INSTRUCTIONS FOR USE

PATIENTS

IFU Version v2.9

INNOVATION SPRINT SRL
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1200 Brussels, Belgium

REF Healthentia – Mobile-app
SN V4.0

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Document History

Document Version	Nature of change	Date
2.6	Updated Supported mobile OS (Minimum Requirements)	01.06.2025
2.7	Updated part integration with other devices (Withings is added)	22.04.2026
2.8	Updated part integration with other devices (Fitbit API is replaced by Google Health API)	28.09.2026
2.9	Description of behavior change coaching content and of wellbeing messages (Information, Chatbot)	23.11.2026

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INFORMATION

The Healthentia App consists of a collection of modules. Several modules are medical software covered by the CE mark according to the European Regulation 2017/745:

- **Virtual Coaching** It allows the user (subject/patient) to interact with an embodied conversational coach for informative and motivational purposes. Coaching content is selected for you with the support of an automated system, from content approved in advance, within a coaching plan your healthcare professional approved. Messages labelled "wellbeing" contain general lifestyle information; they are not part of your medical care and never replace contacting your healthcare team.
- **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.
- **Vital**: The vital signs are both collected from and viewed by mobile app users using widgets.
- **Questionnaires**: It allows the user to communicate outcomes and outcomes scores in a structured manner.
- **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.

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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 serious incident

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

Technical support

Healthentia support service is offered at 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.

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INTENDED PURPOSE

Healthentia App is part of Healthentia solution, a software intended for: a) the collection and transmission of physiological data including heart rate, blood pressure, oxygen saturation, and weight directly to care providers via automated electronic means in combination with validated IoT devices; b) the visualization (subjects-based dashboards) and the mathematical treatment of data (trends analysis, alerts) related to the monitored chronic disease subject's physiological parameters; c) the transmission of patient's outcomes and outcome scores related to patient's health status, health-affecting factors, health-related quality of life, disease knowledge and adherence to treatment through validated questionnaires; d) the user (subject/patient) interaction with a conversational virtual coach for informative and motivational purposes, in order to support subject telemonitoring, decision making and virtual coaching.

CLINICAL BENEFITS

The use of Healthentia allows to:

- Provide objective inputs for healthcare professionals to support diagnosis.
- Highlight evolution of physiological parameters by trends analysis of the patient's inputs
- Allow healthcare professionals to provide the same quality of care and safety as the standard of care.

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CLINICAL INDICATIONS

Telemonitoring of chronic disease (such as heart failure, cancer, COPD, etc.)

CONTRA-INDICATIONS

- Healthentia is not intended for the monitoring of patients in critical situations (operating room, emergency, intensive care).
- Any physical or cognitive condition that, in clinical judgment, would prevent the patient from using Healthentia, e.g. dementia.
- The device should not be used during pregnancy.
- Healthentia App has not been tested with paediatric population. Therefore, Healthentia App is intended for adult use only (>18 years old) and does not cover use by children without supervision.

PATIENTS TARGET GROUP

Chronic disease patients taking part of clinical investigation or a medical treatment

INTENDED USERS

Telemonitored patients and their healthcare professionals

USE ENVIRONMENT AND DURATION

Healthentia App can be used as Remote Patient Monitoring solution for patients that are released from hospital and have to follow a certain treatment. Duration depends on the study or intervention or patient's will.

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.

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- 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.

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Accuracy requirements

The accuracy requirements for IoT devices that are connected to Healthentia are listed below.

measurement	Min. accuracy
Blood pressure	<10mmHg (at least 85% probability)
SpO2	A_{rms} ±2-3% of arterial blood gas values
Heart (RHR, max, …)	±10% of the input rate or ±5 bpm
Weight	±0.5-1.0 kg
Physical activity (steps, …)	n/a
Sleep	n/a

Integration with other devices

Healthentia App is compatible with other devices to collect lifestyle information and vital signs. 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 Google Health 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**
- Withings devices via cellular connectivity (Android & iOS): Smart Blood Pressure monitor - Withings BPM PRO 2*, BPM PRO*, Smart composition scale - Withings Body Pro *

* Device has acceptable accuracy for the intended purpose of Healthentia

** Device does not have acceptable accuracy for the intended purpose of Healthentia and can only be used for measurements that do not require accuracy (e.g. step counter, sleep).

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

These devices constitute a safe combination and currently there is no device specific information on any known restrictions to combinations.

Healthentia displays values in international metrics (m, kg, s) regardless of the preference of the user in his/her IoT device.

MINIMUM REQUIREMENTS

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

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

- Android: 7.0 and above
- iOS: 15.1 and above

Training
No training is required to use the device safely.

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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.

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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.

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1 DOWNLOAD APPLICATION



Download Healthentia APP from iOS AppStore or Google Play Store.

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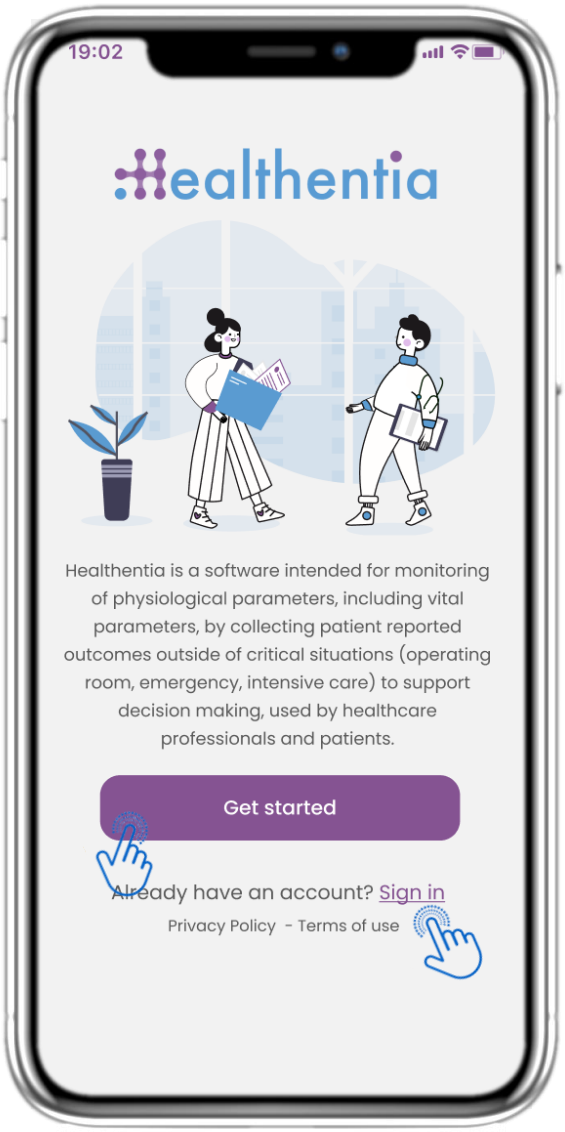
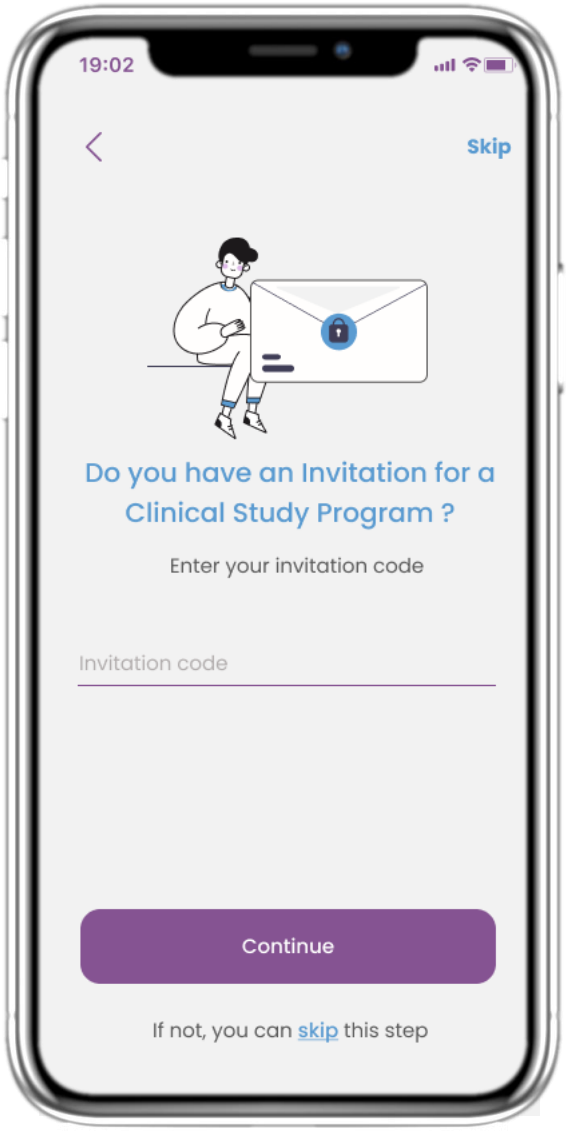
2 WELCOME / REGISTER



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.

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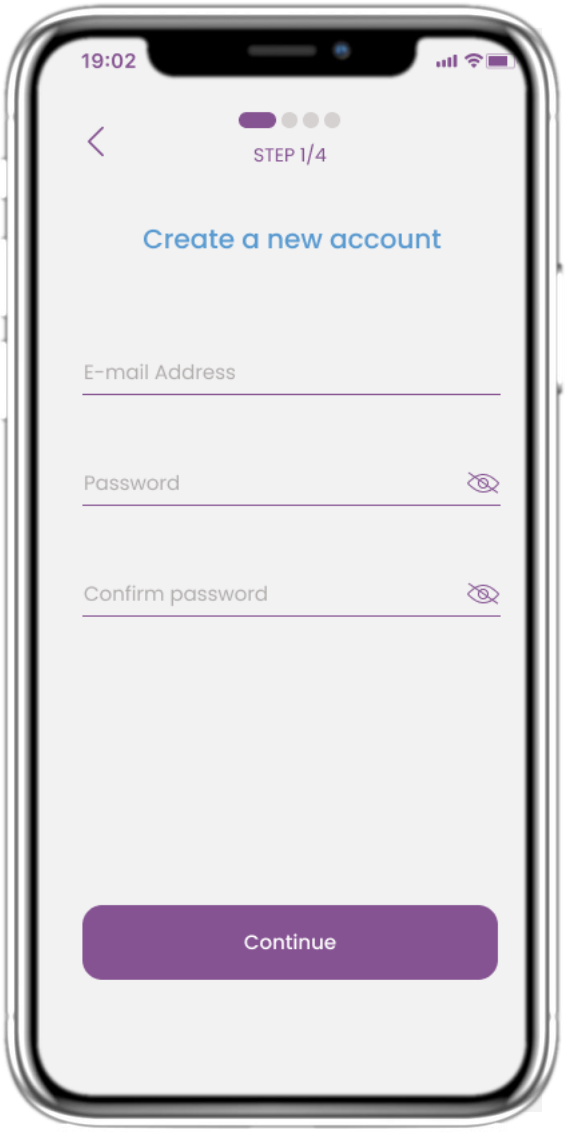
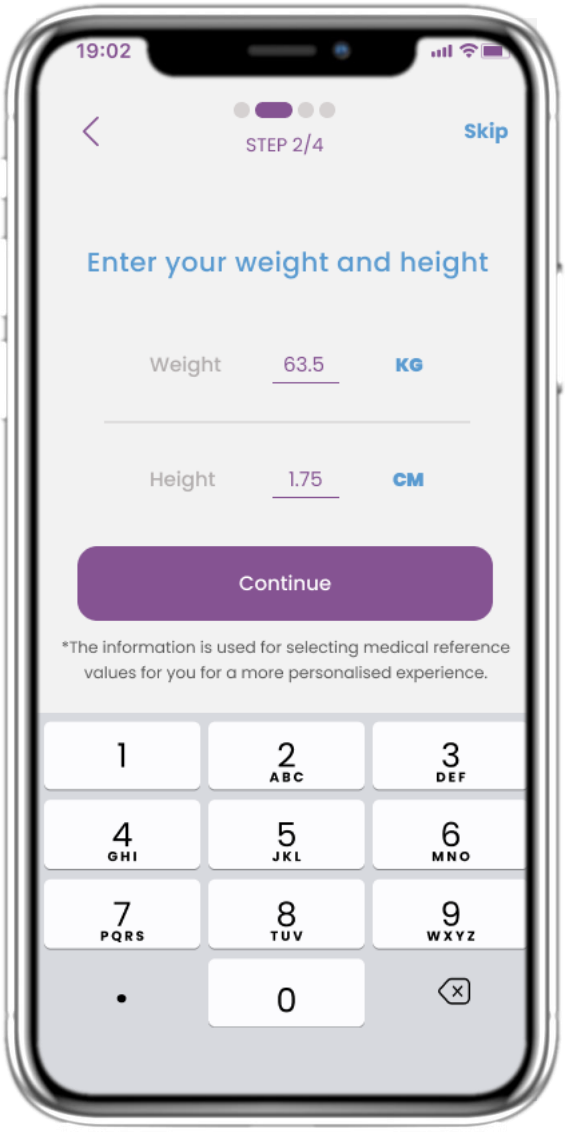
2 ONBOARDING QUESTIONNAIRE



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.

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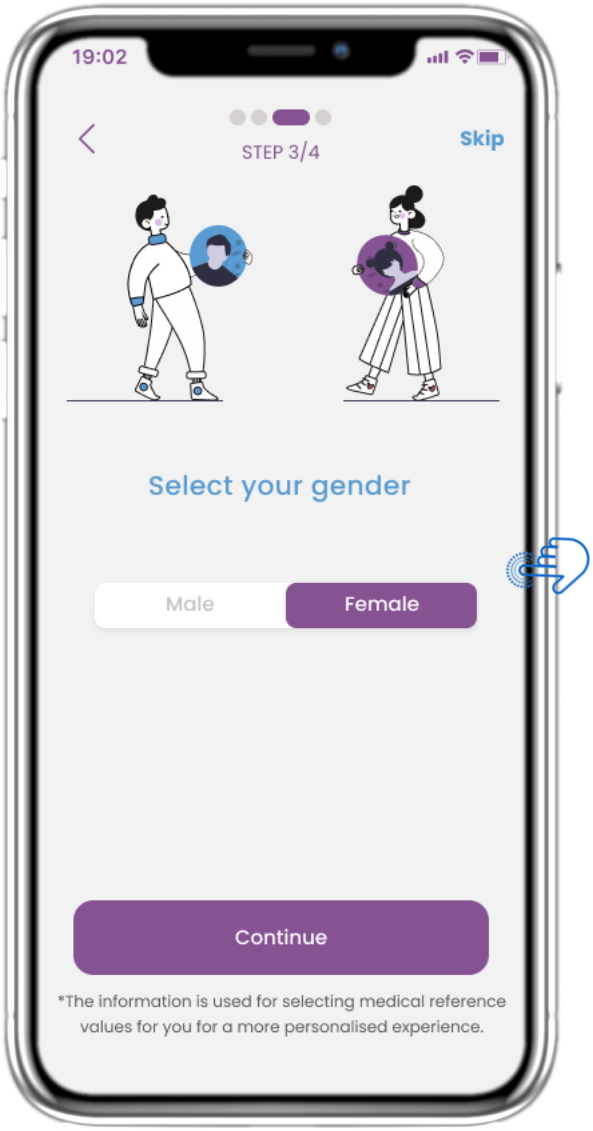
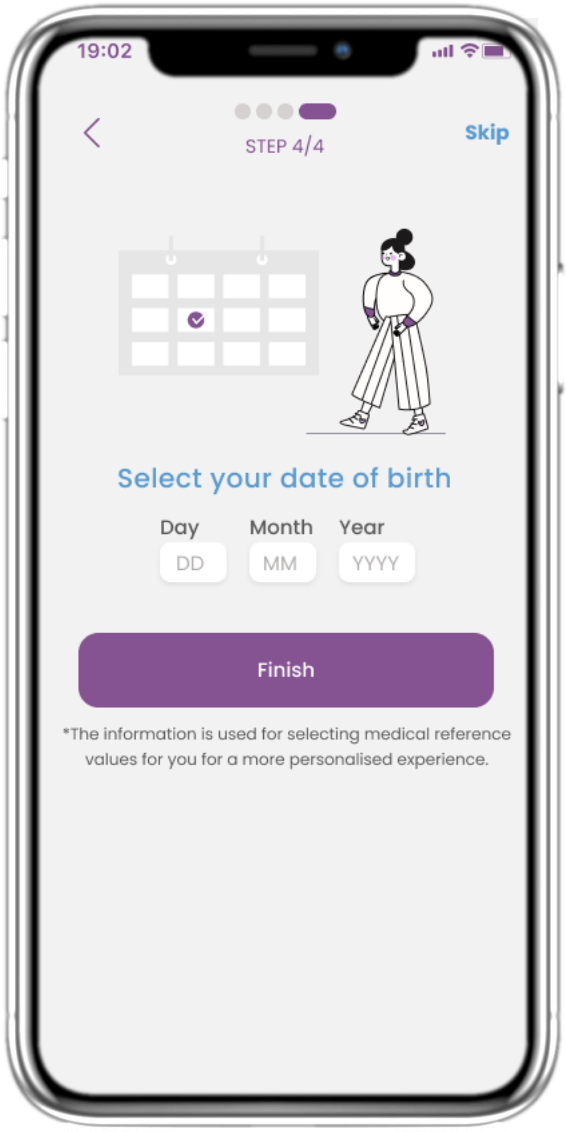
2 ONBOARDING QUESTIONNAIRE



2.5 SELECT GENDER

Pick your gender for your profile.



2.6 SELECT BIRTHDATE

Pick your date of Birth for your profile.

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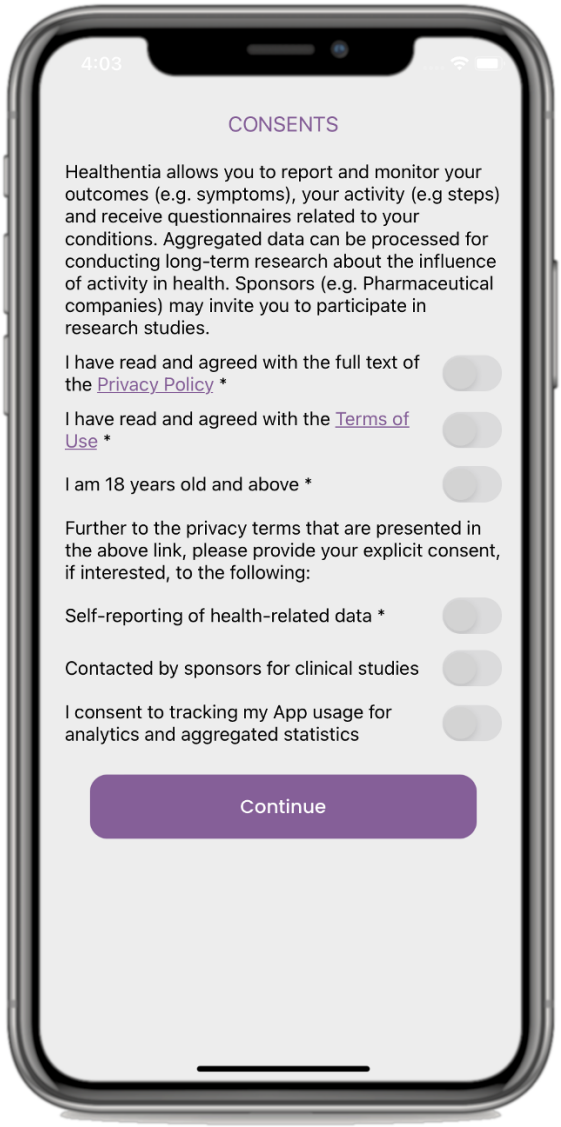
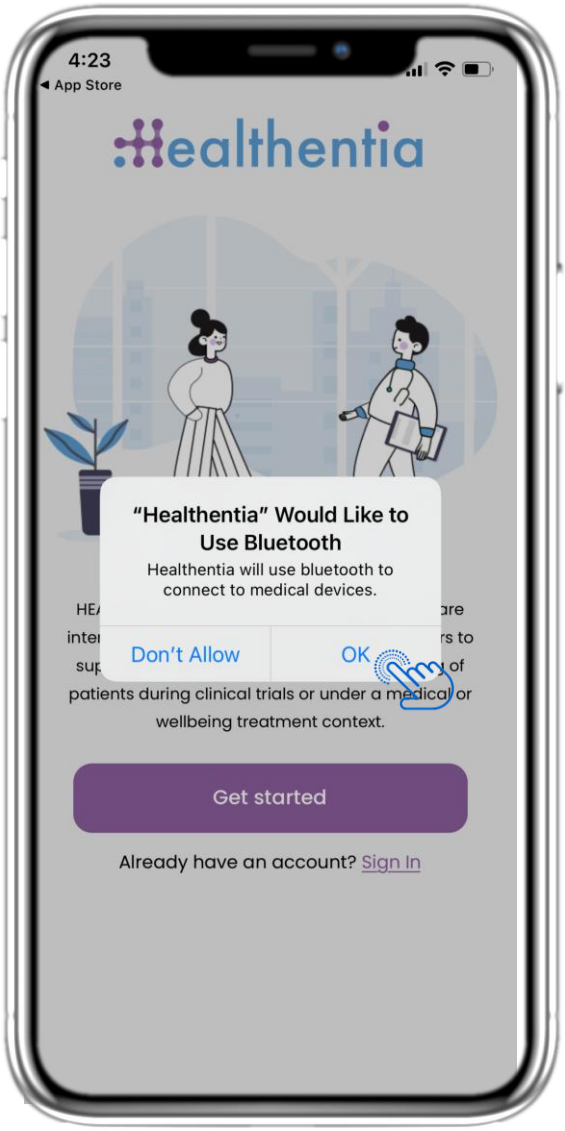
2 CONSENTS / PERMISSIONS





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.

2.9 PERMISSIONS NOTIFICATION

Give permission to the Healthentia app, to send you notifications, use Bluetooth and connect to other devices.

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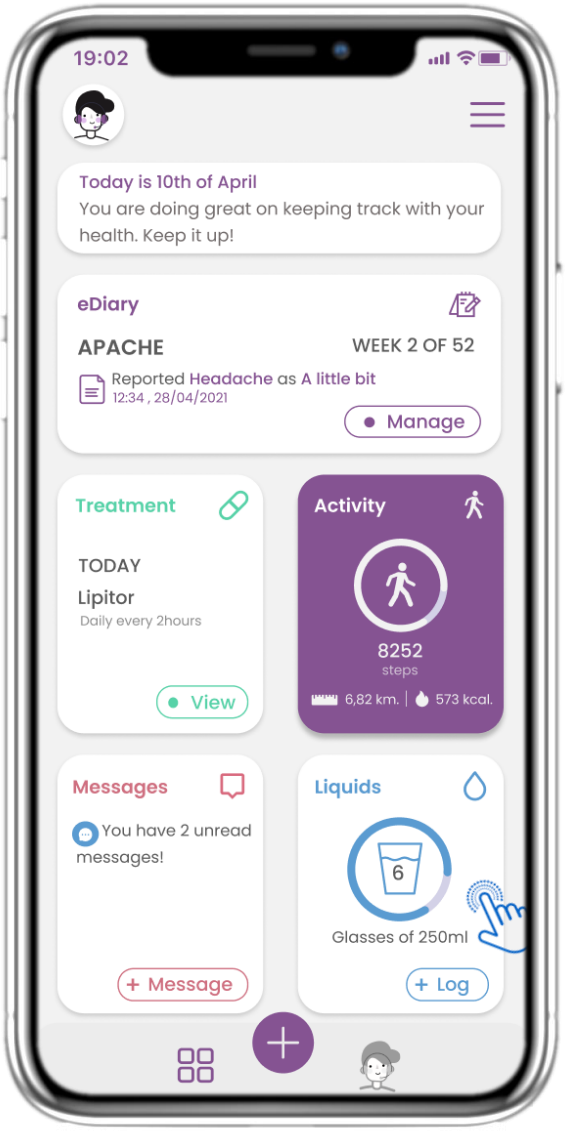
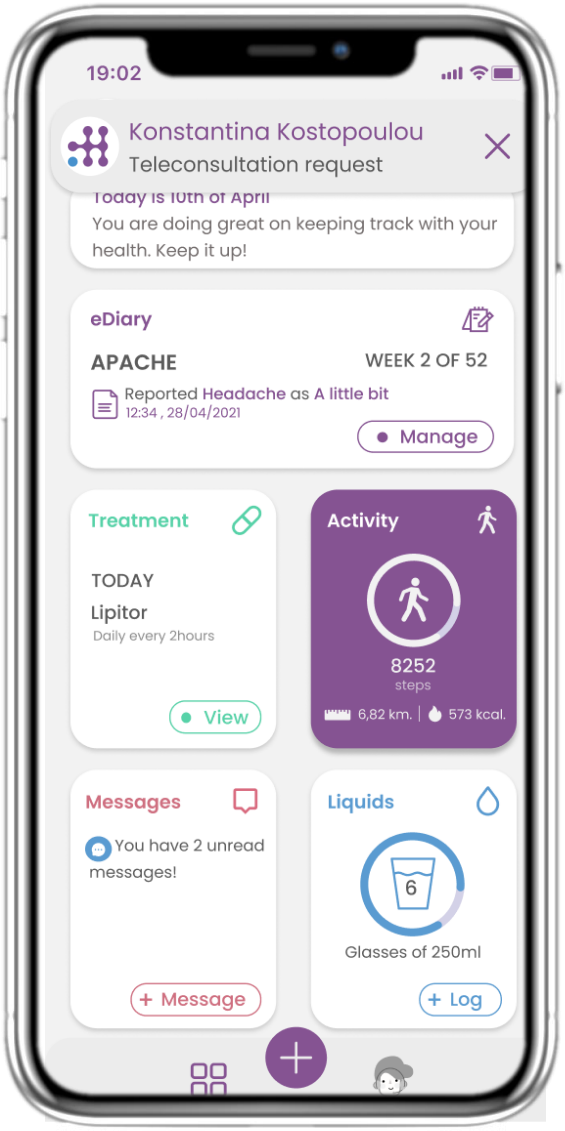
3 HOME & PUSH NOTIFICATIONS





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.

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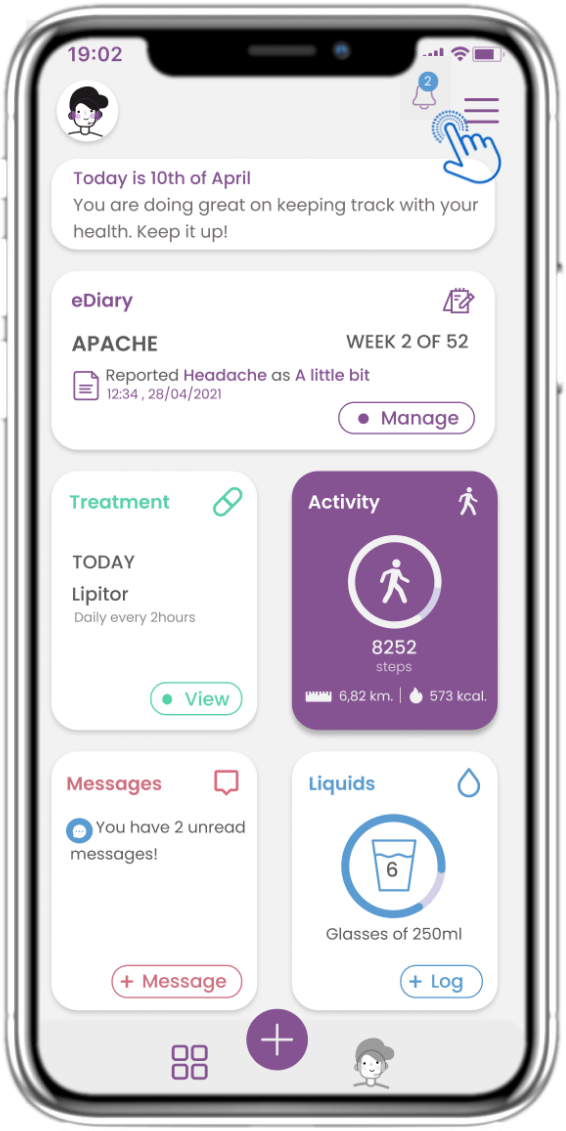
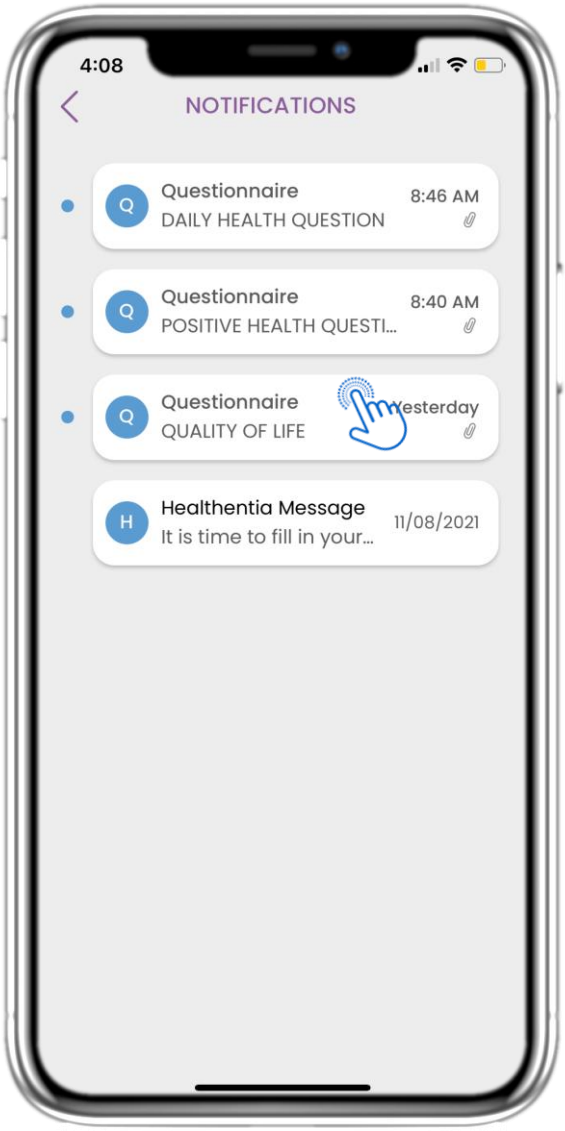
3 HOME & PUSH NOTIFICATIONS



3.3 NOTIFICATIONS

In the HOME page you can see the pending questionnaires in the form of notifications in the upper right corner with bell icon.



3.4 NOTIFICATIONS

In the Notifications page you can find a list of the pending questionnaires you need to answer.

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3 HOME & PUSH NOTIFICATIONS



3.5 FORCED UPDATE

When a new version of the app that is mandatory for update is available, patients see the above information and cannot use the app, unless they click to update.

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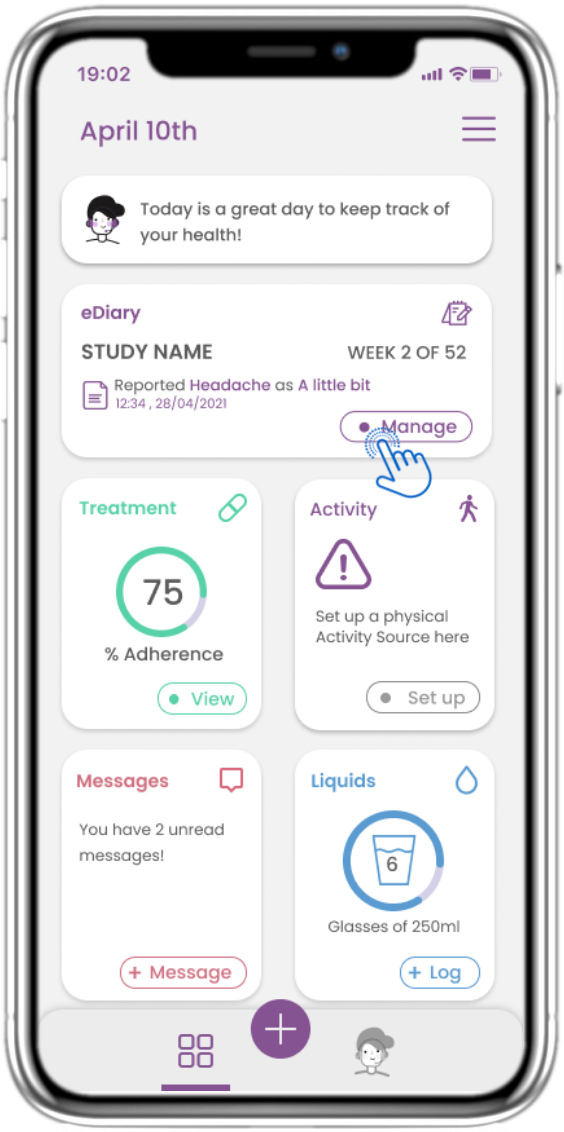
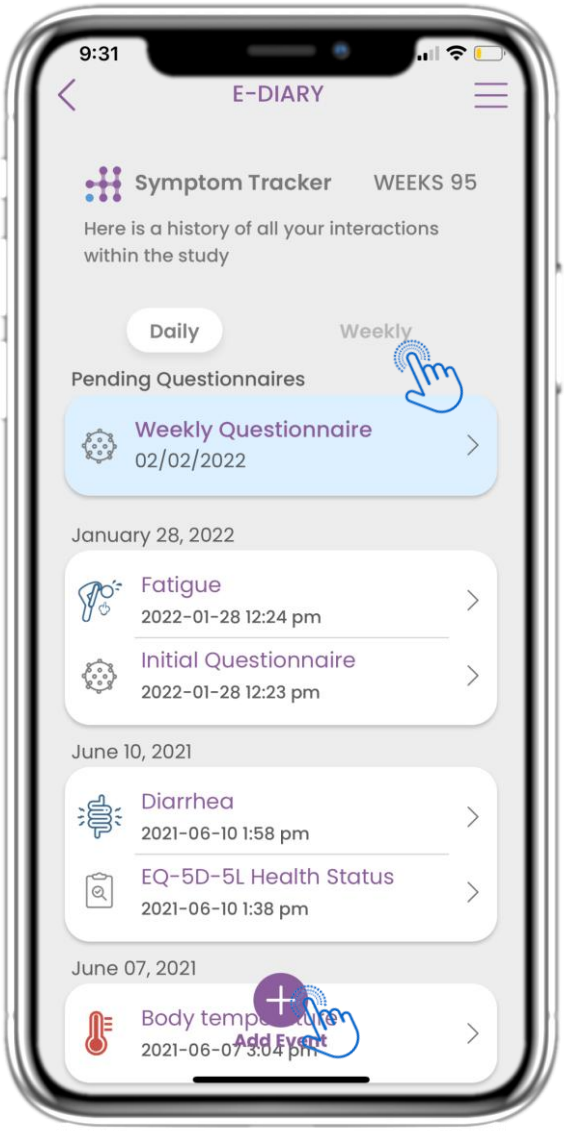
4 HOME WIDGETS



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 and weekly update of your reports and submitted questionnaires. Also you can use the (+) button to add a new event.

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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.

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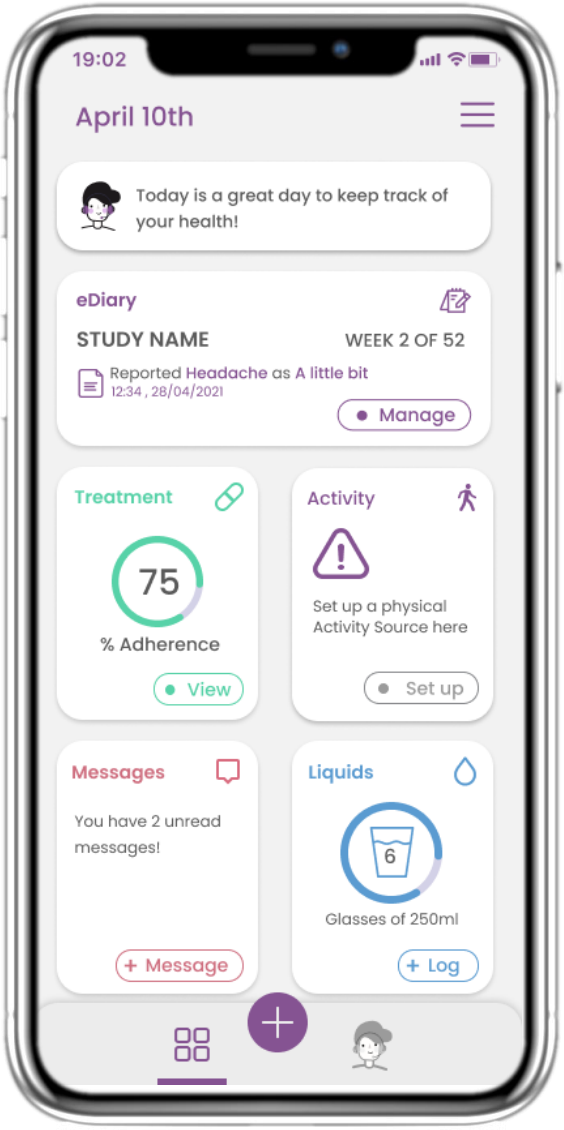
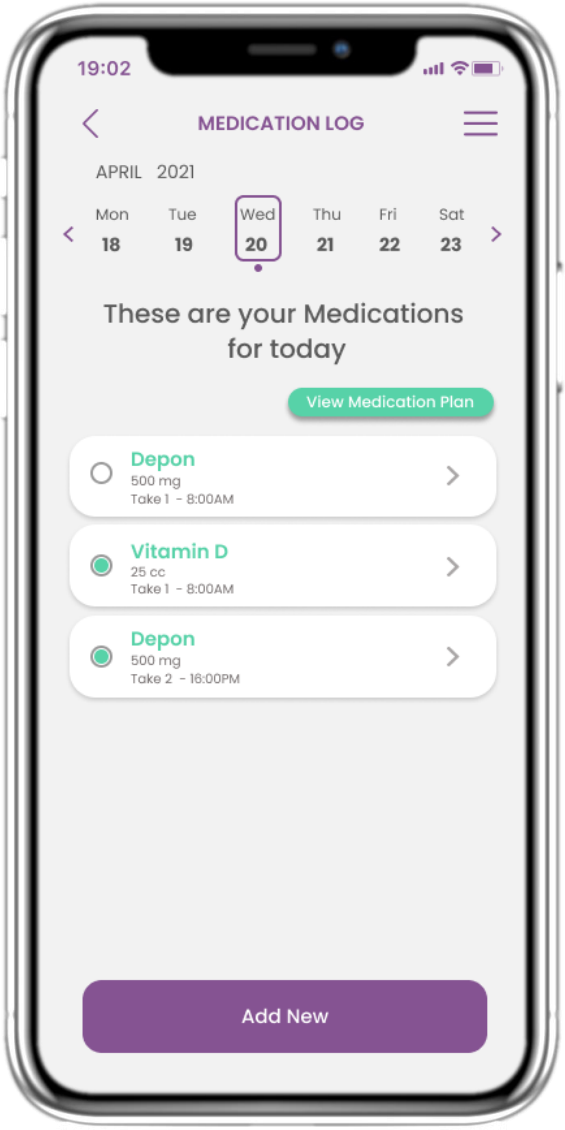
4 HOME WIDGETS



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.

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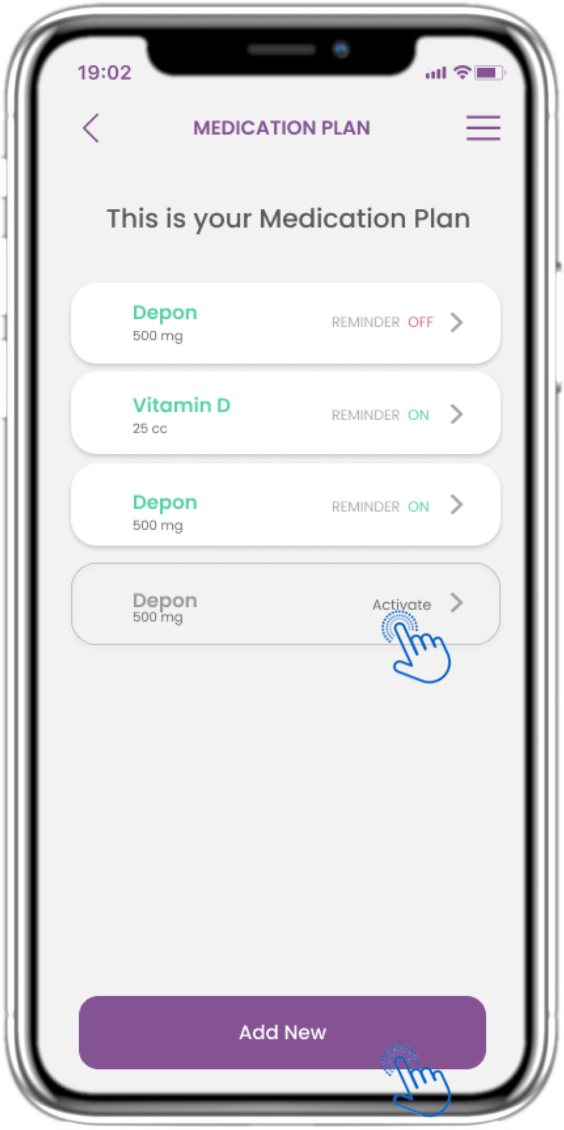
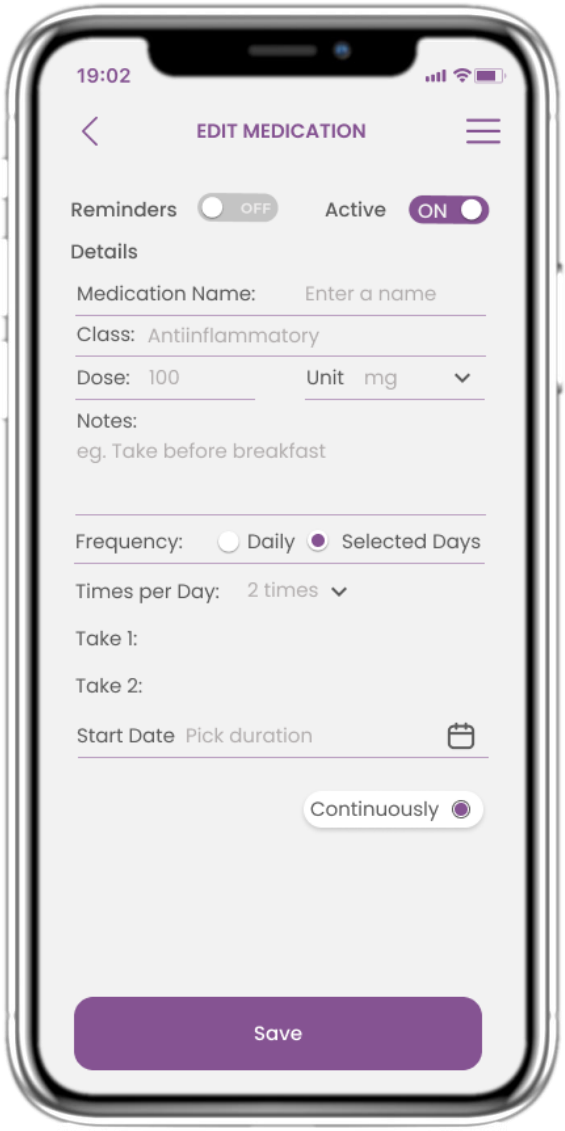
4 HOME WIDGETS





4.7 SEE ALL MEDICATIONS

In the treatment page you can access and configure all treatments

4.8 ADD/EDIT NEW MEDICATON

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

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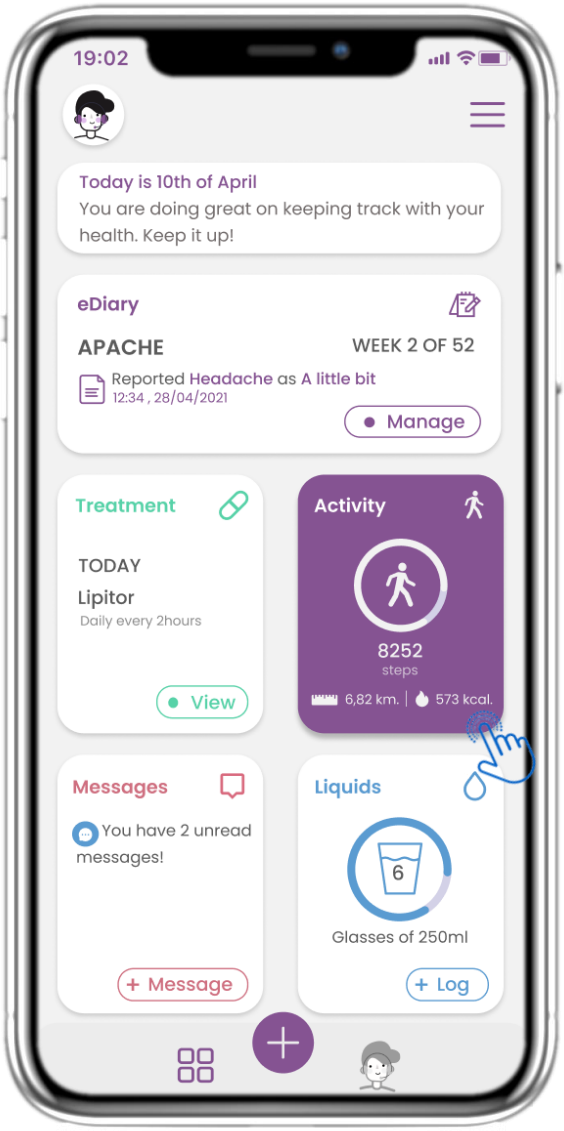
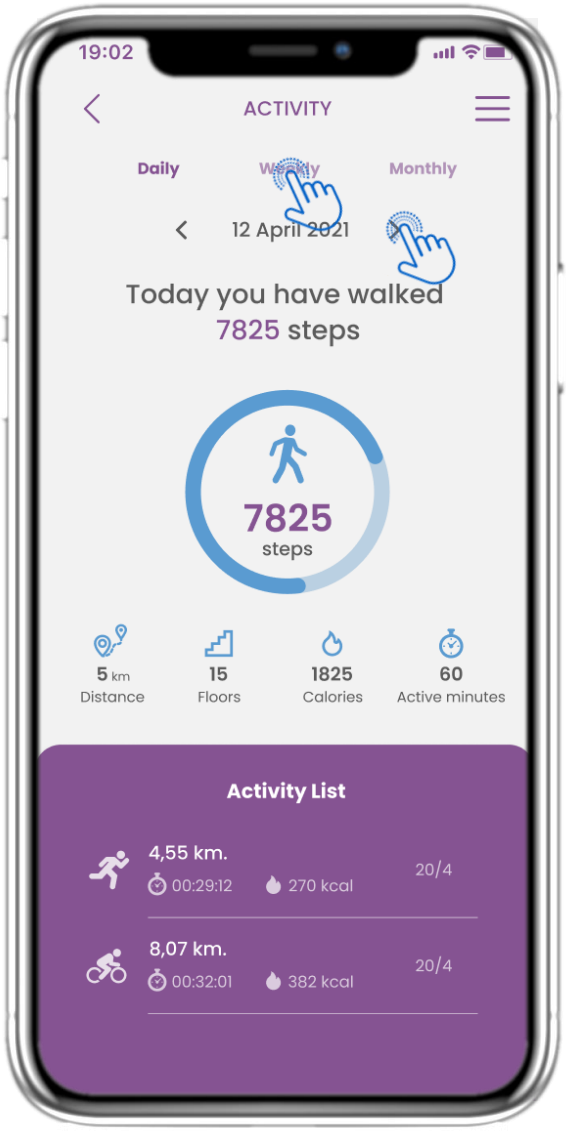
4 HOME WIDGETS





4.9 ACTIVITY

In the HOME page you can find the Activity widget which is used to set up your tracker.

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.

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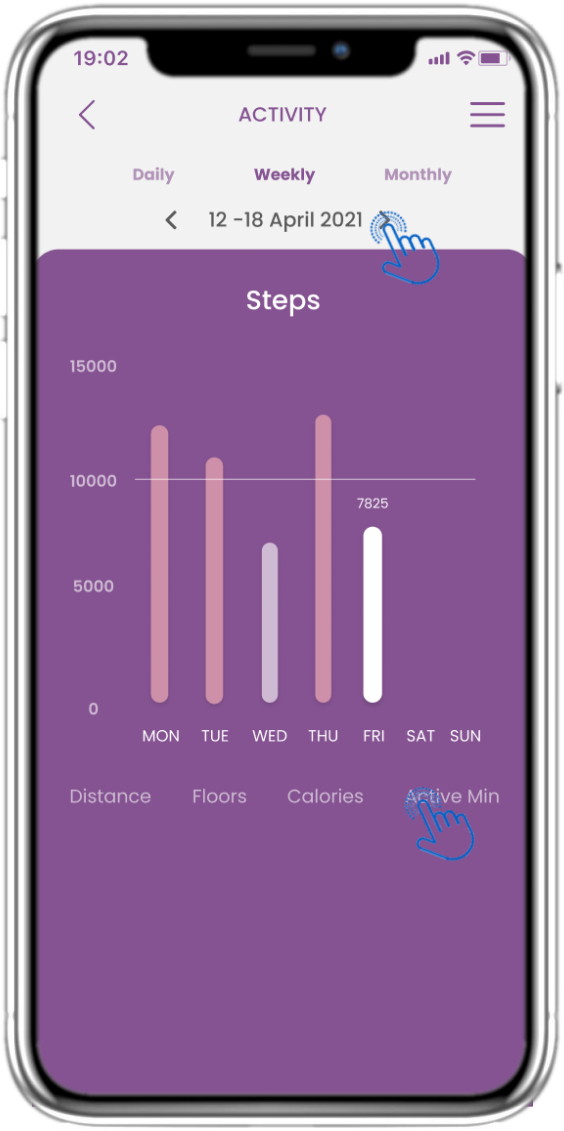
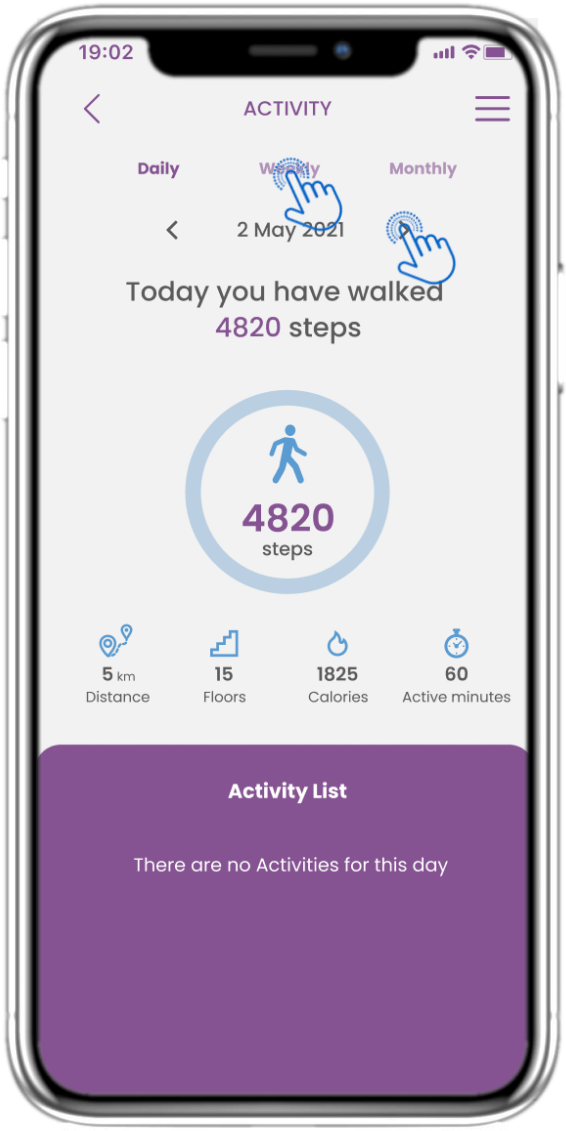
4 HOME WIDGETS





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

No sports activities were collected from the wearable.

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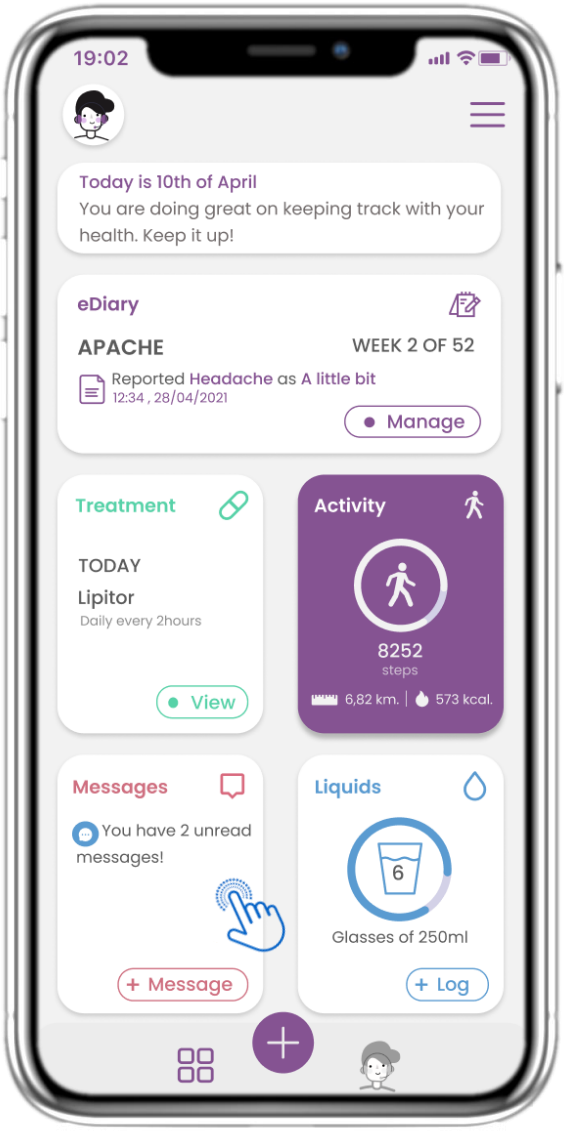
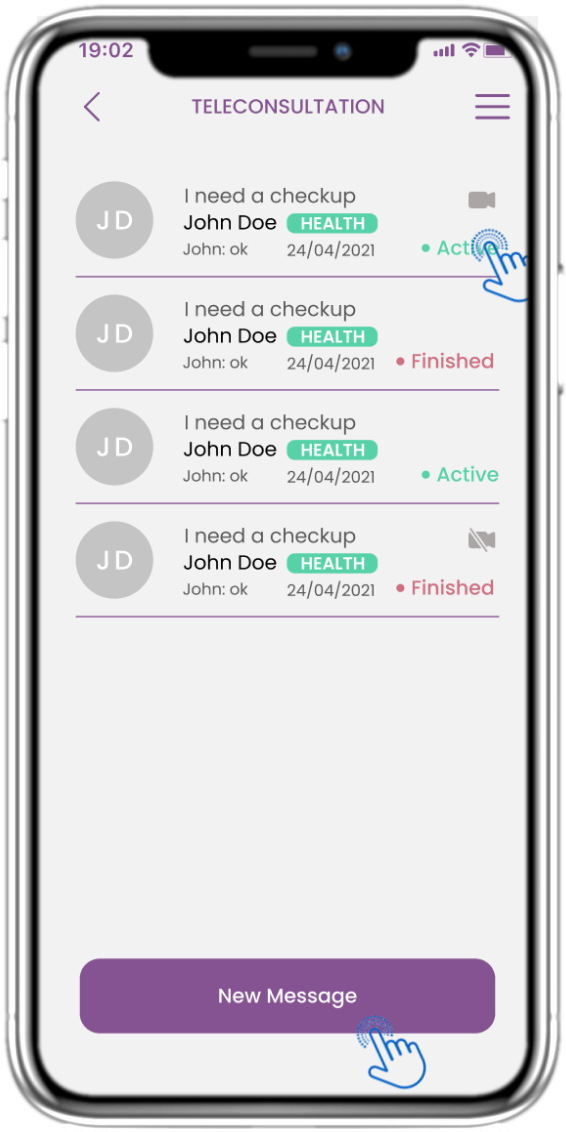
4 HOME WIDGETS



4.13 MESSAGES

In the HOME page you can find the Messages widget which is used to contact your Doctor or Hospital and have also a teleconsultation.



4.14 MESSAGE INBOX PAGE

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

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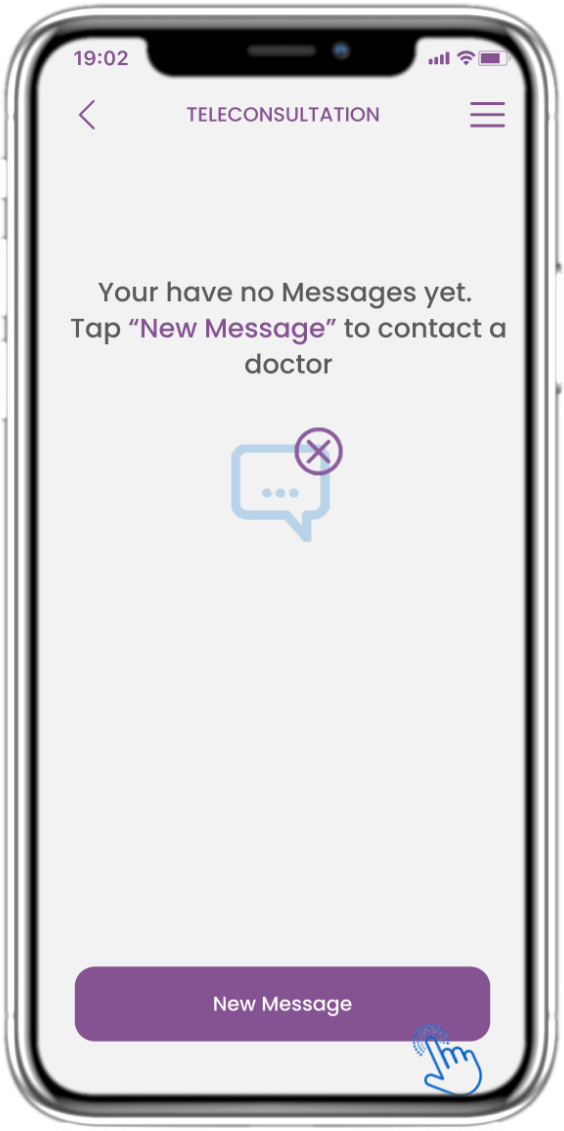
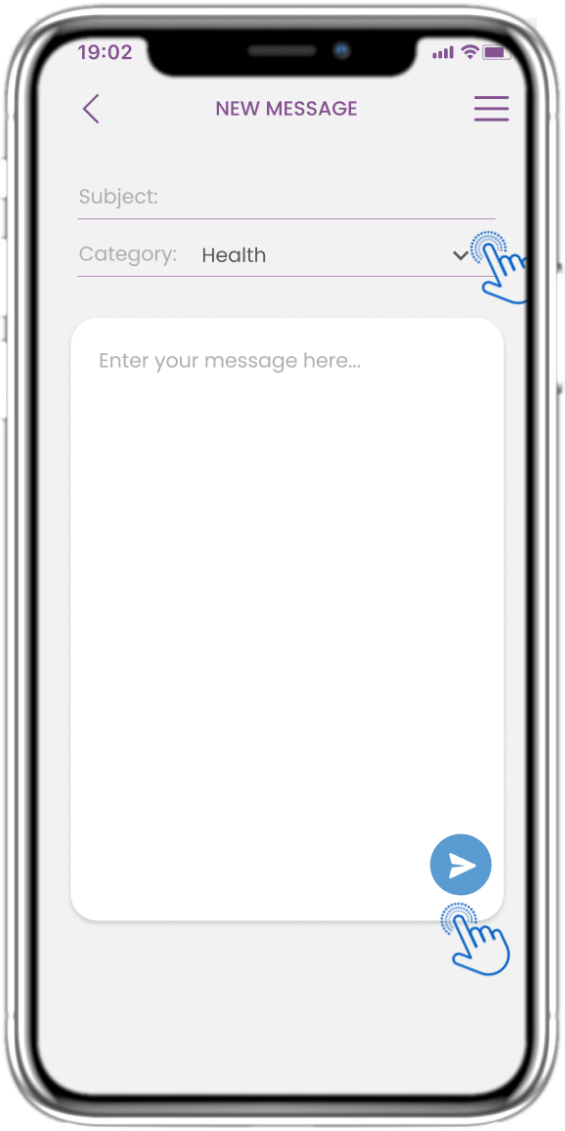
4 HOME WIDGETS



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 and a category defined by the healthcare professional and enter your message.

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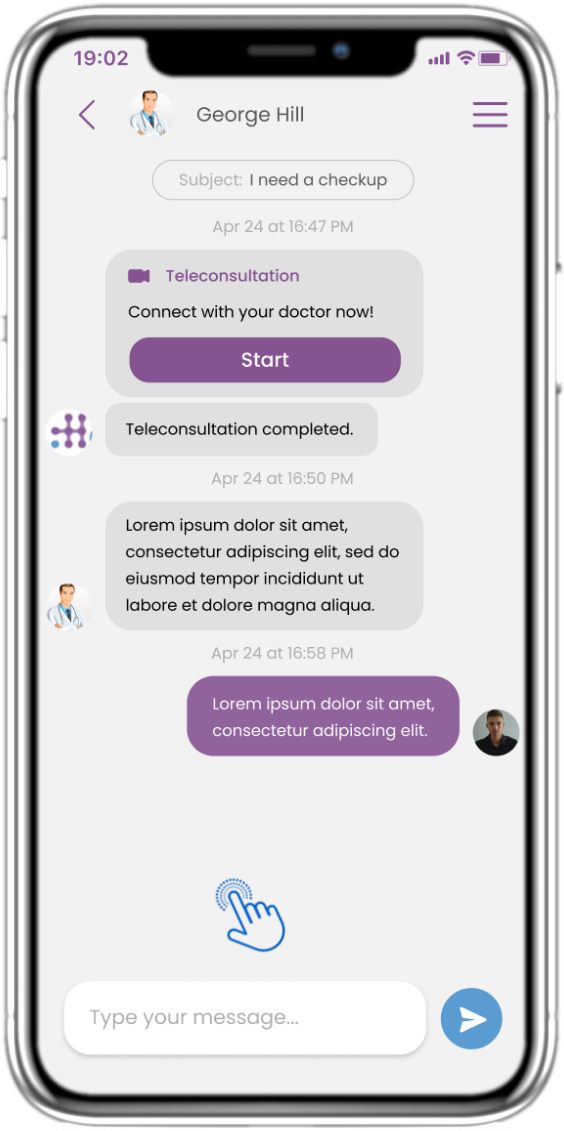
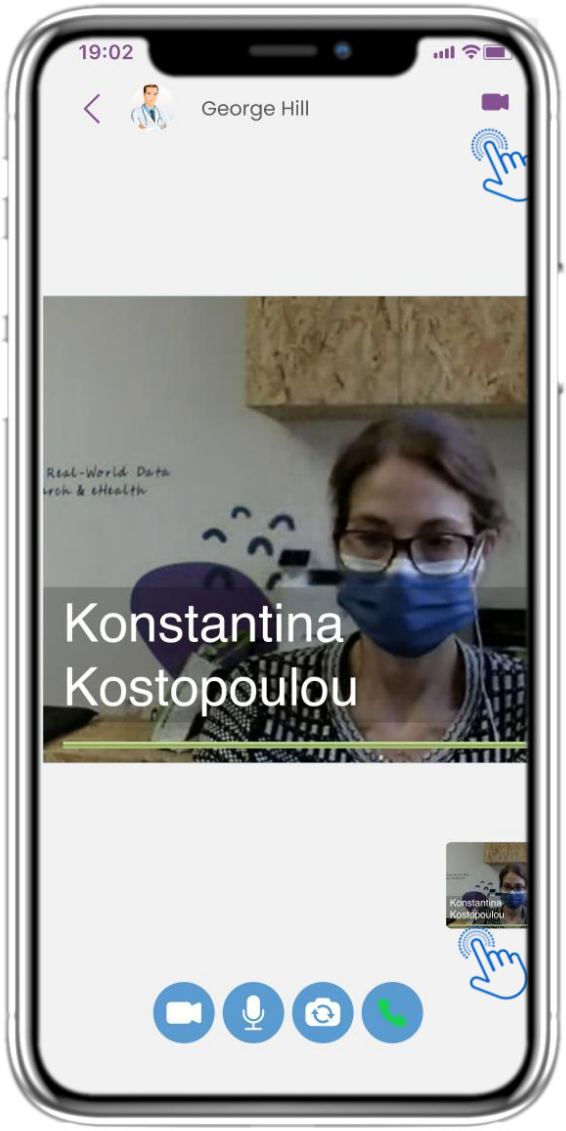
4 HOME WIDGETS





4.17 OPEN MESSAGE

All replies and communication are kept in one conversation. The healthcare professional closes the conversation.

4.18 TELECONSULTATION

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

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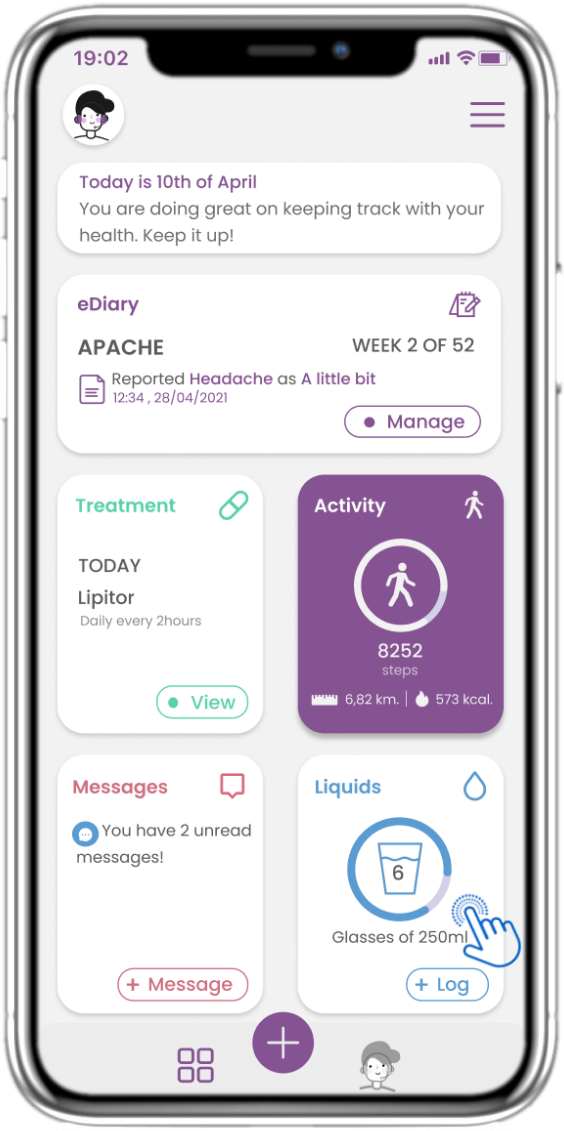
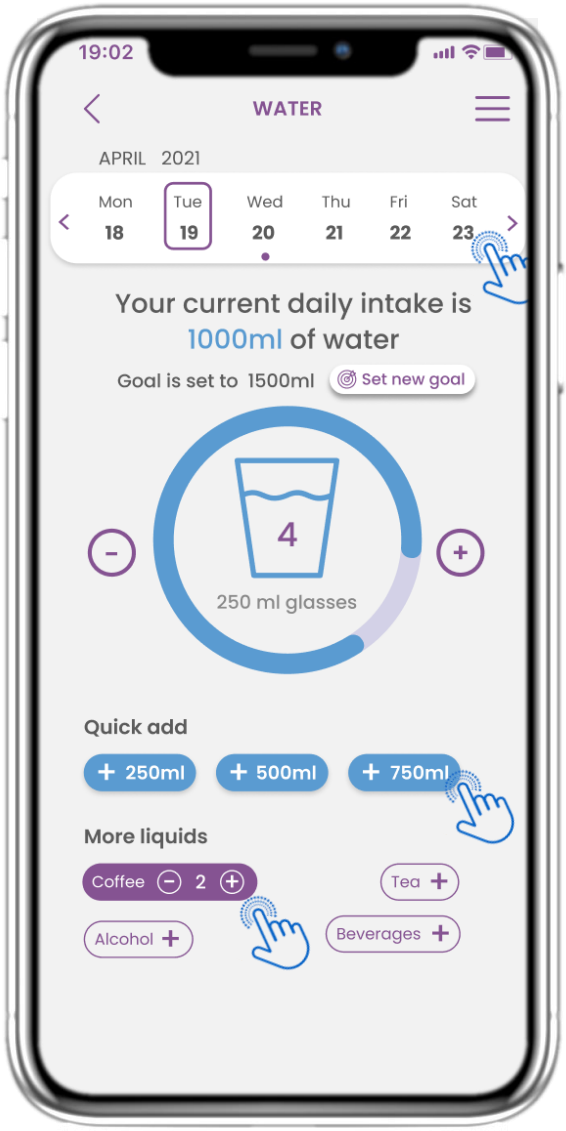
4 HOME WIDGETS





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.

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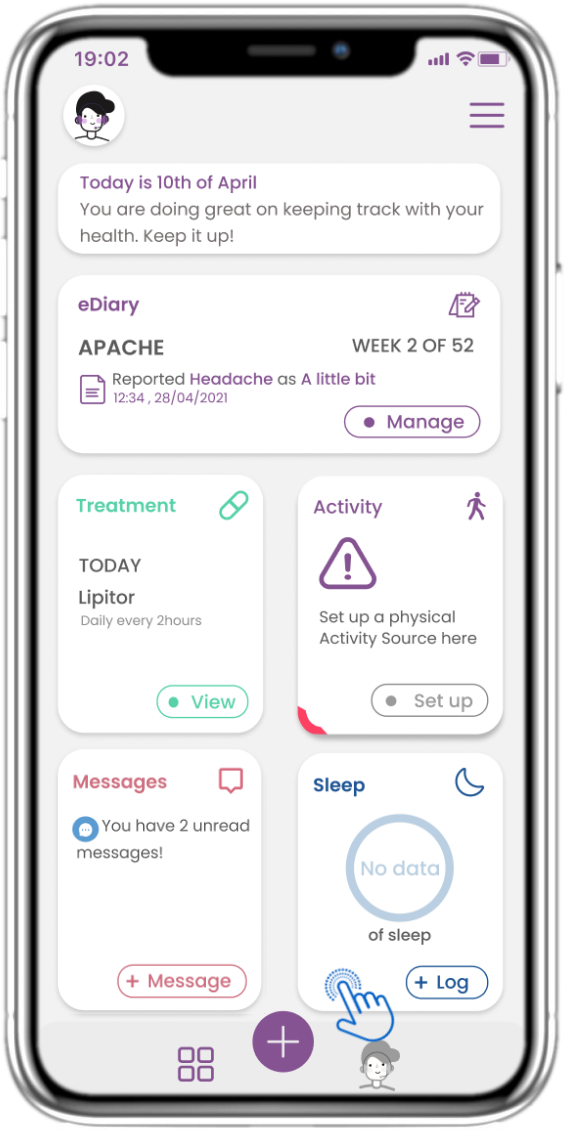
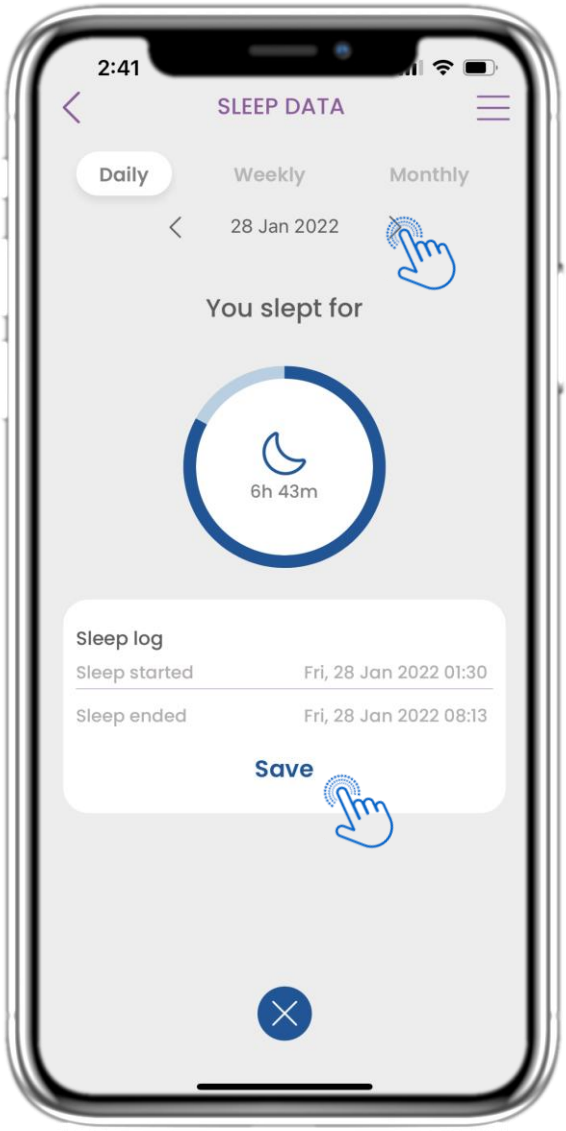
4 HOME WIDGETS





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.

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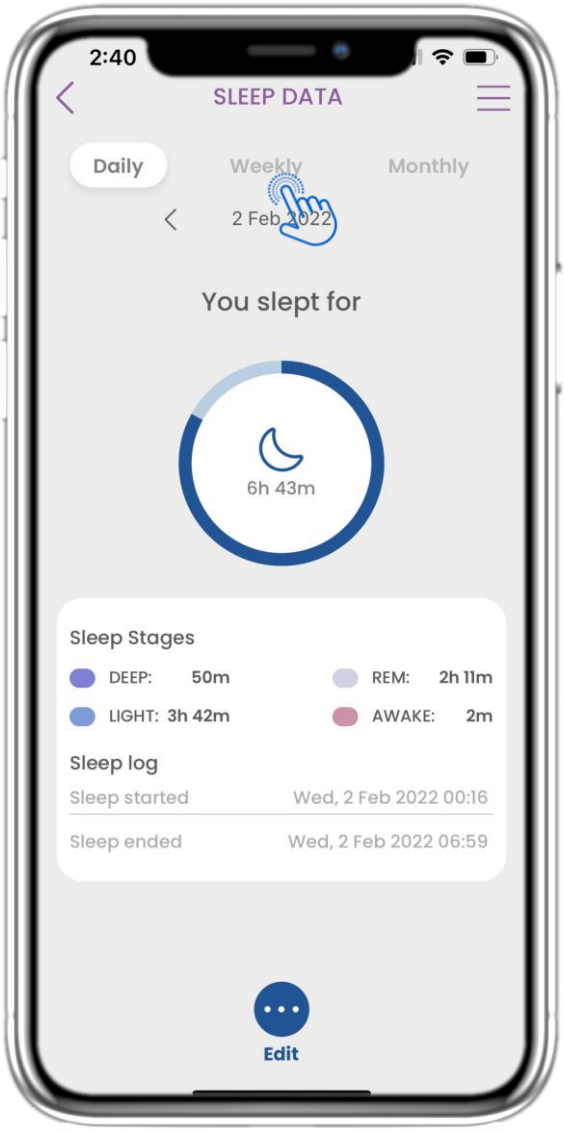
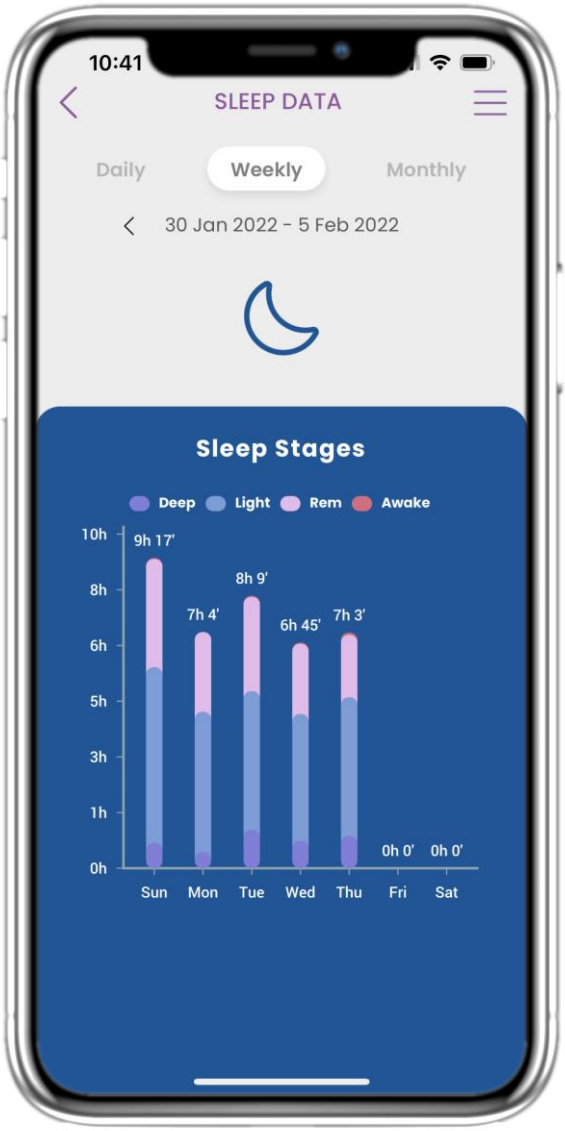
4 HOME WIDGETS



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.

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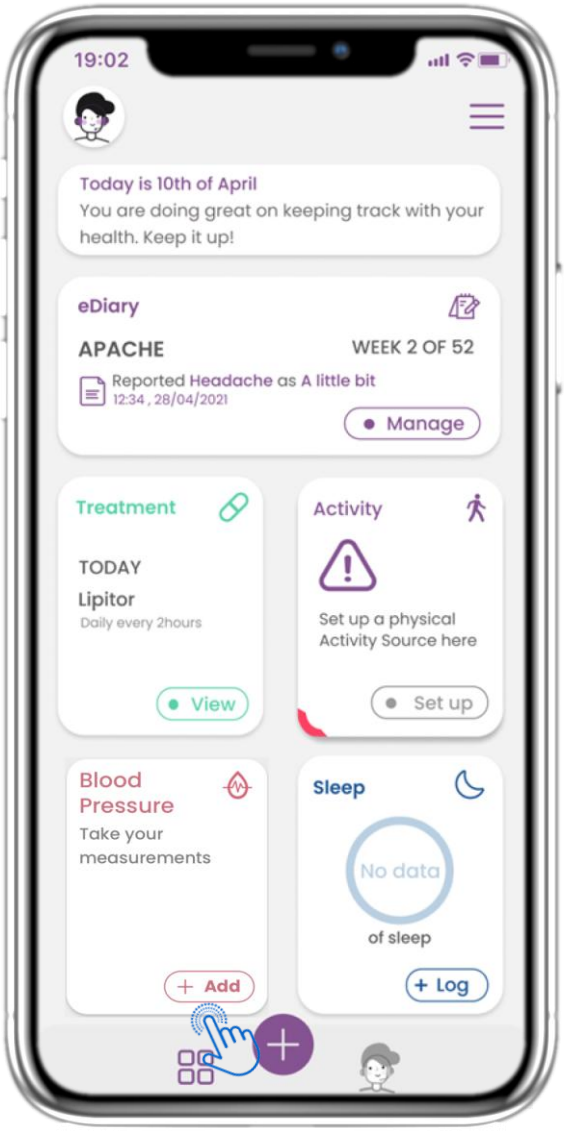
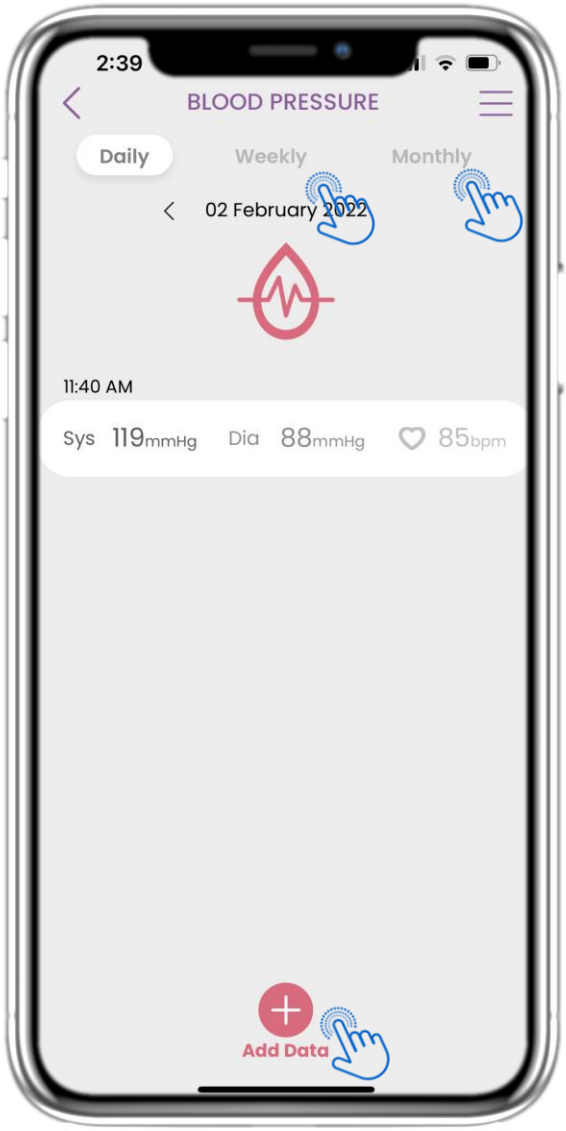
4 HOME WIDGETS





4.25 BLOOD PRESSURE WIDGET

In the HOME page you can find the Blood Pressure widget which is used to collect measurements by a synced blood pressure device.

4.26 BLOOD PRESSURE LOG

In the Blood Pressure page you can add your measurements manually or by syncing a device and navigate between the days in the calendar or view daily data and select to view weekly and monthly also graphs.

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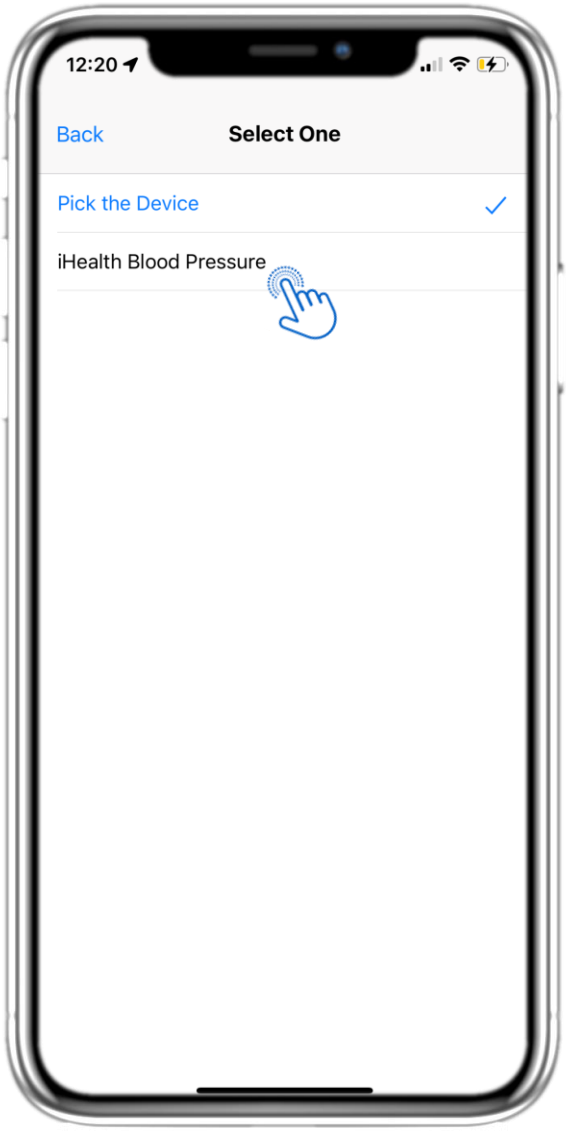
4 HOME WIDGETS



4.27 BLOOD PRESSURE PAGE FROM DEVICE

In the HOME page you can find the Blood Pressure widget which is used to log your blood pressure measurements either manually or collected by a device.



4.28 BLOOD PRESSURE PAGE FROM DEVICE

In the Blood Pressure page you can sync a blood pressure device and collect automatic measurements directly from the device.

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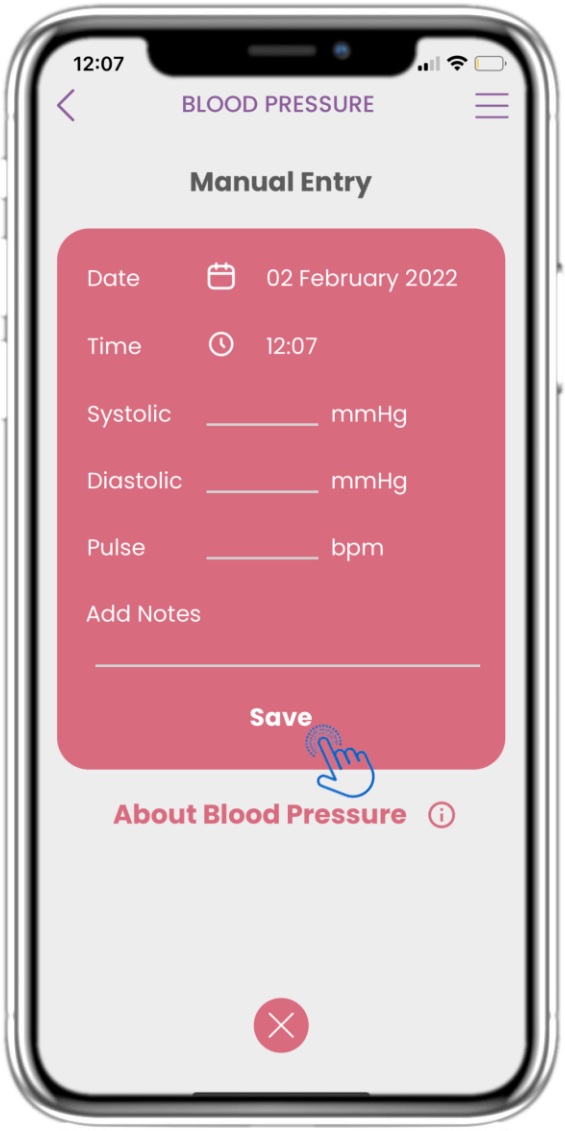
4 HOME WIDGETS



4.29 BLOOD PRESSURE PAGE MANUALLY

Ithe Blood Pressure widget which is used to log your blood pressure measurements either manually or collected by a device.n the HOME page you can find



4.30 BLOOD PRESSURE PAGE MANUALLY

In the Blood Pressure page you can manually add your data and view a list with results.

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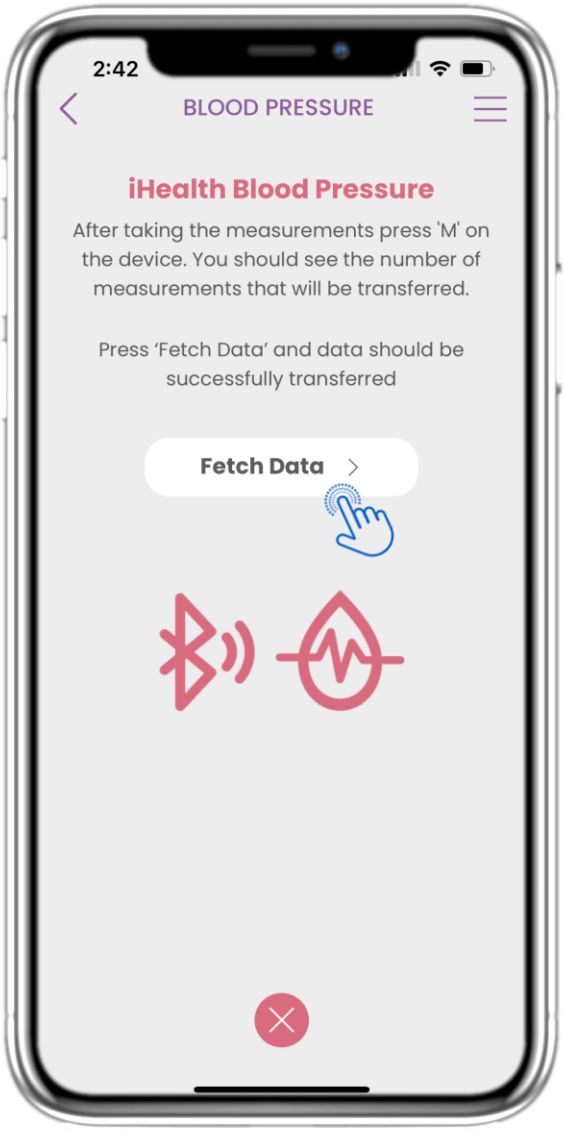
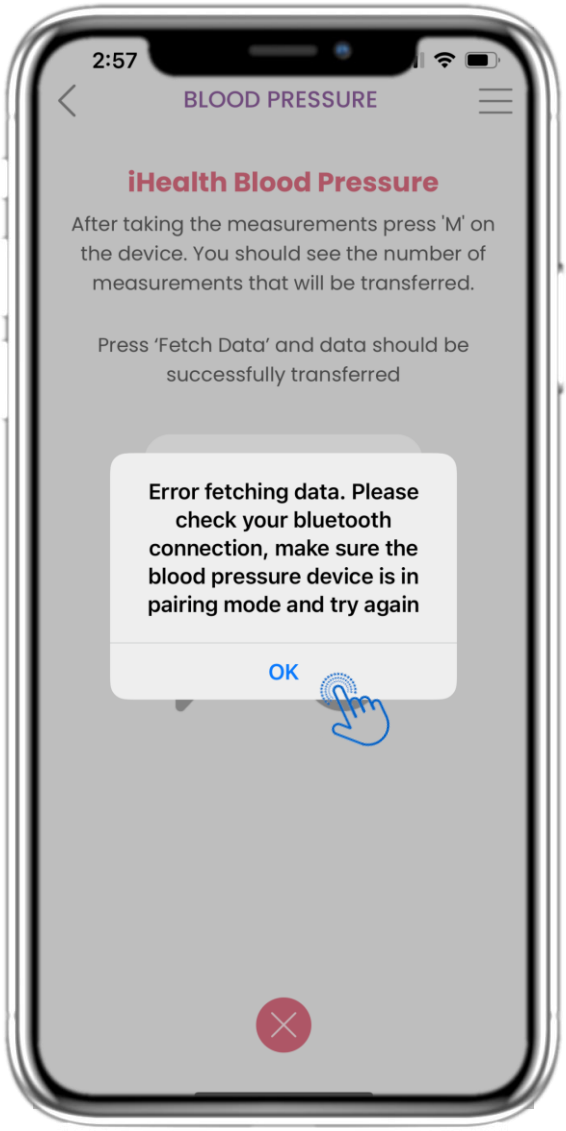
4 HOME WIDGETS



4.31 BLOOD PRESSURE DEVICE SYNC

In the iHealth Blood Pressure page you can find the button to synchronised and collect measurements from the Blood Pressure device.



4.32 BLOOD PRESSURE DEVICE SYNC

If you receive this notification, please check your mobile settings that you have enabled your Bluetooth and make sure the blood pressure device is ready to pair.

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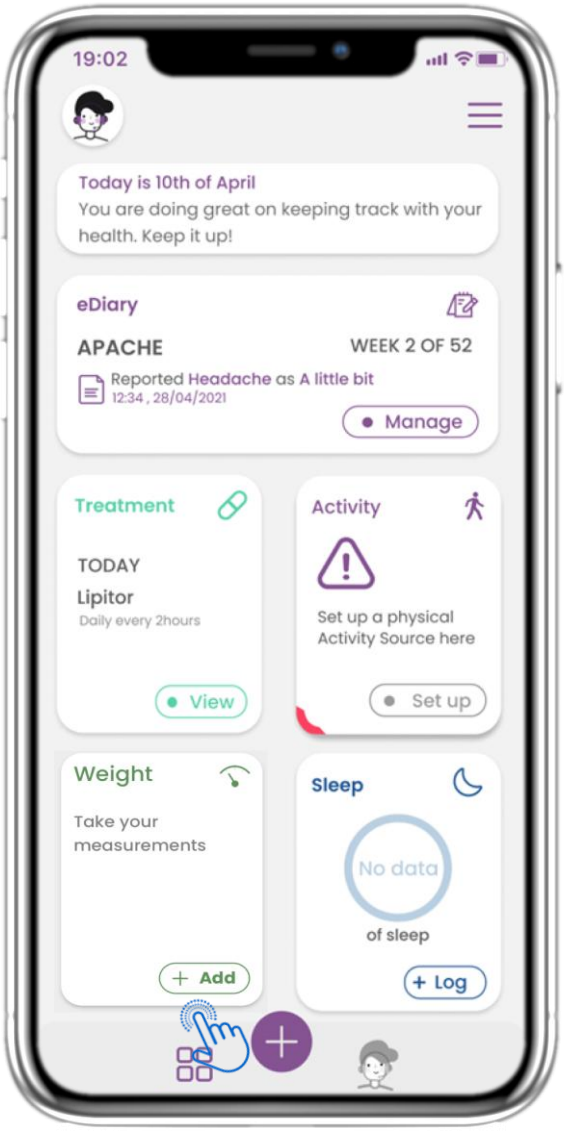
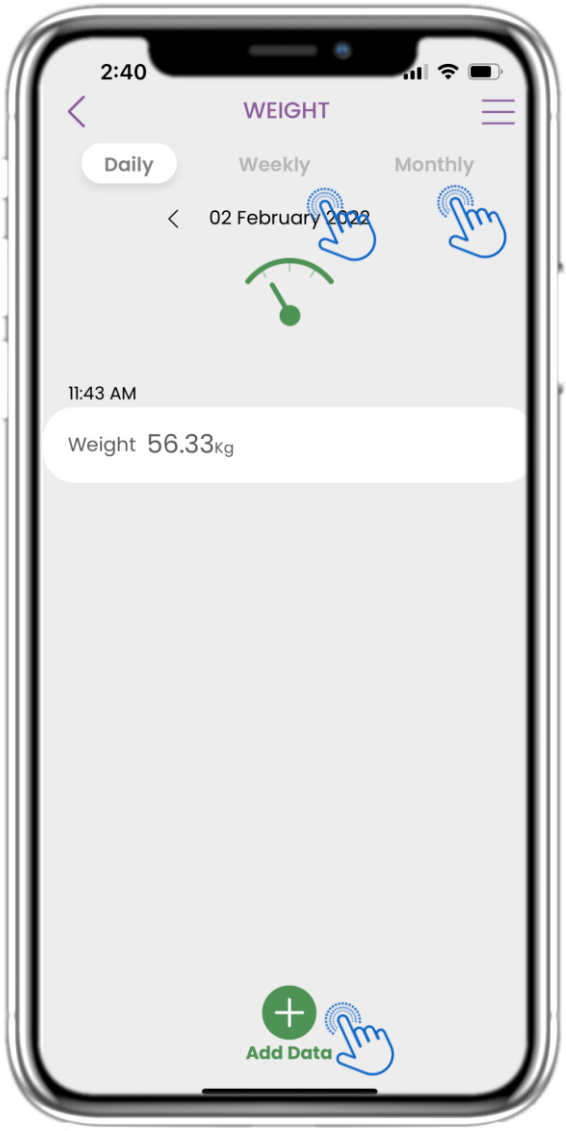
4 HOME WIDGETS





4.33 WEIGHT WIDGET

In the HOME page you can find the Weight widget which is used to collect measurements by a synced weight device.

4.34 WEIGHT LOG

In the Weight page you can add your measurements manually or by syncing a device and navigate between the days in the calendar or view daily data and select to view weekly and monthly also graphs.

REF Healthentia – Mobile-app
SN V4.0

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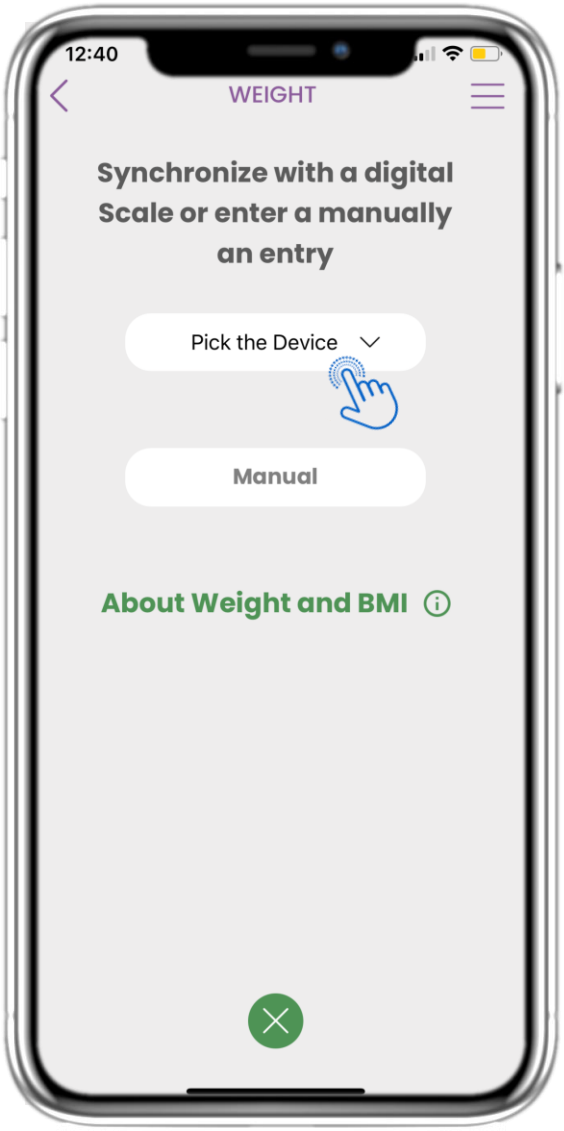
4 HOME WIDGETS



4.35 WEIGHT PAGE FROM DEVICE

In the HOME page you can find the Weight widget which is used to log your weight measurements either manually or collected by a device.



4.36 WEIGHT PAGE FROM DEVICE

In the Weight page you can sync a scale device and collect automatic measurements directly from the device.

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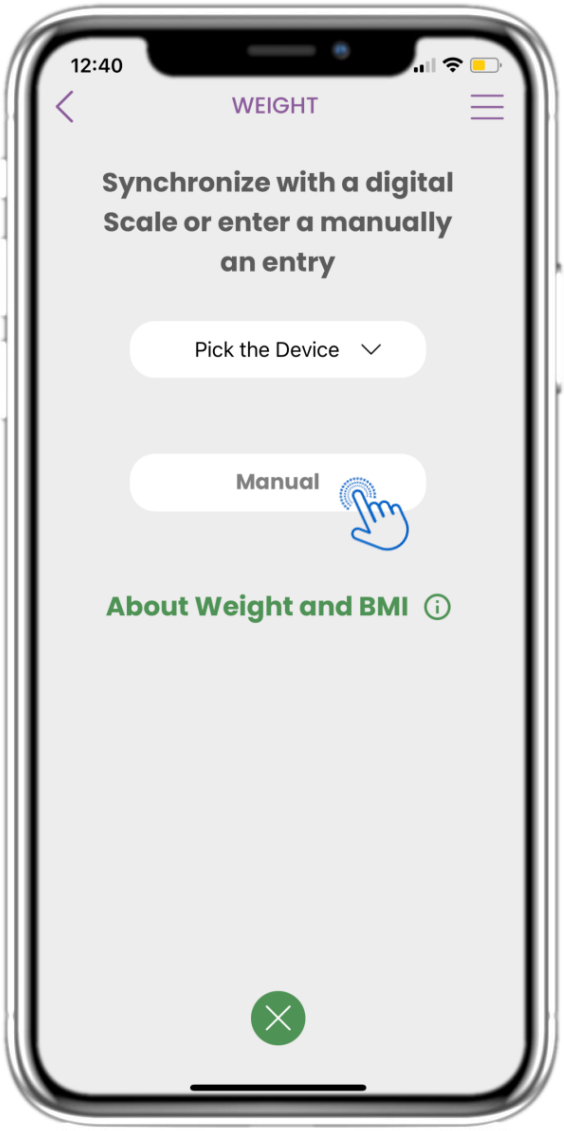
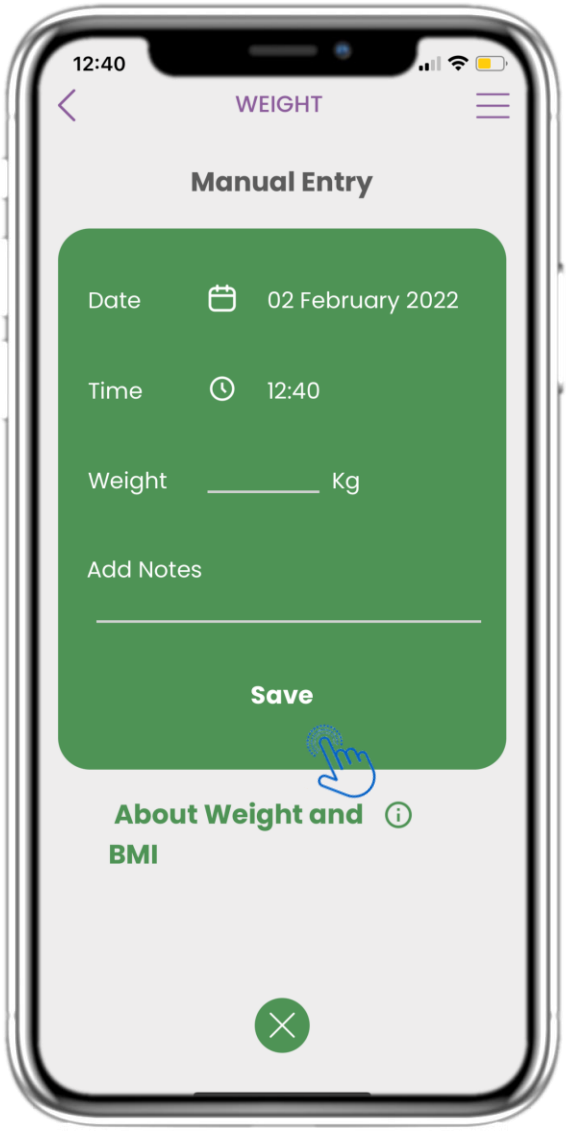
4 HOME WIDGETS



4.37 WEIGHT PAGE MANUALLY

In the HOME page you can find the Weight widget which is used to log your weight measurements either manually or collected by a scale device.



4.38 WEIGHT PAGE MANUALLY

In the Weight page you can manually add your data and view a list with results.

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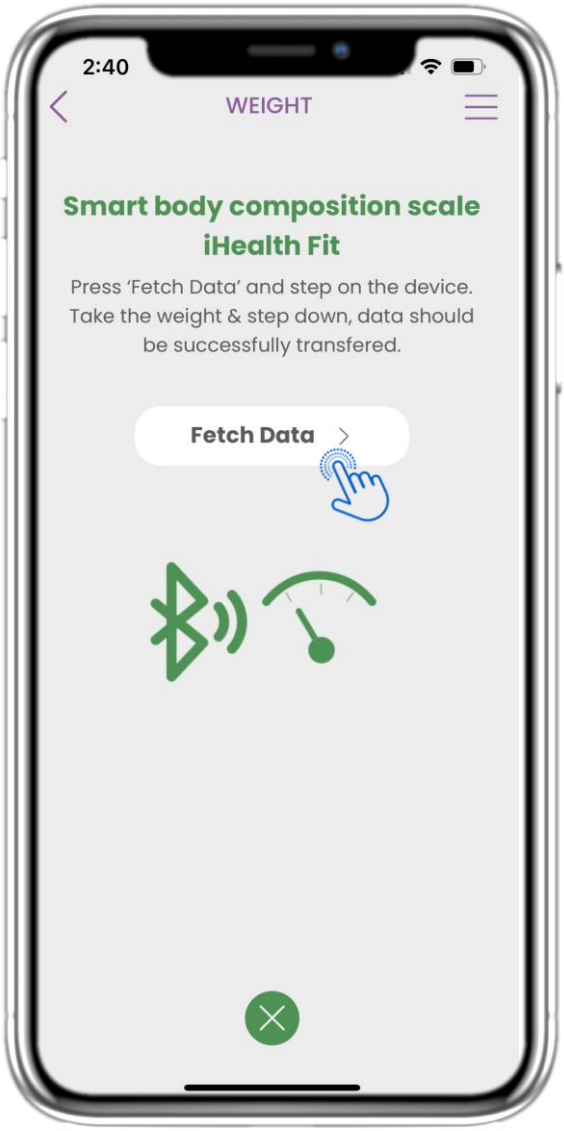
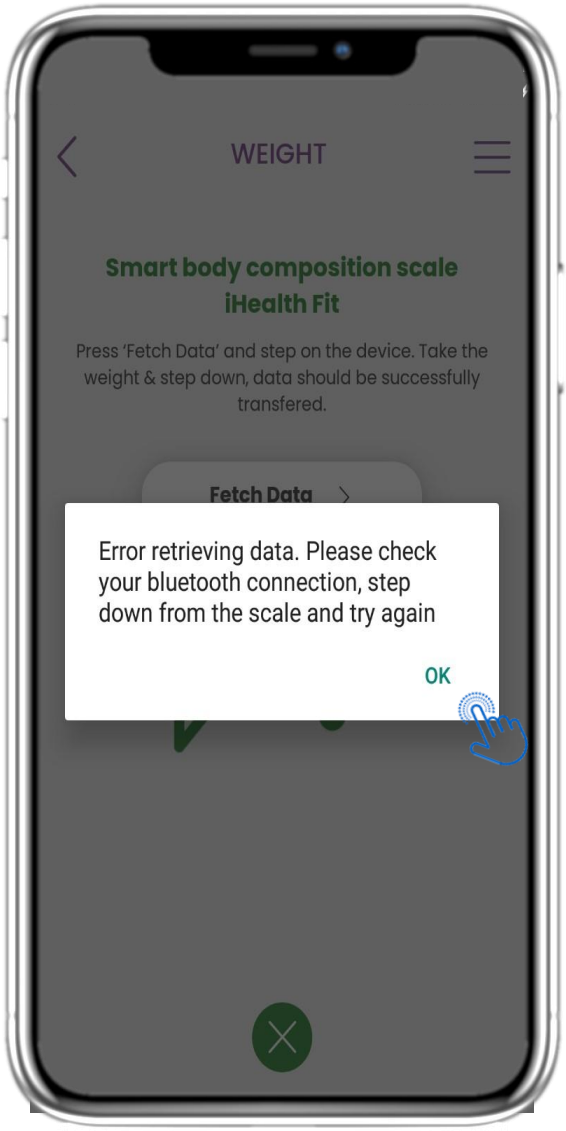
4 HOME WIDGETS



4.39 WEIGHT DEVICE SYNC

In the iHealth Fit Weight page you can find the button to synchronised and collect measurements from the scale device.



4.40 WEIGHT DEVICE SYNC

If you receive this notification, please check your mobile settings that you have enabled your Bluetooth. Please repeat the weighing process from the beginning.

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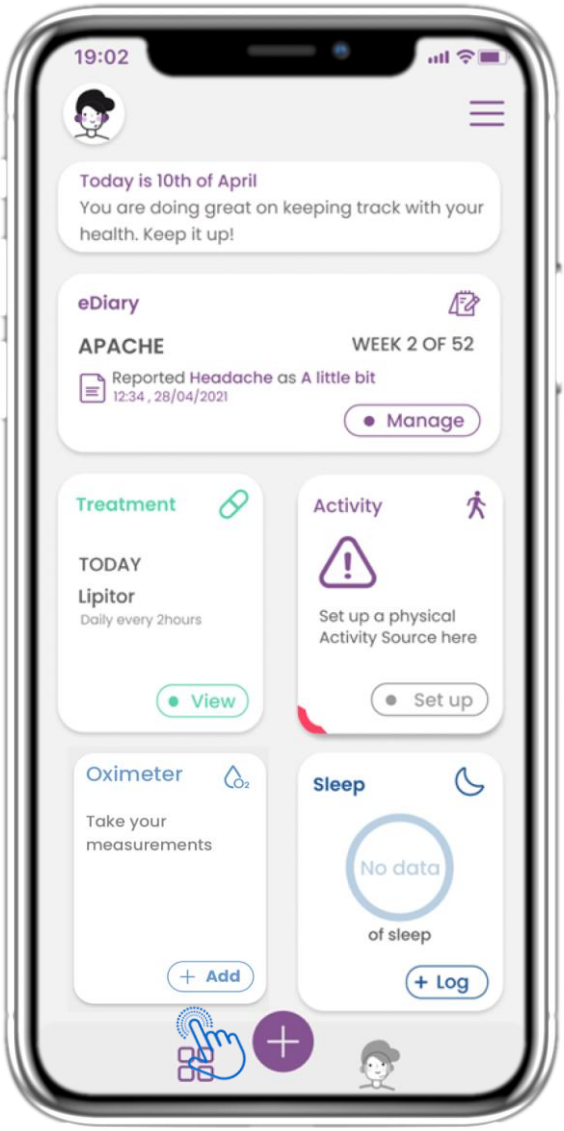
4 HOME WIDGETS





4.41 OXIMETER WIDGET

In the HOME page you can find the Oximeter widget which is used to log your oxygen data either manually or collected by an oximeter device.

4.42 OXIMETER LOG

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

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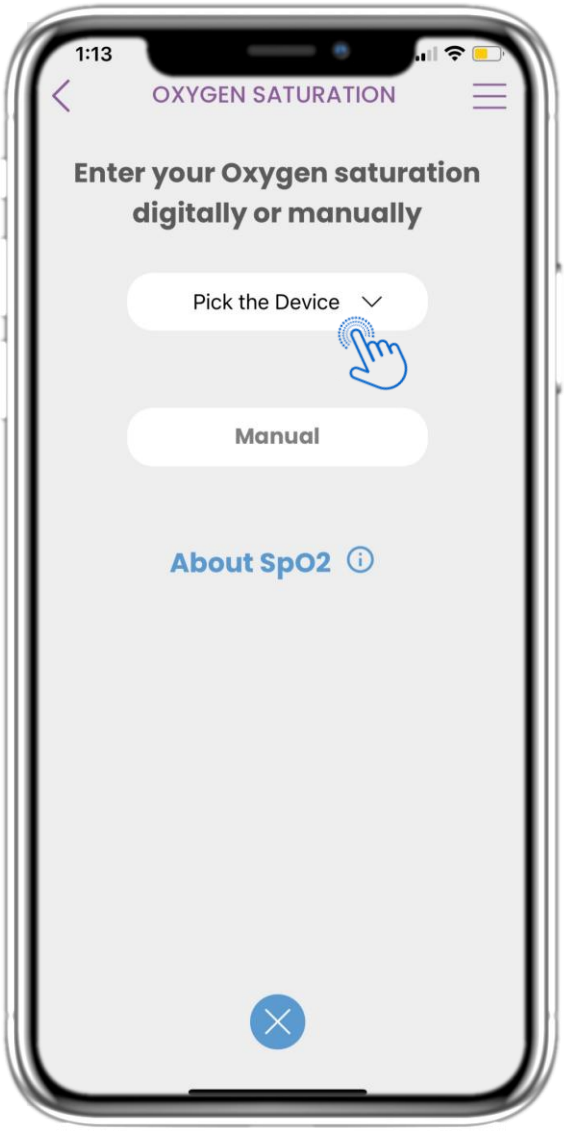
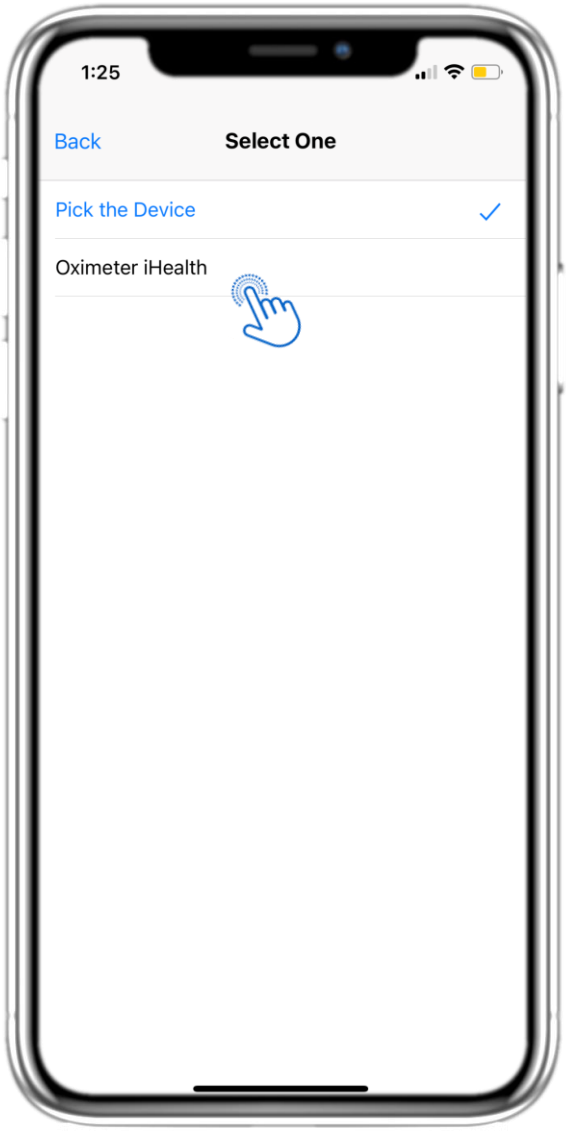
4 HOME WIDGETS





4.43 OXIMETER PAGE FROM DEVICE

In the HOME page you can find the Oximeter widget which is used to log your oxygen measurements either manually or collected by an oximeter device.

4.44 OXIMETER PAGE FROM DEVICE

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

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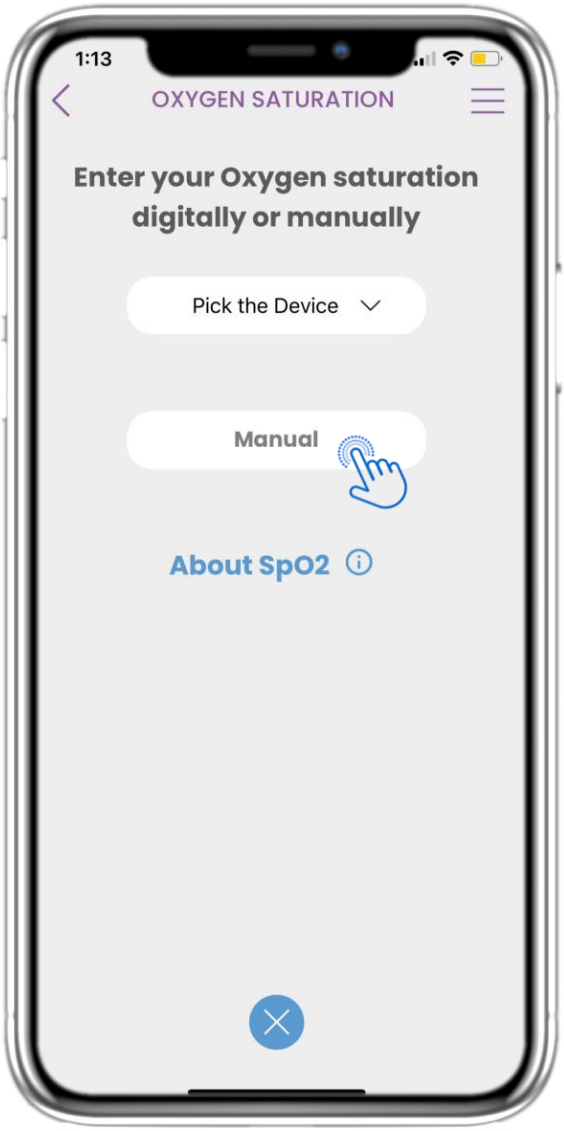
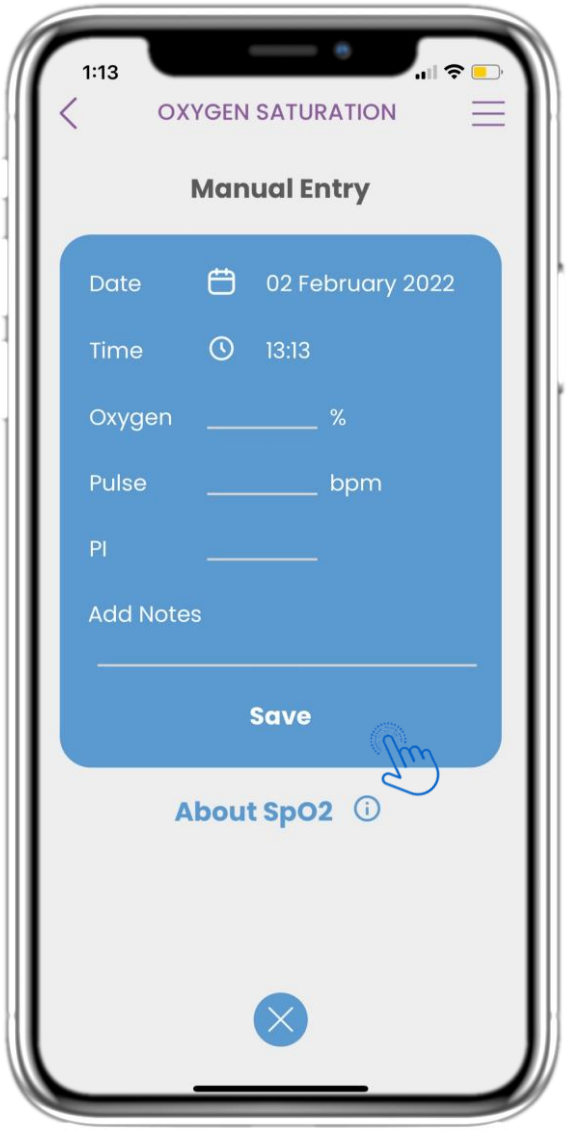
4 HOME WIDGETS





4.45 OXIMETER PAGE MANUALLY

In the HOME page you can find the Oximeter widget which is used to log your oxygen measurements either manually or collected by an oximeter device.

4.46 OXIMETER PAGE MANUALLY

In the Oximeter page you can manually add your data and view a list with results.

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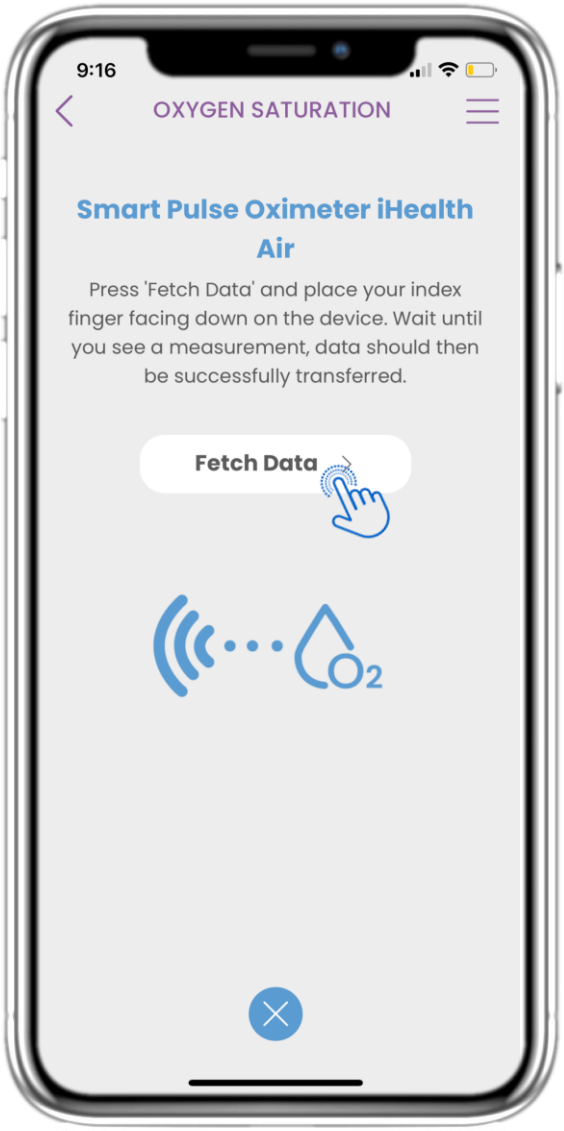
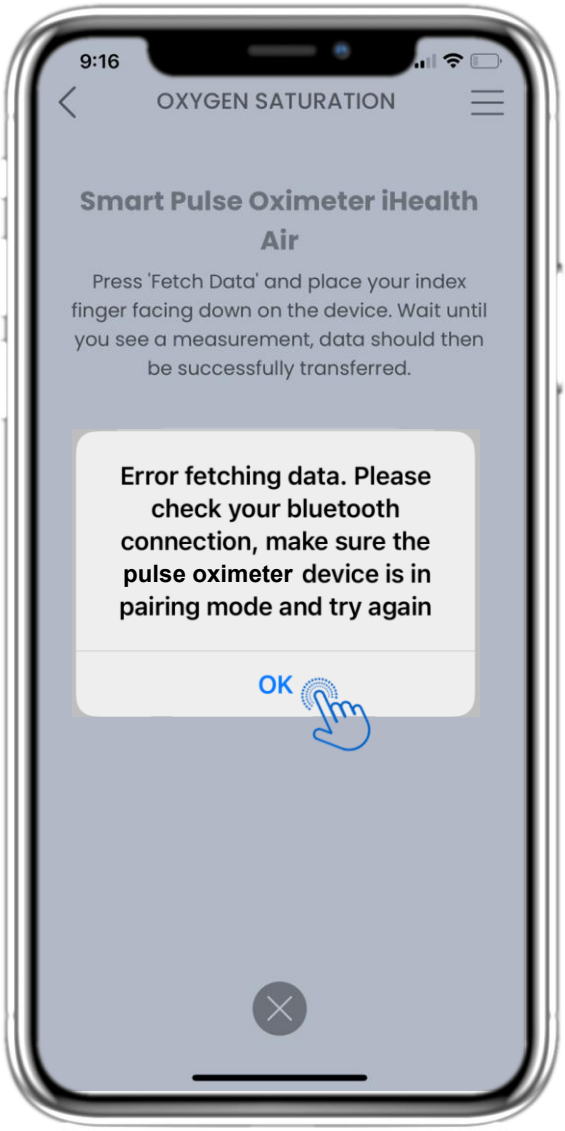
4 HOME WIDGETS



4.47 WEIGHT DEVICE SYNC

In the oxygen saturation page you can find the button to synchronised and collect data from the smart pulse oximeter device.



4.48 WEIGHT DEVICE SYNC

If you receive this notification, please check your mobile settings that you have enabled your Bluetooth and make sure the smart pulse oximeter device is ready to pair.

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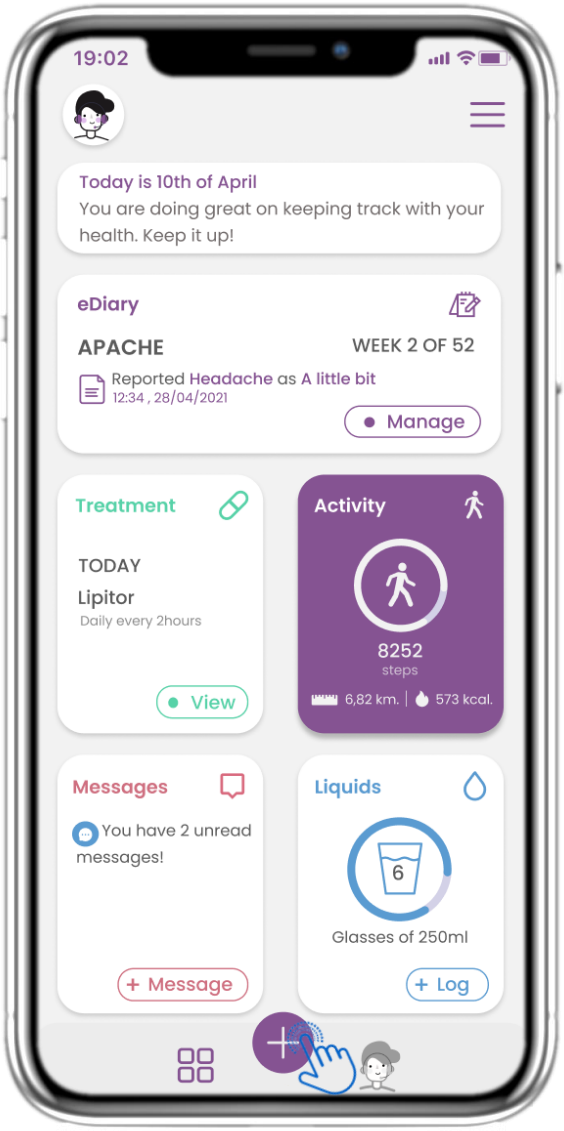
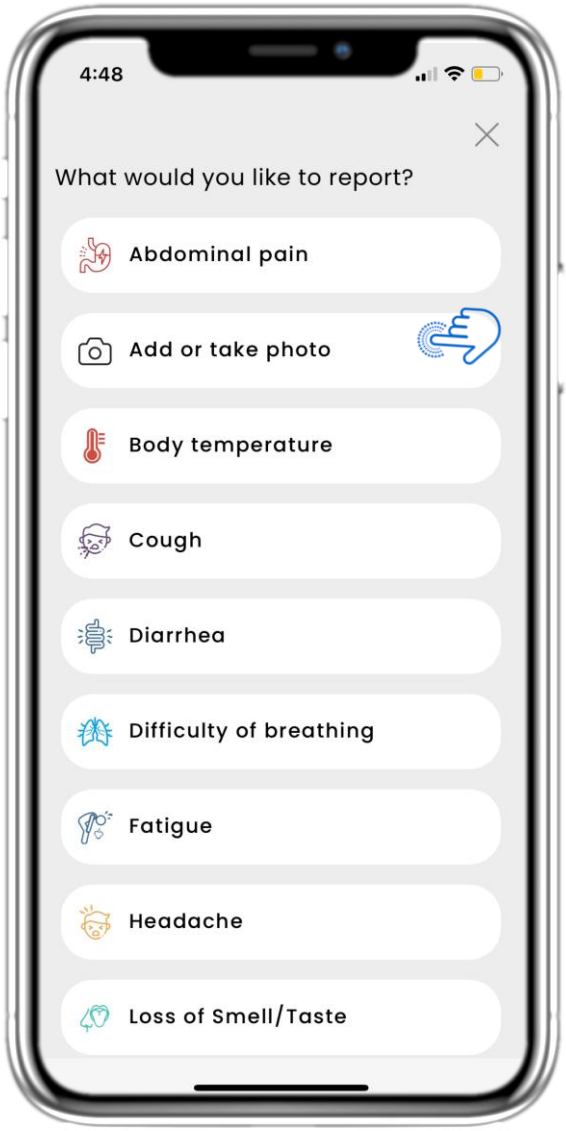
5 ADD REPORTS/ANSWER QUESTIONNAIRES





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 (+).

REF Healthentia – Mobile-app
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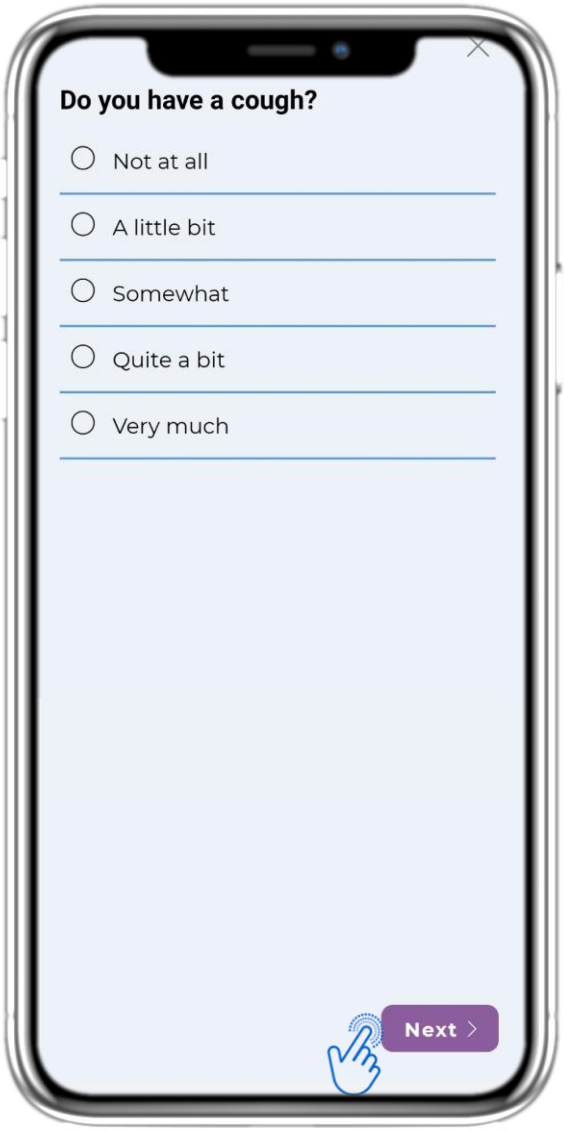
5. ANSWER REPORTS & QUESTIONNAIRES





5.3 ANSWER REPORTS/QUESTIONNAIRES

Answer questionnaire related to symptom you selected. Click NEXT to continue questionnaire. Click OK to submit or CANCEL to leave.

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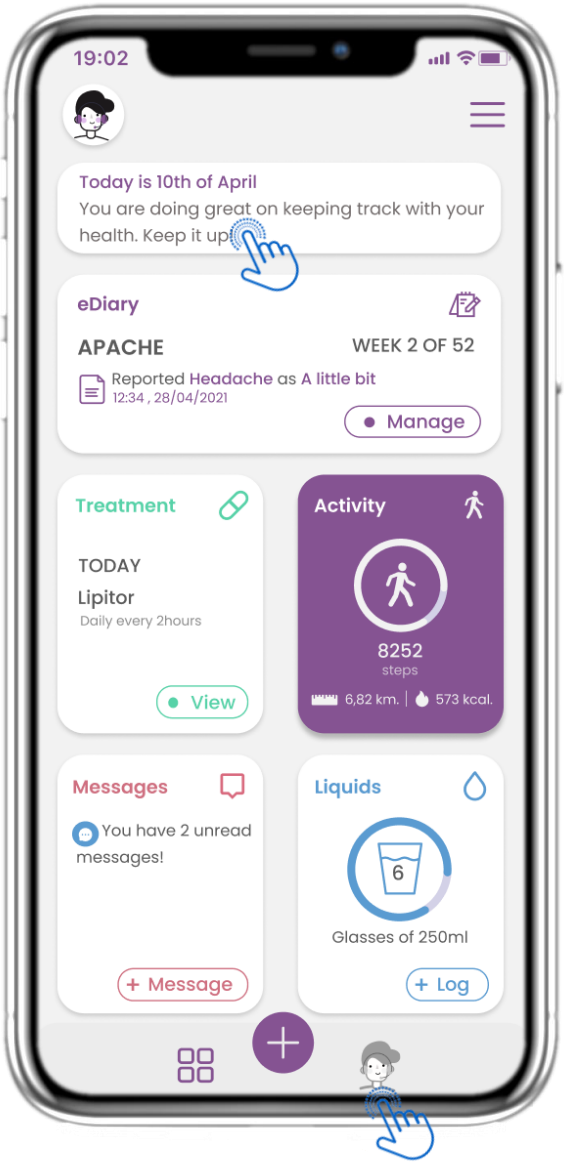
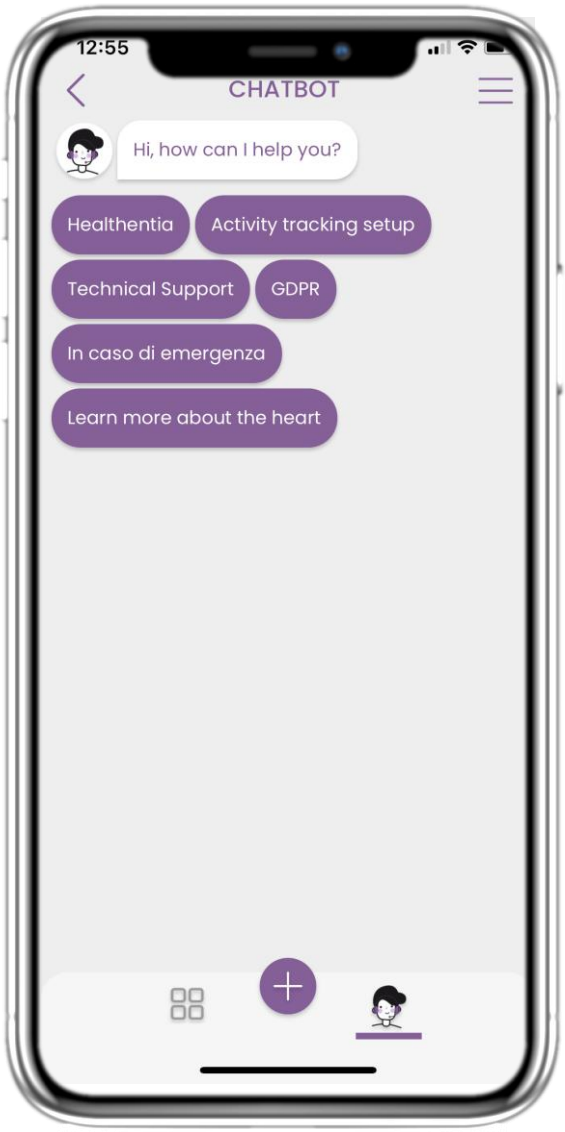
6 CHATBOT



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.

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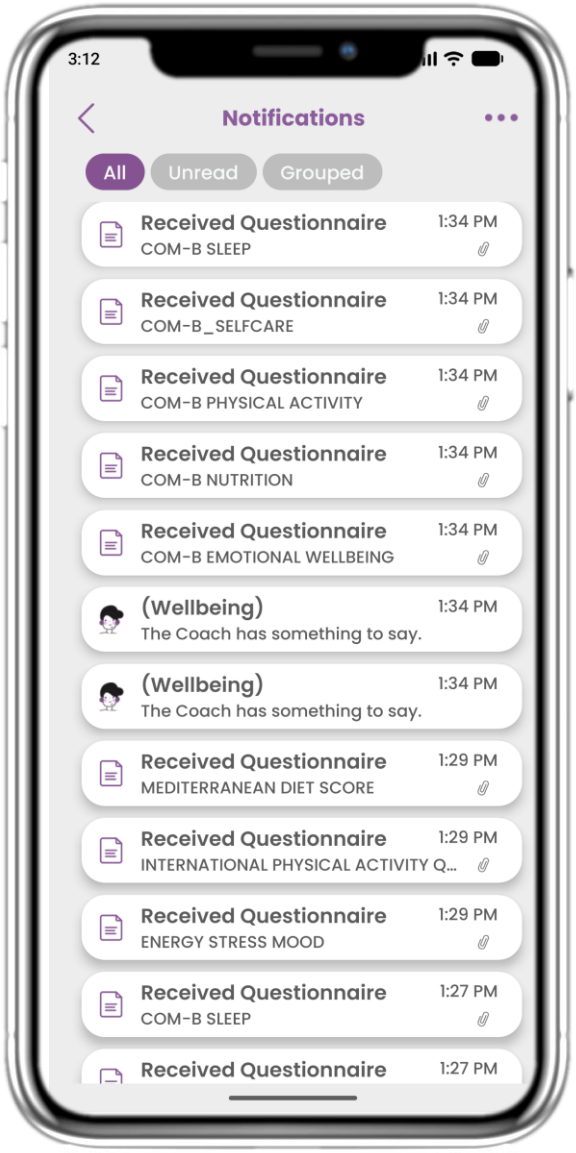
6 CHATBOT / Wellbeing



6.3 CHATBOT / Wellbeing

Two notifications from the Wellbeing module inform the user that the Virtual Coach has a message for them, encouraging them to open and view the coach's guidance or content.

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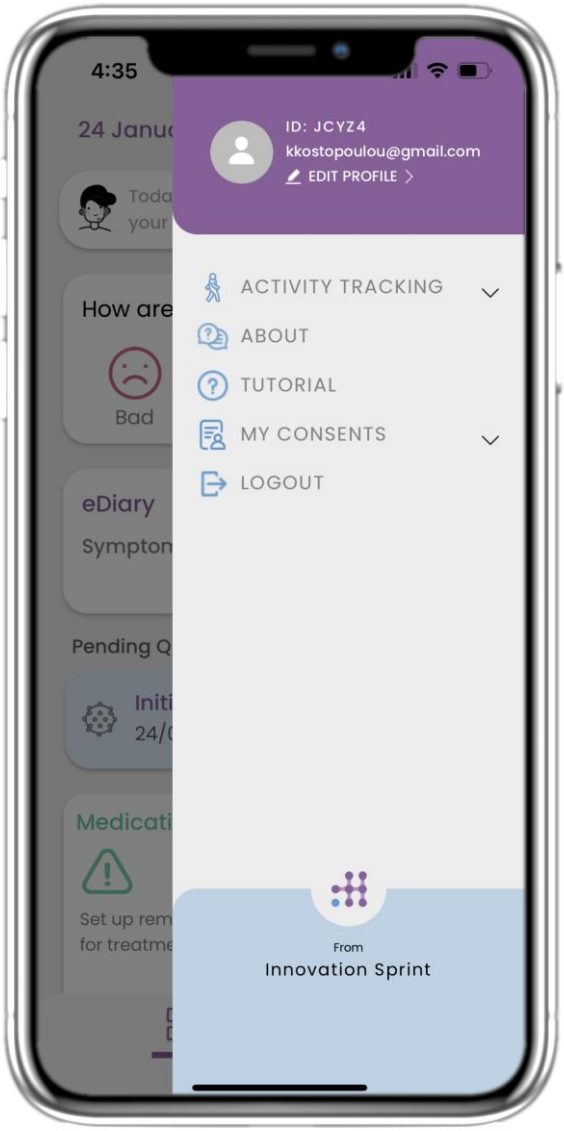
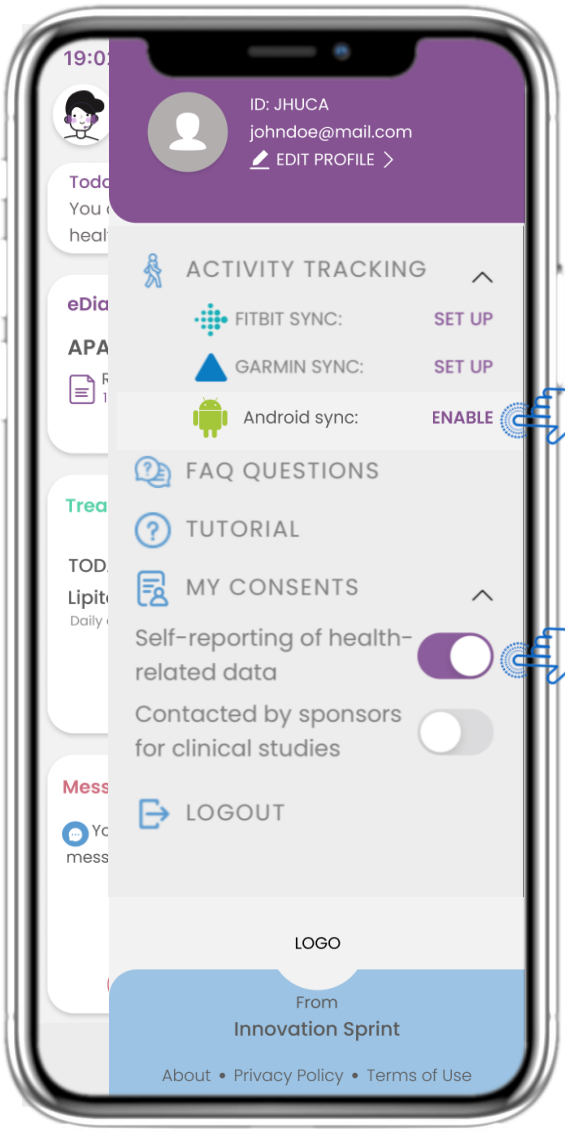
7 MENU SIDEBAR





7.1 SIDEBAR OPTIONS

From the menu bar you can edit your profile, set up your activity tracker and enable or disable the explicit consent that you have entered during the registration.
You can also have access to some content pages like FAQ.

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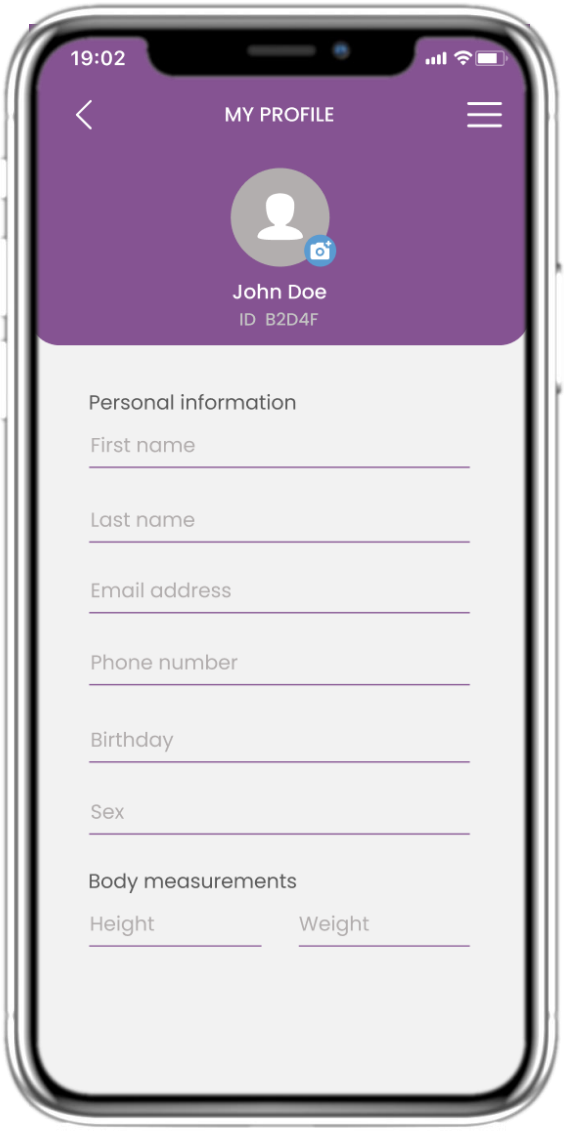
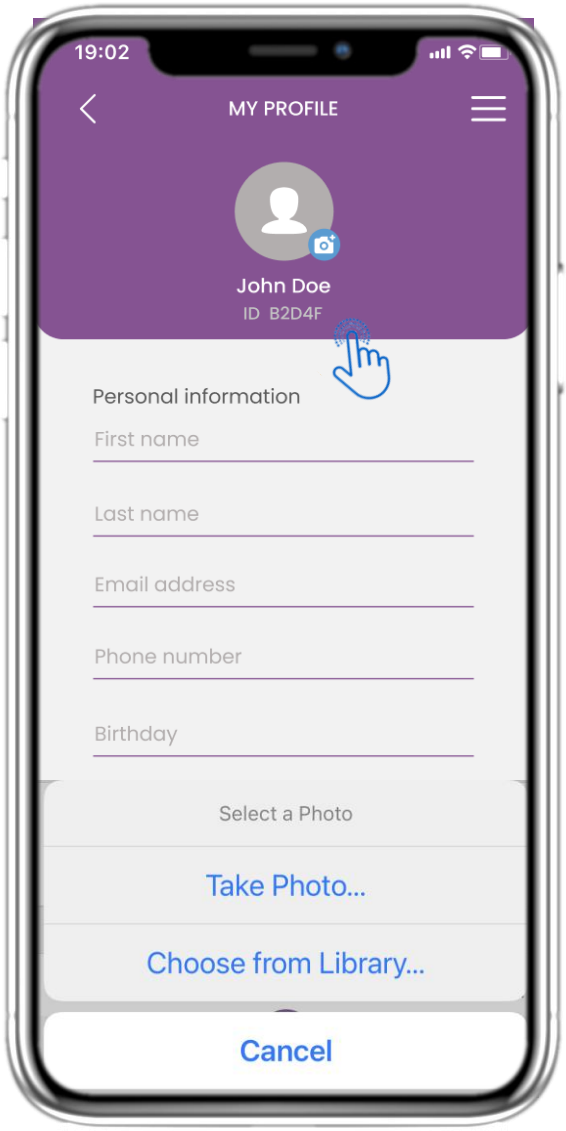
7 MENU – MY PROFILE





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 doctor.

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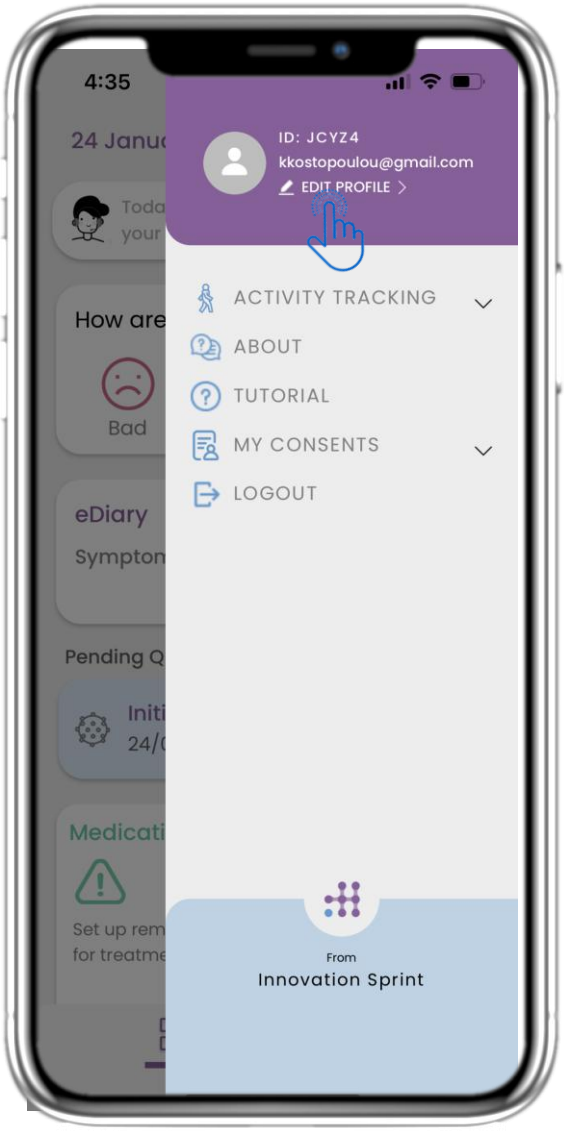
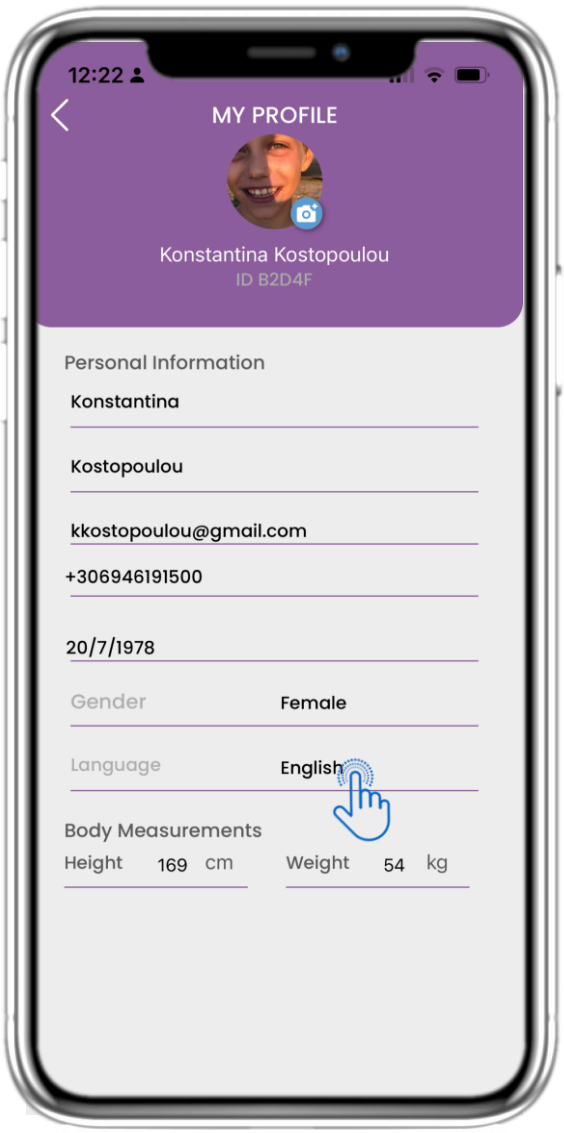
7 MENU – CHANGING LANGUAGES



7.3 MANAGE PROFILE

From the Settings menu go to manage your Profile where you can edit your details



7.4 SWITCHING LANGUAGE

In the Profile page you can switch the language.

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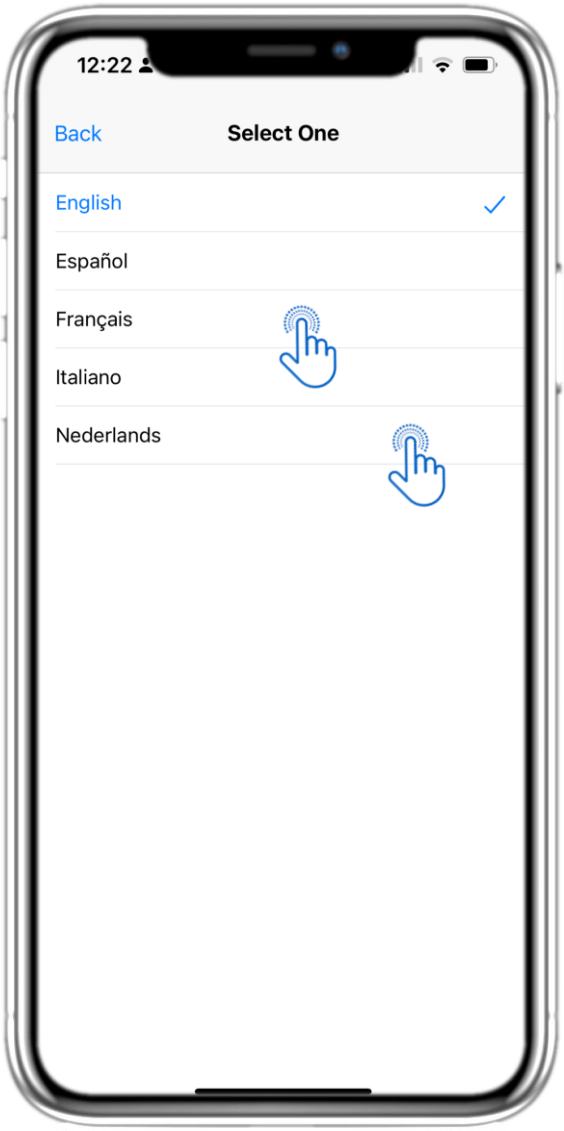
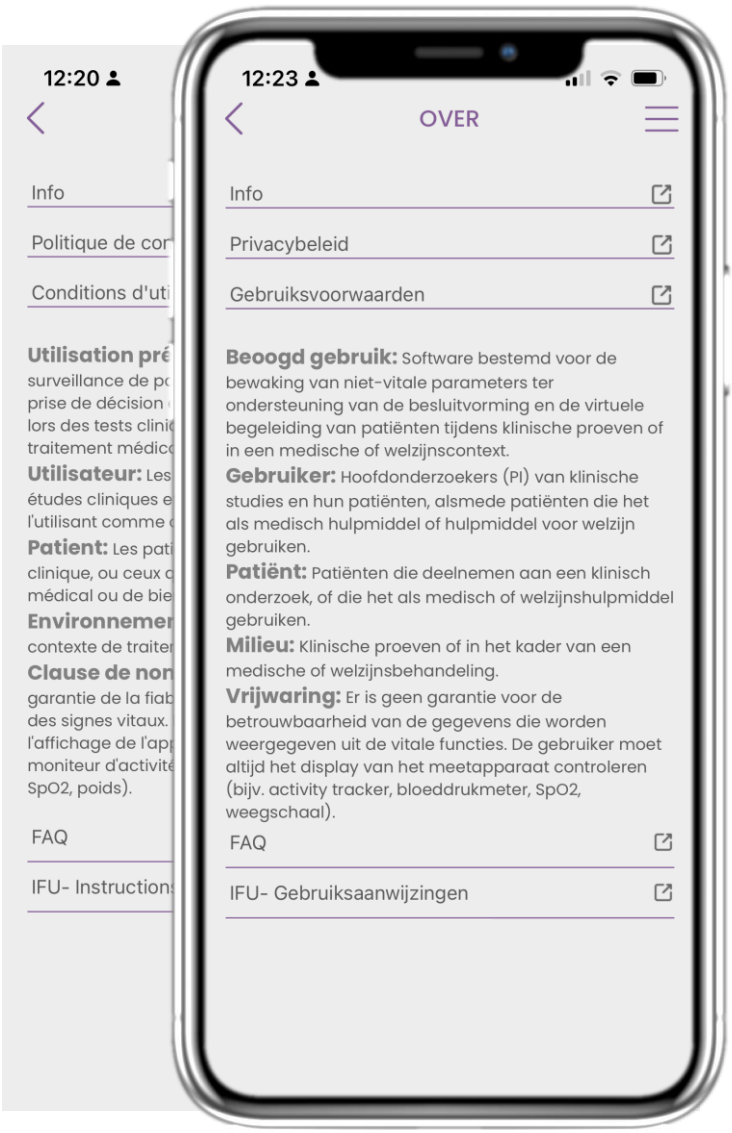
7 MENU – CHANGING LANGUAGES (EXAMPLE)





7.5 PICK LANGUAGE

From the Settings menu go to manage your Profile where you can edit your details

7.6 ABOUT PAGE IN FR & NL

Translated text of the page About

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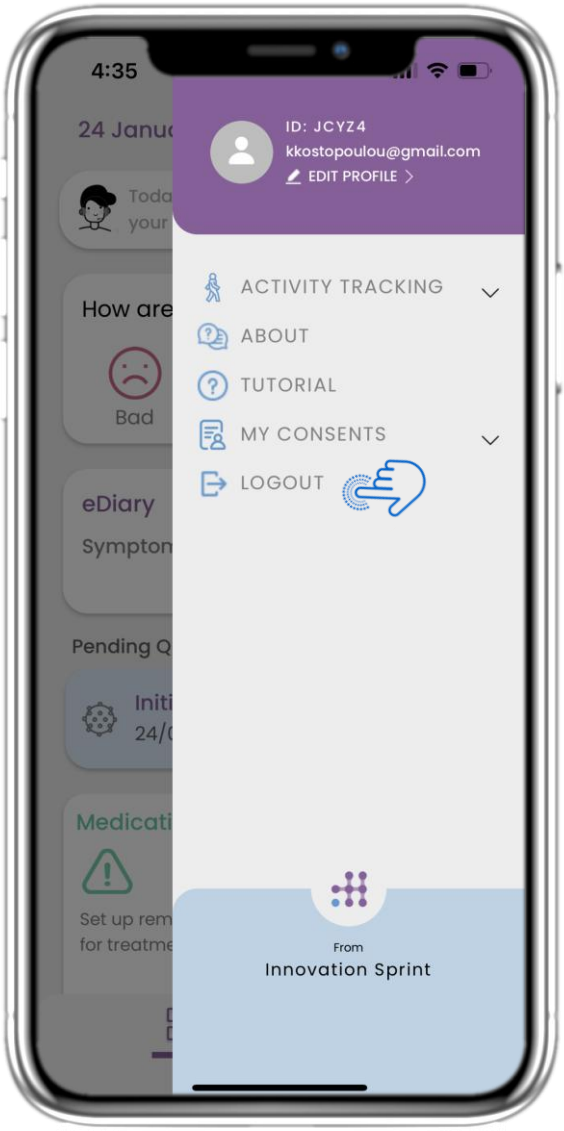
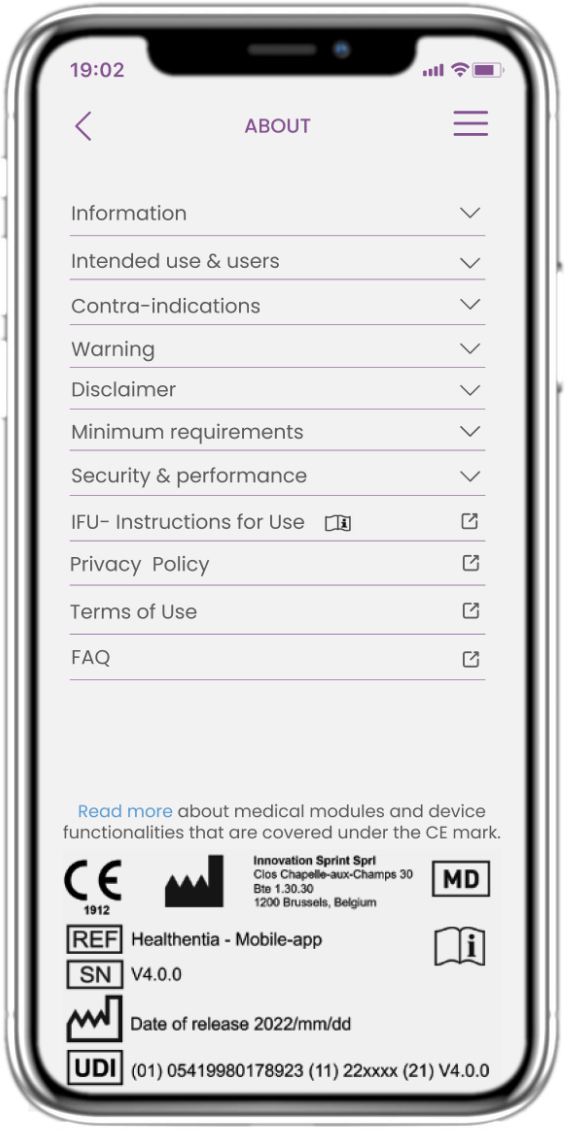
7 MENU – LOGOUT



7.7 LOGOUT

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



7.8 ABOUT– IFU

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

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