



User Manual eHealth Mobile mobile iOS

eHealth Mobile iOS 1.6.x

Heart for Health ICT BV.

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1. App description

1.1 Contact details

Table 1. Primary contact details

Legal manufacturer name*	Puls Kardioloski Center
Address*	Jurija Gagarina 22M 11070 Novi Beograd
SRN*	
Email*	info@puls-kardioloski-centar.rs
Other contact channels	+381 11 7555 000

Table 2. Partner Information

Legal manufacturer name*	Heart for Health ICT BV
Address*	Van Boshuizenstraat 12 1083 BA Amsterdam The Netherlands
SRN*	NL-MF-000002323
Email*	info@heartforhealth.com
Other contact channels	+31 85 273 83 11

2. Purpose of the app

The eHealth Mobile iOS app helps you monitor your health. In the app, you can register and review your measurements (automatically or manually) and these measurements are automatically shared with your healthcare provider in the eHealth Platform. The eHealth Mobile iOS app is intended to support the monitoring of patient health.

2.1 General use of the app

General

- In the menu bar you can navigate to different pages: the start page, the measurements page and the settings page.
- By clicking on the icons at the bottom of the screen, you can navigate to the desired page.

Startpage

- The app receives informative notifications and measurement tasks from the platform. Which tasks or notifications you receive depends on the programme you have been enrolled in by your healthcare provider.
- You can easily perform the tasks by clicking on a task. Depending on the type of measurement, you can choose to perform the measurement manually or with a connected device.

Measurements page

- The measurements page gives you more insight into the measurements made. On the page, you will find graphs per type of measurement for which you have registered or were registered.
- To get a more detailed overview of your measurements, click on one of the observations.
- You will then be taken to a screen where you can see a daily, weekly or monthly overview. If the measurement has been registered by your healthcare provider in the eHealth Platform, the date will say 'Carried out by healthcare provider'.

Settings page

- On the settings page, you can gain insight into several sections. In 'My details' you can see the information known about you to your healthcare provider in the eHealth Platform. If this information is incorrect, you should contact your healthcare provider.
- In "My devices" you can find which devices are available for pairing with the app. You can click on the available devices to pair them.
- In 'My healthcare institutions' you can find the healthcare institutions that are linked to your account. It is possible that you have an account for several healthcare institutions.
- By clicking on 'Privacy and conditions' you will open an in-app browser where you can read the privacy and conditions again. To do this, you must select the healthcare institution to which you belong in order to read the correct Privacy and Conditions. If you do not know which Privacy and Conditions apply to your healthcare institution, please contact your healthcare provider.
- The 'About this app' page has all the information about the app and the app developer. You can also find the user manual here by clicking the button.

Taking measurements

Perform measurement manually

- To perform a measurement manually, select 'manual' during the execution of a measurement.
- Depending on the programme you have subscribed to, input fields are displayed.
- You have to fill in the values by clicking on the input fields. A keyboard will appear that you can use to fill in the values.
- If you have taken the measurement at a different time, you can use the date and time selector to select the correct time.
- When you have entered the input fields, the 'Save measurements' button becomes selectable. You can now save the measurements. A confirmation message follows, read this message to check whether the measurement was sent. Note: The colours of the information screen do not indicate the medical content of the measurement you have taken.
- When the measurement has been sent or saved, it will be reflected on the measurements page.
- You can only add measurements when you are in an active programme. If you are not in an active programme, you can only view your measurements.

Bluetooth connection; Check the connectivity with doctor or eHealth team member

- Check that the app, phone and possibly the measuring device are set up correctly so that your measurements are received by the doctor. You can do this by following the steps below:
- Navigate to the Settings page and click on My details. Are your personal details displayed? Then you have a correct connection with the doctor.
- Navigate to the My Devices page and check that the device you have already connected is in the Paired Devices list.
- It is important to have a working internet connection to be able to send the measurements to the doctor. It is possible to take measurements without an internet connection, but these are only sent to the doctor once the app is connected to the internet. Medical indications

3. Medical Indications

The eHealth platform cannot be used:

- for monitoring life-threatening conditions or situations that require immediate response by caregivers;
- for real-time monitoring of vital functions;
- for patients who are unable to use the medical device in a proper and reliable manner (this is at the discretion of the healthcare professional responsible for the patient's registration);
- by patients who do not benefit from the use of the medical device due to their medical condition (this is at the discretion of the healthcare professional responsible for the patient's registration).

4. User group

The intended user group is patients with a condition that requires remote monitoring, or as preparation for a consultation or medical intervention.

A healthcare provider decides whether to include the patient in the programme. An example of a condition that can be monitored with the eHealth Mobile iOS app is hypertension.

1. Patients to be monitored for a medical intervention, but not with a chronic condition
 - 1.1. There is no specific age for the use within this group
2. Patients collecting health data as input for a consultation, for example for anamnesis or insight into the medical history.
 - 2.1. Life-style factors can be monitored through periodic surveys shared with a patient
3. Patients with chronic conditions
 - 3.1. Mostly patients between 20 and 100 years old. The largest group of users will be between 60 and 80 years old.
 - 3.2. This group may include:
 - 3.2.1. Hypertension patients
4. Patients who are pregnant.
5. Patients should have access to the internet and a mobile phone.
6. Patients should be able to use apps on their phones.

Requirements

- Patients should have access to the internet and a mobile phone.
- Patients should be able to use apps on their phones.

5. Clinical benefit

With the Heart for Health app, you can easily collect data needed for an eHealth programme. The app offers various functionalities, such as notifications and a link to different devices.

You receive a message in the app when it is time to take a measurement or complete a questionnaire. Measurements can be entered manually or by using CE-marked devices such as the iHealth Track, iHealth Lina or Omron HEM-9210. Registered measurements and questionnaires are sent to the caregiver portal. It is also possible to see your own registered measurements in the app.

There are several potential benefits of using the Heart for Health app. Which benefits actually occur depends on several factors, including the eHealth programmes you participate in. Possible benefits are (1) being able to take measurements from your own home, without having to go to the hospital, (2) being able to fill in questionnaires from your own home, without having to go to the hospital, (3) being discharged earlier after an admission, (4) gaining insight into your own measurements, (5) by using the connected devices possibly being able to take 'better' measurements and send better data to your care provider, (5) taking measurements and sending them to your care provider whenever you want, regardless of where you are at that moment.

6. Intended use environment

Patients should use the product in the following environment of use:

1. Home environment
2. When the characteristics of the condition call for it, the patient can use the product outside the home environment in their everyday surroundings.
3. Institutional environment, for training, instruction and support purposes.

7. Pairing devices (only applicable for bluetooth devices)

- You can pair a device by clicking on a task and choosing "Pair device" or selecting a device from "My devices". When pairing a device, follow the steps described in the app.
- It is important that you follow the steps as closely as possible. Also, always check that your Bluetooth is turned on and make sure your batteries are not dead.
- When you have followed all the steps, you can click on the 'Connect' button and you will get a confirmation that your device has been paired.
- In the app, you can see which devices can be paired with the app.

8. Sterilisation, final assembly, calibration, cleaning and disinfection

- It is not necessary to sterilise, assemble, calibrate, clean or disinfect the eHealth Mobile iOS app.
- When using connected devices, this may be applicable on a device level.
- For this you need to follow the instructions of the devices regarding sterilisation, final assembly, calibration, cleaning and disinfection.

9. User training and qualifications

- The user does not need to have any specific training or qualifications to use the eHealth Mobile iOS app. However, it is important that the user carefully follows the instructions of the app and the healthcare provider for correct use of the app.

10. Safety information

- When using paired measuring devices, follow the instructions and safety information of the paired devices. Which devices can be connected to the platform can be found in the app under 'My devices'.

Risk	Precaution
Patient uses platform in a life-threatening situation	<ul style="list-style-type: none"> - The patient should not use the platform in a life-threatening situation or in an emergency. - In the event of a life-threatening situation or emergency, the patient should contact the emergency department and never use the platform.
Patient is not aware of how to act in a life-threatening situation	<i>See above</i>
Patient is not aware that a life-threatening situation exists	<i>See above</i>
Healthcare provider uses the platform for patients in a life-threatening situation	<ul style="list-style-type: none"> - Patient should not use the platform in a life-threatening situation or emergency. - Healthcare provider should not

	Include those who are in a life-threatening situation.
Incorrect patient medical data is displayed to the healthcare provider. The causes may be corruption of the data or other problems in the software.	<ul style="list-style-type: none"> - Caregiver must be aware that incorrect data may be displayed - Caregivers should not make a final decision on the treatment of the patient solely on the basis of the information presented by the platform.
Patient is (temporarily) unable to use the platform. This can lead to dangerous situations as it will not be possible to monitor or correctly evaluate the patient during this time.	<ul style="list-style-type: none"> - The patient must be in possession of a suitable telephone in order to use the device. - The patient is not advised to use the platform in case of internet problems.
Patient is unwilling to use the platform so the healthcare provider is unable to monitor or evaluate the patient	<ul style="list-style-type: none"> - Healthcare provider should only include patients who are willing to participate in the platform.

Patient accidentally sends in incorrect medical data which can lead to erroneous decision making by the healthcare provider about the patient's health	<ul style="list-style-type: none"> - Carer should not make a final decision on the treatment of the patient solely on the basis of the information presented by the platform.
Patient sends in fraudulent medical data, for whatever reason, which can lead to the health care provider making wrong decisions about the patient's health	<ul style="list-style-type: none"> - Caregivers should not make a final decision on the treatment of the patient solely on the basis of the information presented by the platform. - The patient must provide the correct medical data. - The platform should not be used in the event of an emergency or life-threatening situation.
A patient may misinterpret the medical data.	<ul style="list-style-type: none"> - Only the caregiver can correctly interpret the medical data
A healthcare provider may misinterpret medical data.	<ul style="list-style-type: none"> - Caregivers should not make a final decision on the treatment of the patient solely on the basis of the information presented by the platform. - The platform should not be used in an emergency or life-threatening situation.

Due to connectivity problems or other problems with the software, the data collected by a patient is lost. This can lead to a situation where a healthcare professional makes a wrong decision because he does not have all the data.	<ul style="list-style-type: none"> - Patients must be familiar with the use of a hardware device before they connect this device to their mobile application.
Caregiver is not able to use the platform.	<ul style="list-style-type: none"> - Caregiver must use the platform in a safe and controlled working environment with a secure internet connection.
Due to problems in the software, a healthcare provider may not be alerted when high priority data is submitted. This may lead to a situation where a healthcare professional cannot intervene because they are unaware of the patient's situation.	<ul style="list-style-type: none"> - The platform should not be used in an emergency or life-threatening situation.
A healthcare provider cannot contact a treating specialist because of incorrect contact details.	<ul style="list-style-type: none"> - Caregiver must contact the patient's healthcare institution if the contact details of the treating specialist are not present or are incorrect.

A healthcare provider cannot contact a patient because of incorrect contact details.	- Patient should not use the platform in a life-threatening situation or emergency.
Data collected by third-party devices are not received by the eHealth platform, or are received incorrectly.	- Healthcare provider should only include patients who are capable of using third-party devices

11. Identification and labelling

- To identify the app, you can find the version and HASH code on the login screen and the settings screen.
- By navigating to the 'About this app' screen, you can find more information about the labelling of the app.