

Hedia Diabetes Assistant (HDA) Instructions for Use

Version 2.16.4



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1. Intro

1.1. What's in this manual

Hi and welcome, thank you for choosing to use Hedia Diabetes Assistant (HDA). We hope we can make your everyday life with diabetes just a little easier.

This is our user manual. It consists of a lot of information and we know that this can be overwhelming to most of us so we have tried to break it down into different sections.

We advise you to read through the whole **introduction** to ensure that HDA is the right product for you before you get started.

Next step is **setting up your personal diabetes assistant**.

Diabetes isn't easy and there are a lot of things to understand, therefore we strongly advise you to let your healthcare provider help you get all your settings right so you get the most out of your use of HDA.

Now you're good to go.

HDA has a variety of functionalities and for each of these we have created a **"how to" section**. You can go through these guides as many times as you like.

Some of you out there like to know a little bit more about things so we have created a **"Read more" library** where you can dive deeper into the clinical foundation for the different functionalities, find all relevant contact information and see our certificates.

We hope you enjoy your experience with using Hedia Diabetes Assistant.

1.2. Information for use

1.2.1. Intended Use

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

1.2.2. Indications For Use

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

- Type 1 diabetes - insulin-dependent diabetes mellitus
- Type 2 diabetes – 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 13.0 or newer or Android version 8.0 or newer.

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

1.2.3. Contraindications

For safety reasons the product should not be used by children or users with the following conditions;

- Pregnancy
- Gestational diabetes
- Fever

1.2.4. Intended Use Environment

Hedia Diabetes Assistant is intended for use in the following environments:

- Hospitals
- Clinics
- Physician's office
- Home use
- In public spaces

1.2.5. Mode of Action

Hedia Diabetes Assistant is intended for personal use by the patient to log glucose level, food intake, weight, activity level and psychosocial parameters. Blood glucose level can be registered manually or transmitted to Hedia Diabetes Assistant from 3rd party blood glucose meters and smart insulin pens via Near Field Communication (NFC) and Bluetooth. Activity level can be registered manually.

1.2.6. Overall warning/ alerts



Important safety information

Hedia Diabetes Assistant (HDA) is a tool to support your day-to-day diabetes management based on your prescribed diabetes therapy. HDA does not replace professional medical advice or treatment planning with your healthcare professional.

HDA does not prescribe medication but support you with indicate suggestions of what insulin dose to take, how many carbs to eat, when to measure ketones and when to postpone activity. If you are struggling to keep your diabetes stable or wish to adjust your personal settings we advise you to consult with your Healthcare professional to support you in this matter.

HDA can only take provided data into account. Any type errors, not logged insulin injections, not logged carbohydrates or not logged blood glucose measurements will not be considered in the provided recommendations. HDA has setup a range of input limitations to ensure your safety.

We advise you to be mindful of the attention messages you will receive while using HDA, these are there to support your safety and guide you with timely information on recommended actions based on your logged data.

Always rely on your own common sense, your symptoms and what usually is the best way for you to manage your diabetes. You know yourself best.

1.3. What can HDA help you with?

HDA aims to support you in keeping your blood sugar levels within your target ranges.

HDA is a diabetes assistant (application) that supports you in your day-to-day management of diabetes. HDA helps you in your daily diabetes management treatment by advising actions according to your data inputs. HDA supplies you with an indicative bolus dose of insulin or carbohydrates based on your personal data and settings.

In HDA you can:

- Log your blood glucose, insulin, carbohydrate, ketone and activity data
- Use bluetooth or NFC devices to seamlessly transfer data into your logbook or bolus calculations*
- Get an overview of your blood glucose levels over time via an easy to read graf view
- Get an overview of your active insulin based on your logged data
- Use the bolus calculator to support you with bolus carbohydrate recommendations or insulin recommendations
- Use the food database incl. search function and possibility to add personal items
- Get an overview of your logged data you can share with your Healthcare professional

* HDA is based on advanced carbohydrate counting. 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.

1.4. You can use HDA with a variety of third party devices

See the list of compatible devices in the table below.

| Device Type | Device Name | What does it measure? |
|---------------------------|-----------------------------|-------------------------------|
| Blood Glucose Meter (BGM) | Contour® NEXT ONE | Blood Glucose |
| | CareSens N Premier | Blood Glucose |
| | Beurer GL49 | Blood Glucose |
| | GlucoMen® areo | Blood Glucose |
| | GlucoMen® areo 2K meter set | Blood Glucose |
| | Keto-Mojo™ GKI | Blood Glucose & Blood Ketones |
| | CareSens Dual | Blood Glucose & Blood Ketones |
| | VTrust | Blood Glucose |
| Smart Insulin Pen | NovoPen 6® | Insulin data |
| | NovoPen Echo® Plus | Insulin data |

Table 1: Compatible devices for HDA.

2. Setting up your personal diabetes assistant

2.1. HDA account settings (Profile)

When setting up your account for the first time using HDA you will be guided through setting up your personal profile. You can go back and make updates to these settings at any time by going to: "Edit profile".

Your profile settings include following inputs:

- First name
- Diabetes type
- Biological sex

- Date of birth
- Height
- Weight

You can also update your data consent in HDA account settings.

2.2. HDA personal settings

In order to use HDA for bolus calculations you need to input your personal information related to your diabetes therapy regime.

When you use HDA for the first time, you will be asked to personalise the app with your information before the app can be used.

You can make updates to your personal settings at any time by going to “personal settings” via “more” on the menu bar in the HDA app.

2.2.1. Blood glucose (BG)

Under “Personal settings” -> “Blood Glucose” you can change the settings for your blood glucose and change the blood glucose unit that you wish to use.

Under “blood glucose” you can set your target BG, as well as set your limits for low and high blood glucose.

In HDA it is possible to choose between two different BG settings:

“**Daily blood glucose**” which enables you to adjust your high, low and target BG to specific times of the day and night or

“**Overall settings**” which supports a standard high, target and low range unaffected by time of day.

For both settings you may use HDA’s default settings or to personalise them.

We advise you to personalise these to get the most out of HDAs services.



Important safety information

HDA relies on you to provide information to support you in your day-to-day management of diabetes.

When adjusting settings we advise you to consult with your healthcare provider.

Use the toggle to switch on “daily blood glucose” or “overall settings” and adjust your targets accordingly.

Read more about HDA default settings in the [Read more](#) section of the user manual.

Blood glucose

Measure unit x.x

Daily blood glucose

| Time | Low | Target | High |
|--------------|-----|--------|------|
| Night | x.x | x.x | x.x |
| Morning | x.x | x.x | x.x |
| Before lunch | x.x | x.x | x.x |
| Lunch | x.x | x.x | x.x |
| After lunch | x.x | x.x | x.x |
| Evening | x.x | x.x | x.x |
| Bedtime | x.x | x.x | x.x |

Use overall settings

| Low | Target | High |
|-----|--------|------|
| x.x | x.x | x.x |

2.2.2. Ketones

You can log your blood ketone level in HDA if you wish to. Your ketone level will not be taken into account when making a calculation in HDA but may be saved as an entry in your logbook when you make a bolus calculation.

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

HDA will recommend you to measure ketones if your input data indicates a need for this.

Read more about ranges and attention messages in the “read more” section.

2.2.3. Bolus calculator

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

Under “Settings for insulin calculator” you need to input your personal information regarding your general diabetes treatment.

Settings for insulin calculator

| | |
|----------------------|-----|
| Diabetes type | XYZ |
| Treatment type | XYZ |
| Blood glucose unit | XYZ |
| Rapid acting insulin | XYZ |
| Long-acting insulin | XYZ |
| Insulin settings | |

In HDA it is possible to set your treatment type and adjust unit precision.

You can choose between the following treatment types:

- pen with half-unit precision
- pen with whole-unit precision
- pump with the precision of 1 decimal

Under **“insulin settings”** you will need to provide your insulin sensitivity factor and insulin-to-carb ratio. You may choose to either use a fixed insulin-to-carb ratio and insulin sensitivity throughout the day by using the 500 rule and 100/1800 rule or to adjust these to different values throughout the day. You have the opportunity to get help with the 500 rule and the 100/1800 rule here. You can find further information in the **“read more”** section of this manual.

You can revisit and update these settings at any time.

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

You may also choose to adjust your insulin sensitivity and insulin-to-carb ratio to different values throughout the day by using the “your daily insulin requirement”. By choosing this HDA will use these settings rather than the rule based settings when calculating a bolus recommendation for you. We strongly advise that you adjust these settings in collaboration with your healthcare professional.



Important safety information

We advise you to consult with your healthcare professional if you are unsure of what your daily dose is or need further help using the clinical rules described.

The information you provide here is used as a basis to calculate your insulin and carbohydrate recommendations in HDA.

We advise you to be mindful that all your treatment data is correct before making a calculation.

2.3. Activity



Important safety information

You should always consult with your healthcare professional before setting up your activity module in HDA as exercise affects everyone differently.

Under “Activity” in settings you can define how many percent your insulin recommendation will be reduced as a percentage (%). This can be done for “light”, “moderate” and “hard” intensity of exercise.

You can also set your desired blood glucose during physical activity.

The first time you use HDA, the default setting for your desired blood glucose during activity is 9.0 mmol/L (162 mg/dL).

The limits for adjusting your desired blood glucose during physical activity in HDA are 5.0 mmol/L (90 mg/dL) - 13.9 mmol/L (250 mg/dL).

2.4. Smart Insulin Pen

Under “Smart Pen” in settings, you can find all the settings needed for NovoPen. Here you have access to setting up and connecting your NovoPen Echo Plus or NovoPen 6 at any time by pressing “Connect a NovoPen”.

Once a NovoPen is added, the registered pen will be displayed here where you can change the name of the pen as well. Under the settings, you can also find information regarding the device and how to use it. If needed, it is also possible to remove a NovoPen under settings by pressing the cross in the box's upper right corner displaying the registered NovoPen. You can always add the NovoPen again or add a new pen at any time.



Important safety information

Remember only to use your pen with rapid-acting insulin as HDA only supports this type of insulin.

3. How to guides

3.1. How to log Blood Glucose

In Hedia Diabetes Assistant you can log your blood glucose and get an insulin recommendation by following the instructions below:

1. Go to HDA main screen and click “+”.
2. Enter your blood glucose
 - a. manually (by using keyboard or slider) or
 - b. by synchronising with your device
3. Click “Calculate Insulin”.
4. If no logged entries within 4 hours, answer “Have you taken insulin within the last 4 hours?” question.

Success! Your insulin recommendation is displayed on the screen.

5. Click “Transfer to logbook” to save and keep track of your information.

Success! Your blood glucose has been logged.

The screenshot shows a mobile app interface with the title "Enter your current blood glucose". In the center is a large circular gauge with a black segment and the text "XX.X" in the middle. Below the gauge are two input fields: "Add device" and "Add blood ketone level". At the bottom, there is a navigation bar with four icons: three circles and one square.



Important safety information

We advise you to check if the inputted blood glucose was typed in correctly before you take the recommended amount of insulin or take any other action.

3.2. How to log Blood Ketone

In Hedia Diabetes Assistant you can log your blood ketone following the instructions below:

1. Go to HDA main screen and click “+”.
2. Click “Add blood ketone level”.
3. Enter your blood ketone
 - a. manually (by using keyboard or slider) or
 - b. by synchronising with your device
4. Click “Add blood ketones”.
5. Enter your blood glucose (optional)
 - a. manually (by using keyboard or slider) or
 - b. by synchronising with your device
6. Click “Calculate Insulin”.
7. If no logged entries within 4 hours, answer “Have you taken insulin within the last 4 hours?” question.
8. Click “Transfer to logbook” to save and keep track of your information.

Success! Your blood ketone has been logged.

Enter blood ketone levels

XX.X

Add device



Important safety information

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

3.3. How to use bolus calculator with a Smart Insulin Pen

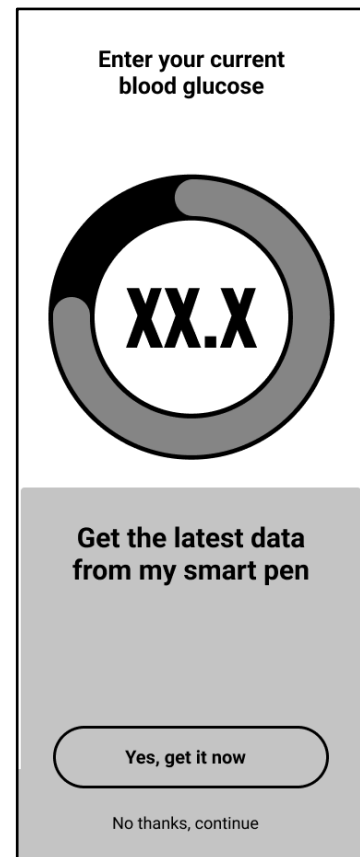
In Hedia Diabetes Assistant you can use data from your smart insulin pen in HDA for the insulin calculation by following the instructions below:

1. Go to HDA main screen and click “+”.
2. Enter your blood glucose
 - a. manually (by using keyboard or slider) or
 - b. by synchronising with your device
3. If you want, enter blood ketone level and/or add food and/or activity.
4. Click “Calculate Insulin”.
5. An info screen appears with the option to use the latest data from NovoPen. Press “Yes, get it now” if you want to get the latest reading.
6. Press “Confirm and calculate insulin” if you want to use the data for the insulin calculation.

Success! The latest insulin data from your smart insulin pen is now taken into account for the insulin recommendation.

7. Click “Transfer to logbook” to save and keep track of your information.

Please note that in order to use data from your smart insulin pen in a calculation go to settings and set up your smart pen.



If some of the readings of data from your NovoPen are different from existing entries in the logbook, HDA will guide you to ensure that your data is only logged once.

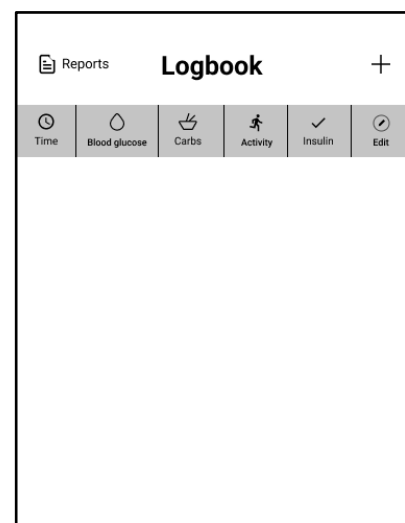
3.4. How to use logbook

In Hedia Diabetes Assistant you can view all your input data in the logbook. You may as well:

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

3.4.1. How to edit a log entry

In Hedia Diabetes Assistant logbook you can edit previous logbook entries by following the instructions below:



1. Go to HDA main screen and click “Logbook”.
2. Click on the logbook entry that you want to modify.
3. Edit existing information.
4. Click “Save” or “Save to logbook”.

Success! Your log entry information has been changed.

3.4.2. How to add a log entry

In Hedia Diabetes Assistant logbook you can add new logbook entries by following the instructions below:

1. Go to HDA main screen and click “Logbook”.
2. Click “+” (in the upper right corner).
3. Add information.
4. Click “Save” or “Save to logbook”.

Success! Your new log entry has been added to the logbook.

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

3.4.3. How to delete a log entry

In Hedia Diabetes Assistant logbook you can delete logbook entries by following the instructions below:

1. Go to HDA main screen and click “Logbook”.
2. Click on the logbook entry that you want to delete.
3. Click “Delete entry”.
4. Confirm changes.

Success! Your log entry has been deleted from the logbook.

3.4.4. How to export a PDF with your logged data

In Hedia Diabetes Assistant logbook you can export a PDF of your logged data by following the instructions below:

1. Go to HDA main screen and click “Logbook”.
2. Click “Reports” (in the upper right corner).
3. Select time frame for exporting your data.
4. Click “Export file”.

Success! Your log entries for the selected time period have been exported as PDF document.

Exported logbook data can be shared with your healthcare professional.

3.5. How to read dashboard

3.5.1. 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. HDA takes active insulin into account in its calculations.

3.5.2. Average blood glucose

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

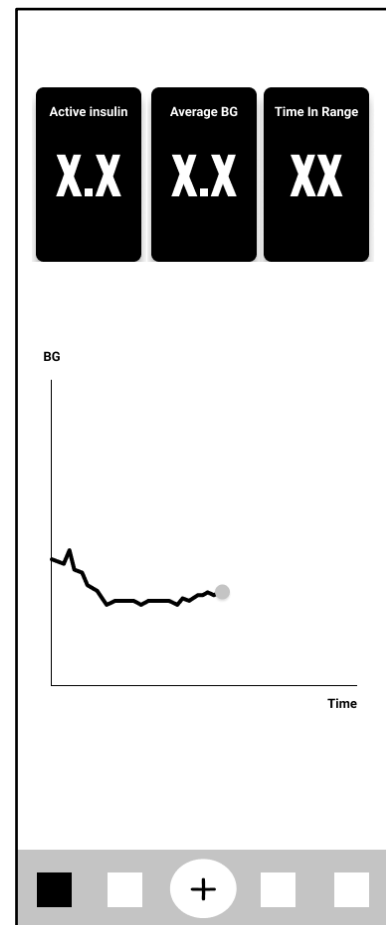
Your average blood glucose is not the same as the HbA1c measurement that is measured by your doctor.

3.5.3. Time-in-range

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

Based on a minimum of 28 blood glucose logs over a period of maximum 14 days HDA calculates the percentage of time **your logs** are in your range. You can see this percentage on the dashboard once you have made 28 logs within a maximum of 14 days.

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



3.6. How to use the bolus calculator

Hedia Diabetes Assistant will calculate your recommended insulin dose based on the amount of active insulin from previous calculations and:

- current blood glucose
- the amount of carbohydrates
- the amount of activity

If your blood sugar is low the calculator will provide a carbohydrate recommendation rather than an insulin recommendation.

In Hedia Diabetes Assistant you can get an insulin recommendation by following the instructions below:

1. Go to HDA main screen and click "+".
2. Enter your blood glucose
 - a. manually (by using keyboard or slider) or

- b. by synchronising with your device
3. Enter carbohydrates (food and drink) (optional).
4. Enter activity (optional).
5. Click “Calculate Insulin”.
6. If no logged entries within 4 hours, answer “Have you taken insulin within the last 4 hours?” question.

Success! Your insulin recommendation is displayed on the screen.

7. Click “Transfer to logbook” to save and keep track of your information.



Important safety information

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

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

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

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

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

3.7. Food database

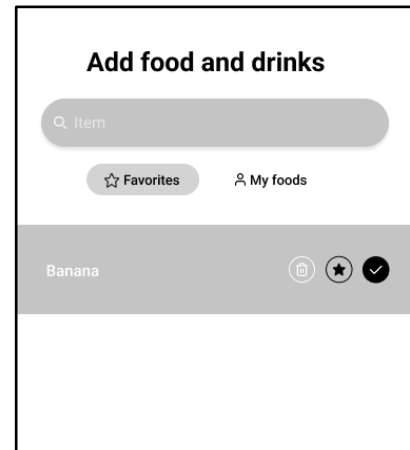
HDA has a built-in food database. Food database can be accessed directly by clicking “Food” button on HDA main screen or via insulin recommendation calculation flow.

3.7.1. How to search for food items

In Hedia Diabetes Assistant food database you can search for food items by following the instructions below:

1. Go to HDA main screen and click “Food”.
2. Click “Search for food item, dish, food, drinks or brands” and type in what you are looking for (e.g. apple). Please note that the search can bring more than one result.
3. Select item from the “Search results”.

Success! Now you have found a food item that you were looking for.



3.7.2. How to add food items as favourites

In Hedia Diabetes Assistant food database you can add food items as your favourites by following the instructions below:

1. Go to HDA main screen and click “Food”.
2. Click “Search for food item, dish, food, drinks or brands” and type in what you are looking for (e.g. apple). Please note that the search can bring more than one result.
3. Find item from the “Search results” and click on the star sign (on the right side of the item).
4. Click “Add to favourites”.

Success! Now you have added one of the food items to your favourites list.

By adding food items as favourites you will avoid searching for the same item again and again. Instead, you will be able to select it quickly and continue with the calculation.

3.7.3. How to create food items

In Hedia Diabetes Assistant food database you can create personal food items by following the instructions below:

1. Go to HDA main screen and click “Food”.
2. Click “My Food” (button next to “Favourites”).
3. Click “Create food”.
4. Fill in the food item related information and click “Create food”.

Success! Now you have created a new food item which appeared on “My food items” list.

3.8. How to connect with 3rd party devices

HDA can connect to blood glucose meters and smart insulin pens via bluetooth and NFC (Near Field Communication).

Before connecting to any blood glucose meter you should:

1. Make sure that your glucose meter is turned on.
2. Check that the time on your blood glucose meter is set correctly.
3. Make sure that the blood glucose reading is made within the last 10 minutes. If you try to sync your blood glucose meter with a reading older than 10 minutes you will be presented with the attention message. You have to remove the strip and scan again.

3.8.1. Sync with bluetooth devices

HDA can connect to blood glucose meters via bluetooth.

3.8.1.1. Supported devices

Device availability may vary depending on region and platform.

Supported blood glucose meters for HDA via bluetooth are as follows:

| Device Type | Device Name |
|---------------------------|--|
| Blood Glucose Meter (BGM) | <ul style="list-style-type: none">● Contour® NEXT ONE● Keto-Mojo™ GKI● CareSens Dual● CareSens N Premier● Beurer GL49● VTrust● FORA 6 Connect (FR, IT, DE) |

Table 2: Compatible devices for HDA via bluetooth.

3.8.1.2. How to connect via bluetooth

A bluetooth glucose meter can be added to HDA by clicking "+" -> "Add a device" -> "Connect device".

1. Go to HDA main screen and click "+".
2. Click "Add a device" and the list of supported devices appears.
3. Click on the device name that you are using (info screen of the device and its connection type appears).
4. Click "Connect and Sync" to pair it. HDA will start searching for devices. Follow the instructions shown on your screen to connect with the specific device.
5. Allow HDA to access bluetooth.

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

3.8.2. Sync with NFC devices

HDA can connect to glucose meters and smart insulin pens via NFC.

3.8.2.1. Supported devices

Device availability may vary depending on region and platform.

Supported blood glucose meters and smart insulin pens for HDA via NFC are as follows:

| Device Type | Device Name |
|---------------------------|--|
| Blood Glucose Meter (BGM) | <ul style="list-style-type: none">● GlucoMen® areo● GlucoMen® areo 2K meter set |
| Smart Insulin Pen | <ul style="list-style-type: none">● NovoPen 6®● NovoPen Echo® Plus |

Table 3: Compatible devices for HDA via NFC.

3.8.2.2. How to connect glucose meters via NFC

A NFC glucose meter can be added to HDA by clicking “+” -> “Add a device” -> “Connect device”.

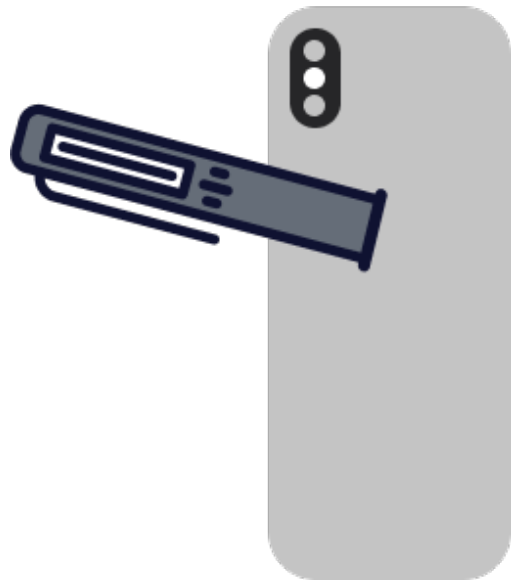
1. Go to HDA main screen and click “+”.
2. Click “Add a device” and the list of supported devices appears.
3. Click on the device name that you are using (info screen of the device and its connection type appears).
4. Click “Connect and Sync” to pair it. A screen will appear with information for scanning using NFC.
5. Allow HDA to access NFC.

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

3.8.2.3. How to connect smart insulin pen via NFC

A smart insulin pen can be connected to HDA via NFC when making an insulin recommendation.

1. Go to HDA main screen and click “+”.
2. Click “Calculate Insulin”.
3. If you have registered your smart pen in settings (see [section 2.4](#)), an info screen appears with the option to use the latest data from the pen.
4. Press “Yes, get it now” if you want to get the latest reading.
5. A screen will appear with information for scanning using NFC. Hold your smart insulin pen against the back of your phone (see picture on the right).
6. HDA will start searching for smart insulin pen and sync to pair devices.
7. Your recent insulin data from the smart insulin pen will now appear in HDA.
8. Press “Confirm and calculate insulin” if you want to use the data for the insulin calculation.



Success! The latest insulin data from your smart insulin pen is now in HDA and will be taken into account for the insulin recommendation.

3.9. Technical

3.9.1. How to login

If you are an existing user and you logged out of the application, you can login back to HDA by following the instructions below:

1. Open Hedia Diabetes Assistant app and click “Existing user”.
2. Enter your email address and click “Next”.
3. Enter your password and click “Next”.

Success! You are logged in to the Hedia Diabetes Assistant app.

3.9.2. How to logout

You can logout from HDA by following the instructions below:

1. Open Hedia Diabetes assistant app and click “More”.
2. Click “Edit Profile” under account settings.
3. Click “Log out”.

Success! You are logged out of the Hedia Diabetes Assistant app.

3.9.3. How to delete user account

You can delete your user account from HDA by following the instructions below:

1. Open Hedia Diabetes Assistant and click “More”.
2. Click “Edit Profile” under account settings and scroll to the bottom.
3. Click “Delete Account”.
4. Enter your email address and click “Delete Account”.
5. Open your email inbox and confirm the account deletion by clicking the link in the email that you have received.

Success! You have deleted your HDA account.

3.9.4. How to change password

You can change your HDA password by following the instructions below:

1. Open Hedia Diabetes Assistant app and click “More”.
2. Click “Edit Profile” under account settings.
3. Click “Password”.
4. Enter your current password, new password and click “Change password”.

Success! You have changed your Hedia Diabetes Assistant password.

3.9.5. How to enable notifications

In Hedia Diabetes Assistant you can enable notifications by following the instructions below:

1. Go to HDA main screen and click “More”.
2. Click “Notifications”.
3. Enable “Medicine reminder” (optional).
4. Enable “Remeasurements”.
5. Select notification frequency by using a slider.

Success! Notifications have been enabled.

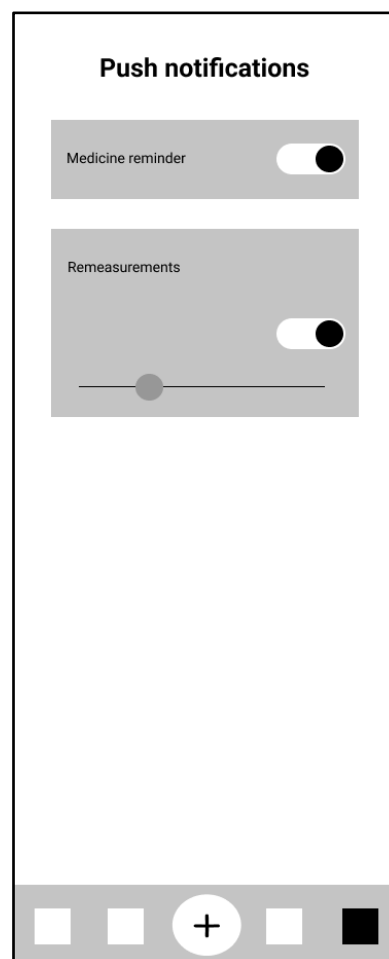
3.9.6. How to disable notifications

In Hedia Diabetes Assistant you can disable notifications by following the instructions below:

1. Go to HDA main screen and click “More”.
2. Click “Notifications”.
3. Disable “Medicine reminder”.
4. Disable “Remeasurements”.

Success! Notifications have been disabled.

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



4. Read more

4.1. Clinical information and safety

4.1.1. Blood glucose

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

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

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

4.1.2. Target area

The recommended blood glucose concentration is maintained within a level of 4-8 mmol/L or 72-144 mg/dL.

A blood glucose concentration below 4 mmol/L (72 mg/dL) is called hypoglycaemia and a blood glucose concentration above 8 mmol/L (144 mg/dL) is called hyperglycaemia.

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

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

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

Table 4: Default for overall settings for blood glucose units in mmol/L.

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

Table 5: Default for overall settings for blood glucose units in mg/dL.

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

4.1.3. Time-in-range (TIR)

Time-in-range is a percentage of the time your blood glucose is within your blood glucose target values. HDA can give you an idea of how much time you are in range by calculating the percentage of time your logs are in your defined range. This calculation in HDA requires a minimum of 28 logs within a maximum of 14 days.

Once the 28 logs within 14 days are available the calculation is made by HDA automatically and will appear on your HDA dashboard under “Time in Range”.

Your time-in-range in HDA is not the same as the HbA1c and is not as accurate as the TIR calculated by your doctor.

4.1.4. Bolus calculator

4.1.4.1. Clinical calculations used in HDA

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

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

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

4.1.4.2. Insulin-to-carb ratio (500 rule)

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

The formula for the 500 rule is:

$500 \div \text{your daily dose (total amount of insulin taken in a day including long-acting insulin)}$

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

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

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

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

- **100 rule**

The formula for the 100 rule is:

$100 \div \text{your daily dose (total amount of insulin taken in a day including long-acting insulin)}$ 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).

- **1800 rule**

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

$1800 \div$ 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 causes a drop in blood glucose of about 36 mg/dl).

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

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

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

4.1.4.4. Meal dose

Your meal dose 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).

4.1.4.5. Correction dose

If your blood glucose is above or below your blood glucose target, HDA recommends a correction dose. If you enter a low blood glucose (hypoglycaemia), HDA will use your insulin sensitivity factor (100 rule/1800 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. In this calculation HDA will take your active insulin into account to minimise the risk of insulin stacking.

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

In case of low blood glucose (hypoglycaemia), HDA does not recommend insulin, but carbohydrates and will not take your active insulin into account but remind you to reassure your blood glucose level to ensure your blood sugar comes back into your target range.

HDA recommends carbohydrates based on the following formula:

Carbohydrate = (Target BG - Current BG) / Insulin Sensitivity factor * Insulin-to-carb ratio

4.1.4.6. Active insulin/insulin on board (IOB)

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 active insulin into account in its correction bolus calculations.

HDA uses the Novorapid curve for these calculations. The maximum plasma concentration of Novorapid is reached after 30-40 minutes ([Ref. 2](#)).

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

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

Table 6: Insulin effect curve.

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. 2](#)).

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

4.1.5. Activity

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

4.1.5.1. How HDA calculates the effect of activity

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

Table 7: Calculated effect of activity in HDA.

4.1.5.2. Intensity of activity

In HDA intensity of activity is divided into light, moderate and hard, and is described using the categorisation from the modified Borg RPE 10 scale ([Ref. 3](#)).

4.1.5.3. Start time of an activity

When you add an activity, you can record when the activity is performed (“I am starting now” or “I have just finished”).

The added activity can then affect the calculations you make for up to 4 hours after the start time of the activity.

The specific way in which a recommendation calculation by HDA is affected by a given PA depends on whether or not the activity is ongoing or has ended. A PA is considered ongoing (green in Figure 2) from its start time until the PA’s duration has elapsed. A PA that has ended can still be associated with and affect calculations for up to 4 hours (yellow in Figure 2) after the end time.

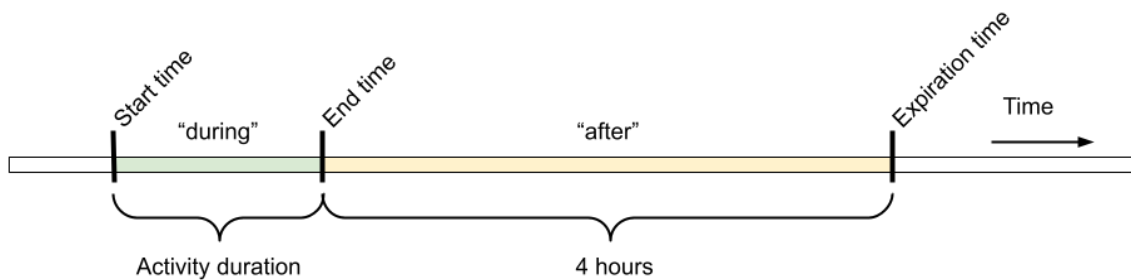


Figure 2: Effect of activity in HDA.

4.1.5.4. Ended activity with 4 hour

Alternatively, if a PA has ended, but it did so less than 4 hours ago, corresponding to the yellow part in the diagram above, only one adjustment will be made during the calculation: At the end of the calculation, the insulin bolus will be reduced by some percentage according to the duration of the entered PA.

The default reduction percentages are displayed in the table below. Note that only an insulin recommendation will be reduced by this percentage. If the calculation result is that additional carbohydrates should be recommended, the recommendation will not be reduced.

| 0 - 29 minutes | 30 - 45 minutes | 46 - 60 minutes |
|----------------|-----------------|-----------------|
| 0% | 50% | 50% |

Table 8: Insulin reduction table. Physical activity module, Hedia Diabetes Assistant.

4.1.6. Ketones






The body's normal source of energy is glucose. When the body doesn't have enough insulin to use glucose for energy the body begins to burn fat for energy.

Ketones are a product of the breakdown of fat. When ketones build up in the blood, they make it more acidic. They are warning signs that diabetes is out of control. High levels of ketones can cause diabetic ketoacidosis (DKA) in anyone with type 1 diabetes and in rare cases also in people with type 2 diabetes.

4.1.6.1. What are the warning signs of diabetic ketoacidosis?

Early symptoms of DKA can include:

- Tiredness
- Nausea or vomiting
- Thirst
- Mouth dryness
- Itching
- Increased urinary frequency.

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


| Blood ketone ranges | Definition | Recommended actions | Ketone Colour indicator |
|--|----------------------------|--|---|
| measured > 16.67 - 31.25 mg/dL within 12 hours | | advice.* | |
| > 3.0 - 8.0 mmol/L > 31.25 - 83.33 mg/dL | Dangerous level of ketones | Your blood ketone value is very high which puts you at great risk of developing diabetic ketoacidosis. We recommend that you get immediate medical care. |  |

Table 9: Blood ketone values, definitions and recommended actions.

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

4.2. List of safety limits in HDA

4.2.1. Insulin recommendation limits

HDA is set with a limit on how much insulin the app recommends.

This maximum is 60 units for one administration/in one dose.

The limit also applies to manual entries and is a precautionary measure to avoid unintentionally large doses.

4.2.2. Blood glucose input limits

If the user has a blood glucose level that is dangerously high or low HDA is not considered the appropriate tool to provide corrective actions. Therefore limits to blood glucose input values are set as:

- Minimum 1.1 mmol/L or 20 mg/dL.
- Maximum 33.3 mmol/L or 600 mg/dL.

4.2.3. Blood glucose target limit

HDA has, as a safety measure, a built-in:

- Minimum target BG of 5 mmol/L or 90 mg/dL
- Maximum target BG 13.9 mmol/L or 250 mg/dL

4.2.4. Activity duration limit

Maximum duration of activity is set to 60min.

4.2.5. Ketone input limits

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

- Minimum limit: 0.0 mmol/L or 0.0 mg/dL
- Maximum limit: 8.0 mmol/L or 83.33 mg/dL

4.2.6. Desired blood glucose during activity

The limits for adjusting your desired blood glucose during physical activity in HDA are as follows:

- Minimum limit 5.0 mmol/L or 90 mg/dL
- Maximum limit 13.9 mmol/L or 250 mg/dL

4.3. Support

If you experience any problems with HDA or have questions send us an email and will be happy to assist you. You can reach us at support@hedia.com.

For more information, please refer to our [Terms and Conditions](#).

4.4. Known software anomalies

This current release contains no known software anomalies.

| Release version | Reference number | Description |
|-----------------|------------------|-------------|
| 2.16.4 | N/A | N/A |

Table 10: Known software anomalies, Hedia Diabetes Assistant.

4.5. Legal information



Date of manufacture:

2024-09-24



Instructions for Use:

Version: 2.16.4

Issued: 2024-09-24



Hedia Diabetes Assistant is regulated as a medical device under Directive 93/42/EEC.



Manufacturer:

Hedia ApS

Emdrupvej 115a, 3rd floor

DK-2400 Copenhagen, Denmark

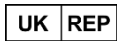
CVR/VAT: 37664618

Contact information:

Email: support@hedia.com



(01)05700002209580(10)2.16.4(8012)2.16.4



UK Representative:

EasyMedicalDevice Limited

125 Deansgate, Manchester, UK M3 2LH, United Kingdom

ukrep@easymedicaldevice.com

+44 161 543 6588

Novo Nordisk A/S:

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4.6. List of references

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