mySugr Pump Control User Manual

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1 Indications for Use

1.1 Intended Use

The mySugr Pump Control software is intended to be used as an aid in diabetes therapy. It is intended to remotely control a compatible insulin pump used by people with diabetes. The mySugr Pump Control software uses wireless communication to communicate with connected pumps, to read data, make changes to the pump's settings, and to manage insulin delivery based on your input.

1.2 Who is the mySugr pump control for?

mySugr Pump Control is designed for users:

- diagnosed with insulin-dependent diabetes
- aged 18 years and above
- undergoing insulin pump therapy
- who have been trained on their insulin pump
- under the guidance of a doctor or other healthcare professional
- who are physically and mentally able to independently manage their diabetes therapy
- who are able to proficiently use a smartphone

1.3 Environment for Use

As a mobile application, mySugr Pump Control can be used in any environment where you would typically and safely use a smartphone.

2 Contraindications

For mySugr Pump Control as a Software product there are no specific Contraindications, however the Contraindications stated in the instructions for use of the connected insulin pump apply.

3 Warnings



3.1 Medical Advice

The mySugr Pump Control 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 long-term blood glucose values (HbA1c). You are responsible for continued self-management of blood glucose, independent of the use of the mySugr Pump Control.

3.2 Inputting the correct data

The mySugr Pump Control depends on the accuracy of the information entered. You are always responsible for verifying settings and insulin doses. If incorrect information is used for administering insulin doses, there is a risk of severe worsening of your health and even death.

3.3 Recommended Updates

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

3.4 Glucose monitoring

Monitoring of glucose results should be conducted using a glucose monitoring device that is compatible with insulin pump therapy. You can manually input data or import data via bluetooth functionality.

3.5 Smartphone security and maintenance

To enhance security when using mySugr Pump Control and to ensure that you are the only one with access, it is required that you have an authentication method (unlock mechanism) installed on your smartphone. Only choose a strong password or other strong authentication method and do not share your password with unauthorized parties.

Allow only trusted applications to have permission to system services, such as Android Accessibility Services.

To ensure correct usability of the mySugr Pump Control, do not use the application on a smartphone with a cracked or damaged screen.

To ensure integrity and security of the mySugr Pump Control, do not use the application on smartphones that are rooted or smartphones that have a Jailbreak installed.

3.6 Potential malicious messages

mySugr will never send you instructions relating to insulin delivery or pump control outside of the mySugr app. If you feel unsure about any message you have received, contact mySugr customer support.

4 Installation

The mySugr Pump Control is an extension of the mySugr Logbook (mySugr app). Just download the mySugr app from the Google Play Store. For more detailed instructions on installation and usage of the mySugr app, please check out the mySugr app user manual.

5 Connecting and disconnecting your pump

5.1 A few things to know before connecting your pump

If a remote control, e.g., an Accu-Chek Insight diabetes manager, is connected to your pump, disconnect it first. To keep you safe, your pump cannot be connected to the mySugr app and to a remote control at the same time.

5.2 Connecting your pump

To connect your pump with the mySugr app turn on Bluetooth on your smartphone.

In the mySugr app, select "Connections" from the side menu in the upper left corner.

Select your pump, e.g., "Accu-Chek Insight", from the list. Tap "Connect".

Then, follow the instructions on the mySugr app.

After you have connected your pump, go back to the mySugr app home screen, where the "My pump" widget is displayed.

5.3 Disconnecting your pump

To disconnect your pump, select "Connections" from the side menu in the upper left corner.

Select your pump from the list.

Tap "Disconnect".

Tap "Confirm".

The "My pump" widget disappears from the mySugr app home screen.

6 My pump widget

The "My pump" widget on the home screen is the starting point for controlling your pump using the mySugr app.

The widget also displays the last time there was a connection to the pump and when pump data was imported into the mySugr app (1).

Tap on "Control pump" (2) to access the "My pump" home screen.



On the "My pump" home screen, you can:

- Check the insulin (1) and battery (2) status
- Find out if your pump is running, paused or stopped
- Deliver a bolus (3)
- Check (4) or cancel (5) an ongoing bolus
- See the last delivered bolus



The icons for the different bolus types look like this (from left to right: standard, extended, multiwave):



The icons for the insulin and battery status are colored in gray. If the insulin level or battery status is low, only the respective icon turns orange. If the insulin or the battery is almost empty, the icon is colored in red (see below).



8 Delivering a bolus

For now, you can only deliver a standard bolus. No extended or multiwave boluses can be delivered.

To deliver a bolus, tap on the "+" icon in the bottom right corner of the mySugr app home screen and then select "Deliver bolus". Alternatively tap on "Control pump" on the "My pump" widget. Once you're on the "My pump" home screen, tap on "Deliver bolus".

IMPORTANT: In case you have not set up an unlock mechanism on your smartphone yet, you will be asked to do so. This is crucial so that only you and no one else can control your pump with your smartphone. Tap on "Open phone settings" and set up your preferred option, e.g. your fingerprint. Afterwards go back from the phone settings to the mySugr app.

Enter the insulin amount and tap "Confirm". You must authorize the bolus delivery. To do so, tap "Authorize" and use the unlock mechanism you have set up. The bolus is sent to the pump and the "Bolus" widget is displayed on the "My pump" home screen. It shows the total bolus amount and the progress of the bolus delivery.

While the bolus is being delivered, it is not possible to deliver another bolus.

To cancel the bolus delivery, tap on "Cancel bolus" on the "Bolus" widget. Once the bolus delivery has been stopped, you can see how much insulin has already been delivered.

While starting or cancelling a bolus, a notification outside of the mySugr app will appear. It will disappear automatically once the connection to the pump was successfully established. A notification will also appear in case there is an error during starting, delivering or cancelling a bolus. Tap on it to check the details within the mySugr app. To be sure that you will be notified, leave the notifications for the mySugr app enabled.

Another way to deliver a bolus is via the **mySugr Bolus Calculator**. After accepting a bolus recommendation, tap on "Deliver with pump". Then authorize the bolus delivery according to the instructions above. For more detailed instructions on setup and usage of the mySugr Bolus Calculator, please check out the mySugr Bolus Calculator user manual.

9 Importing data from your pump

9.1 Imported data

Standard, extended and multiwave boluses are imported from your pump into the mySugr app.

If the mySugr Bolus Calculator was used to deliver a bolus, the split between correction and food insulin is preserved. Otherwise the boluses are imported as correction insulin.

In case you manually logged a bolus before delivering it with the pump, it is automatically merged with the imported bolus if the bolus amount is very similar and both happened within 15 minutes.

9.2 Data visualisation

You can see the imported data in the list of entries on the home screen of the mySugr app.

For each imported bolus, there is a new entry with the date, time and the number of units delivered. The number of units are shown within a tile as shown below.



Once imported, the bolus entry can neither be edited nor deleted.

10 Error and warning messages

The values in the following messages are only examples. You will see different numbers in your message, depending on your personal data.

10.1 During connecting

Oh no, another device is controlling your pump On your pump select: Settings ► Communication ► Remove device Remove other controlling devices and try again → Try again

Connection lost during pairing

Maybe the battery is weak, or your pump is too far away. Please move the pump closer and try connecting it again. \rightarrow Try again

Location services are disabled

You need to enable location services to find your device. Once your device is paired, you can disable them again. \rightarrow Enable Location Services

Bluetooth is disabled

It seems that Bluetooth got disabled while pairing. You need to have Bluetooth enabled to connect your device. → Enable Bluetooth

Oh no, you connected your pump outside the mySugr app

On your phone: please unpair your pump in the Bluetooth settings. On your pump: go to "Settings", then "Communication" and remove your phone. Once you are ready, please try again. → Try again

Oh no, we can't pair to this pump

Unfortunately, this version of the pump doesn't work with the mySugr app. We would advise to get a newer version. \rightarrow Contact support / Return to Connections

Oh no, the verification code is wrong

Are you sure that you are pairing your own pump? Please try again and double-check the code. → Try again

Connection error

Oh no! Pairing with your device failed. Please try again or contact support. → Contact support / Try again

Bolus authorization failed

Try again and complete the bolus authorization successfully.

10.2 When delivering a bolus

The bolus can't be delivered because it's outside of the possible range

Change the bolus amount so that it's above the minimum amount of 0.05 U and below the maximum amount set on your pump.

→ Change bolus amount / Cancel

The bolus can't be delivered because your pump can't be reached

We have tried our best, but still couldn't reach your pump. Make sure that your pump is nearby, Bluetooth is activated and that its display is turned off. \rightarrow Try again / Cancel

→ Try again / Cancel

The bolus can't be delivered because your pump is stopped

To deliver the bolus, start your pump and try again. \rightarrow Try again / Cancel

The bolus can't be delivered because another bolus is running

Only a certain combination of boluses can run at the same time. Wait for one of the boluses to finish, and try again. \rightarrow Try again / Cancel

The bolus can't be delivered

Oh no, something went wrong. To find out more, check your pump.

→ Got it

The bolus delivery can't be verified

To see if the bolus was delivered correctly, check your pump. \rightarrow Cot it

→ Got it

A bolus was already delivered a few minutes ago

A bolus of 5 U was delivered at 16:17. Are you sure that you want to deliver another bolus of 4 U. \rightarrow Yas, deliver bolus now / Cancel bolus

 \rightarrow Yes, deliver bolus now / Cancel bolus

The bolus can't be delivered because the recommendation is not correct anymore

We just now connected to your pump and found out that there was a recent bolus that was not considered in the recommendation. To stay safe, recalculate your bolus. \rightarrow Recalculate bolus / Cancel bolus

The calculated bolus can't be delivered because your blood sugar was measured too long ago

The calculated bolus can only be delivered within 15 minutes after you measured your blood sugar. Please measure your blood sugar again. We know that always pricking yourself is really not fun, but let's do it once more.

→ Measure blood sugar / Cancel bolus

Error when delivering the bolus

Check your pump to see if the bolus was delivered. If not, try to deliver the bolus again with the app and follow the progress there.

Still importing pump data...

You can deliver your first bolus as soon as all pump data has been imported. This can take a while. Try again in a few minutes. \rightarrow Got it

10.3 When cancelling a bolus

The bolus can't be cancelled because your pump can't be reached

Cancel the bolus with your pump. \rightarrow Got it

The bolus has already been cancelled because your pump was stopped

The bolus was already cancelled automatically when your pump was stopped and can no longer be cancelled on your phone.

→ Got it

The bolus cancellation can't be verified

To see if the bolus was cancelled correctly, check your pump.

→ Got it

The bolus amount already delivered can't be displayed because your pump can't be reached

The bolus was cancelled successfully. However, we don't know how much was delivered before the cancellation, because we can't reach your pump. To see how much was delivered, check your pump. \rightarrow Got it

Error when cancelling the bolus

Cancel the bolus with your pump.

10.4 When communicating with the pump

The pump can't be reached because your phone's Bluetooth is disabled

To connect to the pump, let's enable Bluetooth on your phone. \rightarrow Enable Bluetooth / Cancel

11 Deinstallation

To deinstall the mySugr app, please check out the mySugr app user manual.

12 Data Security

Your data is safe with us – this is very important to us (we're users of mySugr too). The mySugr Pump Control 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 <u>Terms and Conditions</u>.

13 Troubleshooting and support

13.1 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

13.2 Support

If you have questions about mySugr, need help with the mySugr Pump Control or the mySugr app, 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.

14 Manufacturer



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