User's Manual

Savvy

Personal CARDiac activity monitoring system - (PCARD)
Osebni sistem za spremljanje srčne aktivnosti - PCARD

CE 1304

Version: UM 1.19.3 Revision date: 31.05.2017

Sales and Service Information

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READ THIS FIRST

1. First read the Section 3.1. about General warnings.
2. Put the Savvy sensor into charging dock.
3. Connect charging dock to recommended charger and to the power supply (220V/110V).
4. The charging process takes approximately 2 hours.
5. Read Section 5 about device setup.
6. Install the mobile application MobECG on your PDA from Google Play Store
7. After the Savvy is charged, put the electrodes according to the instructions in Section 5.2.
8. Activate the mobile ECG service according to the instructions in Section 6.1.
9. Initialize measurements according to the instructions in Section 6.2.
10. Create ECG REPORT as described in Section 6.2.4

Contents

1. Introduction

The medical device is a Personal device for CARDiac activity (PCARD), named and referenced as SAVVY in the remainder of the document. The SAVVY medical device constitutes from a as Savvy sensor, charger, charging dock and mobile application (MobECG). The core of the system is a small and light (21g) Savvy sensor, fixed to the skin using standard self-adhesive electrodes. The Savvy sensor measures the user's differential ECG between two proximal electrodes on the distance of approx. 8,5 cm. The moderate resolution ECG is suitable for long-term personal cardiac activity monitoring during every-day or sport activities, and for clinical use. With a single charge of the built-in battery, the Savvy sensor can run continuously for up to seven days and at least 14 days in stand-by mode. The SAVVY sensor can be recharged using a charging dock station that comes with it. The measurements from the Savvy sensor are transferred through a build-in low power Bluetooth BT4.0 radio to the mobile application on a personal digital assistant (PDA), i.e. smartphone or tablet, which provides storage and graphical presentation of the measurements. User can be a healthy person, person under screening or a patient. The usage of the MD is not limited by age, sex, body weight or height and other personal characteristics.

A Patient can generate ECG REPORT on mobile device in PDF format, which can be printed out or sent by e-mail to the patient Doctor for further diagnose.

2. Terms and conditions

1. Manufacturer and distributor Saving d.o.o., Finžgarjeva 4, Ljubljana, has, with the participation of the Jozef Stefan Institute in Ljubljana, developed the device with the commercial designation Savvy, in accordance with technical data which is an integral part of the user manual of the device.

In accordance with Directive 93/42/EEC on medical devices with a valid amendment, Directive 2007/47/EEC, the developed device is intended to monitor cardiac activity in everyday life, and accordingly with the introductory Directives classified as an active non-invasive medical device labeled IIa.

Medical device Savvy is intended for daily individual use of potential buyer, user, for heart activity monitoring through a single-channel recording of ECG.

Medical device is not intended for a treatment and is not a diagnostic tool in accordance with the rules of the medical profession, as it is stated in the second paragraph of this document (Directive EEC).

In the event that the user feels uncomfortable with regard to cardiac function, he must urgently seek medical assistance, regardless of the conditions shown by the medical device Savvy.

2. Medical device Savvy cannot function independently. It is directly wirelessly connected to a smartphone or tablet, provided it is in the immediate vicinity. Measured conditions of cardiac activity are transmitted to the memory unit with the specific program.

3. Data transfer is carried out with the direct transmission of data from your smartphone or tablet or with the transfer of data to a USB flash drive.

4. The price of a medical device Savvy is determined according to valid price list of the seller.

5. In accordance with warranty statement the seller gives one-year warranty for the medical device Savvy, which is the subject of the sale.

6. An integral part of the contractual relationship is user manual of the medical device Savvy, which together with the general terms and conditions form an integral part of each product that is the subject of sale.

7. With the purchase of the device every customer obtains also user manual, general terms, pin code and the warranty statement.

8. When you first launch mobile application it is required to confirm the statement that the respective buyer is aware of the general terms and conditions of use, otherwise the app cannot be used.

9. In accordance with the provisions of the protection of personal data, with the acceptance of the medical device Savvy the respective buyer allows seller to use and process their personal data and communication about possible novelties, new scientific knowledge, a possible upgrade of the system for the said product and potential vigilance cases. Manufacturer and seller of Saving d.o.o. are in no way obligated to enable access for any system upgrades of said product to customers or users.

10. When buyer pays the invoice, he guarantees that the device is intended solely for his personal or pin code holders use and is not transferable to third parties. The device is according to an explicit request by the seller not transferable and cannot be left to third parties by the buyer.

3. Safety

3.1. General warnings

WARNING! The SAVVY medical device is not intended for individuals with potentially life-threatening arrhythmias or individuals who require inpatient or hospital monitoring.

WARNING! The user must carefully read the instructions for use in the user's manual. The user should be able to operate smart phones or tablets and understand the user's manual. If this is not the case, the device should be used only with the assistance of qualified caregivers who fulfil the above basic requirements.

WARNING! The SAVVY medical device may not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.

WARNING! The SAVVY mobile application may not function properly if not installed on the recommended PDA running recommended mobile operating system, defined in technical specifications.

WARNING! The SAVVY mobile application may stop functioning properly because of intermittent faults in the PDA, wireless connection or Savvy sensor. See troubleshooting section for further instructions.

WARNING! Individuals with known allergies or hypersensitivities to adhesives or hydrogel (electrode material) should not use the SAVVY medical device.

WARNING! To minimize skin irritation, do not place the Savvy sensor over broken or damaged skin.

WARNING! The Savvy sensor is water resistant and it can be worn while showering, but do NOT submerge it in water (for example, in a bath or hot tub, or while swimming).

WARNING! Do not dispose this product as 'unsorted municipal waste'. Prepare it for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE).

WARNING! To protect against electrical shock due to leakage currents, use only SAVVY charging dock with recommended AC/DC power supply defined in technical specifications.

WARNING! When the SAVVY sensor is not in use, it shall be placed in the charging dock and in charging mode in order to ensure that the battery will not be discharged.

WARNING! Use proper, non-aggressive and biocompatible cleaning agents. It is allowed to wipe the device with wet cloth.

WARNING! Measurements obtained by SAVVY equipment/system are intended for use by healthcare professionals only.

WARNING! This equipment/system may cause radio interference or may disrupt the operation or can be disrupted by external nearby equipment.

WARNING! The housing of the Savvy sensor is not UV resistant which can cause depigmentation.

WARNING! As in all ECG measurement procedures that use electrode contact to the skin, body movements, muscle activities, or lose contact between the electrodes and the skin are expected to influence the quality of the measurements.

WARNING! The user must keep the PDA with the SAVVY mobile application in his/her vicinity during measurements. The Savvy sensor must be kept in the Bluetooth range of the PDA (approximately 10 meters, but can vary depending on the PDA and the surrounding). In case of exceeding this distance, the user simply needs to move the equipment within range and the connection will be automatically re-established.

WARNING! Savvy is not recommended for use closer than 4 cm from other devices.

WARNING! Only prescribed charger can be used. Using other chargers can cause unacceptable risks (related to electrical safety and electromagnetic compatibility).

WARNING! Mains plug of battery charger is considered as disconnecting device.

3.2. Precautions

- If you start to feel itching or any kind of discomfort after longer use of the same electrodes, fix the Savvy sensor on another recommended position and/or replace the electrodes.
- The Savvy sensor should be removed prior to external defibrillation or an MRI scan.
- Make sure that the PDA has enough free storage space (at least 2 GB) for saving the measurements.
- Visually check from time to time the quality of the ECG signal.
- Users of the SAVVY mobile application should be aware that the PDA can represent a weak spot in the security chain of the system. By an appropriation of the PDA, a potential attacker could get access to all of the measurements (which can be considered as personal data) stored there. Make sure to secure your PDA, if necessary, to an adequate level using the security features of your PDA.
- See precautions to be taken to prevent adverse events to the Patient and Operator due to electromagnetic disturbances in table in item 9.6.

3.3. Intended operator

The user itself can normally act also as the operator; additionally, a caregiver can act as an operator by assisting the user. In both cases, the operator should fulfil the following issues:

a) Education:
- Not prescribed, see item b),

b) Knowledge:
- Literacy,
- Understanding of all information in the User's manual,
- Recognizing symbols on screen,
- Computer literacy,

c) Skills:
- Placing of two self-adhesive skin electrodes,
- Fixation of the Savvy sensor on the two electrodes,
- Charging the Savvy sensor battery,
- Managing smart phone and/or tablet basic functions
- Managing adequate OS

d) Language understanding
- Slovenian or English
- At least: language used in the User's manual

e) Experience
- Recognition of usual graphical shapes of recorded ECG signal is advisable,
- No other special experience is required.

4. Product description and technical specifications

4.1. Basic equipment

4.1.1. Savvy sensor

The core of the SAVVY system is a small and light **Savvy sensor** (see Figure 1), fixed to the skin of the user by two standard SAE. The Savvy sensor is covered with a waterproof and biocompatible plastic housing. The flexible mechanical construction of the Savvy sensor housing and the flexible connection to the SAE enable adaption of the distance between two SAEs, which prevents an unexpected disconnection of the Savvy sensor during user's movements. The ECG is recorded with a moderate resolution of 125 samples per second.

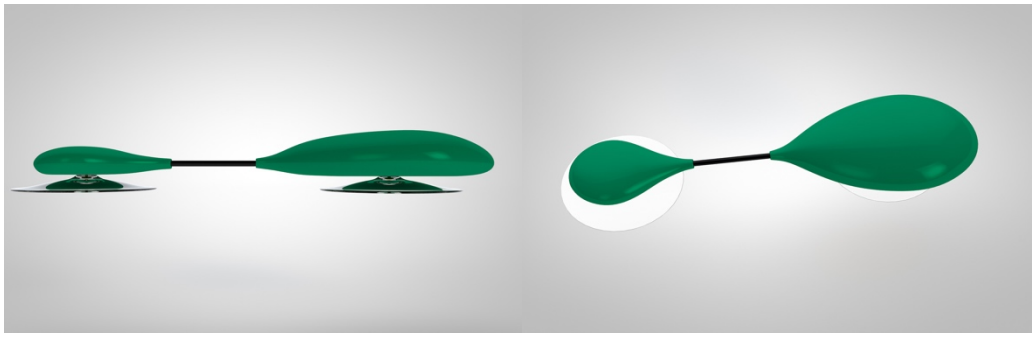


Figure 1: Savvy sensor in biocompatible housing with two self-adhesive electrodes attached.

4.1.2. Charging dock

The **charging dock** (see Figure 2) is essentially a cable extension from charger and the Savvy sensor.

Output VDC: 6,0 V
Max. load: 150 mA

Figure 2: Savvy sensor placed in the charging dock.

4.1.3. Charger

The charger must have the following characteristics:

Model name: VEL05US090-EUJA

Input voltage: 90-264 VAC, Input frequency 47-63Hz

Output VDC: 9,0 V, Max. load: 550 mA, Output power: 6 W, Load regulation: < 5%

Switch type power supply

Operating Temperature range: -0˚C - +60˚C, Storage Temperature: - 40˚C - +85˚C

Efficiency: 78%. Insulation class: II

Electrical safety standard: EN 60950 – 1:2006 +A11:2009+A1:2010-A12:2011

EMC standards tested

- EN61000-3-2, 2006+A2:2009, class A, • EN61000-3-3:2008, class A
- EN61000-4-2 2, • EN61000-4-3 3 A, • EN61000-4-4
- EN61000-4-5, • EN61000-4-6, • EN61000-4-8, • EN55024:2010

Output terminals

- Connector type barrel Jack; 5.5 x 2.1 x 12 mm DC Jack

Dimensions without plug (L×W×H): 55.1 x 24.1 x 35.49 mm

Weight: 80 g

Declaration Reference: Z1A 14 07 57396 271

4.1.4. Mobile application - MobECG

The **MobECG** installed on the PDA main functionalities are:

- Establishing communication between the Savvy sensor and a PDA.

- Visualization of up to 10 seconds of the ongoing measurement.
- Storing the measured data on the PDA storage.
- Interaction with the user.
- Transferring the measurements to a secure storage server or cloud platform.

4.2. Accessories of the medical device

Accessories are sold separately and should be provided by user.

4.2.1. Personal Digital Assistant (PDA)

PDA is an electronic device that runs Android operating system, such as a tablet or a smartphone. A PDA is compatible with the SAVVY software, if it includes:

- Hardware for Bluetooth 4.0 radio communication,
- Android versions 4.3 – 6.0,
- A colour screen,
- At least 2 GB of free storage space,
- Intermittent or permanent Internet connection, for example Wi-Fi radio, Ethernet port, LTE capabilities, etc.; or other means of file transfer between a PDA and a PC,
- A means of point and click user input, such as touchscreen or computer mouse,
- A means of ASCII symbol set input, such as touchscreen or keyboard.

Note that the MobECG application is supported only on Android versions 4.3 - 6.0. The manufacturer gives no guarantees that MobECG will work on later versions of Android until those are thoroughly tested.

Shape, colour and other characteristics of PDA are not prescribed. Off the shelf devices can be used. Two examples are shown in Figure 3.

Figure 3: Two examples of Android based personal digital assistants: smart phone (left) and tablet (right).

4.2.2. Self-Adhesive Electrodes (SAE)

SAE represent the mechanical and electrical interface between the Savvy sensor and skin. They holds the weight of the Savvy sensor and therefore they have to be large enough with diameter or edge dimensions > 50 mm. The SAE must be intended for long-term use which is > 48 hours and must be medically certified, especially regarding the biocompatibility standards in order to prevent skin inflammation or allergies. Below are two examples of recommended SAEs:

1. SKINTACT monitoring ECG electrodes (http://www.skintact.com/48.0.html, see Figure 4 (left)).

Type	T-60
Gel	Aqua-Wet, Silver/Silver Chloride (Ag/Ag Cl)
Backing	Microporous tape
Dimensions	60 mm
Suggested Use	Long term (> 48 hours)

2. NIKOMED monitoring ECG electrodes (www: http://www.nikomedusa.com/stress_lab.cfm), see Figure 4 (right).

Type	No. 2015
Gel	Foam, solid gel, Silver/Silver Chloride (Ag/Ag Cl)
Backing	Clear-Tape, Solid Gel
Dimensions	50 mm
Suggested Use	Long term (> 48 hours)

Figure 4: Two examples of recommended self-adhesive electrodes (SAE).

Equivalent or better electrodes must be purchased from a manufacturer who possesses required evidence for the requested quality. While purchasing electrodes, evidence documents for quality are necessary. Alternative electrodes are matter of a safety testing according to EN 60601-1 and EN 60601-2-47.

4.3. Labels and graphic symbols

The following overview shows the safety symbols and pictograms used in this handbook.

Refer to instruction manual / booklet.

Consult the instructions of the device for information on how to properly use it.

Type BF medical equipment

"Keep dry".

Both temperature limits should be noted next to the upper and lower horizontal lines.

Both humidity limits should be noted next to the upper and lower horizontal lines.

Symbol accompanied by the name and address of the manufacturer.

Waste separation for batteries.

Waste separation for electronics.

Medical equipment with intended radiation (communication purposes)

CE 1304 CE marking with number of Notified body; SIQ, number 1304

Device labelling

Figure 5: Savvy labeling

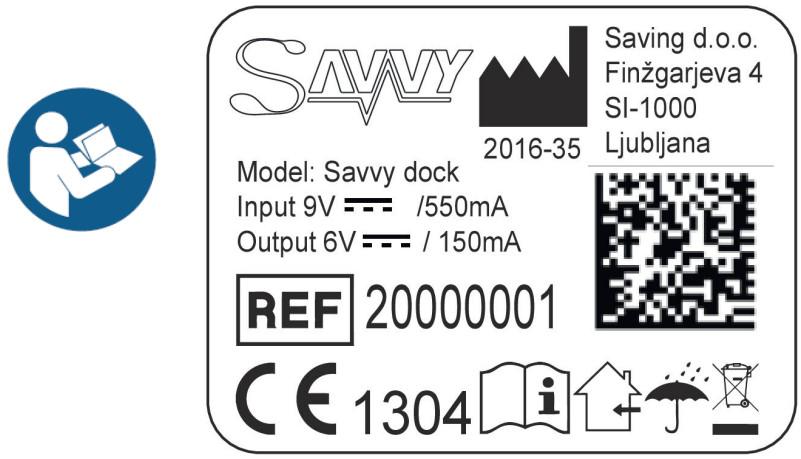


Figure 6: Charging dock labeling

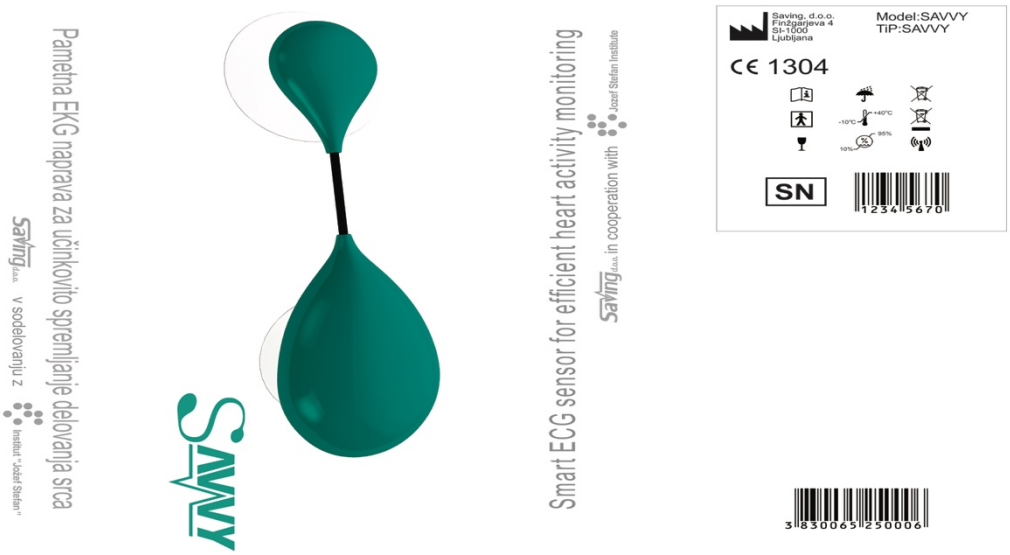


Figure 7: Labeling of packaging

4.4. Environmental and transport conditions

Environmental and transport conditions for the BG and the charging dock are given in the table below:

Environmental conditions	NORMAL OPERATION	TRANSPORTATION AND STORAGE
Environmental temperature:	**-10 ^{0}C to +40 ^{0}C**	**-20 ^{0}C to +70 ^{0}C**
Relative humidity:	**10 % to 95 % (limited condensation)**	**10 % to 95 % (limited condensation)**
Atmospheric pressure:	**700 – 1060 hPa (mB)**	**700 – 1060 hPa (mB)**

All remaining HW components of SAVVY (SAE, PDA) should obey the conditions prescribed by manufacturers.

5. Device setup

5.1. Installation of the mobile application

Install the mobile application MobECG on your PDA from Google Play Store and upon installation confirm all requested permissions. If the user is not experienced with mobile applications, should seek assistance from an operator. After successful installation, the MobECG application icon should appear on the PDA screen. Check regulary for updated version on Google play Store.

Note: in case any function is not understood please contact supplier or producer.

5.2. Positioning of the electrodes

Before initiating the measurements, fix the Savvy sensor to the skin using standard self-adhesive electrodes. First, while the electrodes still have a protective foil, attach them on the Savvy sensor. Then, remove the protective foil from the electrodes and fix the Savvy sensor on cleansed skin. The Savvy sensor should be placed on an appropriate position on the chest where it does not cause discomfort for the user and where the ECG waves are clearly visible. Figure 8 shows several recommended positions of the electrodes, which should provide quality ECG measurements. Additionally, the operator can suggest placing the electrodes on a specific position on the body according to a specific user treatment.

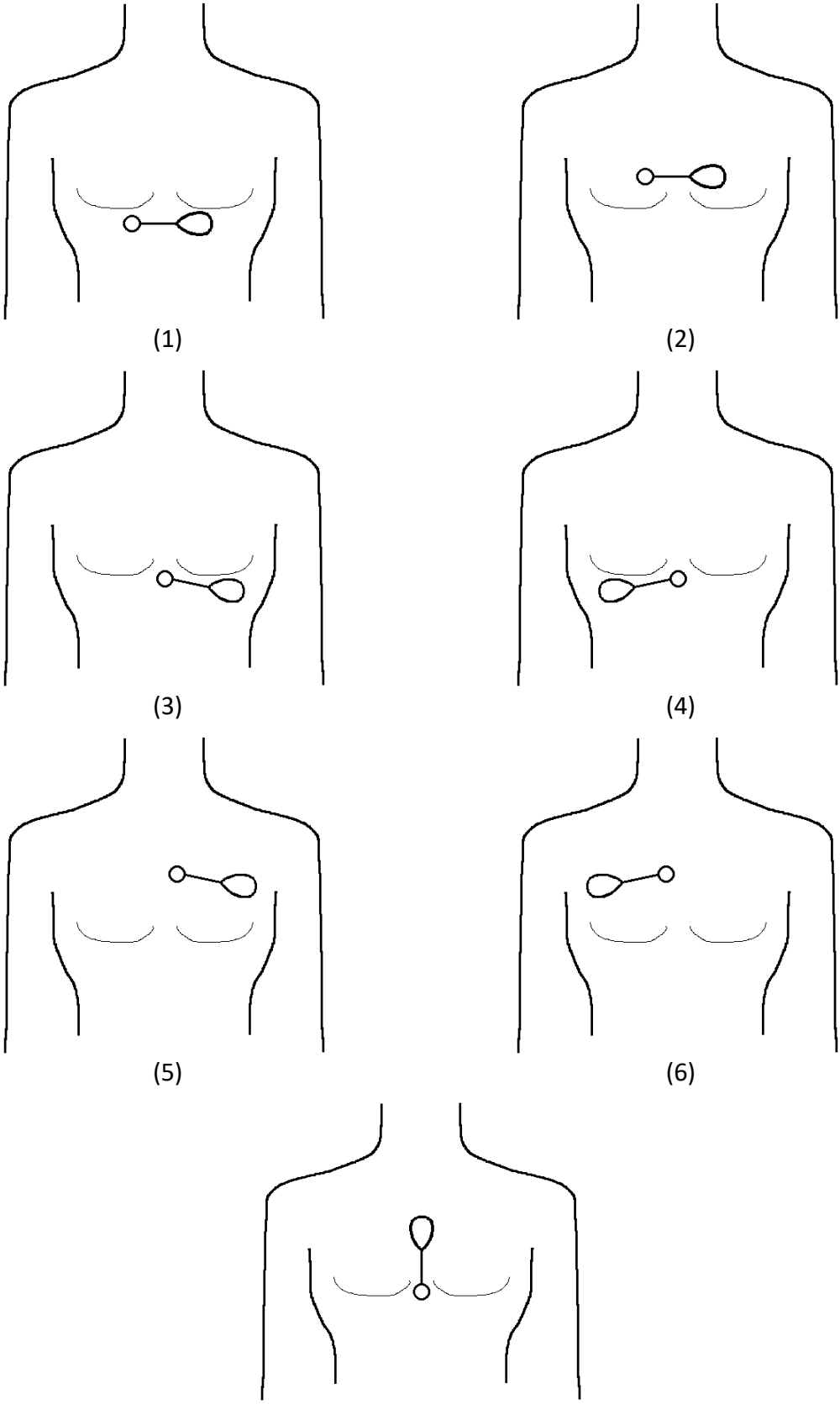


Figure 8: Recommended electrode positions on the body.

6. Device operation

6.1. Initialization

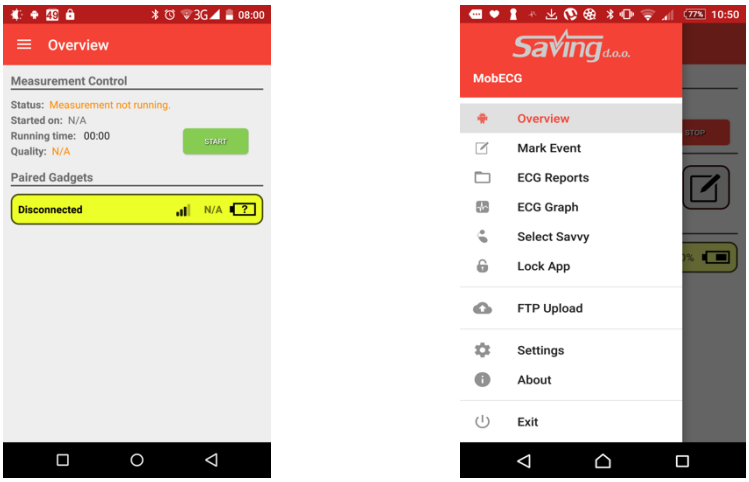
In the following, we show a symbolic design of the MobECG application, because the actual implementation is Android OS dependant.

6.1.1. Activating the MobECG service

Upon installation, the MobECG service is activated with tap on the application icon. When activated, the MobECG application icon will appear on the top task bar of the PDA. For transfer of the measurements from the Savvy sensor to the PDA, MobECG requires that the Bluetooth on the PDA is activated. If not, the application displays a warning that it wants to turn on Bluetooth. Make sure you allow for the Bluetooth to be turned on.

At start-up, the overview screen of MobECG is displayed (Figure 9a). This is considered as the main screen where you can control the measurements (start and stop), and where details about the measurement and paired Savvy sensors are displayed. All other options of the application are available by clicking on the menu at the top left corner (Figure 9b), will appear.

NOTE: The main application screen is the only one that cannot be rotated.



(a) (b)

Figure 9: MobECG symbolic design of (a) the main overview screen and (b) the application menu.

6.1.2. Selection of Savvy sensor

The first step after starting MobECG is to connect the Savvy sensor placed on the body with the application. Click on “Select Savvy” in the application menu. The application will open a screen where it scans for wireless devices in the vicinity of the PDA (Figure 10). The scanning is automatically refreshed with the devices with the highest signal strength floating at the top of the list. You can pause the sorting of list items by clicking on the button named “STOP SORTING”. To select your Savvy sensor, identify its name and MAC address on the list and click on it. A Savvy sensor authorization windows pops up (Figure 10b). Enter the 4-digit PIN provided at the end of this User’s manual and click “OK”. After successful authorization, the Savvy sensor is highlighted yellow (Figure 10c).

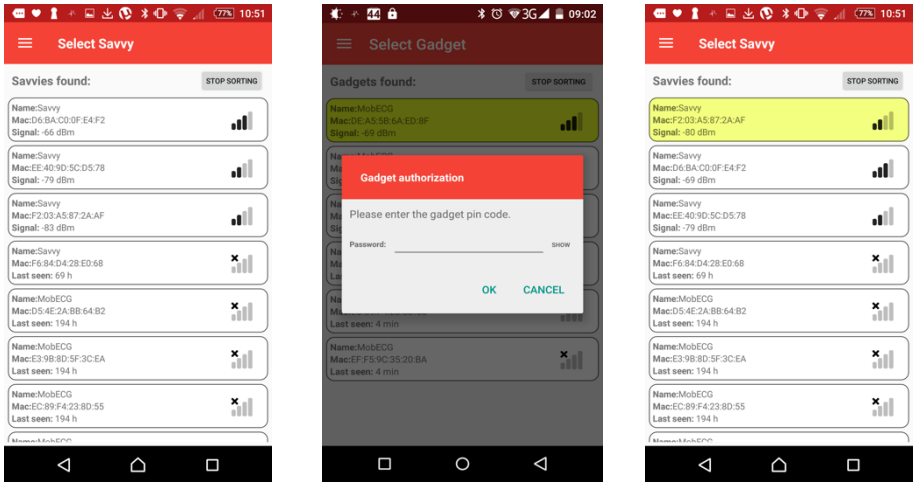
NOTE: The PIN is requested only the first time when the Savvy sensor is paired with the PDA.

6.2. Measurement/Acquisition

6.2.1. Initiation of measurements

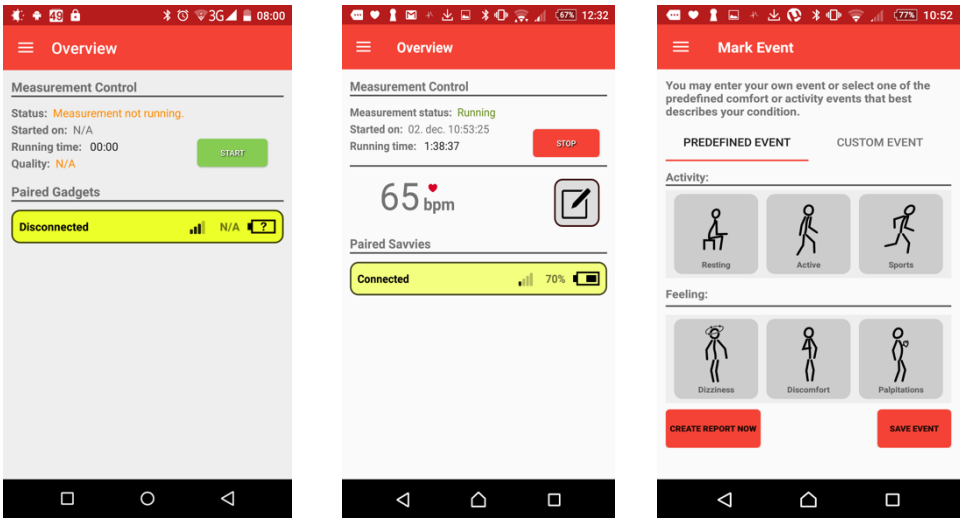
After the Savvy sensor is selected, go back to the main screen of the application by clicking “Back” on the PDA or selecting “Overview” from the application menu. The Savvy sensor is listed in the Select Savvy section of the main screen, displaying its status, signal strength and battery level (Figure 11a). Before a measurement is initiated, the status of the Savvy sensor is disconnected.

To start the measurement, click on the “Start” button. After a short time, the sensor connects to the PDA. The status of the Savvy sensor changes to “Connected”. When a measurement is in progress, the MobECG application icon in the task bar changes in an icon shaped like one ECG beat. Two icons appers on “action bar” – seen on all menus: an icon of BPM and an icon of Mark event, by pressing on bpm icon will open Ecg graph, pressing on Mark event will open Mark event menu.



(a) (b) (c)

Figure 10: Symbolic design of the Savvy sensor selection.



(a) (b) (c)

Figure 11: Symbolic design of the main screen (a) after selection of the Savvy (b) during measurement. (c) Current condition options.

6.2.2. During measurement

The main screen during measurement is shown in Figure 11b. During measurement, the main information about the measurement is displayed in the *Measurement Control* section of the main screen: status (running/not running), start of the measurement (date and time), running time, and quality. Below the Measurement Control, the hearth activity is animated with a small symbolic beating heart and numerical value of BPM (Beats per Minute).

Heart rate (HR) is calculated from the last 10 seconds of measurement (this is the default value. Under "Settings" menu interval can be changed from 5 to 30 seconds. In case less than 5 beats are detected in the HR value in this interval, "NA" will be shown instead of the HR value. The HR value is furthermore limited to between 20 and 250. In case calculated value is outside those limits, "NA" will be shown on the user interface.

NOTE: The BPM detector can report incorrect values in the presence of excessive noise. Please, consider the shown BPM value as informative.

6.2.3. Mark Event

This option is accessible by selecting "Mark Event" from the application menu. A measurement must be started to use this feature. The application offers the option to mark events or specific moments during a measurement, e.g., when some activity is initiated, or when some inconvenience is felt. The button for marking events is also available from the *Measurement Control* on the main screen, next to the heart icon, after the measurement has been started. To mark an event, select either a *predefined event* or a *custom event*. For predefined events, click on one of the displayed icons and then on the save button (Figure 11c). For a custom event, either enter the text into the text field or leave it empty and then click on the save button. Saving the event will change the screen back to the "Overview".

ECG REPORT can be generated either from the Mark Event menu or from the "ECG Reports" menu. The option in the "Mark Event" menu is purely for convenience and produces identical reports. Note that when triggered from the "Mark Event" menu, or from the ongoing measurement in the "ECG Reports" menu, application MobECG will first wait until the desired interval of measurement is recorded and only then start report generation.

Before generating the report, MobECG will present the "Additional report information" dialog, where additional information for the physicians analysing the report, might be presented. Note that information typed in the fields is optional, the information entered will be used only on the report that is being generated, and will be only cached by the MobECG for the use in the same dialog the next time a report is requested. This dialog also gives the option to change the default interval length of ECG plotted on the report. Note that the report will include the ECG from $^1/_2$ interval before the event to $^1/_2$ of interval after the event is marked.

After confirming the dialog, the report will be generated in the background. When it is complete, a notification will appear, with options for viewing or sharing the report. At this point the report will also be stored on the PDA storage to be viewed or shared later. The default storage location is in Documents/MobEcg/Reports/.

NOTE: All feeling icons may indicate potential hazard states. **The SAVVY system does not prevent the consequences of the medical emergencies associated with the symbols.**

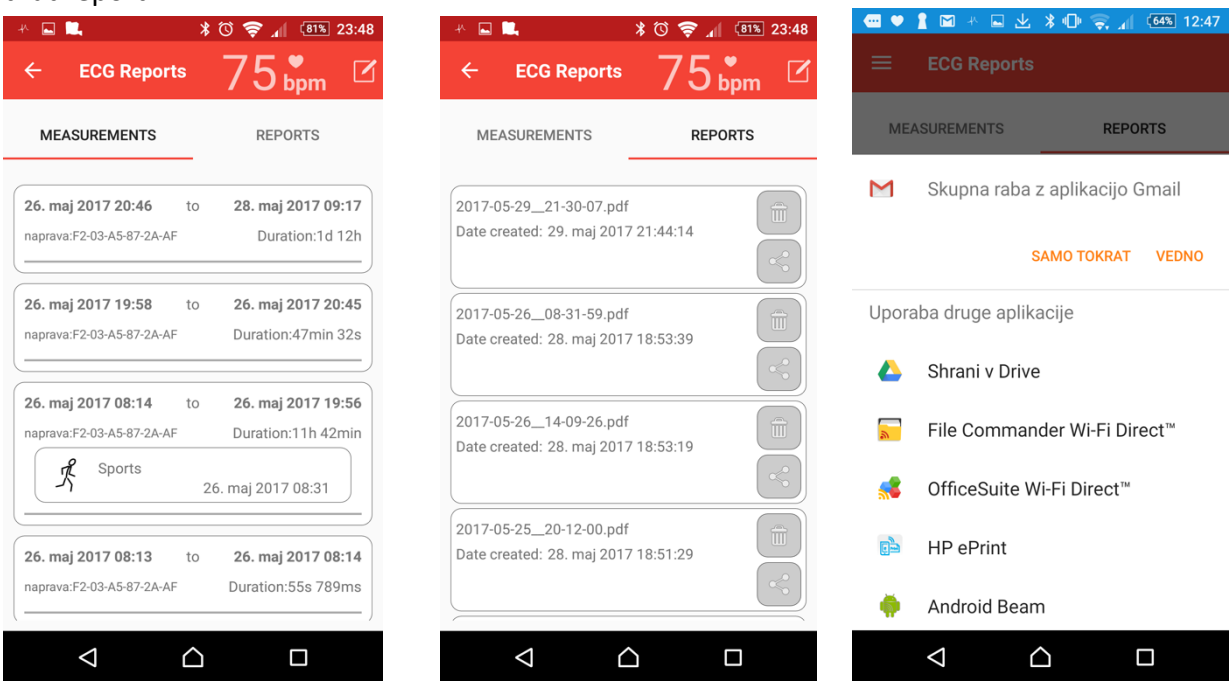
6.2.4. ECG REPORT

This option offers a list of “Measurements” (Figure 12a) and a list of “Reports” (Figure 13b), as two tabs of a tabbed interface.

The tab “Measurements” comprises a list of past and ongoing measurements, and the stored events within those measurements. Measurements are displayed with their start time, end time, and duration. If any events were marked during a given measurement, those events are displayed within the measurement's area with an icon and event text. The icon for event is the is the same that was used when marked the event, or an icon of a heart, if the event was marked as custom text event.

Selecting an existing event gives the option of generating a short ECG report around that event. Selecting a measurement displays a slider for picking a time from the measurement time interval and generating a report around that time.

Sliding the tab “Measurements” (Figure: 12a) to the left brigs the tab “Reports” (Figure: 12b) into the view. This tab comprises a list of reports generated so far. Selecting a given report will open that report in the default PDF viewer, while selecting icon will bring forward all the available sharing options (Figure 12c). Long pressing on a report will show the option of deleting that report.



a.) b.) c.)

Figure 14: ECG REPORTS: (a) Measurements (b) Reports (c) PDA distribution options

The ECG report is a PDF file, that contains an interval of ECG measurement around a picked time or around a marked event. Note that no diagnostic information is presented on the report, only the pure and unmodified ECG measurement, together with the user-provided additional information.

The report comprises the head and the ECG measurement on multiple pages on the size of standard A4 paper. Head is filled with information about the user, the measurement, and the marked event. ECG measurement if plotted in rows of 7,5 seconds each, on top of a blue graph paper. The dimensions of the plotted ECG, which are also marked on the report, are 10 mm per

mV in amplitude and 25 mm per second in time axis (Fill last page of report if timespan ends in the middle of page).

6.2.5. ECG graph

The application provides also an option to visualize the current ECG measurement and BPM. By selecting “ECG Graph” from the application menu or click on the heart icon on the main screen. To return to the main screen, click “Back” on the PDA or select “Overview” from the application menu. Figure 12 shows an example of a good quality ECG signal. Interactive graph zooming option enable zoom in or out x-axis (from 1 to 10 seconds) or y-axis (mV) by fingers.

Note: in case zooming-out area where no grapf exist will appear as no ecg graph exist. Zoom-in areas and graph should be seen on screen.

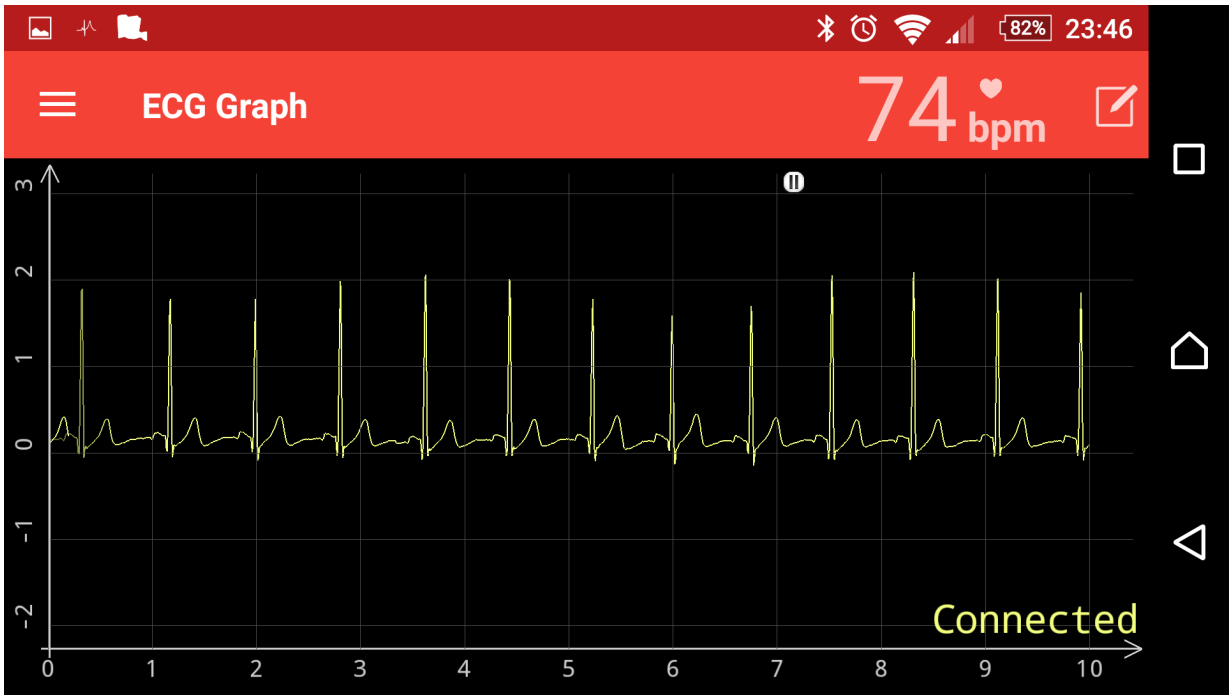
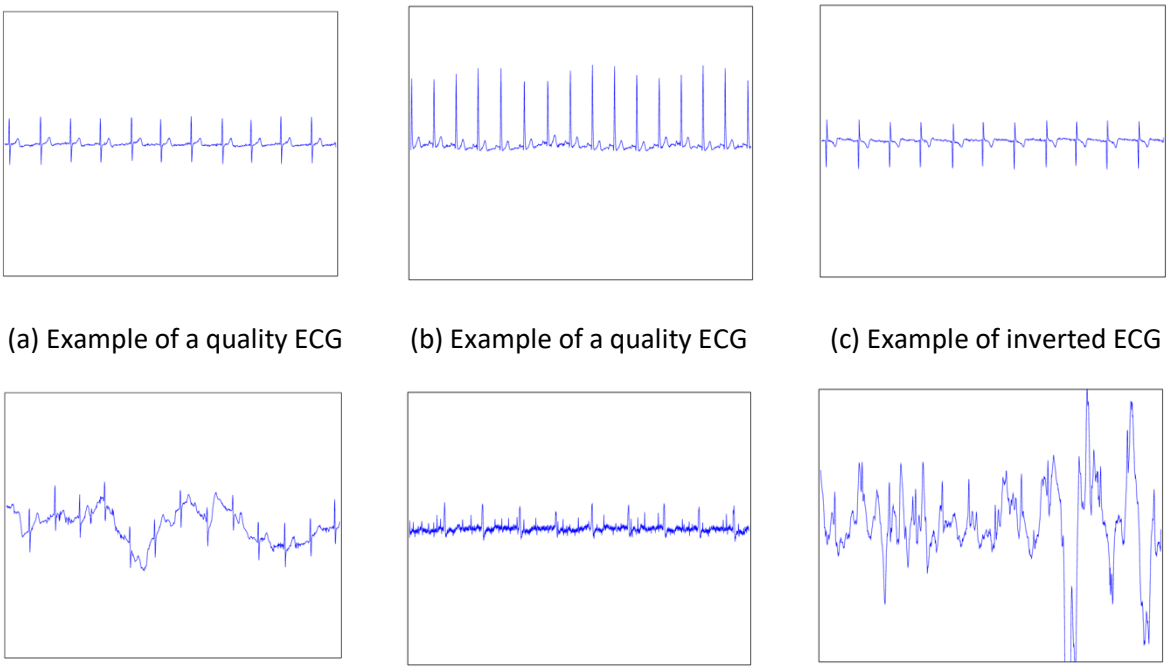


Figure 15: Full screen visualization of the ECG measurement.

Examples, but not limited to, of different signal forms that can be encountered during measurements are shown and described in Figure 13. All forms, except the last one (Figure 16f), are considered as ECG. Two examples of quality ECG signal are shown in Figure 16a and Figure 16b. An inverted ECG can be measured if the placement of the electrodes is reversed (Figure 16c). While this should not be of any concern, for usual ECG form, reverse the placement of the electrodes. When moving the arms or while walking, the ECG base line may wander, which should also not be of any concern (Figure 16d). Example of a noisy ECG signal is on Figure 16e; heartbeat timings may still be obtained from such a signal. Figure 16f shows an example of noise, such as might be caused by a disconnected electrode; there is no ECG signal left in it. Therefore, during the measurement, make sure to check the quality of the ECG signal from time to time. If the ECG signal is not adequate, fix the electrodes on another recommended position from Figure 8, and insure that the ECG signal is good. Usually within a few minutes, a good galvanic contact with the subcutaneous tissue is established and the ECG signal becomes stable.

NOTE: A measurement must be started to use this feature.



(a) Example of a quality ECG (b) Example of a quality ECG (c) Example of inverted ECG

(d) ECG while walking (e) Noisy ECG (f) Noise

Figure 16: Examples of different signals during measurement.

6.2.6. Pause ECG graph during measurement

To temporary pause the visualisation of ECG and see a particular segment currently being detected, just tap on the graph. A pause icon will be displayed at the top of the graphic. To un-pause, tap on the graph once more.

NOTE: This option pauses just the visualization of the measurement. However, the measurement is still being recorded on the PDA. After unpausing, the application will continue displaying the current measurement.

6.2.7. Application screen lock

In order to prevent unwanted actions during measurement, there is an option to lock the screen of the application. When the application screen is locked, users cannot perform any actions, like start/stop measurement or preform setup. However, the user can still browse through the application menu.

To lock the screen of the application, select “Lock app” from the application menu. If the lock option is activated for the first time, users are asked to enter and repeat a password for lock-unlock. To unlock the application screen, select “Unlock app” from the application menu. On the next lock-unlock action, the password will be required only for unlock (lock will be performed without password request).

6.2.8. End measurements

To end the measurement, click on the “Stop” button on the main screen. The status of the sensor will change to “Disconnected”. If you plan to use the same sensor for further measurements, it is preferable to keep it in the list of paired Savvy sensors on the main screen. If you want to remove the Savvy from the list of paired sensors on the main screen, first click

"Select Savvy" from the application menu. Then deselect the yellow highlighted Savvy with one click. The Savvy will be un-highlighted. At the end, click "Back" on your PDA or select "Overview" from the application menu to return to the main screen.

6.3. Application settings

The application settings are available by selecting "Settings" from the application menu. The settings include:

- Visual settings:
  - Oscilloscope gap [s]: Define how much of the ECG line will overlap (default: -0.5 s). If the gap is negative, new data will overlap some of the old data. Note that if the fade interval is longer than the overlap interval, the line might not look like it overlaps at all.
  - Oscilloscope fade interval [s]: Define the length of the ECG line that will be faded (default: 1.0 s). Fading will affect the oldest data shown.
  - Allow automatic Bluetooth resetting: This settings allows application to reset the Bluetooth adaptor without asking for permission. The application will only reset the Bluetooth adaptor if it becomes unresponsive.
- Security settings:
  - Lock the selection of Bluetooth SAVVY: Checking this option will lock current selection of Bluetooth devices and thus guard against accidental changes. (default: Not selected).
  - Set lock screen password: Set or change lock screen password.

Please consult with an operator for further details about the application settings.

6.4. File transfer

The ECG measurements are stored in files in the subfolder *MobECG* in the *Documents* folder of the Android operating system.

6.4.1. Transfer of the measurements on a storage server

If an Internet connection is available, there is an option to transfer the measurement files on a secure storage server. For FTP transfer, select "FTP Upload" from the application menu. A screen, as in Figure 17, appears that requires entering FTP server address, username and password. The application provides options to delete the files on the PDA after upload (tick the checkbox to do so). It is recommended to use this option to insure space availability for further measurements. After entering the required data, click the "Upload" button to begin the transfer.

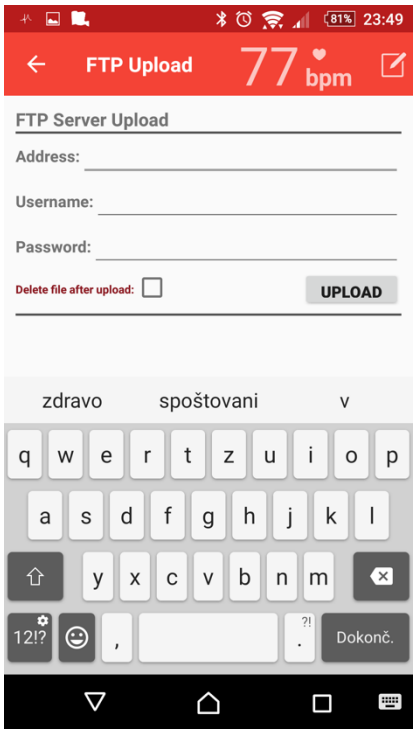


Figure 17: Symbolic design of the FTP Upload screen.

6.4.2. Manual transfer

More advance users of PDAs can also manually transfer the measured data on a personal computer by using means of file transfer from a PDA to other device. It is recommended to delete the measurement files from the PDA after transfer in order to insure space availability for further measurements.

6.5. Application update

To update the application, check regularly for updates on Google Play Store. The application will guide you through the update process.

6.6. Application info

Information about the application, like version and brief description, are available by selecting “About” from the application menu.

Information about the developers are available by selecting “Credits” from the application menu.

6.7. Turning off the device

6.7.1. Continuing measurement in the background

To perform other tasks on the PDA, MobECG can be put in background by clicking on the “back” button of the PDA. If a measurement was started it will continue. Only clicking on Stop button in the “Overview”, Exiting the MobECG via “Exit” option, a MobECG crash, disabling Bluetooth, or a PDA shutdown will stop the measurement.

MobEcg will also continue started measurement if the PDA screen is turned off. Turning the screen off as it will decrease the PDA consumption and enable it to work for longer without recharging.

6.7.2. Exiting from the MobECG application

To exit from MobECG, select “Exit” from the application menu.

NOTE: The application does not turn of the Bluetooth on the PDA on exit. The application stops all measurements on exit.

6.7.3. Removal of the electrodes

After a phase of measurements is finished, you can remove the electrodes together with the Savvy sensor from the body. You can keep the electrodes attached to the Savvy sensor for later measurements, if the gel has started to degrade, detach the electrodes and attach new ones.

NOTE: When the Savvy sensor is not in use, it is necessary to be placed in the charging dock and in charging mode in order to ensure that the battery will not be discharged.

7. Program for measurement visualization – VisECG

Visualization program available at http://www.savvy.si/ can be used to review the measurements after they are finished. The program is originally intended for healthcare professionals. However, there is an option to generate a summary of the measurements. This summary is meant to be generated also by the user itself and further passed on to a medical expert. Other additional analyses are intended for medical experts only. Note that the program is not intended for diagnostics purposes.

7.1. Summary of measured data

To generate the summary of measured data, the measurements need to be first transferred on a local PC (see Section 6.4 File transfer). Then, after starting up the program, select “Open folder overview” from the *File* menu and point to the location of the measurement files in the *Directories* window. When a directory selection is made, the *Files* window will display all the measurement files within the directory. Next, click “OK” and wait for the program to generate a graphical presentation of the ECG measurements (Figure 15). Note that when opening a directory for the first time, this operation might take long time to complete, depending on the number and size of files.

When interacting with the graphical presentation of the directory, the mouse pointer can be positioned over an ECG measurement, the values for average heart rate in BPM (Beats per Minute), number of beats, and percentage of useful ECG signal (beats coverage percentage) for that interval are displayed in a tooltip.

To generate the summary, click on the button “Generate summary”. A PDF summary document of all long-term measurements (longer than 15 minutes) will be generated in the same folder as the measurements. A sample summary document is shown in Figure 16. For each ECG measurement in the summary, the mean heart rate (averaged on 60 second intervals) is plotted with line and all instantaneous heart rates (for all the detected heart beats) are displayed with dots. A minute interval of ECG signal around a marked event is also displayed in the summary. The events which were marked during the measurement on MobECG, e.g., when some activity was initiated, or when some inconvenience has been felt (see Section 6.2.3 Mark Event), are

also marked on the graphs. The summary is intended to be used by medical doctors for interpreting long-term measurement, which can last from a few days to a month.

NOTE: The design of the summary is subject to further changes. Check regularly for VisECG update.

7.2. Additional analysis

A medical expert can further analyse the recorded ECG in more details by selecting any recorded interval. The selected interval is then displayed for further processing and assessment of the ECG waves. Based on the expert analysis, a supplement summary can be generated with eventual remarks and proposals for further treatment procedures.

For more information, see the detailed instructions for the program available by selecting “User manual” from the *Help* menu.

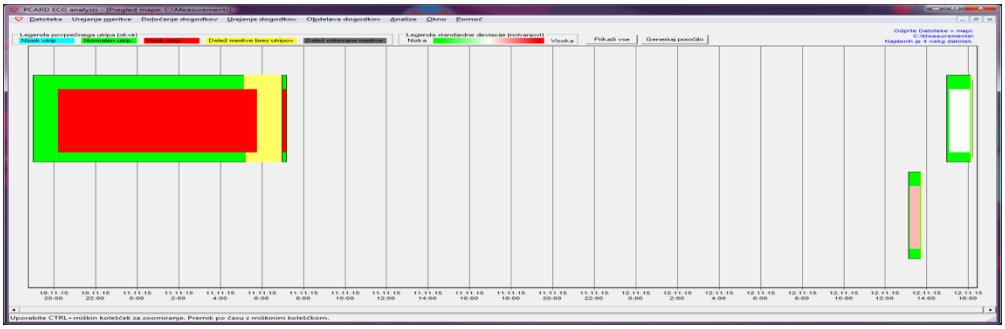


Figure 18: VisECG analysis – symbolic design of the measurement overview screen.

Pregled meritve VisECG	10.5.2016	Avtor poroila:	Ime Priimek
Uporabnik (starost teža)	Ime Priimek	44 let	75 kg
Zaetek in konec merjenja, ime	7.5.2016 6:27:03	9.5.2016 7:03:57	
as in število utripov, povpreni	1 dni 20 ur 3 minut 24 sekund	187860	71.07 BPM
MAX, MIN utrip, deviacija	200 max	20 min	17.08 %
Aktivnosti	Aktivnost		
Poutje	Pocutje		
Opombe	Opombe		

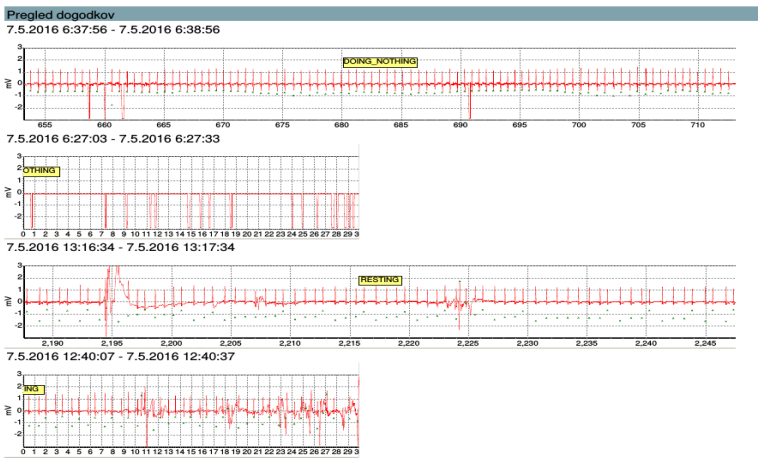


Figure 19: Summary example.

8. Indications and contraindications

8.1. Indications

The SAVVY system is intended to be used for the puposes of heart rhythm monitoring with bluetooth devices. It is capable of detection of abnormally rapid and slow heart rate, and display such in a graphical manner. In addition, recorded EKG signal is of sufficient quality, that, when reviewed on a computer by competent medical personnel, it enables more specific identification of potential arrhythmia.

SAVVY system monitors and displays the ECG instantly on the patient PDA during the measurement (if display on smart phone or tablet is enabled) and after the measurement, the ECG data can be reviewed and analysed by healthcare professionals.

8.2. Contraindications

The SAVVY system is not intended for use by individuals with potentially life-threatening arrhythmias or by individuals who require inpatient or hospital monitoring. Individuals with known allergies or hypersensitivities to adhesives or hydrogel (electrode material) should not use the SAVVY system.

9. Maintenance

All maintenance work must be carried out by a qualified technician authorised by the manufacturer. Only maintenance procedures given in this manual, for example battery charging, visual inspection, cleaning etc., may be carried out by the user.

9.1. Charging the Savvy sensor battery

The Savvy sensor is an internally battery powered equipment.

For charging the Savvy sensor battery, place the Savvy sensor in the charging dock and plug the charger. For full capacity, charge the Savvy sensor battery at least two hours. The light indicator (orange) on the charging dock will turn off when the Savvy sensor battery is fully charged.

NOTE: When the Savvy sensor is not in use, it is necessary to be placed in the charging dock and in charging mode in order to ensure that the battery will not be discharged. Discharged battery void Guarantee.

Figure 20: Savvy sensor placed in the charging dock connected to a Charger, while charging.

9.2. Visual inspection

Visually inspect the device and cable assemblies for the following:

- Savvy sensor casing not broken or cracked
- Charging dock casing not broken or cracked
- Charger casing not broken or cracked
- Charger cable sheathing and connectors undamaged. No kinks in the cable.

Defective units or damaged cables void guarantee and must be replaced immediately prior further use.

9.3. Cleaning instructions

The Savvy sensor, Charging dock, Charger can be cleaned and disinfected only when they are disconnected from power supply and only when fully dry, they can be reconnected to power supply.

The Savvy sensor can be cleaned and disinfected with medical ethyl alcohol or special cleaning agent for medical devices, to ensure compliance with the following requirements:

- Biocompatibility of the housing,
- Aging of the polypropylene,
- Compatibility with adhesive endurance.

The damage caused when using the wrong cleaning agents void product/producer warranty.

It is allowed to wipe the device with wet cloth. While the Savvy sensor is water resistant, do not immerse it in water.

9.4. MobECG application - User maintenance

User must keep the Android environment as specified in the requirements:

- Adequate storage space is maintained on the PDA and personal computer;
- Internet connection on the PDA and the PC is established as required – when transferring measurements to PC or CS;
- Bluetooth radio is enabled on the PDA.
- The PDA is turned on while recording, while the screen can be off.

- Battery on the PDA should be kept charged enough to support long measurements or the PDA should be placed on a charger.

9.5. Product life and storage

Lifetime of the MD is two years. Environmental conditions for storage are given in Section 3.4. Environmental and transport conditions.

9.6. EMC information

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device use RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compiles	

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±2 kV contact (!) ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. (!) Savvy could lost connection; without intervention reconnection is successful within 60s. On charging dock LED could blink during ESD. After discharge small peaks could appear on graph. In case of malfunction due to electrostatic discharge, reset the apparatus by putting it to charging dock.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines (!) ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment. Temporary loss of charging function may occur which is self-recoverable.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle 40% U_T (60 % dip in U_T) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[V1] 3 V [E1] 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=[\frac{3,5}{V_1}]\sqrt{P}$ $d=[\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is 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). Recommended separation distance is 0,04m (4cm). LED blinking on charging dock during Proximity field immunity test. At 710 MHz changes on graph appeared, without influence on time-base of recording. Field strength from fixed RF transmitters as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

10. Troubleshooting

Issue	Possible cause	Possible solution
The sensor does not connect.	PDA Bluetooth is not turned on. The sensor battery is empty. The sensor is not in the range of the PDA Bluetooth.	Turn on the Bluetooth on the PDA. Charge the sensor battery. Move in vicinity of the PDA.
The ECG signal does not look good.	The contact of the electrodes with the skin has loosen.	Replace the electrodes and/or place the electrodes on another position.
The electrodes do not stick to the skin very good.	The gel of the electrodes has degraded or the skin is not clean.	Clean the skin and/or change the electrodes.
The ECG graph has disappeared.	The sensor is not in the PDA Bluetooth range. Wireless connection problems on the PDA or the BG.	Move the Savvy sensor into the vicinity of the PDA. If the problem persists: turn the Bluetooth radio OFF and then back ON. If the problem persists: exit MobECG and start it again. If the problem persists: Put the Savvy sensor on the plugged-in charging dock for a second (the active charging LED indicator should blink). If the problem persists: ask for a technical assistance.

11. Warranty information

For warranty information, please refer to the warranty declaration.

12. Manufacturer data

Name and address	Saving d.o.o. Finžgarjeva ulica 4

	1000 Ljubljana
Official Logo	Saving d.o.o.
Statutory representatives	Boris Simončič, PhD, MD Tina Samardžija
Quality management system (QMS) certificate	ISO 13485:2003

PIN: | | | | |

MAC ADDRESS: | : : : : : |