ViewECG

Medical device system
Patient's User Manual

MD

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Revision 8 | 17 July 2021

READ THIS FIRST

1. First read the Section 6 Safety Measures.
2. Read Section 7 on Terms of use.
3. Read Section 3 on how to install and use the IOS application.
4. Read Section 4 on how to use web application.
5. Read Section 5 on maintenance.

Innovation Technologies is the developer of the ViewECG online heart monitoring platform as a medical device system.

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1. Product Description

ViewECG is a medical device for real-time long-term single-channel ECG monitoring. The device is distributed as a Software-as-a-Service for online ECG monitoring. As such, the software is licensed through subscription, and the data is centrally hosted.

Users monitor their ECG with the use of light, wearable sensors and their smartphones. The software continuously stores and transmits patient data to be reviewed by a doctor online and in real-time, regardless of the patient's location. The software automatically annotates all cardiac rhythm or conduction disturbance and helping the doctor to make a conclusion on detected arrhythmia and heart condition. The measurements done with ViewECG are available online from any device.

Patients with known or suspected heart conditions and health-conscious individuals can use ViewECG to record ECGs daily (or whenever they experience symptoms) and share their measurements with their doctor. An example situation when a patient would use ViewECG is when they feel: dizziness, palpitations, or irregular heartbeats. Doctors can quickly examine the rate and rhythm, screen for arrhythmias, and remotely monitor and manage patients who use ViewECG.

ViewECG consists of:

- A mobile application to collect, view, mark and wirelessly transmit recordings to the ViewECG server; and
- A web application to process and analyze ECG recordings, as well as create reports.

As part of an integrated system, ViewECG works with:

- A light wearable ECG sensor for long-term monitoring, such as the Savvy ECG sensor; and
- A user-supplied compatible smartphone or tablet.

1.1. Intended Users

The medical device is intended to be used by standalone patients and, at times, their doctors or caregivers (Table 1).

User	Role
Doctor	Monitor ECGs, analyze statistical reports, create reports
Patient	Record and upload ECG files and events, preview of ECGs, reports, and events
Caregiver	Preview ECG recordings of a patient, request reports

Table 1: Users and roles.

1.2. Indications

ViewECG is intended to continually record, store and transfer single-channel electrocardiogram (ECG) measurements. It can detect and classify beats and rhythms for the purpose of diagnosing arrhythmia. The ViewECG platform is intended to be used by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals.

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1.3. Contraindications

ViewECG is not intended for use by individuals who require hospital monitoring of a life-threatening arrhythmia. It is intended for personal use to measure and monitor ECG.

The associated ECG sensor has contact with the human skin through the adhesive electrodes, so users should apply the instruction of use for that device and read carefully the corresponding contraindications. For example, individuals that do not know how to use a smartphone need supervised use of the medical device by a caregiver.

1.4. Clinical Benefits

Long-term ECG monitoring has become an indispensable technology for prevention, management and treatment of many cardiac disorders[1]. The diagnoses of syncope or non-sustained rhythm disturbances remain a difficult task in clinical cardiology, leading to multiple out-patient visits, multiple examinations, diagnostic tests and unnecessary hospitalizations[2].

In light of this, all recent Guidelines for the management of: Syncope, Atrial fibrillation, Ventricular arrhythmia and prevention of Sudden Cardiac Death[3] recommended prolonged ECG monitoring - for detection of asymptomatic rhythm disturbances or to correlate symptoms to ECG finding.

The choice of monitoring technique depends on recurrence rate of symptoms and patient preferences. 24 hours Holter - ECG recording is sometimes insufficient due to short-monitoring time, and implantable loop recorders are sometimes unaccepted by the patients due to invasive part of the procedure.

The most important clinical benefit of ViewECG is the large diagnostic yield. Namely, the diagnostic yield of external monitoring systems goes up to 50% in cases where the duration of monitoring is 1 month.[4] Clinical decision support systems are intelligent systems that digitize and provide evidence-based guidelines, clinical pathways, and algorithms facilitating personalized, timely, and evidence-based treatment[5].

[1] Kirchhof, Paulus, et al. "2016 ESC Guidelines for the management of atrial fibrillation developed in collaboration with EACTS", *European heart journal* 37.38 (2016): 2893-2962.

[2] Brignole, Michele, et al. "2018 ESC Guidelines for the diagnosis and management of syncope", *European heart journal* 39.21 (2018): 1883-1948.

[3] ESC Councils "2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death", *European Heart Journal* 36 (2015): 2793-2867.

[4] Locati, E., Moya, A., Oliveira, M., Tanner, H., Willems, R., Lunati, M. and Brignole, M. (2015). External prolonged electrocardiogram monitoring in unexplained syncope and palpitations: results of the SYNARR-Flash study. Europace, 18(8), pp.1265-1272.

[5] Hindricks G, Potpara T, Dagres N, Arbelo E, Bax JJ, Blomstro ̈m-Lundqvist C, Boriani G, Castella M, Dan GA, Dilaveris PE, Fauchier L, Filippatos G, Kalman JM, La Meir M, Lane DA, Lebeau JP, Lettino M, Lip GYH, Pinto FJ, Thomas GN, Valgimigli M, Van Gelder IC, Van Putte BP, Watkins CL. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association of Cardio-Thoracic Surgery (EACTS). Eur Heart J2020;doi:10.1093/eurheartj/ehaa612

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1.5. Labelling

The CE marking for ViewECG medical device system is available on the website and that is visually presented in

Figure 1.

The Declaration of Conformity to the European Union granting the CE marking is available online as well.

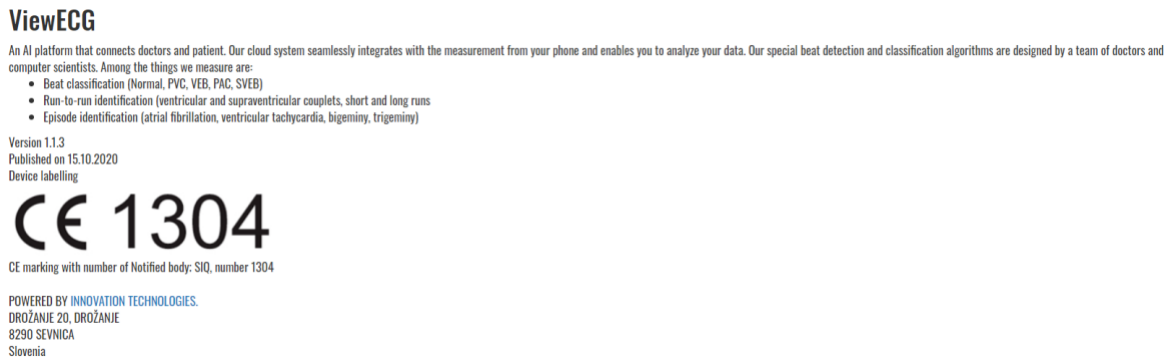

Figure 1: ViewECG marking for CE number.

2. User Requirements

2.1. User Requirements for the Mobile Application

Savvy Heart sensor

ViewECG is intended to be used with an ECG sensor that has already been certified with a CE Mark 1304, such as Savvy. All user instructions and product details are available in the Savvy user manual.

Digital device

A user-supplied smartphone must be used in order to run measurements as the ECG sensor cannot function independently. The ECG data that the sensor collects are stored on the smartphone, not on the sensor itself.

ViewECG is compatible with the following smartphones and tablets:

- iPhone 7/7 Plus, and SE, iPhone 8/iPhone X;
- iPad Air 2 and 3;
- iPad Mini, Mini 2, and Mini 3;
- iPad Pro 9.7-inch; and
- iPod Touch 5G.

The ViewECG mobile application is compatible with iOS versions higher than 10.0.2.

NOTE: The smartphone must have properly functioning Bluetooth receptors to provide proper function of ViewECG.

NOTE: There might be errors during the transmission of ECG files to the server if the smartphone doesn't have Internet connection.

NOTE: The user-supplied smartphone represents the weakest link in the security chain of ViewECG.

NOTE: One of the biggest security risks is a privacy breach. Therefore, it is up to the user to make sure that their smartphone is up to level with the right security features.

2.2. User Requirements for the Web Application

Web browser-enabled computing device

The web application may be accessed on all computing devices with an Internet connection and large enough screen to monitor details of the ECG recordings. The list of devices for the web application include:

- Desktop computer;
- Laptop;
- Tablet; and
- Smartphone.

The hardware requirements of the computing device are:

- At least Intel i3 3rd generation processor or any compatible processor;
- At least 1 GB of free RAM memory;
- At least 10 GB of free disk memory; and
- Internet connection of at least 8 Mbps download speed.

The requirements for the printing unit are:

- A grey-scale printer is sufficient; and

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- Supporting at least 100 dpi resolution.

The constraints for relatively good graphics performance include:

- Screen size at least 9" (22.86 cm) diagonal; and
- Screen resolution at least 1440 * 900 (for 16:10 aspect ratio) or 1600 * 900 (for 16:9 aspect ratio) or 1280×960 (for 4:3 aspect).

The requirements for the operating system and web browser include:

- Any modern operating system can support sufficient performance, including Mac OS, Microsoft Windows, Linux, IOS, Android or similar;
- Web browser that supports Scalar Vector Graphics (SVG). Although most modern web browsers support SVG rendering, not every browser will have the same rendering output due to the individual SVG rendering engines the browsers provide. Therefore, the interface will have optimal appearance and functionalities if using the latest version of the web browser; and
- No additional plug-ins are needed or recommended.

Intended Use

The device can be used both over-the-counter by stand-alone patients and on prescription with the help of a healthcare professional.

Over-the-counter Use

Individuals can use ViewECG as a consumer medical device. They can:

- Measure their ECG and mark events;
- Share events of up to 8 minutes;
- Use the mobile app to browse through their history; and
- Request on-demand reports from medical professionals on the application.

NOTE: Use of the ViewECG web application is limited for patients without qualifications to interpret ECG.

Prescribed Use

Doctors can prescribe this device to monitor their patients remotely. In this case, doctors are in charge of creating and managing their patients' profiles and they have full access to all of the functionalities of the web application. The types of medical use can be further divided into:

- Short term measurement device, for continuous use for between 60 minutes and 30 days;
- Long term measurement device, for continuous use for more than 30 days; and
- Active device intended for diagnosis and monitoring (any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital conduction or rhythm disturbances).

Interpretation skills

Ordinary patient does not need to have any expertise in interpretation of the ECG findings, they are left for doctors and experts. Experience in ECG monitoring software provides a significant advantage in interpreting the findings.

For patients with somewhat serious predetermined cardiac conditions and patient with predispositions for cardiac irregularities, it is highly recommended to be acquainted with the terminology that is related with the medical findings, diagnosis and medications.

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The web-application interfaces follow the classic design principles; hence, the user needs to be averagely acquainted with such applications in order to intuitively manage the monitoring functionalities of the web application. A thorough read of the manual is recommended to make the most of the supported functionalities. The ECG findings are in accordance with the Physionet standard[6] for annotations and episodes.

Diagnostic options

The essential diagnostic options realized by this medical device are:

- Heart rate
- Supraventricular ectopy
- Ventricular ectopy
- Bradycardia data
- Pauses
- ECG strip of representative arrhythmia beats and sequences

More detailed list of declared diagnostic options include:

- QRS complex detection
- Ventricular extra beats (VEB) detection
- Ventricular couplet detection
- Ventricular short run detection
- Ventricular long run detection
- Supreventricular extra beats (SVEB) detection
- Supraventricular couplet detection
- Supraventricular short run detection
- Supraventricular long run detection
- Atrial fibrillation (AF) episode detection
- Ventricular bigeminy and trigeminy detection
- Supraventricular bigeminy and trigeminy detection
- Heart rate variability (HRV) time domain parameters: SDNN, ASDNN, SDANN, RMSSD, pNN50, TINN
- HRV frequency domain parameters: VLF, LF, HF
- Dashboard and report with RR distribution chart, NN spectrum, Poincare plot, and detrended fluctuation analysis.

[6] PhysioBank Annotations - https://www.physionet.org/physiobank/annotations.shtml

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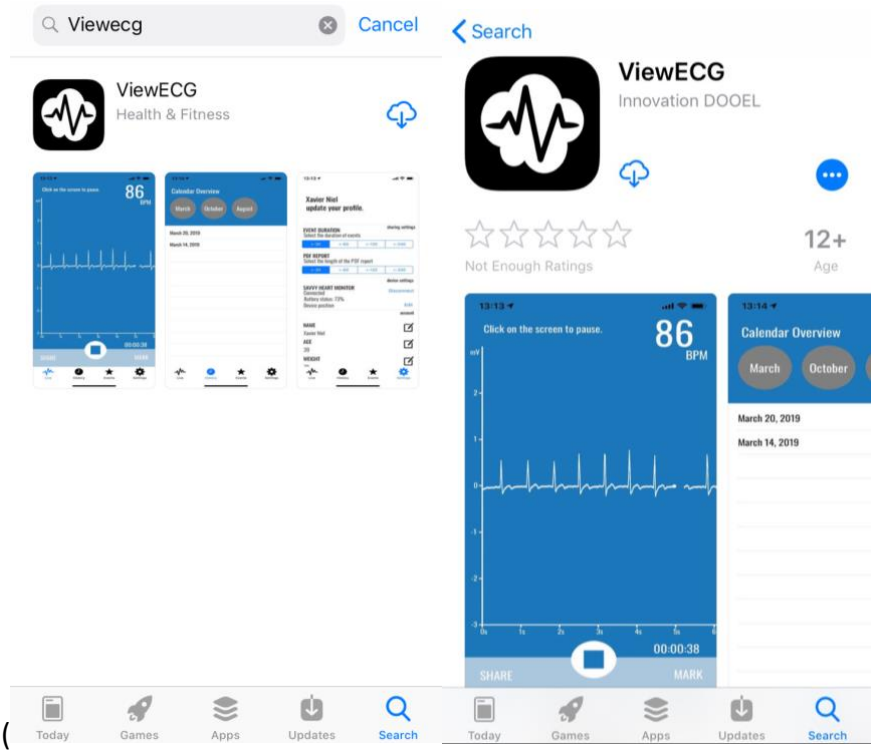
3. How to use the iOS application

3.1. Installation

Download Application

1. Using your smartphone or tablet, search for ViewECG in the iOS App Store



(Figure 2).

2. Download and install the ViewECG phone app.

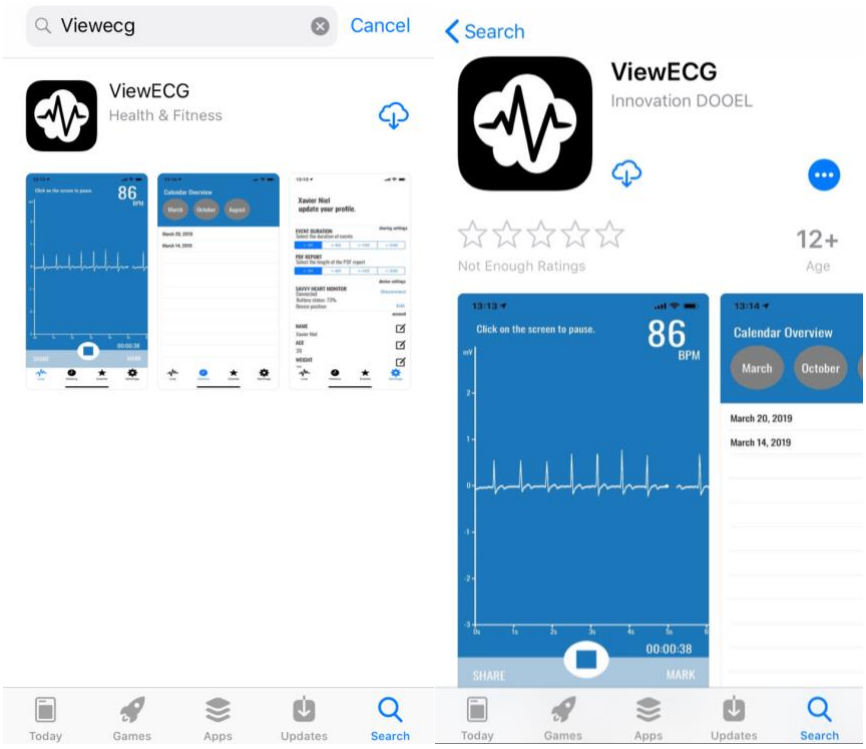


Figure 2: ViewECG on iOS App Store.

Register

Follow the instructions presented when you open the ViewECG phone app for the first time (Figure 3 left). You can go back later and change your information if necessary. Confirmation email will be sent to the email provided and proceeding with the use will be available only after the account confirmation (Figure 4).

Login

Follow the login instructions presented when you open the ViewECG phone app, input the email and password of the associated account (Figure 3 right). A password-reset option is available if needed.

Terms and conditions

On the first login with the newly created account, you should read and agree to the "Terms and Conditions" before proceeding with the use of the ViewECG phone app.

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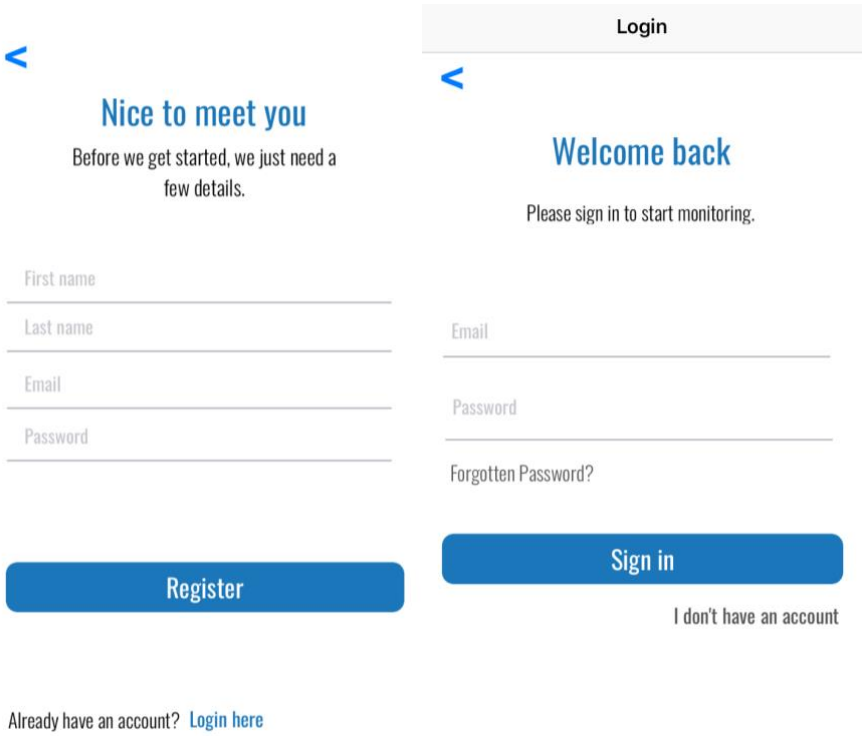

Figure 3: User registration/login.

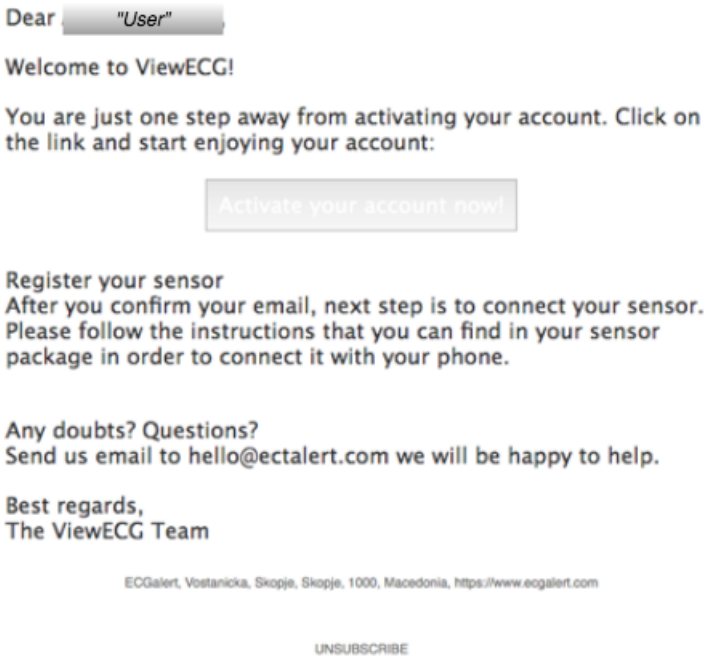

Figure 4: New account confirmation.

Pair Savvy

1. Make sure Bluetooth is turned on your device (Figure 5)
2. Get your device close to Savvy within a distance of less than 5 meters
3. Open the ViewECG app and log in
4. Click on the "Connect to Savvy" button
5. Choose your monitor from the listed Bluetooth devices
6. Enter the pin code of your Savvy heart monitor (can be found on the last page of the Savvy user manual)
7. The Savvy heart monitor will pair

The phone app will remember your heart monitor and connect to it automatically anytime the monitor is near and your phone has Bluetooth on. Re-pairing will only be required when a password is wrongly entered.

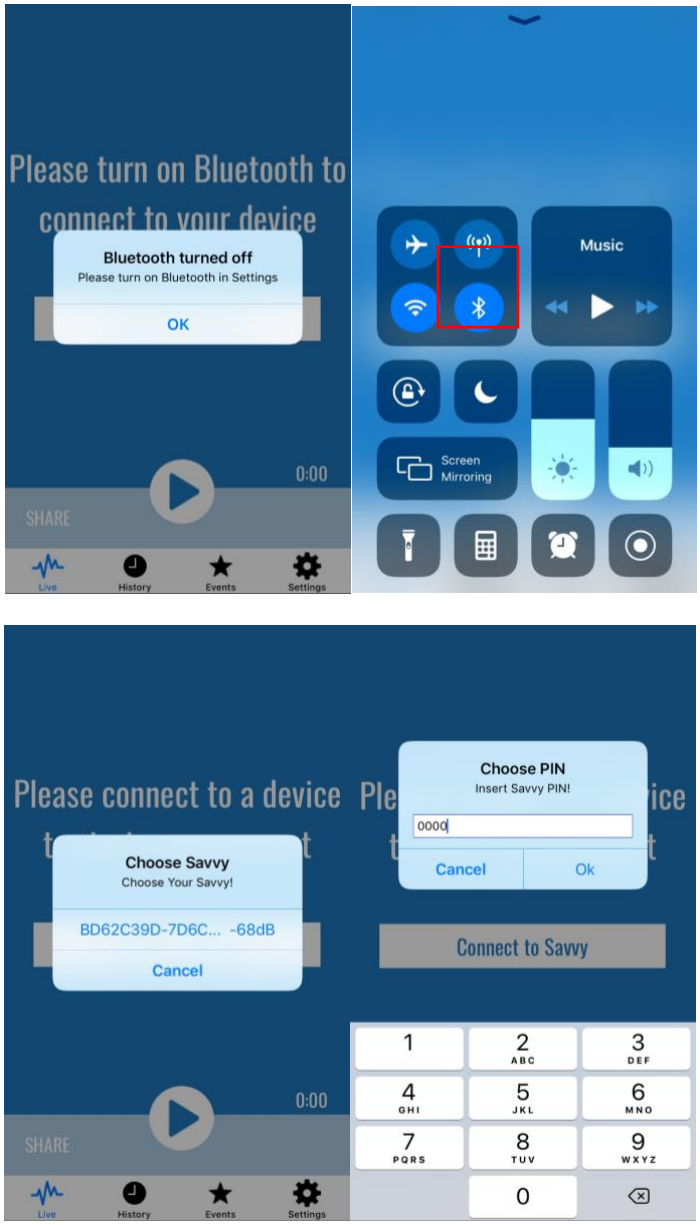

Figure 5: Pair Savvy Bluetooth steps.

3.2. Measurements

Start Measurement

Once you are connected to the Savvy heart monitor click the play button to start measurement (Figure 6).

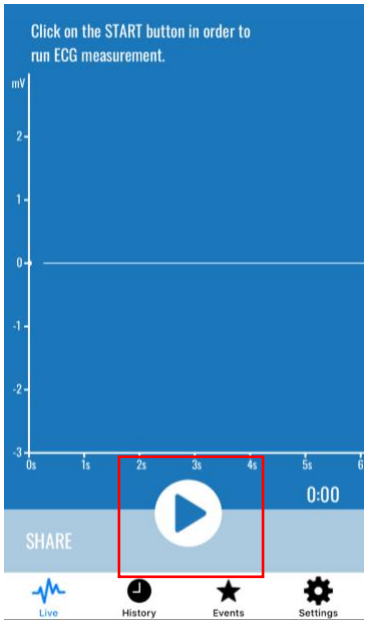

Figure 6: Start measurement.

During measurement

The application will show a visualization of the ECG- signal anytime there is a measurement running. Figure 7 shows an example of a good quality ECG signal.

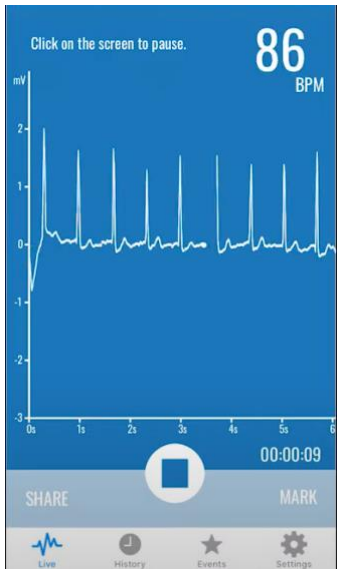

Figure 7: Good quality ECG signal.

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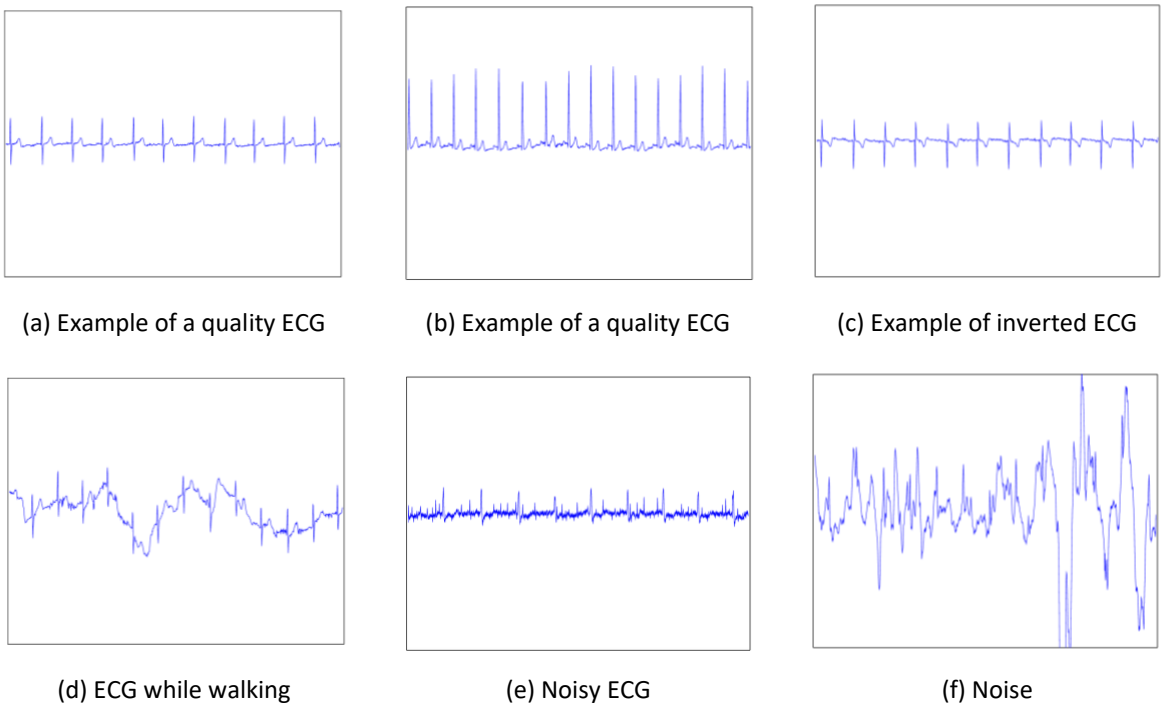
Figure 8 shows examples of different signal forms that can be encountered during measurements. All forms, except the last one (8-f), are considered as ECG. Two examples of quality ECG signal are shown in 8-a and 8-b.

An inverted ECG signal can be displayed if the placement of the electrodes is reversed (8-c). 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 (8-d). Example of a noisy ECG signal is on 8-e; heartbeat timings may still be obtained from such a signal.

Figure 8-f shows an example of noise, which might be caused by a disconnected electrode; and it portrays a bad quality ECG signal. 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, and ensure that the ECG signal is good. Be patient as a good galvanic contact with the subcutaneous tissue is established and the ECG signal usually becomes stable within a few minutes.



(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 8: Examples of different signals during measurement.

Heart rate (HR) is the speed of the heartbeat measured by the number of contractions (beats) of the heart per minute (BPM). ViewECG calculates both instant and average heart rate value. The method of calculation of heart rate is as follows: instant heart rate is calculated from RR intervals between two sequential heartbeats; and the average heart rate is calculated as average from five instant heart rates. In case less than 5 beats are detected for interval od 10 seconds interval, "N/A" will be shown instead of the BPM value. The BPM value is furthermore limited to between 20 and 250. In case calculated value is outside those limits, "N/A" 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 only an estimate, keeping in mind that it might be incorrect when the signal is bad.

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Segments lasting at least 4 seconds and which do not have a detected BPM are called pause. A pause that is longer than 2 seconds is called a micro pause.

Mark Event

This option is accessible by selecting "Mark" from the "Live" screen. 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

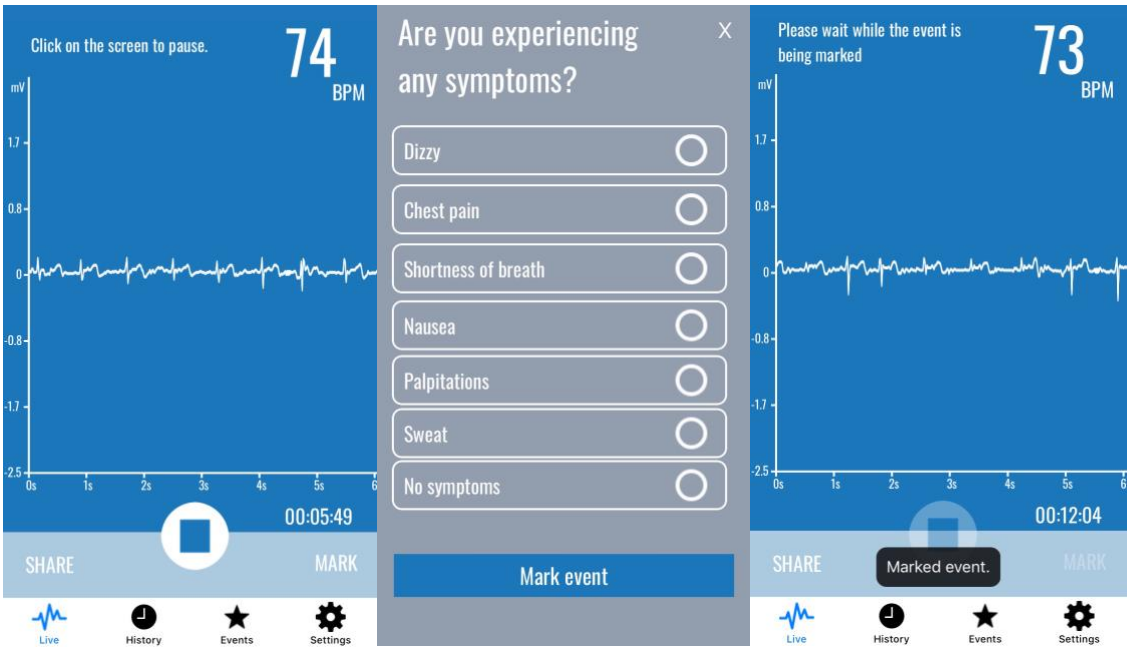

Figure 9). The marked event will include ECG signals 30 seconds prior to clicking the button and 30 seconds after clicking the button.

Marked events are pre-defined with a feeling such as:

- Feeling dizzy;
- Feeling chest pain;
- Feeling shortness of breath;
- Feeling nausea;
- Feeling palpitations;
- Sweating;
- No symptoms; and

with pre-defined duration of 30, 60, 120 or 240 seconds. You can adjust the event duration in "Settings".

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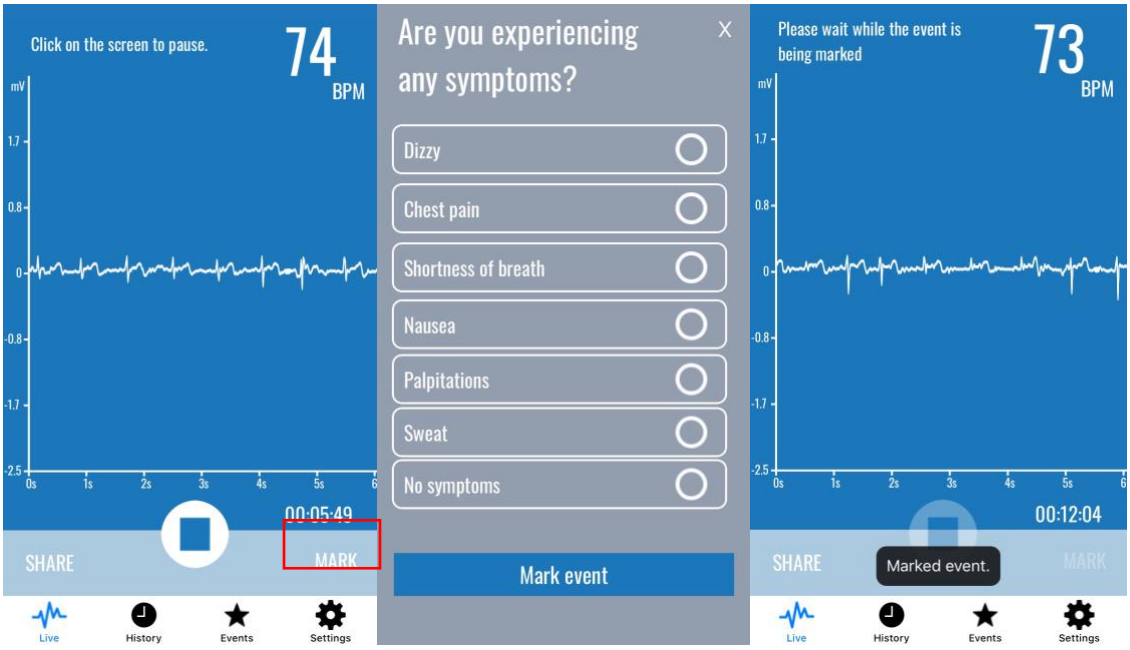
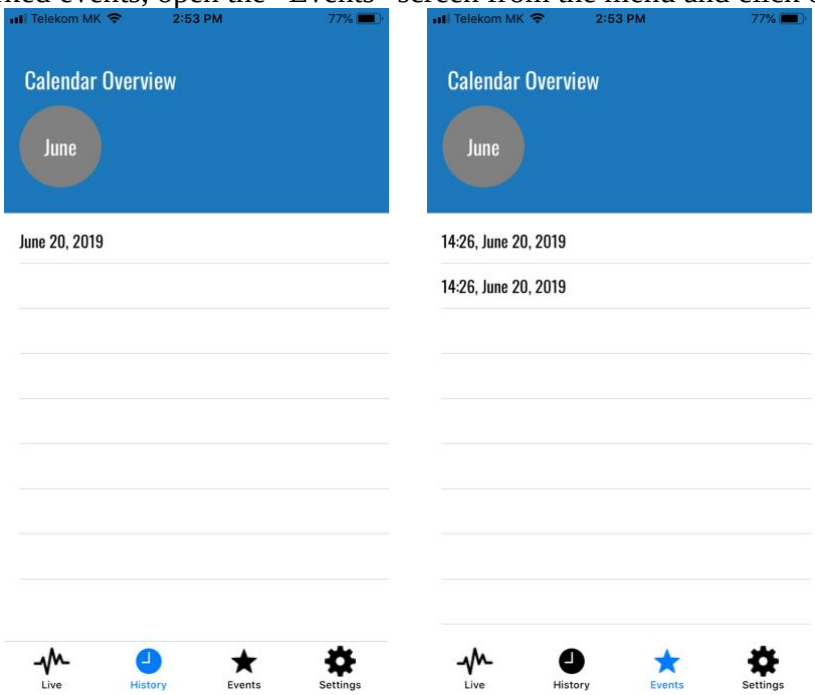


Figure 9: Mark an event button (left), Symptom Marker selector (middle) and Marked event notification (right).

To view marked events, open the "Events" screen from the menu and click on an event (Figure 10 left).



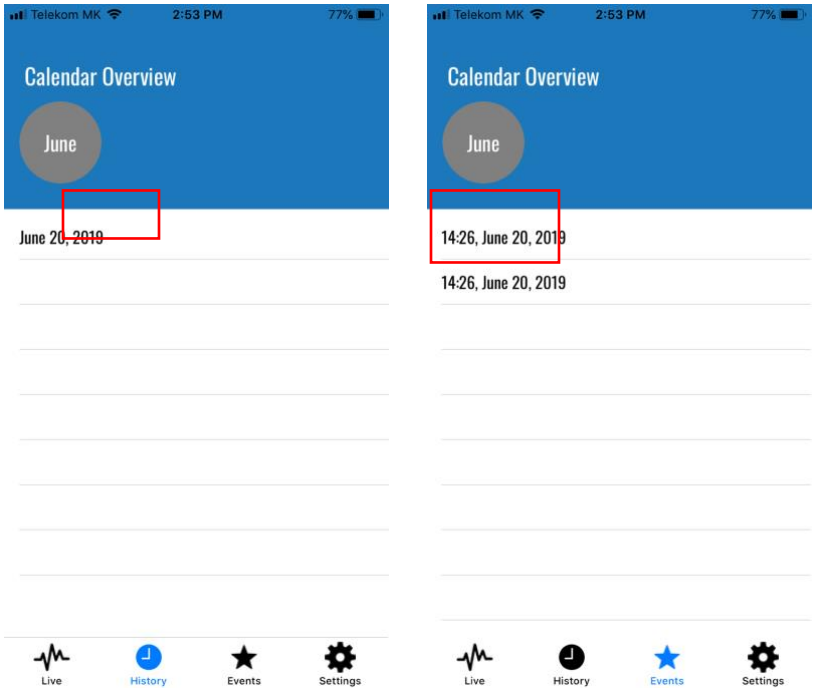
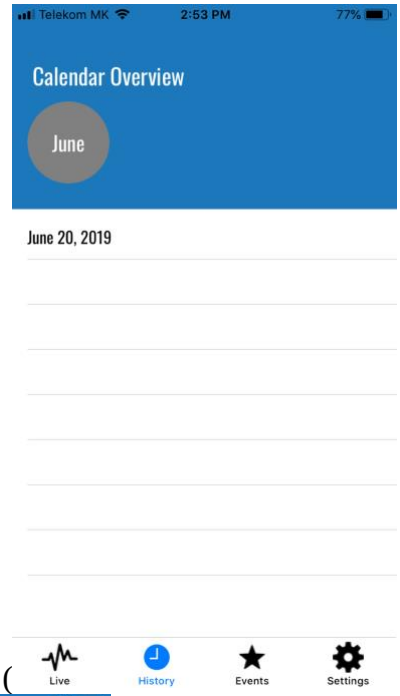


Figure 10: History tab (left) and Events tab (right)

Share

Users can share their current or past measurements in the form of a PDF report by either clicking "Share" from the "Live" screen or from "History". The length of the PDF report can be changed in "Settings".

Browse History



You can use the "History" and "Events" tabs (

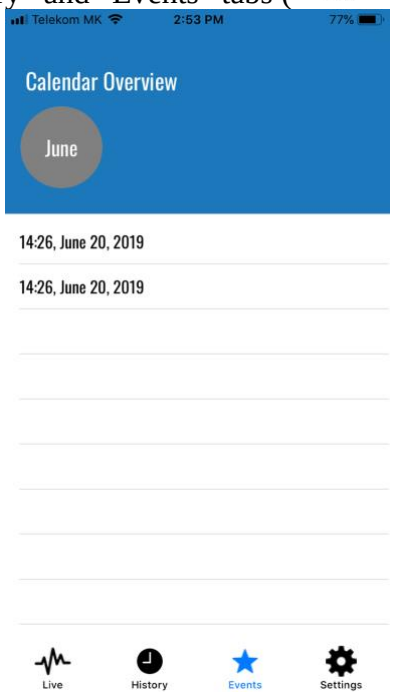


Figure 10) in the main menu to browse through past measurements. Measurements will be kept up to 30 days on the device (or the user can set this period in "Settings"). All your recorded history is accessible on the ViewECG online platform.

Pause Measurement

You can tap to pause and then tap once again to continue the measurement on the "Live" screen. You can also zoom in and zoom out by pinching your fingers.

Stopping Measurement

To stop a measurement:

1) Click the stop button; or
2) Turn off Bluetooth on your device.

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3.3. Settings

Change Settings

The application settings are available by selecting "Settings" from the application menu (Figure 11). The settings include:

- Sharing settings:
  - Event duration: select the duration of events; and
  - PDF report: select the length of the PDF report.
- Device settings:
  - Connection Status;
  - Battery Status; and
  - Device Position.
- Account settings:
  - Name;
  - Age;
  - Weight; and
  - Password.
- Links for "Support", "Terms and Conditions" and "Privacy Policy".
- "Log-out" and "Exit" buttons.

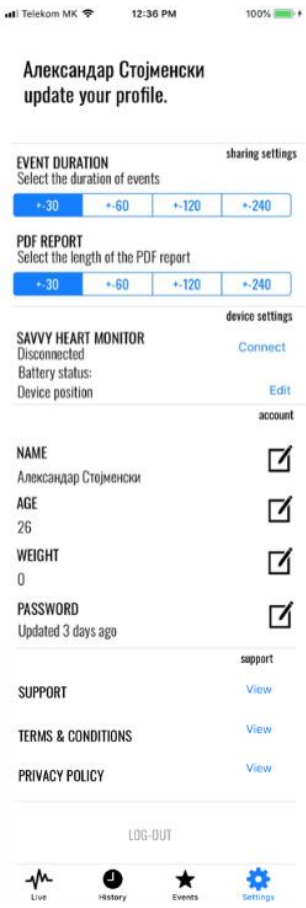

Figure 11: ViewECG app settings screen.

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4. How to use the web application

As a patient you can upload your recorded ECGs and monitor them. You can browse the recorded 30 sec ECG strips or events, print and share them. To start using the application, you need to register and login the application.

4.1. Register and Login

Login page

Prior to use, the user should register according to the following procedure:

1. Open www.viewecg.com to open the login page (Figure 12).
2. If you are not registered, click the "Register here" link (Figure 13).
3. Follow the instructions to register.

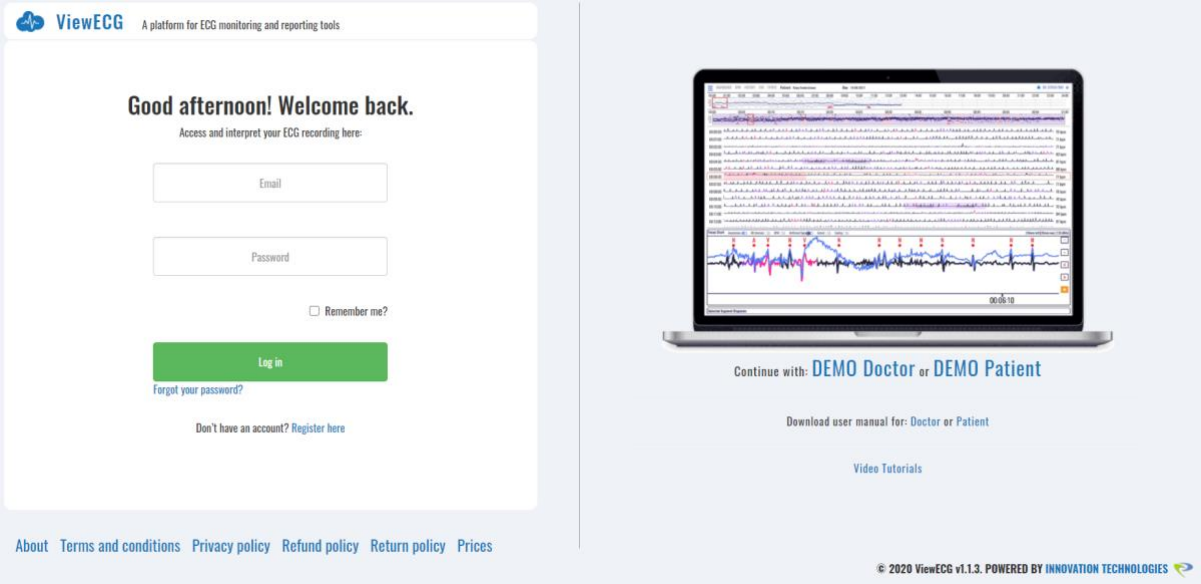

Figure 12: Login page of the web application.

You can change your information afterwards if necessary using the "Settings" option.

Register

To register you need to fill the required data (Figure 13), including email, password, first and last name, gender, date of birth, weight, height, address, city, country, post code, and phone number.

The patient can upload or delete a personal photo.

Checking the field "I'm not a robot" and clicking on "Register", you will receive e-mail with instructions how to confirm your credentials to be registered (Figure 4).

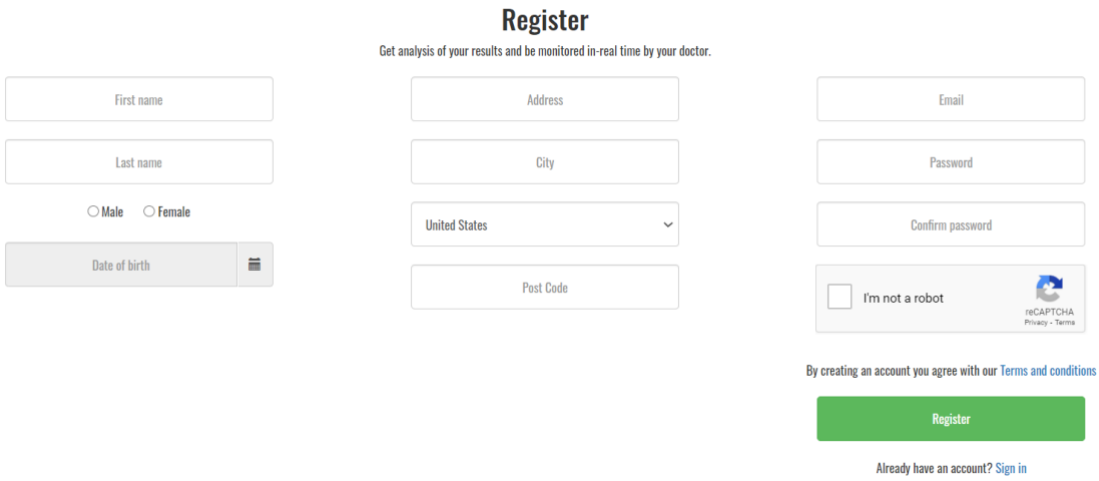

Figure 13: Register page.

NOTE: The system may enforce the user to change the password if the entered password does not contain at least one special character, one capital, one small letter and one digit.

NOTE: The system will prevent the account creation if you have not filled the required fields and those are:

- First name;
- Last name;
- Gender;
- Date of birth;
- Address;
- City;
- Country;
- Post code;
- Email;
- Password; and
- Confirm password.

NOTE: The system may also prevent the user to use an existing username.

If a successful combination of a username and password are entered and all necessary fields are populated the system notifies the user (Figure 14) that the registration was successful and the user needs to read the e-mail and follow the instructions in the e-mail.

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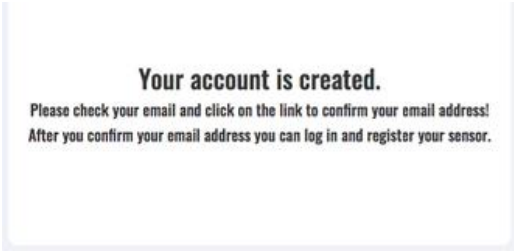

Figure 14: Notification of successful registration.

If the user follows up the instruction in the e-mail (Figure 4) and clicks on the confirmation link, a confirmation on successful registration will appear (Figure 15).

Figure 15: Notification after confirming the registered username.

Forgot password

If the patient has forgotten the username password combination, then a click on the link "Forgot your password?" will open the forgot password form (Figure 16). Click on "Reset your password" button will generate an e-mail with temporary password sent on provided e-mail. The patient can confirm the link received by the e-mail, and then set a new password to log in the web site.

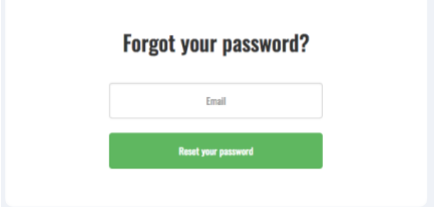

Figure 16: Forgot password form.

Login and access recorded ECGs

The login page is www.viewecg.com.

The user needs to enter a valid username and password and click on "Login" button (Figure 12).

If the user clicks on "Remember me" button, then a cookie is activated on the patient's web browser that remembers the patient credentials, and automatically logs the patient whenever the patient is accessing the login page (Figure 17).

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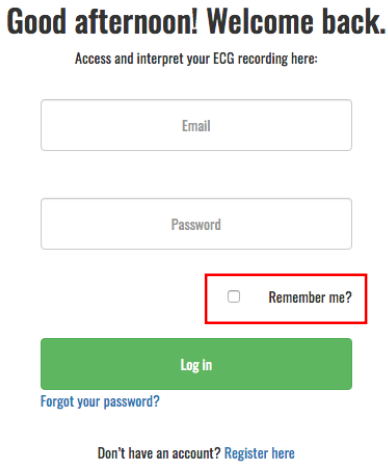

Figure 17: Remember me option.

Demo links and user manuals

Demo links are available on the login page both for the patient and doctor.
User manuals for patients and doctors are also available through provided link on the login page (Figure 18).
There are also available video tutorials for

- Patients;
- Doctors; and
- iOS application.

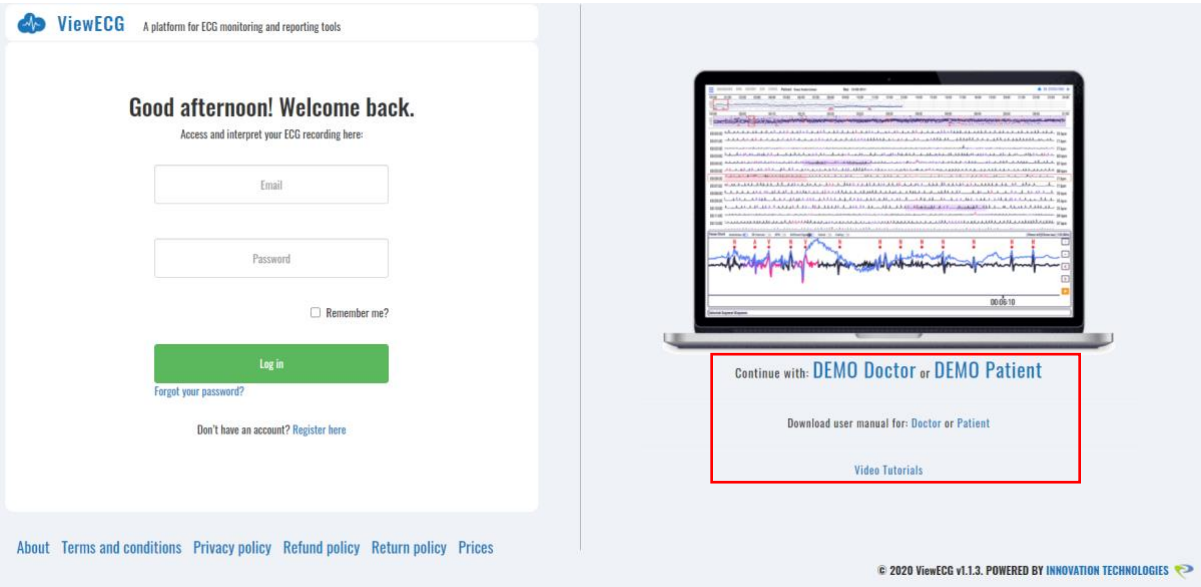

Figure 18: User manuals.

Support and policies

Multiple links are available on the home page of ViewECG and all other website pages (Figure 19). Navigation is between listed links and main website functions.

- About;

- Support (available when user is logged in);
- Terms and conditions;
- Privacy policy;
- Refund policy;
- Return policy; and
- Prices (continues in section Subscription).

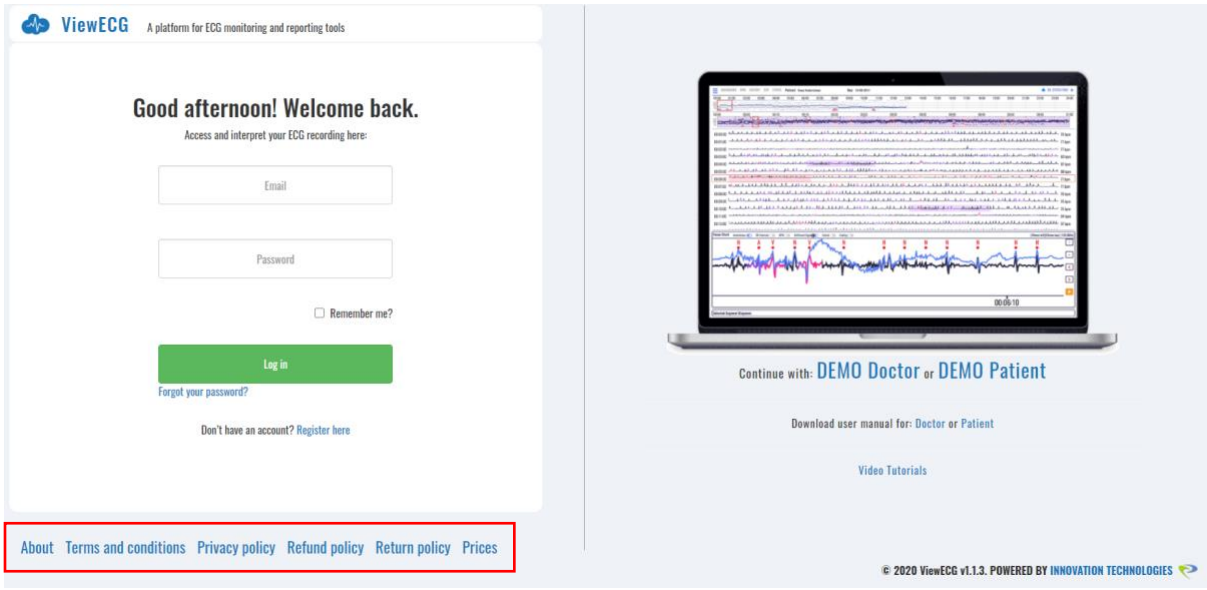

Figure 19: Support and other hyperlinks.

Subscription

ViewECG offers a free trial period for 2-month use and certain functions available to their users. Prior to the end of the 2-month trial period, the user should purchase their subscription package (Figure 20). After selecting the desired option, click the "Buy" button underneath. Confirm the subscription package and the wanted quantity by clicking "Checkout". Before concluding the payment, review the items and click "Confirm & Pay". Provide payment details and click "Confirm".

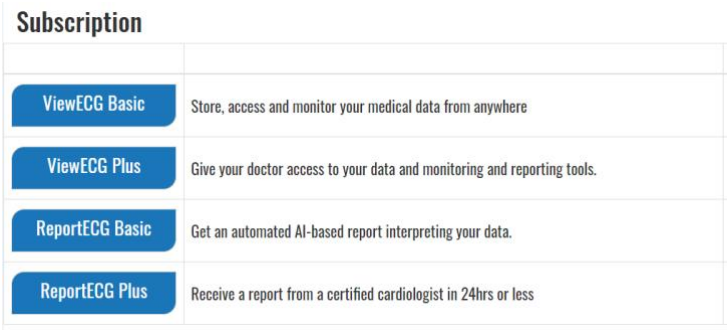

Figure 20: Subscription options.

There are four different types of subscription plans available, the Basic plans are for patient users and the Plus once are for doctor users. The ViewECG plans provide monitoring access

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for both patients and doctors, and the ReportECG provide reporting access to both types of users.

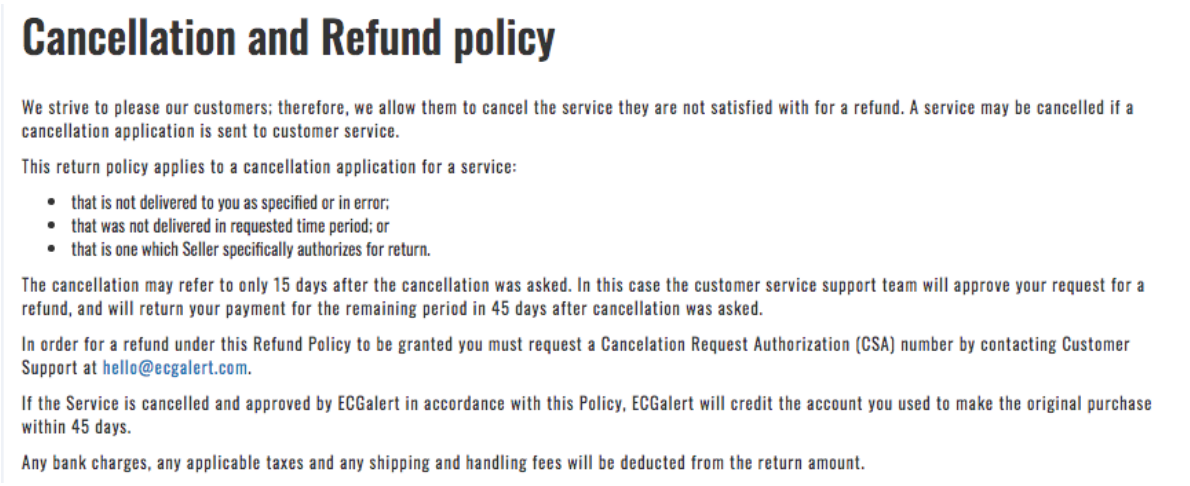
Refund Policy

Order cancelation and return process is defined within the appropriate policy (Figure 21). The policy applies to a cancelation application for a service:

- That is not delivered to you as specified or in error;
- That was not delivered in requested time period; or
- That is one which Seller specifically authorized for return.

In order to a cancelation and refund to be granted, you have to fill in the CRA form with the necessary information:

- First name;
- Last name;
- Email;
- Address
- Subscription plan;
- Subscription start date;
- Invoice number; and
- Reason for cancelation:
  - Unsatisfied by the service;
  - Quality not as expected;
  - Price; or
  - Other.



Cancellation and Refund policy

We strive to please our customers; therefore, we allow them to cancel the service they are not satisfied with for a refund. A service may be cancelled if a cancellation application is sent to customer service.

This return policy applies to a cancellation application for a service:

- that is not delivered to you as specified or in error;
- that was not delivered in requested time period; or
- that is one which Seller specifically authorizes for return.

The cancellation may refer to only 15 days after the cancellation was asked. In this case the customer service support team will approve your request for a refund, and will return your payment for the remaining period in 45 days after cancellation was asked.

In order for a refund under this Refund Policy to be granted you must request a Cancelation Request Authorization (CSA) number by contacting Customer Support at hello@ecgalert.com.

If the Service is cancelled and approved by ECGalert in accordance with this Policy, ECGalert will credit the account you used to make the original purchase within 45 days.

Any bank charges, any applicable taxes and any shipping and handling fees will be deducted from the return amount.

Figure 21: Cancelation and Refund Policy.

Return Policy

Return process is defined with the appropriate policy (Figure 22). The policy applies to returning an undamaged product and is granted by filling in the RMA form with the necessary information:

- First name;
- Last name;
- Email;
- Address;

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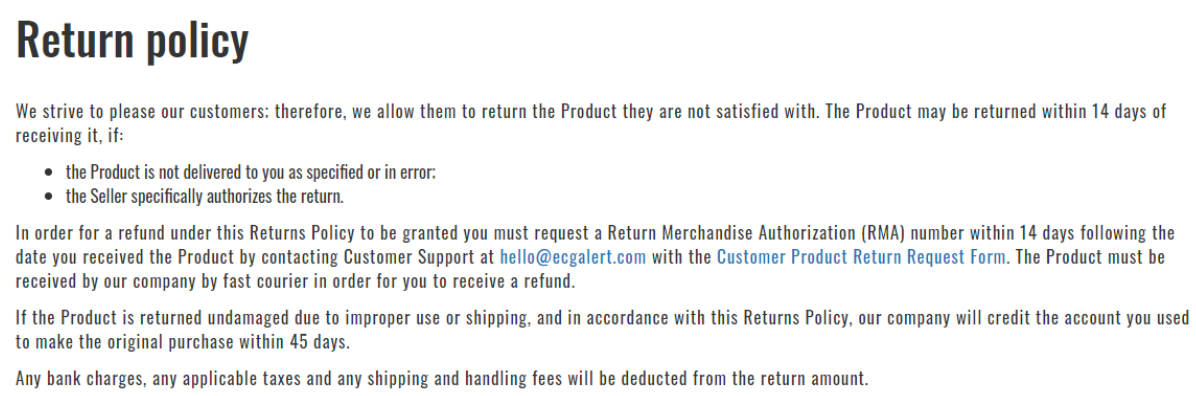
- Product serial number;
- MAC address;
- PIN code;
- Serial number; and
- Reason for return:
    - Defective product;
    - Quality not as expected;
    - Product no longer needed/wanted; or
    - Other.

The page contains a form template that should be filled in with required information and send to the available e-mail address.



Return policy

We strive to please our customers: therefore, we allow them to return the Product they are not satisfied with. The Product may be returned within 14 days of receiving it, if:

- the Product is not delivered to you as specified or in error;
- the Seller specifically authorizes the return.

In order for a refund under this Returns Policy to be granted you must request a Return Merchandise Authorization (RMA) number within 14 days following the date you received the Product by contacting Customer Support at hello@ecgalert.com with the Customer Product Return Request Form. The Product must be received by our company by fast courier in order for you to receive a refund.

If the Product is returned undamaged due to improper use or shipping, and in accordance with this Returns Policy, our company will credit the account you used to make the original purchase within 45 days.

Any bank charges, any applicable taxes and any shipping and handling fees will be deducted from the return amount.

Figure 22: Return Policy.

4.2. Monitoring page

Monitoring is the essence of the application. The monitoring page is displayed once the user logs in the application as registered patient user. It can be also accessed from anywhere by clicking the "ViewECG" logo (ViewECG) in the application header.
When the user first creates their account, the monitoring section displays only a text label that says "You do not have any measurement with your sensor. Please connect your sensor and start new measurement." to the user because there are not yet any uploaded files for monitoring. As soon as the user uploads at least one ECG file, the monitoring page looks as the one displayed on Figure 23.

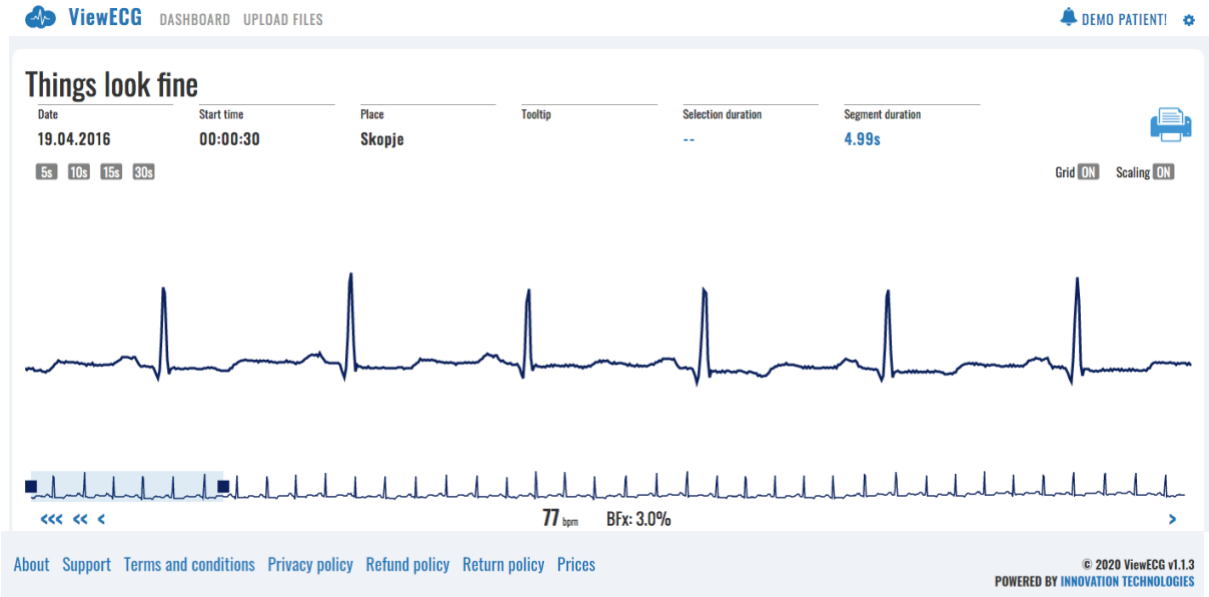


Figure 23: Monitoring page with detected normal sinus rhythm

View ECG header

The monitoring page displays the most recent ECG measurement. The application header contains the ViewECG logo that is a link to the monitoring page. Next to the logo there are two menu options/shortcuts to "Dashboard" and "Upload Files". At the right side, there is a "Warning" icon, the "Patient name" and "Settings" icon. The "Warning" icon is a link to a system-warning message whenever it is available (Figure 24). The "Patient name" is link to personal settings, and the "Settings" icon is a drop-dov

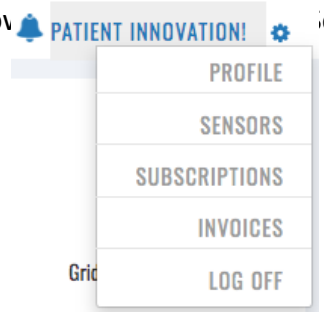


Figure 25). "Subscriptions", "Invoices" and "Log off" link (

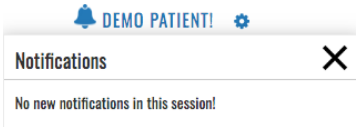


Figure 24: System warning message.

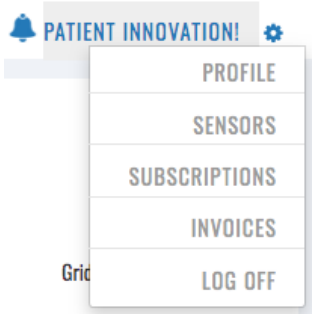


Figure 25: Account settings menu.

Information header

Right below the application header, there is a simple message that informs the patient of current heart ECG condition. The message "Things look fine" appears if there is no detected rhythm or conduction disturbances and is associated to normal sinus rhythm (Figure 26).

Below this message there is patient and measurement information including: date, time, and place. The other fields are associated to tooltip values, selection and segment duration, associated to displayed ECG measurement and graphical processing initiated by the mouse and monitoring tools. At the end of this row there is a "Printer" icon used to print the ECG recording as a pdf file and share the recorded ECG measurement.

Figure 26: Application header.

Control header for monitoring tools

Control header is located below the information header. The control header contains 4 buttons on the left side to choose the window width of the ECG signal to be displayed among values of 5, 10, 15 and 30 seconds. On the right side, there are two toggle buttons ("Grid" and "Scaling") used to toggle on and off the display of a grid or to scale the signal.

A patient may click on "Grid" button and display a regular grid for easier interpretation using a standard resolution of 25 mm/sec and 1 cm/mV (Figure 27).

NOTE: ECG shown in Figure 27 contains a detected premature ventricular contraction (PVC).

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Figure 27: Monitoring page with grid (PVC beat detected).

A click on a "Scale" button will display scaled ECG without grid (Figure 28) and with scaled display where the height of displayed ECG will be maximized according to the allowed space.
NOTE: The ECG shown in Figure 28 contains a detected premature atrial beat (PAC).

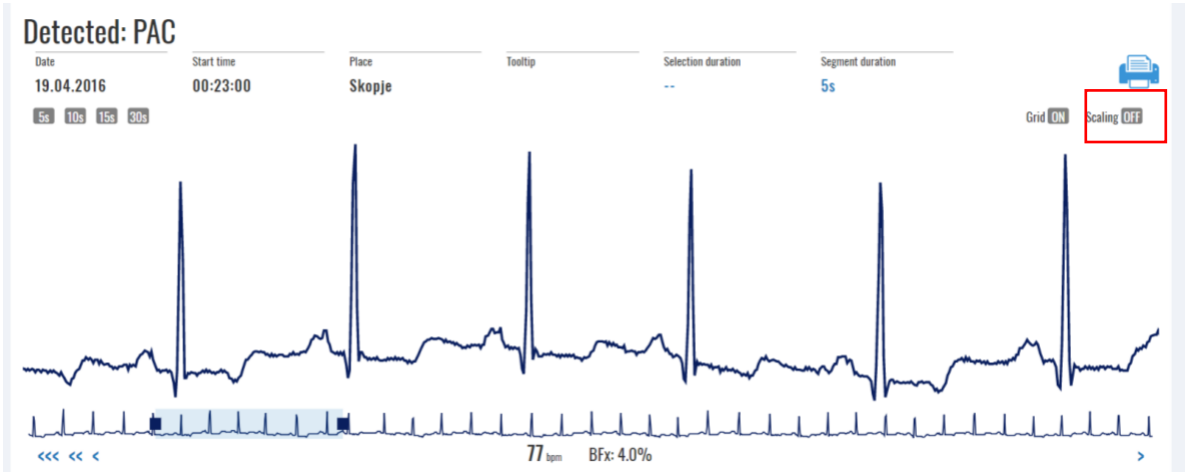

Figure 28: Monitoring page with scaling (PAC beat detected).

Navigation as a monitoring tool

Below the displayed ECG signal there is a navigation slider within a window that covers the displayed area, and at most four navigagation buttons ("|<, <<<, <<, and <") to left and four navigation buttons to the right (">, >>, >>>, and >|"). The number of dispayed navigation buttons depends on the availability of the signal (Figure 29).

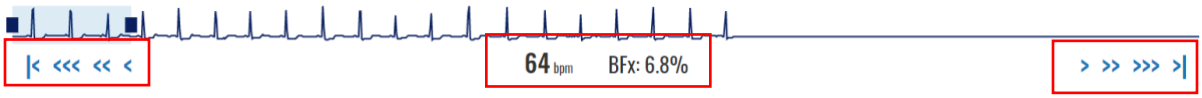

Figure 29: Navigation slider.

The middle part of this navigation header is dedicated to the information about heartbeat rate and beat fluctuation index. The heartbeat rate is displayed in beats per minute (BPM) and the beatfluctation index in percentage (BFx). For example, the values of the 30 second ECG strip from Figure 29 are heartbeat rate of 64 BPM and 6.8% beat fluctuation.
The presented heart rate is calculated as the average BPM for that 30 seconds segment.

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4.3. Monitoring tools

The available monitoring tools include navigation of the displayed window and marking a segment. More specific monitoring tools are available for the doctor in order to enable a sophisticated environment for establishing a diagnosis.

Navigate ECG measurement

The window of displayed ECG can have a standard width of 5 (Figure 30), 10 (Figure 31), 15 (Figure 32) and 30 seconds (Figure 33) accessible by corresponding width control buttons (Figure 27). If the selected width is smaller than 30 seconds, then the selected part of the window that is displayed is marked on the navigation slider. The default value of this slider is the beginning (left side) of the navigation slider.

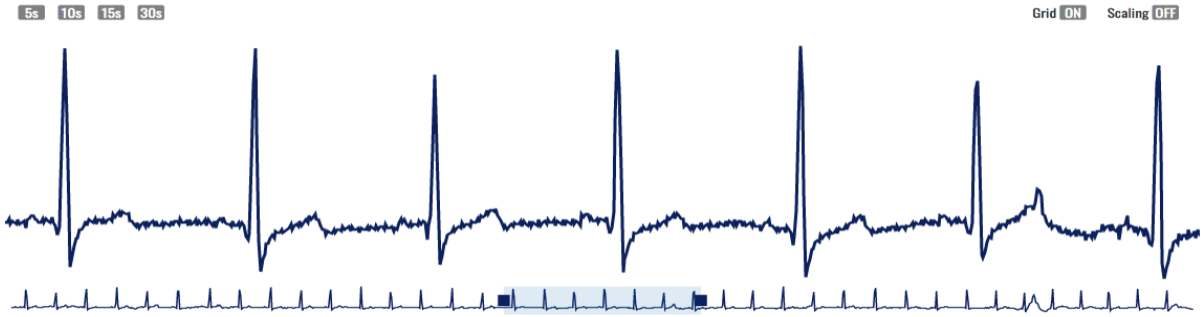

Figure 30: 5 seconds ECG width.

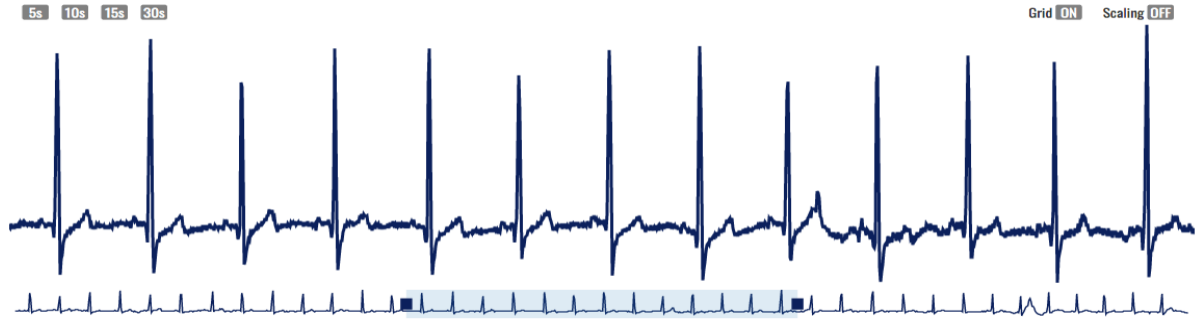

Figure 31: 10 seconds ECG width.

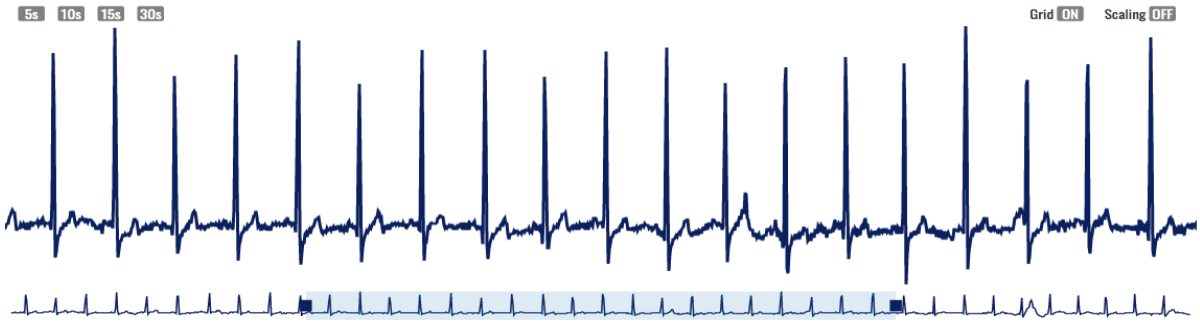

Figure 32: 15 seconds ECG width.

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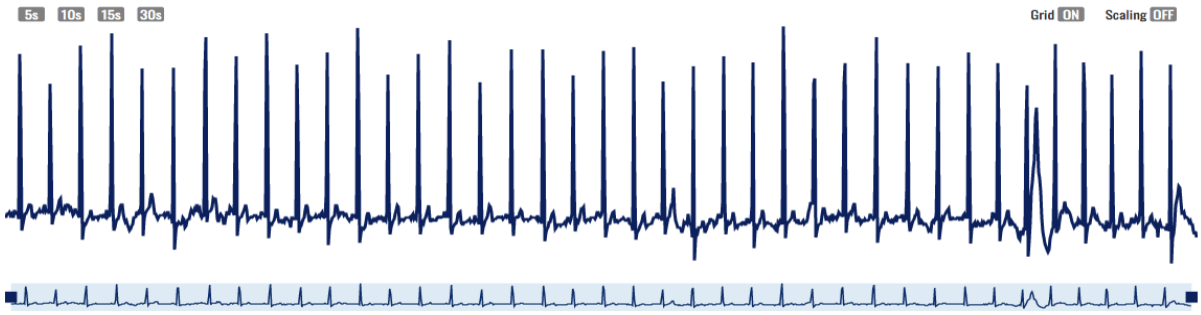

Figure 33: 30 seconds ECG width.

You can move this navigation slider to a specific horizontal position on the slider and display the desired content. Examples are presented in Figure 27 and Figure 28 correspondingly to represent the detected PVC and PAC.

The navigation slider consists of a compact signal chart with duration of 30s and position and span indicator. The compact ECG signal is a representation of the current signal. Its transparency gives the user insight on any present anomalies.

The position and span navigator, as its name indicates, has two functions:

- to navigate (position) the current visible window of the ECG chart section within the 30s ECG segment. This is achieved by "drag and drop" interaction with the navigator body (Figure 34); and

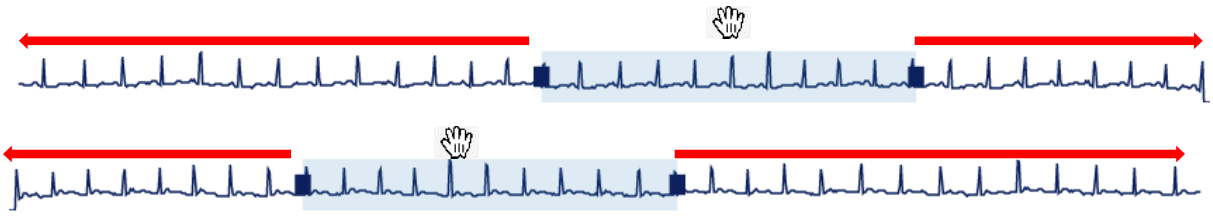

Figure 34: Position navigation.

- to adjust the span of the current visible window of the ECG chart section within the 30s ECG segment. This is achieved by "drag and drop" interaction with the navigator handles (slider margins - Figure 35).

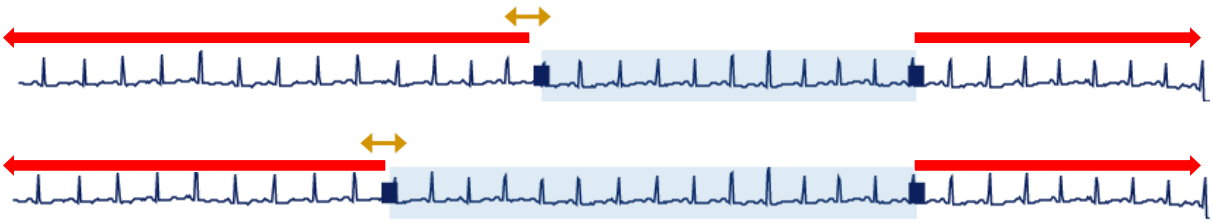

Figure 35: Span adjustment.

NOTE: The shaded widow size depends on the selected window width (such as 5, 10, 15, and 30 seconds - Figure 30; Figure 31; Figure 32 and Figure 33).

You can change the width of the displayed window by sliding the left or right margin of the slider.

All actions on moving the slider window or its margins are realized by "drag and drop" actions on the slider.

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There are also eight types of supplementary additional navigation buttons (Figure 29):

- One straight line and one left arrow ("|<") – displays the first ECG recording available;
- Three left arrows ("<<<") – displays an ECG recorded previous day (24h prior);
- Two left arrows ("<<") – displays an ECG recorded previous hour (1h prior);
- One left arrow ("<")– displays the previous recorded ECG (30 sec prior);
- One right arrow (">") – displays the next recorded ECG (after 30 sec);
- Two right arrows (">>") – displays an ECG recorded next hour (1h after);
- Three right arrows (">>>") – displays an ECG recorded next day (24h after); and
- One right arrow and one straight line (">|") – displays the last ECG recording available.

Mark a segment

When you locate a mouse over a point in the ECG signal then the "Tooltip" (in the personal and measurement info part) shows its current location relative to the start measured in seconds of the ECG strip and the measured electrical value of the ECG signal (Figure 36).
You can mark a segment by a single "drag and drop" mouse action on the visualized ECG (Figure 36) and the width of the marked segment is displayed in seconds under "Selection duration".

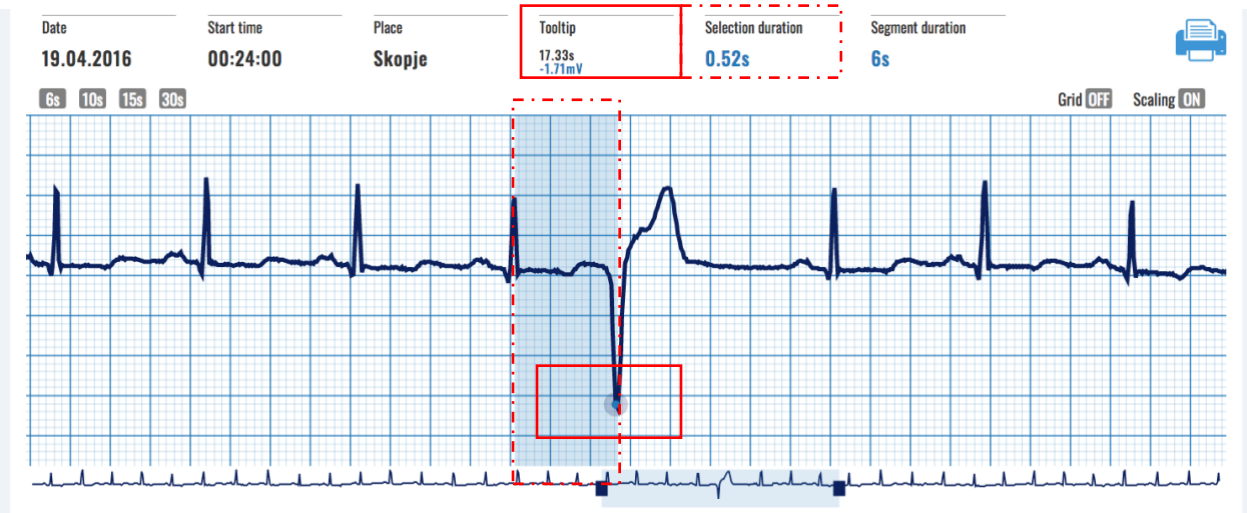

Figure 36: A tooltip under the mouse pointer (showing the value -1.71mV at 17.33 sec relative to the start) and marked segment (with length of 0.52sec between the ventricular beat and preceding normal beat).

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4.4. Dashboard

Clicking the "Dashboard" menu option in the application header accesses the dashboard page. It consists of two sections (Figure 37):

- "Calendar Overview"; and
- "Measurement Summary".

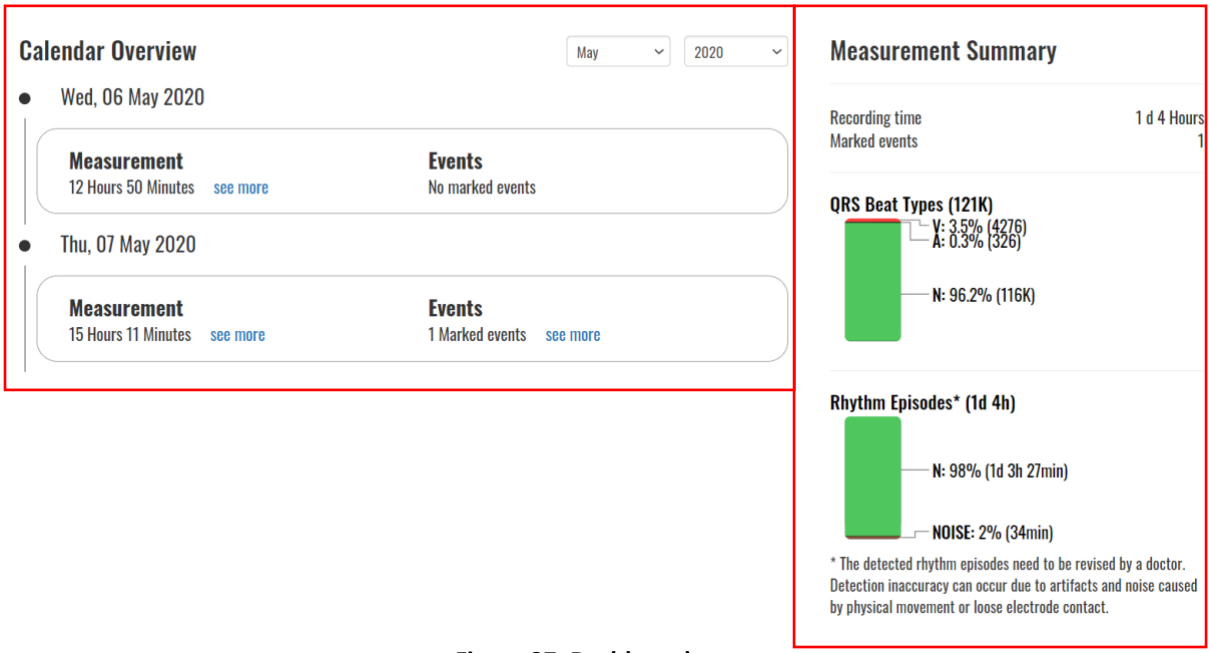
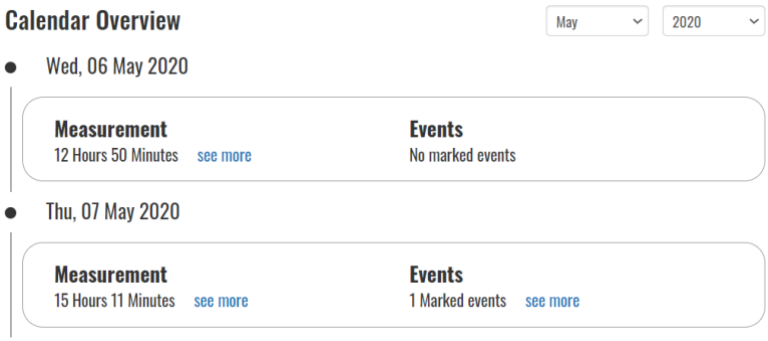


Figure 37: Dashboard page.

Calendar Overview



The calendar overview section (

Figure 38) features a list of all the days within the current month with recordings present. For each day record, there is information on the total measurement time and the number of events. Right next to the "Measurement time", there is "See more" hyperlink which opens the ECG details page with information loaded on the first 30s ECG record in the day. Right next to the "Events" count information there is a "See more" hyperlink that opens the event details page with information loaded on the first event in the day.

The current month is set to the last month for which recordings are present. In the top right corner of the section there are two drop down lists:

- Dropdown list of available years; and
- Dropdown list of available months.

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The dropdown lists serve to choose the month and the year for which the patient wants to see information on. These lists are dynamic, meaning that only the years with present recordings and their corresponding months will be included in the dropdown lists as available selections

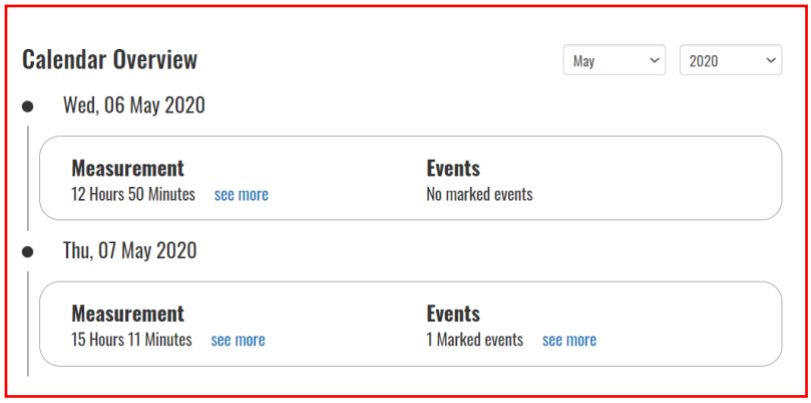
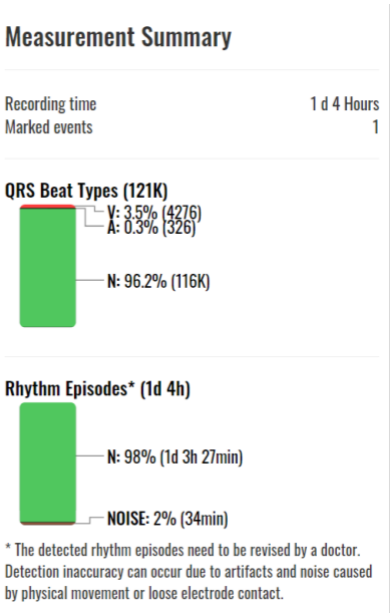


Figure 38: Preview history of measurements

Measurement Summary



The "Measurement summary" section (Figure 39) gives a statistical overview on the current month. It contains information on the sum of recording time ("Recording time") and sum of recorded events ("Marked events"). Below that information, there is a section with information on the percentage of beats ("QRS Beat Types (X)"), where X represents the number of detected beats. Graphically and with percentage are presented the detected Normal beats, PACs with A and PVCs with V.

If there are any detected arrhythmia episodes they will be listed below as "Rhythm Episodes* (Y)", where Y represents the total amount of detected such rhythm episodes. Graphically and with percentage are presented the detected rhythm episodes.

NOTE: * The detected rhythm episodes need to be revised by a doctor. Detection inaccuracy can occur due to artefacts and noise caused by physical movement or loose electrode contact.

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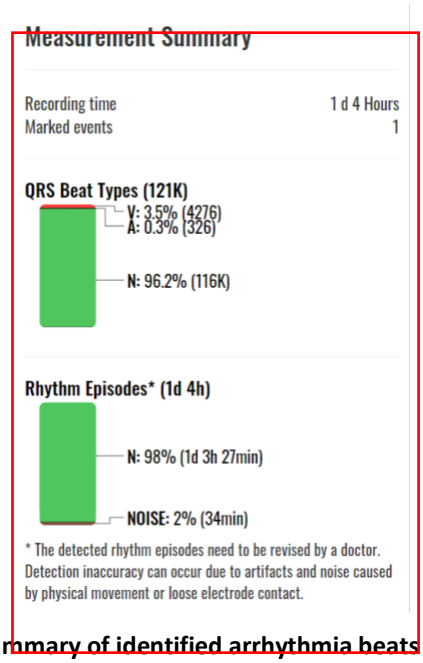

Figure 39: Summary of identified arrhythmia beats and sequences

Browse a particular ECG strip

Within a given measurement you can list 30 sec ECG strips (Figure 40) accessing via the "See more" link provided at the "Dashboard" screen under the "Measurement" section (

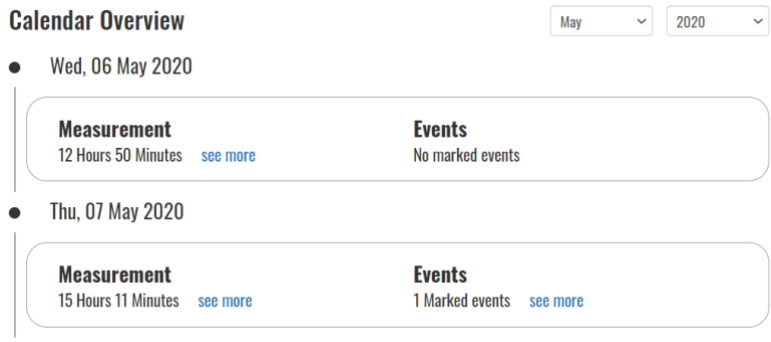

Figure 38).

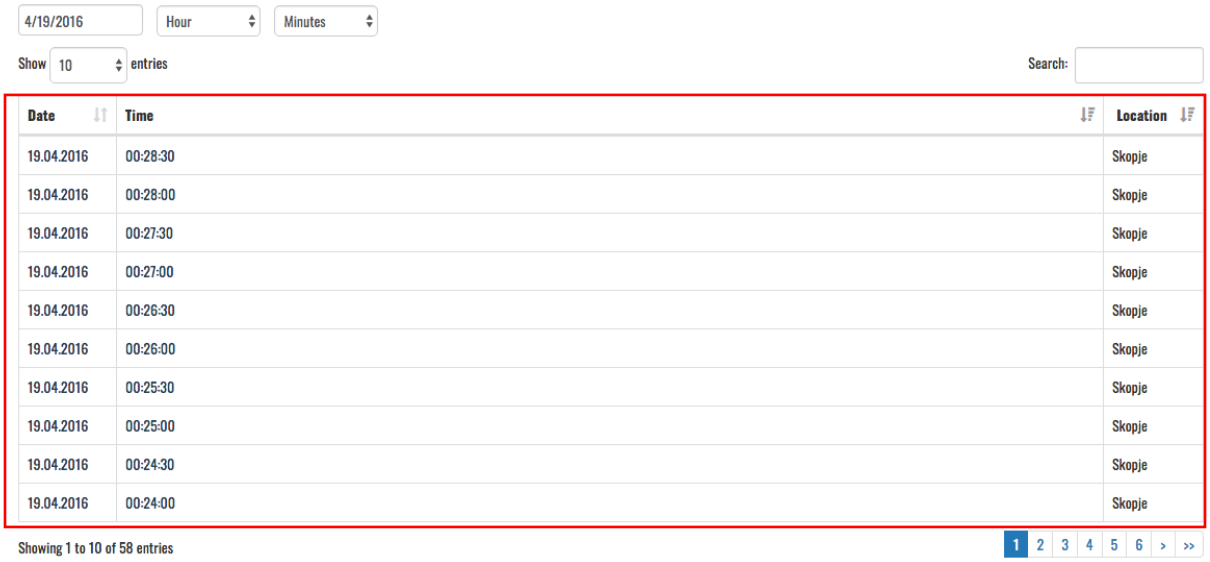

Figure 40: A list of 30 sec ECG strips in the corresponding measurement.

The top header contains three fields that define the date/time for the list of entries to be displayed. By clicking the leftmost field, you can select a "Date" (Figure 41). The displayed calendar enables you clicking a particular date on displayed list, and also move left to the previous month or move right to the next month.

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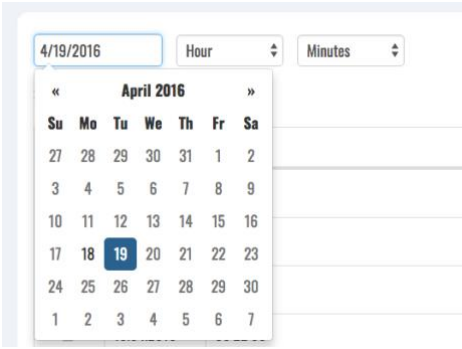

Figure 41: Date time selector.

In addition to selection of a date, you can choose a particular "Hour" or "Minute" by clicking on a corresponding value on displayed drop-down menus.
At the right side of this row there is a "Search" field where you can enter a particular time and activate to display only a selection that satisfies the search criteria.
The list is in a form of a table, where each row displays corresponding data and time stamps. By default, the first 10 entries are listed. You can change the number of displayed entries by clicking on a value on a drop-down list next to "Show entries" (Figure 42). The default value is 10, and it can be changed to 20, 50, 100, or 500 entries.

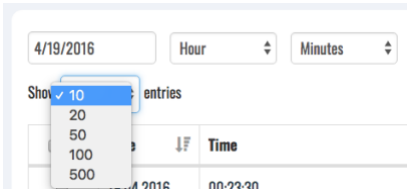

Figure 42: Selecting number of entries to be displayed.

Below the list on the left side there is an information message that shows which entries are displayed in the list.
Navigation between pages can be realized by a navigation tools (Figure 43) found on the right side below the list. You can choose a particular page to be displayed, such as current, and several pages prior and after the current page.
There are navigation buttons (Figure 43) for faster navigation between the pages:

- Two left arrows ("<<") – displays the first recorded 30 sec ECG strip;
- One left arrow ("<") – displays the previous 30 sec ECG strip;
- One right arrow (">") – displays the next 30 sec ECG strip; and
- Two right arrows (">>") – displays the last recorded 30 sec ECG strip.

Figure 43: Navigation tools.

To monitor a particular 30 sec ECG strip, you can click on the corresponding row in the measurement table (Figure 40). Then the monitoring page is displayed (Figure 23) and you can use the explained monitoring tools.

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Browse Events

The list of all events (Figure 44) for the patient is in a form of a table accessed via the "See more" link provided in the "Events" section on "Dashboard" screen. Each row holds information on a single event such as "Date", "Time", "Activity" and "Feeling" during recorded event.

The manipulation with the list of events is similar to the list of measurements, which is explained in the previous section.

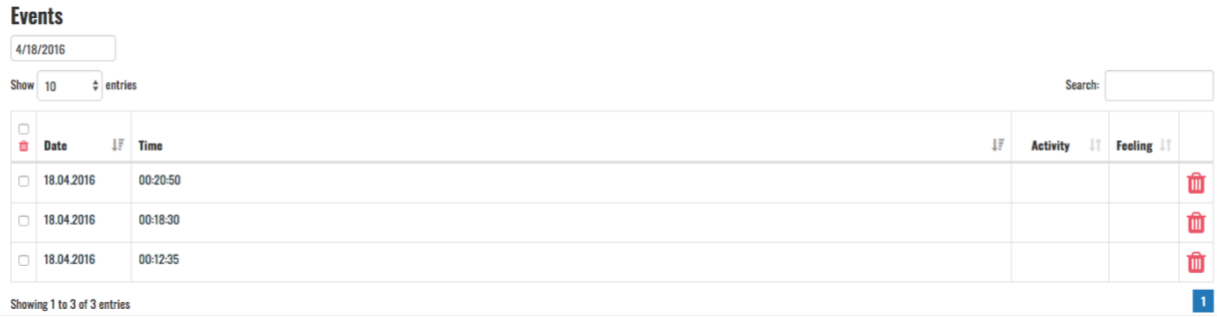

Figure 44: Listing of recorded events.

The user can choose to delete multiple events by clicking on the icon in the header of the select checkbox column, both the selection box and then the "Trash" icon, in that order. This way all events visible will be marked for deletion and the action will require confirmation.

The table can be traversed with the navigation button in the bottom right corner of the table. If there is one page to be displayed, then there is no possibility to navigate through events, since all events are enlisted in the table (Figure 44).

At the end of each row there is a "Trash" icon used to delete the event. An event can be deleted separately by clicking on the "Trash" icon in the corresponding row of the event of by selecting multiple events and clicking on the "Trash" icon above the column containing checkboxes. Before an event is deleted the system is asking for the users confirmation of the action (Figure 45).

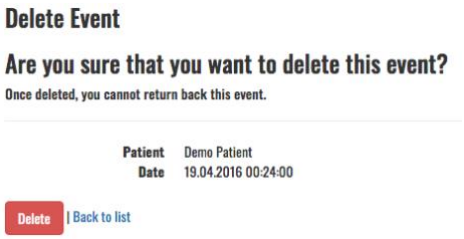

Figure 45: Delete event confirmation.

4.5. Events

An event is recorded or defined by a patient in the case of palpitation or any other symptom the patient is feeling during the measurement. Since it takes some time to mark an event, the application displays usually 30 seconds prior the marking activity and 30 seconds after, so the doctor can analyse better what happened within the marked period.

View Events

To view an event, click on an "Event" from the event's page (Figure 44). The custom header (Figure 46) contains information about the patient and recorded ECG such as date, time, place, activity, feeling and sensor position. There is a "Printing" icon in the right corner of the custom header that opens a printing dialog for the event.

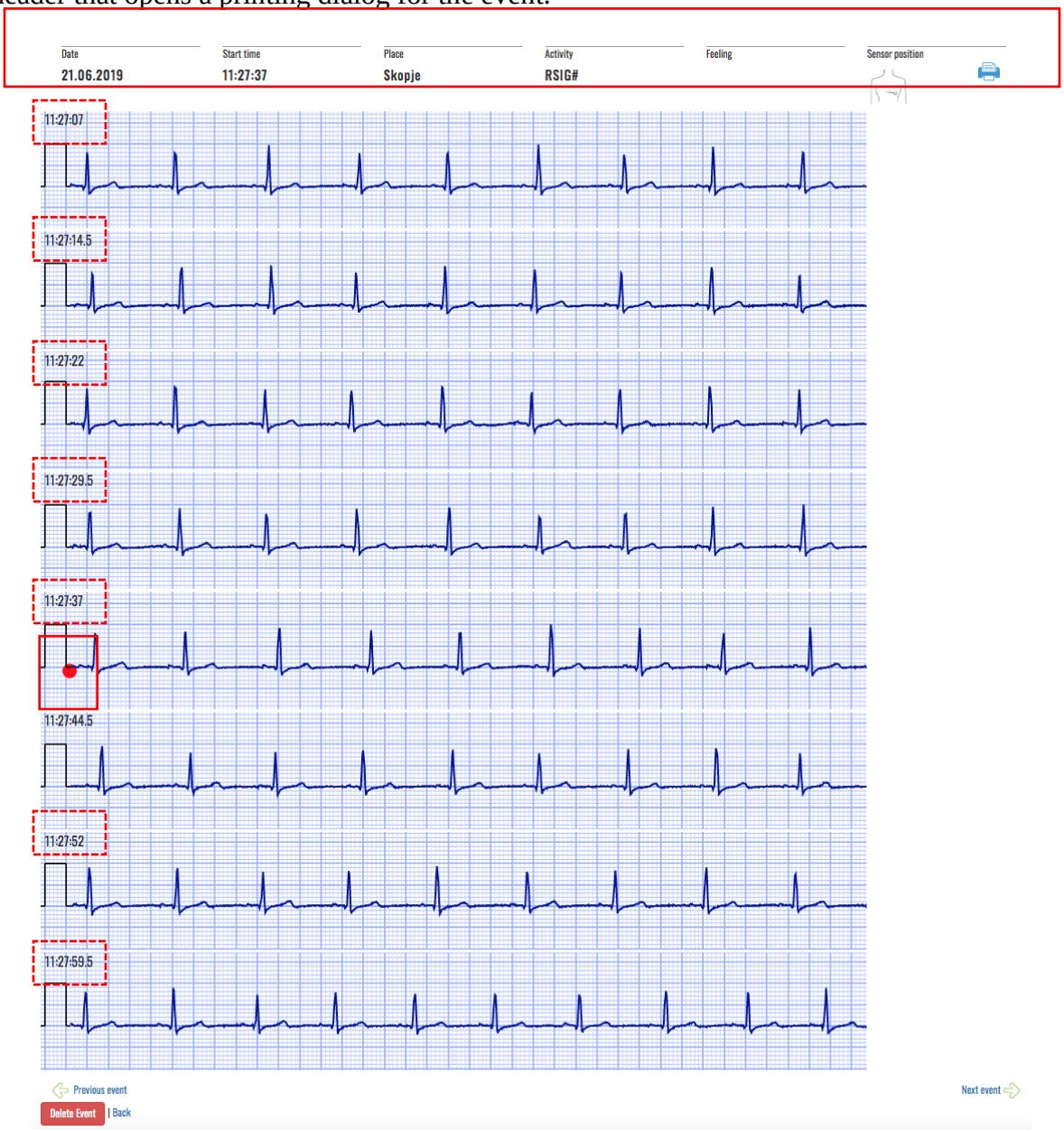

Figure 46: Event details.

The event record is one-minute long. The record contains the ECG signal 30s prior to the marked event timestamp and 30s after the event timestamp. The event timestamp (Figure 46) is marked by a red point in the beginning of the ECG row. In the beginning of each row there is a timestamp printed (Figure 46 dashed line marking).

Navigate Events

Below the ECG strips, there are navigation buttons (Figure 47) that traverse through the patient's events (left arrow and text "Previous event" to display the previous event, and right arrow and text "Next event" to display the next event). Below is a hyperlink "Back" that brings the user back to the list of all events and a "Delete Event" button that allows deletion of the select event with a previous confirmation of the actions (Figure 45).

Figure 47: Navigation through recorded events.

Print and share an event

To print an event, you need to click on the "Printer" icon. Then the operating system message appears asking you to choose a printer output

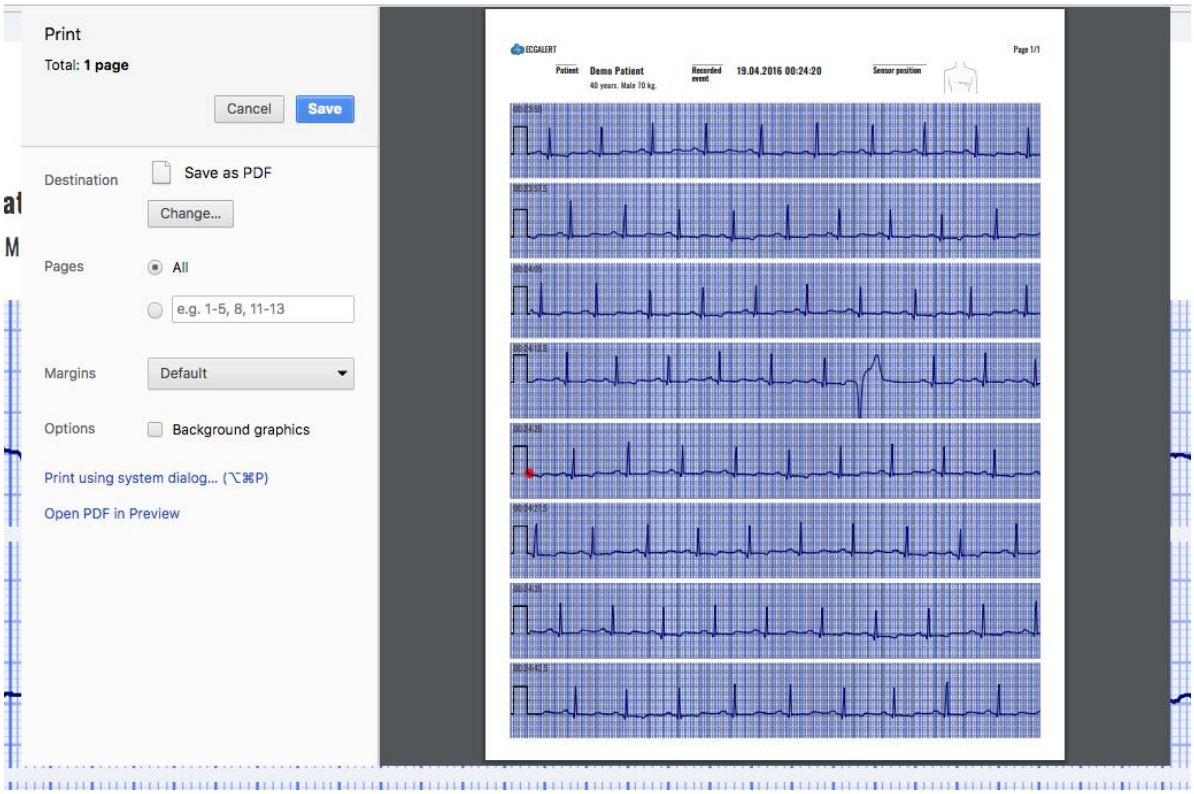

Figure 48).

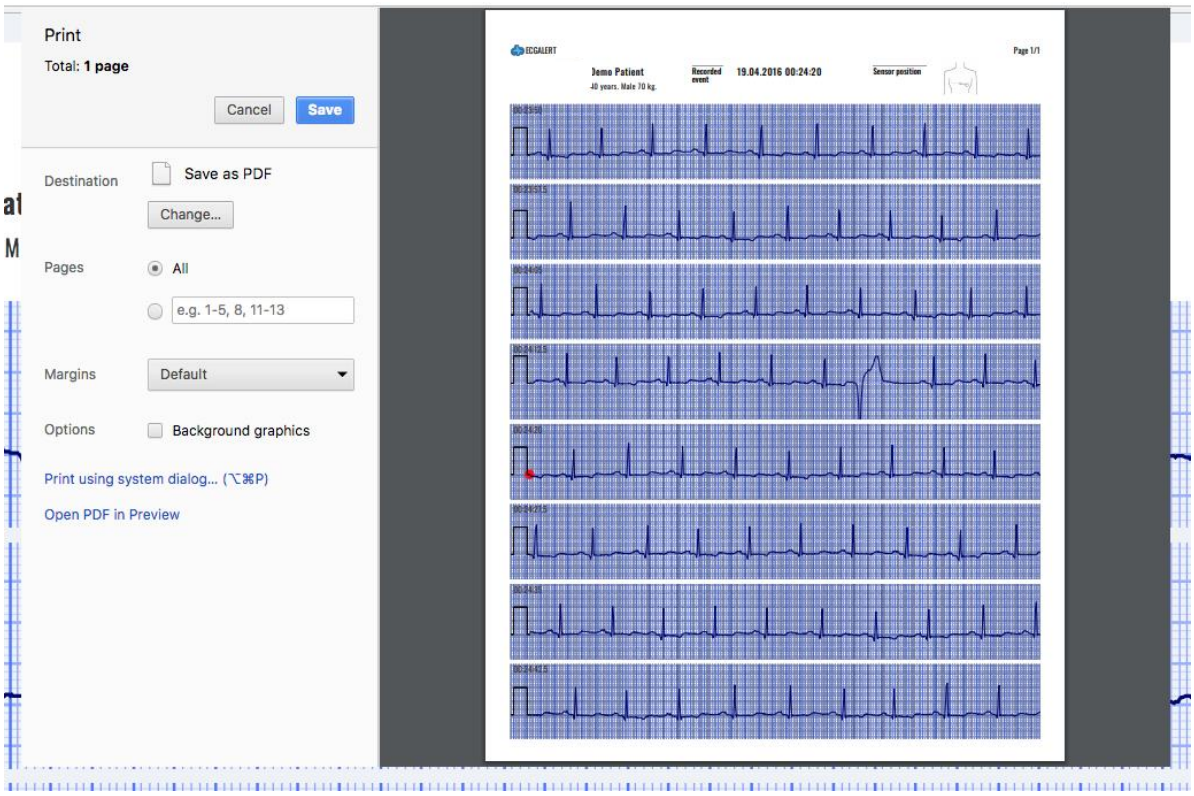

Figure 48: Choose a printer output system message.

Printed event document

You can save it as a pdf file on a selected location on your computing device and then use it for your own purposes, such as send by e-mail or other communication channel.

NOTE: Be careful when sending the pdf file, since it contains personal and medical information (Figure 49).

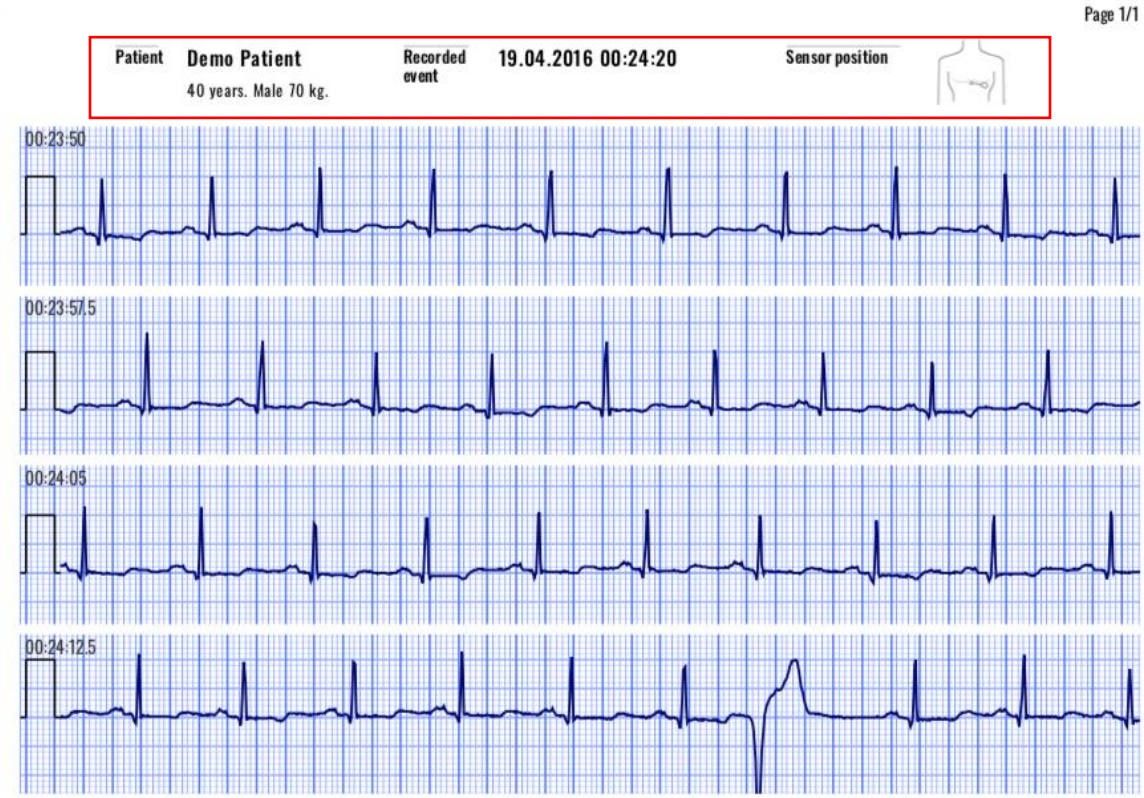

Figure 49: A printed pdf contains personal related information.

Each printed document contains consecutive rows of 7.5 sec ECG strips. One page can contain up to 8 rows, which correspond to 60 seconds event. If the event is defined to be longer, such as 2 or 4 minutes, then the printed pdf will contain 2 or 4 pages.

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4.6. File management

Upload Files

The "Upload files" section (Figure 50) can be accessed via the upload menu option in the application header.

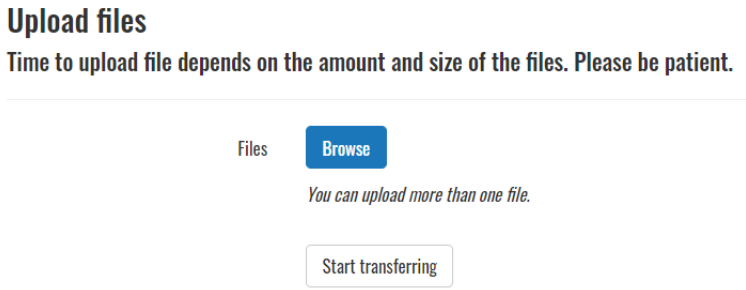

Figure 50: Upload file form.

Upon clicking the "Browse" button, a file browser dialog is opened (Figure 51). You can choose multiple .ecg or .s2 files for upload.

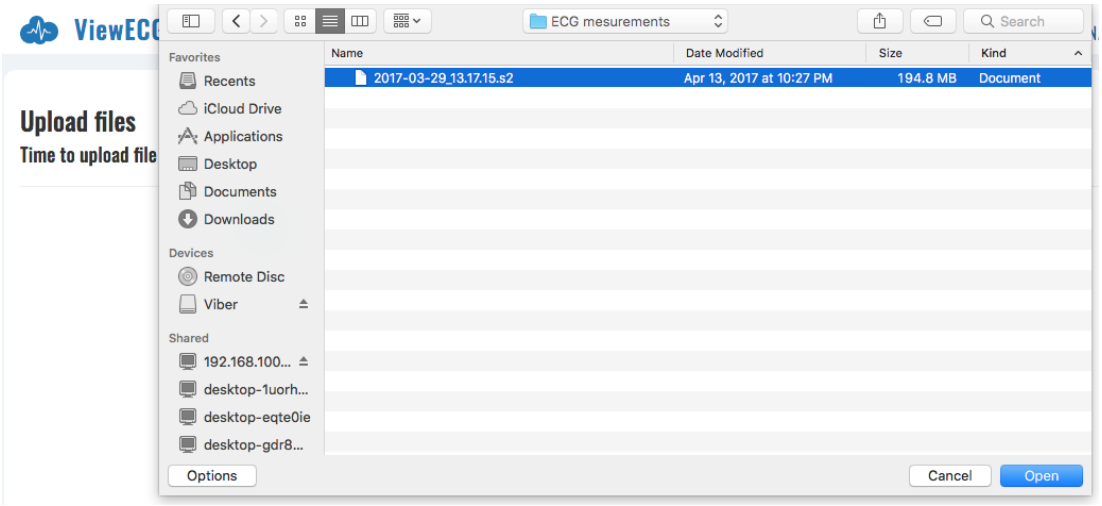

Figure 51: File browsing dialog form to select an ECG or S2 file for upload.

After selecting the file or files you need to click on "Start transferring" button for the upload to begin (Figure 52).

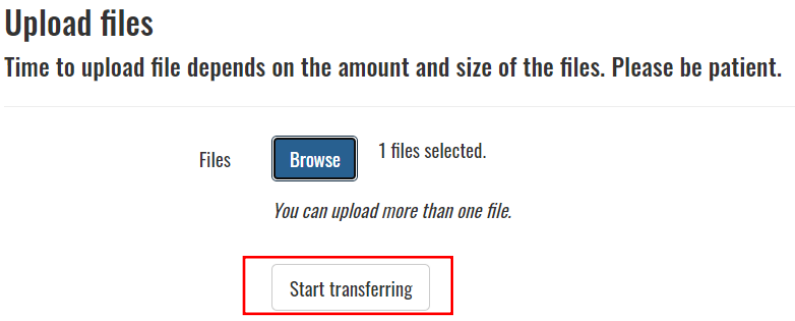

Figure 52: One selected file and ready for transfering.

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System messaging

After selecting the file/s and initiating the transfer, the system will notify you with a file upload in progress status. Once you upload the file a system message is displayed in the warning icon that the file is uploaded and its processing has started (Figure 53).

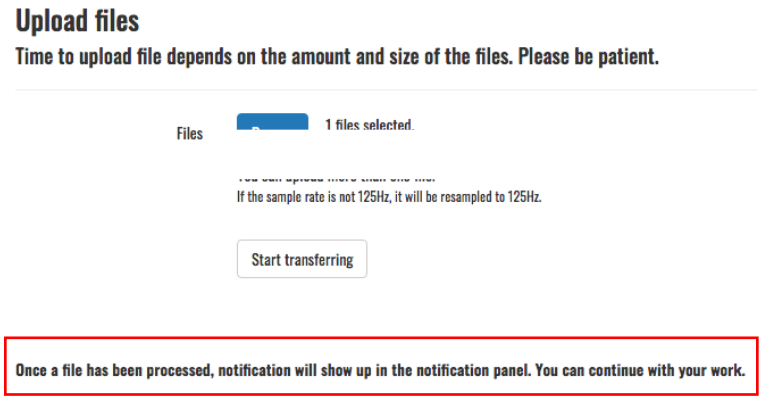

Figure 53: Successful upload and pre-processing status notification.

Another warning message will appear in the "Notification" header section when the file is processed and ready for monitoring (Figure 54).

Figure 54: Successful processing status notification.

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4.7. Settings

You can access the settings drop down menu by clicking on the "Settings" icon located in the application header. The available menu options include "Profile", "Sensors", "Subscriptions", "Invoices" and "Log Off" (Figure 55). You can select the corresponding menu option by clicking on it.

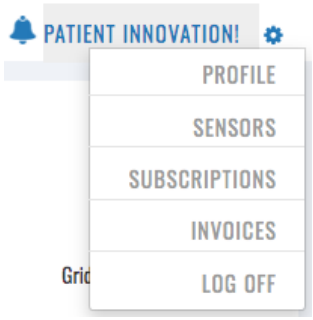

Figure 55: Settings menu.

Profile

The user can adjust the profile content and change account details on a form with a multiple user information fields (Figure 56), including first and last names, gender, date of birth, weight, height, presence of pacemaker, indications, medications, address, city, post code, country, phone number, username (email) and password, code, and language. The option for upload or deletion of personal photo is optional. The displayed code is for information purpose only, and it is allocated by the system.

After the changes, you must click the "Change password" button for the changes to be saved. Some changes will only take effect after the user has logged out and logged in.

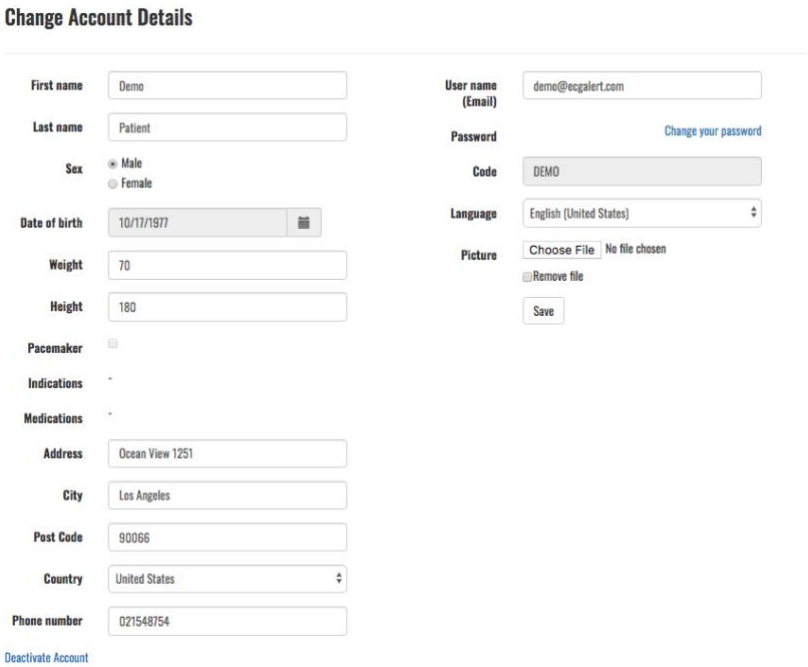

Figure 56: Change account details form.

By clicking on "Change your password" link you are transferred to a corresponding page that allows you change the password (Figure 57). Note that this activity will use you email address and sensitive information to confirm your password change will be sent to your email.

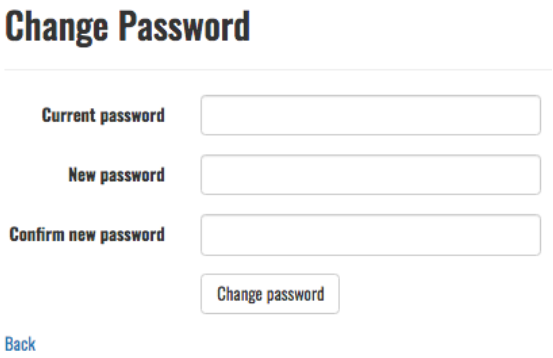

Figure 57: Change password form.

You can deactivate the account by clicking on "Deactivate account". Note that this will delete all personal information and your recordings and you will not be able to reactivate the user account once again. Prior to account deletion, the system will require your confirmation (Figure 58).

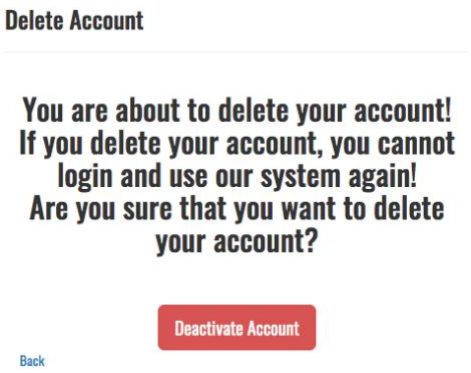

Figure 58: Delete account confirmation.

Sensors page

The user can adjust the information about used sensors via the "Sensors" option on the drop-down "Settings" menu. The details about a specific sensor are accessed by clicking the "Details" button with the associated device (Figure 59). Note that more than one sensor can be used within the same application. The page contains the ordinary navigation options for searching through the sensor list, enlisting more devices together and navigating through pages if any.

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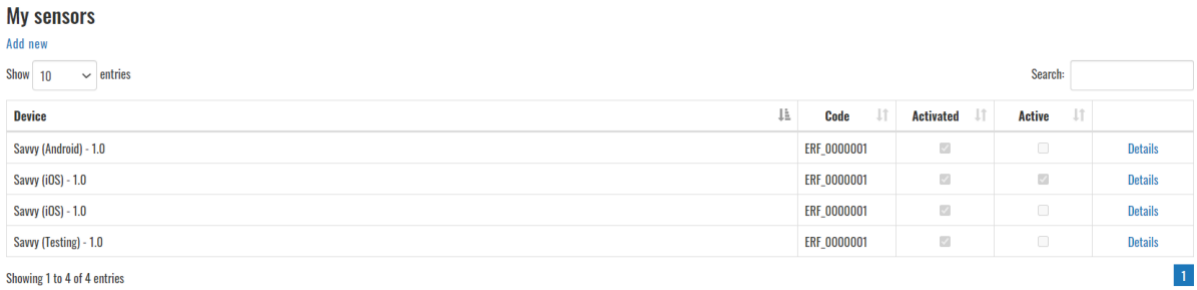

Figure 59: Setting sensors page.

Each device used has the following information: device version, code, description, password code, sample rate, active and activated statuses, date of activation and adding, device being archived or not (Figure 60). The "Back to list" button navigates to the list of all sensors.

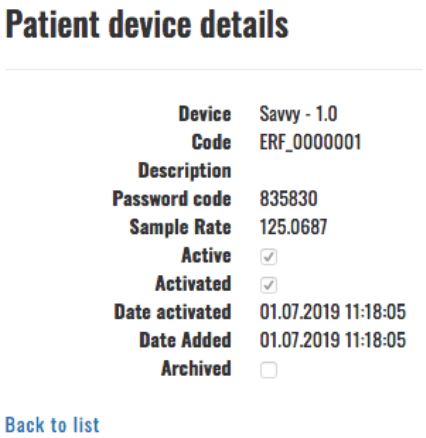

Figure 60: Sensor device details.

To add a new device, click on the "Add new" button and you will be navigated to a page where you can select your new device (Figure 61).

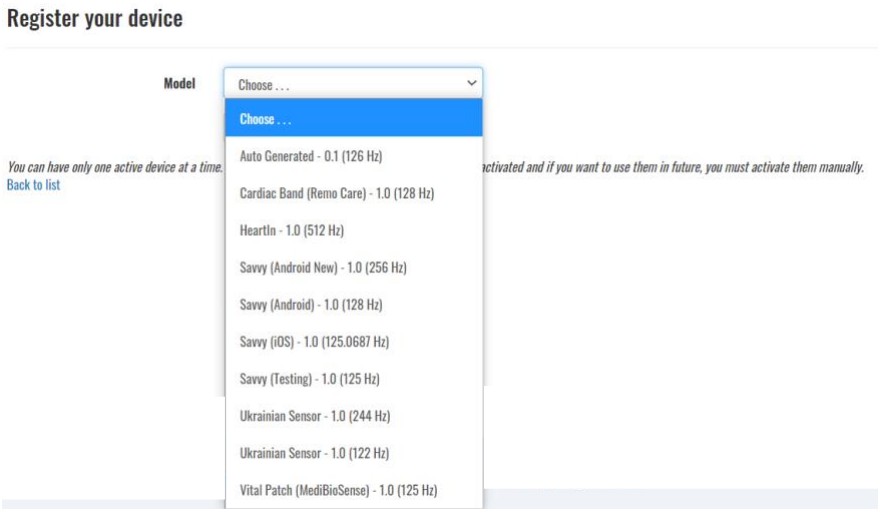

Figure 61: New device.

Subscriptions

"My subscriptions" page shows all subscription plans associated with your account. The details contain the type of subscription, start and end date, active status and the available invoice (Figure 62).

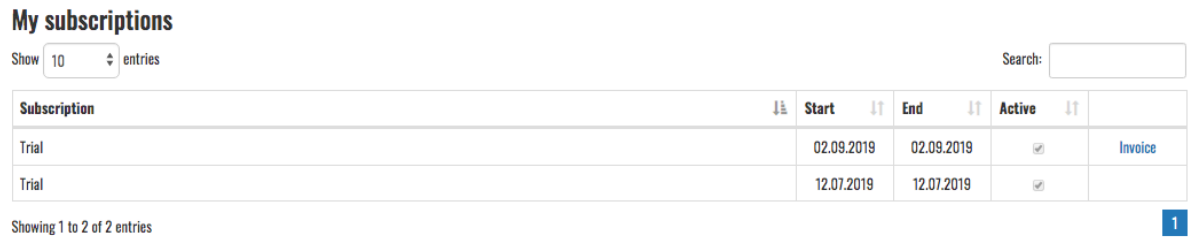

Figure 62: Subscription details.

Invoices

"My invoices" page contains all your invoices and related details. The invoice number, year, name, status, date, due date, amount as well as all details in printable version are available for each purchased subscription plan (Figure 63).

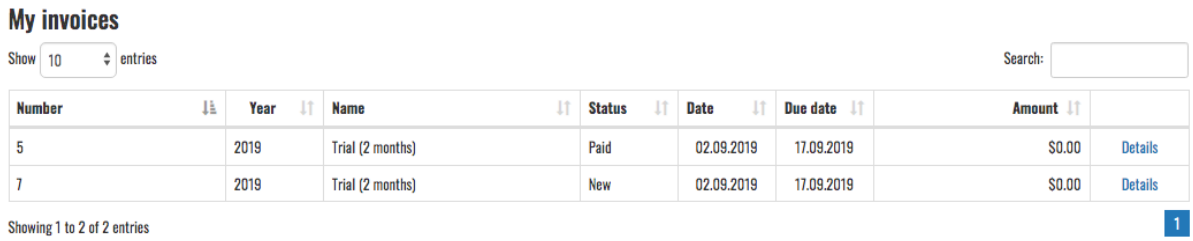

Figure 63: Invoices details.

When clicks on "Details" link on each listed invoice you are navigated to your invoice. The invoice contains details about the payer and the company receiving the payment as well as invoice items and payment amount (Figure 64).

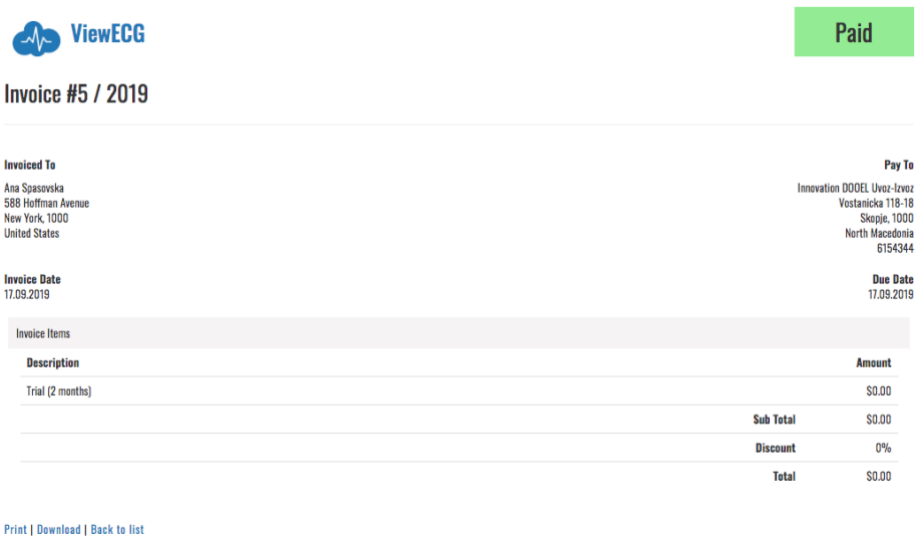

Figure 64: Invoice.

Logging OFF

To log off from the application the user needs to select the corresponding menu option, "Log off" under "Settings".

If the user is not logged off, then when you start the application, it remembers the last login and continues to work with the same user. If the user is logged off, then on the next start of the application, the user needs to log in once again by providing a valid registered username and password combination (Figure 12).

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4.8. Ticketing system

You can access the ticketing system by clicking the Support link on the bottom of each page. This gives you the opportunity to submit any issues or questions related to our product and services.

Technical support

"Technical support" page contains all your tickets and the option to create a ticket in case you don't find a solution to your issue in the pre-defined questions and answers (Figure 65).

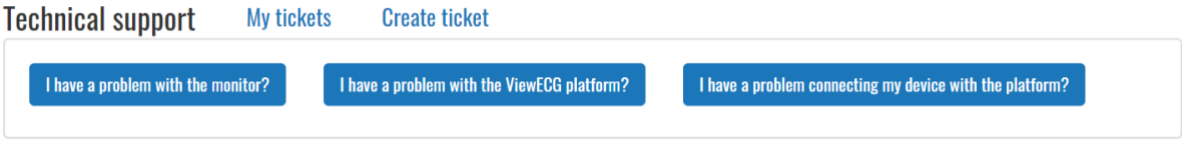

Figure 65: Technical support.

My tickets

"Support tickets" page gives you a preview of the tickets that you have submitted to our team. Each ticket is noted with the day and time it is submitted, unique code, subject of the issue, status and a button to see more details about it (Figure 66). The tickets can have one of the following statuses:

- New (initial status submitted by a user),
- Reassigned (reassigned to a different sector for resolution),
- In progress (status obtained when the issue is being worked on),
- Answered (an answer is being send to the user),
- Close (issue is closed either by the user or the organization) and
- Additional info (status when required additional info).

Figure 66: My tickets.

Ticket details

"Ticket details" page shows you the details of each ticket that you have created (Figure 67). On this page you can see the conversation between you and our support team and the answers we have provided to your questions. You are also able to message us or close the ticket when you feel satisfied with the resolution of the issue.

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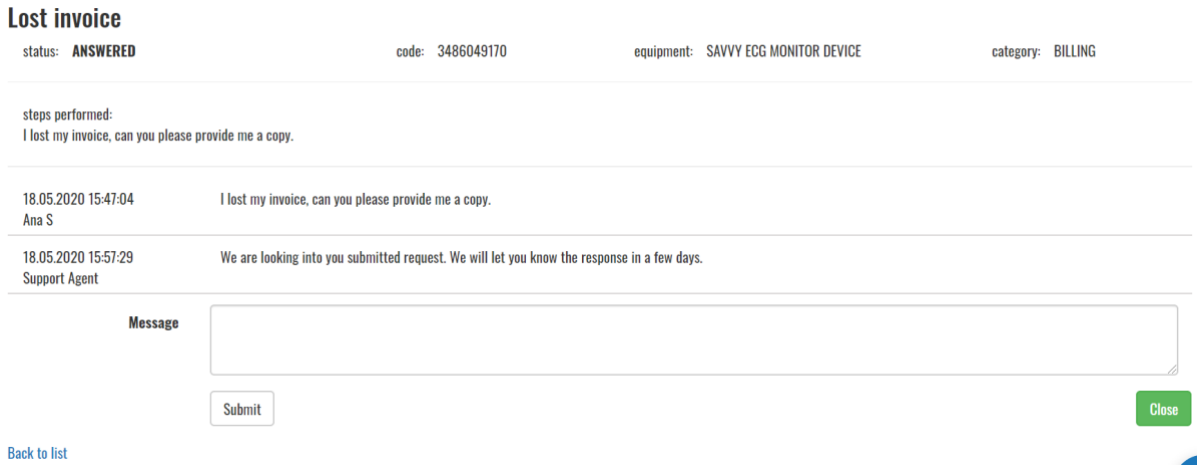

Figure 67: Ticket details.

Create a ticket

"Create a ticket" page gives you the ability to create and submit a ticket to our support team (Figure 68). For a ticket you need to select the equipment the issue is related to:

- Savvy ECG monitoring device
- ViewECG iOS application
- ViewECG Web application

You need to select the category your submission is related to:

- Info
- Billing
- Technical support

Then you need to describe how the problem has occurred and described the problem and details containing the expected and obtained results.

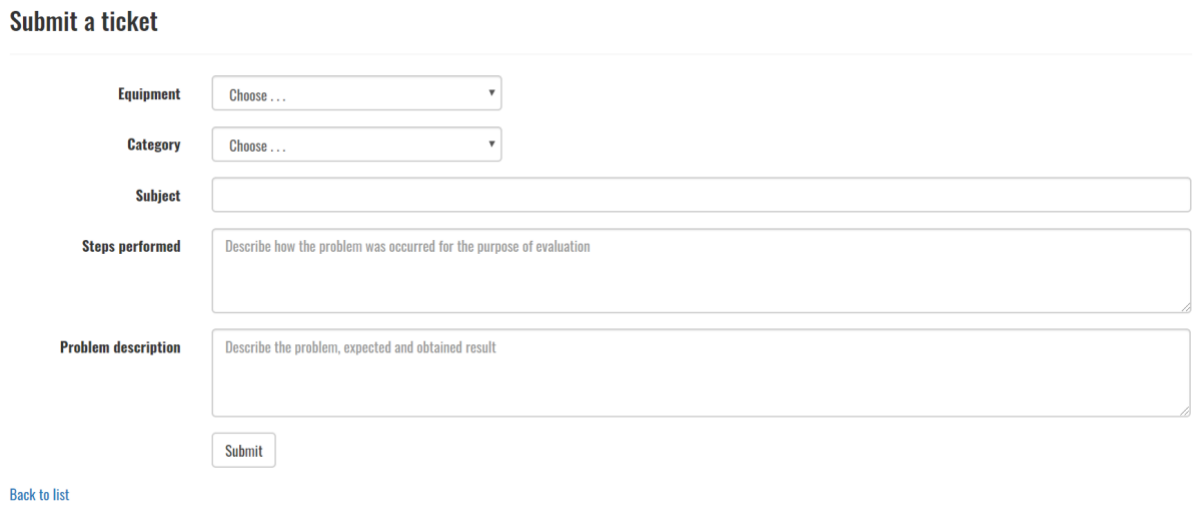

Figure 68: Create a ticket.

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5. Maintenance

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

5.1. Maintenance of the ViewECG application

Maintenance of the ViewECG mobile application

User must keep the digital device environment as specified in the requirements:

- Adequate storage space is maintained on the digital device;
- Internet connection on the digital device is established as required;
- Bluetooth radio is enabled on the digital device;
- The digital device is turned on while recording, while the screen can be off; and
- Battery on the digital device should be kept charged enough to support long measurements or the digital device should be placed on a charger.

Maintenance of the ViewECG web application

There is no need for user maintenance as maintenance is done automatically by the software agent. The sole responsibility of the user is to keep their subscription to ViewECG up to date. All maintenance measures for the computing device with Internet connection apply.

5.2. Maintenance of the ECG sensor

Maintenance and disposal instructions of the ECG sensor are available in the Savvy user manual.

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6. Safety

6.1. General warnings

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

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

WARNING! The ViewECG 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! Measurements obtained by ViewECG medical device are intended for use by healthcare professionals only.

WARNING! The user must keep the smartphone with running mobile application in his/her vicinity during measurements. The Savvy sensor must be kept in the Bluetooth range of the smartphone (approximately 10 meters, but can vary depending on the smartphone 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.

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6.2. Cautions

DO NOT use ViewECG if you require hospital monitoring of a life-threatening arrhythmia.

DO NOT use ViewECG before carefully reading the instructions for use in the user manual. You should be able to operate smart phones or tablets and understand the user manual. If this is not the case, please only use ViewECG with the assistance of a qualified caregiver who fulfils the above mentioned basic requirements.

DO install the recommended mobile and desktop operating system, as specified in the technical specifications, before attempting to use ViewECG.

DO make sure that Bluetooth is functioning on your device and that you have a stable Internet connection as ViewECG may stop functioning properly. See the troubleshooting section for further instructions.

Apply safety measures recommended with Savvy medical device.

Apply safety measures with associated computing devices and accessories.

DO keep your Savvy heart monitor in your vicinity during measurements. The acceptable Bluetooth range is up to 10 meters but can depend on the device and the surrounding. In case you exceed this distance, simply move the equipment within range and the connection will be automatically re-established.

DO consult a healthcare professional about the measurements obtained with ViewECG.

DO visually check the quality of the ECG signal from time to time.

DO contact your healthcare professional as an immediate response to alerting notifications.

DO contact the manufacturer for any malfunction or questionable behaviour of the medical device.

DO contact the manufacturer with any unclear instructions.

DO make sure to secure your device to an adequate level using the security features found in settings. Your digital device can represent a weak spot in the security chain of the system.

Innovation Technology makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision-making.

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6.3. Compliance

This device complies with the following normative documents within CE Mark:

- MDD 93/42/EEC Medical devices directive (EU Council directive)
- IEC 60601-1-6:2010 Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability
- IEC 60601-2-47:2001 Medical electrical equipment — Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
- EN ISO 62304:2006 Medical device software — Software life-cycle processes
- EN ISO 14971:2012 Medical devices — Application of risk management to medical device
- EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- IEC/TR 80002-1:2019 Medical device software – Part 1: Guidance on application of ISO 14971 to medical device software
- ISO/TR 80002-2:2017 Medical device software – Part 2: Validation of software for medical device quality systems
- ANSI/AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
- IEC 62366-1:2015: Medical devices. Application of usability engineering to medical devices
- A full declaration of conformity (DoC) may be consulted here.

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6.4. Troubleshooting

Problem	**Solution**
I can't connect my device to the Savvy heart monitor.	Turn on the Bluetooth on the mobile device. Charge the monitor battery. Move the Savvy monitor into the vicinity of the mobile device.
The ECG signal does not look good.	Replace the electrodes and/or place the electrodes on another position.
The ECG graph has disappeared.	Move the Savvy monitor into the vicinity of the mobile device. If the problem persists: turn the Bluetooth radio OFF and then back ON. If the problem persists: exit the ViewECG app and start it again. If the problem persists: Put the Savvy monitor 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.
I forgot my password and I̓ am unable to reset it	To reset your password, go to https://viewecg.com/ and click "Forgot your password?" link below the Password field, enter your email address, and click Submit. Follow the reset instructions in the email. Note, the reset link contained in the email is only active for a 10 min period.

Table 2: Problems and solutions.

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7. Terms of Use

7.1. Terms & Conditions

General terms of use

1. The device is intended to monitor cardiac activity in everyday life in accordance with Directive 93/42/EEC on medical devices with a valid amendment classified as an active non-invasive medical device labeled IIa. As a class IIa device, ViewECG is intended to allow direct visualization or monitoring of cardiac performance and to diagnose a cardiac performance.
ViewECG is not intended for a treatment in accordance with the rules of the medical profession.
In the event that the user feels uncomfortable with regard to cardiac function, they must urgently seek medical assistance, regardless of the conditions shown by the medical device ViewECG.
2. ViewECG is a system for monitoring cardiac activity. The Savvy heart monitor is stuck on the chest with electrodes. It then wirelessly connects to a smartphone or tablet, provided it is in the immediate vicinity. The measurements are then transmitted to the ViewECG server and can be viewed by the user or their doctor from any device with an Internet connection.
3. Data transfer is carried out wirelessly and it required that your device has a good Bluetooth and Internet connection.
4. The price of ViewECG is determined by Innovation Technologies, who reserves the right to change the price at any time.
5. With the purchase of the device every customer obtains a user manual, general terms, pin code and a warranty statement.
6. When you register an account with ViewECG it is required that you accept the general terms and conditions of use.
7. In accordance with the provisions of the protection of personal data, with the acceptance of the medical device 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.
8. When buyer pays the invoice, he guarantees that the device is intended solely for their personal or pin code holders use and is not transferable to third parties.

Terms & Conditions

These Terms of Use describe rules for visitors of the viewecg.com website (the "**Site**"). This website is owned and operated by Innovation Technologies ("**we**" or "**us**"). The Effective Date of this Terms of Service is January 31, 2018.
These terms of service ("**Terms**") cover your use and access to the services, client software and websites ("**Services**"), as we grant you the right to use our software applications ("**Software**," "**App**"), subject to the terms and conditions of use ("**Terms of Service**") set forth below. The term "**You**" refers to the person visiting the Site and registered as a user. By accessing the Service, it means you acknowledge that you have read, understood and agree to be bound by the Terms of Use, including the privacy policy (together the "**Terms**"). If you do not wish to be bound by these Terms of Service, you may not access or use the Service.

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Service description

The service in this Site is intended to record, display, visualize, store, transmit and interpret electrocardiograms ("**ecg data**"). You, as the user of the service, are responsible for the ECG measurements and data recorded and stored by the service. Your ECG recordings are subject to multiple factors related to your health and activities and for which you are responsible, such as does the measurement correspond to resting heart position (laying in a bed), proper position of the ECG sensor, stickiness of the ECG electrodes, elimination of environmental noise that may corrupt recorded data, establishing proper communication between devices etc. Due to these factors, the service may not set up a proper diagnosis of any heart condition; it will just indicate a possible arrhythmia. It will not automatically warn healthcare professionals or patients to potentially serious heart conditions or abnormal arrhythmias. The service is intended for continuous monitoring and we do not guarantee that the measurement reflects a proper measurement and communication setup, such as enabling a communication between the mobile application and our server due to third party telecommunication providers, or if this communication is interrupted by environmental noise. The user is directly responsible to ensure that telecommunication links work properly and data is transferred on time.

We do not guarantee a response by any physician(s) to messages posted or medical events reported through the service. You should always talk to your healthcare professional for diagnosis and treatment. Although we may enable you to use an optional ECG interpretation service or connect your account to a healthcare provider through our service, we do not automatically review, monitor, evaluate, or analyze any information generated from the service. It is your responsibility to present your medical data to your physician for proper analysis and diagnosis.

Jurisdiction

Unless you are a consumer located in a jurisdiction that prohibits the exclusive use of arbitration for dispute resolution, these Terms provide that all disputes between you and us will be resolved by binding arbitration. You agree to give up your right to go to court to assert or defend your rights under this contract, except for matters that may be taken to small claims court. Your rights will be determined by a neutral arbitrator and not a judge or jury, and your claims cannot be brought as a class action. You may only resolve disputes with us on an individual basis, and may not bring a claim as a plaintiff or a class member in a class, consolidated, or representative action. Class actions, private attorney general actions, and consolidation with other arbitrations aren't allowed.

Use of the Service

The Service is intended only to allow you to upload, view, visualize, share data with your healthcare professional, and use certain data pertaining to you as made available by the Service. You may not access or use the Service for any other purpose. You may use the Service, including any data presented to you on or by the Service, or otherwise hosted or stored by us for you, only for lawful and appropriate purposes on your own behalf, and subject to your full compliance with these Terms and any other guidelines and policies applicable to the Service which we may post from time to time.

Service Information

The materials and information on this website are for your indicative information only. Information you read on this website cannot replace the relationship that you have with your healthcare professional. It represents only an indication of possible detected beats and their classification. We do not practice medicine or provide medical services or advice and the

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This website may contain information that is not approved and cleared for use in your country of residence.

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To access most features of the Service, you must register for an account and agree with the Terms. When you use our Services, you provide us messages, images, data, text, location information, and other types of information ("**User Content**"), such as your name, email, and biometric medical data etc. You agree that the information you provide to us is accurate and that you will keep it accurate and up-to-date at all times. When you register, you will be asked to provide a password. We encourage you to use a distinct and non-obvious username and password combination that is different from what you use for other services.
Your Information is yours and we have taken all necessary measures to keep your data safe. These Terms don't give us any rights to Your User content except for the limited rights that enable us to offer the Services.
We need your permission to do things like hosting Your User content, backing it up, and sharing it when you ask us to. Our Services also provide you with features that may require our systems to access, store and scan Your User content. Once You give us permission to do those things, and this permission extends to trusted third parties we work with. Our Services let you share Your User content with others, so please think carefully about when you share.
You retain the copyrights, including any moral rights, and any other proprietary rights that you may hold in the User Content that you post to the Service; provided that if you choose to link your account to our service or information systems offered by your healthcare provider, any data provided to your healthcare provider may become part of your health record, and that copy of such data may be owned and/or controlled by your healthcare provider under applicable law.
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- cause us to violate any law or regulation.

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By posting or sharing User Content with other users of the Service, or connecting your account to your healthcare provider through our service, you grant those users and/or healthcare providers a non-exclusive license to access and use that User Content as permitted by these Terms and the functionality of the Service.

User Content Disclaimer

We are under no obligation to edit or control User Content that you or other users post or publish, and will not be in any way responsible or liable for User Content. We may, however, at any time and without prior notice, screen, remove, edit, or block any User Content that in our sole judgment violates these Terms or is otherwise objectionable. You understand that when using the Service you will be exposed to User Content from a variety of sources and acknowledge that User Content may be inaccurate, offensive, indecent, or objectionable. To the fullest extent allowed under applicable law, you agree to waive, and do waive, any legal or equitable right or remedy you have or may have against us with respect to User Content. We expressly disclaim any and all liability in connection with User Content, to the fullest extent allowed under applicable law. If notified by a user or content owner that User Content allegedly does not conform to these Terms, we may investigate the allegation and determine in our sole discretion whether to remove the User Content, which we reserve the right to do at any time and without notice.

7.3. Eligibility

By agreeing to these Terms, you represent and warrant to us that:

- you are over 14 years and fully responsible for agreeing with the Terms;
- you have not previously been suspended or removed from the Service; and
- your registration and your use of the Service is in compliance with all applicable laws and regulations in your local jurisdiction.

If you are using the Service on behalf of an entity, organization, or company, you represent and warrant that you have the authority to bind that organization to these Terms and you agree to be bound by these Terms on behalf of that organization.

Right to Modify the Services

We retain the right, in our sole discretion, to implement new elements as part of and/or ancillary to the Services, including changes that may affect the previous mode of operation of the Service. We expect that any such modifications will enhance the overall Service, but it is possible that you may not agree with us. We also reserve the right to establish limits to the nature or size of storage available to you, or your continued ability to access or share, Your User content and other data, and impose other limitations at any time, with or without notice.

In connection with any modification of the Services, we may automatically download software updates on your computers and devices from time to time with the intention of improving, enhancing, repairing and/or further developing the Services. We will endeavor to provide you

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with the option of whether or not to install the update; however, in certain circumstances (e.g., security risks), we may require you to install the update to continue accessing the Services. In all cases, you agree to permit us to deliver these updates to you (and you to receive them) as part of your use of the Services.

Your Responsibilities

You are solely responsible for maintaining the confidentiality of your account and password, and you accept responsibility for all activities that occur under your account. If you have reason to believe that your account is no longer secure, then you must immediately notify us at info@innotech.si.

Your account may automatically expire following any period of inactivity associated with your account in excess of twelve (12) consecutive months. You are responsible for maintaining the accuracy, completeness and confidentiality of Your Information, and you will be responsible for all activities that occur under your account, including activities of others to whom you have provided Your Information. We will not be liable for any loss or damage arising from your failure to provide us with accurate information or to keep Your User content secure. If you discover any unauthorized use of Your User content or suspect that anyone may be able to access it, you should immediately change your password and notify our Customer Support team.

Access to the Service, or to certain features of the Service, may require you to pay fees. Before you pay any fees, you will have an opportunity to review and accept the fees that you will be charged. All fees are non-refundable, to the fullest extent permitted under applicable law. If we change the fees for the Service, including by adding additional fees or charges, we will provide you advance notice of those changes. If you do not accept the changes, we may discontinue providing the Service to you. We will charge the payment method you specify at the time of purchase. You authorize us to charge all sums as described in these Terms, for the Service you select, to that payment method. If you pay any fees with a credit card, we may seek pre-authorization of your credit card account prior to your purchase to verify that the credit card is valid and has the necessary funds or credit available to cover your purchase. The Service may include functionality for activating, updating or canceling recurring payments for periodic charges. If you activate or update recurring payments through the Service, you authorize us to periodically charge, on a going-forward basis and until cancellation of either the recurring payments or your account, all accrued sums on or before the payment due date for the accrued sums. If you use the Service to update or cancel any existing authorized one-time or recurring payment, it may take several business days for the update or cancellation to take effect.

You're free to stop using our Services at any time. If you violate any provision of these Terms, your permission from us to use the Service will terminate automatically. In addition, we may in its sole discretion terminate your user account on the Service or suspend or terminate your access to the Service at any time if you violate any provision of these Terms, if we no longer provide any part of the Services or for any other reason, with or without notice. We also reserve the right to modify or discontinue the Service at any time (including by limiting or discontinuing certain features of the Service), temporarily or permanently, without notice to you. To the fullest extent permitted under applicable law, we will have no liability on account of any change to the Service or any suspension or termination of your access to or use of the Service, provided that if we cease to operate the Service and terminates your access to the Service accordingly, then you will be entitled to a pro-rated refund of any prepaid fees that you

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Subject to the restrictions set forth in these Terms, we grant you a limited, non-exclusive, non-transferable, non-sublicensable, revocable license to install and use the App in object code format on devices that you own or control, solely for use with the Services. By downloading or using our app(s), you:

- Acknowledge that the App is licensed, not sold to you; and
- Acknowledge that third party terms and fees may apply to the use and operation of your device in connection with your use of the App, such as your carrier's terms of services, and fees for phone service, data access, or messaging capabilities, and that you are solely responsible for payment of any and all such fees.
- You represent, warrant, and covenant to us that
- You accept our terms of service and you are responsible for all applicable laws and regulations in your local jurisdiction,
- These Terms have been executed and delivered by you and constitute a valid and binding agreement with you, enforceable against you in accordance with their terms;
- If you are using the Service on behalf of another entity, you are an authorized representative of the entity and have the authority and agree to bind the entity to these Terms;
- You will not access or use the Service except as expressly permitted by these Terms and any additional instructions, guidelines or policies issued by us, including those posted in the Service;
- You will access and use the Service in full compliance with applicable law; and
- all of the information, data and other materials provided by you in support of your account registration are accurate and truthful in all respects.

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- Your access to, use of, or alleged use of, the Service;
- Your violation of any portion of these Terms, any representation, warranty, or agreement referenced in these Terms, or any applicable law or regulation;
- Your violation of any third-party right, including any intellectual property right or publicity, confidentiality, other property, or privacy right;
- Any dispute or issue between you and any third party; and
- All claims arising from or alleging fraud, intentional misconduct, criminal acts, or gross negligence committed by you.

To the fullest extent permitted under applicable law, we reserve the right, at our own expense, to assume the exclusive defense and control of any matter otherwise subject to indemnification by you (without limiting your indemnification obligations with respect to that matter), and in that case, you agree to cooperate with our defense of that claim.

Clinical Interpretation Service

Our clinical interpretation service (the "**Clinical Interpretation Service**") is a third- party resource to import, view, and interpret your data. The Clinical Interpretation Service reports back to us any findings in your data, and we make those findings available to you within the Service. By accepting these Terms, you hereby agree to enrollment in the Clinical Interpretation Service, although your use of the Clinical Interpretation Service is optional. You will only be charged for the Clinical Interpretation Services when and if you ask to them. We reserve the right to change the Clinical Interpretation Service providers or discontinue one or more of the Clinical Interpretation Service offerings. Any reports provided by us and any Clinical Interpretation Service do not suggest a diagnosis. The interpreted report is intended as information for you and to be used by your physician to provide proper diagnosis and treatment, taking into account your complete medical history. Diagnosis based on your data can only be accomplished by your physician. It is your responsibility to present your medical data to your physician for proper analysis and diagnosis. We and the Clinical Interpretation Service providers make no guarantees of the accuracy or clinical significance of the interpretation of your data, due to the lack of information about setup of the ECG measurement including all relevant factors, such as position, stickiness of ECG electrodes, body position, or other environmental factors. Please be aware that your physician may disagree with the interpretation of your data. If you decide to use one of the Clinical Interpretation Services, we will share your information when you give permission through the Service.

Due to telemedicine restrictions, your local jurisdiction may restrict your ability to use the Clinical Interpretation Service. Since you are using a mobile device to collect your data, it is your responsibility to ensure the Clinical Interpretation Service is legal according to your local telemedicine laws, and you are especially granting us access and ask for these services.

7.5. Liability

Modifications to these Terms

We reserve the right, at our discretion, to change these Terms on a going-forward basis at any time. Please check these Terms periodically for changes. If a change to these Terms materially

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modifies your rights or obligations, we will notify you of the modified Terms by email to the address you provided in your user profile and/or in a notification in the Service or on our website. Material modifications will be effective upon your acceptance of such modified Terms or upon your continued use of the Service after we send or post our notification of the changes, whichever is earlier. Immaterial modifications are effective upon publication. Disputes arising under these Terms will be resolved in accordance with the version of these Terms that was in effect at the time the dispute arose. Your sole and exclusive remedy if you do not agree with any modification to these Terms is to cancel your account. You may not amend or modify these Terms under any circumstances.

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