

Beat2Phone ECG Instruction Manual



Beat2Phone ECG

Powered by VitalSignum

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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.



This device complies with:

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

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2 Intended use

The VitalSignum ECG-sensor is intended for use in clinical and non-clinical environment for measuring the electrical activity of the heart via two skin contact electrodes providing a one-lead electrocardiogram accurate enough to detect arrhythmia. The people to be monitored are normal weight adults in need for monitoring their heart condition. The measured data containing the electric activity of the heart over the measured time period is stored as an EDF ECG file, which can be accessed by the healthcare professionals as needed. The sensor is not intended for children and does not provide any automatic analysis or diagnosis.



3 Introduction

The VitalSignum wearable ECG-sensor allows personal, easy, reliable and accurate measurement of a one lead ECG – Electrocardiogram – using an internal battery powered sensor device with 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. The principle of operation is well known from ECG measurement, and similar chest strap-based monitoring of the heartbeat is widely used in sports applications. The 2kHz ECG-voltage sampling frequency in the sensor allows accurate RRI calculation and almost noise-free recording of the whole PQRST sequence with accuracy suitable for medical level analysis.

Up to 24 hours of continuous ECG measurement can be performed and stored into the recording file in the sensor memory and transferred as EDF+ ECG file to a computer for more detailed analysis. The sensor battery is rechargeable using the charging connector accessory.

The adult patient user can perform ECG measurement over extended periods during normal life, including exercise, sleep, and work, using the sensor with the electrode strap. Sensor assignment and use is simple and does not require medical training of the patient users or assisting people. The product allows medical professionals to conduct large scale health surveys and screening cost-efficiently. EDF+ ECG registration data file is easily available for diagnostics from the sensor memory. In addition to ECG, the sensor has an accelerometer for additional posture and activity information.

ECG can be recorded with the Beat2Phone ECG product as instructed in this manual. As a patient user, you will receive the necessary additional instructions from your medical professional. If you have physical or cognitive impairments, you may need assistance for conducting the measurement. As a medical professional, you can assign the product for your patient's use based on your professional judgement of the patient's need and abilities. The use of the device does not require any special skills, training or knowledge from the medical professional besides following the instructions in this manual. When assisting others in use of the product, you should be familiar with the instructions provided in this manual. A patient user can safely use all of the functions of the device, although 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 for children and does not provide any automatic analysis or diagnosis.



3.2 Warnings



- The Beat2Phone ECG is intended for adult users only, do not apply it on children.
- The charging connector may not be used inside the patient area – 1.5m around the patient – inside institutional care facilities. The user of the charging connector must be conscious, aware, and in adequate physical and mental condition.
- Do not use the Beat2Phone charging connector if the sensor Orange LED is lit when the sensor is attached to the connector - the connector is broken and must be replaced.
- Use the electrode strap on healthy skin only. Do not use the device if the skin under the electrode strap is damaged, irritated, sensitive or allergenic. Electrodes will introduce stress on the skin which causes irritation and delays healing of the skin.
- In case of skin irritation appears during the use of the electrode strap stop using the strap and contact medical professional for advice
- Do not attempt self-diagnostics based on the device recordings, always consult a competent medical professional for the needed actions
- Do not immerse the device to water. VitalSignum sensor and charging connector are not waterproof and immersion to water will be detrimental to the device lifetime
- Do not charge the sensor battery in temperatures below 0 degrees or above 40 degrees Celsius.
- Do not place the sensor in or near microwave appliances to avoid damage to the battery.
- Do not use the device with a defibrillator as the high voltage pulse is detrimental to the sensor lifetime. Device is not defibrillation proof.
- Sensor includes a Bluetooth BLEv5.0 radio transmitter, so it shall not be used 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 forces.
- Do not connect the Beat2Phone device or accessories to any other device or accessory other than those specified in this instruction manual.
- Do not place the Beat2Phone sensor closer than 3cm from a pacemaker. The sensor contains a magnet. The pacemaker may enter into asynchronous mode in the presence of a strong magnetic fields. Normal operation usually continues when the magnetic field is removed.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.”
- Do not use near devices that use the frequency of 385 MHz. This frequency causes interference with the ECG measurement.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches)



to any part of the Beat2Phone ECG, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

- 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 a wet charging connector.
- Other than 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 cable in the charging connector can cause strangulation if improperly used.
- The user can be exposed to very small amounts of nickel from the electrode strap snap connectors, which can cause an allergic reaction in sensitive users
- Do not place the charging cable or the electrode strap around your neck; there is a risk of strangulation

3.3 Safety Precautions

- Before using the Beat2Phone sensor, read this manual carefully and keep it at hand for reference to ensure successful and meaningful ECG registrations.
- Do not leave the sensor in reach of small children or pets, the sensor is small enough to be swallowed. Choking can result if the sensor is stuck in the throat blocking air from entering the lungs.
- Do not use, place or store the sensor in extreme environmental conditions, in shower or under water, or at higher than 60 or lower than -20 degrees Celsius temperature. The battery can be damaged, and the sensor ceases to operate.
- Do not use the device in an altitude higher than 2000m. The electrical safety of the device is not guaranteed in low air pressure.
- Take precaution if the use location is less than 1,5km from AM/FM or TV broadcast antennas
- Do not disassemble, try to repair or modify the sensor or its accessories. A tampered device cannot be relied on accurate ECG registrations and cannot be used to draw any conclusions by a medical professional.
- Do not use a damaged device. A broken device cannot be relied on accurate ECG registrations and must be used to draw any conclusions by a medical professional.
- Medical electrical equipment or electrical stimulators attached to the patient's body may degrade Beat2Phone sensor signal quality or produce erroneous results from the biosensor. The potential interaction must be evaluated and authorized by the responsible organization.
- Always ensure a good skin contact for the electrodes by using firmly attached clean electrode strap on clean bare skin. Measurement accuracy suffers from poor electrode contact and important ECG detail for conclusions by a medical professional can be missed.
- Nourish the skin that becomes in contact with the electrodes and let the skin rest by removing the electrode strap in between ECG registrations 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 keep the sensor, the charging connector, and the electrode strap clean. Excessive lint or dust can hinder the performance of the device.



4 Product package

The 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)
- and Beat2Phone ECG Application (GTIN: 6429810109064)

The parts are in three slots inside the box. Sensor and charging connector slot and the electrode strap slot.

The information on the box labelling:

- Beat2Phone ECG Kit package content
- Manufacturer information
- Manufacture date
- Beat2Phone ECG Kit Serial Number readable and bar code format
- Beat2Phone ECG Kit GTIN readable and 2D bar code format in UDI
- Pressure, temperature and humidity limits for transport and storage
- CE mark with NB number

Beat2Phone ECG kit								
<input checked="" type="checkbox"/> ECG Charging connector	<input checked="" type="checkbox"/> ECG Sensor	Weight:	10%	50kPa	-20°C			0598
<input checked="" type="checkbox"/> ECG Electrode strap	<input checked="" type="checkbox"/> Quick guide	0.2 kg						
<input type="checkbox"/> ECG Electrode adapter	<input type="checkbox"/> ECG Electrodes							

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SN 01000001



5 Beat2Phone ECG monitoring overview

The wearable, lightweight, flat and compact sized sensor connects to two skin contact electrodes with an electrode strap. The sensor supports lead off detection to verify proper connection to skin.

Sensor is powered by an internal chargeable Li-ion battery. The same snap connectors that are used for measurement are also used for charging the sensor battery using a patented circuit design and charging connector accessory supplied with the sensor. The fully charged Li-ion battery provides 24 hours of continuous measurement. The charging connector accessory is used for charging the sensor battery. Charging level is indicated by the sensor LEDs and the Beat2Phone application 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.

Sensor flash memory can store 24 hours of ECG and posture (3-axis accelerometer) monitoring data. Memory fill is indicated by the Beat2Phone application GUI indicators. While charging the battery, the recordings can be transferred to the mobile device using the mobile application and stored to the mobile device memory. Keep the mobile device charged.

Sensor has a BLEv5 radio that is used for displaying the ECG and transferring the recordings from the sensor memory to the mobile device with the Beat2Phone application.

The sensor can be turned on by shaking it, after which it's snapped firmly to the electrode strap sensor contacts. The Beat2Phone application detects the sensor via Bluetooth and displays the monitored signal which is then stored to the sensor memory. When a recording is completed, the user ends the measurement using the mobile application. The recording is then transferred from the sensor to the mobile device by placing the sensor to the charging connector that is connected to a power supply. The EDF+ format recording file is then available from the mobile device memory to be shared for analysis, or the mobile application history view can be used to manually browse the recorded ECG signal.

5.1 Recommended mobile devices

The verified list of mobile devices supported by the Beat2Phone ECG device and mobile application can be found at beat2phone.com. At minimum Bluetooth Low Energy BLEv4.2 support is required and BLEv5 is recommended for the mobile device used.



6 ECG recording

ECG can be recorded with the Beat2Phone ECG product as instructed in this manual.

As a patient user, you will receive the necessary additional instructions from your medical professional. If you have physical or cognitive impairments, you may need assistance for conducting the measurement.

As a medical professional, you can assign the product for your patient's use based on your professional judgement of the patient's need and abilities. The use of the device does not require any special skills, training or knowledge from the medical professional besides following the instructions in this manual. When assisting others in use of the product, you should be familiar with the instructions provided in this manual.

A patient user can safely use all the functions of the device, although the professional view in the mobile application is only intended for professional use and cannot be accessed by patient users.

For the ECG recording you need:

- 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 application. The mobile device is not part of the ME System provided by VitalSignum Oy. You will find the parts in the product package.

Make sure that the environment is comfortable, clean and private before attaching the device to your chest. It is also beneficial to have access to electricity for charging the sensor and the mobile device when needed. Use clean hands when touching Beat2Phone parts and do not place any parts on dirty surfaces or places where they may be subject to be damaged by children, pets, falling, wetting, overheating or mechanical forces.

Start with fixing the electrode strap to your chest. Moisten the skin under the electrodes with pure water to ensure good contact. After the strap is fixed, check that the Beat2Phone application is running on the mobile device. Turn on the sensor by slapping it against your palm. The blinking green LED indicates the sensor is on. If the sensor does not turn on, try charging it.

NOTE! Before sensor is turned on and connected to the strap, it is recommended to check the battery charge by inserting the sensor to the powered charging connector. Lit green LED indicates fully charged and ready to use.

Attach the sensor to the sensor snap connectors so that the LEDs are facing up and the heart symbol is the right way. The green LED starts blinking at the pace of your heartbeat when the sensor detects your pulse. Let the sensor stabilize for two minutes before using the mobile application for recording the measurement.



6.1 Fixing the ECG skin contact electrodes

Proper electrode placement and low impedance contact to skin are important prerequisites for good quality ECG measurement. The electrode strap for one lead ECG is positioned as depicted in Figure 1. Position adjustment to achieve best possible signal can be done within the limits of the electrode strap.



Figure 1: The Beat2Phone sensor properly attached to chest with the electrode strap.

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

Apply some moisture (water) with a damp cloth to electrode strap contacts before using the strap. This will improve the electrical contact between the skin and electrodes.



WARNING:

Do not use the device if the skin under the electrode strap is damaged, irritated, sensitive or shows allergic reaction.

The electrode strap can irritate the skin. It is important to clean the strap and care for the skin in between the use of the electrodes.



NOTE! The electrode strap is only intended for personal use during a single 1-2 weeks 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 Beat2Phone ECG application from the Google Play Store on Android mobile devices.

For professional use, the application comes pre-installed on the mobile device, and the mobile device is locked in a way 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. A patient user can safely use all the functions of the device, although the professional view in the mobile application is only intended for professional use and cannot be accessed by patient users.

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.

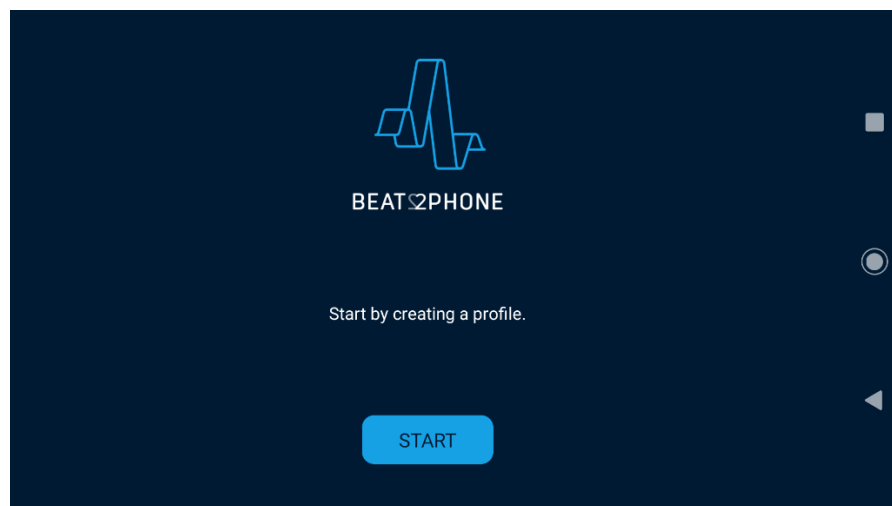


Figure 2: The view when the app is opened for the first time.

After creating the professional profile, the **professional start view** is served. This view is also served if the mobile device already has an existing private or



professional profile defined. In this case you can open the profiles view by touching the top right corner symbol. You can select and create a new professional profile or restore an existing one in the profiles view. NOTE: if you enter in a private personal profile you cannot join an organization and enter patients as private user views are served.

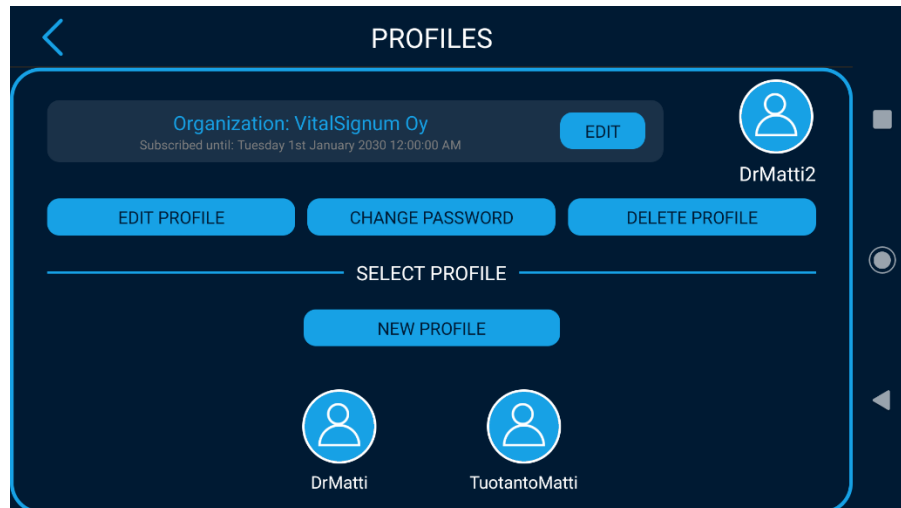


Figure 3: The profile management view

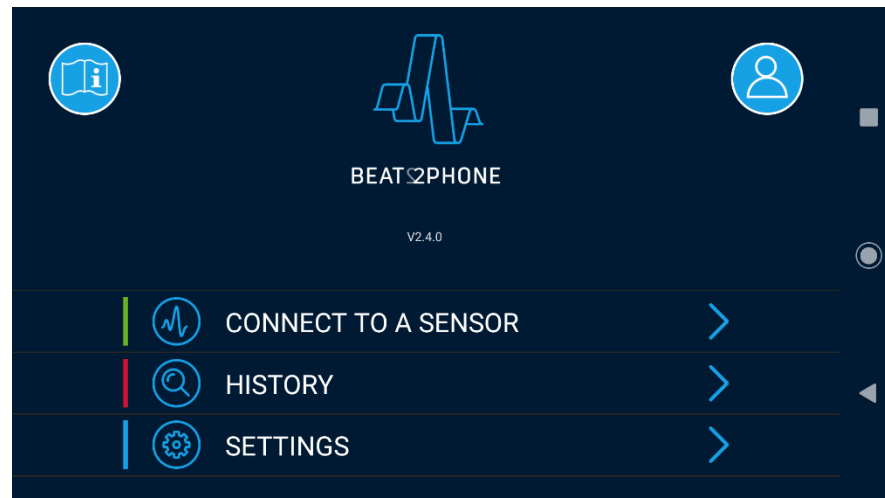


Figure 4: The professional start view.

First, join with your professional organization by opening the user profile menu from the top right corner. In the profile view, you can see all your organizations on the top of the screen as a professional user. Select **JOIN if joining for the first time or EDIT if joining another organization**. A list of organization you can join is 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**. Only after joining an organization, patient profiles for the organization can be created. NOTE: patient profiles are managed under the PATIENTS start menu item.

The sensor intended for the patient connection needs to be selected, after which the next professional start view is served. Select CONNECT TO A SENSOR, and a list of active sensors detected is shown. Then, select the sensor that is intended for the patient by looking at the MAC address of the sensor (for example MAC: c0:2a:b9:26:1d:98) printed on the back of the sensor that matches the one you select from the list – see [Used markings, safety signs and symbols](#).

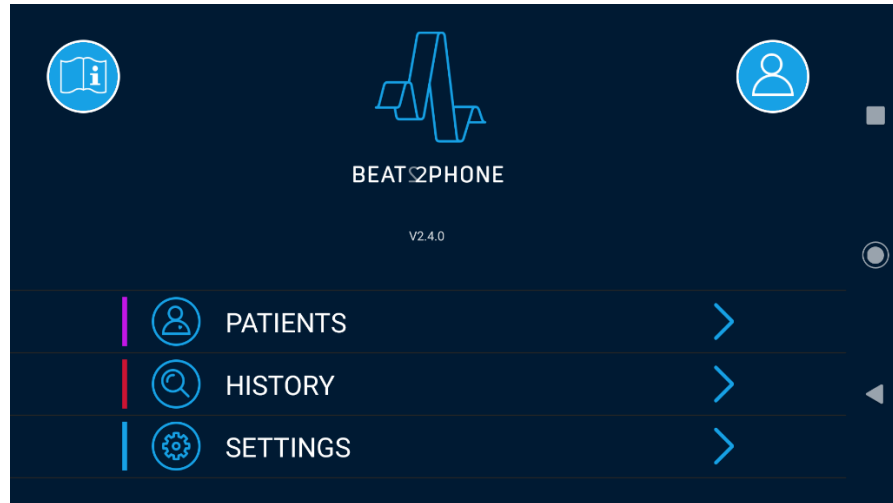


Figure 5: The professional start view after connecting to a sensor.

The sensor wireless communication is sensitive to 5GHz radio signal interference. If there is difficulty finding the sensor try a different location with less signal disturbance.

As a professional user, you can create/delete/modify profiles, change your password, modify all application settings, and view all the patient's recording history in the mobile device. You cannot start ECG-recording from the professional start view.

To conduct patient measurements, a **patient profile** must be created or selected by the professional user under the PATIENTS view. When creating the patient profile, the user's organization and a unique patient identifier is requested from the professional user. After the patient profile is created and selected, the patient start view is served. The patient monitoring period begins when the first patient recording is started, the patient device is selected, and no device selection is required for starting the patient measurement. The professional user ID and password is needed to log out from the patient start view and return to the professional start view. Logging out from the patient profile will end the patient monitoring period.

A patient profile can be deleted by touching a patient profile in the patient selection/creation view and choosing DELETE.

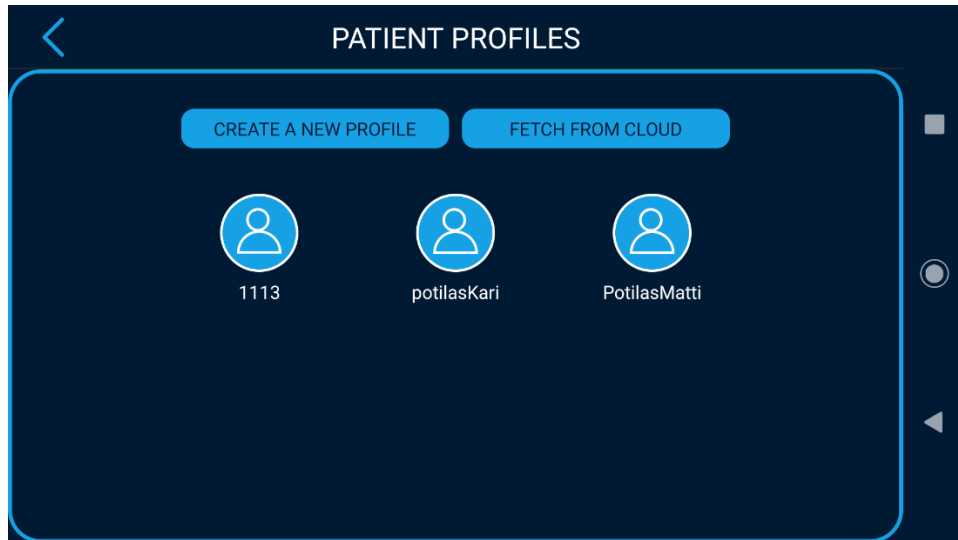


Figure 6: The patient selection/creation view

6.2.2 Application - patient user

Recording is started by touching the **patient start view** green 'start' button FIGURE (5).

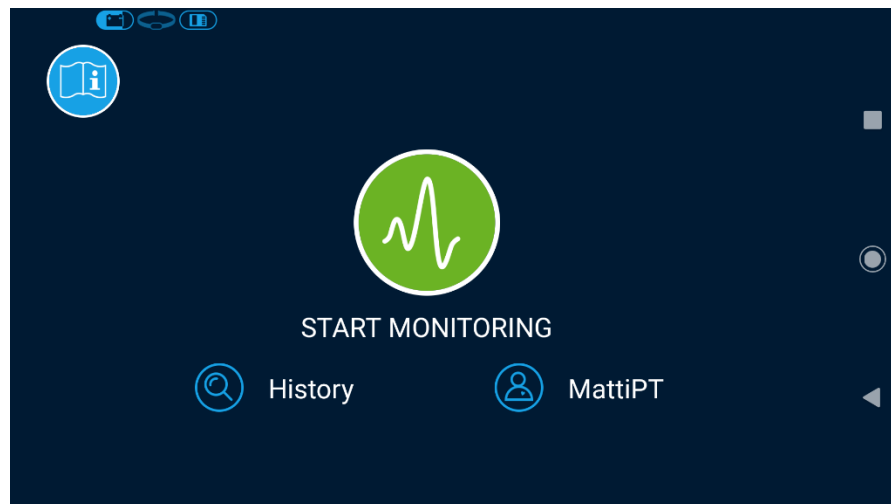


Figure 7: The patient start view.

The live ECG-signal becomes visible on the mobile device screen along with the heart rate curve in the **patient monitoring view**. The yellow number indicates heart rate in beats per minute, and the yellow curve indicates the heart rate curve. If the 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. The live monitoring screen turns off in 60 seconds to save the mobile device and sensor battery. Measurement is ongoing and data is stored. The recording time is visible on



the right top corner of the screen. The monitoring view has a 'Stop' -button for ending the recording. There is also a 'marker' button for user annotations in the patient monitoring mode.

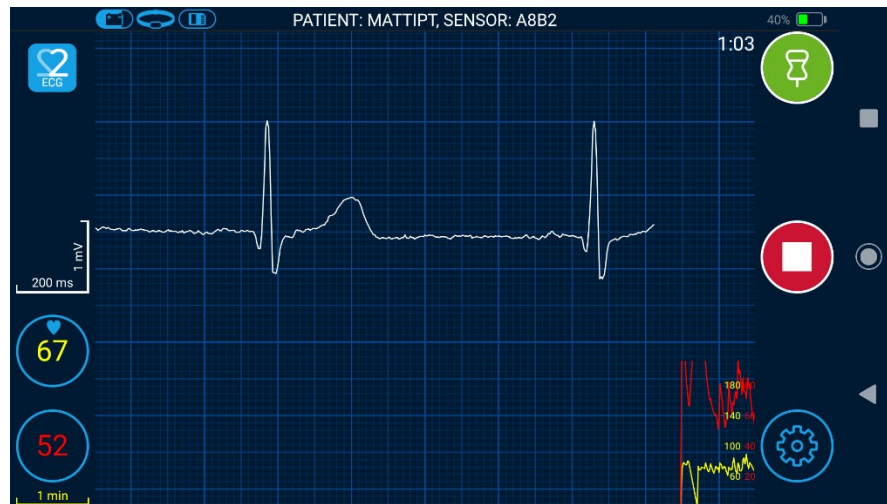


Figure 8: The patient monitoring view.

During the measurement, the patient can add a marking/annotation to the recording in the **patient annotation view**, which opens when you open the application in the mobile device after the monitoring view has turned off. Keep the mobile device close by to enable timely annotations.

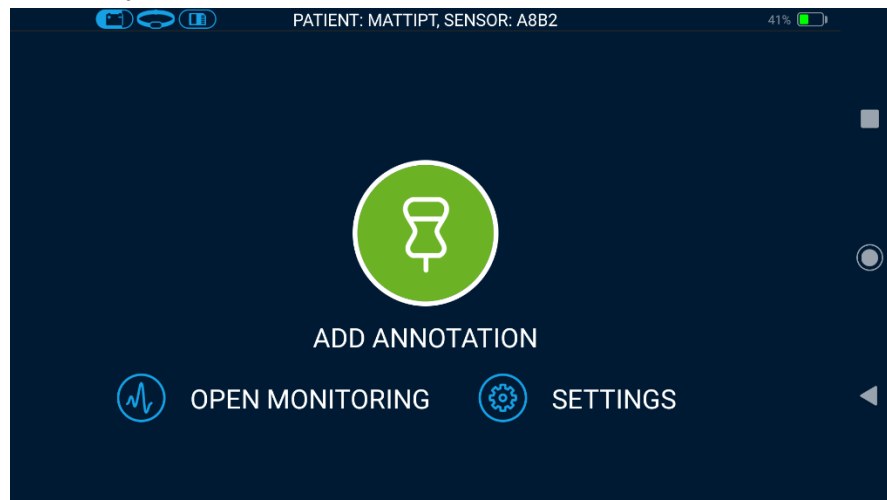


Figure 9: The patient annotation view.

Touching the Marker-symbol opens a list of annotation types to select from. Annotation time is the time the dialog is opened. After an annotation is made, the application returns to the annotation view for 30 seconds before turning the screen off.



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

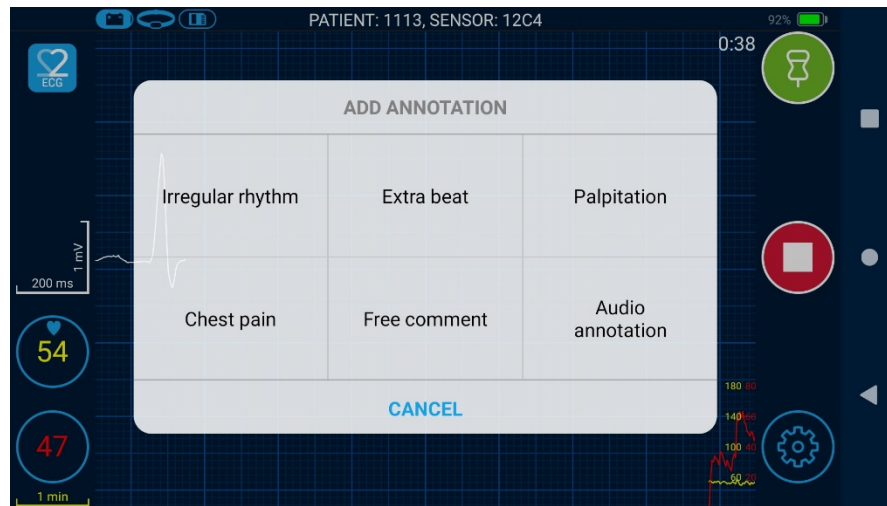


Figure 10: The annotation selection view.

The patient can also return to the monitoring view during the measurement by opening the application and touching the Start-symbol in the annotation view. The live ECG signal is shown for 60 seconds in the monitoring view before the screen turns off. In the monitoring view, the patient can make annotations and stop the measurement.

The patient can stop the measurement by selecting the monitoring view and touching the stop-symbol. The ECG recording is stored in the sensor memory, which can be read by the application and stored as an EDF+ -file in the mobile device memory, from where it can be retrieved for analysis by a qualified medical professional.

NOTE! When the sensor memory is full, the sensor will begin overwriting the old recordings with new ones, effectively destroying the old recordings. Remember to transfer the recordings from the sensor to the mobile device after recording for 24 hours if you don't want to lose any recordings.

In the top part of the start view and the monitoring view, the status of the sensor battery, the status of the electrodes, and the status of the sensor memory are displayed. In addition, in the monitoring view, the last four digits of the sensor MAC address as well as the mobile device battery charge are displayed.



Figure 11 From left to right: sensor battery status, leads on/off, sensor memory status



6.2.3 *Application - consumer user*

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

6.3 **Shutdown procedure**

The measurement can be stopped by selecting the monitoring view and touching the stop-symbol. When the measurement has stopped, remove the sensor from the electrode strap and place it to the charging dock that is connected to a DC power supply. Remove the electrode strap. Clean and nourish the skin carefully after removing the electrode strap.

To shut down the paired sensor with the application, remove the sensor from charger, choose **SETTINGS -> SENSOR INFORMATION -> POWER OFF SENSOR**. The sensor can be powered on again by placing it in the charging connector. Only the professional user can shut down the sensor. Sensors are shut down at the factory to prevent the sensor starting to operate and the battery discharging during transport.

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

6.4 **Uploading and Viewing the recordings in the sensor- professional user**

Recordings stored in the sensor memory must be transferred to the mobile device before viewing of the recordings is possible in the application. After the recording is stopped, detach the sensor from the strap and place it in the charging connector. Connect the charging connector to mains power supply. The application will display a file upload dialogue to start transferring the stored files to the mobile device. The mobile device must be within few meters from the sensor to transfer the files.

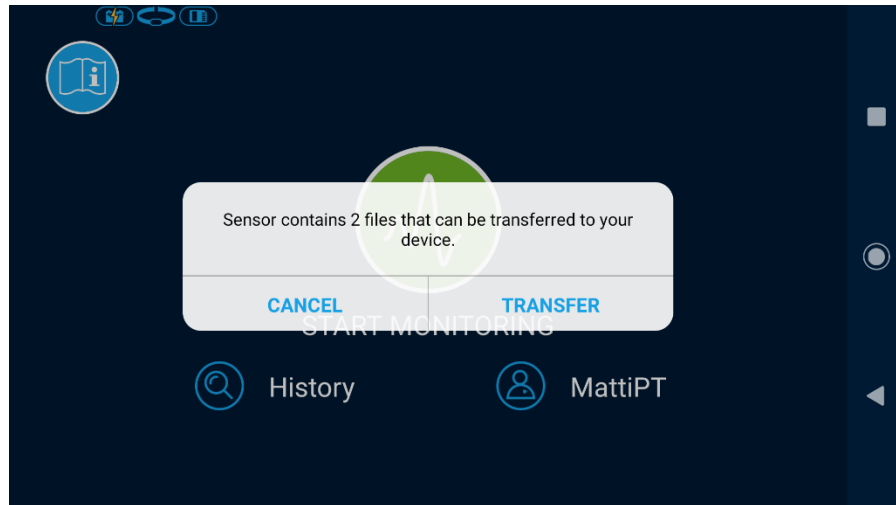


Figure 12: The file upload dialogue.

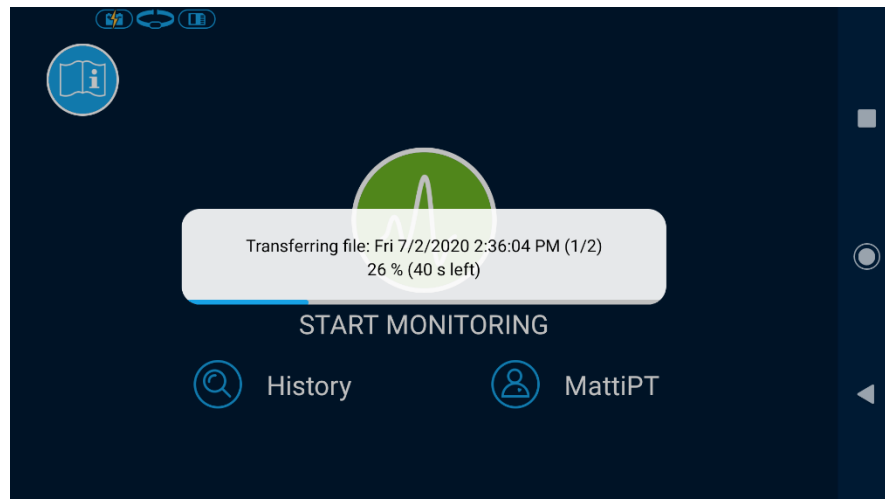


Figure 13: Transferring the file.

All the patient ECG recordings in the mobile device can be viewed in the **professional history view**. List view is the default view showing the latest patient recording on top. The recording is opened for viewing from the list by touching the list item. In case the recording is still in the sensor memory, a memory card icon will be shown next to the list item. Touching this list item will start uploading the recording file from the sensor to the mobile device.

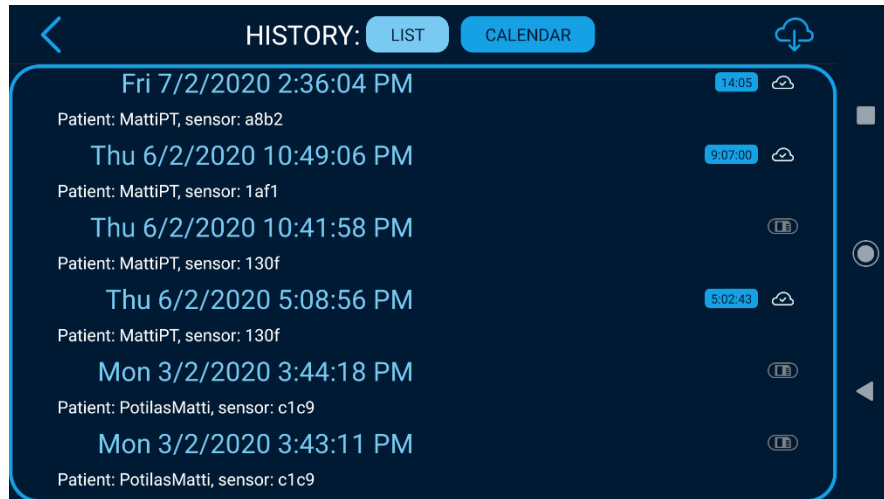


Figure 14: The history list view.

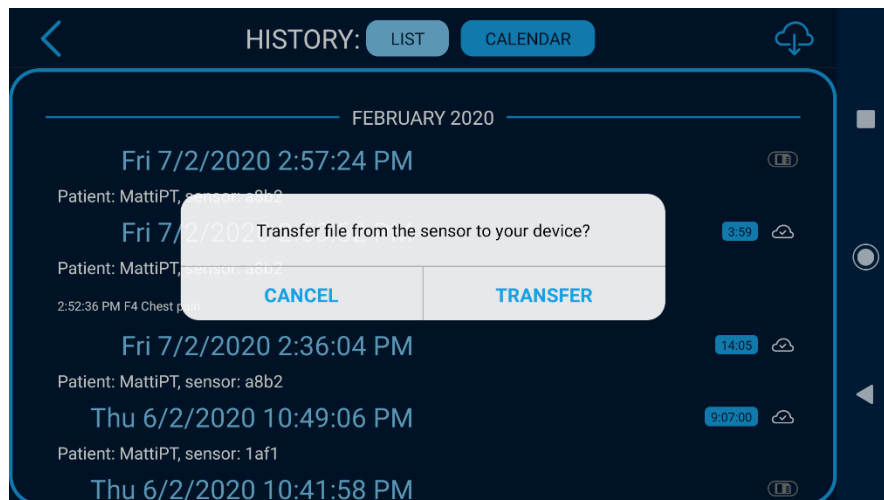


Figure 15: File transfer dialogue in the history view.

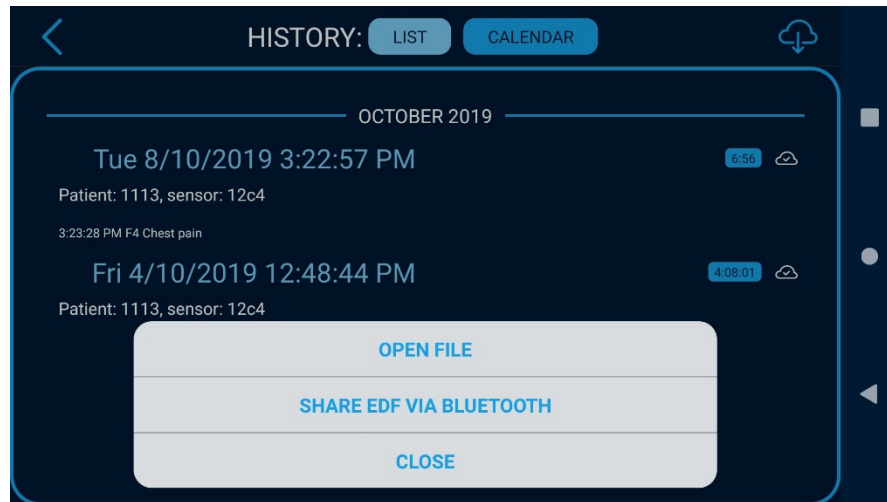


Figure 16: Opening the file in the history view.

Select 'OPEN FILE' in the history view to see the recording as the monitoring view, with few important additions: the PQRST measurement tool, the mm paper view/share tool, and the professional annotation tool. In addition, a trash button is available for deleting the recording. Settings for heart rate histogram apply only in the history view. The mobile device touch screen allows the user to move the HR and ECG graphs by dragging and swiping. Horizontal zoom by fingers is also available. Default scales are returned by touching the Beat2Phone heart icon.

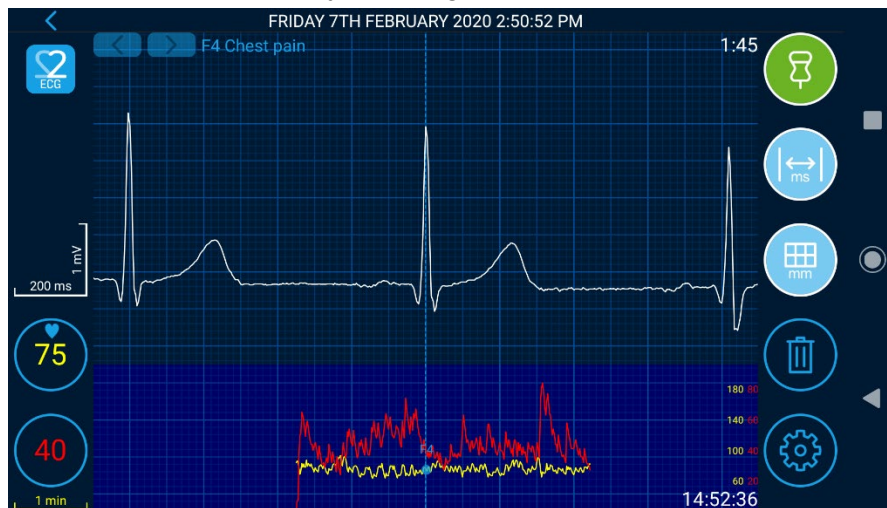


Figure 17: The history view of a recording.

Select 'SHARE EDF VIA BLUETOOTH' to access the ECG recording in EDF+ format and transfer it to another device, for example a computer. You must pair your computer with the mobile device and set it to receive files via Bluetooth. The EDF+ file can be opened with various programs that can be downloaded from the internet, for example from physionet.org.



6.5 Uploading and Viewing the recordings in the sensor - patient user

Recordings stored in the sensor memory must be transferred to the mobile device before viewing of the recordings is possible in the application. After the recording is stopped, detach the sensor from the strap and place it in the charging connector. Connect the charging connector connected to mains power supply. The application will display a file upload dialogue to start transferring the 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. See figures 12-15.

Patients can upload and view their own ECG recordings in the mobile device in the **patient history view**. Patients cannot delete their recordings but can share the EDF+ file.

Time for the measurements is taken from the mobile device, in which it is recommended to use the date, time and time zone from the network provider.

6.6 Identifying proper ECG waveform

If the electrodes are not properly attached, if the user is moving a lot, or if the user is very close to some electronic devices, the ECG signal can be too noisy for analysis. Pacemaker worn by the user may cause visible notches on the recorded ECG signal of the user. In the presence of disturbance or artefacts, the heart rate is not correctly calculated and can be displayed as exceptionally high. Observe warnings and avoid situations that cause signal artefacts. Here are some examples of proper ECG and noisy ECG (or no ECG at all).

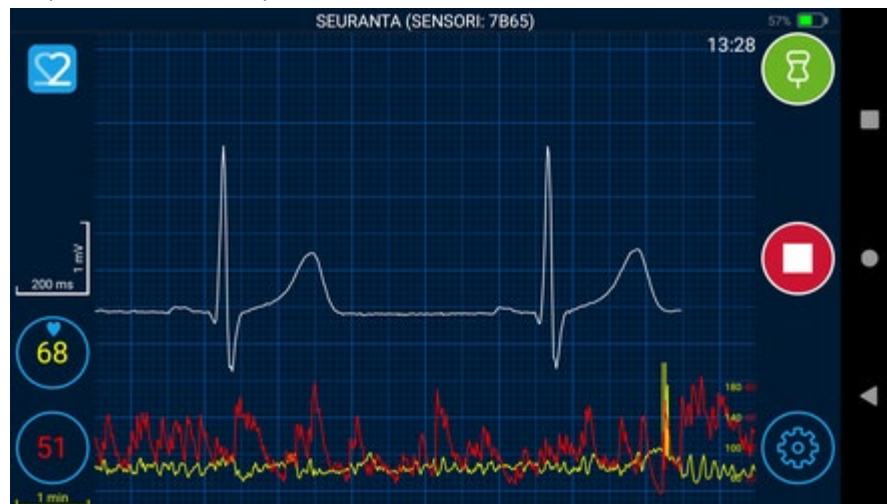


Figure 18: A proper ECG waveform.

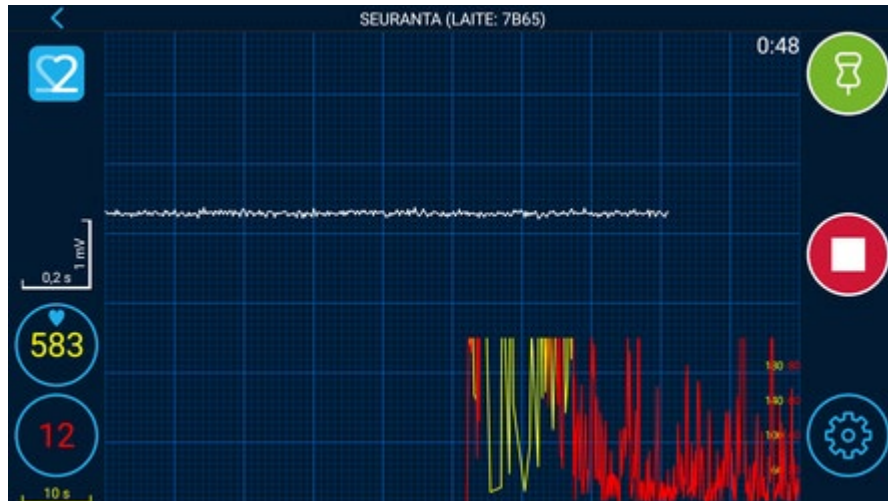


Figure 19: The sensor is not attached to the electrodes, or the electrodes are not attached to skin.

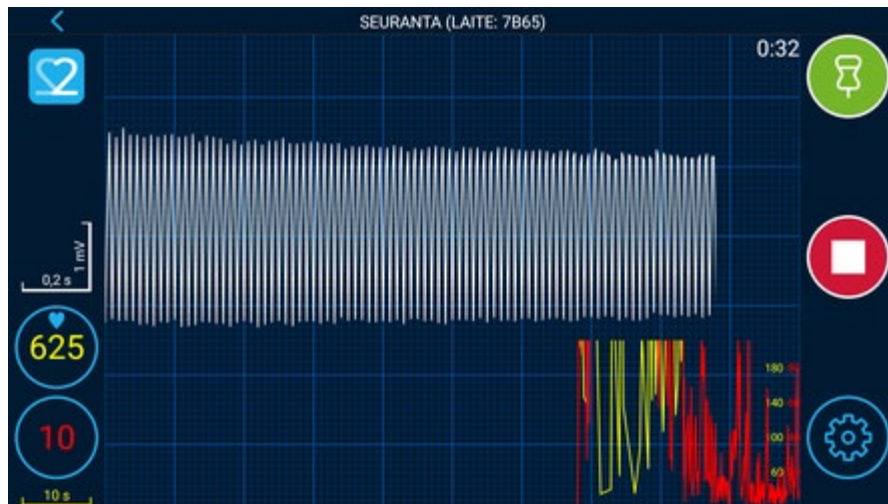


Figure 20: The sensor is not attached to the electrodes, or the electrodes are not attached to skin. The sensor is near electronic devices.

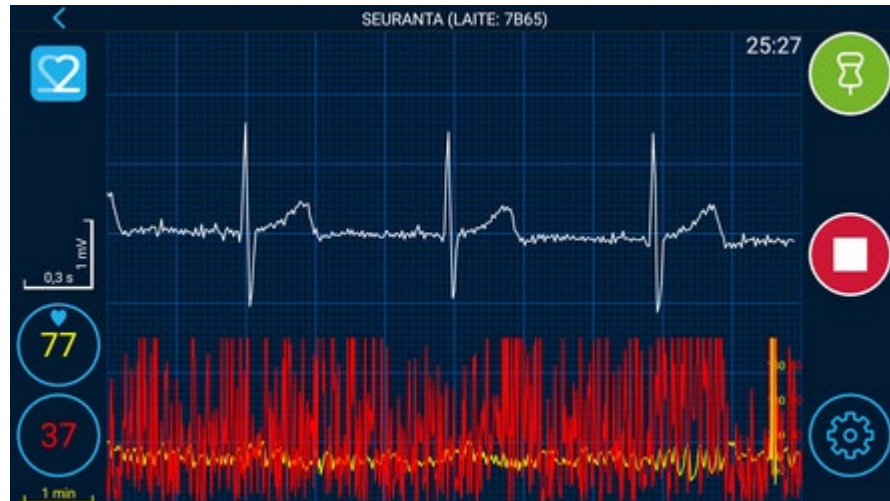


Figure 21: The skin-electrode contact is not good.

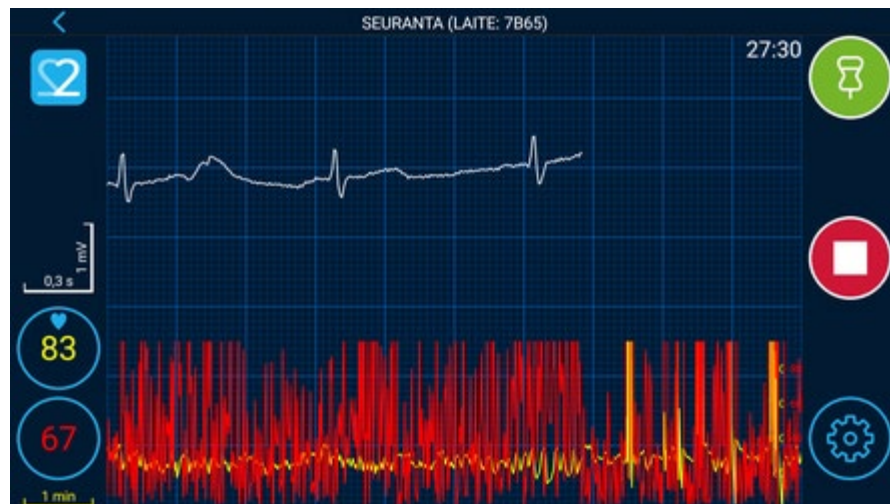


Figure 22: The electrodes are not placed correctly, and the signal is not strong enough.

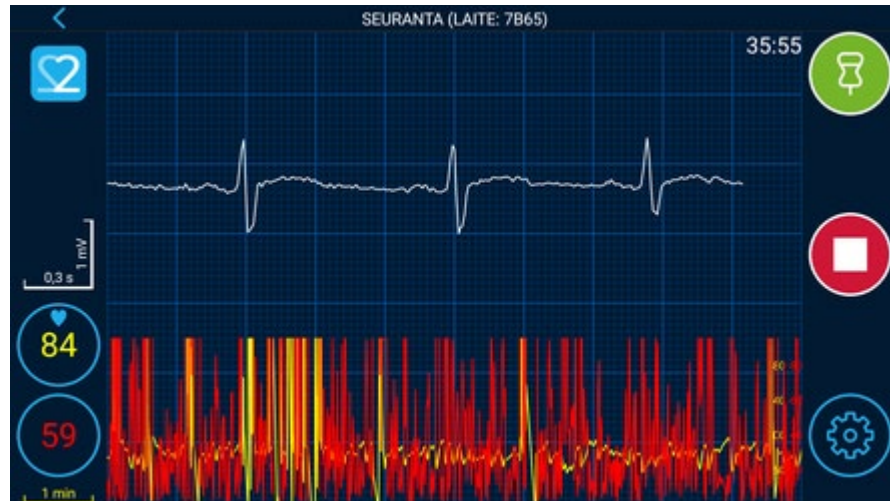


Figure 23: The electrodes are not placed correctly, and the signal is not strong enough.

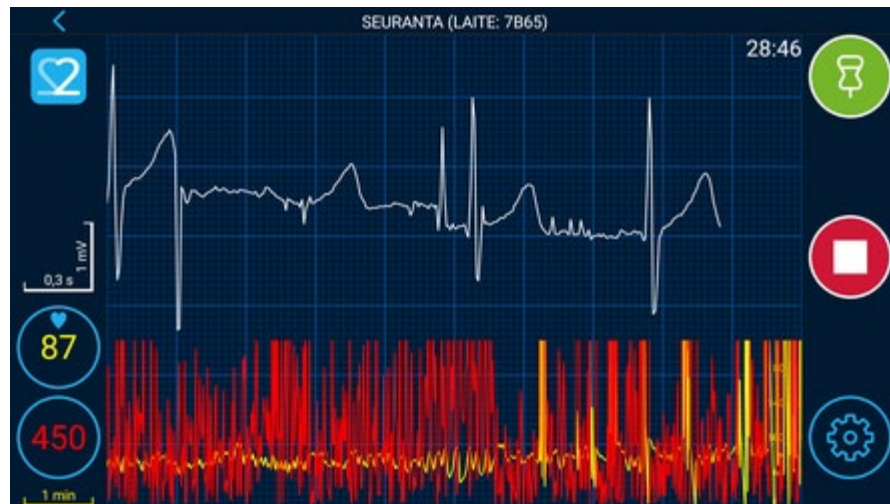


Figure 24: The skin-electrode or the electrode-sensor contact is loose.



Figure 25: The sensor is upside down in the electrode strap.

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 from the mobile application and attaches it to the charging station. It can also appear if, for some reason, the sensor has stopped the measurement, for example if the sensor battery has run out. Choose **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. The message also appears 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 put it to the charging station to continue.

6.8 Mode of operation ON/OFF

During the 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 takes 2h. The duty cycle consists of ECG registration to sensor memory - ON time - and the 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 the 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 10uV accuracy. Poor electrode connection and chest movement cause signal degradation that can hide ECG details.



The ECG measurement frequency is 2000 Hz. The heartbeat display accuracy is one beat per minute, and the HRV display accuracy is one millisecond.

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

6.10 Sensor battery charging

The sensor battery is recommended to be fully charged before starting long term monitoring. Fresh battery capacity enables 24h monitoring. Battery capacity drops after multiple charging sessions, and once 12h maximum recording time is reached, it is recommended to replace the sensor. The recommended recharge time for a fully exhausted battery is 90 minutes. The sensor lifetime is determined by the number of charging cycles until only half battery capacity is attained.

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

First, snap the sensor to the charging connector. The sensor and the connector shape ensure right polarity connection. Before connecting to the supply mains, the orange LED indicates leads off if there is still some power in the battery. Next, connect the charging connector to the supply mains. The sensor LEDs will be lit to indicate charging status. See Figures 24 and 25. Do not use a wet charging connector, charge in wet conditions or too high temperatures.

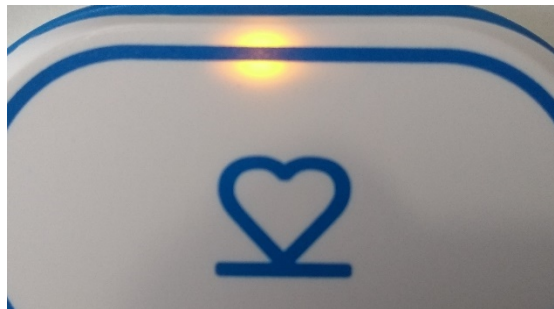


Figure 26: The sensor is charging but not yet fully charged. White LED is lit.

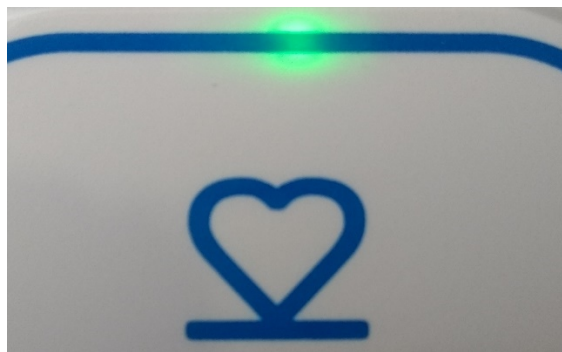


Figure 27: The sensor is fully charged. Green LED is lit.



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 the charging using the BLE wireless connection.

When being charged, the sensor White LED indicates that the sensor is charging. Green LED indicates that the sensor is fully charged. 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 may be removed from the charging connector.

NOTE! The Beat2Phone ECG Charging Connector cannot be used with the older Beat2Phone Sensor.

NOTE! Do not place the charger to a position in which it is 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 damage to the battery.

Do not use a wet charging connector

6.11 Sensor and charging connector visual indicators

The sensor has four LEDs. Green, White, Orange and Blue. They are used to indicate the sensor state. Any other LED behaviour indicates that the device is damaged and shall not be used.

- When 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 te-tee sequence.
- When the sensor is turned on and properly connected to skin via the chest electrodes, and heartbeat is detected, the Green LED is blinking at the pace of the heart rate.
- When the sensor is turned on and properly connected to skin via the chest electrodes, but heartbeat is not detected, the Orange LED is blinking with one second blinks every 300 milliseconds – leads on, no heartbeat.
- When the sensor is turned on but not properly connected to skin via the chest electrodes the Orange LED is blinking once per 3 seconds – 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 is lit until the battery is fully charged. → CAUTION: do not remove from charger before fully charged.
- When the sensor is connected to the powered charging connector and is fully charged, the Green LED is lit.



- When a recording is being transferred from the sensor memory to the mobile device, the Blue LED is blinking rapidly.
- When the sensor is turned on and less than 5% of battery is left, the Orange LED is blinking once per second.
- When a charging circuit malfunction is detected, and the sensor is connected to the charging connector, the Orange LED is blinking rapidly.
- When sensor is on and connected to charging connector without supply mains the Orange LED blinks leads on, no heartbeat detected.

Further visual indicators are available via the Beat2Phone ECG application running on a mobile device with BLE connection to the sensor.

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



Figure 28: The heart symbol indicating 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 memory.

The application main menu provides a dialogue for connecting to an active sensor. A list of active sensors is displayed, and the user must choose the sensor by selecting the matching the MAC Address visible on the sensor label with the MAC address visible on the application selection list. Once the selection is done the application will only connect the that sensor, until the connection is released in the application settings menu by selecting FORGET SENSOR (mac address).

Once the recording is started the sensor does not require the application for storing the recording to the sensor memory.

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

The professional and consumer users can verify the right sensor connection from the Settings, Sensor information where the Id must match the Mac address on the sensor device label.



It is the responsibility of the professional to ensure that the patient is properly identified by a unique profile ID and is given the right 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. Application will reconnect to assigned sensor once mobile device is operational.



7 Maintenance and Service

The user must charge the sensor battery at regular intervals. See Sensor battery charging. The battery is non-replaceable, so the whole sensor must be replaced by new one after the observed operation time of a fully charged device is 12h or less. ECG registration is not possible when the sensor is being charged. Charging is not possible when the sensor is connected to the 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 user can clean the sensor, charging connector with cable, and the electrode strap by a clean cloth dampened by water, hand disinfection fluid or wipes (Kilto Cleanisept, Easydes). Do not clean the sensor, strap or charging connector while in use or charging. The cleaning of the sensor must be performed at **minimum once a day** or every time the registration is stopped, and **always between the change of users**.

The electrode strap can be washed between uses by the patient. The strap can be machine-washed in 30 degrees Celsius, and only with mild detergents. A single electrode strap is intended to be used by a single patient; a new patient shall receive a new electrode strap. The used electrode strap can be disposed of with household waste.

The Beat2Phone ECG application runs on a mobile device which must be operational, so regular charging of the mobile device is required.

All mentioned maintenance and service can be performed by both the professional user and the patient user.



WARNING!

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

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

There are no repairable parts in the Beat2Phone ECG system. Repair service personnel is not required. A broken device shall be disposed of as instructed in this manual.

7.1 Sensor firmware update

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

The preconditions for the sensor firmware update 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 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 under the required pre-conditions. The update takes a couple of minutes, during which the sensor must be kept unconnected from the charging connector.

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

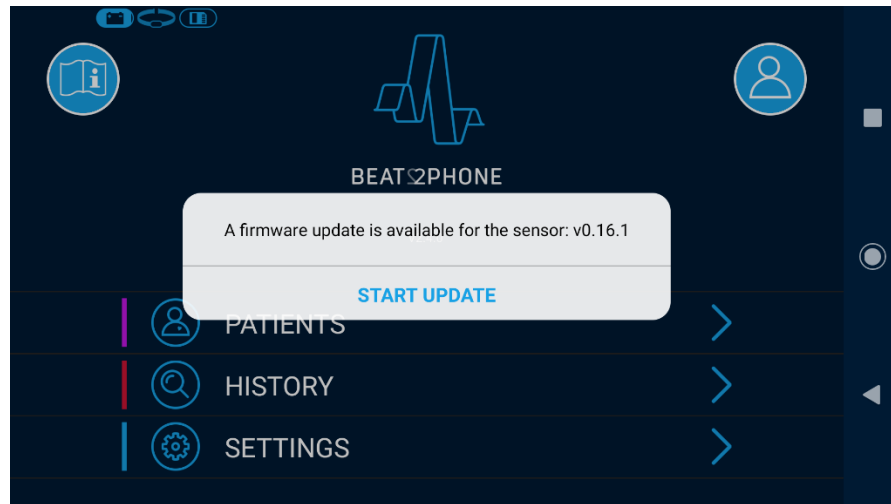


Figure 29: The firmware update prompt

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**. In 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 cannot be charged or attached to a patient during the test, and it should be kept away from other electronic devices.

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

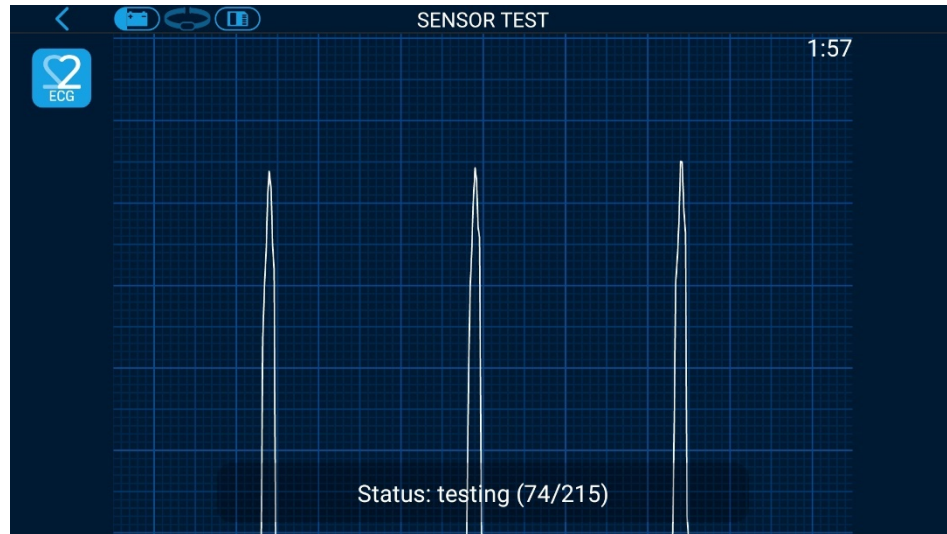


Figure 30: The sensor test view.

7.3 Disposal

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, the charging connector contains electronics, so they shall be left to electronics recycling at the end of their life. The strap can be disposed as part of household waste.

7.4 Beat2Phone ECG application update

Manufacturer provides updates to the Beat2Phone ECG application via two channels: Google Play store and device management software.

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



8 Problem resolution

Sensor does not turn on even with a firm slap: Check the battery by placing the sensor to the charging connector. If the green LED is lit, detach the sensor from the charger and slap 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 that the electrodes are connected properly.

Electrodes start irritating the skin: Nourish the skin that becomes 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 that 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, try placing the sensor in the charging connector for a few seconds and then try again.

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

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

Mobile device battery is empty: Charge the mobile device.

Mobile device is unresponsive: Please see 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.

The green LED is not blinking at the pace of the heartbeat in the sensor when the sensor is attached to chest: Check the battery by placing the sensor to the charging connector 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 help, contact the manufacturer for a replacement.



9 Accessories

The original accessories for the Beat2Phone ECG sensor are

- Beat2Phone ECG electrode strap (GTIN: 6429810109033).
- Beat2Phone ECG charging connector with AC power adapter (GTIN: 6429810109019)

The user shall only replace the accessories with original Beat2Phone accessories with no impact on the Beat2Phone ECG system performance and user safety.

When using the Beat2Phone ECG sensor, the Beat2Phone ECG electrode strap shall never be replaced with any electrodes and associated wiring/leads other than original accessories specified in this manual.



WARNING!

Other 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 also 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	35g
Beat2Phone ECG charging connector	94g



10 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 events 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

11 Regulatory Information


Compliance to

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

11.1 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 centimetres and 1 meter in depth.	21, protected from touch by fingers and objects greater than 12 millimetres. 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 assure that it is used in such an environment.			
Emissions test	Compliance		Electromagnetic environment – guidance
RF emissions below 1GHz CISPR 11, EN 55011	30-230 MHz at 10m	30 dBuV/m	The Beat2Phone ECG must emit electromagnetic energy (BLEv5) in order to perform its intended function. Nearby electronic equipment may be affected.
	230-1000 MHz at 10m	37 dBuV/m	
Harmonic emissions IEC 61000-3-2	Class A		The Beat2Phone ECG is suitable for use in home healthcare environment and those directly connected to the public low-voltage power supply 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 mitigation measures, such as re-orienting or relocating The Beat2Phone ECG or shielding the location. Average 50, Quasi-peak 60 dBuV
Conducted disturbance EN 55011	Class B, 150kHz to 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 assure that it is used in such an environment.			
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 be used no 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: $d = \sqrt{P} * 1.17m$ $d = \sqrt{P} * 1.17m$ 80-800MHz $d = \sqrt{P} * 2.33m$ 800MHz to 2,7GHz 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). Field strengths from 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	6V	
Radiated RF IEC 61000-4-3	80 MHz to 2,7 GHz	10 V/m	
Proximity fields from RF wireless 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, 30A/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, 100kHz 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 location in which the Beat2Phone ECG is used 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. Over the frequency range 150 kHz to 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 frequency of transmitter m		
	150 kHz to 80 MHz outside ISM bands $d = \sqrt{P} * 1.17m$	80 MHz to 800 MHz $d = \sqrt{P} * 1.17m$	800 MHz to 2,7 GHz $d = \sqrt{P} * 2.33m$
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
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>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.</p> <p>NOTE 3 An additional factor of 10/3 has been incorporated into the formulae used in 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 it is inadvertently brought into patient areas.</p> <p>NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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

11.2 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 3.7V/295mAh, rechargeable, non-replaceable
- IP Classification
- Non-continuous operation mode, max duty cycle 22h/2h
- Orientation heart symbol.
- Disposal
- Unique device identifier (UDI) number

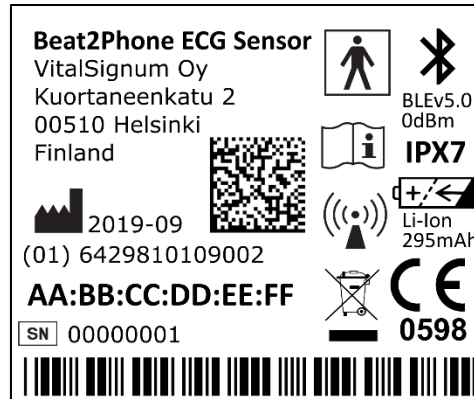


Figure 31: The sensor label

The charging connector markings:

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

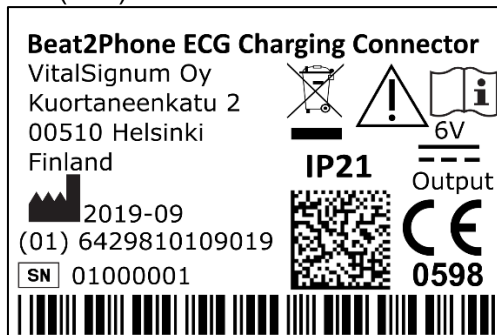


Figure 32: The charging connector label

Electrode strap markings:

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

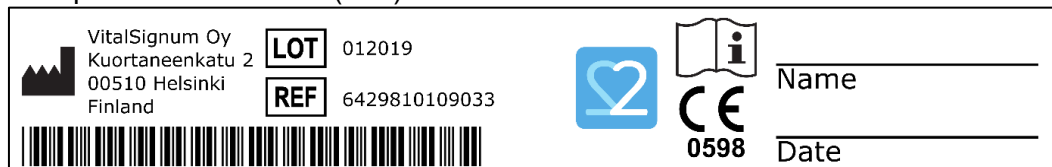


Figure 33: The electrode strap label













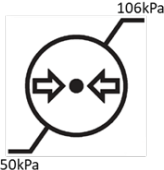
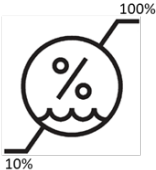
UDI number is generated from the company prefix, sensor and the charging connector serial numbers, batch codes, manufacturing dates, software versions etc. Each device and all its accessories have their own UDI numbers.

UDI number contains 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 sensor and the charging connector serial number and batch number. For the 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 centimetres and 1 meter in depth.
	Manufacturer.	IP21	Protected from touch by fingers and objects greater than 12 millimetres. Protected from vertically dripping water.
	Consult instructions for Use.	SN	Serial number.
 XXXX	CE marking conformity.	REF	Reference number.
	DO NOT THROW IN TRASH. Properly dispose of EEE (Electrical and Electronic Equipment). EU WEEE (European Union Directive for Waste of Electronic and Electrical Equipment)		To identify a type BF applied part complying 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 the temperature limits to which the medical device can be safely exposed.		Indicates a medical device that needs to be protected from moisture.
	Indicates pressure limits to which the medical device can be safely exposed.		Indicates humidity limits to which the medical device can be safely exposed.



	<p>Warning; Magnetic field</p>		<p>Refer to instruction manual.</p>
	<p>Rechargeable battery</p>		<p>Bluetooth</p>
	<p>Attention: Read all warnings and precautions in instructions for use.</p>		



12 Technical Description

Technical specifications	
ECG sampling frequency	2000 Hz, averaged to 500 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	35mm*63mm*14mm
Weight	20 g
Operating time	24 hours
Bluetooth Low Energy - BLEv5	ERP 0dBm, 2,4-2,483GHz, 2MHz wide channel, GFSK

12.1 Environment

The Beat2Phone ECG equipment can be safely used in the home environment of the user and 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 in a professional healthcare facility except the Beat2Phone ECG charging connector, patient environment being 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 in an altitude higher than 2000m.

The sensor has ESD protection components that protect the measurement electronics so that ECG registration continues to work after the ESD. The sensor is not defibrillation proof. The sensor is not tested for compatibility with HF surgical equipment.

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



The battery level can be checked with the Beat2Phone ECG application or by inserting the sensor to the charging connector connected to DC power supply and observing the sensor LEDs.

Environmental conditions for usage, charging, transport and storage			
	Usage	Charging	Transport & storage
Temperature	from -20 to +40 °C	from 0 to +40 °C	from -20 to +60 °C
Humidity	from 10% to 90%	from 20% to 80%	from 10% to 90%
Pressure	from 800 to 1060 hPa	from 800 to 1060 hPa	from 500 to 1060 hPa

NOTE! Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State.

12.2 Transport and storage

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



13 Change History

Date	Revision	Changes	Valid From
7.2.2020	1.0	Approved	7.2.2020
19.3.2020	2.0	3.2 added warning on skin irritation, 5.1 added BLE requirements, 6.2 added consumer user, 6.2.1 clarified JOIN, 6.2.2 added note on annotations for feedback, 6.2.3 added for consumer user, 6.6 added pacemaker impact, 6.11 added other LED behaviour remark, 6.12 added on mobile device connection, 7 modified cleaning agents, added mobile device charging, added 7.4 application update, 8 added mobile device.	19.3.2020
30.3.2020	2.1	Added HR calculation to 6.9.	30.3.2020
3.4.2020	2.2	6.1 fixed allergenic issue in the warning, 6.9 RRI in milliseconds.	6.4.2020
5.6.2020	2.3	6.11 modified orange LED behaviour, ECO-009	19.8.2020