

# mySugr Bolus Calculator App User Manual

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#### Indications for use

#### Intended use

The mySugr Bolus Calculator, as a function of the mySugr Logbook app, is intended for the management of insulin dependent diabetes by calculating a bolus insulin dose or carbohydrate intake based on therapy data of the patient.

Before its use, the intended user performs a setup using patient-specific target blood glucose, carbohydrate to insulin ratio, insulin correction factor and insulin acting time parameters provided by the responsible healthcare professional. For the calculation, in addition to the setup parameters, the algorithm uses current blood glucose values, planned carbohydrate intake and the active insulin which is calculated based on the insulin action curves of the respective insulin type.

# Who is the mySugr Bolus Calculator for?

- The mySugr Bolus Calculator is designed for users:
- · diagnosed with insulin dependent diabetes aged 18 years and above
- treated with short-acting human insulin or rapid-acting analog insulin
- · undergoing intensified insulin therapy in the form of
- Multiple Daily Injections (MDI) or Continuous Subcutaneous Insulin Infusion (CSII)
- under guidance of a doctor or other healthcare professional
- who are physically and mentally able to independently manage their diabetes therapy
- · able to proficiently use a smartphone

#### **Environment for use**

As a mobile application, the mySugr Bolus Calculator can be used in any environment where the user would typically and safely use a smartphone.

#### **Contraindications**

#### Circumstances for bolus calculation

The mySugr Bolus Calculator can not be used when:

- the user's blood glucose is below 20 mg/dL or 1.2 mmol/L
- the user's blood glucose is above 500 mg/dL or 27.7 mmol/L
- the time of the log entry containing input data for the calculation is older than 15 minutes

#### Insulin restrictions

The mySugr Bolus Calculator may only be used with the <u>insulins listed</u> in the app settings and must especially not be used with either combination or long acting insulin.

The mySugr Bolus Calculator must only be set up and used with a single insulin type. Multiple insulin use is not permitted with this device.

# **Warnings**

#### The mySugr Bolus Calculator does not replace professional medical advice

The mySugr Bolus Calculator is used to support the treatment of diabetes, however it cannot replace regular visits to a doctor/diabetes care team. You still require professional and regular review of your long-term blood sugar values. You are responsible for continued self management of your blood sugar, independent of use of the mySugr Bolus Calculator.

Review and optimization of the mySugr Bolus Calculator parameters should be carried out during regular doctor visits.

## The mySugr Bolus Calculator depends on you inputting the correct data

The mySugr Bolus Calculator depends on the accuracy of information entered. It will not work correctly if you enter an inaccurate blood glucose value or carbohydrate count or mistype a therapy factor. You are always responsible for verifying the recommended insulin dose and using your best judgement based on personal experience.

## The mySugr Bolus Calculator is more accurate when used with current blood glucose

Bolus advice can be obtained without a current blood glucose value, however this option is not recommended for your safety. Calculations for insulin dosing without currentblood glucose levels increases your risk for hypoglycemia (low blood glucose) and hyperglycemia (high blood glucose). Please discuss this option and its risks with your healthcare professional.

#### The mySugr Bolus Calculator cannot assess specific circumstances

The mySugr Bolus Calculator cannot assess, nor compensate for circumstances such as the influence of stress, illness, or activity on your daily therapy. These individual circumstances may a9ect the required insulin dose and need to be monitored and adjusted as necessary for your individual therapy.

#### **Recommended updates**

To ensure safe and optimized running of the mySugr Bolus Calculator, it is recommended that you install software updates as soon as they are available.

#### Smartphone security and maintenance

To enhance security when using the mySugr Bolus

Calculator and to ensure that only you have access to it, it is required you have an authentication method (unlock mechanism) installed on your smartphone for initial setup of the mySugr Bolus Calculator and to update settings. You are advised to choose a strong password or other strong authentication method and to not share your password with unauthorised parties.

You are advised to only allow trusted applications to have permission to system services.

To ensure correct usability of the mySugr Bolus Calculator, you are advised to not use the application on a smartphone with a cracked or damaged screen.

To ensure integrity and security, the mySugr Bolus Calculator must not be used on smartphones that are rooted or smartphones that have a Jailbreak installed.

# The mySugr Bolus Calculator is for personal use only

Setup and usage of the mySugr Bolus Calculator is for your personal use only. Do not share the mySugr Bolus Calculator with other persons with diabetes to request bolus recommendations even if therapy conditions are similar as this could lead to serious medical harm.

# Installation

The mySugr Bolus Calculator is an extension of the mySugr Logbook. Just download the mySugr Logbook from the Apple App Store or the Google Play Store. For more detailed instructions on installation and usage of the mySugr Logbook, please check out the mySugr Logbook User Manual.

# Calculation

### **Activation**

To get started, open a new entry screen in the mySugr Logbook by selecting the '+' button (Figure 1). Import or manually input your blood sugar value and/or carb value and select the "Calculate" button in the Bolus Calculator field (Figure 2).

For each imported bolus, there is a new "Insulin (bolus)" entry with the date, time and the number of units delivered

The number of units is shown within a tile as shown below.



Figure 1: Open a new entry screen



Figure 2: Select the "Calculate" button

In some locations, the first time you use the mySugr Bolus Calculator we will ask you to unlock the mySugr Bolus Calculator by entering the activation code provided by your healthcare professional (Figures 3 and 4). If you are not asked for an activation code, you will be able to continue and set up your mySugr Bolus Calculator.



**Figure 3:** Activation code on protocol sheet (depending on your location)



Figure 4: Unlock your mySugr Bolus Calculator (depending on your location)

**IMPORTANT:** You have the possibility to add/remove and move the fields of your entry screen with the "Customize cells" button within the mySugr Logbook (Figure 5).

Tap the eye icon to show/hide cells (Figure 6). Please be aware that this function can have an impact on what you see in the log entry screen. If "Insulin (food)" and "Insulin(correction)" are hidden, the mySugr Bolus Calculator will also be hidden. Note: "Insulin (food)" and "Insulin (correction)" are grouped together and cannot be moved separately.



Figure 5: Customise cells

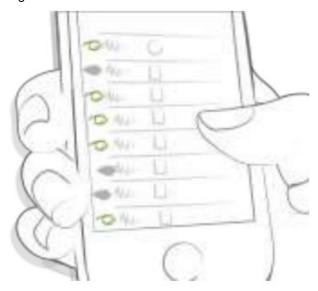


Figure 6: Show/hide cells

## Set up

To use the mySugr Bolus Calculator you need to set up a passcode, touch or face ID on your phone to make sure that only you can configure or change your mySugr Bolus Calculator settings. Before being able to receive any bolus recommendation, you will be asked a handful of questions about your personalized settings.

## Important definitions and default values

**Active insulin:** Insulin currently in the body that is working to lower blood sugar. This amount does not include any insulin that is working to account for carb intake. It also does not include basal insulin.

**Target range:** Acceptable upper and lower blood sugar level when fasting or before a meal (Default: 80–130 mg/dL or 4.4–7.2 mmol/L).

**Hypoglycemia:** The setting below which the blood sugar level is considered hypoglycemic (Default: 70 mg/dL or 3.9 mmol/L). In that situation you will be prompted with a recommendation to eat an appropriate amount of carbs.

**O9set time:** Expected amount of time before insulin begins to lower blood sugar levels in the body (Default: 60 minutes).

**Acting time:** Total length of time the insulin is expected to be e9ective at lowering blood sugar (Default: 4 hours and 30 minutes).

**Maximum bolus:** The maximum amount of insulin to be delivered at one time. This serves as a safety measure against unintended large boluses by asking your for added confirmation (Default: 25 U).

**Insulin increments:** The amount in units (U), usually 0.1 U 0.5 U or 1 U, by which your insulin dose is adjusted (Default: 1 U).

**Meal rise:** The maximum increase in your blood sugar level that is to be tolerated after a meal without the need for an additional correction bolus (Default: 75 mg/dL or 4.2 mmol/L).

**IMPORTANT:** These settings determine how your insulin dose is calculated, and as you can imagine, it's important to get them right. Please do not choose your settings without consulting your doctor or healthcare professional.

To ensure that the mySugr Bolus Calculator settings fit your diabetes therapy, you will be asked to review your settings every three months.

# **Time-dependent settings**

To define your settings per time period:

- Select "time-dependent" (iOS, Figure 7a) or enable "timedependent setting" (Android, Figure 7b) during the setup flow
- Select the time period and enter/edit the adequate value
- Repeat for each time period a9ected as each time period ends when the next one begins



Figure 7a: Switch to time-dependent settings (iOS)

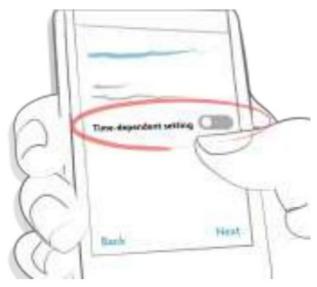


Figure 7b: Switch to time-dependent settings (Android)

**IMPORTANT:** Always consult with your healthcare professional about actions you should take (if any) when using multiple time periods and travelling to a di9erent time zone.

# Calculate

## Receive bolus advice

To calculate an insulin bolus, please follow the steps below:

- 1. Create a new log entry
- 2. Enter your current blood sugar value and/or intended carb intake
- 3. Select the "Calculate" button
- 4. Confirm that you haven't injected any insulin recently in order to receive the calculation result based on your settings and your log entries (more details in 5.5. Active insulin).



Figure 8: Enter your data



Figure 9: Select "Calculate"

## Bolus advice without entering blood sugar value

It is possible to receive bolus advice without entering a current blood sugar value. The recommended bolus amount will only reflect the insulin required for the meal or carbs you enter.

Note: Using a blood sugar result will ensure the most accurate bolus advice recommendation.

# Bolus advice with hypo blood sugar result

If your blood sugar is below your set hypo limit, an insulin recommendation will not be provided. Instead, you will receive a recommendation to eat a calculated amount of carbs in order to raise your blood sugar into your target range. For accuracy, please record the amount of carbs you will actually consume in your log entry.

### **Negative correction insulin**

When your blood sugar value is above your hypo limit and below the lower boundary of your target range, the mySugr Bolus Calculator may calculate a negative correction insulin.

This negative value is accounted for in the meal correction if you are planning to eat.

#### Confirm

It is possible that the recommendation doesn't suit your therapy habits or the way you currently feel. This is the reason why you are always able to dismiss or accept a recommendation, keeping you in control of your therapy and ensuring that your mySugr Logbook is as accurate as possible.

Typically, the calculation result is:

• an insulin dose, when your blood sugar is too high—the result field is coloured turquoise (Figures 10a and 10b) a carb intake, when a hypo (low blood sugar) is likely to occur without additional carbs. In this case – the result field is coloured yellow (Figures 11a and 11b)

To confirm or dismiss your recommendation:

• Select the "Accept" button if you agree with the suggested result. The calculated values will automatically split into the "Insulin (Food)" and "Insulin (Corr.)" lines, based on the provided entries (blood sugar level and / or carbs). If you want to adjust the insulin amounts after selecting the "Accept" button, you can edit them manually (Figures 10b and 11b).

• Select the "Dismiss" button if you feel that the recommendation doesn't fit your current state or your therapy habits. This action will simply close the mySugr Bolus Calculator section so you can add your insulin values manually in the "Insulin (food)" and "Insulin (corr.)" lines.



Figure 10a: Insulin bolus recommendation



Figure 10b: Edit Insulin recommendation

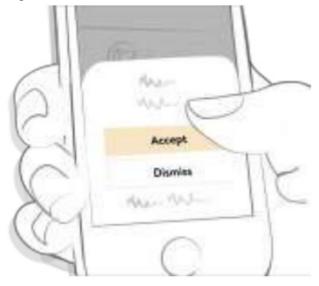


Figure 11a: Carbs recommendation

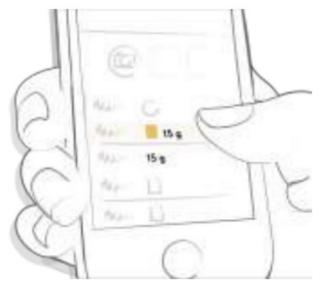


Figure 11b: Edit Carb recommendation

IMPORTANT: The mySugr Bolus Calculator makes insulin dose suggestions based on the information you enter. If the information you entered is incorrect or incomplete, the resulting insulin dose suggestion will not be accurate! Additionally, please consider that the calculation does not consider influences like stress, activity, illness, or other factors which may a9ect your blood sugar.

#### **Active insulin**

The mySugr Bolus Calculator also continuously calculates your active insulin. This is based on the last insulin doses you logged as correction insulin and your personal settings for the duration of the insulin acting time. Note: active insulin does not include any insulin that is working to account for carb intake. It also does not include basal insulin.

The active insulin value will be shown with each calculation as part of the calculation formula on the information screen

To read this information about your (active) insulin and your previous injections while using the mySugr Bolus Calculator, select the "i" button on iOS (Figure 12a and 12b) or "details" on Android (Figure 12c and 12d).



Figure 12a: Show bolus calculation info during recommendation (iOS)



Figure 12b: Show bolus calculation info after accepting a recommendation (iOS)

Figure 12c: Show bolus calculation info during recommendation (Android)

Figure 12d: Show bolus calculation info after accepting a recommendation (Android)

#### Save

Select "Save" to record your entry (Figure 13). By saving the log entry, the confirmed insulin dose (food and correction) or carb suggestion will be saved in the corresponding fields in the mySugr Logbook.

**Note:** please note that correction and food boluses will be saved and displayed separately in the mySugr Logbook. Your active insulin value is only accessible during the bolus calculation and will not be saved and displayed in the mySugr Logbook.



Figure 13a: Save entry (top navigation)



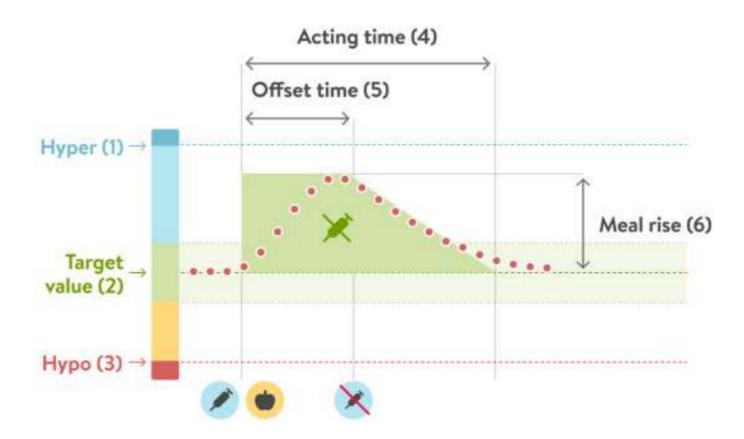
Figure 13b: Save entry (button)



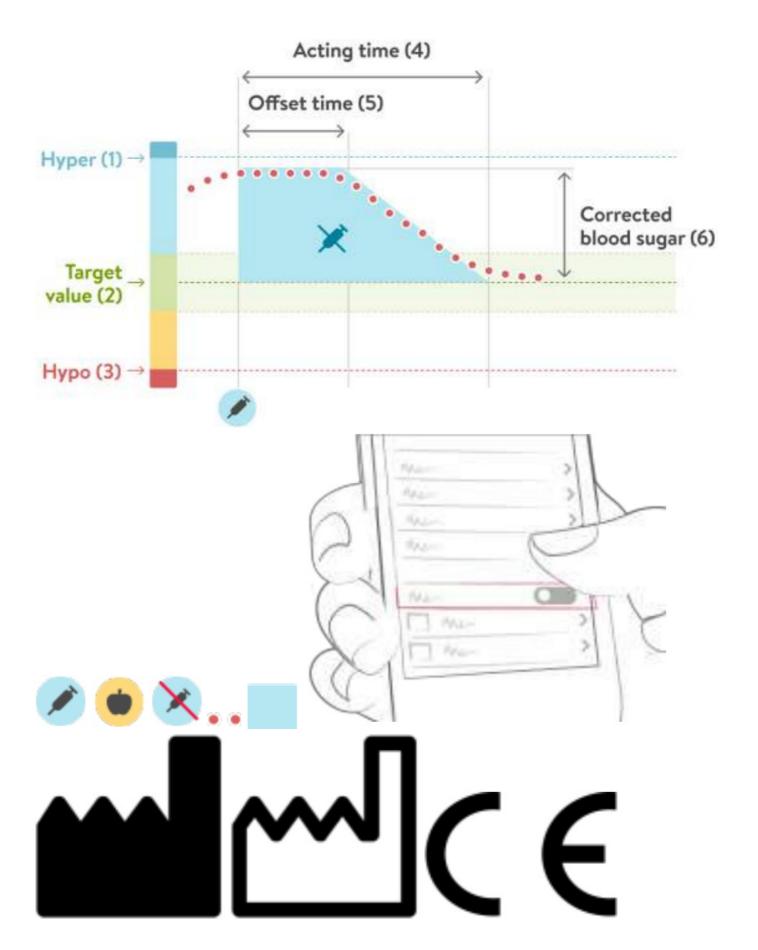
# Additional parameter explanations

# **Advanced definitions**

The following factors help to make sure that the mySugr Bolus Calculator does not recommend a second bolus for a blood sugar event e.g. meal intake or a high blood sugar level, that has already been covered by a previous insulin bolus.







## **Documents / Resources**

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mySugr Bolus Calculator App [pdf] User Manual Bolus Calculator App, Calculator App, App

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 the time of the log entry containing input data for the

# References

- Market Install | mySugr.com
- A Bem-vindo à Accu-Chek | Brasil
- <u>\* mySugr Helpcenter</u>
- User Manual

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