to manufacturer indications for use)
  - Regular human insulin (for injections only)

endo.digital Algorithm is intended to be used for patients with:

- Type 1 diabetes over the age of 6, using an insulin pump or subcutaneous insulin injections.
- Type 2 diabetes over the age of 10, who use subcutaneous insulin injections.

endo.digital Algorithm is indicated for use by healthcare professionals when analyzing CGM, SMBG and/or insulin delivery data to generate recommendations for optimizing a patient's insulin treatment plan for basal therapy and/or bolus therapy and/or glucose targets; without considering the full clinical status of a particular patient. endo.digital Algorithm does not replace clinical judgement.

endo.digital Bolus Calculator

endo.digital Bolus Calculator, a component of the DreaMed Diary App, is a diabetes management tool for people with type 1 diabetes above the age of 6 and type 2 diabetes above the age of 10, who use subcutaneous insulin injections therapy (not for pump use). This tool can help calculate their rapid acting analogs for insulin bolus doses based on user-entered blood glucose and/or meal information.

The initial setup of the user's treatment plans, and bolus calculator settings must be performed by a healthcare provider.

Contraindications for endo.digital Algorithm

- endo.digital algorithm is not intended to send recommendations directly to patients before they are reviewed and approved by a certified HCP. This health care provider must take the entire clinical status of the patient into consideration before send recommendations.
- endo.digital algorithm is not recommended for patients that change their concomitant glucose-lowering therapies or who alter their current therapy dose while using the endo.digital device. Since endo.digital only analyzes the insulin dosing history data and assumes that all other elements that affect glucose levels are stable, the effect of changing or altering the dose of other glucose-lowering therapies will not be taken into consideration by endo.digital. This could result in a false conclusion about the changes to the patient's insulin treatment plan and may lead to potential harm.
- endo.digital algorithm is not recommended for pregnant women. endo.digital has not been tested in this population.
- endo.digital algorithm is not intended for use with patients who use automated insulin dosing (AID) systems, such as closed-loop or artificial pancreas. endo.digital has not been tested with these devices. endo.digital cannot identify the pump model or operating mode. Although endo.digital has various design mitigations that can help detect when AID systems are used in closed loop mode; and although it will usually prevent the system from providing recommendations for pump parameter changes, it cannot detect closed loop insulin delivery 100% of the time. Therefore, you must pay attention to pump information and the pump's operating mode and not accept endo.digital recommendations if the user was using the AID system in a closed loop mode.
- endo.digital algorithm is not intended for use by patients who use insulin(s) other than the types indicated above. endo.digital has not been tested with other types of insulins. Using endo.digital with other types of insulin may lead to the potential harms listed below.
- endo.digital algorithm is not recommended for patients who have changed their insulin type within the last 21 days. Since endo.digital only analyzes the current plan, the effect of changing the insulin type during the analysis period is not taken into consideration. This could result in a false conclusion in regard to changes to the patient's insulin treatment plan and may lead to potential harm.
- endo.digital algorithm is not intended for use by patients treated with intravenous (IV) insulin injections, or by a combination of insulin injections and/or IV insulin and insulin pump therapy. Since endo.digital analyzes the insulin dosing history, it assumes a certain insulin delivery methodology as per the physician settings of the patient profile. Using endo.digital in the above manner could result in a false conclusion in regard to changes to the patient's insulin treatment plan and may lead to potential harm.

Please ensure that your patient is an appropriate candidate for the endo.digital algorithm before starting them on this program.

Potential Harm

Information is recorded in the DreaMed Diary app and then shared with your healthcare provider. There are potential risks associated if the shared information is inaccurate or misleading. Potential risks include –

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

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.

General Cautions

- Please read the entire user manual before using the app.
- If something in a new treatment plan is unclear, contact your Health Care Provider for clarification before beginning to use your new plan.
- The data that is logged in this app is used by your healthcare provider to adjust your treatment plan. If you have not been using your sensor according to the manufacturer's instructions for use or if you have any other special circumstances that could influence this adjustment, such as illness, significant change of diet or exercise regime, change in medication or significant change in your physical condition, be sure to share this information with your healthcare provider.
- If you are using the bolus calculator, make sure you have correctly logged in all bolus events in the last four hours so that active insulin is correctly calculated.
- Data is not monitored in real time and should not be used as an emergency channel. In case of an emergency, dial 911.
- Configure your smartphone to take their date and time settings directly from the network in order to capture your events correctly.

Chapter 1 – Introduction

The chapter introduces the DreaMed Diary app.

About the DreaMed Diary App

This User Manual provides information about DreaMed Diary App software version 02.00.00 and onwards.

The DreaMed Diary app provides an easy way to log and track your condition and receive treatment plans from your healthcare provider.

With the Diary app, you can track your blood glucose levels, insulin delivery, physical activity, as well as carbs and meal information.

DreaMed Diary enables you to view and edit your insulin treatment plan as given to you by your healthcare professional, to take it with you wherever you go. If you are treated with a plan other than DreaMed Diary's supported basal bolus plans, you may use the DreaMed Diary app for logging and share your data with your healthcare provider and receive messages regarding your treatment plan.

A bolus calculator is available to help you calculate your boluses according to your healthcare provider's instructions if you are using a compatible treatment plan (carbs counting).

Connecting to Your Healthcare Professional

After being invited by your healthcare provider, the DreaMed Diary app can automatically transmit your daily progress to your healthcare professional, who can then view it. If your healthcare provider added your treatment plan to endo.digital, it automatically appears in your app. Then (when necessary), your healthcare professional can generate a new optimal insulin delivery recommendation plan. This new recommendation plan is automatically saved in your DreaMed Diary app for you to see and use.

NOTE: The DreaMed Diary app provides a full set of diary logging and tracking features regardless of whether you are connected to your healthcare professional or not.

Connecting to Glucose Sensors

If you are using a Dexcom Continuous Glucose Monitor (CGM) sensor, the sensor only needs to be connected to the app once. After the sensor is connected to the app, sensor data does not continuously appear in the DreaMed Diary app but is available to your healthcare provider when needed. This feature is only available in the USA. When the Dexcom CGM is connected to the DreaMed Diary app, the only events that you may need to enter in your diary are your insulin injections and your meals.

NOTE: If at any point you change your Dexcom password make sure you disconnect and then reconnect to Dexcom using your new password.

iOS or Android

The DreaMed Diary app is suited for both iPhone and Android users. The DreaMed Diary app can integrate with the Apple Health app for Apple users. This feature is not available for Android platforms.

- **For iOS Devices –** Requires iOS 12.4 or later. Compatible with iPhone, iPad and iPod touch.
- **For Android Devices –** Requires device from the following brands – Samsung, LG or Google, from Android 6.0 or later. The app is compatible with most models.

Chapter 2 – Using DreaMed Diary

The chapter describes the workflow for using the DreaMed Diary application.

1 **Setting Up Your endo.digital Account –** Your healthcare professional will formally invite you to endo.digital by sending an invitation email that contains a unique link. After receiving your invitation, tap the link on your mobile device to set up your endo.digital account credentials. You may refer to page 13 for more details.

2 **Onboarding –** Download the DreaMed Diary app from the Google Play store Google Play or the Apple App store App Store, launch it and log in to DreaMed Diary . The first time you launch the app, it automatically guides you through the process to connect your Dexcom sensor. You may refer to page 14 for more information.

3 **Verifying General Settings –** The DreaMed Diary app is provided with various settings that define its behavior. These things are typically set up for you by your healthcare professional. You have the option to review and or modify these settings in the **Settings** ⚙ ➔ **General Settings**, as described on page 52. Although this step is optional, it is highly recommended that you check the general settings to confirm that the carbs are in the proper units for you, and to change them if necessary. You may refer to page 20 for more information.

4 **Reviewing Your Treatment Plan –** The DreaMed Diary enables you to view and edit your treatment plan. The initial plan should be set by your healthcare provider. You can review your plan by using the **Plan** menu. You may refer to page 36 for more information.

5 **Using the Diary,** page 22 **–** Use the DreaMed Diary to log one or more of the following – insulin dosages, glucose level measurements, amount of carbs, meal sizes, physical activities or any other free text event.

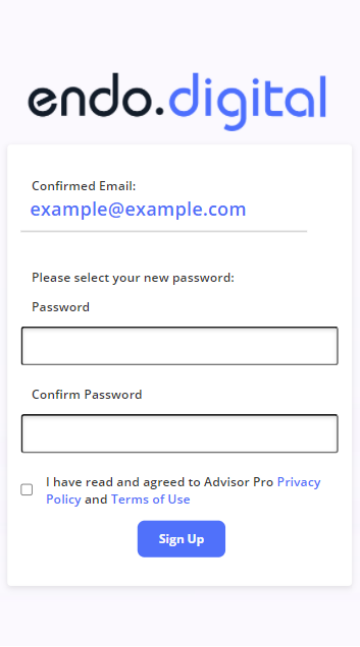
6 **Reviewing a New Treatment Plan,** page 27 **–** Your healthcare professional may send you a new/modified treatment plan recommendation, which is automatically saved in your DreaMed Diary.

7 **Calculating using a Bolus Calculator –** You can also calculate an insulin dose using the bolus calculator when using a supported treatment plan (see page 57). This feature can be added to your app by your healthcare provider.

Step 1, Setting Up Your endo.digital Account

Your healthcare professional will formally invite you to endo.digital by sending an invitation email that contains a unique link. This link is valid for 72 hours. If the link expires, your healthcare professional must send you a new one (using the email available in endo.digital).

After receiving your invitation, tap the link on your mobile device to set up your endo.digital username and password. The password must be at least eight characters, and contain at least one upper-case letter, one lower-case letter, as well as a number or a special character. You must also confirm your acceptance of the endo.digital terms of use.



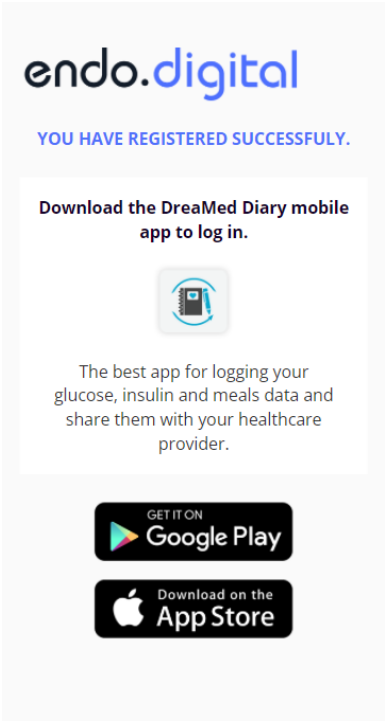
After entering your credentials, tap **Sign Up**.

Step 2, Onboarding

Downloading

- **To download the DreaMed Diary App –**

1 From the Google Play store App Store or the Apple App store , download the DreaMed Diary app –

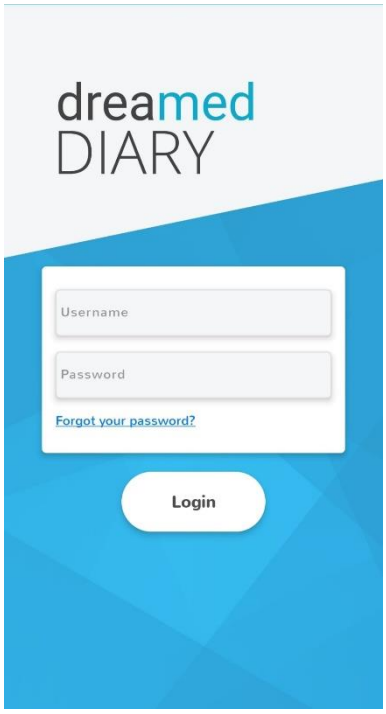


Logging In

- **To log in –**

1 **After the app has been installed, launch it by tapping the DreaMed Diary app icon –**

The following displays –



2 Enter the username and password you created and then tap the **Login** button.

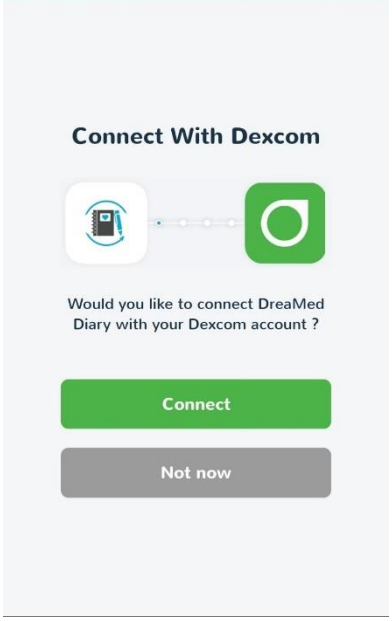
If this is the first time that you are logging in, then a few additional screens are displayed which guide you through the process of setting up your DreaMed Diary app, as described below.

Logging In for the First Time

The first time the DreaMed Diary app is launched, follow the displayed instructions, as described below.

To set up the application the first time it is launched –

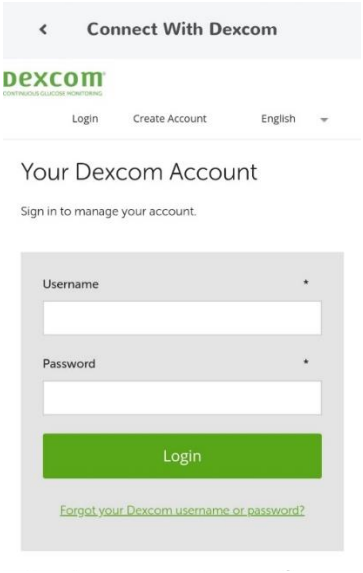
1 The following screen may be displayed to enable you to connect your DreaMed Diary to a Dexcom Continuous Glucose Monitor (CGM) Clarity account.



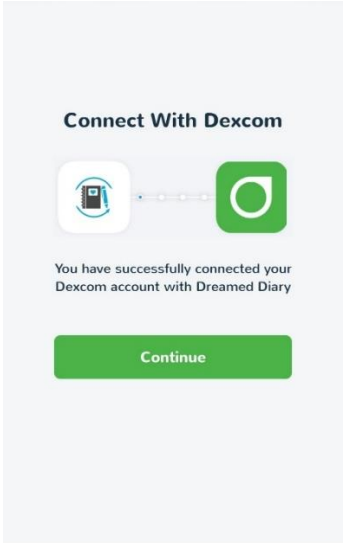
2 If you do not have a Dexcom CGM, tap the **Not Now** button and skip to the next step.

If you have a Dexcom CGM, then perform the following –

- Tap the **Connect Your Dexcom Account** button and follow the displayed instructions.



- Enter your Dexcom account username and password and tap the **Login** button.
- Enter your full name and then tap the **Authorize** button.

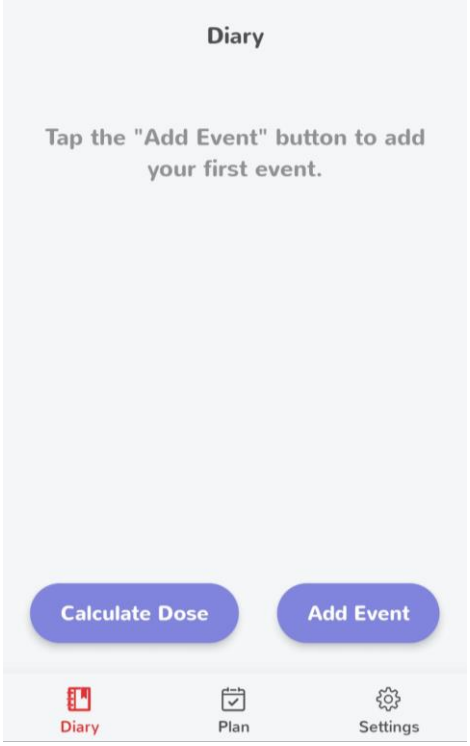


- The DreaMed Diary app and your healthcare provider will then be able to automatically access your glucose information from the Dexcom cloud in order to provide you better treatment recommendations.

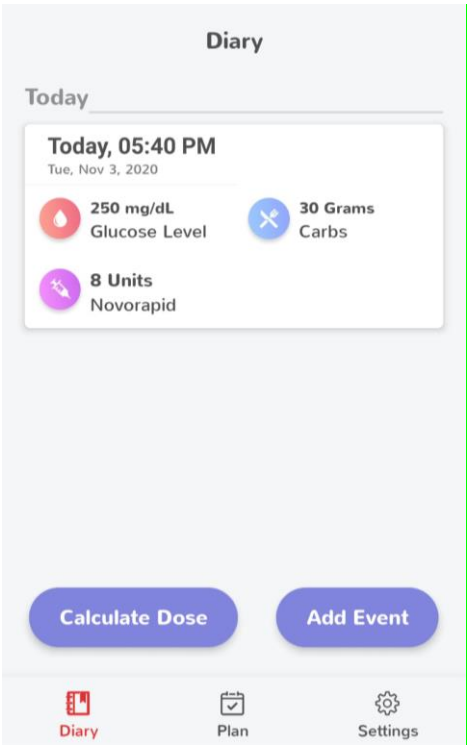
If you have skipped this part, you can always connect to the Dexcom sensor using the Connected Devices section in the settings.

3 The Diary screen is then displayed showing the entered diary events (also called *diary entries*). These events are entered into the diary by you (as described on page 22).

If this is the first time that you have logged in, the Diary screen displays empty, as shown below. In this case proceed to *Step 4,* Reviewing *Your Treatment Plan* on page 21.



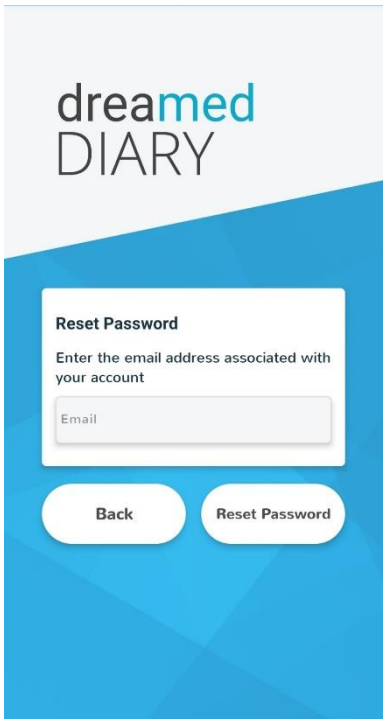
After you have entered your first event, the Diary screen appears as follows –



Refer to page 22 for a description of how to enter diary events.

Forgot Your Password or Account Locked

- **If you forgot your password, or your account is locked –**
  - Tap **Forgot your password?** in the login screen. The following will be displayed:



Fill in your email address used as your username to the app, and tap **Reset password**.

Check your inbox for an email with instructions how to unlock your account and select a new password.

Logging Out

▶ **To log out of the DreaMed Diary app –**

- Tap **Settings** and then the **Profile** button and select the **Logout** option.

Step 3, Verifying General Settings

The DreaMed Diary app is provided with various settings that define its behavior. These things are typically set up for you by your healthcare professional.

NOTE: It is highly recommended to configure your smartphone to take their 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**.

Step 4, Reviewing Your Treatment Plan

Your first treatment plan may be set by your healthcare provider. After your healthcare provider sets it for you, it appears in your **Plan** menu. This option enables you to view and edit the treatment plan recommended to you by your healthcare professional.

Caution

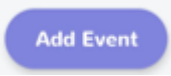
It is highly recommended to update your Plan Settings if you have changed your treatment plan. Keeping your Plan Settings up-to-date not only provides you with quick access to your treatment plan, but enables your healthcare professional to view it at your request or as part of a visit, as well as to modify the plan as needed.

You may refer to the *Plan* Settings section on page 36 for more information.

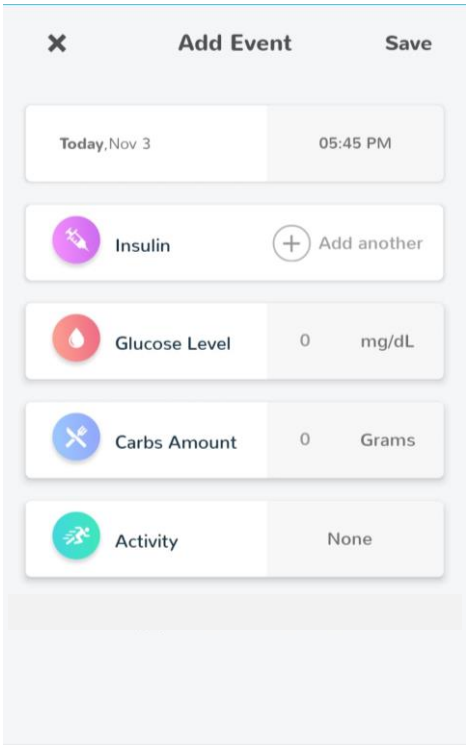
Step 5, Using the Diary

The following describes how to use your DreaMed Diary in order to log blood glucose measurements, meals and special events. Event entries should be added at the time that they actually occur. However, if you enter an event later, you have the option to specify the time and date that it occurred.

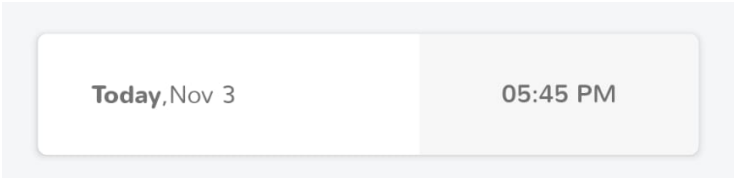
▶ **To add an event to the diary –**

1 Tap the **Add Event** 

button. The following displays –



2 The top of this screen shows the current date and time. By default, this will be the date and time assigned to the new diary event that is created. To change this, tap on the date and/or the time. Use the displayed date picker and/or time picker to specify when the event occurred.



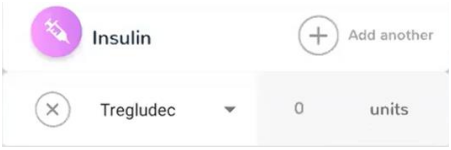
NOTE: It is important to be as precise as possible when specifying the time and date when the event occurred.

3 Create diary events by entering one or more of the following types of information –

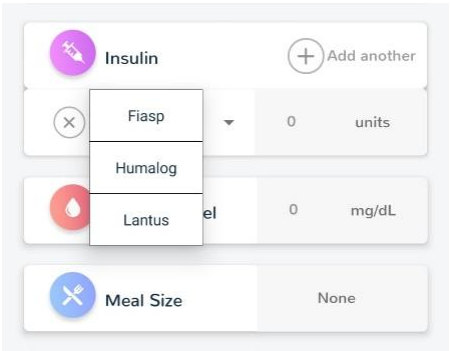
- **Insulin,** page 23
- **Glucose Level,** page 25
- **Carbs Amount/Meal Size,** page 25
- **Activity,** page 26

Insulin

- Tap **+ Add another** to display the option to add an insulin dosage event. For example, as shown below –

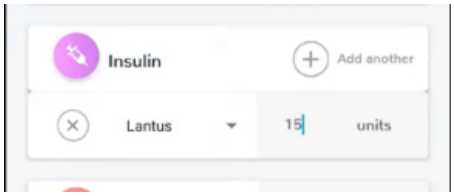


- Tap an insulin type name to display a selection list of insulin types, as shown below –

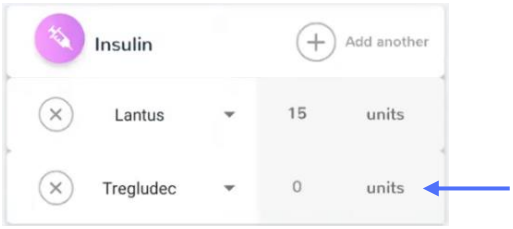


- Select one of the displayed insulin types from the dropdown menu.
- After your plan has been set, the dropdown list only shows insulin types that appear in your plan (typically a long-acting insulin type and a short-acting insulin type).

- Tap the **Units** field to display a numeric keypad and enter the quantity of units, as shown below –



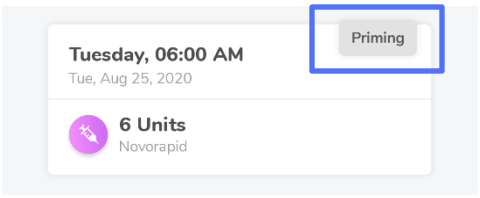
- If you are dosing additional insulin brands at the same time, then tap **+ Add another** to display an additional row for entering another insulin dosage, as shown below **–**

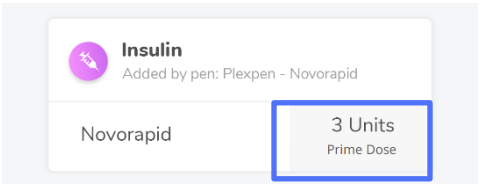


- Select the insulin brand and enter the quantity of units in the same way as described above.
- To delete an insulin dosage row that you entered, tap ⊗ on the left of the row.

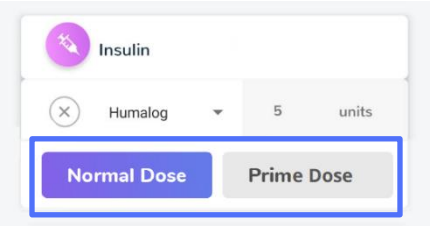
Prime Doses

When a dose is reported directly from a connected pen, some doses may be identified as prime doses. These events will be clearly indicated as such.

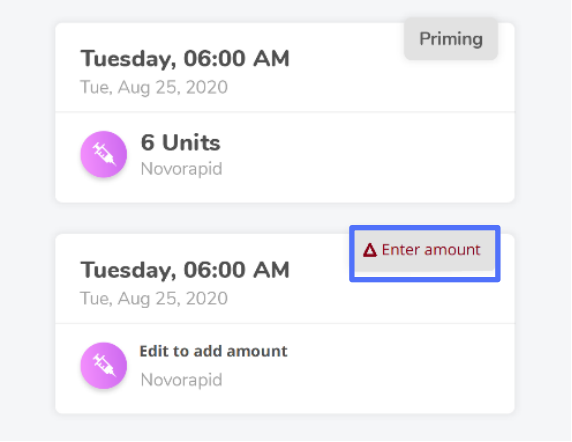




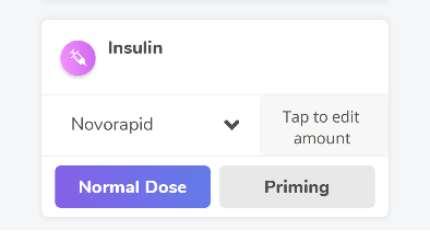
If a dose was identified as a prime dose by mistake, or vice versa, you should edit the event and mark a dose as a normal dose or a prime dose by tapping on the relevant button.



In addition, some doses may come from the connected pen with an indication that the dose amount is unreliable (e.g. a dose was captured without the amount, the amount is unreliable or the dose was indicated as a dose that was not finished). In this case, a clear indication will appear in the diary.



Enter the event and tap the amount to add an insulin amount.



Glucose Level

Enter the glucose level that you measured in **mg/dL**.

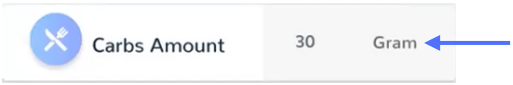
Carbs Amount/Meal Size

The next type of entry differs according to how the settings of your DreaMed Diary app have been defined.

NOTE: The type of field that appears here is typically defined by your healthcare professional. However, if needed you can modify it in the **Count Carbs** field in the **General Settings** screen, as described on page 52.

One of the following options may appear on this diary event screen. This field is controlled by the **Count Carbs** option in the **General Settings** screen. When **Count Carbs** is on, you enter the carb amount and when **Count Carbs** is off, you enter the meal size –

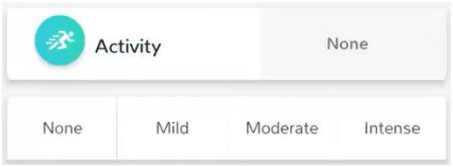
- **Carbs Amount –** Enables you to enter an amount of carbs in **Grams, 10 Gram** units or **15 Gram** units.



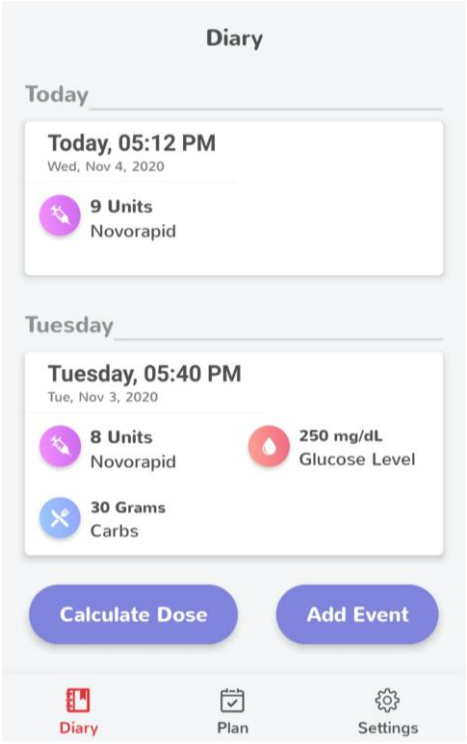
- **Meal Size –** Enables you to estimate the amount of carbs in the meal consumed. Tap this field to select whether the meal was **Small**, **Normal** or **Large** (as shown below) relative to what you usually consume at that time of the day.

Activity

Tap this field to select whether the activity you performed was **Mild**, **Moderate** or **Intense** (as shown below) relative to your usual physical activity.



- After you have finished entering all the relevant information about the event, tap the **Save** button to save this entry in your diary. This event then appears at the top of your Diary screen (page 32). For example, as shown below –



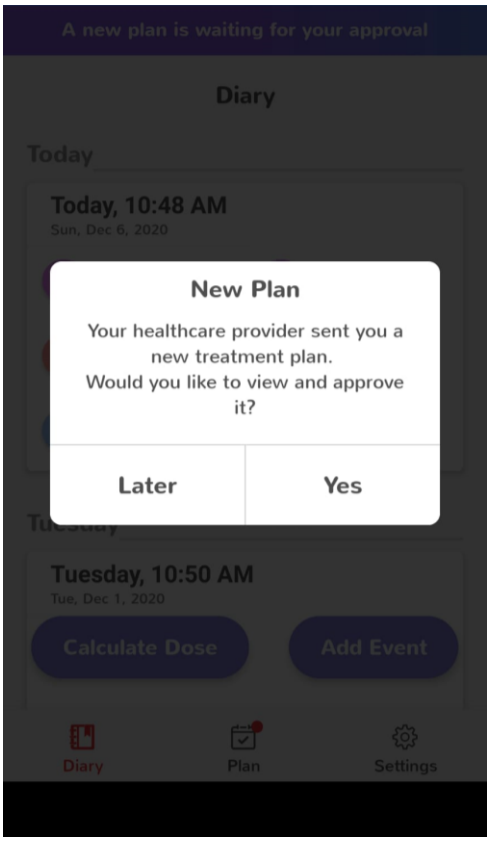
You may refer to page 32 for more information about your Diary screen.

Step 6, Reviewing a New Recommended Treatment Plan

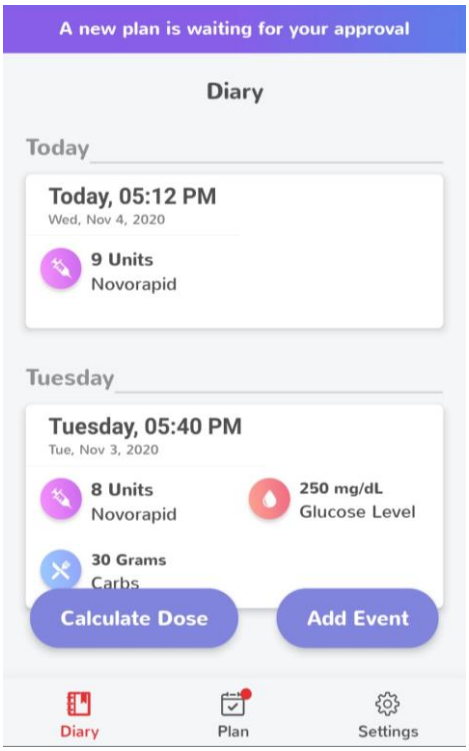
Your healthcare professional may send you a new/modified treatment plan recommendation.

NOTE: Recommendation plans include a Basal plan and a Bolus plan.

On your next login, or use of the plan to the DreaMed Diary app, the following displays –



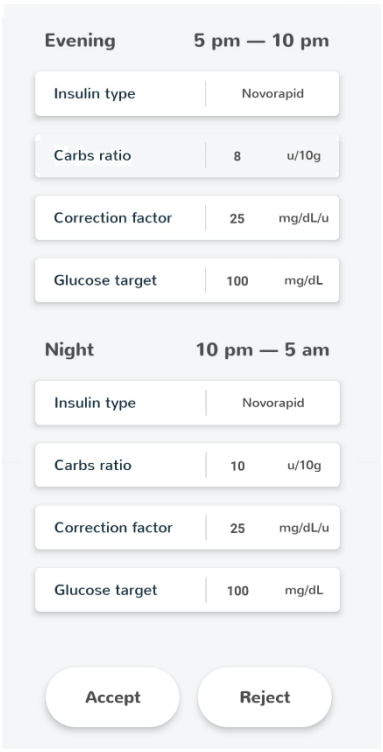
Tap **Yes** to review the plan now or tap **Later** to review it at another time. If you tap **Later**, a purple bar appears across the top of the screen to indicate the availability of a plan for your review and approval. This bar also displays in other screens in the application.


A new plan is waiting for your approval
Diary
Today
Today, 05:12 PM
Wed, Nov 4, 2020
9 Units
Novorapid
Tuesday
Tuesday, 05:40 PM
Tue, Nov 3, 2020
8 Units
Novorapid
250 mg/dL
Glucose Level
30 Grams
Carbs
Calculate Dose
Add Event
Diary
Plan
Settings

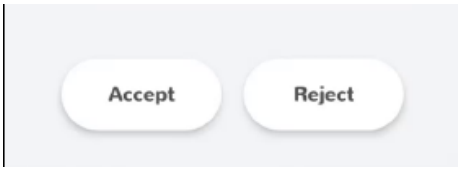
After you tap **Yes**, you can view the details of the plan sent to you by your healthcare provider. The top of the screen shows the date when the plan was sent to you. In addition, the plan may show a message from your healthcare provider, along with the recommended Basal plan and Bolus plan.

The Basal plan shows the recommended injections, including the time of day, the type of insulin and the number of units to deliver. There may be up to two injections, each containing this information.

The Bolus plan recommendation is described in the *Plan Settings* section on page 36.



The bolus plan is according to your treatment plan – fixed meal, meal estimation, sliding scale or carb counting. After reviewing the plan, scroll to the bottom of the screen and tap Accept to approve the plan or tap Reject to reject it. You can always edit your plan later, using the **Edit** button in the top right corner of the Plan screen. Your healthcare professional will know your selection (accepting or rejecting the plan).



Chapter 3 – DreaMed Diary Screens

The chapter describes the screens of the DreaMed Diary app.

Three icons appear at the bottom of the screen for accessing the DreaMed Diary app's main screens –

 **Diary –** Displays a chronological list of each diary entry and enables you to enter new diary events or edit previous ones. You may refer to page 32 for more information.

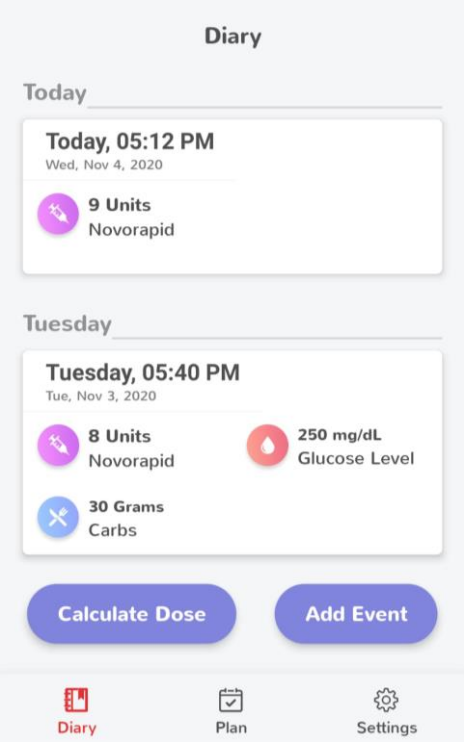
 **Plan –** Displays the treatment plan assigned to you by your healthcare professional and/or enables you to modify it. You may refer to page 36 for more information.

 **Settings –** Enables you to modify various settings that affect how the DreaMed Diary app behaves, such as the way carb events are reported. Typically, your healthcare professional will set these things up for you. You may refer to page 49 for more information.

Diary

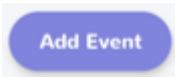
The Diary screen displays a chronological list of each diary entry. This means that the most recent diary entry appears at the top. You can scroll down to view previous entries.

In addition, the Diary screen may show the **Calculate Dose** button which opens the bolus calculator, if this option has been enabled for you by your healthcare provider. The Bolus Calculator helps you calculate how much insulin you need to inject, based on your plan. For more details, see page 57.

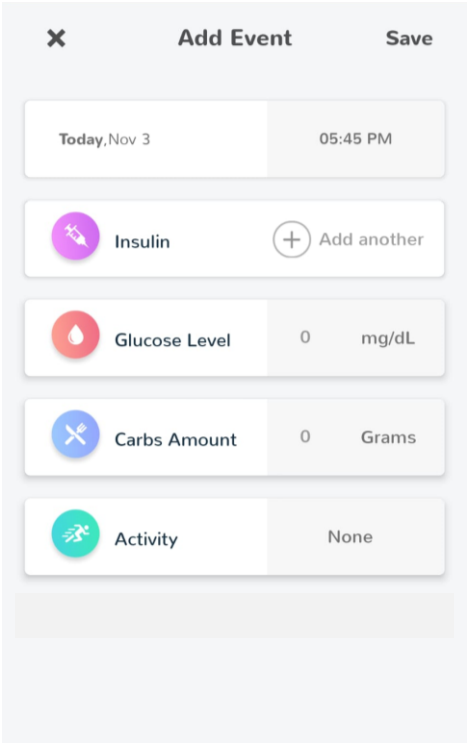


Each entry appears as a card that specifies the date and time that was defined for the entry.

To add an event –

- Tap the **Add Event** 

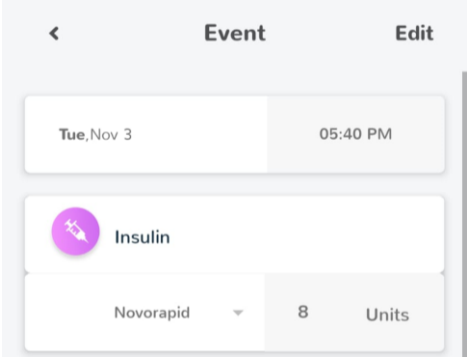
button to display the Event screen in which you can describe the event.



You may refer to page 22 for a description of how to add a diary entry.

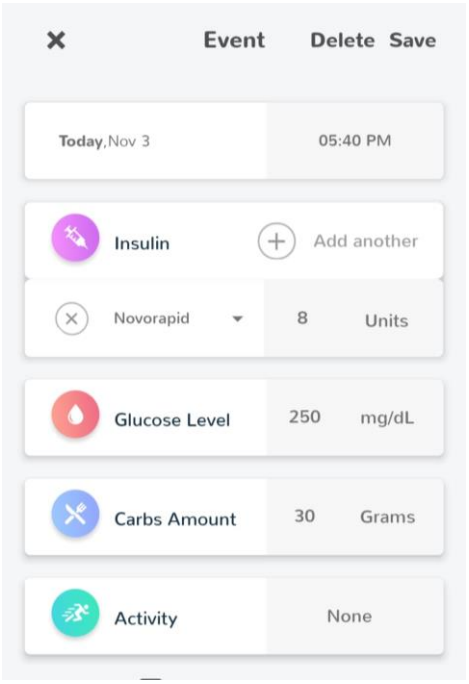
To display the details of this diary entry or to edit it –

- Simply tap on the diary entry card in the Diary screen to display the event's details in the Event screen.
- Tap the **<** on the top left of the screen if you want to return to the Diary screen.
- For example, as shown below –



You may refer to page 22 for a description of the options in each entry.

- **To edit the event –**
  - Simply tap on the **Edit** button and edit the required fields.
  - Tap the **Save** button if you want to save.
  - Tap **X** on the top left of the screen if you want to discard your changes.



To delete an event –

- Tap the diary entry card in the Diary screen to display the Event screen. Then, tap the **Edit** button, then tap the **Delete** button at the top of the screen to delete the event.

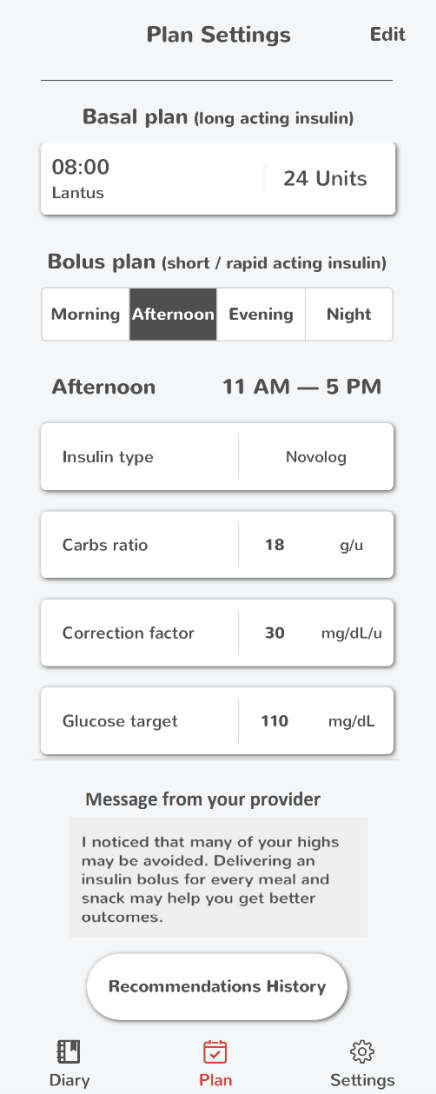
Plan Settings

The **Plan Settings** menu displays the treatment plan assigned to you by your healthcare professional and/or enables you to modify it. This screen is only available for users who use specific endo.digital's supported treatment plans. If your plan is not supported by endo.digital, an Inbox screen will appear instead (see Inbox section)

NOTE: A red dot on the **Plan**  icon indicates that a new plan is available from your healthcare provider.

Initially, this treatment plan must be entered by your healthcare provider.

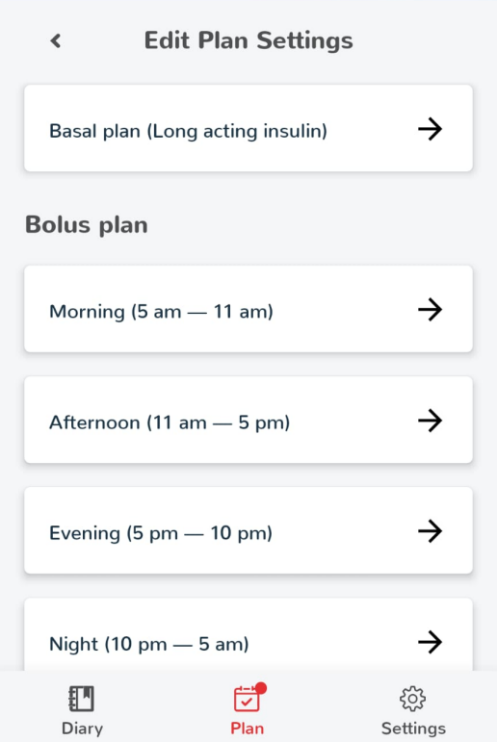
From time to time, your healthcare professional may decide to modify your treatment plan using the endo.digital see Step 6, Reviewing a New Recommended Treatment Plan for more information. In some cases, you may receive your new treatment plan by email, in your electronic medical records or on paper. In these cases, enter the **Plan Settings** screen to view your plan (shown below) **–**



To View Your New Plan

Alternatively, to manually adjust a new plan, tap the **Edit** button and then modify the plan as needed.

WARNING	**WARNING –** Editing your plan settings in this manner will affect the bolus calculator recommendation. Therefore, you must communicate with your healthcare provider before doing so.



To Edit the Basal or Bolus Plans

Configure the following options, as necessary –

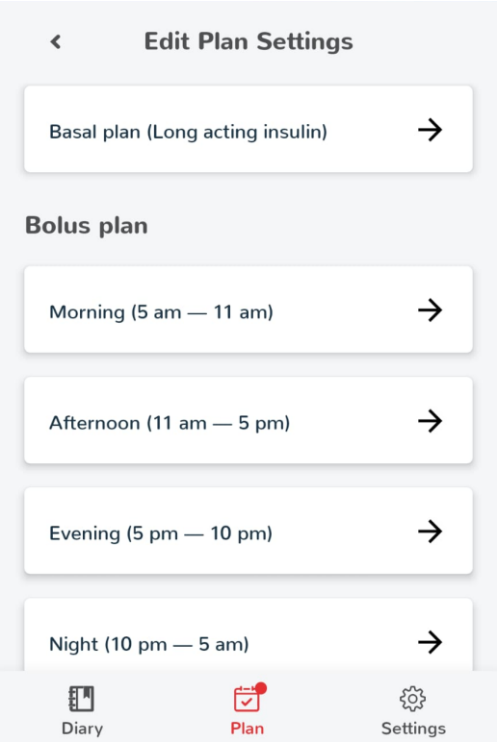
- **Basal,** page 39
- **Bolus,** page 42

Basal Plan

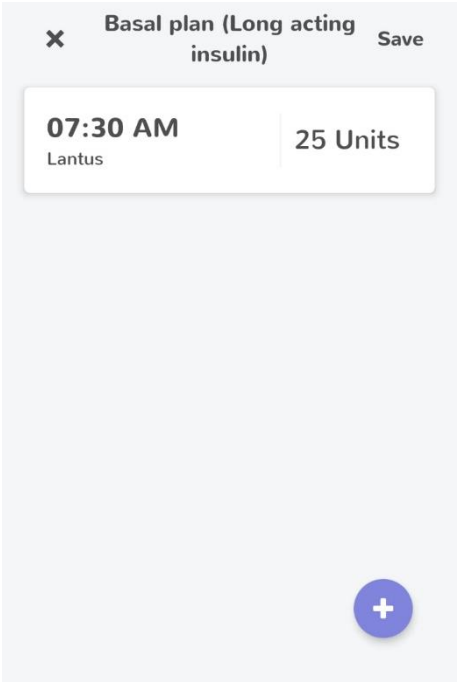
- Your Basal plan or Long acting insulin plan includes one or two daily injections. Each injection displays the time it should be taken, the type of insulin and the amount of units.

- **To edit your Basal Plan –**

1 Tap the **Plan** icon, then tap the **Edit** button at the top right corner of the screen.

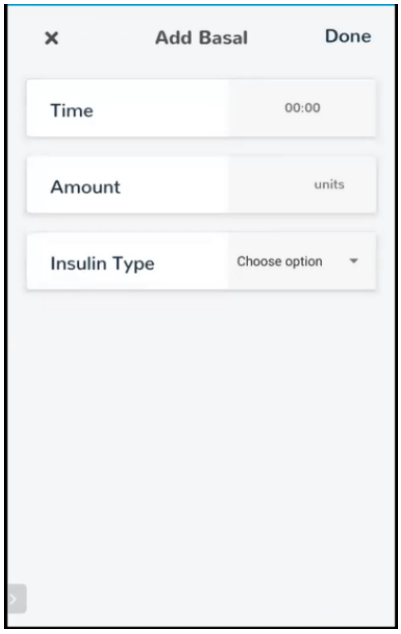


2 select the **Basal** plan (Long acting insulin) option. The following screen displays –



3 To edit an existing injection, simply tap on the injection record, edit the **time, insulin amount** or the **insulin type**, and tap **Done**. After returning to the Basal plan screen, tap **Save** to save your changes.

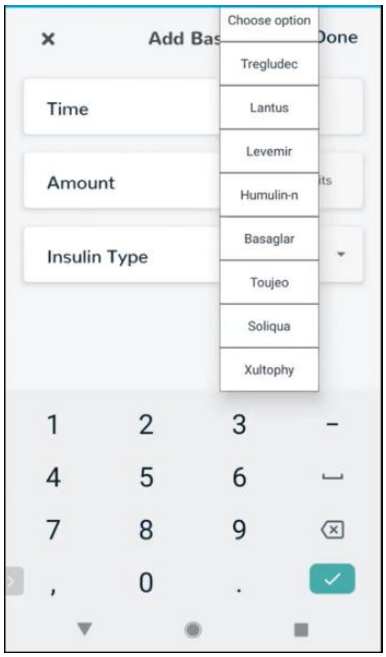
4 Tap the  button to add a new Basal Plan dosage time. The following displays –



5 Tap the **Time** field to specify the time of day that you have been ordered to take insulin for basal.

6 Tap the **Amount** fields to specify the quantity of units of the dosage at the time of day specified in the **Time** field (described above).

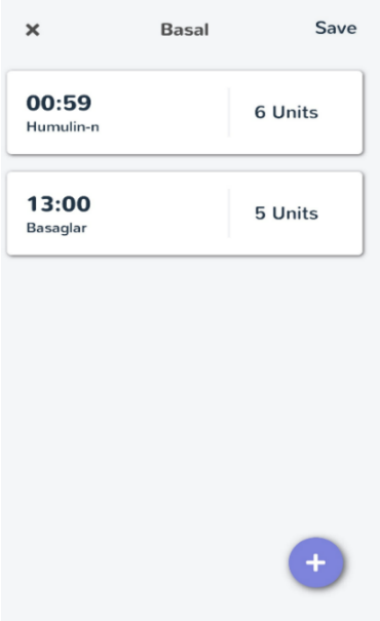
7 In the **Insulin Type** field, tap **Choose option** to display a dropdown menu of long-term insulin brands for basal, as shown below –



Instead of being offered a long list of insulin brands, only the insulin types that you define here appear for selection as your long-acting insulins when you add an event.

8 Tap **Done** after you have completed this dosage definition. The new entry appears in the **Basal Plan** screen.

9 Tap the button to add another Basal Plan dosage time. You can add up to two injections basal injections, as shown below –



10 Tap **Save**.

NOTE: Adding a basal injection without saving means that the plan is not saved.

Bolus Plan

One of the following types of Bolus treatment plans may be assigned to you by your healthcare provider:

- **Fixed meal with sliding scale correction**: this mode is for people who eat roughly the same amount of carbs per each meal and use a glucose scale to find the amount to deliver their correction bolus. The meal bolus includes the amount of insulin you should deliver for each meal of the day: Breakfast, Lunch, Dinner, and Night meal. To add correction to your meal bolus, measure your pre-meal blood glucose, find the range of the glucose value that includes your current glucose, and add to your meal insulin dose the amount of insulin for correction.
- **Meal estimation with sliding scale correction**: this mode is for people who can estimate the size of each meal and use a glucose scale to find the amount to deliver their correction bolus. For each meal there are 3 different meal sizes: small, normal, or large. To add correction to your meal bolus, measure your pre-meal blood glucose, find the range of the glucose value that includes your current glucose, and add to your meal insulin dose the amount of insulin for correction.
- **Sliding scale** mode is for people who eat roughly the same amount of carbs in their meals and use the scale to find the amount to deliver for the meal and the correction together. For example, this is a plan where you measure your pre-meal blood glucose, find the range of the glucose value and then deliver the amount of insulin based on that meal.

- **Counting carbs** mode is for those who use carb ratios and correction factors to calculate each bolus according to their glucose level and the amount of carbs they are about to eat.

NOTE: This setting does not affect your Basal plan.

NOTE: the Fixed Meal plan and the Meal Estimation plan cannot be edited in your Diary app.

▶ **To edit your Bolus plan –**

1 Tap the **Plan** button.

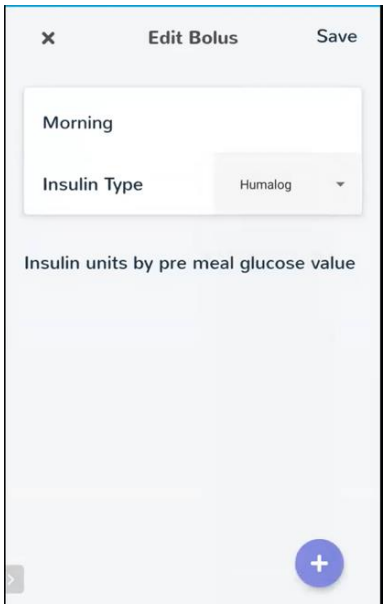
2 Tap the **Edit** button to display your Basal and Bolus plans.

3 Select the **Bolus** option.

The options described on the following pages are the same for **Morning**, **Afternoon**, **Evening** and **Night**.

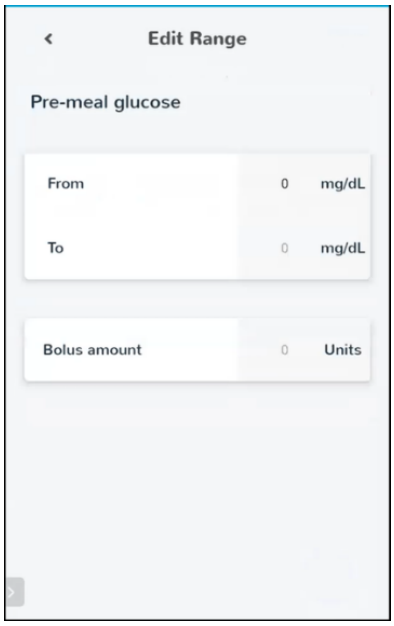
Sliding scale plan

For the **Sliding scale** plan (see page 42), tapping **Morning**, **Afternoon**, **Evening** or **Night** displays the screen on the left –



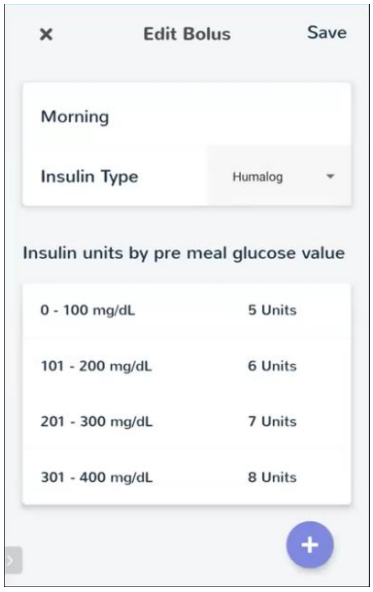
1 Tap the **Insulin Type** field to select the insulin type to be added to the plan, such as **Humalog**. Instead of being offered a long list of insulin brands, only the insulin types that you define here will appear for selection as your short-acting insulins when you add an event.

- In this next step, you will specify various ranges of pre-meal glucose and the Bolus amount (quantity of units) of the dosage to be administered.
- Tap the + button, The following displays –

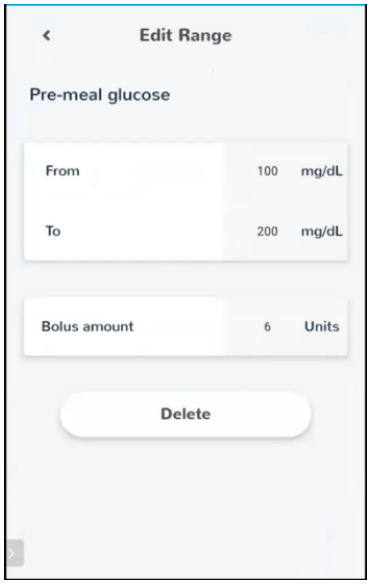


- In the **From** field, specify the lower range value of pre-meal glucose.
- In the **To** field, specify the upper range value of pre-meal glucose. This value must be larger than the value in the **From** field.
- In the **Bolus amount** field, specify the quantity of insulin to administer when your pre-meal glucose is within the range defined above.
- Repeat the steps above as many times as necessary in order to define all possible ranges of pre-meal glucose and the quantity of insulin to administer for each.
- The value that you enter in the **From** field of each new range row, must be larger than the value in the **To** field of the row that precedes it.

2 After you have completed defining all ranges, tap **Done** to display the entire Bolus Treatment Plan. For example, as shown below –



3 If needed, you can delete or edit any of these range rows by tapping on it. The following displays, which enables you to modify the values or to delete the range row entirely –



To modify the values, simply select different values in the **From**, **To** or **Bolus amount** fields.

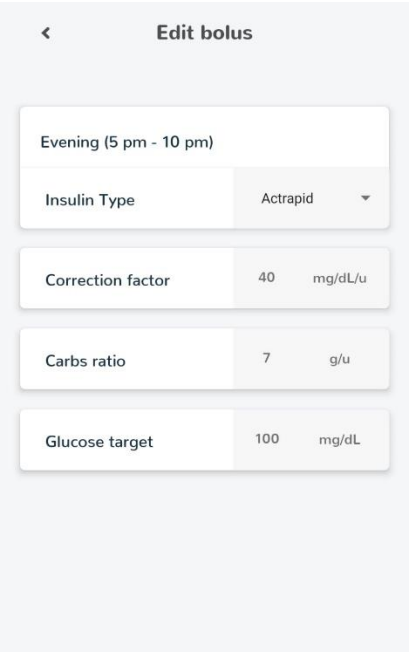
To delete an entry, tap the **Delete** button. The plan is automatically updated to fill in any gap that was created by deleting a range row. This ensures that the table covers the entire range of possible pre-meal glucose values. The plan automatically assigns the same quantity of units as the previous row plus one. You should change this default value, as necessary.

NOTE: We recommend carefully reviewing the pre-meal glucose range values and Bolus amounts in this table before saving.

4 Tap **Save**.

Carbs counting plan

For the **Carbs counting** plan (see page 42), tapping **Morning**, **Afternoon**, **Evening** or **Night** displays the following –



1 Tap the **Insulin Type** field to select a short acting insulin type to be added to the plan, such as **Novorapid**. Instead of being offered a long list of insulin brands, only the insulin types that you define here will appear for selection as your short-acting insulins when you add an event.

2 Modify the **Correction Factor** field according to the recommendation provided by your healthcare professional.

3 Modify the **Carbs ratio** field according to the recommendation provided by your healthcare professional.

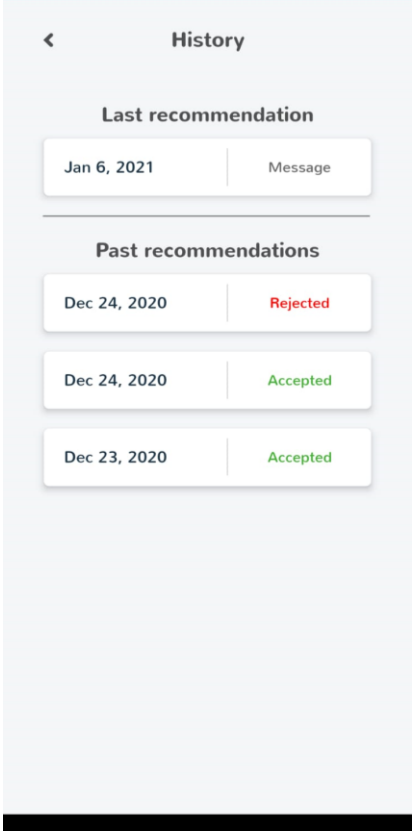
4 Modify the **Glucose Target** field according to the glucose target recommendation provided by your healthcare professional.

5 Tap **Save**.

Recommendations history

To view your recommendations coming from your healthcare provider, tab the **Recommendations history** button below your plan. This button will appear when at least one recommendation was shared with you by your healthcare provider.

You will see the following screen:



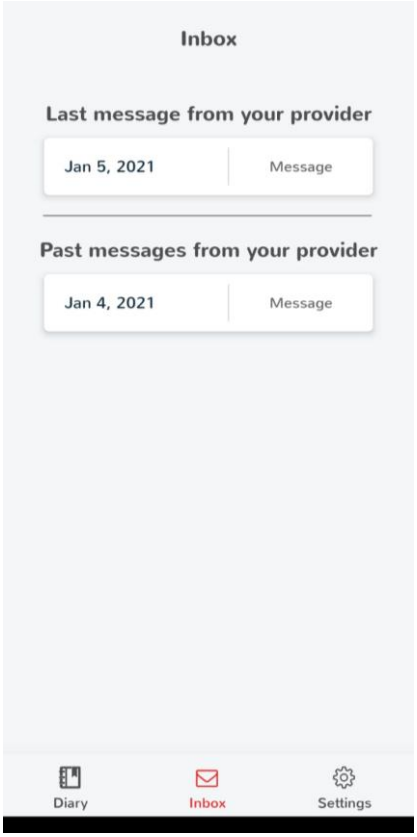
The last recommendation received will appear at the top of the screen, and the rest of the past recommendations are listed below. Tap a recommendation to view it.

Recommendations records show the date of the recommendation and your decision whether to approve or reject them. Recommendations that were not approved or rejected will appear as 'pending'. In some cases, your healthcare provider will share with you a textual message. These messages will be indicated as such. In some cases, your healthcare provider will use these messages to ask you to change your plan on your own. Be sure to use the edit button in the Plan screen to edit your plan accordingly.

Inbox

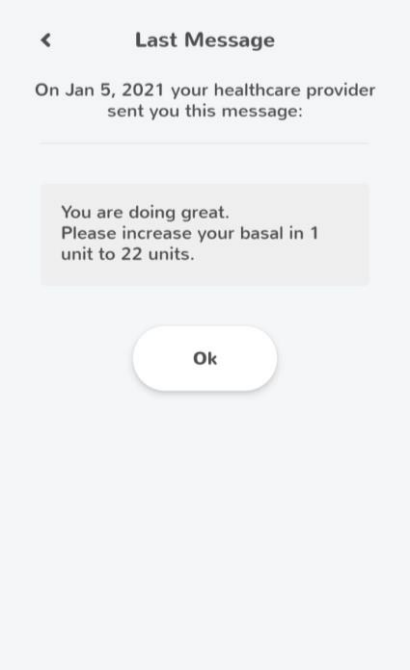
The **Inbox** menu displays incoming messages coming from your healthcare provider. This screen may be enabled by your healthcare provider and is only available for some users.

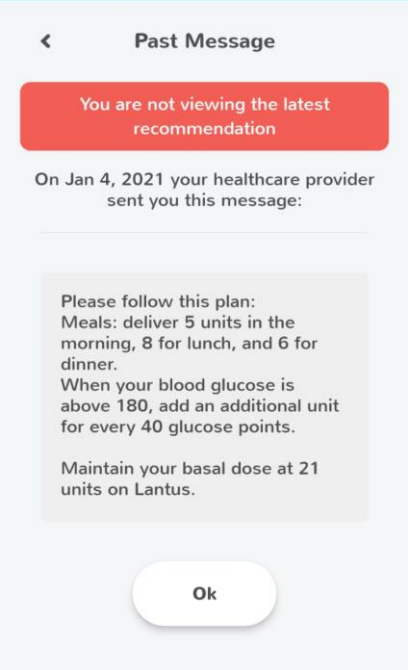
The last message received will appear at the top of the screen, and the rest of the past messages are listed below.



When a new message arrives, a popup message should appear and allow you to view it. Tap **Yes** to view it, or **Later** to close the notification. You can go at any time to the Inbox screen to view it.

View a message:



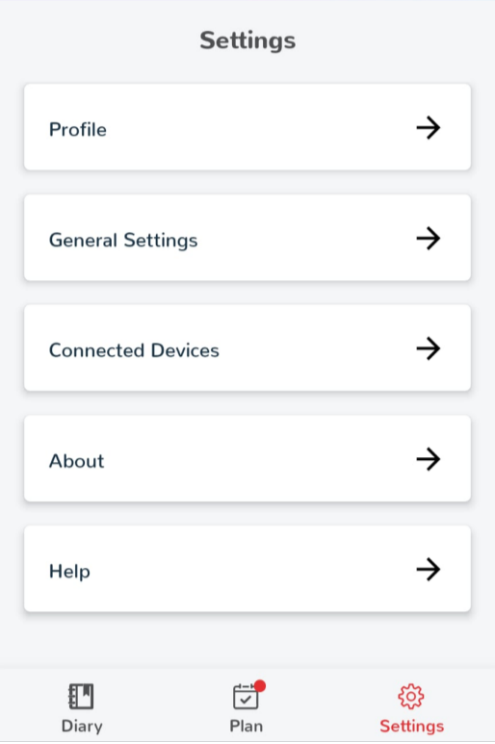


When viewing a message that is not your latest, a clear alert will appear at top of the screen.

Settings

The DreaMed Diary app is provided with various settings that define its behavior and how some things appear on the screen, such as how carb events are reported. Typically, your healthcare professional will set these things up for you. If needed, you can modify them in the **Settings** screen, as described below.

WARNING	**WARNING –** Before using the Bolus Calculator, make sure recommended to configure your smartphone to take their 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**. Using an incorrect time while using the bolus calculator may lead to potential harm.



The following setting options are provided –

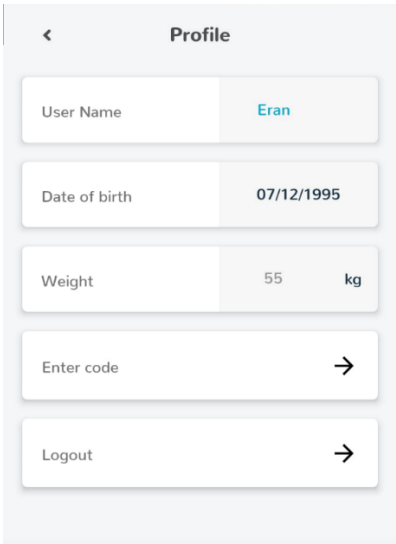
- **Profile,** page 51
- **General Settings,** page 52
- **Connected Devices,** page 53
- **About,** page 55
- **Help,** a link to this guide.

Profile

The **Profile** screen enables you to enter identifying information about yourself, as shown below.

▶ **To access the Profile screen –**

1 Tap **Settings** and then the **Profile** button. The following displays –



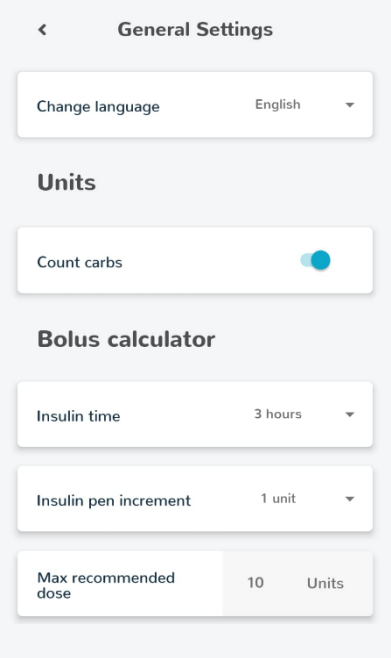
Your **User Name** was assigned to you when you were registered to the DreaMed Diary app by your healthcare professional and cannot be changed.

2 Fill out information about yourself, as follows –

- **Date of Birth/Weight –** You have the option to modify these as needed. It is not mandatory to enter these values. Weight must be entered in kilos.
- **Enter Code –** In special cases, you may be instructed to use this field to enter a code provided to you by your healthcare provider.

3 The **Logout** option logs you out of the app.

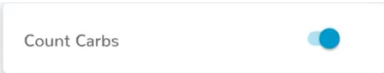
General Settings



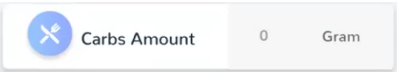
Change Language

The **Change language** option enables you to select the language of the user interface. Currently, English and Hebrew are available.

Count Carbs



When the **Count Carbs** option is **ON** (as shown above), when you add a new event (diary entry) the **Carb Amounts** field appears, as shown below and as described on page 25 –



Otherwise, when this option is not selected , the **Meal Size** field appears when you add an event, as shown below and as described on page 25 –

Bolus calculator settings

The following settings will appear only if your healthcare provider has enabled the bolus calculator in your app:

Active Insulin Time

The **Active Insulin Time** is the time used to calculate the insulin onboard for your bolus calculator and will initially be set by your healthcare provider.

Insulin Pen Increment

This setting determines the increment of the insulin pen being used. Options are 0.5 unit or 1 unit.

Maximum Recommended Dose

This option determines the maximum amount of insulin that the bolus calculator can recommend. This setting is usually set by your healthcare provider. If the setting was not defined for you (and it is defaulted to 99 units), you can set it to ensure that the bolus calculator will not recommend doses that are not suitable for you.

Connected Devices

Tap the **Connected Devices** button in the Settings section to connect your DreaMed Diary app to one of the following devices –

Connecting to a Dexcom Sensor

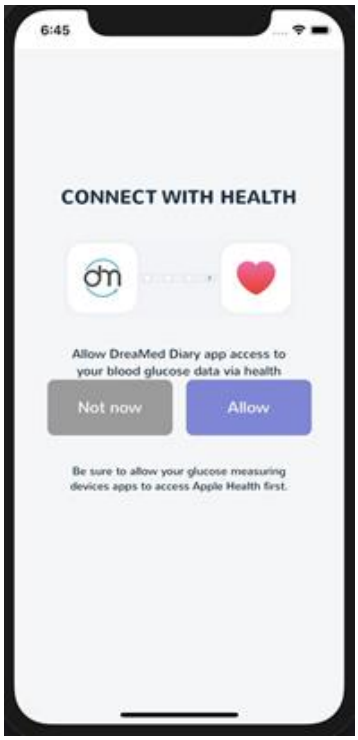
To connect the DreaMed Diary app to a Dexcom sensor, following the instructions described on page 16.

Connecting a Dexcom Sensor to Apple Health

Apple Health is only available on iOS devices.

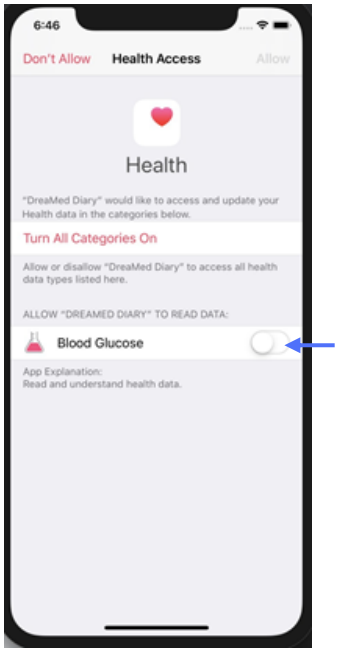
▶ **To connect to a Dexcom sensor using Apple Health –**

1 Select **Apple Health** to display the following –

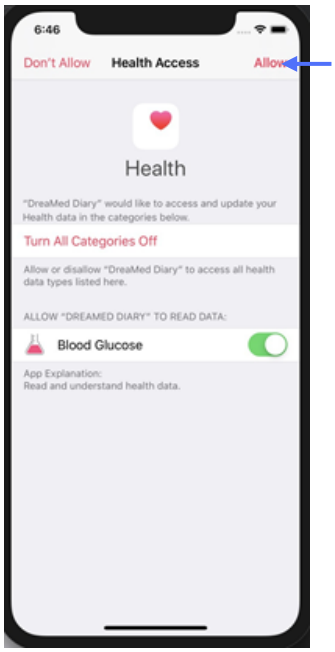


2 Tap **Allow** to enable DreaMed Diary to access blood glucose data in Apple Health.

3 In the following screen, turn on the **Blood Glucose** option.



The following screen displays –



4 Tap **Allow**.

About

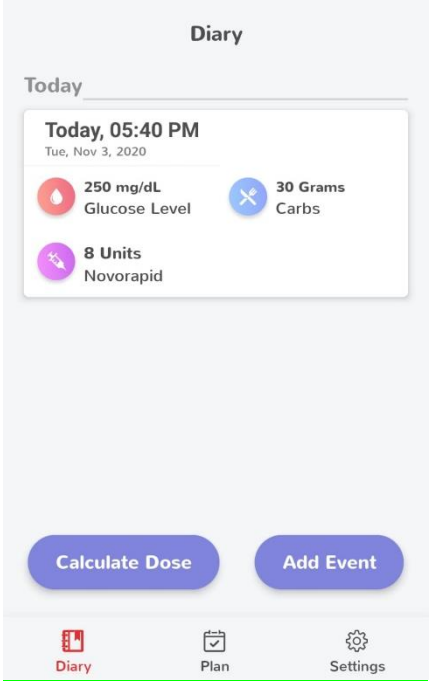
Displays the DreaMed Diary app version number.

Help

Opens this user manual.

Chapter 4 – Using the Bolus Calculator

If your healthcare professional has enabled you to access the Bolus Calculator, the **Calculate Dose** button will be displayed on the Diary main screen, as shown below. The Bolus Calculator helps you calculate the amount of insulin you need to inject for your bolus, based on your current bolus plan. The Bolus Calculator can currently be used by users who use carb counting treatment plans.



WARNING

Before using the Bolus Calculator, make sure that your bolus plan is correct and up to date. Using an incorrect or an outdated treatment plan may lead to potential harm.

Caution

In order to prevent potential insulin overdose, make sure that all of your bolus injections from the last four hours are logged correctly in the diary.

WARNING

It is highly recommended to configure your smartphone 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**.

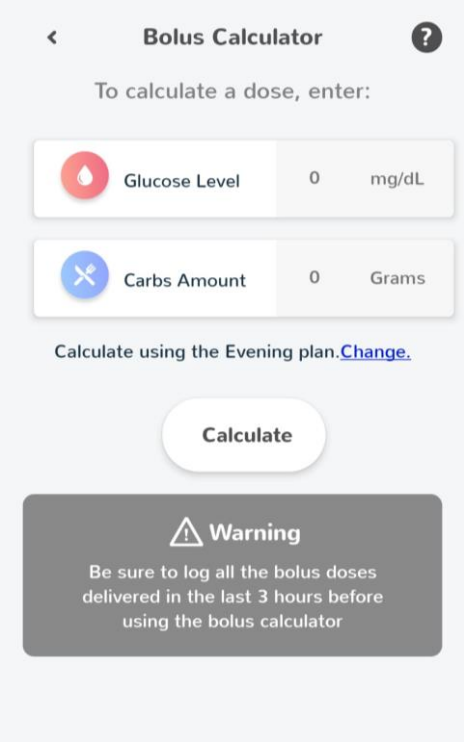
iOS: In the **Settings** menu ➔ **General** ➔ **Date & Time** ➔ turn on **Set automatically.**

Tap the **Calculate Dose** button and follow the displayed instructions for calculating your bolus. Enter your measured blood glucose level and the carbs amount you anticipate eating. You can enter either of these values or both for the calculation.

Caution — Be sure to use your current blood glucose level. Using an incorrect or outdated blood glucose level may lead to potential harm.

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.

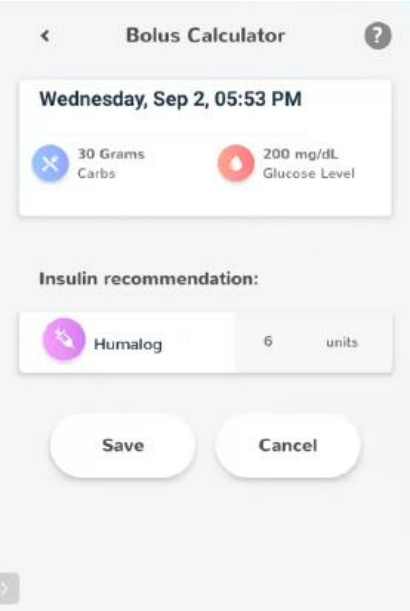


Tap the help button at the top right corner of the screen to view a quick bolus calculator guide.

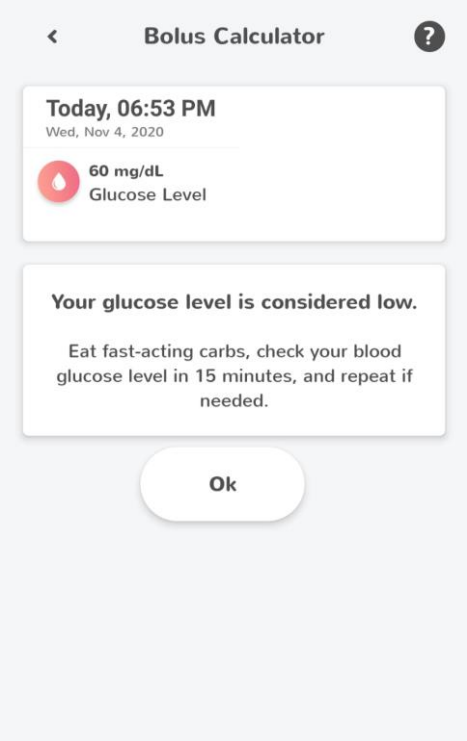
Tap **Calculate** to generate the bolus recommendation.

Caution Be sure to log all your insulin events from the last four hours or at least as specified in the **Active Insulin Time** found in your general settings (see page 53).

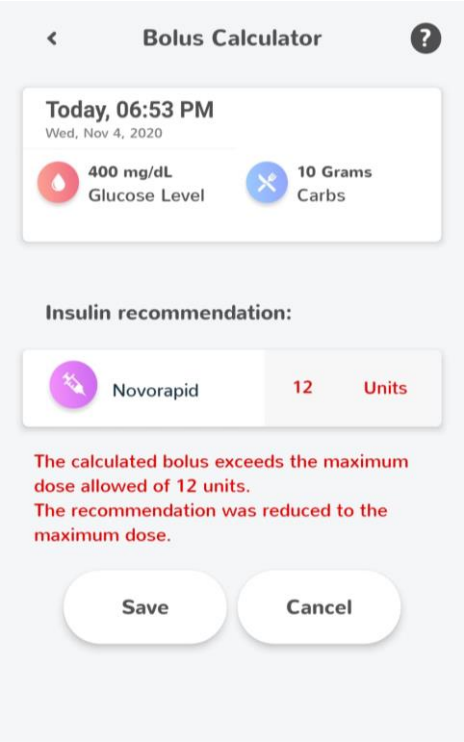
A recommendation is generated for the bolus. Tap **Save** to confirm that you intend to inject the amount of insulin recommended by the Bolus Calculator and to save the event in your diary. If you need to modify the recommended amount, you can do so and then tap **Save** to confirm that you intend to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



If your blood glucose is below 70mg/dl and you have not entered any carbs, 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.



The following screen displays when more than the **Maximum Recommended Dose** (see page 53) is recommended for the bolus.



Bolus calculator algorithm

The bolus calculator uses the following equation to calculate the suggested amount of bolus:

$$Bolus = Meal\ Bolus + Correction\ Bolus$$

Note:

- *The calculated bolus amount is rounded down to the nearest insulin pen resolution.*
- *The calculated bolus amount cannot exceed the maximum bolus amount, as defined in the general settings section, or go below 0 Units.*

The amount for the meal depends on the carbohydrate intake and the carbohydrate ratio (CR) at the time of the bolus, and calculated as follows:

$$Meal\ Bolus = \frac{Carbohydrate\ intake}{CR}$$

Note: If the CR is in 15- or 10-units exchange, $Meal\ bolus = carbohydreate \times CR$.

The correction bolus calculation depends on the entered glucose level (BG) and the bolus plan's correction factor (CF) and Target BG.
If BG is below the target glucose value, the correction bolus is calculated as follows:

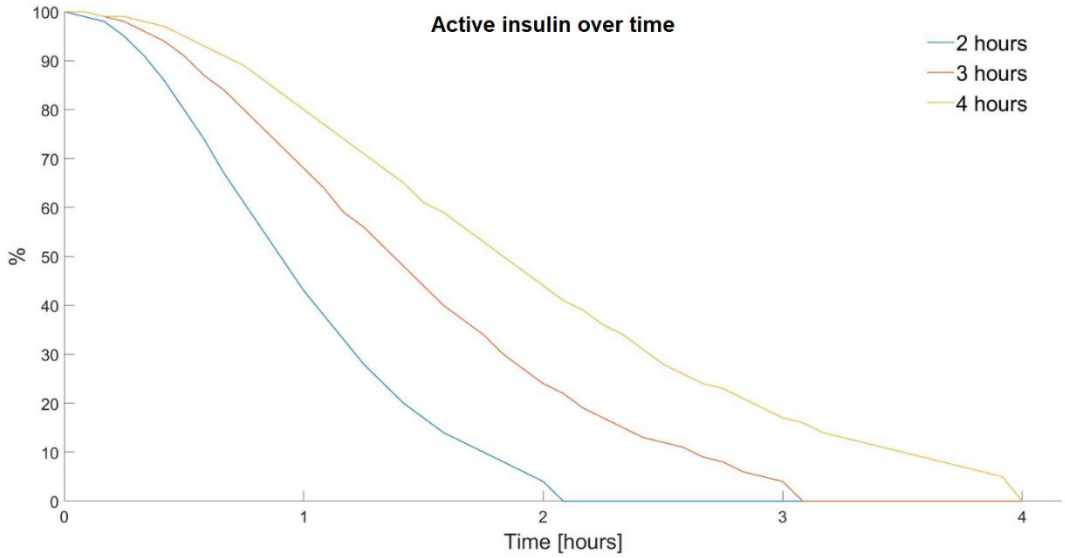
$$Correction\ Bolus = \frac{BG - Target\ BG}{CF}$$

If BG is above (or equal) the target glucose value, the correction bolus is calculated as follows, however will never be reduced below 0:

$$Correction\ Bolus = \frac{BG - Target\ BG}{CF} - Active\ Insulin$$

Note: In practice, the AI is calculated using the following decays:[1]

[1] Adapted from Mudaliar et al, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501



The total dose is calculated by adding the meal dose and the correction dose, rounded to the nearest pen increment.

Example I: Eating, BG above target, no AI and rounding the recommended amount

Carbohydrates intake (g)	45
Carbohydrate Ratio ($\frac{g}{U}$):	10
Current BG (mg/dL):	200
Target BG (mg/dL):	100
Correction Factor ($\frac{mg/dL}{U}$):	50
Active Insulin (AI):	0
Pen resolution (Units)	1

$$Meal\ Bolus = \frac{grams\ of\ carb\ intake}{CR} = \frac{45}{10} = 4.5\ U$$

$$\text{Correction Bolus} = \frac{BG - Target\ BG}{CF} - AI = \frac{200 - 100}{50} - 0 = 2\ U$$

$$\text{Suggested bolus} = 4.5 + 2 = 6.5 \xrightarrow{Round\ down} 6\ U$$

Example II: Eating, BG above target, with AI that nullifies the correction amount

Carbohydrates intake (g):	50
Carbohydrate Ratio ($\frac{g}{U}$):	1: 10
Current BG (mg/dL):	200
Target BG (mg/dL):	100
Correction Factor ($\frac{mg/dL}{U}$):	50
Active Insulin (AI):	3
Pen resolution (Units)	1

$$Meal\ Bolus = \frac{grams\ of\ carb\ intake}{CR} = \frac{50}{10} = 5\ U$$

$$\text{Correction Bolus} = \frac{BG - Target\ BG}{CF} - AI = \frac{200 - 100}{50} - 3 = -1 \xrightarrow{nullify\ value} 0\ U$$

$$\text{Suggested bolus} = 5 + 0 = 5\ \text{U}$$

Example III: Eating, BG below target, with AI and round up negative correction when glucose below target

Carbohydrates intake (g):	50
Carbohydrate Ratio ($\frac{g}{U}$):	1: 10
Current BG (mg/dL):	60
Target BG (mg/dL):	100
Correction Factor ($\frac{mg/dL}{U}$):	50
Active Insulin (AI):	1
Pen resolution (Units)	0.5

$$Meal\ Bolus = \frac{grams\ of\ carb\ intake}{CR} = \frac{50}{10} = 5\ U$$

$$\text{Correction Bolus} = \frac{BG - Target\ BG}{CF} = \frac{60 - 100}{50} = -0.8\ U$$

$$\text{Suggested bolus} = 5\ + (-0.8\ ) = 4.2 \xrightarrow{rounded\ down} 4\ U$$

Example IV: Not eating, BG above target, with AI

Carbohydrates intake (g): 0

Carbohydrate Ratio ($\frac{g}{U}$): 1: 10

Current BG (mg/dL): 250

Target BG (mg/dL): 100

Correction Factor ($\frac{mg/dL}{U}$): 50

Active Insulin (AI): 1

$$Meal\ Bolus = \frac{grams\ of\ carb\ intake}{CR} = \frac{0}{10} = 0\ U$$

$$\text{Correction Bolus} = \frac{BG - Target\ BG}{CF} - AI = \frac{250 - 100}{50} - 1 = 2\ U$$

$$\text{Suggested bolus} = 0\ + 2\ = 2\ \text{U}$$

Example V: Eating, No current BG, with AI

Carbohydrates intake (g): 45

Carbohydrate Ratio ($\frac{g}{U}$): 1: 10

Current BG (mg/dL): -

Target BG (mg/dL): 100

Correction Factor ($\frac{mg/dL}{U}$): 50

Active Insulin (AI): 0.5

$$Meal\ Bolus = \frac{grams\ of\ carb\ intake}{CR} = \frac{45}{10} = 4.5\ U$$

$$\text{Correction Bolus} = 0\ U$$

$$\text{Suggested bolus} = 4.5 + 0 = 4.5\ \text{U}$$

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