ENGLISH

USER MANUAL

Hedia Diabetes Assistant

Version 2.6.2

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Terminology

Hedia diabetes Assistant = HDA

Blood glucose level = BGL

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 and 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 9.0 or newer or Android version 4.4 or newer.

Based on blood glucose as the fifth vital physiological parameter in diabetes care (ref. 1 og 2) and estimation of carbohydrate intake, physical activity and active insulin, at a given time, it aids in the improvement of managing the patients 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 by being action-advising in 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 diabetes assistant 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.

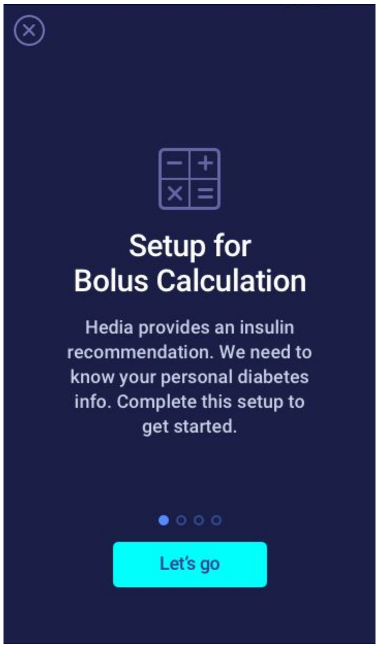
Contact us if you have any questions or experience any errors. An overview of contact information is provided at the back of the user manual.

1.4. With HDA you get:

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

2. First Calculation

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

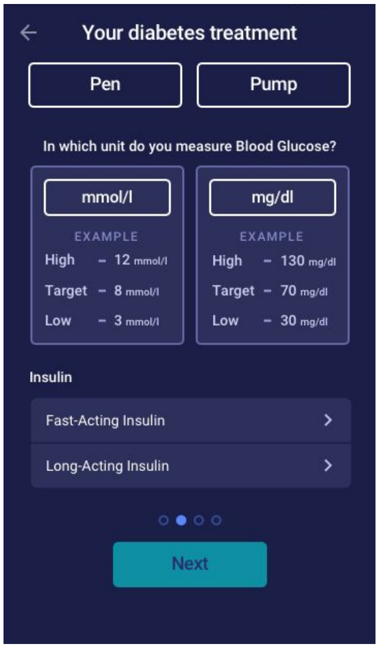


Setup for Bolus Calculation

Hedia provides an insulin recommendation. We need to know your personal diabetes info. Complete this setup to get started.

2.1. Diabetes treatment

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


Your diabetes treatment
Pen
Pump

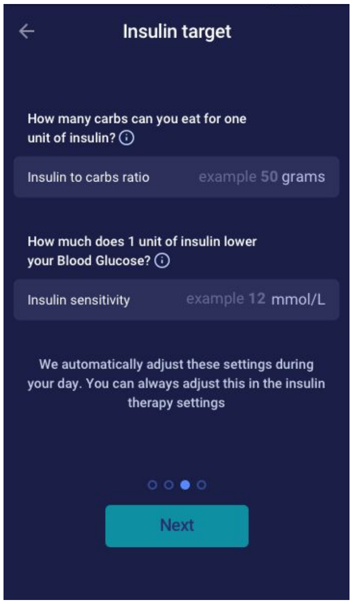
In which unit do you measure Blood Glucose?

mmol/l		mg/dl	
EXAMPLE		EXAMPLE	
High	– 12 mmol/l	High	– 130 mg/dl
Target	– 8 mmol/l	Target	– 70 mg/dl
Low	– 3 mmol/l	Low	– 30 mg/dl

Insulin
Fast-Acting Insulin
Long-Acting Insulin
Next

2.2. Insulin settings

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


Insulin target

How many carbs can you eat for one unit of insulin?

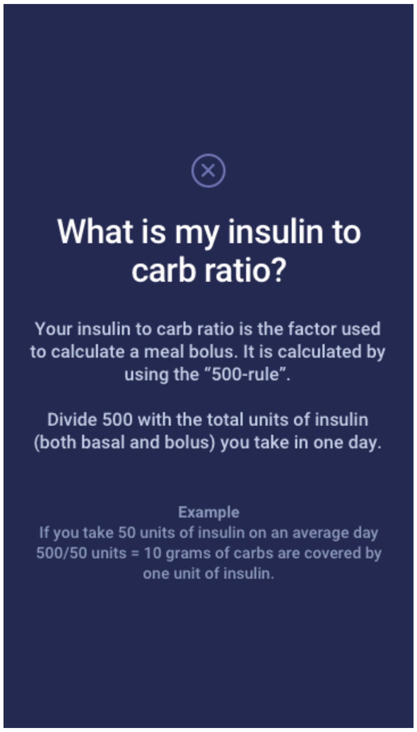
Insulin to carbs ratio — example 50 grams

How much does 1 unit of insulin lower your Blood Glucose?

Insulin sensitivity — example 12 mmol/L

We automatically adjust these settings during your day. You can always adjust this in the insulin therapy settings

Next

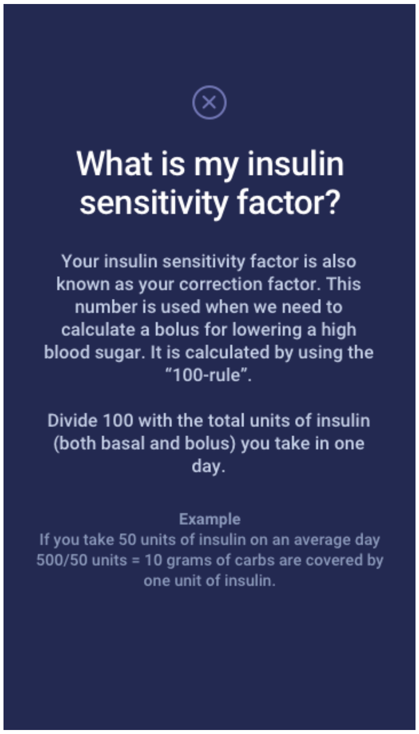


What is my insulin to carb ratio?

Your insulin to carb ratio is the factor used to calculate a meal bolus. It is calculated by using the “500-rule”.

Divide 500 with the total units of insulin (both basal and bolus) you take in one day.

Example
If you take 50 units of insulin on an average day
500/50 units = 10 grams of carbs are covered by one unit of insulin.



What is my insulin sensitivity factor?

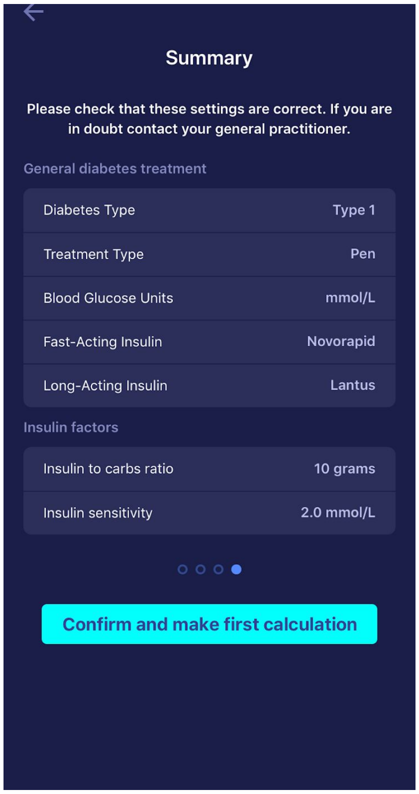
Your insulin sensitivity factor is also known as your correction factor. This number is used when we need to calculate a bolus for lowering a high blood sugar. It is calculated by using the “100-rule”.

Divide 100 with the total units of insulin (both basal and bolus) you take in one day.

Example
If you take 50 units of insulin on an average day
500/50 units = 10 grams of carbs are covered by one unit of insulin.

2.3. Summary

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



Summary

Please check that these settings are correct. If you are in doubt contact your general practitioner.

General diabetes treatment

Diabetes Type	Type 1
Treatment Type	Pen
Blood Glucose Units	mmol/L
Fast-Acting Insulin	Novorapid
Long-Acting Insulin	Lantus

Insulin factors

Insulin to carbs ratio	10 grams
Insulin sensitivity	2.0 mmol/L

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 its called “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.

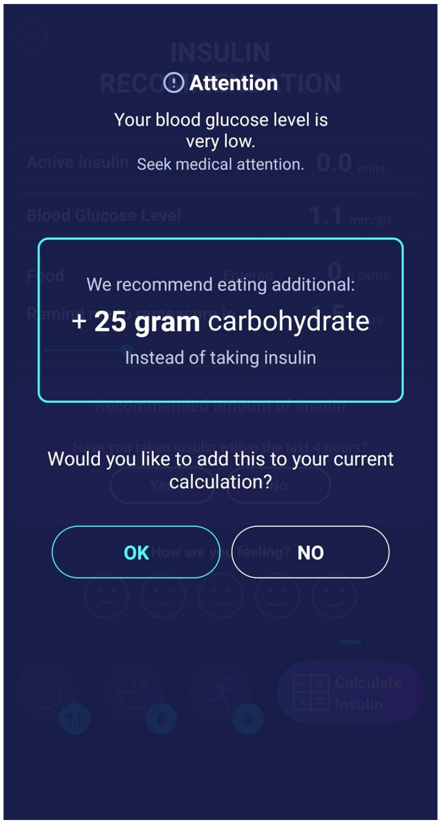
3.2. Attention pop-ups and notices

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 to be aware of. When you receive an attention pop-up, it’s important to make sure that all your entries are correct.

HDA has built-in limits for e.g. insulin, blood glucose and carbohydrate inputs, 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:



Attention

Your blood glucose level is very low.

Seek medical attention.

We recommend eating additional:

+ **25 gram** carbohydrate

Instead of taking insulin

Would you like to add this to your current calculation?

3.4. Notifications

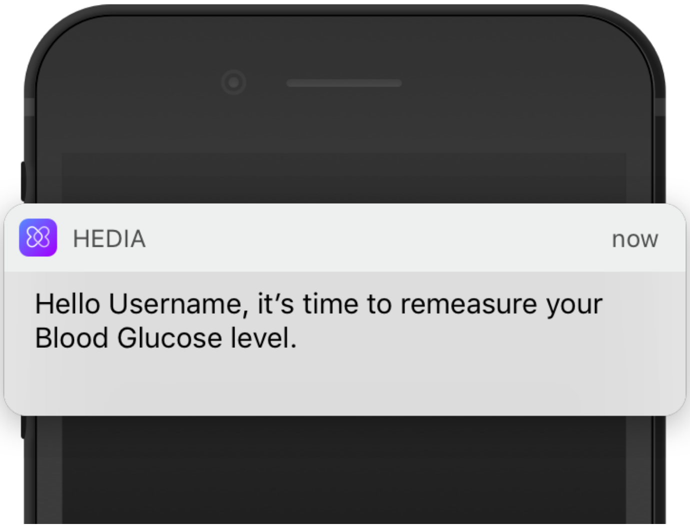
Once you have used HDA and transferred data to your logbook, HDA is set to give a notification after 1.5 hours. This notification is based on the effect profile of rapid acting insulin and is intended to remind you to measure your blood glucose, so a potential high or low blood glucose can be corrected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

If you do this control measurement of your blood glucose, HDA will be able to help you stabilize your blood glucose level. 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. Notifications (default settings)

- 1 1/2 hour after an insulin dose



Hello Username, it’s time to remeasure your Blood Glucose level.

3.5. Insulin calculator

The use of HDA requires understanding of your diabetes treatment. Therefore, you should work closely with your diabetes therapist 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 can’t judge your current situation independently of your discretion and can't 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 popup 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 can't 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.

Insulin doses taken before HDA has been used for the first time, HDA can't take into account in the calculations. The same applies to administered insulin doses and consumed meals which you do not not register in HDA.

We recommend that you continuously update HDA to the extent that updates are available in the AppStore or Google Play and 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 level 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. Meaning the app functions are available off and online. All HDA's calculations are based on these two algorithms.

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

This is an expression of how many grams of carbohydrate one unit of insulin covers.

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 on one unit of fast-acting insulin.

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

3.6.2.1. 100 rule

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)

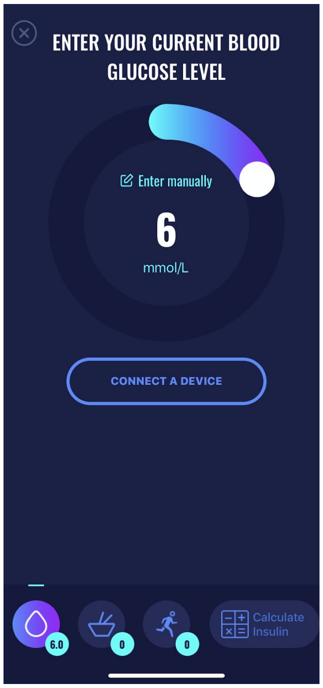
Example: 50 IU per day gives the following: 1800/50 = 36 (one unit of insulin covers 36 grams of carbohydrates).

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 can't 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.

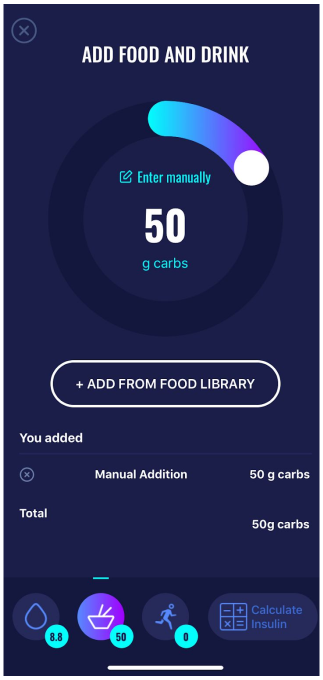
3.6.3. How to calculate your recommended insulin dose in HDA


ENTER YOUR CURRENT BLOOD GLUCOSE LEVEL
Enter manually
CONNECT A DEVICE
Calculate Insulin

6 mmol/L

6.0 · 0 · 0

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


ADD FOOD AND DRINK
Enter manually
+ ADD FROM FOOD LIBRARY
Calculate Insulin

50 g carbs

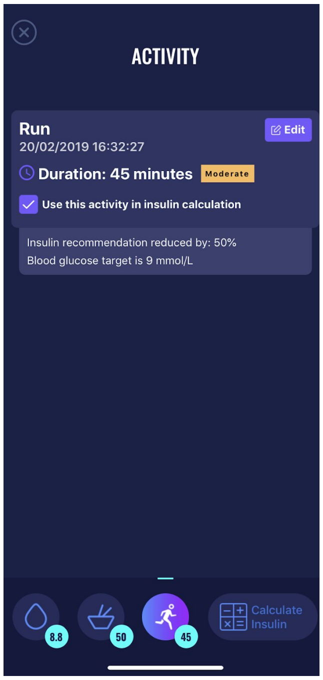
You added

Manual Addition 50 g carbs

Total 50g carbs

8.8 · 50 · 0

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


ACTIVITY
Edit
Calculate Insulin

Run

20/02/2019 16:32:27

Duration: 45 minutes Moderate

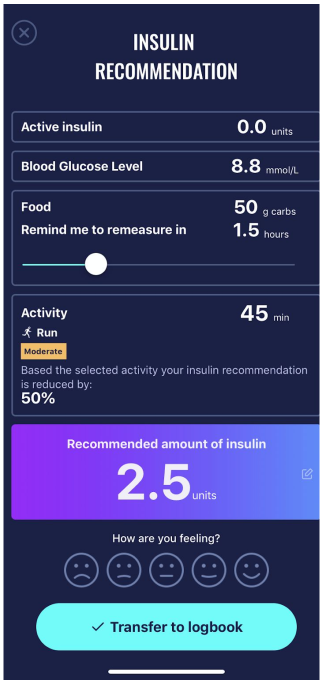
☑ Use this activity in insulin calculation

Insulin recommendation reduced by: 50%

Blood glucose target is 9 mmol/L

8.8 · 50 · 45

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


INSULIN RECOMMENDATION
How are you feeling?
Transfer to logbook

Active insulin 0.0 units

Blood Glucose Level 8.8 mmol/L

Food 50 g carbs

Remind me to remeasure in 1.5 hours

Activity 45 min

Run

Moderate

Based the selected activity your insulin recommendation is reduced by:

50%

Recommended amount of insulin

2.5 units

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. Calculation is based on: 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).

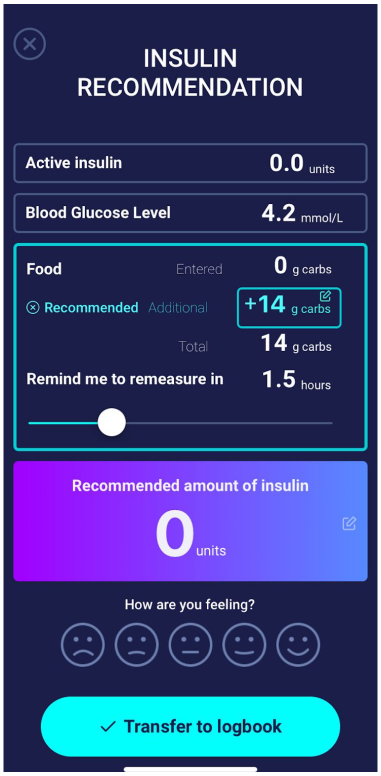
3.6.5. Correction dose (Corr)

If your blood glucose level 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 depends 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 the risk of insulin shock. In this situation, a correction dose is not calculated.



INSULIN RECOMMENDATION

Active insulin 0.0 units

Blood Glucose Level 4.2 mmol/L

Food Entered 0 g carbs

Recommended Additional +14 g carbs

Total 14 g carbs

Remind me to remeasure in 1.5 hours

Recommended amount of insulin 0 units

How are you feeling?

4. Blood glucose

Blood glucose is indicated in HDA as mmol/L or mg/dL.
In HDA it is possible to type in a blood glucose level from 1.1 mmol/L - 33.3 mmol/L.
For the unit mg/dL it is possible to type in a blood glucose level from 20 mg/dL - 600 mg/dL.

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

HDA will also recommend the user to measure for ketones if two consecutive blood glucose measurements has 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: BGL entered in the calculator

BGL in mmol/L and mg/dL	Definition	Attention messages
< 1.1 mmol/L 20 mg/dL	**Insulin shock** Not possible to input data below, in HDA.	
1.2 - 2 mmol/L 22 - 36 mg/dL	**Severe hypoglycemia (insulin shock)** No recommendation for insulin.	*"Attention: Your blood glucose level is very low. Seek medical attention. We recommend eating addional: X gram carbohydrate. Instead of taken insulin".*
2.1 - 3.5 mmol/L 38 - 64 mg/dL	**Hypoglycemia (insulin reaction)** No recommendation for insulin.	*"Attention. Your blood glucose level is low. You will be reminded to measure your blood glucose level in 15 min. We recommend eating additional: X gram carbohydrate. Instead of taking insulin".*
3.6 - 4 mmol/L 65 - 70 mg/dL	**Mild hypoglycemia** *"We recommend eating additional: X gram of carbohyrate. Instead of taking insulin".* If carbohydrates is logged - HDA will recommend a bolus insulin dose for the carbohydrates withdrawn the correction factor, corresponding to the low blood glucose level.	No attention message.
4.1 - 7 mmol/L 74 - 130 mg/dL	**Normal glycemia** Insulin recommendation as usual.	No attention message.
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.
2. time measured above 15 mmol/L within 6 hours 2. time measured above 270 mg/dL within 6 hours	**Severe hyperglycemia**	*"Attention: You have a high blood glucose level you should take insulin and measure ketones in your urine. You will be reminded to measure your blood glucose level in 15 min".* If activity is logged an attention message will occur: *"You have a high blood glucose level you should take insulin and measure ketones in your urine. You will be reminded to measure your blood glucose level in 15. min.*

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.

Default of the overall settings for blood glucose level is seen below (table 2 and table 3):

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

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

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

Low BGL	Target BGL	High BGL
< 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 **9.2.1 Blood glucose**, *table 12: Limits for adjusting BGL values in HDA in mmol/L and mg/dL*)

HDA has, as a safety measure, a built-in minimum target BGL of 4 mmol/L or 72 mg/dL and 13 mmol/L or 234 mg/dL as the maximum target BGL.

4.2. Average blood glucose

HDA needs a minimum of 28 calculations over a period of maximum 14 days to calculate your average BGL. Your average BGL 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 data within this time period is enough to provide a sufficiently accurate estimate of your average BGL.

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 calculations 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.

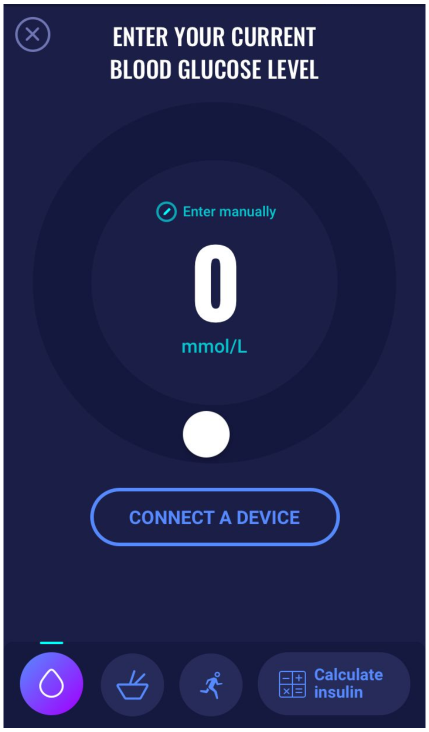
4.4. Sync with devices

HDA is compatible with the following devices via NFC (table 4):

Table 4: Compatible devices for HDA via NFC

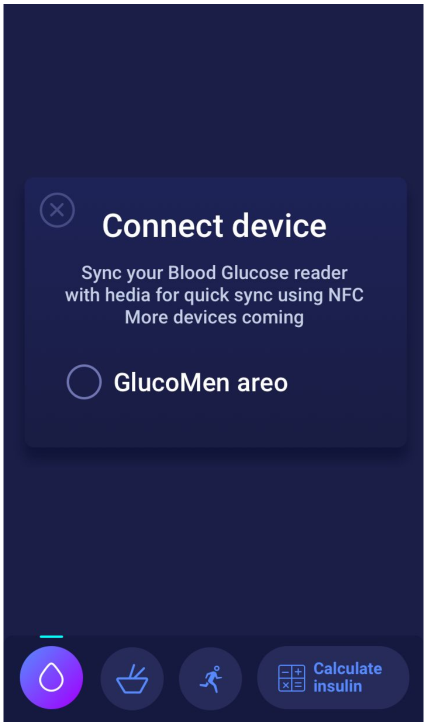
Device Name	From serial nr and onwards on iOS	Manufacturer
GlucoMen® areo	EQ493	A. Menarini Diagnostics S.r.l.
GlucoMen® areo 2K meter set	HC109	A. Menarini Diagnostics S.r.l.

How to setup blood glucose monitor in HDA and how to use.



ENTER YOUR CURRENT BLOOD GLUCOSE LEVEL

On the "Enter your current Blood Glucose Level" screen. You can press "Connect A Device" button to start the setup.

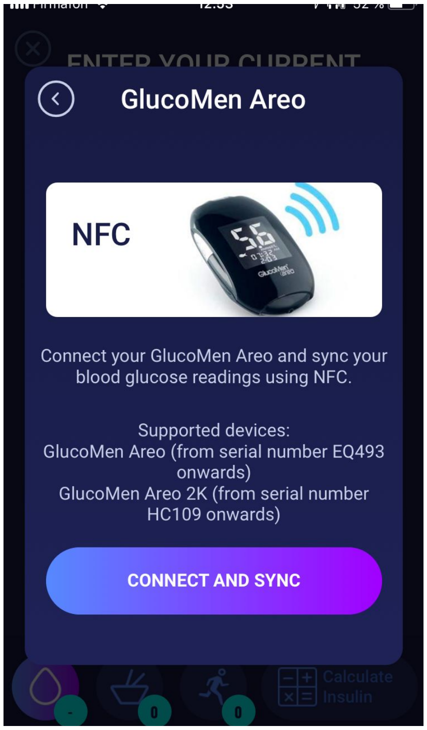


Connect device

Sync your Blood Glucose reader with hedia for quick sync using NFC
More devices coming

○ GlucoMen areo

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

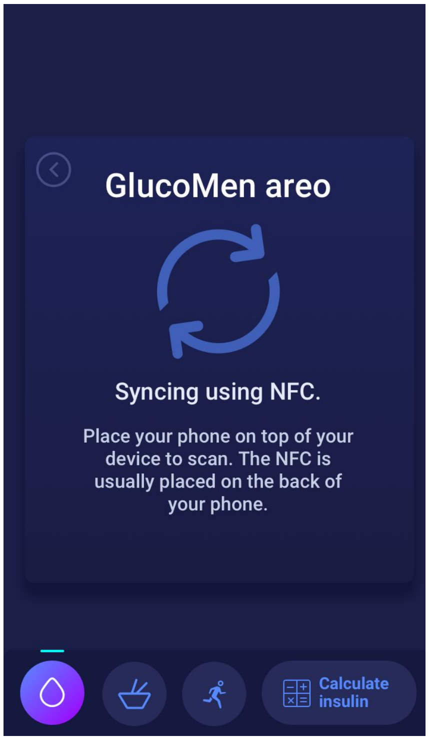


GlucoMen Areo

Connect your GlucoMen Areo and sync your blood glucose readings using NFC.

Supported devices:
GlucoMen Areo (from serial number EQ493 onwards)
GlucoMen Areo 2K (from serial number HC109 onwards)

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



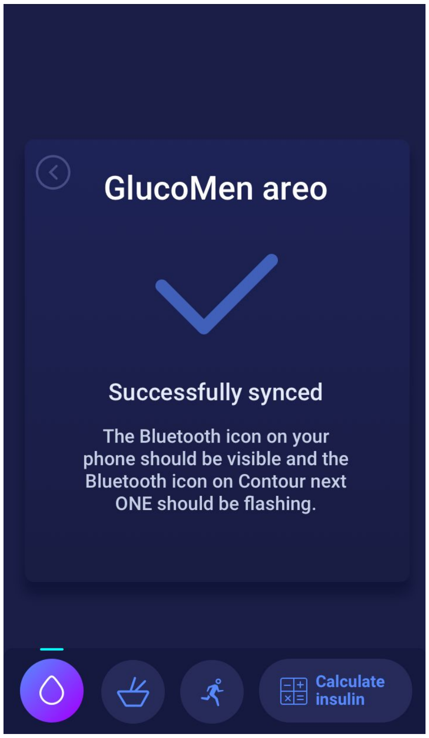
GlucoMen areo

Syncing using NFC.

Place your phone on top of your device to scan. The NFC is usually placed on the back of your phone.

Calculate insulin

A loading screen will appear with information on the connection type.



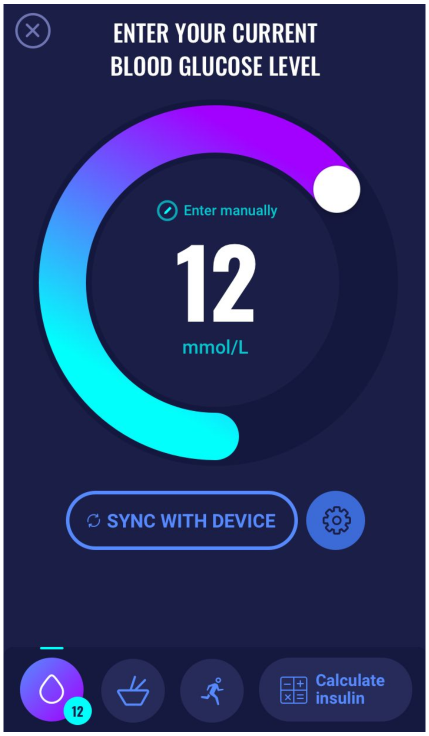
GlucoMen areo

Successfully synced

The Bluetooth icon on your phone should be visible and the Bluetooth icon on Contour next ONE should be flashing.

Calculate insulin

When the sync is successful a success screen will appear and disappear.



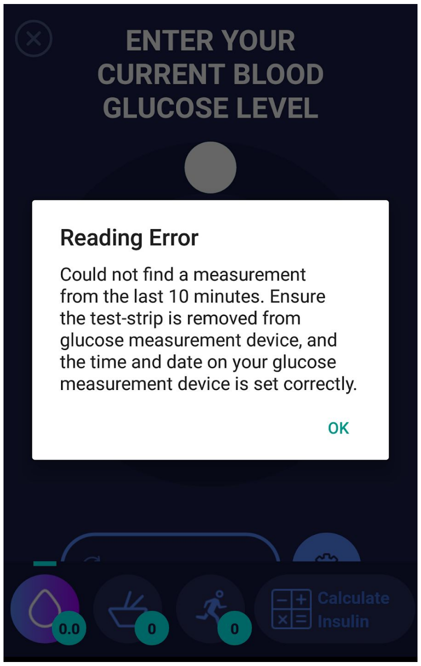
ENTER YOUR CURRENT BLOOD GLUCOSE LEVEL

Enter manually
12
mmol/L
SYNC WITH DEVICE
12
Calculate insulin

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

4. 4. 1 Synchronization error

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.



ENTER YOUR CURRENT BLOOD GLUCOSE LEVEL

Reading Error

Could not find a measurement from the last 10 minutes. Ensure the test-strip is removed from glucose measurement device, and the time and date on your glucose measurement device is set correctly.

OK
0.0
0
0
Calculate insulin

5. 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 5.3. Food database).

In HDA the limit for entering carbohydrates pr. meal is:
- low limit: 0 g of carbohydrates
- high limit: more than 300 g of carbohydrates

5.1. 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.

5.1.1. Correction dose after a meal

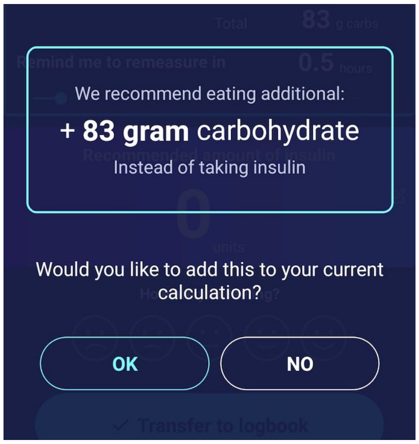
It is important not to make corrections due to the increase in BGL that is expected to happen after a meal to avoid insulin stacking. This is because all carbohydrates from previously logged meals have already been taken into account in previous boluses and the appropriate amount of insulin to lower the BGL 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 6.1 active insulin.

5.2. 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 BGL - Current BGL) / Insulin Sensitivity factor * Insulin-to-carb ratio

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



We recommend eating additional:

+ 83 gram carbohydrate

Instead of taking insulin

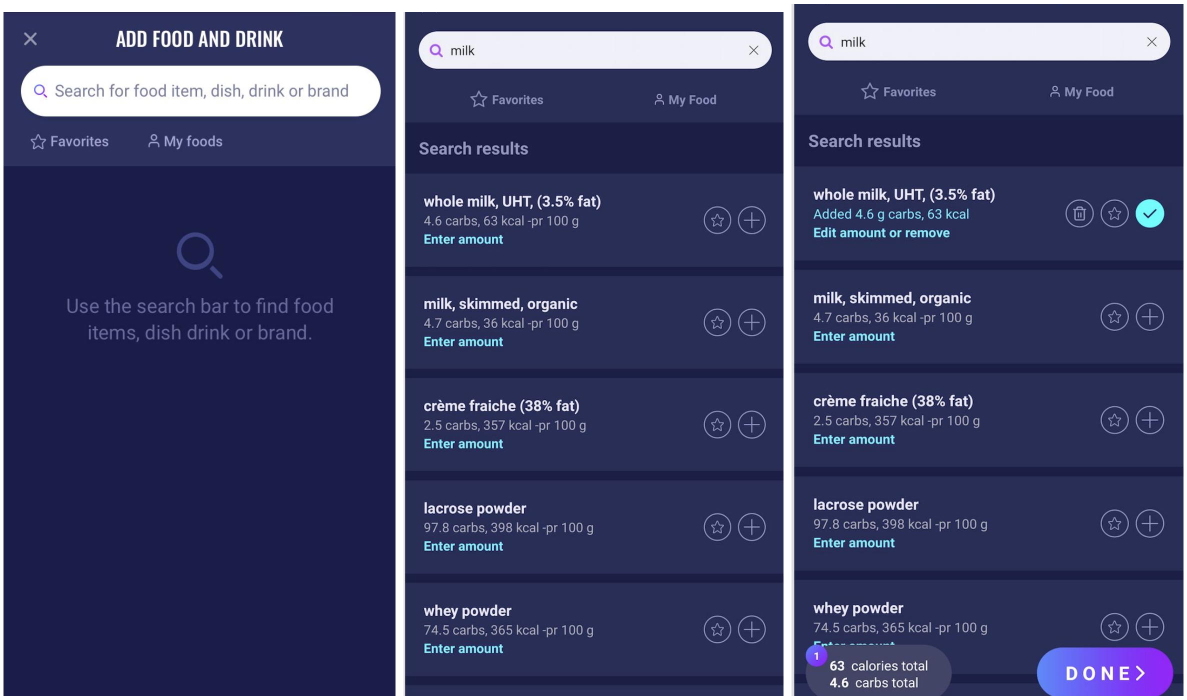
Would you like to add this to your current calculation?

5.3. 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.

5.3.1. Search for food items

Bottom menu shows currently selected amount of carbs and calories



ADD FOOD AND DRINK

Search for food item, dish, drink or brand

Use the search bar to find food items, dish drink or brand.

milk

Search results

whole milk, UHT, (3.5% fat)
4.6 carbs, 63 kcal -pr 100 g
Enter amount

milk, skimmed, organic
4.7 carbs, 36 kcal -pr 100 g
Enter amount

crème fraiche (38% fat)
2.5 carbs, 357 kcal -pr 100 g
Enter amount

lacrose powder
97.8 carbs, 398 kcal -pr 100 g
Enter amount

whey powder
74.5 carbs, 365 kcal -pr 100 g
Enter amount

milk

Search results

whole milk, UHT, (3.5% fat)
Added 4.6 g carbs, 63 kcal
Edit amount or remove

milk, skimmed, organic
4.7 carbs, 36 kcal -pr 100 g
Enter amount

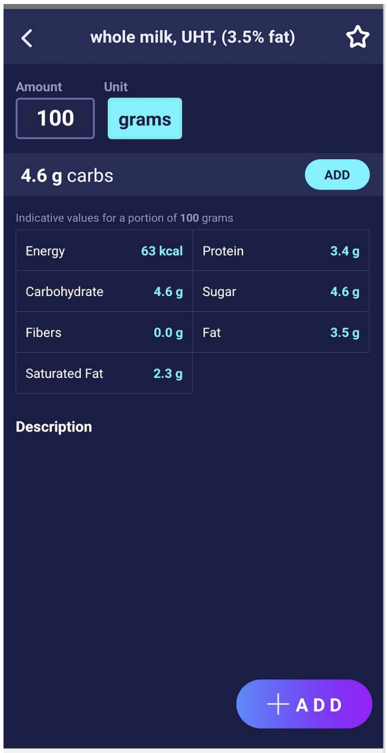
crème fraiche (38% fat)
2.5 carbs, 357 kcal -pr 100 g
Enter amount

lacrose powder
97.8 carbs, 398 kcal -pr 100 g
Enter amount

whey powder
74.5 carbs, 365 kcal -pr 100 g

1
63 calories total
4.6 carbs total

Adjust amount of food item, the default amount unit is grams.



whole milk, UHT, (3.5% fat)

Amount: 100
Unit: grams

4.6 g carbs

Indicative values for a portion of **100** grams

Energy	63 kcal	Protein	3.4 g
Carbohydrate	4.6 g	Sugar	4.6 g
Fibers	0.0 g	Fat	3.5 g
Saturated Fat	2.3 g		

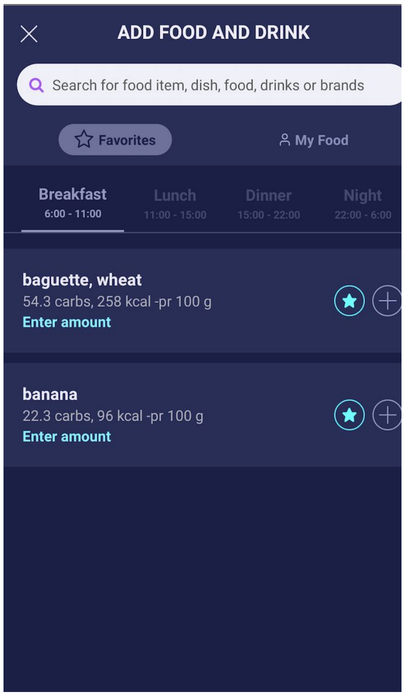
Description

5.3.2. Favorites

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

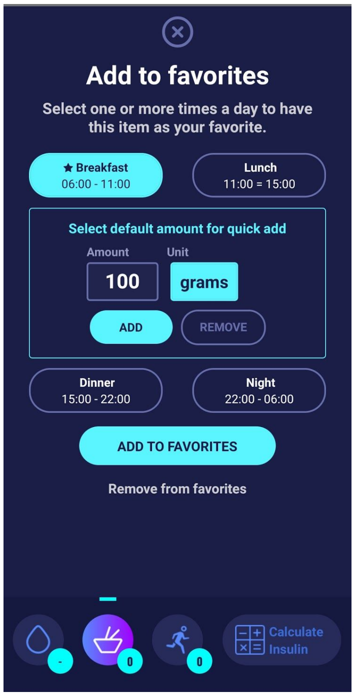
Favorites can be added to the intervals
- Breakfast 6:00-11:00
- Lunch 11:00 - 15:00

- Dinner 15:00 - 22:00
- Night 22:00 - 6:00


ADD FOOD AND DRINK
Search for food item, dish, food, drinks or brands
Favorites
My Food
Breakfast
6:00 - 11:00
Lunch
11:00 - 15:00
Dinner
15:00 - 22:00
Night
22:00 - 6:00
Enter amount
Enter amount

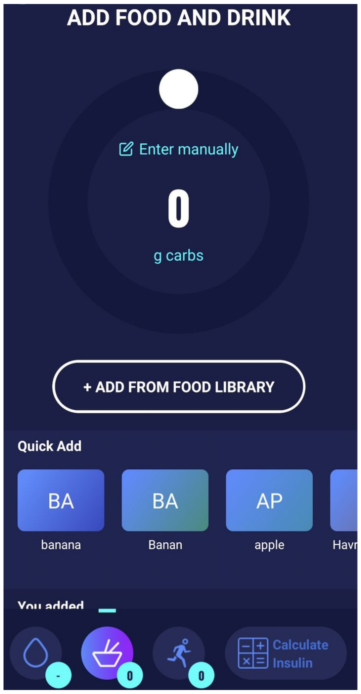
baguette, wheat
54.3 carbs, 258 kcal -pr 100 g

banana
22.3 carbs, 96 kcal -pr 100 g


Add to favorites
Breakfast
06:00 - 11:00
Lunch
11:00 = 15:00
Select default amount for quick add
Amount
Unit
ADD
REMOVE
Dinner
15:00 - 22:00
Night
22:00 - 06:00
ADD TO FAVORITES
Remove from favorites
Calculate Insulin

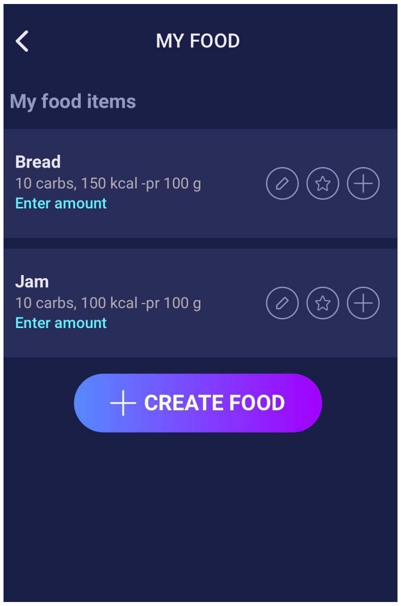
Select one or more times a day to have this item as your favorite.

Amount: 100
Unit: grams


ADD FOOD AND DRINK
Enter manually
0
g carbs
+ ADD FROM FOOD LIBRARY
Quick Add
BA
banana
BA
Banan
AP
apple
Havr
You added
Calculate Insulin

5.3.3. My food

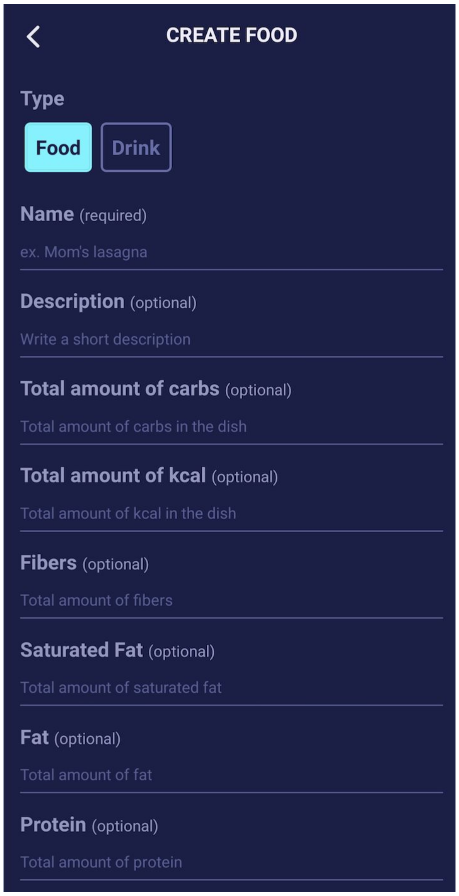
Personal food items can be added under **My foods**


MY FOOD
My food items
Enter amount
Enter amount
CREATE FOOD

Bread
10 carbs, 150 kcal -pr 100 g

Jam
10 carbs, 100 kcal -pr 100 g

5.3.4. Create food



Type

Name (required)
ex. Mom's lasagna

Description (optional)
Write a short description

Total amount of carbs (optional)
Total amount of carbs in the dish

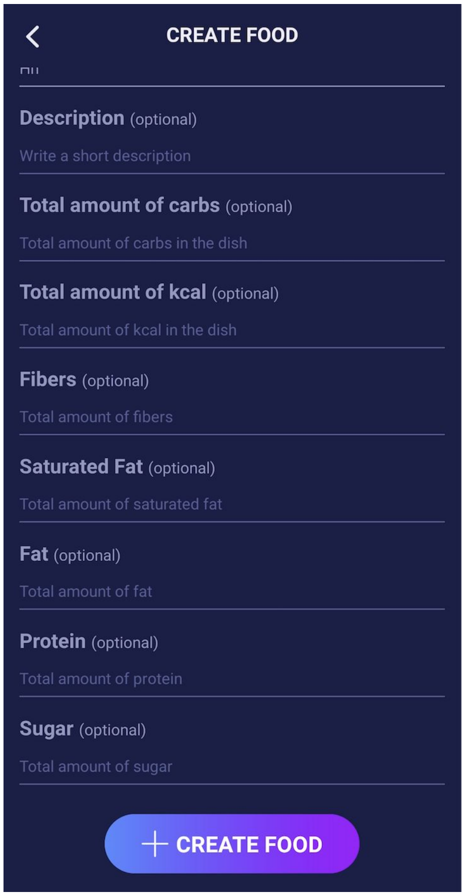
Total amount of kcal (optional)
Total amount of kcal in the dish

Fibers (optional)
Total amount of fibers

Saturated Fat (optional)
Total amount of saturated fat

Fat (optional)
Total amount of fat

Protein (optional)
Total amount of protein



Description (optional)
Write a short description

Total amount of carbs (optional)
Total amount of carbs in the dish

Total amount of kcal (optional)
Total amount of kcal in the dish

Fibers (optional)
Total amount of fibers

Saturated Fat (optional)
Total amount of saturated fat

Fat (optional)
Total amount of fat

Protein (optional)
Total amount of protein

Sugar (optional)
Total amount of sugar

6. Insulin

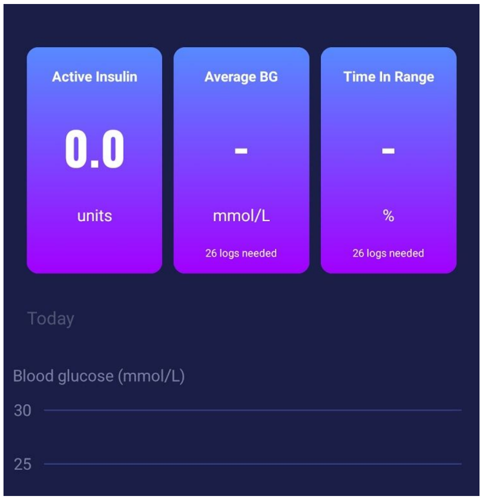
HDA’s calculations are based on a fast-acting insulin analogue. The ’Insulin recommendation’ page in HDA shows the calculations for HDA's recommendations.

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.

6.1. 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 takes into account active insulin 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].


Active Insulin
0.0
units
Average BG
-
mmol/L
26 logs needed
Time In Range
-
%
26 logs needed
Today
Blood glucose (mmol/L)
30
25

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 5):

Table 5: 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. 4, 5].

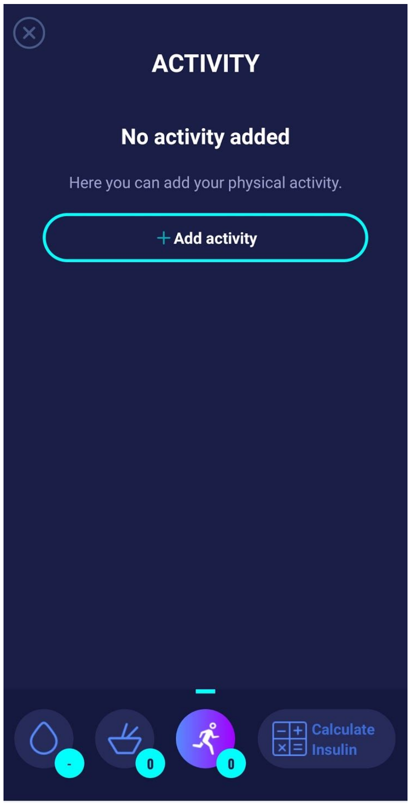
If the user has not documented any bolus insulin within the last 4 hours, HDA asks: *Have you taken insulin within the last 4 hours?* If yes, the user is asked to enter the amount of insulin injected within the last 4 hours.

6.2. 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 apply to manual entries and are a precautionary measure to avoid unintentionally large doses.

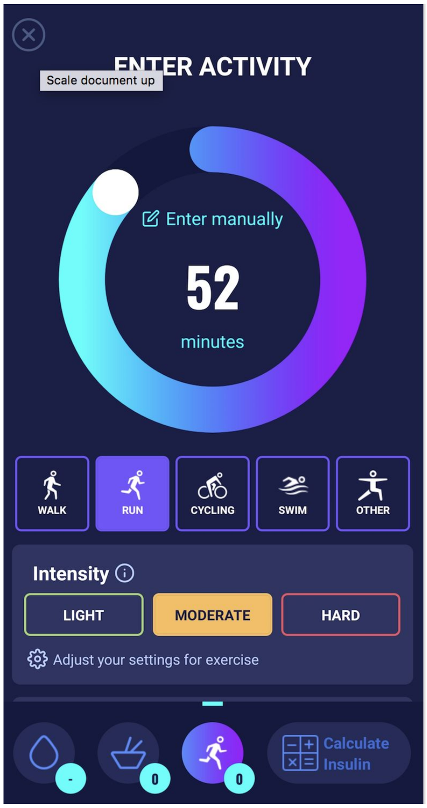
7. Activity

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


ACTIVITY

No activity added

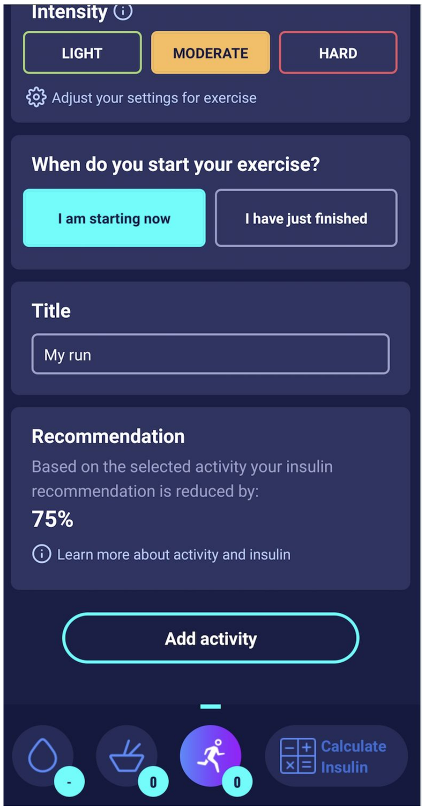
Here you can add your physical activity.
+ Add activity
-
0
0
Calculate Insulin


ENTER ACTIVITY

Enter manually

52 minutes

Intensity: MODERATE
Scale document up
WALK
RUN
CYCLING
SWIM
OTHER
Intensity
LIGHT
MODERATE
HARD
Adjust your settings for exercise
-
0
0
Calculate Insulin


Intensity: MODERATE

When do you start your exercise? I am starting now

Title: My run

Recommendation

Based on the selected activity your insulin recommendation is reduced by:

75%
Intensity
LIGHT
MODERATE
HARD
Adjust your settings for exercise
I am starting now
I have just finished
Learn more about activity and insulin
Add activity
-
0
0
Calculate Insulin

7.1. 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 exercise prescription. If you experience any pain or difficulty during activity, stop and consult your healthcare provider.

7.2. How HDA calculates the effect of activity

Tabel 6: Calculated effect of activity in HDA

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

7.3. Duration of activity

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

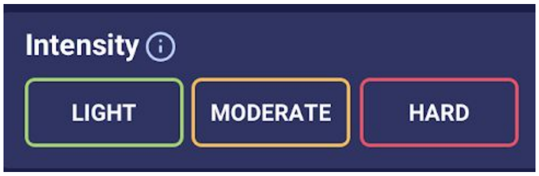
7.4. Type of activity

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.

7.5. Intensity of activity

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

Next to intensity you’ll see an “i” in a circle, push the icon for more information related to the use of the BORG scale.



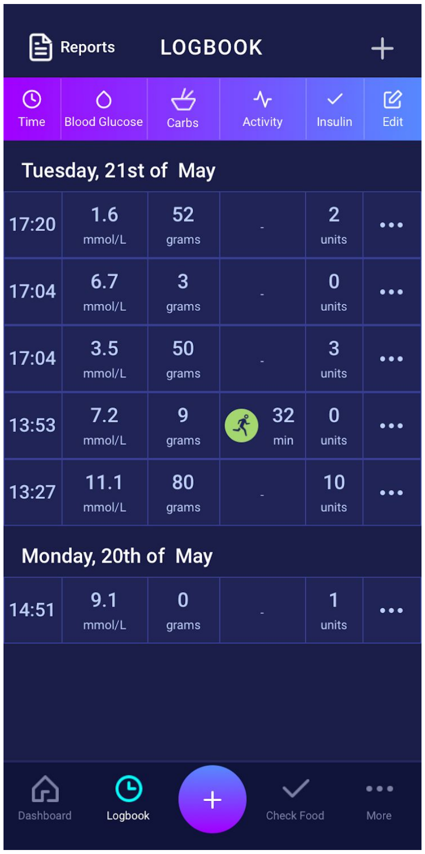
7.6. Activity start, title and recommendation

When you add activity, you can log this in advance, or log it after.
Activity will only affect the first calculation made after the start time of the activity. However, only if this calculation is made within 4 hours from the start time of the activity.

8. 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



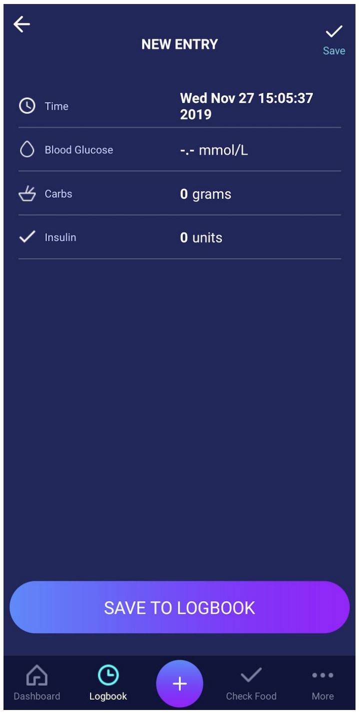
Time	Blood Glucose	Carbs	Activity	Insulin	Edit
Tuesday, 21st of May					
17:20	1.6 mmol/L	52 grams	-	2 units	•••
17:04	6.7 mmol/L	3 grams	-	0 units	•••
17:04	3.5 mmol/L	50 grams	-	3 units	•••
13:53	7.2 mmol/L	9 grams	32 min	0 units	•••
13:27	11.1 mmol/L	80 grams	-	10 units	•••
Monday, 20th of May					
14:51	9.1 mmol/L	0 grams	-	1 units	•••

8.1. Edit and Create entry

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

To edit an entry you tap on the desired logbook entry.

You create a new entry by pressing the (+) icon on the logbook screen (in the upper right corner).



NEW ENTRY

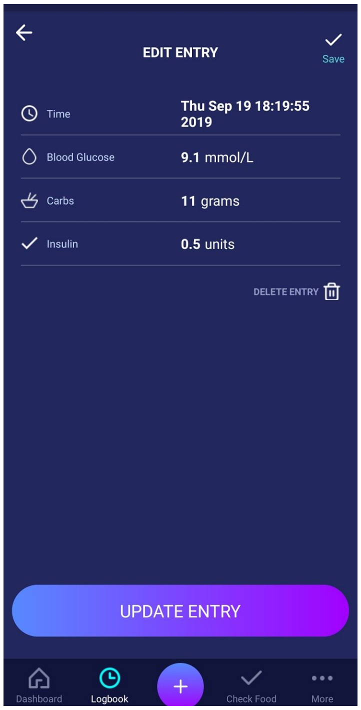
Time: Wed Nov 27 15:05:37 2019

Blood Glucose: -.- mmol/L

Carbs: 0 grams

Insulin: 0 units

Save
SAVE TO LOGBOOK
Dashboard
Logbook
+
Check Food
More



EDIT ENTRY

Time: Thu Sep 19 18:19:55 2019

Blood Glucose: 9.1 mmol/L

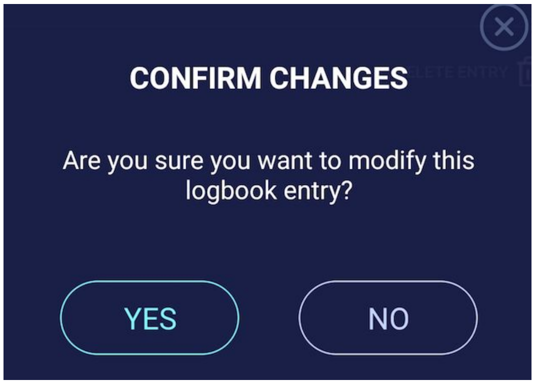
Carbs: 11 grams

Insulin: 0.5 units

Save
DELETE ENTRY
UPDATE ENTRY
Dashboard
Logbook
+
Check Food
More

8.2. 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.

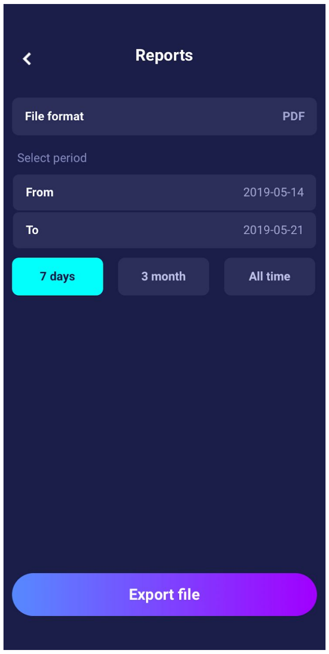


CONFIRM CHANGES

Are you sure you want to modify this logbook entry?

8.3 Export logbook entries

By tapping Reports on 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.

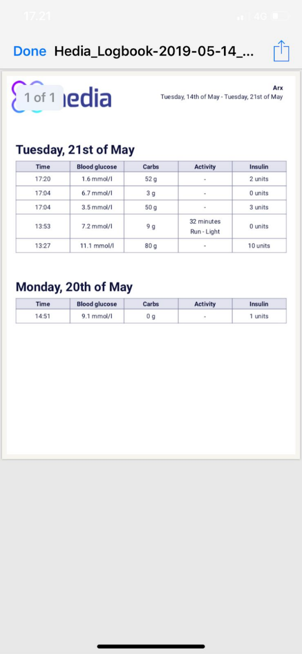


File format PDF

Select period

From 2019-05-14

To 2019-05-21



Hedia_Logbook-2019-05-14_...

Arx
Tuesday, 14th of May - Tuesday, 21st of May

Tuesday, 21st of May

Time	Blood glucose	Carbs	Activity	Insulin
17:20	1.6 mmol/l	52 g	-	2 units
17:04	6.7 mmol/l	3 g	-	0 units
17:04	3.5 mmol/l	50 g	-	3 units
13:53	7.2 mmol/l	9 g	32 minutes Run - Light	0 units
13:27	11.1 mmol/l	80 g	-	10 units

Monday, 20th of May

Time	Blood glucose	Carbs	Activity	Insulin
14:51	9.1 mmol/l	0 g	-	1 units

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

9. Settings

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

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

9.1. Account Settings

9.1.1. Edit Profile

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

- First name
- Diabetes Type
- Gender
- Date of birth
- Height
- Weight

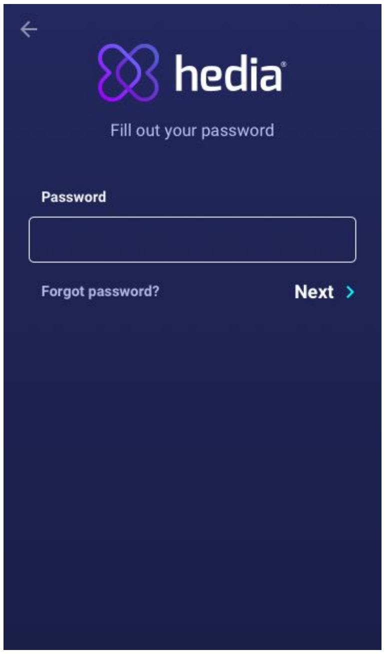
You can also change your data consent.

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 0.5 gram

9.1.2. Forgot password

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



Fill out your password

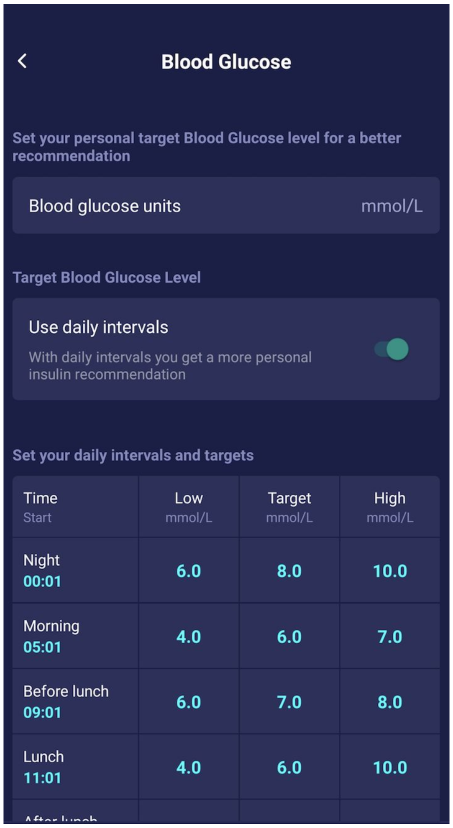
Password

☐

9.2. Personal Settings

9.2.1. Blood Glucose

Under ‘Blood Glucose’ you can change the settings for your blood glucose and change blood glucose units. Under ’blood glucose ’ you can set your target BGL, as well as set your limits for low and high blood glucose.



Blood Glucose

Set your personal target Blood Glucose level for a better recommendation

Blood glucose units: mmol/L

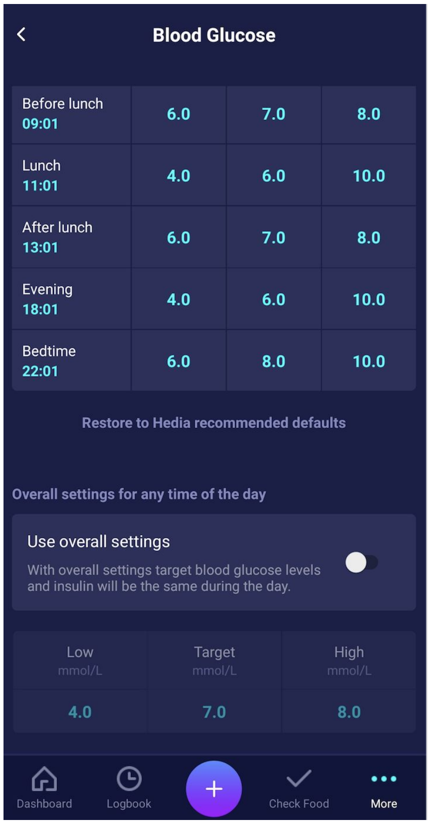
Target Blood Glucose Level

Use daily intervals ●

With daily intervals you get a more personal insulin recommendation

Set your daily intervals and targets

Time Start	Low mmol/L	Target mmol/L	High mmol/L
Night 00:01	6.0	8.0	10.0
Morning 05:01	4.0	6.0	7.0
Before lunch 09:01	6.0	7.0	8.0
Lunch 11:01	4.0	6.0	10.0



Blood Glucose

Before lunch 09:01	6.0	7.0	8.0
Lunch 11:01	4.0	6.0	10.0
After lunch 13:01	6.0	7.0	8.0
Evening 18:01	4.0	6.0	10.0
Bedtime 22:01	6.0	8.0	10.0

Restore to Hedia recommended defaults

Overall settings for any time of the day

Use overall settings ○

With overall settings target blood glucose levels and insulin will be the same during the day.

Low mmol/L	Target mmol/L	High mmol/L
4.0	7.0	8.0

In Blood Glucose settings you are able to adjust the desired BGL for ‘low’, ‘target’ and ‘high’ using:

- daily intervals or
- use overall settings

The default settings for daily intervals in HDA is divided into seven time periods throughout the day as seen below (table 7):

Table 7: 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 blood glucose level for daily intervals divided into the seven time periods (table 8 and table 9):

Table 8: Default blood glucose units in mmol/L divided into the seven time periods.

Period of time	Low BGL	Target BGL	High BGL
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 9: Default blood glucose settings in mg/dL divided into the seven time periods.

Period of time	Low BGL	Target BGL	High BGL
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 glucose level for overall settings is seen below (table 10 and table 11):

Table 10: Default for overall settings for blood glucose units in mmol/L

Low BGL	**Target BGL**	**High BGL**
<4 mmol/L	6 mmol/L	> 8 mmol/L

Table 11: Default for overall settings for blood glucose units in mg/dL

Low BGL	**Target BGL**	**High BGL**
< 72 mg/dL	108 mg/dL	> 144 mg/dL

For safety and to minimize risks of hypoglycemia the limit for adjusting BGL values in the settings is (table 12):

Table 12: Limits for adjusting BGL values in HDA in mmol/L and mg/dL

Setting	**Value**
Low BGL minimum	4 mmol/L (72 mg/dL)
Low BGL maximum	6 mmol/L (108 mg/dL)
Target BGL minimum	4 mmol/L (72 mg/dL)
Target BGL maximum	10 mmol/L (180 mg/dL)
High BGL minimum	6 mmol/L (108 mg/dL)
High BGL maximum	13 mmol/L (234 mg/dL)

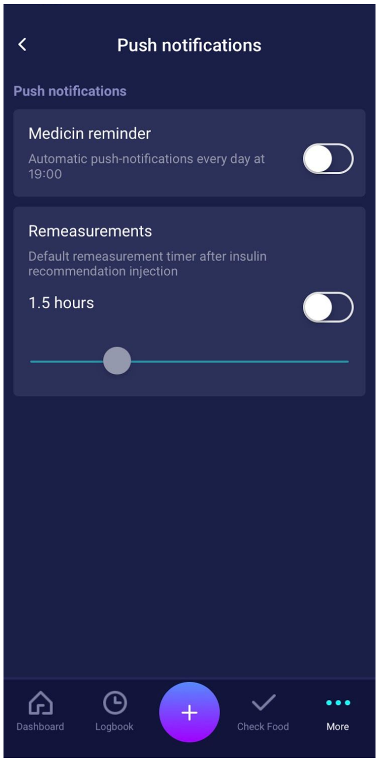
9.3. Notifications

9.3.1. Medicine reminder

You can activate and set a daily ‘medicine reminder’ with a custom time of day.

9.3.2. Remeasurements

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



Push notifications

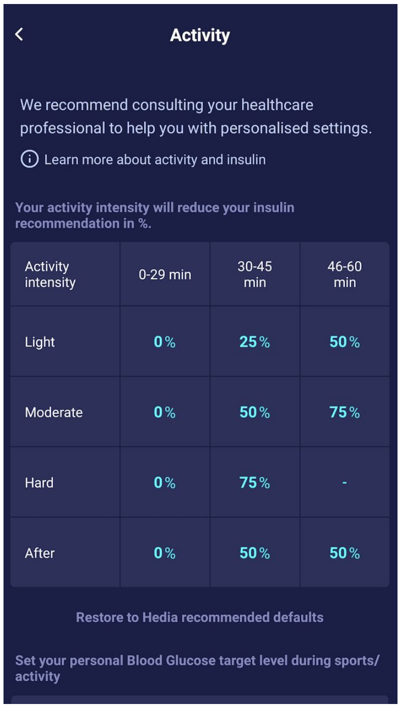
Push notifications

Medicin reminder
Automatic push-notifications every day at 19:00

Remeasurements
Default remeasurement timer after insulin recommendation injection
1.5 hours

9.4. Activity

Under 'Activity' you can define the percentage, which will reduce your insulin recommendation in percentage (%). This can be done for "light", "moderate" and "hard" intensity.



Activity

We recommend consulting your healthcare professional to help you with personalised settings.

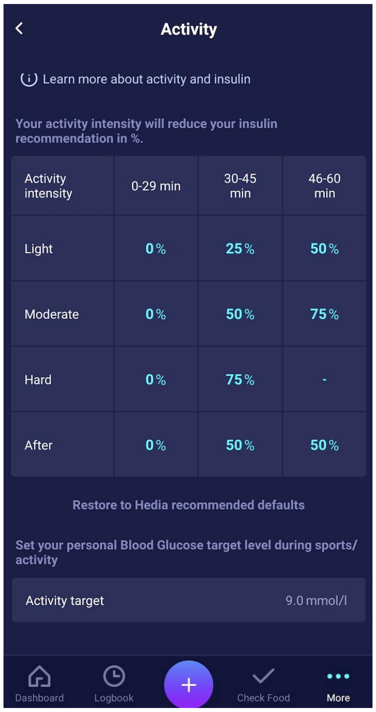
Learn more about activity and insulin

Your activity intensity will reduce your insulin recommendation in %.

Activity intensity	0-29 min	30-45 min	46-60 min
Light	0 %	25 %	50 %
Moderate	0 %	50 %	75 %
Hard	0 %	75 %	-
After	0 %	50 %	50 %

Restore to Hedia recommended defaults

Set your personal Blood Glucose target level during sports/ activity



Activity

Learn more about activity and insulin

Your activity intensity will reduce your insulin recommendation in %.

Activity intensity	0-29 min	30-45 min	46-60 min
Light	0 %	25 %	50 %
Moderate	0 %	50 %	75 %
Hard	0 %	75 %	-
After	0 %	50 %	50 %

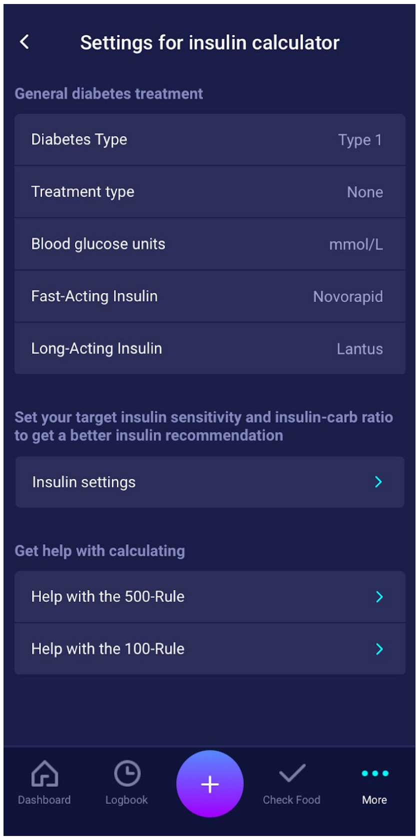
Restore to Hedia recommended defaults

Set your personal Blood Glucose target level during sports/ activity

Activity target 9.0 mmol/l

9.5. 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.



Settings for insulin calculator

General diabetes treatment

Diabetes Type: Type 1
Treatment type: None
Blood glucose units: mmol/L
Fast-Acting Insulin: Novorapid
Long-Acting Insulin: Lantus

Set your target insulin sensitivity and insulin-carb ratio to get a better insulin recommendation

Insulin settings
Get help with calculating
Help with the 500-Rule
Help with the 100-Rule
Dashboard
Logbook
Check Food
More

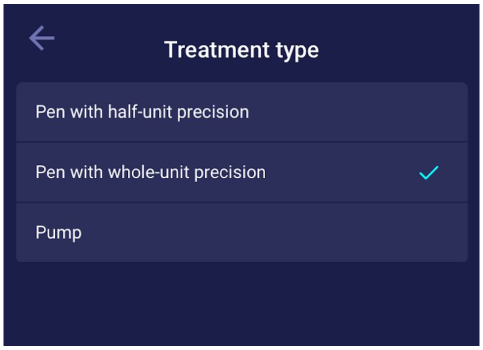
9.5.1 Treatment type

In HDA it is possible to choose between pen or pump as 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

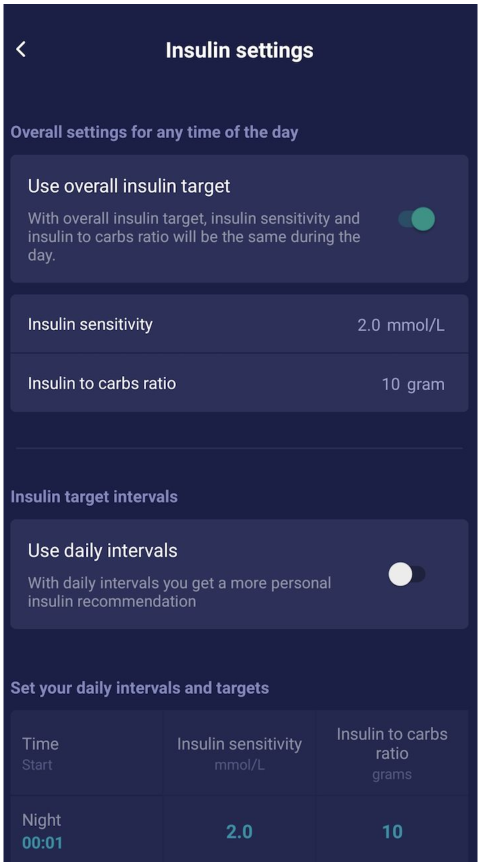


Treatment type

Pen with half-unit precision
Pen with whole-unit precision ✓
Pump

9.5.2 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 13: Limits for adjusting the insulin sensitivity factor and insulin-to-carb ratio*).



Overall settings for any time of the day

Use overall insulin target

With overall insulin target, insulin sensitivity and insulin to carbs ratio will be the same during the day.

Insulin sensitivity 2.0 mmol/L

Insulin to carbs ratio 10 gram

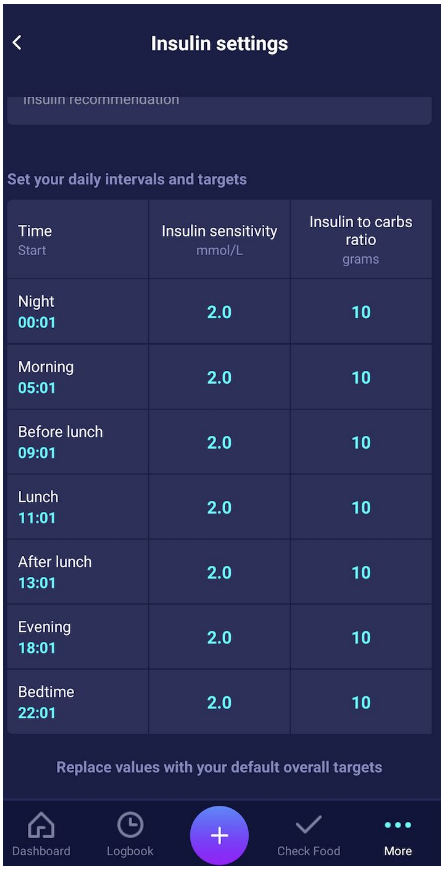
Insulin target intervals

Use daily intervals

With daily intervals you get a more personal insulin recommendation

Set your daily intervals and targets

Time Start	Insulin sensitivity mmol/L	Insulin to carbs ratio grams
Night 00:01	2.0	10



Set your daily intervals and targets

Time Start	Insulin sensitivity mmol/L	Insulin to carbs ratio grams
Night 00:01	2.0	10
Morning 05:01	2.0	10
Before lunch 09:01	2.0	10
Lunch 11:01	2.0	10
After lunch 13:01	2.0	10
Evening 18:01	2.0	10
Bedtime 22:01	2.0	10

Replace values with your default overall targets

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

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

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

Table 13: 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 “Daily intervals” both insulin sensitivity factor and insulin-to-carb ratio is the same for all seven time periods and is based on your settings from the log-in process.

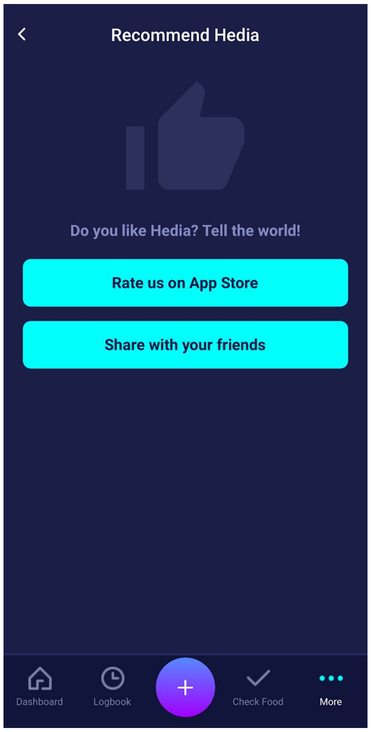
The default settings for daily intervals in HDA is divided into seven time periods throughout the day as seen below (table 14):

Table 14: 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

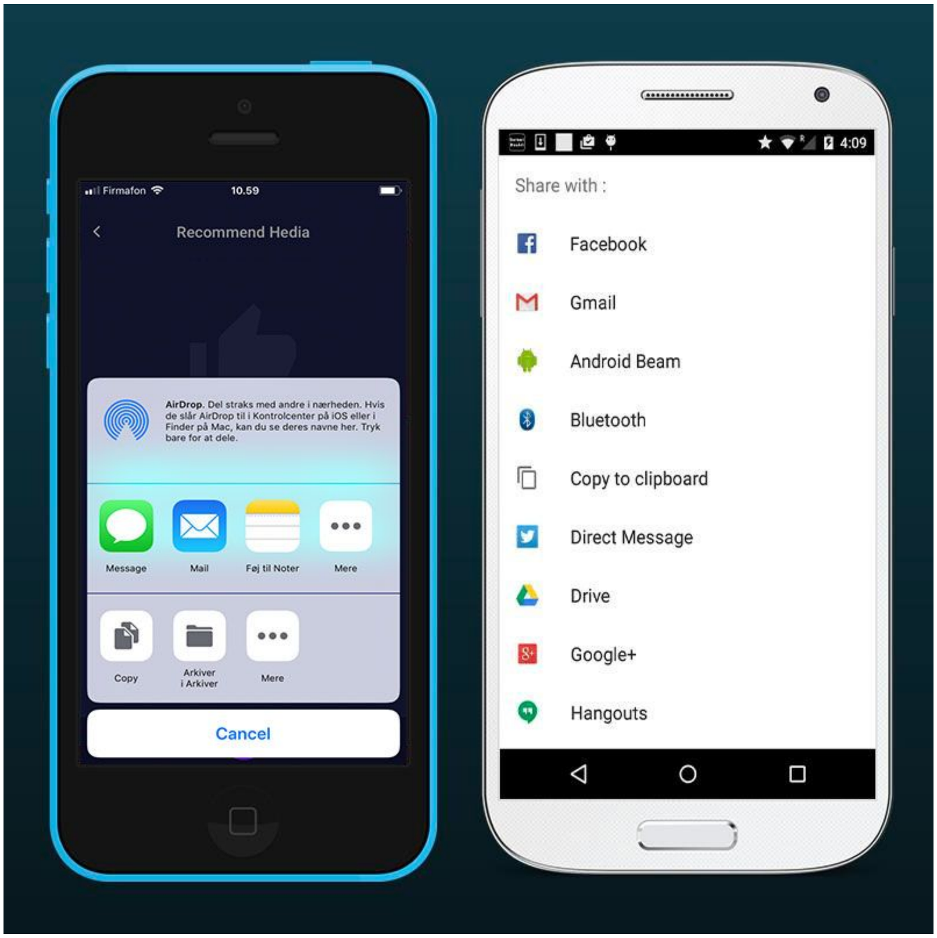
9.6. Recommend HDA

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


Recommend Hedia
Rate us on App Store
Share with your friends
Dashboard
Logbook
+
Check Food
More

Do you like Hedia? Tell the world!

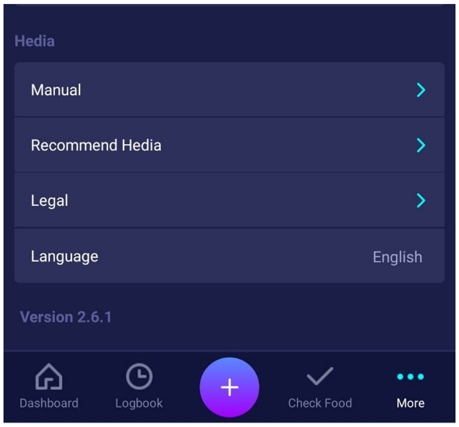
Additionally with the “Share with your friends” you can share a link to download HDA, using different apps on your phone.


Firmafon
10.59
Recommend Hedia
Message
Mail
Føj til Noter
Mere
Copy
Arkiver i Arkiver
Mere
Cancel
4:09
Share with :
Facebook
Gmail
Android Beam
Bluetooth
Copy to clipboard
Direct Message
Drive
Google+
Hangouts

AirDrop. Del straks med andre i nærheden. Hvis de slår AirDrop til i Kontrolcenter på iOS eller i Finder på Mac, kan du se deres navne her. Tryk bare for at dele.

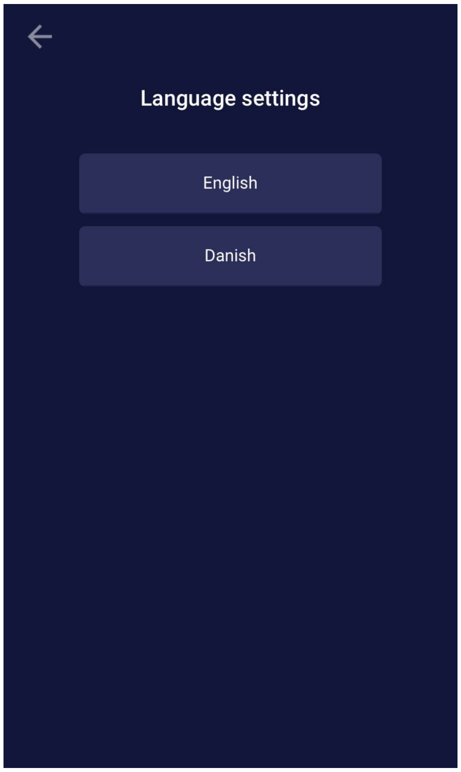
9.7. Change language

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


Hedia
Manual
Recommend Hedia
Legal
Dashboard
Logbook
Check Food
More

Language English

Version 2.6.1



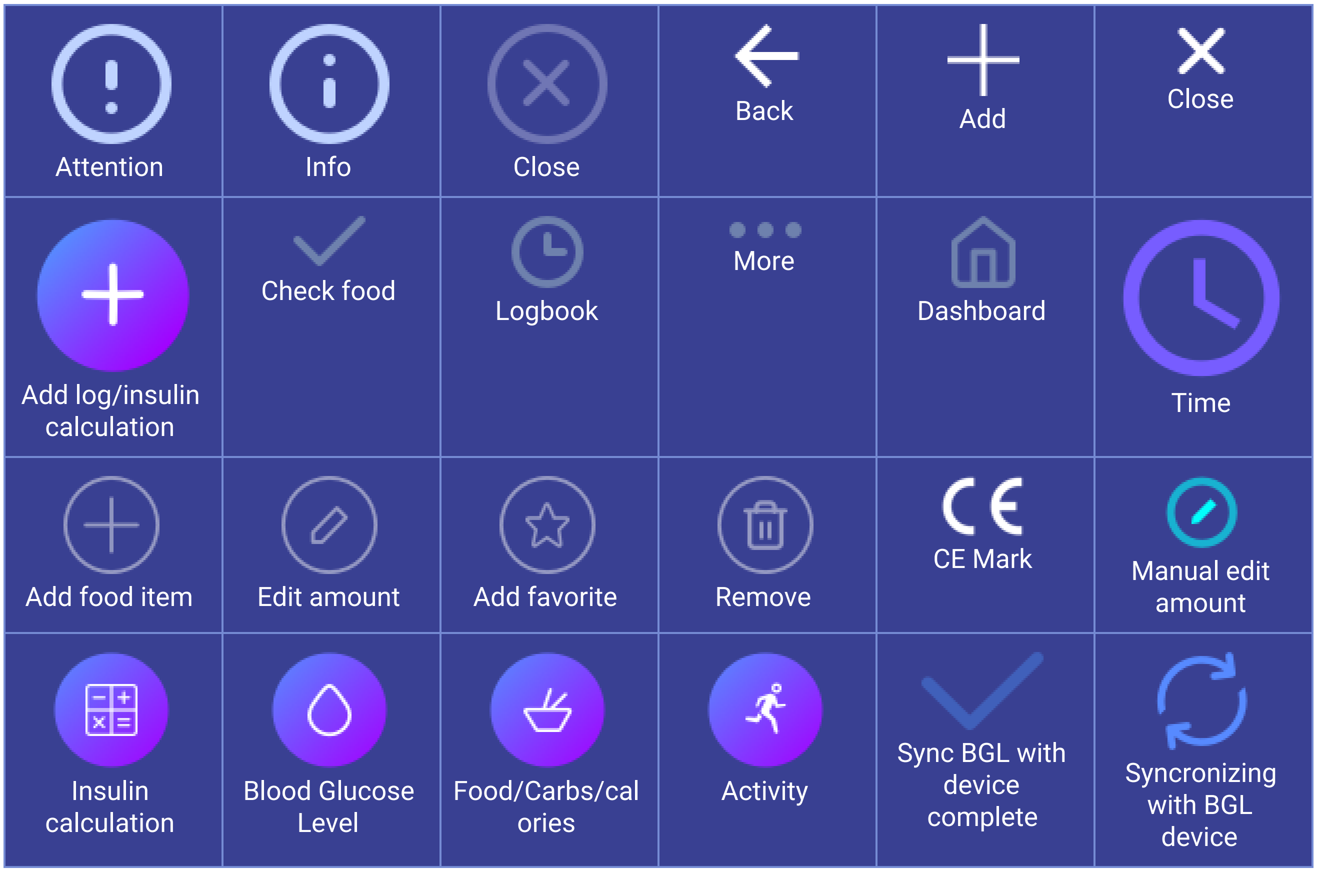
Language settings

English

Danish

10. Icons

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



Attention	Info	Close	Back	Add	Close
Add log/insulin calculation	Check food	Logbook	More	Dashboard	Time
Add food item	Edit amount	Add favorite	Remove	CE Mark	Manual edit amount
Insulin calculation	Blood Glucose Level	Food/Carbs/calories	Activity	Sync BGL with device complete	Syncronizing with BGL device

Settings for BGL 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	

11. Reporting of errors

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.

12. Contact Information

	Date of manufacture: 2019-12-05	
	Manufacturer: Hedia ApS Fruebjergvej 3 DK-2100 Copenhagen, Denmark CVR/VAT: 37664618	Contact information: email: hello@hedia.co Phone: +45 7174 1663

User Manual, Version. 2.6.2 Issued: 2019-12-06

13. List of references

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2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5190964/pdf/sensors-16-01983.pdf
3. https://pro.medicin.dk/Medicin/Praeparater/2605
4. https://rxed.eu/en/n/NovoRapid/5/#4_1__What_NovoRapid_is_and_what_it_is_used_for
5. https://pro.medicin.dk/Medicin/Praeparater/2605