ENGLISH

USER MANUAL

Hedia Diabetes Assistant

Version 2.11.1

CE
0123

www.hedia.co Fruebjergvej 3, DK-2100 Copenhagen, Denmark support@hedia.co

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Terminology

Hedia Diabetes Assistant = HDA

Blood glucose = BG

1. Intended use

HDA is a medical mobile application (standalone software) with no body contact, intended to monitor blood glucose and to support in the decision making of the optimal bolus insulin dose for management of insulin-dependent diabetes by providing the user with an indicative bolus insulin dose.

1.1. Indications for use

HDA is indicated as an aid for adult patients 18+ years which are diagnosed with:

- Type 1 diabetes - insulin-dependent diabetes mellitus
- Type 2 diabetes on basal-bolus insulin regimen – multiple-dose insulin therapy,

and who have cognitive and physical skills to use mobile applications and who use rapid-acting insulin. The users are smartphone users with operating systems iOS 11.0 or newer or Android version 5.0 or newer.

Based on blood glucose as the fifth vital physiological parameter in diabetes care (Ref. 1 and Ref. 2) and estimation of carbohydrate intake, physical activity and insulin on board (hereafter IOB), it aids in the improvement of managing the patient's diabetes by providing guidance on general lifestyle management, carbohydrate intake and bolus calculation.

1.2. Contraindications

For safety reasons the system should not be used by children or patients with the following conditions:

- Pregnancy
- Gestational diabetes
- Fever

1.3. Introduction to HDA

HDA is a diabetes assistant (application) that supports you in the decision making of the optimal bolus insulin dose for daily management of your diabetes. HDA helps you in your daily diabetes management treatment advising action in connection with the calculation of insulin dose. HDA is based on advanced carbohydrate counting and is a tool for those who want an easier life with diabetes. HDA uses known formulas to calculate an indicative recommended insulin dose based on your current blood glucose, your carbohydrate intake, your activity level, and the amount of active insulin you have in your body.

In this user guide you will learn how HDA should be used in the daily management of your diabetes. In order to use the app correctly and securely, you must understand its operation, display messages and all the different features. To get the most out of HDA it is important that you enter as much data as possible to track and manage your diabetes and the data should be as accurate as possible to obtain the optimal insulin dosage. This is the only way to get the most out of HDA.

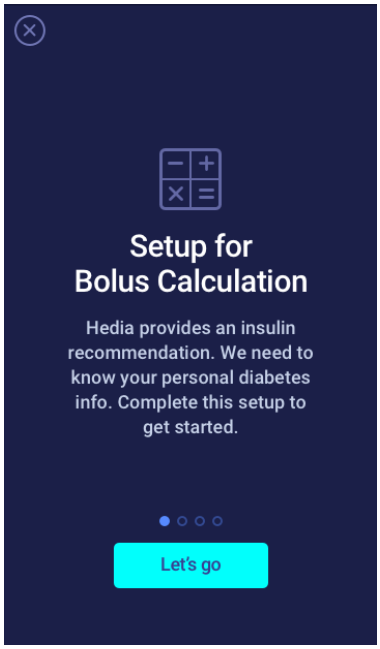
Contact us if you have any questions or experience any errors. An overview of contact information is provided at the end of the user manual.

1.4. With HDA you get:

- Easy and fast data entry
- Overview of active insulin
- Insulin calculator
- Logbook
- Clear graph of your blood glucose
- Food database incl. search function and add function
- Activity

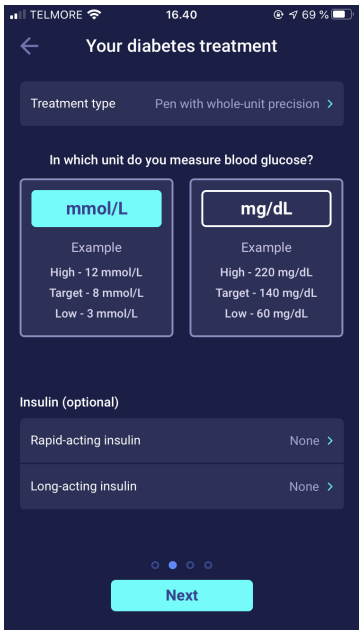
2. First Calculation

The first time making an insulin calculation you need to set up the Bolus Calculator.



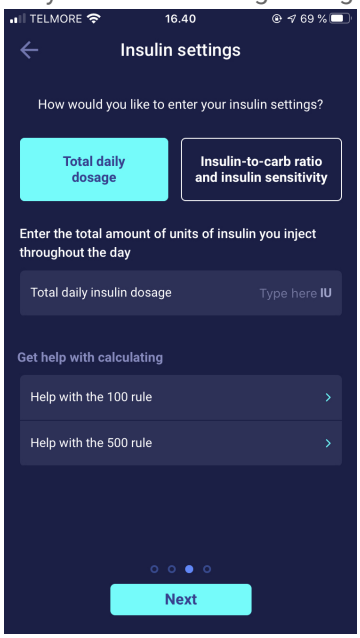
2.1. Diabetes treatment

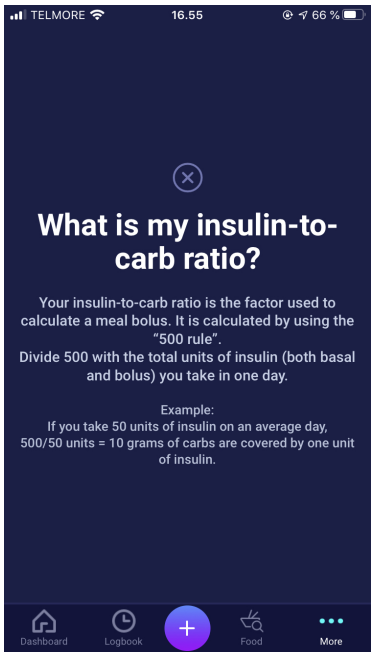
Make personal settings for pen/pump, units and types of insulin

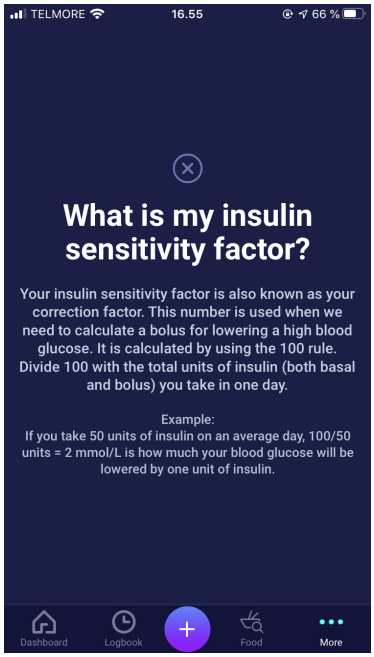


2.2. Insulin settings

Set your insulin settings using the 500 rule and the 100/1800 rule .

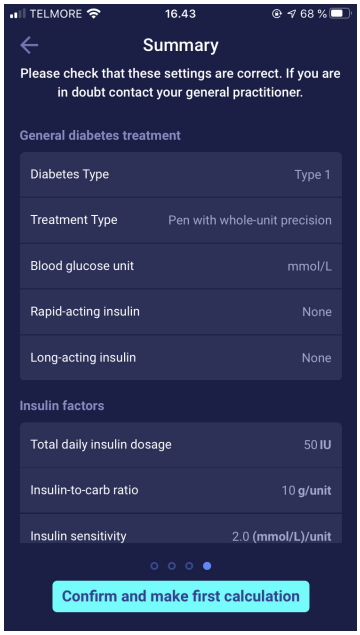






2.3. Summary

A summary of your inputs for the insulin recommendation. You need to check if it is correct and confirm.



3. Insulin calculator and Attention notices

3.1. Introduction

When you use HDA for the first time, you will be asked to personalize the app with your information before the app can be used. In HDA this is named “first time calculation”. These settings relate to your insulin-to-carbohydrate ratio (hereafter insulin-to-carb ratio) and your insulin sensitivity factor. It is important that these settings are set correctly to provide you with a correct indicative bolus insulin dose. We recommend that you consult your diabetes therapist before setting up the features and start using HDA. You can only access the insulin calculator if you fill out the required fields in the “first time calculation”-flow.

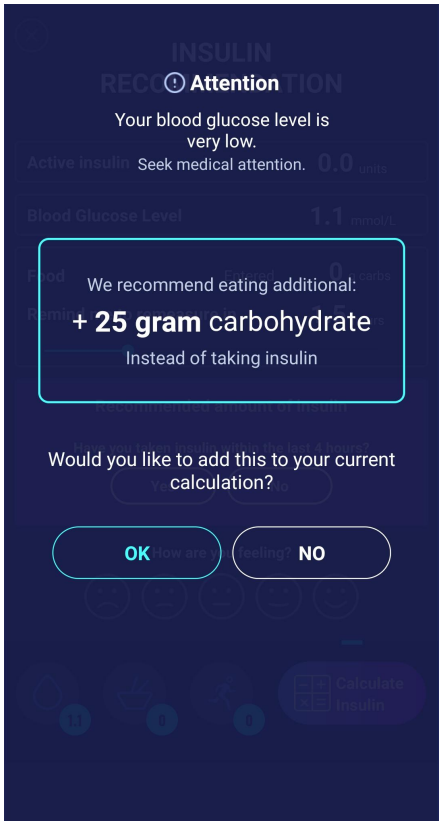
3.2. Attention pop-ups and notices

In order to ensure your safety as a HDA user, we have developed a number of attention pop-up messages, notifications and confirmations of your entries. You must pay close attention to these messages and always make sure your data is correct.

3.3. Attention pop-ups

To secure you as a user, we have implemented a number of attention pop-ups that we would strongly recommend you be aware of. When you receive an attention pop-up, it is important to make sure that all your entries are correct.

HDA has built-in limits (e.g. for insulin, blood glucose and carbohydrate input), thus entries exceeding the given limits are recognised and you will receive an attention pop-up and be prompted to check your entries. Below is an example of what an attention pop-up can look like in HDA:



3.4. Notifications

Once you have used HDA and transferred data to your logbook, HDA is set to give a notification after 1.5 hours. This notification is based on the effect profile of rapid-acting insulin and is intended to remind you to measure your blood glucose, so a potential high or low blood glucose can be corrected immediately.

If you do this control measurement of your blood glucose, HDA will be able to help you stabilize your blood glucose. HDA will use your new blood glucose measurement to assess whether you are on the right curve to your desired target blood glucose. If you are outside of this curve, HDA will recommend you a correction dose or guide you to ingest X grams of carbohydrate so that the risk of low or high blood glucose is minimized.

You can set this notification yourself from 30 minutes and up to 6 hours (half-hour intervals), on the “insulin recommendation” page. You can also turn the notification on or off on the “insulin recommendation” page.

3.4.1. Turn off notifications

To turn off notifications from Hedia completely, please refer to your phone manufacturer’s instructions on how to turn off app notifications in general phone settings.

3.5. Insulin calculator

The use of HDA requires understanding of your diabetes treatment. Therefore, you should work closely with your healthcare professional and be fully aware of your diabetes treatment. The insulin calculator helps you calculate your current amount of insulin based on your entered information. Therefore, you must be able to accurately assess your current situation.

The insulin calculator calculates your insulin dose based on your following informations;

- The insulin-to-carb ratio and insulin sensitivity factor you entered under settings or before your first insulin calculation
- Your current entered blood glucose
- Entered amount of carbohydrates
- Activity
- Active insulin is calculated from above inputs

The insulin calculator is only indicative. The insulin calculator cannot judge your current situation independently of your discretion and cannot correct any incorrect entries. HDA has built-in limits for blood glucose and carbohydrate inputs. Thus, entries exceeding these given limits are recognised and you will receive an attention pop-up and be prompted to check the input for your own safety. However, as long as entries fall within the built-in limits, the accuracy of your entries cannot be verified by HDA.

Therefore, no attention pop-ups appear if your entries are plausible (located within acceptable range) but incorrect. It is therefore important that you check that all your entries are correct.

Always compare HDA's results with your actual condition and adjust the recommended dose if necessary.

The insulin doses which have been taken before using HDA for the first time cannot be taken into account in the calculations in HDA. The same applies to administered insulin doses and consumed meals which previously have not been registered in HDA.

We recommend that you continuously update HDA to the extent that updates are available in the App Store or Google Play; the app will prompt you to do so.

3.6. Clinical calculations used in HDA

The insulin dose recommended by HDA consists of two components: a recommendation for a meal dose that covers your intake of carbohydrates and a recommendation for a correction dose for adjusting your blood glucose if it is above or below your desired blood glucose target.

HDA is based on advanced carbohydrate counting and the calculations in HDA are based on known and frequently used formulas.

The insulin-to-carb ratio (500 rule) and insulin sensitivity factor (100 rule or 1800 rule) are, at any given time, active in the background of the app. This means that the app functions are available offline and online. All HDA's calculations are based on these two algorithms.

3.6.1. Insulin-to-carb ratio (500 rule):

This is an expression of how many grams of carbohydrate one unit of insulin covers. This applies to both units of blood glucose measurement (mmol/L and mg/dL).

The formula for the 500 rule is:

500 ÷ your daily dose (total amount of insulin taken in a day including long-acting insulin)

Example: 50 IU per day gives the following: 500/50 = 10 (one unit of insulin counteracts 10 grams of carbohydrates).

3.6.2. Insulin sensitivity factor/correction dose (100 rule or 1800 rule):

This is an expression of how much your blood glucose can be expected to fall with one unit of rapid-acting insulin.

Depending on whether you measure your blood glucose in mmol/L or mg/dL, HDA will calculate your correction dose using the 100 rule or the 1800-rule.

3.6.2.1. 100 rule

The formula for the 100 rule is:

100 ÷ your daily dose (total amount of insulin taken in a day including long-acting insulin) If you measure your blood glucose in mmol/L HDA will calculate your correction dose by applying the 100 rule.

Example: 50 IU per day gives the following: 100/50 = 2 (one unit of insulin causes a drop in blood glucose of about 2 mmol/L).

3.6.2.2. 1800 rule

If you measure your blood glucose in mg/dL, HDA will calculate your correction dose by applying the 1800-rule.

1800 ÷ your daily dose (total amount of insulin taken in a day including long-acting insulin)

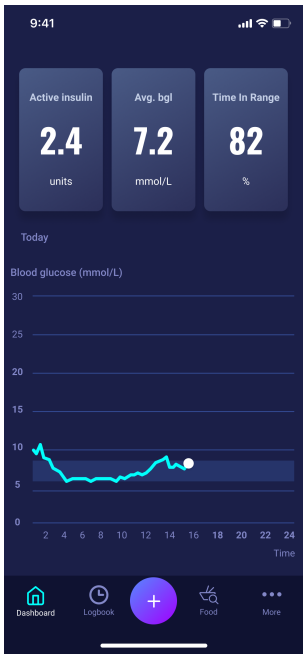
Example: 50 IU per day gives the following: 1800/50 = 36 (one unit of insulin covers 36 grams of carbohydrates).

Each formula is used by HDA to calculate your insulin-to-carb ratio, as well as your insulin sensitivity factor.

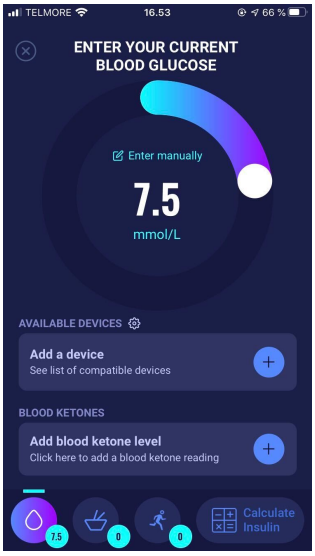
The insulin-to-carb ratio and insulin sensitivity factor must be entered in HDA before the first insulin calculation can be made. HDA cannot be used until these settings are made, as HDA makes all its calculations based on these two formulas.

Under Settings, you can change your settings for your insulin-to-carb ratio, as well as your insulin sensitivity factor. In addition, HDA can help you with the 500 and the 100/1800 rule.

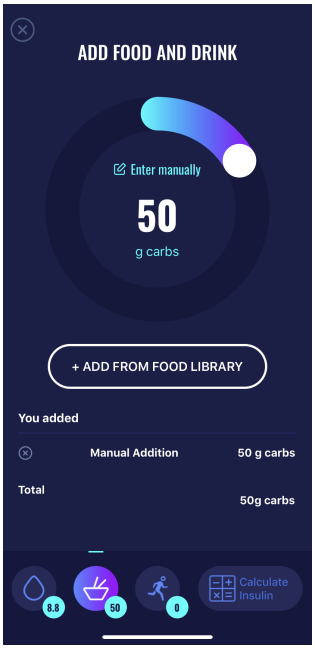
3.6.3. How to calculate your recommended insulin dose in HDA



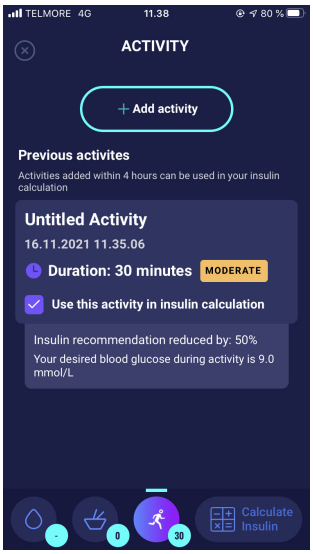
Press “+” on the dashboard to start a new insulin calculation.



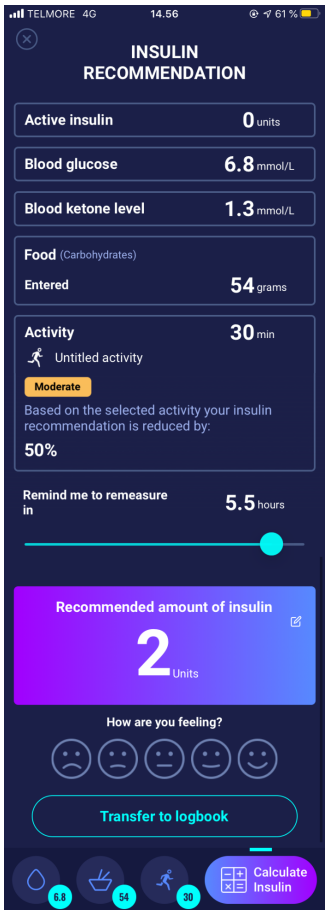
Enter your current blood glucose. Or connect with blood glucose monitor.



Enter amount of carbs to eat or drink. Enter manually or use food database.



Add activity to your calculation. Set amount of time, kind, intensity and time of activity.



Based on the previous inputs HDA calculates a recommended amount of insulin.

HDA will calculate your recommended insulin dose based on your current blood glucose, the amount of carbohydrates you entered, the amount of activity you have added and the amount of active insulin from previous calculations. The calculations can be seen on the “insulin recommendation” screen at your recommended insulin dose. The “insulin recommendation” screen shows your current entered data (see picture above).

The calculation is based on the following formula: meal dose (food) + correction dose (corr) - active insulin - activity.

3.6.4. Meal dose (food)

Your meal dose (food) is the amount of insulin to be administered to cover the amount of carbohydrates you have entered. Calculations are performed based on your insulin-to-carb ratio (500 rule).

3.6.5. Correction dose (corr)

If your blood glucose is above or below your blood glucose target, HDA recommends a correction dose. If you enter a low blood glucose (hypoglycaemia), HDA will use your insulin sensitivity factor (100 rule) to calculate how many units of rapid-acting insulin should be ***withdrawn*** from the recommended insulin dose.

If you enter a high blood glucose (hyperglycaemia), HDA will use your insulin sensitivity factor (100 rule/1800 rule) to calculate how many units of rapid-acting insulin should be ***added*** to your recommended dose.

The calculations of a correction dose depend on your current blood glucose entries in the app, your insulin sensitivity factor, and if you plan to eat.

If your blood glucose is low, you will be asked to eat a certain amount of carbohydrates to prevent further low blood glucose and prevent the risk of insulin shock. In this situation, a correction dose is not calculated.

TELMORE 4G
14.57
60 %
INSULIN RECOMMENDATION
Active insulin
0 units
Blood glucose
2.3 mmol/L
Blood ketone level
1.3 mmol/L
Food (Carbohydrates)
Entered
0 grams
Recommended
Additional
34 grams
Total
34 grams
Activity
30 min
Untitled activity
Moderate
Based on the selected activity your insulin recommendation is reduced by:
50%
Remind me to remeasure in
04.5 hours
Recommended amount of insulin
Have you taken insulin within the last 4 hours?
Yes
No
How are you feeling?
2.3
0
30
Calculate Insulin

4. Blood glucose

Blood glucose is indicated in HDA as mmol/L or mg/dL.

In HDA it is possible to type in blood glucose between 1.1 mmol/L and 33.3 mmol/L. For the mg/dL unit, it is possible to type in blood glucose between 20 mg/dL and 600 mg/dL. These limits also apply to blood glucose transferred from your blood glucose meter. If your blood glucose meter shows a lower value than the one allowed in HDA, HDA will transfer 1.1 mmol/L or 20 mg/dL. If your blood glucose meter shows a higher value than the one allowed in HDA, HDA will transfer 33.3 mmol/L or 600 mg/dL.

HDA will recommend you to measure for ketones if a blood glucose measurement is above 15 mmol/L or 270 mg/dL and you are about to do activity.

HDA will also recommend you to measure for ketones if two blood glucose measurements have been above 15 mmol/L or 270 mg/dL within the last 6 hours.

See standard limits and attention messages on the next page (table 1):

Table 1 : Standard limits for attention messages in HDA: BG entered in the calculator

BG in mmol/L and mg/dL	Definition	Attention messages
< 1.1 mmol/L 20 mg/dL	**Insulin shock** Not possible to input data below 1.1 mmol/L or 20 mg/dL in HDA.	No attention message.
1.2 - 2 mmol/L 22 - 36 mg/dL	**Severe hypoglycemia (insulin shock)** No recommendation for insulin.	*"Attention. Your blood glucose is very low. Take glucagon or eat carbohydrates if possible. Seek medical attention. You will be reminded to measure your blood glucose in 15 min. We recommend eating an additional: X grams of carbohydrate Instead of taking insulin".*
2.1 - 3.5 mmol/L 38 - 64 mg/dL	**Hypoglycemia (insulin reaction)** No recommendation for insulin.	*"Attention. Your blood glucose is low. You will be reminded to measure your blood glucose in 15 min. We recommend eating an additional: X grams of carbohydrate Instead of taking insulin".*
3.6 - 4 mmol/L 65 - 70 mg/dL	**Mild hypoglycemia** *"We recommend eating an additional: X grams of carbohydrate instead of taking insulin".* If additional carbohydrates are logged, HDA will recommend a bolus insulin dose for the amount of carbohydrates logged, minus the units of insulin corresponding to the low blood glucose. You will therefore receive a smaller dose of insulin with your meal, to avoid further low blood glucose.	No attention message.
4.1 - 7 mmol/L	**Normal glycemia**	No attention message.

74 - 130 mg/dL	Insulin recommendation as usual.	
7.1 - 14.9 mmol/L 128 - 268 mg/dL	**Mild hyperglycemia** Insulin recommendation as usual.	No attention message.
15 - 33.3 mmol/L 270 - 600 mg/dL	**Hyperglycemia**	No attention message. If **activity** is logged an attention message will occur: *"You have a high blood glucose. You should take insulin and measure ketones in your urine. You will be reminded to measure your blood glucose in 15. min."*
Two measurements above 15 mmol/L two times within 6 hours Two measurements above 270 mg/dL within 6 hours	**Severe hyperglycemia**	*"Attention. You have a high blood glucose. You should take rapid-acting insulin and measure ketones."*

4.1. Target area

The recommended blood glucose concentration is maintained within a level of 4-8 mmol/L or 72-144 mg/dL. A blood glucose concentration below 4 mmol/L (72 mg/dL) is called hypoglycaemia and a blood glucose concentration above 8 mmol/L (144 mg/dL) is called hyperglycaemia.

When you use HDA for the first time, the app is set with the following default blood glucose targets.

The default for the overall settings for blood glucose can be seen below (table 2 and table 3):

Table 2: Default for overall settings for blood glucose units in mmol/L

Low BG	Target BG	High BG
< 4 mmol/L	6 mmol/L	> 10 mmol/L

Table 3: Default for overall settings for blood glucose units in mg/dL

Low BG	Target BG	High BG
< 72 mg/dL	108 mg/dL	> 180 mg/dL

4.1.1. Blood glucose settings (default)

Target blood glucose: **6** mmol/L or **108** mg/dL

Blood glucose limits:
Low blood glucose : < **4** mmol/L or **72** mg/dL
High blood glucose : > **10** mmol/L or **180** mg/dL

You can choose to change these settings according to your needs, within HDA's defined limits for blood glucose (see section **10.2.1 Blood glucose**, *table 13: Limits for adjusting BG values in HDA in mmol/L and mg/dL*)

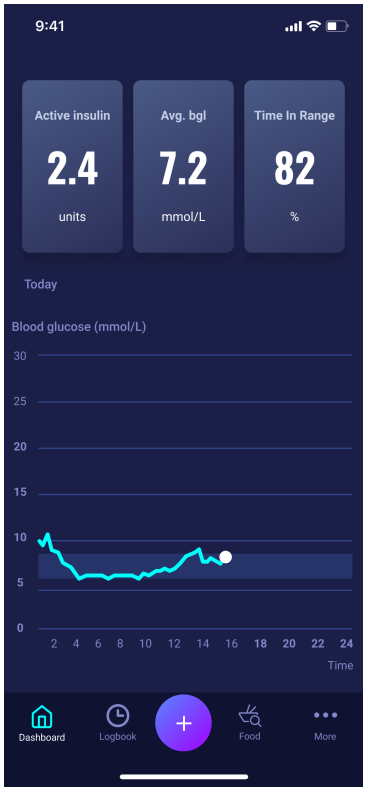
HDA has, as a safety measure: a built-in minimum target BG of 5 mmol/L or 90 mg/dL and 13.9 mmol/L or 250 mg/dL as the maximum target BG.

4.2. Average blood glucose

HDA needs a minimum of 28 blood glucose logs over a period of maximum 14 days to calculate your average BG. Your average BG appears on the dashboard.

Your average blood glucose is not the same as the HbA1c measurement that is measured by your doctor.

The amount of blood glucose data within this time period is enough to provide a sufficiently accurate estimate of your average BG.

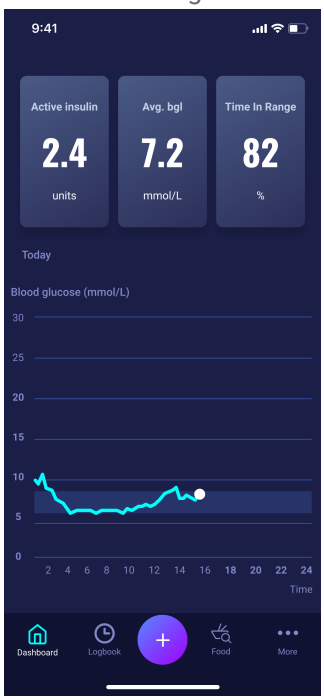


4.3. Time-in-range

Time-in-range is a percentage of the time your blood glucose is within your blood glucose target values.

HDA needs a minimum of 28 blood glucose logs over a period of maximum 14 days to calculate your time-in-range. Your average time-in-range appears on the dashboard.

Your time-in-range is not the same as the HbA1c/a1c measurement that is measured by your doctor.



4.4. Sync with devices

HDA is compatible with the following devices via NFC or Bluetooth:

Table 4: Compatible devices for HDA via NFC

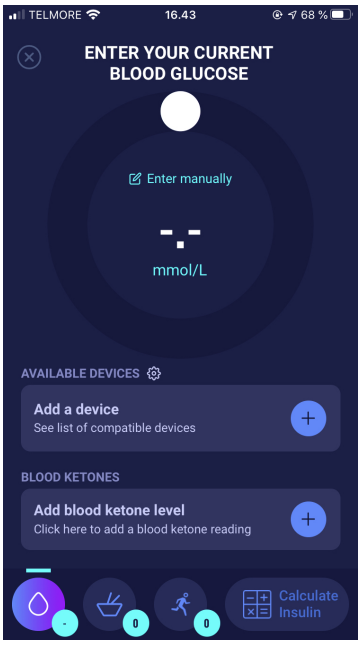
Device Name	From serial no. and onwards on iOS	Manufacturer
GlucoMen® areo	EQ493	A. Menarini Diagnostics S.r.l.
GlucoMen® areo 2K meter set	HC109	A. Menarini Diagnostics S.r.l.

Table 4.1: Compatible devices for HDA via Bluetooth

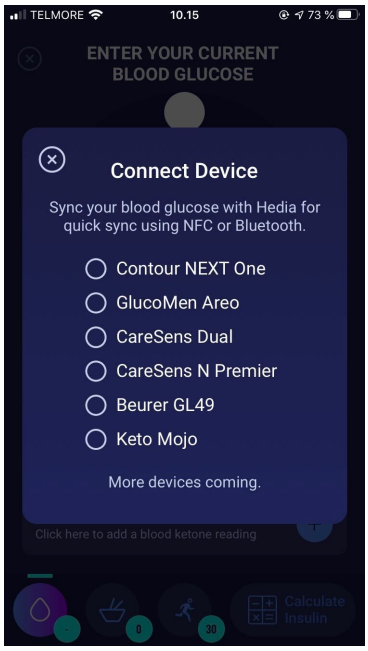
Device Name	Manufacturer
Contour® NEXT ONE	Ascensia Diabetes Care Holdings AG
Keto-Mojo™ GKI	Keto-Mojo Europe BV
CareSens Dual	I-Sens GmbH
CareSens N Premier	I-Sens GmbH
GL49	Beurer GmbH

4.4.1 How to set up and use Glucomen Areo and Glucomen Areo 2K in HDA via NFC

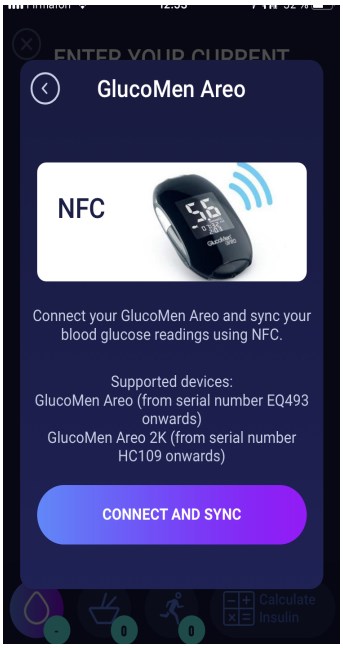
When you want to sync HDA with your GlucoMen Areo or your Glucomen Areo 2K, it is important that you start by making a new, current blood glucose measurement, as well as checking that the time on your blood glucose meter is set correctly. Next, follow the guide below to set up your devices.



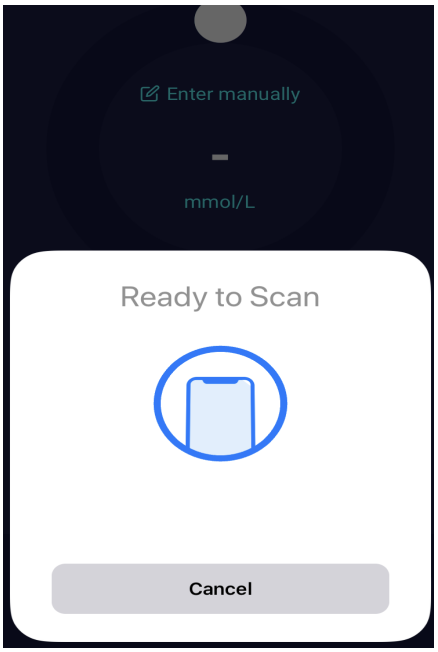
On the “Enter your current blood glucose” screen, you can press “Connect A Device” to start the setup.



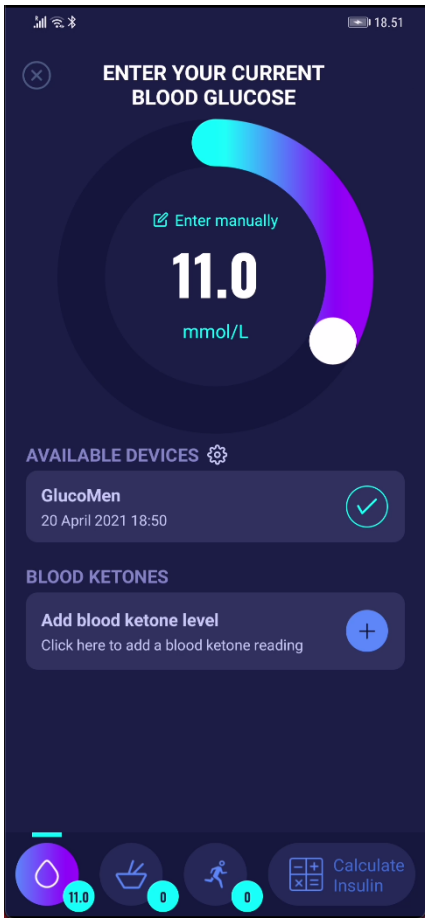
A list of the supported devices will appear. Tap on the desired device.



An info screen of the device and its connection type appears. Tap “connect” and sync to pair device.



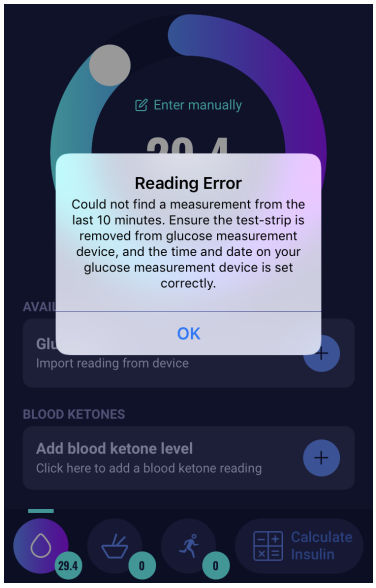
A screen will appear with information for scanning using NFC.



The latest reading from the device is now in HDA. The added device is now default, and will sync using the “Sync with device” button.

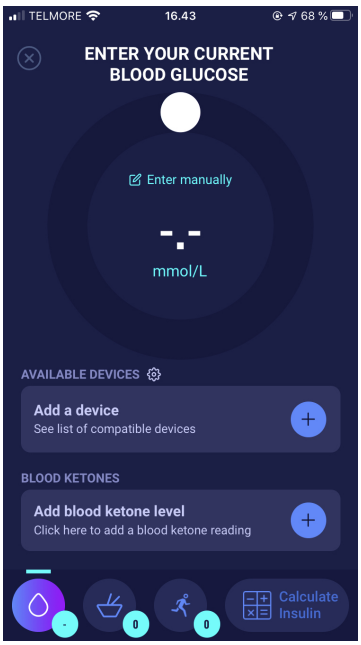
4.4.1.1 Synchronization error GlucoMen Areo

If you try to sync your GlucoMen Areo with a reading older than 10 minutes you are presented with the following reading error. You have to remove the strip and scan again.

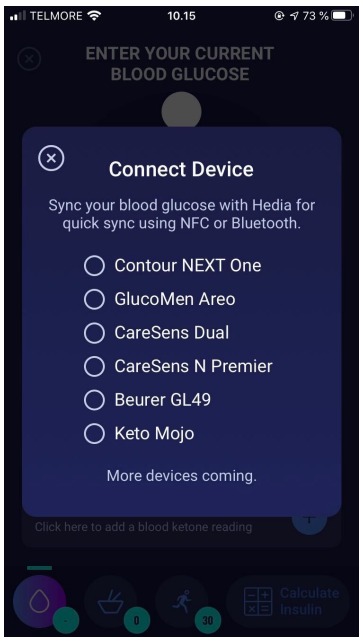


4.4.2 How to set up and use your blood glucose meter via Bluetooth in HDA

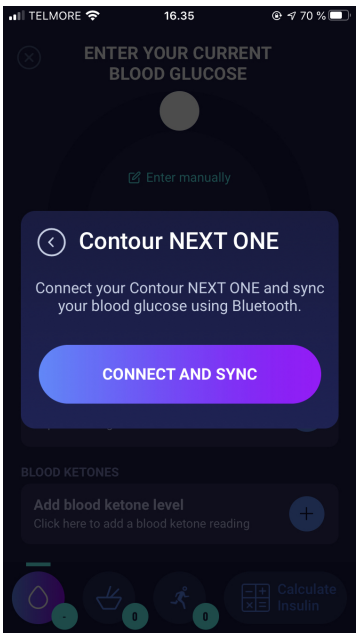
When you want to sync HDA with your blood glucose meter, it is important that you start by making a new, current blood glucose measurement, as well as checking that the time on your blood glucose meter is set correctly. Next, follow the guide below to set up your device. The screenshots apply to the setup of Contour NEXT ONE.



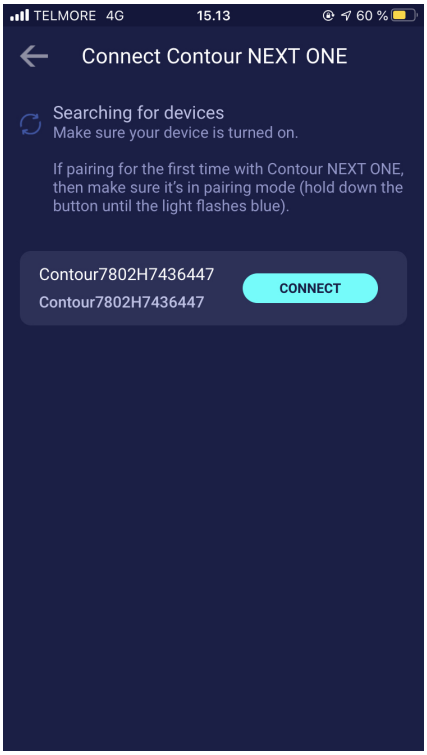
On the “Enter your current Blood Glucose” screen, you can press “Connect new device” to start the setup.



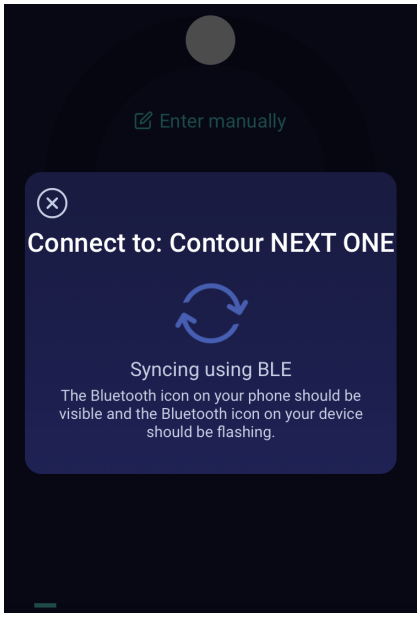
A list of the supported devices will appear. Tap on the desired device.



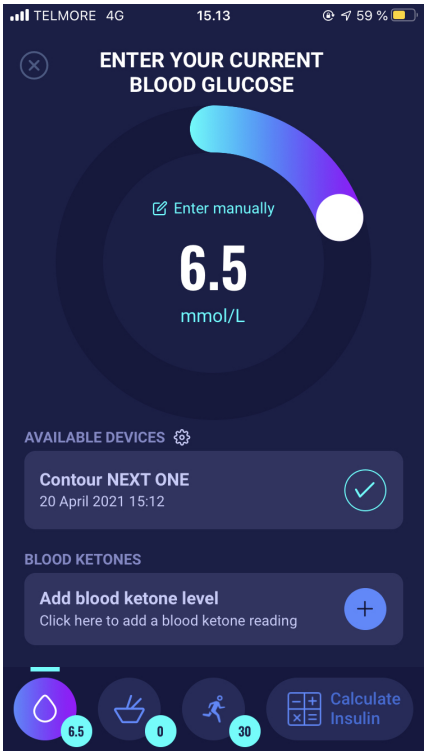
An info screen of the device and its connection type appears. Tap “connect” and sync to pair devices.



HDA will start searching for devices. Follow the instructions shown on your screen to connect with the specific device.



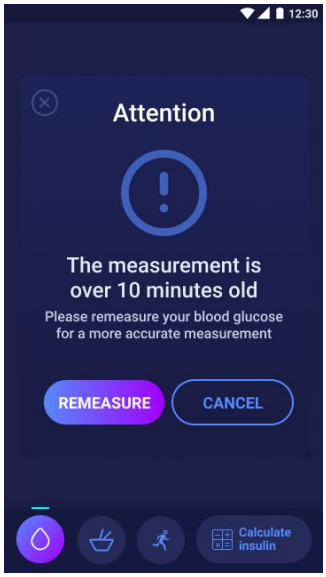
HDA will sync with the selected device using Bluetooth. Make sure the blood glucose reading is made within the last 10 minutes.



The latest reading from the device is now in HDA. The added device is now default, and will sync using the "Sync with device" button.

4.4.2.1 Synchronization error

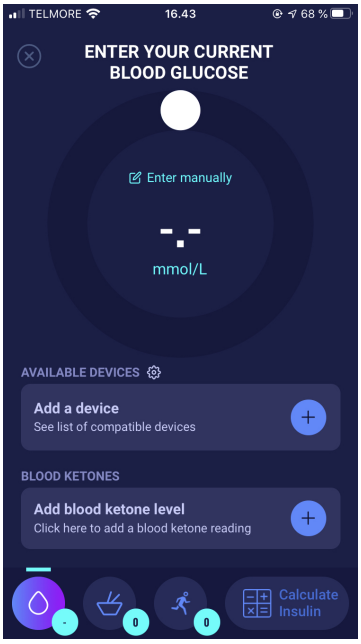
If you try to sync your blood glucose meter with a reading older than 10 minutes you are presented with the following reading error. You will have to make a new blood glucose reading and sync again.



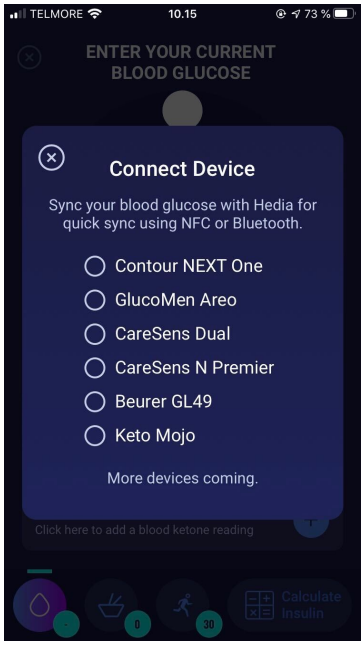
4.4.3 How to set up and use Keto-Mojo GKI in HDA via Bluetooth

With Keto-Mojo GKI it is possible to measure both your BG and your blood ketone level. Both BGs and blood ketone levels can be entered in HDA. For more information about how to set up and log blood ketones in HDA with your Keto-Mojo GKI device, go to section 5.3.

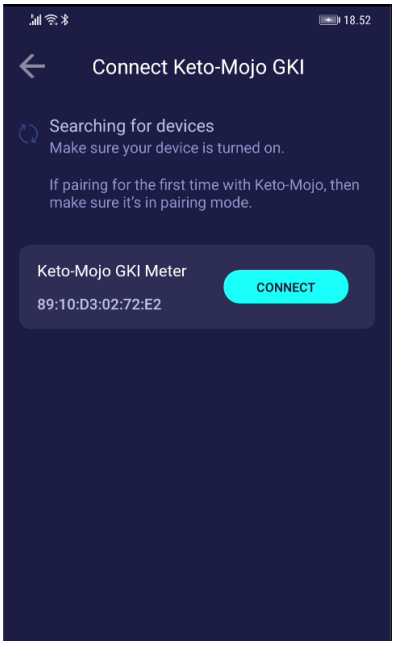
When you want to sync HDA with your Keto-Mojo GKI for measuring your BG, it is important that you start by making a new, current blood glucose measurement, as well as checking that the time on your blood glucose meter is set correctly. Next, follow the guide below to set up your device.



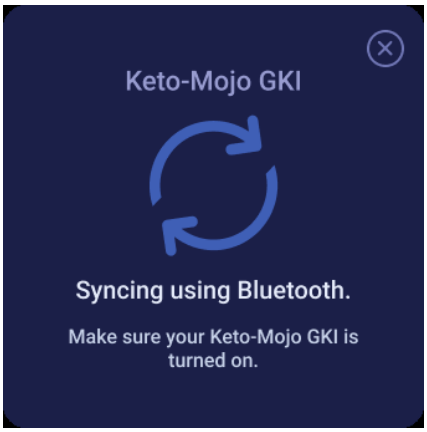
On the “Enter your current blood glucose” screen, you can press “Add a device” to start the setup.



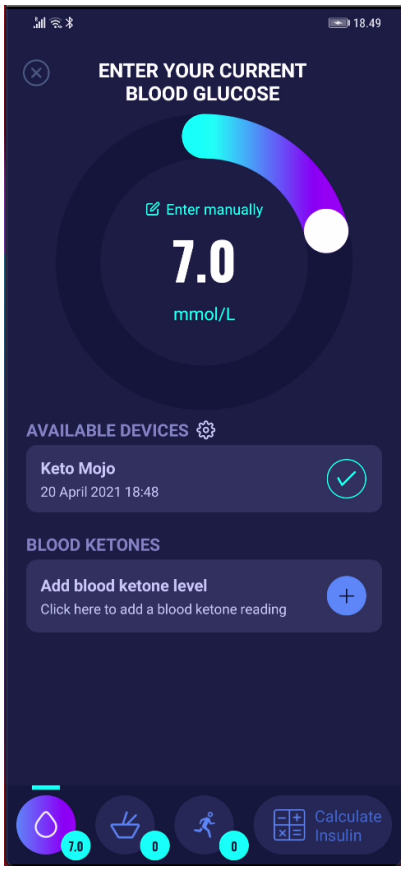
A list of the supported devices will appear. Tap on the desired device.



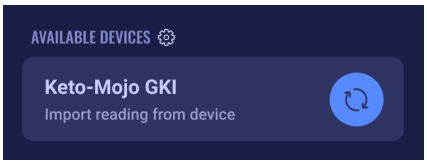
An info screen of the device and its connection type appears.
HDA will start searching for the Keto-Mojo GKI device. If pairing for the first time with Keto-Mojo, then make sure it’s in pairing mode..
Hold down the button until the light turns blue, and it will appear on the list as shown above.
Tap “connect” to pair the device.



HDA will sync with the selected Keto-Mojo GKI using Bluetooth. Make sure the blood glucose reading is made within the last 10 minutes.



The latest blood glucose reading from your device is now in HDA.

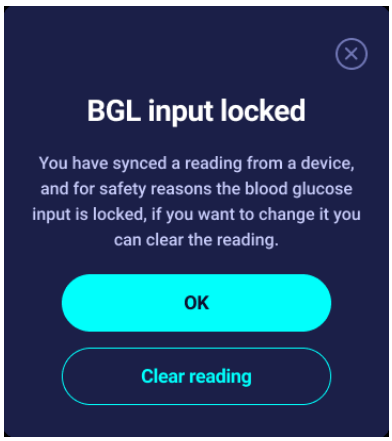


The added Keto-Mojo GKI device is now default and available, and will sync using the “Import reading from device” button.

4.5 Blood glucose input locked after synchronisation

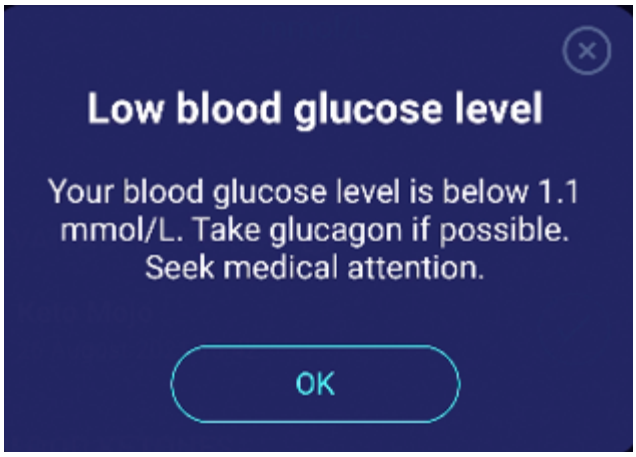
After your device has been connected and has transferred the latest reading to HDA, the screen titled “Enter your current blood glucose” will be locked. This means that you can not change the blood glucose displayed on the screen, either manually or by using the circular slider.

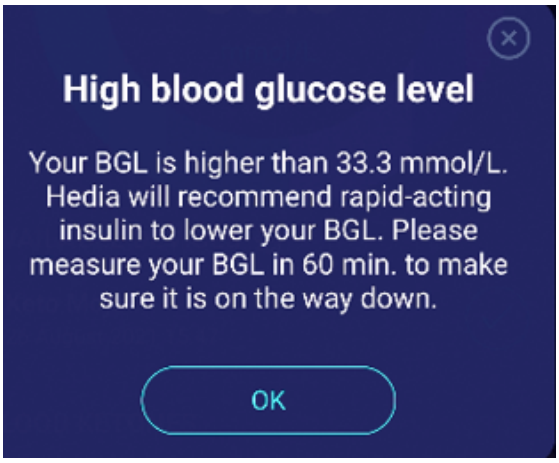
If you want to change the blood glucose you must tap the circular slider on the screen. After doing so, a message will appear on the screen stating that the blood glucose input is locked. Then, press “clear reading” which will delete the synchronisation with the device and reset the measurement. Now you can start the measurement once again (see picture below).



4.6 Alerts for low and high blood glucose when syncing from device

If you have transferred a blood glucose measurement, that is either lower than 1.1 mmol/L or higher than 33.3 mmol/L, from your device to HDA, you will see the following warning messages on your screen (see pictures below).



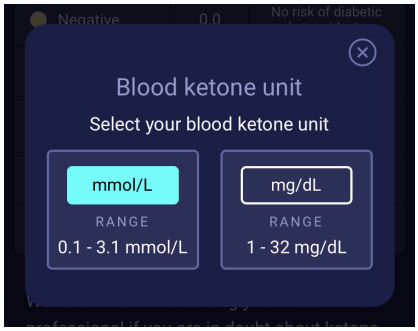


5. Blood ketones

In HDA it is possible to add and log your blood ketone level. Please note that it is ONLY possible to enter blood ketone levels in HDA and NOT ketones measured in urine or breath. The blood ketone unit can be indicated as either mmol/L or mg/dL.

5.1 Blood ketone units

Blood ketone levels are indicated in HDA as mmol/L or mg/dL. When you enter a blood ketone level for the first time in HDA, the blood ketone unit must be chosen manually. Which unit you need to select depends on the blood ketone meter that you are using.



5.2 Blood ketone ranges

In HDA there is a minimum and a maximum limit for entering a blood ketone level.

The limits for entering a blood ketone level with the unit mmol/L are the following:

- minimum limit: 0.0 mmol/L
- maximum limit: 8.0 mmol/L

The limits for entering a blood ketone level with the unit mg/dL are the following:

- minimum limit: 0.0 mg/dL
- maximum limit: 83.33 mg/dL

When entering your blood ketone level, an attention message and reminder will appear depending on the blood ketone level you have entered.
The ranges for blood ketone levels and related attention messages and reminders can be seen below (table 5):

Table 5: Blood ketone values, definitions, attention messages and reminders

Blood ketone ranges	Definition	Action/Attention message	Reminder
0.0 mmol/L 0.0 mg/dL	Negative	You have a normal blood ketone value. No action needed.	No reminder
> 0.0 - 0.6 mmol/L > 0.0 - 6.25 mg/dL	Normal ketone level	You have a normal blood ketone value. No action needed.	No reminder
> 0.6 - 1.6 mmol/L > 6.25 - 16.67 mg/dL	Slightly increased ketone level	Your blood ketone value is slightly increased. We recommend that you test again in 4-6 hours to see if the value has lowered.*	We recommend that you remeasure blood ketones in 4-6 hours.
> 1.6 - 3.0 mmol/L > 16.67 - 31.25 mg/dL	High level of ketones	Your blood ketone value is high and could present a risk of diabetic ketoacidosis. We recommend that you test again in 3-4 hours.*	We recommend that you remeasure blood ketones in 3-4 hours.
2. time measured > 1.6 - 3.0 mmol/L within 12 hours 2. time measured > 16.67 - 31.25 mg/dL within 12 hours	High level of ketones	Your blood ketone value is still high and could present a risk of diabetic ketoacidosis. We advise you to contact your healthcare team for advice.*	We recommend that you remeasure blood ketones in 1-3 hours.

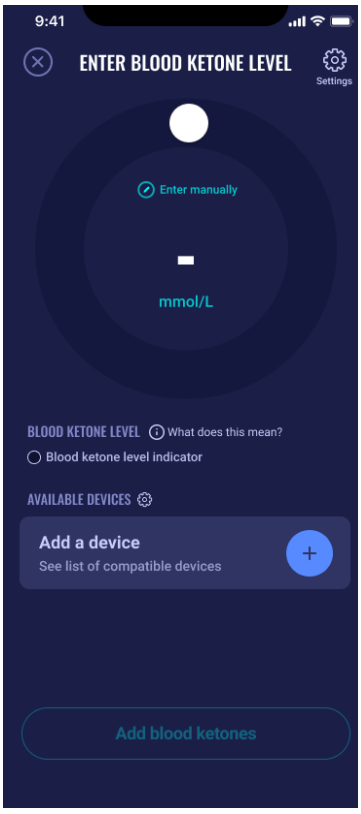
> 3.0 - 8.0 mmol/L > 31.25 - 83.33 mg/dL	Dangerous level of ketones	Your blood ketone value is very high which puts you at great risk of developing diabetic ketoacidosis. We recommend that you get immediate medical care.	We recommend that you remeasure blood ketones in 1 hour.

*If you have not entered your BG, you will be reminded to measure your BG and administer rapid-acting insulin accordingly.

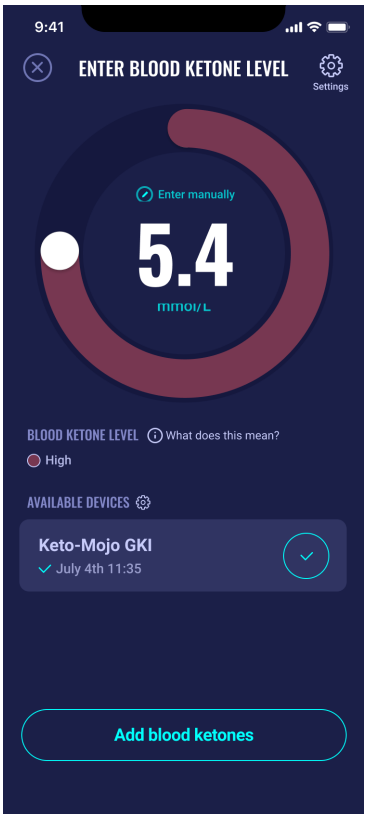
5.3 How to log your blood ketone level in HDA

In HDA it is possible to add your blood ketone level to the separate screen titled “Enter blood ketone level”. This can be accessed in the bottom of the screen “Enter your current blood glucose” where you enter your current BG as a part of the insulin calculation (see section 3.6.3).

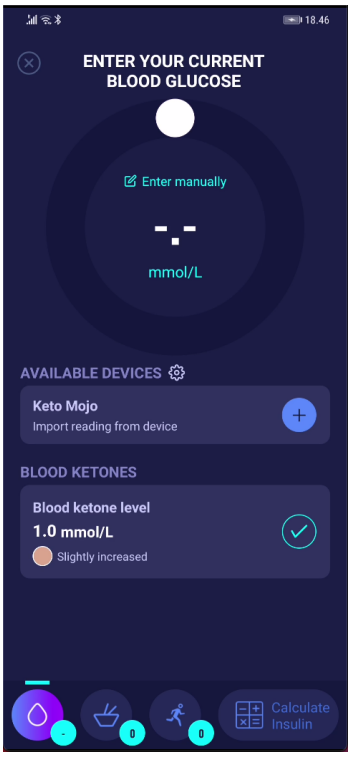
You can log your blood ketone level as a part of your insulin calculation flow or you can log your blood ketone level without making an insulin calculation by going to the “Enter blood ketone level” screen and then add it to your logbook. To see how to log blood ketones levels only, see visual description below.



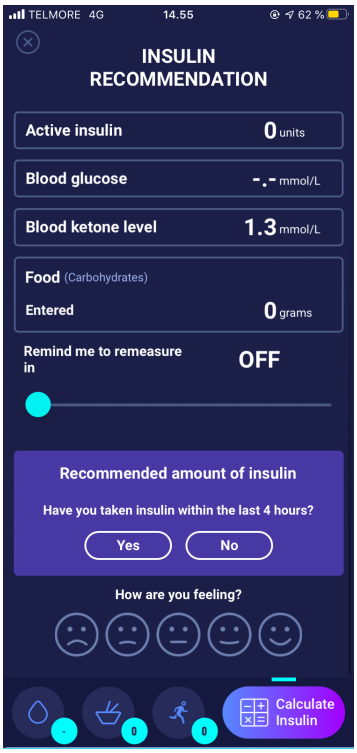
On the “Enter blood ketone level” screen, you can either enter your blood ketone level manually or connect with Keto-Mojo GKI device.



When you have entered the blood ketone level either manually or via Keto-Mojo GKI, then press “Add blood ketones” in the bottom of the screen.

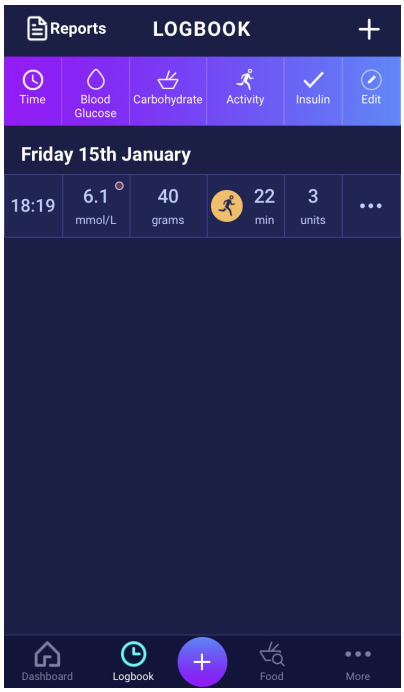


Now the blood ketone level is added on the “Enter your current blood glucose ” screen under “Blood ketones”. To log the blood ketone level only ,simply press the “Calculate insulin” button.



The blood ketone level will now be shown in the calculation as the only element. Press “Transfer to logbook” to add the blood ketone level to your logbook.

When you have logged your blood ketone level, you will be able to see a symbol (a coloured dot) in your logbook next to your BG. The colour of the symbol will also be an indicator of the ketone level.

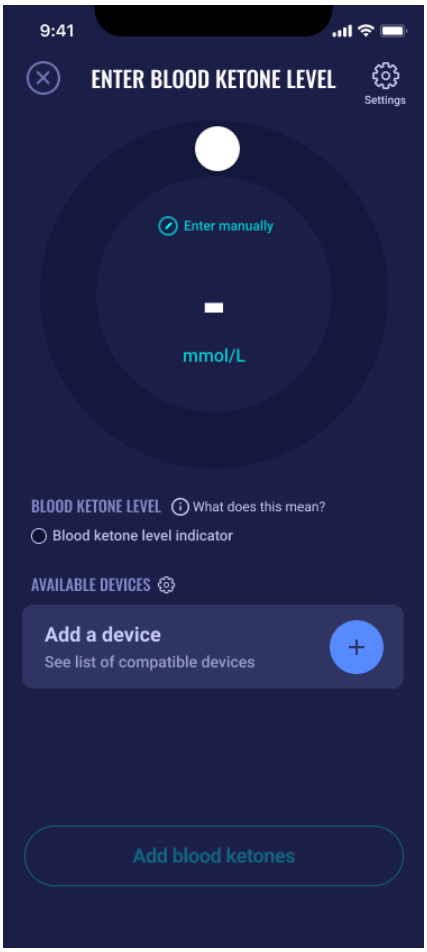


Your blood ketone entry will be marked with a colour which indicates the level of ketones in your blood. To see which level the different colours indicate, go to section 10.2.2.1.

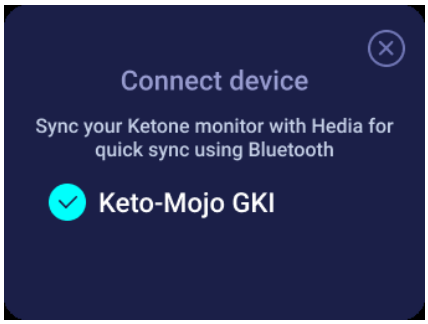
5.3.1 How to set up and use Keto-Mojo GKI for blood ketone measurements in HDA via Bluetooth

With Keto-Mojo GKI it is possible to measure both your BG and your blood ketone level.
If you want to read more about how to set up and use Keto-Mojo GKI for measuring your BG, see section 4.4.3.

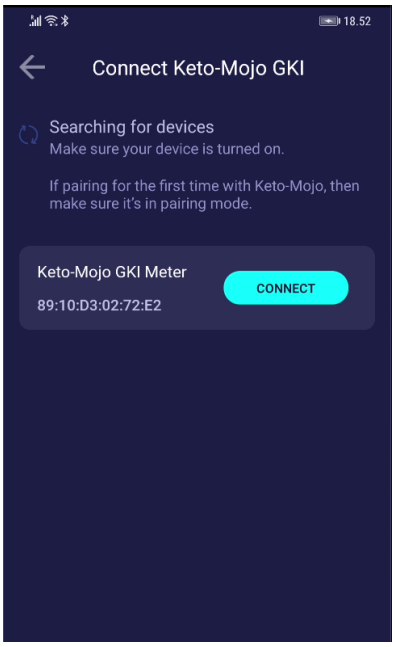
When you want to sync HDA with your Keto-Mojo GKI for measuring your blood ketone level, follow the guide below to set up your device.



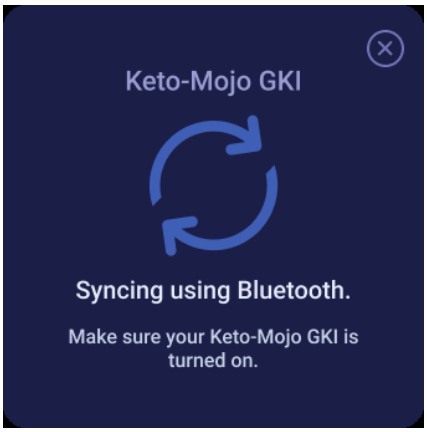
On the “Enter blood ketone level” screen, you can press “Add a device” to start the setup.



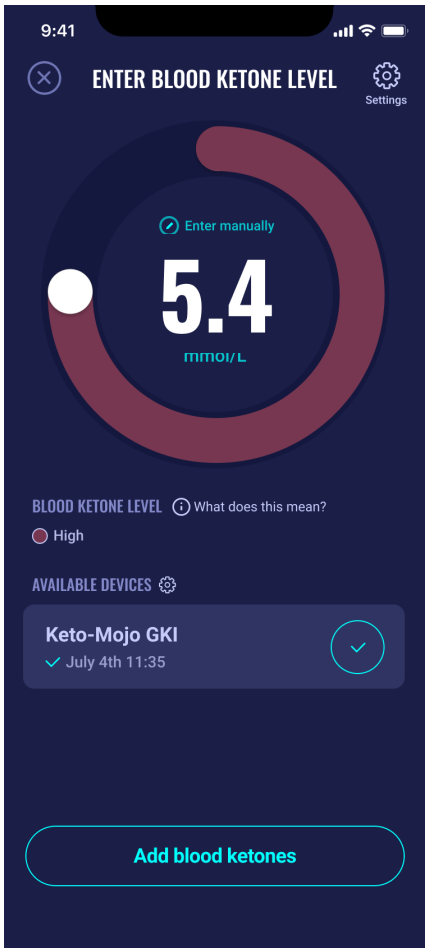
The supported device will appear on the screen. Tap on the desired device.



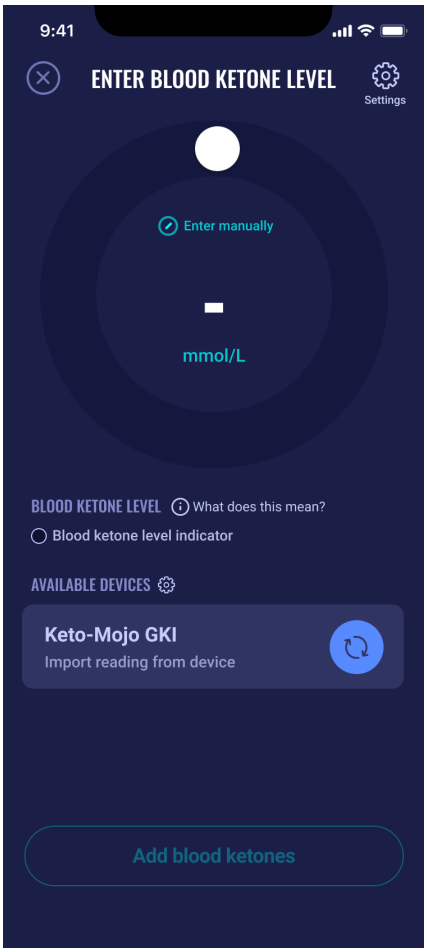
An info screen of the device and its connection type appears.
HDA will start searching for the Keto-Mojo GKI device. If pairing for the first time with Keto-Mojo, then make sure it’s in pairing mode.
Hold down the button until the light turns blue, and it will appear on the list as shown above. Press connect.
Tap “connect” and sync to pair device.



HDA will sync with the selected Keto-Mojo GKI using Bluetooth.
Make sure your blood ketone reading is made within the last 60 minutes.
HDA will add the latest reading which has been made within the last 60 minutes.



The latest reading from the device is now in HDA.



The added device is now default and available, and will sync using the “Import reading from device” button.

6. Food

In HDA carbohydrates are entered in grams, with no decimals, the same applies for carbohydrates recommended by HDA in case of hypoglycemia.

In HDA it is possible to:

- enter the amount of carbohydrates manually or
- choose one or more food items in the food database, where HDA will estimate what nutrients the food items contain, including carbohydrates (see section 6.3. Food database).

In HDA the limits for entering carbohydrates per meal are the following:

- low limit: 0 g of carbohydrates
- high limit: more than 300 g of carbohydrates

6.1. Subsequent meals

HDA calculates insulin for all meals entered based on the amount of carbohydrate you enter. If you eat more meals or snacks in a short period of time, HDA will add a meal dose for each meal.

6.1.1. Correction dose after a meal

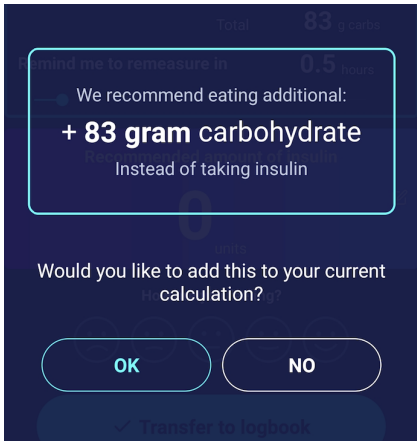
It is important not to make corrections due to the increase in BG that is expected to happen after a meal to avoid insulin stacking. This is because all carbohydrates from previously logged meals have already been taken into account in previous boluses and the appropriate amount of insulin to lower the BG after the expected rise have already been recommended. Injecting more insulin would eventually lower your blood glucose too much. To avoid insulin stacking, HDA takes active insulin into account in its calculations. To read more about active insulin, see section 7.1 active insulin.

6.2. Carbohydrate suggestions

In case of low blood glucose (hypoglycaemia), HDA does not recommend insulin, but carbohydrates.

HDA recommends carbohydrates based on the following formula:
Carbohydrate = (Target BG - Current BG) / Insulin Sensitivity factor * Insulin-to-carb ratio

The recommended amount of carbohydrates will appear on the “insulin recommendation” screen, under “food”.

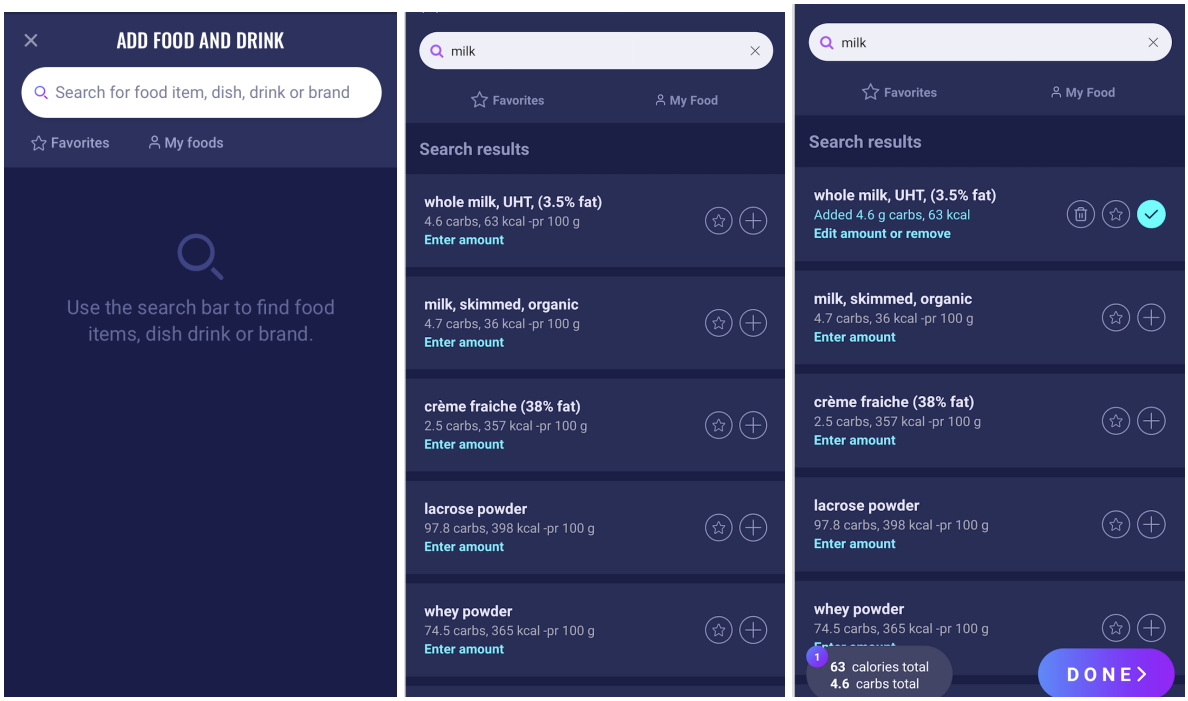


6.3. Food database

HDA has a built-in food database with 1700 food items. It can be accessed on the “Food and Drinks” page in the insulin recommendation calculation flow.

6.3.1. Search for food items

The bottom menu shows currently selected amount of carbs and calories



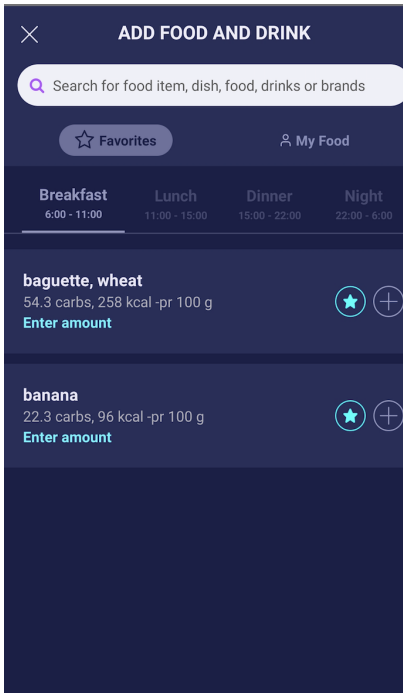
Adjust amount of food item. The default amount unit is grams.

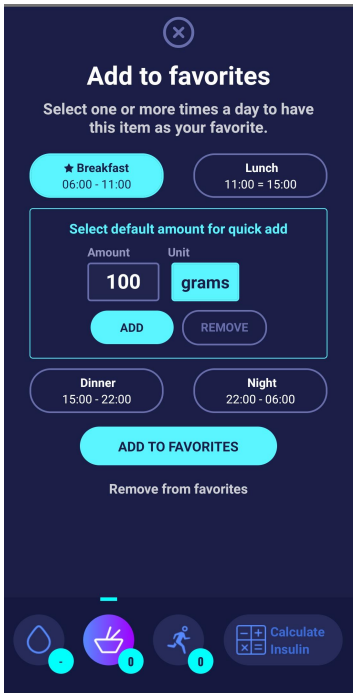
6.3.2. Favorites

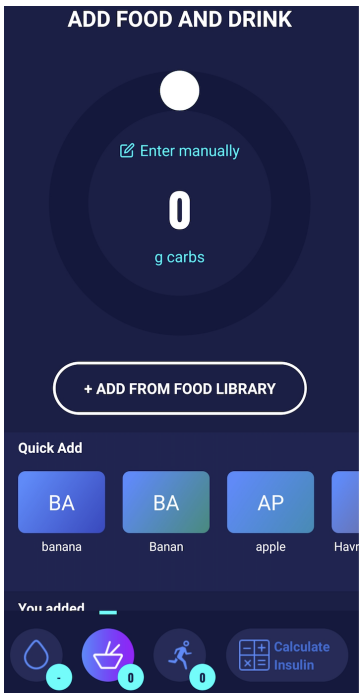
Your meals will appear on the “food” screen when you have added them as a favorite.

Favorites can be added to the intervals

- Breakfast 6:00-11:00
- Lunch 11:00 - 15:00
- Dinner 15:00 - 22:00
- Night 22:00 - 6:00

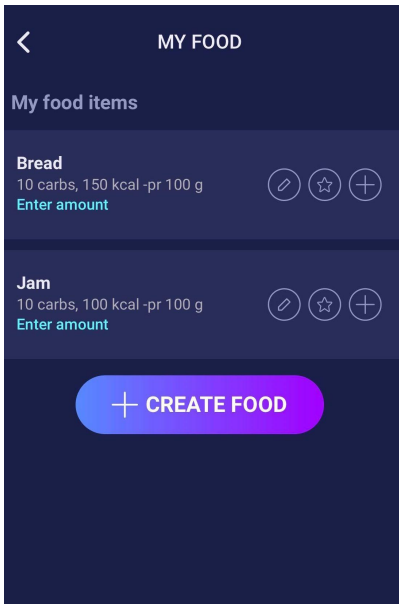




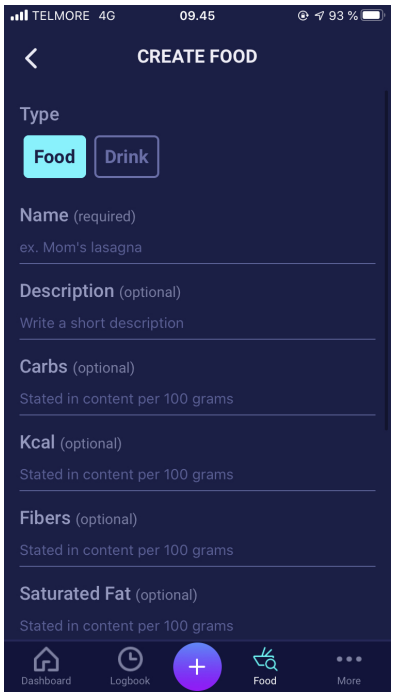


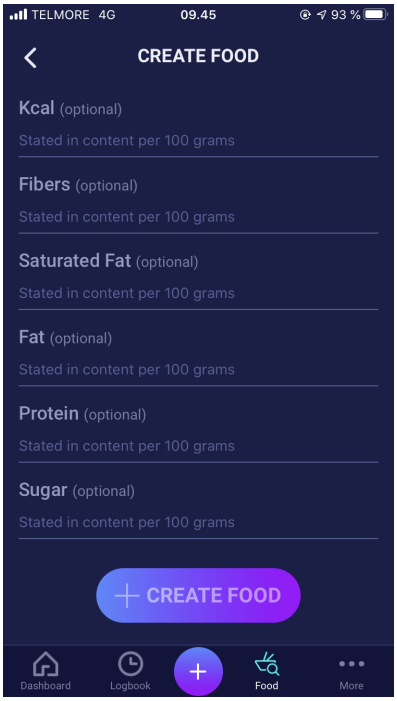
6.3.3. My food

Personal food items can be added under **My foods**



6.3.4. Create food





7. Insulin

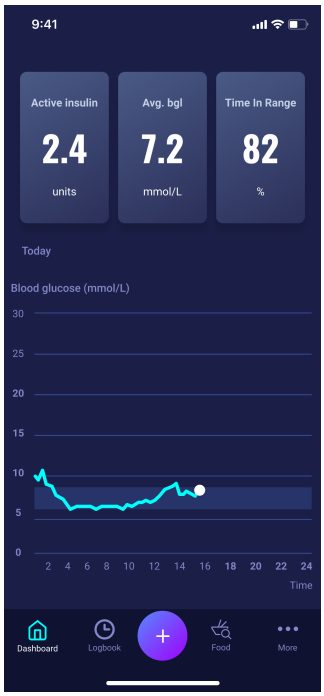
HDA's calculations are based on a rapid-acting insulin analogue. The "Insulin recommendation" page in HDA shows the calculations for HDA's recommendations.

This calculation shows how many units of insulin HDA recommends. In addition, active insulin appears in the calculations. It is important that you as a user check HDA's calculations before approving a dose.

7.1. Active insulin

Active Insulin tells how many units of rapid-acting insulin are left in the body and still working. HDA automatically calculates the amount of active insulin and displays it on the dashboard and on the "insulin recommendation" page. HDA takesactive insulin into account in its calculations.

HDA uses the Novorapid curve for these calculations. The maximum plasma concentration of Novorapid is reached after 30-40 minutes (Ref. 3).



The effect on blood glucose concentration occurs 10-20 minutes after subcutaneous injection and is maximal between 1 and 3 hours. Duration is 3-5 hours, depending on dose (1). HDA's calculations thus look like this (table 6):

Table 6: Insulin effect curve

Insulin effect curve					
Time (hours)	1	2	3	4	5
Percentage (%)	29	47	19	5	0

The curve is furthermore divided into 4 x 15 min for the first hour and 2 x 30 min for the next 3 hours to make calculations based on the most precise amount of active insulin as possible (Ref. 3).

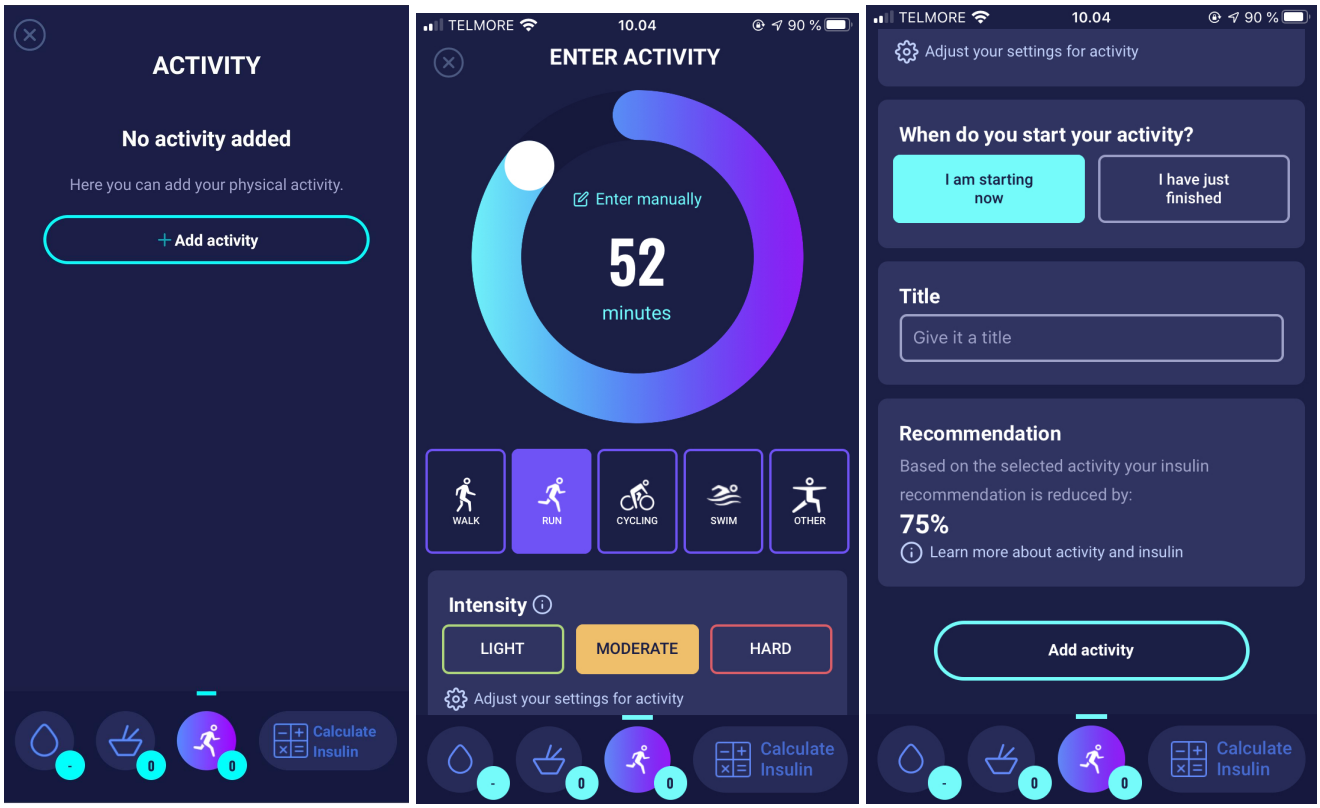
If you have not documented any bolus insulin within the last 4 hours, HDA asks: *Have you taken rapid-acting insulin within the last 4 hours?* If yes, you are asked to enter the amount of rapid-acting insulin injected within the last 4 hours.

7.2. Maximum insulin dose

HDA is set with a limit on how much insulin the app recommends. This maximum is 50 units for one administration/in one dose. The limit also applies to manual entries and is a precautionary measure to avoid unintentionally large doses.

8. Activity

In HDA you can add your activity to the calculation of your insulin recommendation, either before or after an activity.



8.1. Activity levels in HDA and their effect

To rate your perceived exertion, HDA uses “The Borg Rating of Perceived Exertion” which is a way of measuring your physical activity intensity level.

Perceived exertion is how hard you feel like your body is working. It is based on the physical sensations you experience during physical activity, including increased heart rate, increased respiration or breathing rate, increased sweating, and muscle fatigue. Although this is a subjective measure, your exertion rating may provide a fairly good estimate of your actual heart rate during physical activity.

Always consult your physician before beginning any activity. This general information is not intended to diagnose any medical condition or to replace your healthcare professional. Consult with your healthcare professional to design an appropriate physical activity prescription. If you experience any pain or difficulty during activity, stop and consult your healthcare provider.

8.2. How HDA calculates the effect of activity

Table 7: Calculated effect of activity in HDA

	Intensity			
Duration	**Light activity**	**Medium activity**	**Hard activity**	**Post activity**
0-29 minutes	0 %	0 %	0 %	0 %
30-45 minutes	25 %	50 %	75 %	50 %
46-60 minutes	50 %	75 %	--- Text ---	50 %
More than 60 minutes	Consult healthcare professional			
Starting target BG	9 mmol/L or 162 mg/dL			

8.3. Duration of activity

When using the activity module in HDA the circular slider can set the time spent on physical activity up to 60 minutes.

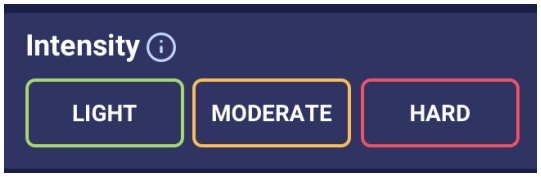
8.4. Type of activity

After setting the duration of your activity, you can add the type of activity you have performed. You do this by clicking on the icon below the circular slider.

8.5. Intensity of activity

The next step is to enter how intense your activity is going to be/has been. You do this by pushing “light”, “moderate” or “hard”. The chosen intensity enables the activity effect on the insulin algorithm.

Next to intensity is an “i” in a circle. Push the icon for more information related to the use of the BORG scale.



8.6. Start time of an activity

When you add an activity, you can record when the activity is performed (“I am starting now” or “I have just finished”).
The added activity can then affect the calculations you make for up to 4 hours after the start time of the activity.

If you want to use the same activity in your subsequent calculations, this will be visible on the “activity” page for 4 hours from the start time of the activity. The same activity can thus be selected in future calculations for 4 hours from the start time of the activity. Consequently, the effect of your activity in percentage can be deducted from your calculation 4 hours after you have been active.

Make sure to create a new activity if you are physically active again within the 4 hours, rather than re-selecting the old activity. This is important as the start time of your activity affects the percentage deducted from your calculation (see section 8.2 How HDA calculates the effect of activity).

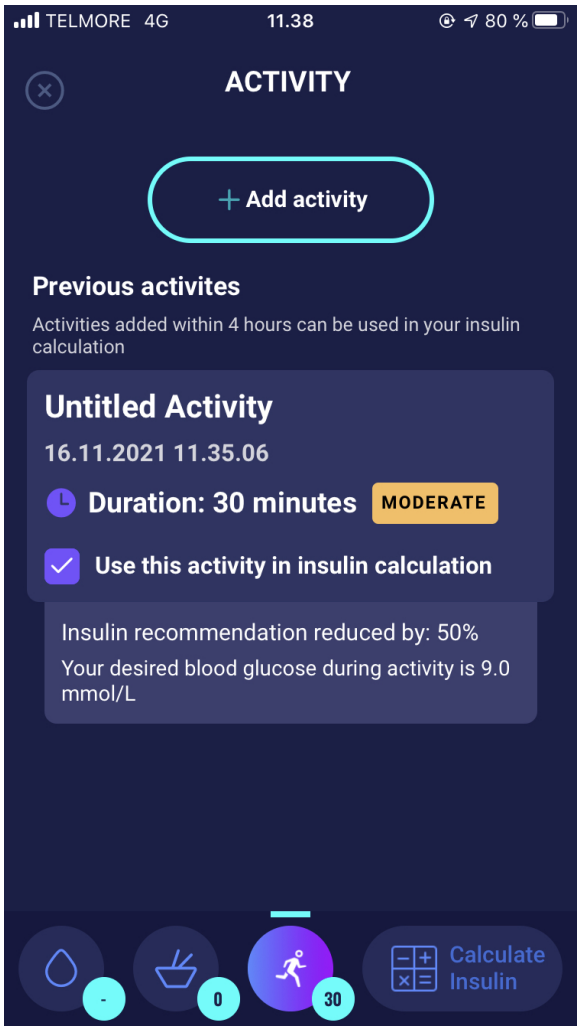
8.6.1 Add additional activity instances

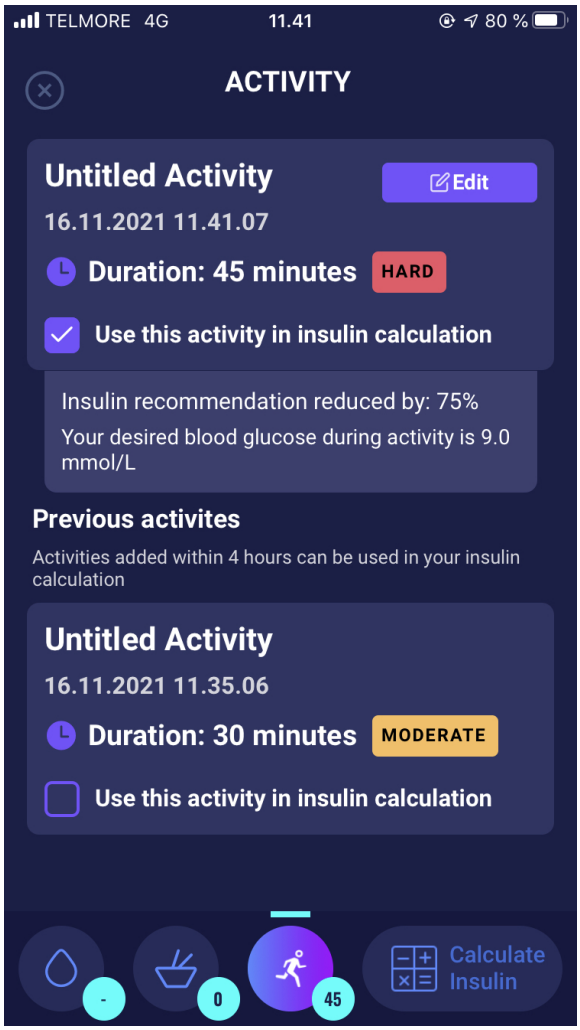
It is possible to create a new activity even though you have added an activity within the last 4 hours.

If you are physically active within the 4 hours since your last activity, then create a new activity by pressing the "+ Add activity" button. This button is shown above the previous activity (see picture below).

The activities which are added within the last 4 hours will be shown under "Activity" and can be used for the calculation of the insulin recommendation. It is only possible to choose one activity for the calculation. HDA takes into account the activity marked with a tick (see picture below).

The more physically active you are – both in terms of time interval and intensity – the higher impact the activity has on the blood glucose. HDA will therefore include the activity with the highest impact in the insulin calculation unless you choose an activity yourself to include.

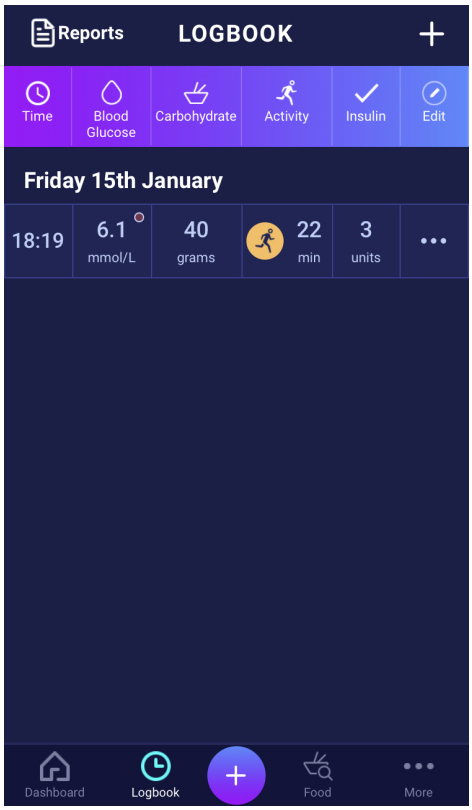




9. Logbook

It is possible to access all of your entered data in your logbook and to

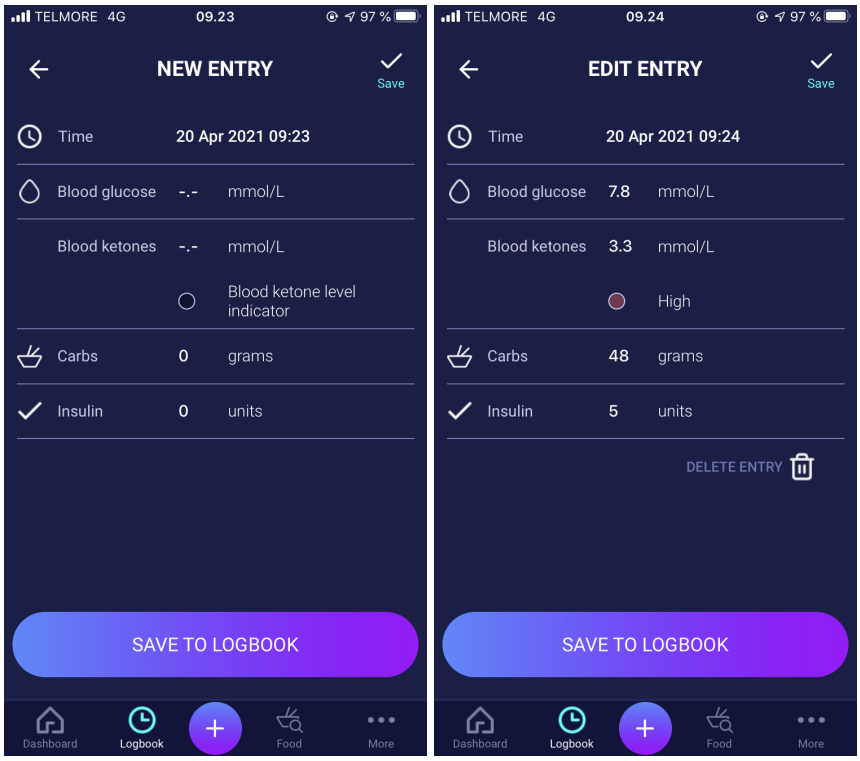
- Export a PDF of your data
- Add a log
- Delete a log
- Edit a log



9.1. Edit and Create entry

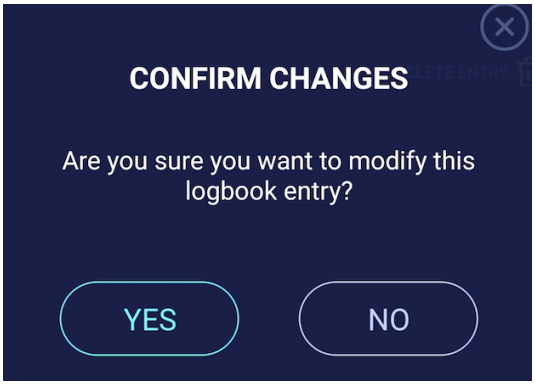
It is possible to edit previous logbook entries and create new ones. If you edit or create new entries within 4 hours from current time HDA will calculate the remaining amount of active insulin and subtract it from your future calculations.

To edit an entry, tap on the desired logbook entry.
Create a new entry by pressing the (+) icon on the logbook screen (in the upper right corner).



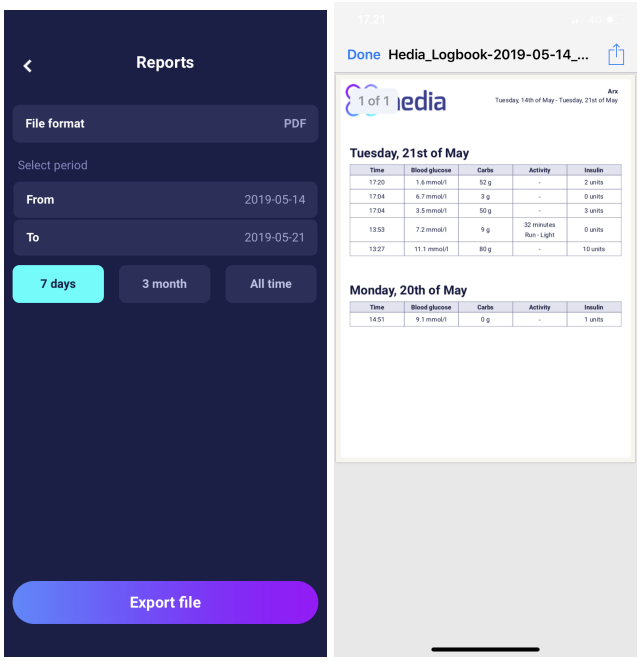
9.2. Edit entries less than 4 hours after logging

If you edit the parameters of a calculation in the logbook less than 4 hours after logging you are presented with the following pop-up. HDA needs this information to update your calculated active insulin for future calculations of your insulin recommendations.



9.3 Export logbook entries

By tapping “Reports” in the Logbook, you can select the format and time frame for exporting your data. This report can be very useful to show your health professional at your next planned consultation.



The file can be sent with the built-in platforms in your phone.

10. Settings

Under settings, you have the option to change your settings for:

- your profile
- password
- turning notifications on or off
- blood glucose
- insulin-to-carb ratio
- insulin sensitivity factor
- activity
- food

10.1. Account Settings

10.1.1. Edit Profile

Under “Edit profile” you are able to input the following:

- First name
- Diabetes Type
- Biological sex
- Date of birth
- Height
- Weight

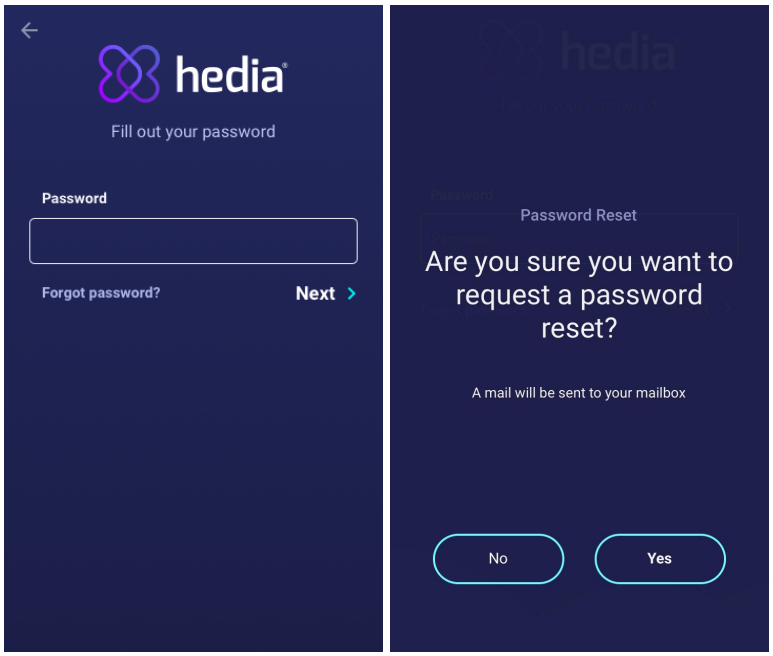
You can also change your data consent.

In HDA it is possible to type in a weight and height in profile settings, within the following limits:

- height: 50 cm - 220 cm, with a precision of 0.5 cm
- weight: 35 kg - 300 kg, with a precision of 0.1 kilo

10.1.2. Forgot password

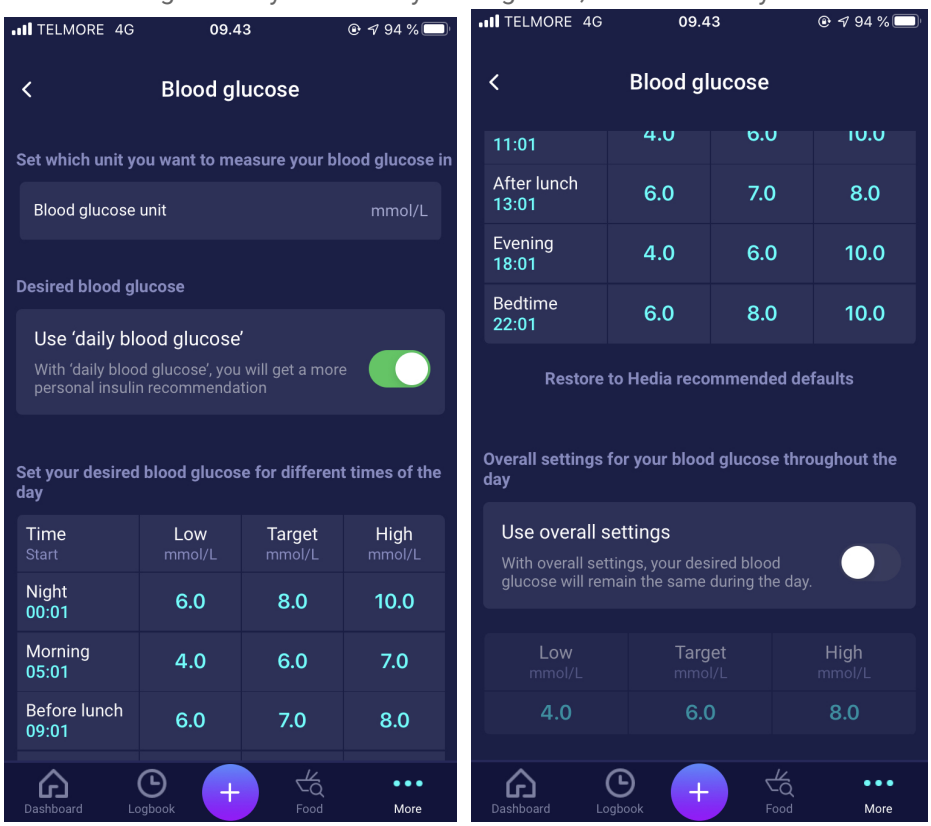
If you have forgotten your password when signing in to HDA, you can tap the “Forgot Password” button. An email with instructions to reset your password will be sent to the email used to sign in.



10.2. Personal Settings

10.2.1. Blood Glucose

Under “Blood Glucose” you can change the settings for your blood glucose and change the blood glucose unit. Under “blood glucose” you can set your target BG, as well as set your limits for low and high blood glucose.



In “Blood Glucose” settings you are able to adjust the desired BG for “low”, “target”, and “high” using:

- “daily blood glucose” or
- overall settings for your blood glucose

The default settings for “daily blood glucose” in HDA is divided into seven time periods throughout the day as seen below (table 8):

Table 8: Default settings for the seven time periods in HDA

No.	Time period	Time of day
1.	00:01 - 05:00	Night
2.	05:01 - 09:00	Morning
3.	09:01 - 11:00	Before lunch
4.	11:01 - 13:00	Lunch
5.	13:01 - 18:00	After lunch
6.	18:01 - 22:00	Evening
7.	22:01 - 00:00	Bedtime

Default settings for “daily blood glucose” divided into the seven time periods (table 9 and table 10):

Table 9: Default blood glucose units in mmol/L divided into the seven time periods.

Period of time	Low BG	Target BG	High BG
1. Night	6 mmol/L	8 mmol/L	10 mmol/L
2. Morning	4 mmol/L	6 mmol/L	7 mmol/L
3. Before lunch	6 mmol/L	7 mmol/L	8 mmol/L
4. Lunch	4 mmol/L	6 mmol/L	10 mmol/L
5. After lunch	6 mmol/L	7 mmol/L	8 mmol/L
6. Evening	4 mmol/L	6 mmol/L	10 mmol/L
7. Bedtime	6 mmol/L	8 mmol/L	10 mmol/L

Table 10: Default blood glucose settings in mg/dL divided into the seven time periods.

Period of time	Low BG	Target BG	High BG
1. Night	108 mg/dL	144 mg/dL	180 mg/dL
2. Morning	72 mg/dL	108 mg/dL	126 mg/dL
3. Before lunch	108 mg/dL	126 mg/dL	144 mg/dL
4. Lunch	72 mg/dL	108 mg/dL	180 mg/dL
5. After lunch	108 mg/dL	126 mg/dL	144 mg/dL
6. Evening	72 mg/dL	108 mg/dL	180 mg/dL
7. Bedtime	108 mg/dL	144 mg/dL	180 mg/dL

Default settings for blood glucosefor overall settings is seen below (table 11 and table 12):

Table 11: Default for overall settings for blood glucose units in mmol/L

Low BG	Target BG	High BG
<4 mmol/L	6 mmol/L	> 8 mmol/L

Table 12: Default for overall settings for blood glucose units in mg/dL

Low BG	Target BG	High BG
< 72 mg/dL	108 mg/dL	> 144 mg/dL

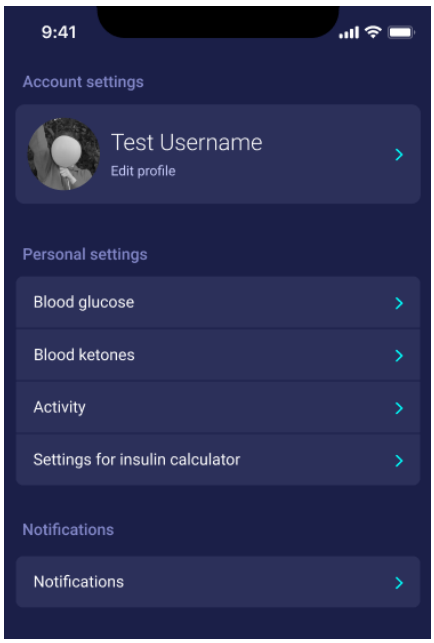
For safety and to minimize risks of hypoglycemia, the limit for adjusting BG values in the settings is (table 13):

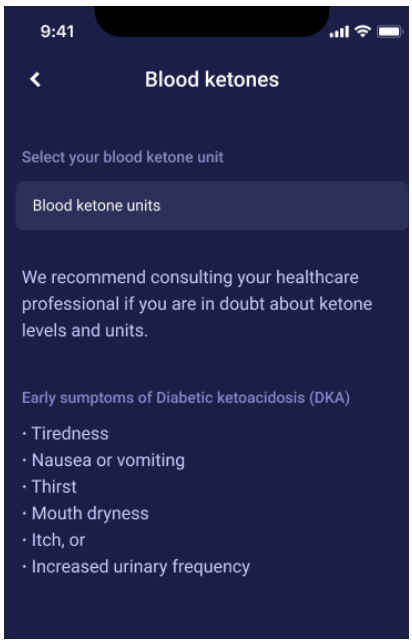
Table 13: Limits for adjusting BG values in HDA in mmol/L and mg/dL

Setting	Value
Low BG minimum	3.0 mmol/L (54 mg/dL)
Low BG maximum	6 mmol/L (108 mg/dL)
Target BG minimum	5.0 mmol/L (90 mg/dL)
Target BG maximum	13.9 mmol/L (250 mg/dL)
High BG minimum	7.0 mmol/L (126 mg/dL)
High BG maximum	20 mmol/L (360 mg/dL)

10.2.2. Blood Ketones

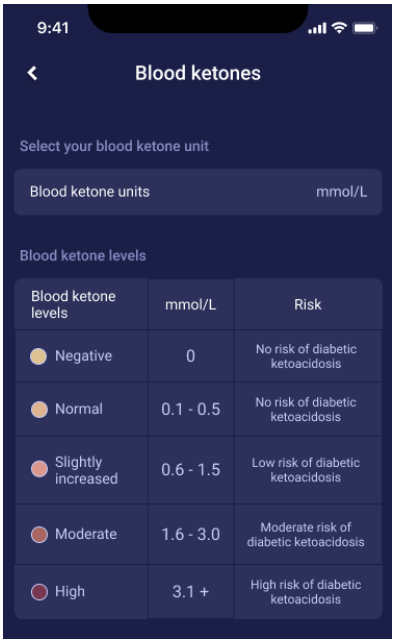
Under “Personal settings” you can find settings for blood ketones where you can select and change your blood ketone unit. Under the settings for blood ketones you can also find information regarding ketones and diabetic ketoacidosis.





10.2.2.1 Blood ketone colour indicators

Your blood ketone entry will be marked with a colour which indicates the level of ketones in your blood. The different colours and respective ranges and risks related to the range of ketone levels is shown in this table under blood ketone settings and can be seen below. A light beige colour indicates a negative/normal blood ketone level with no/low risk of diabetic ketoacidosis and a dark red colour indicates a high level of blood ketones and a high risk of diabetic ketoacidosis.



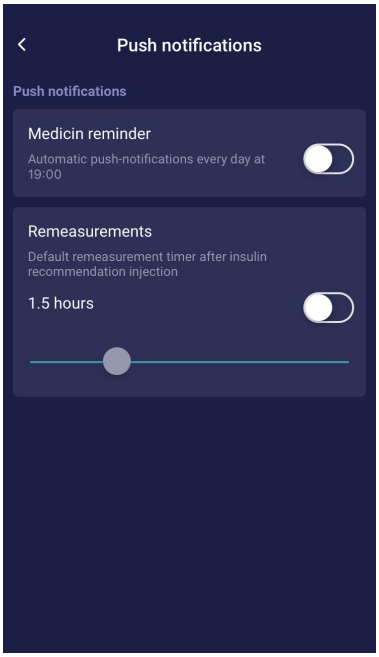
10.3. Notifications

10.3.1. Medicine reminder

You can activate and set a daily “medicine reminder” with a custom time of day.

10.3.2. Remeasurements

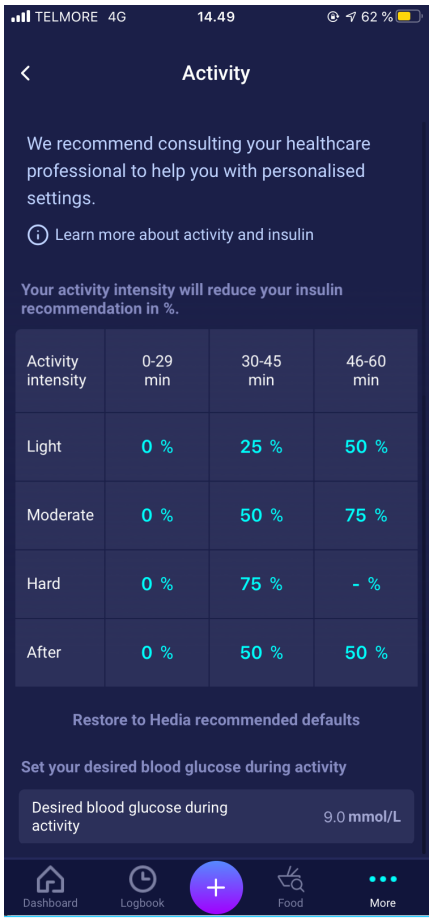
You can activate and set the amount of hours from 0.5 hours to 6 hours for push notifications after the insulin recommendation log.
The default setting is 1.5 hours.



10.4. Activity

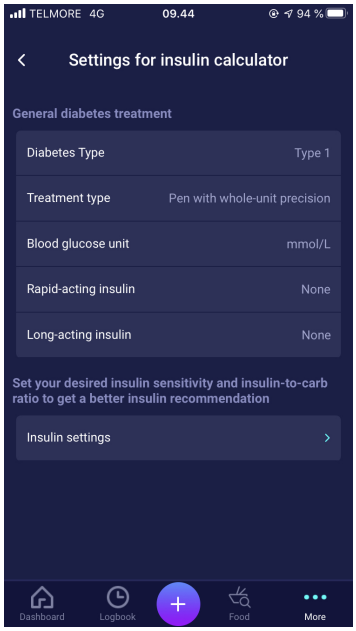
Under “Activity” you can define the percentage, which will reduce your insulin recommendation as a percentage (%). This can be done for “light”, “moderate” and “hard” intensity.

You can also set your desired blood glucose during physical activity. The first time you use HDA, the default setting for your desired blood glucose during activity is 9.0 mmol/L (162 mg/dL). The limits for adjusting your desired blood glucose during physical activity in HDA are 5.0 mmol/L (90 mg/dL) - 13.9 mmol/L (250 mg/dL).



10.5. Settings for Insulin Calculation

Under “Settings for insulin calculator” you can change your settings for your general diabetes treatment, change your insulin sensitivity factor and insulin-to-carb ratio, and you have the opportunity to get help with the 500 rule and the 100/1800 rule.



10.5.1 Treatment type

In HDA it is possible to choose between “pen” or “pump” as the treatment type. When choosing “pen” it is possible to choose between the following two unit precision options:

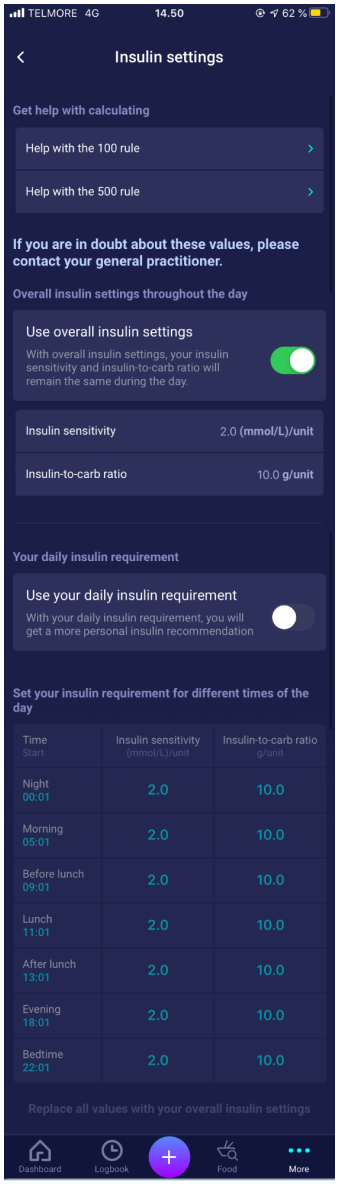
- pen with half-unit precision
- pen with whole-unit precision

When choosing pump it is possible to choose the following:

- pump with the precision of 1 decimal

10.5.2 Insulin settings

Under “Insulin settings” you can see your calculated insulin-to-carb ratio and insulin sensitivity factor. These settings are calculated based on your entries during your first calculation setup.
You have the ability to adjust your insulin-to-carb ratio and insulin sensitivity factor, within the limits of HDA (*table 14: Limits for adjusting the insulin sensitivity factor and insulin-to-carb ratio*).



In “Insulin settings” you can set your insulin settings throughout the day using

- an overall setting for insulin sensitivity factor and insulin-to-carb ratio (use overall insulin settings) or
- you can set your daily intervals for insulin sensitivity factor and insulin-to-carb ratio (use your daily insulin requirement)

Insulin sensitivity factor and insulin-to-carb ratio can be adjusted in insulin settings for both “Overall insulin settings” and for “Daily insulin requirement ”.

Table 14: Limits for adjusting the insulin sensitivity factor and insulin-to-carb ratio

	mmol/L	**mg/dL**
Insulin sensitivity factor	• Minimum 0.3 mmol/L • Maximum 10 mmol/L	• Minimum 1.5 mg/dL • Maximum 50 mg/dL
Insulin-to-carb ratio	• Minimum 1 g carbohydrates per unit of insulin • Maximum 50 g carbohydrates per unit of insulin	• Minimum 1 g carbohydrates per unit of insulin • Maximum 50 g carbohydrates per unit of insulin

When using “Your daily insulin requirement ”, both the insulin sensitivity factor and the insulin-to-carb ratio are the same for all seven time periods and are based on your settings from the log-in process. If you want different settings in the seven periods, then you have to change it yourself under “Set your insulin requirement for different times of the day”.

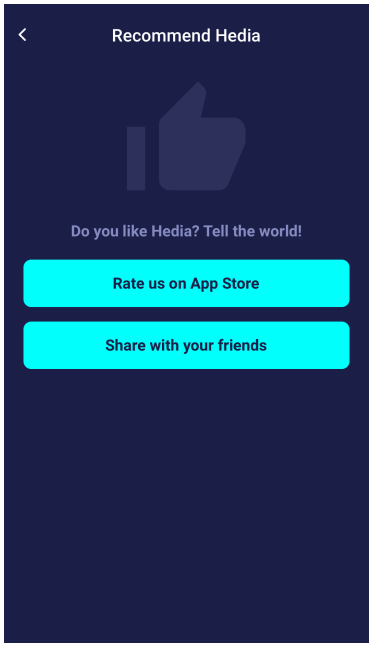
The default settings for daily insulin requirement in HDA are divided into seven time periods throughout the day as seen below (table 15):

Table 15: Default settings for the seven periods in HDA

No.	Time period	Time of day
1.	00:01 - 05:00	Night
2.	05:01 - 09:00	Morning
3.	09:01 - 11:00	Before lunch
4.	11:01 - 13:00	Lunch
5.	13:01 - 18:00	After lunch
6.	18:01 - 22:00	Evening
7.	22:01 - 00:00	Bedtime

10.6. Recommend HDA

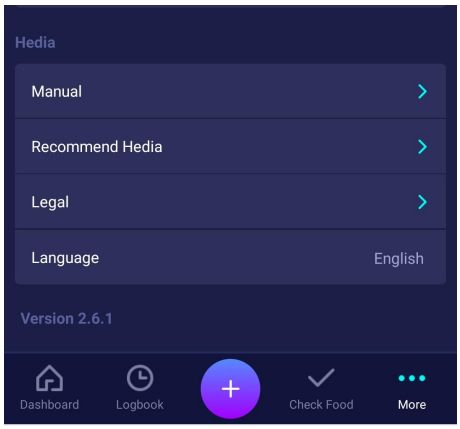
We provide a link to App Store/Google Play to give a rating/review of HDA.

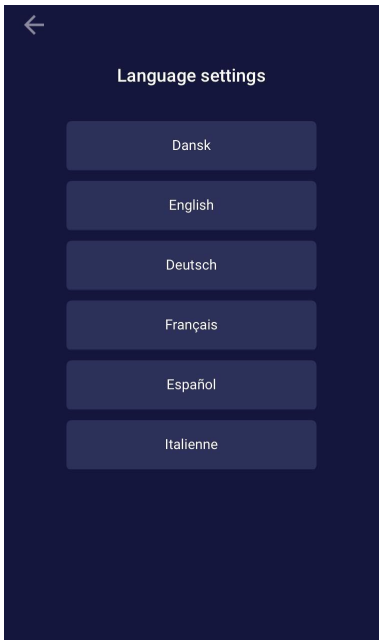


Additionally with the “Share with your friends” you can share a link to download HDA, using different apps on your phone.

10.7. Change language

To change the language in HDA press the “Language” box under “More” to select the desired language.





11. Icons

HDA uses icons to make the app's design more manageable and user-friendly.
In table 16 you can see an overview of the icons that HDA uses. Table 16:

Attention	Info	Close	Back	Add	Close
Add log/insulin calculation	Check food	Logbook	More	Dashboard	Time
Add food item	Edit amount	Add favorite	Remove	0123 CE Mark	Manual edit amount
Insulin calculation	Blood Glucose	Food/Carbs/calories	Activity	Sync BG with device complete	Synchronizing with BG device
Settings for BG device	Walk	Run	Bike	Other	Swim
Mood - sad inactive	Mood - Semi sad inactive	Mood - neutral inactive	Mood - Semi happy inactive	Mood - Happy inactive	Recent food items
Mood - sad active	Mood - Semi sad active	Mood - neutral active	Mood - Semi happy active	Mood - Happy active	My food items
Favorite food item	Search	Date of manufacturer	Manufacturer	Reports	User Manual
Negative ketone level indicator	Normal ketone level indicator	Slightly increased ketone level indicator	Moderate ketone level indicator	High ketone level indicator	UDI-DI

12. Support

You or your relatives can report errors or omissions by emailing us at support@hedia.co. By reporting errors, you can help us provide more information about the safety and performance of this app, as well as ensure you and other users against errors.

For more information, please refer to our Terms and Conditions

13. Contact Information

Date of manufacture:
2021-11-20

Manufacturer:
Hedia ApS
Fruebjergvej 3
DK-2100 Copenhagen, Denmark
CVR/VAT: 37664618

Contact information:
Email: support@hedia.co

GTIN: (01)05700002209535(10)2.11.1(8012)2.11.1

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14. List of references

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