Beat2Phone ECG Instruction Manual

Beat2Phone ECG

Powered by VitalSignum

Version: 2.8
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Contents

1 Instruction Manual

1.1 VitalSignum Oy Beat2Phone kit

Trademark: Beat2Phone

Model: ECG

The Beat2Phone ECG kit (GTIN: 6429810109040) consists of the following products:

- Beat2Phone ECG Sensor (GTIN: 6429810109002)
- Beat2Phone ECG Charging Connector (GTIN: 6429810109019)
- Beat2Phone ECG Electrode Strap (GTIN: 6429810109033)
- Beat2Phone ECG Application (GTIN: 6429810109064)

The information in this document is subject to change without prior notice.

CE **0598**

This device complies with the following:

- Medical Device Directive 93/42/EEC
- RoHS Directive 2011/65/EU

VitalSignum Oy
Health Innovation Village,
Kuortaneenkatu 2,
00510 Helsinki, Finland.
Tel. +358 20 741 2500
www.beat2phone.com
info@vitalsignum.com

2 Intended use

The VitalSignum ECG-sensor is intended for use in clinical and non-clinical environments for measuring the electrical activity of the heart via two skin contact electrodes that provide a single-lead electrocardiogram accurate enough to detect arrhythmia. It is suitable for monitoring adults of normal weight that require heart condition monitoring. The collected data on electric activity of the heart over the measured time period is stored as an EDF ECG file that can be accessed by healthcare professionals as needed. The sensor is not intended for children, nor does it provide any automatic analysis or diagnosis functions.

3 Introduction

The wearable VitalSignum ECG sensor allows personal, easy, reliable, and accurate measurement of a single-lead ECG (electrocardiogram). It uses an internal battery-powered sensor device equipped with ECG registration memory for measuring voltage across skin contact electrodes, and a mobile device application for ECG display and sensor control. The sensor connects to an electrode strap with snap connectors. This principle of operation is well-established for ECG measurement, and similar chest strap-based heartbeat monitors are widely used for sports applications. The 2 kHz ECG voltage sampling frequency of the sensor allows for accurate RRI calculation and nearly noise-free recording of the entire PQRST sequence with accuracy suitable for medical-level analysis.

The device supports up to 24 hours of continuous ECG measurement with data stored into the sensor memory as a recording file. The file can then be transferred as an EDF+ ECG file to a computer for more detailed analysis. The sensor battery can be recharged with the charging connector accessory.

Adult patient users can take ECG measurements over extended periods during their daily activities, for example, when they are exercising, sleeping or working out, by wearing the sensor with its electrode strap. Sensor configuration and use is simple and does not require any medical training from the patient users or persons assisting them. The product allows medical professionals to conduct large scale health surveys and screenings cost-efficiently. The EDF+ ECG registration data file is easily available from the sensor memory for further diagnostics. In addition to the ECG function, the sensor is equipped with an accelerometer for recording additional posture and activity information.

ECG data can be recorded using the Beat2Phone ECG product as instructed in this manual. Patient users will receive any necessary additional instructions from their medical professional and should follow the instructions closely. Persons with physical or cognitive impairments may need assistance for conducting the measurement. Medical professionals can assign the product to a patient for use based on their professional judgement of the patient's need and abilities. Use of the device does not require any special skills, training or knowledge from the medical professional, other than following the instructions in this manual. If assisting others with using the product, familiarize yourself with the instructions provided in this manual. Patient users can safely use all device functions, but the Professional view in the mobile application is only intended for professional use and cannot be accessed by Patient users.

3.1 Contraindications

- The Beat2Phone ECG Sensor cannot be used simultaneously with a defibrillator.
- The sensor is not intended to be used by children, nor does it provide any automatic analysis or diagnosis functions.

3.2 Warnings

- The Beat2Phone ECG is only intended for adult users. Do not use it for children.
- The charging connector may not be used inside the patient area (within 1.5 m around the patient) in institutional care facilities. Users of the charging connector must be conscious, aware, and in adequate physical and mental condition for operating the device.
- Use the electrode strap only on healthy skin. Do not use the device if skin under the electrode strap is damaged, irritated, sensitive or susceptible to allergic reactions. The electrodes will place stress on the skin. This can cause irritation and delay healing of the skin.
- If the use of the electrode strap causes skin irritation, stop using the strap and contact a medical professional for advice.
- Do not attempt self-diagnosis based on device recordings. Always seek professional medical advice before acting on any results.
- Do not immerse the device in water. The VitalSignum charging connector is not waterproof. Immersion in water is detrimental to device lifetime.
- Do not charge the sensor battery in temperatures below 0 degrees or above 40 degrees Celsius.
- Do not place the sensor in microwave appliances or near them to avoid damaging the battery.
- Do not use the device with a defibrillator, as a high voltage pulse will be detrimental to sensor lifetime. The device is not defibrillation-proof.
- The sensor includes a Bluetooth BLE 5.0 radio transmitter. Do not use it in environments with special restrictions on electronic device radio emission. Avoid proximity with interfering devices.
- Do not use the Beat2Phone device during an MRI scan or in a location where it will be exposed to strong electromagnetic fields.
- Do not connect the Beat2Phone device or accessories to any device or accessory other than those specified in this instruction manual.
- Do not place the Beat2Phone sensor within 3 centimeters of a pacemaker. The sensor contains a magnet. Pacemakers may go into asynchronous mode in the presence of strong magnetic fields.
- Use of this equipment adjacent to or stacked with other equipment should be avoided, as this can result in improper operation. If such use is necessary, this equipment and the other equipment used should be closely observed to verify normal operation.
- Do not use this device near other devices that operate on the 385 MHz frequency. This frequency causes interference with ECG measurement.
- Portable RF communication equipment (including peripherals, such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from any part of the Beat2Phone ECG, including cables specified by the manufacturer. Otherwise, the performance of this equipment could be degraded.
- No modification of this device is allowed.
- Do not use the device in an environment where the oxygen level is 40% or higher, or in presence of flammable gases.
- Do not touch the charging connector pins.
- Do not use the charging connector if it is wet.

- Using non-original cables and accessories may negatively affect EMC performance, expected sensor lifetime, and accuracy of the ECG registration.
- Do not connect the charger to an additional multiple-socket outlet or extension cord.
- The charging connector cable can cause asphyxiation if improperly used.
- Users may be exposed to very small amounts of nickel from the electrode strap snap connectors which can cause allergic reactions in sensitive users.
- Do not place the charging cable or the electrode strap around your neck to avoid risk of asphyxiation.
- The transfer of recordings from a sensor to a mobile device is temporarily stopped when receiving phone calls. Occasionally, the transfer process may be cancelled altogether and must be restarted.
-

3.3 Safety Precautions

- Before using the Beat2Phone Sensor, read through this manual carefully. Always keep it at hand for easy reference to ensure successful and meaningful ECG registrations.
- Do not leave the sensor in reach of small children or pets, as the sensor is small enough to be swallowed. The sensor getting stuck in a person's throat can block airflow to the lungs and result in asphyxiation.
- Do not use, place or store the sensor in extreme environmental conditions, in a shower or under water, or at temperatures of higher than 60 or lower than –20 degrees Celsius. This can damage the battery and cause the sensor to malfunction.
- Do not use the device at an altitude of higher than 2000 m. The electrical safety of the device is not guaranteed in low air pressure.
- Take precaution when using the device less than 1,5 km from AM/FM or TV broadcast antennas.
- Do not disassemble or try to repair or modify the sensor or its accessories. A device that has been tampered with cannot be relied on for accurate ECG registrations, and any data recorded by such a device is not suitable for drawing any meaningful conclusions by a medical professional.
- Do not use the device if it is damaged. Damaged devices cannot be relied on for accurate ECG registration data, and any such recordings must not be used for drawing any meaningful conclusions by a medical professional.
- Medical electrical equipment or electrical stimulators attached to a patient may degrade the Beat2Phone sensor's signal quality or lead to erroneous readings from the biosensor. Any potential interactions between other equipment must be evaluated and authorized by a responsible organization before such use.
- To ensure good skin contact for the electrodes, always firmly attach the clean electrode strap on clean, bare skin. Poor electrode contact will degrade measurement accuracy and may lead to loss of important ECG registration details which medical professionals need to draw accurate conclusions based on the data.
- Remember to nourish the skin that comes in contact with the electrodes and remove the electrode strap between ECG registrations to let the skin rest to avoid skin irritation due to prolonged exposure to the electrodes.
- Contact the manufacturer if there are changes in the performance of the device.
- Keep the mobile device away from unauthorized persons to protect your personal health data.

- Always make sure the sensor, the charging connector, and the electrode strap are clean. Excessive lint or dust can hinder the performance of the device.

4 Product package

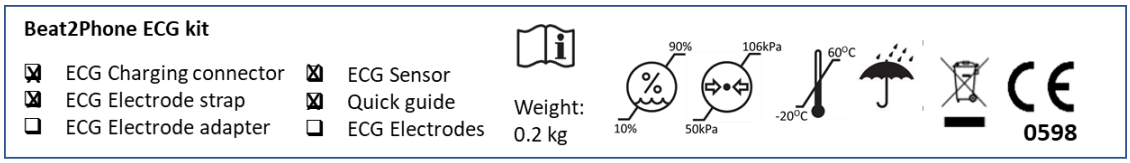
The Beat2Phone ECG kit (GTIN: 6429810109040) consists of the following products

- Beat2Phone ECG Sensor (GTIN: 6429810109002)
- Beat2Phone ECG Charging Connector (GTIN: 6429810109019)
- Beat2Phone ECG Electrode Strap (GTIN: 6429810109033)
- Beat2Phone ECG Application (GTIN: 6429810109064)

These products are placed in three slots inside the product kit. There packaging has slots for the sensor, the charging connector, and the electrode strap.

Labelling information on the package:

- Beat2Phone ECG Kit package contents
- Manufacturer information
- Manufacture date
- Beat2Phone ECG Kit Serial Number in written and barcode format
- Beat2Phone ECG Kit GTIN in written and 2D barcode format in UDI
- Pressure, temperature and humidity limits for transport and storage
- CE marking with NB number



5 Beat2Phone ECG monitoring: An overview

The Beat2Phone ECG Sensor is a wearable, lightweight, flat and compact sensor that connects to two skin contact electrodes with an electrode strap. The sensor supports lead-off detection to ensure proper skin connection.

It is powered by an internal chargeable Li-ion battery. The snap connectors used for measurement can also be used for charging the sensor battery thanks to a patented circuit design and a charging connector accessory supplied with the sensor. The fully charged Li-ion battery provides 24 hours of continuous measurement capability. The charging connector accessory is used for charging the sensor battery. Charging level is shown by the sensor LEDs and the Beat2Phone application's GUI indicators. Charging time for an empty battery is 90 minutes. The non-continuous operation duty cycle is 24 hours ON and 2 hours OFF.

The sensor's flash memory can store 24 hours of ECG registration data and posture (3-axis accelerometer) monitoring data. Memory use is shown by the Beat2Phone application's GUI indicators. While charging the battery, recordings can be transferred to the mobile device using the mobile application and then stored to the mobile device memory. Keep your mobile device charged.

The sensor has a BLE 5 radio that is used for displaying ECG information as well as transferring recordings from the sensor memory to a mobile device that has the Beat2Phone application installed.

The sensor can be turned on by shaking it. Once on, snap the sensor firmly onto the electrode strap's sensor contacts. The Beat2Phone application detects the sensor via a Bluetooth connection. The application will display the monitored signal and store it to sensor memory. Once a recording is completed, the user can end the measurement with the mobile application. To transfer a recording from the sensor to the mobile device, place the sensor in the charging connector and make sure the charging connector is connected to mains. When transferred, the EDF+ format recording file can be shared from the mobile device memory for analysis, or the mobile application's history view can be used for manually examining the recorded ECG signal.

5.1 Recommended mobile devices

A verified list of mobile devices supported by the Beat2Phone ECG device and mobile application can be found at *beat2phone.com*. Minimum requirement is support for Bluetooth Low Energy (BLE) 4.2. Using a mobile device that supports BLE 5 is recommended.

6 ECG recording

The ECG data can be recorded using the Beat2Phone ECG product as instructed in this manual.

Patient users will receive any necessary additional instructions from their medical professional and should follow the instructions closely. Persons with physical or cognitive impairments may need assistance for conducting the measurement.

Medical professionals can assign the product to a patient for use based on their professional judgement of the patient's need and abilities. Use of the device does not require any special skills, training or knowledge from the medical professional, other than following the instructions in this manual. If assisting others with using the product, familiarize yourself with the instructions provided in this manual.

Patient users can safely use all device functions, but the Professional view in the mobile application is only intended for professional use and cannot be accessed by patient users.

For ECG recording you will need the following:

- Beat2Phone ECG Electrode Strap
- Beat2Phone ECG Sensor and Charging Connector
- Beat2Phone ECG Application installed to a mobile device

The ME System consists of the Beat2Phone ECG Sensor, charging connector, electrode strap, and the mobile application. The mobile device is not part of the ME System provided by VitalSignum Oy. All provided parts are in the product package.

Make sure you’re in a comfortable, clean and private environment before attaching the device to your chest. Having access to an electric connection for charging the sensor and the mobile device is also beneficial. Make sure your hands are clean when handling any part of Beat2Phone and do not place any of it parts on unclean surfaces or in place where they may be damaged by children, pets, falling, water, overheating or mechanical forces.

Start by attaching the electrode strap to your chest. Moisten the skin under the electrodes with clean water to ensure good contact. After the strap is attached, check that the Beat2Phone application is running on the mobile device. Turn on the sensor by slapping it against your palm. A blinking green LED indicates that the sensor is on. If the sensor fails to turn on, try charging it.

NOTE! Before turning the sensor on and connecting it to the strap, you should check the battery charge by connecting the sensor to the powered charging connector. A green LED indicates the device is fully charged and ready to use.

Attach the sensor to the sensor snap connectors ensuring the LEDs are facing up and the heart symbol is turned the right way around. A green LED starts blinking at the pace of your heartbeat once the sensor detects your pulse. Allow the sensor to stabilize for two minutes before using the mobile application for recording measurements.

NOTE! If a recording is started immediately after taking the sensor from charging, the ECG signal may be skewed so that it is not visible for the first minutes of the recording. Allow the sensor to stabilize for two minutes before

using the mobile application for recording measurements. The ECG skew is indicated in the application with a notification “Detecting ECG…” until the signal level stabilizes to normal.

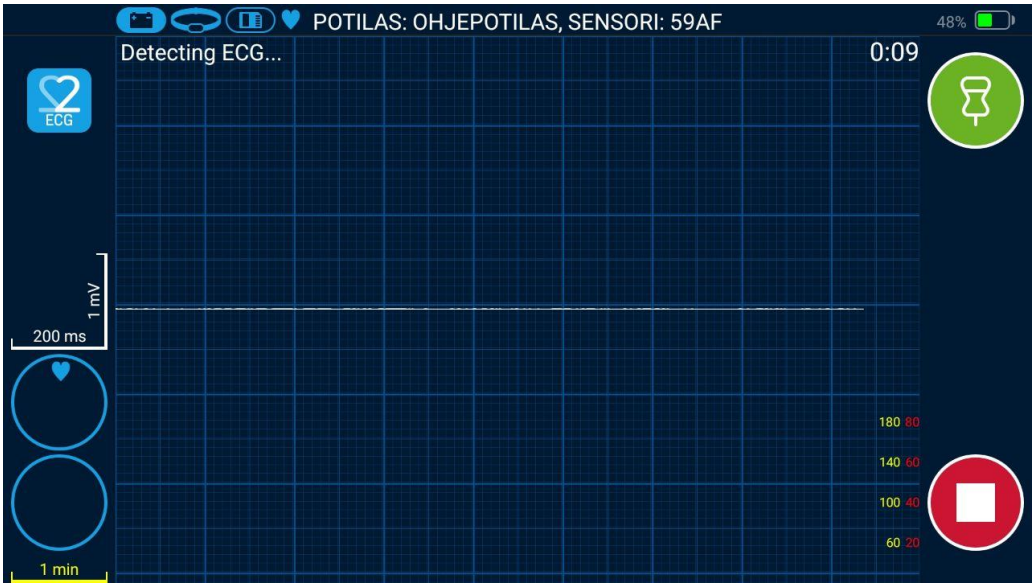


Figure 6-1: Detecting ECG...

6.1 Attaching the ECG skin contact electrodes

Proper electrode placement and low impedance contact to skin are important prerequisites for high quality ECG measurement. The electrode strap for the single-lead ECG should be placed across the chest as depicted inFigure 6-2. Adjust the electrode strap to achieve the best possible signal.

Figure 6-2: The Beat2Phone sensor properly attached to the chest with the electrode strap.

Gently clean the skin under the electrode strap with a wet wipe before placing the electrode strap on the skin. No electrode gel or paste is needed for skin contact.

Moisten the electrode strap contacts with a damp cloth (moistened with water) before using the strap. This improves the electrical contact between the skin and electrodes.

WARNING:
Do not use the device if skin under the electrode strap is damaged, irritated, sensitive or indicates an allergic reaction.

The electrode strap can cause skin irritation. It is important to clean the strap and care for the skin between using the electrodes.

NOTE! The electrode strap is only intended for personal use during a single 1-2 week monitoring period.

Sensor is sensitive to ESD, so the electrode strap shall be placed firmly on the chest before turning on and connecting the sensor to the snap contacts. Before removing the electrode strap from the chest, the sensor shall first be detached from the snap contacts. See chapter 8 for problem resolution in case the sensor is unresponsive.

6.2 Beat2Phone ECG Application

Consumer users can install the Beat2Phone ECG Application on Android mobile devices from Google Play Store, and on IPhone from the Apple store.

The Android mobile device provided for professional users and patients as part of the VitalSignum service is locked so that the user cannot access anything else on the mobile device other than the Beat2Phone ECG Application. The application includes different views and functions for professional users and patient users. Patient users can safely use all device functions, but the Professional view in the mobile application is only intended for professional use and cannot be accessed by patient users.

Internet connection is required for the mobile application full functionality. User profile creation, restoration and changes do not work without an Internet connection. ECG registration does not require Internet access once the profile is activated.

6.2.1 Application - professional user

When the application is opened for the first time in the mobile device, it prompts you to create a profile. You can either create a new profile or restore an existing profile to the mobile device. For a new profile, you are asked to select between a private personal profile or a professional profile. Select the professional profile for the healthcare application, and set a username, password and your organizational email address.

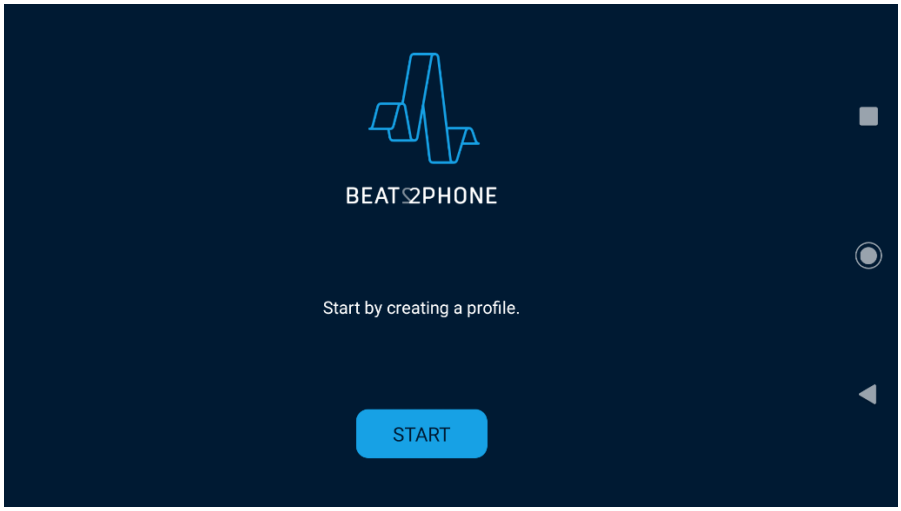


Figure 6-3: View when app is opened for the first time.

When a professional profile has been created, the **Professional start view** is displayed. This view is also shown if the mobile device already has a private or professional profile defined. In this case you can open the Profiles view by tapping the symbol at the top right. You can select and create a new Professional profile or restore an existing profile in the Profiles view. NOTE: When using a private Personal profile you cannot join an organization and enter patient information. Personal profile users will only see Private user views.

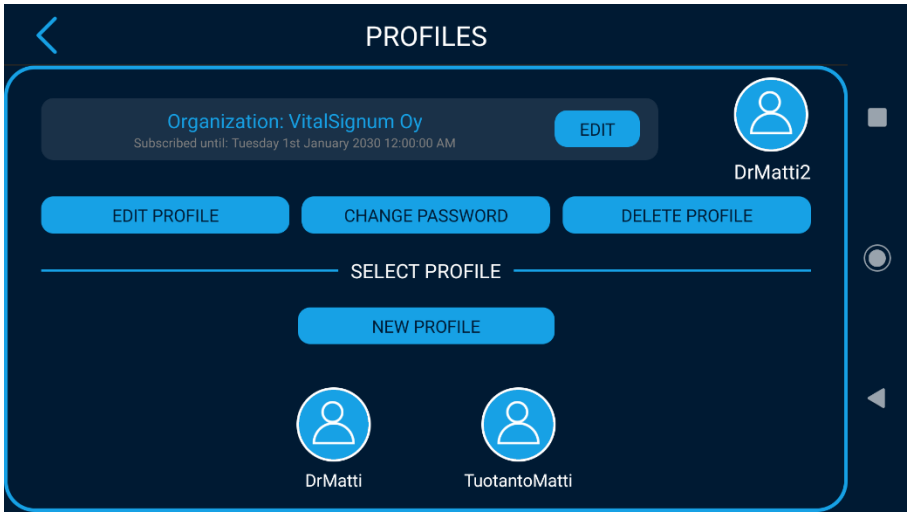


Figure 6-4: Profile management view

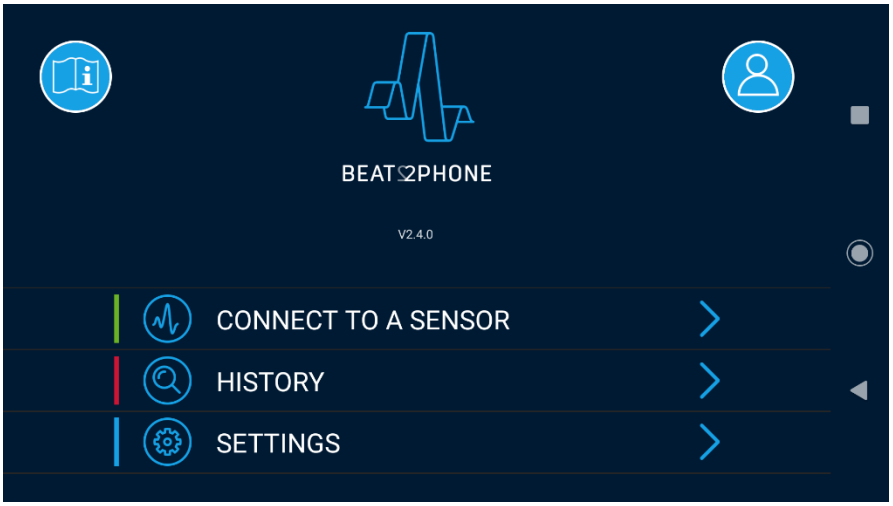


Figure 6-5: Professional start view.

First, join with your professional organization by opening the User profile menu from the top right corner. A Professional user will see all organizations listed at the top of the screen of the Profile view. Select **JOIN** if joining for the first time or **EDIT** if joining **another** existing organization. A list of organizations you can join gets displayed. Select **JOIN** and **SEND**. The organization administrator will receive your request to join the organization. If the request is approved, you will receive a join code in your organizational email address, after which you can input the code and join the organization by selecting, **I HAVE A CODE**. Patient profiles for the organization can only be created after an organization is joined. NOTE: Patient profiles can be managed under the PATIENTS start menu item.

When the sensor that will be used for the patient connection is selected, the Professional Start View shown below will be displayed. Select CONNECT TO A SENSOR, and a list of detected active sensors will be displayed. After this, select the sensor intended for this patient by checking the MAC address (for example MAC**:** c0:2a:b9:26:1d:98) of the sensor selected from the list. You can find the MAC address printed on the back of the sensor. For more information see Markings, safety signs and symbols.

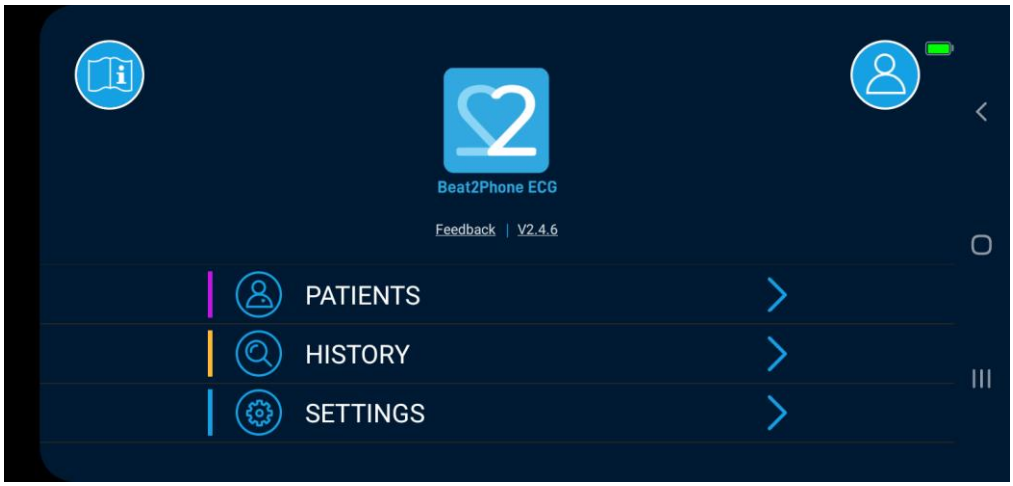


Figure 6-6: Professional start view shown after connecting the sensor.

The sensor wireless communication is sensitive to interference from 5 GHz radio signals. If finding the sensor proves difficult, try a different location with less signal disturbance.

Professional users can create, delete and modify profiles, change their passwords, modify all application settings, and view the entire patient recording history in the mobile device. You cannot start ECG recordings from the Professional start view.

To conduct patient measurements, the professional user must create or select a **Patient profile** in the Patients view.

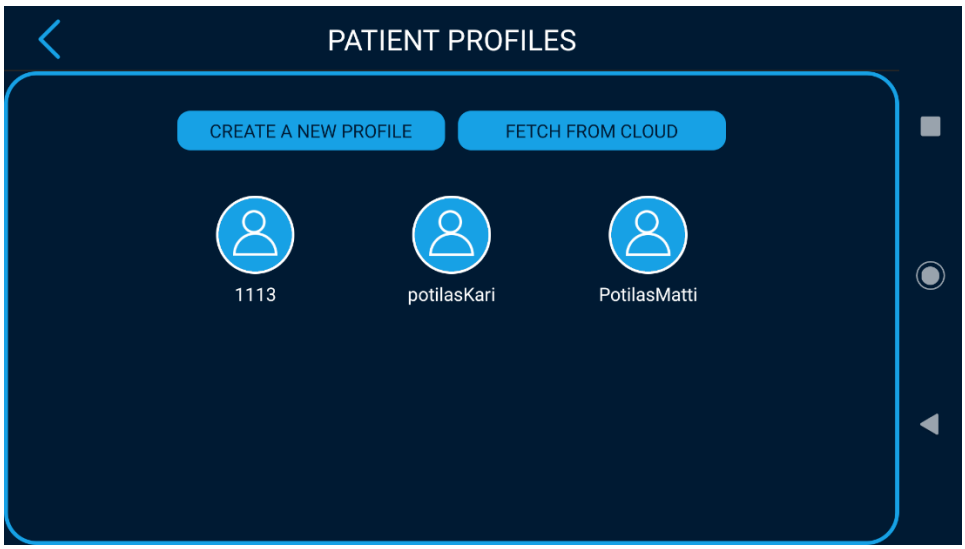


Figure 6-7: Patient selection/creation view

When creating a Patient profile, the Professional user must enter the user's organization and a unique patient identifier. When the Patient profile is created and selected, the Patient start view is displayed. The patient monitoring period begins when the first patient recording is started, and the patient device selected. There is no need to select anything in the device to begin the patient's ECG measurement. The professional user's ID and password are needed to log out of the Patient start view and to return to the Professional start view. Logging out of the Patient profile will end the patient monitoring period.

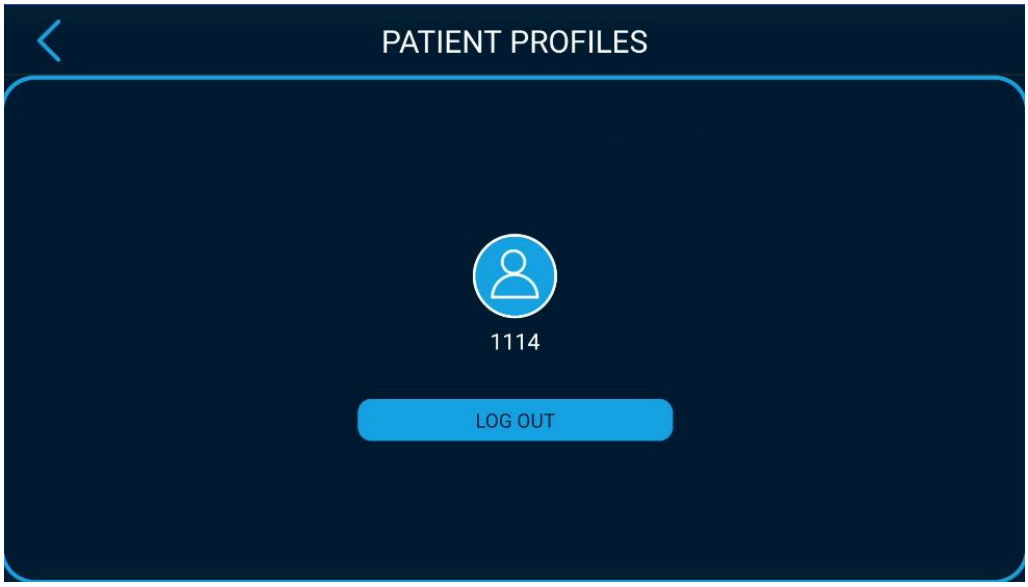


Figure 6-8 Change patient: logout

A Patient profile can be deleted by tapping the Patient profile in the Patient selection/creation view and choosing DELETE.

The connected sensor can be disconnected from start view in the settings menu in case the mobile device needs to connect to another sensor – see 6.12.

6.2.2 *Application – Patient user*

To start recording, tap the green 'Monitoring' button in the **Patient start view** shown in Figure 6-9.

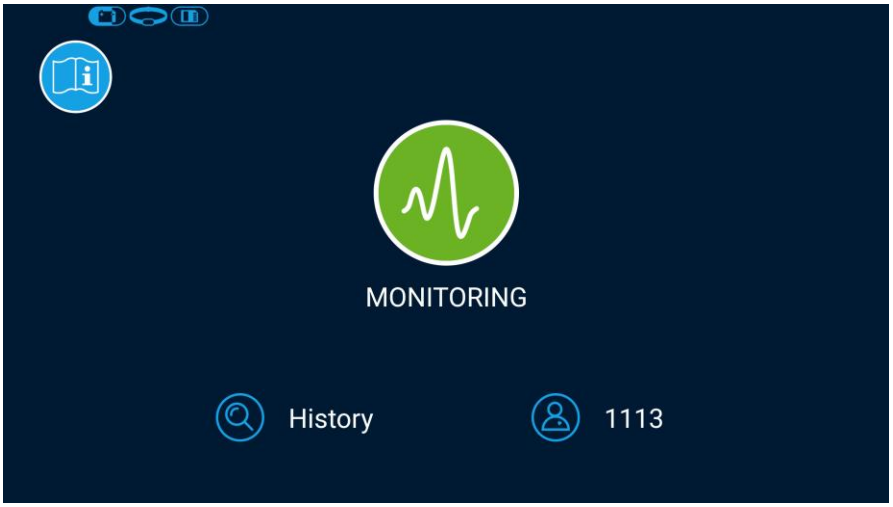


Figure 6-9: Patient start view.

The mobile device's **Patient monitoring view** displays the live ECG signal and the heart rate curve. The yellow number indicates heart rate in beats per minute, and the yellow curve indicates the heart rate curve. If display of heart rate variability (HRV) is enabled in the settings, the red number indicates the HRV in milliseconds, and the red curve indicates the HRV curve. To save the batteries of both the mobile device and the sensor, the live monitoring screen can be turned

off by turning the mobile device screen off. Measurement is ongoing and data is stored. Recording time is shown at the top right corner of the screen. The monitoring view has a Stop button for ending the recording. You can also use a 'marker' button for making annotations in the patient monitoring mode.

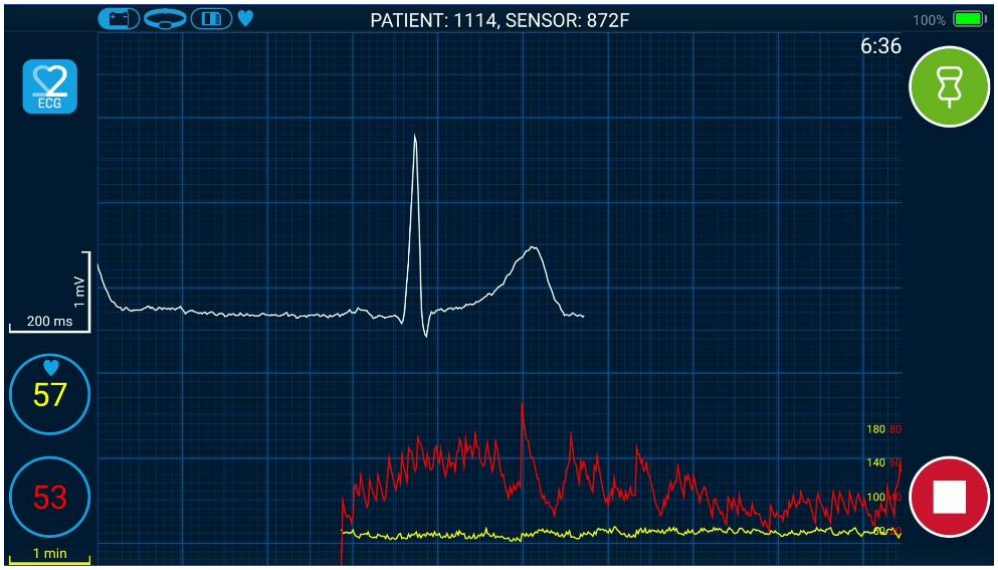


Figure 6-10: Patient monitoring view.

During measurement, the patient can add a marking/annotation to the recording in the **Patient annotation view**, which is displayed when you open the application in the mobile device after turning the mobile device screen off. Keep your mobile device close by to enable timely annotations.

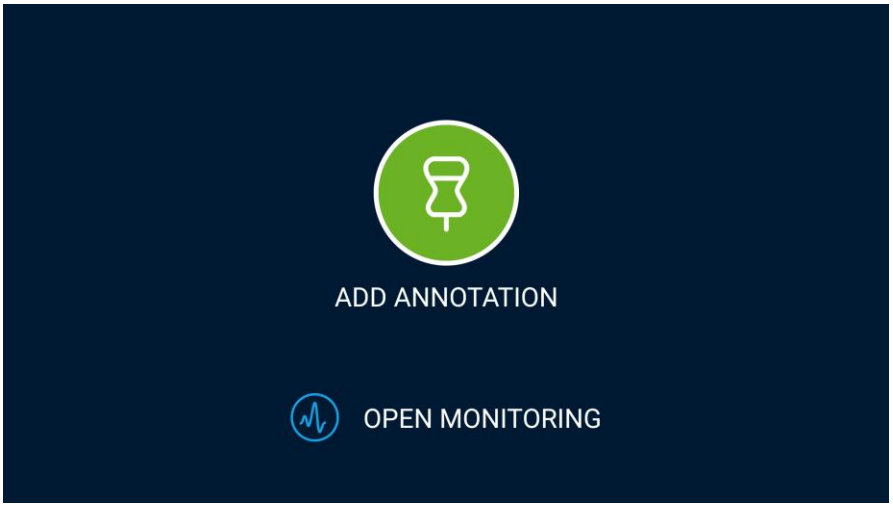


Figure 6-11: Patient annotation view.

Tapping the Marker symbol brings up a list of annotation types to select from. Annotation time refers to the time the dialog is opened. After an annotation has been made, the application returns to the annotation view.

NOTE! Use the “Free comment” or “Audio annotation” options to provide feedback on any uncomfort during the measurement, including skin irritation.

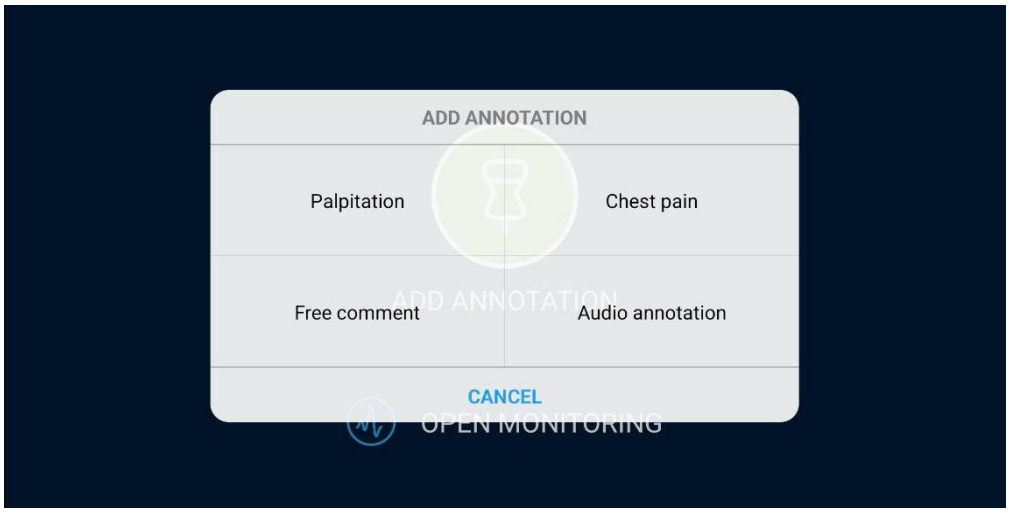


Figure 6-12: Annotation selection view.

The patient can also return to the Monitoring view during measurement by opening the application and tapping the Open Monitoring symbol in the Annotation view. The live ECG signal is shown in the monitoring view until the screen is turned off. In the Monitoring view, patients can make annotations and stop the measurement.

The patient can stop measurement by selecting the Monitoring view and tapping the Stop symbol. The application sends a “Do you want to stop monitoring” message to confirm stopping the recording. The user can then discard the message or stop the recording. In addition, this message reminds the user of un-transferred sensor recordings older than 14 hours and/or that the sensor battery charge is low and needs charging.

When the measurement has stopped, detach the sensor from the electrode strap and place it in the charging dock connected to a DC power supply. Remove the electrode strap. Clean and nourish skin after removing the electrode strap.

The ECG recording is stored in the sensor memory and can be read by the application.

NOTE! When the sensor memory is full, the sensor will begin overwriting old recordings with new ones, effectively destroying old recordings. Remember to transfer recordings from the sensor to the mobile device after recording for 24 hours to avoid losing any recordings.

The top part of the Start view and the Monitoring view shows the status of the sensor battery, the status of the electrodes, and the status of the sensor memory. The Monitoring view will additionally show the last four digits of the sensor MAC address as well as the mobile device battery charge. Touching the icon displays more info on the status.

Figure 6-13: Left to right – Sensor battery status, leads on/off, sensor memory status, and monitoring ongoing status

The blue heart icon indicates that sensor has monitoring ongoing. This is useful in case the application stops for some reason and opens to the monitoring start view – sensor ongoing monitoring status is visible.

6.2.3 *Application - consumer user*

A private consumer user can do measurements and use all the tools and options a professional user has available. The key differences are that a private user cannot join an organization and cannot create patient profiles; a private user can only perform measurements on themselves. A private user only has to create a profile and connect the sensor, after which measurements can be started.

NOTE! A consumer user is required to accept the privacy statement in order to activate the user profile.
NOTE! In profile settings, a consumer user can choose to store recordings in the cloud.

6.2.4 *Cloud storage for the recordings*

The patient recordings are stored to the Beat2Phone ECG cloud service when SETTINGS-> ‘Save history to cloud’ is selected.

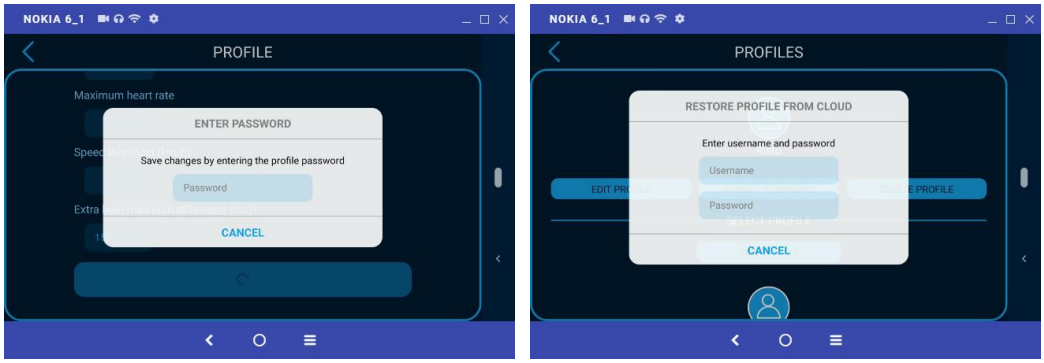
Consumer users’ recordings are stored to the Beat2Phone ECG cloud service selected by the user. SETTINGS option is only available if the cloud storage option has been selected and the user has purchased a license for the service.

The cloud is used only for storing recordings and markings. No data is processed in the cloud service.

Data stored in the cloud can be retrieved to any supported mobile device via the HISTORY view.

6.2.5 *Profile changes*

Professional and consumer users can edit their profile information from the profile management view by selecting EDIT PROFILE, making changes and confirming them with a profile password or a combination of a profile username and a password.



Users can change their personal details, password and their consent for cloud storage.

Internet connection is required when profile changes are made.

6.3 Shutdown procedure

To power off the paired sensor with the application, remove sensor from charger, choose **SETTINGS** -> **SENSOR INFORMATION** -> **POWER OFF SENSOR**. The sensor can be powered on again by placing it in the charging connector that is connected to mains. Patient users cannot shut down the sensor. Sensors are shut down at the factory to prevent sensors from starting to operate and battery from discharging during transport.

The sensor will also go to sleep mode automatically when not in use or when moved, and not charging. In this case shaking the sensor will turn it on.

6.4 Uploading and viewing recordings in the sensor: Professional users

Recordings stored in the sensor memory must be transferred to the mobile device before the recordings can be viewed in the application. After the patient monitoring has ended, detach the sensor from the strap and place it in the charging connector. Connect the charging connector to mains. A file upload dialog will be displayed in the application to start transfer of stored files to the mobile device. The mobile device must be within few meters from the sensor to transfer the files.

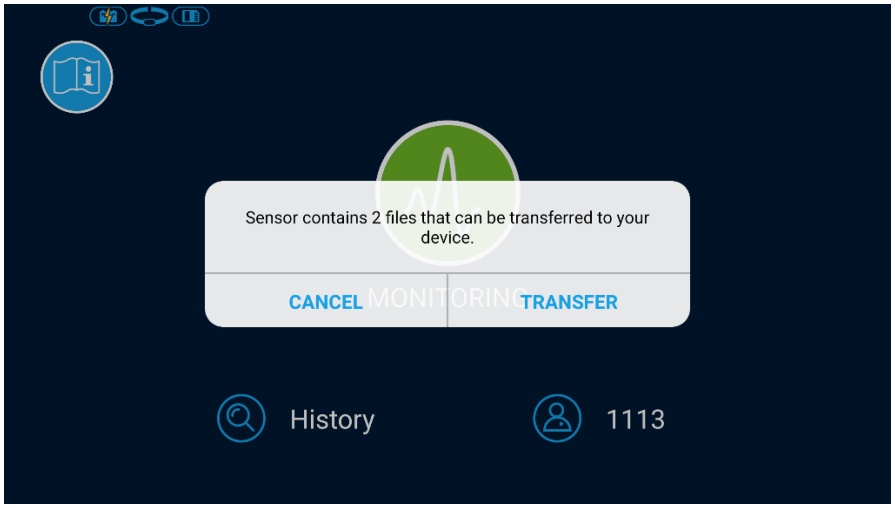


Figure 6-14: File upload dialog.

The transfer can be cancelled. However, the registration remains in the sensor and must be transferred later.

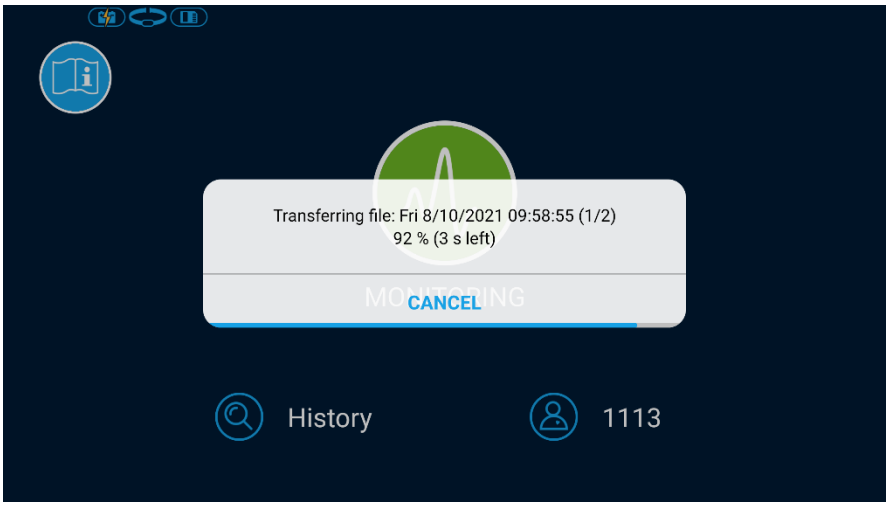
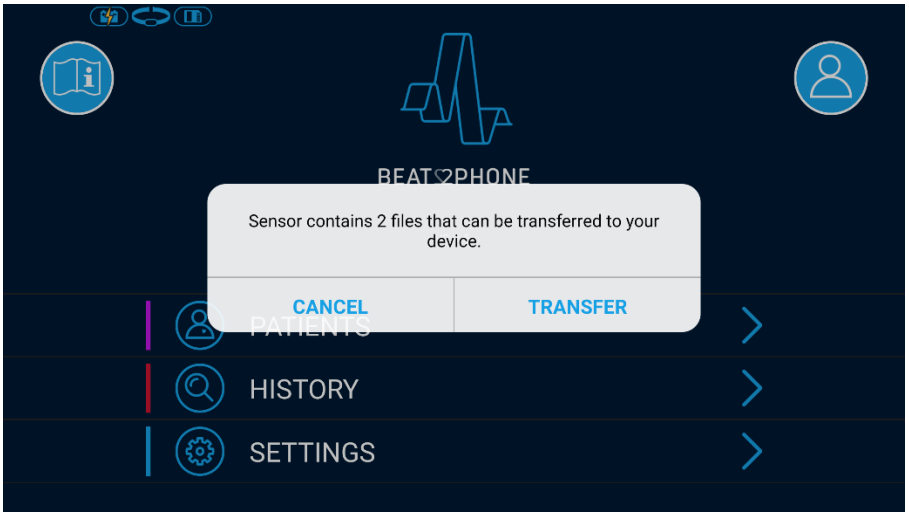


Figure 6-15: Transferring a file.

If you log out from patient mode before connecting the sensor to a charger, you will be prompted to transfer files after you have returned to the professional start view (Fig. 4), provided that the sensor connection has not been removed with the setting “Forget sensor…”.



All patient ECG recordings in the mobile device can be viewed in the **Professional history view**. The default view is the List view, showing the newest patient recording on top. To open a recording for viewing from the list, tap the list item. If the recording is still in the sensor memory, a memory card icon will be displayed next to it. Tapping the list item will start upload of the recording file from the sensor to the mobile device.

The measurement time is taken from the mobile device. We recommended that the date, time and time zone settings in the mobile device are automatically obtained from network service provider.

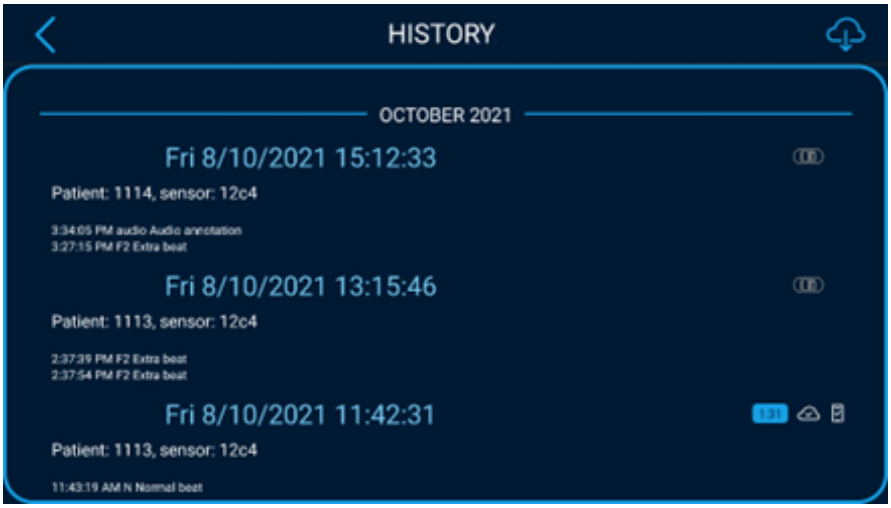


Figure 6-16: History list view.

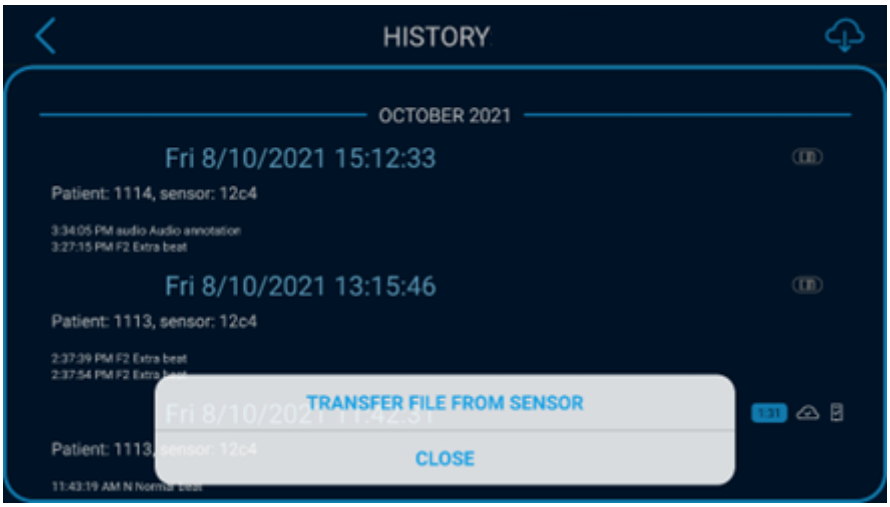


Figure 6-17: File transfer dialogue in the History view.

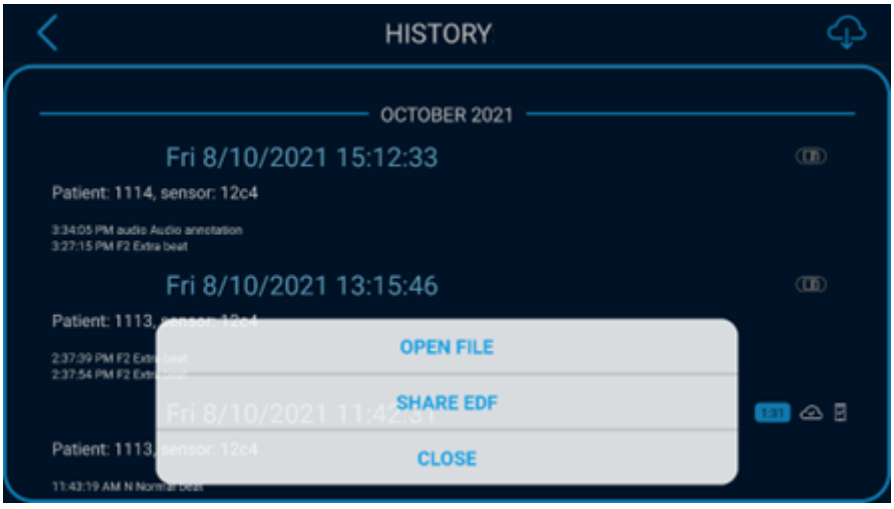


Figure 6-18: Opening a file in the History view.

Select **OPEN FILE** in the History view to see the recording as it was shown in the monitoring view with a few important additions. These are the PQRST measurement tool, the mm paper view/share tool, and the professional annotation tool. Also, a trashcan button can be used for deleting the recording. Settings for heart rate histogram apply only in the History view. Users can move the HR and ECG graphs on a mobile device's touchscreen by dragging and swiping. Horizontal zoom by fingers is also available. To restore the default scale, touch the Beat2Phone heart icon.

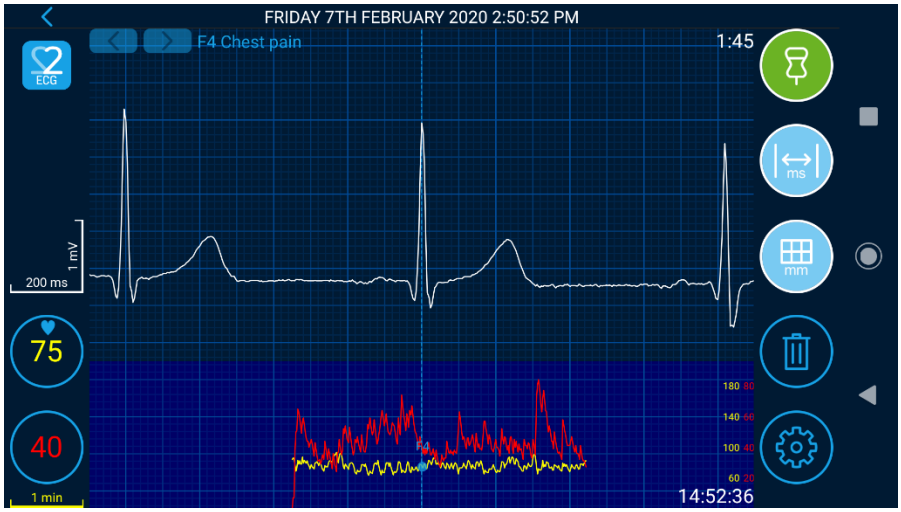


Figure 6-19: The History view of a recording.

Select SHARE EDF to access the ECG recording in EDF+ format and transfer it to another device, for example a computer. The EDF+ file can be opened with various programs that are downloadable from the internet, for example from physionet.org.

6.4.1 *PQRST measurement tool*

To open the PQRST measurement tool, touch the measurement tool button indicated in Figure.

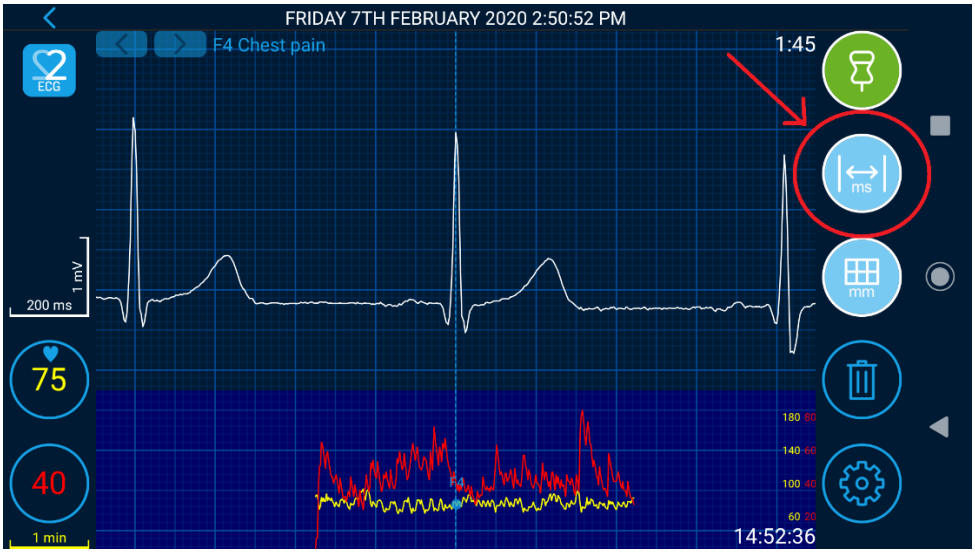


Figure 6-20: PQRST measurement tool button

After touching the button, several new buttons appear, indicating the beginning and end of the P wave, the beginning and end of the QRS complex, and the end of the T wave. Move the vertical light blue dashed line to a location and press the corresponding button to mark it on the ECG graph. Repeat for every button. The system calculates the intervals and displays them in milliseconds.

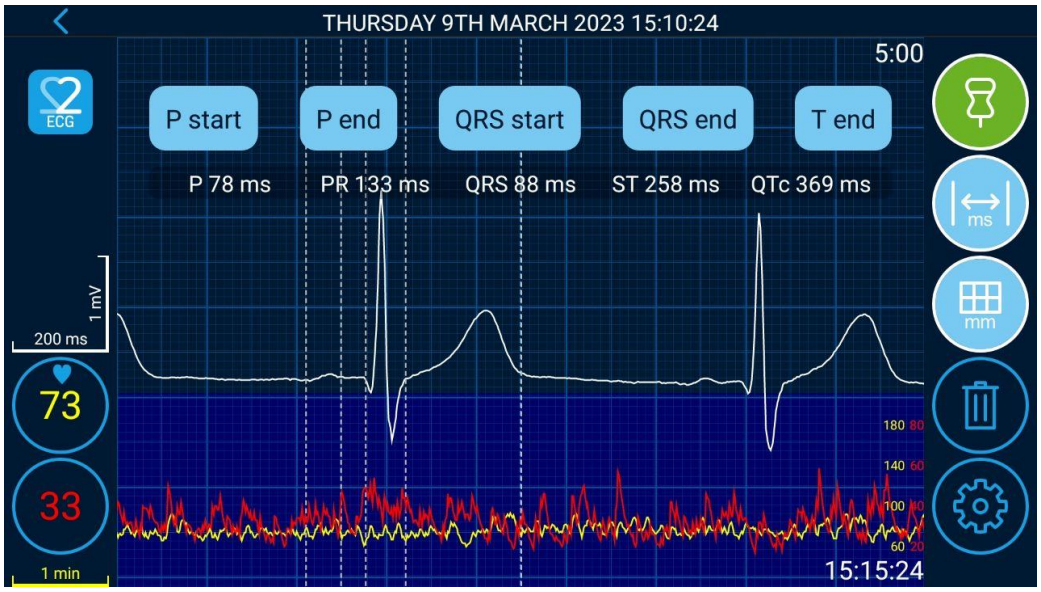


Figure 6-21: PQRST measurement

6.4.2 *Millimeter paper viewing and sharing*

To open the millimeter paper view, touch the millimeter paper view button indicated inFigure 6-22.

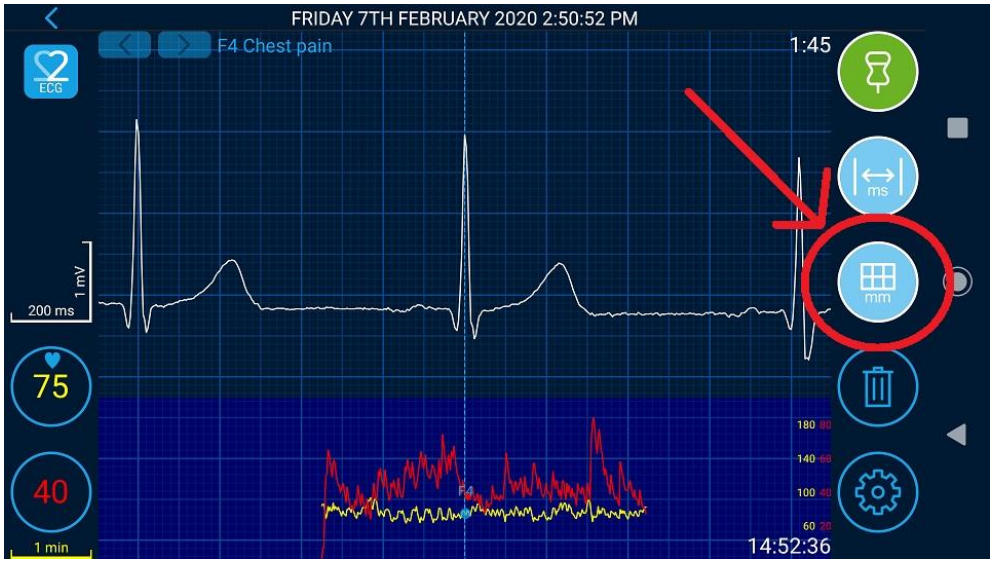


Figure 6-22: Millimeter paper view button

The millimeter paper view opens. In this view, you can see 30 seconds of ECG in a standard millimeter paper format, 15 seconds before and 15 seconds after the selected location in the ECG recording. To share the mm paper via email, touch the email button indicated inFigure 6-23.

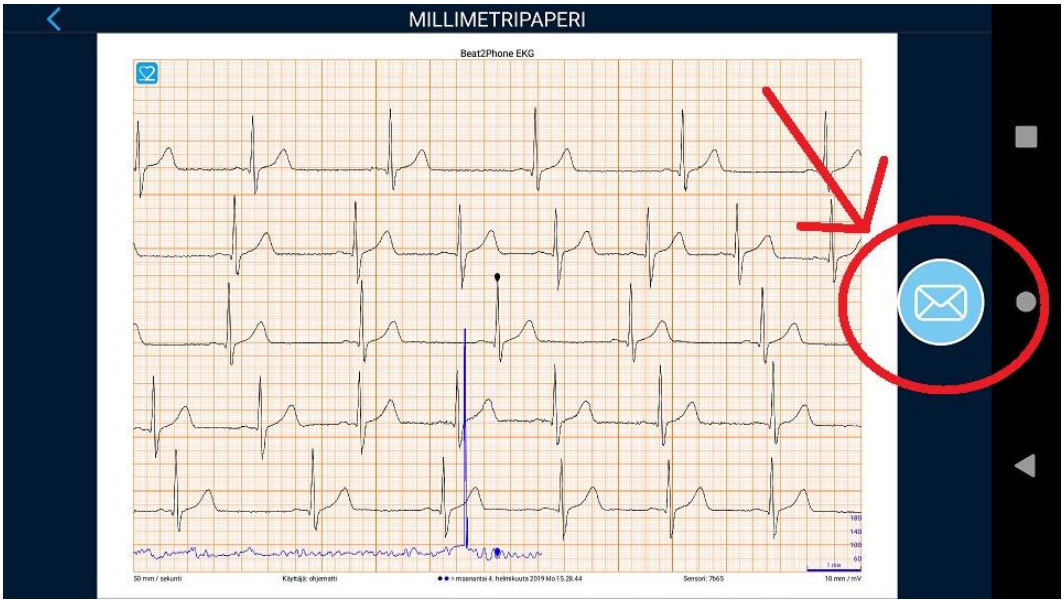


Figure 6-23: The email button

The email button opens your email if you have one configured in your mobile device. The mm paper will be automatically attached to the email. Select the recipient(s) you want to send the mm paper to and send the email. The mm paper will be sent as an image file that can be opened with normal image viewing software.

6.5 Uploading and viewing sensor recordings: Patient user

Recordings stored in the sensor memory must be transferred to the mobile device before the recordings can be viewed in the application. After recording is stopped, detach the sensor from the strap and place it in the charging connector. Connect the charging connector to a mains power supply. A file upload dialog will be displayed in the application to start transfer of stored files to the mobile device. The mobile device must be within few meters from the sensor to transfer the files. An individual recording can also be transferred by selection in the History view. SeeFigure 6-14 to Figure 6-17.

Patients can upload, view and annotate their own ECG recordings in the mobile device in the **Patient history view**. Patients cannot delete their recordings or share the EDF+ files.

The measurement time is taken from the mobile device. We recommended that the date, time and time zone settings in the mobile device are automatically obtained from network service provider.

6.6 Identifying problems with recorded ECG waveforms

If the electrodes are not properly attached, the user is moving too much, or the user is very close to some electronic devices, the ECG signal can be too noisy for analysis. If the user wears a pacemaker, it may cause visible notches on the recorded ECG signal. In the presence of disturbances or artefacts, the heart rate will not be correctly calculated and could be displayed as exceptionally high. Observe any warnings and avoid situations that cause signal artefacts. Here are some examples of proper and noisy ECG signals (or missing ECG signals).

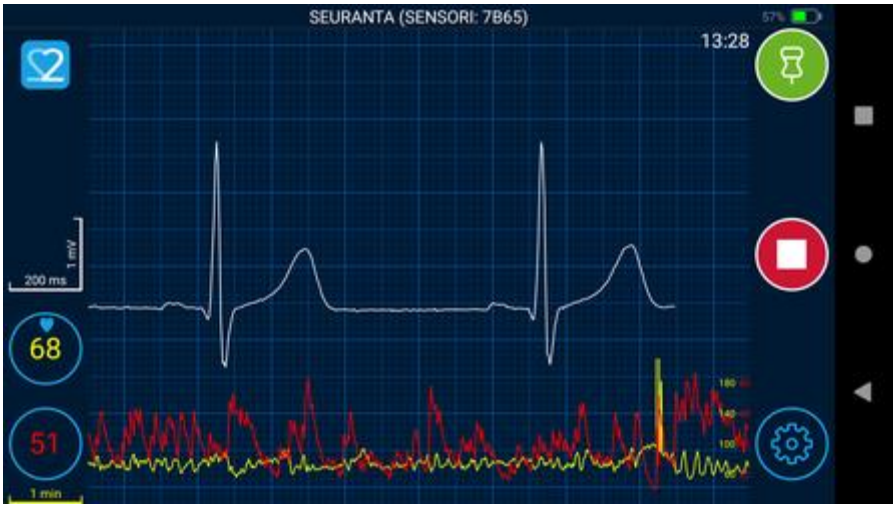


Figure 6-24: A proper ECG waveform.

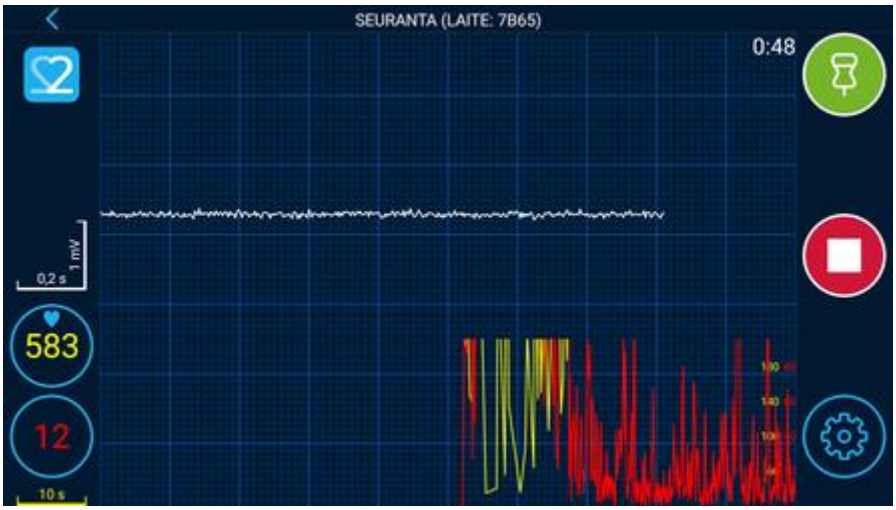


Figure 6-25: Waveform when sensor not attached to the electrodes, or electrodes not attached to skin.

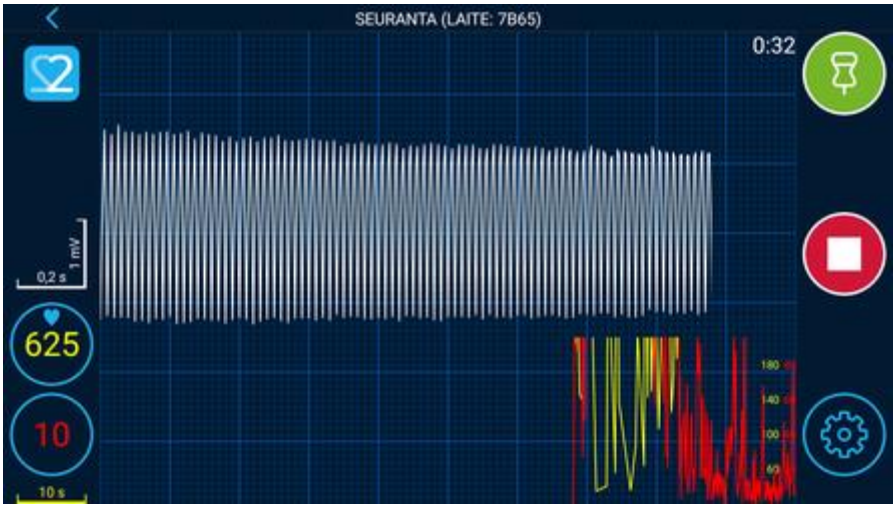


Figure 6-26: Waveform when sensor not attached to the electrodes, or electrodes not attached to skin. The sensor is near electronic devices.

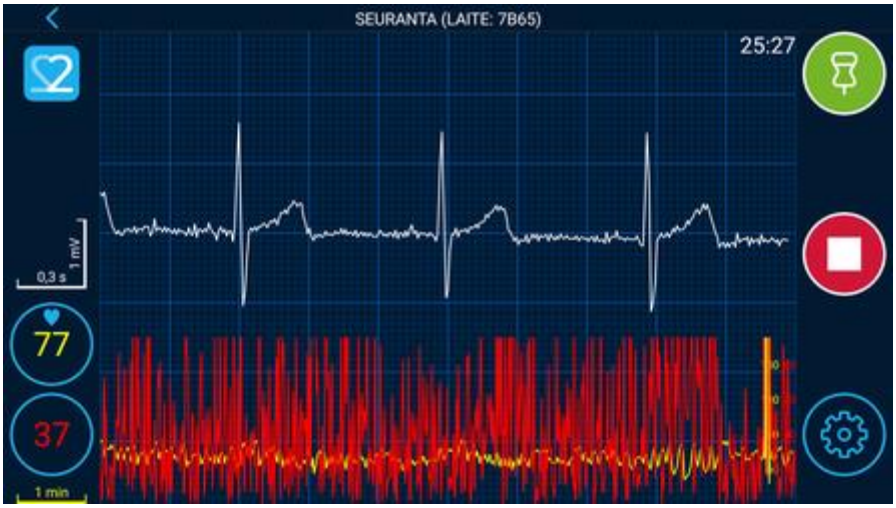


Figure 6-27: Skin-electrode contact is not good.

Figure 6-28: Electrodes are not placed correctly, and the signal is not strong enough.

Figure 6-29: Electrodes are not placed correctly, and the signal is not strong enough.

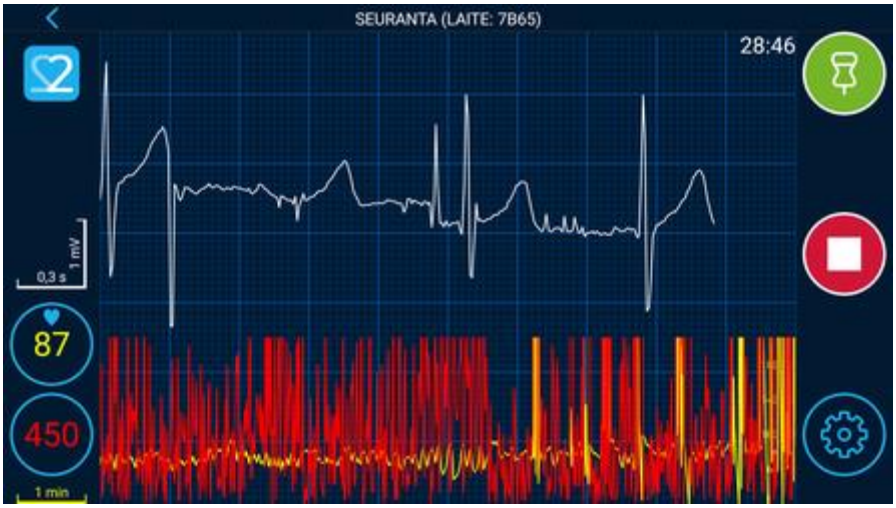


Figure 6-30: Skin-electrode or electrode-sensor contact is loose.

Figure 6-31: The sensor is upside down in the electrode strap.

Someone wearing a pacemaker can see pacing spikes of about 2 ms in length at various positions in relation to the PQRST complex, depending on the pace mode of the pacer.

6.7 Beat2Phone application messages

For some reason monitoring has stopped in the sensor – This message appears if the user removes the sensor from the electrode strap without stopping the measurement in the mobile application and then connects the sensor to the charging connector. This message can also appear if, for some reason, the sensor has stopped the measurement, for example if the sensor battery has run out. Select **DISMISS** to continue.

Something went wrong: This message appears if the user tries to create a profile, restore a profile, or edit a profile while the mobile device is not connected to the internet. Enable mobile data or connect to a wi-fi network to continue. This message can also appear if the user tries to transfer recordings from the sensor

to the mobile device while the sensor is not powered on. Shake the sensor or place it in the charging station to continue.

6.8 Mode of operation ON/OFF

During monitoring, the sensor operation mode is non-continuous, as the sensor operation time is limited to 24 hours by memory capacity and charging an empty battery and reading a full memory will take 2 hours. The duty cycle consists of ECG registration to sensor memory – ON time – and reading of the memory and charging the sensor – OFF time. For maximum ON time, both the memory and the battery capacity must be full when starting ECG registration. 24/2 duty cycle may not be the most practical for users, whereas 11/1 may suit better for daily monitoring with morning and evening maintenance breaks.

6.9 Measurement accuracy

The sensor measures the electrode voltage at 10 uV accuracy. Poor electrode connection and chest movement will cause signal degradation that can hide ECG details. The ECG measurement frequency is 2000 Hz. Heartbeat display accuracy is one beat per minute, and the HRV display accuracy is one millisecond.

The heart rate in beats per second is calculated as 60000/RRI, where RRI is the R-peak to R-peak Interval in milliseconds.

The maximum heart rate displayed by the application is 299. The minimum displayed heart rate is 20. The maximum heart rate variability displayed is 200, and the minimum is 0.

6.10 Sensor battery: Charging

The sensor battery should be fully charged before starting long-term monitoring. Full battery capacity enables 24 hours of monitoring. Battery capacity will drop after multiple charge cycles, and once the 12 h maximum recording time is reached, replacing the sensor is recommended. The recommended recharge time for a fully exhausted battery is 90 minutes. Sensor lifetime is determined by the number of charge cycles until only one half of battery capacity can be attained.

The provided charging connector accessory must be used for charging the sensor battery in temperatures between 0 and 40 degrees Celsius. A broken charging connector must be replaced with a working one before the sensor is charged.

First, snap the sensor onto the charging connector. The shape of the sensor and the connector ensure right polarity during connection. Before connecting to power mains, the orange LED indicates leads-off if there is still some power in the battery. Next, connect the charging connector to mains power supply. The sensor LEDs will light up to indicate charging status. See Figure 6-32 and Figure 6-33. Do not use a wet charging connector, charge in wet conditions, or at too high temperatures.

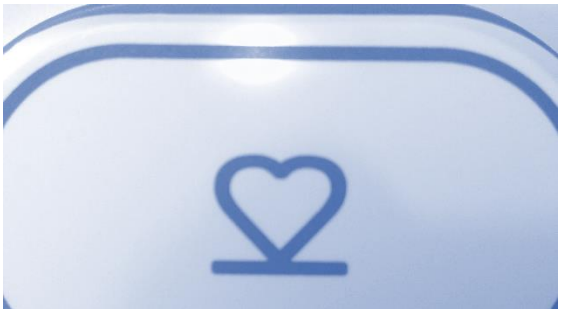


Figure 6-32: Sensor is charging but not yet fully charged. White LED is lit.

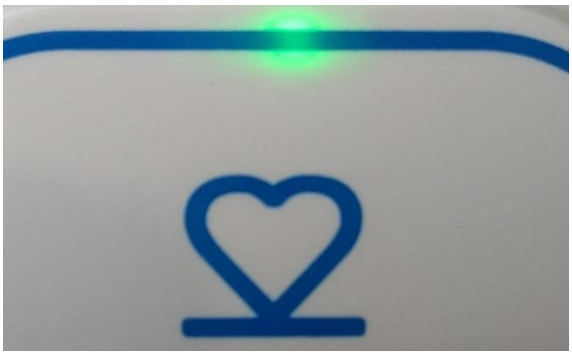


Figure 6-33: Sensor is fully charged. Green LED is lit.

When the sensor is being charged, the ECG electrodes cannot be connected, and ECG measurement is not possible. The sensor memory, however, is readable by the mobile application during charging using the BLE wireless connection.

During charging the sensor's white LED indicates that the sensor is charging. Green LED indicates a fully charged sensor. An Orange LED indicates failure to charge. If no Sensor LED is lit, check the charger connection.

Once the green LED is lit, the battery is fully charged, and the sensor shall be removed from the charging connector.

Do not store the sensor in the charging connector disconnected from mains since the battery will drain through the mains adapter. It is best to keep a fully charged sensor disconnected until it is taken in use and connected to the Beat2Phone ECG electrode strap placed around the chest.

Use the procedure described in Shutdown procedure if the sensor is unused for extended periods of time. This minimizes the battery leakage and prevents unintended turn on of the sensor.

NOTE! The Beat2Phone ECG Charging Connector cannot be used with the older Beat2Phone sensor.
NOTE! Do not place the charger in a position where it will be difficult to operate.

Warning!
Do not charge the sensor battery in temperatures below 0 Celcius.
Do not place the sensor in or near microwave appliances to avoid damaging the battery.
Do not use a wet charging connector

6.11 Sensor and charging connector: Visual indicators

The sensor is equipped with four LED indicators: Green, White, Orange and Blue. These are used to indicate the sensor state. Any other LED behaviour indicates that the device is damaged and should not be used.

- If no LED is lit, the sensor is turned off, or the battery is empty.
- When the sensor is turned on by movement a Green LED blinks five times in a short-short-long flash sequence.
- When the sensor is turned on, properly connected to skin via the chest electrodes, and heartbeat is detected, the Green LED will blink at the same pace as the heart rate.
- When the sensor is turned on and properly connected to skin via the chest electrodes, but no heartbeat is not detected, the Orange LED will turn on for one second every 300 milliseconds. This indicates leads on, but no heartbeat.
- When the sensor is turned on but not properly connected to skin via the chest electrodes, the Orange LED will blink once every 3 seconds. This indicates leads off. → CAUTION: check electrodes connection.
- When the sensor is connected to the powered charging connector and is not yet fully charged, the White LED stays lit until battery is fully charged. → CAUTION: Do not remove from charger until fully charged.
- When the sensor is connected to the powered charging connector and fully charged, the Green LED will be lit.
- When a recording is being transferred from the sensor memory to the mobile device, the Blue LED will blink rapidly.
- When the sensor is turned on and less than 5% of battery is left, the Orange LED will blink once per second.
- When a charging circuit malfunction is detected, with the sensor is connected to the charging connector, the Orange LED is blinking rapidly.
- When the sensor is on and connected to a charging connector without mains connection, the orange LED blinks leads on, no heartbeat detected.

More visual indicators are available in the Beat2Phone ECG Application that's running on a mobile device with a BLE connection to the sensor.

The heart symbol on the sensor lid indicates correct connection orientation, if the tip of the heart points down when connected to the strap on the chest.

Figure 6-34: The heart symbol indicates the correct orientation of the sensor.

6.12 Sensor connection to the mobile device

The Beat2Phone application runs on a mobile device and needs a connection to the sensor to start monitoring and recording the live ECG signal, to stop the recording, and to retrieve the recording from the sensor's memory.

The application's main menu includes a dialog for connecting an active sensor. A list of active sensors is displayed, and the user must choose the sensor by selecting the matching MAC Address on the sensor label with the MAC address visible on the Beat2Phone ECG Android[1] application selection list. Once the selection is done, the application will only connect that sensor, until it is disconnected in the application settings menu by selecting FORGET SENSOR (MAC address).

Once the recording is started, the sensor does not need the application to store the recording to its memory.

An active sensor provides the application with information about battery charge, memory usage and electrode leads connection which the application can monitor per the connected sensor.

Professional and consumer users can verify the correct sensor connection from Settings -> Sensor information where the ID must match the MAC address on the sensor device label.

It is the responsibility of the professional user to ensure that the patient is properly identified with a unique profile ID and is given the correct connected sensor to use during the monitoring period. A patient user cannot disconnect from the assigned sensor.

The mobile device and the application must be on for the connection to work. The application will reconnect to an assigned sensor once the mobile device is operational.

6.13 Communication and data security

The mobile application profile creation requires an Internet connection. In case the connection is missing the profile addition, restoration, deletion and modification are not available.

Professional user must enter the following information:

[1] The iOS version of the Beat2Phone ECG Application does not include the MAC address in the selection list.

- Username, which may contain characters 0-9, A-Z and a to z and must be 3-16 characters long
- User's email address
- Password, which must be at least 6 characters long, special characters are allowed.

In addition the professional user must join an organization to be able to add patients.

Patient user has no profile information obligations.

Consumer user must enter the following information:

- Username, which may contain characters 0-9, A-Z and a to z and must be 3-16 characters long
- User's first name and last name
- User's email address
- Password, which must be at least 6 characters long, special characters are allowed.

In addition, the consumer user must read and agree to privacy policy and select if cloud service is enabled of not.

When agreeing to privacy policy the user profile information is stored to cloud and can be retrieved to any supported user's mobile device. If not agreed the profile cannot be created.

If the cloud service is not enabled, the registrations do not go to the cloud storage from the mobile device and cannot be retrieved from the cloud storage.

Once created the profiles can be edited under the mobile application profiles. Profile changes require user authentication to take effect.

Profiles can also be modified through the Beat2Phone ECG service GUI by logging in to account settings, where user email and/or password can be changed.

Forgotten password can be reset through the Beat2Phone ECG service GUI login page. Reset pin code is sent to the profile email address.

Username(s) can also be retrieved through the Beat2Phone ECG service GUI login page. Username is sent to the profile email address.

The mobile application will prompt the user when Internet connection needed is missing.

The mobile application will prompt to user to update the application version to the latest released one to provide the best usability and data security for the user.

7 Maintenance and Service

The user must charge the sensor battery regularly. See the section Sensor battery: Charging. The battery is non-replaceable. The entire sensor must be replaced when observed operation time of a fully charged device has gone down to 12 hours or less. ECG registration is not possible when the sensor is being charged. Charging is not possible when the sensor is connected to patient electrodes. Expected service life of the sensor and the charging connector is 500 charging cycles, or 2 years from the date of purchase.

The sensor, charging connector with cable, and the electrode strap can be cleaned with a clean damp cloth, using hand disinfection fluid or wipes (Kiilto Cleanisept, Easydes). Do not clean the sensor, strap or charging connector while they are in use or charging. The sensor must be cleaned **at least once per day** or every time registration is stopped, and **always when users change**.

The electrode strap can be washed between uses by the patient. The strap can be machine-washed in 40 degrees Celsius, but only using mild detergents. A single electrode strap is intended to be used by a single patient; each new patient should receive a new electrode strap. Used electrode straps can be disposed of with household waste.

Occasionally, residual oxidation may accumulate on the sensor snaps, which causes large artifacts in the ECG signal. The oxidation is usually not visible but can be identified from the poor signal quality. Clean the sensor snaps by using the service kit. Service kit is available free of charge.

The Beat2Phone ECG Application runs on a mobile device which must be operational. This requires the mobile device to be charged regularly.

All maintenance and service mentioned here can be performed by both professional users and patient users.

WARNING!

Do not immerse the sensor or charging connector in any fluid, including water.

For maintenance of skin contact electrodes, follow the instructions provided with the electrodes.

There are no repairable parts in the Beat2Phone ECG system. Repair service personnel are not required. Broken devices should be disposed of as instructed in this manual.

7.1 Updating the sensor firmware

The sensor supports firmware updates over the BLE connection using the Beat2Phone ECG mobile application – over the air (OTA) updates.

The preconditions to update the sensor firmware are:

- Sensor is unconnected from the Beat2Phone Charging Connector.
- Sensor has at least 50% battery charge remaining.

- Beat2Phone application is in the normal or professional user profile's start menu view and connected to the sensor and Internet.
- There is a new version of the firmware available.

The application will prompt the user to update the firmware if these preconditions are met. The update takes a few minutes. The sensor must not be connected to the charging connector during this time.

NOTE! Firmware update is not possible in the patient profile.

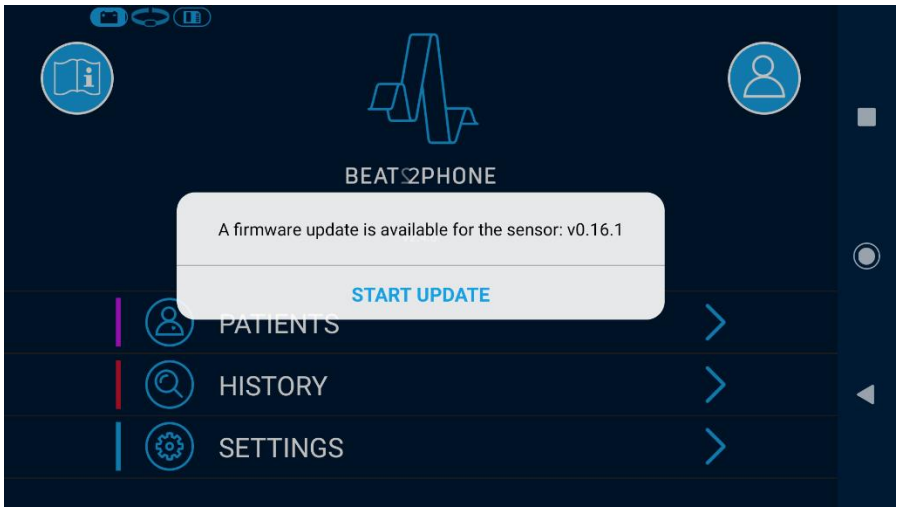


Figure 7-1: The firmware update prompt

7.2 Testing the sensor

The sensor can be tested to see if it is functioning normally. To start the test, choose **SETTINGS** -> **SENSOR INFORMATION** -> **TEST SENSOR**. During the test, the sensor sends a test signal to the mobile device. If the test signal is generated and sent to the mobile device correctly, the test is passed. The test lasts around 3 minutes. The sensor should not be charged or attached to a patient during the test, and it should be kept away from other electronic devices.

Testing should be performed regularly to ensure that the sensor is working as intended. Only the professional user can perform the test.

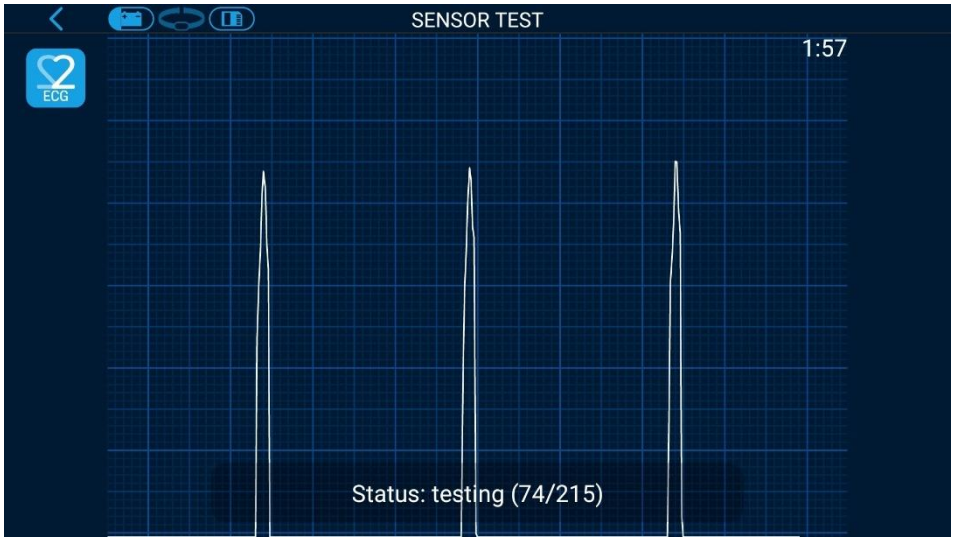


Figure 7-2: The sensor test view.

7.3 Disposal

The Beat2Phone ECG must be disposed of in accordance with Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

The sensor contains electronics and a Li-ion battery, and the charging connector contains electronics, so these parts must be recycled appropriately as electronic waster at the end of their lifetime. The strap can be disposed with household waste.

7.4 Beat2Phone ECG Application update

The manufacturer provides updates for the Beat2Phone ECG Application via two channels: Google Play Store and device management software.

Users without device management support can get updates through the Play Store. Users with device management support are provided updates by the device management service.

8 List of symbols used in the mobile application

Symbols			
Symbol	Explanation	Symbol	Explanation
	Open the instruction manual.		Open the profile view.
	Start a recording.		Add an annotation to the recording.
	Stop the recording.		Segment duration measurement tool.
	Millimeter paper from the recording.		Send the millimeter paper.
	Delete the recording.		Open settings.
	Mobile device battery level indicator.		Sensor battery level indicator, blinks when battery is low.
	Electrode contact indicator. Leads on.		Electrode contact indicator. Leads off. Blinking.
	Sensor memory status indicator. 0% full to 100% full. 0% in the picture.		Sensor battery is charging.

	A recording is ongoing.		Retrieve recordings from cloud.
	Recording is in the sensor memory but is not transferred to the mobile device.		Recording is transferred to the mobile device.
	Recording is not uploaded to cloud.		Recording is uploaded to cloud.

9 Problem resolution

Sensor does not turn on even with a firm slap: Check the battery by placing the sensor in the charging connector. If the green LED is lit, detach the sensor from the charger and slap it again. If the white LED is lit, let the sensor charge until the green LED is lit.

Electrodes are not properly connected: The application indicates poor connection or no connection. Check the condition of the electrode strap. If the electrode strap is damaged, contact the manufacturer for a replacement. Otherwise, connect the electrodes properly.

The signal quality is poor: Make sure the electrodes are connected properly. Make sure that the electrode strap is appropriately tightened. If these steps do not resolve the issue, there might be residual oxidation on the sensor snaps. Clean the sensor snaps by using the service kit provided.

Electrodes start irritating the skin: Nourish the skin that comes in contact with the electrodes and let the skin rest by removing the electrodes in between ECG registrations to avoid skin irritation due to prolonged exposure to the electrodes.

User profile cannot be created: Make sure the mobile device has Internet connection available. Creating a user profile requires access to the Beat2Phone cloud service, which requires internet connection. Each user ID must be unique.

Mobile application does not find the sensor: First, wait for the list of detected sensors to update. If the sensor is still not found, try a different location with less radio interference. If the sensor is still not found after this, try placing the sensor in the charging connector for a few seconds and then try again.

Sensor memory is full: Place the sensor in the charging connector to initiate file transfer from the sensor to the mobile device.

Sensor battery is empty: Place the sensor in the charging connector to charge it.

Mobile device battery is empty: Charge the mobile device.

Mobile device is unresponsive: Please see the mobile device's instructions for problem resolution.

The Orange LED indicating technical failure is lit on the sensor: Contact the manufacturer for a replacement. Do not continue using the device.

When the sensor is turned on, properly connected to skin via the chest electrodes, and heartbeat is detected, the Green LED will blink at the same pace as the heart rate. Check the battery by placing the sensor in the charging connector that's connected to a charger. If the green LED is lit, detach the sensor from the charger. If the white LED is lit, let the sensor charge until the green LED is lit. If charging the sensor does not solve the problem, contact the manufacturer for a replacement.

There are red dots appearing on the ECG graph during recording: This indicates a problem with the Bluetooth connection between the sensor and the mobile device. Make sure that the mobile device is near the sensor and that there is nothing blocking the signal. Try rebooting your mobile device. Try resetting the sensor Bluetooth by placing it to a powered charging station and then removing. Note that this stops the recording, and it must be restarted. If these steps do not

help, your mobile device might be incompatible with the Beat2Phone ECG sensor.

10 Accessories

The original accessories for the Beat2Phone ECG Sensor are the following:

- Beat2Phone ECG Electrode Strap (GTIN: 6429810109033).
- Beat2Phone ECG Charging Connector with AC power adapter (GTIN: 6429810109019)
- The user should only replace the accessories using original Beat2Phone accessories to ensure that there is no effect on the Beat2Phone ECG system performance and user safety.
- When using the Beat2Phone ECG Sensor, the Beat2Phone ECG Electrode Strap should never be replaced with any electrodes and associated wiring/leads other than original accessories specified in this manual.

WARNING!
Using non-original cables and accessories may negatively affect EMC performance, expected sensor lifetime, and accuracy of the ECG registration.

The Beat2Phone ECG Electrode Strap, which is in contact with the patient during measurement, is made from a mixture of nylon and polyester yarn. The patient can be exposed to small amounts of nickel from the sensor snap connectors during the measurement if the patient is sweating.

Mass of accessories	
Beat2Phone ECG Electrode Strap	35 g
Beat2Phone ECG Charging Connector	94 g

11 Contacting the manufacturer

See www.beat2phone.com for VitalSignum Oy company contact details. Users can contact the manufacturer via email info@vitalsignum.com for reporting unexpected operation or issues when using the device, and for assistance and questions about setting up using and maintaining the device.

Company headquarters address is:

VitalSignum Oy

Health Innovation Village

Kuortaneenkatu 2

00510 Helsinki

Finland

12 Regulatory Information

Compliant with the following:

- EN 60601-1:2005
- EN 60601-1-2:2015
- EN 60601-1-6:2007
- EN 60601-1-11:2015
- EN 60601-2-47:2015

12.1 Classification

Classification	Sensor	Charging connector
Medical device classification, MDD 93/42/EEC	IIa	
IP	X7, not tested for protection against dust ingress. Protected from immersion between 15 centimeters and 1 meter in depth.	21, protected from touch by fingers and objects greater than 12 millimeters. Protected from vertically dripping water.
Protection against electric shock	Internally Powered, Class II when connected to charging connector	Class II
Applied parts	Type BF, Beat2Phone ECG Electrode Strap	-
Mode of operation	Non-continuous 22h/2h ON/OFF	Non-continuous 2h/22h ON/OFF
Input voltage range	Charging cycles = 500	100-240 VAC, 50-60 Hz
Usage type	transit-operable, body-worn	portable
EMC (CISPR11:2009)	Class B, group 1	

Guidance and manufacturer's declaration – electromagnetic emissions			
The Beat2Phone ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the Beat2Phone ECG should ensure that it is used in an environment of the specified type.			
Emissions test	**Compliance**		**Electromagnetic environment – guidance**
RF emissions below 1 GHz CISPR 11, EN 55011	30-230 MHz at 10 m	30 dBuV/m	The Beat2Phone ECG must emit electromagnetic energy (BLE 5) in order to perform its intended function. Nearby electronic equipment may be affected.
	230-1000 MHz at 10 m	37 dBuV/m	
Harmonic emissions IEC 61000-3-2	Class A		The Beat2Phone ECG is suitable for use in a home healthcare environment and in environments directly connected to the public low-voltage power network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take measures to mitigate the effects, such as re-orienting or relocating the Beat2Phone ECG or shielding its location. Average 50, Quasi-peak 60 dBuV
Conducted disturbance EN 55011	Class B, 150 kHz – 30 MHz		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant		

Guidance and manufacturer's declaration – electromagnetic immunity
The Beat2Phone ECG is intended for use in the electromagnetic environment specified below. The customer or the user of the Beat2Phone ECG should ensure that it is used in an environment of the specified type.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should not be used any closer to any part of the Beat2Phone ECG, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = \sqrt{P} * 1.17\ m$ $d = \sqrt{P} * 1.17\ m$ 80 – 800 MHz $d = \sqrt{P} * 2.33\ m$ 800 MHz – 2,7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). The strengths of fields produced by fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
	ISM and amateur radio bands between 0.15 MHz and 80 MHz	6 V	
Radiated RF IEC 61000-4-3	80 MHz to 2.7 GHz	10 V/m	
Proximity fields from wireless RF communications equipment IEC 61000-4-3	Proximity fields @ ISM bands according to: Table 9	Table 9 of 60601-1-2:2015	
ESD EN 61000-4-2	Contact discharge (direct/indirect)	8 kV	
	Air discharge (direct)	2, 4, 8, 15 kV	
Power frequency magnetic fields EN 61000-4-8	Power-frequency magnetic field, 30 A/m	Continuous field (50/60 Hz)	
Power supply networks voltage dips and interruptions EN 61000-4-11	Voltage reduction 100 %, 0.5, 1, 250 cycles	10, 20, 5000 ms	
	Voltage reduction 70%, 25 cycles	500 ms	
Surge EN 61000-4-5	Line to line	+/- 0.5, 1.0 kV	
Electrical fast transient burst EN 61000-4-4	Individual supply lines, 100 kHz rate	2 kV	
	All combinations of supply lines and earth, 100 kHz rate		

NOTE These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the Beat2Phone ECG use location exceeds the applicable RF compliance level above, the Beat2Phone ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Beat2Phone ECG. In the the frequency range 150 kHz – 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Beat2Phone ECG

The Beat2Phone ECG is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Beat2Phone ECG can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Beat2Phone ECG as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (P) W	**Separation distance according to transmitter frequency m**		
	150 kHz – 80 MHz outside ISM bands $\boldsymbol{d = \sqrt{P} * 1.17m}$	80 MHz – 800 MHz $\boldsymbol{d = \sqrt{P} * 1.17m}$	800 MHz – 2.7 GHz $\boldsymbol{d = \sqrt{P} * 2.33m}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 Mhz, the separation distance for the higher frequency range applies.

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3: An additional factor of 10/3 has been incorporated into the formulae used for calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if inadvertently brought into patient areas.

NOTE 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EMC test setup specified in EN 60601-2-47 Figure 202.101 was used in testing.

12.2 Used markings, safety signs and symbols

The sensor markings:

- Product type: Beat2Phone ECG Sensor
- Manufacturer: www.beat2phone.com
- Radio
- Serial number
- MAC address
- Recycling
- Battery type is Li-ion 3.7 V / 295 mAh, rechargeable, non-replaceable
- IP Classification
- Non-continuous operation mode, max duty cycle 22h/2h
- Orientation heart symbol.
- Disposal
- Unique device identifier (UDI) number

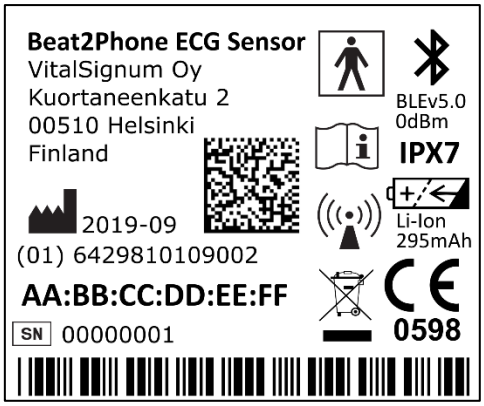


Figure 12-1: The sensor label

The charging connector markings:

- Product type: Beat2Phone ECG Charging Connector
- Manufacturer: www.beat2phone.com
- supply markings, 6 V DC, 6 W
- IP Classification IP21
- Orientation heart symbol.
- Disposal
- Unique device identifier (UDI) number

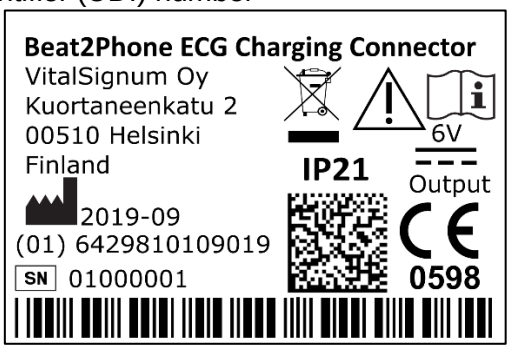


Figure 12-2: The charging connector label

Electrode strap markings:

- Product type: Beat2Phone ECG Electrode Strap
- Disposal
- Unique device identifier (UDI) number

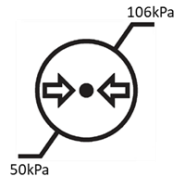
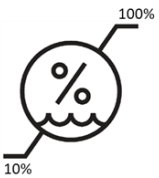
Figure 12-3: The electrode strap label

UDI number is generated from the company prefix, sensor and the charging connector serial numbers, batch codes, manufacturing dates, software versions and other data. Each device and all its accessories have their own UDI numbers.

The UDI number has two parts: UDI-DI (device identifier) and UDI-PI (production identifier). DI is a combination of company prefix and the specific GTIN code for the sensor, charging connector, electrode strap, and all accessories and software related to the device.

UDI-PI is a combination of the sensor's and the charging connector's serial number and batch number. For device accessories, UDI-PI is the date of manufacture.

NOTE! Standard electrode lead markings do not apply for the Beat2Phone ECG Electrode Strap as no ECG cables are used and only one bipolar lead is measured by the sensor.

General symbols			
Symbol	Explanation	Symbol	Explanation
	General warning sign	IPX7	Not tested for protection against dust ingress. Protected from immersion between 15 centimeters and 1 meter in depth.
	Manufacturer	IP21	Protected from touch by fingers and objects greater than 12 millimeters. Protected from vertically dripping water.
	See instructions for use.	SN	Serial number
CE xxxx	CE marking conformity	REF	Reference number
	DO NOT PUT INTO TRASH. Properly dispose of EEE (Electrical and Electronic Equipment). EU WEEE (European Union Directive for Waste of Electronic and Electrical Equipment)		Identifies a BF type applied part compliant with IEC 60601-1. **IEC/TR 60878** Graphical Symbols for Electrical Equipment in Medical Practice.
	Direct Current		Electromagnetic interference may occur in the vicinity of equipment marked with this symbol.
	Indicates temperature limits the medical device can be safely exposed to.		Indicates a medical device that needs to be protected against moisture.
	Indicates pressure limits the medical device can be safely exposed to.		Indicates humidity limits the medical device can be safely exposed to.

	Warning; Magnetic field		Refer to instruction manual.
	Rechargeable battery		Bluetooth
	Attention: Read all warnings and precautions in instruc-tions for use.		

Symbols			
Symbol	Explanation	Symbol	Explanation
	Open the instruction manual.		Open the profile view.
	Start a recording.		Add an annotation to the recording.
	Stop the recording.		Segment duration measurement tool.
	Millimeter paper from the recording.		Send the millimeter paper.
	Delete the recording.		Open settings.
	Mobile device battery level indicator.		Sensor battery level indicator, blinks when battery is low.
	Electrode contact indicator. Leads on.		Electrode contact indicator. Leads off. Blinking.
	Sensor memory status indicator. 0% full to 100% full. 0% in the picture.		Sensor battery is charging.

	A recording is ongoing.		Retrieve recordings from cloud.
	Recording is in the sensor memory but is not transferred to the mobile device.		Recording is transferred to the mobile device.
	Recording is not uploaded to cloud.		Recording is uploaded to cloud.

13 Technical Description

Technical Specifications	
ECG sampling frequency	2048 Hz, averaged to 512 Hz
ECG precision	16 bits
ECG bandwidth	0.05-250 Hz
Display accuracy for heartbeat	1 beat per minute
Display accuracy for HRV	1 millisecond
Accelerometer sampling frequency	25 Hz
Accelerometer precision	16 bits
File format	EDF
Memory capacity	1 GB
Power source	3.8 V Li-ion polymer battery
Dimensions	35 mm * 63 mm * 14 mm
Weight	20 g
Operating time	24 hours
Bluetooth Low Energy - BLE 5	ERP 0 dBm, 2.4 – 2.483 GHz, 2 MHz wide channel, GFSK

13.1 Environment

The Beat2Phone ECG equipment can be safely used in the user's home environment in any other environments where it is permissible to use consumer mobile electronic communication devices.

All parts of the Beat2Phone ECG device can be used within the patient environment of professional healthcare facilities except the Beat2Phone ECG Charging Connector. Patient environment is defined as an area within 1.5 meters from the patient.

Do not use the device in temperatures below –20 degrees Celsius or over 40 degrees Celsius. Do not use the device at an altitude of higher than 2,000 m.

The sensor has ESD protection components that protect the measurement electronics so that ECG registration will continue working after the ESD. The sensor is not defibrillation-proof. The sensor is not tested for compatibility with HF surgical equipment.

The sensor is battery-operated. The sensor battery is charged using the provided charging connector. The sensor cannot be connected to ECG electrodes while in the charging connector.

Battery level can be checked with the Beat2Phone ECG Application or by placing the sensor in the charging connector connected to a DC power supply and observing the sensor LEDs.

Environmental conditions for use, charging, transport and storage			
	Use	**Charging**	**Transport & storage**
Temperature	–20 to +40 °C	0 to +40 °C	–20 to +60 °C
Humidity	10% to 90%	20% to 80%	10% to 90%
Pressure	800 to 1060 hPa	800 to 1060 hPa	500 to 1060 hPa

NOTE! Any serious incidents that occur in relation to this device should be reported to both the manufacturer and a competent authority of the Member State.

13.2 Transport and storage

After the sensor is removed from its protective packaging it is recommended to store it in room temperature and dry conditions. Do not subject the sensor to storage and transport in temperatures below –20 and above 60 Celsius.

List of figures