ViewECG

Medical Device System
Patient's User Manual

MD

Revision 13 | May 27, 2025

⚠️ READ THIS FIRST

1. First, Read Section 1. Safety Measures.
2. Read Section 6 on Terms of Use.
3. Read Section 4 on how to use the web application.
4. Read Section 5 on maintenance.

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Contents

Abbreviations

Table 1 presents the potential problems and corresponding solutions.

Table 1: Description of abbreviations.

Abbreviation	Description
A beat	Atrial heartbeat
AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
API	Application Programming Interface
ASDNN	Average of 5-minute SDNN
BPM	Beats per Minute
ECG	Electrocardiogram
FDA	Food and Drug Administration
HF	High Frequency
HRV	Heart Rate Variability
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
LBBB	Left Bundle Branch Block
LF	Low Frequency
LF/HF	Ratio between Low Frequency and High Frequency domains
MAC address	Media Access Control address
MDCG	Medical Device Coordination Group Document
MDR	Medical Device Regulation
N beat	Normal heartbeat
NN	The time interval between two successive Normal heartbeats
NN50	Number of NN intervals longer than 50 ms
pNN50	Percentage of NN intervals longer than 50 ms
QRS	A representation of a heartbeat in the ECG
R peak	The peak corresponding to ventricular contraction in the ECG
RBBB	Right Bundle Branch Block
RMSSD	Root Mean Square of successive differences
RR	The time interval between two successive R peaks
SDANN	Standard Deviation of Average Normal-to-Normal (NN) intervals
SDNN	Standard Deviation of NN intervals
SVG	Scalable Vector Graphics
ULF	Ultra Low Frequency
URL	Uniform Resource Locator
V beat	Ventricular heartbeat
VLF	Very Low Frequency

Symbols

Table 2 presents the potential problems and corresponding solutions.

Table 2: List of symbols according to EN ISO 15223-1:2021.

Symbol	Description
⚠	General Warning Sign / "Attention" Caution, Consult Accompanying Documents
	Manufacturer
MD	Medical Device
	Consult Instructions for Use
CE	European Conformity

1. Safety

1.1. General Warnings

WARNING! Any serious incident related to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 is required to possess sufficient skills to use a web browser and navigate web pages.

WARNING! The user must carefully read the user's manual instructions.

WARNING! Detections are merely an indication; a proper diagnosis can only be established by a qualified medical professional.

WARNING! Interpretation results are not intended to be the sole means of diagnosis.

WARNING! Incorrect detections are possible for patients with heart rates exceeding 180 beats per minute (BPM) or those under 18 years of age.

WARNING! The algorithms in ViewECG have limitations in the arrhythmias specified in the user manual and may incorrectly handle specific patient populations or conditions for which they were not trained.

WARNING! Heartbeats in patients with Right Bundle Branch Block (RBBB) or Left Bundle Branch Block (LBBB) have a wide QRS duration greater than 80ms and are beyond the indications for use.

WARNING! Performance specifications may not be met if environmental conditions fall outside the recommended ranges.

WARNING! This medical device can only be accessed by a computing device connected to the Internet.

WARNING! The application will not work during a system update.

WARNING! Communication and processing of the incoming ECG data stream may be prolonged for up to 30 seconds.

WARNING! Muscle and environmental noise can corrupt the ECG signal and become uninterpretable, leading to misinterpretations.

WARNING! Noisy signals may be misinterpreted.

WARNING! Using multiple sensors simultaneously can cause problems.

WARNING! Your username and password should be kept secure!

WARNING! Be aware of cybersecurity attacks and prevent your data and credentials from being used by the ViewECG system.

WARNING! If a cybersecurity incident is detected, we will notify you via alternative means, such as telephone, text message, or mail.

1.2. Cautions

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

DO NOT use ViewECG before carefully reading the user manual instructions. You should be able to browse and operate a website. If this is not the case, please use ViewECG only with the assistance of a qualified caregiver who meets the above-mentioned basic requirements.

Install the recommended operating systems and web browsers for the computing device with access to the medical device, as specified in the technical specifications, before using ViewECG.

Install the latest releases and security patches for the operating systems and web browsers of the computing device that allows access to ViewECG to prevent cybersecurity attacks.

Apply safety measures when using computing equipment to access medical devices.

Follow the instructions in the user manual to avoid bad performance.

Follow the instructions in the user manual for the environmental conditions of your computing device to access the medical device.

Follow the instructions in the user manual for the hardware requirements of your computing device to access the medical device.

Adjust the brightness level to observe details in monitoring.

Consult a healthcare professional about the measurements obtained with ViewECG.

Contact your healthcare professional immediately in response to alert notifications.

Perform a visual check of the signal and avoid noisy signals!

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

Contact the manufacturer with any instructions that require clarification.

Request caregiver assistance in the event of a disability.

Secure the medical device adequately using the security features in the settings. Your digital device can represent a weak spot in the system's security chain.

Innovation Technology does not warrant any data or information that is collected erroneously by the device or that is misused or malfunctions due to abuse, accidents, alterations, neglect, or failure to maintain the products as instructed. Interpretations made by this device are potential findings, not complete diagnoses of cardiac conditions. A medical professional should review all interpretations for clinical decision-making.

1.3. Residual Risks

⚠️ DO install the latest recommended releases and security patches for the operating systems and web browsers of the computing device that allows access to ViewECG to prevent cybersecurity attacks.

Residual risks (Table 3) are those that remain after risk control measures have been applied and evaluated and are accepted as conditionally acceptable risks.

Table 3: Residual risks.

Risk	Description	Consequence	Reason
Power supply problems due to grid or bad connections	Stability of the power supply of computing device	System malfunction	Connectivity issues, battery failure, or interference.
Algorithms cannot detect all required features	Noise or low sampling rate prevents detection of signal patterns	Errors in beat detection and classification	Edge cases may not be fully covered
ECG data is corrupted	Bad contact of an ECG electrode causes low amplitudes and generates noise	Errors in beat detection and classification	Noise, motion artifacts, or atypical but benign ECG variations
Real-time monitoring interruptions	Communication may prolong and interrupt real-time processing	Delayed response	Communication issues due to bandwidth limitations
Corrupted signal by a lot of noise prevents good detection	False positive result	Detection of an arrhythmia when none is present	Noise, motion artifacts, or atypical but benign ECG variations.
Bad signal due to bad contact prevents good diagnosis	False negative result	Missed detections and classifications	Some arrhythmias may mimic normal ECG signals; algorithm limitations or data artifacts.
Attacker breaks the password	User has selected weak password	Unauthorized access	Encryption and security updates cannot prevent user's weak password
Transmitted data includes sensitive information	Sensitive data included in internal file system structure	Exposure of personal data	Encryption and security updates cannot prevent user's careless communication
Handling of input without well-formed syntax	The validity of input is classified without syntax and semantic check	System malfunction	Interoperability Failures - Lack of adherence to standards or data format mismatches

Risk	Description	Consequence	Reason
Handling of input without complete specification of a particular element	Input sequences may cause indefinite wait	System malfunction	Interoperability Failures - Lack of adherence to standards or data format mismatches
Incorrect return value or status code not indicating an error	Incorrect return value or status code that does not indicate an error	System malfunction	Interoperability Failures - Lack of adherence to standards or data format mismatches
Insufficient verification of a well-formed, valid, consistent request	An attacker could effectively perform any operations as the victim	System malfunction	Even with encryption and new cybersecurity attacks are possible
Insufficiently control on received requests	A request for contents without checks of the destination	System malfunction	Even with encryption and new cybersecurity attacks are possible

1.4. Compliance

ViewECG medical device complies with FDA-recognized consensus standards and guides:

- ANSI/AAMI ISO 14971:2019 Medical devices — Application of risk management to medical devices,
- ANSI/AAMI/IEC/TR 80002-1:2009 Medical device software - Part 1: Guidance on the application of ANSI/AAMI/ISO 14971:2019 to medical device software
- ANSI/AAMI/IEC 62304:2006 (First Edition) + A1:2015 (or IEC 62304:2015 CSV) - Medical device software: Software life-cycle processes
- ANSI/AAMI EC57:2012 - Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- ANSI/AAMI/IEC 60601-2-47:2012 (Second Edition)/® 2016 for use in conjunction with IEC 60601-1:2005 (Third Edition) Medical electrical equipment — Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems,
- Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, from Oct. 28, 2003
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff from Sep 27, 2023
- ANSI/AAMI ISO 13485:2016 + A11:2021 Medical devices — Quality management systems — Requirements for regulatory purposes,
- IEC 60601-6:2010, AMD1:2013 for use in conjunction with IEC 62366:2007, AMD1:2014 and IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1) - General requirements for safety – Collateral Standard: Usability
- ANSI/AAMI IEC 62366-1:2015 + Amd 1:2020, Medical devices — Part 1: Application of usability engineering to medical devices.

ViewECG medical device complies with harmonized European standards:

- EU MDR 2017/745 Medical device regulation (EU Parliament and the Council),
- MDD 93/42/EC Medical devices directive (EU Council directive),
- Guideline MDCG 2019-14, Explanatory note on MDR codes,
- Medical Device Coordination Group Document MDCG 2019-16 Guidance on Cybersecurity for medical devices from Dec 2019
- IEC 81001-5-1:2021 Health software and health IT systems safety, effectiveness, and security – Part 5-1: Security – Activities in the product life cycle
- EN ISO 13485:2016 + A11:2021 Medical devices — Quality management systems — Requirements for regulatory purposes,
- EN ISO/IEC 27001:2022 Information technology – Security techniques – Information security management systems – Requirements,
- EN ISO 9001:2015 Information security management systems – Requirements,
- EN ISO 14971:2019 Medical devices — Application of risk management to medical devices,
- EN IEC 60601-1-6:2010 + Amd1:2013 + Amd2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability,
- EN IEC 60601-2-47:2015 Medical electrical equipment — Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems,

- 2021/2226 EU Regulation on rules on electronic instructions for use of medical devices,
- EN IEC 62304:2006 + Amd 1:2015 Medical device software — Software life-cycle processes and
- EN IEC 62366-1:2015 + Amd 1:2020, Medical devices — Part 1: Application of usability engineering to medical devices.
- A full Declaration of Conformity (DCD) can be found here.

1.5. Troubleshooting

Table 4 presents the potential problems and corresponding solutions.

Table 4: Problems and solutions.

Problem	Solution
I forgot my password and I 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.
No graphics represent the ECG signal	Check if you use the latest browser capable of displaying SVG graphics.

1.5. Troubleshooting

2. Introduction

2.1. Summary Information

ViewECG is a software medical device with a web application for clients for real-time, long-term ECG monitoring and an Application Programming Interface (API) that interacts with other software modules. It is distributed as Software-as-a-Service for cloud-based ECG monitoring. As such, the software is licensed through subscription, and the data is centrally hosted.

Users measure their ECG using an external third-party FDA-approved light, wearable ECG sensor, and a computing device or transmitter capable of transferring ECG data to ViewECG. ViewECG software stores and processes the incoming ECG data continuously so doctors can review them online and in real-time, regardless of the patient's location. The software automatically annotates all abnormal cardiac functions, and the doctor or educated professional can review detected arrhythmia.

The subject device is not for life-supporting or sustaining systems. Interpretation results are not intended to be the sole means of diagnosis. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG patterns, patient background, clinical history, symptoms, and other diagnostic information. The patient measures ECG in a home or healthcare facility/hospital and transfers ECG data by a computing device via the Internet.

The measurements processed by ViewECG, including the monitoring and reporting tools, are remotely available online on any computing device connected to the Internet with a web browser.

Patients with known or suspected heart conditions and health-conscious individuals can use ViewECG to record ECG daily (or whenever they experience symptoms) and share their measurements with their doctor. Doctors may prescribe the medical device for patients who need long-term heart monitoring. Another example of a patient using ViewECG is when they feel dizziness, palpitations, irregular heartbeats, or chest pain. Doctors can quickly examine the heartbeats and rhythm, screen for arrhythmias, and remotely monitor and manage patients who use ViewECG. It creates an autonomous system for analyzing ECG recordings when integrated with other computing devices that provide ECG measurements and wearable ECG patches, like VitalPatch.

ViewECG consists of:

- A web application to process ECG recordings and create reports.

As part of an integrated system, ViewECG works with:

- A light wearable ECG sensor for long-term monitoring, like the VitalPatch sensor, and
- A user-supplied compatible smartphone or tablet.

ViewECG detects cardiac beats/arrhythmias and intervals, complying with ANSI/AAMI EC57:2012 and ANSI/AAMI/IEC 60601-2-47:2012 (Second Edition)/® 2016, including:

- Heartbeat QRS detection,
- Sinus Arrest pause detection,
- Heart Rate measurement,
- Non-paced arrhythmia interpretation,
- Ventricular ectopic beat detection,
- Supraventricular ectopic beat detection,
- Detection of Ventricular couplets, short and long-run,
- Detection of Supraventricular couplets, short and long-run,
- Detection of Normal Sinus Rhythm,

- Detection of Sinus node Bradycardia and Tachycardia,
- Detection of Supraventricular Tachyarrhythmia,
- Detection of Ventricular Tachycardia,
- Detection of Supraventricular Bigeminy and Trigeminy,
- Detection of Ventricular Bigeminy and Trigeminy,
- Detection of Atrial Fibrillation,
- Heart Rate Variability (HRV) measurement,
- Time domain HRV: SDNN, ASDNN, SDANN, RMSSD, NN50, pNN50,
- Frequency domain HRV: ULF, VLF, LF, HF, LF/HF.

In addition to detecting and classifying various arrhythmias, ViewECG provides monitoring tools for displaying ECG strips and representative arrhythmia beats, segments, intervals, and sequences, easy and fast navigation, and a dashboard of detected beats and rhythms.

The reporting tools provide essential summary information, visual diagrams, histograms and charts, and representative ECG strips to facilitate doctors' easy compilation of reports.

2.2. Intended Use

Description of Intended Users

The intended users are patients, caregivers, and healthcare professionals.

A *patient* will use a smartphone to monitor the ECG, upload measurements to the cloud, and view the recorded ECGs on the cloud platform.

Caregivers will be notified about their patients' measurements and can access the recorded ECGs on the cloud platform.

A *doctor* can access the recorded ECGs on the cloud platform, use diagnostic software, analyze long-term measurements, heartbeat functions, and alarm signals, detect arrhythmia, and generate a report.

Typical patient info: age: 18-75 with good psycho-mental state.

A caregiver or assistive person may instruct patients with disabilities on how to use this medical device.

A patient familiar with computing technology and the Internet, who browses websites in their everyday life, will only need minimal instruction on how to use the software.

Instructions for use are needed. A patient should be familiar with computing technology, including Internet websites and smartphones, and will only require minimal instruction on how to use the software.

Indications of Use

ViewECG is intended to continually receive, store, process, and display single-channel electrocardiogram signals for real-time remote cardiac telemetry by healthcare professionals or health-conscious individuals. It detects and classifies beats, runs, rates, and rhythm episodes. The cloud-based platform is intended for patients 18 or older with known or suspected low-risk heart conditions who need or desire long-term 24/7 heart monitoring. Patients at elevated risk of serious cardiovascular events that would require prompt intervention are excluded from use.

A healthcare professional can prescribe ViewECG to enable monitoring and reporting tools for arrhythmia detections and classifications. The healthcare professional then renders a diagnosis based on clinical judgment and experience. Individuals can also use it over the counter to preview a dashboard of automatic arrhythmia detections monitoring their measurements.

Medical Indications

The essential detection and classification options realized by this medical device and included in the standard EN IEC 60601-2-47:2015 or EC 57:2012 are:
- Heart rate
- Supraventricular ectopy
- Ventricular ectopy
- Bradycardia data
- Pauses
- ECG strip of representative arrhythmia beats and sequences

A more detailed list of declared diagnostic options includes:
- QRS complex detection
- VEB detection
- Ventricular couplet detection
- Ventricular short-run detection
- Ventricular long-run detection

- SVEB detection
- Supraventricular couplet detection
- Supraventricular short-run detection
- Supraventricular long-run detection
- AF episode detection
- Ventricular bigeminy and trigeminy detection
- Supraventricular bigeminy and trigeminy detection
- 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, Poincaré plot, and detrended fluctuation analysis.

Contraindications

The device is a software application and does not incorporate any medicinal substance or pose any hazardous situation to the patient's body.

No contraindications or precautions are required for the use of the ViewECG medical device.

An external medical device, such as VitalPatch or another wearable ECG sensor, is in contact with the body through gel electrodes (patches). In contrast, the ViewECG medical device is software that can be used via smartphones, tablets, or any other computing device with an Internet connection.

ViewECG is not intended for use by individuals who require hospital monitoring of a life-threatening arrhythmia.

Individuals who are unfamiliar with using a computing device for web browsing often require assistance from a caregiver.

2.3. Clinical Benefits

Long-term ECG monitoring has become indispensable for preventing, managing, and treating many cardiac disorders[1]. The diagnosis of syncope or non-sustained rhythm disturbances remains a difficult task in clinical cardiology, leading to multiple outpatient visits, multiple examinations, diagnostic tests, and unnecessary hospitalizations[2]. Considering this, all recent Guidelines for managing Syncope, Atrial fibrillation, Ventricular arrhythmia, and prevention of Sudden Cardiac Death[3] recommend prolonged ECG monitoring for the detection of asymptomatic rhythm disturbances or to correlate symptoms to ECG findings.

The choice of monitoring technique depends on the recurrence rate of symptoms and patient preferences. 24-hour Holter ECG recordings are sometimes insufficient due to their short monitoring time, and patients often do not accept implantable loop recorders because of the invasive nature of the procedure.

The most significant clinical benefit of ViewECG is its high diagnostic yield. The diagnostic yield of external monitoring systems increases to 50% in cases where the monitoring duration

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[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.

is one 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].

Expected clinical benefits are:

- The medical device can serve as a telemedicine tool to monitor heart function and identify harmful rhythms or conduction disturbances.
- The medical device can serve as an alternative to a Holter ECG device.
- The medical device serves as an alternative to an implantable loop recorder.
- The medical device serves as an efficient reporting tool that summarizes detected arrhythmias, aiding medical doctors in establishing a diagnosis.
- The medical device is suitable for real-time monitoring of heart conditions in outpatients.

The potential advance beyond the State-of-the-Art is expected to be:

- The device can be used for long-term monitoring for more than two days, such as one week, two weeks, or longer.
- The device, which employs a non-invasive method, can serve as an alternative to an implantable loop recorder.
- The device enables remote, real-time, continuous ECG monitoring, similar to that in intensive care units, for outpatients without the need for hospitalization.
- The device facilitates earlier hospital discharge after surgery, thereby reducing hospital stays.
- Real-time ECG monitoring and detection of different heart rhythm disturbances can help identify underlying severe heart conditions and prevent serious consequences.

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[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] Thoracic Surgery (EACTS). Eur Heart J2020; doi:10.1093/eurheartj/ehaa612

2.4. Summary of Safety and Clinical Performance

The ViewECG medical device is a software application that features a web-based interface capable of accepting ECG files. It enables a monitoring tool with visualization and navigation through ECGs, as well as a reporting tool that summarizes findings about detected beats, heart rate, heartbeat type, and rhythm episodes.

The ViewECG medical device meets the declared performance, as determined through an analysis of the safety and performance requirements outlined in the standard EN 60601-2-47:2015.

This clinical evaluation describes the capabilities of the ViewECG medical device in providing ECG monitoring for diagnostic purposes. It conforms to the declared intended purpose by analyzing the supporting documentation and following the required evaluation procedure outlined in the standard.

In the clinical evaluation, the device was assessed for its diagnostic performance under normal operating conditions, supported by relevant clinical evidence. The annotations created for ECG recordings conform to those in the evaluation databases. The achieved sensitivity and positive predictive results are more than sufficient for the device's clinical performance. The relative errors in the detection process were less than 0.5%, aligning with the best and well-established results in the literature and state-of-the-art analysis.

The evaluation standard EN 60601-2-47:2015 outlines the evaluation methodology, which includes detecting QRS complexes, performing beat-by-beat analysis, conducting run-to-run analysis, comparing episodes, visually inspecting ECG strips, reviewing the physician's report, and verifying consistency with reference data. Records from four databases are utilized in the evaluation process. The appraisal of data obtained during the evaluation and analysis of results confirmed that all necessary safety measures have been implemented and comply with state-of-the-art technology and current standards.

The obtained performance is on a high level, reaching over 99.80% sensitivity and positive predictivity of QRS complex detection for the overall evaluation, 93% for Ventricular ectopic beats (VEB) sensitivity, 86% positive predictivity, and 79% of Supraventricular ectopic beats (SVEB) sensitivity, and 94% positive predictivity. The algorithm has been proven to perform satisfactorily in cases where the signal-to-noise ratio exceeds 12 dB. The performance of detecting runs is also high, reaching over 70% sensitivity and 88% positive predictive value for detecting VEB and SVEB couplets, as well as short and long runs. Atrial fibrillation (AF) detection performance is also high, with a sensitivity of 96% and a positive predictive value of 82%. The visual inspection of the reports and ECG graphs confirmed that they correspond to state-of-the-art performance.

The clinical evaluation process assessed the risk-benefit profile, target groups, and intended use of the medical device. After implementing control measures to mitigate identified risks, the risk is estimated to be low. The benefits are estimated to be high, and the medical device is deemed successful in processing one-channel ECG recordings. The ViewECG medical device can detect significant arrhythmias, including beat classification, identification of ventricular and supraventricular beats, and episodes of atrial fibrillation.

The clinical evaluation confirmed that the safety and performance of the ViewECG medical device comply with MDR 2017/745 and EN 60601-2-47:2015 standards. The ViewECG medical device enhances existing techniques (ECG-Holter and implantable loop recorder) with a superior alternative.

2.5. Labeling

ViewECG is web-based software accessible via a URL address. Proper identification is marked with the assigned device logo, product name ViewECG, and the corresponding website domain (Table 5).

Table 5: Device Identification.

Feature	Identification
Device name	ViewECG
Device logo	
Domain/website	viewecg.com

The user manual and instruction videos provide instructions on how to access and operate the software.

https://viewecg.com/Documents/UserManuals/ViewECG_Doctors_User_Manual.pdf
https://viewecg.com/Documents/UserManuals/ViewECG_Patients_User_Manual.pdf
https://viewecg.com/Home/VideoTutorials

The Software Version identifies and describes a version of a software module (application) or interim change (i.e., changes that occur between versions) to the previously released version.

The purchase model is pay-per-use on a weekly or daily basis.

The CE marking for the ViewECG medical device system is available on the website and visually presented in Figure 1.

ViewECG MD

An AI platform that connects doctors and patient. Our cloud system seamlessly integrates with the measurement from your phone and enables you to analyze your data. Our special beat detection and classification algorithms are designed by a team of doctors and computer scientists. Among the things we measure are:
- Beat classification (Normal, PVC, VEB, PAC, SVEB)
- Run-to-run identification (ventricular and supraventricular couplets, short and long runs)
- Episode identification (atrial fibrillation, ventricular tachycardia, bigeminy, trigeminy)

Version 1.1.6
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Device labelling

CE 1304

CE marking with number of Notified body; SIQ, number 1304
UDI-DI: 3830085990001Z8

POWERED BY INNOVATION TECHNOLOGIES.
DROŽANJE 20, DROŽANJE
8290 SEVNICA
Slovenia

Figure 1: ViewECG marking for CE number.

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

3. Device Description

3.1. Web browser-enabled computing device

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

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

The hardware requirements of the computing device are:

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

The requirements for the printing unit are:

- A grey-scale printer is sufficient, and
- Supporting at least 100 dpi resolution.

The constraints for relatively good graphics performance include:

- Screen size must be at least 9 inches (22.86 cm) diagonal; and
- Screen resolution of at least 1440 x 900 (for 16:10 aspect ratio), 1600 x 900 (for 16:9 aspect ratio), or 1280 x 960 (for 4:3 aspect ratio).

The requirements for the operating system and web browser include:

- Any modern operating system with an officially supported latest release can provide sufficient performance, including Mac OS, Microsoft Windows, IOS, Android, or similar (the latest versions with support as of the time of the release of this document are Mac Sequoia 5.4 (24E248), MS Windows 11 release 24H2, IOS 18.4, Android 15 'Vanilla Ice Cream').
- A web browser that supports Scalable Vector Graphics (SVG) and satisfies the minimum requirements for web browsing. Tested web browsers as of the time of the release of this document are Safari Version 18.4 (20621.1.15.11.10), Google Chrome Version 135.0.7049.85 (Official Build) (64-bit), and Google Chrome Version 134.0.6998.167 (Official Build) (arm64). 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.
- The user needs to update the operating system and web browser with the latest version and security patches to prevent unauthorized access and cybersecurity attacks.

3.2. Intended Use

ViewECG is intended to continually receive, store, process, and display single-channel electrocardiogram signals for real-time remote cardiac telemetry by healthcare professionals or health-conscious individuals. It detects and classifies beats, runs, rates, and rhythm episodes. The cloud-based platform is intended for patients 18 or older with known or suspected low-risk heart conditions. These patients need or desire long-term 24/7 heart monitoring. Patients at elevated risk of serious cardiovascular events that would require prompt intervention are excluded from use.

A healthcare professional can prescribe ViewECG to enable monitoring and reporting tools for arrhythmia detections and classifications. The healthcare professional then renders a diagnosis based on clinical judgment and experience. Individuals can also use it to preview a dashboard of automatic arrhythmia detections monitoring their measurements.

3.3. Functional Description

Prescribed Use Only

Individuals can use ViewECG as a consumer medical device. They can:
- Preview ECG measurements,
- Navigate through ECG measurements,
- Preview a dashboard of automatic detections of arrhythmia detections,
- Print and share events with their doctor 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.

Doctors can prescribe this device to monitor their patients remotely. In this case, doctors can create and manage their patients' profiles with full access to all functionalities. They can access the monitoring and reporting tools, analyze the ECG strips and dashboard of automatic detections, edit and review the findings, and create a medical report.

Interpretation Skills

Ordinary patients do not need expertise interpreting the ECG findings; they are left to doctors and experts. Experience in ECG monitoring software provides a significant advantage in interpreting the findings.

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

The web application interfaces follow classic design principles; hence, the user needs to be averagely acquainted with such applications to manage the monitoring functionalities of the web application intuitively. A thorough user manual reading is recommended to understand the most supported functionalities. The ECG findings are aligned with the Physionet specification[6] of annotations and episodes.

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

3.4. Detection Options

The essential detection options realized by this medical device are:
- Heart rate,
- Supraventricular ectopy,
- Ventricular ectopy,
- Bradycardia data,
- Pauses, and
- ECG strip of representative arrhythmia beats and sequences.

A more detailed list of declared detection options includes:
- Heartbeat QRS detection,
- Sinus Arrest pause detection,
- Heart Rate measurement,
- Non-paced arrhythmia interpretation,
- Ventricular ectopic beat detection,
- Supraventricular ectopic beat detection,
- Detection of Ventricular couplets, short and long-run,
- Detection of Supraventricular couplets, short and long-run,
- Detection of Normal Sinus Rhythm,
- Detection of Sinus node Bradycardia and Tachycardia,
- Detection of Supraventricular Tachyarrhythmia,
- Detection of Ventricular Tachycardia,
- Detection of Supraventricular Bigeminy and Trigeminy,
- Detection of Ventricular Bigeminy and Trigeminy,
- Detection of Atrial Fibrillation,
- Heart Rate Variability (HRV) measurement,
- Time domain HRV: SDNN, ASDNN, SDANN, RMSSD, NN50, pNN50,
- Frequency domain HRV: ULF, VLF, LF, HF, LF/HF.

3.5. Register and Log-In Procedures

The service provider must register the doctor to access the web application. To enter the home page, a standard login procedure with a username and password is applied.

4. How to Use the Medical Device

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

4.1. Register and Log In

Login Page

Before use, the user should register according to the following procedure:
1. Open www.viewecg.com to open the login page (Figure 2).
2. If you are not registered, click the "Register here" link (Figure 3).
3. Follow the instructions to register.
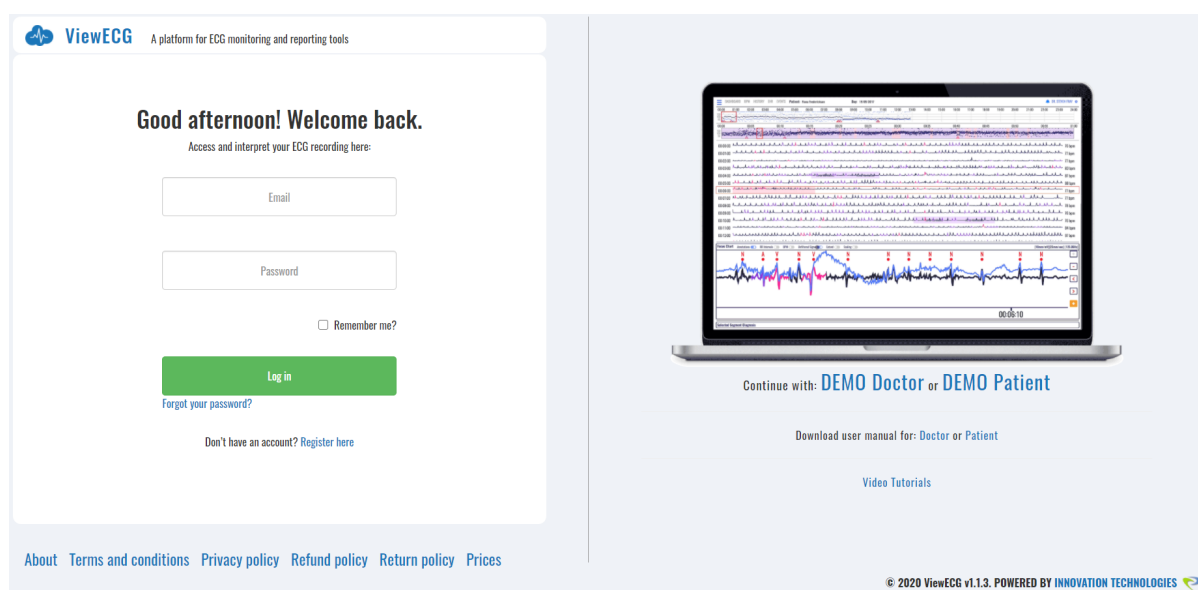
Figure 2: Login page of the ViewECG application.

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

Register

To register, you need to fill in the required data (Figure 3), including email, password, first and last name, gender, date of birth, weight, height, address, city, country, postcode, and phone number.

The patient can upload or delete a personal photo.

If you check the field "I'm not a robot" and click "Register," you will receive an email with instructions on confirming your credentials to register.

Register

Get analysis of your results and be monitored in-real time by your doctor.


Figure 3: ViewECG Register page.

NOTE: The system may force 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 in the required fields, and those are:

- First name,
- Last name,
- Gender,
- Date of birth,
- Address,
- City,
- Country,
- Postcode,
- Email,
- Password, and
- Confirm password.

NOTE: The system may also prevent the user from using an existing username. If a successful combination of a username and password is entered and all necessary fields are populated, the system notifies the user that the registration was successful (Figure 4). The user needs to read the email and follow the instructions.
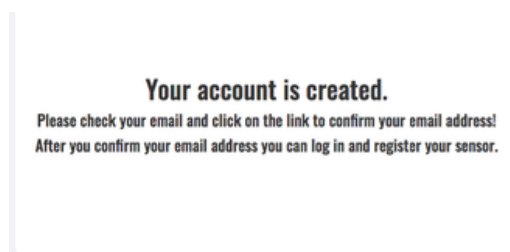
Figure 4: Notification of successful registration.

If the user follows the e-mail instructions and clicks on the confirmation link, a confirmation of successful registration will appear (Figure 5).

Thank you for confirming your
email. Please Click here to Log in

Figure 5: Notification after confirming the registered username.

Forgot Password

If the patient has forgotten the username-password combination, clicking on the link "Forgot your password?" will open the forgot password form (Figure 6). Clicking the "Reset your password" button will generate an email with a temporary password sent to the provided email address. The patient can confirm the link received by the email and then set a new password to log in to the website.

Forgot your password?

Email

Reset your password

Figure 6: ViewECG Forgot password form.

Log In and Access Recorded ECGs

The login page is www.viewecg.com. The user must enter a valid username and password and click the "Login" button (Figure 2).
By clicking the "Remember me" button, a cookie on the patient's web browser remembers the patient's credentials and automatically logs the patient whenever the patient is accessing the login page (Figure 7).

Good afternoon! Welcome back.

Access and interpret your ECG recording here:

Email

Password

☐ Remember me?

Log in

Forgot your password?

Don't have an account? Register here

Figure 7: ViewECG Remember me option.

Demo Links and User Manuals

Demo links are available on the login page for both patients and doctors. User manuals for patients and doctors are also available through the provided link on the login page (Figure 8). There are also available video tutorials for patients and doctors.
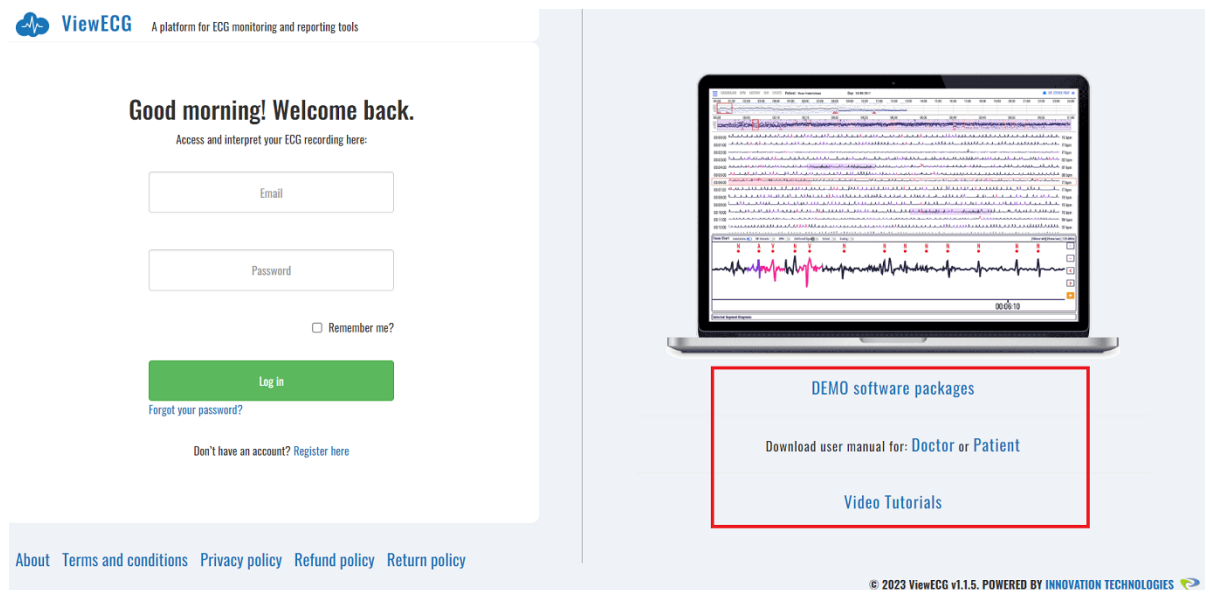
Figure 8: ViewECG application - links to demos, user manuals, and video tutorials.

Support and Policies

Multiple links are available on the home page of ViewECG and all other website pages (Figure 9). Navigation is between listed links and main website functions.

- About,
- Support (available when the user is logged in),
- Terms and conditions,
- Privacy policy,
- Refund policy, and
- Return policy.
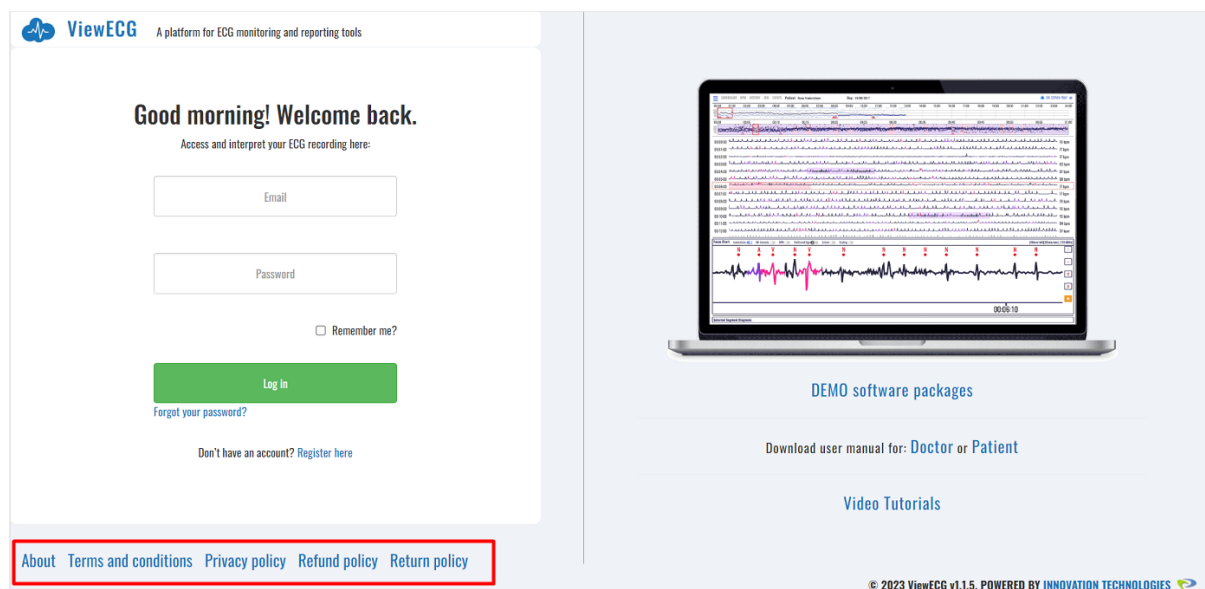
Figure 9: ViewECG links to support and other hyperlinks.

Subscription

ViewECG offers its users a free trial period for specific functions. Before the end of the trial period, the user should purchase their subscription package (Figure 10). After selecting the desired option, click the "Buy" button underneath. Confirm the subscription package and the desired quantity by clicking "Checkout." Before concluding the payment, review the items and click "Confirm & Pay." Provide payment details and click "Confirm."

Figure 10: ViewECG application subscription options.

There are four different types of subscription plans available. The Basic plans are for patient users, and the Plus plans are for doctor users. The ViewECG plans to provide monitoring access for patients and doctors, and the ReportECG provides reporting access to both types of users.

Refund Policy

Order cancellation and return process is defined within the appropriate policy (Figure 11). 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 the requested period or
- That is one that the Seller specifically authorized for return.

To cancel the product and be granted a refund, you must fill in the Cancelation Request Authorization form with the necessary information:

- First name,
- Last name,
- Email,
- Address,
- Subscription plan,
- Subscription start date,
- Invoice number, and
- Reason for cancelation:
  - Unsatisfied with 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 11: ViewECG Cancelation and Refund Policy.

Return Policy

The return process is defined with the appropriate policy (Figure 12). 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,
- 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 the required information and sent 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 12: ViewECG Return Policy.

4.2. Monitoring Page

Monitoring is the essence of the application. The monitoring page is displayed once the user logs in as a registered patient user. It can also be 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 ECG sensor and start a new measurement or upload the ECG measurement." because no files have been uploaded for monitoring. As soon as the user uploads at least one ECG file, the monitoring page looks like the one displayed in Figure 23.
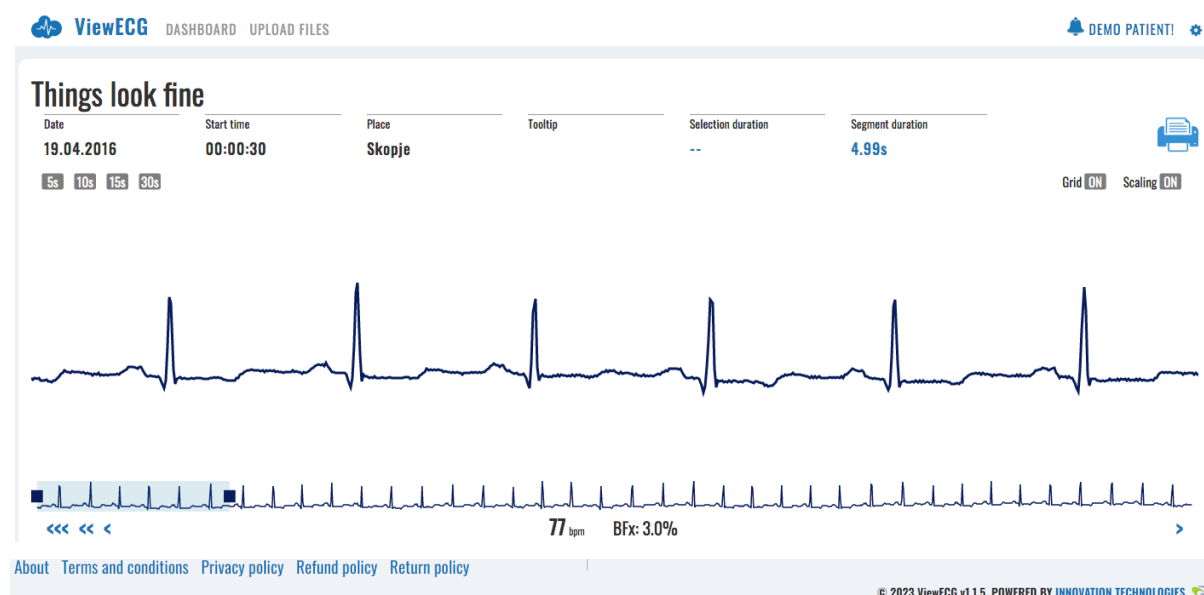

Figure 13: ViewECG monitoring page with detected normal sinus rhythm.

ViewECG Header

The monitoring page displays the most recent ECG measurement. The application header contains the ViewECG logo, which links to the monitoring page. Next to the logo are two menu options/shortcuts to "Dashboard" and "Upload Files." On the right side, there is a "Warning" icon, the "Patient name" icon, and the "Settings" icon. The "Warning" icon links to a system warning message whenever available (Figure 14).
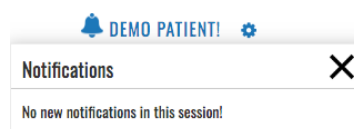

Figure 14: ViewECG System warning message.

The "Patient name" is linked to personal settings, and the "Settings" icon is a drop-down menu to "Profile," "Sensors," "Subscriptions," "Invoices," and "Log off" links (Figure 15).
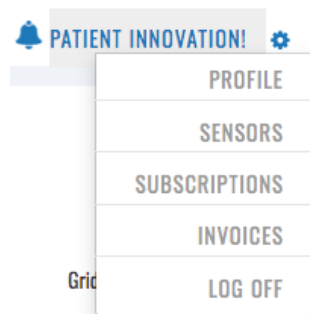
Figure 15: ViewECG Account settings menu.

Information Header

Right below the application header is a simple message that informs the patient of the current heart ECG condition. The message "Things look fine" appears if there are no detected rhythm or conduction disturbances and is associated with normal sinus rhythm (Figure 16). Below this message is patient and measurement information, including date, time, and place. The other fields are associated with tooltip values, selection, and segment duration, associated with displayed ECG measurement and graphical processing initiated by the mouse and monitoring tools. A "Printer" icon is used at the end of this row to print the ECG recording as a PDF file and share the recorded ECG measurement.

Figure 16: ViewECG application header.

Control Header for Monitoring Tools

The control header is located below the information header. On the left side, four buttons allow you to choose the window width of the ECG signal to be displayed, which can be 5, 10, 15, or 30 seconds. On the right side, two toggle buttons ("Grid" and "Scaling") allow you to toggle on and off the display of a grid or to scale the signal.

A patient may click the "Grid" button to display a regular grid for more straightforward interpretation, using a standard resolution of 25 mm/sec and 1 cm/mV (Figure 17).

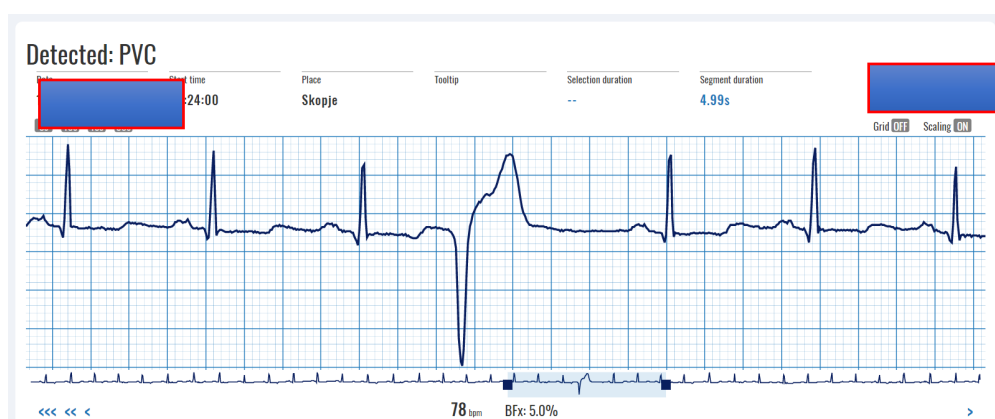**NOTE:** ECG shown in Figure 27 contains a detected premature ventricular contraction (PVC).

Figure 17: ViewECG monitoring page with grid (PVC beat detected).

A click on a "Scale" button will display a scaled ECG without a grid (Figure 18) and a scaled display in which the displayed ECG's height is maximized according to the allowed space.
NOTE: The ECG shown in Figure 18 contains a detected Premature Atrial Beat (PAC).
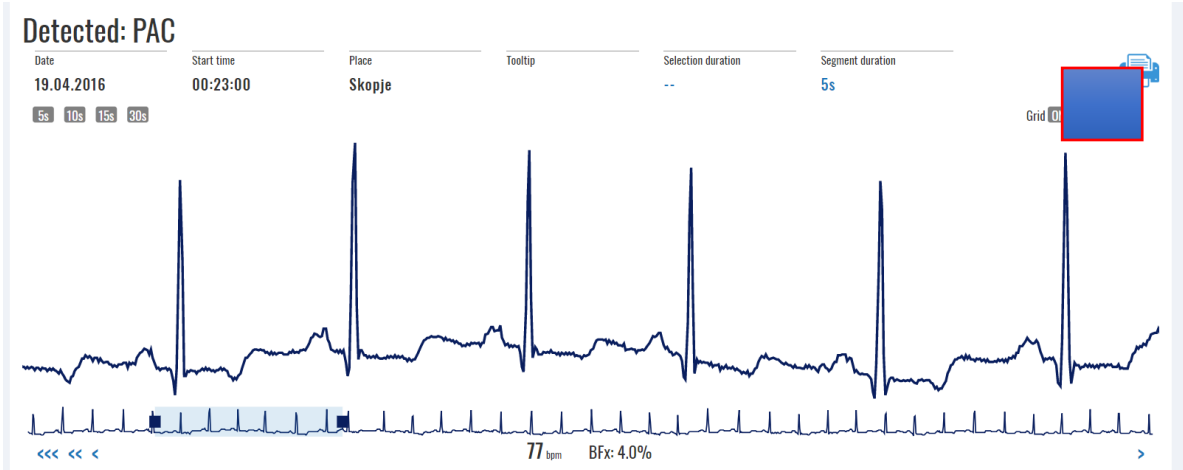

Figure 18: ViewECG monitoring page with scaling (PAC beat detected).

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 navigation buttons ("|<, <<<, <<, and <") to the left and four navigation buttons to the right (">, >>, >>>, and >|"). The number of displayed navigation buttons depends on the availability of the signal (Figure 19).

Figure 19: ViewECG navigation slider.

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

4.3. Monitoring Tools

The available monitoring tools include navigating the displayed window and marking a segment. The doctor can use more specific monitoring tools to enable a sophisticated environment for establishing a diagnosis.

Navigate an ECG Measurement

The window of the displayed ECG can have a standard width of 5 seconds (Figure 20), 10 seconds (Figure 21), 15 seconds (Figure 22), or 30 seconds (Figure 23), accessible by corresponding width control buttons (Figure 17). If the selected width is smaller than 30 seconds, the selected part of the displayed window is marked on the navigation slider. The default value of this slider is the beginning (left side) of the navigation slider.
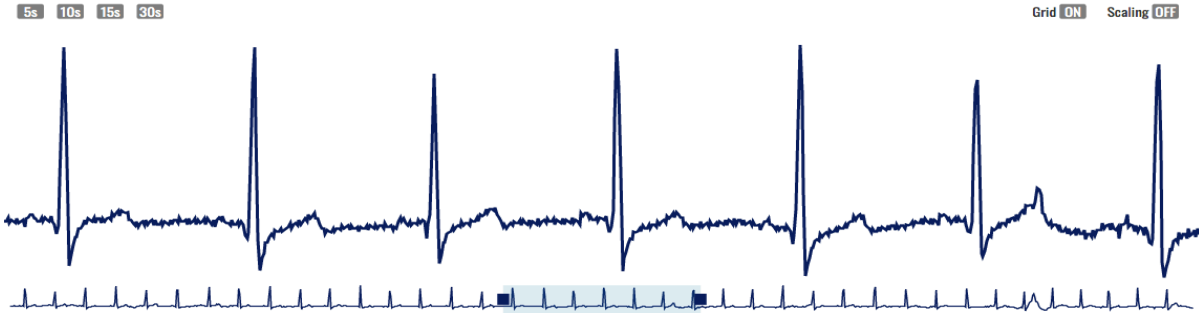
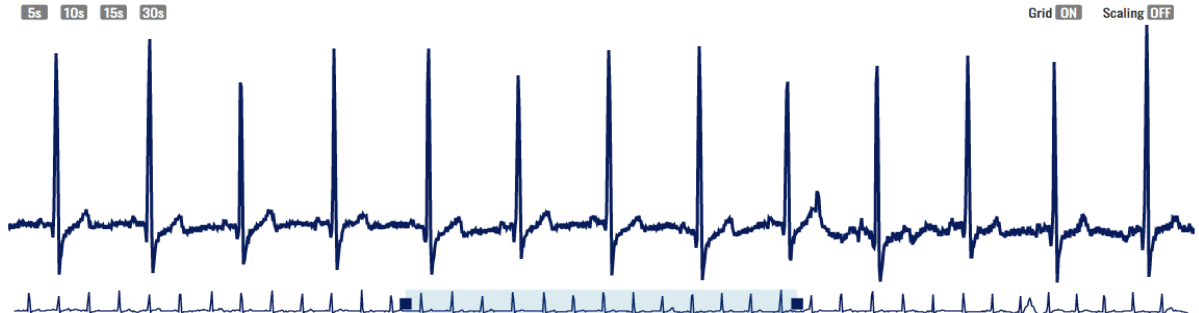**Figure 20: ViewECG preview of a 5-second ECG.**

Figure 21: ViewECG preview of a 10-second ECG.
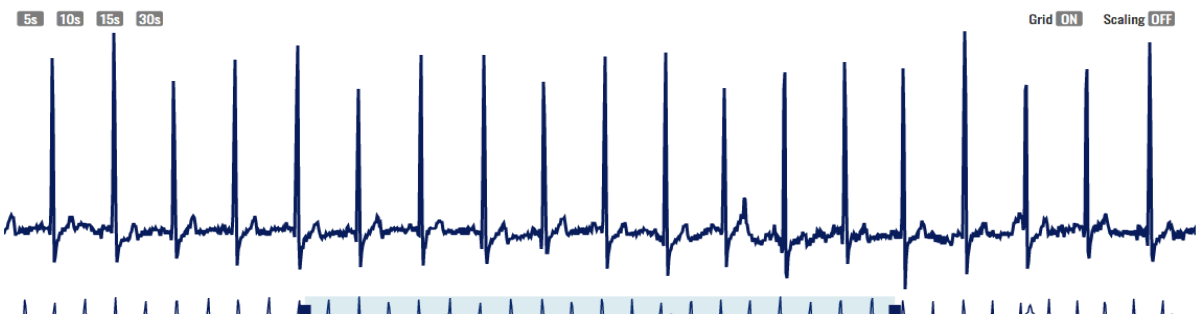

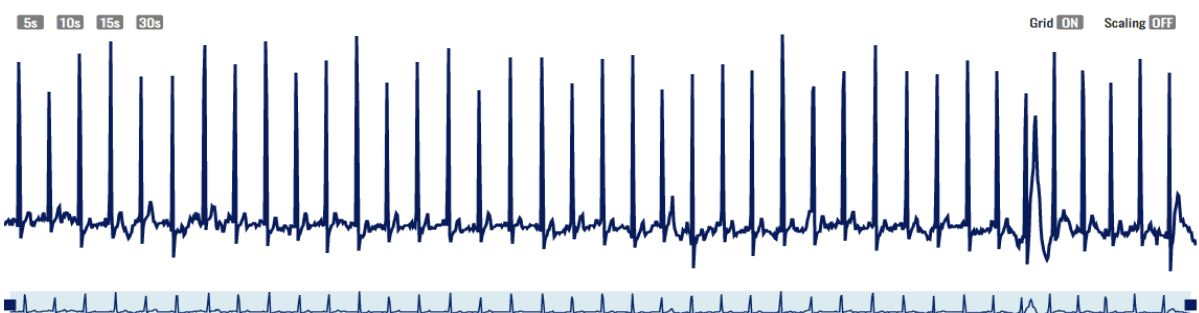**Figure 22: ViewECG preview of a 15-second ECG.**

Figure 23: ViewECG preview of a 30-second ECG.

You can move this navigation slider to a specific horizontal position on the slider and display the desired content. Examples are presented in Figure 17 and Figure 18 correspondingly to represent the detected PVC and PAC.

The navigation slider consists of a 30-second-long compact signal chart and a position and span indicator. The compact ECG signal represents the current signal, and its transparency gives the user insight into any present anomalies.

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

- 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 24) and to:
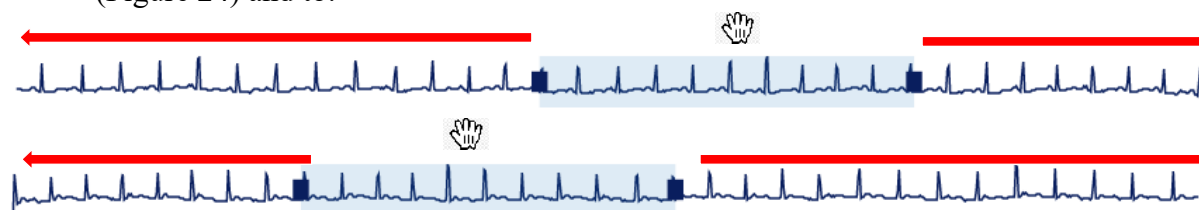
Figure 24: ViewECG navigation position.

- Adjust the span of the current visible window of the ECG chart section within the 30s ECG segment. This is achieved by the "drag and drop" interaction of navigator handles (slider margins - Figure 25).
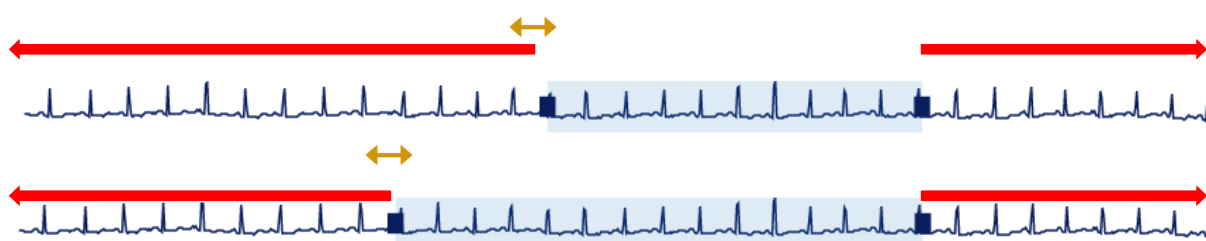
Figure 25: ViewECG span adjustment.

NOTE: The shaded window size depends on the selected window width (5, 10, 15, and 30 seconds, as presented in Figure 20, Figure 21, Figure 22, and Figure 23).

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.

There are also eight types of supplementary additional navigation buttons (Figure 19):

- One straight line and one left arrow ("|<") – displays the first ECG recording available,
- Three left arrows ("<<<") – displays an ECG recorded the previous day (24 hours prior),
- Two left arrows ("<<") – display an ECG recorded the previous hour (1h prior),
- One left arrow ("<")– displays the previous recorded ECG (30 seconds prior),
- One right arrow (">") – displays the following recorded ECG (after 30 seconds),
- Two right arrows (">>") – display an ECG recorded the next hour (1 hour after),
- Three right arrows (">>>") – display an ECG recorded the next day (24h after) and
- One right arrow and one straight line (">|") – display 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 26).

You can mark a segment by a single "drag and drop" mouse action on the visualized ECG (Figure 26), and the width of the marked segment is displayed in seconds under "Selection duration."
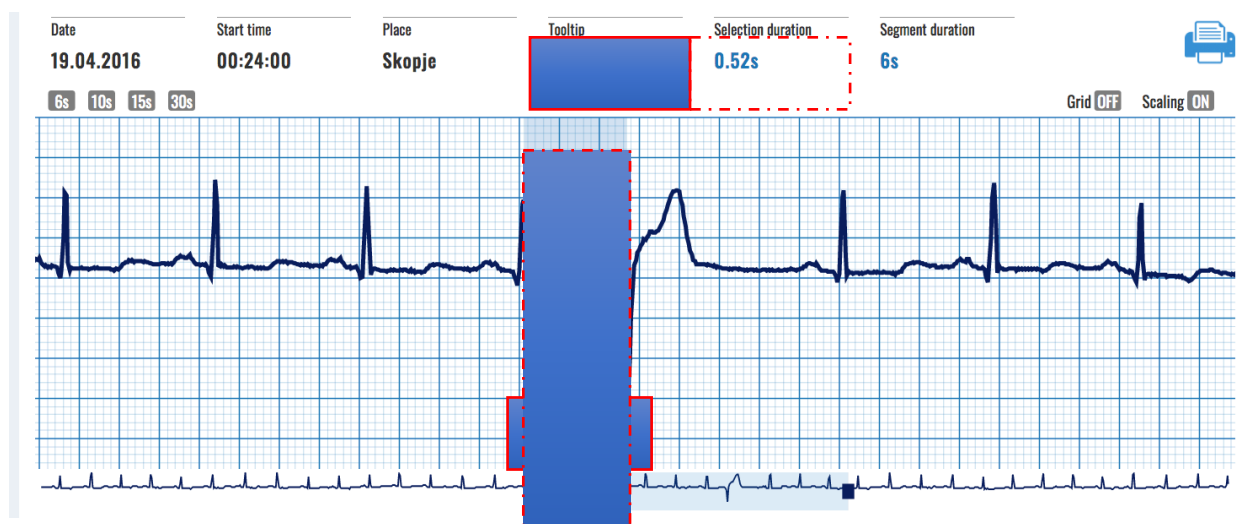
Figure 26: A tooltip under the mouse pointer (showing the value -1.71mV at 17.33-sec relative to the start) and marked segment (with a length of 0.52sec between the ventricular beat and preceding a Normal beat).

4.4. Dashboard

Clicking the "Dashboard" menu option in the application header accesses the dashboard page. It consists of two sections (Figure 27):

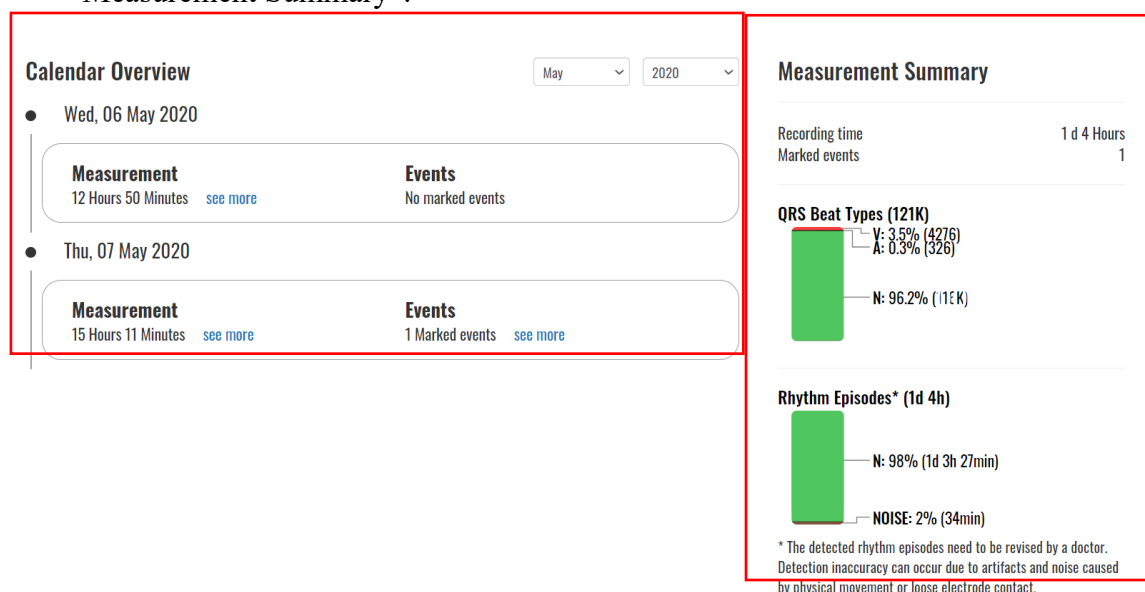- "Calendar Overview", and
- "Measurement Summary".

**Figure 27: ViewECG application dashboard.**

Calendar Overview

The calendar overview section (Figure 28) 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" is a "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 is a "See more" hyperlink that opens the event details page with information loaded on the day's first event.

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:
- A dropdown list of available years and
- A dropdown list of available months.
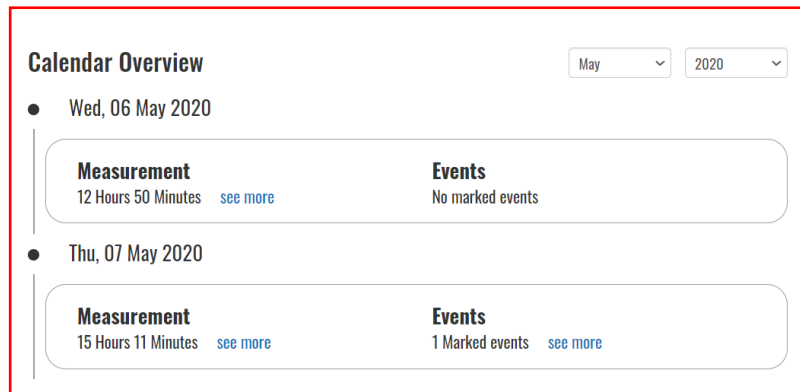
Figure 28: ViewECG application - preview history of measurements.

The dropdown lists allow patients to choose the month and year they want to see information. These lists are dynamic, meaning only the years with present recordings and their corresponding months will be included as available selections.

Measurement Summary

The "Measurement summary" section (Figure 29) gives a statistical overview of the current month. It contains information on the sum of recording time ("Recording time") and a 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 percentages presented, the detected rhythm episodes.

NOTE: * The detected rhythm episodes need to be revised by a doctor. Detection inaccuracy can occur due to artifacts and noise caused by physical movement or loose electrode contact.
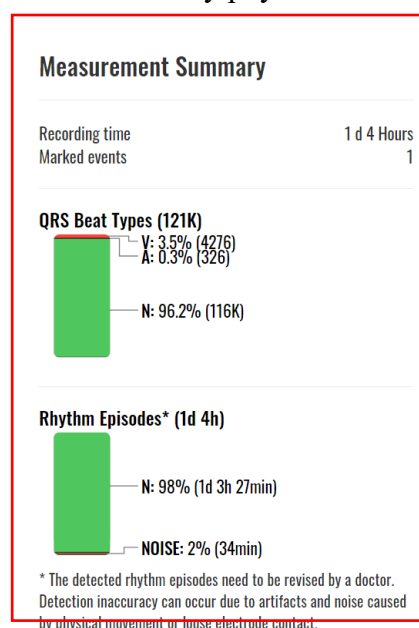
Figure 29: ViewECG application - Summary of identified arrhythmia beats and sequences.

Browse a Particular ECG Strip

Within a given measurement, you can list 30-second ECG strips (Figure 30), which you can access via the "See more" link provided at the "Dashboard" screen under the "Measurement" section (Figure 28).


Figure 30: A list of 30-second 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 31). The displayed calendar lets you click a particular date on the list and move left to the previous month or right to the next month.
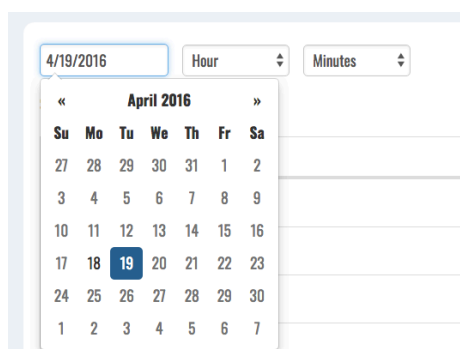

Figure 31: Date time selector.

In addition to selecting a date, you can choose a particular "Hour" or "Minute" by clicking on a corresponding value in the displayed drop-down menus.

At the right side of this row is a "Search" field where you can enter a particular time and activate the option to display only a selection that satisfies the search criteria.

The list is a table, where each row displays corresponding data and time stamps. By default, the first ten 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 32). The default value is 10, which can be changed to 20, 50, 100, or 500 entries.
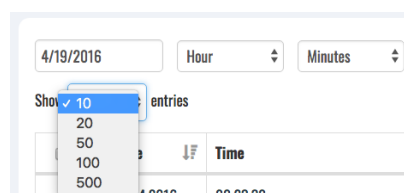
Figure 32: Selecting the number of entries to be displayed.

Below the list on the left is an information message showing which entries are displayed. Navigation between pages can be realized using the navigation tools (Figure 33) on the right side below the list. You can choose a particular page to be displayed, such as the current page, and several pages before and after it.

There are navigation buttons (Figure 33) 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 (">>") – display the last recorded 30-second ECG strip.

Figure 33: ViewECG application navigation tools.

To monitor a particular 30-second ECG strip, click on the corresponding row in the measurement table (Figure 30). Then, the monitoring page is displayed (Figure 13), and you can use the explained monitoring tools.

Browse Events

The list of all events (Figure 34) for the patient is a table accessed via the "See more" link provided in the "Events" section on the "Dashboard" screen. Each row holds information on a single event, such as "Date," "Time," "Activity," and "Feeling" during the recorded event.

The manipulation of the events list is like that of the list of measurements, which is explained in the previous section.


Figure 34: Listing of recorded events.

In that order, 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—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. If there is one page to be

displayed, there is no possibility of navigating through events since all events are listed in the table (Figure 34).

At the end of each row, a "Trash" icon can delete an event. An event can be deleted separately by clicking the "Trash" icon in the corresponding row, selecting multiple events, and clicking on the "Trash" icon above the checkbox column. Before an event is deleted, the system asks for the user's confirmation of the action (Figure 35).
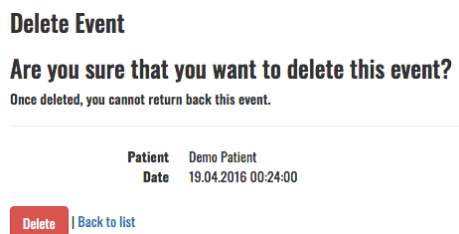
Figure 35: Delete event confirmation.

4.5. Events

A patient records or defines an event in the case of a pulse or any other symptom the patient is feeling during the measurement. Since marking an event takes some time, the application usually displays 30 seconds before the marking activity and 30 seconds after so the doctor can better analyze what happened within the marked period.

View Events

To view an event, click "Event" from the event's page (Figure 34). The custom header (Figure 36) contains information about the patient and recorded ECG, such as date, time, place, activity, feeling, and sensor position. A "Printing" icon in the right corner of the custom header opens a printing dialog for the event.
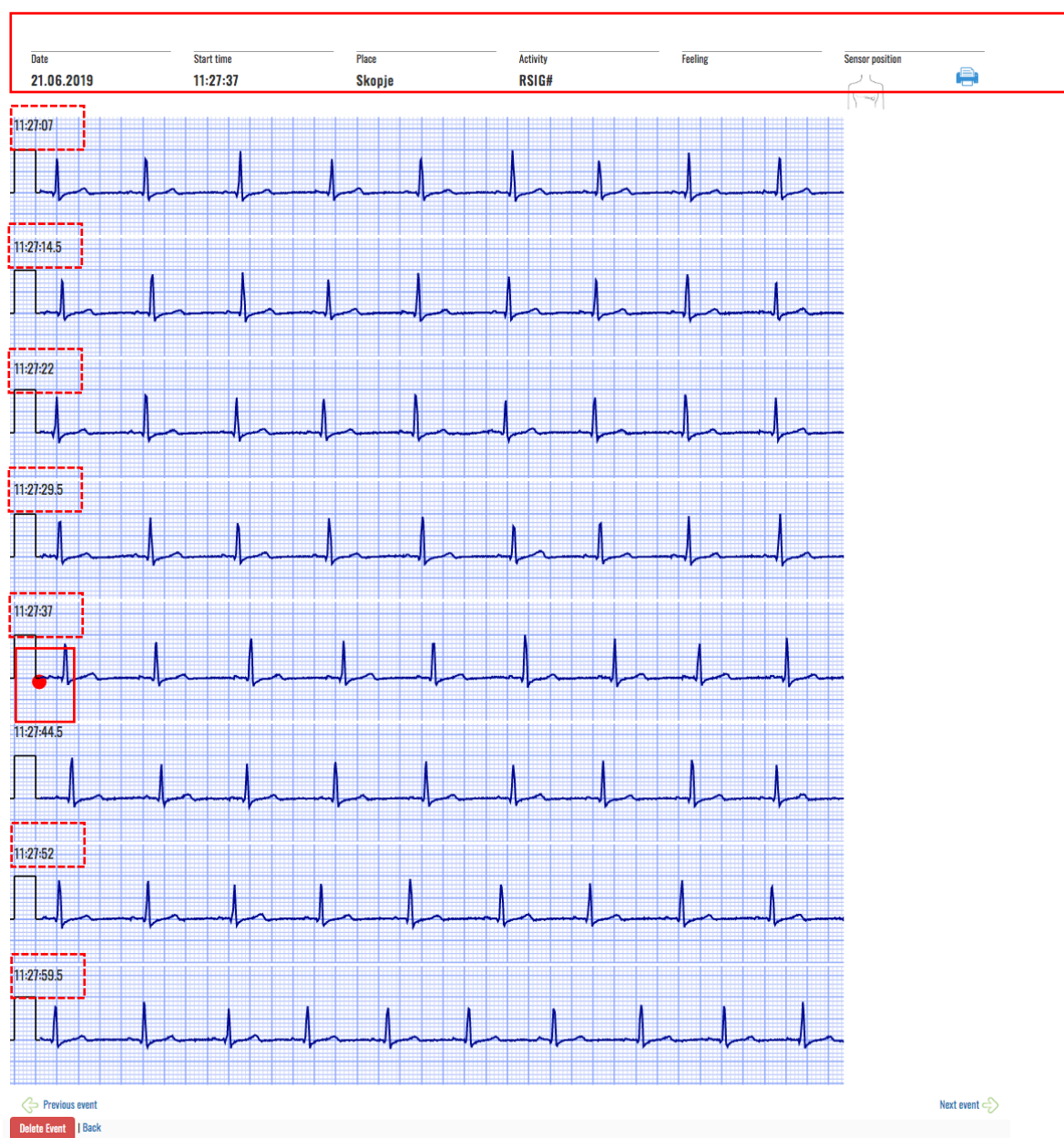

Figure 36: ViewECG application event details.

The event record is one minute long. The record contains the ECG signal 30 seconds before the marked event timestamp and 30 seconds after the event timestamp. The event timestamp (Figure 36) is marked by a red point at the beginning of the ECG row. A timestamp is printed at the beginning of each row (Figure 36 dashed line marking).

Navigate Events

Below the ECG strips, there are navigation buttons (Figure 37) 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 selected event with a previous confirmation of the actions (Figure 35).
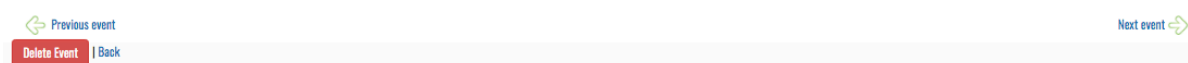

Figure 37: Navigation through recorded events.

Print and Share an Event

To print an event, click on the "Printer" icon. The operating system message will then appear, asking you to choose a printer output (Figure 38).
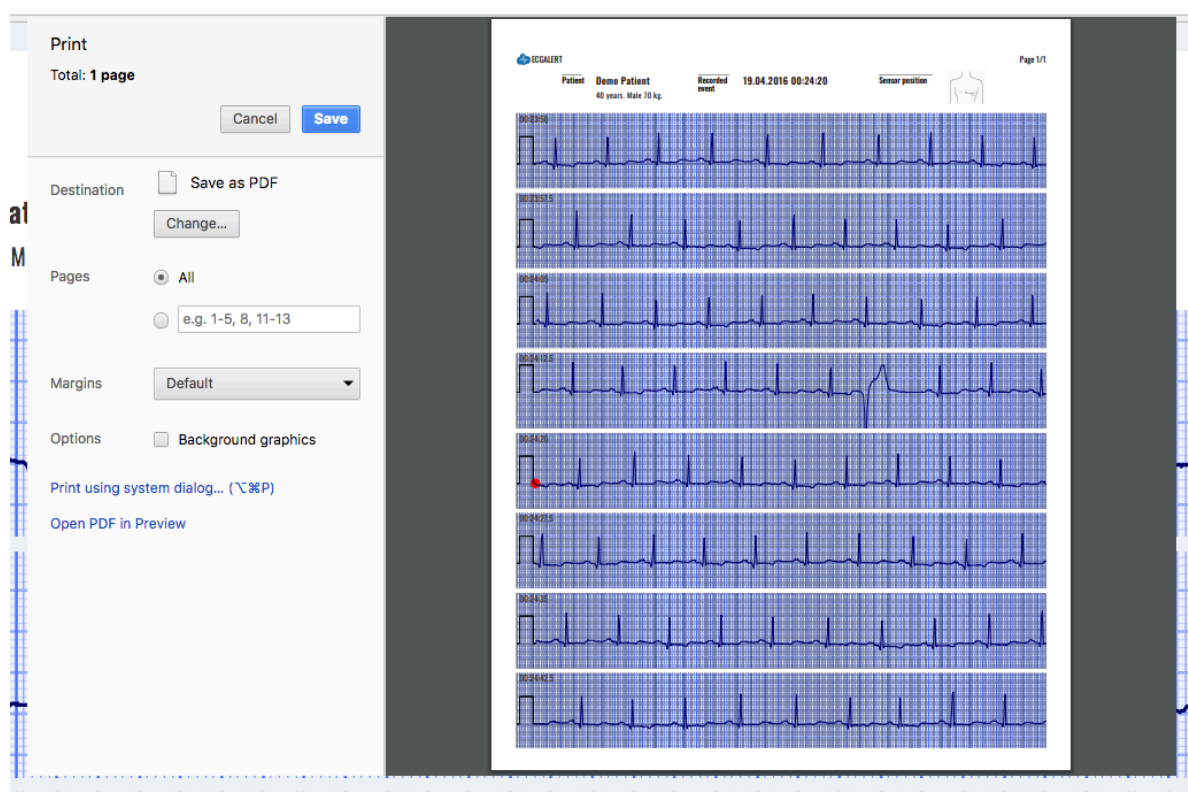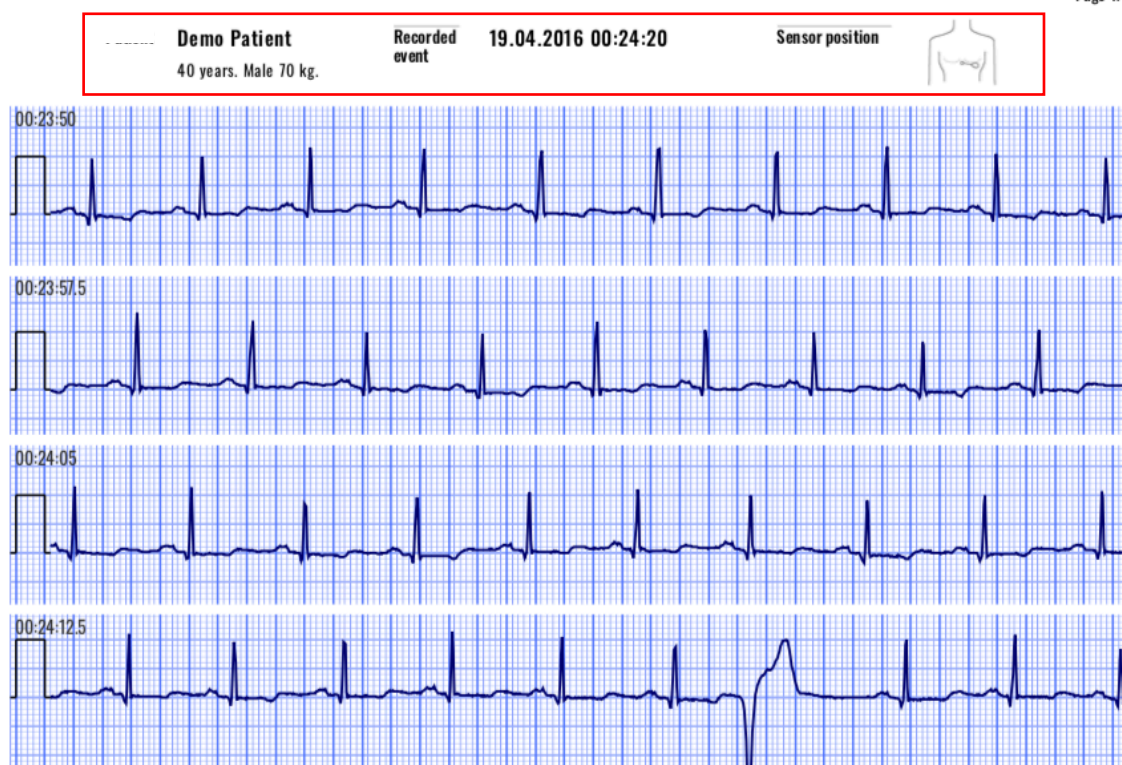

Figure 38: Choose a printer output system message.

Printed Event Document

You can save it as a PDF file in a selected location on your computing device and then use it for your purposes, such as sending it by e-mail or other communication channels.
NOTE: Please be careful when sending the PDF file, as it contains personal and medical information (Figure 39).

Figure 39: A printed PDF contains personal-related information.

Each printed document contains consecutive rows of 7.5-second ECG strips. One page can contain up to 8 rows corresponding to 60-second events. If the event is defined to be longer, such as 2 or 4 minutes, then the printed PDF will contain 2 or 4 pages.

4.6. File Management

Upload Files

The "Upload files" section (Figure 40) can be accessed via the upload menu option in the application header.
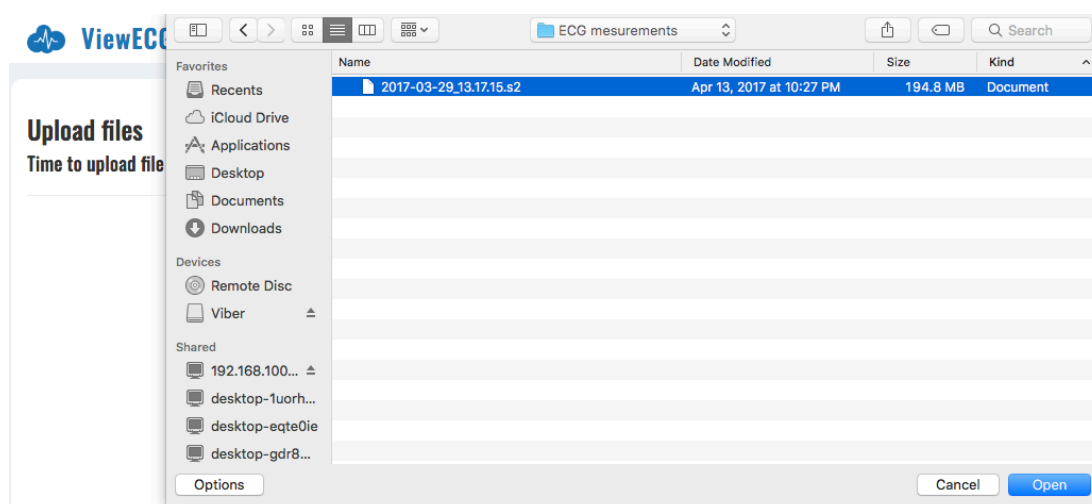

Figure 40: Upload file form.

Upon clicking the "Browse" button, a file browser dialog opens (Figure 41). You can choose to upload multiple ECG or .s2 files.

Figure 41: File browsing dialog form to select an ECG or S2 file for upload.

After selecting the file or files, click the "Start transferring" button to begin the upload (Figure 42).
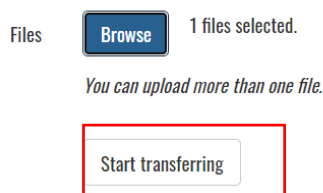
Figure 42: One selected file is ready for transfer.

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 will appear in the warning icon that the file has been uploaded and its processing has started (Figure 43).
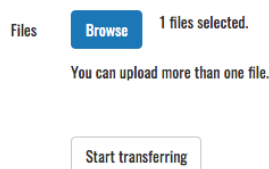
Figure 43: Successful upload and pre-processing status notification.

When the file is processed and ready for monitoring, another warning message will appear in the "Notification" header section (Figure 44).

Figure 44: Status notification about successful processing.

4.7. Settings

You can access the settings drop-down menu by clicking the "Settings" icon in the application header. The available menu options include "Profile," "Sensors," "Subscriptions," "Invoices," and "Log Off" (Figure 45). You can select the corresponding menu option by clicking on it.
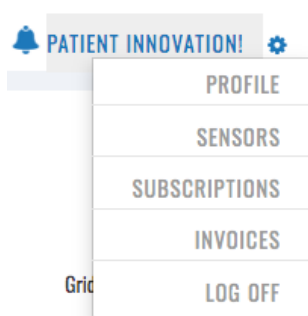
Figure 45: ViewECG application Settings menu.

Profile

The user can adjust the profile content and change account details on a form with multiple user information fields (Figure 46), including first and last names, gender, date of birth, weight, height, presence of a pacemaker, indications, medications, address, city, postcode, country, phone number, username (email) and password, code, and language. The option to upload or delete personal photos is optional. The displayed code is for information purposes only, and the system allocates it.

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

Change Account Details

Figure 46: Change account details form.

By clicking on the "Change your password" link, you are transferred to a corresponding page that allows you to change the password (Figure 47). Note that this activity will use your email address and sensitive information to confirm your password change, which will be sent to your email.

Figure 47: 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 cannot reactivate the user account again. Before account deletion, the system will require confirmation (Figure 48).

Figure 48: Delete account confirmation.

ViewECG Medical Device System	PATIENT'S USER MANUAL	Identification	PUM-013
		Issued	27.05.2025
		Approved	27.05.2025

Sensor's 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 49). 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.

Figure 49: ViewECG Setting sensors page.

Each device has the following information: device version, code, description, password code, sample rate, active and activated statuses, date of activation and adding, and whether the device is archived (Figure 50). The "Back to list" button navigates to the list of all sensors.

Figure 50: Sensor device details.

To add a new device, click the "Add new" button. This will take you to a page where you can select your new device (Figure 51).

Figure 51: Selecting a new device.

Subscriptions

The "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 52).

My subscriptions

Show 10 entries   Search:

Subscription	Start	End	Active	
Trial	02.09.2019	02.09.2019	☑	Invoice
Trial	12.07.2019	12.07.2019	☑	

Showing 1 to 2 of 2 entries   1

Figure 52: Subscription details.

Invoices

The "My invoices" page contains all your invoices and related details. The invoice number, year, name, status, date, due date, amount, and all details in printable versions are available for each purchased subscription plan (Figure 53).

My invoices

Show 10 entries   Search:

Number	Year	Name	Status	Date	Due date	Amount	
5	2019	Trial (2 months)	Paid	02.09.2019	17.09.2019	$0.00	Details
7	2019	Trial (2 months)	New	02.09.2019	17.09.2019	$0.00	Details

Showing 1 to 2 of 2 entries   1

Figure 53: Invoice details.

When you click on the "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 the payment amount (Figure 54).

ViewECG   Paid

Invoice #5 / 2019

Invoiced To	**Pay To**
Ana Spasovska	Innovation DOOEL Uvoz-Izvoz
588 Hoffman Avenue	Vostanicka 118-18
New York, 1000	Skopje, 1000
United States	North Macedonia
	6154344

Invoice Date	**Due Date**
17.09.2019	17.09.2019

Invoice Items

Description	Amount
Trial (2 months)	$0.00
Sub Total	$0.00
Discount	0%
Total	$0.00

Print | Download | Back to list

Figure 54: Invoice details.

Logging OFF

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

If the user is not logged off, when you start the application, it will remember the last login and continue working with the same user. If the user is logged off, then on the next start of the application, the user must log in again by providing a valid registered username and password combination (Figure 2).

4.8. Ticketing System

You can access the ticketing system by clicking the Support link at the bottom of each page. This allows you to submit any issues or questions about our products and services.

Technical Support

The "Technical support" page contains all your tickets and the option to create a ticket in the pre-defined questions and answers if you don't find a solution to your issue (Figure 55).
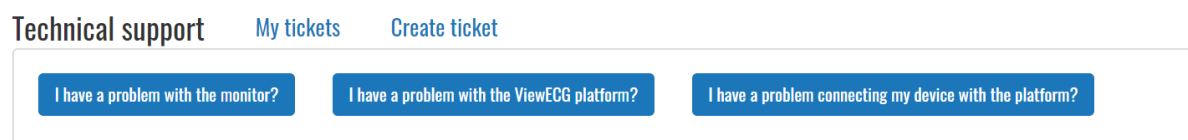
Figure 55: ViewECG Technical support.

My tickets

The "Support tickets" page previews the tickets you submitted to our team. Each ticket is noted with the day and time submitted, unique code, subject of the issue, status, and a button to see more details about it (Figure 56). 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 sent to the user),
- Close (issue is closed either by the user or the organization) and
- Additional info (status when additional info is required).

Figure 56: My tickets page.

Ticket Details

The "Ticket details" page shows you the details of each ticket you created (Figure 57). On this page, you can see the conversation between you and our support team and the answers we have provided to your questions. You can also message us or close the ticket when you feel satisfied with the resolution of the issue.

Figure 57: Ticket details.

Create a Ticket

The "Create a ticket" page allows you to create and submit a ticket to our support team (Figure 58). You need to select the category your submission is related to:

- Info,
- Billing, and
- Technical support.

Then, it would be best if you described how the problem occurred and explained it in detail, containing the expected and obtained results.

Figure 58: ViewECG application on Apple Store.

5. Maintenance

There is no need for user maintenance, as maintenance is done automatically by the software agent and delivered as a software-as-a-service product.

The user's sole responsibility is to keep their subscription to ViewECG up to date.

All maintenance measures for the computing device with an Internet connection apply.

6. Terms of Use

6.1. Terms and Conditions

General Terms of Use

The device is intended to monitor daily cardiac activity following Directive 93/42/EEC on medical devices with a valid amendment classified as an active noninvasive medical device labeled IIa. As a class IIa device, ViewECG is intended to allow direct visualization or monitoring of cardiac performance and to detect cardiac performance. ViewECG is not intended for treatment by the rules of the medical profession. If the user feels uncomfortable concerning cardiac function, they must urgently seek medical assistance, regardless of the conditions shown by the medical device ViewECG.

1. ViewECG is a system for monitoring cardiac activity for measurements transmitted to the ViewECG server. It can be viewed by the user or their doctor from any device with an Internet connection.
2. Data transfer is carried out wirelessly, requiring your device to have a good Bluetooth and Internet connection.
3. Innovation Technologies determines the price of ViewECG and reserves the right to change it at any time.
4. Every customer obtains a user manual, general terms, pin code, and warranty statement with the purchase of the device.
5. When you register an account with ViewECG, you must accept the general terms and conditions of use.
6. Following the provisions of the protection of personal data, with the acceptance of the medical device, the respective buyer allows sellers 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.
7. When a buyer pays the invoice, he guarantees that the device is intended solely for their personal or pin code holder use and is not transferable to third parties.

Terms

These Terms of Use describe rules for visitors to the viewecg.com website (the "Site"). Innovation Technologies ("we" or "us") owns and operates this website. These Terms of Service are effective 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. "You" refers to the person visiting the Site and registering as a user. Accessing the Service means you acknowledge that you have read, understood, and agree to be bound by the Terms of Use, including the privacy policy (together with the "**Terms**"). If you do not wish to be bound by these Terms of Service, you may not access or use the Service.

Service Description

The service on this Site is intended to record, display, visualize, store, transmit, and interpret electrocardiograms ("ECG **data**"). As the service user, you 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 corresponds to resting heart position (laying in a bed), the proper position

of the ECG sensor, the stickiness of the ECG electrodes, elimination of environmental noise that may corrupt recorded data, establishing adequate 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 of potentially serious heart conditions or abnormal arrhythmias. The service is intended for continuous monitoring. We do not guarantee that the measurement reflects a proper measurement and communication setup, such as enabling 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 ensures that telecommunication links work correctly and data is transferred on time.

We do not guarantee any physician(s) response to messages posted or medical events reported through the service. Talking to your healthcare professional for diagnosis and treatment would be best. 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. You are responsible for presenting your medical data to your physician for proper analysis and diagnosis.

Jurisdiction

Unless you are a consumer 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, not a judge or jury, and your claims cannot be considered a class action. You may only resolve disputes with us individually and 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 only allows you to upload, view, visualize, share data with your healthcare professional and use specific data about 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 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 information only. Information you read on this website cannot replace your relationship 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; the information on this website should not be considered medical advice. Third parties may be engaged to provide other information, and you should always talk to your healthcare professional for diagnosis and treatment. Health information changes quickly. Therefore, it is always best to confirm information with your healthcare professional. This website may contain information that needs to be approved and cleared for use in your country of residence.

6.2. Your Information and Permissions

To access most Service features, 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, biometric medical data, etc. You agree that the information you provide to us is accurate and that you will always keep it accurate and up-to-date. 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 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 host Your User Content, back it up, and share it when you ask us to. Our Services also provide features that may require our systems to access, store, and scan Your User content. Once you permit us to do those things, 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. 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. Your healthcare provider may own and control that copy of such data under applicable law.

You are solely responsible for your User Content and the consequences of posting or publishing User Content. By posting or publishing User Content, you affirm, represent, and warrant that:

- You are the creator and owner of the User Content or have the necessary licenses, rights, consents, and permissions to authorize us and users of the Service to use and distribute your User Content as required to exercise the licenses granted by you in this section, in the manner contemplated by us, the Service, and these Terms; and
- Your User Content, and the use of your User Content as contemplated by these Terms, does not and will not:
  - infringe, violate, or misappropriate any third-party right, including any copyright, trademark, patent, trade secret, moral right, privacy right, right of publicity, or any other intellectual property or proprietary right;
  - slander, defame, libel, or invade the right of privacy, publicity, or other property rights of any other person; or
  - cause us to violate any law or regulation.

Limited License Grant

By posting or publishing User Content, you grant us a perpetual, irrevocable, worldwide, nonexclusive, royalty-free, fully paid, transferable right and license (with the right to sublicense) to use, host, store, transfer, display, perform, reproduce, modify, create derivative works of, and distribute your User Content, in whole or in part, for any purpose by our Privacy Policy, in any media formats and through any media channels now known or hereafter developed. We may also create anonymized data and images from your User Content, which will no longer be your User Content. You irrevocably and forever waive any rights regarding your User Content being altered or manipulated in any way that may be objectionable to you. We reserve the right to refuse to accept, post, display, or transmit any of your User Content at its sole discretion.

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

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 various 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 concerning User Content. We expressly disclaim any 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.

6.3. Eligibility

By agreeing to these Terms, you represent and warrant to us that:
* You are over 18 years old and entirely responsible for agreeing with the Terms;
* You have not previously been suspended or removed from the Service and
* Your registration and use of the Service are 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 agree to be bound by them 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 ancillary to the Services, including changes that may affect the previous mode of operation of the Service. We expect any such modifications to enhance the overall Service, but you may disagree 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 occasionally to improve, enhance, repair, and further develop the Services. We will endeavor to provide you 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 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 for more than 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 accurate information or keep Your User content secure. Suppose you discover any unauthorized use of Your User Content or suspect anyone can access it. In that case, you should immediately change your password and notify our Customer Support team.

Access to the Service, or 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. We will provide advance notice if we change the service fees, including adding additional fees or charges. If you do not accept the changes, we may discontinue providing the Service to you. We will charge you using the payment method you specified at the time of purchase. You authorize us to charge all sums described in these Terms for the Service you select to that payment method. Suppose you pay any fees with a credit card. In that case, we may seek pre-authorization of your credit card account before 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. Suppose you activate or update recurring payments through the Service. In that case,

you authorize us to charge periodically, 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. 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 terminate your access to the Service accordingly, then you will be entitled to a prorated refund of any prepaid fees that you have paid to us for the use of the Service. Upon the termination of your account or this agreement for any reason, we may, at its option, delete any data associated with your account.

6.4. License

Innovation Technologies owns and operates the Service. The documents, information, and content available on the Service, including visual interfaces, graphics, design, compilation, information, data, computer code (including source code or object code), products, software, services, and all other elements of the Service are protected by copyright and other intellectual property laws throughout the world. All copyright and other proprietary notices on any Site Content must be retained on any copies made thereof. Any unauthorized reproduction, modification, distribution, public display, or performance of any Site Content is strictly prohibited. We and our suppliers reserve all rights not granted in these Terms. Except as expressly authorized by us, you may not use the Materials. We reserve all rights to the Materials not granted expressly in these Terms.

To use our service on various computing devices, you do not need to install client software besides a sophisticated web browser on your computers, tablets, and smartphones. You are responsible for obtaining those devices and paying for their connectivity and data plans. We have no responsibility for the availability of the Internet and other telecommunication services necessary to access the Services or for their functioning.

Subject to the restrictions outlined 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 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 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 by 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
- The information, data, and other materials you provided supporting your account registration are accurate and truthful.

You may not use or export the Services or any of our Software. Without limitation, our Software may not be:

- Exported or re-exported into any countries or
- Provided to or used by anyone not registered to the system.

Indemnity

You agree to indemnify and hold us and our subsidiaries, affiliates, officers, agents, employees, advertisers, and partners harmless from and against any claims, liabilities, damages (actual and

consequential), losses, and expenses (including legal and other professional fees) arising out of or in any way connected with:

- 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 concerning 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 that imports, views, and interprets your data. The Clinical Interpretation Service reports any findings in your data, and we make those findings available to you within the Service. By accepting these Terms, you agree to enroll 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 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 we provide, and Clinical Interpretation Services 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, considering your complete medical history. Diagnosis based on your data can only be accomplished by your physician. You are responsible for presenting 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 the 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 permit 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 asking for these services.

6.5. 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. Suppose a change to these Terms materially modifies your rights or obligations. In that case, we will email you the modified Terms to the address you provided in your user profile and notify the Service or our website. Material modifications will be effective upon your acceptance of such modified Terms or 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 by the version that was in effect when 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.

Disclaimers; No Warranties

We strive to provide excellent Services, but there are certain things that we can't guarantee. TO THE FULLEST EXTENT PERMITTED BY LAW, WE AND OUR AFFILIATES, SUPPLIERS, AND DISTRIBUTORS MAKE NO WARRANTIES, EITHER EXPRESS OR IMPLIED, ABOUT THE SERVICES. YOUR USE OF THE SERVICES, PURCHASE, AND USE OF ANY PRODUCTS ARE ALL AT YOUR SOLE RISK. THE SERVICES ARE PROVIDED "AS IS." AND PRODUCTS ARE SOLD ON AN "AS IS" AND "AS AVAILABLE" BASIS. WE ALSO DISCLAIM ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. OUR ENTITIES DISCLAIM ALL WARRANTIES OF ANY KIND, WHETHER EXPRESS OR IMPLIED, RELATING TO THE SERVICE, ALL MATERIALS AND CONTENT AVAILABLE THROUGH THE SERVICE, AND ANY SOFTWARE OR HARDWARE ASSOCIATED OR USED WITH THE SERVICE, OR THE AVAILABILITY OF ANY OF THE PRECEDING, INCLUDING ANY WARRANTY AS TO WHETHER THE ECG DATA OR OTHER INFORMATION AVAILABLE ON OR TRANSMITTED BY THE SERVICE IS TRUE, COMPLETE OR ACCURATE. YOU SPECIFICALLY ACKNOWLEDGE AND AGREE THAT WE ARE NOT RESPONSIBLE FOR ANY HEALTHCARE OR RELATED DECISIONS MADE BY YOU OR YOUR HEALTHCARE PROFESSIONAL BASED UPON DATA COLLECTED, TRANSMITTED, OR DISPLAYED BY OR ON THE SERVICE, WHETHER SUCH DATA IS ACCURATE OR INACCURATE. THE ENTITIES DO NOT WARRANT THAT THE SERVICE OR ANY PORTION OF THE SERVICE, OR ANY MATERIALS OR CONTENT OFFERED THROUGH THE SERVICE, WILL BE UNINTERRUPTED, SECURE, OR FREE OF ERRORS, VIRUSES, OR OTHER HARMFUL COMPONENTS AND DO NOT WARRANT THAT ANY OF THOSE ISSUES WILL BE CORRECTED.

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