mySugr Bolus Calculator User Manual

Version: 3.0.10_iOS - 2022-03-28

1 Indications for use

1.1 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.

1.2 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

1.3 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.

2 Contraindications

2.1 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

2.2 Insulin restrictions

The mySugr Bolus Calculator may only be used with the insulins listed 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.

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. 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 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.

3.3 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 current blood 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.

3.4 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.

3.5 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.

3.6 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 Bolus Calculator must not be used on smartphones that are rooted or smartphones that have a Jailbreak installed.

3.7 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.

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 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 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 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

5.2 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 Bolus Calculator settings. Before being able to receive any bolus recommendation, you will be asked a handful of questions about your personalized settings.

5.2.1 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.

Offset 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 effective 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.

5.2.2 Time-dependent settings

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.

To define your settings per time period:

- Select "time-dependent" (iOS, Figure 7a) or enable "time-dependent setting" (Android, Figure 7b) during the setup flow
- Select the time period and enter/edit the adequate value
- Repeat for each time period affected 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 different time zone.

5.3 Calculate

5.3.1 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.

5.4 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.

iOS

Android

Figure 10a: Insulin bolus recommendation

Figure 10b: Edit Insulin recommendation

iOS

Android

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 affect your blood sugar.

5.5 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)

5.6 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.

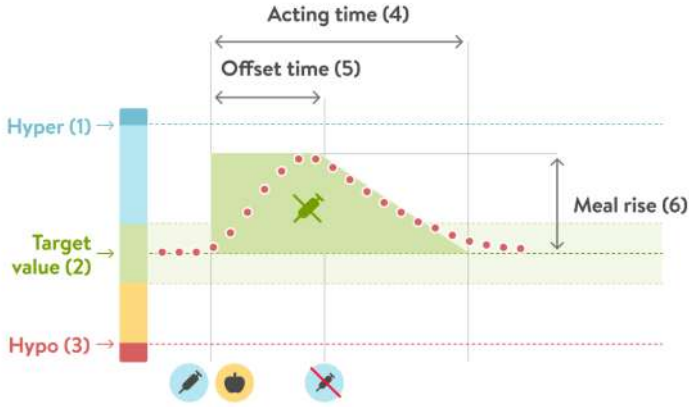
Figure 13a: Save entry (top navigation)

Figure 13b: Save entry (button)

5.7 Additional parameter explanations

5.7.1 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.



Bolus	Meal	Bolus not required
Current blood sugar value		
Allowed blood sugar value: Meal rise		
1: Hyperglycemia; 2: Target value; 3: Hypoglycemia; 4: Acting time; 5: Offset time; 6: Meal rise		

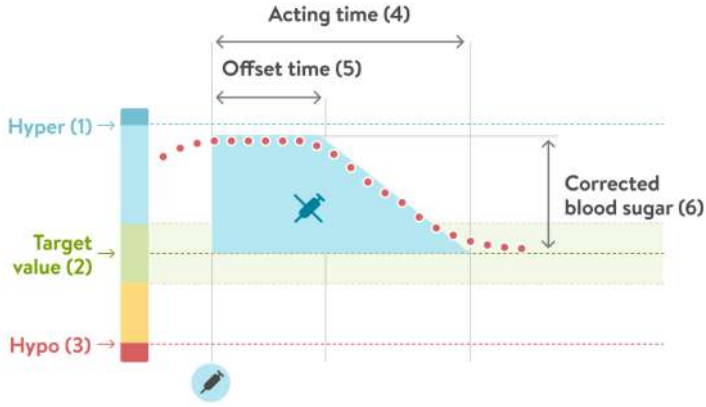
Diagram 1

Meal rise
After a meal, blood sugar levels usually increase by a noticeable amount, even in people without diabetes. Depending on the type of meal, your blood sugar level can reach a maximum about an hour after your meal and return to its original level after another one to two hours. This is a normal process and so the mySugr Bolus Calculator takes this into account using “meal rise”.

The dotted line shows how your blood sugar level might change after a carb bolus (Diagram 1). The mySugr Bolus Calculator tolerates an increased blood sugar level within the “meal rise range” (green) without calculating an extra correction bolus. When you enter a carb amount the “meal rise” setting is added to the blood sugar target value. How long the meal rise lasts (the width of the green area) is determined by the “offset time” and the “acting time”.

The currently allowed blood sugar value considers the following factors:

- The upper limit of the “target range” for your current “time block”
- Blood sugar values that were tolerated as a “meal rise” and which have had a carb bolus that is still active (acting time)
- The expected reduction of your blood sugar level due to the effect of insulin during the “acting time” (the decrease between the end of “offset time” and end of “acting time”)
- Excursions beyond the “target value” that have had a correction bolus that is still active (acting time)



Bolus	Meal	Bolus not required
Current blood sugar value		
Allowed blood sugar value: Corrected blood sugar		
1: Hyperglycemia; 2: Target value; 3: Hypoglycemia; 4: Acting time; 5: Offset time; 6: Corrected blood sugar		

Diagram 2

Acting time

The acting time is the time for which the insulin delivered as a bolus is still effective. It is the whole time for which an increase in blood sugar after a carb bolus or a correction bolus is taken into account. The mySugr Bolus Calculator will not recommend a correction bolus for this time if your current blood sugar level is less than the blood sugar level covered by the previous bolus (meal rise or a corrected high blood sugar).

To choose the correct value, you should know the following information as per discussions with your healthcare professional:

- The upper limit of the “target range” for your current “time block”
- Blood sugar values that were tolerated as a “meal rise” and which have had a carb bolus that is still active (acting time)
- The expected reduction of your blood sugar level due to the effect of insulin during the “acting time” (the decrease between the end of “offset time” and end of “acting time”)
- Excursions beyond the “target value” that have had a correction bolus that is still active (acting time)

Offset time

The offset time is the time before the insulin begins to lower blood sugar levels. After the offset time, your blood sugar level should decrease because of the insulin, and at the end of the acting time it should return to the target level. The offset time must be at least 45 minutes, and the maximum value will be limited by the acting time that you choose. You and your healthcare professional should discuss what offset time is appropriate for you.

Correction bolus only

The mySugr Bolus Calculator always compares your blood sugar result with the currently allowed target range, and not just with the target value for the current time block. Diagram 2 above shows an example: The first correction bolus remains active during the acting time (the width of the blue area). If a measured value falls within the currently allowed blood sugar value (height of the blue area), no new correction bolus is calculated.

5.7.2 Mathematical basis for bolus calculations

Below is a list of the most important formulas and principles that the mySugr Bolus Calculator uses to calculate your bolus.

$$\text{Carbs bolus} = \text{Carbs intake} \times \left(\frac{\text{Insulin}}{\underset{\text{from carb / insulin ratio}}{\text{Carbs}}} \right)$$

$$\text{Correction bolus} = \left(\text{Current blood sugar} - \text{Currently allowed blood sugar*} \right) \times \left(\frac{\text{Insulin}}{\underset{\text{from insulin correction factor}}{\Delta\text{Blood sugar**}}} \right)$$

Generally, a correction bolus is calculated only if your current blood sugar value is above the hypo blood sugar warning limit and outside of the target range. Additionally, it must be above the currently allowed blood sugar value. Only correction boluses greater than 0 will trigger an acting time.

* Currently allowed blood sugar value = The blood sugar value used in the calculation of a correction bolus, taking into account time block settings (target range mean value), currently active meals (meal rise), and currently acting correction boluses (active insulin).

** Δ Blood sugar = The difference between current blood sugar level and target blood sugar level.

6 Deactivation

The mySugr Bolus Calculator can be deactivated (or reactivated) within the mySugr Logbook settings. Go to “More/Profile & Settings/Insulin therapy” (iOS) or “Profile & Settings/Settings” (Android) and disable the mySugr Bolus Calculator using the “Use Bolus Calculator” switch button (Figure 14).

Figure 14: Disable Bolus Calculator

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 Device Regulation (EU) 2017/745) 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 and Conditions.

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 mySugr Bolus Calculator or the mySugr Logbook, or have noticed a mistake or problem, please contact us immediately at 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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Jurisdiction: Commercial Court of Vienna, Austria
VAT Number: ATU67061939

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10 Country information

10.1 Australia

Australian Sponsor:
Roche Diabetes Care Australia
2 Julius Avenue
North Ryde NSW 2113

10.2 Brazil

Registered by: Roche Diabetes Care Brasil Ltda.
CNPJ: 23.552.212/0001-87
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