

Oviva App Version 4

User manual



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Please read this manual carefully before you start using the Oviva App.

1. Product description

1.1 Intended use

The Oviva App operates within dietetic care settings, with treatment plans assisting the patient to change their diet and lifestyle so that they are able to improve their health, reduce disease burden and achieve beneficial clinical outcomes.

1.2 Indication for use

Patients present with diagnoses including over- and under-nutrition, endocrine and metabolic diseases, allergy and intolerances, gastroenterological and oncological diseases.

1.3 Who is the Oviva App for?

The Oviva App is intended for a patient population, that is:

- diagnosed with a diet-related condition: over- and under-nutrition, endocrine and metabolic diseases, allergy and intolerances, gastroenterology concerns and oncological diseases;
- aged 18 years and above, or under parental guidance;
- under the guidance of a doctor or other healthcare professional;
- able and motivated to make agreed dietary and lifestyle changes as agreed with an Oviva healthcare professional;
- has access to and knowledge of using a smartphone and smartphone applications.

1.4 Clinical Benefit

Our remote approach allows us to provide high-frequency healthcare professional guidance and support at a time to suit the user. This includes the provision of evidence-based information on food, nutrients and food labels, as well as behaviour modification techniques and tailored recipes.

2. Contraindications

There are no known contraindications for the use of the Oviva App.

3. Warnings

- The Oviva App is a registered medical device and is used to support the treatment of diet-related conditions, but cannot replace a visit to your doctor/care team.
- The Oviva App does not interpret or make decisions on the data it conveys nor is it intended to provide automated treatment decisions or to be used as a substitute for professional judgment.
- All medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare provider.
- Please seek advice from a doctor on any health issues, concerns or circumstances. Never delay or disregard medical advice based on information from the Oviva App.
- If you are at risk or need urgent care, contact the emergency services.
- The food suggestions provided by the app are based on an algorithm. The algorithm takes into account your main diet preferences e.g. vegan, vegetarian but might not consider possible intolerances or allergies. Always consult with your healthcare professional first if you are unsure.

- Update your healthcare professional on any changes of medications or diagnosis with any new medical condition.
- The content provided by the app is personalised based on the information you have provided. If you are unsure or if you think the content does not align with your intolerances, allergies or specific diets such as vegan, vegetarian or with your health condition then consult with your healthcare professional first.

4. Precautions

- Mention all your food related allergies and intolerances to your Oviva healthcare professional.
- Your Oviva account is personal and should not be shared with other users.
- Make sure to keep the Oviva App updated so that you always have the latest version. Oviva recommends setting your smartphone to update the app automatically.
- The Oviva App should not be used on rooted devices or on smartphones that have a jailbreak installed.
- Make sure to enter correct data in the Oviva App whenever you are asked.
- Make sure that you pair the Oviva App with the relevant Bluetooth device that tracks your personal data (in case it is used)
- Always review transferred data from an external device in your Oviva App
- The values of calories, carbohydrates, fibre, sugar, protein, salt and fat are generated by artificial intelligence. Please contact our support if you think the delivered values are inaccurate or wrong.

5. Product instructions

5.1 Log into your Oviva App

The Oviva App is limited to Oviva users only, therefore it is not accessible to the general public.

Your login details will be sent to you, either by email or SMS, once you are referred to Oviva and your account has been created.

Step 1: Download the Oviva App

Install the app from the [Apple App Store](#) or [Google Play Store](#).

Step 2a: Log in using your email

You will receive an email from Oviva with your login password.

Once you receive this email:

- Tap on the button 'Start';
- Tap on the button 'Log in via email';
- Enter your email and password;
- Tap on the button 'Log in';
- You should now be logged in to the app.

If you forget your password:

- Tap on the button 'Forgotten password';
- Enter your email and tap on the button 'Submit';
- If the email entered exists in our system, you will receive an email from us to reset your password;
- In the email - tap on the link to change your password;
- Enter the new password twice and click "Confirm".

Step 2b: Log in using your mobile phone number

- Tap on the button 'Start';
- Tap on the button 'Log in via mobile number';
- Select your country;
- Tap on the button 'Verify';
- If the mobile number and date of birth that you entered are available in our system, you will receive an SMS with a verification code;
- Enter the verification code and tap on the button 'Confirm';
- You should now be logged in the app.

Step 3: Accept the Terms & Conditions and Privacy Policy

To use the Oviva App, you will need to accept the Terms & Condition and Privacy Policy, the latest version can be found on our website oviva.com.

5.2 Logging an entry

There are a number of different elements you can log in the Oviva App, such as meal / snack, body weight, activity, mood and more (see below). You can view your entries in your Home and Progress screens to see trends, patterns and progress.

Your health care professional can see all of your entries which enables them to provide personalised advice and support.

Important note

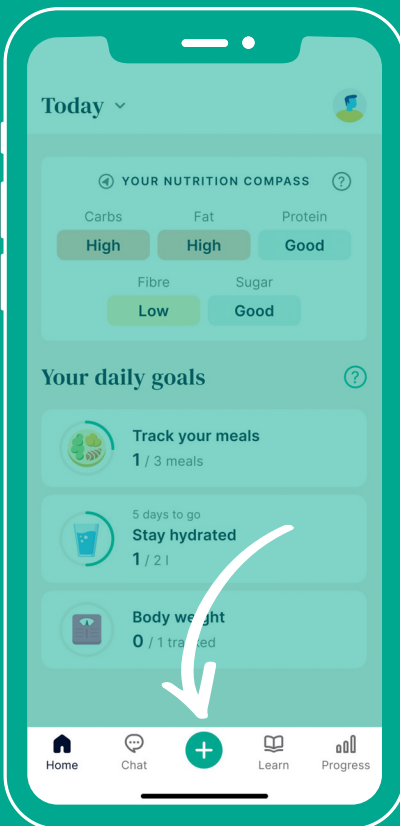
You can only log an entry when you are connected to the internet.

5. Product instructions - Logging an entry

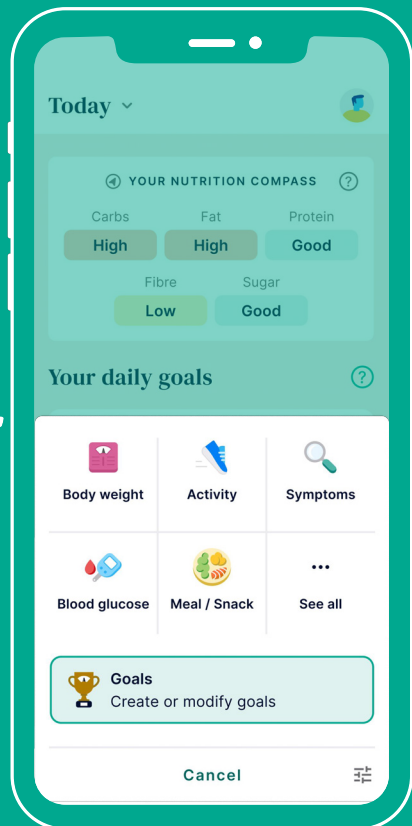


1. To log a new entry, tap on the Plus (+) button in the bottom navigation bar.
2. A menu will appear, in which you can pick the type of entry you want to log.

1.



2.

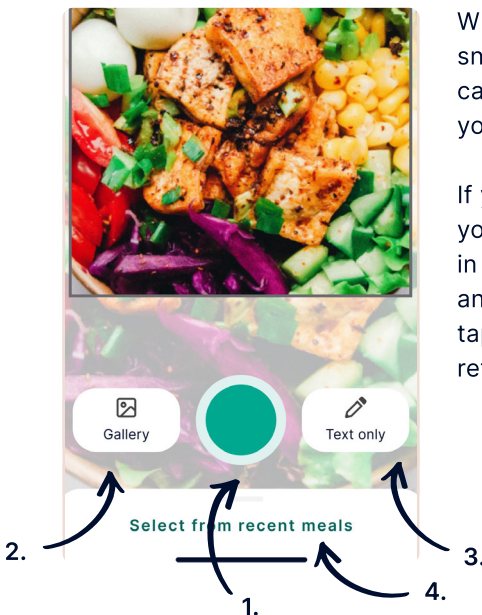




Meal / Snack

The more meals and snacks you log, the better the feedback your health care professional can provide. You can keep track of your meal / snack by:

1. Taking a picture when you are in the Oviva App;
2. Uploading a picture from your gallery by tapping on the "Gallery" button;
3. Describing it with text by tapping on 'Only text'.
4. Select from a collection of recently logged meals and snacks via photo or text by tapping on "Select from recent meals"



When adding a photo of your meal / snack (the recommended option) you can also add a note to describe what you had by tapping on 'add a note'.

If you are uploading a photo from your gallery or describing your food in text only, you can select the date and time that you had your meal by tapping on the 'When?' so the entry reflects when you actually ate.



Body weight

Even if weight loss/gain is not your main focus, it can still be useful to keep track and stay informed about your body weight and health. We recommend logging a body weight once per week.



Activity

Once you select an activity (scroll through the list or enter its name), enter the duration in hours & minutes.

You can track your steps by syncing the Oviva app with Apple Health, Google Fit or a Fitbit if you have one. Go to the 'Home' screen, and access the settings by tapping on the profile picture in the top right of the screen to do so.



Blood glucose

If you have been diagnosed with diabetes and you need to check your blood glucose levels, you can keep a log in the app. This helps your health care professional understand how you are managing your condition and help you deal with any high or low readings.

Remember to update your health care professional on any changes to your medications or if you are diagnosed with any new medical conditions.



Symptoms

If you experience gastrointestinal (stomach) symptoms, you can log them in the app so that your health care professional can support you.

You can rate a symptom severity from 0 (symptom not present) to 10 (severe symptom).



Mood

You can log your mood and how you are feeling. This can help you to be more aware of how your mood fluctuates throughout the day or week and how that may impact your behaviour.



Blood pressure

To keep track of your cardiovascular health, you can log your systolic and diastolic blood pressure.



Drinks

You can keep track of your hydration by logging a drinks entry for every liquid you drink. You can specify the amount of fluid and the type (e.g. water, coffee, juice).



Waist circumference

Alongside logging your body weight, logging your waist circumference is also good practice to keep track of your progress, especially if you are trying to lose abdominal fat (weight around your middle).



Bowel movements

Your stools are a valuable indicator of your gastrointestinal health. You can log the type using the Bristol Stool Chart within the app.



Learn

Keeping up to date with your learn content is essential to give you the knowledge, and therefore tools, to achieve your health goals.

Logging an entry with Bluetooth

It is possible to log a weight, steps, blood glucose or blood pressure entry through Bluetooth. To do so, you must have a physical device for measuring those data types (e.g. blood glucose monitor) that follows the Bluetooth low energy (BLE 4.0) standard. To log an entry via Bluetooth:

- Ensure your phone has Bluetooth enabled, and that you gave the Oviva app permission to use your phone's Bluetooth
- Navigate to the settings, and enter the Bluetooth screen
- Browse for available devices and pair your Oviva app with your desired device
- Stay on the screen while the app reads the data, your log will be automatically created, and you will receive a confirmation message on your screen

5.3 Home

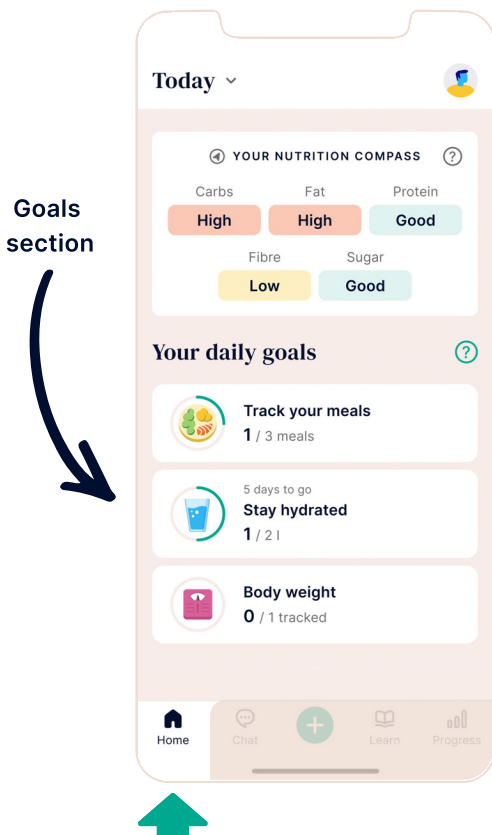
In the Home section, you can see your active goals for that day, goals that are up for review, if any, and all your logs. You can review previous days by tapping on the desired day of the week at the top of the page, or by swiping the screen left and right. You can also review previous weeks by tapping on the arrows at the top of the page.

Daily Goals

In the Daily Goals section you can see all active goals for that day. On the left you will see a progress bar (a circle) showing your progress towards the goal. This will eventually become a checkmark when the goal is complete. Tapping a goal will check off the goal or takes you to the related feature where you can enter a value needed to complete the goal.

Reviewing a goal

Most daily goals are active for a 14-day period. Once the period is over, they will move to the goal review section. Tapping on a goal that is up for review will bring you to the review screen. There, you can choose to repeat, adjust, or delete a goal based on information about your goal completion and achievement.



Creating a goal

You can add a new goal by tapping the plus (+) button and selecting "Goals" at the bottom of the menu. You'll see a list of habits you might want to focus on and, within each habit, a list of daily goals you can track. Find the one that's right for you and follow the guided steps to set your daily goal. (Select active days and add reminders)

Editing an active goal

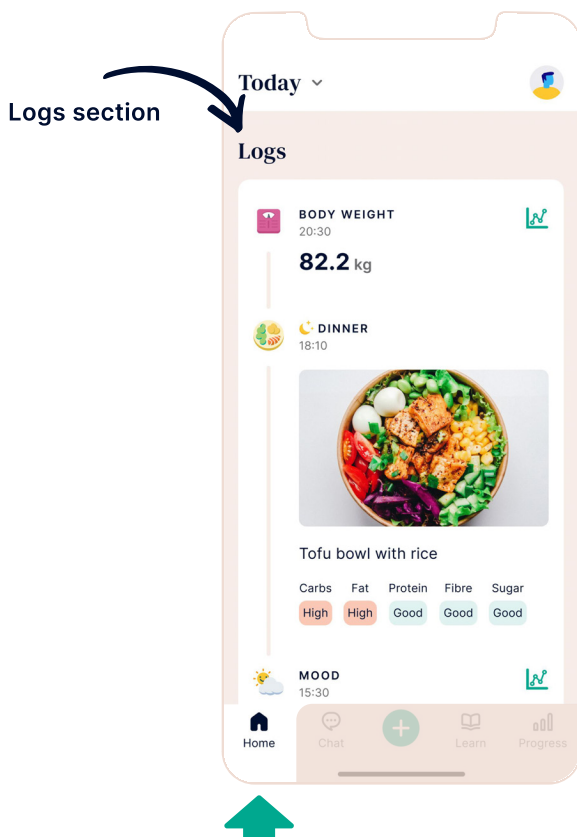
You can edit an active daily goal by tapping the plus (+) button and selecting "Goals" at the bottom of the menu. From there, navigate to the active goal you want to modify, and tap on it. Update the elements you wish to change (Active days, reminders, objective) and click save. The changes will be applied from today onwards (not retrospectively). Alternatively, you may swipe from right to left on an active goal cell in the home tab to trigger the edit screen.

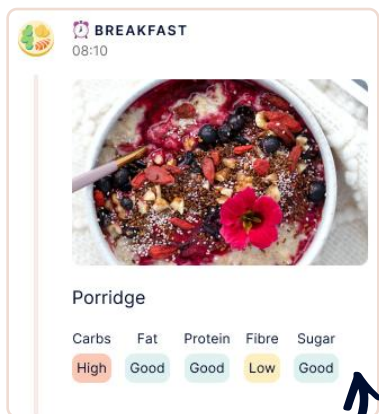
Deleting an active goal

You can delete an active daily goal by tapping the plus (+) button and selecting "Goals" at the bottom of the menu. From there, navigate to the active goal you want to delete and tap on it. You can then tap on the delete button to remove the goal. Alternatively, you may swipe from right to left on an active goal cell in the home tab to trigger the edit screen to delete active goals.

Logs

In the Logs section, you can see all your entries for that day, presented in chronological order with the most recent at the top. By tapping on an entry you can edit/delete it or go to the graph to see your progress over time.

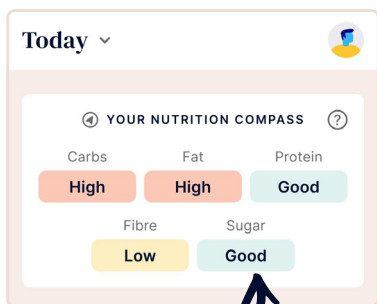




**Instant meal
feedback**

Instant meal feedback

After logging a meal or snack, you'll receive feedback in the "Logs" section. This feedback helps you understand if your meal or snack was too low, in the optimal range, or too high in terms of carbs, protein, fats, fiber, and sugar. Use this feedback as a reflection tool to see what you can improve for next time.



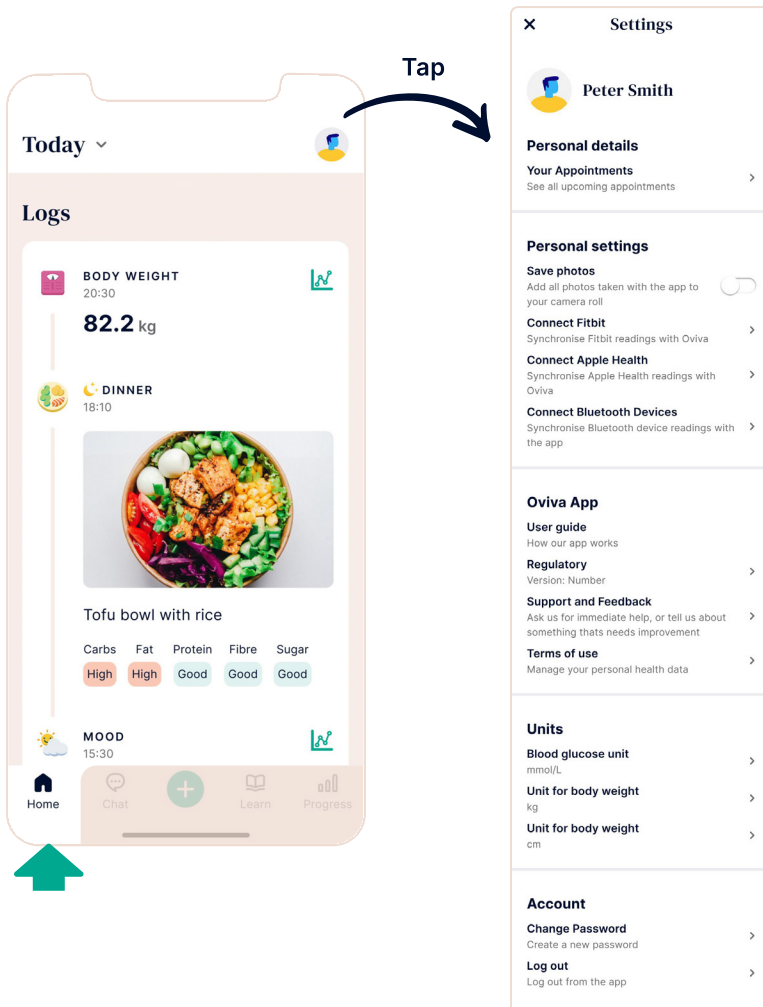
Nutrition compass

Nutrition compass

At the top of your home screen, you'll find an overview of your daily intake of carbs, protein, fats, fiber, and sugar. If a pointer is low, consider eating more from that category. If you're in the optimal range, you're doing great! If it's high, you've eaten too much from that category, and you might want to limit your intake for the rest of the day. Use this compass to guide your decisions throughout the day and help you plan your next steps.

Settings

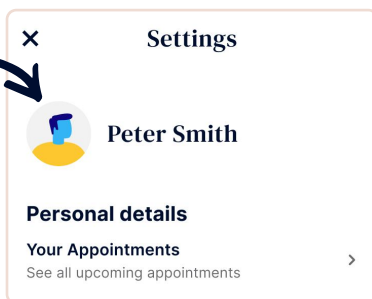
You can access the settings by tapping on the profile picture in the top right of the screen. You can connect or disconnect your camera roll, Apple Health or Google Fit, Fitbit, and Bluetooth; Update your profile picture; View your upcoming appointments; Access regulatory information; View and manage your consents; Change units of your logs; Log out.



Profile picture

Note that to update your profile picture, you can simply tap on the image at the top of the settings screen, you can then take a picture or upload it from your gallery. Your profile picture will be visible to you and your health care professional.

Tap to change
profile picture

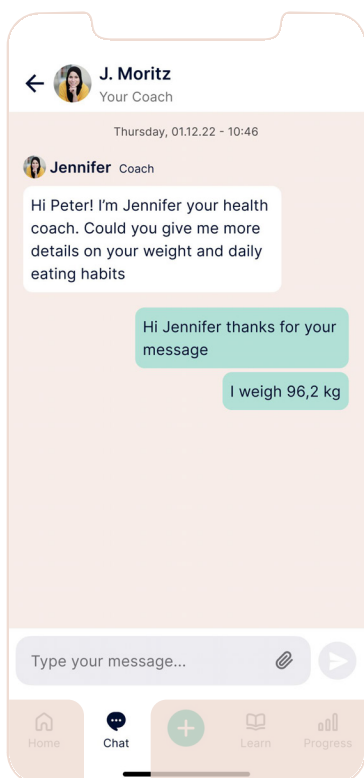


5.4 Chat

In this section of the app you can chat with your health care professional and other patients (only if you are part of a group chat as part of your programme).

If you are not part of a group, you will only see the chat with your health care professional. If you are part of a group, you will see a list with all of your chats.

Within a chat you can send messages and images directly to your health care professional or group as well as view their responses, advice and comments.



Use the chat to:

- Ask questions
- Share your successes and challenges
- Get support and motivation from your healthcare professional

Tip

You can reply directly to a message by long pressing on it or swiping it to the right.

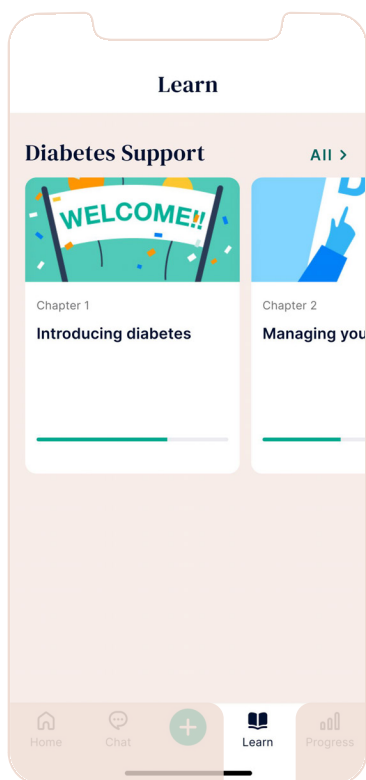
Note

Remember NOT to send any urgent clinical questions or last minute appointment changes via the app as your health care professional may not check it every day. If you require any urgent support or you are at risk, contact the emergency services.

5.5 Learn

For your programme, there are supporting materials and content on the Oviva Learn which you will work through during the programme by tapping on 'Learn'. A programme is a structured education course composed of different modules.

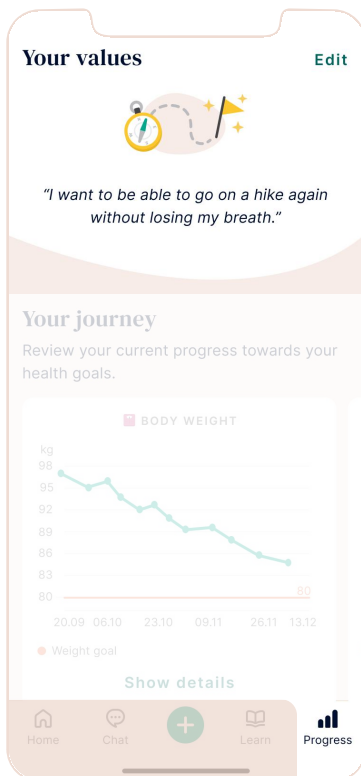
Independent to your programme, Oviva recommends content picks which are tailored to your specific interests and needs. When available, picks are gradually unlocked.



To access the content, tap on the 'Learn' button and select your lesson. You can navigate through the Learn programme by using the next and back button. Content can be made of different items, such as articles, videos, podcasts and quizzes.

5.6 Progress

The 'Progress' section is about giving you feedback on how well you are progressing towards your goal. In this section, you will be able to add your own values for what you want to achieve with your journey at Oviva, visualize your progress with various graphs, as well as getting actionable feedback on your diet.



Your Values

In 'Your values', you can write your motivation, a quote or your end goal so that it is always visible as a reminder for you. To update your values, tap on the edit button, modify your text at will, and press save.

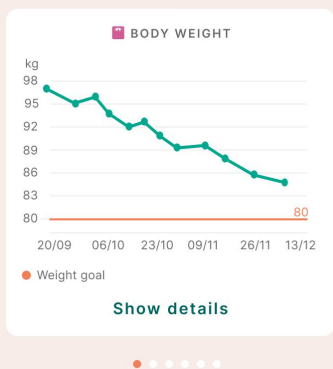


Graphs

The Progress screen features a variety of graphs that will help you keep track of how well you are doing in terms of sticking to your health habits, as well as on the evolution of your health metrics themselves.

Your journey

Review your current progress towards your health goals.




'Your Journey' section

In the your journey section, you will find key information on your health progress. You'll see different health graphs depending on what you log into the app, in carousel form, so you can quickly see and reflect on your progress with Oviva. Additionally, you can tap on the 'show details' button on any graph to see the detailed graph data.

In this detailed view, you will see any entries that you logged for that specific measurement. You can change the window of time by tapping on the Daily, Weekly and Monthly tabs at the top of the screen.


Your habits

The more you repeat the habits that matter to you the easier they get.



Fluid intake

See how your habit changes

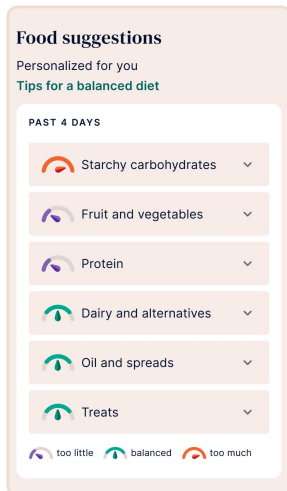


Activity

See how your habit changes

'Your habits' section

Changing your habits is key to a better health. In this section, you can track how well you are doing in terms of your activity and fluid intake. Simply tap on the desired row to see more information about it.



Food suggestions

You need to take picture logs of two meals in the past two days to see the food suggestions. It gives you a detailed breakdown of whether you're eating too much, too little or in a balanced way in each food category, based on accepted healthy eating guidelines. You can view detailed information by tapping each category. It gives you personalized feedback on what to add or remove from your diet to achieve a healthy and balanced lifestyle.



Warning

Note that while we will gather information on your overall dietary preferences (e.g. vegetarian, vegan, etc) to inform your food suggestions, we cannot cover all cases (e.g. allergies, intolerances). Always consult with your healthcare professional first if you are unsure.

6. Additional information

6.1 Help & Support

If you have any problems using the app, speak to your healthcare professional who will be able to help. Alternatively you can reach our technical support via support@oviva.com.

Please report any serious incident that has occurred in relation to the Oviva App with no delay via support@oviva.com.

If you need this user manual in paper form, you can request it free of charge via support@oviva.com.

6.2 Supported platforms

The Oviva App can be used on:

- iOS smartphones running on iOS 16.0 or higher.
- Android smartphones running on Android 10.0.0 or higher.








6.3 Environment for Use

None specific. Oviva App can be used wherever a smartphone can be used. Only use the app in a secure environment. In public WIFI, connect to secured networks whenever possible.

6.4 Supported devices for importing data via Bluetooth

All devices used to measure weight, blood glucose, blood pressure, and activity (steps), and that support the Bluetooth low energy standard (BLE 4.0) may be connect to the Oviva app. To learn how to do this, please refer to section 5.2 - Logging a entry with Bluetooth.

6.5 Symbol glossary

Symbol	Meaning
	Manufacturer
	Caution
	Authorized representative in the European Community
	CE Mark with ID number of certification body
	Oviva App logo
	Medical Device
	Consult instructions for use

6.6 Regulatory and safety notices

Europe (EU/EFTA)

Declaration of conformity with regard to the EU MDR 2017/745.
Oviva AG is authorised to apply the CE mark on its product, thereby declaring conformity provisions of the European Union Regulation of Medical Devices (Regulation (EU) 2017/745). The complete declaration of conformity can be found in the specific product section at oviva.com/quality.

Name of the manufacturer:

Oviva AG

UDI-DIs:

07649993906017 (iOS)

07649993906031 (Android)

Address of the manufacturer:

Oviva AG, Zürcherstrasse 64, CH-8852 Altendorf, Switzerland



MT Promedt Consulting GmbH, Ernst-Heckel-Strasse 7, 66386 St. Ingbert, Germany

Certification Body TÜV Süd Product Service GmbH, ID 0123

Importer for Germany: Oviva AG Potsdam, Dortusstrasse 48, 14467 Potsdam

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