Healthentia

Quick Start Guide

Healthentia version 3.11
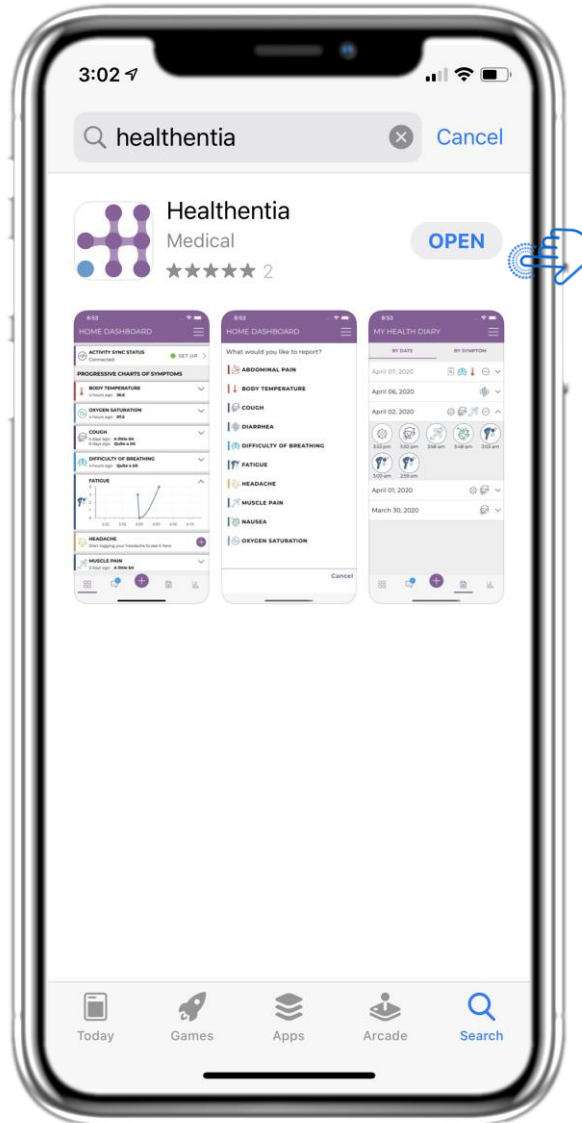issue date: 03-02-2025

CE

Innovation Sprint Sprl
Clos Chapelle-aux-Champs 30
Bte 1.30.30
1200 Brussels, Belgium

v3 (25/05/2021)

1 DOWNLOAD APPLICATION

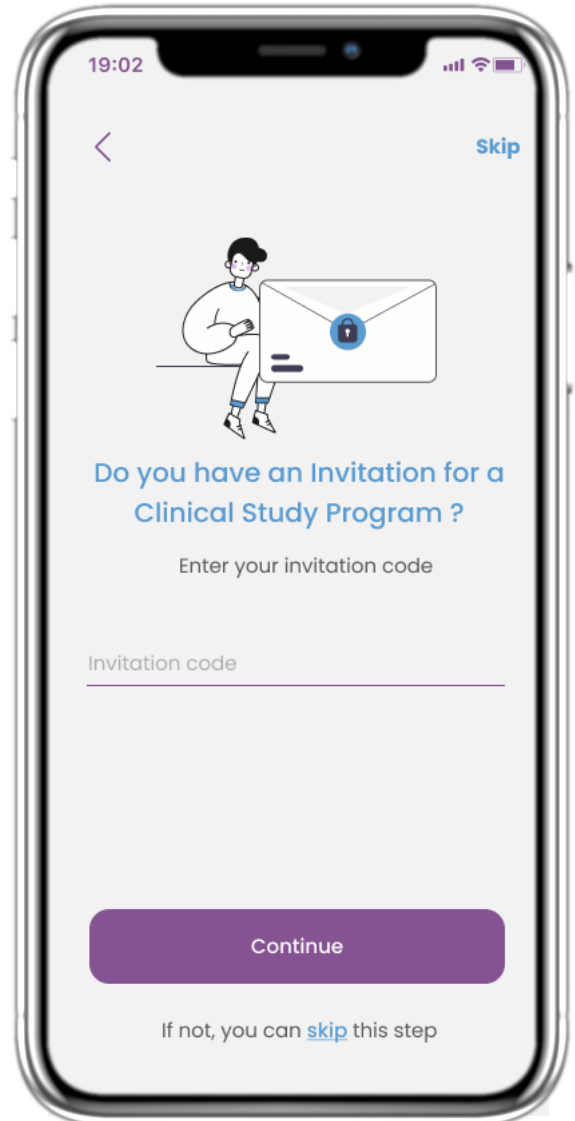Download Healthentia APP
from iOS AppStore or Google
Play Store.

2 WELCOME / REGISTER

2.1 WELCOME PAGE

Welcome page of Healthentia with intended use of Medical Device. Options to Register by pressing "Get started" or "Sign in".

2.2 INVITATION CODE

If you have received an invitation Code you can enter it here or else skip.

2 ONBOARDING QUESTIONNAIRE

2.3 REGISTER

Register a new account with an email and a strong password.

2.4 ENTER WEIGHT-HEIGHT

Enter your weight and height for your profile.

2 ONBOARDING QUESTIONNAIRE
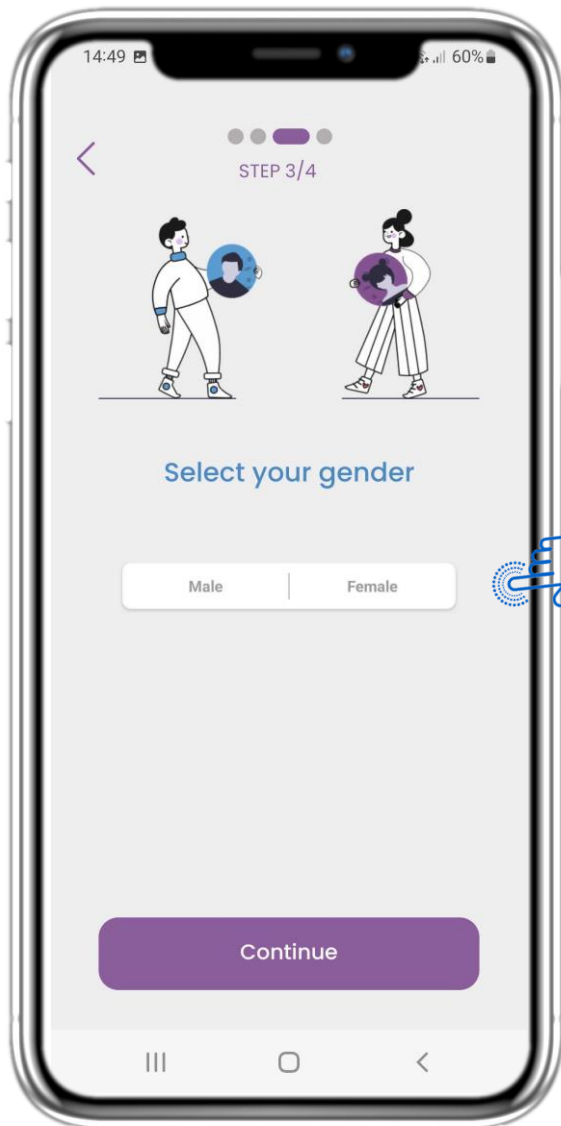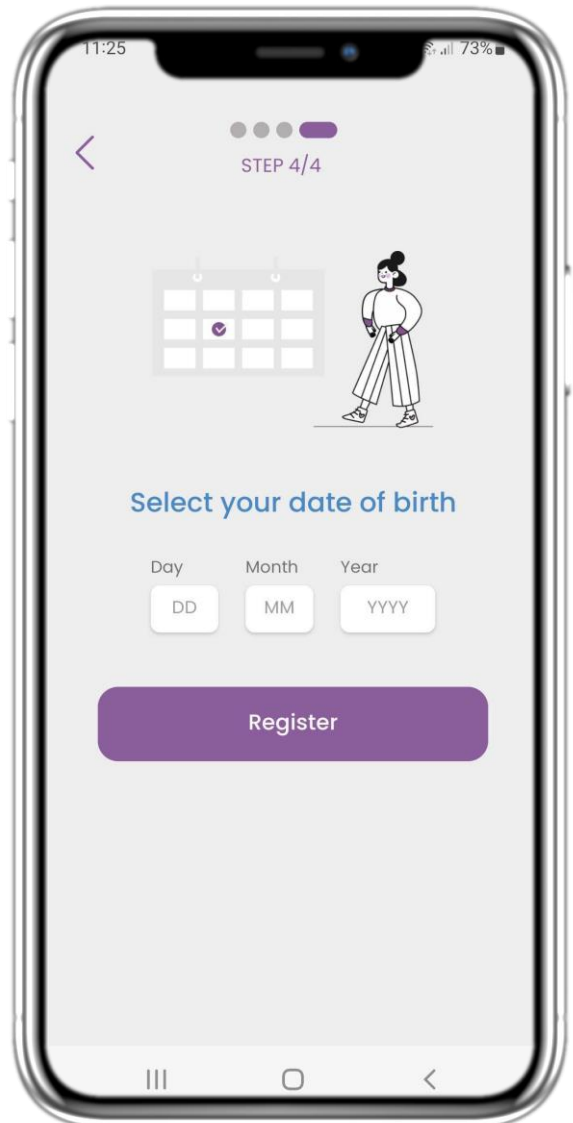

2.5 SELECT GENDER
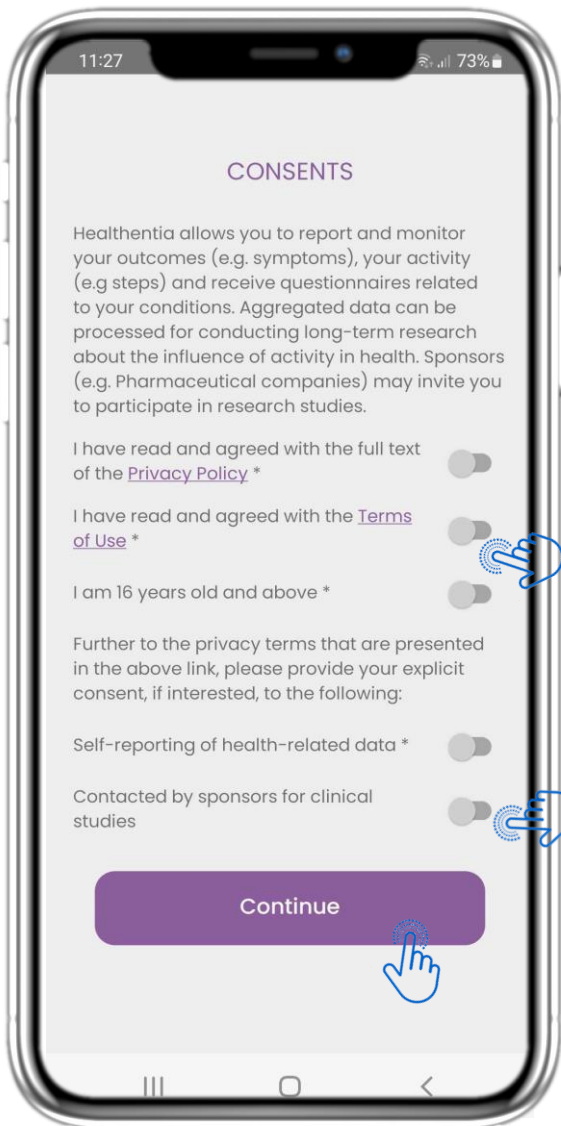
Pick your gender for your profile.

2.6 SELECT BIRTHDATE

Pick your date of Birth for your profile.

2 CONSENTS / INVITATION CODE

2.7 CONSENTS PAGE

Select if you agree to share your data anonymously for research purposes.
Read and agree to the Terms and Privacy Policy of Healthentia and indicate your preferences concerning the explicit consents.

3 HOME & PUSH NOTIFICATIONS
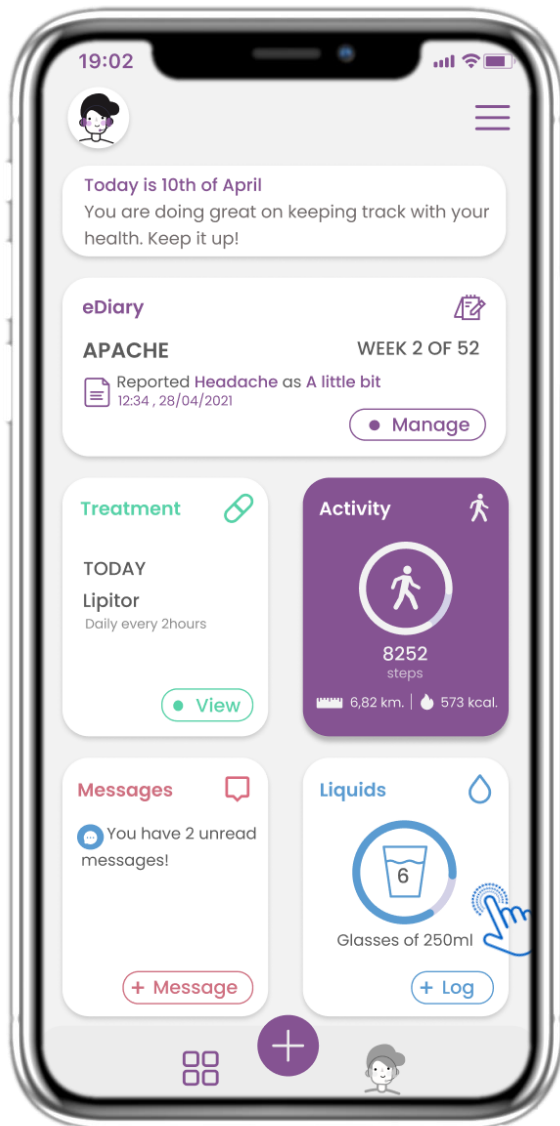
3.1 HOME

In the HOME page you get greeted by the chatbot that announces the pending questionnaires. Below HOME is comprised of the different widgets configured for the specific study.
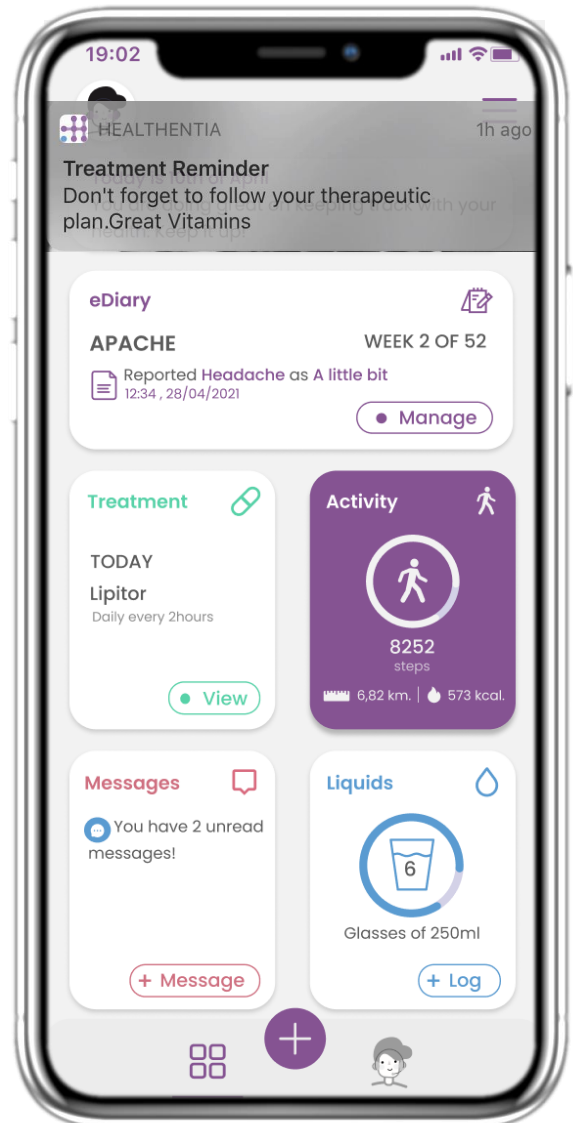
3.2 PUSH NOTIFICATIONS

Healthentia asks you to allow notifications from your settings and so questionnaire and treatment reminders can be received.

4 HOME WIDGETS

4.1 eDIARY WIDGET

In the HOME page you can find the eDiary widget which is used as a journal of your Study or therapy monitoring.
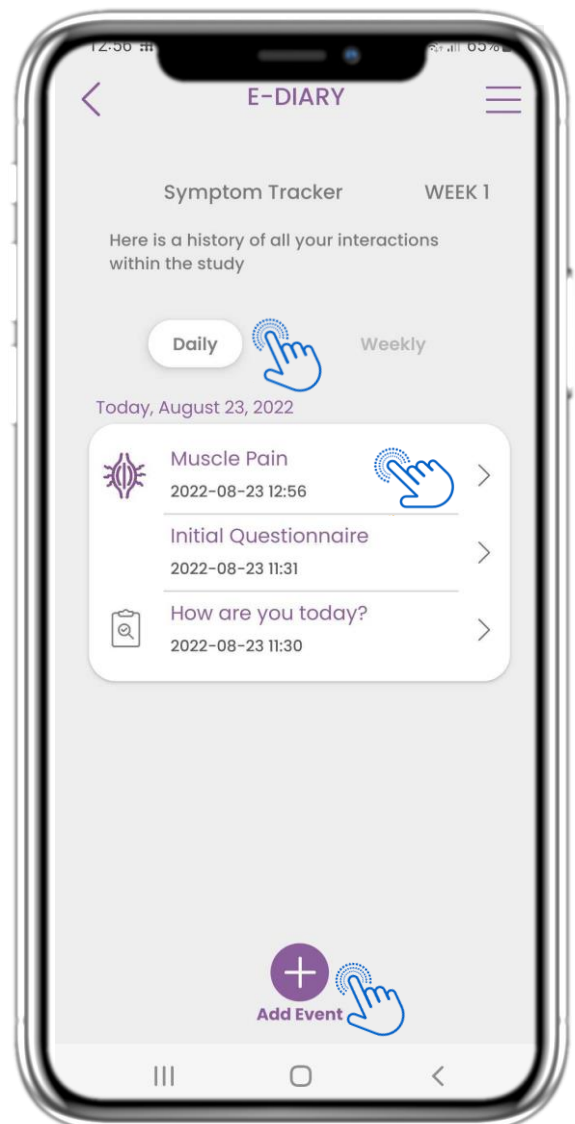
4.2 eDIARY PAGE

In the eDiary page you can find a daily update of your reports and submitted questionnaires.

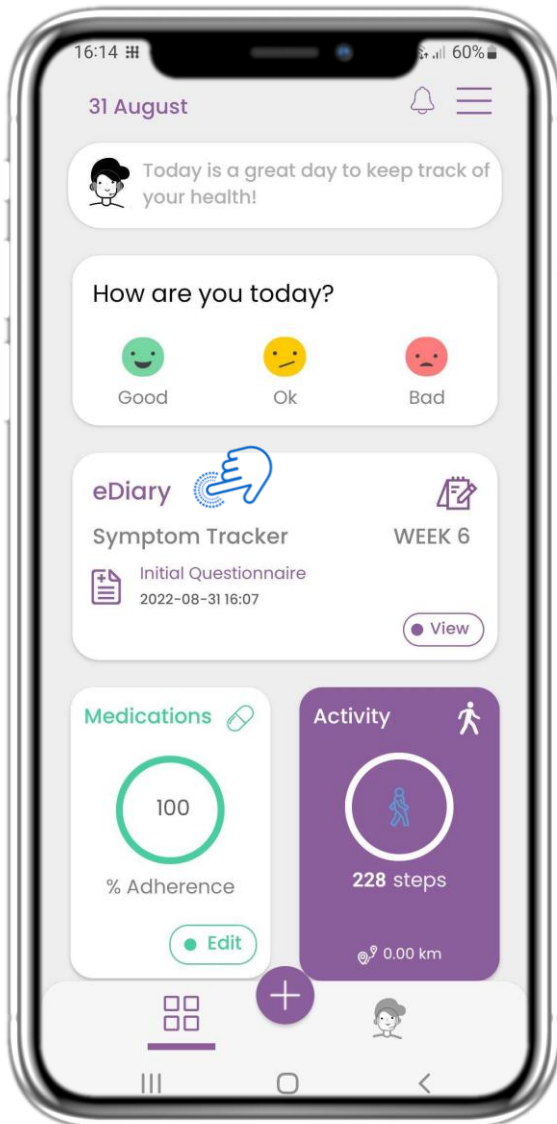# 4 HOME WIDGETS

4.3 eDIARY INSIGHTS

If the study allows to show graphs of symptoms to the user there will be a button to open this page. With the calendar you can move back and front the weeks.

4.4 VIEW REPORTED ANSWERS

Submitted questionnaires with the answers can be viewed.

4 HOME WIDGETS
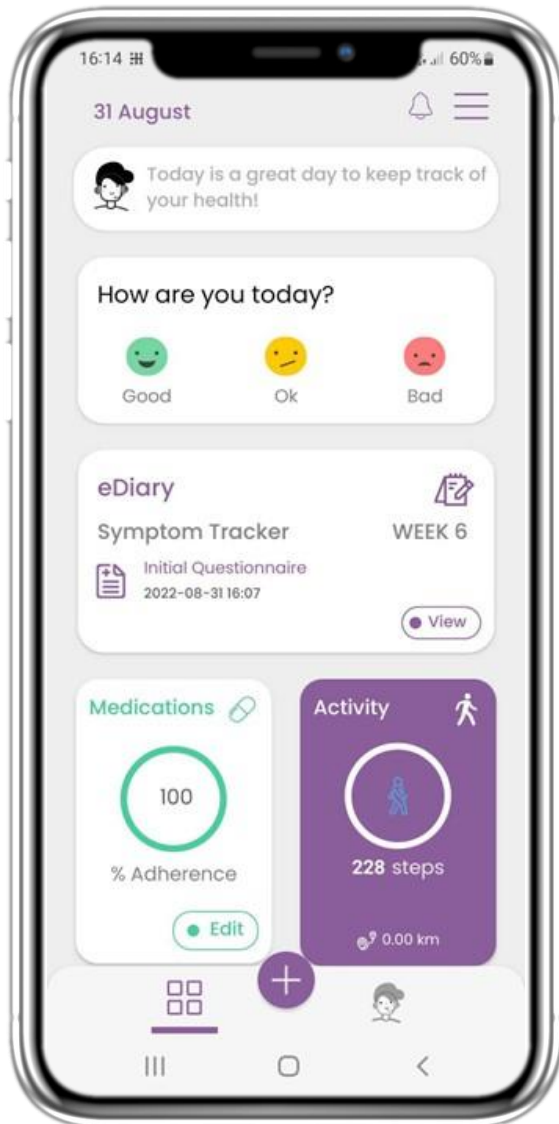
4.5 MEDICATION WIDGET

In the HOME page you can find the medication widget which is used to set up your therapy plan.
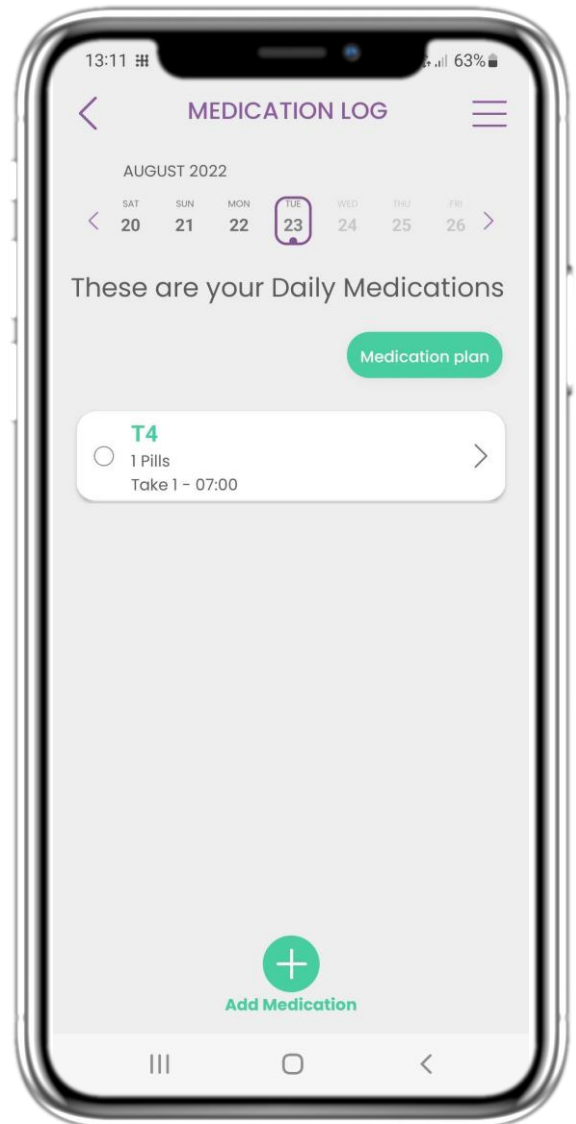
4.6 MEDICATION LOG

In the Medication Log page you can find a daily schedule of your medication takes. You can access and edit them or add a new one.

4 HOME WIDGETS
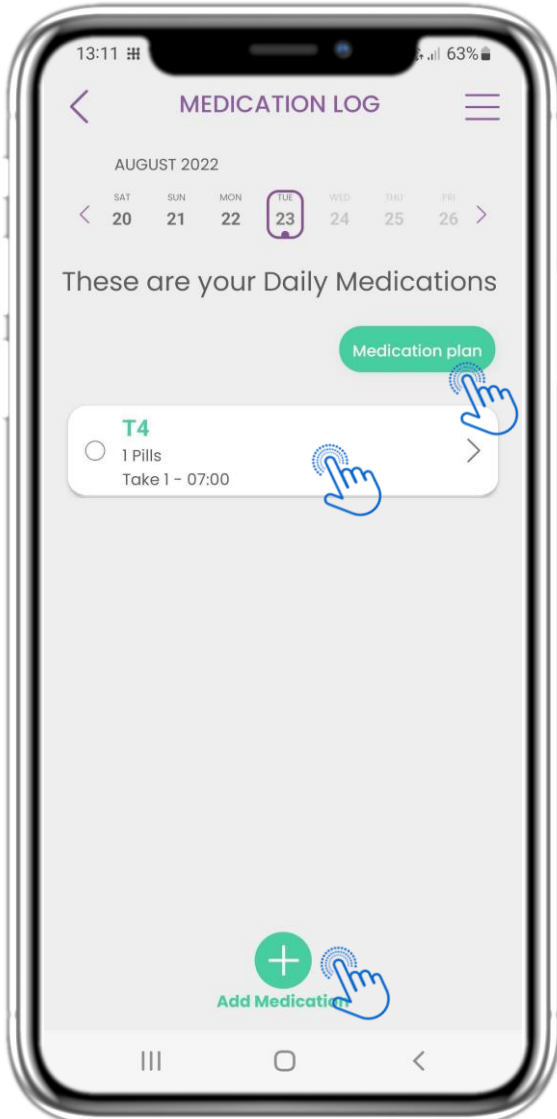
4.7 SEE ALL MEDICATIONS

In the Medication page you can access and configure all medications you have inserted. Clinician prescribed medication cannot be edited
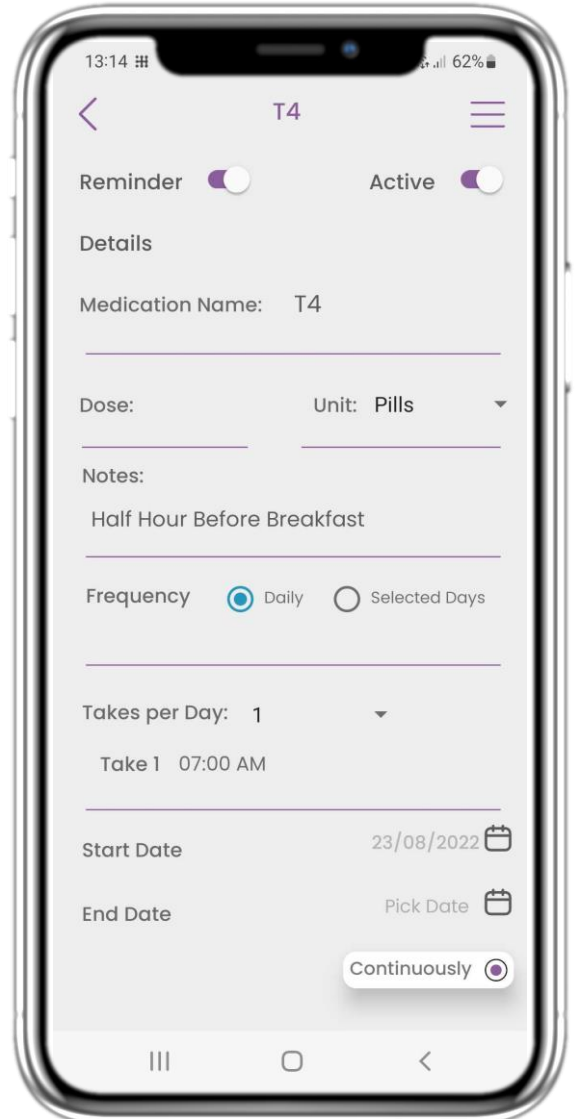
4.8 ADD/ EDIT NEW MEDICATION

In the New Medication page you can configure a name, frequency, duration and add a reminder.

4 HOME WIDGETS
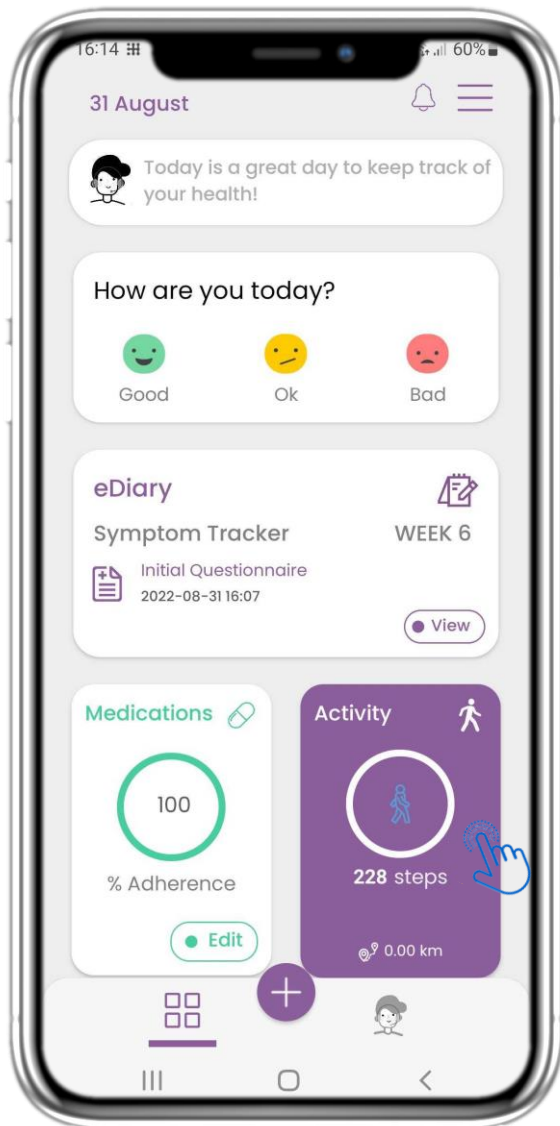
4.9 ACTIVITY

In the HOME page you can find the Activity widget which is used to set up your tracker and monitor Steps.
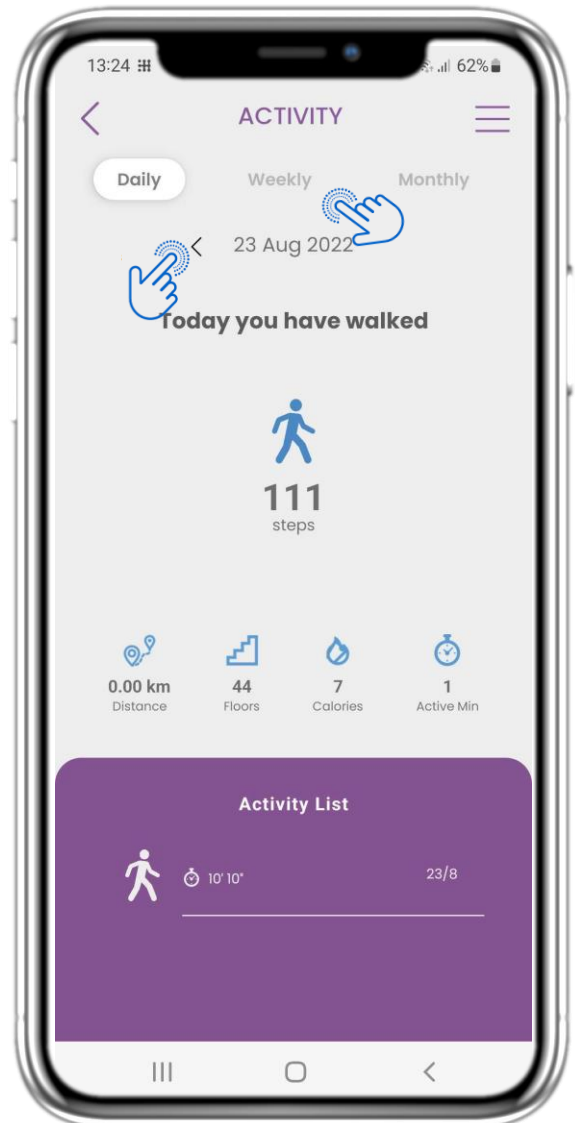
4.10 ACTIVITY PAGE

In the Activity page you can monitor Daily Steps, Distance, Floors, Calories and active min. With the calendar you move between the days and by pressing weekly you go to the graphs.

4 HOME WIDGETS
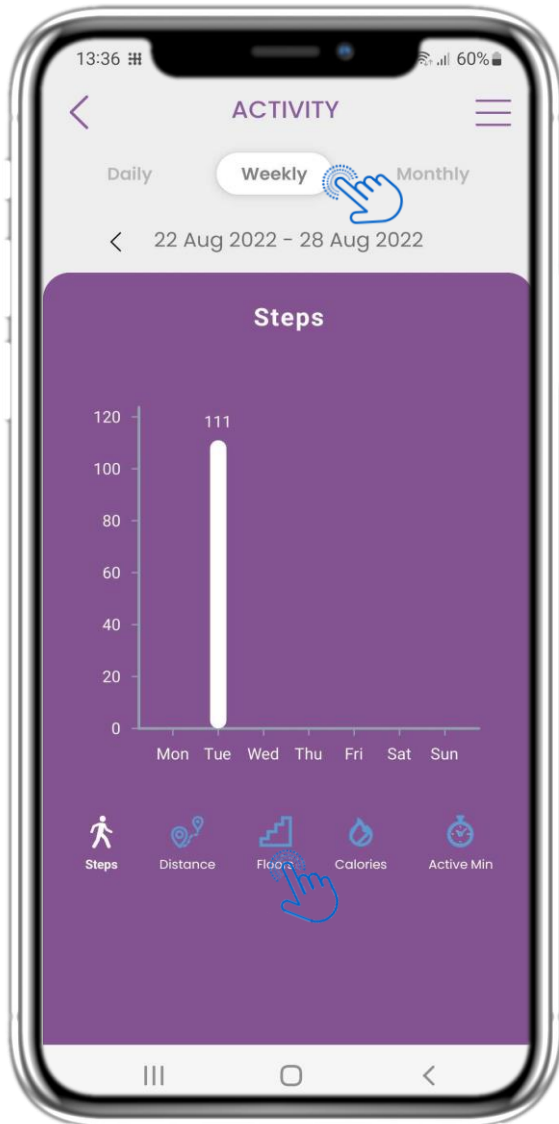
4.11 ACTIVITY GRAPHS

In the weekly ACTIVITY Graphs page you can find weekly Steps, Distance, Floors, Calories and active min.
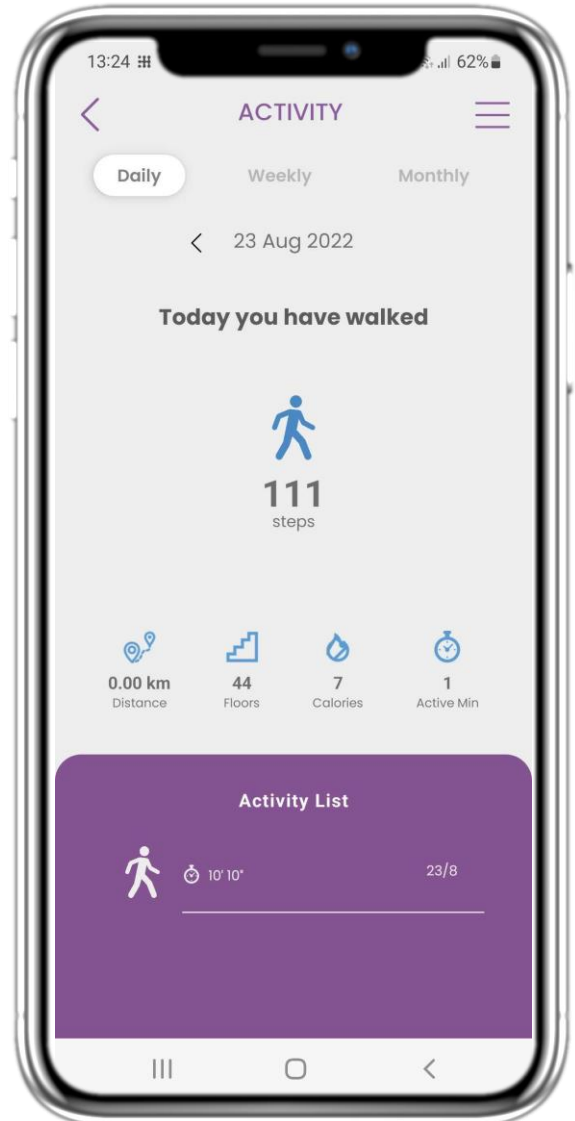
4.12 ACTIVITY PAGE

If the Activity list is empty, there were no sports activities reported on the wearable.

4 HOME WIDGETS
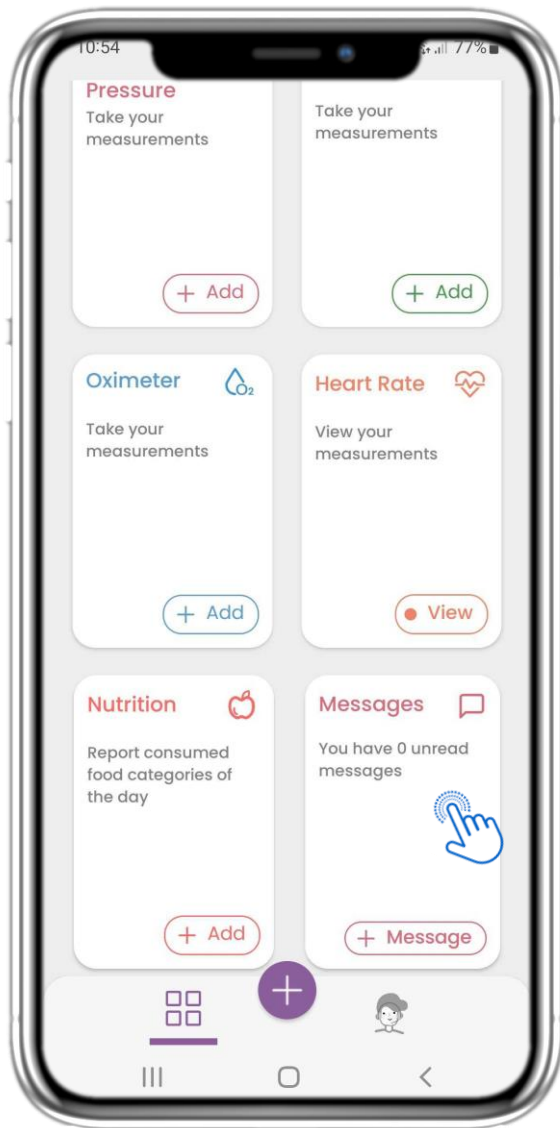
4.13 MESSAGES

In the HOME page you can find the Messages widget which is used to contact your Clinical team and through this widget teleconsultation is available.
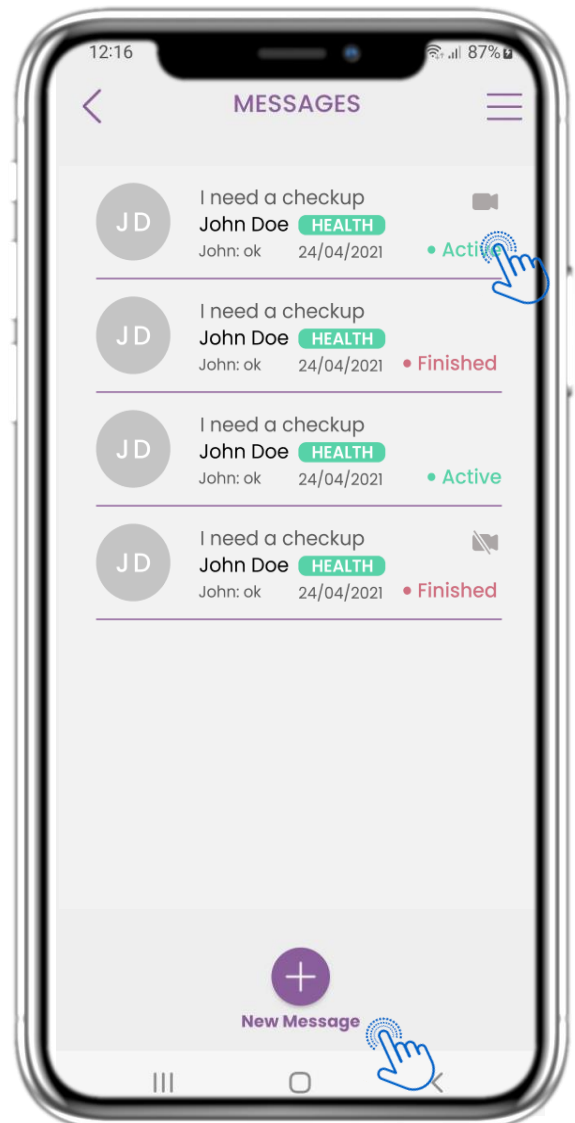
4.14 MESSAGE INBOX PAGE

In the Message page you can see the communication with the clinical team. Create a new message or access the teleconsultation room.

4 HOME WIDGETS
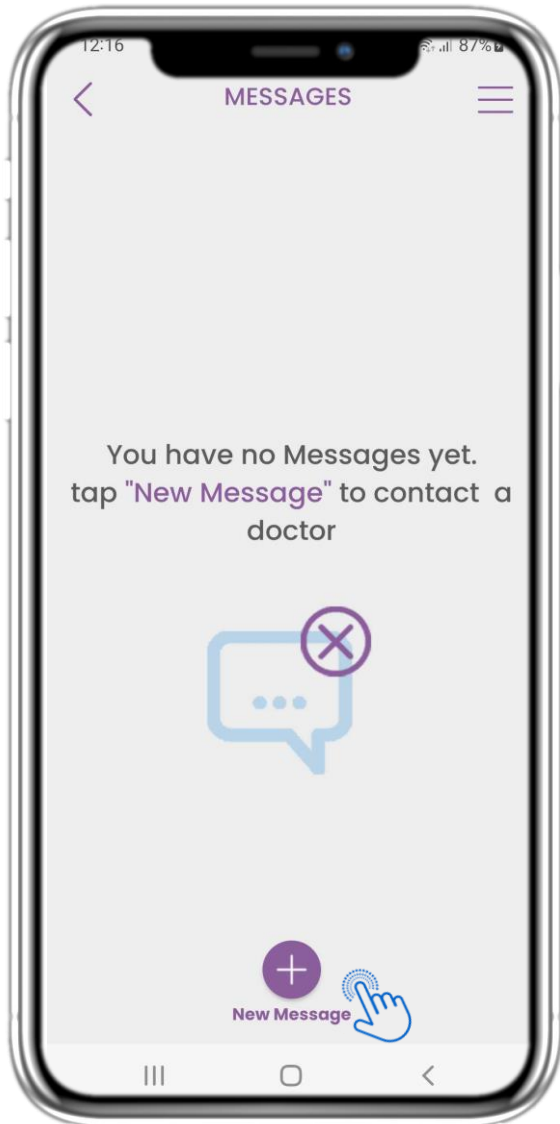
4.15 NO MESSAGES

If there are no messages this is how the page looks.
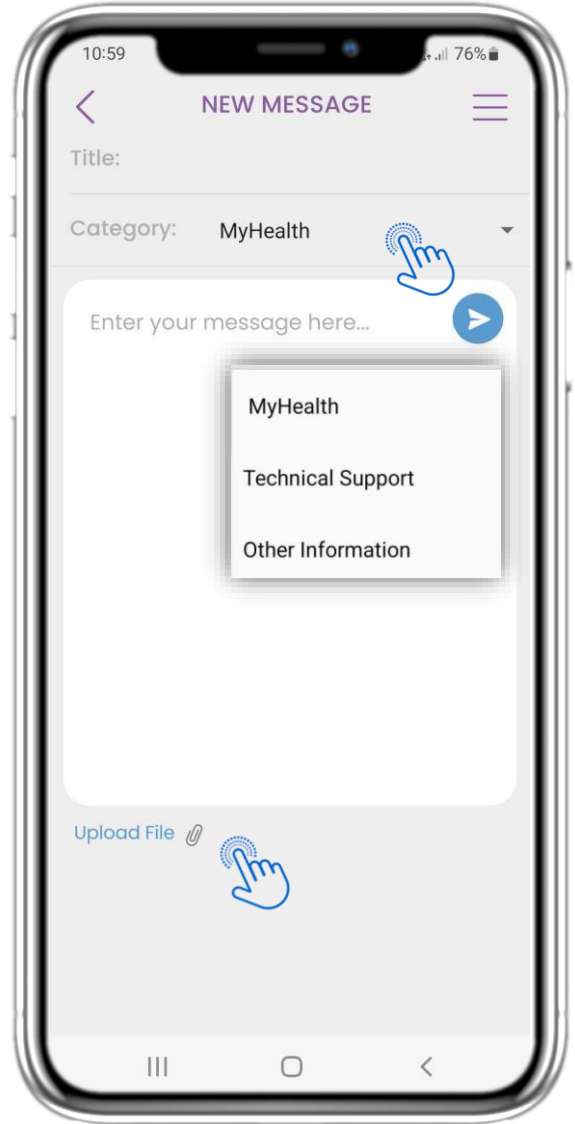
4.16 CREATE NEW MESSAGE

In the Message box you can select a Subject title and a category like health related, technical or other and enter your message and/or upload a file.

4 HOME WIDGETS
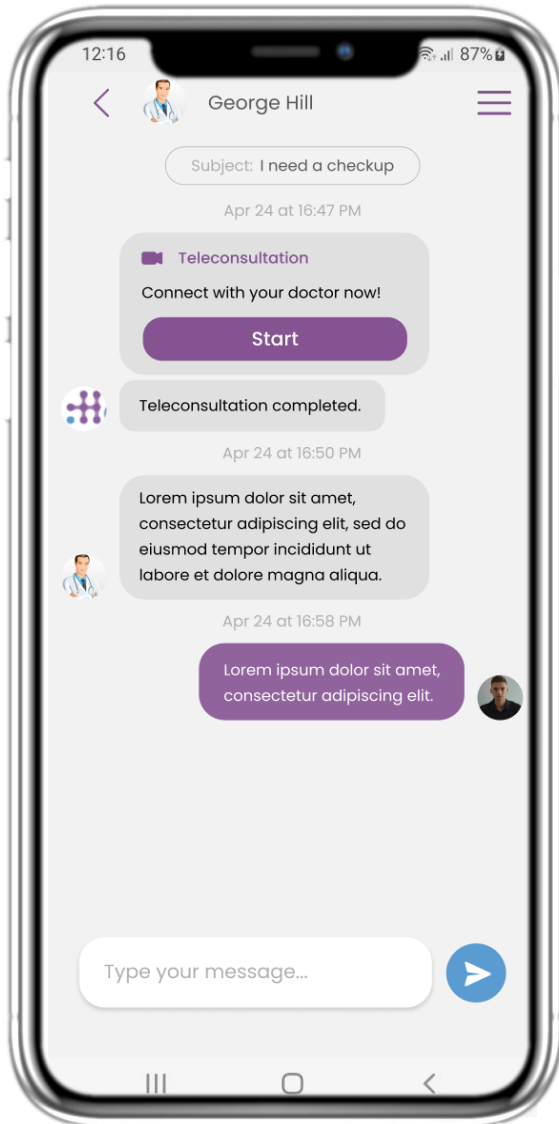
4.17 OPEN MESSAGE

All replies and communication are kept in one conversation. The clinical team closes the conversation.

4.18 TELECONSULTATION

In the Message conversation the clinical team can start a teleconsultation that will allow in a 15min window the user to enter.

4 HOME WIDGETS
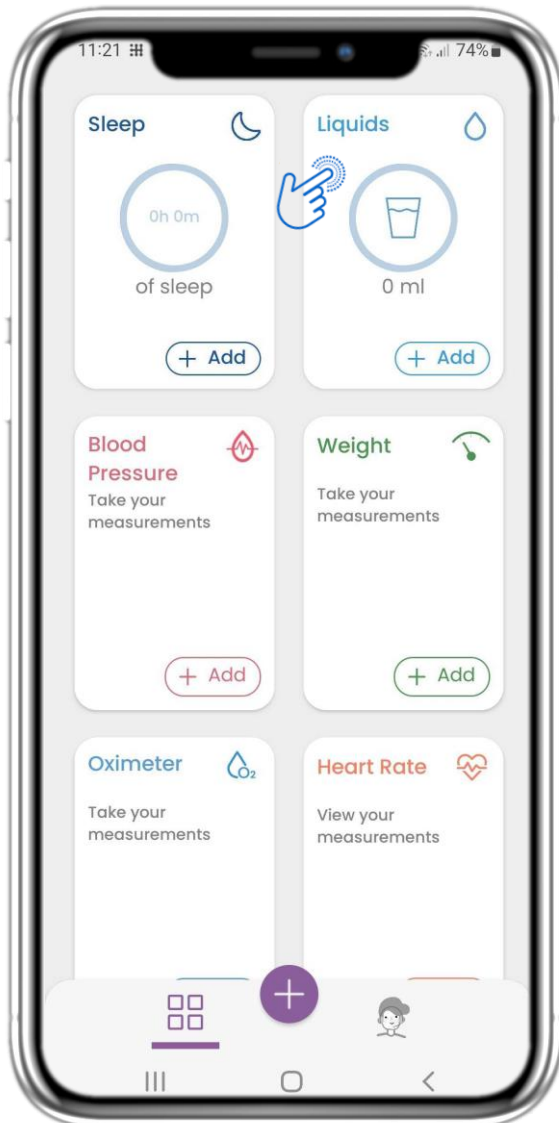
4.19 LIQUID WIDGET

In the HOME page you can find the Liquid widget which is used to log your water and other liquid intakes daily.
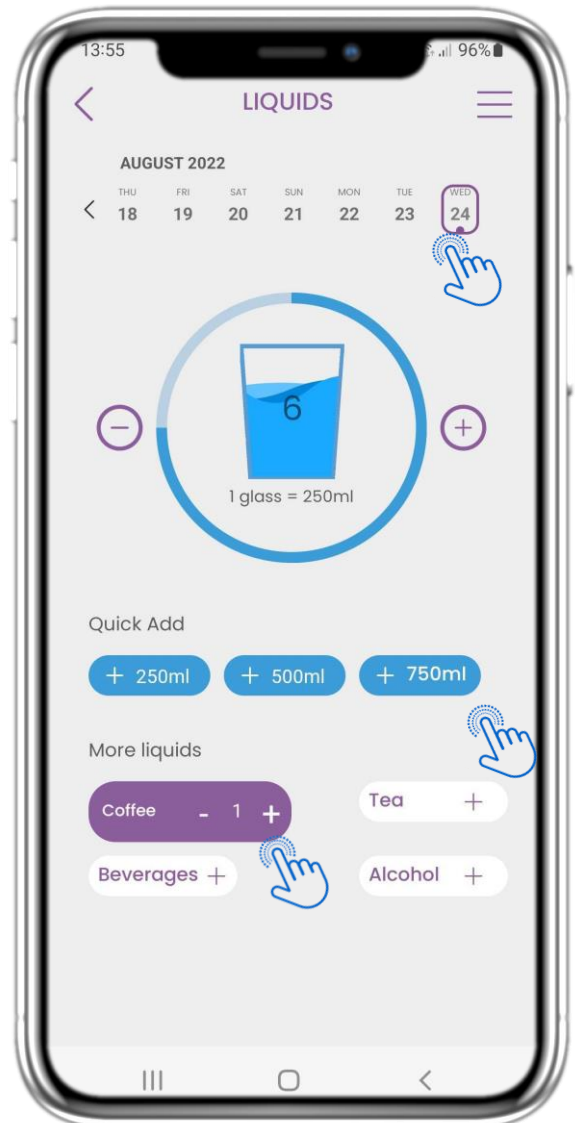
4.20 LIQUID PAGE

In the Liquid page you can add glasses of water with quick 250-500-750ml buttons and add other liquids like coffee or beverages.

4 HOME WIDGETS
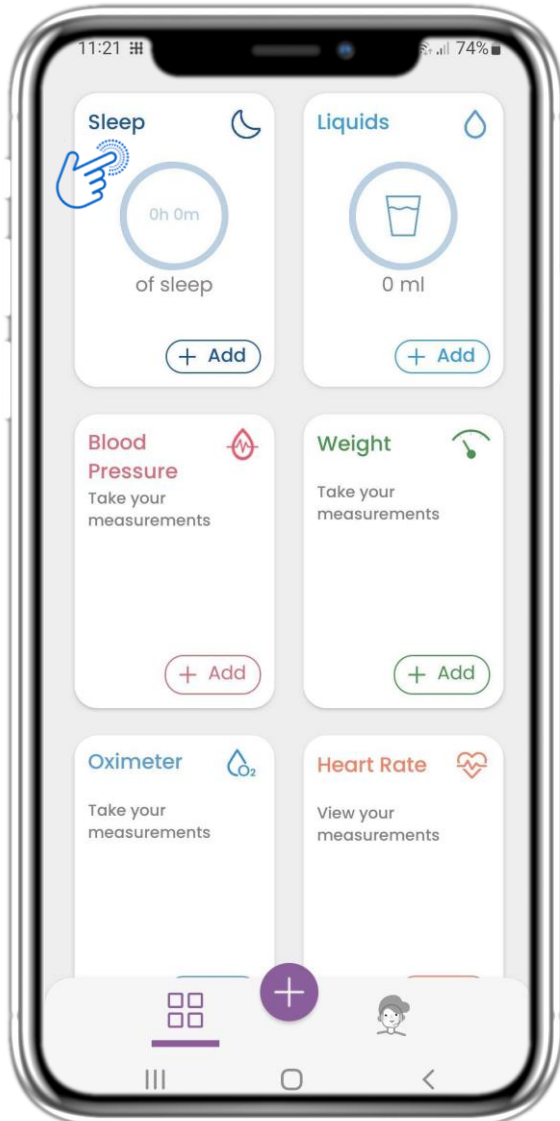
4.21 SLEEP WIDGET

In the HOME page you can find the Sleep widget which is used to log your sleep either manually or collected by a wearable.
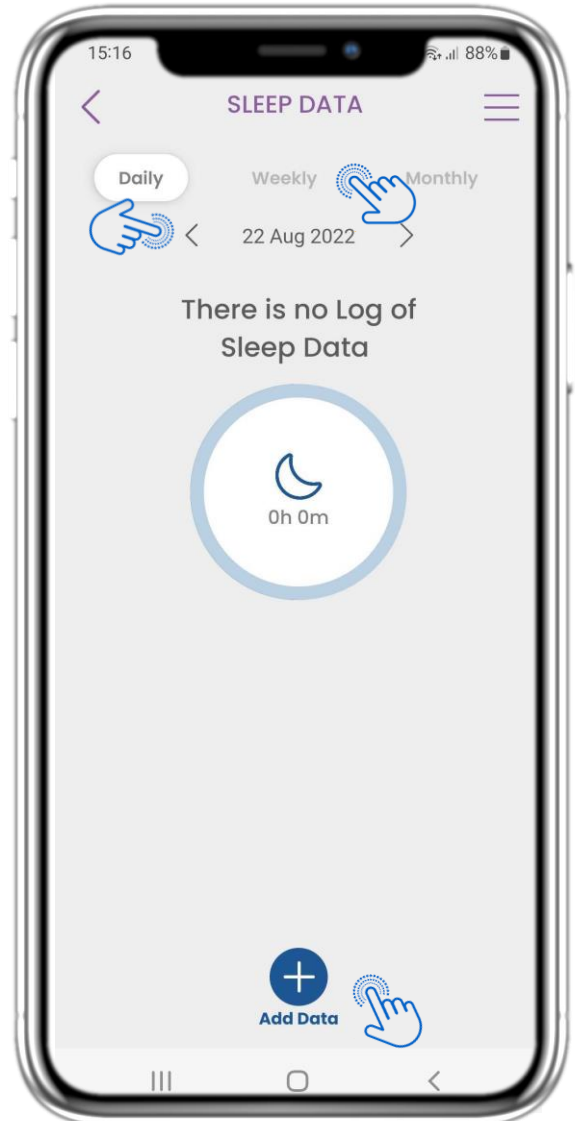
4.22 SLEEP PAGE LOG

In the Sleep page you can manually add your sleep and navigate between the days in the calendar or view daily sleep data and select to view weekly also graphs.

4 HOME WIDGETS
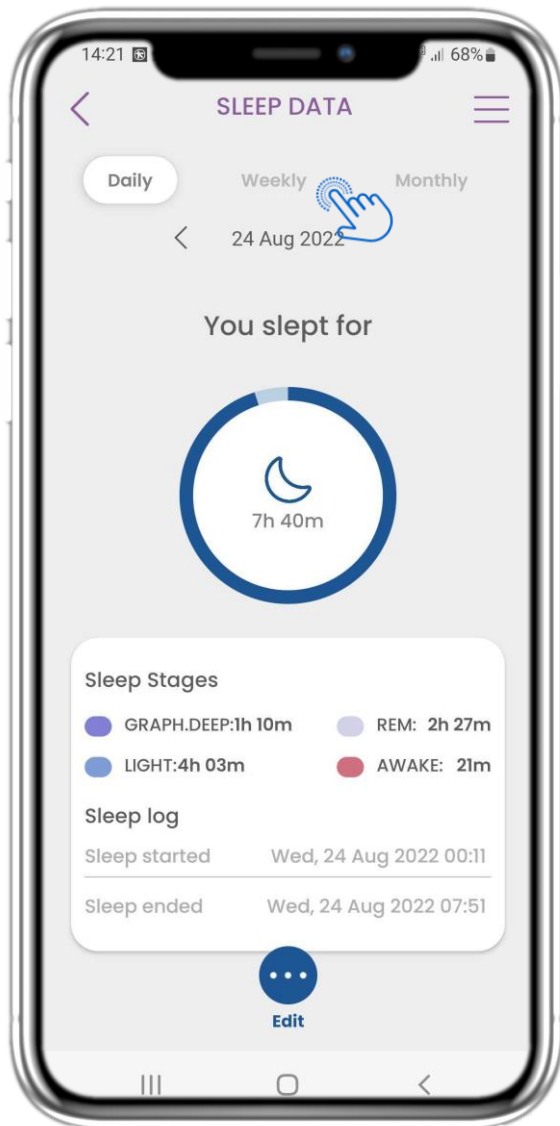
4.23 SLEEP PAGE FROM WEARABLE

In the HOME page you can find the Sleep widget which is used to log your sleep either manually or collected by a wearable.
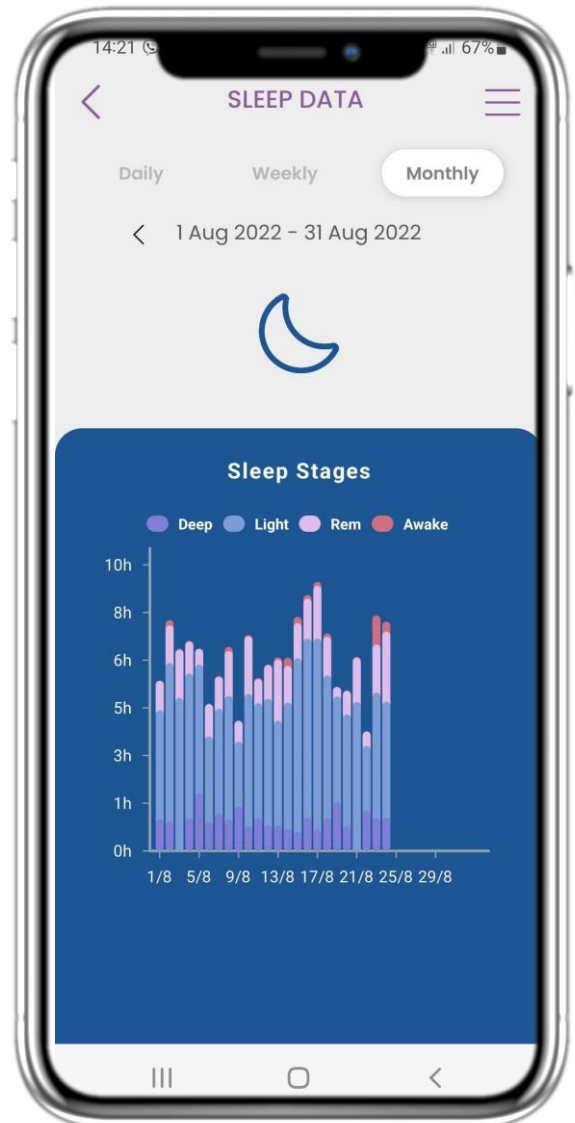
4.24 SLEEP PAGE

In the Sleep page you can manually add your sleep and navigate between the days in the calendar or view daily sleep data and select to view weekly also graphs.

4 HOME WIDGETS
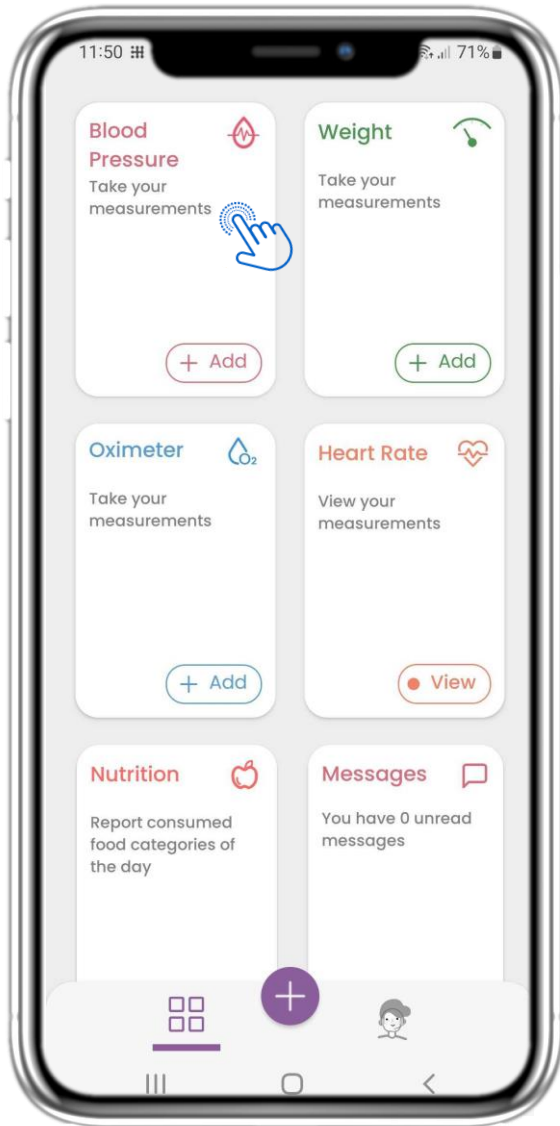
4.25 BLOOD PRESSURE WIDGET

In the HOME page you can find the Blood Pressure widget which is used to log your blood pressure. In the Blood Pressure page you can log your blood pressure and navigate between the days in the calendar or view daily data and select to view weekly also graphs.

4 HOME WIDGETS

4.25 BLOOD PRESSURE WIDGET

You can log your blood pressure either manually or collected by a synced device or a wearable.

4 HOME WIDGETS
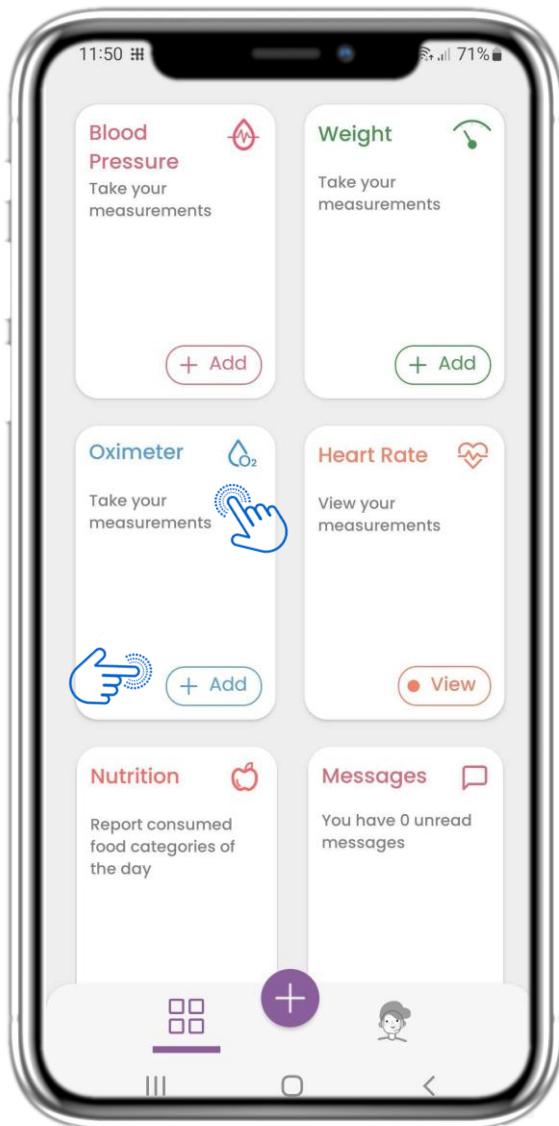
4.26 OXIMETER WIDGET

In the HOME page you can find the Oximeter widget which is used to log your oxygen saturation.

In the Oximeter page you can log your oxygen saturation and navigate between the days in the calendar or view daily data and select to view weekly also graphs.
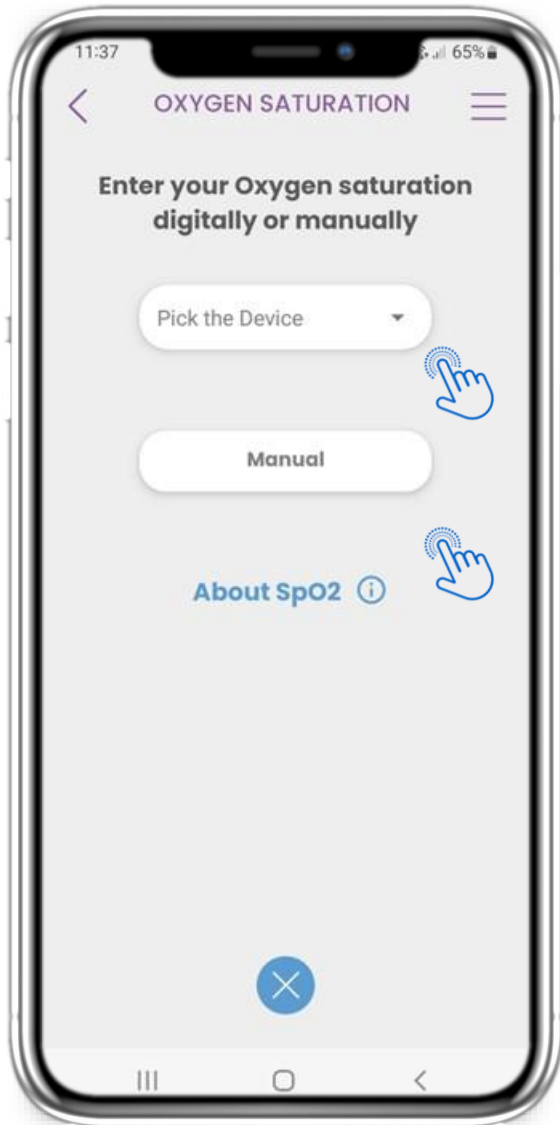
4 HOME WIDGETS

4.26 OXIMETER WIDGET

You can log your oxygen saturation either manually or collected by a synced device or a wearable.
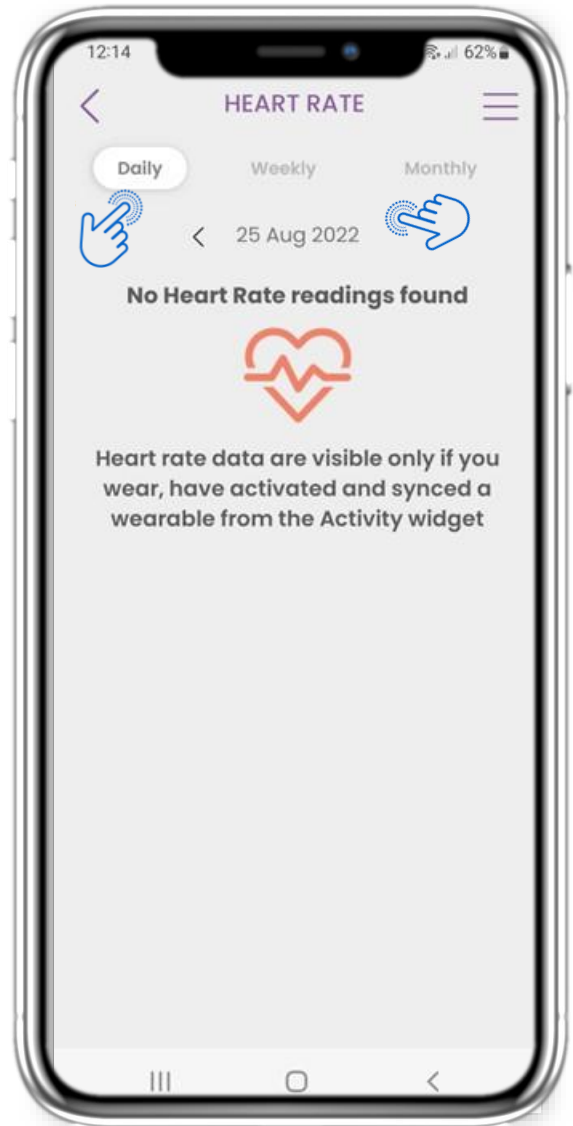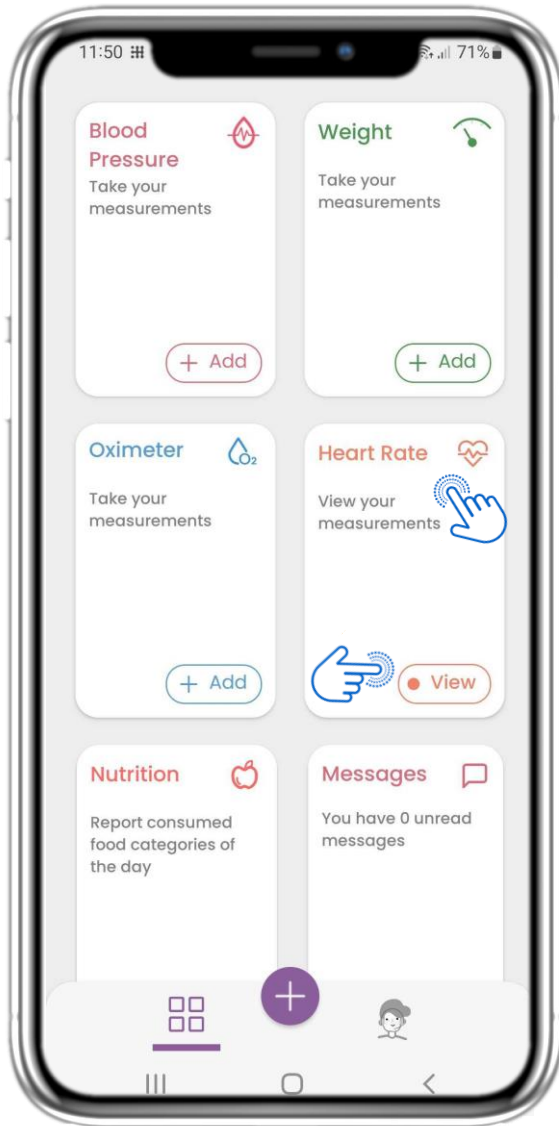
4 HOME WIDGETS

4.27 HEART RATE WIDGET

In the HOME page you can find the Heart Rate widget which is used to log your heart rate.
In the Heart Rate page you can navigate between the days in the calendar or view daily data and select to view monthly also graphs.

4 HOME WIDGETS

4.27 HEART RATE WIDGET

You can log your heart rate data if you wear, have activated and synced a wearable from the Activity widget.

4 HOME WIDGETS
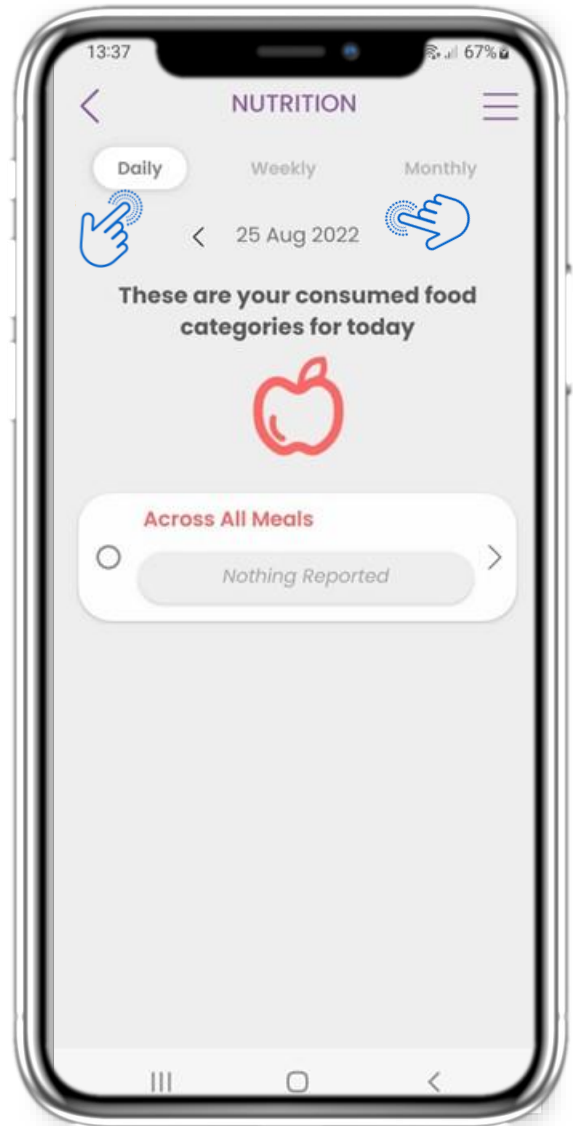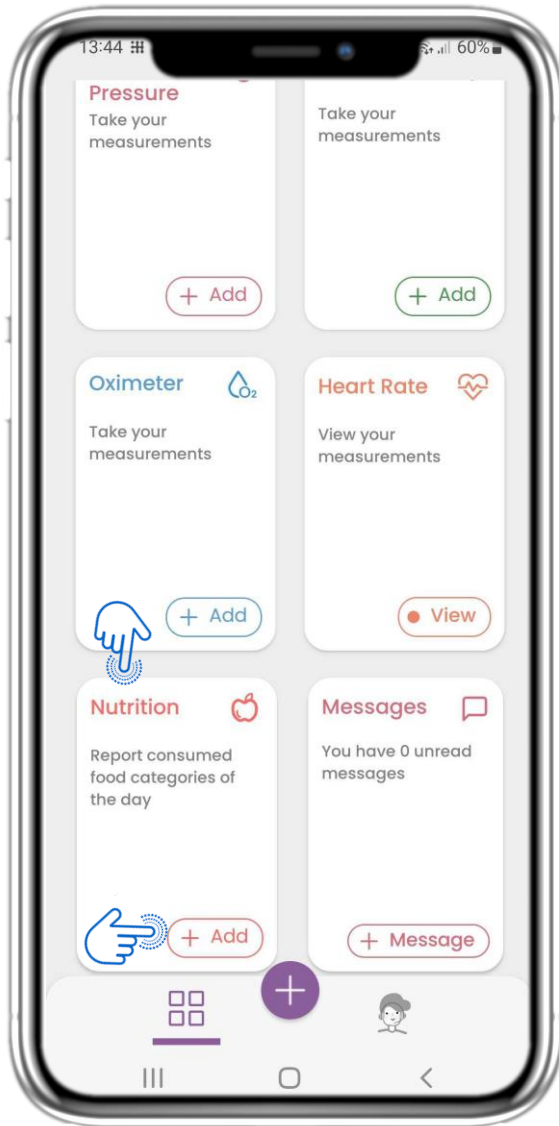
4.28 NUTRITION WIDGET

In the HOME page you can find the Nutrition widget which is used to log your consumed food categories.
In the Nutrition page you can navigate between the days in the calendar or view daily data.

4 HOME WIDGETS
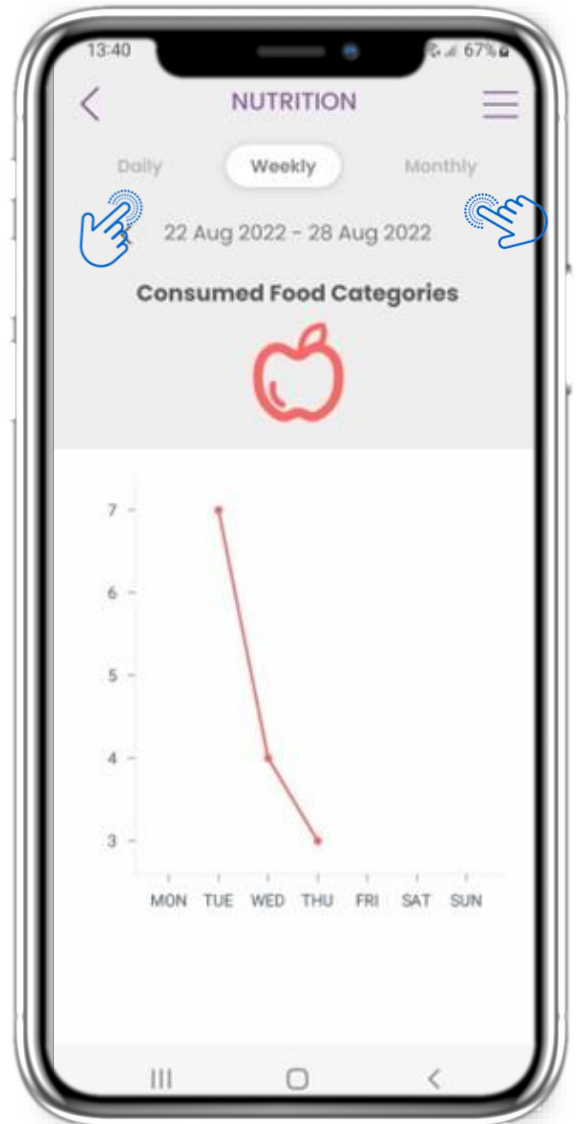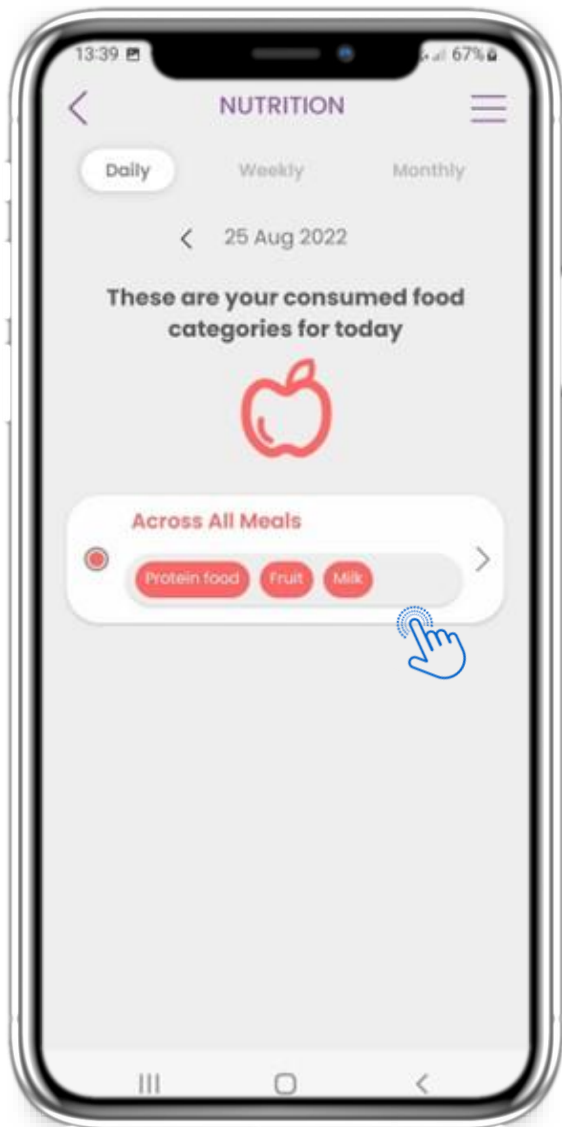
4.28 NUTRITION WIDGET

You can log your consumed food categories by choosing them from a drop down list and select to view weekly/ monthly graphs.

5 ADD REPORTS/ ANSWER QUESTIONNAIRES
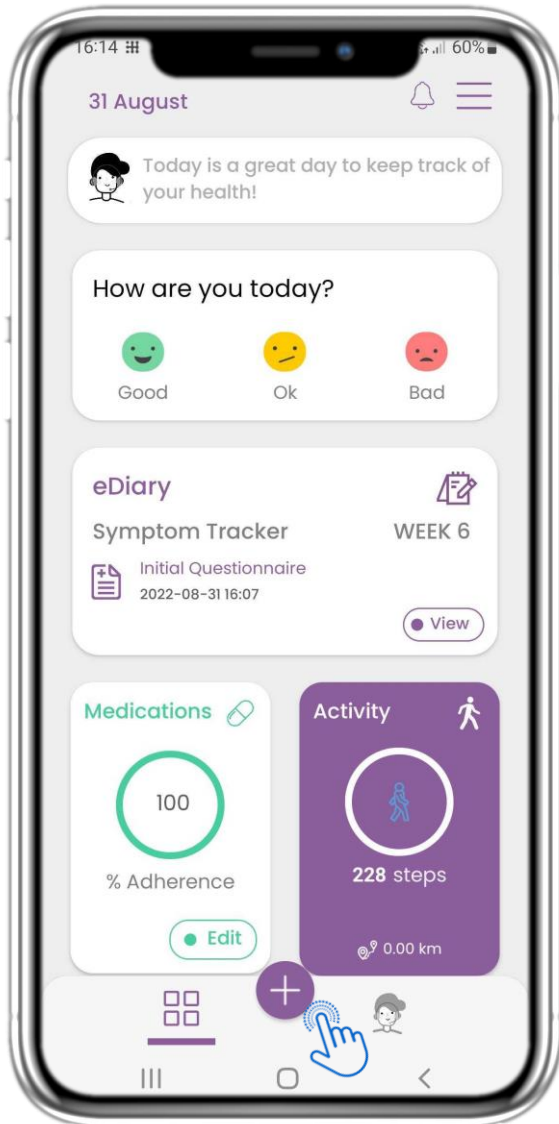
5.1 ADD REPORTS/ SYMPTOMS

From the bottom bar you can select to add reports
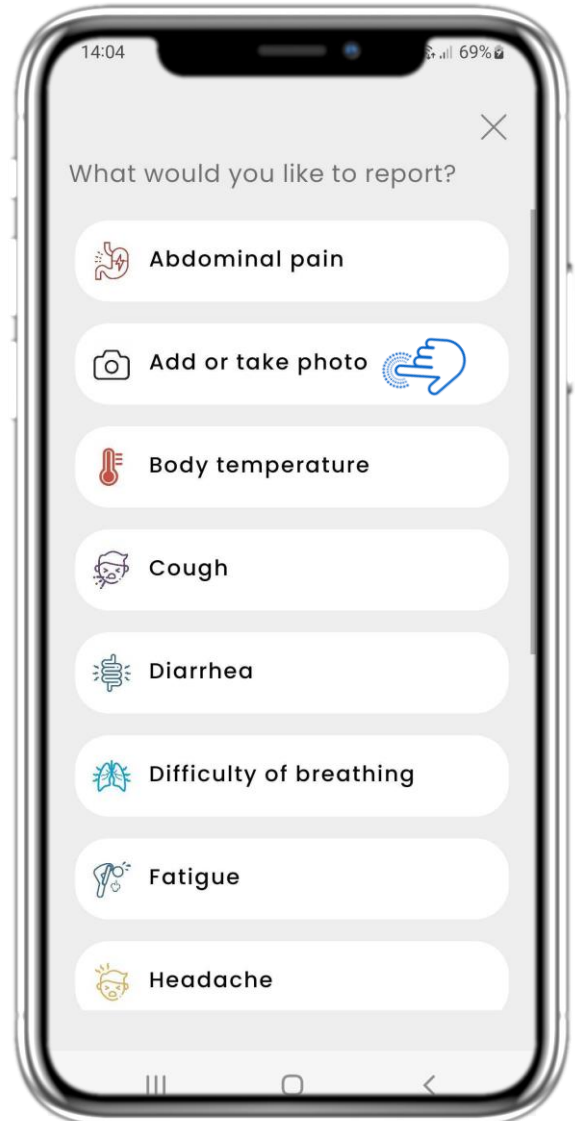
5.2 ADD REPORTS/ SYMPTOMS

Opens a list of available questionnaires to ADD report or Symptom from the central (+).

5. ANSWER REPORTS & QUESTIONNAIRES
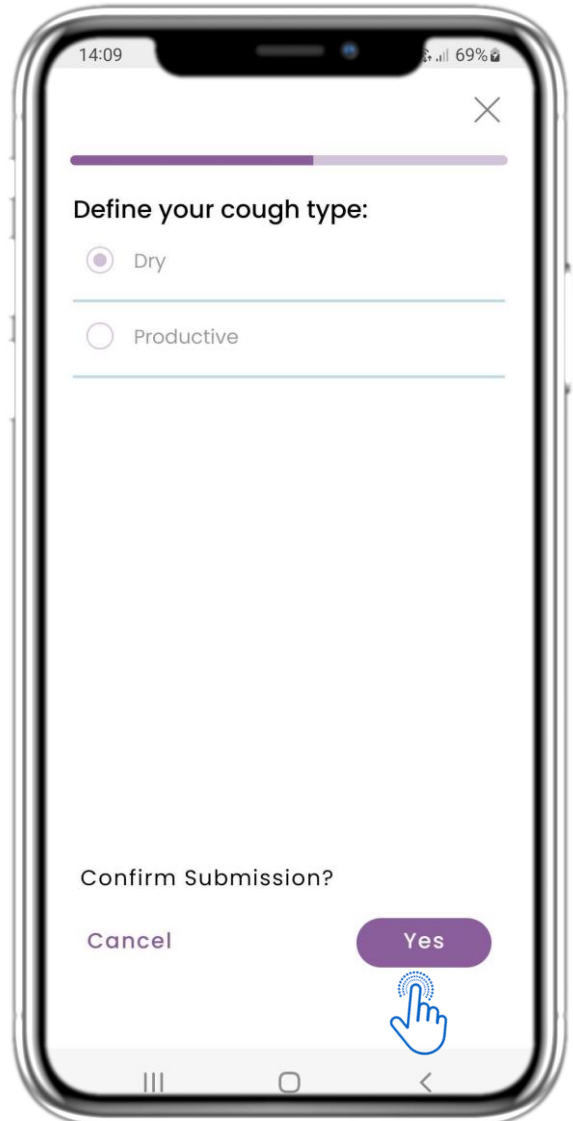
5.3 ANSWER REPORTS/ QUESTIONNAIRES

Answer questionnaire related to symptom you selected. Define the day & time the symptom started. Click NEXT/PREVIOUS to navigate in the questionnaire. Click Yes to confirm submission or CANCEL to exit.

6 CHATBOT
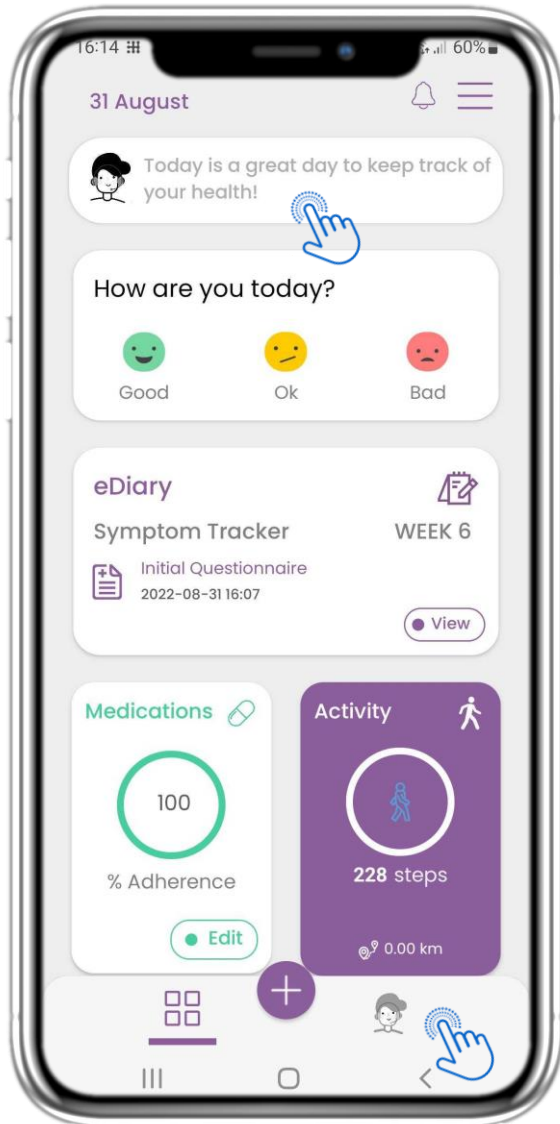
6.1 CHATBOT

From the bottom bar you can select to move to the chatbot or from the message at the top.
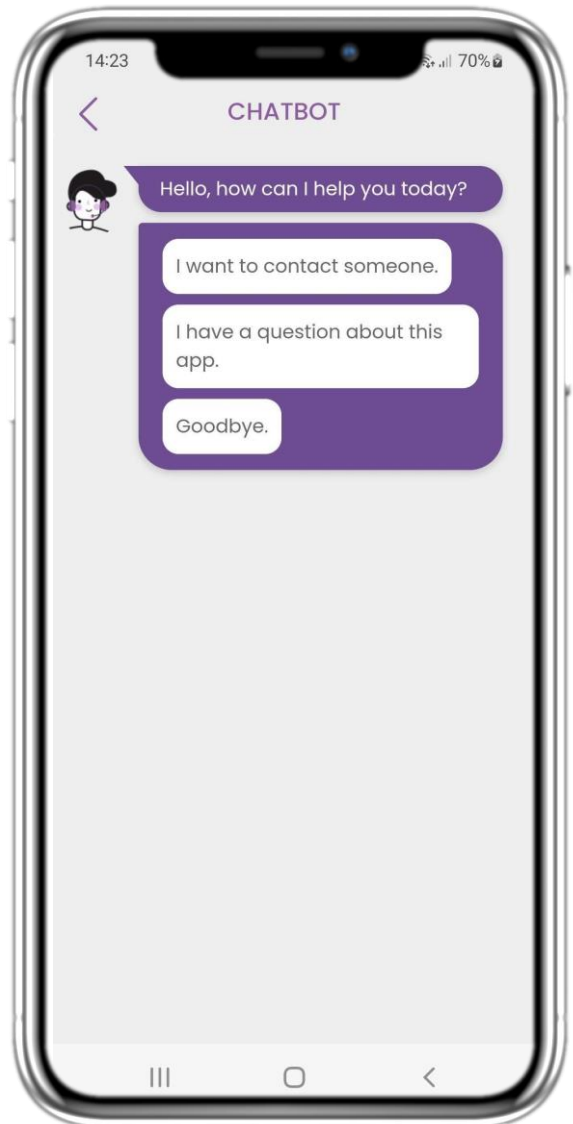
6.2 CHATBOT CONVERSATION

In the Chatbot you are greeted and shown any pending questionnaires. Chatbot gives you available options of questions and answers.

7 MENU SIDEBAR
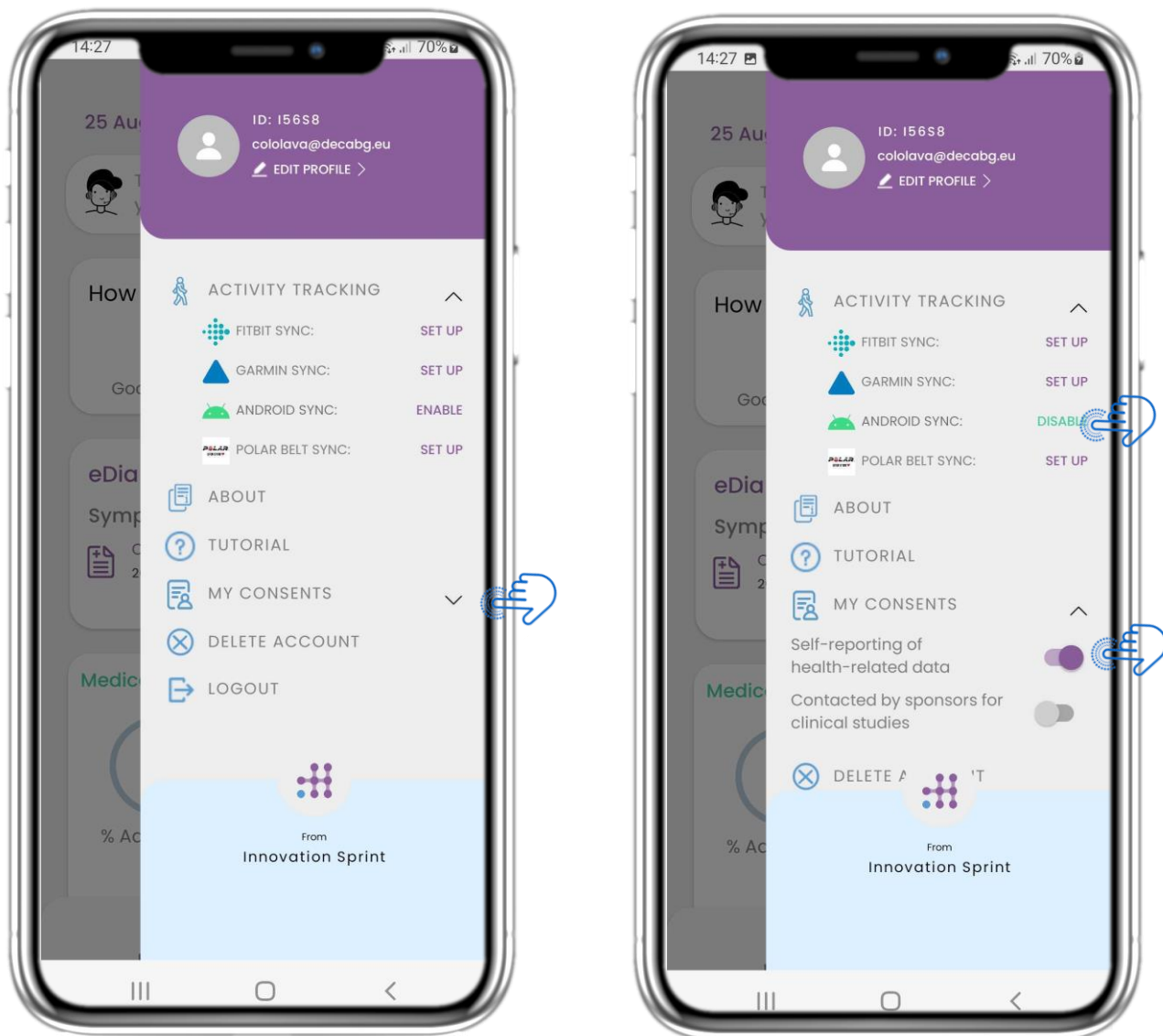
7.1 SIDEBAR OPTIONS

From the menu bar you can edit your profile, set up your activity tracker and enable or disable the optional consents from the registration.
You can also have access to some content pages like Study Information or FAQ

7 MENU - MY PROFILE
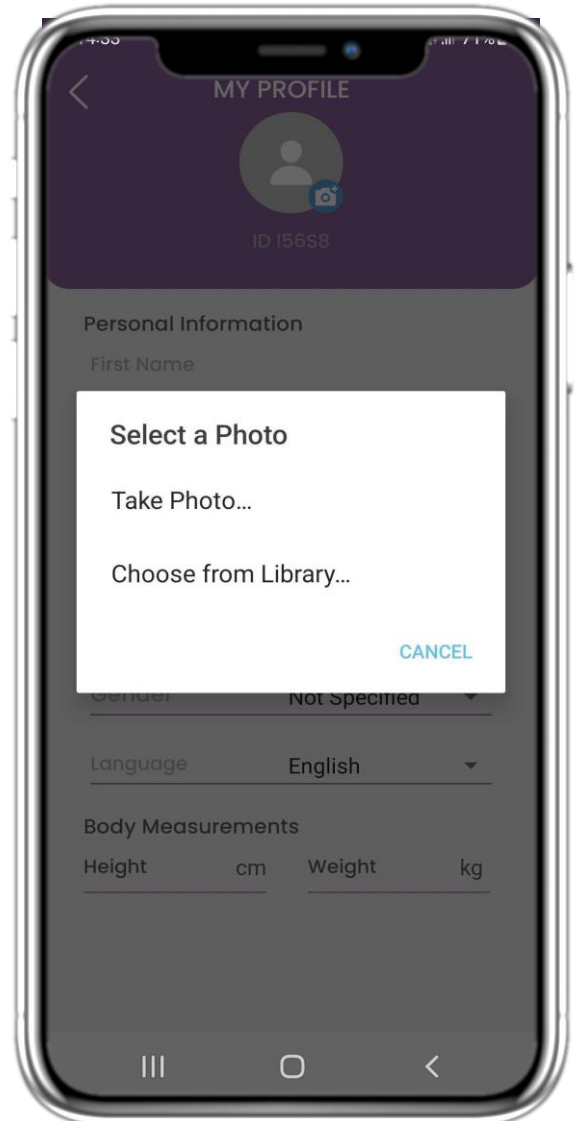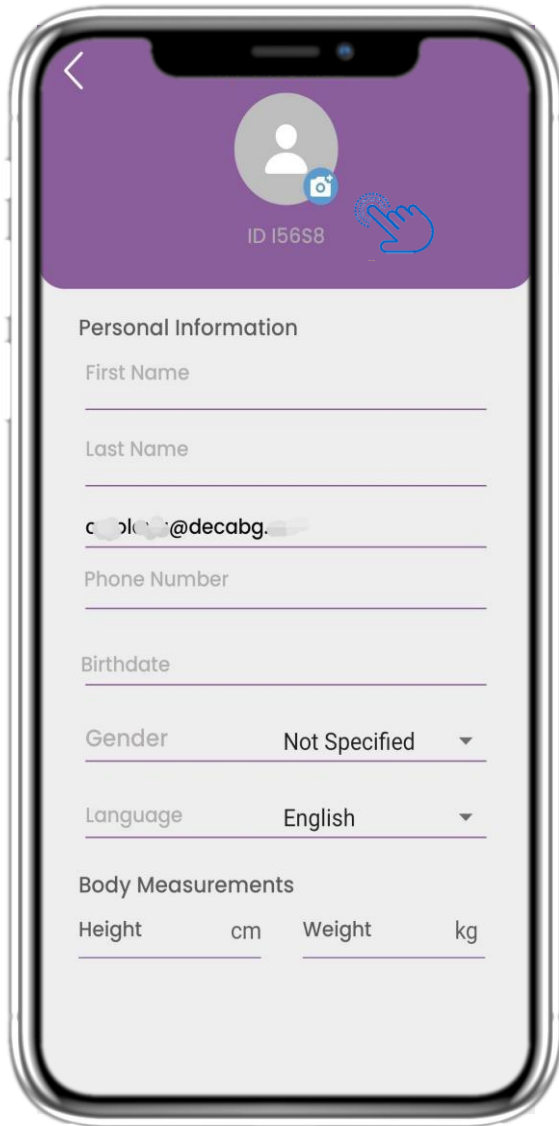
7.2 EDIT PROFILE

You can edit your profile and pick a picture also. The ID is the identification number that will be used for communication with the clinical team.

7 MENU – LOGOUT – DELETE ACCOUNT
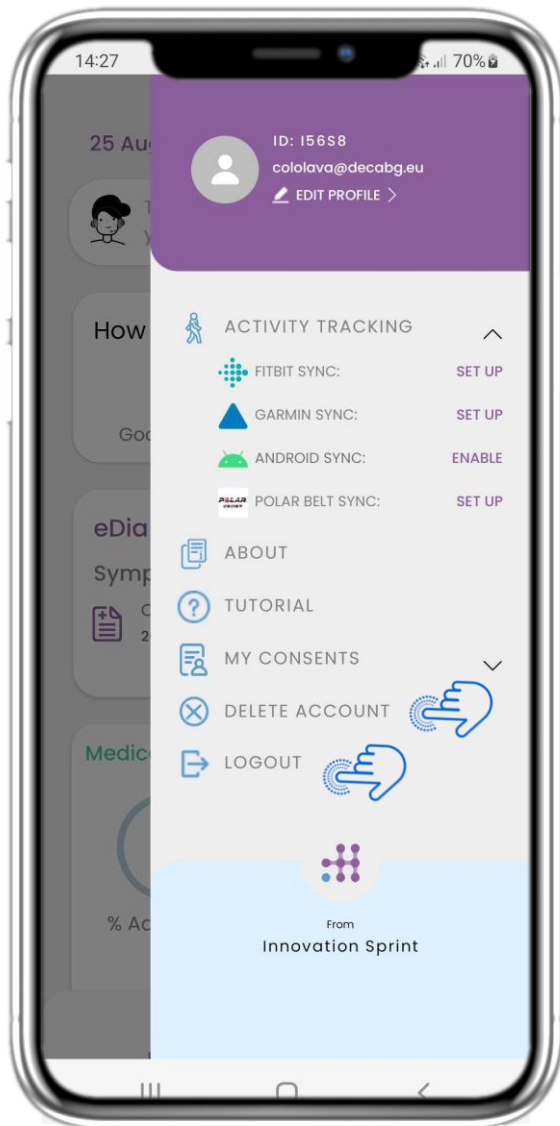
7.3 LOGOUT

Select LOGOUT. Remember that Healthentia cannot track data when logged out.

7.4 DELETE ACCOUNT

Select DELETE ACCOUNT to send a deletion request for your account to be deleted.
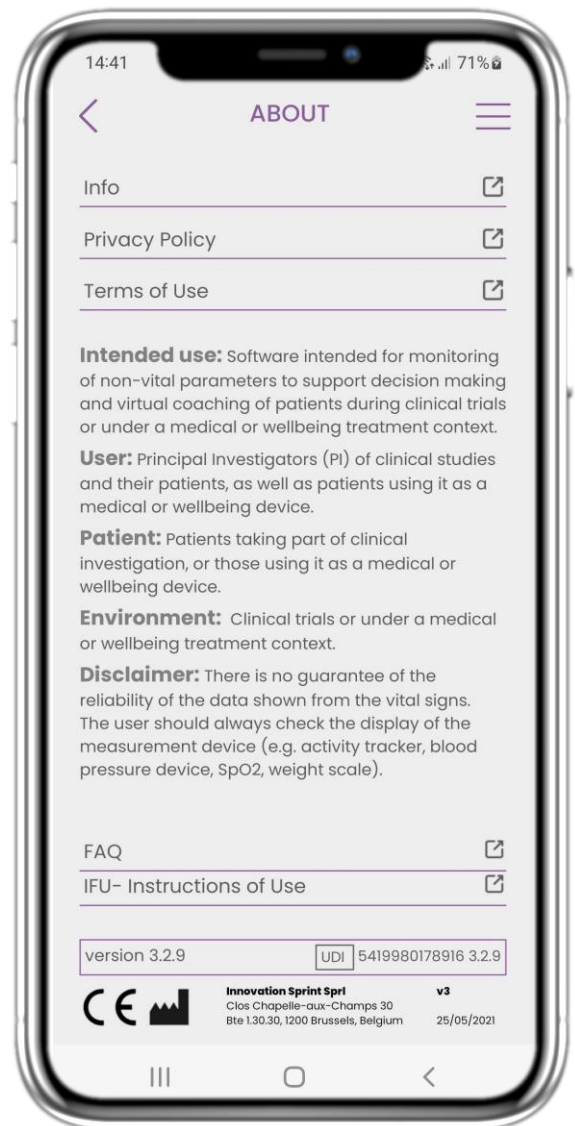
7.5 ABOUT- IFU

In the ABOUT page you can find all information related to the use of Healthentia app.

Information

Healthentia consists of a collection of modules. Several modules are medical software covered by the CE mark (Class I per rule 12 of Annex IX of Directive 93/42/EEC):

- Virtual Coaching: It allows the user (subject/patient) to interact with an embodied conversational coach for informative and motivational purposes.

- eDiary: The e-Diary enables the presentation of any reported outcomes of the patient, in the form of a list, grouped by day or outcome (symptom). In this way, patients can have anytime access to their electronic Diary and see the progress of their reported outcomes.

- Physical activity: The physical activity widget gives an overview on the steps walked.

- Sleep: The sleep widget gives an overview on the sleep duration.

- Liquid consumption: The liquid consumption widget gives an overview on the water consumed.

- Nutrition: The nutrition widget offers the ability to see and edit the consumption of different food categories of interest.

- Weight: The weight widget offers the ability to add manually and through a digital scale, measure and view the weight.

For more information, please visit: https://healthentia.com

For any privacy-related questions or requests, you can contact: dpo@healthentia.com

For general questions, you can contact: info@healthentia.com

Report of a serious incident

For any serious incident that has occurred in relation to the Healthentia Medical Device App, you can contact the manufacturer (Innovation Sprint Sprl) at: support@healthentia.com and the authority having jurisdiction in your locale.

Technical support

Healthentia support service is offered at a best-effort level.

For any technical support queries, you can contact: support@healthentia.com

Our support team will reply to you within 1 working day.

Paper-version of IFU

If you would like a paper version of the instructions for use, please contact the manufacturer at the following e-mail address: info@healthentia.com.
It will be delivered within 7 calendar days after receiving the request.

Intended use & user

Intended Use: The intended use of the device is: Software intended for monitoring non-vital parameters to support decision-making and virtual coaching of patients during clinical trials or under a medical or well-being treatment context.

User: Principal Investigators (PI) of clinical studies and their patients, as well as patients using it as a medical or well-being device.

Contra-indications

- Any physical or cognitive condition that, in clinical judgment, would prevent the patient from using Healthentia, e.g., dementia.

- The device is not intended to replace the care of a health care professional, including prescription, diagnosis, or treatment. The device should not be used during pregnancy.

- Healthentia has not been tested on the pediatric population. Therefore, Healthentia is intended for adult use only (>18 years old) and does not cover use by children.

- Consult periodically the Alerts dashboard as it may influence the follow-up of your patients.

Warnings

- Healthentia is not monitored in real-time by healthcare personnel; it is intended for non-emergency communication only. In case of an emergency, contact your care unit or the emergency number by phone.

- In some special cases, the self-care advice and instructions provided by Healthentia may not be applicable to your situation.

- If you have questions about your care, symptoms, and management, contact your healthcare team.

- The device is not intended to replace the care of a healthcare professional, including prescription, diagnosis, or treatment.

- Telemonitoring does not replace regular check-ups with your doctor. Consult your doctor in case of severe and persistent symptoms.

- In combination with Healthentia, use only measuring devices for which the technical performances (accuracy, precision) have been verified by your healthcare provider as it may affect the outcome of your monitoring.

- Verify the consistency of your clinical data and the good transfer of them to your healthcare provider as the quality of the diagnosis and treatment is partially based on this information.

Disclaimer

Your healthcare provider is responsible of the final assessment of your diagnosis and treatment.

Healthentia is providing information to support diagnostic and therapeutic decision, but the overall clinical context should be taken into consideration before taking any decision.

Minimum requirements

Supported hardware

Any smartphone that is using the supported Operating System (OS) – see below- is a supported hardware device.

Supported mobile OS

Healthentia App supports the following operating systems in the Android and iOS platforms:

- Android: 6.0 and above

- iOS: 10.0 and above

Integration with other devices

Healthentia App is compatible with other devices. The supported devices intended for use together with Healthentia are:

- Garmin trackers and watches via the Garmin API (Android & iOS): Fenix 5 pro, Fenix 6 pro, Forerunner 945, Vivoactive 4, Vivosmart 4, Venu 2S,

- Fitbit trackers and watches via the Fitbit API (Android & iOS): Versa, Inspire 2

- iHealth devices via Bluetooth (Android & iOS): Connected Blood Pressure Monitor iHealth Track (KN-550BT), Smart body composition scale iHealth Fit (HS2S), Smart Pulse Oximeter - iHealth Air (POM3)

- Polar belt via the Polar API (Android & iOS): H9

In combination with Healthentia, use only measuring devices prescribed by your healthcare provider as it may affect the outcome of your monitoring.

Healthentia is not intended to monitor vital parameters. For the avoidance of doubt, such parameters are highlighted in the application, so that users are informed about them. Furthermore, there is no guarantee of the reliability of the data shown and the user should always refer to the display of the measurement device (e.g., activity tracker).

Training

No training is required to use the device safely.

Security & performance

Security

Innovation Sprint is committed to protecting the security of data subject's information and takes reasonable precautions to protect it, including protection against unauthorised access, necessary to run the software as intended. In this context, Innovation Sprint regularly evaluates and reviews technologies, facilities, procedures and potential risks to maintain the security and privacy of users' data, paying particular attention to role-based access and logging of health data access. Moreover, any potential changes to software applications, provided services and/or hardware systems are properly justified, evaluated and registered based on international best practices and standards.

- Avoid using public wi-fi networks to connect to Healthentia when you are about to add and/or manage health data and/or your profile details.

- Do not use jailbroken devices.

- Passwords should be at least eight (8) characters long, contain characters from three of the following four groups: Lowercase letters, Uppercase letters, Numbers (0-9), Special characters.

- Never store your passwords on your devices.

- Change your passwords at least every six months.

- Install an anti-malware program on your devices and update it regularly.

- Make sure that each e-mail you register in Healthentia corresponds to you.

- Ignore and delete messages of doubtful origin and do not follow links that include and refer to websites.

- Do not reveal by phone, e-mail, Internet form, or social media, confidential information such as your username, password.

- Always use the most up-to-date versions of your device operating system and Healthentia App.

- The user is suggested to keep the Bluetooth setting in "not discoverable" (transmission disabled) and switch to "discoverable" mode only when he/she wants to use it.

- The user should avoid storing critical information (account credentials) on his/her Bluetooth-enabled devices.

- If the user is going to connect with a device via Bluetooth, it is strongly suggested to activate this connection in a safe place.

Performance

Provide objective inputs for healthcare professionals to support diagnosis and patient management; Highlight evolution of physiological parameters by trends analysis of the patient's inputs; Increase patient's adherence to treatment