ENGLISH

USER MANUAL

For Hedia Diabetes Assistant

version 2.1.0

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1 Intended use **4**
1.1 Indications for use 4
1.3 Contraindications 4
1.5 Introduction to HDA 4
1.6 With HDA you get: 5

2 First Calculation **5**
2.1 Diabetes treatment 6
2.2 Insulin target 6
2.4 Summary 7

3 Insulin Guide and Attentions notices **7**
3.1 Introduction 7
3.2 Attention pop-ups and Notices 8
3.3 Attention pop-ups 8
3.5 Notifications 8
3.5.1 Notifications (default settings) 9
3.7 insulin guide calculation 9
3.8 Clinical calculations used in HDA 10
3.8.1 Insulin-to-carb ratio (500 rule mmol/l): 10
3.8.2 Insulin sensitivity/correction dose (100 rule or 1800 rule): 10
3.8.2.1 100 rule 10
3.8.2.2 1800 rule 11
3.8.3 How to calculate your recommended insulin dose in HDA 11
3.8.4 Meal dose (food) 12
3.8.6 Correction dose (Corr) 12

4 Blood glucose **13**
4.1 Target area 13
4.1.1 Blood glucose settings (default) 13
4.2 Average blood glucose (Avg. blood glucose) 13
4.3 Time in range 13
4.4 Sync with devices 13

5 Food **15**
5.1 Subsequent meals 15
5.1.1 Correction dose after a meal 15
5.1.2 Settings for subsequent meals (default) 15
5.2 Carbohydrate suggestions 16
5.3 Food database 16
5.3.1 Search for food item. 16
5.3.2 Favorites 17
5.3.3 My food 17
5.3.4 Create food 18

6 Insulin **18**
6.2 Insulin on Board (IOB) 19
6.3 Maximum insulin dose 19
7 Activity **19**
7.1 Activity levels in HDA and their effect. 20
7.2 How HDA calculate the effect of activity 20
7.3 Duration of activity 21
7.4 Type of activity 21
7.5 Intensity of activity 21
7.6 Activity start, title and recommendation 21
8 Logbook **21**
8.1 Edit and Create entry 22
8.2 Changing entries less than 4 hours after logging 23
9 Settings **23**
9.1 Account Settings 23
9.1.1 Edit Profile 23
9.2 Personal Settings 24
9.2.1 Blood Glucose 24
9.3 Notifications 25
9.3.1 Medicine reminder 25
9.3.2 Remeasurements 25
9.4 Activity 26
9.5 Settings for Bolus Calculation 26
Recommend HDA 27
Change language 28
10 Icons **29**
11 Reporting of errors **30**
12 Contact Information **30**

Terminology

Hedia diabetes Assistant = HDA

Blood glucose level = BGL

1. Intended use

Hedia Diabetes Assistant (HDA) is a medical mobile application (standalone software) with no body contact, intended as a support in the decision making of the optimal Bolus insulin dose for management of insulin dependent type 1 and 2 diabetes by providing the user an indicative Bolus insulin dose.

1.1. Indications for use

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

- Type 1 diabetes - insulin dependent diabetes mellitus
- Type 2 diabetes on basal-bolus insulin regimen – multiple dose insulin therapy
- Have cognitive skills to use mobile applications, and 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 level and estimation of carbohydrate intake, physical activity and active insulin in the body, at a given time, it aids in the improvement of managing the patient's diabetes by providing guidance on general lifestyle management, carbohydrate intake and bolus calculation.

1.3. Contraindications

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

- Pregnancy
- Gestational diabetes
- Patients without visual capabilities to use a mobile application on a smartphone (blind or heavily visually impaired)
- Color blind
- Amputation of fingers
- Fever
- Dementia

1.5. 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 a 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.

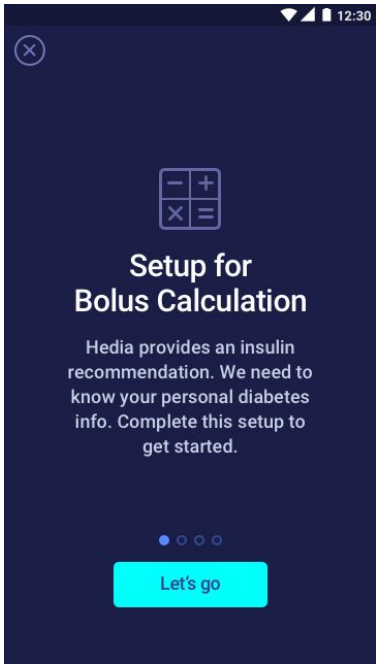
Contact us if you have any questions or experience any errors. An overview of contact information is provided at the back of the user manual.

1.6. With HDA you get:

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

2. First Calculation

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

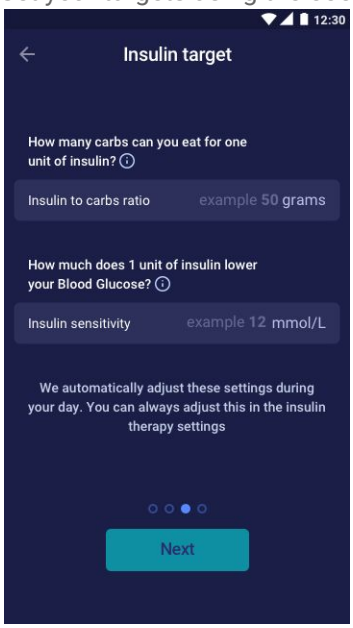


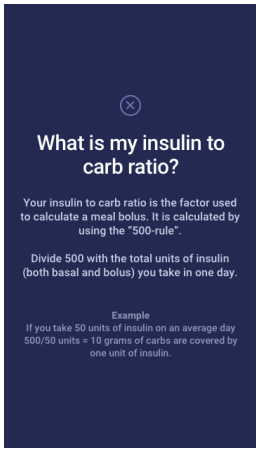
2.1. Diabetes treatment

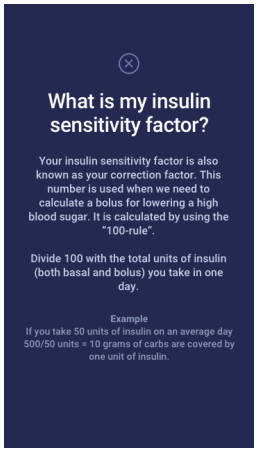
Make personal settings for pen/pump, units and types of insulin

2.2. Insulin target

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

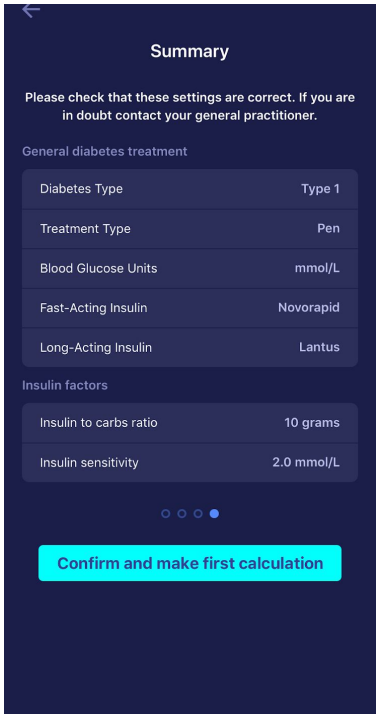






2.4. Summary

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



3. Insulin Guide and Attentions 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 carbohydrate insulin ratio and your insulin sensitivity. 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. The app only works if you have set the required features. A guide to setting up applocated further down in the user guide.

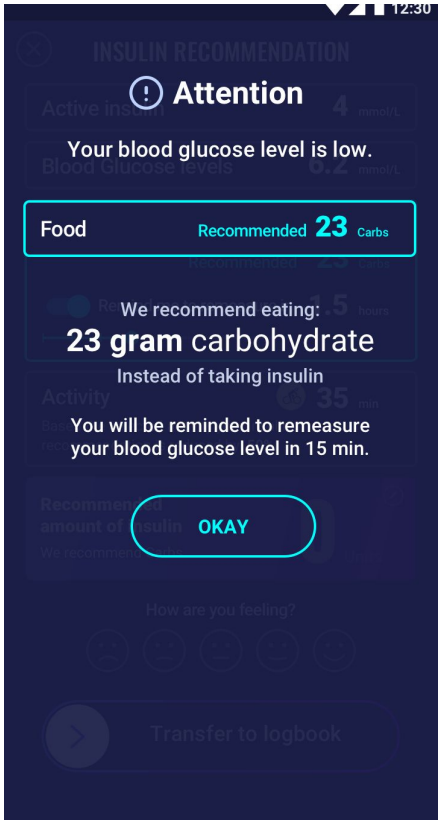
3.2. Attention pop-ups and notices

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 a 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:



3.5. Notifications

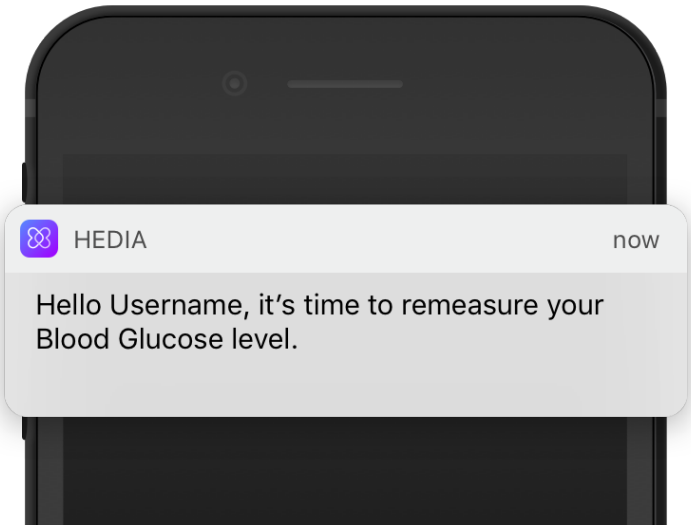
Once you have used HDA and transferred data to your logbook, HDA is set to give a notification after 1.5 hours. This notification is based on the effect profile of NovoRapid and is intended to remind you to measure your blood sugar, so a potential high or low blood sugar can be corrected immediately.
If you do this control measurement of your blood sugar, 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 blood sugar. 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 sugar is minimized.

You can set this notification yourself to 30 minutes, 1 hour, 1.5 hour or 2 hours, on the 'insulin' page. You can also turn the notification on or off on the 'insulin' page.
Once you have entered a meal and taken insulin for this, you will receive a blood glucose notification 4 hours later. This notification is reset at each meal. I.e. if you eat several meals consecutively, the 4-hour notification will only follow the last entered meal. This is a default setting, so we can check if you hit your desired blood sugar after 4 hours and to see if your carbohydrate-insulin ratio and insulin sensitivity settings should be corrected. This notification can be disabled under settings.

3.5.1. Notifications (default settings)

- 1 1/2 hour after an insulin dose

- 4 hours after an insulin dose and a corresponding meal



3.7. Insulin guide calculation

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 guide 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 guide calculates your insulin dose based on the following information which you enter.

- The Insulin to Carb and insulin sensitivity factor you set under settings and in your first insulin calculation
- Your currently entered blood glucose
- The amount of carbohydrate
- Your recent meal's impact on your blood glucose
- Insulin on board (IOB) calculated from above inputs

The insulin guide is only indicative. The Insulin guide can't judge your current situation independently of your own discretion and can't correct any incorrect entries. HDA has built-in limits for blood glucose and carbohydrate inputs, thus entries exceeding 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 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 and the app will prompt you to do so.

3.8. 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 level.

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.

3.8.1. 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 g of carbohydrates).

3.8.2. Insulin sensitivity/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.

3.8.2.1. 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).

3.8.2.2. 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)

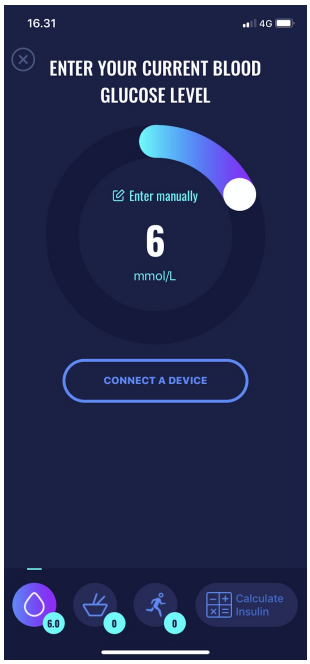
Example: 50 IU per day gives the following: 1800/50 = 10 (one unit of insulin covers 10 g of carbohydrates).

Each formula is used by HDA to calculate your insulin-to-carb ratio, as well as insulin sensitivity factor. Calculations are made the first time HDA is used. HDA can't be used until these settings are made, as HDA makes all its calculations based on these two formulas.

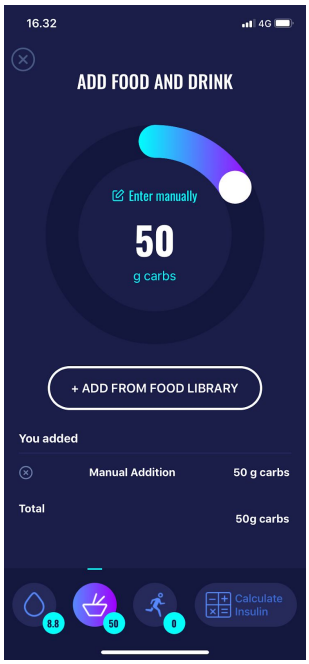
Under Settings, you can change your settings for your insulin-to-carb ratio, as well as your insulin sensitivity

factor/correction factor. In addition, you can also get help with how to apply the 500 rule and the 100/1800 rule.

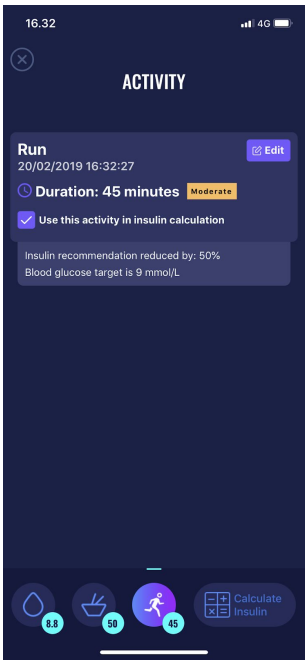
3.8.3. How to calculate your recommended insulin dose in HDA



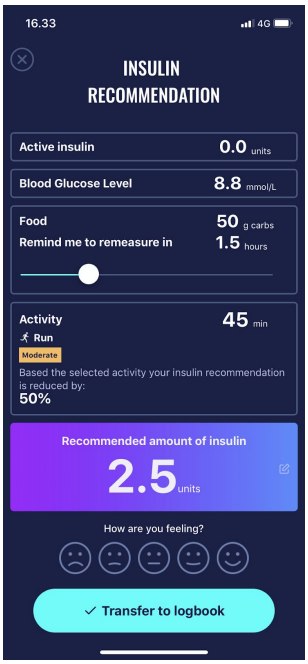
Enter current blood glucose level. Or connect with blood glucose monitor.



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.

The calculations on which your recommended dose is based can be seen Next to your recommended dose/units. See picture below, here you will find your calculated insulin dose for your meal (food), the activity, the calculated correction dose (Corr) and how much insulin on board (IOB) HDA takes into account in your calculated recommended dose. The calculation is based on: meal dose (food) + Correction dose (Corr) - IOB - Activity.

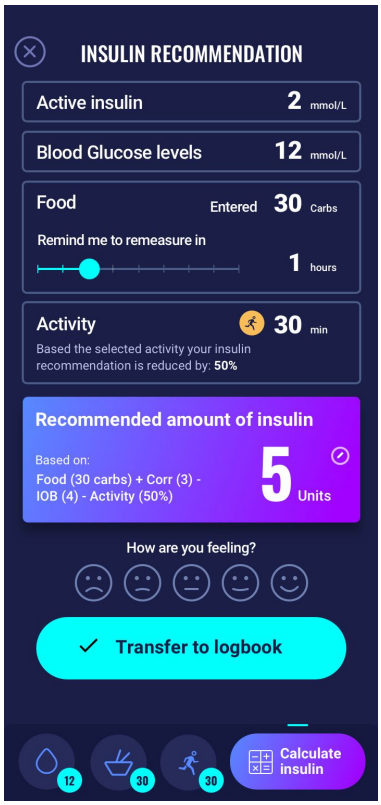
3.8.4. Meal dose (food)

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).

3.8.6. Correction dose (Corr)

If your blood glucose level is above or below your target blood glucose, HDA recommends a correction dose. At low blood glucose (hypoglycaemia), HDA uses your insulin sensitivity factor (100 rule) to calculate how many

units should be ***withdrawn*** from the recommended insulin dose. At high blood glucose (hyperglycaemia), HDA uses your insulin sensitivity factor (100 rule/1800 rule) to calculate how many units should be ***added*** to your recommended dose. The calculations of a correction dose depends on your entries in the app on your current blood glucose, your insulin sensitivity factor, and whether you plan to eat. The result of these calculations is shown below your recommended insulin dose, on the page 'insulin',
in the blue/purple box on the 'insulin recommendation page' showing 'recommended amount of insulin'. 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. In the case of low blood glucose, you will see a minus (-) in front of your correction dose, which means this amount will be deducted from your insulin recommendation. In case of high blood glucose you will see a plus (+) in front of your correction dose, which means this amount will be added to your insulin recommendation, see the picture below.



4. Blood glucose

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

4.1. Target area

The normal blood glucose concentration is maintained within a normal level of 4-8 mmol/L or 72-144 mg/dl. A blood glucose concentration below normal levels is called hypoglycaemia and a blood glucose concentration above normal levels is called hyperglycaemia.
When you use HDA for the first time, the app is set with the following default blood glucose target:

4.1.1. Blood glucose settings (default)

My target blood glucose : 6 mmol/L or 108 mg/dl
My 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 set these according to what you need, within HDA's defined limits for blood glucose .

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 (Avg. blood glucose)

HDA needs a minimum of 28 calculations over a maximum 14 day period 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 being made by your doctor. The amount of data within this time period is enough to provide a sufficiently accurate estimate of average BGL.

4.3. Time in range

HDA needs a minimum of 28 calculations over a maximum 14 day period 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 being made by your doctor.

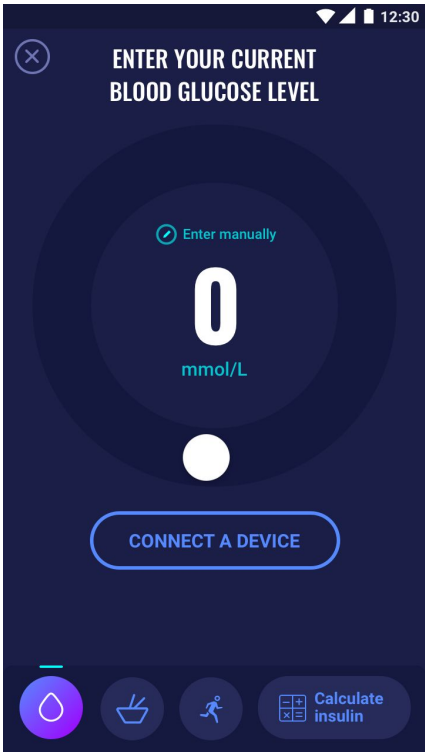
4.4. Sync with devices

HDA is compatible with the following devices:

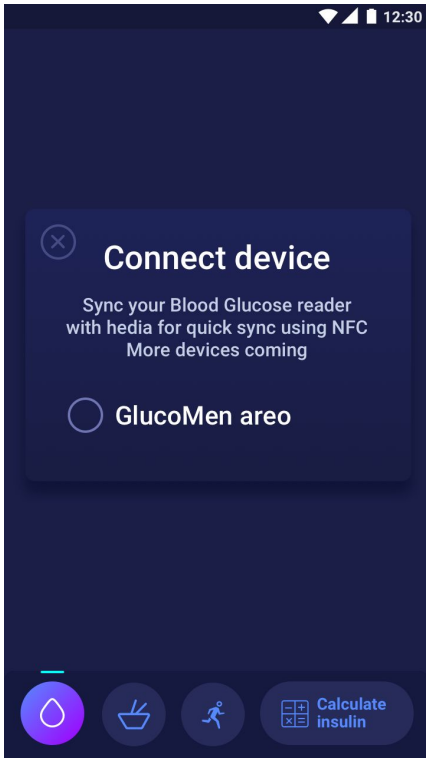
Device Name	Product Code	Manufacturer
GlucoMen® areo	46280	A. Menarini Diagnostics S.r.l.
GlucoMen® areo 2K meter set	48010	A. Menarini Diagnostics S.r.l.

Table 1

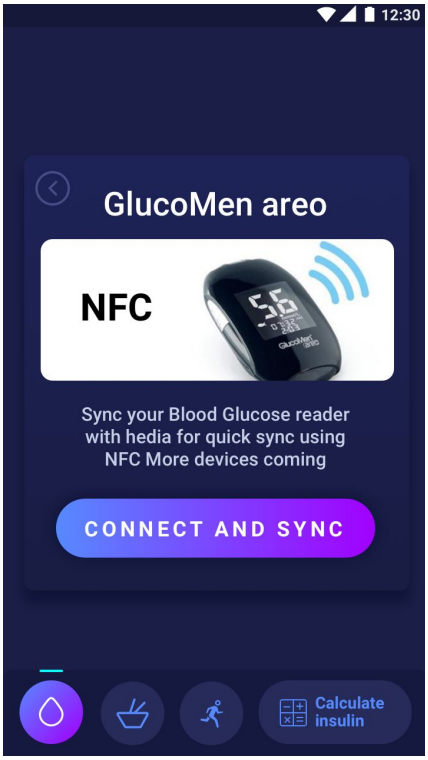
How to setup blood glucose monitor in HDA and how to use.



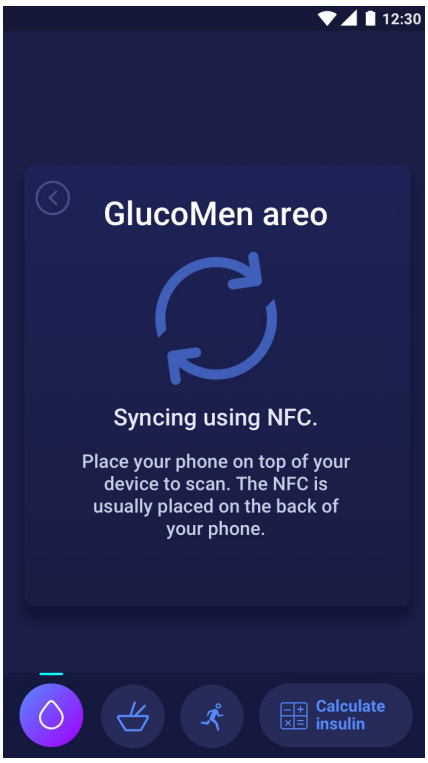
On the "Enter Blood Glucose Level screen. You can press "Connect A Device" button to start the setup.



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

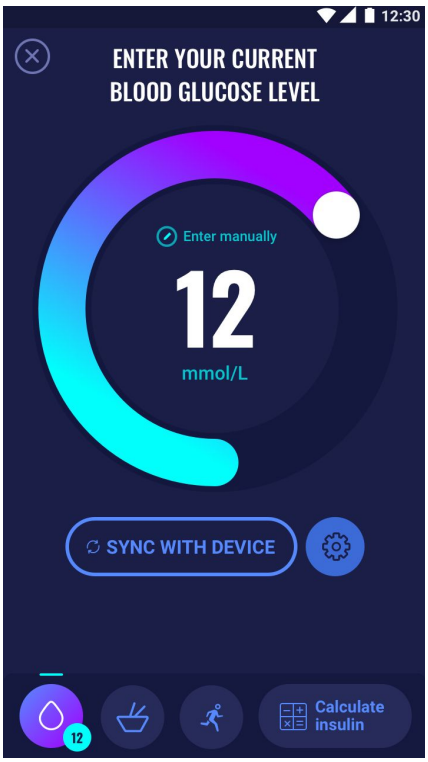


An info screen of the device and its connection type. Tap connect and sync to pair device.



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

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



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.

5. Food

Food is recorded in HDA as grams 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

HDA takes into account an acceptable increase in blood glucose after a meal. In this way, the risk of insulin stacking (occurs when a bolus of shorter acting insulin is given within 4 hours of an earlier bolus) is reduced if you use HDA for subsequent corrections.

5.1.2. Settings for subsequent meals (default)

- Acceptable blood glucose increase after a meal - **3** mmol/L or 54 mg/dl
- Duration of acceptable blood glucose increase - **1** hour

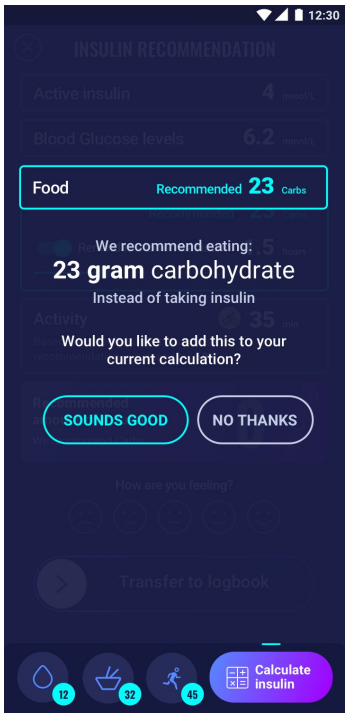
If you eat more than one meal after another HDA will accept an increase of 3 mmol/L or 54 mg/dl before it recommends a further correction dose. These default settings can be adjusted under settings within HDA's defined limits.

5.2. Carbohydrate suggestions

In case of hypoglycaemia HDA does not recommend insulin, but carbohydrates.

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

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

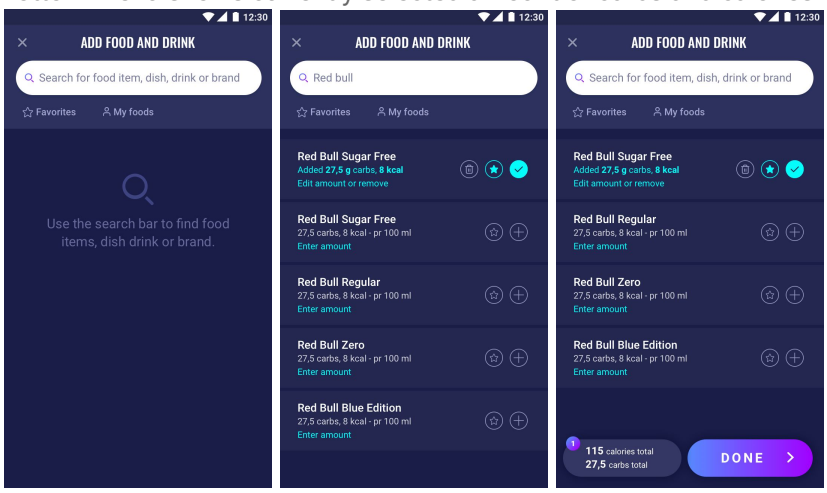


5.3. Food database

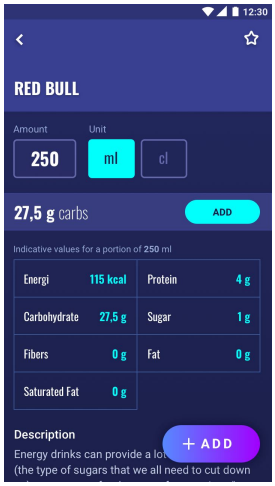
HDA has a built-in food database with 1700 food items. It can be accessed on the 'Food and Drinks' page in the insulin recommendation calculation flow.

5.3.1. Search for food items.

Bottom menu shows currently selected amount of carbs and calories



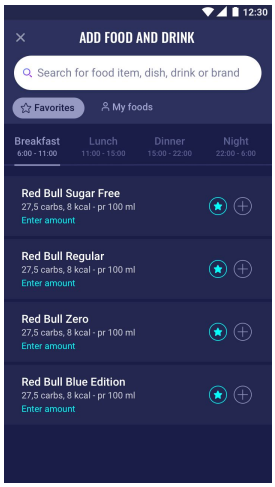
Adjust amount of food item, the default amount unit is ml and cl for liquids and gram for solids.

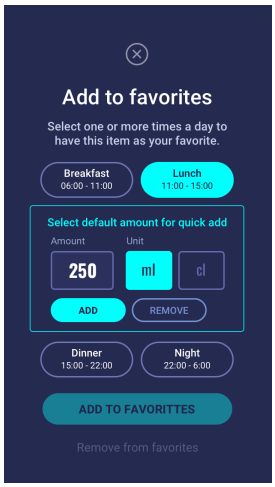


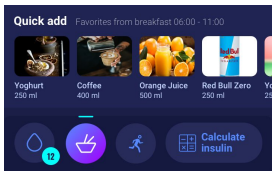
5.3.2. Favorites

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

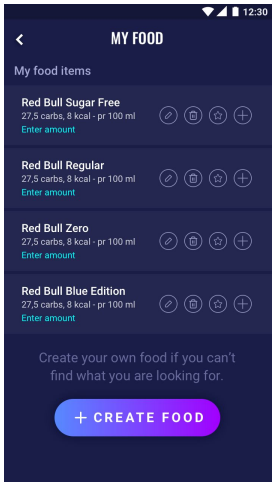




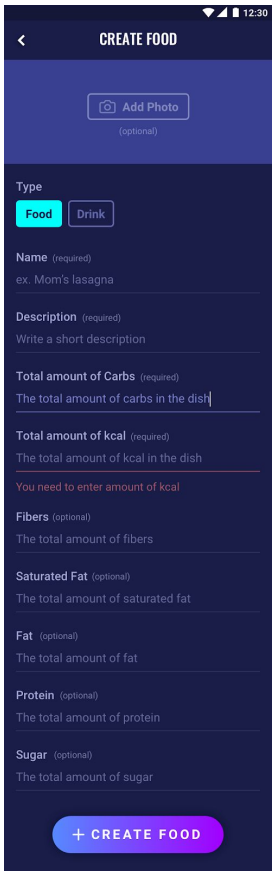


5.3.3. My food

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



5.3.4. Create food



6. Insulin

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

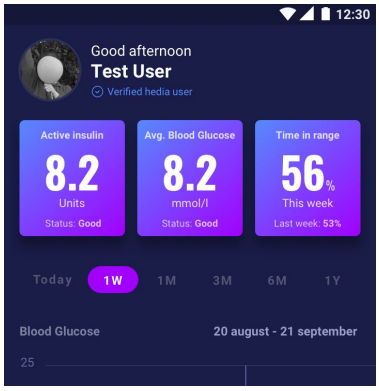
This calculation shows how many units of insulin HDA recommends. In addition, insulin on board (IOB) appears in the calculations. It is important that you as a user check HDA's calculations before approving a dose.

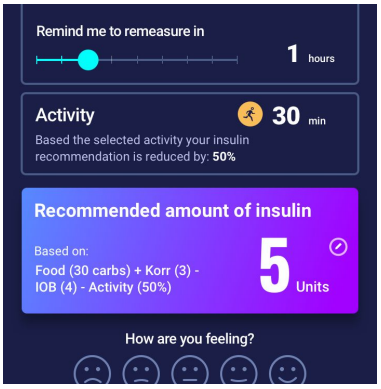
6.2. Insulin on Board (IOB)

Insulin on Board or Active Insulin tells how many units of rapid 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' page.

HDA takes into account insulin on board in its calculations.

HDA uses the Novorapid curve for these calculations. The maximum plasma concentration of Novorapid is reached after 30-40 minutes.
Reference: https://pro.medicin.dk/Medicin/Praeparater/2605





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:

Insulin effect curve					
Time	1	2	3	4	5
	29%	47%	19%	5%	0%

Table 2

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.

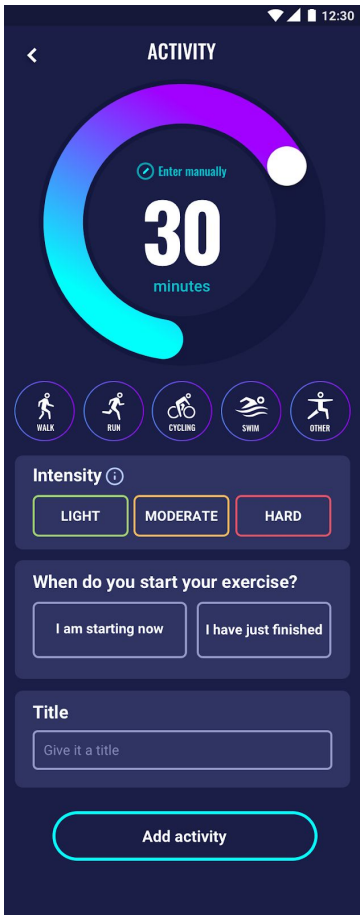
References:
https://rxed.eu/en/n/NovoRapid/5/#4_1__What_NovoRapid_is_and_what_it_is_used_for
https://pro.medicin.dk/Medicin/Praeparater/2605

6.3. Maximum insulin dose

HDA is set with a limit on how much insulin the app recommends. This maximum is 60 units for one administration/in one dose. HDA is also set with an attention popup when a recommended dose exceeds 20 units. These limits 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 insulin recommendation, either before or after an activity.



7.1. Activity levels in HDA and their effect.

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

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

Always consult your physician before beginning any exercise program. 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 with these exercises, stop and consult your healthcare provider.

7.2. How HDA calculates the effect of activity

	Intensity			
Duration Intensity	Mild exercise	Medium exercise	Hard exercise	Post exercise

0-29 min	0 %	0 %	0 %	0 %
30-45 min	25 %	50 %	75 %	50 %
46-60 min	50 %	75%	--- Text ---	50 %
More than 60 min	Consult healthcare professional			
Starting target BGL	9 mmol/L or 162 mg/dl			

Table 3

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 min.

7.4. Type of activity

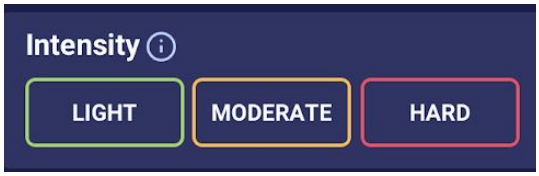
After setting the duration of the activity, you can tell HDA which type of activity you have performed. You do this by clicking on the icon below the circular slider.

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 shown in *Table 3*

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.

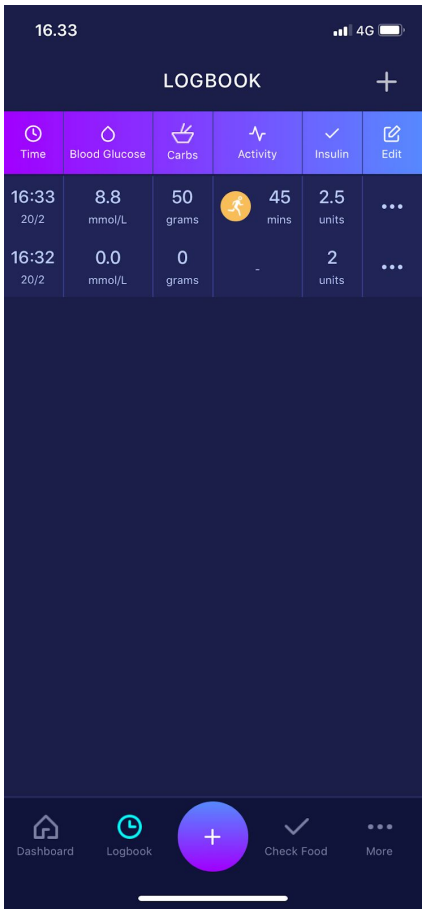


7.6. Activity start, title and recommendation

When you exercise, you can log this in advance, or log it after your exercise.
Physical 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.

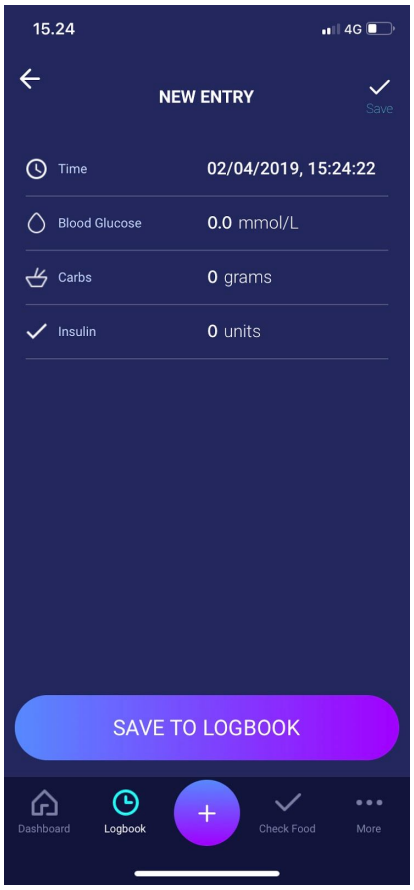
8. Logbook

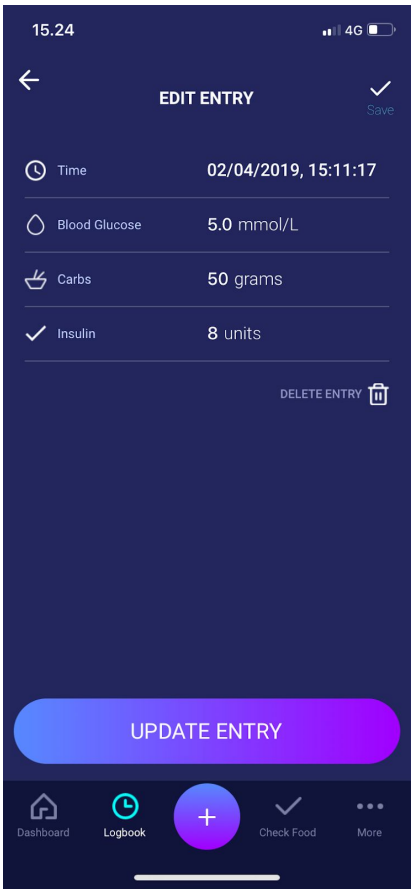
It is possible to access all of your entered data in your logbook.



8.1. Edit and Create entry

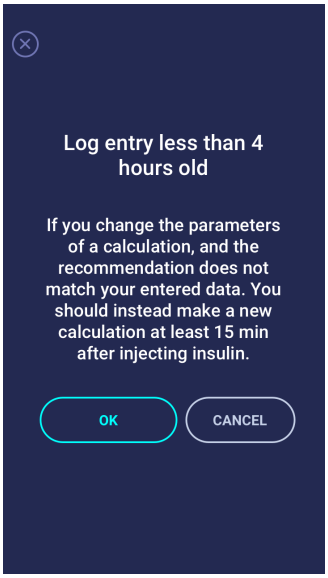
It is possible to edit previous logbook entries and create new.
To edit an entry you tap on the desired logbook entry.
You create a new by pressing the (+) icon on the logbook screen.





8.2. Changing entries less than 4 hours after logging

If you change the parameters of a calculation in the logbook less than 4 hours after logging you are presented with the following pop-up.



9. Settings

Under Settings, you have the option to change your settings for; your profile, change password, turn notifications on or off and change your settings for blood glucose, carbohydrate insulin rate, insulin sensitivity, activity and food.

9.1. Account Settings

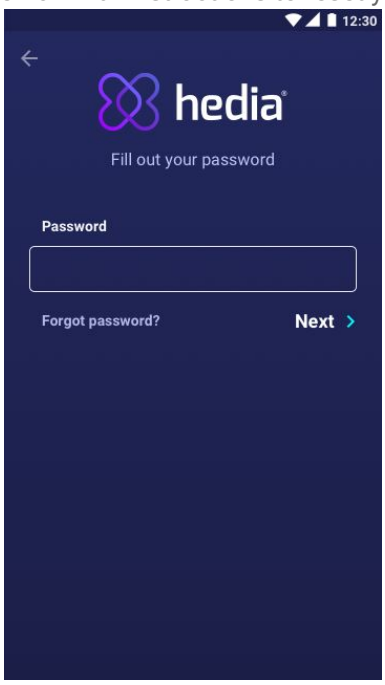
9.1.1. Edit Profile

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

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

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.



9.2. Personal Settings

9.2.1. Blood Glucose

Under ‘Blood Glucose’ you can change the settings for 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 .

Daily intervals

You are able to adjust the desired BGL for ‘low’, ‘target’ and ‘high’ in the daily intervals.

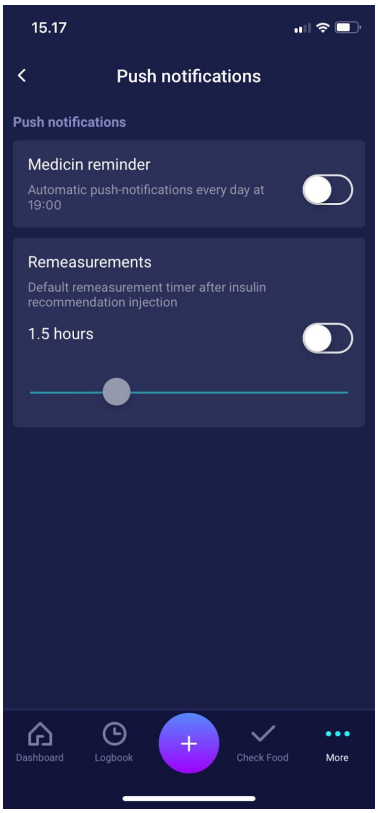
9.3. Notifications

9.3.1. Medicine reminder

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

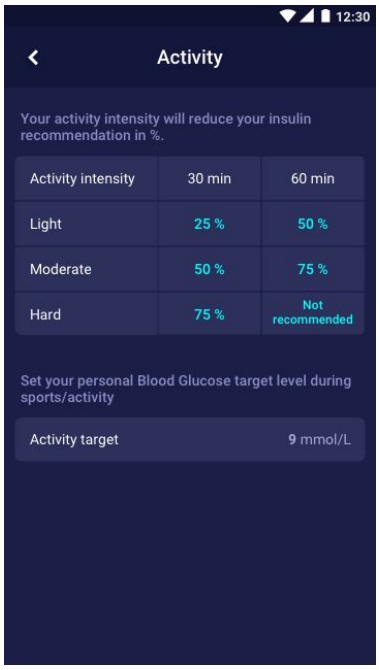
9.3.2. Remeasurements

You can activate and set the amount of hours from 0-6 for push-notification after insulin recommendation log. The default setting is 1.5 hours.



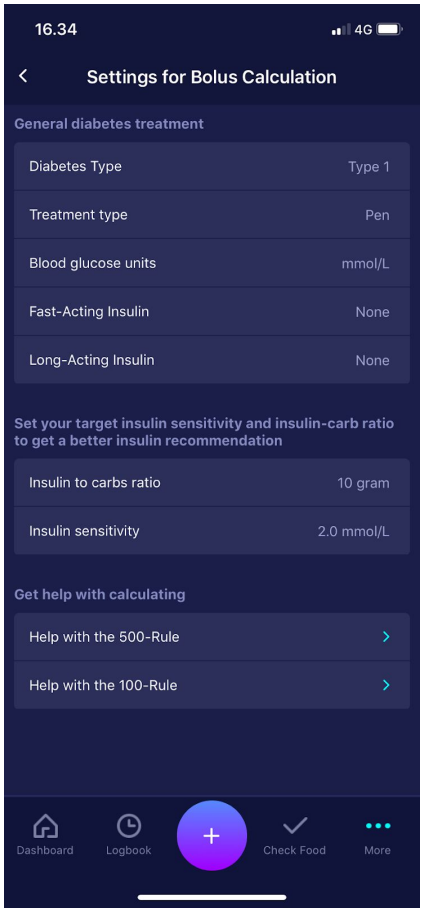
9.4. Activity

Under 'Activity' you can define the percentage, which will reduce your insulin recommendation in %. This can be done for "Light", "Moderate" and "Hard" intensity.



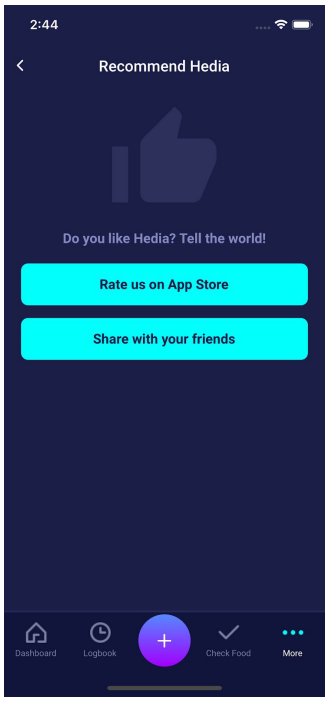
9.5. Settings for Bolus Calculation

Under insulin-to-carb ratio & insulin sensitivity, 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 total daily dosage, insulin-to-carb ratio and insulin sensitivity factor, within the limits of HDA.
In addition, you have the opportunity to get help calculating the 500-rule and the 100-rule.

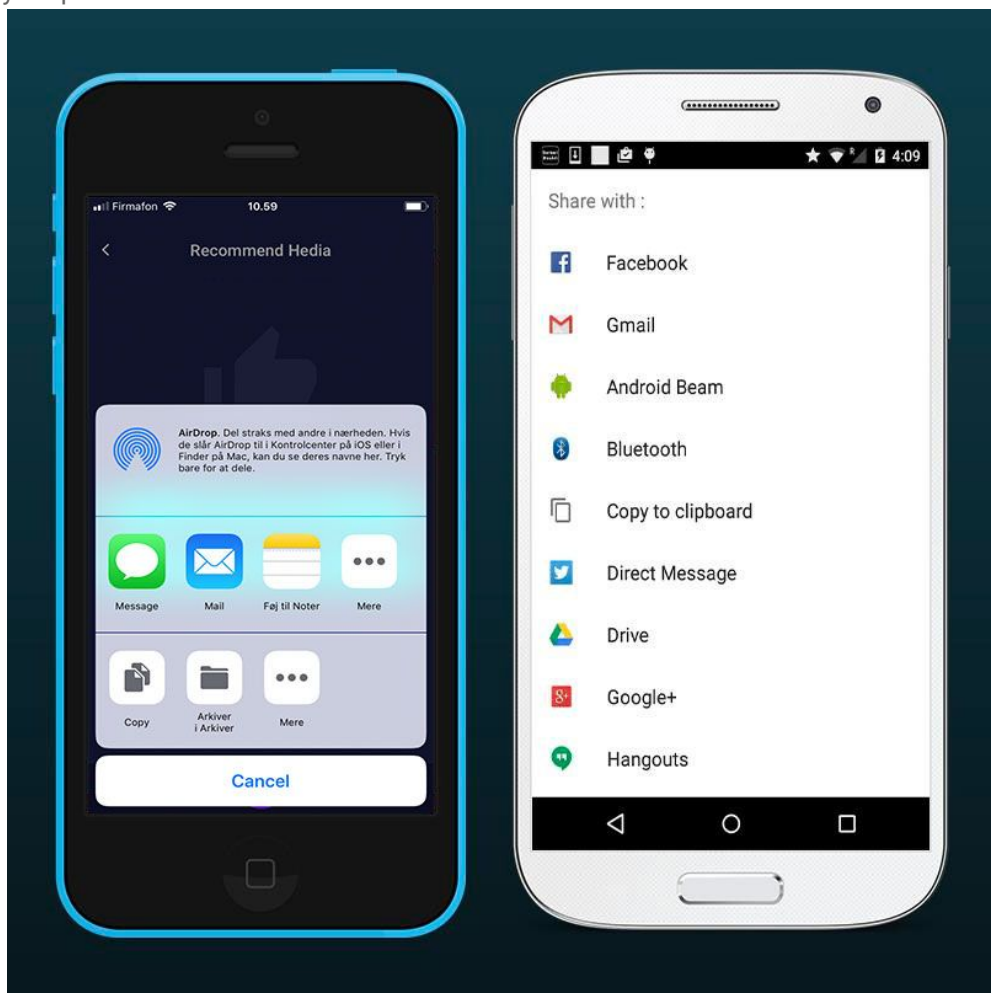


9.6. Recommend HDA

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

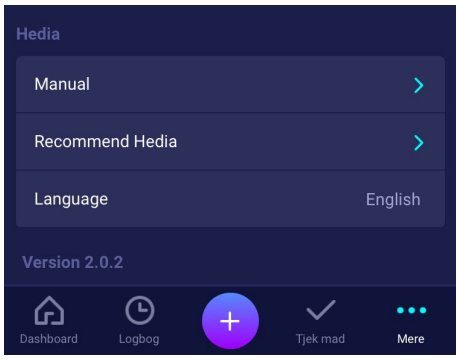


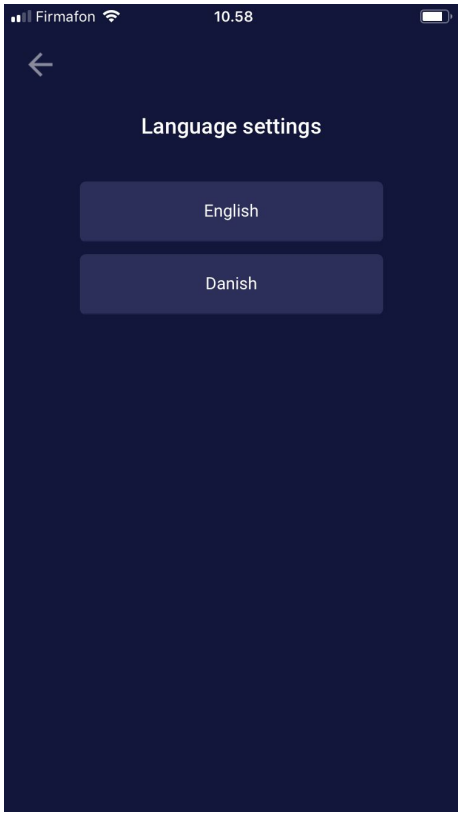
Additionally with the “Share with your friends” you can share a link to download HDA, using different apps on your phone..



9.7. Change language

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





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.

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
Favorit food item	Search	Date of manufacturer	Manufacturer		

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:
2019-02-19

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User Manual, Version. 1.1 Issued: DD/MM/YYYY

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