Hedia Diabetes Assistant

Instructions for Use

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1 Introduction

We advise you to read through the whole introduction to ensure that Hedia Diabetes Assistant is the right product for you before you get started.

We strongly advise you to let your healthcare provider help you get all your settings right, so you get the most out of Hedia Diabetes Assistant.

In Hedia Diabetes Assistant you can:

- Get insulin or carbohydrate recommendations based on your current glucose, recent insulin, carbohydrate intake, and physical activity.
- Use connected devices to transfer data into your logbook or bolus calculations.
- Get an overview of your glucose levels over time.
- Get an overview of your active insulin.
- Use the built-in food library or add your personal food items.
- Share your logged data with your healthcare professional.

2 Intended purpose

2.1 Intended Use

Hedia Diabetes Assistant is a multi-platform application (software as a medical device) with no body contact, intended to support the decision-making of rapid-acting bolus insulin dose for the management of insulin-dependent diabetes by providing the user with an insulin bolus dose recommendation.

2.2 Indications for Use

Hedia Diabetes Assistant is intended to be used when the user would normally check glucose and inject insulin. The indications for using Hedia Diabetes Assistant are:

- Type 1 or 2 diabetes treated with rapid-acting insulin.
- The user has to have the cognitive and physical skills to use mobile applications.

The users' insulin treatment is prescribed, monitored, and managed by their health care professional (HCP).

2.3 Contraindications

For safety reasons, Hedia Diabetes Assistant should not be used by persons with the following conditions.

- Pregnancy
- Gestational diabetes
- Under the age of 18 years

Warning. Do not use Hedia Diabetes Assistant if you are pregnant. You are at risk of high blood glucose.

2.4 Intended Patient Population

Adults (Age 18+ years) living with Type 1 or Type 2 diabetes on insulin treatment.

Warning. Do not use Hedia Diabetes Assistant if you are under 18 years old. You are at risk of low- or high blood glucose.

2.5 Intended User

The intended users of Hedia Diabetes Assistant are laypersons, who are adults (age 18+ years), living with type 1 or type 2 diabetes and using rapid-acting insulin. The intended user profile is further characterized by having cognitive and physical skills to use mobile applications.

2.6 Intended Use Environment

- The primary use environments would be home use and public spaces.
- Physician's offices, hospitals and clinics could be possible use-environments during setup and changing the settings, should the user choose to seek guidance from healthcare professionals for these tasks.

2.7 Clinical Benefits

Hedia Diabetes Assistant is intended to:

- Maintain glycemic control for users
- Increase glycemic control for users with suboptimal glycemic control
- No increase in risk of hypoglycemia for users
- No increase in risk of hyperglycemia for users

2.8 Clinical risks

Hedia Diabetes Assistant provides bolus insulin dose recommendations and clinical risks associated with Hedia Diabetes Assistant stem from the users' insulin treatment and underlying diabetes. Thus,

there is a risk of both hypo- and hyperglycemia when using Hedia Diabetes Assistant as these are inherent direct and indirect risks of using insulin in diabetes treatment.

3 Warnings and risks

3.1 Warnings

Warning. Do not use Hedia Diabetes Assistant if you are under 18 years old. You are at risk of low- or high blood glucose.
Warning. You are at risk of low- or high blood glucose if you enter wrong treatment parameters. Contact your health care professional if you do not know your insulin sensitivity factor, your insulin-to-carb ratio, or how to calculate them.
Warning. If you perform physical activity with a low blood glucose you are at risk of post-exercise low blood glucose.
Warning. If you perform physical activity with a very high blood glucose, OR a moderately high blood glucose plus elevated blood ketones, you are at risk of high blood glucose and ketoacidosis.
Warning. If you have severe high blood glucose and you do not act accordingly, you are at risk of ketoacidosis.
Warning. If you have a fever and do not adjust your insulin accordingly, you are at risk of high blood glucose and/or ketoacidosis.
Warning. Do not use Hedia Diabetes Assistant if you are pregnant. You are at risk of high blood glucose.
Warning. Please consult with your healthcare professional before changing the settings for physical activity. You are at risk of low- and high blood glucose if the settings are incorrect.
Warning. Be sure to check if the entered blood glucose is correct. You are at risk of low-and high blood glucose if the value is incorrect.
Warning: Be sure to check if the entered carbohydrate amount is correct before taking the recommended amount of insulin or take any other action. You are at risk of low- and high blood glucose if the value is incorrect.
Warning: Be sure to check if the entered physical activity intensity and duration are correct before taking the recommended amount of insulin, or take any other action. You are at risk of low- and high blood glucose if the value is incorrect.

Warning: Only enter rapid-acting insulin as input for your calculations. You are at risk of low- and high blood glucose if you enter long-acting insulin in your calculations.
Warning. Hedia Diabetes Assistant has a safety limit on how much insulin can be recommended, and will never recommend more than 60 units per calculation. If your recommendation would have been higher than 60 units, it will be limited for safety reasons. You are at risk of high blood glucose if you need more than 60 units of insulin.

Table 1: Warnings for Hedia Diabetes Assistant.

3.2 Residual risks

When performing physical activity, there is a risk of post-exercise low blood glucose. Hedia Diabetes Assistant will reduce your insulin recommendation when you input physical activity in a bolus calculation. However, it does not remove the risk of post-exercise low blood glucose and you should always pay close attention to your blood glucose after physical activity.
Hedia Diabetes Assistant is developed in accordance with relevant international standards and is tested to prevent software errors. However, software errors are possible and can cause your insulin calculation to be inaccurate, leading to the risk low- or high blood glucose.
If you provide incorrect input, there is a risk of low- and high blood glucose.
When you have a fever, your insulin sensitivity factor tends to decrease. Hedia Diabetes Assistant does not take this into account when recommending an insulin bolus dose. Thus, there is a risk of high blood glucose if you use Hedia Diabetes Assistant when you have a fever.
Hedia Diabetes Assistant does not take active insulin into account when your blood glucose is lower than the value you have set as the target for your desired blood glucose. If you have taken insulin within the last 4 hours and are performing an insulin calculation while your blood glucose is below the value that you have specified as the target for your desired blood glucose, you are at risk of low blood glucose.

Table 2: Residual risks in Hedia Diabetes Assistant.

4 Data Security and Protection

In order to protect your data and your private information, you should never share your Hedia account password with others. Employees at Hedia will never ask for your password.

It is recommended that you install the latest software updates, including updates to your mobile operating system, browsers, and Hedia Diabetes Assistant as soon as they are available.

Unsecured networks increase the risk of confidential data being compromised. Therefore, Hedia Diabetes Assistant should only be used on secure networks.

4.1 Data residual risks

For products requiring internet access, there is a risk that data or product access can be compromised through product inaccessibility, unauthorized data modification, or data theft. You can contribute to improved security by taking the precautions described in the section *Data Security and Protection*.

5 Setup and Settings

5.1 Account and Profile

When creating your Hedia account and setting up Hedia Diabetes Assistant for the first time, you will be guided through setting up your personal profile. After the initial setup, you can edit your profile and Hedia account in Settings.

Your profile includes:

- Date of birth
- Diabetes type
- Biological sex
- Height
- Weight

Your Hedia account includes:

- Name
- Country (cannot be changed)
- Language
- E-mail
- Password
- Consent for research
- Consent for marketing

5.2 Personal settings

When you use Hedia Diabetes Assistant for the first time, you will be asked to personalise the product with your information before the product can be used.

It is important to keep your personal settings up to date, including your insulin sensitivity and insulin-to-carbohydrate ratio, to ensure accurate insulin recommendations. Hedia Diabetes Assistant relies on these settings to provide accurate recommendations.

Review and update your settings regularly, especially following any adjustments to your treatment plan by your healthcare professional.

You can make updates to your personal settings at any time by going to Settings.

Warning. You are at risk of low- or high blood glucose if you enter wrong treatment parameters.

Contact your health care professional if you do not know your insulin sensitivity factor, your insulin-to-carb ratio, or how to calculate them.

5.3 Glucose settings

Under Settings > Glucose you can change the settings for your glucose and change the glucose unit that you wish to use.

You can choose between two different glucose target settings:

1. **Fixed target.** Set a single glucose target for all times of the day. The range for high and low also stays the same.
2. **Variable target.** Set different glucose targets for different times of the day. The range for high and low can also vary during the day.

For both settings, you can use Hedia Diabetes Assistant's default settings, or personalise them.

We advise you to personalise these to get the most out of Hedia Diabetes Assistant.

The values for low and high do not affect your calculations. They only control the visual display of your target range on the Dashboard graph.

Warning. Be sure to check if the entered blood glucose is correct. You are at risk of low- and high blood glucose if the value is incorrect.

5.4 Insulin settings

Under Settings > Insulin you can change the settings for your insulin treatment, your insulin-to-carb ratio, and your insulin sensitivity.

You can choose between two different insulin settings:

1. **Fixed insulin settings.** Set one insulin sensitivity and insulin-to-carb ratio for all times of the day.
2. **Variable insulin settings.** Set different insulin sensitivities and insulin-to-carb ratios for different times of the day.

Warning. You are at risk of low- or high blood glucose if you enter wrong treatment parameters.

Contact your health care professional if you do not know your insulin sensitivity factor, your insulin-to-carb ratio, or how to calculate them.

5.5 Physical activity settings

Warning. Please consult with your healthcare professional before changing the settings for physical activity. You are at risk of low- and high blood glucose if the settings are incorrect.

Under Settings > Physical Activity, you can define how much your insulin recommendation will be reduced as a percentage (%). This can be done for Light, Moderate, and Hard intensity.

- **Light activity.** Feels like you can maintain for hours. Easy to breathe and carry a conversation
- **Moderate activity.** Breathing heavily, can hold short conversations. Still somewhat comfortable, but becoming noticeably more challenging
- **Hard activity.** Borderline uncomfortable. Short of breath, can speak a sentence

You can also set your desired glucose target during physical activity. This is important to avoid post-exercise low glucose. The default setting for your desired glucose target during activity is 8.0 mmol/L (144 mg/dL).

Warning: Be sure to check if the entered physical activity intensity and duration are correct before taking the recommended amount of insulin, or take any other action. You are at risk of low- and high blood glucose if the value is incorrect.

Warning. If you perform physical activity with a low blood glucose you are at risk of post-exercise low blood glucose.

Warning. If you perform physical activity with a very high blood glucose, OR a moderately high blood glucose plus elevated blood ketones, you are at risk of high blood glucose and ketoacidosis.

5.6 Connected Devices

Device availability may vary depending on region and platform.

5.6.1 Compatible Devices

Device availability may vary depending on region and platform.

Type	Name	Measurement	Connection
CGM	Dexcom G6 and newer	Interstitial glucose	Internet
Glucose Meter (BGM)	BSI VTrust	Blood Glucose	Bluetooth
	CareSens Dual	Blood Glucose	Bluetooth
	CareSens N Premier	Blood Glucose	Bluetooth
	Contour® NEXT ONE	Blood Glucose	Bluetooth
	FORA 6 Connect	Blood Glucose	Bluetooth
	Keto-MojoTM GKI	Blood Glucose	Bluetooth
Smart Pen	NovoPen 6®	Insulin data	NFC
	NovoPen Echo® Plus	Insulin data	NFC

Table 3: Compatible devices for Hedia Diabetes Assistant.

5.6.2 Connecting a CGM

Data from your CGM sensor is delivered to Hedia Diabetes Assistant with a 3-hour delay. To see your current CGM sensor data, always use readings directly from your CGM app.

Hedia uses your delayed CGM data to show you personalized graphs and trends.

To connect your CGM, go to Settings > CGM and follow the instructions. Device availability may vary depending on region and platform.

You can remove a connected CGM by going to Settings > CGM and tapping on the device again.

5.6.3 Connecting a Glucose Meter

To connect your glucose meter, go to Settings > Glucose Meters and follow the instructions. Device availability may vary depending on region and platform.

Once your device is connected, it will be available the next time you do a calculation.

You can remove a connected glucose meter by going to Settings > Glucose Meters and tapping on the device again.

5.6.4 Connecting a Smart Pen

To connect your smart pen, go to Settings > Smart Pens, and set up your smart pen. Device availability may vary depending on region and platform.

Once your device is connected, it will be available the next time you do a calculation.

You can remove a connected smart pen by going to Settings > Smart Pens.

5.7 Connected Services

Hedia Diabetes Assistant can integrate with external services to import your recent glucose measurement on your behalf, for use in your calculations and recommendations.

Integration availability may vary depending on region and platform.

Warning. Be sure to check if the entered blood glucose is correct. You are at risk of low- and high blood glucose if the value is incorrect.

5.8 Notifications and reminders

Notification availability may vary depending on platform.

You can allow Hedia Diabetes Assistant to send you reminders in your phone's settings. By allowing Hedia Diabetes Assistant to send you push notifications, you can get reminders to take your daily medicine, and to re-measure your glucose.

In the Notifications screen, you can set the time for your medicine reminder, and toggle the reminder on/off.

You can also set when you'd like to be reminded to remeasure your glucose, after receiving a recommendation. You can also toggle the reminder on/off.

6 Using the Bolus Calculator

Hedia Diabetes Assistant will calculate a recommended rapid-acting insulin dose based on:

- Your active insulin from previous injections
- Your current glucose level
- Your carbohydrate intake
- Your physical activity
- Your personal treatment parameters: Glucose target, insulin-to-carb ratio, and insulin sensitivity.

Your recommendation may also include other advice, such as to eat carbohydrates or to postpone your physical activity.

6.1 Starting a new calculation

To start a new bolus calculation, tap the Plus button in the bottom navigation bar. This will open a new calculation, where you can enter recent insulin, current glucose, carbohydrates, and physical activity.

Once you have entered your desired values, you will need to approve a summary, before receiving your recommendation.

6.2 Reviewing Recent Insulin

As the first step in a new calculation, you will have to review your recent rapid-acting insulin injections.

This step is important, as your recent rapid-acting insulin injections are factored in when calculating your recommendation.

- If the list of recent rapid-acting insulin looks correct, confirm and proceed.
- If the list is missing any recent rapid-acting insulin injections, add them before proceeding.
- If any of the registrations are incorrect, edit them before proceeding.

Warning: Only use rapid-acting insulin when entering insulin doses in Hedia Diabetes Assistant. You are at risk of low- and high blood glucose if you enter long-acting insulin.

6.2.1 Importing data from your Smart Pen

If you have connected your smart pen, you can import recent rapid-acting insulin injections.

To connect your smart pen, go to Settings > Smart Pens, and set up your smart pen. Smart Pen availability may vary depending on region.

If data from your smart pen are different from existing entries in the Logbook, you will be guided through a series of steps to ensure that your injections are only logged once.

6.3 Entering your Glucose value

On the Glucose screen, you can manually enter your current glucose value, or import it from a supported connected device.

Your glucose value should be as recent as possible and may not be more than 10 minutes old.

6.3.1 Importing data from your glucose meter

If you have connected your glucose meter, you can import your recent measurement.

To connect your glucose meter, go to Settings > Glucose Meters, and set up your device. Glucose meter availability may vary depending on region.

Warning. Be sure to check if the entered glucose is correct. You are at risk of low- and high blood glucose if the value is incorrect.

Warning. If you have severe high blood glucose and you do not act accordingly, you are at risk of ketoacidosis.

6.4 Entering Carbohydrates

On the Carbohydrates screen, you can manually enter your carbohydrate intake, or search the built-in Food Library.

As you add foods and drinks to your calculation, you can see the total carbohydrate amount at the bottom of the Carbohydrates screen.

6.4.1 Using the Food Library

In the Food Library you can search for foods and drinks in the built-in library. Your can also create your own items based on your favorite dishes or add that unique item that wasn't in the built-in library.

When adding from the Food Library, you enter the amount of food in weight, or volume for drinks. Based on the entered weight or volume, the carbohydrate amount will automatically be calculated for you, and can be added to your calculation.

Warning. Be sure to check if the entered carbohydrate amount is correct before taking the recommended amount of insulin, or take any other action. You are at risk of low- and high blood glucose if the value is incorrect.

6.5 Adding Physical Activity

On the Physical Activity screen, you can add your physical activity to take it into account in your recommendation.

When creating a new physical activity, set your starting time, duration and intensity. Once filled in, you will get a preview of how it will affect your recommendation.

Once a physical activity is created, is stays active in the system for a period, to reflect that physical activity can affect your body for a while beyond the duration of the activity itself.

Warning: Be sure to check if the entered physical activity intensity and duration are correct before taking the recommended amount of insulin, or take any other action. You are at risk of low- and high blood glucose if the value is incorrect.

Warning. If you perform physical activity with a low blood glucose you are at risk of post-exercise low blood glucose.

Warning. If you perform physical activity with a very high blood glucose, OR a moderately high blood glucose plus elevated blood ketones, you are at risk of high blood glucose and ketoacidosis.

6.6 Confirming the Summary

On the Summary screen, you need to review that all entries are correct, to ensure a safe and accurate insulin recommendation.

Once you have reviewed your entries, swipe the slider to confirm and get your calculation.

6.7 Viewing your Recommendation

On the Recommendation screen, you can see your recommended amount of rapid-acting insulin.

Your recommendation may also include other advice, such as to eat carbohydrates or adjust your physical activity.

If you want to see the input that went into your calculation, you can expand the calculation details.

To leave the Recommendation screen, save the recommendation. It can now be viewed in your Logbook, and will be counted into your active insulin.

If you want to redo or delete your calculation, you can delete it. Deleting your recommendation will remove it from the Logbook, and prevent it from being counted into your active insulin.

Warning. Hedia Diabetes Assistant has a safety limit on how much insulin can be recommended, and will never recommend more than 60 units per calculation. If your recommendation would have been higher than 60 units, it will be limited for safety reasons. You are at risk of high blood glucose if you need more than 60 units of insulin.

6.7.1 Changing the recommended insulin amount

If you decide to take another insulin dose than then one recommended, be sure to change the amount. This will ensure that your active insulin is accounted for correctly in your next calculation.

You can change the insulin amount before saving the recommendation. If you decide to change the insulin amount after saving your recommendation, you can adjust the insulin amount via the Logbook screen.

7 Logbook

In the Logbook screen, you can view all your past recommendations, along with all your personal log entries. You can also export your data, for sharing with your healthcare professional.

7.1 Recommendations

Inside each recommendation you can view the recommended amount of rapid-acting insulin, any recommended extra carbohydrates, and the calculation details.

If you took another amount of rapid-acting insulin than the one recommended, you can change the amount and save it. If you change the insulin amount in a recent recommendation, it may affect the active insulin in your next calculation.

Warning: Only use rapid-acting insulin when entering insulin doses in Hedia Diabetes Assistant. You are at risk of low- and high blood glucose if you enter long-acting insulin.

7.2 Personal Logs

You can create a personal log at any time, to keep track of your glucose level, rapid-acting insulin, carbohydrates, and more.

Logged rapid-acting insulin may affect the active insulin in your next calculation.

7.3 Exporting and sharing your logs

In the Logbook screen, tap the export button at the top of the screen, and select a time period. Once your PDF is generated, You can share it with your healthcare professional.

8 Dashboard

The Dashboard screen gives you a visual overview of your numbers and data.

8.1 Active insulin

Active Insulin shows how many units of rapid-acting insulin are left in your body and still working, based on your recent logs and recommendations. Your active rapid-acting insulin is taken into account in calculations and recommendations.

8.2 My Day

The glucose graph shows your logged glucose throughout the day. Your glucose target range is highlighted on the graph.

Tap to see more details about your daily glucose alongside your rapid-acting insulin, carbohydrates, and physical activity.

8.3 Glucose average

This section shows the average value of your glucose over a period of 14 days. Your average glucose is different than HbA1c, which is measured by your healthcare professional.

If you have a CGM connected, the numbers will be based on your CGM data. Otherwise, the numbers will be based on the glucose values you have logged as part of insulin calculations, or in the Logbook.

Tap to see more details about your glucose and compare different time periods.

8.4 Carbohydrates average

This section shows your average daily carbohydrate intake over a period of 14 days.

Tap to see more details about your carbohydrate intake and compare different time periods.

8.5 Rapid-acting insulin average

This section shows your average daily intake of rapid-acting insulin over a period of 14 days.

Tap to see more details about your rapid-acting insulin and compare different time periods.

9 Food Library

The Food screen allows you to toggle between a built-in library of foods and drinks, and a list of items you've created yourself.

9.1 Searching the built-in library

In the Library tab, you can search for foods and drinks in the built-in library, allowing you to quickly look up how many carbohydrates are in contained in common foods and drinks.

You can also find a list of frequently used items.

9.2 Adding your own food

In the My Food tab, you can create your favorite dish or add any items that aren't in the built-in library.

All you need to create a new item is to choose whether it's a food or a drink, enter a name, and enter the amount of carbohydrates it contains.

Once saved, it will be available for quick adding whenever you are making a calculation.

10 Clinical information and safety

10.1 Glucose

Glucose is indicated as mmol/L or mg/dL.

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

Hedia Diabetes Assistant will recommend you to measure blood ketones if a glucose measurement is above 20 mmol/L or 360 mg/dL.

Warning. Be sure to check if the entered blood glucose is correct. You are at risk of low- and high blood glucose if the value is incorrect.

Warning. If you have severe high blood glucose and you do not act accordingly, you are at risk of ketoacidosis.

10.2 Target glucose

The recommended glucose concentration before you eat is 4.4-7.2 mmol/L (80-130 mg/dL) and no higher than 10 mmol/L (180 mg/dL) after you eat. A glucose concentration below 3.9 mmol/L (70 mg/dL) is called hypoglycaemia (low blood glucose) and a glucose concentration above 8 mmol/L (144 mg/dL) is called hyperglycaemia (high blood glucose).

When you use Hedia Diabetes Assistant for the first time, it has the following default glucose targets.

Time of day	**Target glucose**
00:00 - 04:59	8.0 mmol/L 144 mg/dL
05:00 - 08:59	6.0 mmol/L 108 mg/dL
09:00 - 10:59	7.0 mmol/L 126 mg/dL
11:00 - 12:59	6.0 mmol/L 108 mg/dL
13:00 - 17:59	7.0 mmol/L 126 mg/dL
18:00 - 21:59	6.0 mmol/L 108 mg/dL
22:00 - 23:59	8.0 mmol/L 144 mg/dL

Table 6: Default values for Variable Target settings for glucose units in mmol/L and mg/dL.

Hedia Diabetes Assistant has, as a safety measure, a built-in minimum target glucose of 4.4 mmol/L or 79 mg/dL and 13.9 mmol/L or 250 mg/dL as the maximum target glucose.

10.3 Clinical calculations

The insulin dose recommended by Hedia Diabetes Assistant consists of two components: a recommendation for a meal dose based on your intake of carbohydrates and insulin-to-carb ratio and a recommendation for a correction dose based on your glucose and insulin sensitivity factor. Active insulin is only subtracted from the correction dose.

When you enter physical activity the final insulin recommendation (meal dose + correction dose) is reduced by a fixed percentage based on the intensity and duration of the physical activity.

Hedia Diabetes Assistant is based on advanced carbohydrate counting, and the calculations are based on evidence-based formulas.

10.4 Insulin-to-carbohydrate ratio

Your insulin-to-carb ratio is used when a bolus recommendation is calculated. It is calculated by dividing 500 with your total units of daily insulin (both rapid-acting and long-acting).

Example:

If you take a total of 50 units of insulin per day, you need to divide 500 with 50, which equals 10. This means that 1 unit of insulin will cover 10 grams of carbohydrates.

500 / 50 = 10

The formula provided is evidence-based but might not be the most optimal setting for you. Contact your health care professional for help with setting up your insulin-to-carb ratio and insulin sensitivity factor.

Under Settings, you can change your settings for your insulin-to-carb ratio. In addition, Hedia Diabetes Assistant can help you calculate the insulin-to-carb ratio based on the formula above, the first time you set up Hedia Diabetes Assistant.

Warning. You are at risk of low- or high blood glucose if you enter wrong treatment parameters.

Contact your health care professional if you do not know your insulin sensitivity factor, your insulin-to-carb ratio, or how to calculate them.

10.5 Insulin sensitivity

Your insulin sensitivity factor is used when a bolus recommendation is calculated.

If you use mmol/L	**If you use mg/dL**
Your insulin sensitivity is calculated by dividing 109 with your total units of daily insulin (both rapid-acting and long-acting). Example: If you take a total of 50 units of insulin per day, you need to divide 109 with 50, which equals 2.2. This means that 1 unit of insulin will lower your blood glucose by 2.2 mmol/L. 109 / 50 = 2.2	Your insulin sensitivity is calculated by dividing 1960 with your total units of daily insulin (both rapid-acting and long-acting). Example: If you take a total of 50 units of insulin per day, you need to divide 1960 with 50, which equals 39.2 mg/dL. This means that 1 unit of insulin will lower your blood glucose by 39.2 mg/dL. 1960 / 50 = 39.2

Table 7: Insulin sensitivity calculation for glucose units in mmol/L and mg/dL.

The formulas provided are evidence-based but might not be the most optimal settings for you. Contact your health care professional for help with setting up your insulin-to-carb ratio and insulin sensitivity factor.

Under Settings, you can change your settings for your insulin sensitivity factor. In addition, Hedia Diabetes Assistant can help you calculate the insulin sensitivity factor based on the formula above, the first time you setup Hedia Diabetes Assistant.

Warning. You are at risk of low- or high blood glucose if you enter wrong treatment parameters.

Contact your health care professional if you do not know your insulin sensitivity factor, your insulin-to-carb ratio, or how to calculate them.

10.6 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. Note that it is not possible to calculate a meal dose alone, as Hedia Diabetes Assistant requires a glucose measurement with each calculation.

Warning. Be sure to check if the entered carbohydrate amount is correct before taking the recommended amount of insulin, or take any other action. You are at risk of low- and high blood glucose if the value is incorrect.

10.7 Correction dose

If your glucose is above or below your glucose target, Hedia Diabetes Assistant recommends a correction dose. Calculations are based on your insulin sensitivity factor.

If you enter a glucose lower than your target, Hedia Diabetes Assistant will calculate how many units of rapid-acting insulin should be ***withdrawn*** from the recommended insulin dose. If this results in a "negative" insulin dosage, Hedia Diabetes Assistant will instead recommend ingesting carbohydrates.

If your glucose is low (below 3.9 mmol/L or 70 mg/dL), Hedia Diabetes Assistant will recommend at least 15 grams of carbohydrates. If you are low and have already added carbohydrates to your calculation, your recommended insulin dose will be reduced by an amount equivalent to 15 grams of carbohydrates.

If you enter a glucose higher than your target, Hedia Diabetes Assistant will calculate how many units of rapid-acting insulin should be ***added*** to your recommended dose. In this calculation Hedia Diabetes Assistant will take your active insulin into account to minimise the risk of insulin stacking.

Warning. Be sure to check if the entered blood glucose is correct. You are at risk of low- and high blood glucose if the value is incorrect.

10.8 Active insulin (insulin on board)

Active Insulin tells how many units of rapid-acting insulin are left in the body and still working. Hedia Diabetes Assistant automatically calculates the amount of active insulin and displays it on the dashboard and on the Recommendation screen. Hedia Diabetes Assistant takes active insulin into account in the correction bolus calculations.

To calculate how much insulin is remaining, Hedia Diabetes Assistant uses information published by the manufacturer of Novorapid.

Depending on the type of rapid-acting insulin, the effect starts after about 10-20 minutes after subcutaneous injection and is maximal between 1 and 3 hours.

If you have not documented any bolus insulin within the last 4 hours, Hedia Diabetes Assistant asks if you have 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.

10.9 Physical activity

Warning. Please consult with your healthcare professional before changing the settings for physical activity. You are at risk of low- and high blood glucose if the settings are incorrect.

In Hedia Diabetes Assistant you can add your physical activity to the calculation of your insulin recommendation, either before or after an activity.

Physical activity will reduce your final insulin recommendation to prevent post-exercise low blood glucose. Hedia Diabetes Assistant can recommend you eat carbohydrates before the physical activity if your glucose is below the target glucose for physical activity.

Your insulin sensitivity will increase when you perform physical activity. This means that the insulin you take will reduce your glucose more than normally. This can lead to post-exercise low blood glucose. Because of this, Hedia Diabetes Assistant will reduce the insulin bolus recommendation based on the duration and intensity of the physical activity and increase your glucose target during physical activity. You can change how much the insulin recommendation is reduced and how much the glucose target is increased in the settings for physical activity.

When inputting physical activity in Hedia Diabetes Assistant, you will need to select the intensity of the physical activity you plan to perform.

- **Light activity.** Feels like you can maintain for hours. Easy to breathe and carry a conversation
- **Moderate activity.** Breathing heavily, can hold short conversations. Still somewhat comfortable, but becoming noticeably more challenging
- **Hard activity.** Borderline uncomfortable. Short of breath, can speak a sentence

Light activity will be labelled green, moderate activity will be labelled orange and hard activity will be labelled red to indicate the intensity.

The following values are used depending on the intensity and duration of your physical activity.

	Intensity		
Duration	**Light activity**	**Medium activity**	**Hard activity**
0-29 minutes	0 %	0 %	0 %
30-45 minutes	25 %	50 %	75 %
46-60 minutes	50 %	75 %	Not supported
Default glucose target during physical activity	8 mmol/L or 144 mg/dL		

Table 8: Calculated effect of activity in Hedia Diabetes Assistant. Hedia Diabetes Assistant does not support hard physical activity for more than 45 minutes.

If you have completed the physical activity and later make a bolus insulin calculation, the following values are used to reduce the insulin recommendation:

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

Table 9: Insulin reduction table.

The specific way in which an insulin recommendation is affected by a given physical activity depends on whether the activity is ongoing or has ended. A physical activity is considered ongoing (green in Figure 2) from its start time until the physical activity's duration has elapsed.

A physical activity that has ended can still be associated with and affect calculations after the end time (yellow in Figure 2). This means that your insulin recommendation can be reduced up to four hours after you are done with the physical activity.

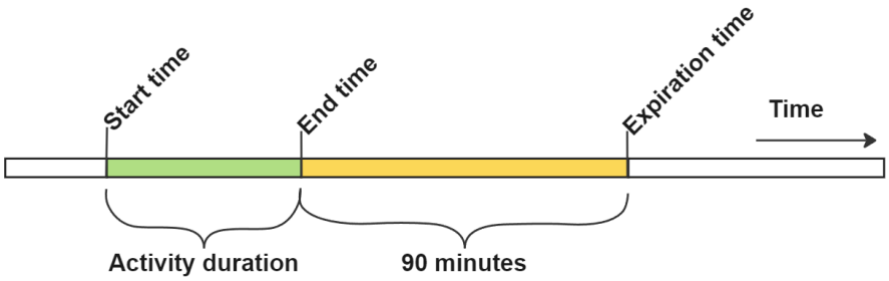

Figure 2: Effect of activity in Hedia Diabetes Assistant.

Warning: Be sure to check if the entered physical activity intensity and duration are correct before taking the recommended amount of insulin, or take any other action. You are at risk of low- and high blood glucose if the value is incorrect.

Warning. If you perform physical activity with a low blood glucose you are at risk of post-exercise low blood glucose.

Warning. If you perform physical activity with a very high blood glucose, OR a moderately high blood glucose plus elevated blood ketones, you are at risk of high blood glucose and ketoacidosis.

10.10 Ketones

Ketones are a product of the breakdown of fat. When ketones build up in the blood, they make the blood more acidic. Low levels of ketones are considered normal, but high levels of ketones can cause diabetic ketoacidosis in anyone with type 1 diabetes and in rare cases also in people with type 2 diabetes.

If your blood ketone level is elevated, Hedia Diabetes Assistant will display a message informing you of appropriate actions.

Warning. If you have a fever and do not adjust your insulin accordingly, you are at risk of high blood glucose and/or ketoacidosis.

Warning. If you have severe high blood glucose and you do not act accordingly, you are at risk of ketoacidosis.

11 Safety limits

11.1 Insulin recommendation limits

Hedia Diabetes Assistant has a safety limit on how much insulin can be recommended. This maximum is 60 units per recommendation. The limit also applies to manual entries, and is a precautionary measure to avoid unintentionally large doses.

Warning. Hedia Diabetes Assistant has a safety limit on how much insulin can be recommended, and will never recommend more than 60 units per calculation. If your recommendation would have been higher than 60 units, it will be limited for safety reasons. You are at risk of high blood glucose if you need more than 60 units of insulin.

11.2 Glucose input limits

Hedia Diabetes Assistant has limits on the level of glucose that is possible to enter. This is to ensure that extreme values cannot be entered.

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

11.3 Glucose target limit

Hedia Diabetes Assistant has a limit on acceptable values for glucose targets. This is to ensure that inappropriate values are not entered.

- Minimum target glucose of 4.4 mmol/L or 79 mg/dL
- Maximum target glucose 13.9 mmol/L or 250 mg/dL

11.4 Activity duration limit

Maximum duration of activity is set to 60 min.

11.5 Insulin reduction limit

Insulin can be reduced by up to 75% during, or after physical activity.

11.6 Ketone input limits

The limits for entering blood ketones are the following:

- Minimum ketone limit: 0.0 mmol/L
- Maximum ketone limit: 8.0 mmol/L

11.7 Glucose target during physical activity

The limits for adjusting your desired glucose target during physical activity in Hedia Diabetes Assistant are as follows:

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

Note that your glucose target during physical activity cannot be lower than your regular glucose target.

12 Support

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

In case of serious incidents in connection with the use of this medical device, please contact Hedia ApS customer service, and your National Competent Authority.

For more information, please refer to our Terms and Conditions.

13 Legal information

	**Legal Manufacturer** Hedia ApS Emdrupvej 115a, 3rd floor DK-2400 Copenhagen, Denmark CVR/VAT: 37664618 Contact information: Email: support@hedia.com
	**Instruction For Use** Issue date: 2025-06-30 (Product version 3.3.0)
CE 0123 MD	**CE mark** Hedia Diabetes Assistant is regulated as a medical device under Medical Device Regulation (EU) 2017/745.
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Novo Nordisk A/S:

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