

# mySugr Bolus Calculator User Manual

Version: 2.1.16\_Android - 2020-04-22

## 1 Indications for Use

### 1.1 Intended Use

The mySugr Bolus Calculator is intended for the management of insulin dependent diabetes by calculating a bolus insulin dose or carbohydrate intake based on your entered data. Before its use, you perform a set-up by providing your specific target blood sugar, insulin to carbohydrate ratio, insulin sensitivity parameters and insulin action time. For the calculation, in addition to the set-up parameters that you provide, the algorithm uses current blood sugar values, ingested carbohydrates and the current insulin on board which is calculated based on the insulin action curves of the respective insulin type.

### 1.2 Who is the mySugr Bolus Calculator for?

The mySugr Bolus Calculator has been tailor-made for people:

- diagnosed with diabetes
- aged 18 years and above
- under the supervision 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

### 1.3 Environment for Use

As a mobile application, the mySugr Bolus Calculator can be used in any environment where there is an internet connection and where mobile phone use is permitted.

## 2 Contraindications

### 2.1 The Bolus Calculation can not be conducted under some circumstances

The bolus calculation cannot be performed when:

- you are in a state of hypoglycemia (blood sugar value is below your defined target range)
- your blood sugar is above 500 mg/dL or 27.7 mmol/L
- the time of the log entry is not within the last 15 minutes.

### 2.2 The mySugr Bolus Calculator has some insulin restrictions

The mySugr Bolus Calculator may only be used with the insulins listed in the app settings and should especially not be

used with either combination or long acting insulin.

## **2.3 Smartphone restrictions**

The mySugr Bolus Calculator should not be used on rooted devices or devices that have a Jailbreak installed.

## **3 Warnings**



### **3.1 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 (HbA1c). 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.

### **3.2 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 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.

### **3.3 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 affect the required insulin dose and need to be monitored and adjusted as necessary for your individual therapy.

### **3.4 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.

## **4 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.

## 5 Calculation

### 5.1 Activate

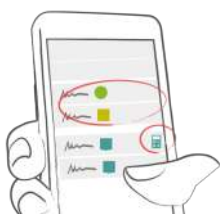
To get started, open a new entry screen in the mySugr Logbook and tap on the calculator symbol (just above the insulin fields). The first time you use the Bolus Calculator, we'll ask you a handful of questions about your personalized settings.

**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 diabetes coach.

### 5.2 Calculate

To calculate an insulin dose, enter your current blood sugar value and/or intended carb intake and then press the calculator symbol.

The Bolus Calculator window will open and show the calculation result. Typically, the calculation result is an insulin dose, and the window is colored turquoise. However, the Bolus Calculator may suggest carbohydrates! This is because you have enough insulin on board from a previous insulin dose and that a hypo (low blood sugar) is likely to occur without additional carbs. In that case, the result will be colored olive.



### 5.3 Confirm

If you agree with the suggested result, press the confirm button. The calculated values will automatically be saved in the mySugr Logbook and the Bolus Calculator window will close.

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

your blood sugar.



## 5.4 IOB (Insulin on Board)

The Bolus Calculator also continually calculates your IOB based on the last insulin doses you logged and your personal settings for the duration of insulin action. The IOB value will be shown with each calculation as part of the calculation formula. If there is no IOB, the Bolus Calculator will show a pop-up message asking you to confirm that you haven't taken any insulin recently. If you remember a bolus you took earlier (within your duration of insulin action time) but forgot to log, you should select "Cancel" on the pop-up message. Make a new entry with the details of that previous bolus (remember to adjust the time as needed in that entry) so that the Bolus Calculator will factor that IOB into the result.

**IMPORTANT:** Only confirm that you have no IOB when you are sure that you did not inject insulin within the active insulin duration.

## 5.5 Save

By saving the log entry, the confirmed insulin dose (food and correction) or carb suggestion will be saved in the corresponding fields. Note: neither result sum of the bolus / carb correction nor the IOB will be saved in the log entry.

## 6 Deactivation

The mySugr Bolus Calculator can be activated or deactivated within the mySugr Logbook settings.

To uninstall the mySugr Logbook, please check out the mySugr Logbook User Manual.

## 7 Data Security

Your data is safe with us — this is very important to us (we're users of mySugr too). The mySugr Bolus Calculator is a registered medical device (Medical Devices Directive 93/42/EEC) and carries the CE mark. As such, it is required to meet the highest data security and reliability standards.

For more information, please refer to our privacy notice within our [Terms Of Service](#)

## 8 Troubleshooting and Support

## 8.1 Troubleshooting

We care about you. That's why we have people with diabetes to take care of your questions, worries and concerns.

For quick troubleshooting, visit our [FAQs page](#)

## 8.2 Support

If you have questions about mySugr, need help with the Bolus Calculator or app, or have noticed a mistake or problem, please contact us immediately at [support@mysugr.com](mailto:support@mysugr.com).

You can also call us on:

- + 1 (855) 337-7847 (US toll-free)
- + 44 800-011-9897 (UK toll-free)
- + 43 720 884555 (Austria)
- + 49 511 874 26938 (Germany)

In the event of any serious incidents occurring in relation to usage of this medical device, please contact mySugr customer support and your local competent authority.

## 9 Manufacturer



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## **10 Country Information**

Australian Sponsor:

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