






# T1D1

## Instructions for Use

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# 1. Symbols

	Warning / safety instruction
	Important note
	Manufacturer
	Indicates that the item is a medical device
	See operating instructions

## 2. Introduction

This user guide will explain how to use the T1D1 mobile application. Read it carefully before you use T1D1.



**You should read this manual before use. Not adhering to the instructions could result in too much or too little insulin being delivered. This could lead to severe hypoglycemia or hyperglycemia.**

**It is advised that individuals who are blind or have visual impairments refrain from using T1D1 unless they have the support of a sighted person trained in its operation.**

### 2.1. System Description

The T1D1 mobile application helps you calculate your insulin doses using current glucose and carbohydrates. With the app, you can track your insulin doses and share your therapy with healthcare professionals or family members. The insulin dose calculations provided by T1D1 are meant for patients from age 12 with type 1 diabetes mellitus who are undergoing multiple daily injection (MDI) therapy.

The use of dose calculators in collaboration with experienced healthcare professionals has been found to optimize glycemic control among MDI patients. Furthermore, dose calculators have been shown to alleviate patient concerns related to hypoglycemia and enhance patient confidence in managing their diabetes effectively.

#### 2.1.1. Key Features

- Calculate insulin doses using current glucose and carbohydrates
- View and share diabetes therapy reports with your healthcare provider
- Create insulin calculator profiles for specific situations and daytimes
- Store and retrieve carbohydrate information of foods in a personal food library
- Access all key features while offline

#### 2.1.2. Support

- Onboarding wizard within the app
- Quick Guide link within the app
- User Manual link within the app

### 3. Indications for Use


The T1D1 application is indicated to assist with the management of Type 1 diabetes by people with diabetes age 12 and older by calculating insulin dose based on user entered data.

A healthcare professional must provide the patient-specific target blood glucose, insulin-to-carbohydrate ratios, and the correction factor (also known as the insulin sensitivity factor) to be programmed into the software.

### 4. Contraindications

The T1D1 application is not intended for anyone unable or unwilling:

- To test blood glucose (BG) levels as recommended by a healthcare provider
- Maintain sufficient diabetes self-care skills
- Visit a healthcare provider regularly


	<p><b>Important Pediatric User Information</b></p> <p>The provided guidelines aim to assist young patients and their caregivers in effectively handling the T1D1 app. Before using T1D1, patient caregivers need to consult a healthcare professional to determine the suitability of this system for the young patient.</p> <p>In cases where patients are not independently managing their condition, they must be constantly monitored by a caregiver. Accidental presses of buttons could lead to unintended recording of doses or modifications in the settings. These modifications have the potential to trigger episodes of either low blood glucose or high blood glucose, which may result in severe harm or even fatality.</p>
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## 5. Supported Devices

The T1D1 application is compatible with smartphones with the following operating systems:

- iOS 15 or later
- Android 9 or later


To ensure continuous compatibility, the app will request to install updates. At the same time, please make sure that you install the latest operating system on your device and check that your device has enough memory storage. Otherwise, you will not be able to install the app or log insulin doses. The T1D1 application is for single-patient use only.


	<b>To ensure integrity and security, T1D1 must not be used on devices that are rooted or have a Jailbreak installed.</b>
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## 6. Getting Started

The following steps get you started using the T1D1 application:

1. Download the T1D1 application from the official Apple App Store or the Google Play Store and install it on your device.
2. Open the application.
3. Create a new account (or log in to the application using an existing account).
4. Follow the steps in the onboarding wizard.

	<b>Download the T1D1 app from the Apple App Store or the Google Play Store. Do not attempt to install T1D1 via any other channels.</b>
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	<b>Do not share your credentials with other persons, as they might change important settings, which may lead to inaccurate bolus calculations.</b>
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## 6.1. Onboarding Wizard



**To use the T1D1 app safely, it is extremely important that the calculator settings are correct. Proceed only after they have been reviewed by your healthcare provider.**

Before you can use the app, your healthcare provider needs to provide the settings for the dose calculator and your long-acting insulin. In the best case, bring your mobile device with the T1D1 application to your healthcare provider and together enter the dose calculator settings and the basal (long-acting) insulin dose.

1. First, select the **Glucose unit** (*mg/dL* is the common unit type in the USA)
2. Enter the **blood glucose target** that has been defined by your healthcare provider. This is the blood glucose level you want to achieve.
3. Enter the **correction factor** (sometimes also referred to as Insulin Sensitivity Factor) that has been defined by your healthcare provider. This is the amount your blood glucose is lowered by 1 unit of insulin.
4. Enter the **carb ratio** that has been defined by your healthcare provider. This is the number of grams of carbohydrates covered by 1 unit of insulin.
5. Enter the **basal insulin** (long-acting) units that have been defined by your healthcare provider.
6. In the last step, carefully review your settings and acknowledge that the settings have been approved by your healthcare provider, by tapping the checkbox.

If it is not possible to do the onboarding together with your healthcare provider, you can enter the provided settings yourself and send your healthcare provider a screenshot to approve the correctness of the settings.

## 7. Bolus Insulin Calculation

Before using the insulin dose calculator please take a few minutes to better understand the insulin bolus calculation and read about factors that may affect the insulin dose you need to achieve your target blood glucose level. Better understanding these factors and the bolus calculation will help avoid making mistakes that may result in too much or too little insulin, which could lead to hypoglycemia or hyperglycemia.

The bolus insulin (BI) calculation sums up two components that account for the insulin you need to achieve your target blood glucose (BG) level: The Meal Insulin and the Correction Insulin.

**Meal Insulin** reflects the insulin dose your body needs to control the carbohydrates consumed in a meal.

The Meal Insulin dose is calculated by dividing the carbohydrates (CHO) in a meal by your specific insulin-to-carbohydrate ratio (ICR). The ICR is prescribed by your healthcare provider.

$$\text{Meal Insulin} = \frac{\text{CHO}}{\text{ICR}}$$

The **Correction Insulin**, reflects the insulin dose you need to correct for a currently elevated blood glucose level (i.e. a Current BG value that is higher than the Target BG value). Therefore, the Correction Insulin accounts for the difference between your measured Current BG and the Target BG. This difference is divided by your specific Correction Factor (CF).

$$\text{Correction Insulin} = \frac{\text{Current BG} - \text{Target BG}}{\text{CF}}$$

Putting all together boils down to the following formula:

$$\text{Bolus Insulin} = \frac{\text{CHO}}{\text{ICR}} + \frac{\text{Current BG} - \text{Target BG}}{\text{CF}}$$


Note that you can display the formula on the bolus calculation screen. The formula will be filled with your entered values and will help you to oversee the calculation. To activate this feature, navigate to **Settings/Advanced Settings/Display formula**.

### 7.1. Negative Correction

Sometimes your current BG level may be lower than the target BG. By examining the formula, it becomes evident that the Correction Insulin becomes negative. This means that there is no need for additional insulin to correct the current BG level because it is already lower than the desired target BG. The negative value in the Correction Insulin reduces the overall bolus insulin dose. This is called a negative correction.



Some patients do not take into account a negative correction and only consider the Meal Insulin in this situation. In other words, they set the Correction Insulin to zero if it becomes negative. If your healthcare provider advises you to do likewise and omit any negative Correction Insulin, you can disable negative correction by navigating to **Settings/Advanced Settings/Negative correction**.

	<b>If you are unsure about enabling/disabling Negative correction, please ask your healthcare provider for guidance.</b>
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## 7.2. Insulin on Board - Insulin Stacking

Another factor that should be considered when calculating your bolus insulin is the insulin on board (IOB). The IOB (sometimes referred to as Active Insulin) is the insulin that is still actively working in the body after a previous insulin dose. IOB still has the potential to lower your blood glucose and should be taken into account when calculating a new dose of bolus insulin. By reducing your bolus calculation you can avoid administering too much insulin.

Related to IOB is insulin stacking. Stacking is when you give yourself a bolus dose before the active insulin is fully absorbed. Talk to your healthcare provider to know how much time you should wait in-between boluses.

	<b>Ask your healthcare provider how to handle insulin on board and avoid insulin stacking, when calculating bolus insulin.</b>
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To help you keep an eye on IOB, the T1D1 application shows on top of the bolus calculator screen how long it has been since your last logged insulin dose for a period of 4 hours.

Note that basal (long-acting) insulin is not considered in Insulin on Board.

## 7.3. Physical Activity

Also physical activity can have a significant impact on bolus insulin calculation because exercise can affect blood glucose levels and insulin sensitivity. Physical activity enhances insulin sensitivity, meaning that the body's response to insulin becomes more efficient during and after exercise. As a result, less insulin may be required to achieve the same blood glucose-lowering effect. Thus, exercise can lead to changes in blood glucose levels. Depending on the intensity, duration and type of activity, blood glucose levels may either decrease or increase during or after exercise. Therefore, seek advice from your healthcare provider on how you should adjust your bolus calculation.

The T1D1 application offers the functionality of *insulin calculator profiles* (see section [12 Settings - Calculator Profiles](#)) where you can define calculation settings for specific situations, such as insulin administration before sports.

## 7.4. Day-Time Dependent Fluctuations





Your bolus calculation may also change over the course of a day due to various factors that affect insulin sensitivity and individual insulin requirements. Insulin sensitivity may be higher in the morning and lower in the afternoon or evening. This means that the ICR used to calculate the bolus dose may need to be adjusted accordingly. It may also make sense to adjust Target BG throughout the day, for example, to avoid night-time hypoglycemia. Therefore, it is advisable to discuss potential adjustments in the diabetes management plan with your personal healthcare provider.

You can make adjustments for day-time dependent fluctuations in the *insulin calculator profiles* (see section [12 Settings - Calculator Profiles](#)) where you can define calculation settings for specific situations, such as for breakfast, lunch, dinner, and nighttime.

## 7.5. Other Factors

Besides the factors discussed, many other variables impact insulin therapy and often vary between individuals. To gain better control of your insulin therapy, keep a regular insulin log and most importantly frequently measure your blood glucose. This will not only keep you safe but will help your healthcare provider to optimize your treatment plan together with you.

## 8. Insulin Bolus Calculator

	<p><b>It is extremely important that the calculator settings are correct. Proceed only after they have been reviewed by your healthcare provider.</b></p>
	<p><b>Before administering an insulin dose, always check your inputs and settings. The calculated dose is a suggestion; you decide to follow it or rely on your own judgment. The calculator does not account for all factors like activity, illness, alcohol use, etc.</b></p>
	<p><b>Always check your blood glucose after administering insulin and take any necessary measures. If you are unsure, contact a healthcare professional immediately.</b></p>
	<p><b>Only use the medication for bolus insulin that has been prescribed by your healthcare provider. If you are unsure if the medication is the correct one, ask your healthcare provider.</b></p>

To use the Insulin Bolus Calculator tap on *Calculator* in the navigation bar.

**Important: If you have logged Bolus (rapid-acting) insulin in the last 4 hours a message will inform you on the top of the screen to let you know you may still have insulin on board.**

1. Select the insulin calculator profile (see [12 Settings - Calculator Profiles](#)). If you have not enabled multiple profiles, choose Bolus (rapid-acting) insulin.
2. Enter your measured current blood glucose level.
3. Enter the Carbohydrates you will consume **in grams**.
4. Hit *Calculate* - the recommended insulin dose will be displayed.
5. Now, you can add a note, for example, if you plan to do sports later and hence take less insulin than recommended. You can adjust the recommended insulin after logging it.
6. By tapping *Log it*, your insulin calculation along with the note is saved to the insulin log.

The screenshot shows the Insulin Bolus Calculator app interface. At the top, the time is 9:41 and the user is identified as John Deo. The app is set to a target of 150mg/dL. The interface is divided into three numbered sections: 1. Insulin profile: A dropdown menu is set to 'Bolus (rapid-acting) insulin'. 2. Blood glucose: A text input field contains 'e.g., 125'. 3. Total carbs: A text input field contains 'e.g., 25'. Below these sections is a large grey 'Calculate' button. At the bottom of the screen is a numeric keypad with digits 1-9, 0, and a backspace key.


## 9. Logging Basal (long-acting) Insulin



**Only use the medication for basal insulin that has been prescribed by your healthcare provider. If you are unsure if the medication is the correct one, ask your healthcare provider.**

By selecting Basal (long-acting) insulin on the Calculator screen, you can log your basal (long-acting) insulin so you can remember when you took your long-acting shot of insulin. The units of insulin are defined during the onboarding.

# 10. Insulin Log



**Make sure to log all the insulin you have taken. Only with a complete log of your insulin therapy, your healthcare provider can give reasonable recommendations for your therapy.**

To view, edit, and share your Insulin Log, tap on *Log* in the navigation bar.

### View

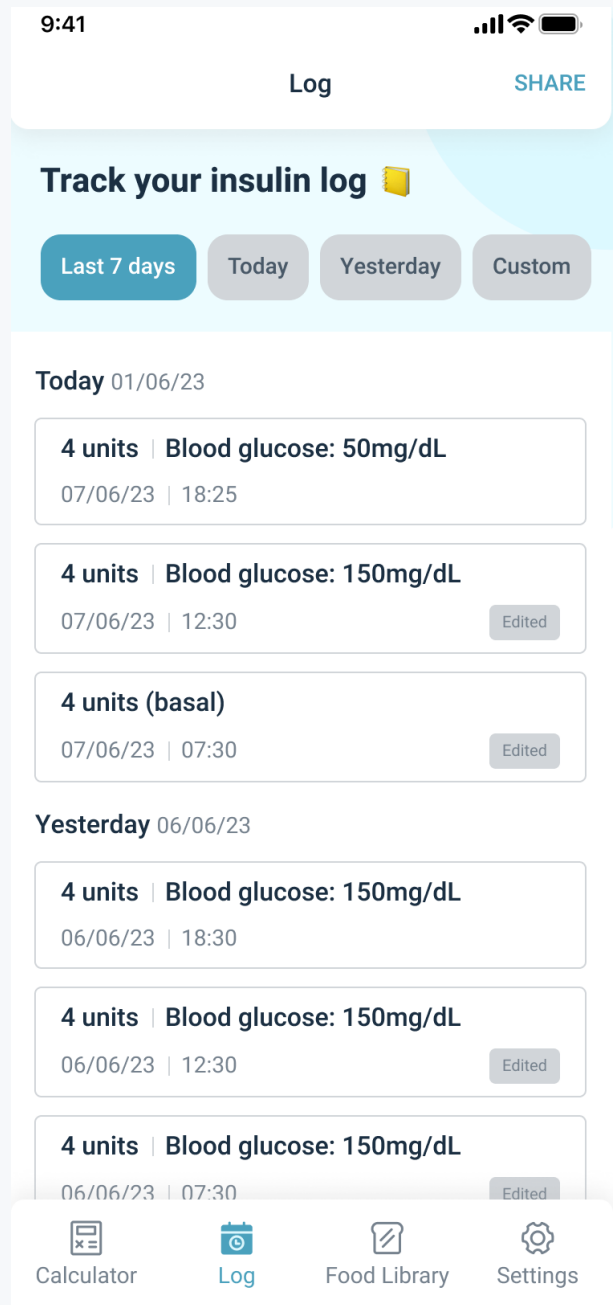
All insulin logs are listed here chronologically. You see the insulin units for logged basal (long-acting) insulin, and insulin units and the blood glucose for logged bolus (rapid-acting) insulin. Tapping on a specific log opens a detailed view with more information.

### Edit

If you want to edit or add any information to a log, tap on one of the entries and then tap on the pencil icon in the top right corner. Note that the app will indicate if changes were made to the log.

### Share

If you want to share an insulin log, tap on the *SHARE* button on the top right. You can modify the date range if needed and then tap *Share*. Now, two CSV files are ready to be shared. In one file, all logs are tabulated with all the settings and entered values. The other CSV file summarizes your insulin logs for each day.



The screenshot shows the 'Log' screen of the app. At the top, the time is 9:41 and there are status icons for signal, Wi-Fi, and battery. The title 'Log' is centered, and a 'SHARE' button is in the top right. Below the title is a section titled 'Track your insulin log' with a yellow sticky note icon. Underneath are four filter buttons: 'Last 7 days' (highlighted in blue), 'Today', 'Yesterday', and 'Custom'. The main content area shows a list of logs for 'Today 01/06/23'. Each log entry is in a rounded rectangle and includes: '4 units | Blood glucose: 50mg/dL' (18:25), '4 units | Blood glucose: 150mg/dL' (12:30, with an 'Edited' button), and '4 units (basal)' (07:30, with an 'Edited' button). Below this is a section for 'Yesterday 06/06/23' with three similar log entries, each with an 'Edited' button. At the bottom is a navigation bar with four icons: Calculator, Log (highlighted), Food Library, and Settings.

# 11. Food Library

To use the Food Library, click on the Food Library icon in the navigation bar.

The Food Library allows you to create a list of the foods you commonly eat, so you don't have to look up or calculate carbohydrates all the time. The Food Library will help you keep track of your foods, their carb amounts, quantities, and any notes that you have.

### Add food

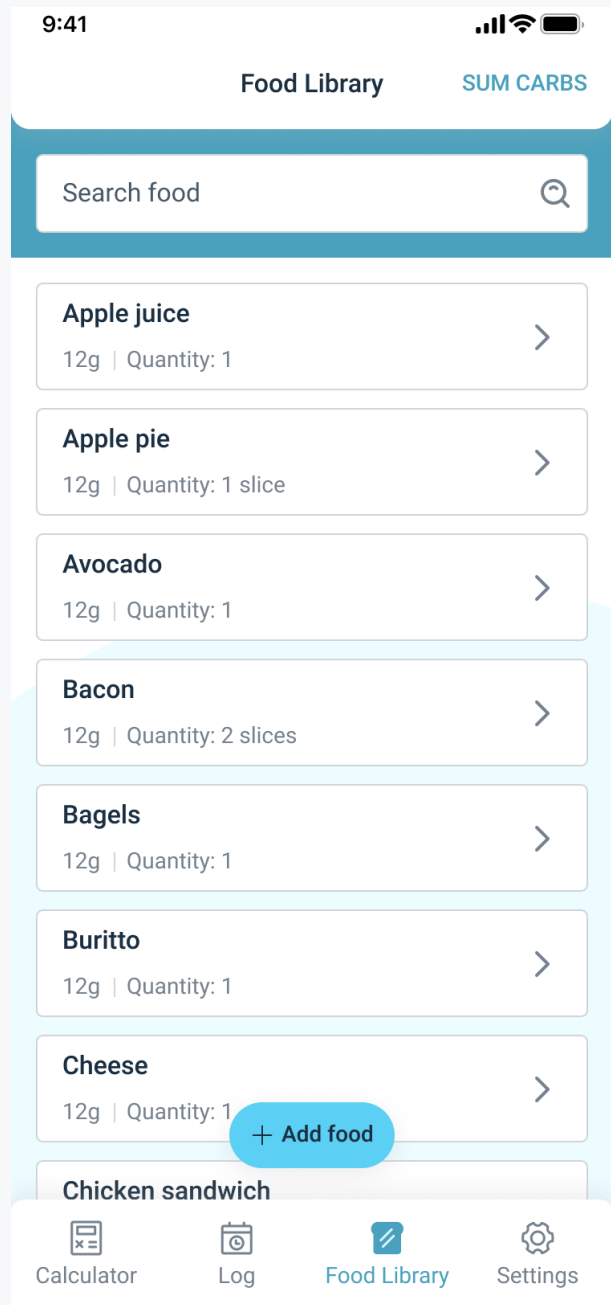
Tap on the *Add Food* button (at the bottom of the screen) and enter the food name, the carbohydrate amount in grams, the food's quantity, and any note.

**Important! When adding a food item to your food library, please always carefully check if the carbohydrate value is correct. You can do this by:**

- checking the carbohydrate value on the label of a packaged product,
- looking it up online on diabetes management websites ([www.cdc.gov, diabetes.org](http://www.cdc.gov/diabetes.org))
- looking up the food item on a curated nutrition facts database such as <https://fdc.nal.usda.gov/>.

### Calculate the total amount of carbs of multiple foods

Tapping on the *SUM CARBS* button on the top right corner of the screen lets you select foods for which the total amount of carbs is displayed on top of the screen.



## 12. Settings - Calculator Profiles

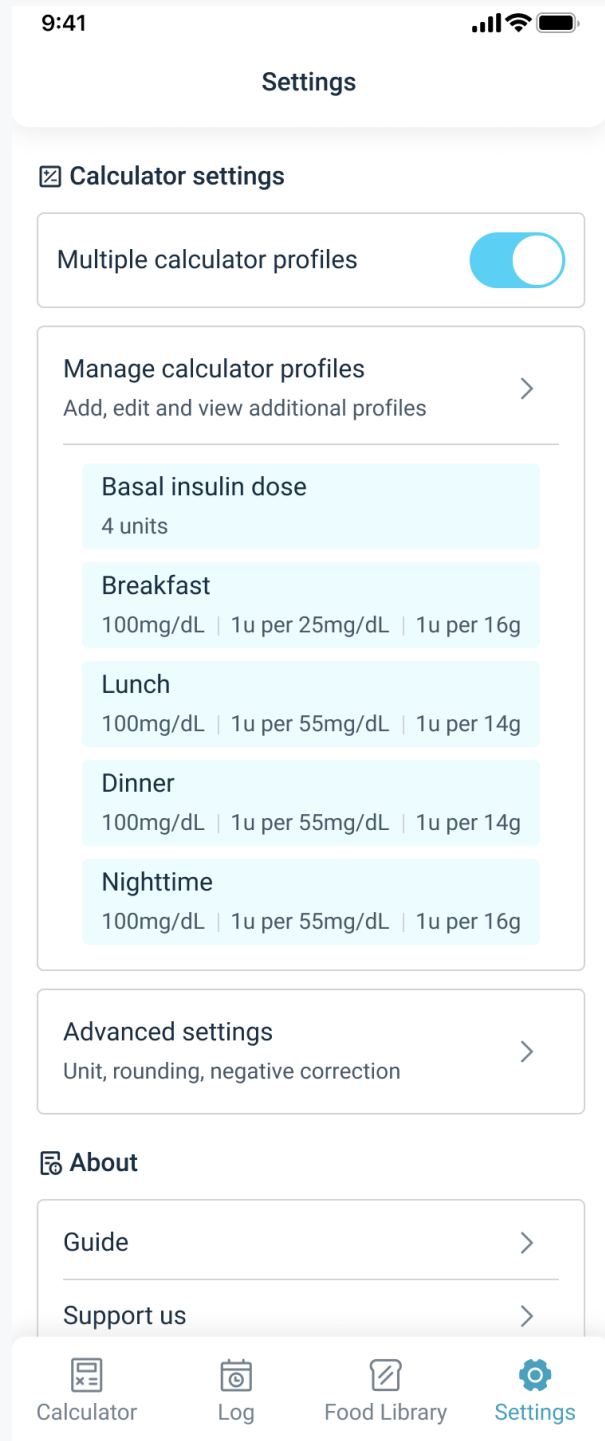
As outlined in the section [Bolus Insulin Calculation](#) you may want to have specific calculator settings for various situations.

For example, your insulin-to-carbohydrate ratio might differ between breakfast and dinner, or you want to adjust the bolus insulin calculation before doing sports. For this, you can enable Multiple calculator profiles at the top of the *Settings* screen.

Enabling Multiple calculator profiles creates four typical profiles (Breakfast, Lunch, Dinner, and Nighttime) with the settings defined in the Onboarding Wizard.

You can add more profiles, delete profiles, change the name of a profile, re-arrange the display order, and adjust all the settings. To do this, tap on *Manage calculator profiles*.

**Important: It is extremely important that the calculator settings are correct. Proceed only after they have been reviewed by your healthcare provider.**





# 13. Settings - Advanced Settings

## Negative correction

In the Advanced Settings you can enable/disable the Negative correction. Refer to the section [Negative Correction](#) for more information.

**Important: If you are unsure about enabling/disabling Negative correction, please ask your healthcare provider for guidance.**

## Glucose unit

Here, the blood glucose unit can be changed. This affects the settings of your target blood glucose and the correction factor. If you change the glucose unit, the currently set values are automatically adjusted by the application.

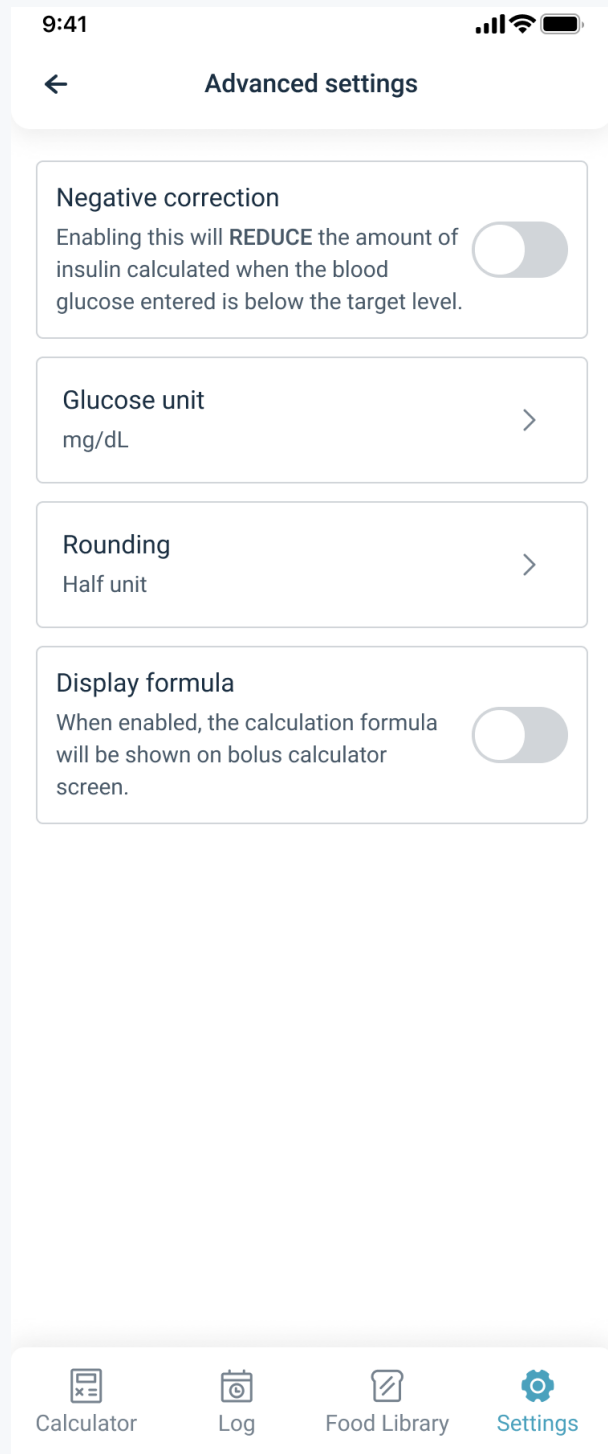
**Important: Do not change the Glucose unit, unless your healthcare provider advises you to do so.**

## Rounding

Rounding defines how the bolus (rapid-acting) units are displayed in the calculator. You can choose between no rounding, and rounding the insulin dose to half units or rounding to full units. Make a choice based on what your healthcare provider recommends.

## Display formula

When enabled, the calculation formula is displayed on the bolus calculator screen to help you review the calculation.



# 14. Important Information

## **Apple Legal Notice**

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## 14.1. Contact



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