



EkiYou V1.1.1

LABELLING AND Instruction for use

Table of content

1. Labelling.....	3
2. Indication of use	5
2.1. Intended use	5
2.2. Clinical benefits.....	5
2.3. Who is the EkiYou app for?	5
2.4. What devices does the application work on?	6
2.5. Environment for use.....	6
2.6. Compatibility with medical devices	6
3. Precautions	7
3.1. User restrictions	7
3.2. Before the first use.....	7
3.3. Conditions of use	7
3.4. Warning.....	8
3.5. Side effects	8
4. Support and maintenance	9
4.1. Maintenance	9
4.2. Troubleshooting	9
4.3. Support contacts	9
5. Application functionalities guide	10
5.1. Summary.....	10
5.2. Detailed use description.....	11
5.2.1. Installation.....	11
5.2.2. Onboarding	12
5.2.3. Synchronization	17
5.2.4. Home page	20
5.2.5. Calculate Bolus.....	22
5.2.6. Logbook	32
5.2.7. Tendency page	38
5.2.8. Profile.....	40
5.2.9. Academy	50
5.2.10. Uninstallation	50
6. Data security	51

1. Labelling



Medical device regulation (EU) 2017/745



EkiYou is a medical device, a standalone software under the format of a mobile application that allows patients to evaluate the adequate bolus dose to take depending on their meal and physical activity.



EkiYou is a single patient multiple use software

Version of the medical device software: V1.1.1



- *IOS:*
UDI-PI: (01)3770023969000(8012)V1.1.1
 - *ANDROID:*
UDI-PI: (01)3770023969017(8012)V1.1.1
 - *IOS:*
-



- *ANDROID:*

UDI: 3770023969000



3 770023 969000

UDI: 3770023969017



3 770023 969017



Date of manufacture: 2023-10-24



Use by: 2025-10-23

This product is designed, developed, and maintained by:



DiappyMed
Cap Alpha, 3 avenue de l'Europe
34830 Clapiers - Occitanie
France



Made in France

Before using the software, please read the user manual.

You can find it, in the electronic format (eIFU), in the EkiYou application or in the following website in PDF format:



<https://diappymed.com/en/ekiyou001ifu-en/>

If needed, you can also ask for a paper version by contacting us at ekiyou@diappymed.com

Once all the required information are provided, you will receive a confirmation mail upon your request and your paper version will be delivered to you within 7 days.

Special operating instruction may apply, please refer to instruction for use.

Warning and precautions may apply please refer to instruction for use before using the application.

You can find it, in the electronic format (eIFU), in the EkiYou application or in the following website in PDF format:



<https://diappymed.com/en/ekiyou001ifu-en/>

If needed, you can also ask for a paper version by contacting us at ekiyou@diappymed.com

Once all the required information are provided, you will receive a confirmation mail upon your request and your paper version will be delivered to you within 7 days.



Do not use this medical device if you are under 18 years old.

Do not use this medical device if you are pregnant.

Do not use this medical device if you have gastroparesis.

Before using the software, please read the user manual.

You can find it, in the electronic format (eIFU), in the EkiYou application or in the following website in PDF format:



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Once all the required information are provided, you will receive a confirmation mail upon your request and your paper version will be delivered to you within 7 days.



For more information, please visit the website:

<https://www.diappymed.com>

2. Indication of use

2.1. Intended use

EkiYou medical device is a standalone software under the format of a mobile application that allows patients to evaluate the adequate bolus dose to take depending on their meal and physical activity. It allows patient to:

- Calculate their meal carbohydrates and nutrients through an integrated food database:
 - Users can search aliments via search bar, or code bar scanning.
 - Users can set the quantity of each aliment using physical units or containers (ex. 330 ml of coke or 1 can of coke).
 - Users can also add aliments with their specific quantities or menus to their favorites for quick selection.

Note: a menu is a set of aliments and their quantities.

- Calculate their meal insulin needs, taking account of the glycemia level, the carbohydrates, and the selected physical activity.
- Calculate bolus corrections needed during hyperglycemic state.
- Be reminded of their programmed basal dose for people using Multiple Daily Injections.

EkiYou does also provide the following features:

- Consult a logbook with all past injections and blood glucose data
- Connect to some blood glucose meters and continuous glucose monitoring devices (cf. [COMPATIBILITY WITH MEDICAL DEVICES](#))
- Consult tendency indicators for a better management of the diabetes.
- Consult educational sheets on diabetes, nutrition, or other general subjects.

2.2. Clinical benefits

EkiYou provides the following clinical benefits:

- Carbohydrates counting assisted by a valid and verified food database for functional insulin therapy use and precise carbohydrate counting.
- Personalized bolus calculation, resulting in improved blood glucose control. Studies shows that using EkiYou allows to have more meals followed by in-range glycemia, with less bolus corrections and without increasing hypoglycemia risks.

2.3. Who is the EkiYou app for?

EkiYou has been developed and only meant to be used by people:

- Diagnosed with diabetes under basal-bolus regimen
- Aged 18 years and above
- Living in European countries where French and English are accepted without the need for another language. The target countries are France and Luxemburg.
- Non-pregnant women
- Able to read and use a smartphone
- With no visual deficiency needing specific smartphone typography
- With basic smartphone device usage knowledge.

- With or without prior education to carbohydrate counting and functional insulin therapy.

2.4. What devices does the application work on?

EkiYou application can be used on any IOS devices with IOS 12 or higher and on Android devices with Android 5.0 or higher.

2.5. Environment for use

As a mobile application, EkiYou application can be used in any environment where mobile phone use is permitted.

While EkiYou is best used in an online mode with an active internet connection, the application works both in online and offline mode.

2.6. Compatibility with medical devices

For this version, you can only pair your EkiYou application with the **continuous glucose monitoring devices (CGM) by Dexcom** to actively recover, log and display your blood glucose values.

*Note: EkiYou recovers data and functions with all Dexcom devices that are managed via their **Dexcom API version 3.0.6+***

Note: The connectivity with Dexcom CGM recover blood glucose values with a three-hour delay, and its used mainly to display tendencies and daily statistics (cf. [TENDENCY PAGE](#)). Therefore, the recovered values from Dexcom will never be used in dose recommendation calculation. Hence, for each bolus calculation (cf. [ADD RECENT GLYCEMIA](#)) You must manually provide a recent blood glucose value.

3. Precautions



3.1. User restrictions

- Not to be used by persons under 18 years old.
- Not to be used by pregnant persons.
- Requires sufficient visual acuity, as well as fluency in reading and writing in the language used on the device.
- Requires at least basic smartphone device usage skills.
- To have instructed and informed your physician of your wish to use the application.
- Not to be used by patients with gastroparesis.
- Not to be used by patients treated by another insulin regimen other than the basal-bolus regimen.

3.2. Before the first use

- Read the user guide before any use of the application.
- A connection to the internet is needed to download and install the application, create a new account, login the created and valid account, subscribe to the applications services, and complete the application onboarding and first usage set up.
- If you know your Insulin to carb ratio and correction factor keep note of them as you need to input them in the application; if you don't know them keep note of your total daily bolus (rapid-acting insulin) injections dosage and your total basal (slow-acting insulin or total daily basal rate) injections dosage.
- Keep note of your actual used blood glucose units (mg/dl or mmol/l) and your insulin to carb ratio unit (U/10g or g/U) given by your physician.
- In case of any doubt while entering your parameters, please refer to your caregiver or contact us for technical guidance.

Note: Insulin is measured in International Units (units); most insulin is U-100, which means that 100 units of insulin are equal to 1 ml.

3.3. Conditions of use

- Rigorous and regular testing of blood glucose level is necessary.
- Always install and use the latest version of the application.
- Check your smartphone battery, we recommend you keep a charger or a power bank with you.
- Always enter and log taken injections dosage in your application.
- Always enter the dose of injected insulin, whether it is the same as or different from the recommended bolus.

- Your account data (email, password, credit card ...) must never be communicated under any circumstances as they will never be asked by the DiappyMed and EkiYou support teams. You should never give them this data.
- In the event of a serious incident related to use of the medical device, contact us immediately and report the incident to the relevant authorities in your country.
- You should always report to your clinical physician any undesirable effects or events related to your blood glucose variations and diabetes information.

3.4. Warning

- EkiYou does not replace a doctor and is not meant to reduce the frequency of the doctor's consultations. It must be programmed with the parameters given by the doctor, and each change on these parameters should be discussed with the doctor.
- EkiYou depends on the precision and the quality of the user's inputs. In case of a wrong glycemia input, a wrong meal input, or a wrong physical activity description, the bolus advice can be erroneous. The user is meant to check the bolus advice and compare it to his personal experience to reduce errors due to wrong inputs. The user can choose to adjust the bolus dose proposed.
- EkiYou cannot evaluate your bolus needs during specific situations like illness or stress. In those situations, the user should adjust the bolus recommendation using his personal experience.
- EkiYou is not intended for use during pregnancy. In case of pregnancy, please refer to your doctor to get specific instructions for your diabetes management.
- EkiYou is not intended for patients with gastroparesis. In case of gastroparesis onset, please refer to your doctor to get specific instructions for your diabetes management.
- EkiYou can be used with the insulins available in the application. In case of insulin change, you may need to stop using the EkiYou device for your insulin dose calculation.

3.5. Side effects

EkiYou bolus calculation depends on your input and parameters, by consequence in some cases you can experience a mild hypoglycemia, or a hyperglycemia like for all insulin therapies.

Note: To reduce at maximum those side effects, EkiYou control all the data entered in the application or displayed to you and hence produced by the system, to ensure the value's integrity and accuracy. If the value is deemed inaccurate a warning message will be displayed to warn you about checking the values and data entered.

4. Support and maintenance

4.1. Maintenance

EkiYou will be continuously maintained by DiappyMed teams, hence, always ensure that you have the last version of the application. You will always be informed of the release of a new version. All outstanding issues and bugs will be listed in the application release notes.

4.2. Troubleshooting

- You can always contact us either in app via the contact us page, or through our support contacts and our team will take care of your questions, worries, and concerns.
- If the app becomes slow to use, check to close the opened apps in the background, try to close and reopen the application.
- If the app crashed or stopped working, try to close, and reopen the application. If this problem persists, contact the support team.
- For quick troubleshooting, check the in-app FAQ.

4.3. Support contacts

If you have questions about EkiYou, need help with the app, or have noticed a mistake or problem, please contact us immediately at:

ekiyou@diappymed.com

Or via the application contact us page.

5. Application functionalities guide

5.1. Summary

The following functionalities are implemented in the application and will be described in detailed in the corresponding section:

- The installation and the subscription and access to the application
- Data synchronization
- Access to an injection and blood glucose graph
- Application customization for language and unit options
- Login via email and password or logout
- Auto-login via pin-code or biometrics
- Password management
- Account management
- Account data management
- Therapy data management
- Blood glucose measure consultation and management
- Post-injection blood glucose measure reminders
- Injection doses consultation and management
- Access to a safe food database
- Menu bucket filling via:
 - searching all aliments
 - barcode scanning
 - favorites
- Menu bucket consultation and management
- Favorites management
- Physical activity management for bolus calculation
- Bolus calculation for meals
- Bolus correction out of meals
- Low glycemic level alert
- High glycemic level alert
- Basal injection reminders
- Follow-up on personal tendencies
- Connected glucometers management
- Blood glucose measures recovery from connected glucometers
- Access to academic and educational content
- Access to the Application's:
 - User guide
 - FAQ
 - Terms and conditions/ Privacy Policy
- Support requests handling
- Notification of important information and updates
- Verification of data integrity

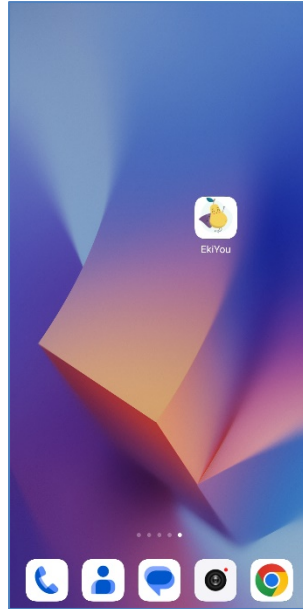
For all the data entered in the application or displayed to the user and hence produced by the system, a control is put in place to ensure the value's integrity and accuracy.

5.2. Detailed use description

5.2.1. Installation

To install the EkiYou application and discover the solution which will help you in your daily life: Go to the Apple Store (IOS) or to the Google Play (Android), and Search for EkiYou in the search bar and download it.

To launch the application, simply click on the EkiYou logo on your phone home page.



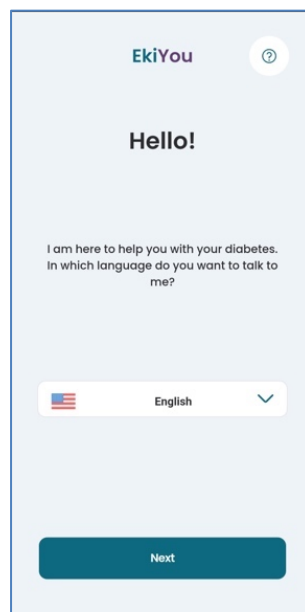
5.2.2. Onboarding

At the first installation of the application, you will be guided and presented to the application through the onboarding. You will be asked to select your preferred application language. And then be asked either to create a new account to use EkiYou, or to login with a valid account if you already have an account.

5.2.2.1. Select language

EkiYou is available in multiple languages, at the first usage, you will be asked to choose your preferred language from available options.

note: You can always change the language in the configuration page in your account space (cf. [CONFIGURATION](#))



5.2.2.2. Create account

To create your account, you need to:

- Have a valid email address.
- Create a new password (the password must contain at least 12 characters including at least 1 lowercase letter, 1 uppercase letter and 1 number)
- Be over 18 years old.
- Read and accept to the terms and conditions/Privacy Policy. Make sure to read the terms and conditions/Privacy Policy carefully before you agree to them.

EkiYou

Inscription

Email*

Password*

The password must contain at least 12 characters, including at least 1 lowercase letter, 1 uppercase letter, 1 digit, and 1 special character

Confirm password*

I confirm that I have read the [Instructions for use](#), am 18 years old or older, have diabetes following a basal-bolus regimen, and am a resident of an authorized country to use the application.

I accept the [Terms and Conditions & Privacy Policy](#)

Create an account

Already have an account? [Login](#)

After creating your account, you will receive an email asking you to verify your email address in order to ensure its authenticity.

5.2.2.3. Create account errors

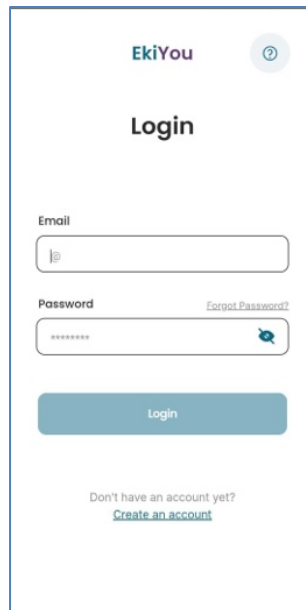
When you create your account, several errors may occur such as:

- The email or password don't respect a valid format
- The email you've entered is already linked with an existing account, you'll be asked to provide a new email address
- You didn't receive the verification email. In this case, you can request to send a new verification email.

5.2.2.4. Login

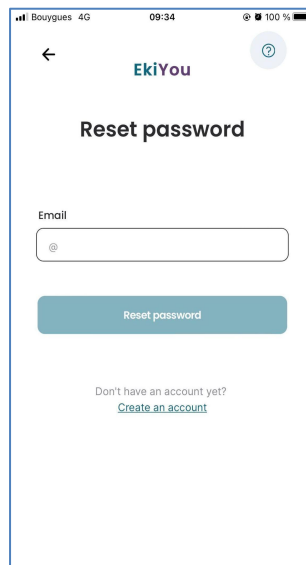
After verifying your email address, you can go to the login page and login to your account. Your account will be linked to the application and your login credential will be saved to allow for autologin to the application. If you choose to logout, your account will be dissociated, and you will need to login for a new access (cf. **LOGOUT**).

Your account will always be protected as a double authentication by pin code and biometrics are put in place to protect you from a third-party access to the application (cf. **MANAGING PIN CODE**).



5.2.2.5. Forgot password

In case in you don't remember your password, you can request to change your password by clicking on the "**forgot password**" button, an email will be sent to you with instructions and a link to reset your password.

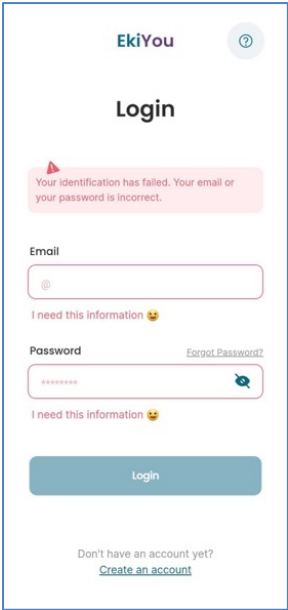


5.2.2.6. Login errors

When logging in, multiple errors can occur and are due to the following reasons:

- You are trying to login without internet access. Indeed, an internet connection is required for any login with email and password.
- You've entered the wrong password. If you've forgotten your password, a password reset request can be made.
- Your account has been deactivated following your request and you are unable to reactivate it. In this case, make sure to contact the technical support (cf. [SUPPORT CONTACTS](#))

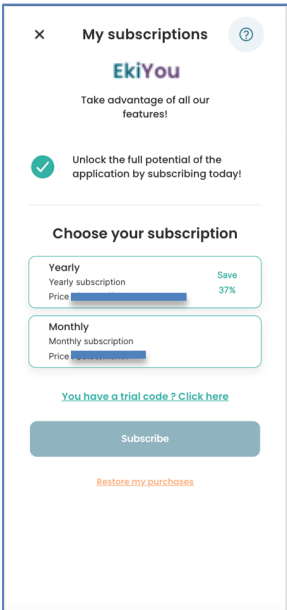
For any other errors, make sure that your entered email address and/or password are accurate. In all cases you can contact the support team to assist you with your access issues (cf. [SUPPORT CONTACTS](#)).



5.2.2.7.Subscription activation:

Once you've created your account, it is mandatory to subscribe to the application offers before you can access it features. To do this, you have two options:

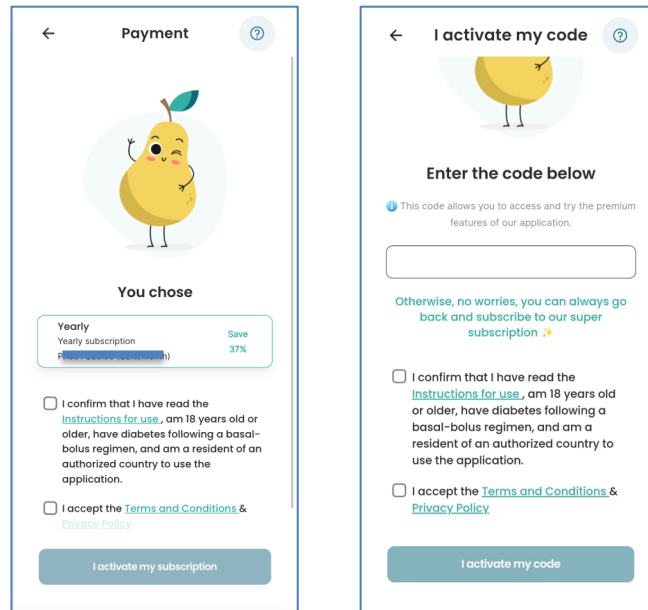
- Either you subscribe to the application by in-app purchase offers
- Or you can subscribe via activation codes.



Note: The in-app purchases offer in the screenshot are just examples and can be different in the application.

In both cases, you must:

- Have already created and validated your account.
- Read and accept the terms and conditions. Please read the terms and conditions carefully before accepting them.
- Read and accept the fact that you are part of the intended population.
- Choose the offer that best correspond to your needs and subscribe.

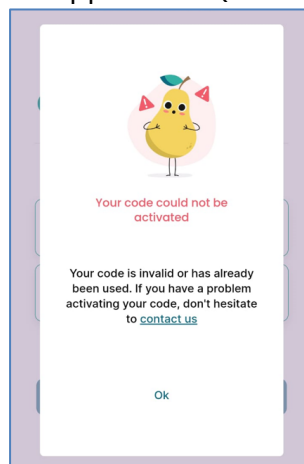


5.2.2.8.Subscription errors:

When activating your subscription, several errors may occur, such as:

- The activation code does not respect a valid code. Please ensure that you enter the code correctly, and avoid typographical errors such as the number zero and the letter o, or confusion between the letters l and i.
- Your payment failure.

In any circumstance you can contact technical assistance if you have difficulties to subscribe to our offer or to activate your application. (cf. [SUPPORT CONTACTS](#))



Notes:

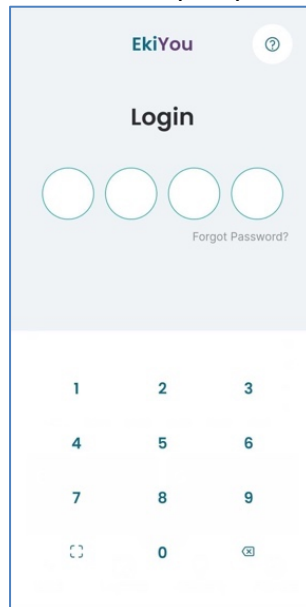
- You have not received the confirmation e-mail. In this case, please contact our support team, who will get back to you as soon as possible (cf. [SUPPORT CONTACTS](#)).
- If you have an active subscription that is displayed on the Play Store or App Store platforms and the application does not detect these subscriptions, you will be able to request to restore your purchase from the application.

5.2.3. Synchronization

5.2.3.1. Managing Pin code

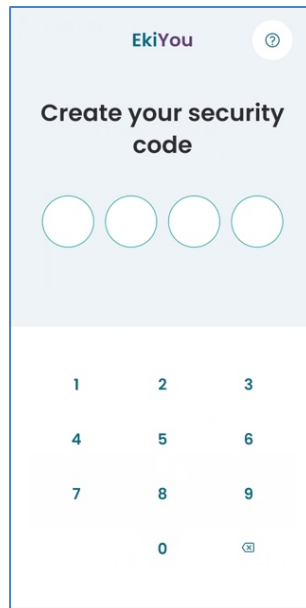
Pin code, or biometrics login are put in place to secure the application from unwanted third-party access.

Therefore, you can have secure access by inputting your secured pin code or by using finger identification or face recognition that are set up in your smartphone device.



If you forgot your pin code, you could click on the **forgot pin code** hyperlink and you will be redirected to your login page (cf. [LOGIN](#)) to ensure your identity.

The application will detect automatically if you must create a new Pin Code and will redirect you automatically to create it.



5.2.3.2.Synchronization

To maintain the offline and online mode environment and to ensure data protection, the application will redirect you to the synchronization page. During the synchronization, you must not close his application!

The synchronization ensures data protection and safeguard by keeping a secure copy in a secure cloud server. As well, ensure that your EkiYou application recovers your data when changing your phone or reinstalling the application.

5.2.3.3.Application First use

At the first usage of the application, or when your data are incomplete and needed, the application will redirect you to fill in your profile information.

- Starting by app **configuration page**:
For more information about the page please refer to [CONFIGURATION](#)
- When filling the page successfully, the next step is to fill in **account** information:
For more information about the page please refer to [ACCOUNT](#)
- And finally, fill in the **medical file** information:
For more information about these pages please refer to [MEDICAL FILE](#)

When the process is complete, the application will synchronize the rest of the needed data. (cf. [SYNCHRONIZATION](#))

My settings

Let's start with that 😊

Language*

Blood sugar unit*
 mg/dl mmol/l

Insulin carbohydrate ratios (ICR) unit*
 u/10g g/u

Display options*
 I would like to see the calories (you can change this option at any time)
 Yes No

preferences*
 I want to receive information to
 I want to receive information to

Next

My information

It won't be long 😊

First name*

Last Name*

Sex*
 Female Male

Birth date (DD/MM/YYYY)*

Country*

Next

Incomplete inputs

My medical file

By sharing this information with me I could better help you 🙌

Measurement
 Height*
 cm

Weight*
 kg

Diabetes and injections
 Diabetes type*

Injection system*

Next

Incomplete inputs

Calculation parameters

Last step ✅

Calculation parameters
 Do you know your insulin carbohydrate ratios (ICR) and your correction factor?
 Yes No

Basal Injection
 Long acting insulin daily dose
 Units

Long acting insulin injection (HH:MM)

Bolus Injection
 Rapid acting insulin daily dose
 Units

Average daily dose
 50 Units

Your insulin carbohydrate ratios (ICR) (u/10g)

Breakfast
 -

Lunch
 -

Snack
 -

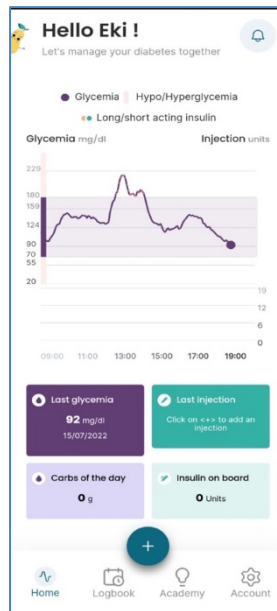
Dinner
 -

Your correction factor

Next

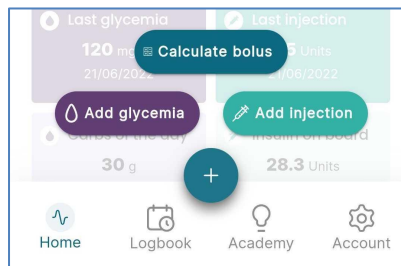
5.2.4. Home page

The home page will give you access to the blood glucose and injections graph, to the important information blocs and to the notifications.



The bottom navigation bar allows you to access the other parts of the application.

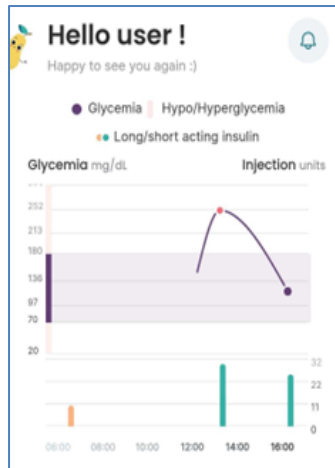
Once clicked the plus button will display additional buttons in order to access the add injection (cf. [ADD INJECTION](#)) and add blood glucose (cf. [ADD GLYCEMIA](#)) pages or to start the bolus calculation (cf. [CALCULATE BOLUS](#)) process.



5.2.4.1. Blood glucose injection Graph

When you access the home page, you will find the injection and blood glucose. This graph allows you to consult all the blood glucose measures and injection doses entered within an interval of 10 hours. In this graph you will be able to see the evolution of these two values and distinguish between the bolus injection doses (in green) and the basal injections doses (in orange). The highlighted area in purple corresponds to the interval in which your blood glucose level is ordinary and is displayed by a dot in purple. Otherwise, if your blood glucose level is above or lower than that interval the dot corresponding to it will be displayed in red.

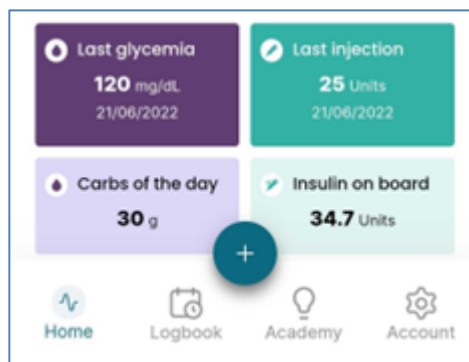
Note: If your blood glucose level is above the interval, then you are in a state of hyperglycemia. If your blood glucose level is below the interval than you are in a state of hypoglycemia.



5.2.4.2. Last activities cards

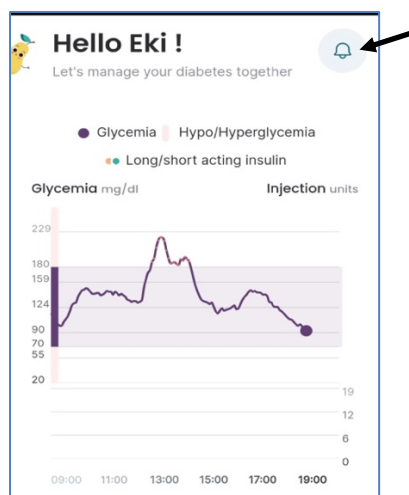
Under the graph you can see tiles that contain the following information for specific days:

- Last entered blood glucose measure
- Last entered injection dose
- Consumed carbohydrates of the day
- The insulin on board (or also known as active insulin)



5.2.4.3. View Notifications

The bell button will allow you to view the Important information and updates.



The application can send you different types of notifications:

- **Basal reminder:** A notification to remind you to inject your long-acting insulin dose.
- **Post-injection blood glucose reminder:** A notification to remind you to check up on your blood glucose level after you've injected an insulin dose.
- **Important information and updates:** A notification to inform you of the latest updates and the most important details.

5.2.5. Calculate Bolus

EkiYou, provides you with rapid (bolus) insulin dosage recommendations. The process is simple as you need to complete 3 main steps:

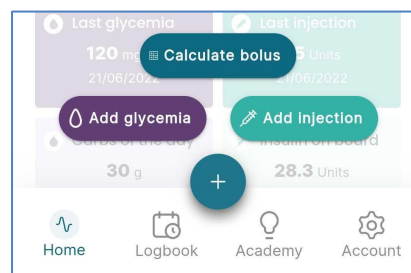
1. Add your meal (if you want to take a meal).
2. Add a physical activity either before or after the injection of your insulin dosage (if you did a physical activity).
3. Add a recent Blood sugar measure.

Note: Before starting the bolus calculation, you must log in the EkiYou application all your injected rapid (bolus) insulin injections that you may have taken during your day (cf. [MANAGE INJECTION](#)), as it is essential to keep track of your active insulin (insulin on board).

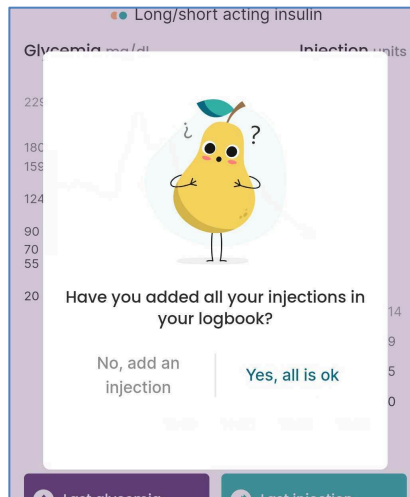
The active insulin corresponds to the insulin still present in your body after the previous rapid insulin injections (bolus) and which will therefore continue to act to lower your blood sugar or compensate for your meal during digestion.

Calculating this active insulin and subtracting it from the next bolus, if necessary, allows you to avoid having too much insulin which will lead to hypoglycemia. Therefore, it is important to inform the other boluses manually, to take them into account in the bolus calculations.

To start the process, you must simply click on the plus button on your bottom navigation bar and select calculate bolus.



You will be asked to confirm that your injections are up to date when confirming you will be taken to the first step (cf. [ADD A MEAL](#)).



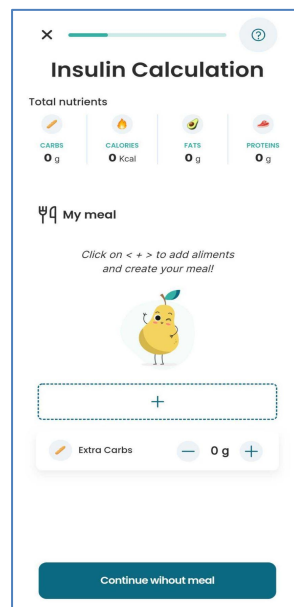
In the other case you will be redirected to your logbook to check and/or add missing injections (cf. [LOGBOOK](#)).

5.2.5.1. Add a meal

After you have verified that all your injections have been logged in successfully, you need to complete your first bolus calculation step. This page displays the carbohydrates, lipids, proteins, and calories of your meal.

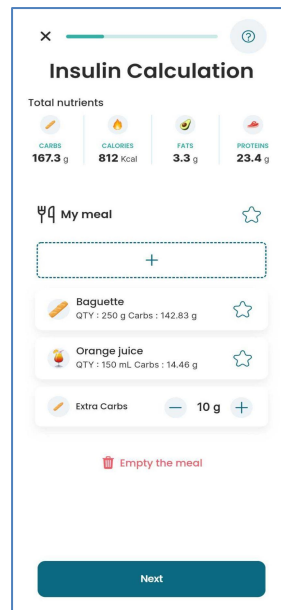
Note: You can decide to hide calories of your meal by going to the page **configuration** (cf. [CONFIGURATION](#)).

In case you do not want to consume a meal, you can skip to the next step.



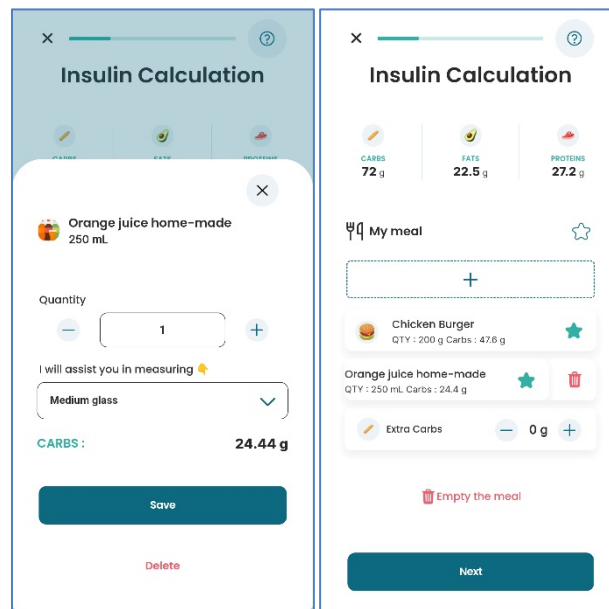
To start adding aliments you need to click on the plus button at the center of your screen. (cf. [FILLING YOUR MENU](#))

Note: you can add your carbohydrates manually if you know the nutritional value of your meal.



Note: your meal is saved until you complete all the bolus corrections steps, therefore you could prepare your meal and continue the process at another time.

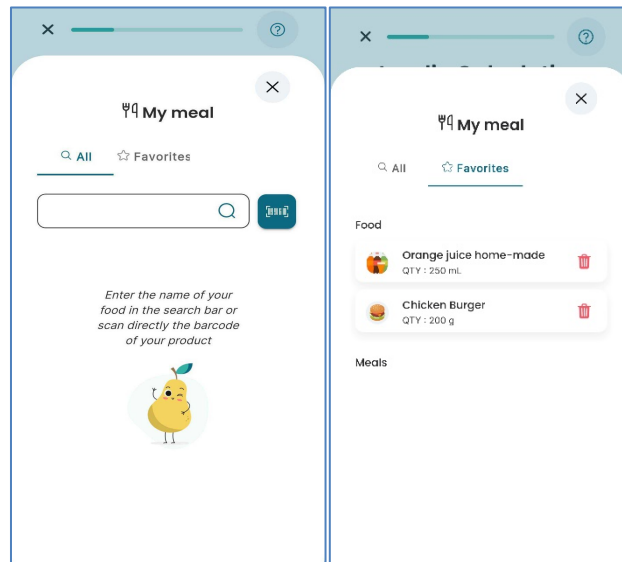
Once your aliment is added, you can modify the quantities of your aliment (cf. [SETTING THE ALIMENT QUANTITY](#)) and/or removing them from your existing meal (you can remove aliments faster if you swipe left your aliment and click on the red delete button).



You can also add single aliments to your favorite list or add your whole meal as a favorite by clicking at the star button beside each of the items. (cf. [MANAGE FAVORITE](#)).

5.2.5.2. Filling your menu

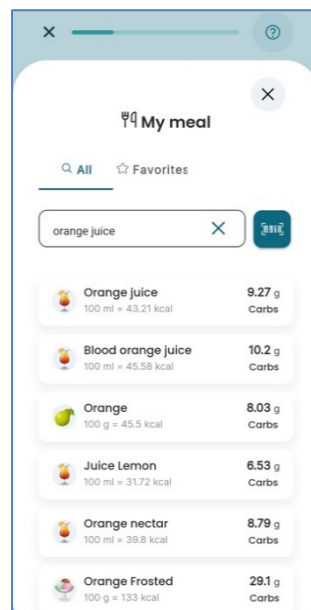
When clicking on the add meal button you can add your meals by searching aliments directly by typing in the search bar (cf. [SEARCH ALIMENTS](#)), by scanning using the barcode (cf. [SCAN ALIMENTS](#)) or going to your favorites sections and adding aliments or meals from your favorite's list (cf. [SELECT FROM FAVORITE](#)).



5.2.5.3. Search aliments

To search for your aliment simply begin typing in the search bar, as you type a list of result will be displayed.

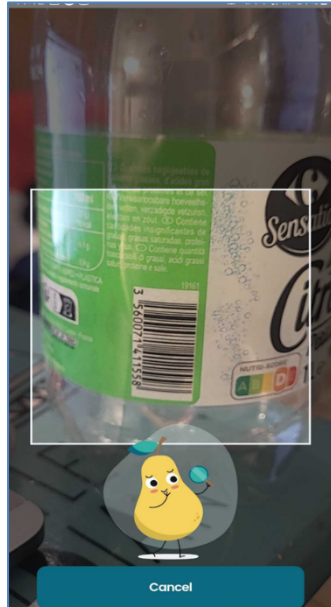
Select the aliment you want to add and fill in the quantity details (cf. [SETTING THE ALIMENT QUANTITY](#)).



Note: If your aliment wasn't found in the initial result list try narrowing down your research for example if you want to drink a glass of "orange juice" and you search "juice" try narrowing down you're searching by typing either "orange juice" or "juice orange".

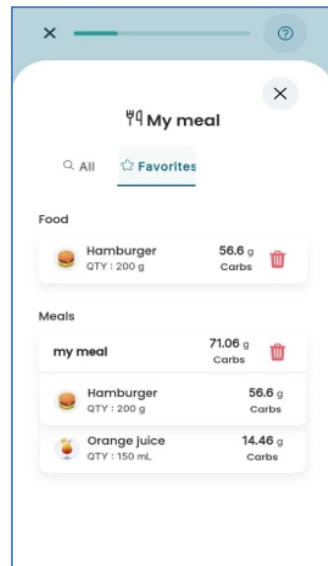
5.2.5.4. Scan aliments

By clicking at the barcode logo button beside the search bar you can find your aliments by directly scanning your product barcode.



5.2.5.5. Select from favorite

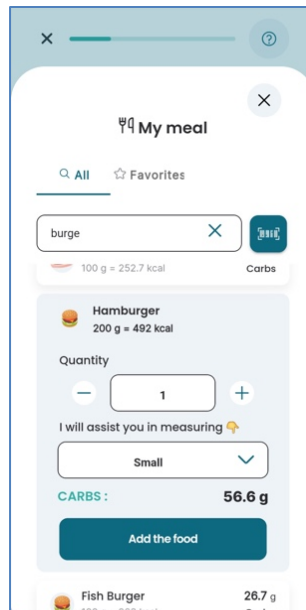
In the favorite section, you can directly add a saved favorite aliment or saved meal into your menu.



5.2.5.6. Setting the aliment quantity

When trying to add an aliment to your menu, or if you want to edit a chosen aliment you will need to fill in the aliment quantity in the unit of your choice.

Or You could select a utensil (cup, large plate, small plate...) and choose its number.



5.2.5.7. Add Physical activity

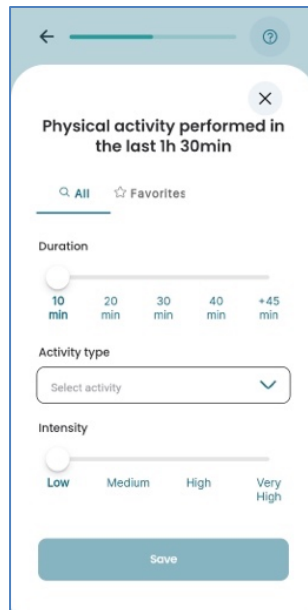
5.2.5.7.1. Add your physical activity

If you plan to do a physical activity in the 90 min following your injection or already did a physical activity in the 90 min before your injection, you need to add them in this step, as it will be taken into consideration when calculating your insulin dosage.

Note: If you do not have a physical activity to add, then you can skip this step.



Start by clicking on the plus button corresponding to the time slot of your physical activity.



The physical activity you perform around your meal have a significant impact on your blood glucose, so it is important to take this into account when adjusting your insulin boluses. Conversely, activity performed more than 90 minutes ago, or that will be performed well after 90 minutes, is not to be reported and does not impact your meal goals.

As it is difficult to evaluate how much you need to decrease your insulin dose, we will guide you. First you must indicate the duration of your activity, choose the type of activity in the drop-down menu. This allows us to know by how much we will reduce your insulin bolus. In the last step, you must indicate the intensity of your activity. To give you a guideline, you can follow these tips:

- If during the activity you can talk without difficulty, then its intensity is low.
- If during the activity your heart rate increases, and you speak with a jerky rhythm (word by word), then it is a medium intensity. In most cases, this is what you will choose.
- If during the activity you cannot speak, then it is a high intensity.
- Very high intensity is for very few people and is often for athletes who are pushing their bodies to the limit.

After adding a physical activity, you can have the option to save it in your physical activity favorite list. So, the next time you can directly go to the favorite section and add it directly to your corresponding physical activity time slot.

5.2.5.8.Add recent glycemia

To evaluate correctly your insulin needs for a meal, it is recommended to measure your blood glucose near your meal intake and bolus injection. This means in the last 15 minutes before your meal.

After measuring your blood glucose and calculating your insulin dose, it is recommended to take your bolus just before consuming your meal. The insulin action is slower than your

meal carbohydrate ingestion; this allows to reduce the impact of your hyperglycemic peak that follows your meal.

In this page you will be asked to fill in your actual blood glucose level and fill it in.

← ?

Insulin Calculation

In order to calculate the dose accurately, I need a blood glucose reading of less than 15 minutes 🕒

Glycemia

110 mg/dl

Next

In the case you added a recent blood glucose value, or the application recovered it from your connected device, it will automatically be chosen for you. You will have the option to change it if you have a more recent value taken.

← ?

Insulin Calculation

In order to calculate the dose accurately, I need a blood glucose reading of less than 15 minutes 🕒

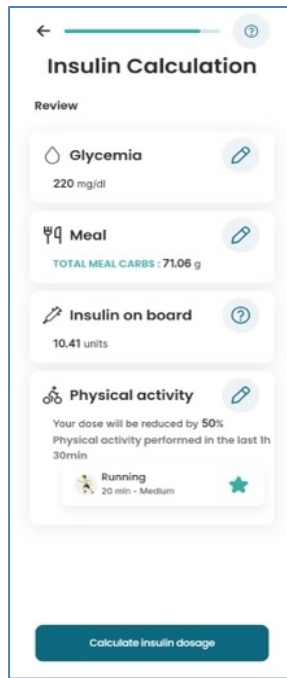
Glycemia ✎

110 mg/dl
Recovered at 10:32

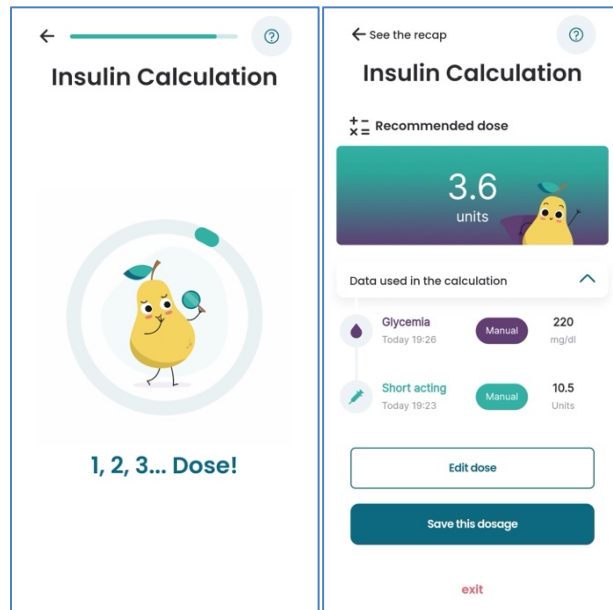
Next

5.2.5.9. Recap and calculate the recommended dose

After finishing all the preceding steps, you will arrive at the recap page to verify the validity of your data. Your active insulin (insulin on board) will be calculated and displayed for you.

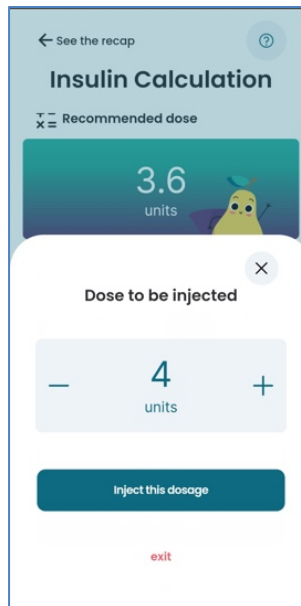


You can go back any time to each of the steps to correct or add on your given information. And when you are sure of the given information you can proceed to the next and final step: the bolus recommendation.



A bolus recommendation will be proposed to you, you can either:

- Accept by click on the save button
- modify by click on the modify button and incrementing and decrementing the bolus as you see fit

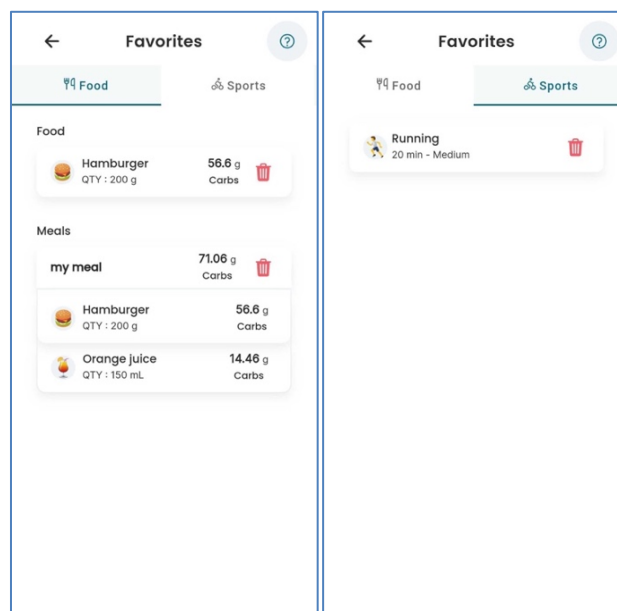


- or reject the recommendation and cancel the bolus calculation.

5.2.5.10. Manage favorite

Outside the bolus calculation steps, you can view and manage these lists by going to Profile on the bottom navigation bar and then by clicking on favorites (cf. [PROFILE](#)).

You can view and/or remove your saved favorite aliments or menu in the aliment section. You can view and/or remove your saved favorite physical activity in the physical activity section.



5.2.5.11. Calculate a correction bolus

At any moment when you are in hyperglycemia state, you can calculate a correction bolus by entering a glycemia. To do this, click on button "+" and "Add blood sugar". (cf. [IN CASE OF HYPER GLYCEMIA](#)).

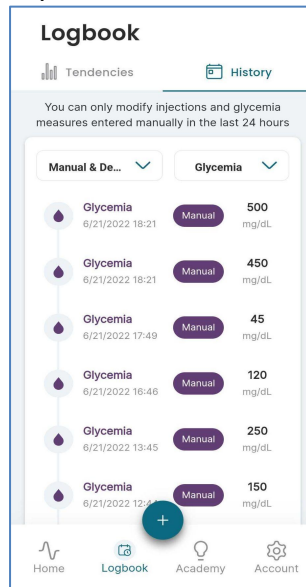
5.2.6. Logbook

The logbook space will give you access to multiple pages that will allow you to consult, edit or delete your injections and your blood glucose measures.

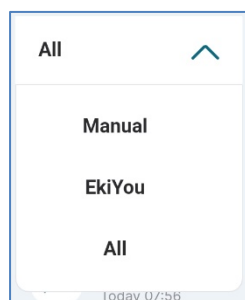
5.2.6.1. Manage Glycemia

All the blood glucose (glycemia) measures registered in the application, whether you've entered them manually or they've been recovered from one of your connected devices can be found in the logbook space.

You can choose to consult manually entered blood glucose or automatically recovered blood glucose together or separately.



The select button will allow you to either display only the device recovered blood glucose, the manually entered blood glucose or both.



5.2.6.2. Add glycemia

To add a new blood glucose (glycemia) measure, you will have to provide the date and time, if different than the actual date and time, of the blood glucose measurement and the blood glucose value. This information will have to be entered in the add blood glucose page where you can also add a note to register a commentary, or an important information related to the blood glucose measure.

← ?

Add glycemia

Enter your glycemia measures regularly for a better monitoring

Date and time of the measure:

21/06/2022 📅

17:30 🕒

Glycemia measure:

Your glycemia mg/dL

Note (optional)

Your note

Add my glycemia

5.2.6.3. Edit glycemia measures

Any blood glucose (glycemia) measure that you have entered manually can be edited. You can change the blood glucose value, time, or date in the edit blood glucose page. However, not be changed to date time that is older than 24 hours from the current date time.

Logbook

Tendencies History

Manual & De... All

Update my glycemia ✕

Date and time of the measure:

21/06/2022 📅

12:44 🕒

Glycemia measure:

150 mg/dL

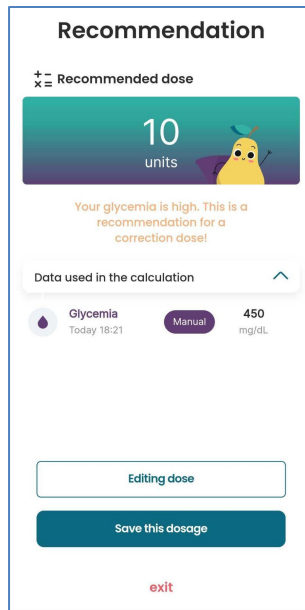
Note (optional)

Your note

Save

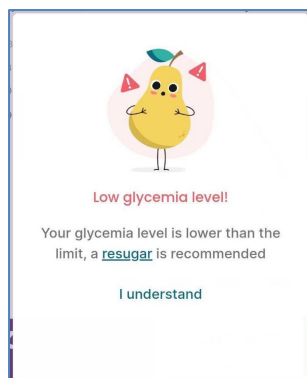
5.2.6.4. In case of hyper glycemia

If you enter a blood glucose that is higher than a certain level, a bolus correction will be recommended to you based on your configured therapy data and your recently entered injections.



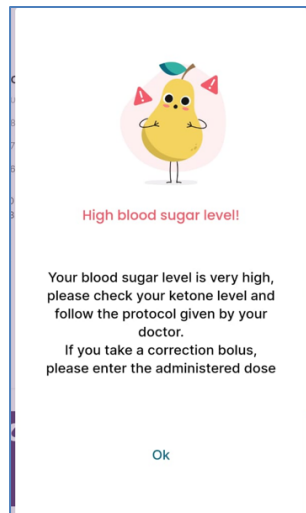
5.2.6.5. In case of hypoglycemia

If you enter a blood glucose that is lower than a specific threshold, then a pop will alert you of your low glycaemic level.



5.2.6.6. Very high hyperglycemia alert:

If you enter a blood glucose value that is higher than 350 mg/dl (20 mmol/l) , then a pop will remind you to follow in priority the protocol given by your doctor, and to check your ketone level.



5.2.6.7. Manage injection

5.2.6.7.1. Add injection

To manually add a new injection, some information will need to be provided based on the type of injection to be added in the add injection page. There are two types of injections that can be added: a bolus injection (cf. **BOLUS INJECTION**) and a basal injection (cf. **BASAL INJECTION**). For any added injection you will be able to add a note that may include any important information that you want to remember or save for the added injection.

← Add injection ?

Enter all the injections taken outside the application for a better monitoring

Insulin type:

Short acting Long acting

Injection:

Your injection Units

NovoRapid

Insulin type:

Meal Correction

Date and time of the injection:

22/06/2022

17:20

Glycemia measure:

Your glycemia mg/dL

Note (optional)

Add my injection

For both types of injections, the insulin brand used is displayed and you can directly change it, if different than the one configured in your account (cf. **GENERAL INFORMATION ERROR! REFERENCE SOURCE NOT FOUND.**), by clicking on the displayed insulin brand from the add injection page.

Injection:

Your injection
Units

[NovoRapid](#)

Bolus insulin change for this injection

NovoRapid
▼

Otherwise, some injections can be added automatically through the application's other functionalities (cf. [CALCULATE BOLUS, IN CASE OF HYPER GLYCEMIA](#))

5.2.6.7.2. Basal injection

If you choose to add a basal injection, then you will need to provide the following information:

- The time and date of the injection (if different than the current date and time)
- The injected insulin doses

5.2.6.7.3. Bolus injection

If you choose to add a bolus injection, then you will need to provide the following information:

- The time and date of the injection (if different than the current date and time)
- The type of the bolus injection: Correction bolus or Meal Bolus
- The injected insulin doses
- The blood glucose measure at the time of the injection, that will be linked to the injection and can only be modified through the edit injection page.

Note: If you add more than three consecutive bolus injections or two injections with a total dose superior to 50, then a warning will be displayed in the add injection page informing you to check the integrity of the values entered.

5.2.6.7.3.1. Correction bolus

If the bolus injection you're registering is used to correct your blood glucose level, then you can select correction as a bolus type, and no additional information will be required.

Insulin type:

🍴 Meal

✎ Correction

5.2.6.7.3.2. Meal bolus

If the bolus injection is used to compensate for the carbohydrates considered during a meal, the bolus injection type you should choose is meal. When choosing a meal as a type you will be able to add a quantity of carbohydrates that the dose is used to compensate.

Insulin type:

Meal Correction

Number of carbs in your meal (optional)

Your carbs quantity (optional) **g**

5.2.6.7.4. Edit injection

All the registered injections can be edited, in the span of 24 hours after they were added, in order to change the provided parameters. So, if you want to change any information you have entered for a bolus or basal injection, you can access the edit injection page.

Update my injection ×

Insulin type:

Short acting

Injection:

10 Units

[NovoRapid](#)

Insulin type:

Meal Correction

Date and time of the injection:

28/06/2022 📅

09:22 🕒

Glycemia measure:

150 mg/dL

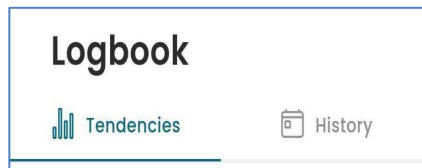
Note (optional)

Your note

In this page you will also be able to delete an injection if needed.

5.2.7. Tendency page

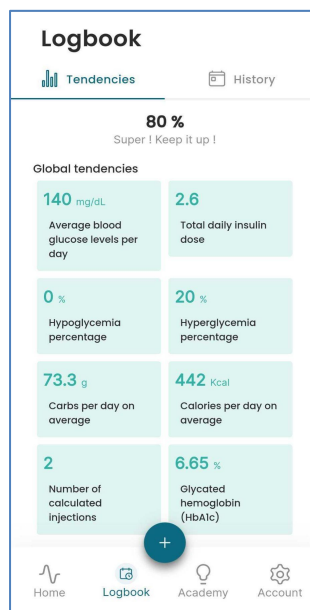
The tendency page is accessible after entering the logbook space, indeed you can either consult your injections and blood glucose history or access your tendencies.



In the tendency page, you will find helpful indicators that will give you an overview of the evolution of your glycaemic levels and insulin therapy over a specific period.

The following indicators will be based on the data you've entered and will be presented to you:

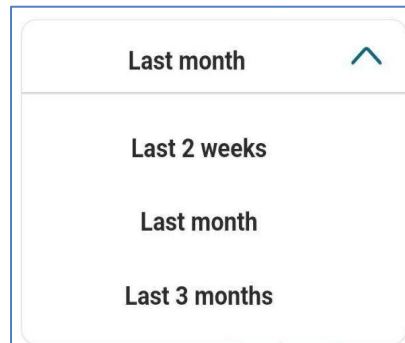
- Percentage of time where your blood glucose level was in range between 70 mg/dl and 180 mg/dl (3.9 mmol/l and 10 mmol/l)
- Percentage of time where blood glucose level was lower than 70 mg/dl (hypoglycemia)
- Percentage of time where blood glucose level was higher than 180 mg/dl (hyperglycemia)
- The mean blood glucose value of all the entered blood glucose values for the selected period
- The average Total insulin daily dose injected for the selected period
- The mean number of carbohydrates and calories consumed per day for the selected period
- Number of bolus calculations executed for the selected period
- Estimated HbA1c calculated on the basis of all blood glucose values that were inputted in the application.



For all the indicators listed above, you will be able to select one of the following periods of times:

- 2 weeks

- 1 month
- 3 months

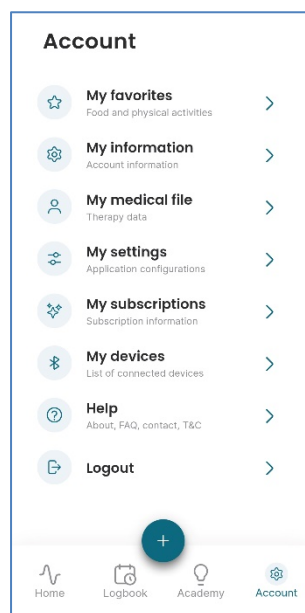


5.2.8. Profile

The "**Profile**" section provides all the information you will need to setup your account and change your configuration settings.

It will give you access to:

- The Favorites panel (cf. [MANAGE FAVORITE](#))
- Personal information (cf. [ACCOUNT](#))
- My Medical file (cf. [MEDICAL FILE](#))
- Application settings (cf. [CONFIGURATION](#))
- Connected Devices: (cf. [DEVICES](#))
- General Information about the application (cf. [ABOUT US](#))
- Help section and FAQ (cf. [HELP PAGE](#))

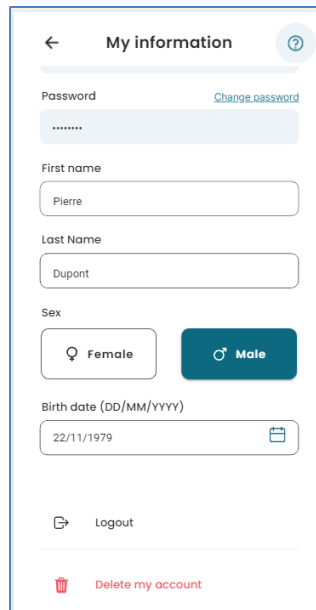


5.2.8.1.Account

This section contains your personal information that you entered when you created your account.

Except for the email, through this page you can:

- Modify your personal information
- Change your password
- Logout from your account
- Delete your account



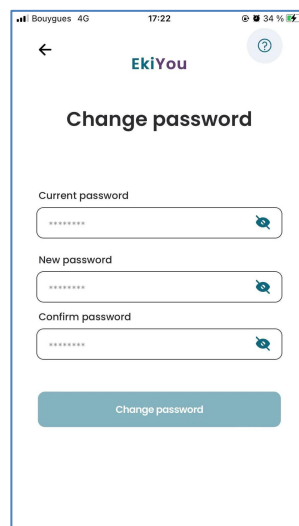
5.2.8.1.1. Logout

To logout from the application, you must go to the profile section and click on logout, a confirmation message will ask you to validate or not your choice

5.2.8.1.2. Change account password

If you want to change your account password, go to my account, and click on the change password link.

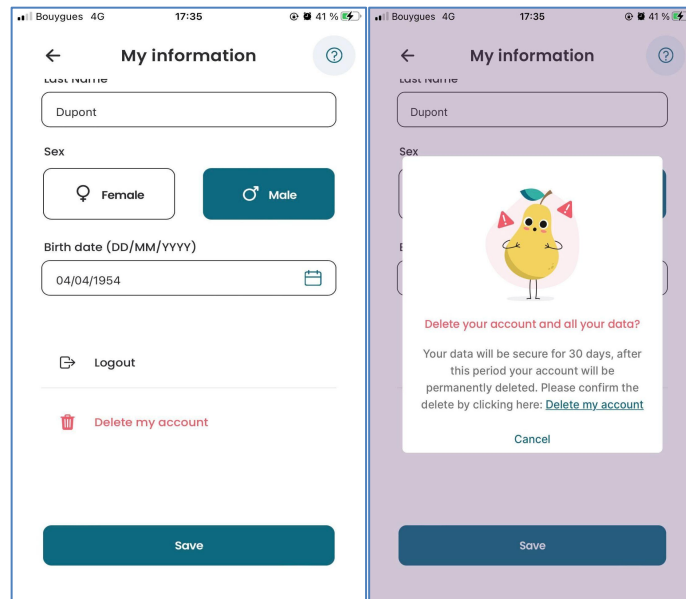
Once done you will be redirected to the page dedicated to this process.



5.2.8.1.3. Delete account

If you want to delete your account, go to my information, and select "delete my account" a confirmation message will ask you if you want to confirm your choice.

Your personal data will be stored for 30 days, after which time your account will be permanently deleted.



5.2.8.2. Medical File

My Medical File page is a summary of personal information and measurement settings you can access at any time for a possible change.

5.2.8.2.1. General information

This page will allow you to fill in the information related to your morphology and the treatment plan that your doctor has asked you to follow to regulate your blood sugar daily. It is organized as follows:

- Morphological (height and weight)
- Type of diabetes (type I or type II)
- Injection system (Pen, Pump)

If you choose the pen as your injection system, you will be asked to provide the following information:

- Bolus (fast-acting insulin) injection pen brand.
- Bolus insulin brand (fast-acting insulin brand)
- Basal (long-acting insulin) injection pen brand
- Basal insulin brand (long-acting insulin)

If you choose a pump as your injection system, then the following information will be required:

- Fast-acting insulin brand used in your pump

The screenshot shows a mobile application interface titled "My medical file". At the top, there are navigation icons for "Info" and "Parameters". The "Parameters" section is active and contains the following fields:

- Measurement**
 - Height*: 180 cm
 - Weight*: 80 kg
- Diabetes and injections**
 - Diabetes type*: Type 1
 - Injection system*: Pen
 - Bolus injection pen*: Fiasp FlexTouch
 - Bolus insulin*: Lexemir Flexpen

A "Save" button is located at the bottom of the form.

5.2.8.2.2. Calculation Parameters

This page is the final page of the application configuration, and it will allow you to fill in information related to your calculation personalized parameters.

To guide in filling in this page, we will explain to you each required field and information needed and how to fill it:

- **Total insulin daily dose?**
- **What is basal insulin?**
- **What is Rapid-acting insulin boluses?**
- **What are Insulin to carb ratios, and correction factor?**

Note: these guides can also be found in the FAQ sections inside the EkiYou application.

Total insulin daily dose?

Is the sum of you daily long-acting (**basal**) dose and daily fact-acting dose (**bolus**).

To use EkiYou, we need some information that will allow us to calculate your insulin doses. First, we need to know your daily long-acting **insulin dose**, or if you have a pump, you can find your **total daily basal insulin**, which you can round up.

Second, each day you take several boluses of rapid insulin, mainly at mealtime. Although these doses may vary from day to day, we need to know your **average estimate of the total boluses** you take per day.

With these two parameters, we calculate your **total daily insulin dose**; once this dose is calculated, we can estimate your **correction factor** and **carbohydrate ratios**. This method is used in case you do not know your correction factor or carbohydrate ratios. **In case your doctor has calculated them for you, and you know how to handle them, it is highly recommended to enter them for even more personalization.**

If you have trouble configuring your application, don't hesitate to talk to your diabetologist, or contact us.

What is basal insulin?

Basal insulin covers your vital insulin needs daily. It gives your body the amount of insulin it needs (no more, no less) to function properly without meals and at night.

If you are using insulin pens, it is usually an injection that you give each day at a fixed time in the morning or evening (this is called a long-acting insulin, such as Toujeo, Tresiba, Lantus, ...).

To properly set up the application, simply enter the dose that your doctor has prescribed, and enter the time at which you should take the injection so that you can get a reminder on your phone.

On the other hand, if you use an insulin pump (fast insulin is used), it is programmed with a basal rate that continuously diffuses a little insulin throughout the day (which gives a similar effect to the injection of slow insulin). To set up the application properly, you can find your daily basal insulin, which is the sum of your basal rate delivered for 24 hours, on your insulin pump.

What is Fast-acting insulin boluses?

The fast insulin boluses allow you to cover your insulin needs during your meals, but also to correct your blood sugar if necessary.

You therefore give 3 to 4 injections a day with your rapid insulin pen, or by using your insulin pump. These doses may vary from day to day, especially on special days, but generally remain in the same order of magnitude, as they depend mainly on our diet.

To properly set up the application, we need the total of these boluses per day.

For example, if you take:

- Between 4 and 5 units of insulin in the morning for your breakfast.
- Between 5 and 7 units of insulin for your lunch.
- Sometimes a one-unit insulin shot in the afternoon if you have high blood sugar.
- And 5 units of insulin for your dinner

So, the total of your boluses to fill out is about: $4 + 5 + 1 + 5 =$ **15 Units**.

What are Insulin to carb ratios, and correction factor?

Insulin to carb ratios, and correction factor are terms that are generally known by people who practice functional insulin therapy, and who more accurately calculate their rapid insulin boluses based on their meals and blood glucose levels.

Carbohydrate ratios let you know how much insulin you need for each amount of carbohydrate you eat.

The correction factor (sometimes also called "insulin sensitivity") tells you how much one unit of insulin lowers your blood sugar.

If you're not sure what they are, or if these terms seem abstract to you, click NO on this question, it will be easier for you. We use mathematical formulas to calculate these values for you, based on your total daily insulin dose.

The image displays three sequential screenshots of a mobile application interface for configuring insulin pump parameters. Each screen is titled "My medical file" and has "Info" and "Parameters" tabs. The first screen, "Calculation parameters", asks if the user knows their insulin carbohydrate ratios (ICR) and correction factor, with "No" selected. It also shows a "Basal insulin daily dose" of 30 units. The second screen, "Bolus injection", shows a "Rapid acting insulin daily dose" of 20 units and an "Average daily dose" of 50 units. The third screen, "Your insulin carbohydrate ratios (ICR)* (u/10g)", shows ratios for Breakfast (1, 06Am ↔ 10Am), Lunch (1, 10Am ↔ 03Pm), Snack (1, 03Pm ↔ 06Pm), and Dinner (1, 06Pm ↔ 06Am), along with a "Your correction factor*" of 36 mg/dl. Each screen has a "Save" button at the bottom.

5.2.8.3. Configuration

Blood glucose measurement units: In most devices in France, your blood glucose is displayed in mg/dl, which means that it ranges from 40 mg/dl to over 400 mg/dl when you are hyperglycemic.

However, you may express your blood glucose by saying I have 1.30 grams; this is 130 mg/dl, so multiply by 100 to get the right value.

For your information, in other countries this value is expressed in mmol/L, for values between 2 mmol/l and over 22 mmol/l.

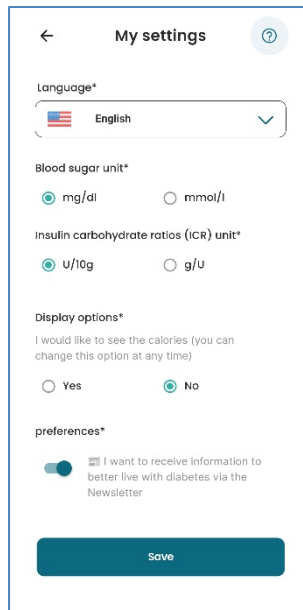
Units of carbohydrate ratios: Carbohydrate ratios are expressed in U/10g or in g/U.

The **U/10g** unit is most often used when you calculate your own boluses. The values are usually no more than 5 U/10g and give you an idea of how much insulin you need for every 10 grams of carbohydrate consumed.

For insulin pump users, the most frequently used unit is **g/U**; and gives values above 5 g/U. With this unit, we express how many grams of carbohydrate are needed for each unit of insulin.

For example, 1 U/10g is 10 g/U; and 0.5 U/10g is 20 g/U.

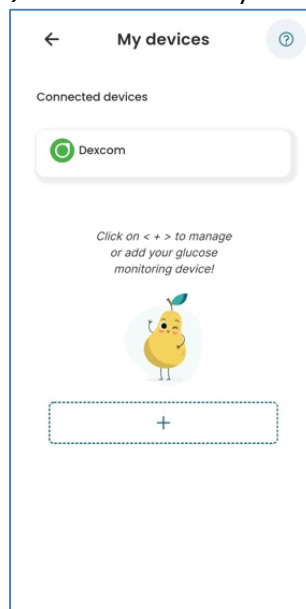
If you do not know your carbohydrate ratios, we advise you not to change units, we will calculate them for you.



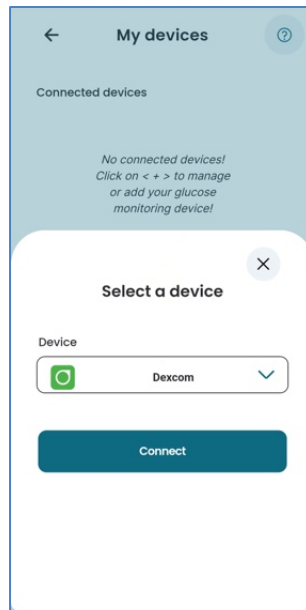
5.2.8.4.Devices

This section is intended for the management of your connected devices. This feature will allow you to choose the device you want to use in the application and to connect it. After choosing your device, the instructions to connect it and use it in the application will be displayed.

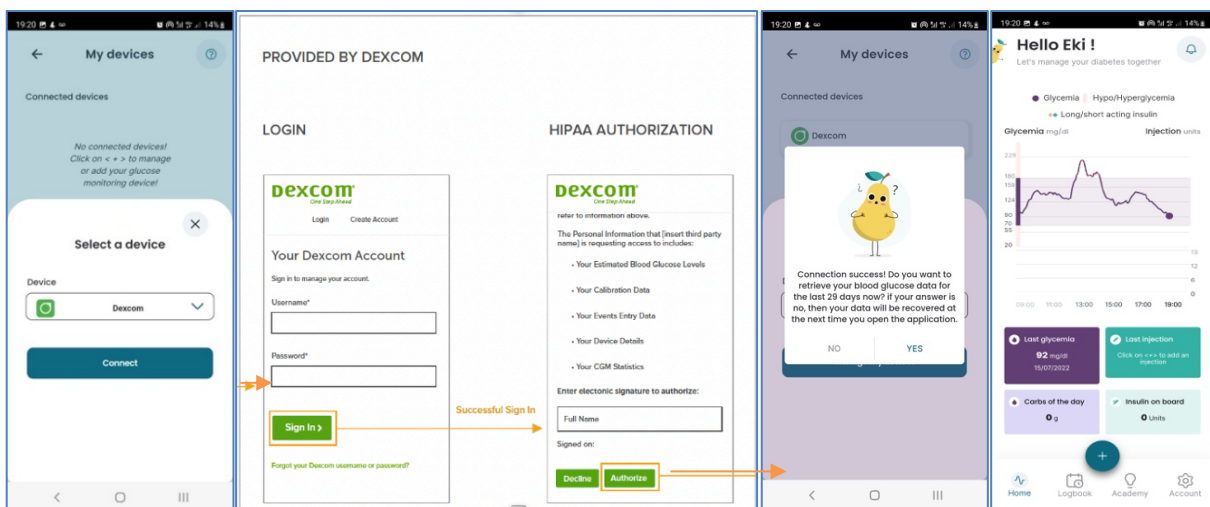
For this EkiYou version you can only add a connectivity with Dexcom continuous blood glucose monitoring devices (CGM). You can start by clicking on the **"add"** button.



And select the Dexcom connectivity from the list.



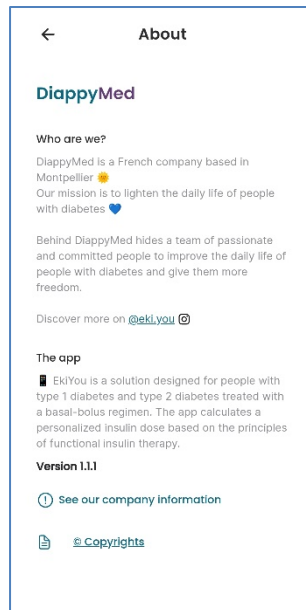
When you click connect, you will be redirected automatically to the Dexcom login page, where you must enter your Dexcom username and password. After authenticating, you will be presented with an authorization statement. This authorization is required so that you grant Dexcom the right to share your data with the EkiYou application. The basic flow of this process as it appears to the user is illustrated below:



After the process is done you will be redirected back to the application. The application will actively recover your Dexcom CGM data (with a three-hour delay) that you can see in your logbook or on your home page glycemia graph.

5.2.8.5. About us

This section gives you information about the DiappyMed company and the development versions of the application. You can also access from this page to the contact us (cf. [CONTACT US](#)) and terms and condition/Privacy Policy (cf. [TERMS AND CONDITIONS](#)) sections.



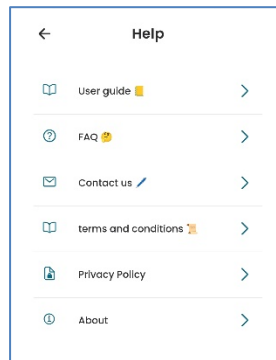
5.2.8.5.1. Terms and conditions/Privacy Policy

In this page, you will be able to consult and read, at any time, the terms and conditions/Privacy Policy that apply for the usage of the application.

5.2.8.6. Help page

The help page will allow to get access to three sections of the application:

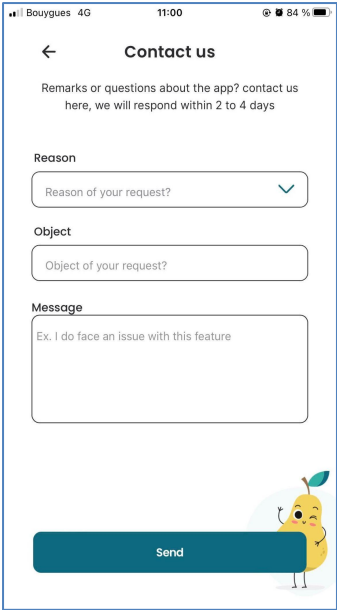
- The user guide: you'll be able to access the document you're currently reading directly from the application
- The FAQ (cf. [FAQ](#))
- The contact us page (cf. [CONTACT US](#))



5.2.8.6.1. Contact us

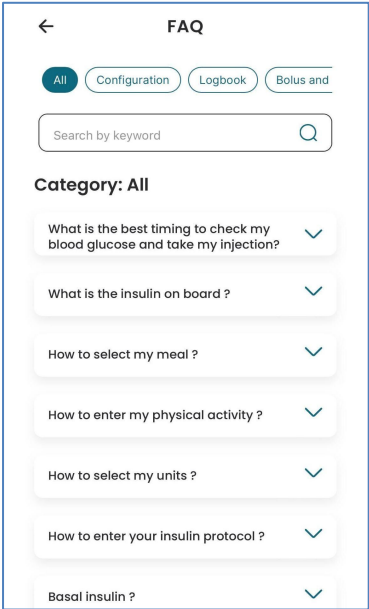
In the contact us, you will be able to send a request about a variety of topics to the application's support team. You can send a request to get more information about a specific functionality, to ask a question that you didn't find in the FAQ page (cf. [FAQ](#)), to report any bug or anomaly that you have found in the application or for any other reason. For each request we have set up, you just have to choose the reason of your request from a list of reasons and fill out subject of your request along with the message you need to send.

After you've sent your message, the support will receive and handle it accordingly. A response will be sent to you within 2 to 4 days.



5.2.8.6.2. FAQ

The FAQ is a list of frequently asked questions and their answers available directly on the EkiYou application which tries to answer all the questions that users may have. You can consult the FAQ either by category according to well-defined themes or by searching directly for your question via the search bar.

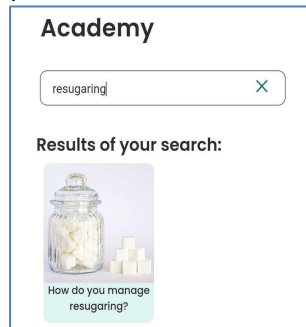


5.2.9. Academy

In the academy, you'll be able to access a variety of educational content to help you be informed and stay up to date with the most important information and latest discoveries about various topics surrounding diabetes.



The content is organized by category. Every category will contain multiple articles that provide you with information about a specific topic. In the academy space, you can either search for a specific article by entering keywords contained in the title or by author or filter the content by category. When filtering by category, you will be able to choose categories that cater to your needs and lifestyle.



5.2.10. Uninstallation

To uninstall EkiYou simply click on the logo on your mobile device home page or app page and choose to uninstall the App.

6. Data security

EkiYou is a registered medical device under EU MDR 2017/745. It is certified and carries the CE mark. As such and following the EU GDPR 2016/679 regulations as well as FR Health Data Storage HDS, your data is stored safely with us.

When in online mode, your data is synchronized regularly to back up your data safely in our cloud database and recovered immediately to your mobile device in case the data is lost or corrupted.

Please refer to our terms or use (CGU) and Privacy Policy for more information.