



Quick Start Guide



Healthentia version 3.1

issue date: 03-12-2021

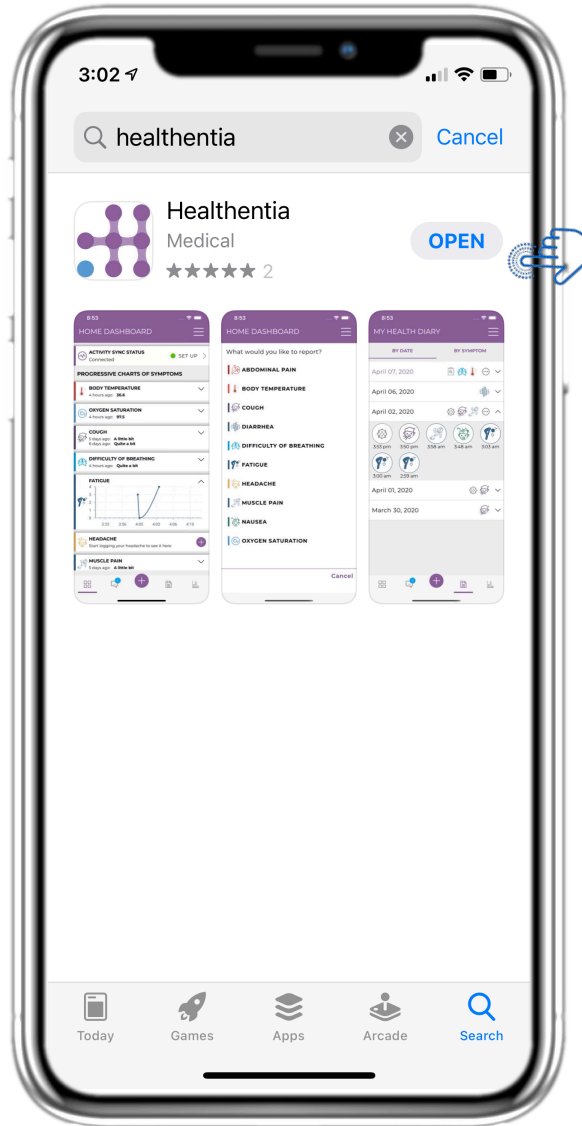


Innovation Sprint Sprl
Clos Chapelle-aux-Champs 30
Bte 1.30.30
1200 Brussels, Belgium

v3 (25/05/2021)



1 DOWNLOAD APPLICATION



Download Healthentia APP from iOS AppStore or Google Play Store.

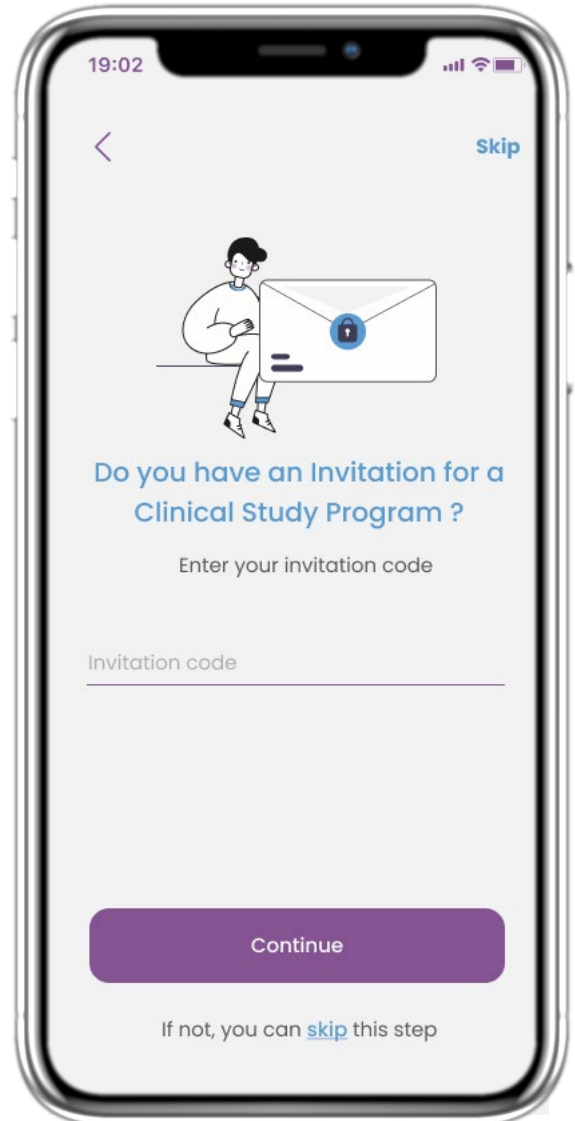


2 WELCOME / REGISTER



2.1 WELCOME PAGE

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

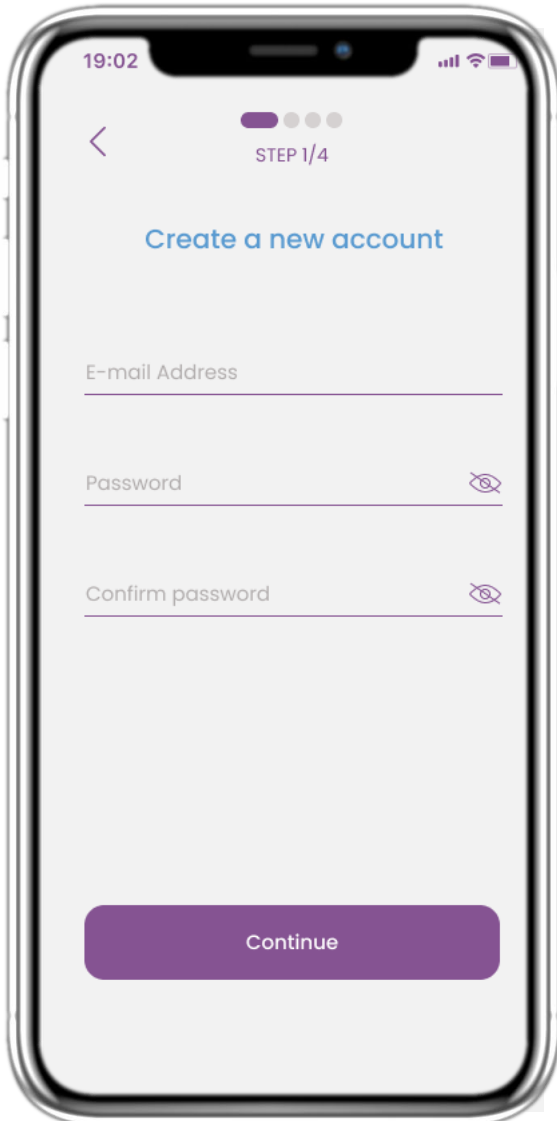


2.2 INVITATION CODE

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

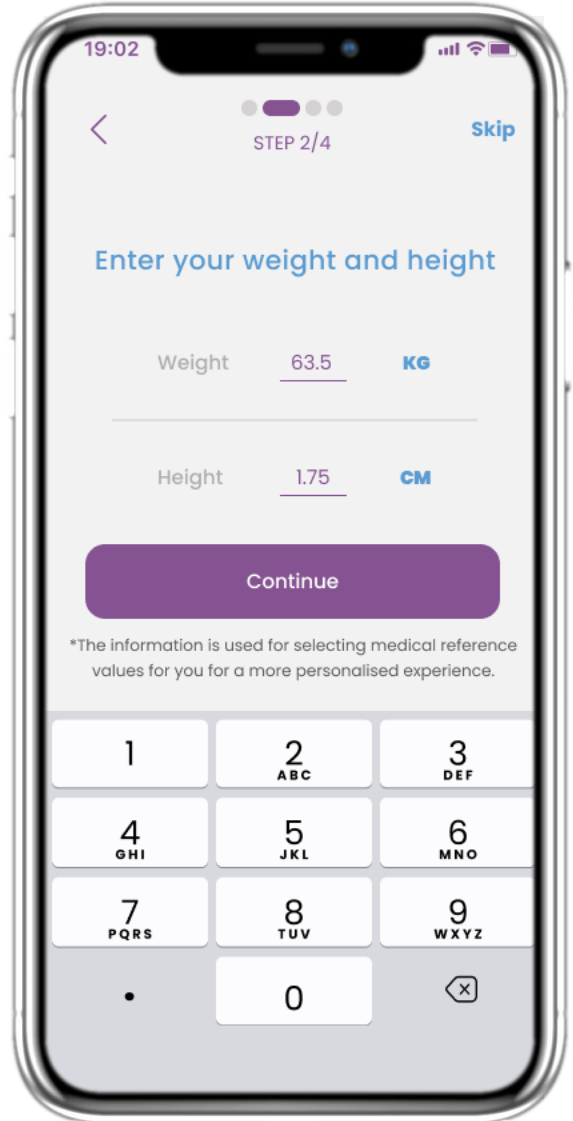


2 ONBOARDING QUESTIONNAIRE



2.3 REGISTER

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

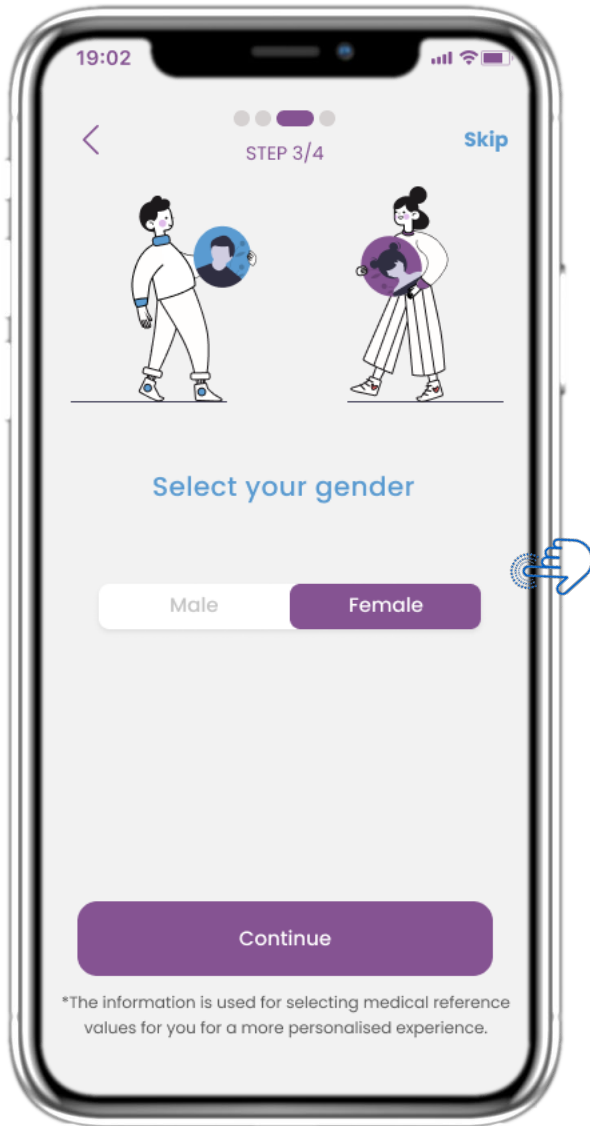


2.4 ENTER WEIGHT-HEIGHT

Enter your weight and height for your profile.

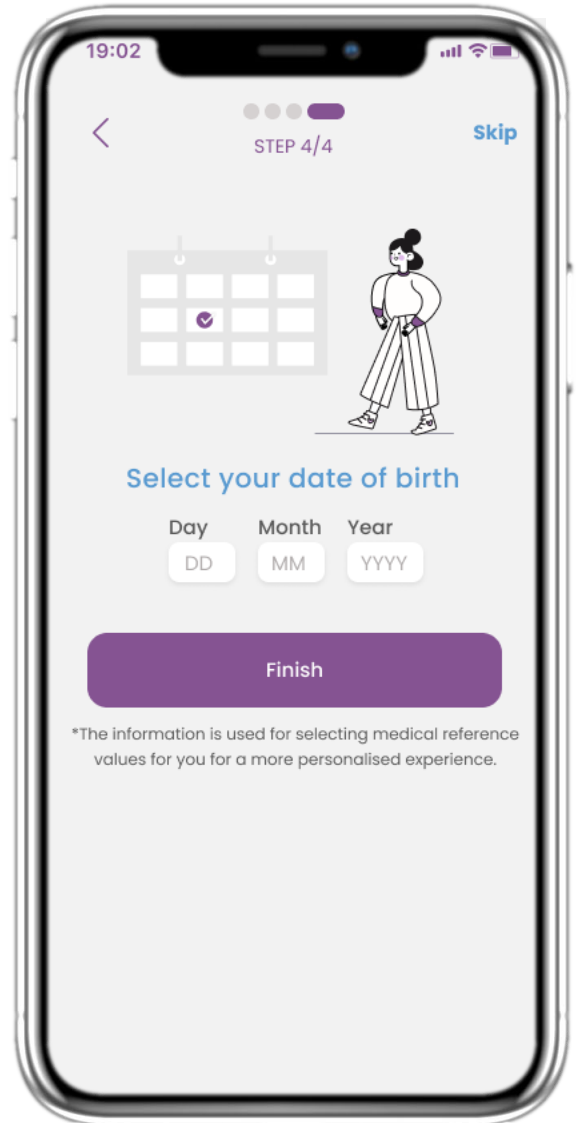


2 ONBOARDING QUESTIONNAIRE



2.5 SELECT GENDER

Pick your gender for your profile.

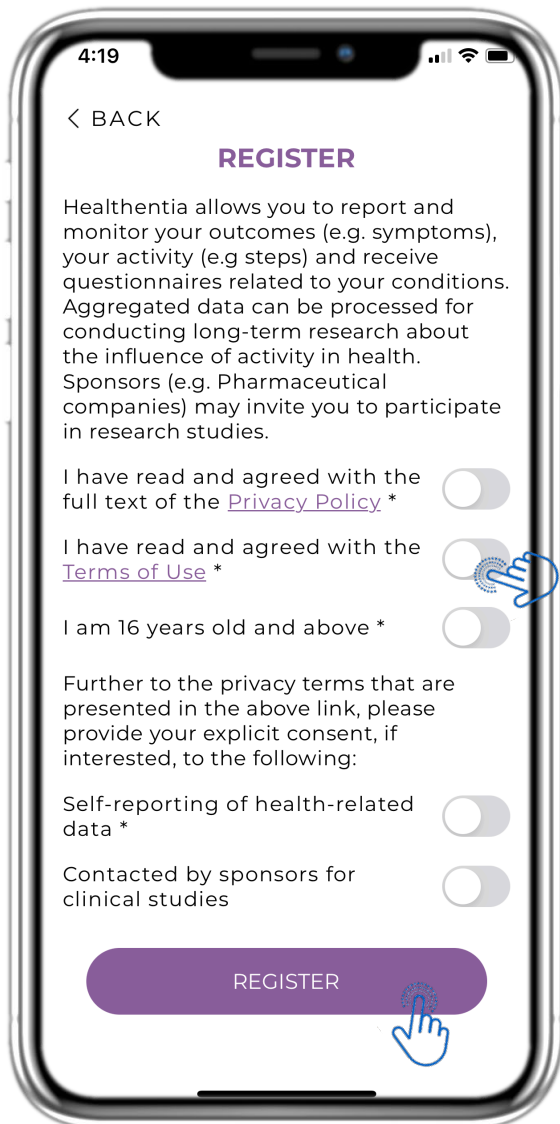


2.6 SELECT BIRTHDATE

Pick your date of Birth for your profile.



2 CONSENTS / INVITATION CODE



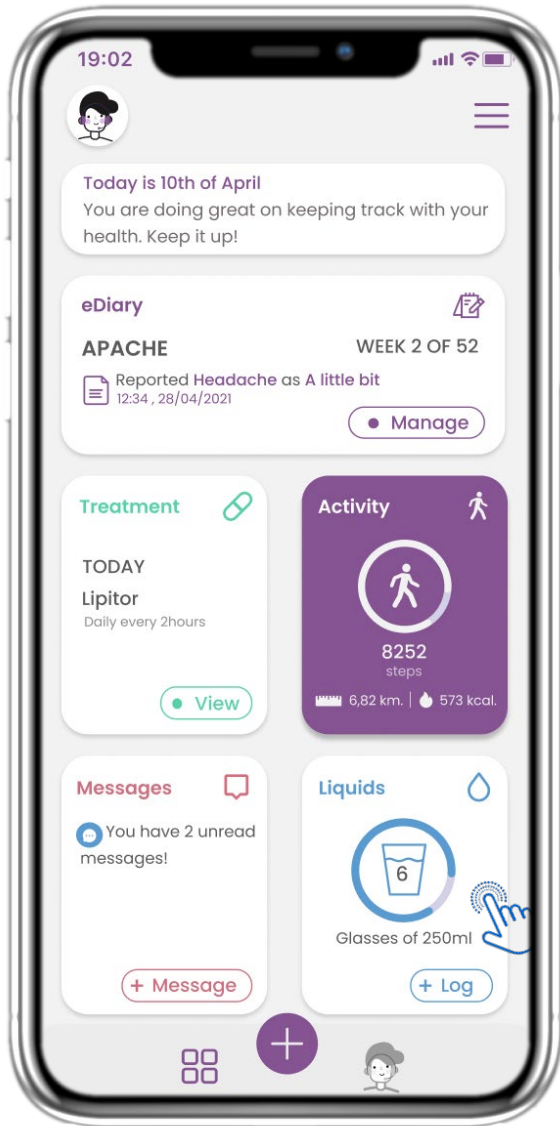
2.7 CONSENTS PAGE

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.

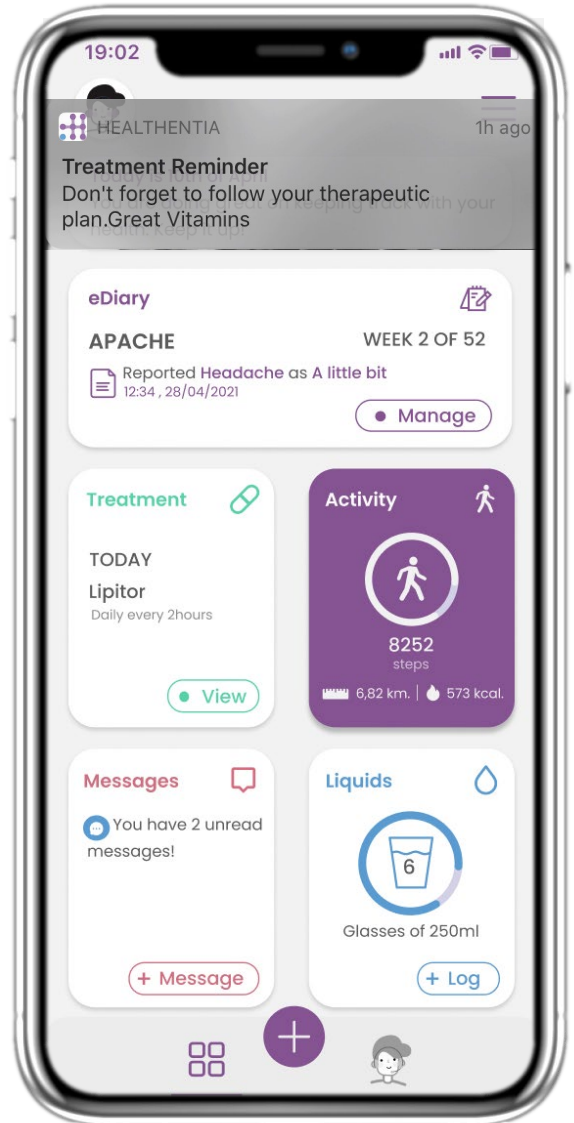


3 HOME & PUSH NOTIFICATIONS



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.

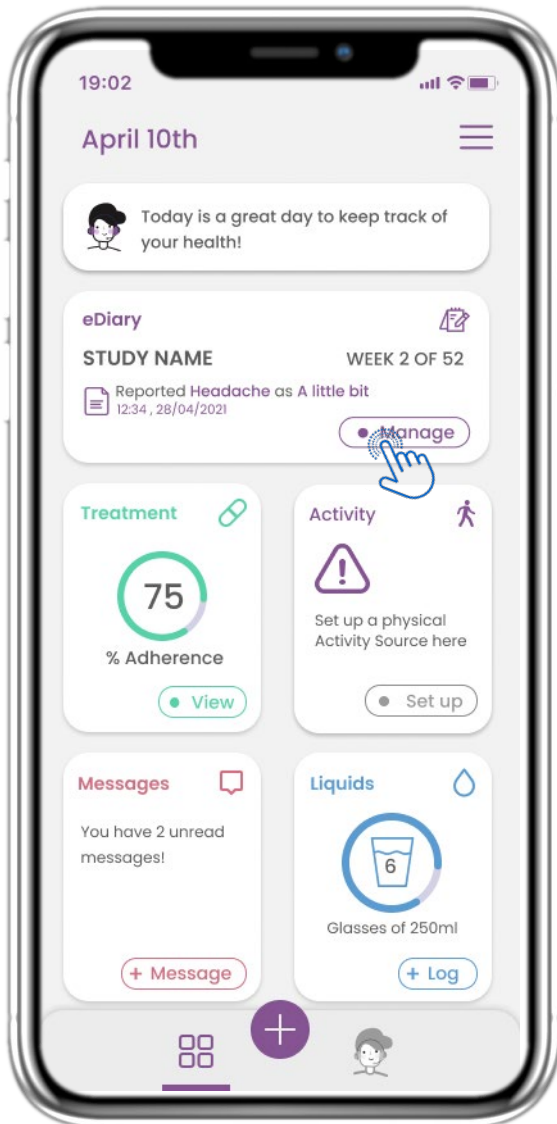


3.2 PUSH NOTIFICATIONS

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

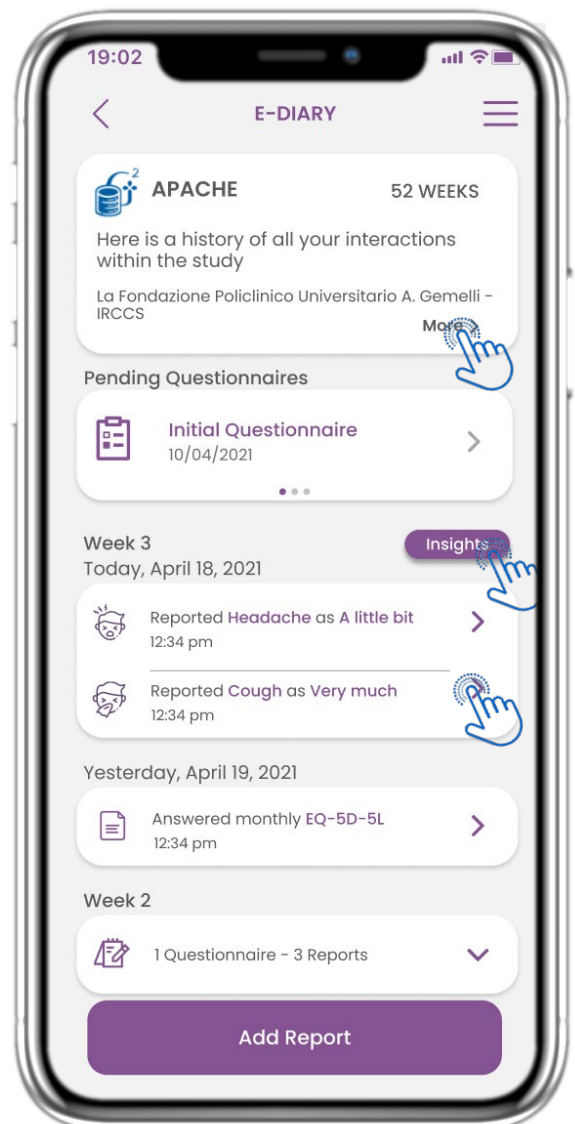


4 HOME WIDGETS



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.

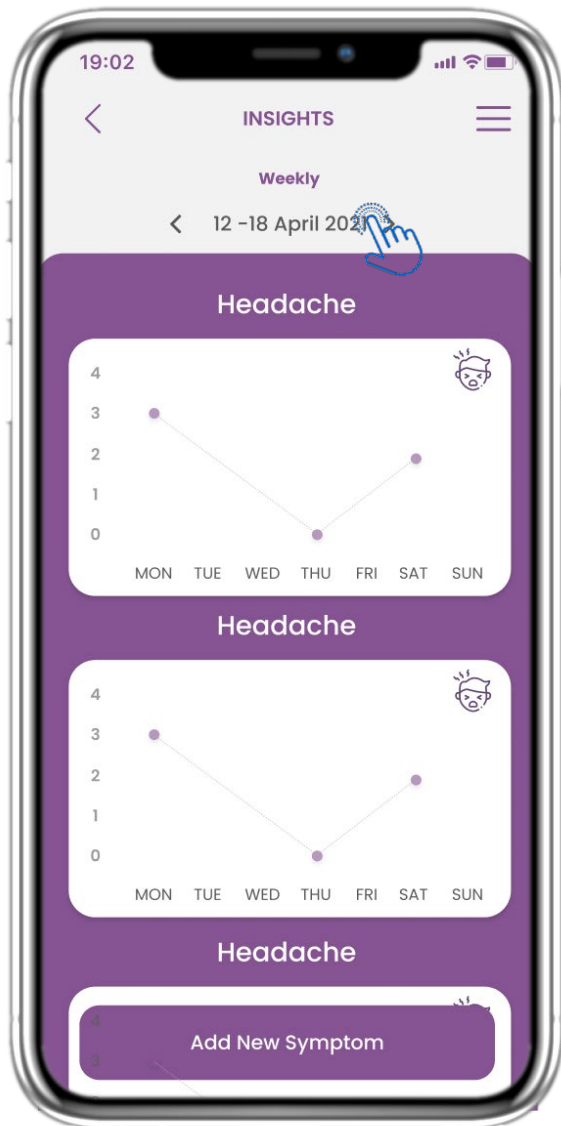


4.2 eDIARY PAGE

In the eDiary page you can find a daily update of your reports and submitted questionnaires as well as the link to a Study page that will have more information regarding your Study adherence. Also a link for Insights.



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.

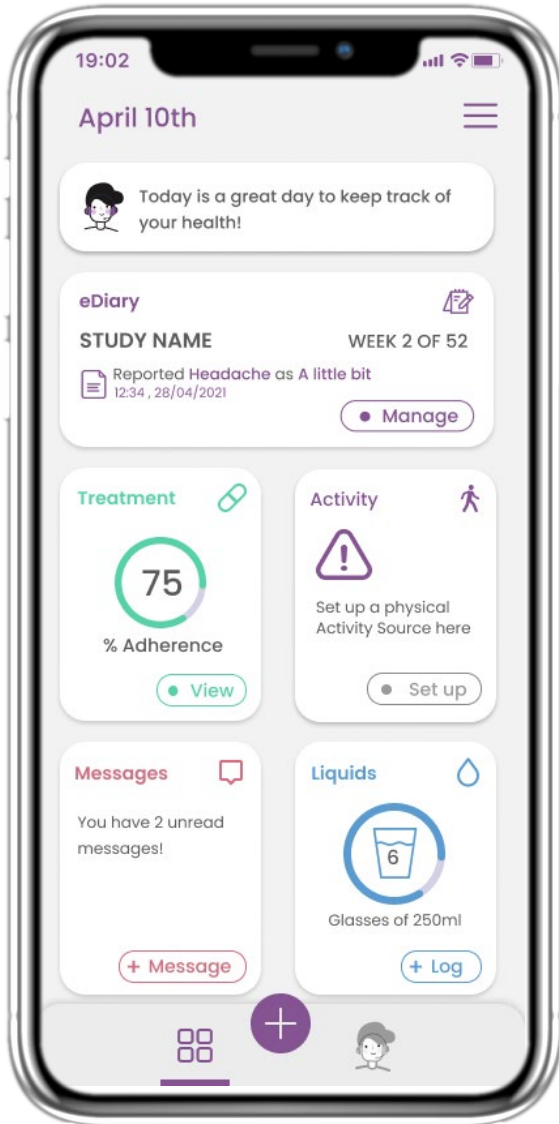


4.4 VIEW REPORTED ANSWERS

Submitted questionnaires with the answers can be viewed.

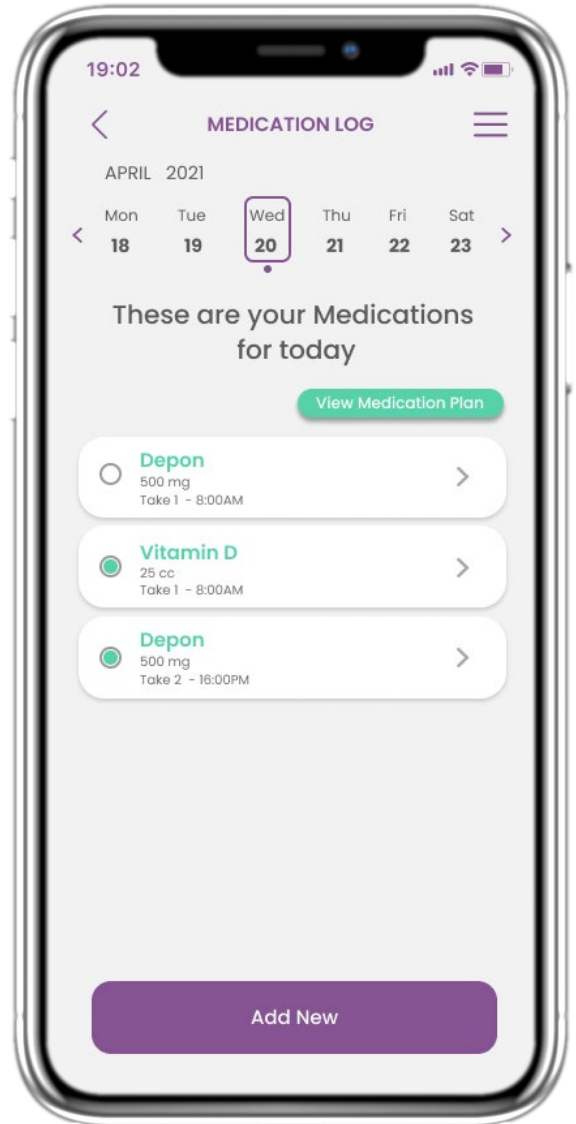


4 HOME WIDGETS



4.5 MEDICATION WIDGET

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

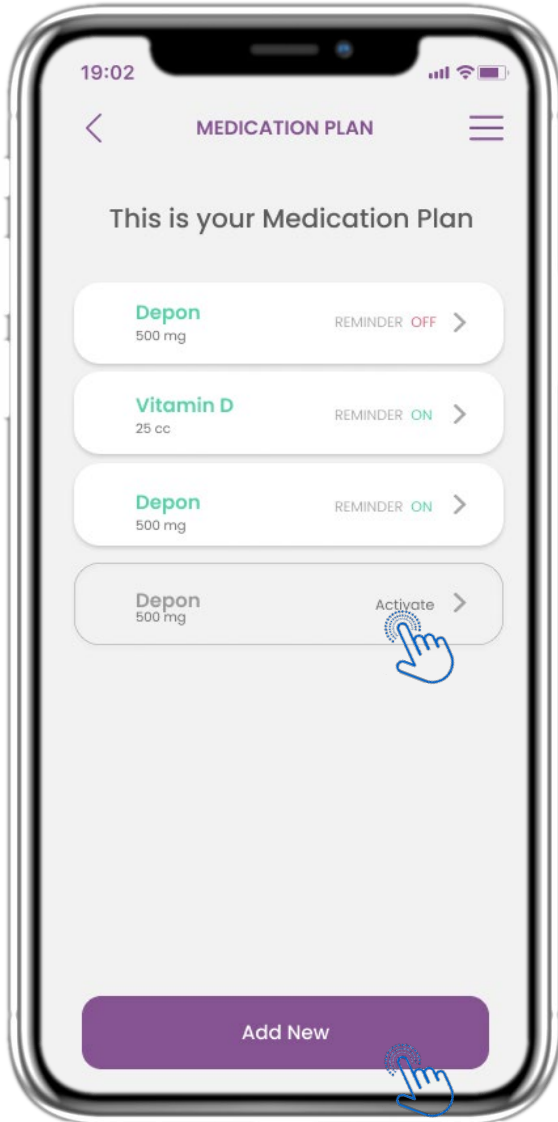


4.6 MEDICATION LOG

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.

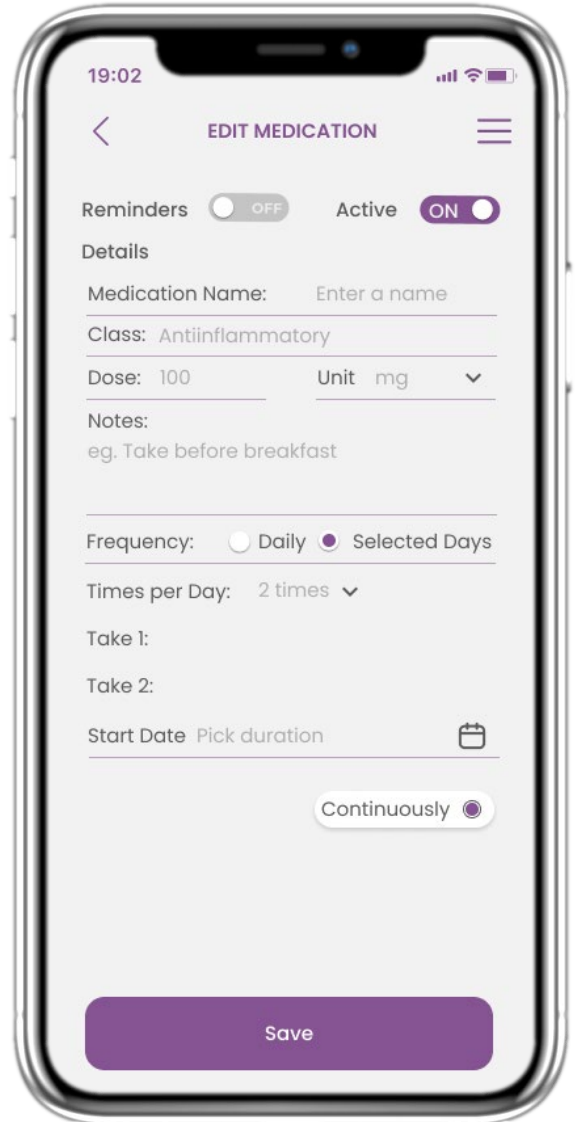


4 HOME WIDGETS



4.7 SEE ALL MEDICATIONS

In the treatment page you can access and configure all treatments



4.8 ADD/EDIT NEW MEDICATION

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

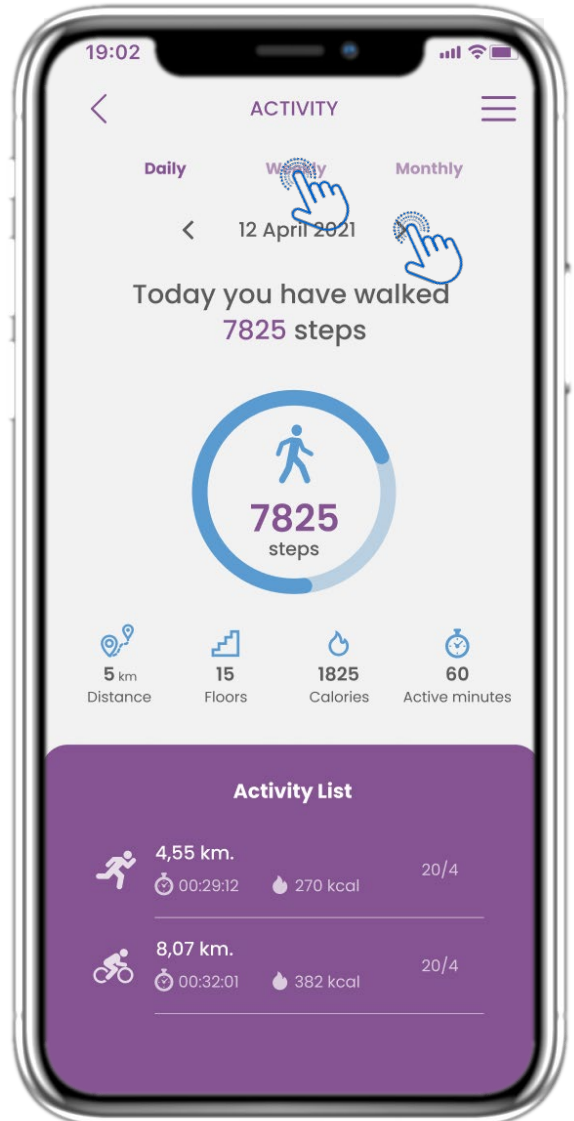


4 HOME WIDGETS



4.9 ACTIVITY

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

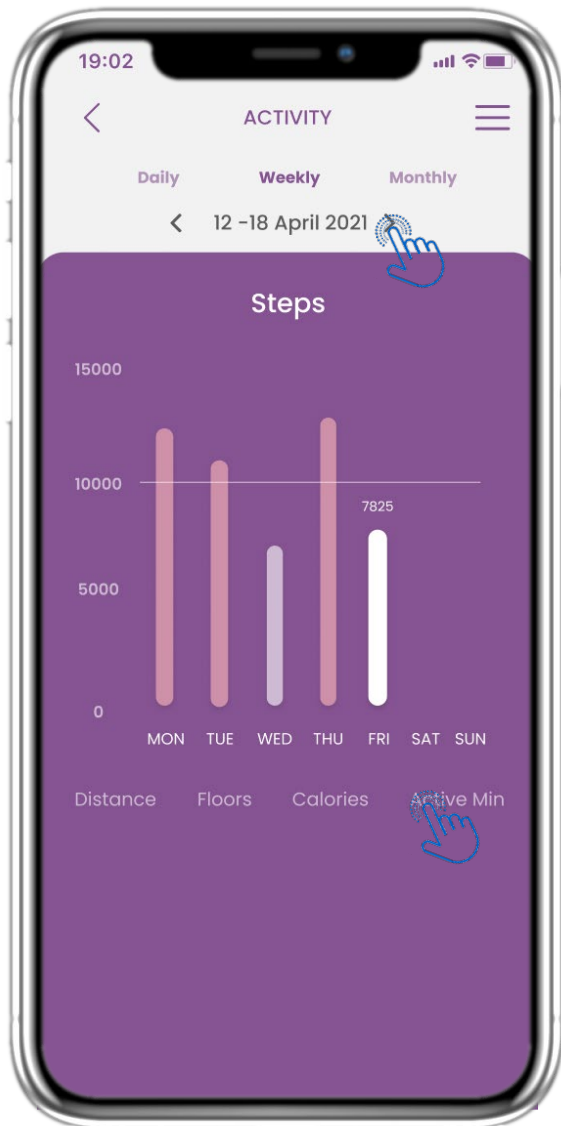


4.10 ACTIVITY PAGE

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.

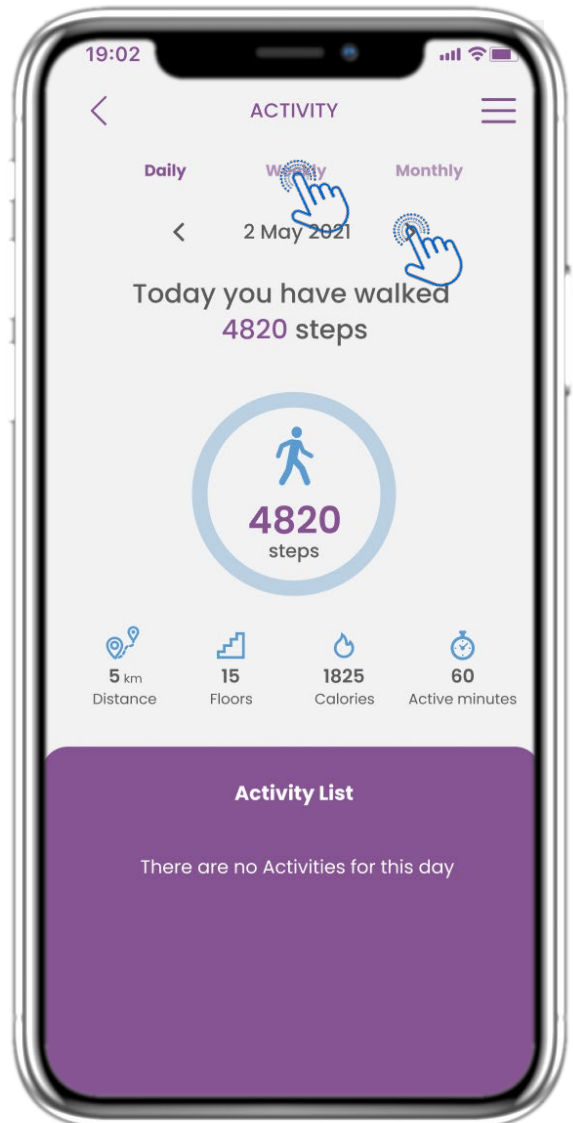


4 HOME WIDGETS



4.11 ACTIVITY GRAPHS

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

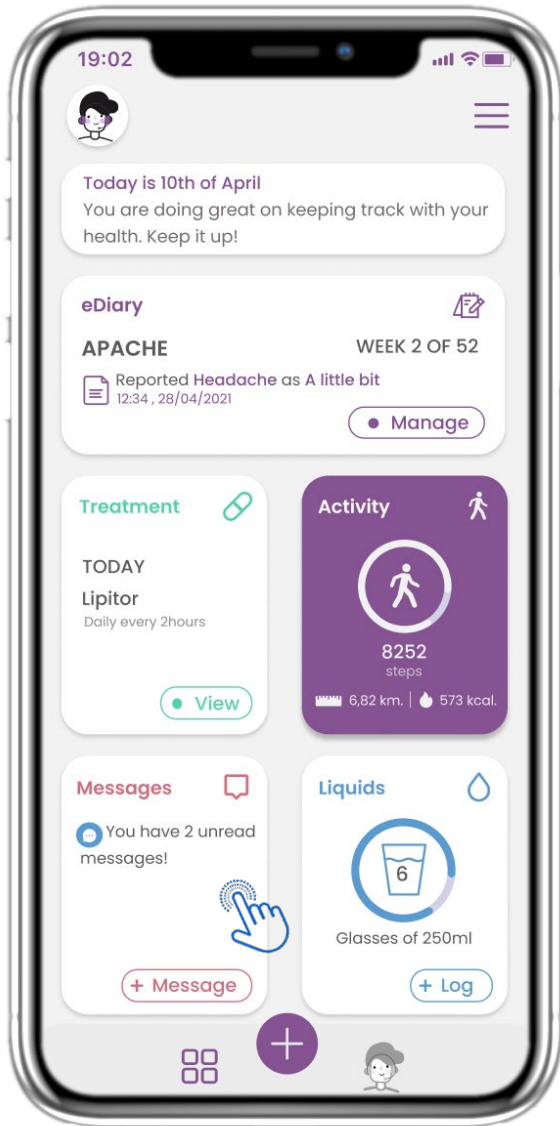


4.12 ACTIVITY PAGE

No sports activities were collected from the wearable.

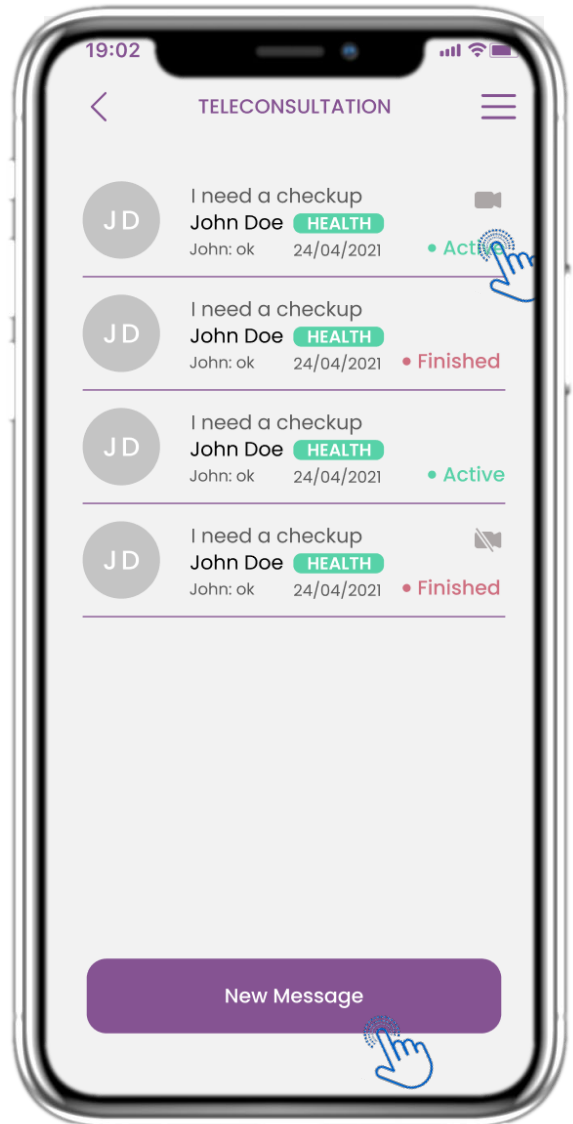


4 HOME WIDGETS



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.

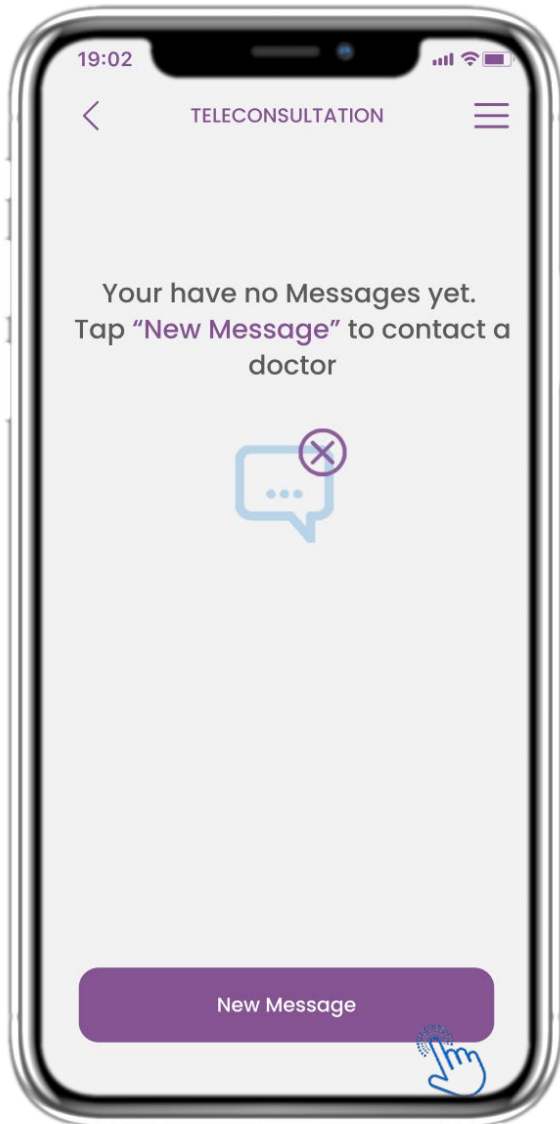


4.14 MESSAGE INBOX PAGE

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

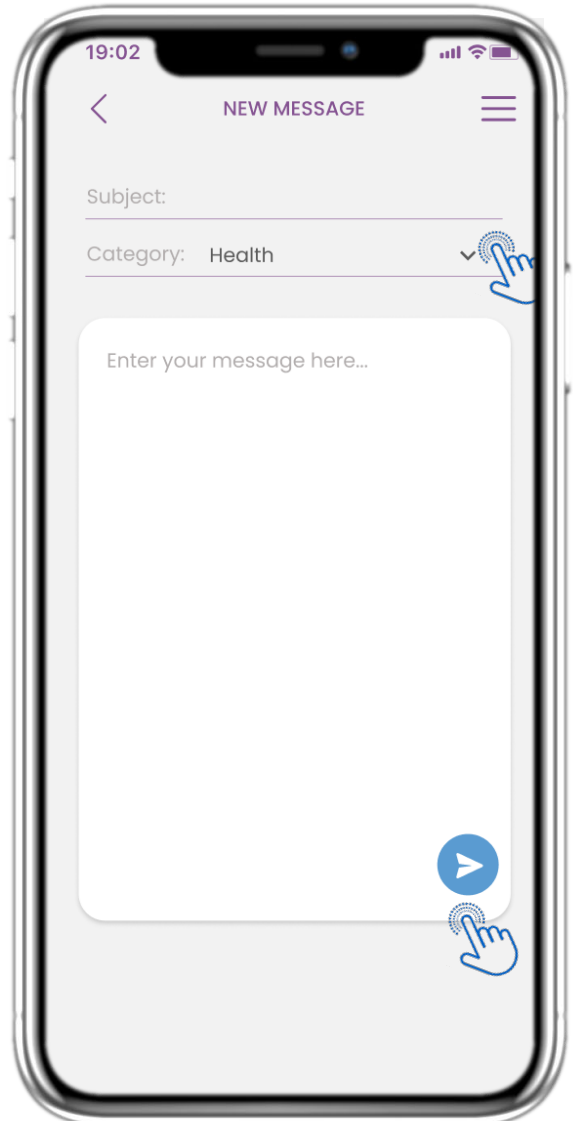


4 HOME WIDGETS



4.15 NO MESSAGES

If there are no messages this is how the page looks.

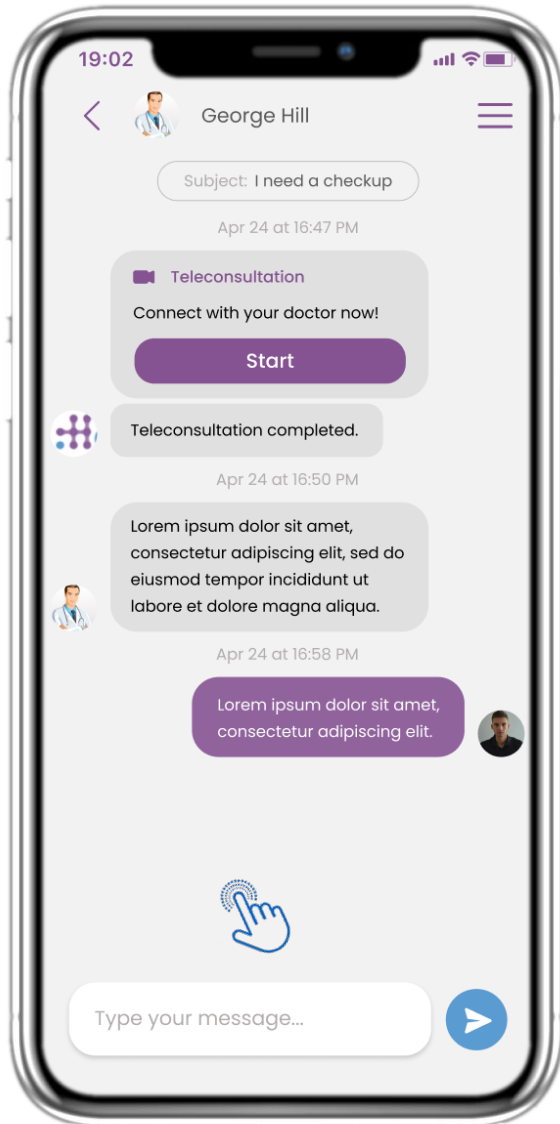


4.16 CREATE NEW MESSAGE

In the Message box you can select a Subject and a category defined by the healthcare professional and enter your message.



4 HOME WIDGETS



4.17 OPEN MESSAGE

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

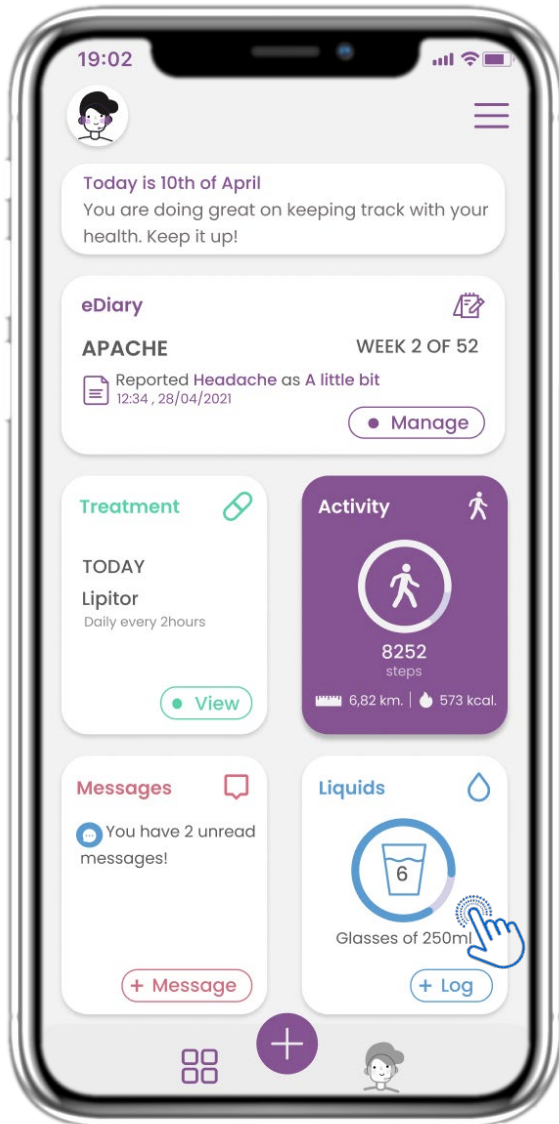


4.18 TELECONSULTATION

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

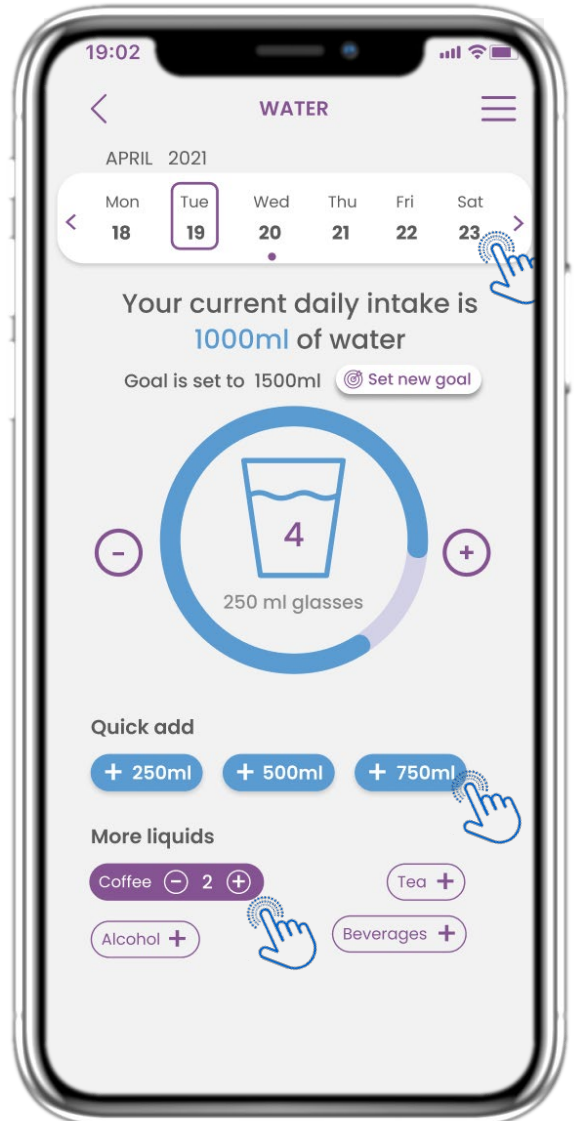


4 HOME WIDGETS



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.

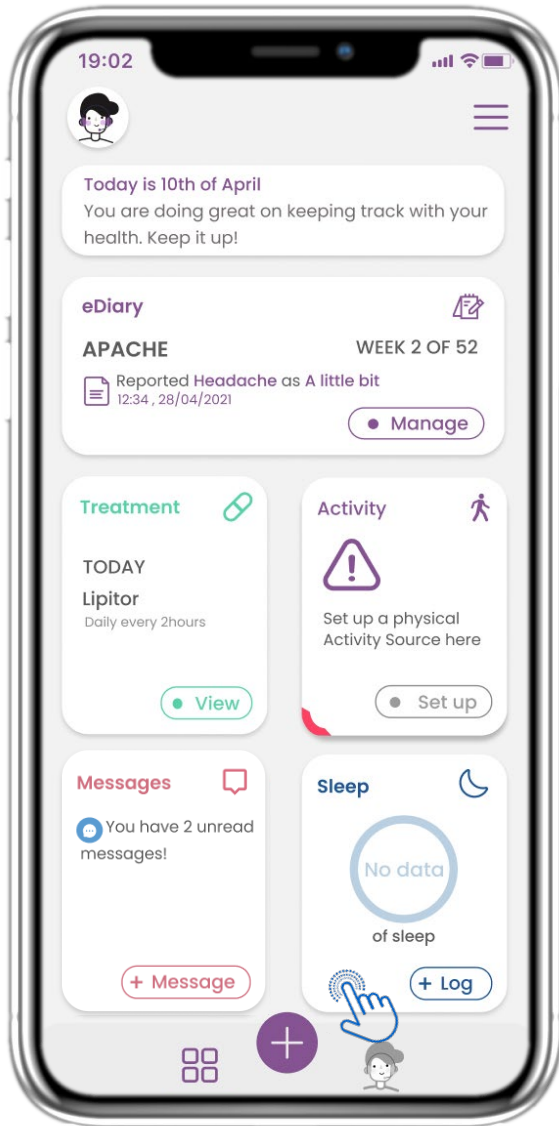


4.20 LIQUID PAGE

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

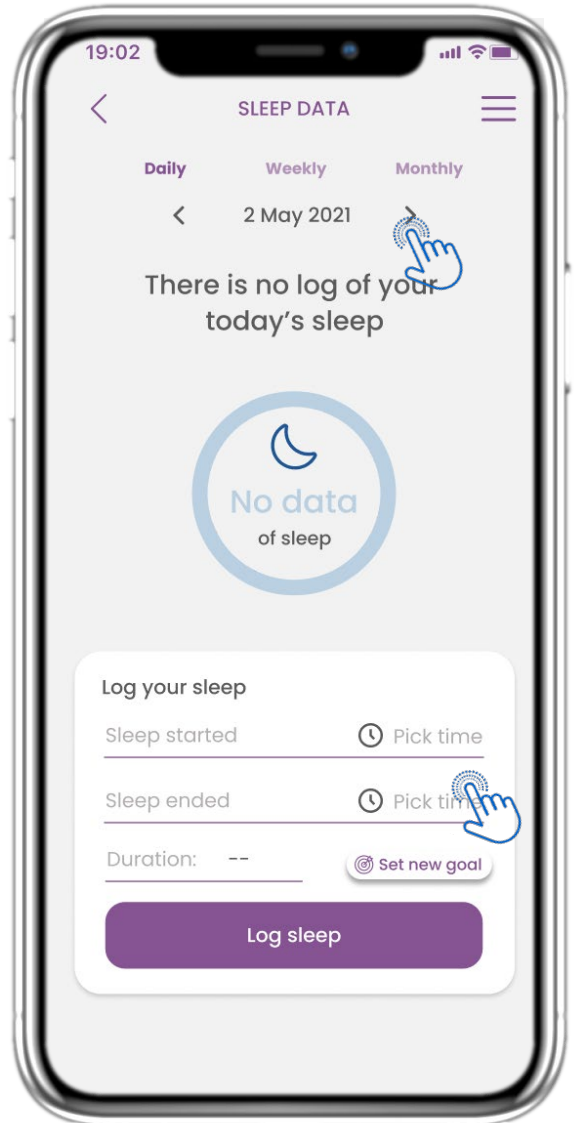


4 HOME WIDGETS



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.

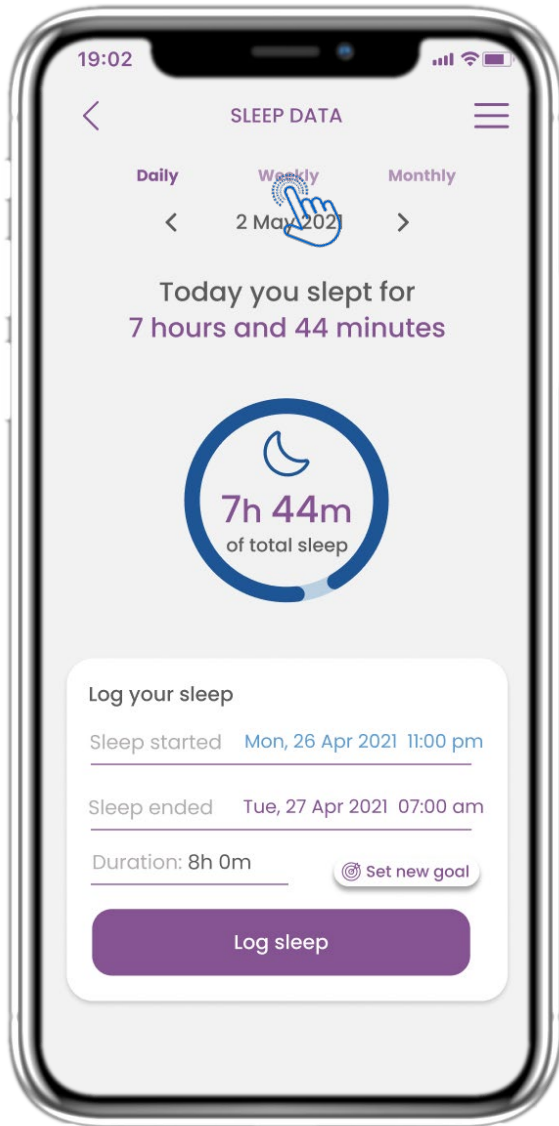


4.22 SLEEP PAGE LOG

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.

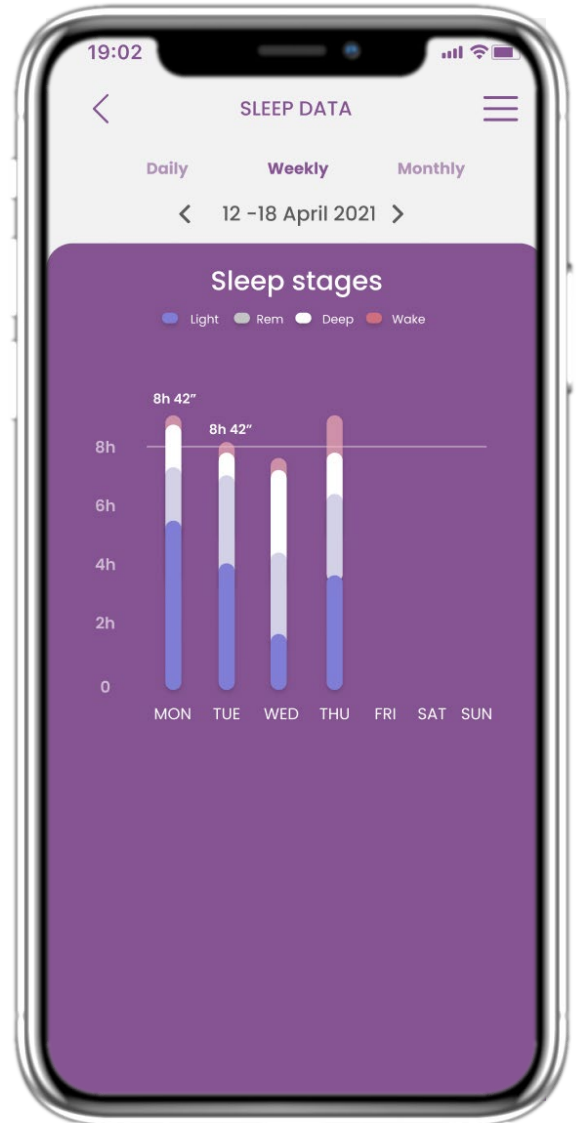


4 HOME WIDGETS



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.

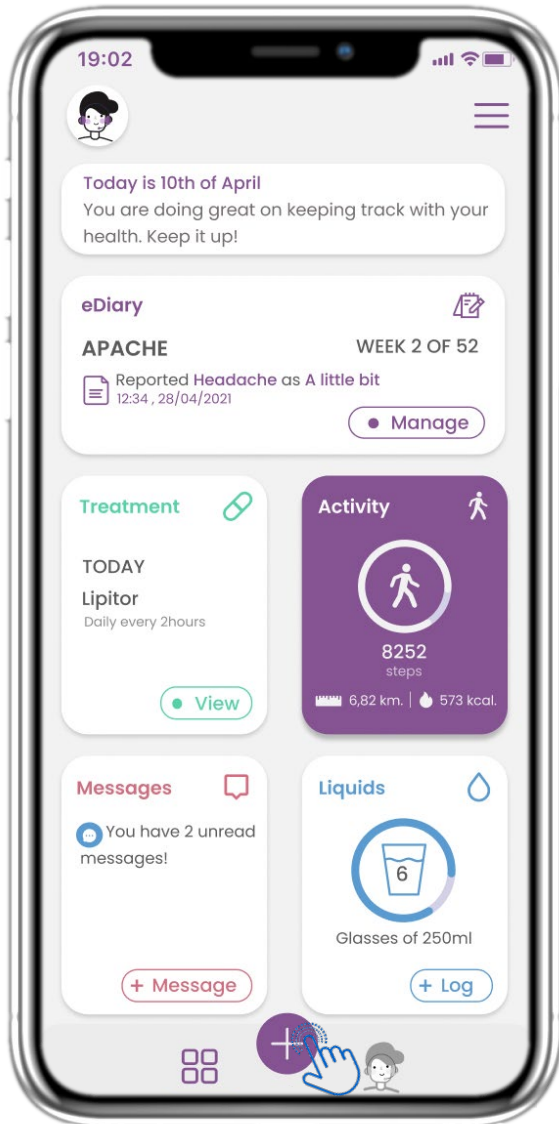


4.24 SLEEP PAGE

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.

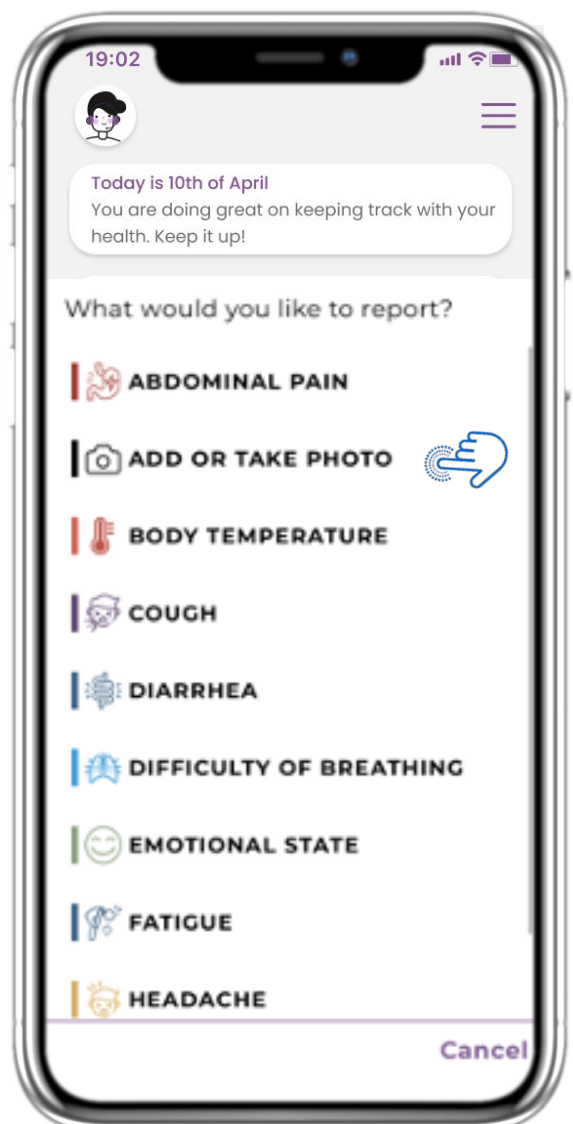


5 ADD REPORTS/ANSWER QUESTIONNAIRES



5.1 ADD REPORTS / SYMPTOMS

From the bottom bar you can select to add reports

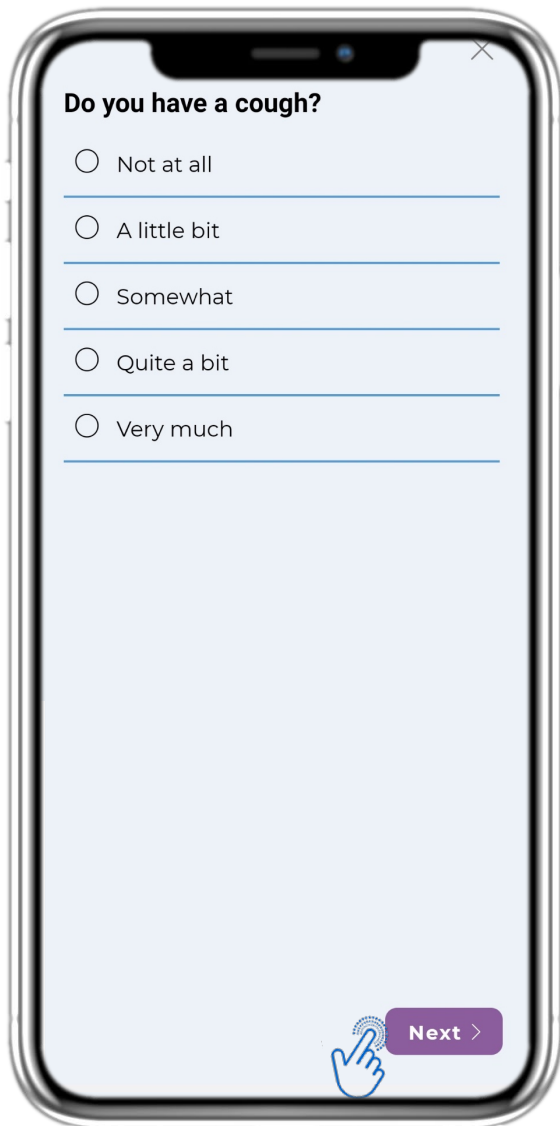


5.2 ADD REPORTS / SYMPTOMS

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



5. ANSWER REPORTS & QUESTIONNAIRES

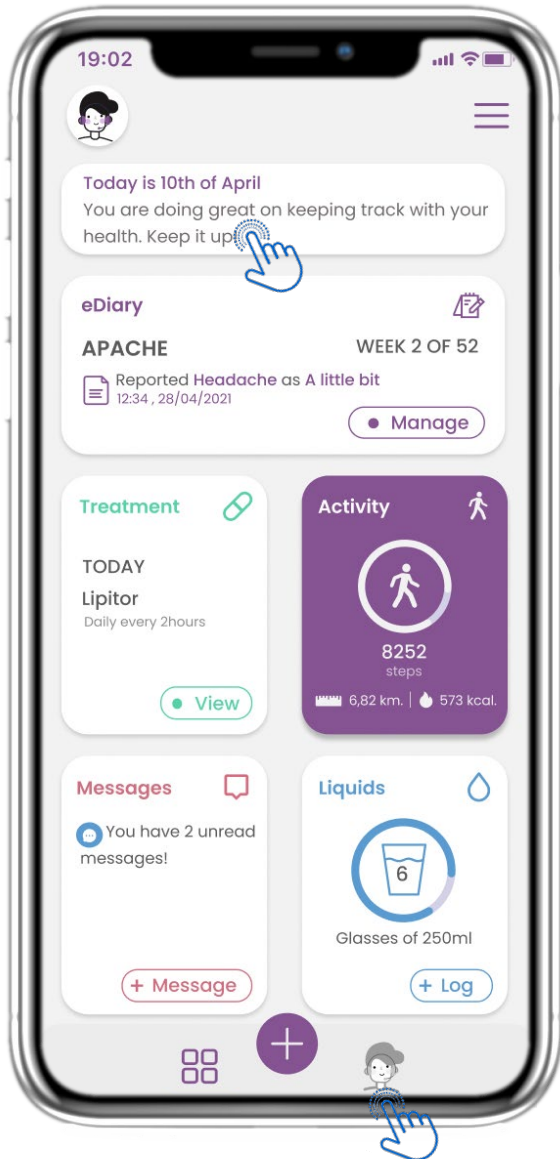


5.3 ANSWER REPORTS/QUESTIONNAIRES

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



6 CHATBOT



6.1 CHATBOT

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

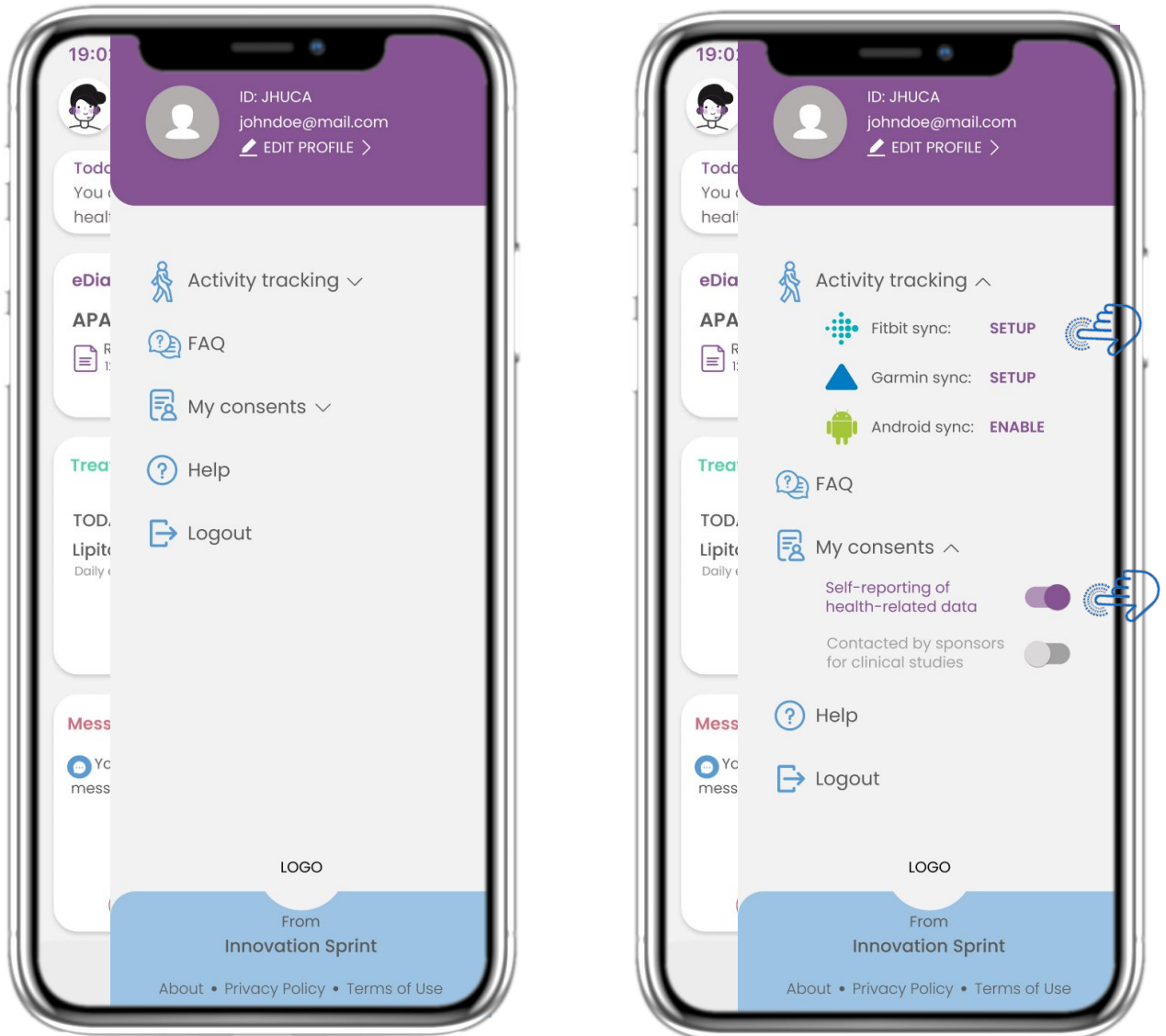


6.2 CHATBOT CONVERSATION

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



7 MENU SIDEBAR



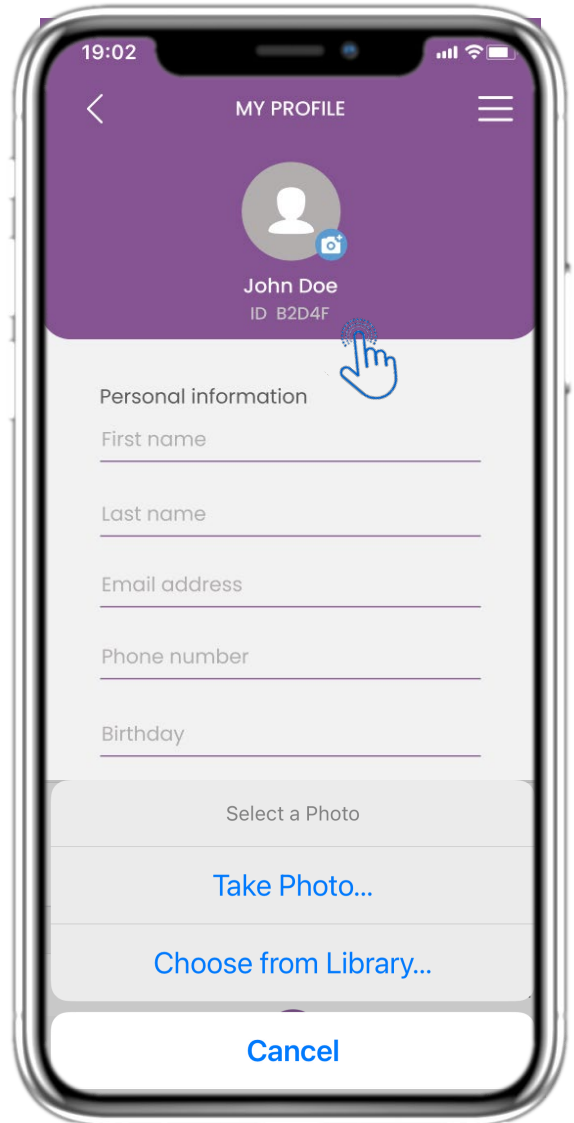
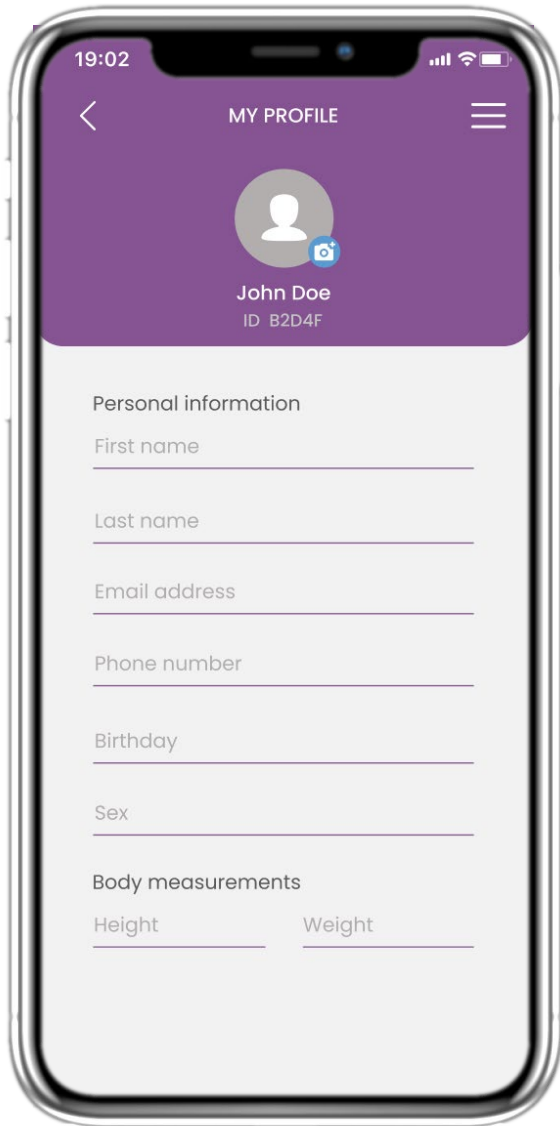
7.1 SIDEBAR OPTIONS

From the menu bar you can edit your profile, set up your activity tracker and enable or disable the explicit consent that you have entered during the registration.

You can also have access to some content pages like FAQ.



7 MENU - MY PROFILE

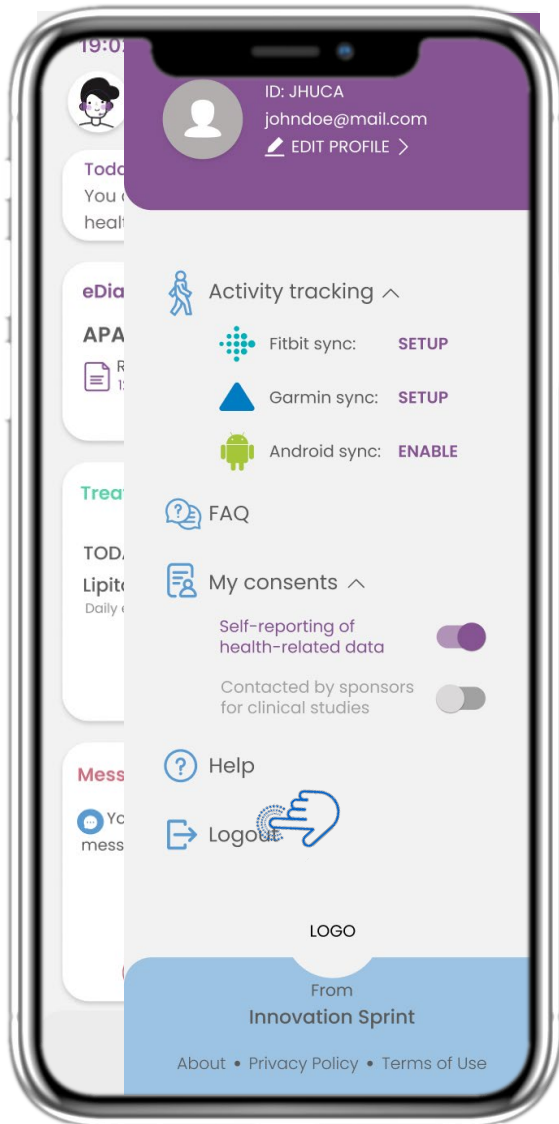


7.2 EDIT PROFILE

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

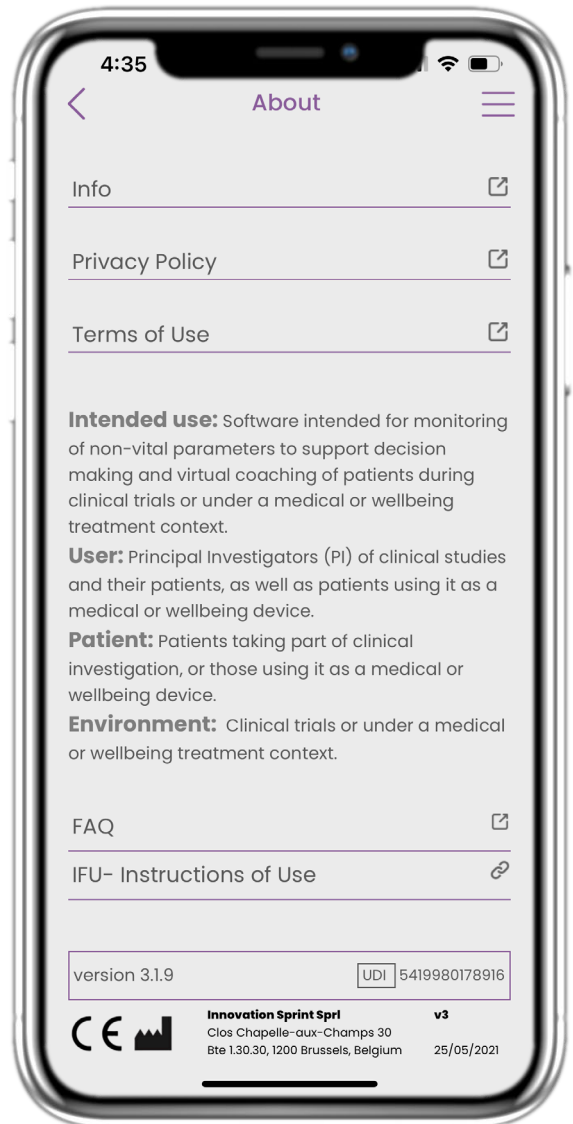


7 MENU - LOGOUT



7.3 LOGOUT

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



7.4 ABOUT- IFU

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





ABOUT

The Healthentia platform, consisting of the Healthentia App and Portal, is considered as an active device. The platform consists of a collection of modules and most of them are non-medical module, there is however a module in the web application that complies with the definition of a medical device according to medical device directive 93/42/EEC. This module monitors non vital parameters to support decision making during clinical trial.

Per rule 12 of the Annex IX of the Directive 93/42/EEC, the HEALTHENTIA Platform is classified as a Class I Medical device.

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 Sprl) 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.

DISCLAIMER

Healthentia is a decision support tool, in which case the physician retains full responsibility for the medical decisions made.

The use of Healthentia is reserved for applications outside of critical situations (operating room, emergency, intensive care).





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 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 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)
- Fitbit trackers and watches via the Fitbit API (Android & iOS)
- iHealth devices via Bluetooth (Android & iOS)
- Any device that is integrated via iHealth Kit (iOS)

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

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.

Performance

Healthentia is a Class I medical device software intended for Software intended for monitoring of non-vital parameters to support decision making and virtual coaching of patients during clinical trials or under a medical or wellbeing treatment context.

Given the absence of direct interaction with the human body, and therefore the independence of the performance from the user, the clinical performance of the device depends only on its technical performance.

